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Key Points

There is limited and conflicting evidence in support of multifaceted bowel management programs for managing neurogenic bowel dysfunction.

There is a need for further research to examine the optimal level of dietary fibre intake in patients with SCI.

Digital rectal stimulation increases motility in the left colon in individuals with reflex neurogenic bowel dysfunction after SCI.

Digital evacuation of stool is a common intervention for bowel management after SCI, reducing duration of bowel management and fecal incontinence.

Polyethylene glycol-based bisacodyl suppositories (10 mg.) are faster in stimulating reflex evacuation as part of a bowel management program in persons with an upper motor neuron SCI than bisacodyl in vegetable oil suppositories.

There is contrasting evidence on the effectiveness of abdominal massage in treating neurogenic bowel dysfunction. Further research is needed.

Electrical stimulation of the abdominal wall muscles can improve bowel management for individuals with tetraplegia, however, it may cause autonomic dysreflexia.

Functional magnetic stimulation may reduce colonic transit time in individuals with SCI, however, more research is required and may not be clinically applicable.

Transanal irrigation can improve both upper motor neuron and lower motor neuron bowel dysfunction in individuals with chronic neurogenic bowel dysfunction following SCI.

The Malone Antegrade Continence Enema is a safe and effective treatment for significant GI problems in persons with SCI when conservative and transanal irrigation are unsuccessful or inappropriate.

Pulsed water transanal irrigation may help to remove stool in individuals with SCI.

In very small studies prucalopride, metoclopramide, neostigmine, and fampridine have been found to improve constipation in individuals with SCI, though more research is required on prokinetic agents prior to their regular use in neurogenic bowel dysfunction.

Elective stoma formation is a safe and effective treatment for significant neurogenic bowel management problems and perianal pressure ulcers in persons with SCI, and greatly improves their quality of life.

Most importantly, having a regular bowel management routine can allow predictable, timed BM, and avoid back up and unplanned episodes.

There is limited evidence that a washing toilet seat with visual feedback may assist bowel care.

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1 Executive Summary

1.1 What is bowel dysfunction?

An injury to the spinal cord and/or cauda equina can result in neural damage affecting sensation to and control of the rectum, anus, or sphincters, and a reduced activity of the intestines affecting regular bowel evacuation – a cluster of issues characterized in people with SCI as Neurogenic Bowel Dysfunction (NBD) (Leduc et al. 2002; Gondim et al. 2001; Menter et al. 1997; Rajendran et al. 1992; Lynch & Frizelle 2006; Fajardo et al. 2003).

Common problems of the gastrointestinal tract associated with NBD include:

- Constipation: bowel evacuation less than 3 times per week and/or incomplete bowel emptying due to hard, dry feces (<u>Johns et al. 2021</u>; <u>Faaborg et al. 2008</u>; <u>Finnerup et al. 2008</u>; <u>Lynch et al. 2000</u>)
- Fecal incontinence: unintentional leaking from the bowels (Johns et al. 2021)
- Fecal impaction (<u>Faaborg et al. 2008</u>; <u>Finnerup et al. 2008</u>; <u>Lynch et al. 2000</u>): hard, dry stool gets trapped in the anus or rectum
- Abdominal pain and bloating (<u>Johns et al. 2021</u>; <u>Correa & Rotter 2000</u>)
- Anorectal pain (Johns et al. 2021)
- Hemorrhoids: swollen veins around the anus (Correa & Rotter 2000)
- Rectal prolapse: the rectum slips through the anus (<u>Correa & Rotter 2000</u>).

1.2 What methods of bowel management are there?

"Bowel program" or "bowel routine" refers to the overall management program that someone with SCI may use to ensure their bowels continue to be healthy and functional. Activities that are part of a bowel routine may include nutrition, fluid intake, timing, rectal stimulation, irrigation, abdominal massage and/or adjunctive medications. "Bowel care" refers to the process of facilitating bowel evacuation either in a hospital/health care setting or outside.

Many techniques for your bowel program or bowel routine can be used, including interventions ranging from conservative management techniques to surgical procedures to assistive devices.

<u>Conservative bowel management</u> will usually employ a few techniques in an individualized program or routine, and it is implied that these techniques are added in a stepwise fashion, that is, from least to most invasive. Techniques may include dietary modifications especially re: fibre and fluid, digital rectal stimulation, digital removal of stool, abdominal massage, stimulation of the gastrocolic reflex, and use of oral or rectal medications (suppositories, enemas). Such a program will usually be performed on a daily or alternate day basis and until stool consistency is regulated and more ideal, depending on the needs of the individual.

<u>Colostomy and ileostomy</u> are generally considered after conservative methods fail. Other motives for choosing surgical interventions may be because they are less time consuming, are

appropriate for severe constipation or fecal impaction, decrease cases of autonomic dysreflexia or pain, and avoid diseases or contamination of existing pressure injuries near the anus.

Many studies support colostomy and ileostomy for its ability to simplify bowel routines (reduce the time spent on bowel care, increase independence, and decrease trips to the hospital due to gastrointestinal problems).

To help people with SCI succeed in managing their bowel problems, some <u>assistive devices</u> are available, including modified toilet seats, standing tables, assisted ambulation training, and anorectal biofeedback. They can be used as part of a bowel care routine, though there is limited research in this area.

1.3 What are the limitations of bowel management techniques?

The efficacy of a bowel management technique relies on many factors. Factors such as diet and medication can be modified to optimize bowel care while other factors such as medications a person takes to manage other conditions of their SCI may be harder to change. Thus, a bowel care routine tailored to the individual and considering all aspects of their health will help avoid potential risks and maximize their effectiveness.

Furthermore, how well a bowel care technique works is dependent on how well the person with SCI follows their routine. Sticking to a planned time and frequency of bowel emptying can help train the bowels and result in more predictable bowel activity.

Annual evaluations of bowel management are also recommended by the <u>Consortium for Spinal Cord Medicine guidelines (2020)</u> and the <u>Multidisciplinary Association of Spinal Cord Injury Professionals guidelines (MASCIP 2012)</u>. This is to determine whether changes to a bowel program are needed and to ensure that the program remains appropriate and effective for a person with SCI.

2 Introduction

Bowel dysfunction due to spinal cord injury (SCI) results in a constellation of problems termed "neurogenic bowel dysfunction" (NBD), which may include fecal incontinence, severe constipation or fecal impaction, and damage to quality of life (Emmanuel 2010; Byrne et al. 2002; Correa & Rotter 2000; Stiens et al. 1997; Glickman & Kamm 1996; Longo et al. 1995).

Even when a bowel routine to manage the problem is effective, it can be onerous and may take up to 1-2 hours per session, repeated every day or alternate days throughout post-injury life. It can interfere significantly with the person's education, work, and social life and presents a major challenge to quality of life, independence, and community reintegration after SCI. Loss of bowel control may have greater impact than loss of ability to ambulate (Frost et al. 1993) and is a source of anxiety and distress (Ng et al. 2005; Glickman & Kamm 1996; Coggrave et al. 2009; Coggrave & Norton 2010). Ineffective bowel care results in social isolation (Byrne et al. 2002), inability to work, and admissions to acute services for treatment of fecal impaction and bowel obstruction when constipation escalates. Treatment of bowel dysfunction is often a top priority for people with

SCI and their health care providers (Pazzi et al. 2021; Anderson 2004; NASCIC, 2019).

INNERVATION OF THE GI SYSTEM

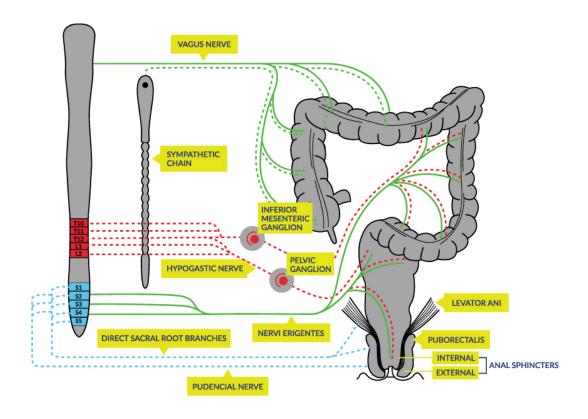


Figure 1:1 Innervation of the gastrointestinal (GI) system. Schematic diagram of the autonomic and somatic innervations of the lower GI tract and pelvic floor. The brainstem, spinal cord and sympathetic chain are shown on the left, and the colon, rectum and pelvic floor on the right. Sympathetic innervation (dashed lines) originates from the thoracic and upper lumbar regions; parasympathetic innervation (solid lines) originates from the vagus nerve (to the upper GI and colon up to the colonic flexure) and from the sacral region of the spinal cord (to areas below the splenic flexure). Dotted lines represent the mixed nerves supplying the somatic innervation to the musculature of the external anal sphincter and the pelvic floor.

2.1 Assessment of Neurogenic Bowel

The clinical practice guidelines (CPG) for Management of Neurogenic Bowel Dysfunction (Consortium for Spinal Cord Injury Medicine, 2020) recommend several evaluations for the assessment of neurogenic bowel. After defining the level and completeness of SCI according to the ISNCSCI scale, a comprehensive evaluation of bowel function, impairment, possible

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complications, GI history, and physical examination of the abdomen/rectum should be completed at the onset of injury, annually as care continues, or if significant GI changes occur, to gain a sufficient understanding of one's bowel function to inform management. The CPG (Consortium for Spinal Cord Injury Medicine, 2020) also describes more involved diagnostical tools should standard examination not be sufficient. These include abdominal x-ray, computer tomography (CT), colonic transit time testing, wireless motility capsule, anorectal manometry, anorectal physiological testing via balloon expulsion, and defecography as diagnostic tools that may help identify symptoms, prevent the progression of complications, and plan for proper intervention.

Table 1. Assessment and Diagnostic Tools for Neurogenic Bowel

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Alexander et al. 2009 International Systematic Review N=7 studies	Objective: To review specific objectives and processes to evaluate SCI outcome measures with psychometric properties, such as internal and external validity, developed by spinal cord injury organizations (i.e., ASIA, ICCP, ICORD, ISCOS and SCOPE). Methods: a framework was used for the appraisal of evidence	 Most of the information found assessing colon and rectal function included anal manometry, rectal EMG, rectal impedance planimetry and colonic transit time. These methods provide valuable information about anorectal physiology, but their use is limited by extensive equipment needs and a lack of psychometric properties. Total or segmental colorectal transit times determined by oral intake of radio-opaque markers and subsequent abdominal X-rays have been extensively used; however, the reproducibility and the association between colorectal transit times and bowel symptoms remain to be described. The Neurogenic Bowel Dysfunction Score has been used in populations of people with SCI (the NBD score was subsequently validated for adult patients with SCI). The Fecal Incontinence Scales includes QoL measures (participant response questionnaires), attempting to quantify participation, but were not

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
		specifically designed or validated for SCI. 5. A Cochrane review concluded that treatment of bowel dysfunction in central neurological diseases must remain empirical, until large well-designed trials have been carried out.
Emmanuel et al. 2009 UK Cohort Level 2 N=81; N=55 with SCI	Objective: Bowel dysfunction is common after spinal cord injury (SCI). We aimed to determine whether hindgut testing of autonomic innervation provides insight into presence of symptoms, altered motor function (transit) and level of injury. Population: N=55 with SCI (45 male, mean age 36, range 19-68 y); Complete SCI (mean time since injury 34 months, range 13-134) N=24 (18 male, mean age 34) had lesions above T5 N=31 (27 male, mean age 37) had lesions below T5 N=26 non-SCI controls (17 female; mean age 36, range 18-61) Treatment: Underwent laser Doppler flowmetry Outcome Measures: Laser Doppler studies of rectal mucosal blood flow, Radio-opaque marker transit study to measure whole gut transit, assessment of rectal sensation measured by balloon distention and electrosensation measured by bipolar ring electrode, Anal sphincter manometry to assess anorectal parameters	 32/55 SCI participants had slow whole gut transit. People with subjective constipation had significantly more retained markers than those without (mean markers 49 vs 22, respectively, p=0.007). Rectal electrosensory thresholds were more abnormal in those with slow transit vs. normal transit (65.3 vs 44.1 mA, respectively, P<0.04). Transmucosal rectal sensation was abnormal in all patients, significantly greater in those complaining of constipation compared with those without (67.3 vs 41.6 respectively, p<0.01). SCI participants with constipation had significantly lower mucosal blood flow than asymptomatic SCI participants (mean 183 vs 267 FU, n=55, p<0.04). The participants with slow transit had lower blood flow than did those with measured normal transit (mean 180 vs 273 FU, n=55, slow vs normal transit P<0.03). Compared to control, resting blood flow was greater in participants with lesions above T5 (200 vs 238, respectively, p=0.056) and similar in those with lesions below T5 (203 vs 213 FU, respectively, p=0.345).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Park et al. 2013 Korea Cohort Level 2 N=44	Objective: To evaluate the usefulness of plain abdominal radiography as an evaluation method for bowel dysfunction in patients with spinal cord injury (SCI). Population: 44 people with SCI (39 males and 5 females). Mean age: 50.2±16.9y (range 22-76 y) Mean time since injury: 23±37.8 months 11 complete SCI, 33 incomplete SCI. 22 cervical, 17 thoracic, 5 lumbar 11 AIS A, 8 AIS B, 10 AIS C, 14 AIS D, 1 AIS E Treatment: To evaluate the usefulness of plain abdominal radiography as an evaluation method for bowel dysfunction in patients with spinal cord injury (SCI). Outcome Measures: Starreveld scores and Leech scores were used to examine the degree of stool retention, analyzed from the plain abdominal radiographs. Constipation score was measured using the Rome II Diagnostic Criteria. Colonic transit time was measured using 1 capsule of Kolomark with 20 marker rings with radio-opacity for 3 days at 9am.	 As right colon transit time increased, stool retention score at ascending colon increased; as left colon transit time increased, stool retention score at descending colon increased (p<0.05). As rectosigmoid colon transit time increased, stool retention score at the transverse colon decreased (p<0.01). As right colon transit time increased, stool retention score at ascending colon increased; as left colon transit time increased, stool retention score at descending colon increased (p<0.01). As total colon transit time increased, both the Starreveld score (p<0.05) and Leech score (p<0.01) significantly increased. Starreveld score measured with the plain abdominal radiograph was 3.4±0.7 at the ascending colon; 1.8±0.86 at the transverse colon, 2.83±0.82 at the descending colon, and 2.14±1.0 at the rectosigmoid colon. It was measured as 10.19±2.45 at the total colon. Leech score was 3.28±0.7 at the right colon, 2.8±0.8 at the left colon, and 2.35 ± 0.85 at the rectosigmoid colon. It was measured as 8.45±1.83 at the total colon. Megacolon was identified in 14 people at the ascending colon. Megarectum was identified in 11 people. 5 people showed both megacolon and megarectum. Group with megacolon had CTT of 60.60±12.03 vs. group without

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
		megacolon with CTT 49.17 ± 20.56 (p<0.05). 8. Rectosigmoid colon and colon transit times according to the presence/absence of megarectum did not show a statistically significant difference.
Kim et al. 2016b Korea Prospective controlled trial Level 2 N=32	Objective: The aim of this study was to determine the efficacy of measuring the diameter and area of the rectum using ultrasonography as an additional parameter for the evaluation of neurogenic bowel in patients with spinal cord injury (SCI). Population: N=16 UMNB Female: 25% Age: 63.4 ± 12.7 y Level: 100% cervical Severity: 1 ASIA A, 0 ASIA B, 2 ASIA C, 13 ASIA D Time since injury: 132.7 ± 178.6 Days N=16 LMNB group Female: N= 5 Age: 47.9 ± 13.9 y Level: 8 cervical 4 thoracic 4 lumbar Severity: 6 ASIA A 1ASIA B 1 ASIA C 8 ASIA D Time since injury: 44.7 ± 49.5Y Treatment: Ultrasound was applied on the abdomen and measured the diameter and area of the rectum	 Comparing both groups, patients in the UMNB group had a significantly smaller mean rectal diameter than those in the LMNB group after defecation (P = 0.022) There was a significant difference in rectal area reduction after defecation between the UMNB and LMNB groups (p=0.005) Rectal diameter was significantly reduced after defecation in the UMNB group (p=0.023) but not in the LMNB group (p=0.735)

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	were measured twice each before and after defecation, respectively. Outcome Measure: Ultrasonography to measure the diameter and area of the rectum to evaluate NBD in SCI.	
Putz et al. 2020 Germany Cohort Level 2 N=20	Objective: The main aim of this study is to evaluate whether magnetic resonance (MR) defecography can provide objective parameters correlating with the clinical manifestations of neurogenic bowel dysfunction (NBD) in participants with SCI. Population: 20 participants with sensorimotor complete traumatic AIS-A SCI with neurological level of injury between TI-TIO, previously included in the MR defecography feasibility study (Putz et al. 2017) Treatment: Previously published MR defecography parameters (anorectal angle (ARA), hiatal descent (M-line) and hiatal width (H-line)) of twenty participants with SCI were now compared to a standardized clinical assessment of NBD. Descriptive statistics, correlations and t-tests for independent samples were calculated. Outcome Measures: MR-defecography procedure to measure pelvic floor parameters: by 2 images of the pelvic floor (one at rest and one during defecation) where differences were calculated for ARA, hiatal descent, and hiatal width of the levator plate.	 People suffering from frequent incontinence episodes had higher anorectal angle (ARA) values at rest (p=0.00018) and hiatal descent (M-line) values at rest (p=0.045) compared to those with rare incontinence episodes. For people without NBD, pelvic floor parameters increased from rest to defecation. 9/20 people with SCI had abnormal pelvic floor movement, indicated by negative delta for either ARA, H and M (from resting to defecation values). Those who had abnormal pelvic floor movement showed a trend toward more severe NBD presentation (higher mean NBD score of 15 compared to 11 in people without any negative parameter values (p=0.061). Other parameters such as age, time since injury, level of injury, and routine bowel evacuation practice had no correlation to the obtained parameters.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Putz et al. 2017 Germany Cohort Level 2 N=20	Objective: To investigate whether MR-defecography can be employed in sensorimotor complete spinal cord injury (SCI) subjects as a potential diagnostic tool to detect defecational disorders associated with neurogenic bowel dysfunction (NBD) using standard parameters for obstructed defecation. Population: Sensorimotor complete traumatic SCI, AIS-A, and level of injury between TI-TIO. Time since injury was mean 20y (range 3-50y). 2/20 participants female. Mean age 47y (range 19-70y) Treatment: Defecation was successfully induced by eliciting the defecational reflex after rectal filling with ultrasonic gel, application of two lecicarbon suppositories and digital rectal stimulation. Examination was performed with patients in left lateral decubitus position using T2-weighted turbo spin echo sequence in the sagittal plane at rest (TE 89ms, TR 3220ms, FOV 300mm, matrix 512×512, ST 4mm) and ultrafast-T2-weighted-sequence in the sagittal plane with repeating measurements (TE 1.54ms, TR 3.51ms, FOV 400mm, matrix 256×256, ST 6mm). Changes of anorectal angle (ARA), anorectal descent (ARJ) and pelvic floor weakness were documented and measured data was compared to reference values of asymptomatic non-SCI subjects in the literature to assess feasibility. Outcome Measures: MR-defecography as a diagnostic tool to	 MR-defecography was feasible in all participants. Measurement results: Mean anorectal angle (ARA) and hiatal width (H-line) were significantly increased at rest and evacuation in comparison to non-SCI reference values (p<0.001). Significant increase of mean levator plate (M-line) descent during induced defecation (p<0.001).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	detect defecation disorders associated with NBD in people with sensorimotor complete SCI. Grading systems for pelvic floor weakness, including hiatal widening, levator plate descent and rectal descent. All images analyzed for the presence of anterior rectocele and vesiocele.	
Williams et al. 2012 USA Prospective controlled trial Level 2 N=20	Objective: To assess whether SmartPill technology can be applied in persons with SCI. Population: N=20 SCI (10% female) 12 paraplegia (mean age 52±14 years; mean duration of injury 15±11 years; 8 complete motor/sensory and 4 incomplete motor/sensory) 8 tetraplegia (mean age 41±9 years; mean duration of injury 14±12 years; 4 complete motor/sensory injury and 4 incomplete) 10 non-SCI (8 male 2 female; 40±12 years). Outcome measures: SmartPill capsule tracked gastric emptying time (GET), colonic transit time (CTT), whole gut transit time (WGTT), maximum gastric acidity.	 GET, CTT, and WGTT were prolonged in the SCI group compared to the non-SCI group (10.6±7.2 vs 3.5±1.0h, P<0.01; 52.3±42.9 vs 14.2±7.6 h, P=0.01; 3.3±2.5 vs 1.0±0.7 days, P<0.01; respectively). Minimum values of gastric pH were similar in SCI and non-SCI group (1.1±0. 8 vs 1.0±0.8 pH units, P>0.6, respectively). No significant differences in GET, CTT, WGTT, and maximum gastric acidity between paraplegia and tetraplegia groups.
Fynne et al. 2012 Denmark Prospective controlled trial Level 2 N=34; N=19 with SCI	Objective: To study orocecal transit time and gastric emptying (GE) in patients with SCI. Population: N=19 with SCI; median age 54 y; median time since injury 75 months (range 10-528); 7 complete, 12 incomplete; 8 level of injury above T6; 3 ASIA A, 3 ASIA C, 2 ASIA D 11 at the conus medullaris or cauda equine (3 ASIA A, 4 ASIA B, 2 ASIA C, 2 ASIA D) N=15 non-SCI; median age 32 y	 The magnetic pill reached cecum in only 3/19 participants with SCI during the 6-hour protocol vs. 11/15 in the control group (p<0.001). Median orocecal transit time was > 360 min in people with SCI vs 340 min in the control group (p<0.001). Orocecal transit time was prolonged in people with low SCI (p<0.01) and high injury (p<0.01) compared to people in the control group.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Treatment: Subjects ingested a small magnetic pill that subsequently was tracked by the Motility Tracking System - MTS-1 (Motilis, Lausanne, Switzerland). Outcome Measures: Ingested magnetic pill was tracked by the Motility Tracking System to measure orocecal transit time, and bowel motility patterns.	4. No significant difference in gastric emptying between people with SCI (median 35 min, range 10-232) and the control group (median 25 min, range 1-135) (p=0.60). Frequency of gastric contractions was the same for people with SCI and the control group (median 2.9 per min range 2.7-3.1, median 2.9 per min range 1.7-3.2, respectively; p=0.30). Basic frequency of small intestinal contractions was the same in SCI (median 10/min, range 10-15) and the control group (median 10/min, range 9-11) (p=0.30).
Krogh et al. 2000 Denmark Prospective controlled trial Level 2 N=26; N=10 SCI	Objective: To compare total gastrointestinal transit times (GITT) and segmental colorectal transit times (CTT) in SCI patients with acute and chronic lesions to those of healthy volunteers. Furthermore, to examine the impact of time elapsed since injury on GITT and CTT, and finally to compare the pattern of colorectal dysfunction in patients with supraconal versus conal/cauda equina lesions. Population: N=10 SCI (6 men, 4 women, age 21-57y, median 36 y); all had lesions of the conus medullaris (n=8) or the cauda equina (n=2); 1 motor/sensory complete, 9 motor/sensory incomplete; time since injury 3 mo-9y (median 4y); 8 traumatic injury, 2 disc prolapse N=16 non-SCI controls (10 men, 6 women, age 22-42y, median 30y) Treatment: Patients took 10 radioopaque markers on six consecutive days and an abdominal X-ray was taken on day 7. GITT and	 Median colorectal emptying during defecation was 81% of the counts within the rectosigmoid in controls vs. 27% of the counts within the rectosigmoid in people with conal/cauda equina lesions reporting normal defecation (n=6; p<0.001). Median antegrade transport was significantly different between the control group and conal/cauda equina lesion group reporting normal defecation without clysma (n=6) for the rectosigmoid (82% vs. 27%, respectively, p<0.001) and descending colon (38% vs 4%, respectively; p<0.02). The transverse and caecum/ascending colon did not show significant differences in median antegrade transport between the groups. The cumulated transit time of the segments was significantly longer in people with SCI (median 2.7 days; range 0.2-4.2 days) than the

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	CTTs were computed from the number of markers in the entire colorectum and in each colorectal segment respectively. Outcome Measures: Colorectal scintigraphy and radio-opaque markers to measure colonic transit times at defecation and through each colorectal segment; degree of colonic emptying	control group (median 0.7 days; range 0-1.4 days) (p<0.05).
Trivedi et al. 2016 UK Cohort Level 2 N=44; N=24 SCI	Objective: Supraconal spinal cord injury (SCI) and lower motor neurone spinal cord injury (LMN-SCI) cause bowel dysfunction; colorectal compliance may further define its pathophysiology. The aim of this study was to investigate rectal (RC) and sigmoid (SC) compliance and anorectal physiology parameters, in these subjects. Population: SCI N=24 18 complete SCI 8 complete SCI level above T5 10 Complete SCI level above T5 10 Complete SCI level below T10 Control Group: N=20 Female: 60% Age: 44 (23-78)y SCI group: individuals with supraconal SCI and bowel dysfunction were recruited. Median age (range): 45 (24-66)y Female: 41.7%. 13 individuals had LMN- Treatment: Staircase distensions were performed using a barostat.	 Three-way analysis showed that those with complete SCI level above T5 had significantly lower anal resting pressure (46±10 cmH₂O vs. 79±7 cmH₂O, P<0.05) compared to those with level below TIO and controls. Incomplete SCI participants had a similar relaxation amplitude to controls, whereas complete SCI led to a significantly greater reduction in percentage amplitude compared with both controls (p<0.01) and incomplete SCI (p<0.01). Three-way analysis between controls, complete, and incomplete SCI showed no differences in compliance. Analysis of complete SCI above T5 and below TIO revealed that those with SCI above T5 had higher RC compared with both controls and those with injury below TIO (p<0.05). Mean rectal compliance (RC) in SCI was significantly higher than in controls (p<0.05), and significantly lower in LMN-SCI than in controls (p=0.0021). SC was also significantly higher in SCI compared with controls (p=0.0021). Those with complete SCI

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Anorectal manometry, including rectoanal inhibitory reflex (RAIR) measurement, was performed in all. Outcome Measures: NBD bowel symptoms, rectoanal inhibitory reflex (RAIR), rectal (RC) and sigmoid (SC) compliance	level above T5 had a significantly higher SC than controls (p<0.01). No significant difference in SC between LMN-SCI and control groups.

Discussion

A comprehensive assessment of NBD after SCI is used to understand an individual's bowel function, prevent the progression of complications, and plan for proper interventions and management techniques (CSCM, 2020). The clinical diagnosis is done through a physical examination including anal tone, sensation, voluntary contractions and reflexes, and combined with patient history is usually enough to inform treatment, however other times, more sophisticated diagnostics are wanted.

Prolonged colonic transit time related to defecation disorders can be identified using wireless motility capsules, radio-opaque markers, and scintigraphy (CSCM, 2020; Alexander et al., 2009). Scintigraphy involves the administration of radionuclide and image capture of the abdomen using a gamma camera (CSCM, 2020). With this method, Krogh et al. (2002) found differences in the degree of colorectal emptying between controls (N=16) and people with conal/cauda equina lesions who reported normal defecation (N=6) (53% of the rectosigmoid vs. 0-44%, respectively, p<0.001). Findings also showed that the cumulated transit time was significantly longer in people with SCI (median 2.7 days; range 0.2-4.2 days) than in the control group (median 0.7 days; range 0-1.4 days; p<0.05) (Krogh et al. 2002). The distribution and passage of ingested radio-opaque markers throughout the colon segments are tracked to measure colonic transit time (CSCM, 2020; Krogh et al. 2002). Another study found that people with SCI who reported constipation symptoms had more retained markers than those who did not report symptoms (mean markers 49 vs 22, respectively, p=0.007) (Emmanuel et al. 2009).

Wireless motility capsules may be a useful and inexpensive alternative to gaining information about bowel motility patterns, such as gastric emptying times, small intestine transit, and total colorectal transit (CSCM, 2020; Tate et al. 2023). By using Smart Pill capsules, Williams et al. (2012) found that between the SCI and non-SCI groups, gastric emptying time (10.6±7.2 vs 3.5±1.0h, p<0.01), colonic transit time (52.3±42.9 vs 14.2±7.6 h, p=0.01), and whole gut transit time (3.3±2.5 vs 1.0±0.7 days, p<0.01) were prolonged in the SCI group. Similarly, Fynne et al. (2012) measured bowel motility patterns with a magnetic tracking pill and observed longer orocecal transit times in people with low SCI (p<0.01) and high SCI (p<0.01) compared to non-

SCI controls. Although, they reported no significant difference in gastric emptying between people with SCI and the non-SCI controls (p=0.60) (Fynne et al. 2012). Abdominal radiography can also aid in identifying the presence and degree of stool in the colon and the colonic segments. Four scoring methods exist to assess severity of fecal loading on abdominal radiographs in constipated patients (Barr-, Starreveld-, Blethyn- and Leech scores). Park et al. (2013) analyzed fecal loading from radiographs in people with SCI and found there was a positive correlation between these scores and total colon transit time (Starreveld score (p<0.05) and Leech score (p<0.01)).

Physiological procedures such as anorectal manometry, determining resting and squeeze pressure, and anorectal sensibility testing can provide good diagnostic information (<u>Alexander et al., 2009</u>). <u>Trivedi et al. (2016</u>) found that people with SCI had higher rectal and sigmoid compliance than controls (p<0.05 and p=0.002, respectively) which may contribute to constipation symptoms. With a balloon expulsion test, anal manometry can help detect defecation disorders related to pelvic floor dysfunction in incomplete SCI and quantitative measures of rectal volume sensations/anorectal pressure during rest and squeeze (<u>Tate et al. 2023</u>). Although, use of anorectal manometry may be limited by the extensive equipment required (<u>Alexander et al. 2009</u>).

Other tools studied in SCI include defecography and ultrasound, primarily used when anorectal manometry/balloon expulsion tests are inconclusive, or when anatomic causes of obstruction are suspected (CSCM, 2020; Tate et al. 2023). The American Gastroenterological Association (AGA) and American College of Gastroenterology (ACG) recommend the use of defecography, a radiological imaging procedure that instills barium into the anorectum under fluoroscopy, when anorectal manometry and balloon expulsion tests are inconclusive (CSCM, 2020). Two studies (Putz et al. 2020; N=20; Putz et al. 2017; N=20) demonstrate the safety and feasibility of 3T-MR defecography as a diagnostic tool in NBD constipation examinations for people with complete paraplegia; with this method, they found that anorectal parameters significantly differ between SCI and non-SCI groups. Lastly, Kim et al. (2016b) examined the use of ultrasound to measure rectal diameter and area in people with SCI and NBD. Findings showed that after defecation, these parameters were smaller in people with UMN bowel compared to those with LMN bowel.

Conclusion

A clinical physical examination and a detailed patient history are key to diagnosing type of NBD in people with SCI.

There is level 2 evidence (<u>Emmanuel et al. 2009</u>) that laser Doppler flowmetry can identify altered autonomic innervation, which was evident in people with injury above the level of sympathetic outflow to the gut (T5).

There is level 2 evidence (<u>Park et al. 2013</u>) that plain abdominal radiography can be used as a simple and convenient method to evaluate bowel dysfunction in people with SCI.

There is level 2 evidence (<u>Kim et al. 2016b</u>) that rectal ultrasound can be used to determine differences in rectal diameter and area for people with UMN and LMN bowels.

There is level 2 evidence (<u>Putz et al. 2020</u>) that MR-defecography can detect objective parameters related to bowel incontinence and pelvic floor dyssynergia in NBD.

There is level 2 evidence (<u>Putz et al. 2017</u>) that 3T MR-defecography is a safe diagnostic tool for the visualization of pelvic floor parameters in people with complete paraplegia.

There is level 2 evidence (Williams et al. 2012) that SmartPill technology can detect prolonged gastric emptying, colonic transit time, and whole gut transit time in people with SCI (compared to people without SCI), demonstrating a safe, non-invasive method for GI investigation.

There is level 2 evidence (<u>Fynne et al. 2012</u>) that orally ingested magnetic pill tracked by the Motility Tracking System (MTS-1) can identify prolonged colonic transit times and provide information about gastric emptying and small intestinal contractions.

There is level 2 evidence (<u>Krogh et al. 2002</u>) that colorectal scintigraphy can help identify differences in the degree of colorectal emptying between SCI and non-SCI individuals.

2 Predictors of Bowel Dysfunction Post-SCI and Resulting Quality of Life (QOL).

2.1 What factors predict or affect the extent of bowel dysfunction?

2.1.1 Level of Injury

The vertebral level (or level of injury) to the spinal cord often determines how much function or dysfunction a person with SCI will have. Bowel dysfunction generally presents in two forms: hyperreflexic (or "spastic") and areflexic (or "flaccid"). It is also often characterized as Upper Motor Neuron (UMN) bowel syndrome or Lower Motor Neuron (LMN) bowel syndrome.

A hyperreflexic bowel is due to an upper motor neuron injury usually above T12 (i.e., originates from a spinal cord injury above the conus medullaris which contains the sacral reflex centre). It is distinguished by the increased tone of the colon and anus. The anal sphincter remains contracted, which leads to difficulty for stool to exit out the body. If left unmanaged, constipation and severe fecal impaction can occur. Fecal incontinence (losing stool involuntarily) is still possible because rectal reflexes are still functional. These reflexes may be triggered by the presence of stool, a suppository, or enema, which can cause stool to be propelled out involuntarily.

The second form of bowel dysfunction, are flexic bowel, is due to a lower motor neuron injury usually below T12, such as an injury at the cell bodies of the conus medullaris or distal (sacral roots or cauda equina). Unlike a hyperreflexic bowel, an are flexic bowel features a flaccid sphincter and decreased activity of the intestines (distal to transverse colon) and the loss of rectal reflexes. The outcome of this is severe increase in transit time through the large intestine. The increased transit time and slow movement through the lower colon allows for excess fluids

to be absorbed from the stool, often leading to hard, difficult to evacuate stool, which in combination leads to severe constipation. On the other hand, loss of sphincter tone and voluntary control leads to incontinence.

2.1.2 Completeness of Injury

The completeness of an injury also plays a role in determining the extent of a bowel problem. For incomplete individuals, some sense of how full the rectal is may still be intact along with the ability to control the sphincter. Even so, bowel activity may be abnormal or weakened.

Table 2a. Predictors of Bowel Dysfunction and QOL

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Pavese et al. 2019 Europe Longitudinal Level 2 N=1250	Objectives: To derive and validate a model for predicting the achievement of independent bowel management, with reliable bowel movements and continence, at 1 year after traumatic SCI Population: N: Derivation: 1250 Validation: 186 Level (D/V grp): C1-C8: 617/88 T1-T12: 451/60 L1-L5: 147/19 S1-S5: 2/15 AIS A: 556/60 AIS B: 140/17 AIS C: 192/37 AIS D: 341/54 AIS E: 3/0 Etiology: Traumatic Age: 42.5 (17.6)/ 44.3 (18.3) Female: 20.3%/16.1% Treatment: N/A Outcome Measures: Independent bowel management with regular bowel movements and appropriate timing. ISNCSCI, SCIM II	 The first predictor identified was the ISNCSCI total motor score. The aROC of the simplified model, based on this single predictor, was 0.837 (95% CI: 0.815-0.859). A sensitivity analysis found the aROC was 0.820 (95% CI: 0.768 to 0.883). The second predictor was item 3a in SCIMs II and III. The addition of this second predictor to the first predictor conferred a small, but significant (P=.0035) increase in the predictive performance of the derivation cohort (aROC=0.848; 95% CI: 0.827-0.870). The validation cohort confirmed that both models had very high predictive powers. The aROC of the model based only on the total motor score was 0.817 (95% CI: 0.754- 0.881); the aROC of the model based on the 2 predictors—that is, the ISNCSCI total motor score and item 3a of the SCIM—was 0.836 (95% CI: 0.775-0.896). The addition of item 3a of the SCIM in the validation cohort did not significantly improve the model (P=.2315).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	and III scores.	4. Derivation group, at initial assessment 13.4% patients exhibited independent, efficient bowel management. Of these, 91.6% showed unchanged bowel management at 1-year follow-up. One year after SCI all 1250 participants showed independent, efficient bowel management.
Lynch et al. 2000 New Zealand Case-control Level 3 N=1135 (467 SCI)	Objectives: Describe the bowel function of SCI patients and compare this with a general community control group. Population: N=467 SCI, 668 control (CON) (47% response rate) Mean Age (range): SCI: 43.5 (15-89) CON: 45.3 (17-78) Median Time since Injury (IQR): + Female: SCI/CON (83/83) Study Duration: Treatment: N/A Outcome Measures: 1. Bowel function 2. Incidence of incontinence 3. Methods of defecation 4. QoL	 92.3% of CON were never affected by incontinence, compared with 43.9% SCI patients (P<0.0001). 8.1% of SCI patients always have their everyday lives affected by incontinence, compared with 0.4% of controls. SCI patients with complete injuries were more likely to have incontinence affect their lives (11.5% always affected) than those with incomplete injuries (4.7% always affected). SCI patients with higher injuries, either complete (P<0.0001) or incomplete (P=0.0002) required assistance more frequently than other SCI patients. 82.3% of those with complete high injuries required assistance, compared with 14.3% of those with complete lumbosacral lesions. Fecal incontinence was also higher for people with complete SCI vs. incomplete SCI. Incontinence affected quality of life for 62% of SCI patients, compared with 8% of controls.
Attabib et al. 2021 Canada Retrospective	Objectives: To examine factors associated with improvement in lower-extremity	Earlier rehab onset was the only significant predictor for more bowel improvement (p=0.005),

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Analysis Level 3 N=214	motor scores (LEMSs), as well as recovery in ability to walk and bowel and bladder function after TCEI (Traumatic cauda equina injury) Population: N=214 total, 92 had bowel/bladder data available Level: L1, L2, L3-S3 AIS A: 48 AIS B: 30 AIS C: 39 AIS D: 90 Etiology: Fall (n=102), Transport (58), sports (30), other (19) Mean Age at injury (SD): 39.9 +- 17.3 Median Time since Injury to surgery (IQR): 26.5 (53.0) % Female: 50 (23%) Treatment: Examined factors associated with recovery in motor strength, walking ability, and bowel and bladder function to aid in prognosis and establishing rehabilitation goals. Outcome Measures: 1. Motor score 2. Recovery in walking 3. Recovery in Bowel and bladder function	after adjusting for injury characteristics and time to surgery. 2. Voluntary anal contractions (VAC) at admission had significantly higher bowel scores. This resulted in smaller gains, as noticed by the change in bowel scores between VAC at admission and no VAC (VAC 1 vs VAC 5, p=0.0005). 3. Of the 87 patients with bowel dysfunction at rehabilitation admission, 24% had recovery (FIM = 7 on bowel subscore) at discharge. 4. Median change in both bowel and bladder score from admission to discharge was an increase of 4 points.
Khan et al. 2021 USA Case-control Level 3 N=277	Objectives: To predict independence in bowel function 1 year after SCI by evaluating the external validity of logistic regression models, developed on a multicenter European SCI (EMSCI) dataset, against a prospectively accrued North American SCI dataset. Population: N=277 patients derived from three prospective multicenter SCI studies	1. The simplified logistic regression model, using only Total Motor Score (UEMS + LEMS from ISNCSCI) had a positive predictive value of bowel independence at 1-year post-SCI of 89.3%, and a negative predictive value of 74.0% (aROC of 0.869 (95% confidence interval: [0.826,0.911]) with an accuracy of 81.2%, a sensitivity of 75.5%, and a specificity of 88.5%.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	based in North America. Level of injury: C1-C8: 198 (71.5%) T1-T12: 46 (16.6%) L1-L5: 12 (4.3%) S1-S5: 21 (7.6%) Severity of neurological deficit: AIS A: 80 (29.7%) AIS B: 32 (12.6%) AIS C: 34 (12.6%) AIS D: 110 (40.9%) AIS E: 11 (4.1%) Treatment: N/A Outcome Measures: The primary outcome measure of this study was independence in bowel function as defined by regular bowel movements requiring no assistance and fewer than 2 episodes per month of bowel incontinence. From the NACTN, STASCIS, and NASCIS III datasets, patients were included with functional data at baseline and 1-year post-injury, as assessed using the Spinal Cord Independence Measure (SCIM) and the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI). Two logistic regression models developed by the EMSCI group from Pavese et al. (2019) – simplified (total motor score UEMS and LEMS from ISNCSCI) and full (total motor score plus SCIM 3a – independence in upper body dressing). External validation was evaluated for both models by assessing their discrimination, calibration, and clinical utility. Discrimination and calibration were assessed using ROC	 The full logistic regression model, using Total Motor Score and SCIM 3a (independence in upper body dressing) had a positive predictive value of bowel independence at 1-year post-SCI of 84.8%, and a negative predictive value of 72.7%. The full model demonstrated an aROC of 0.864 (95% confidence interval: [0.822,0.906]) with an accuracy of 78.7%, a sensitivity of 75.5%, and a specificity of 82.8%. The calibration curve of the full model had a slope of 0.93 and an intercept of -0.46, while the the calibration curve of the simplified model demonstrated a slope of 1.13 with an intercept of 0.03, and unlike the calibration plot for the full model, displayed good calibration across the full range of observed probabilities). The difference in the calibration curve scores indicates that both the simplified model (using Total Motor Score and the SCIM Upper Body Dressing score) at good at predicting who will have bowel function independence at 1-year post-SCI. However, the simplified model is better at predicting those above the probability threshold. In other words, for people who are more likely to achieve independence in bowel function (i.e., at larger observed probabilities, the full model tended to overestimate the chances of complete independence in bowel function in bowel function).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	curves and calibration curves, respectively, while clinical utility was assessed using decision curve.	
Squair et al. 2019 Canada Survey Level 5 N=47,868	Objectives: To estimate the prevalence of bladder and gastrointestinal dysfunction in the SCI population, to compare their odds with the non-SCI population and to assess the relationship of lesion level and severity on the odds for experiencing bladder and GI dysfunction. Population: study used Population-level data from the Canadian Community Health Survey (CCHS) and the SCI Community Survey. N=47,868 Female: 50.3% Median age: 55 to 59 y Treatment: N/A Outcome Measures: Spinal Cord Injury Community Survey: Bowel dysfunction items were: "In the past 12 months have you experienced this problem—Constipation?"; and "In the past 12 months have you experienced this problem—Bowel incontinence?" Each outcome was scored on a 0 to 5 scale ranging from "Never" to "Every day".	 SCI was associated with increased odds of bowel disorders (aOR = 2.3, CI: 1.5–3.4), as well as gastric ulcers (aOR: 3.3, CI: 2.1–4.8), even after adjusting for key confounding variables. Complete SCI was associated with increased odds of bowel incontinence (aOR=2.1, CI: 1.7–2.6).
Dietz et al. 2021 USA Retrospective Observational Level 5 N=11,131	Objective: To understand the changes in bowel management needs over time following SCI Population: N=17,492 with known bowel management N=11,131 included those who had at least 1 follow-up visit at 5, 10, 15, 20 and 25 years post discharge	1. At the time of discharge from inpatient rehabilitation, the majority of individuals required total assistance (38.8%), whereas those with complete independence with bowel care represented a minority of the sample (10%). Participants in the total assistance category predominantly sustained an

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Age: 45.5% 15-19 yrs 28% 30-44 yrs 17.8% 45-59 yrs 8.8% 60+ yrs Level 48% Cervical 36% thoracic 10% lumbar 0.3% sacrum 0% normal 5.7% unknown AIS: 45.7% A 12.2% B 14.5% C 24.1% D 0% E 3.5% Unknown 47.5% paraplegia 49.5% tetraplegia 0% normal 3% unknown Female: 20.7% Treatment: N/A Outcome Measures: Degree of independence with bowel management from discharge and across time	injury at the cervical spinal cord level (p < .0001). 2. At 5 years, the majority of participants' functional bowel management classification had shifted to modified independence (34.7%) (p<.0001). Prevalence of modified independence classification remained statistically comparable at 10 (p=.9797), 15 (p=.6730), 20 (p=.2216), and 25 (p=.0975) years after discharge. 3. Shift in bowel management was more likely to occur within the first 5 years after SCI (p<0.0001). After 25 years, the distribution in those groups was statistically comparable to the 5-year distribution (p>.05). 4. The largest shift in bowel management occurred in participants who required minimal contact assistance (most classified as AIS A and paraplegia, toward a less dependent bowel management strategy that persisted throughout the 25-year follow up).
Stoffel et al. 2021 USA Cross sectional Level 5 N=1,373	Objective: To identify variables associated with severe bowel symptoms in spinal cord injured people. Population: Age: 44 (13) yrs Female: 40% ASIA: 26% A, 16% B, 11% C, 3% D, 0.3% E, 31% unknown	1. Severe bowel symptoms were reported in 570 (42%) On multivariable logistic regression, every point increase of AD total score was associated with 5% increased odds of having more severe bowel symptoms [OR 1.05 95% CI 1.03–1.10].

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Level of injury: 5% high cervical, 39% low cervical, 20% high thoracic, 27% low thoracic, 9% lumbar/sacral Years since injury: 14 (11) yrs Treatment: N/A Outcome Measures: Bowel symptoms were assessed by the Neurogenic Bowel Dysfunction (NBD) score and patients scoring ≥14 was categorized as having severe bowel symptoms. Autonomic dysreflexia (AD) severity was measured using a six-item questionnaire and reported as total AD score (0–24). Bladder management was categorized as: voiding, clean intermittent catheterization (CIC), surgery (augmentation/diversion) or indwelling catheter.	2. SCI people with indwelling catheters (OR=2.16, 95% CI 1.40–3.32) or reconstructive surgery (OR=1.79, 95% CI 1.08–3.32) were almost twice as likely to report more severe bowel symptoms than those performing CIC.
Jiang et al. 2019 North America Cohort Level 2 N=801	Objective: To assess the prevalence of adverse events after traumatic SCI and to evaluate the effects on long-term clinical outcome Population: N=801 Female: 22% Median age (IQR): 46 (29-59) years Etiology: 39.8% fall 37.5% motor vehicle accidents 6.1% other Severity: 37.6% AIS A 11.7% AIS B 14.7% AIS C 28.5% AIS D 7.5% AIS E Level: 70.9% cervical	 In adjusted analysis accounting for age, injury severity and level, acute AEs were found to be an independent predictor for rectal sphincter function (OR, 7.86; 95% CI, 4.31–14.32) at 6 months postinjury. There were 2,303 recorded acute AEs; the most prevalent AEs were: pneumonia (218 occurrences, 9.5% of all recorded AEs), respiratory failure (207; 9.0%), anemia (197; 8.6%), urinary tract infection (139; 6.0%), pleural effusion (92; 4.0%), bradycardia (93; 4.0%), depression (89; 3.9%), and sacral ulcers (72; 3.1%). AIS score was a predictive factor of a higher incidence of secondary adverse events in multivariable analysis (p< 0.001; ORs vs. AIS D = AIS C 2.13 (1.40–3.24); AIS B 3.25 (2.18–4.85), AIS A 4.70 (3.52–6.27).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	22.3% thoracic 6.7% lumbar/sacral Treatment: N/A Outcome Measures: ISNCSCI examinations, Functional Independence Measure (FIM), Spinal Cord Independence Measure (SCIM) Version 2, and the Walking Index for SCI measures Adverse Events measured: Included multiple events as classified by system – Respiratory, Cardiac Arrhythmias, Infectious, Gastrointestinal, Renal, and Neuropsychiatric.	
Elmelund et al. 2019 Denmark Cross-sectional Level 5 N=684	Objectives: Investigate the prevalence of, and conditions associated with, fecal incontinence in women with SCI. Population: N=684 Level: AIS A: 32 AIS B: 18 AIS C: 50 AIS D: 354 AIS E: 3 Cervical: 224 Thoracic: 173 Lumbar: 76 Sacral: 12 Etiology: Traumatic (sports, assault, transport, fall, other cause), nontraumatic (congenital, degenerative, benign tumor, malignant tumor, vascular, infection, other) Mean Age: 54.6 ± 19.8 % Female: 100%	 Of 436 women, 21% presented with normal bowel function, 79% had some neurogenic bowel dysfunction. 433 received treatment with chemical stimulants, oral laxatives, or surgical treatment. Of 599 women, 210 had experienced fecal incontinence (FI) within the last 3 months, 125 (21%) experienced on average daily-to-monthly FI. Digital evacuation/stimulation was associated with a higher risk of FI monthly (p=0.002), compared with no digital evacuation/stimulation. >=3 defecations/day & chemical, medical, or surgical treatment was associated with higher risk of daily-to-weekly FI compared with less frequent defecation (p=0.0003). Most prominent risk factor of FI was myelomeningocele compared with other etiologies

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Treatment: N/A Outcome Measures: Bowel function, urinary bladder function, QOL, neurologic level/completeness/ etiology of injury, mobility status, and spousal relationship	(OR=5.17). 6. FI was significantly associated with permanent use of wheelchair compared with no walking aids (p<0.0001 and p=0.04), a more complete paraplegic injury compared with a less complete injury at any level, follow-up after injury <3 months (p<0.0001 and p=0.004) and increasing age (p=0.03).
Pazzi et al. 2021 USA Cross-sectional Level 5 N=364	Objectives: To determine the goals of people with SCI who are considering experimental therapies – a) whether sociodemographic factors, injury-specific characteristics and concerns over adverse events influence those goals and/or participation in experimental therapies and clinical trials; and (b) whether people with SCI feel they have adequate information about experimental therapies and clinical trials. Population: N=364 Age: 15.2% 18-34 y 26.9% 35-49 y 56.2% 50-74 y 1.7% 75 or older y Level: 48.7% cervical 40.6% thoracic 10.7% lumbar/sacral Time since injury: 19.3% under 5 years 25.1% 5-10 years 33.9% 10-28 years 21.6% 30+ years Female: 36%	 The most frequently cited functional goals were improvement in bowel and bladder function and elimination of dysreflexia (60.4%). Most respondents (83.7%) had sought information about experimental therapies, and just under half (47.8%) had received one. Several goals were influenced by age and level and completeness of injury, and most respondents (93.4%) wanted more information about experimental therapies.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Treatment: N/A Outcome Measures: Survey asking people with SCI sociodemographic questions, injury characteristics and their goals for function as well as perspectives on participating in clinical trials/experimental therapies.	
Tate et al. 2016 North America Cross-sectional Level 5 N=291	Objectives: To assess the factors associated with methods of bowel management and bowel-related complications; and to determine the risk factors associated with bowel complications and overall bowel dysfunction. Population: N=291 Level (%): Incomplete paraplegia: 12.7 Complete paraplegia: 32.0 Incomplete tetraplegia: 26.1 Complete tetraplegia: 29.2 Etiology: Traumatic Age (mean): 50.7 +- 12.5 Time since injury (mean): 20 +- 10.5 yrs Female (%): 26.1 Treatment: N/A Outcome Measures: The Bowel and Bladder Treatment Index (BBTI), Fecal Incontinence Severity Index (FISI), Neurogenic Bowel Dysfunction Score (NBD) and self-report of constipation or incontinence, etc.	 Increased likelihood of incontinence was associated with not having a colostomy or ileostomy (p<.05); not being married or having a significant other (p<.05); timing of one's bowel program to occur at a regular time (p=.005); being able to delay defecation (p<.05); presence of constipation (p<.05); higher NBD scores (p<.0005); increased frequency of urinary incontinence (p<.05); and higher consumption of diuretics (p<.05). The model for constipation had a chi-square of 135.656 and Nagelkerke R²=.510. Factors associated with being less likely to have constipation included younger age (p=.05); race/ethnicity (p<.05), with whites being less likely to have constipation than blacks (p<.005); incomplete tetraplegia versus complete tetraplegia (p<.05); having normal defecation (p=.01); and less frequent bowel movements (p<.0005). Conversely, having a history of bowel surgery (p<.05); using laxatives, medications, or both, as a main method (p<.0005); receiving caregiver services (p<.05); and experiencing more frequent abdominal pain (p<.005) were all

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
		associated with constipation. 4. The model for bowel dysfunction has an F statistic of 9.590 and an adjusted R²=.265 Having incomplete paraplegia (p<.05), complete paraplegia (p<.01), or incomplete tetraplegia (p<.05) were all associated with less bowel dysfunction, as were whether participants used laxatives/oral medications as a main method of bowel management (p<.05), had higher fiber intake (p<.05), and lower scores on the FISI (p<.0005).
Liu et al. 2010 Taiwan Cross-sectional Level 5 N=232	Objective: To analyze the predictors of severe neurogenic bowel dysfunction (NBD) in persons with spinal cord injury (SCI). Population: N=232 (142/61% responded) Level: AIS 38 A, 34 B, 33 C, 37 D Etiology: vehicular accidents (42.9%), falls (28.2%), sports (6.3%) and violence (3.5%). others (19.1%) Age: Mean 45.2 years; Range 18 - 84 years Duration: 1–2 years - 42 3–5 years - 31 6–9 years - 23 >10 years - 46 % Female: 25.4 Treatment: N/A Outcome Measures: NBD score, Beck Depression Inventory, demographic factors, and injury-related factors	 Multiple logistic regression analysis showed that those with a cervical injury (odds ratios (OR 10.5, 95% CI 1.6–67.7) or a thoracic injury (OR 7.1, 95% CI 1.2–40.3) had a higher risk of severe NBD than those with a lumbar injury. People with American Spinal Injury Association Impairment Scale (AIS) A had a 12.8-fold higher risk of severe NBD than persons with AIS D (OR 12.8, 95% CI 3.3–50.1). Longer duration of injury (>10 years) was another risk factor of severe NBD. Moderate-to-severe depression was associated with reduced bowel function.
Adriaansen et al. 2015 Netherlands	Objectives: Aim of the current study was to describe long-term bowel management and NBD in individuals who have been living with an SCI for	Participants using surgical bowel management were significantly older (p=.008) and had a significantly longer TSI (p=.002)

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Cross-sectional Level 5 N=258	at least 10 years in The Netherlands Population: N=258 Level (%): AIS A: 70% AIS B: 12% AIS C: 9% AIS D: 9% Etiology: 90% traumatic Mean Age (range): 48 (29-65) Mean time since Injury (range): 24 (10-47) % Female: 27 (%) Treatment: N/A Outcome Measures: 1. Bowel management and bowel problems using international SCI bowel function data set 2. Constipation (Rome III criteria) 3. Bowel management (spinal cord independence measure) 4. Satisfaction 5. NBD score	than those using TAI. They also had longer TSI than those using a conservative bowel management method (p=.002). 2. 36% of the participants suffered from severe NBD. Participants with severe NBD decreased over time from 44% to 26%, and an increase in TSI was significantly correlated with a decrease in the total NBD score (p=.003). 3. Severe NBD was also positively associated with completeness of the lesion (p=.010) and was negatively associated with increasing age (p=.038). 4. Severe NBD as the dependent variable showed that completeness of the lesion (OR=1.98, p=.046), use of suppositories (OR=4.02, p<.001), and digital evacuation (OR=2.40, p=.003) were significant predictors of severe NBD. 5. Dissatisfaction with bowel management was associated with having perianal problems (p=.005), constipation (p=.001), and severe NBD (p<.001). 6. Satisfaction with bowel management as the dependent variable showed that constipation (OR=3.16, p=.003) and severe NBD (OR=3.53, p=.001) were significant predictors of dissatisfaction with bowel management.

Table 2b. Quality of Life

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Khadour et al. 2023 China Observational Level 5 N=294	Objective: This study aimed to describe the bowel programmers utilized by people with SCI in China and the impact of bowel dysfunction on the quality of life (QoL). Population: The two questionnaires were sent to 413 SCI patients. Two hundred ninety-four participants (43.1±14.5 years of age; men, 71.8%) responded. Treatment: N/A Outcome Measures: A neurogenic bowel dysfunction (NBD) score is a questionnaire developed to evaluate the severity of neurogenic bowel dysfunction. A Short Form-12 (SF-12) was designed to measure the quality of life in people with SCI. Demographic and medical status information was extracted from their medical records.	1. This study found a significant association between the QoL score and the time used for each defecation, autonomic dysreflexia (AD) symptoms, taking medication to treat fecal incontinence, using digital stimulation, having uncontrollable flatus and perianal skin problems.
Gong et al. 2021 China Cross-sectional Level 5 N=101	Objective: To determine the aspects of excretory dysfunction most influential in determining the quality of life of survivors of spinal cord injury. Population: N=101 Female: 25.4% Age: 40.5 ± 15.27 years	 The results of the univariate analysis showed that patients with traumatic SCI, sacral injury, or cauda equina syndrome, suffering bladder or bowel accidents (p<0.001), with more than one bladder or bowel complication (p<0.001), and those with an NBDS ≥14 (p<0.001), reported poorer QOL. The results of the linear regression analysis showed that poor excretion-related QOL was associated with bowel accidents (β=12.280, 95% confidence interval: 5.479–19.081).

61.4% 18-45 y 26.7% 46-60 y 11.9% 61-90 y Level: 28.7% cervical, 48.5% thoracic 8.9% lumbar. 13.9% sacral and CES Severity: 39.6% complete, 60.4% incomplete Etiology: 83.2% traumatic; 16.8% non-traumatic Treatment: N/A **Outcome Measures:** Questionnaire asking re: demographic characteristics: gender, age, level of education, marital status, and employment status. The injury's etiology, severity, level, and the time since the injury were extracted from the patient's medical records. **Objectives:** To describe the 1. Time to complete current bowel care relationships between bowel routine (p<.001) and severity of AD symptoms during bowel care (p=0.036) care, AD, and QoL in people were the only significant predictors of with SCI. QOL after adjusting for confounds. Population: 2. Secondary predictors of QOL were level of injury (p=0.027), number of bowel N=287 (73%completion rate, Inskip et al. 2018 management approaches used to n=210) complete bowel care (p=0.001). Canada Level: 3. Fatigue and number of bowel Cross-sectional management approaches use (p<.001) Cervical: 45% best predict severity of AD symptoms Level 5 experienced during bowel care. Thoracic: 45% 4. Bowel had a more significant impact on N=287 Lumbar: 9% OOL than effects of sex dysfunction (p=0.024), bladder dysfunction (p<.0001), Sacral: 1% pain (p=0.013), spasticity (p<.0001), using a wheelchair (p<.0011), and skin integrity Complete: 30% issues (p<.0001). Mean Age (SD): 49.2 <u>+</u> 13.2 Mean Time since Injury (SD):

	17.1 <u>+</u> 12.9 years	
	Treatment: N/A	
	Outcome Measures:	
	1. Bowel management	
	2. QoL	
	3. Cardiovascular symptoms	
Pires et al. 2018 EU Cross-sectional N=64	Objective: To assess the impact of bowel dysfunction on ICF domains and QoL in SCI people.	 50.1% of participants had moderate or severe bowel dysfunction. The greatest impact in ICF domains was personal and environmental factors (39.1% financial costs, 45.3% in need of assistance, 45.3% emotional health, 46.9% loss of privacy). There is a strong association between negative impact on QoL and severity of bowel dysfunction (p<0.05).
	Population:	
	N=64	
	Level: 39.1% cervical, 39.1% thoracic, 21.9% lumbar, AIS 39.1% A 12.5% B 17.2% C 13.3% D	
	Etiology: 71.9% traumatic, 28.1% non-traumatic	
	Age: Mean 56.6 years, SD 15.6 years, Range 24-91 years	
	Duration: 6.9 years	
	% Female: 34.4%	
	Treatment: N/A	
	Outcome Measures: demographic data, lesion characteristics, bowel management methods currently and at last inpatient discharge, Neurogenic Bowel Dysfunction Score, impact on ICF domains and QoL	
<u>Liu et al. 2009</u>	Objective: To assess the	1. Approximately half of the persons with
Taiwan	relationship between the severity of neurogenic bowel	spinal cord injury (46.9%) had moderate to severe degrees of neurogenic bowel
Cross-sectional	and health-related quality of life in persons with spinal cord	dysfunction. Bowel dysfunction caused
Level 5	injury.	major restrictions in social activities and in the QoL in 39% of persons with SCI.
N=128	Population:	Severity of NBD across neurological classifications varied significantly, that is

N=128 (~60% response rate)

Level: 36 tetraplegia ASI A, B, C (28.1%), 58 persons had paraplegia ASI A, B, C (45.3%), and 34 persons had paresis AIS D (26.6%).

Etiology: vehicular accidents (56.3%),

falls (25.8%), sports (3.1%), violence (3.1%) or other causes (11.7%)

Age: Mean 48.3 years, Range 13 – 84 years

Duration: 1–2 years (32.1%), 3–5 years (21.9%), 6–10 years (16.4%) and over 10 years (29.6%).

% Female: 25.8% None

Complications: 24 had a highlevel cord injury and needed help filling in their answers.

Source: 214 persons with an International

Classification of Diseases-9 (ICD-9) diagnosis of SCI, who were admitted to the rehabilitative department of a medical centre in

southern Taiwan between 2002 and 2006

Treatment: N/A

Outcome Measures: Short-Form 36 (SF-36) and NBD score.

people with higher AIS motor scores had more NBD (p=0.001).

3. There is a significant relation between the NBD score and physical functioning (r=-0.70, p<0.001) and the Physical component score of the SF-36 (r=-0.58, p<0.001).

Braaf et al. 2017

Australia Qualitative

N=22

Objective: To describe the experiences of bowel and bladder dysfunction on social activities and relationships in people living in the community with SCI.

Population: N=22

Altered social relationships:

- The constant need to manage bladder and bowel issues negatively impacted on the initiation and conduct of social relationships.
- 2. Participants perceived themselves as a "burden" because of their loss of

Level: Paraplegia (complete & incomplete): 7; Tetraplegia (complete): 8; Tetraplegia (incomplete): 7

Etiology: Transport: 11; Sport and recreational injuries: 5; other including farming accidents, falls or acquired injury: 6

Age (mean, SD): 51.9 (12.9)

Duration of Injury:

<=15 yrs: 10

>15 yrs: 12

Female: n=6

Treatment: N/A

Outcome Measures:

Interview topics:

- 1. Problem and methods of bladder/bowel management
- 2. Barriers and facilitators
- 3. Social, community, emotional and financial impacts

independence in managing bowel and bladder function. The need for assistance with bladder management systems and dealing with incontinence negatively impacted some close personal relationships.

Keeping it personal to support social relationships:

- Despite the considerable impact of bowel and bladder dysfunction on their daily lives, information about this issue (incontinence) was only shared with friends and family if participants perceived it to be necessary
- 2. While desiring privacy, participants also wanted greater understanding from friends about such SCI issues

Lack of adequate bathrooms is a social barrier:

 Social interaction outside the home was affected by available bathroom facilities. Significant uneasiness arose for participants when access to bathrooms was restricted, such as in private residences.

Social support and networks promote social participation:

- Social activities were facilitated when participants had good social support (such as physical and emotional), as bowel and bladder dysfunction were perceived to be more manageable.
- 2. Inadequate carer support was reported as a major barrier to social engagement outside the home

Moderated social activities:

- Participation in social activities was profoundly reduced and disrupted by illness, stomach upsets, routines for regular bowel function and stress and anxiety about managing outside the home
- 2. Daily routine Routines to manage bowel dysfunction were reported to be

- inflexible and time consuming. Strict bowel routines did not guarantee reliable attendance at social occasions.
- 3. Stress & anxiety Most participants described embarrassing situations when management of their bowel and bladder dysfunction had failed, causing stress & anxiety. Negative emotions and a reduced enjoyment of social activities resulted from concerns of bowel/bladder dysfunction. To alleviate stress and anxiety, participants limited their travel to familiar local areas, reduced the number of activities in which they engaged, and developed a preference for staying at home.
- 4. Changing plans Many participants went into social isolation when experiencing frequent episodes of illness. Even when feeling well, participants could not guarantee their presence at social events.

Adaptation for social engagement:

- Although the management of bowel and bladder dysfunction consistently raised challenges for participation in social activities, some participants reported making psychological and lifestyle adjustments to minimize their impact.
- Acceptance Reaching acceptance entailed a positive attitude, prioritization of activities, formulating a plan to manage the problem and being flexible with social plans.
- Modified diet To reduce the anxiety, stress and embarrassment associated with unplanned bowel actions, participants reduced their intake of food, consumed specialized diets, and confined their meals to a certain time of day.
- Planning Some participants made plans to reduce potential issues or to be prepared to deal with problems should they arise.

Home - To balance the complexities of

	managing bowel and bladder dysfunction in the built environment, with the desire to participate in social activities, some participants preferred people to visit them in their home environment.
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Neurogenic Bowel Dysfunction (NBD) is common in people with SCI; estimates range from 30-95% of people with SCI having some kind of bowel dysfunction, with approximately half (40-50%) having moderate to severe degrees of NBD (Elmelund et al. 2019; Stoffel et al. 2021; Liu et al. 2009; Liu et al. 2010).

Some research shows that level of injury can predict bowel outcomes post-SCI. <u>Liu et al. (2009</u>; N=128; 2010; N=142) reported that the risk of having severe NBD was approximately 13 times greater in people with SCI scored AIS A compared with AIS D. <u>Liu et al. (2010</u>; N=232) similarly found that those with a cervical injury (odds ratio (OR 10.5, 95% CI 1.6–67.7) or a thoracic injury (OR 7.1, 95% CI 1.2–40.3) had a higher risk of severe NBD than those with a lumbar injury. <u>Lynch et al (2000</u> N=467 SCI, 668 control) also reported that the higher the level of injury, the more often people with SCI will require assistance or care (p≤0.0002).

People with complete SCI are also approximately 2x more likely to have severe NBD than those with incomplete SCI (p=0.01) (aOR=2.1, CI: 1.7–2.6 - Squair et al. 2019; N=47,868; OR=1.98, p=0.046 - Adriaansen et al. 2015; N=258). Tate et al. (2016; N=291) found paraplegia (complete and incomplete) and incomplete tetraplegia to be significantly (all p≤0.05) associated with reduced bowel dysfunction. Lynch et al. (2000; N=467 SCI, 668 control) also found that incontinence was more likely to affect the life of a person with SCI if they had a complete injury.

Other research shows additional factors that can predict bowel dysfunction in people with SCI. Pavese et al. (2019; N=684) and Khan et al. (2021; N=277) found that the ISNCSCI exam total motor score could predict independent bowel function 1-year following SCI with more than 80% accuracy (Pavese et al. 2019; N=167; Khan et al. 2021; N=277; aROC 0.864-0.869). Elmelund et al. (2019; N=684) found three key components that were associated with fecal incontinence in SCI: wheelchair use compared with walking without aids (p<0.0001 and p=0.04), completeness of the paraplegic injury (p<0.0001 and p=0.04), and increased age (p=0.03).

Understandably, NBD and the need to manage bowel issues may cause significant stress and anxiety and has a negative impact on people with SCI, and on their quality of life (QoL) (Braaf et al. 2017). Social interaction outside someone's own home is often limited by limited or inaccessible bathroom facilities (Braaf et al. 2017). Inskip et al. (2018) found that NBD had a more significant impact on QOL than sexual dysfunction (p=0.024), bladder dysfunction (p<.0001), pain (p=0.013), spasticity (p<.0001), using a wheelchair (p<.0011), and skin integrity issues (p<.0001). Research also shows that people with SCI are 1.8x more likely to be unemployed, and that 54-70% of people with SCI and bowel dysfunction say it affects their social life and relationships (Inskip et al. 2018). Pazzi et al. (2021; N=354) found that people with

SCI most often cite improvement in bowel/bladder function and elimination of dysreflexia (60.4%) when asked about their functional goals. Conversely, other research shows that satisfaction with bowel care programs is reported to increase QoL in people with SCI, as does having adequate social and/or carer support (Braaf et al. 2017).

Conclusion

There is level 2 evidence that (<u>Pavese et al. 2019</u>) ISNCSCI total motor score could predict independent, reliable bowel management at one year after SCI for 81-84% of participants.

There is level 2 evidence (<u>Jiang et al. 2019</u>) that people who experience adverse events within six months post traumatic SCI were more likely to have bowel function impairment.

There is level 3 evidence (<u>Attabib et al. 2021</u>) that a shorter time from injury to rehab admission was a significant predictor for improved bowel function.

There is level 3 evidence (<u>Lynch et al. 2000</u>) that incontinence was more likely to affect the life of a person with SCI if they had a complete injury. They also reported that the higher the level of injury (incomplete and complete) the more often assistance is required ($p \le 0.0002$).

There is level 5 evidence (<u>Squair et al. 2019</u>) that SCI is associated with increased odds of bowel disorders and gastric ulcers, with complete SCI being associated with increased odds of bowel incontinence.

There is level 5 evidence (<u>Elmelund et al. 2019</u>) that daily to monthly bowel dysfunction was more commonly associated with permanent use of a wheelchair, a more complete injury, increasing age, and injury follow-up of less than three months.

There is level 5 evidence (<u>Tate et al. 2016</u>; <u>Adriaansen et al. 2015</u>) having incomplete paraplegia (p<.05), complete paraplegia (p<.01), or incomplete tetraplegia (p<.05) were all associated with less bowel dysfunction.

There is level 5 evidence (<u>Liu et al. 2009</u>; <u>Liu et al. 2010</u>) that NBD is common in people with SCI (30-95% have some kind of bowel dysfunction) and that odds for severe NBD are up to 13x greater for people with AIS A vs. AIS D, 10x greater for people with cervical injuries, and 7x greater for people with thoracic injuries vs. those with lumbar injuries.

There is level 5 evidence (<u>Dietz et al. 2021</u>) that bowel management is more likely to change within the first five years after SCI.

There is level 5 evidence (<u>Pazzi et al. 2021</u>) that bowel function improvement is among the most common functional goals for people with SCI seeking experimental therapies. These goals may be influenced by age, level, and completeness of injury.

There is level 5 evidence (Gong et al. 2021) that patients with traumatic SCI, sacral injury, or cauda equina syndrome who suffer bladder or bowel accidents (p<0.001), with more than one bladder or bowel complication (p<0.001), and those with an NBDS \geq 14 (p<0.001), reported poorer QOL.

There is level 5 evidence (<u>Stoffel et al. 2021</u>) that almost half of people with SCI experience severe bowel symptoms, which may be associated with more severe autonomic dysreflexia, having an indwelling catheter, or reconstructive surgery.

There is level 5 evidence (<u>Inskip et al. 2018</u>) that bowel dysfunction had a more significant impact on QOL than effects of sex dysfunction (p=0.024), bladder dysfunction (p<.0001), pain (p=0.013), spasticity (p<.0001), using a wheelchair (p<.0011), and skin integrity issues (p<.0001).

3 Neurogenic Bowel Dysfunction and Management

The colon and anorectum are innervated by the sympathetic and parasympathetic autonomic nervous system with somatic innervation to the external sphincter as shown in Figure 1. Disrupted autonomic control of the gastrointestinal (GI) tract is one of the primary causes for neurogenic bowel dysfunction, leading to delayed gastric emptying (Leduc et al. 2002; Gondim et al. 2001; Menter et al. 1997; Rajendran et al. 1992; Fealey et al. 1984) and poor colonic motility (Lynch & Frizelle 2006; Fajardo et al. 2003). This results in prolonged bowel transit time (Brading & Ramalingam 2006; Krogh et al. 2000; Stone et al. 1990a; Lynch et al. 2001), constipation (Faaborg et al. 2008; Finnerup et al. 2008; Lynch et al. 2000), and postprandial (after eating a meal) abdominal distension (Stone et al. 1990a). Left unmanaged, people with neurogenic bowel dysfunction will experience profound constipation and fecal impaction as effective spontaneous evacuation does not occur. In addition, lost or impaired anorectal sensation and loss of somatic voluntary motor control of the external sphincter can lead to unpredictable fecal incontinence. The neurogenic changes are compounded by reduced mobility, polypharmacy, and poor dietary intake.

The gastrointestinal tract has an enteric nervous system divided into the submucosal (Meissner's) and myenteric (Auerbach's) plexuses. The enteric system controls gut secretions, blood flow, and muscular activity giving the colon its inherent ability to produce peristalsis. While the autonomic and somatic neural input is disrupted in SCI, the enteric system remains intact.

There are two general patterns in the clinical presentation of bowel dysfunction: injury above the conus medullaris results in upper motor neuron (UMN) bowel syndrome while injury of either the cell bodies within the sacral reflex centre of the conus medullaris or damage to the nerve roots of the cauda equina results in lower motor neuron (LMN) bowel syndrome (Singal et al. 2006; Stiens et al. 1997).

The UMN bowel, or hyperreflexic bowel, is characterized by increased colonic wall and anal tone. Voluntary (cortical) control of the external anal sphincter is lost or impaired and the sphincter remains tight, thereby promoting retention of stool; however, fecal incontinence can and does occur. Although there is loss of supraspinal control, the nerve connections between the spinal cord and the colon remain intact; therefore, there is preserved reflex coordination and stool propulsion. The UMN syndrome is typically associated with constipation and fecal retention at least in part due to external anal sphincter overactivity (Stiens et al. 1997). Stool

evacuation in these individuals occurs in response to stimulation of reflex activity, such as presence of feces in the rectum, a suppository, enema, or digital rectal stimulation.

The LMN bowel, or areflexic bowel, is characterized by the loss of centrally-mediated (spinal cord) peristalsis and loss of reflex activity, resulting in slow stool propulsion and impaired reflex stool evacuation. A segmental colonic peristalsis occurs only due to the activity of the enteric nervous system, which is slower and less efficient than the centrally-mediated peristalsis. The result is increased bowel transit times with the production of drier and round-shaped stool. LMN bowel syndrome is commonly associated with constipation and a significant risk of incontinence due to the atonic external anal sphincter and lack of control over the puborecatlis and levator ani muscles; coordinated actions of these striated muscles are important in maintaining continence.

Completeness of injury also has a significant impact on bowel function in people with SCI. Those with an incomplete injury may retain some sensation of rectal fullness and some ability to control evacuation. However, residual rectal sensation may be abnormal and motor control impaired, resulting in fecal urgency or constipation due to disordered defecation reflexes. There are always exceptions to how bowel dysfunction manifests in people with SCI, so careful assessment and a rectal examination are necessary.

Table 3. Typical Clinical Presentations in Bowel Functions Following SCI (Singal et al. 2006)

	Upper Motor Neuron lesion	Lower Motor Neuron lesion
Level	>T10 vertebral or T12 spinal segment	<∏0 vertebral or ∏2 spinal segment
Time from cecum to anus	Increased	Increased
Motility of left colon	Decreased	Decreased
External anal sphincter	Spastic paralysis	Flaccid paralysis
Sympathetic output	Absent with lesions > T6 spinal segment	Retained
Symptoms	Constipation Difficulty with evacuation Incontinence	Constipation Difficulty with evacuation Incontinence
Fecal impaction	Proximal colon	Rectal
Autonomic dysreflexia	Common	Rare
Reflex defecation	Present	Not known

To achieve fecal continence and avoid constipation, management of NBD depends upon regular and frequent pre-emptive interventions to empty the bowel at a planned time and frequency. A strict routine using dietary manipulation, rectal stimulants, oral laxatives, and/or physical interventions such as abdominal massage, digital rectal stimulation and manual evacuation of stool is required to establish control over this profoundly important bodily function. Such multifaceted programs are the most used programs for bowel management after SCI (Coggrave et al. 2009) but evidence to support these programs is lacking and much trial and error is involved in development of an effective bowel routine for each person.

Common GI problems reported by up to 41% of people with SCI include abdominal pain and bloating, hemorrhoids, and rectal prolapse (<u>Correa & Rotter 2000</u>). Prolonged bowel evacuation is also common, particularly in people with chronic injuries (<u>Coggrave et al. 2009</u>; <u>Kirk et al. 1997</u>; <u>Lynch et al. 2000</u>), this is as disabling as ineffective management and is associated with anxiety (<u>Glickman & Kamm 1996</u>). The prevalence of chronic GI symptoms increases with time after injury, suggesting that these problems are acquired and potentially preventable (<u>Rajendran et al. 1992</u>).

Autonomic dysreflexia (AD) is a disorder in which people with SCI above the 6th thoracic vertebra (T6) are at risk and is characterized by an abnormal reaction to stimuli below the level of the SCI, resulting in a massive rise in blood pressure that can lead to adverse events including brain hemorrhage and even death. Bowel dysfunction is the second most common cause of AD (<u>Furusawa et al. 2007</u>; <u>Cosman & Vu 2005</u>). Other dangerous complications, though much rarer than AD, like sigmoid volvulus, intestinal obstruction, perianal abscess, and stercoral perforation may also develop (<u>Banwell et al. 1993</u>).

It is important to emphasize that each patient with SCI is unique and that individual bowel programs need to be person-specific. The program will reflect not just residual bowel function and functional abilities but also the person's goals, lifestyle, and social circumstances. The effectiveness of a bowel program (how well they maintain continence, complete evacuation within a timely manner, etc.) should be re-evaluated regularly and modified as needed.

3.1 General Bowel Management Systematic Reviews

Table 4. General Bowel Management Systematic Review

Authors; Country Date included in the review Total Sample Size Score	Methods Databases Level of Evidence	Conclusions
Krassioukov et al. 2010 Canada	Objectives: To systematically review the evidence for the management of neurogenic bowel in individuals with SCI.	1. Multifaceted bowel management programs are the first approach to neurogenic bowel programs and are supported by lower-level evidence (3 prepost studies, level 4).

Authors; Country Date included in the review Total Sample Size Score	Methods Databases Level of Evidence	Conclusions
Published articles from 1950 to July 2009 N=57 studies AMSTAR: 5	Methods: Literature search for randomized-controlled trials (RCTs), prospective cohort, case–control, pre–post studies, and case reports assessing pharmacological and non-pharmacological interventions for management of neurogenic bowel after SCI. PEDRo Scale was used to grade RCTs (0-11). Databases: PubMed/MEDLINE, CINAHL, EMBASE, PsycINFO.	 More than one intervention is usually necessary for individuals to develop an effective bowel routine (e.g., digital rectal stimulation with diet and fluid intake). Evidence is low for non-pharmacological approaches and high for pharmacological interventions. Diet and fluid intake are important components of multifaceted bowel management programs. Transanal irrigation is a promising technique to reduce constipation and fecal incontinence Colostomy is a safe, effective method of managing severe and chronic GI problems, and assist with treating perianal pressure ulcers in persons with SCI.
Coggrave et al. 2014 UK Published articles up to June 2012 N=20 studies AMSTAR: 9	Objectives: To determine the effects of management strategies for faecal incontinence and constipation in people with a neurological disease or injury affecting the central nervous system. Methods: Literature search for randomized and quasirandomized studies evaluating any type of intervention for management of fecal incontinence and constipation in people with central neurological disease or injury. Only SCI findings are reported. Databases: Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, CINAHL, search of relevant journals and conference proceedings.	 Small trials demonstrated statistically significant improvement in total bowel care time comparing: intramuscular neostigmine-glycopyrrolate and placebo (mean difference (MD)=23.3 min) bisacodyl in polyethylene glycol suppository (43 min) compared with bisacodyl in vegetable oil suppository (74.5 min) and use of an abdominal electrical stimulation belt vs no stimulation (MD=29.3 min). One trial showed transanal irrigation significantly improved a range of outcomes compared to conservative management. There was higher patient satisfaction with this method. Three trials of cisapride were withdrawn from the review as the drug is no longer available.
Stoffel et al. 2018	Objectives:	1. Patients with injuries above the conus

Authors; Country Date included in the review Total Sample Size Score	Methods Databases Level of Evidence	Conclusions
USA Topic paper SIU-ICUD joint consultation	The purpose of the SIU-ICUD workgroup was to identify, assess, and summarize evidence and expert opinion-based themes and recommendations regarding bowel function and management in SCI populations Methods: A workgroup was formed, and a literature search was completed of English manuscripts regarding neurogenic bowel management Databases: N/A	medullaris (above approximately L1–L2) generally have symptoms of increased bowel motility and poor anorectal sphincter relaxation. 2. Patients with injuries below the conus medullaris (below approximately L2) are more likely to have an areflexic colon and low anal sphincter tone. 3. Retrospective studies also suggest that complete SCI lesions result in slower colon transit time compared to incomplete injuries (Valles et al 2009). 4. Severity of neurogenic bowel symptoms affect overall physical functioning and QOL in SCI patients. 5. QOL survey data demonstrate that constipation, fecal incontinence, and fecal urgency are the most common bothersome bowel symptoms in SCI patients. 6. High-fiber diet may increase colon transit time, resulting in more constipation in SCI patients 7. Transanal irrigation is an effective, lowmorbidity intervention for refractory neurogenic bowel in SCI patients. 8. Colostomy may significantly reduce stool transit time in SCI patients compared to conservative bowel management plans. 9. Colostomy may offer better QOL compared to ileostomy.

Two relevant systematic reviews and one topic paper were found. Krassioukov et al. (2010) reviewed all research literature published from 1950 to July 2009 related to neurogenic bowel management in individuals with SCI. They reported that although multifaceted bowel management programs are commonly used, only lower levels of evidence support these programs. Coggrave et al. (2014) found 20 randomized or quasi-randomized trials published up to June 2012. There was evidence that the duration of bowel care could be significantly reduced through use of drugs and electrical stimulation, and that transanal irrigation improved a range of outcomes. Both reviews noted that there is a need for more high-quality research in the field of

bowel management for SCI patients. Future trials should include evaluation of the "acceptability of the intervention to patients and the effect on their quality of life".

4 Conservative Bowel Management

A conservative bowel program will combine a number of interventions in an individualized routine and may include dietary modifications especially re: fibre and fluid, digital rectal stimulation, digital removal of stool, abdominal massage, stimulation of the gastrocolic reflex, and use of oral or rectal medications (suppositories, enemas). Such a program will usually be performed on a daily or alternate day basis and until stool consistency is regulated and more ideal, depending on the needs of the individual. Conservative bowel management also implies that interventions are used on a stepwise basis – from least to most invasive.



Bristol Stool Scale – a commonly used tool in health care to discuss and quantify bowel movements. Most health care providers deem that 3 or 4 on the Bristol Stool Scale is "normal" or "ideal".

The <u>Consortium for Spinal Cord Medicine guidelines (2020)</u> and the <u>Multidisciplinary Association of Spinal Cord Injury Professionals guidelines (MASCIP 2012)</u> recommend that a conservative multifaceted bowel program should be developed initially in the rehabilitation phase following injury and that a comprehensive evaluation of bowel function and management is undertaken at least annually. The evaluation may include a patient history (including level and completeness of SCI, detailed history of current bowel routine management, stool form, continence and time spent on evacuation, diet and fluid intake, relevant medical conditions and medications, extent of care provision and home adaptations) and a detailed physical examination

(including neurological examination to ascertain upper motor neuron vs. lower motor neuron type of neurogenic bowel and a rectal examination).

4.1 Multifaceted Programs

Multifaceted programs include several different interventions combined in a bowel routine to promote effective and timely fecal evacuation.

Table 5a. Multifaceted Bowel Management Programs – Interventions

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Zhang et al. 2018b China RCT Level 1 (PEDro=6) N=184	Objective: To study the effect of quantitative assessment-based nursing intervention on the bowel function and life quality of patients with neurogenic bowel dysfunction after spinal cord injury. Population: N=184 (92 in observational, 92 in control) (127 completed full treatment) Level: 73 complete, 58 lumbosacral, 40 cervical, 13 thoracic Age: range 35-70 years % Female: 38.6% Treatment: Quantitative assessment-based nursing intervention using a multifaceted approach to identify the most urgent care needs, reduce complications, and promote the rehabilitation of the disease. Compared regular nursing which included disease health education, psychological care, dietary guidance, and promoting bowel patency Outcome Measures: Recovery of bowel function, QoL and satisfaction	 Compared with the control group, the observational group had higher scores for QoL (including physical function, general health, social functioning, role-emotional, mental health) (p<0.001). Compared with the control group, the observational group had lower scores for bowel function (including bloating, constipation, prolonged defecation, defecation drug dependence, and fecal incontinence) (p<0.05). Higher satisfaction rates were recorded for the observational group (95.56% vs. 83.7%, p<0.01).
Coggrave & Norton 2010 UK RCT Level 1 (PEDro=7) N=68	Objective: High-quality evidence for interventions in bowel management (BM) after spinal cord injury (SCI) is lacking and BM programs are developed empirically. This randomized, controlled trial compared usual care with a stepwise protocol based on earlier published work to examine whether	1. There was no difference between the groups in the level of intervention at which bowel evacuation was completed (p=0.4-0.1). There were also no significant differences between experimental and control

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	systematic use of less invasive interventions could reduce the need for oral laxatives and invasive interventions such as manual evacuation, and improve BM outcomes in individuals with chronic SCI. Population: Experimental group: 24M 11F; Median age = 49.5yrs; 17 AIS-A, 5 AIS-B, 4 AIS-C, 9 AIS-D. Control group: 21M 12F; Median age = 47 yrs; 19 AIS-A, 3 AIS-B, 2 AIS-C, 9 AIS-D. Treatment: 6-week, 8-stepwise protocol designed by Badiali et al. (1997) 1) simulation of gastro-colic reflex 20 min before starting bowel care followed by: 2) abdominal massage; 3) perianal digitation; 4) anorectal digitation; 5) glycerin suppositories; 6) rectal stimulants; 7) manual evacuation; 8) stimulant oral laxative. The control group maintained their usual bowel routine to achieve evacuation. Outcome Measures: duration of bowel movement and level of the 8-stepwise protocol reached to attain consistent evacuation.	group re: time to first stool, percentage of BM episodes were stool was passed, stool consistency or diet and fluid intake. 2. Less invasive interventions (i.e., steps 1-5) did not reduce the need for more invasive interventions (i.e., steps 6-8). 3. Though bowel care was longer in the experimental group (weekly mean 48 to 67 min) vs. control group (weekly mean 32 to 37 min), it was only significant in week 6 (p=0.05) 4. Significantly more participants dropped out of the study from the experimental group, raising questions re: bias of results.
Ozisler et al. 2015 Turkey Prospective controlled trial Level 2 N=55	Objective: Determine gastrointestinal problems associated with neurogenic bowel dysfunction in spinal cord injury patients and to assess the efficacy of bowel program on gastrointestinal problems and the severity of neurogenic bowel dysfunction. Population: N=55 (42M/13F) patients with Mean (SD) age 33.01 (12.25) Mean (SD) time since SCI 162.0 (110.1) days 37 complete SCI, 18 incomplete SCI Treatment: 2 bowel programs administered depending on upper (UMN) or lower (LMN) motor neuron bowel dysfunction classification. Unique to UMN program: oral medication, glycerin suppository	 Significantly decreased % of motor complete SCI patients after treatment with constipation (-16%), abdominal distension (-25%), and abdominal pain (-16%). No significant change in % of patients with gastrointestinal problems in motor incomplete SCI patients. Significantly decreased use of oral medication, enema, and manual evacuation after treatment. Significant decreases in NBD scores in both motor complete (17.45±6.37 to 11.4±3.58) and incomplete patients (8.44±9.39)

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Common between programs: enema, digital stimulation, sit on toilet or lie on side in bed, diet & fluid regulation Outcome Measures: GI problems, method of bowel management, NBD Score	to 5.22±6.38) after treatment. 5. Mean NBD score significantly higher in motor complete patients than in motor incomplete patients both before and after treatment.
Correa & Rotter 2000 Chile Pre-post Level 4 N=38	Objective: To assess the state of the neurological bowel in spinal cord injured (SCI) patients, design and apply a program for the comprehensive management of neurogenic bowel and evaluate outcome. Population: Age: range 19-71 yrs; 21 participants with complete injuries (2 with tetraplegia and 19 with paraplegia), 10 with incomplete injuries, 7 with conus medullaris and cauda equina; Duration of injury: range 5 months -16 yrs. Treatment: Intestinal program administration with 6-month follow-up. The program involved monthly evaluations of the patient's intestinal function, symptoms, and complications. Patients were educated on inadequate practices of evacuation and medications were changed when appropriate. Outcome Measures: Difficult Intestinal Evacuation (DIE) scale; colonic transit time; anorectal manometry; rectocolonoscopy; GI symptoms.	 At onset of study, there were significant differences between DIE scores in participants who had a regular bowel habit and those who did not (p=.01) and between those who took constipation inducing medication and those who did not (p=.004). Measures of DIE that decreased significantly after using the bowel program were hard stools (26.5% to 2.9%; p=0.004) and evacuation time>45 min (26.5% to 11.8%; p=0.015). Participants felt their DIE scores after their SCI worsened (from 2.6% to 26.3%) compared to before their SCI (based on subjective recall). Gastrointestinal symptoms that decreased significantly before and after the program were abdominal distension (50% to 23.5%; p=.008), rectal bleeding (44.1% to 8.8%; p=.001), and fecal incontinence (50% to 17.6%; p=.001). Bowel practices that reduced significantly before and after program were manual extraction (52.9% to 20.6%; p=.001) and use of non-recommended laxatives (23.5% to 0%; p=.003).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Coggrave et al. 2006a UK Pre-post Level 4 N=17	Objective: Determine the effectiveness of use of laxatives in bowel management Population: 14M 3F; Age: mean 41.2 yrs, range 19-59yrs; 8 cervical, 8 thoracic, 1 conus medullaris; all participants had motor compete SCI. Treatment: Baseline bowel management routine (2 weeks observation) was compared with bowel management following introduction of the modified progressive protocol (4 weeks of observation) designed by Badiali et al. (1997) with the addition of manual evacuation. Outcome Measures: Comparison of the number of bowel management episodes requiring laxative use at baseline and under the progressive protocol; duration of bowel management episodes.	 For 12 participants, use of the progressive protocol resulted in an increase in the number of successful bowel management episodes without the use of laxatives. Total number of successful bowel management episodes requiring laxative decreased significantly from 62.8% (baseline observation) to 23.1% (in protocol phase). In 3 participants, there were fewer successful bowel management episodes with use of the protocol. Mean duration of bowel management episodes was less with use of the protocol than during baseline (51.8 vs. 73.5 minutes). There was a significant decrease in proportion of the bowel management episodes requiring manual evacuation in the protocol phase than in the baseline phase (87.6% versus 27%).
Badiali et al. 1997 Italy Pre-post Level 4 N=10	Objective: Determine the effects of different therapies used to treat chronic severe constipation Population: 5M 5F; Age: mean 33yrs, range 20-60yrs; Level of injury: C3 to L4 Treatment: Multifaceted intervention including diet, water intake, and evacuation schedule (15g/day fibre, 1500ml/24hr water) Outcome Measures: Bowel movement frequency, bowel habit (regular intestinal schedule), total and segmental large-bowel transit time.	 Bowel frequency was reported to have increased at the end of training. By the end of the study period the total GI transit time was significantly reduced (146+/-45 before vs 93+/-49 h).

Table 5b. Methods of Bowel Management – Cross-Sectional Data

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Tate et al. 2016 North America Cross-sectional Level 5 N=291	Objective: Assess the factors associated with methods of bowel management and bowel-related complications; and (2) determine the risk factors associated with bowel complications and overall bowel dysfunction. Population: N=291 Level: Incomplete paraplegia: 12.7 Complete paraplegia: 32.0 Incomplete tetraplegia: 26.1 Complete tetraplegia: 29.2 Etiology: Traumatic Age: 50.7 +- 12.5 Time since injury: 20 +- 10.5 yrs Female: 26.1 Treatment: N/A Outcome Measures: The Bowel and Bladder Treatment Index (BBTI), Fecal Incontinence Severity Index (FISI), Neurogenic Bowel Dysfunction Score (NBD) and self-report of constipation or incontinence, etc.	1. Having a history of bowel surgery (P<.05); using laxatives, medications, or both, as a main method (P<.0005); receiving caregiver services (P<.05); and experiencing more frequent abdominal pain (P<.005) were all associated with constipation.
Adriaansen et al. 2015 Netherlands Cross-sectional Level 5 N=258	Objective: To describe long-term bowel management and NBD in individuals who have been living with an SCI for at least 10 years in The Netherlands Population: N=258 Level (%): AIS A: 70% AIS B: 12% AIS C: 9% AIS D: 9% Etiology: 90% traumatic Mean Age (range): 48 (29-65)	1. The most commonly used defecation methods (as main or supplementary method) were digital evacuation (35%) and mini enemas (31%).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Mean time since Injury (range): 24 (10-47) % Female: 27 (%) Study Duration: Nov 2011 - Feb 2014 Treatment: N/A Outcome Measures: 1. Bowel management and bowel problems using international SCI bowel function data set 2. Constipation (Rome III criteria) 3. Bowel management (spinal cord independence measure) 4. Satisfaction 5. NBD score	
Khadour et al. 2023 China Observational Level 5 N=294	Objective: This study aimed to describe the bowel programs utilized by people with SCI in China and the impact of bowel dysfunction on the quality of life (QoL). Population: The two questionnaires were sent to 413 SCI patients. Two hundred ninetyfour participants (43.1±14.5 years of age; men, 71.8%) responded. Treatment: N/A Outcome Measures: A neurogenic bowel dysfunction (NBD) score is a questionnaire developed to evaluate the severity of neurogenic bowel dysfunction. A Short Form-12 (SF-12) was designed to measure the quality of life in people with SCI. Demographic and medical status information was extracted from their medical records.	1. Most of the respondents performed their bowel movement daily 153 (52.0%), a defecation time was 31–60 min among 70 (23.8%) of them, 149 (50.7%) used medication (drops or liquid) to treat constipation, and 169 (57.5%) used digital stimulation more than once per week to boost the bowel evacuation.

Table 5c. Education

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Borsh et al. 2019 USA Cohort Level 2 N=52	Objective: To establish a neurogenic bowel program after SCI in the acute care setting, examine clinician knowledge and ability to deliver the NB program, and evaluate patient knowledge satisfaction and QOL Population: N=52 Age at injury: mean 39.3±17.4 y 37% paraplegia 63% tetraplegia Level: 62% cervical; 27% thoracic; 12% lumbar; 40% ASIA A; 10% ASIA B; 25% ASIA C; 13% ASIA D; 2% ASIA E; 10% unknown Outcome Measures: Pre- and post-education surveys were given to health care providers and patients to measure change in knowledge of NB. Patient survey also included satisfaction and quality of life questions related to health, pain, and self-care taken from the Quality of Life Index-SCI version III. Demographic information, injury characteristics, and bowel medication lists which were extracted from the medical record.	 77 nurses/patient care technicians and 19 PTs and OTs completed the posteducation survey, which reported that knowledge of CPGs improved for all questions after the education in-service. Patient knowledge increased significantly from preeducation to post-education including understanding what a SCI is (p=0.02), level of injury (p=0.016), use of suppositories (p=0.008), and digital stimulation (p=0.001).
Cabigon et al. 2019 USA Cross-sectional Level 5 N=27	Objective: The aim of the study was to illustrate how interprofessional collaboration led to utilizing resources of the inpatient rehabilitation facility's peer mentor program and incorporating peer mentors into bowel education for persons with SCI. Population: People with SCI who have issues with bowel management N=27 out of 28 responded to the survey Outcome Measures: 8-item Likert scale evaluation survey with three open-ended questions to assess the utility of incorporating peer mentors into bowel	 Results showed that the education program was useful, should be continued, and include the peer mentors. Responses from open-ended questions included themes related to knowledge, adherence, and taking charge of one's own care. Interprofessional collaboration and involvement of peer mentors as co-presenters in SCI bowel education were feasible. Majority of individuals reported it helped them

education	understand the importance of following a program.
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A combination of interventions, or a multi-faceted program, as components of a comprehensive bowel routine, is often recommended for the management of neurogenic bowel following SCI. These include dietary modification, anorectal stimulation, manual evacuation, timing the performance of the bowel routine to follow food intake (thus taking advantage of gastro-colic and recto-colonic reflexes), and a variety of pharmacological agents, oral and rectal. Unfortunately, only a limited number of studies evaluated the effects of "multi-faceted programs" on bowel function in people with SCI that were comparable. From the results of three pre-post studies and one RCT, it is apparent that response to the protocols is highly individualized. Badiali et al.'s (1997) multifaceted bowel management program effectively reduced gastrointestinal transit time while Correa and Rotter's (2000) program reduced the incidence of difficult evacuation. Coggrave et al. (2006a) modified the bowel management program originally proposed by Badiali et al. (1997) by including an additional step of manual evacuation and found a significant decrease in the number of bowel movement episodes requiring laxatives (from 62.8% to 23.1%) and a significant decrease in mean duration of bowel management episodes. As these three studies incorporated several factors into the bowel management programs including diet, fluid consumption, and routine bowel practice, it is not possible to determine the key factor.

Coggrave and Norton (2010) conducted a 6-week RCT in which the management program was systematically applied from less invasive to most invasive and was compared to the control group's usual bowel care. The authors wanted to examine whether systematic use of less invasive interventions (i.e., the first few steps in the management program: simulation of gastro-colic reflex, 20 min before starting bowel care, abdominal massage, perianal digitation, anorectal digitation, and glycerin suppositories), could reduce the need for oral laxatives or more invasive interventions such as rectal stimulants and manual evacuation. However, there was no difference between the groups in the level of intervention at which bowel evacuation was completed (p=0.4-0.1). There were also no significant differences in time to first stool, percentage of BM episodes where stool was passed, stool consistency, or diet and fluid intake. The need for oral laxatives and invasive interventions was not reduced (p=0.4). The only significant group difference was that bowel care was significantly longer in the experimental group than the control group at week six (p=0.05). Differences between this RCT and previous studies mentioned could be due to the samples; in the earlier studies, the participants were younger and injured for less time - both factors that are commonly associated with less frequent use of medicated rectal stimulants, manual evacuation, and oral laxatives (Coggrave et al. 2009).

Zhang et al. (2018b) investigated a quantitative assessment-based nursing approach which included adjusted nurse-patient ratios, dietary modification, abdominal massage, abdominal muscle exercise (breathing and defecation), digital rectal stimulation, and manual evacuation for people with severe constipation in comparison to regular nursing (dietary education, disease health education, psychological care, and catharsis by drugs or artificial means). Findings showed

that abdominal distention, constipation, drug-dependency, defecation time, and fecal incontinence were significantly lower compared to controls (p<0.05). In addition, physical functioning, bodily pain, general health, vitality, social functioning, and mental health significantly increased over time (p<0.01).

Hwang et al. (2017) interviewed 131 people with pediatric onset SCI to see what multi-faceted programs people were using re: bowel management. Initially, rectal suppositories/enemas, digital stimulation, oral laxatives (or a combination of these methods) were most common. Interestingly, changes in the type of bowel program over time depended on level and completeness of injury. Paraplegia was associated with a 5x higher likelihood of using manual evacuation (p=0.002), decreased odds of using rectal suppositories or enemas (90% less likely; p<0.001) and oral laxatives (65% less likely; p=0.012) compared to tetraplegia. People with complete SCI were 3x more likely to use oral laxatives over time compared to people with incomplete SCI (p=0.012).

Johns et al. (2021) explain the importance of bowel management education for people to gain independence and improve their quality of life. One case consultation (Cabigon et al. 2019; N=27) investigated the implementation of a peer mentor program for people with SCI finding bowel management difficult. Peer mentors, or people who had been living with injury for at least two years, had a strong ability to manage their care, and increase engagement with their community. The people who received the peer mentorship rated the program highly. The majority felt that this program helped them understand the importance of bowel management, recognize their own future independence through the peer mentor, and would recommend the program to others. A cohort study by Borsh et al. (2019) implemented an education program for bowel after SCI; they found that patient knowledge increased significantly from pre-education to post-education including understanding what a SCI is (p = 0.02), level of injury (p = 0.016), use of suppositories (p = 0.008), and digital stimulation (p = 0.001).

Conclusion

There is level 1 evidence (from one RCT; <u>Zhang et al. 2018b</u>) that people who received quantitative assessment-based nursing improved quality of life and scores for bloating, constipation, prolonged defecation, defecation drug dependence, and fecal incontinence compared to those who received regular nursing, as well as higher satisfaction and quality of life.

There is level 1 evidence (from one RCT; <u>Coggrave & Norton 2010</u>) that systematic use of less invasive interventions does not reduce the need for oral laxatives or more invasive interventions such as rectal stimulants and manual evacuation.

There is level 1 evidence (<u>Coggrave & Norton 2010</u>) that use of a multifaceted bowel management program may increase the duration of bowel management.

There is level 2 evidence (Borsh et al. 2019) that patient knowledge increased significantly from pre-education to post-education including understanding of what a SCI is and with bowel management techniques.

There is level 2 evidence (Ozisler et al. 2015) that bowel programs administered depending on upper (UMN) or lower (LMN) motor neuron bowel dysfunction classification significantly

decreased NBD scores in people with both motor complete and motor incomplete SCI, though there were no significant change in % of motor incomplete SCI patients with gastrointestinal problems.

There is level 4 evidence (from three pre-post studies - <u>Coggrave et al. 2006a</u>; <u>Correa and Rotter 2000</u>; <u>Badiali et al. 1997</u>) that multifaceted bowel management programs may reduce GI transit time, incidences of difficult evacuations, and duration of time required for bowel management.

There is level 5 evidence from one study (<u>Hwang et al. 2017</u>) that bowel management changes over time with increased use of manual evacuation, colostomy, and oral laxatives, and decreased use of rectal suppositories/enemas particularly in individuals with paraplegia.

There is level 5 evidence (<u>Cabigon et al. 2019</u>) that peer mentorship may be a feasible education method for neurogenic bowel management.

There is level 5 evidence (<u>Adriaansen et al. 2015</u>) that the most used defecation methods were digital evacuation (35%) and mini enemas (31%).

There is level 5 evidence (<u>Khadour et al. 2023</u>) that most of the respondents performed their bowel movement daily (52.0%), defecation time was 31–60 min among 23.8% of them, 50.7% used medication (drops or liquid) to treat constipation, and 57.5% used digital stimulation more than once per week to boost the bowel evacuation.

There is level 5 evidence ($\underline{\text{Tate et al. 2016}}$) that less bowel dysfunction was associated with participants using laxatives/oral medications as a main method of bowel management (P<.05), having a higher fiber intake (p<.05), and lower scores on the FISI (p<.0005).

Key Points

It is difficult to summarize the evidence on multifaceted bowel management programs for people with SCI likely due to the wide variation in what constitutes "multi-faceted".

Most clinicians follow a conservative approach to bowel management in people with SCI, introducing treatments in a stepwise fashion from least invasive to most.

4.2 Dietary Fibre and the Microbiome

It is well known that fibre, in appropriate quantities, is an important part of a healthy diet. There are different types of fibre, each benefiting the body in different ways. Soluble fibre mixes with water in the intestine to form a gel-like substance, which acts as a trap to collect certain body wastes and then move them out of the body. Insoluble fibre absorbs and holds water, producing uniform stool and helping to push gut contents through the digestive system quickly. Insoluble fibre in appropriate amounts and with additional fluid intake can promote bowel regularity and improve constipation.

The <u>Consortium for Spinal Cord Medicine (2020)</u> recommends an initial diet with no less than 15 grams of fibre daily, and the <u>Multidisciplinary Association of Spinal Cord Injury Professionals (MASCIP) (2009)</u> group recommends an average intake of 18 grams, however, they acknowledge that adjustments should be made if problems arise with stool consistency. It is currently not recommended to uniformly place individuals with SCI on high fibre diets due to individual differences and tolerances (Consortium for Spinal Cord Medicine, 2020).

Table 6. Dietary Fibre for Managing Neurogenic Bowel After a Spinal Cord Injury and the Microbiome

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Lin et al. 2020 China Prospective controlled trial Level 2 N=46	Objective: To investigate alterations in fecal microbiome in people with SCI Population: SCI group: N=23 Female: 17.3% Age: 32 ± 2.23 years Time since injury: 11 ± 2.68 months Level: 3 cervical; 12 thoracic; 8 lumbar Severity: 5 complete; 18 incomplete Control group: N: 23 Female: 34.8% Age: 28 ± 3.45 years Outcome Measures: Microbial communities in the feces of 23 patients and 23 healthy controls were investigated using high-throughput Illumina Miseq sequencing targeting the V3-V4 region of the 16S ribosomal RNA (rRNA) gene. The relative abundances between the fecal microbiota at the genus level in patients with SCI and healthy individuals were determined using cluster analysis.	 People with SCI exhibited microbiome dysbiosis. While there were no significant differences in fecal microbiome alpha diversity (richness and diversity) the structure and quantity significantly differed between SCI and control group (p<0.05) 18 operational taxonomic units (OTU) were more abundant in the control group while 27 OTUs were significantly more abundant in the SCI group.
Gungor et al. 2016 Prospective controlled trial	Objective : To characterize the gut microbiota in adult SCI patients with different types of bowel dysfunction.	Results demonstrate that butyrate-producing members are specifically reduced in SCI

Level 2 **Population:** patients compared to healthy controls. N=30 N=40 2. Compared to the control group, Level: Pseudobutyrivibrio, Dialister an 15 above T6 in the UMN group d Megamonas genera were 15 with cauda equina syndrome in the significantly lower in UMN LMN group group (p=0.019, p=0.042 and 10 controls p=0.029 respectively, Tukey's Severity: HSD test) and All patients with SCI had ASIA-A Roseburia, Pseudobutyrivibrio a injuries nd Megamonas genera were significantly lower in LMN UMN group: N=15 group (p=0.019, p=0.002 and Age: 35.0 (9.5) p=0.031 respectively, Tukey's Female: 13.3% HSD test) when compared to Time since injury: 21.0(13.0–105.0) healthy controls. months 3. The Marvinbryantia genus Level: C4 (n=1, 6.7%); C5 (n=1, 6.7%); C6 count was significantly lower in (n=1, 6.7%); C7 (n=1, 6.7%); T3 (n=1, 6.7%); UMN bowel dysfunction group T4 (n=4, 26.7%); T5 (n=6, 40.0%) (p=0.021, Tukey's HSD test when LMN group: N=15 compared to the LMN group. Age: 34.0 (8.9) years Female: 6.7% Time since injury: 18.0(13.0-94.0) months Etiology: 46.7% motor vehicle collisions 26.7% fall 26.7% gunshot wound Level: T12 (n=5, 33.3%) L1 (n=9, 60.0%) L2 (n=1, 6.7%). Control group: Age: 34.4 (8.0) years Female: 0% Outcome Measures: Gut microbial patterns were determined from stool samples **Objective:** To document neurogenic bowel management of male patients Zhang et al. 2018a

China Prospective Controlled Trial Level 2 N=66

with chronic traumatic complete SCI in the centre, perform comparative analysis of intestinal aut microbiota in male patients with chronic traumatic complete SCI versus males without SCI and explore the association between intestinal microbiota with

- 1. Individuals with quadriplegia showed longer time to defecate, higher NBD scores and heavier neurogenic bowel.
- 2. Individuals with quadriplegia showed longer time to defecate. higher NBD scores and heavier neurogenic bowel

serum biomarkers and neurogenic bowel symptoms

Population:

43 SCI

23 non-SCI controls

Female: 0%

Level:

20 tetraplegia

23 paraplegia

Etiology:

37.2% traffic accidents

20.9% bruised by heavy object

20.9% fall from height

Outcome Measures: microbial diversity by stool sampling; DNA extraction and PCR amplification, Illumina MiSeq sequencing

- symptoms than those with paraplegia.
- Gut microbiota diversity in the SCI \group was reduced and had structurally different composition compared to those in the non-SCI adult male group.
- 4. In the SCI group, the abundance of Veillonellaceae and Prevotellaceae increased, while Bacteroidaceae and Bacteroides decreased.
- 5. The abundance of
 Bacteroidaceae and
 Bacteroides in the quadriplegia
 group and
 Acidaminococcaceae, Blautia,
 Porphyromonadaceae, and
 Lachnoclostridium in the
 paraplegia group were
 significantly higher than the
 control group.
- Microbial community structure was significantly associated with serum biomarkers (GLU, HDL, CR, and CRP), NBD defecation time, and COURSE.
- 7. STAMP analysis showed a significant difference (p<0.05) between the constipation and non-constipation groups (Welch's t-test) in Bifidobacterium on the genus level.
- 8. STAMP analysis showed that Megamonas was significantly higher (p<0.05) in the bloating group, and Alistipes was significantly higher (p<0.05) in the without bloating group on the genus level.

Yu et al. 2021

China Case-control study Level 3 N=69 **Objective:** To explore the hypothesis that 1) the composition and function of gut microbiota are different among patients with complete thoracic SCI, patients with incomplete thoracic SCI and people without SCI and 2) the features of gut microbiota are correlated with the serum biomarkers

- For the SCI group, there was reduced diversity of the gut microbiota, and alpha diversity had decreased gradually with an increase in the degree of damage.
- 2. Gut microbiota in the SCI group was distinct from non-SCI

and implicated in biological functions related to recovery of thoracic SCI

Population:

N=69

Level:

21 Complete thoracic SCI

24 Incomplete thoracic SCI

24 Healthy

Etiology:

18 motor vehicle collisions12 fall from elevated height

7 bruised by heavy object

Time since injury: 5.64 ± 2.52 months

Outcome Measures:

NBD score was used to evaluate bowel function for those with SCI. The alpha diversity was determined based on four indices, including observed OTUs (a measure of species richness), Shannon index (a measure of species richness and species evenness), Faith's phylogenetic diversity (a measure of species richness), and Pielou's evenness.

participants.

- 3. CTSCI group exhibited further deviation in gut microbiota composition than the ITSCI group compared to healthy individuals.
- 4. Four serum biomarkers were found to be correlated with most differential genera.
- 5. SCI accounted for 9.8% (adnois P<0.001) of the gut microbiota variance at the genus level, while the effect size was higher than that observed for other individual. characteristic features, including sex, age, BMI, and clinical serum biomarkers.

Objective: To investigate the effects and safety of the aqueous extract of the dried, immature fruit of *Poncirus trifoliata* (L.) Raf., known as *Poncirus fructus* (PF), in spinal cord injury (SCI) patients with neurogenic bowel.

Population:

N=31 SCI patients with neurogenic bowel (25 were included)

Age: 50.9±17.3 years, Range 18-88

years

Level: 14 cervical, 11 thoracolumbar, 5 AIS A, 5 AIS B, 4 AIS C, 11 AIS D

Etiology: 19 traumatic, 1 transverse myelitis, 5 other

Duration of injury: 5.3±6.0 months % Female: 3 females (12%)

Intervention: Poncirus fructus (PF) administered in dosages of 800 mg each prior to breakfast and lunch for 14 days.

Outcome Measures: Bowel outcomes before and after

- 1. Significant decrease in mean (SD) constipation score (4.60±3.35 to 3.48±2.42) (p=0.04).
- 2. The Bristol stool scores before and after administration were significantly different (3.52 \pm 1.33 to 4.32 \pm 1.44 points) (p=0.03).
- Stool retention score before and after administration of PF was represented with low significance (7.25 +/- 1.60 – 6.46 +/- 1.53 points) in the whole colon (p < 0.05).
- 4. Colon transit time was significantly in terms of the whole transit time shortened (57.41 ± 20.7 to 41.2 ± 25.5 hours), in right colon (14.4±16.2 to 10.1±12.1h), and in left colon (21.8±12.3 to 14.8±11.8h) (p<0.05).
- 5. Side effects were observed in 7 people (28.0%) consisting of 2 people with soft stools and

Kim et al. 2016a South Korea

Pre-post Level 4 N=31

	administration of PF for 2 weeks. Survey of defecation patterns, plain abdominal radiography, colonic transit times, and side effects	5 people with diarrhea.
Cameron et al. 1996 Australia Case Series Level 4 N=11	Objective: Assess the nutrient intake of SCI patients, to determine baseline transit time, stool weight and evacuation time and to assess the effect of addition of bran on large bowel function Population: Age: range 19-53yrs; Level of injury: C4-T12; 1 participant with incomplete injury and 10 with complete injuries; 7 participants with tetraplegia and 4 with paraplegia. All participants were in their first rehabilitation program 1-4 months after injury. Treatment: In phase 1 (week 1), participants ate a normal hospital diet and maintained their bowel routine. In phase 2 (week 2-4), fibre intake was increased with the addition of 40g Kellogg's All Bran. Outcome Measures: stool weight, total and segmental transit time, bowel evacuation time and dietary intake.	 Following the addition of bran, dietary fibre intake significantly increased from 25g/d to 31g/d. Mean colonic transit time significantly lengthened from 28.2 hours to 42.2 hours.

Though many people with SCI report that adjusting their diet improves bowel function (Coggrave et al. 2006b), there is little evidence to support this in general. Cameron et al. (1996) looked at increasing dietary fibre and found that this does not have the same effect in people with SCI as has been previously demonstrated in people without neurogenic bowel dysfunction. Rather, the effect may be the opposite of the desired result. Therefore, adding more fibre alone does not improve bowel function; for individuals with low fibre intake and constipation, fibre in the diet may be increased gradually and the effect on bowel function carefully observed. More evidence is required to assess the effectiveness of adding fibre to the diet of individuals with SCI.

Kim et al. (2016a) in a pre-post study, investigated the effect of the dried immature fruit of Poncirus trifoliata, known as Poncirus fructus which is widely used as a traditional medicine in Eastern Asia for the treatment of gastrointestinal disorders but had only been studied in animal models or participants with intact gastrointestinal tracts. Although statistically significant improvements in 25 individuals with SCI were noted in constipation, Bristol stool scale, CTT and stool retention, 28% of participants had adverse events particularly loose stool or diarrhea. The authors note that the mechanism of action, extraction methods and dosing requirements are neither clear nor standardized.

There is evidence that suggests people with SCI have different microbiome diversity and structural composition compared to people without SCI (<u>Faber et al. 2021</u>; <u>Gungor et al. 2016</u>; <u>Zhang et al. 2018a</u>). Specifically, <u>Gungor et al. (2016</u>) reported that butyrate-producing bacteria are reduced in people with SCI and that bacteria genera significantly differ between UMN and LMN groups. Furthermore, <u>Yu et al. (2021)</u> reported that people with complete SCI had larger reductions and composition variation than those with incomplete SCI in comparison to people without SCI. However, another study reports there are no significant differences in diversity, but rather structure and quantity (p<0.05) (<u>Lin et al. 2020</u>; N=46).

Conclusion

There is level 2 evidence (<u>Gungor et al. 2016</u>; <u>Zhang et al. 2018a</u>), level 3 evidence (<u>Yu et al. 2021</u>) and one systematic review (<u>Faber et al. 2021</u>; N=14 studies) that indicate people with SCI have reduced diversity of gut microbiota compared to people without SCI. The systematic review reports that individuals with complete thoracic SCI exhibit larger composition variation and reductions in microbiome diversity from healthy individuals than those who have incomplete thoracic SCI.

There is level 2 evidence (<u>Lin et al. 2020</u>) that people with SCI show microbiome dysbiosis due to the structure and quantity of microbiota, whereas alpha diversity did not significantly differ in comparison to healthy individuals.

There is level 4 evidence from one pre-post test (<u>Kim et al. 2016a</u>) that dosages of the aqueous extract Poncirus fructus (PF) may improve stool retention, colon motility and constipation symptoms of neurogenic bowel.

There is level 4 evidence (from one case series; <u>Cameron et al. 1996</u>) that indicates high fibre diets may lengthen colonic transit time in individuals with SCI.

Key Points

At present, there is no evidence that a high fibre diet alone is effective in managing NBD in people with SCI.

The gut microbiome differs between people with and without SCI. Numerous factors may affect its composition, including UMN/LMN injury or completeness of injury. Further evidence is required on whether these differences affect bowel function after SCI.

4.3 Stimulation of Reflexes in the Gastrointestinal Tract

Utilization of the preserved gastrointestinal reflexes can be beneficial in bowel management following SCI. The gastro-colic reflex is stimulated by gastric distention due to eating and can activate bowel motility and promote defecation (Sloots et al. 2003; Ford et al. 1995). Digital

stimulation of anorectal reflexes has been shown to result in increased rectal contractions and could be useful in bowel evacuation following SCI (Shafik et al. 2000).

Table 7a. Systematic Review of Digital Rectal Reflex Stimulation of the Gastrointestinal Tract

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Wincentak et al. 2021 Canada Scoping Review N=33 studies	Objective: To review the evidence on the use of digital rectal stimulation (DRS) for bowel management in individuals with SCI, what beneficial and adverse outcomes have been studied, and people's experiences using DRS Methods: Used the five stages proposed by Arksey and O'Malley for performing a scoping review. Articles that had information on the use of digital rectal stimulation alone or with a combination of treatments were included Databases: MEDLINE, EMBASE, CINAHL, Cochrane CENTRAL, and Cochrane Incontinence Group from 1990 to November 2019	 Out of 34 reported outcomes found, the most reported were defecation time (n=16) and incontinence (n=15) 12 experimental and quasiexperimental studies were found. Three studies investigated DRS as a primary intervention. DRS: supplemental intervention DRS in the remaining studies were used in combination with other interventions. 18 observational studies were found, which studied ulcers, hemorrhoids and rectal abscess. They also primarily studied incontinence, satisfaction, QoL, constipation and abdominal pain. 2 qualitive studies were found, which investigated the experience of caregivers and individuals re SCI and bowel.
Nelson & Orr et al. 2021 US Systematic Review N=11 studies	Objective: To determine evidence for digital rectal stimulation (DRS) as an intervention in the management of upper motor neuron neurogenic bowels (UMN-NB) in persons with spinal cord injury (SCI). Methods: Included research articles and practice guidelines evaluating UMN neurogenic bowel treatments and the use of DRS	 There was moderate evidence for DRS in persons with SCI and UMN-NB. There was evidence of the physiologic effect of DRS inducing contractions for evacuating the bowel and support for combining DRS with other treatment regimens.

Databases: OvidMedline, PubMed and the Cochrane databases	
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Table 7b. Digital Rectal Reflex Stimulation – Interventions

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Faaborg et al. 2014 Denmark RCT Level 1 (PEDro = 8) N=11	Objective: Study aimed at investigating autonomic responses to digital rectal evacuation (DE), transanal irrigation (TAI) with 500 ml and filling cystometry (FC) in SCI. Population: N= 8 people with SCI (AIS A) at or above T6 N= 3 people with SCI (AIS A) at TIO-L2 Treatment: Digital rectal evacuation, transanal irrigation (TAI), filling cystometry (FC) Outcome Measures: During each examination 4-week diary of daily autonomic dysreflexia (AD) episodes was completed before and after participation	 The people with SCI above T6 had AD during all three examinations. Systolic blood pressure (sBP) increased less during TAI (36mmHg, range 30–63) than during digital evacuation (57mmHg, range 41–75; P<0.05) or FC (61mmHg, range 55-100; p<0.02). The difference in sBP between digital evacuation and FC was not significant. No participants with SCI at TIO-L2 had AD symptoms during any of the examinations
Shafik et al. 2000 Egypt Prospective Controlled Trial Level 2 N=27	Objective: Determine whether defecation induced by digital-rectal stimulation is mediated through a reflex mechanism. Population: The group of 18 healthy volunteers had a mean age of 36.6 ± 9.7 years (range 20-51). 8 were women and 10 were men. The SCI group with paraplegia were age 35.1 ± 11.2 years; range 18-50. Treatment: Anal canal dilation by inflatable balloon Outcome Measures: Rectal pressure measured by water-	 Mean basal rectal pressure was not significantly different in the SCI group compared to the healthy volunteer group (p>0.05) There was a significant increase in rectal pressure when the anal balloon was inflated to 6, 8 and 10 mL (p<0.001, p<0.001, and p<0.001 respectively), but no significant pressure response for 2mL and 4mL balloon inflations.

	perfused 10 F catheter connected to pneumohydraulic capillary infusion system	
Korsten et al. 2007 USA Pre-post Level 4 N=6	Objective: Assess the effect of DRS on colonic motility. Population: Six male participants with SCI (4 with paraplegia [3 complete, 1 incomplete]; 2 with tetraplegia [1 complete, 1 incomplete); Age: mean 50.2yrs, range 44-50yrs; Level of injury: C5-TIO; AIS A-C; Duration of injury: 10-29yrs. Treatment: Digital rectal stimulation to facilitate bowel evacuation. Outcome Measures: Colorectal manometry: mean number of peristaltic waves per minute; amplitude of contractions; colonic motility.	 Compared with no digital rectal stimulation (0 waves/min), the mean number of peristaltic waves/min increased during digital rectal stimulation (1.9±0.5/min) and immediately after digital rectal stimulation (1.5±0.3/min) (mean ± SEM). Average amplitude of the peristaltic contractions was 43.4±2.2 mmHg (range 0.7-250 mmHg). Peristaltic contractions in the left colon were accompanied by increased motility of the left colon and improvement in evacuation of barium as documented by fluoroscopy.

Table 7c. Digital Rectal Reflex Stimulation – Cross-Sectional Data

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Haas et al. 2005 Switzerland Cross-sectional Level 5 N=837	Objective: To analyse bowel management in patients with spinal cord injury (SCI) especially the occurrence of unplanned bowel evacuations and duration of planned bowel evacuation. Population: 837 SCI patients (642M, 186F) from 29 rehabilitation facilities in Austria, Germany, the Netherlands and Switzerland. Injury level: 42% cervical, 45.3% thoracic, 12.7% lumbar. Treatment: Questionnaire Outcome Measures: method of evacuation, rate of incontinence, rate of bowel symptoms	 Oral laxatives were significantly associated with increased unplanned bowel evacuations and longer episodes of bowel care (n=444; p<.001). Fewer unplanned evacuations were significantly associated with manual removal and/or digital rectal stimulation (n=35; p<.05) Manual evacuation associated significantly with shorter duration of bowel evacuation (<60 min) (n=64; p<.05).

Digital rectal stimulation (DRS) is often used and studied in combination with other bowel management methods (Nelson & Orr, 2021; Wincentak et al. 2021). Haas et al. (2005) reported that people who used a combination of DRS with manual removal of feces were 70% less likely to have an unplanned bowel evacuation (p<0.05).

Only one single pre-post study was found to investigate DRS as the primary intervention, where the results showed increased peristaltic waves in the left colon, thus increasing motility in this segment and aiding evacuation of stool for those with reflex bowel dysfunction (Korsten et al. 2007; N=6). Another study found that anal balloon inflation to dilate the rectum significantly increased rectal pressure at 6, 8, and 10 mL of inflation (p<0.001), demonstrating how DRS may induce rectal contractions for defecation through the anorectal excitatory reflex (Shafik et al. 2000). Stimulation of anorectal reflexes in people with SCI above the conus can therefore be incorporated into bowel routines; pharmacological rectal stimulants can be used to trigger evacuation at a chosen time in combination with digital rectal stimulation.

The risk of AD with DRS was evident in an RCT (<u>Faaborg et al. 2014</u>), who found that people with an injury above T6 demonstrated a larger systolic blood pressure increase after DRS compared to transanal irrigation methods (the authors used inconsistent terminology such as "digital anorectal stimulation" and "digital anorectal evacuation"). Although, cross-sectional data shows DRS is one of the most used interventions for bowel management (<u>Inskip et al. 2018</u>; N=287, <u>Tate et al. 2023</u>; N=18).

Conclusion

There is level 1 evidence (<u>Faaborg et al. 2014</u>) that people with a SCI above T6 demonstrated a larger systolic blood pressure increase after digital rectal stimulation compared to those using transanal irrigation.

There is level 2 evidence (Shafik et al. 2000) that anal dilation may be used to evoke the anorectal excitatory reflex.

There is level 4 evidence (from one pre-post study; <u>Korsten et al. 2007</u>) that digital rectal stimulation increases motility in the left colon.

Key Points

Digital rectal stimulation may increase motility in the left colon in individuals with reflex neurogenic bowel dysfunction after SCI.

4.4 Manual Evacuation of Feces

Manual evacuation of feces involves the use of a single gloved and lubricated finger to remove feces from the rectum. It is used by individuals with both hyperreflexic and areflexic bowel

dysfunction. Coggrave et al. (2009) (n=1334) reported that manual evacuation of feces for people with SCI was found to be the most commonly used intervention, carried out by 56% of respondents. A systematic review (Solomons & Woodward, 2013) found that digital stimulation and digital removal of feces were associated with the lowest rates of unplanned bowel evacuations and less time spent on bowel care and (Haas et al. 2005) concluded that digital removal of feces is a necessary component of bowel care for many people with SCI.

Table 8. Manual Evacuation of Feces Systematic Review

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Solomons & Woodward 2013 Britain Systematically reviewed articles from electronic databases no date limits applied N=7 Level of evidence: Methodological quality not assessed Type of study: 1 RCT 4 case-controls 1 cross-sectional 1 case-control AMSTAR: 2	Objective: Assess the quality of evidence available on digital removal of feces for people with SCI. Method: Systematic literature review of the quality of evidence available on fecal manual evacuation for individuals with SCI. Databases: CINAHL, British Nursing index, EMBASE, Medline	 All seven of the papers discussed in this review were of limited reliability as they studied heterogeneous populations. Bowel protocols should not be carried out rigidly but rather should be used in guided experimentation to assist the SCI patient to find a bowel management program that works for them. Digital rectal removal of feces remains a necessary intervention for many patients. More research and training are needed on this and other neurogenic bowel management. The low status of bowel care in nursing and wider society needs to be challenged so that people with SCI can benefit from high quality bowel care and associated improvements in quality of life.

Table 9. Manual Evacuation of Feces – Cross-Sectional Data

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Coggrave et al. 2009 UK Pre-post Level 4 N=1334	Objective: To describe bowel management in community-dwelling spinal cord-injured (SCI) individuals and to explore associations between age, injury, dependency, problems, interventions and satisfaction. Population: 1334 SCI outpatients aged 19-91 yrs. Treatment: Postal survey Outcome Measures: method of evacuation; number of interventions used before finding a successful protocol; assistance with bowel care.	 56% of respondents used digital rectal evacuation; 36% stimulant laxatives, 15% osmotic, 6% bulk formers, 3% stool softeners. Median number of interventions used by an individual was 3. More than 1/3 of respondents needed assistance with bowel care. Digital evacuation was associated with better outcomes in independent individuals with thoracic lesions.
Correa & Rotter 2000 Chile Pre-post Level 4 N=38	Objective: To assess the state of the neurological bowel in spinal cord injured (SCI) patients, design and apply a program for the comprehensive management of neurogenic bowel and evaluate outcome. Population: Age: range 19-71 yrs; 21 participants with complete injuries (2 with tetraplegia and 19 with paraplegia), 10 with incomplete injuries, 7 with conus medullaris and cauda equina; Duration of injury: range 5 months -16 yrs. Treatment: Intestinal program administration with 6-month follow-up. The program involved monthly evaluations of the patient's intestinal function, symptoms, and complications. Patients were educated on inadequate practices of evacuation and medications were changed when appropriate. Manual evacuation was discouraged as high-risk.	 When comparing pre and post lesion intestinal function at the onset of the study, there was significantly decreased frequency of defecations, ranging from 8.2(+3.8) to 5.2(+3.6) times a week (p<0.001; t paired). Evacuation time significantly increased, ranging from 9.7(+0.9) to 24.1(+23.9) min (p<0.001; t paired). Participants felt their DIE scores after their SCI worsened (from 2.6% to 26.3%) compared to before their SCI (based on subjective recall). The most frequent GI symptom was abdominal distention. The incidence of abdominal distention was reduced from 50% to 23.5% after the program. With the intestinal program, the incidence of DIE was reduced from 26.3% to 8.8% and episodes of manual extraction was reduced from 53% to 37%. An objective to eliminate use of manual evacuation, stimulant laxatives and/or enemas was successful in that 19 patients were

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Outcome Measures: Difficult Intestinal Evacuation (DIE) scale; colonic transit time; anorectal manometry; recto-colonoscopy; GI symptoms.	using manual evacuation daily pre- trial while only 8 did post-trial.

Although there are few intervention studies, there are reports of people using manual evacuation for bowel management alongside other methods. Solomons & Woodward (2013) reviewed 7 articles which used manual evacuation as part of a bowel management protocol. They found that manual evacuation was commonly used in individuals with SCI (Coggrave et al. 2006b; Coggrave et al. 2009) and was effective in reducing the number of unplanned bowel evacuations with digital rectal stimulation (Haas et al. 2005) but had a high self-reported rate of constipation (Menter et al. 1997). Conversely, Haas et al. (2005) reported a decrease in bowel evacuation time with manual evacuation.

Conclusion

Manual evacuation is a key method in conservative bowel management practice and is commonly and widely employed. It reduces number of unplanned bowel evacuations. There is conflicting evidence on the effect of manual evacuation on duration of bowel evacuation, though some research shows that it decreases bowel management time.

Key Points

Digital evacuation of stool is a common intervention for bowel management after SCI, typically reducing duration of bowel management and fecal incontinence.

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4.5 Abdominal Massage

Table 10. Abdominal Massage – Interventions

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Hu et al. 2013 China Pre-post Level 4 N=20	Objective: To observe the effects of manual therapy on bowel function of patients with spinal cord injury. Population: Thoracic SCI (13M, 7F); Mean (SD) age: 39.70 (5.25) yrs. Treatment: Abdominal massage was applied to the surface of the abdomen along the small intestine, the ascending, transverse, descending and sigmoid colon, for 60 sessions during the bowel routine (5 times/wk for 12 wks). Outcome Measures: Bowel time, dosage of glycerine enema.	1. A statistically significant improvement was found in the mean (SD) time of bowel movement (decreased from 94.0 (16.4) min to 60.5 (10.5) minutes) and dosage of glycerine enema (decreased from 68.15 (8.9) mL to 31.5 (11.8) mL) after abdominal massage treatment for 3 months.
Ayas et al. 2006 Turkey Pre-post Level 4 N=24	Objective: To investigate the effect of abdominal massage on clinical aspects of bowel dysfunction and colonic transit time in patients with spinal cord injury. Twenty-four patients were placed on a standard bowel program (phase I), after which abdominal massage was added to the regimen (phase II). Parameters of gastrointestinal system function and colonic transit times were evaluated. Population: Age: mean 39.8yrs, range 33.1-46.6yrs; Level of injury: C4-L3, 10 participants with supraconal lesions, 14 with caudal/conal lesions; 15 with complete SCI and 9 with incomplete SCI; FIM score: mean 76.3, range 68.9-83.7; Duration of injury: mean 136.5 days, range 70.1-203 Treatment: Addition of abdominal massage beginning at the cecum and extending along the length of the colon to the rectum (phase II) to a standard bowel program (phase I)	 Mean (SD) frequency of defecation significantly increased from 3.79(2.15) (range 2.75-4.55) to 4.61(2.17) (range 3.67-5.54) per week. Mean (SD) total colonic transit time significantly decreased from 90.60(32.67) (range 75.87-110.47) hours to 72(34.10) (range 58.49-94.40) hours with abdominal massage.

	Outcome Measures: Colonic transit times, frequency of defecation	
Janssen et al. 2014 Netherlands Post-test Level 4 N=21	Objective: To evaluate the effects of noninvasive abdominal massage using an electromechanical apparatus on bowel function in individuals with SCI and chronic bowel problems. This easy-to-use apparatus can be applied by the patients at home without the help of a therapist. Population: N=21 people (18M, 3F) with cervical SCI (N=15 completed study) Mean (SD, range) age 56.5 years (11, 38-79) Mean (SD) time since injury 221 months (146) AIS-A/B/C-D: 8/2/11 13 tetraplegia, 8 paraplegia 8 complete, 13 incomplete Treatment: Daily electromechanical abdominal massage for 20min for 10 weeks Outcome Measures: Questionnaire on defecation, side effects, and user satisfaction.	 Fecal consistency: 13/15 reported no change, 2/15 reported softer consistency. Fecal shape: 14/15 reported no change, 1/15 reported sausage-shaped. Fecal amount: 8/15 reported no change, 3/15 reported increase, 1/15 reported decrease, 3/15 reported variable. Time to defecation: 6/15 reported no change, 6/15 reported shorter, 3/15 reported variable. Fecal incontinence: all reported no change. Flatulence: 12/15 reported no change, 2/15 reported fewer, 1/15 reported more Overall treatment evaluation: 2/15 reported yery good, 2/15 reported good, 4/15 reported adequate, 7/15 reported insufficient. Only frequencies were reported in this study.

Ayas and colleagues (2006) reported on people with SCI who received at least 15 minutes of abdominal massage beginning at the cecum and extending along the length of the colon to the rectum during their regular bowel routine. Differences were found in the frequency of defecation and mean colonic transit time between phase I, when participants participated in a standard bowel program in which they received a standard diet containing 15-20 g of fiber/day and underwent daily digital stimulation, and phase II, when the participants continued to receive this standard care and had the addition of abdominal massage when attempting bowel evacuation. However, these differences were statistically insignificant, possibly due to a small and heterogeneous sample. In the study by Hu et al. (2013), manual therapy was applied to the intestine and along the colon. A statistically significant improvement was seen in the mean time of bowel movements as well as dosage of glycerine enema needed. The sample in this study was also very small but was homogenous. Janssen et al. (2014) studied the use of electromechanical massage applied to the transverse colon in a heterogeneous group of 21 individuals with SCI and self-reported neurogenic bowel dysfunction. The device was used daily for 20 minutes by six participants, every other day by nine participants and less frequently by the rest and was used at a separate time from the bowel care routine in all participants. Four participants (19%) did not

complete the study due to pain or unwanted change in stool consistency precipitated by the device. Despite some positive change in some aspects of bowel function for some patients (time to result in 6, consistency in 2, amount in 3), none of the fifteen participants who completed the trial reported feeling better or more confident about their bowel function. Further suitably powered studies are required in the SCI population to determine the effectiveness of manual abdominal massage as an intervention for neurogenic bowel dysfunction. It is less clear that further studies on asynchronous electromechanical massage of limited parts of the colon are warranted.

One pilot study investigated the use of osteopathic manipulative treatment on abdominal regions of the body and its effect on NBD after SCI (<u>Tamburella et al. 2022</u>). Though this study was small, they found statistically significant differences in the osteo group vs. the control group in visual analogue scale scores on sense of constipation and swelling.

Conclusion

There is level 4 evidence (from one pre-post study; <u>Ayas et al. 2006</u>) that abdominal massage is ineffective for treating the neurogenic bowel.

There is conflicting level 4 evidence (from one pre-post study; <u>Hu et al. 2013</u>) that abdominal massage is effective in reducing bowel movement time as well as dosage of glycerine enemas.

There is level 4 evidence (from one pre-post study; <u>Janssen et al. 2014</u>) that electromechanical massage of the transverse colon is ineffective for treating the neurogenic bowel.

Key Points

There is contrasting evidence on the effectiveness of abdominal massage in treating neurogenic bowel dysfunction. Further research is needed.

4.6 Electrical and Magnetic Stimulation

Several electrical or magnetic stimulation methods have been proposed and tested for their ability to improve bowel function in individuals with upper motor neuron SCI. These techniques are varied, from the relatively inexpensive and non-invasive abdominal muscle stimulation belt (Korsten et al. 2004) and percutaneous peripheral nerve stimulation (Mentes et al. 2007), to more complex and invasive techniques including implantation of epineural electrodes (Davis et al. 2001) and epidural or anterior sacral root electrodes (Chia et al. 1996; Binnie et al. 1991; MacDonagh et al. 1990) for functional electrical stimulation. Magnetic stimulation techniques have also been used; a magnetic field is generated to induce an electric field, which then generates sufficient current to stimulate the peripheral nerves (Lin et al. 2002).

After upper motor neuron SCI, bowel reflex centres within the sacral spinal cord may be released from descending inhibition and may be influenced by somatic input (<u>Frost et al. 1993</u>). Several studies have shown that electrical or magnetic stimulation of the somatic nervous system

can bring about an alteration in visceral function in humans. For example, <u>Riedy et al. (2000)</u> showed that short periods of electrical stimulation with perianal electrodes resulted in an increase in anal pressures.

Table 11a. Systematic Review on Electrical and Magnetic Stimulation

Author Year; Country Score Research Design Total Sample Size	Methods	Conclusions
Parittotokkaporn et al. 2020 New Zealand Systematic review N=46 studies	Objective: To perform a systematic literature review of clinical studies investigating the use of non-invasive neuromodulation in restoring bowel, bladder and sexual functions following SCI Methods: The review was designed using the PRISMA checklist and eligible studies included a clinical design based on human populations, participants over 18 years old with SCI, non-invasive neuromodulation/stimulation as the intervention, and diagnostic criteria of neurogenic bowel/bladder dysfunction Databases: PubMed/Medline, EMBASE, Web of Science, Scopus and Cochrane databases, with reference lists from previous publications	 43/46 studies reported improvements in bowel (5/5), bladder (32/35) and sexual dysfunction (6/6) in people with SCI. For people with SCI, an increase in rectal pressure at application and a decrease in colonic transit the following few weeks was observed in studies that applied acute functional magnetic stimulation (Lin et al. 2001; Morren et al. 2001; Tsai et al. 2009).
Deng et al. 2018 Systematic Review China N=11 studies	Objective: To perform a systematic review of the clinical trial evidence on electrical stimulation for the treatment of neurogenic bowel dysfunction (NBD) after spinal cord injury (SCI). Methods: Systematic literature search of studies limited to English/Chinese which had a controlled clinical design based on human population, people with SCI, disorders of bowel function as the main outcome, and electrical stimulation as the intervention. Databases: PubMed/Medline, EMBASE, Cochrane Central Register of Controlled Trials, and China National Knowledge Infrastructure databases, and the reference lists in the included studies	 Majority of studies reported that electrical stimulation was safe and effective for people with NBD after SCI. Many reported it was noninvasive approach that was easy to use. Most studies reported that fecal incontinence episodes decreased.

Author Year; Country Score Research Design Total Sample Size	Methods	Conclusions
Worsoe et al. 2013 Denmark Systematically reviewed articles from databases listed to the right (dates searched not listed) Number of studies not listed Level of evidence: methodological quality not assessed Type of study: No RCTs, all lower- level studies AMSTAR: 2	Objective: Review NBD treated by sacral anterior root stimulation (SARS), sacral nerve stimulation, magnetic stimulation, and nerve re-routing Method: Systematic literature search of neurogenic bowel disorder in patients with SCI treated by sacral anterior root stimulation (SARS), sacral nerve stimulation (SNS), peripheral nerve stimulation, magnetic stimulation, and nerve rerouting. Databases: PubMed, Embase, Scopus, Cochrane Library	 SARS improves bowel function in some patients with complete SCI. Nerve re-routing may facilitate defecation through mechanical stimulation of dermatomes in patients with complete or incomplete SCI or myelomeningocele. SNS can reduce NBD in selected patients with a variety of incomplete neurologic lesions. Peripheral stimulation using electrical stimulation or magnetic stimulation may present non-invasive alternatives.

Table 11b. Functional Electrical or Magnetic Stimulation – Interventions and Case Series

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Korsten et al. 2004 USA RCT Level 1 (PEDro = 6) N=8	Objective: Assess colonic motor activity using a solid-state manometry probe Population: 8 male participants (6 tetraplegia; 2 paraplegia); age mean(SD): 48(14)yrs; duration of injury mean(SD):13(8)yrs. Treatment: An abdominal belt with embedded electrodes was wrapped around at the umbilicus level and was used in conjunction with the participant's regular bowel care but activation of the device was randomized. Participants used the belt for six bowel care sessions over 2 weeks (the belt was activated for three sessions and deactivated for three	1. Time to first stool and time for total bowel care were significantly shortened in the 6 participants with tetraplegia (p<0.01), but not in the 2 participants with paraplegia (p=0.02).

Author Year; Country Score Research Design Total Sample Size	Methods Outcome	
	sessions). Outcome Measures: Time to first stool, time for total bowel care.	
Hascakova-Bartova et al. 2008 Belgium Prospective controlled trial Level 2 N=10	Objective: The effect of abdominal neuromuscular electrical stimulation (NMES) in patients with spinal cord injury. The principal parameters observed in this study are lung capacity, colonic transit, patient satisfaction of used method and of aesthetics effect on abdominal wall. Population: 7 participants in the electrical stimulation group (ESG) with level of injury ≥ T10 and complete paralysis of abdominal muscles (6M 1F; mean (SD) age: 42(19) yrs). 3 additional participants (all male, ages 25, 43, 63) were in the placebo group (PG). Treatment: Surface abdominal neuromuscular electrical stimulation. administered 25 min/day, 5 days/wk, for 8 wks Outcome Measures: colonic transit measured by radiopaque markers	 Accelerated colonic transit (ascending, transverse, and descending colon) in all participants who received treatment. The ESG group had a significant decrease in % of number of markers in the ascending, transverse, and descending colon after the NMES treatment (8.86 +/- 8.65% markers before NMES vs. 4.57 +/-5.99% after NMES). No significant changes in the colonic transit for PG (% number of markers in the A+T+D colon: before NMES = 9.17 +/- 5.91 vs. 9.17 +/-5.04).
Tsai et al. 2009 Taiwan Pre-post Level 4 N=22	Objective: The aims of this study were to assess the usefulness of functional magnetic stimulation in controlling neurogenic bowel dysfunction in spinal cord injured patients with supraconal and conal/caudal lesions, and to investigate the efficacy of this regimen with a 3-month follow-up. Population: 22 chronic SCI participants with intractable neurogenic bowel dysfunction (19M, 3F), mean age 46.7 yrs, range 22–65yrs); divided into group 1 (supraconal lesion, N=15) and group 2 (incomplete conal/caudal lesion, N=7) Treatment: Participants underwent a 3-week stimulation period, consisting of 20-min stimulation sessions twice a day.	 Mean colonic transit times decreased from 62.6 hrs to 50.4 hrs. Frequency of laxative use, unsuccessful evacuation attempts, feeling of incomplete defecation, difficulty with evacuation, and time taken to evacuate significantly decreased. Mean scores on the KESS significantly decreased from 24.5 to 19.2 points, indicating a significant overall

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Each session contained 10 min of thoracic nerve stimulation with the centre of the coil placed at the T9 spinal process, and another 10 min of lumbosacral nerve stimulation with the coil at the L3 spinal process. Participants underwent stimulation from a sitting position. The stimulation intensities were set at 50% on the first day, 60% on the second day, and then stabilized at 70% for the remaining days. The stimulation frequency, burst length, and interburst intervals were fixed at 20 Hz, 2 sec, and 28 sec, respectively. Outcome Measures: Colonic transit times; Knowles-Eccersley-Scott Symptom Questionnaire (KESS, evaluates frequency of bowel movement using existing therapy, difficulty of evacuation, laxative use, and time taken for bowel evacuation)	improvement in bowel symptoms.
Lin et al. 2001 USA Pre-post Level 4 N=15	Objective: To evaluate the usefulness of functional magnetic stimulation (FMS) as a noninvasive method to stimulate the colon in individuals with spinal cord injury (SCI). Population: 13 SCI, 2 non-SCI controls; Level of injury: C3-L1; Duration of injury 11-35 yrs (protocol 2 only); AIS classes: 7 A, 3 B, 1 C. Treatment: FMS was delivered via a magnetic coil placed on the transabdominal (suprapubic region while participants lay supine) and lumbosacral (L3-L4 along midline) regions. Protocol 1: measured the immediate effects of FMS on rectal pressure Protocol 2: measured the effects of FMS on total and segmental colonic transit times after a 5-week stimulation period (20 min sessions twice a day). Outcomes were collected before and after the 5-wk stimulation program. Outcome Measures: rectal pressure, total and segmental colonic transit times	 Rectal pressures increased with sacrolumbar stimulation, and with transabdominal stimulation. After protocol 2, the mean (SD) colonic transit times decreased from 105.2(6.66) to 89.4(6.94) hours.
Lin et al. 2002 USA	Objective: To evaluate the effect of functional magnetic stimulation (FMS) on	Gastric emptying time post-stimulation was

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Pre-post Level 4 N=9	gastric emptying in able-bodied and spinal cord injury (SCI) subjects. Population: 4 participants with SCI between C3-C7, AIS class: 3 B,1 D; 5 controls, mean (SD) age: 42(5.8) yrs Treatment: Each individual participated in a 3-day protocol; day 1: baseline gastric emptying study, day 2: no change in the eating pattern and no intervention, day 3: participants received functional magnetic stimulation (FMS) while undergoing a second gastric emptying study. Outcome Measure: Rate of gastric emptying and time to reach gastric emptying half time (GEt _{1/2})	significantly shorter than the baseline for both AB and SCI groups. Mean (SE) GE _{t1/2} for the groups were: AB: baseline= 36(2.9); post- stim=33(3.1) SCI: baseline=84(11.1); post-stim=59(12.7). 2. There was significantly more gastric emptying at 30, 60, 90 and 120 min after FMS than at baseline. For the SCI group, % of gastric emptying at 30, 60, 90 and 120 min were: - baseline: 6(2.9); 16(7.6); 38(5.2); 55(6.7) - post-stim: 26(8); 49(10.2); 61(9); 69(8.6).
Worsoe et al. 2012 Denmark Pre-post Level 4 N=7	Objective: To study the effect of acute DGN stimulation on the rectal cross sectional area (CSA) in SCI patients. Population: Participants with supraconal SCI (6M, 1F); Age: median (range) age: 50 (39-67); median (range) DOI: 19 (12-33). Treatment: Dorsal genital nerve (DGN) stimulation using an amplitude of twice the genito-anal reflex threshold. A pressure controlled phasic rectal distension protocol was repeated 4 times with participants randomized to stimulation during 1st and 3rd distension series or 2nd and 4th distension series. Outcome Measures: Rectal cross-sectional area (CSA) and rectal pressure	 Median rectal CSA was smaller with than without stimulation in all patients at 20cmH₂O distension pressure (median decrease of 9%) and in 6/7 patients at 30cmH₂O distension pressure (median decrease 4%) above resting rectal pressure. Rectal pressure-CSA relation was significantly reduced during stimulation at 20cmH₂O and 30cmH₂O distension.

Table 11c. Implanted Electrical Stimulation Systems – Interventions and Case Series

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Sievert et al. 2010 Germany Case-control Level 3 N=16	Objective: Aim was to investigate potential influences on human nerves and pelvic organs through early implantation of bilateral sacral nerve modulators (SNMs) in complete spinal cord injury (SCI) patients during the acute bladderareflexia phase Population: 16 males with complete traumatic SCI (>T12, AIS A); 10 in treatment group, 6 controls; mean age 31 (range 19-47) Treatment: Implanted with tined lead electrode/sacral nerve modulator (SNM) at third sacral foramen. Control group prescribed oral antimuscarinics. Outcome Measures: Participants provided bladder, bowel and erectile function diaries and answered questionnaires including laxative use	 SNM group reported they felt there was sufficient colon movement without oral laxatives. SNM group has improved bowel movement control (incontinence events decreased) All SNM participants reported significantly better quality of life than the controls. The specific SCI questionnaire used was not mentioned and no scores were given. No intra- or post-operative complications were reported for the implant participants.
Lombardi et al. 2011 Italy Retrospective Data Review Level 4 N=75	Objective: To assess the concomitant clinical improvement in incomplete spinal cord injury patients (SCIPs) suffering from neurogenic bowel symptoms (NBSs), neurogenic lower urinary tract symptoms (NLUTSs) and neurogenic erectile dysfunction (NED) using sacral neuromodulation (SNM) for NBSs and NLUTSs. Population: 75 males with incomplete SCI who received permanent SNM implantation; Age:18-75yrs; year post injury>6 months; suffering from neurogenic bowel symptoms (NBS), neurogenic lower urinary tract symptoms, and/or neurogenic erectile dysfunction refractory to conservative management	 Mean follow-up period from SNM permanent implantation to final visit was 53 months. Patients presenting with NBS improved all parameters by at least 50% compared with baseline for mean (SD) number of occurrences of fecal incontinence (4.33 (1.66) vs 1.25 (1.17)); days with pads (4.5 (1.51) vs 1.33 (1.16)) and Wexner scores (13.66 (1.50) vs 5.83 (0.98)) per week at baseline vs final visit. A significant improvement (20%) in SF-36 scores for all patients compared with baseline. Il adverse reactions were reported (5 individuals required change in stimulation sensation, 2 experienced loss of efficacy, 1

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Treatment: Sacral neuromodulation implantation (Medtronic, Inc) Stage 1- electrode inserted percutaneously in third sacral foramina. Stage 2- Permanent implantable pulse generator implanted in patient's buttock only if main symptoms improved by at least 50% during phase 1. Follow-ups scheduled at 1, 3, 6 months post implantation, and subsequently every 6 months Outcome Measures: SF-36 health survey questionnaire; number of fecal incontinence episodes per week; number of evacuations per week and Wexner score (severity of fecal incontinence)	reported pain per leg spasticity, 2 reported pain at implanted pulse generator site, 1 reported adverse change in bowel function.
Holzer et al. 2007 Austria Pre-post Level 4 N=36	Objective: To assess the outcome of SNS in a cohort of patients with incontinence of neurological aetiology. Population: 36 participants with SCI from spinal cord surgery, 11 from spinal cord trauma, 4 from meningomyelocele; 14M 22F; median age 49 (range 10-79) yrs. Treatment: Sacral nerve stimulation in the sacral foramina S2-S4; follow up after 12 and 24 months for those who underwent permanent implantation after initial evaluation (N=29) Outcome Measures: Number of incontinence episodes, maximum resting and squeeze anal canal pressure, American Society of Colorectal Surgeons (ASCRS) Quality of Life questionnaire	 Median number of incontinence episodes decreased from 7 (range 4-15) to 2 (range 0-5) in 21 days. There were statistically significant improvements in maximum resting and squeeze anal pressure after 12 and 24 months. There was significant improvement in the ASCRS Quality of Life questionnaire for participants who underwent permanent implantation.
Chen & Liao 2015	Objective: The primary aim was to assess the clinical effects of sacral	75.0% rate of improvement for constipation during testing.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
China Case series Level 4 N=23	neuromodulation (SNM) for neurogenic bladder and/or bowel dysfunction with multiple symptoms secondary to spinal cord disease or injury. Population: N=23 (17M, 6F) with spinal cord injury or disease underwent SNM testing (7-28 days): Mean (SD) age 37.3 (2.9) Mean (SD) time since onset 15.5 (3.6) years 9 SCI, 9 myelomeningocele 2 complete, 21 incomplete N=13 (10M, 3F) of which underwent permanent SNM implantation: Mean (SD) age 34.1 (3.2) Mean (SD) time since onset 14.4 (4.8) years Treatment: Sacral neuromodulation (SNM) Outcome Measures: Constipation (Wexner score) and bladder measures	 After implantation, 12/13 experienced improvement in constipation; 11 of which experienced ≥50% improvement. Loss of effect on constipation in 1 patient at 3 months post implantation. Significant reduction in Wexner score (for those with urinary incontinence; N=9) from baseline to testing phase and from baseline to follow-up (17.5±2.0 months after implantation) stage.
Lombardi et al. 2009 Italy Case-series Level 4 N=23	Objective: Efficacy and safety of sacral neuromodulation (SNM) in incomplete spinal cord-injured patients (SCIPs) affected by chronic neurogenic bowel symptoms (NBSs). Population: 15M 8F; 2 cervical, 9 thoracic, 13 lumbar; mean (SD) age = 36(9) years; 12 participants had constipation (C), 11 had fecal incontinence (FI). Treatment: sacral neuromodulation - unilateral implantation in the foramen sacral S3 root Outcome Measures: Wexner questionnaire, SF-36, number of fecal evacuations per week, time per defecation.	 Mean time from neurological diagnosis to SNM therapy was 41 months (range 18-96). Mean follow-up time from SNM implantation to final visit was 44.3 months (range 18-96). Both the constipation and fecal incontinence groups experienced significant improvements in the: Wexner score: C group: pre-SNM=19.91, post-SNM final visit=6.82 FI group: pre-SNM=13.09, post-SMN final visit=4.91 had increased evacuations per week: C group: pre-SNM=1.65, post-SNM final visit=4.98

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
		 had decreased number of fecal incontinence per week Fl group: pre-SNM=4.55, post-SMN final visit=1.32 reduced time per defecation: C group: pre-SNM=45.85, post-SNM final visit=11.67 min. had a decreased number of pads used/day fecal incontinence: pre-SNM=2.36, post-SMN final visit=0.95 Both groups had a significant improvement in the mental and general health subscales of the SF-36. A total of 1038 months yielded 12 adverse events in 5 patients: 4 related to pain at generator site, 3 to spasticity pain in lower limbs, 1 to excessive tingling in vaginal area, and 4 for battery changes.
Valles et al. 2009 Spain Pre-post Level 4 N=18	Objective: The purposes of this study were to analyze the clinical response of bowel function to the sacral anterior root stimulator and to evaluate physiologic factors that could determine its efficacy. Population: 9M 9 F; 4 cervical, 13 thoracic, 1 lumbar; AIS: 14 A, 1 B, 3 C; mean age 39 yrs (range 18-63 yrs) Treatment: Sacral anterior root stimulator, follow up from 12-21 months post implantation Outcome Measures: Use of laxatives, number of bowel evacuation methods used, frequency of and time dedicated to bowel movements, prevalence of constipation, Wexner questionnaire	 After implantation, fewer patients took laxatives (10 vs. 13) and patients used significantly less methods to evacuate bowel (1.5 vs. 2.1) The frequency of bowel movements significantly increased (10 vs. 6 participants had bowel movements every day), and time dedicated decreased (11 vs. 9 participants dedicated <30min) but was not significant. Prevalence of constipation significantly decreased (7 vs. 11); episodes of fecal incontinence increased (18 vs. 16) and the mean Wexner score decreased (4.6 vs. 5.2) but these results were not significant.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Kachourbos & Creasey 2000 USA Pre-post Level 4 N=16	Objective: To promote health with a neurogenic bladder and bowel using the VOCARE Bladder and Bowel Control System. Population: Adults with SCI (demographics not reported) and a history of bowel complications Treatment: Implantation of sacral roots electrodes (S1-S3) with rhizotomy at the conus medularis. Stimulation was delivered via use of VOCARE Bladder and Bowel Control System (Finetech-Brindley stimulator). Outcome Measures: Bowel program times; occurrence of autonomic dysreflexia due to bowel movement; quality of life regarding dependence, socialization, sense of control, and overall quality of life	 Bowel program times were reduced from a mean of 5.4 hours per week pre-operatively to 2.0 hours per week post-operatively. Autonomic dysreflexia due to bowel movements was eliminated. Users reported a greater sense of independence, increased socialization, greater control over their lives, improved self-image, decreased feelings of depression, improved interpersonal relationships and an overall improvement in quality of life.
Jarrett et al. 2005 USA Pre-post Level 4 N=12	Objective: This study examined the use of sacral nerve stimulation (SNS) to treat faecal incontinence in patients with partial spinal injury. Population: 6 participants with SCI from disc prolapse, 4 from trauma, and 1 from spinal stenosis; 4M 9F; median age 58yrs (range 39-73). Exclusion criteria: paraplegia. Treatment: Temporary sacral nerve stimulation, permanent implant if participants demonstrated positive results, median follow up is 12 months (range 6-24) Outcome Measures: Frequency of incontinence; resting and squeeze anal canal pressure ASCRS QoL questionnaire; SF-36 quality of life questionnaire	 1. 12 participants demonstrated positive results and underwent permanent implantation. 2. Mean (SD) frequency of incontinence decreased from 9.33 (7.64) episodes per week at baseline to 2.39 (3.69) at last follow up. 3. ASCRS QoL coping score significantly improved; the SF-36 QoL scores did not change. 3. Neither resting nor squeeze anal canal pressure changed significantly compared to baseline.
<u>Gstaltner et al. 2008</u> Austria	Objective: Treatment of faecal incontinence by permanent sacral nerve stimulation (SNS) in patients	Improved fecal continence in all 5 participants (median score of Wexner score decreased

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Pre-post Level 4 N=11	suffering from cauda equina syndrome (CES). Population: Cauda equine syndrome with flaccid paresis of the anal sphincter muscle and fecal incontinence Treatment: Participants underwent percutaneous nerve evaluation (PNE); following this analysis, a period of external temporary sacral nerve stimulation was performed in both sides of the S2 or S3, and if the patient showed improvements in outcome measures, a permanent stimulator was implanted (N=5) Outcome Measures: Wexner questionnaire, participants' subjective perceptions of quality of life determined through interview.	from pre-SNS (15 (9-19)) to post-SNS (5(2-9)). 2. Reported perianal sensitivity and deliberate retention of feces improved in all 5 participants. 3. Reported improved quality of life in all 5 participants. 4. One complication was reported - one patient had minimal leakage of cerebrospinal fluid following the PNE, after removal of the needle, no further symptoms were reported.
Chia et al. 1996 Singapore Pre-post Level 4 N=8	Objective: This study evaluated the effect of anterior sacral roots stimulator implants on bowel function of patients with spinal cord trauma. Population: Level of injury: 4 C4-C6, 4 T3-T11; 6M: 2F; Age: mean 40, range 20-53yrs. All participants suffered from severe constipation (≤2 bowel movements/week and/or straining at stool for >25% of the time) Treatment: Anterior sacral roots electrodes (S2,3,4) implanted for electrical stimulation. Outcome Measures: Bowel frequency, laxative use, suppository use, need for digital evacuation, anorectal manometry	 6/8 patients had improvement in bowel function: 4/6 were able to evacuate spontaneously after stimulation, 1 described digital evacuation as "easier," 1 used an occasional suppository without the need to digitally evacuate. Six participants with improved bowel routine also showed increased recto-anal pressure immediately after stimulation.

Table 11d. Electrical and Magnetic Stimulation - Cross-Sectional Data

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Bourbeau et al. 2020 Cross-sectional Level 5 N=370	Objective: To investigate the needs and priorities of people with SCI for managing neurogenic bladder and bowel function and to determine their willingness to adopt neuromodulation interventions for these functions Population: Female: 27% Age: 50 (22) years Age at injury: 29 (24) years Time since injury: 12(22) years Outcome Measures: Voice of Customer survey tool by Survey Monkey to explore perspectives of individuals living with SCI, specifically regarding demographics, bladder function, bowel function and attitudes towards nerve stimulation.	 Maintaining fecal continence, gaining more predictability in bowel routine, and reducing time needed for bowel management were the top priorities reported for restoring bowel function. Wearing a device with wires connecting to electrodes on skin and having to don and doff the system daily as needed was the biggest concern regarding external stimulation systems. Experiencing problems with the implant that required a revision surgery or surgical removal of whole system was the biggest concern for implanted systems. 61% of participants were willing to accept an external device and 41% for implanted device to achieve improved bladder or bowel function.
Rasmussen et al. 2015 Germany Cross-sectional Level 5 N=277	Objective: To evaluate the long-term effect of sacral anterior root stimulator (SARS) on neurogenic bowel dysfunction in a large, well defined SCI cohort. Population: N=277 (145M, 132F) Median (range) age 49 (19-80) Median (range) time from SCI to SARS surgery 10 (0-49) years Median (range) time from SARS surgery to follow-up 13 (1-25) years AIS-A/B/C: 234/38/5 131 cervical, 143 thoracic, 3 lumbar Treatment: SARS implantation Outcome Measures: 1-10 visual analog scale (VAS) questionnaire on SARS satisfaction and bowel dysfunction, NBD score, St. Marks fecal incontinence score, Cleveland	 Median (range) overall satisfaction with SARS 10 (0-10) Significant changes before and after SARS in median (range) of: Overall severity of bowel symptoms: 6 (4-8) to 4 (2-6) NBD score: 17 (11-21) to 11 (9-15) St. Marks score: 4 (0-7) to 4 (0-5) Cleveland score: (6-10) to 6 (4-8) Lower total dependence on assistance, use of suppositories, digital evacuation, and mini enemas after SARS

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	constipation score	

Discussion

Bourbeau and colleagues (2020) investigated neurogenic bowel function management needs and found that people's willingness to use neuromodulation interventions depended on their priorities and the device's invasiveness. 61% of participants were willing to adopt an external device, but the largest concern regarding these methods were having to turn on and off the system while wearing wired electrodes. For implanted devices, the largest concern was requiring future surgery to correct complications or remove the implanted device. Fewer people (41%) were willing to adopt this method in comparison to external neuromodulation interventions. Overall, maintaining fecal incontinence, gaining bowel routine predictability, and reducing time of bowel management were some of the highest priorities identified (Bourbeau et al. 2020).

A systematic review reports that functional magnetic stimulation is a common, non-invasive treatment for neurogenic bowel (<u>Parittotokkaporn et al. 2020</u>). The use of functional magnetic stimulation decreased mean colonic transit time (<u>Tsai et al. 2009</u>; (62.6-50.4 hours); <u>Lin et al. 2002</u>; <u>Lin et al. 2001</u>; 105.2(6.66) to 89.4(6.94) hours), as did stimulation of the abdominal muscles (<u>Hascakova-Bartova et al. 2009</u>; <u>Korsten et al. 2004</u>). While preliminary results for posterior tibial nerve stimulation in individuals with SCI appear promising, it is important to note that the statistical significance of the improvements in clinical and physiological parameters were not reported and the study involved only two participants (<u>Mentes et al. 2007</u>).

Another systematic review found that majority of studies report electrical stimulation as a safe and effective treatment for people with neurogenic bowel (<u>Deng et al. 2018</u>). Subsequent studies using sacral anterior root stimulation or sacral neuromodulation yielded improvements in bowel function, including reduced constipation on the Wexner questionnaire (<u>Chen & Liao 2015</u>), better spontaneous evacuation (<u>Lombardi et al. 2011</u>; <u>Sievert et al. 2010</u>; <u>Chia et al. 1996</u>), reduced bowel program times (<u>Kachourbos and Creasey 2000</u>, <u>Valles et al. 2009</u>, <u>Lombardi et al. 2009</u>), elimination of autonomic dysreflexia related to bowel management (<u>Kachourbos and Creasey 2000</u>), elimination of manual help for defecation (<u>Macdonagh et al. 1990</u>). Both <u>Holzer et al. (2007</u>), and increased quality of life (<u>Sievert et al. 2010</u>; <u>Lombardi et al. 2011</u>; <u>Lombardi et al. 2009</u>; <u>Holzer et al. 2007</u>; <u>Kachourbos and Creasey 2000</u>).

Worsoe et al.'s (2013) review of nerve stimulation techniques in neurogenic bowel dysfunction viewed neurostimulation as a way of re-establishing neurogenic control and alleviating symptoms. They reported that the sacral anterior root stimulator improves bowel function in some patients with complete SCI while sacral nerve stimulation can improve function in selected patients with a variety of incomplete neurologic lesions. They also suggest that peripheral stimulation using electrical stimulation or magnetic stimulation may offer non-invasive

treatment alternatives for neurogenic bowels. However, they concluded that due to the lack of research evidence required to support informed choice, the latter techniques should be reserved for research at present.

There are currently investigations of epidural spinal cord stimulation for restoring volitional movement and autonomic responses related to bowel after SCI, which are outlined in Table 23 below.

Conclusions

There is one systematic review (<u>Deng et al. 2018</u>) that electrical stimulation for neurogenic bowel dysfunction treatment is a safe and effective intervention.

There is one systematic review (<u>Parittotokkaporn et al. 2020</u>) that reports non-invasive neuromodulation treatment is commonly used to affect colonic transit time and anorectal pressure, although results are not always definitive.

One systematic review (<u>Worsoe et al. 2013</u>) supports that sacral anterior root stimulation, sacral nerve stimulation, peripheral nerve stimulation, magnetic stimulation and nerve rerouting therapies may also improve bowel function for people with SCI and NBD.

There is level 1 evidence (from one RCT; <u>Korsten et al. 2004</u>) that electrical stimulation of the abdominal wall muscles can improve bowel management for individuals with tetraplegia.

There is level 2 evidence from one prospective controlled trial (<u>Hascakova-Bartova et al. 2008</u>) that neuromuscular electrical stimulation of the abdominal muscles has a positive effect on colonic transit activity in majority of the abdominal segments, but decreases lung capacity in people with SCI.

There is level 4 evidence (<u>Worsoe et al. 2012</u>) that acute dorsal genital nerve (DGN) stimulation reduces rectal cross-sectional area (CSA) and rectal pressure-CSA relation for people with complete supraconal SCI.

There is level 4 evidence (<u>Chen & Liao, 2015</u>) that found chronic sacral neuromodulation is a safe treatment that improves constipation, although it may not resolve all neurogenic bowel symptoms alone.

There is level 4 evidence (from eight pre-post studies; <u>Rasmussen 2015</u>, <u>Valles et al. 2009</u>; <u>Gstaltner et al. 2008</u>; <u>Kachourbos and Creasey 2000</u>; <u>Holzer et al. 2007</u>; <u>Jarret et al. 2005</u>; <u>Lombardi et al. 2011</u>; <u>Chia et al. 1996</u>) that supports the use of sacral anterior root stimulation to reduce constipation and incontinence and improve neurogenic bowel dysfunction in individuals with SCI. One study (<u>Rasmussen 2015</u>) concluded that the effect of stimulation does not seem to decrease with time.

There is level 4 evidence (from three pre-post studies; <u>Tsai et al. 2009</u>, Lin et al. <u>2001</u>, <u>2002</u>) that functional magnetic stimulation may reduce colonic transit time in individuals with SCI.

There is level 5 evidence (one survey; <u>Bourbeau et al. 2020</u>) that majority of people with SCI and NBD are willing to use neuromodulation interventions if they are safe, easy and non-invasive procedures, with fecal continence management as a priority.

There is level 3 evidence (<u>Sievert et al. 2010</u>) that early bilateral sacral nerve modulator implantation improves bowel movement control and may increase quality of life for people with complete SCI.

There is level 4 evidence (<u>Lombardi et al. 2009</u>) that sacral neuromodulation improves defecation time, constipation, fecal incontinence, and quality of life in people with incomplete SCI and neurogenic bowel symptoms.

There is level 4 evidence (MacDonagh et al. 1990) that people with complete supraconal spinal cord lesions can achieve defecation with shorter times and constipation improvements with the use of Brindley-Finetech intradural sacral anterior root stimulation.

Key Points

Electrical stimulation of the abdominal wall muscles can improve bowel management for individuals with tetraplegia.

Functional magnetic stimulation may reduce colonic transit time in individuals with SCI.

Sacral anterior root stimulation may reduce severe constipation, incontinence, and NBD in people with SCI. This intervention is not available at all centres and if combined with dorsal rhizotomy, patients may lose reflex erections, so discussion with health care providers is necessary.

4.7 Bowel Irrigation Techniques

Transanal irrigation (TAI) is a process of facilitating evacuation of stool from the bowel by passing water (or other liquids) in via the anus in a quantity sufficient to reach beyond the rectum into the colon. Pulsed water irrigation uses an electrical pump to deliver intermittent, rapid pulses of warm water into the rectum/colon to break up stool and to stimulate peristalsis (Puet et al. 1997). The enema continence catheter was a specially designed catheter with an inflatable balloon, originally developed by Shandling and Gilmour (1987) for bowel management in individuals with spina bifida. The catheter was inserted into the rectum and the balloon inflated to hold the catheter in place. After the irrigation was administered under gravity, the balloon was deflated, the catheter removed, and the bowel contents emptied. In 2006 Christensen et al. assessed the use of the newly developed Peristeen Anal Irrigation system (Coloplast A/S, Kokkedal, Denmark). This system consists of a rectal balloon catheter, a manual pump, and a water container. The catheter is inserted into the rectum and the balloon inflated to hold the catheter in place while tap water is administered using the manual pump (Christensen et al. 2006).

Antegrade irrigation introduces water to the colon (caecum) via a surgically formed non-reflux stoma. Irrigation may be delivered via the stoma using a manual or powered pump, or by gravity. The Malone antegrade continence enema (MACE or ACE) is a continent catheterizable stoma, connecting from the external abdominal wall to the caecum, through which a catheter is inserted. An enema can then be given via the catheter.

During both transanal and antegrade irrigation a rectal balloon catheter or rectal cone without a balloon is placed into the rectum and removed once irrigation is completed for controlled voiding of the rectum.

Table 12a. Systematic Review on Irrigation Techniques for Neurogenic Bowel

	The restrict of the section of	recliniques for Neurogenic Bowei
Author Year; Country Score Research Design Total Sample Size	Methods	Outcomes
Christensen & Krogh, 2010 Denmark Systematically reviewed articles up until August 2009	Objective: Represent the continuum of increasing evidence and knowledge of transanal irrigation for disordered defecation: from proof in principle through better knowledge of the physiology, towards establishing the indications and ensuring the safety of the treatment.	 17 studies evaluated transanal irrigation in adults; of these, 4 were studies with SCI patients. Treatment was regarded as successful in 53% of all cases; categorized by predominant symptom, success was achieved in constipation (45%), fecal incontinence (47%) and in the mixed symptom group (59%). 2. In a multi-centre RCT with SCI patients, patients treated with transanal irrigation had fewer complaints of constipation, less
N=27 studies (4 studies with SCI patients)	Method: Systematic literature search for published reports on transanal irrigation was	fecal incontinence, improved symptom- related QoL and reduced time consumption on bowel management than patients using best supportive bowel care
Level of evidence: Methodological quality not assessed	conducted. Participants of interest were self-administered transanal irrigation, indications, techniques, outcomes, modes of action,	without irrigation. Also, symptoms of AD were lower in this study, suggesting transanal irrigation may have a protective effect against AD. 3. A significantly better symptom-related QoL was found in the irrigation group
Type of study:	complications, quality of life	compared with patients treated with a
1 multi-centre, RCT (SCI) all others had no control AMSTAR: 3	and quality of methods used. Databases: Medline, Embase, CINAHL, Cochrane Library, completed studies from the internet-based trial register (www.clinicaltrials.gov)	conservative bowel regime w/o irrigation for the domains "coping/behavior" and "embarassment". 4. A cost-effectiveness analysis with an SCI population indicates that transanal irrigation is cheaper and more effective than conservative bowel management, when taking into account aggregate costs

Author Year; Country Score Research Design Total Sample Size	Methods	Outcomes
		of carer help, treatment of UTIs and associated loss of production productivity.
Emmanuel 2010 UK Systematically reviewed articles (no dates specified) N=23 studies (6 SCI) Level of evidence: Strengths and limitations were assessed for each study Type of study: 1 RCT, the rest were retrospective or observational AMSTAR: 2	Objective: Emmanuel A. Review of the efficacy and safety of transanal irrigation for neurogenic bowel dysfunction. Spinal Cord. 2010;48:664-73 Method: Systematic literature search for published reports on TAI in NBD participants. No restrictions on articles by size or design. Databases: Pubmed	 In a RCT of TAI with Peristeen compared with conservative bowel management, significant results in favor of TAI were found for all outcome measures (both symptom burden and QoL). At the end of the RCT, 20/45 patients originally randomized to conservative management switched to TAI; at 10-week follow-up, the outcomes of the initial report were confirmed. Another study reported 68% success for fecal incontinence and 63% for constipation with Peristeen and tap water. 2 studies each with follow-up of nearly 10 years have described the successful long-term use of TAI in the SCI population. For patients with traumatic SCI, the success rates were 50% for complete injuries, 58% for high incomplete injuries and 53% for low incomplete injuries. The second long-term follow-up reported success for 62% of patients with SCI.

Table 12b. Consensus Review on Irrigation Techniques for Neurogenic Bowel

Author Year; Country Score Research Desig Total Sample Si	Methods	Outcomes
Emmanuel et a 2013	Objective: To provide a consensus expert review	Indications for TAI include: patients with NBD, primary or secondary functional bowel
UK (internation panel of expert	s) (TAI).	disorders. Contraindications for TAI include: stenosis, colorectal cancers, inflammatory bowel diseases, acute diverticulitis, ischaemic
N=20 non- pediatric article	Methods: a consensus group of specialists from a range of nations (Denmark, France,	colitis. 2. Optimal patient selection: conservative treatment including biofeedback should be

Author Year; Country Score Research Design Total Sample Size	Methods	Outcomes
	Germany, Italy, the Netherlands, UK) and disciplines (physicians, surgeons, physiology experts, rehab specialists) who have experience in prescribing and monitoring patients using TAI assimilated emerging literature and clinical experience, reaching consensus through a round table discussion process. Databases: PubMed, Athens	tried without success before TAI is performed. Low rectal volume at urge to defecate and low maximal rectal capacity were significantly associated with a successful outcome of TAI. 3. Clinical examination and preparation: a specialist health-care professional should be consulted before TAI. Bowel diaries and symptom scoring systems should be used. Fecal impaction must be excluded and treated before starting TAI. 4. Patient training: comprehensive training is essential - written info should be available, training a patient until they are comfortable with irrigation is necessary. Patients should be taught to recognise the symptoms of colonic perforation and what actions to take.

Table 13. Irrigation Techniques for Neurogenic Bowel After Spinal Cord Injury -Interventions and Case Series

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Christensen et al. 2006 Denmark RCT Level 1 (PEDro = 7) N=87	Objective: The aim of the present study was to compare transanal irrigation with conservative bowel management (best supportive bowel care without irrigation). Population: 1) TAI group: ≥T9: 3 complete, 5 incomplete; TI0-L2: 1 complete, 1 incomplete; L3-S1: 1 incomplete); Age: mean 47.5 yrs; 29M 13F. 2) Conservative bowel management (CBM) group: ≥T9: 22 complete, 11 incomplete; TI0-L2: 1 complete, 3 incomplete; L3-S1, 8	 The TAI group had significantly improved scores over the CBM group for the following scales: CCCSS: TAI=10.3(4.4); CBM=13.2(3.4) FIGS: TAI= 5(4.6); CBM=7.3(4) NBD: TAI=10.4(6.8); CBM=13.3(6.4) TAI group scored non-significantly better on 2/4 domains of the symptom-related quality-of-life tool and significantly better on the domains coping/behaviour (TAI=2.8(0.8) vs CBM=2.4(0.7)) and embarrassment (TAI=3.2(0.8) vs CBM=2.8(0.9)).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	incomplete Age: mean 50.6yrs; 33M 12F Treatment: TAI (Peristeen Anal Irrigation system) or conservative bowel management (Paralyzed Veterans of America clinical practice guidelines) for 10 weeks. Outcome Measures: Cleveland Clinic constipation scoring system (CCCSS), St. Mark's fecal incontinence grading scale (FIGS), American Society of Colon and Rectal Surgeons fecal incontinence score (symptom-related QOL scale), NBD score.	 Improvement found in the TAI group as a whole was not confined to the more physically able patients. At weeks 7-10 participants had reduced time spent on bowel management each day, and reported being less dependent on help. The reported frequency of urinary tract infection during weeks 1-10 was lower in the TAI group (TAI=5.9%, CBM=15.5%).
	Effect Sizes: Forest plot of standardized mean differences (SMD ± 95%C.I.) as calculated from pre- and post-intervention data Christensen et al. 2006; Transanal Irrigation (Peristeen)	
	Cleveland Constipation Score St. Mark's Fecal Incontinence Grade NBD Score ASCRS FIS - Lifestyle ASCRS FIS - Coping/Behaviour ASCRS FIS - Depression/Self-perception ASCRS FIS - Embarrassment NBS - Bowel Function NBS - Influence on Daily Activities NBS - General Satisfaction -2 -1.5 Favours ASCRS FIS = modified American Society of Colon ar NBS = Numeric Box Scale	Control SMD(95%C.I.) Favours Treatment
Emmanuel et al. 2021 Europe Open, prospective efficacy study	Objective: To investigate the short- term efficacy and safety of an electronic transanal irrigation system called Navina Smart in	1. Per protocol analysis on 52 participants showed significant decrease in mean NBD score from 17.8 to 10 (p<0.00001).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Level 2 N=89	people with neurogenic bowel dysfunction Population: N=89 Mean age: 48 y Female: 31% N: 52 in per protocol set Mean age: 47.6 years 23 ASIA A 7 ASIA B 8 ASIA C 13 ASIA D 1 missing data Treatment: Transanal irrigation (TAI) system Navina smart Outcome Measures: NBD score was measured at baseline and 3 month follow-up. A 5-point scale measured subjective satisfaction with bowel management	 Significant NBD score reduction after three months from 17.75 ± 4.87to 9.94 ± 5.26 (p<0.0001). For those with severe symptoms and NBD score greater than or equal to 14, mean NBD scores decreased from 19.4 to 10.9 (p<0.0001). Baseline number of participants with severe symptoms decreased to 16 at the three month follow up (79% to 31%). Bowel management satisfaction increased from mean 1.85 at baseline to mean 3.67 after 3 months (p<0.0001). Moderate correlation (correlation coefficient= 0.46) between NBD score and satisfaction with bowel management (p=0.0006). After 3 months of using Navina Smart, participants significantly reduced time spent on daily bowel management from mean 73.5 minutes to 46.4 minutes (range visit 1 0–360 min (±61.9), visit 2 10–120 (±20.5), p = 0.0007). Decrease in the need of other methods of bowel management besides transanal irrigation from a total of 225 at baseline to 158 at 3 months. Number of participants that required pads did not significantly decrease in participants with fecal incontinence (17 at baseline, 11 at 3 months).
Kim et al. 2013 Korea Longitudinal Level 2 N=52	Objective: To investigate the outcome of transanal irrigation (TAI) in patients with spinal cord injury (SCI) and to identify factors	 Compliance with the use of TAI at 1, 3, and 6 months was 31/52 (59.6%), 25/52 (48.1%) and 18/52 (34.6%). At 6 months, the noncompliant group contained a higher proportion of tetraplegics than

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	significantly related to clinical success. Population: Level of injury: 28 tetraplegics, 24 paraplegics; 41M 11F; Mean (SD) age: 44.5 (11.0) yrs; mean (SD) DOI: 92.9 (118.4) months Treatment: Transanal irrigation (TAI) Outcome Measures: Compliance rate, questionnaire on demographics, bowel care habits, frequency and time needed to defecate, intestinal symptoms, need for assistance during bowel management, participant satisfaction and quality of life, adverse events	paraplegics and a higher need for assistance during bowel management. At 6 months, 6/28 (21.4%) of tetraplegia patients and 12/24 (50%) paraplegic patients were using TAI. 3. In the compliant group, defecation time decreased from baseline to 6 months and quality of life increased from baseline to 6 months.
Smith & Decter 2015 USA Prospective Cohort Level 2 N=17	Objective: Patients with spinal cord injury (SCI) often suffer from severe constipation/fecal incontinence. The antegrade continence enema (ACE) procedure is often used to control these distressing symptoms when medical management fails. Improvement in the quality of life (QOL) following the ACE procedure has been demonstrated in patients with fecal incontinence of various etiologies. We assess the impact of the ACE procedure on QOL in patients with fecal incontinence due to SCI. Population: N=17 (12M, 5F) Mean (range) age at surgery 33 (6-49) Mean (range) time post SCI at surgery 10 (1-30) years Mean time from surgery to follow-up 56 (4-102) months 10 paraplegia, 7 tetraplegia 9 thoracic, 8 cervical	 Significant increase in mean (SD) of all categories of FIQL after surgery: Lifestyle: 2.3 (0.9) to 3.7 (0.5) Coping/Behaviour: 2.2 (0.9) to 3.8 (0.3) Depression/self-perception: 2.8 (0.9) to 3.8 (0.4) Embarrassment: 2.2 (1.1) to 3.8 (0.3) Three patients developed stomal stenosis and one developed delayed small-bowel obstruction after surgery.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	N=5 excluded due to completing pre-operative survey after surgery (N=12 remain for final analysis) Treatment: Anterograde continence enema (ACE) Outcome Measures: Fecal incontinence quality of life (FIQL) instrument	
Christensen et al. 2000 Denmark Case-control Level 3 N=29; 19 SCI	Objective: To evaluate results of the Enema Continence Catheter (ECC) and the Malone Antegrade Continence Enema (MACE) applied in patients with severe neurogenic colorectal dysfunction. Population: 1) TAI (enema continence catheter): N=21 participants (15/21 were SCI); 10M 11F; Age: mean (range) 39.9 (7-72) yrs; for SCI participants: Level of injury: 3 supraconal (T2 incomplete, T4 complete, T11 complete), 12 incomplete conal or cauda equina injuries; follow-up: mean (range) 16 (1-51) months 2) MACE: 8 patients, (4/8 were SCI); 3M 5F; Age: mean 32.8 years, range 15-66; 2 supraconal SCIs (C5-6 and T2, incomplete); mean follow-up 38 months, range 4-77 Treatment: TAI (enema continence catheter) vs. MACE (out of 8 MACE patients, 3 had tried ECC previously) Outcome Measures: questionnaire on colorectal function, practical procedure, impact on daily living and quality of life, general satisfaction of the patient with the treatment	 Overall success with TAI was found in 12/21 patients (57%). In patients with fecal incontinence, TAI was successful in 8/11 (73%), while 4/10 (40%) with constipation were successfully treated. Overall success with the MACE was found in 7/8 (87%) patients. Successful treatment with TAI or the MACE was followed by significant improvement in quality of life.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Ethans et al. 2022 Canada Pre-post Level 4 N=12	Objective: Neurologic bowel incontinence and dysfunction are common with Cauda Equina Syndrome (CES). The study objective was to evaluate the efficacy of Peristeen Anal Irrigation System (PAIS)™ in people with CES. Population: 12 participants with a mean age of 46.2 years (range 34–72 years, 4 females) with Cauda Equina Syndrome (CES) Treatment: used PAISTM bowel routine for 10 weeks. Outcome Measures: Change in Neurogenic Bowel Dysfunction Score (NBD) over 10 weeks relative to baseline. Secondary outcomes: Change in St. Mark's Fecal Incontinence score (SMFI), Cleveland Clinic Constipation score (CCC), and modified Rectal Surgeons Fecal Incontinence Quality of Life Score (QOL) at week 1, 2, 4, 6, 8 and 10 compared to baseline, and self-rating of bowel function at baseline and 10 weeks. Additionally, colonic transit times were assessed using the radioactive markers (Sitzmarks) method.	 Ten participants completed the study. Post-intervention primary outcome NBD score improved (p<0.01). Secondary outcomes also improved significantly, including SMFI (p<0.01), CCC (p<0.01), QOL (p<0.01), self-rating of bowel function (p<0.01), and transit time improved by 22% (p<0.05). No significant adverse effects were recorded.
Faaborg et al. 2009 Denmark Post-test Level 4 N=211	Objective: Short-term results find transanal colonic irrigation (TAI) favourable in the treatment of neurogenic bowel dysfunction (NBD). Therefore, long-term results need to be described. Population: 96M 115F with neurogenic bowel dysfunction; age: median 49yrs, range 7-81 yrs, who were introduced to transanal irrigation between 1994-2007. 74 traumatic SCI participants; 10 high	 Successful outcomes in 98 (46%) of participants after a mean follow-up of 19 months (range 1-114 months). Dropout rate of 20% in the first 3 months of using TAI. Success rate 3 years after introduction of TAI was 35%. The male gender, mixed symptoms (patients suffering from both constipation and fecal incontinence), and prolonged colorectal transit times were

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	complete, 12 high incomplete, 14 low complete, 38 low incomplete. Treatment: TAI (Enema continence catheter; same as that used in Christensen et al. 2000) Outcome Measures: Rate of success (treatment was considered successful if the patient is currently using TAI, if the patient used TAI until he/she died, or if the patient's symptoms resolved while using TAI) as evaluated by a questionnaire, as well as the patient's medical records; incidence of bowel perforation and other side effects	significantly correlated with successful outcomes. 5. Chance One non-lethal bowel perforation occurred in approximately 50,000 irrigations (0.002%), whereas minor side effects were observed in 48%. 6. Other minor side effects (such as abdominal pain, minor rectal bleeding, and general discomfort) were observed in 48% of participants.
Puet et al. 1997 USA Case series Level 4 N=173	Objective: To evaluate the efficacy of Pulsed Irrigation Evacuation (PIE) for the clearing of fecal impactions in patients with a neuropathic bowel. Population: 15 complete tetraplegia, 28 incomplete tetraplegia, 35 complete paraplegia, 95 incomplete paraplegia; 31 patients with pulsed irrigation evacuation (PIE). Treatment: Pulsed TAI: intermittent, rapid pulses of warm water to break up stool impactions and stimulate peristalsis. Outcome Measures: Efficacy of technique (percentage success in removing stool), outpatient use	 Successful in removing stool in all but three patients. Il patients had multiple procedures. 162 procedures were performed on 4 outpatients on a regular basis because they otherwise could not develop an effective bowel routine with the standard digital stimulation, suppositories, or mini enemas.
Worsoe et al. 2008 Denmark Case series Level 4 N=80	Objective: Review long-term results in a large group of adult patients treated with antegrade colonic enema and antegrade colonic enema combined with a colostomy.	1. 69 participants were available for follow up, of whom 43 were still using ACE and 8 had their symptoms resolved; ACE success rate was 74%

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Population: 64F 16M; Age: mean (range) 51 (17-84) yrs. Main symptom was constipation for 48 participants, fecal incontinence for 20 and a combination of both in 12. Treatment: Antegrade colonic enema (ACE), or ACE combined with colostomy Outcome Measures: A 44-item questionnaire, including whether the patient is still using ACE and if not, why; functional results and side effects of ACE; overall satisfaction with bowel function and quality of life; success of treatment, defined as participants still using ACE or bowel symptoms resolved because of ACE	 Complications occurred in 30 participants, including wound infection, urinary tract infection, stenosis of the appendicostomy, and problems with catheterization 34 of the 43 patients still using ACE were satisfied or very satisfied with the results; on a 0-100 scale, mean values for subjective bowel function was 12 before and improved to 81 after ACE
Christensen et al. 2008 Europe Pre-post Level 4 N=62	Objective: To compare symptoms of neurogenic bowel dysfunction in patients with spinal cord injury (SCI) at baseline and after 10 weeks of treatment with transanal irrigation and to identify possible factors that could predict outcome of the treatment. Population: 45M 17F; mean (SD) age: 47.5 (15.5) yrs; level of injury: supraconal for 61, conal/cauda equina (S2-S4) for 1. 55/62 completed the study Treatment: TAI (Peristeen Anal Irrigation) for a 10-week period Outcome Measures: Cleveland Clinic constipation scoring system (CCCSS), St Mark's fecal incontinence grading system (FIGS), Neurogenic bowel dysfunction (NBD) score (higher scores = worse outcomes)	 Participants' CCCSS mean scores significantly improved from 13.5 to 10.2. Participants' FIGS mean scores significantly improved from 8.5 to 4.5. Participants' NBD mean scores significantly improved from 15.3 to 10.8. Peristeen Anal Irrigation significantly improved constipation, anal continence, and symptom-related quality of life in SCI participants

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Del Popolo et al. 2008 Italy Pre-post Level 4 N=36	Objective: To evaluate the effects of Peristeen Anal Irrigation on NBD and patient quality of life (QoL). Population: SCI patients with severe NBD and unsatisfactory bowel management; 32/36 completed the study. Cause of SCI: 42.4% trauma, 36.4% spina bifida, 6.1% MS, 3% surgery, 9.1% other, 3% not recorded. 39.4% sensory complete, 42.4% sensory incomplete, 18.2% not specified. Treatment: TAI (Peristeen Anal Irrigation) for three weeks Outcome Measures: Quality of life questionnaire (scale and nominal variables), participants' opinions on their intestinal functionality, use of pharmaceuticals, dependence on caregivers, incidence of incontinence and constipation, abdominal pain or discomfort	 Significant increase in the scores on the quality of life questionnaire, and on intestinal functionality opinion scores. Significant decrease in abdominal pain or discomfort. For the statement regarding abdominal pain or discomfort before or after evacuation, before: 9 answered never, 5 rarely, 6 occasionally, 6 often, 7 always; after: 24 never, 6 rarely, 3 occasionally. Significant decrease in incidence of fecal or gas incontinence. For the statement regarding gas incontinence, Before: 10 answered never, 9 rarely, 8 occasionally, 3 often, 2 always; After: 15 never, 11 rarely, 5 occasionally, 1 often, 1 always. Significant improvement of constipation (63% of participants experiencing constipation reported improvements). For the statement regarding difficult/painful exertion in connection with evacuation, Before: 5 answered never, 5 rarely, 4 occasionally, 10 often, 9 always; After: 21 never, 9 rarely, 3 occasionally, 1 often. 28.6% of participants reduced or eliminated their use of pharmaceuticals
Teichman et al. 1998 USA Retrospective chart review Level 4 N=7; 4 SCI	Objective: To describe the outcomes of adults with neurogenic bowel disease who underwent a Malone antegrade continence enema procedure with or without concomitant urinary diversion. Population: N=4 SCI participants Level of injury: 2 C6, 1 C7, 1 T5; all	 3/4 SCI participants experienced fecal incontinence prior to the operation. All became continent as a result of the operation. Pre-operatively, SCI participants' toileting times ranged from 1-4 hours as a result of their bowel status. Post-operatively, these participants were able to evacuate

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	males; Age: mean (range) 32.5 22-47yrs; Mean follow-up: 11 months Treatment: Malone antegrade continence enema (MACE) Outcome Measures: Number of fecal incontinence episodes per week, time for evacuation, bowel management episodes attempted	within 30 minutes or less. 3. Autonomic dysreflexia secondary to neurogenic bowel was resolved post-operatively.
Teichman et al. 2003 USA Retrospective chart review Level 4 N=6; 3 SCI	Objective: To determine the long-term outcomes from the Malone antegrade continence enema (ACE) procedure in adult neurogenic patients. Population: N=3 participants with SCI Level of injury: T5 complete, C6 complete, C7 incomplete; all males; Age: mean (range) 36 (29-47) yrs; Treatment: Malone antegrade continence enema (MACE) with mean follow-up 4.5 years Outcome Measures: Bowel incontinence; subjective patient satisfaction (patients were asked: "do you consider the surgical procedure beneficial to you" and "if you could do the ACE procedure again, would you?")	 2/3 participants experienced fecal incontinence prior to the operation. Post-operatively, both these participants became continent. All 3 participants were satisfied with their outcomes and rated their quality of life higher after their MACE procedure compared with beforehand. 3 participants experienced prolonged toileting pre-operatively as a result of bowel status. Post-operatively, the group had a significant reduction in their toileting times (pre-ACE mean (SD) time: 190(45) vs post-ACE: 28(20) min).

Discussion

Two review papers published in 2010 looked at transanal irrigation in the neurogenic population (<u>Emmanuel 2010</u>) and both the neurogenic and wider population (<u>Christensen & Krogh 2010</u>) respectively.

Both reviews concluded that the use of transanal irrigation resulted in significant improvements in incontinence, constipation, time spent on bowel care, autonomic symptoms around bowel management and quality of life, in comparison to conservative management in individuals with SCI. Irrigation was found to be a safe procedure, as the risk of bowel perforation was approximated as 1/50,000 irrigations. No adverse changes in rectal or colonic function were

associated with irrigation use. However, in the long term a significant proportion of users stop using irrigation. The cause of this is not clear but thorough preparation and training for irrigation and continuing support whilst establishing a new regimen are thought to improve compliance.

An international group of specialists from a range of disciplines, experienced in transanal irrigation, have published a consensus review (Emmanuel et al. 2013) that provides guidance regarding patient selection, indications and contraindications for transanal irrigation and a step-by-step approach to treatment and follow-up. Absolute contraindications include anal or rectal stenosis, active inflammatory bowel disease, acute diverticulitis, colorectal cancer, ischaemic colitis, rectal surgery within the previous 3 months or endoscopic polylectomy within the previous 4 weeks. Relative contraindications include severe diverticulosis, long term steroid medication, painful anal conditions, planned or current pregnancy, and severe autonomic dysreflexia. Fecal loading/impaction should be treated before irrigation is instigated. No clear patient selection criteria have been identified; any individual whose bowel management is ineffective, lacks contraindications above, and who is suitably motivated may benefit from transanal irrigation. The importance of training the patient and their caregiver, as well as providing follow up support, while establishing an individualized program is emphasized.

The evidence for irrigation is mostly in people with chronic SCI with upper motor neuron bowel dysfunction. However, in a small study <u>Ethans et al. (2022)</u> found improvements in all measures of incontinence scores, constipation severity, improved transit times, and satisfaction, including in people with LMN bowel dysfunction.

There is a need to explore its potential in the subacute rehabilitation phase. Further research is also required to determine the cause of the reduction in use of irrigation over time and how this can be improved, and to develop clear patient selection criteria.

In people with SCI for whom transanal irrigation is ineffective or inappropriate, the Malone antegrade continence enema (MACE) can eliminate fecal incontinence (Worsoe et al. 2008; Teichman et al. 2003; Christensen et al. 2000; Teichman et al. 1998), reduce time spent on bowel care (Worsoe et al. 2008; Teichman et al. 2003; Teichman et al. 1998), improve quality of life (Teichman et al. 2003; Christensen et al. 2000; Smith & Decter 2015), resolve autonomic dysreflexia secondary to the neurogenic bowel (Teichman et al. 1998), and successfully treat constipation (Christensen et al. 2000). Smith & Decter (2015) found three of the twelve patients (25%) in their cohort study (mean follow-up 56 months) developed stomal stenosis and one developed delayed small bowel obstruction.

<u>Christensen et al. (2000)</u> compared the efficacy of MACE with the enema continence catheter in people with SCI and reported successful treatment of fecal incontinence, slow transit or constipation, and obstructed defecation.

Conclusions

There is level 1 evidence (from one RCT; <u>Christensen et al. 2006</u>) that supports the use of transanal irrigation (Peristeen Anal Irrigation system) over conservative bowel treatment (as

outlined by the Paralyzed Veterans of America clinical practice guidelines) in individuals with chronic SCI and bowel management problems.

There is level 2, 3, and 4 evidence (from four retrospective reviews and one longitudinal cohort; Teichman et al. 1998; Christensen et al. 2000; Teichman et al. 2003; Worsoe et al. 2008; Smith & Decter, 2015) that the Malone Antegrade Continence Enema successfully treats neurogenic bowel dysfunction.

There is level 3 evidence (from one retrospective review; <u>Christensen et al. 2000</u>) that the enema continence catheter can be used to treat neurogenic bowel dysfunction.

There is level 4 evidence (from one case series, one cross-sectional, and three non-randomized cohort studies) (<u>Del Popolo et al. 2008</u>, <u>Christensen et al. 2008</u>, <u>Faaborg et al. 2009</u>, <u>Kim et al. 2013</u>) that supports the use of transanal irrigation to manage neurogenic bowel dysfunction.

There is level 4 evidence (from one case series; <u>Puet et al. 1997</u>) that supports using pulsed water irrigation (intermittent rapid pulses) to remove stool in individuals with SCI.

There is level 4 evidence (<u>Ethans et al. 2022</u>) that PAISTM, as a non-pharmaceutical method of bowel management is effective and has the potential to improve symptoms of bowel dysfunction in people with CES.

Key Points

Transanal irrigation can improve all bowel management outcomes in people with chronic neurogenic bowel dysfunction following SCI.

The Malone Antegrade Continence Enema is a safe and effective treatment for significant GI problems in persons with SCI when conservative and transanal irrigation are unsuccessful or inappropriate.

Pulsed water transanal irrigation may help to remove stool in people with SCI.

4.8 Pharmacological Management

A systematic review on the pharmacological management of NBD (<u>Johns et al. 2021</u>) identified the medications used by people with SCI. These include oral laxatives, prokinetic agents, rectal laxatives (suppositories and enemas), and narcotic antagonists. However, findings show that these pharmacological agents have relatively little evidence to support their use in NBD management for the SCI population (<u>Johns et al. 2021</u>).

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Table 14. Systematic Review on Pharmacological Management

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Johns et al. 2021 USA, Europe, Canada N=28 studies	Objective: To examine the literature on pharmacological agents used to manage neurogenic bowel dysfunction of individuals with SCI or MS N=26 studies SCI, 2 studies MS Methods: Studies were included if the population was SCI or MS, included bowel-related outcomes, and if the independent variable was some form of medication and/or medicated suppository Databases: Medline, Embase, and CINAHL up to June 2020	 Oral Laxatives Polyethylene glycol (PEG), magnesium hydroxide, docusate sodium, lactulose, bisacodyl, and sennosides were used in current treatment. Prescription relies on expertise and evidence from the general population, but studies do not investigate long-term usage: suggest prescribing a simple agent to start as it may have fewer adverse effects for people with constipation (starting the night before bowel routine, usually every other day or 3x/week). Reassess regimen in the following weeks, aiming for ideal stool consistency and improved evacuation. Prokinetic Drugs Metoclopramide and neostigmine are not used in current management. Prucalopride is recommended to treat constipation when there is a lack of responsiveness to laxatives, but there is little evidence demonstrating its efficacy for people with NBD and SCI. Potassium channel blocker Fampridine is not currently used for bowel management after SCI. Two RCTs examined fampridine and bowel changes as a secondary outcome in which findings indicate possible improvements, although further study is required. Suppositories and Enemas Suppositories are commonly used but there is a lack of evidence in the SCI population; current medications used include polyethylene glycol, sodium citrate, bisacodyl, sennosides, docusate sodium. Cross sectional studies report that suppositories may be used by people with more severe NBD.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
		 Multiple studies report that polyethylene glycol-based bisacodyl had higher efficacy compared to hydrogenated vegetable-oil based (HVB) bisacodyl, although HVB suppositories are more common due to lower costs and higher availability. Mini-enema can be used as a suppository alternative if bowel care is taking too long, they may be more tolerable and easier to insert.
		5. Narcotics Antagonist - Common option for pain management; current
		medications include naloxegol, lubiprostone, methylnaltrexone bromide. - No evidence found specific to SCI and opioid-induced constipation or narcotic antagonist.

4.8.1 Pharmacological Stimulants: Oral and Rectal Laxatives

Oral and rectal laxatives used in current neurogenic bowel management can include stool softeners, osmotic laxatives, and stimulant laxatives:

Stool softeners: Promote stool passage by increasing the water in stool via lowering the surface tension at the oil-water surface interface (e.g., Docusate sodium) (<u>Johns et al. 2021</u>)

Osmotic laxatives: Promote stool passage by increasing the water in stool via osmosis, (e.g., Polyethylene glycol, magnesium hydroxide, docusate sodium, lactulose) (<u>Johns et al. 2021</u>)

Stimulant laxatives: Promote colonic transit by activating contractions of the intestinal walls (e.g., Bisacodyl, sennosides) (<u>Johns et al. 2021</u>)

Oral laxatives are commonly used to treat constipation, but studies typically investigate rectal administration and/or prescription grade laxatives in neurogenic bowel management with SCI. Pharmacological rectal stimulants (suppositories and enemas) are a common component of a successful bowel management program, used by up to 60% of individuals with UMN bowel dysfunction (Coggrave et al. 2009). The two most commonly used are the glycerin suppository, which provides a mild local stimulus and lubrication, and the bisacodyl (dulcolax) suppository, which provides a dose of stimulant laxative directly to the colonic mucosa producing peristalsis throughout the colon. Other options include polyethylene glycol suppository, sennosides suppository, sodium hydrogen carbonate suppositories, sodium citrate and glycerol micro-enema and docusate sodium micro-enema (Johns et al. 2021).

Table 15a. Systematic Reviews on Suppository/Enema Use for Neurogenic Bowel After SCI

Author Year; Country Score Research Design Total Sample Size	Methods		Outcome
Yi et al. 2014 China Published articles up to February 2014	Objective: To compare the efficacies of vegetable oil based bisacodyl (VOB) and polyethylene glycol based bisacodyl (PGB) suppositories in treating patients with neurogenic bowel dysfunction (NBD) after spinal cord injury (SCI). Methods: Literature search for randomized controlled trials (RCTs), controlled clinical trials (CCT) comparing vegetable oil based (VOB) and polyethylene glycol based (PGB) suppositories	 2. 3. 	group difference in time to flatus and defecation period (shorter in PGB group) (N=2).
N=3 AMSTAR: 3	Databases: US NLM, NIH (PubMed), MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials (CCTR), Chinese National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), Wanfang, VIP (VIP Database for Chinese Technical Periodicals)	5.	No significant between-group difference in time to clean up (N=2).

Table 15b. Treatment Studies Using Rectal Laxatives for Neurogenic Bowel

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
House & Stiens 1997; USA RCT Level 1 (PEDro = 7) N=15	Objective: To compare the effectiveness of hydrogenated vegetable oil-based bisacodyl (HVB) suppositories, polyethylene glycol-based bisacodyl (PGB) suppositories, and polyethylene glycol-based, glycerine, docusate sodium mini-enemas (TVC) in subjects with upper motor neuron spinal cord lesions. Population: 9 participants with cervical injuries, 6 with thoracic injuries (II complete, 4 incomplete); Age range: 26-61; Duration of injury: 3 months to 45 yrs Treatment: At each regularly scheduled bowel care session, insertion of either a 10 mg hydrogenated vegetable-oil base (HVB) or 10 mg polyethylene glycol base (PGB) suppository. Additionally, 10 participants received 3 TVC (polyethylene glycol-based, glycerine, docusate sodium mini-enemas). Outcome Measures: time to flatus, flatus to stool flow, defe-cation period, time to transfer cystometrogram, intracolonic pressure, colonic motor and myoelectrical activity	 Mean time to flatus (min): PGB (15) significantly less time than HVB (32) Mean time from flatus to stool flow (min): No significant differences. HVB=6.7, PGB=5.5, TVC=3.9. Defecation Period (mean in min): PGB (20) significantly less time than HVB (36). TVC=17. Total time for bowel program (mean in min): PGB suppositories (43) significantly decreased bowel care time compared to HVB (74.5). TVC=37.
Frisbie 1997 USA Prospective controlled trial Level 2 N=19	Objective: To test its effectiveness for bowel care in myopathy patients, a bisacodyl suppository based in polyethylene glycol (PEGBS) was compared with a conventional bisacodyl suppository based in hydrogenated vegetable oil (HVOBS). Population: Level of injury: TI-7 (15 cervical, 4 thoracic); Age: mean (range) 64 (41-81)yrs; Duration of injury: mean (range) 19 (3-51)yrs. Treatment: A PGB vs HVB bisacodyl suppository Outcome Measures: Average time for complete bowel evacuation	1. All patients experienced a shortening of bowel care time with PGB. Average time for bowel evacuation was 2.4 hours (range 1.0-4.5 hours) with HVB and 1.1 hours (range 0.3 to 1.8 hours) with PGB.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Dunn & Galka 1994 USA Pre-post Level 4 N=14	Objective: To compare the Therevac SB "mini-enema" with bisacodyl suppositories in the bowel management programs of patients with spinal cord injury (SCI). Population: Level of injury: C5-L1, (5 tetraplegics, 9 paraplegics); Age: range 27-67yrs; Duration of injury: range 2-38yrs Treatment: Phase 1: bisacodyl suppositories for five bowel programs for baseline data. Phase 2: docusate sodium mini enema (Theravac SB) for the next five bowel programs. Phase 3: bisacodyl for five more bowel programs Outcome Measures: Self-reported diary including time of insertion of the rectal medication; time of first evacuation; time required to complete the first evacuation; other interventions used; bowel problems between bowel programs	 1. 10 participants complete all treatment phases. 2. Of these 10 participants, the mean evacuation time was significantly reduced with Theravac SB (phase 2) compared to the mean times with both the bisacodyl interventions (phase 1 and 3) 3. No significant difference in evacuation time between the first (phase 1) and second (phase 3) bisacodyl interventions.
Round et al. 2021 Canada Case series Level 4 N=161	Objective: To explore the association between bowel dysfunction and use of laxatives and opioids in an acute rehabilitation setting following SCI Population: N=161 Age: 48.1 ± 19.1 y Etiology: 64% traumatic Time since injury: 52.8 ± 56.8 days Female: 30.4% On admission: Cervical 74 (45.9%) AIS A + B 25 (15.5%) AIS C + D 49 (30.4%) Thoracic 39 (24.2%) AIS A + B 21 (13.0%) AIS C + D 18 (11.2%) Lumbosacral 48 (29.8%) AIS A + B 18 (11.2%)	Frequency of bowel movement with laxatives 1. Frequency of bowel movement (BM) was negatively correlated with number of laxatives used at admission (r=-0.28, p<0.001) and discharge (r=-0.16, p=0.035). 2. Frequency of BM was negatively correlated with the number of laxatives used at admission only for the UMM (r=-0.218, p=0.022) and LMN groups (r=-0.384, p=0.006). Frequency of fecal incontinence (FI) 1. No correlation at admission between laxative use and FI, but a positive correlation at

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	AIS C + D 30 (18.6%) At discharge: Cervical 69 (42.8%) AIS A + B 20 (12.4%) AIS C + D 49 (30.4%) Thoracic 34 (21.1%) AIS A + B 13 (8.1%) AIS C + D 21 (13.0%) Lumbosacral 58 (36.1%) AIS A + B 12 (7.5%) AIS C + D 45 (28.0%) AIS E 1 (0.6%) Treatment: N/A Outcome Measures: Frequency of bowel movements with laxatives, frequency of fecal incontinence episodes, opioid and laxative usage	discharge (r=0.194, p=0.014). Opioids 1. Overall, no correlation between average dose of opioids and frequency of BM at admission. Although, a negative correlation between average dose of opioids and BM frequency at discharge (r=-0.20, p=0.009) confirms the constipating effect of opioids. 2. For the UMN group there was a positive correlation between BM frequency and average dose of opioids at admission (r=0.3.50, p=0.006), but not for the LMN group. 3. No correlation at admission or discharge between average dose of opioids and FI frequency.

Discussion

Pharmacological rectal agents (suppositories or enemas) are commonly used by individuals with SCI to stimulate reflex evacuation at the time chosen for bowel care. They are an essential element of a bowel program for many individuals with upper motor neuron bowel though there is little evidence to support most of the suppositories and enemas used. However, the effectiveness of the HVB bisacodyl suppositories compared to the PGB suppositories has been examined. The total bowel care time with the PGB suppository is significantly less (Stiens et al. 1998; Frisbie 1997; Dunn & Galka 1994) compared to HVB suppository. House and Stiens (1997) compared the effectiveness of HVB, PGB and docusate glycerin (mini-enema) in participants with upper motor neuron lesions. Results showed a significant decrease in bowel care time using the PGB suppository and the mini-enema as compared with the HVB suppositories.

In documenting the use of laxatives and opioids in people with SCI and their effects on bowel outcomes, Round et al. (2021) found that the number of people using laxatives and opioids significantly decreased between admission and discharge (p=0.004 and p=0.001, respectively). Findings showed that laxatives were positively correlated with fecal incontinence frequency at discharge, but not at admission. Also, the average dose of opioids demonstrated a constipating

effect with higher dosages at discharge (p=0.009). There is little evidence on opioid-induced constipation and narcotic agonists in the SCI population (<u>Johns et al. 2021</u>), but the American Gastroenterological Association (AGA) Guidelines recommend laxatives as first line treatment, followed by narcotic antagonists (PAMORA drugs) such as naloxegol, methylnaltrexone, and naldemedine. <u>Johns et al. (2021)</u> also identified the oral opioid antagonist lubiprostone which is currently used in NBD.

Based on the poor evidence and the myriad of potential side effects, opioids may be considered in neuropathic pain treatment only as add-on therapy to anticonvulsants, always considering the risk-benefit ratio, particularly re: someone's bowels, and opioids are not suggested at all as a singular therapy for SCI related neuropathic pain (<u>Franz et al. 2019</u>).

Conclusions

There is level 1 evidence (from systematic review; <u>Yi et al. 2014</u>) to support PGB suppositories for bowel management. There is a clinically significant decrease in the total bowel care time, time to flatus and defecation period.

There is evidence from one systematic review (<u>Johns et al. 2021</u>) that PGB bisacodyl suppositories demonstrate a higher efficacy than HVB bisacodyl suppositories in most studies, although findings show HVB bisacodyl is more commonly used due to lower costs and higher availability.

There is level 1 evidence from one RCT (<u>House & Stiens, 1997</u>) that bowel care time decreases with the use of PGB bisacodyl suppositories or docusate sodium mini-enemas in comparison to HVB bisacodyl suppositories. PGB bisacodyl suppositories and docusate sodium mini-enemas demonstrated similar effects on bowel care in comparison to each other.

There is level 2 evidence (<u>Stiens 1998</u>) that found PGB bisacodyl suppositories significantly reduce total time of bowel care and time of defecation when compared to HVB bisacodyl suppositories.

There is level 2 evidence (<u>Frisbie 1997</u>) that bowel care time reduces by half with the use of PGB bisacodyl suppositories in comparison to HVB bisacodyl suppositories.

There is level 4 evidence (<u>Dunn & Galka, 1994</u>) that mean evacuation time significantly decreases with the use of Therevac SB "mini-enema" in comparison to bisacodyl suppositories.

There is level 4 evidence (<u>Round et al. 2021</u>) that the use of opioids decreases bowel movement frequency and has a constipating effect. Laxative use was associated with higher fecal incontinence at discharge.

Key Points

PGB bisacodyl suppositories (10 mg.) are more effective in stimulating reflex evacuation as part of a bowel management program in persons with an upper motor neuron SCI than bisacodyl in vegetable oil suppositories.

4.8.2 Prokinetic Agents

Chronic constipation is a common problem after SCI, with a prevalence of up to 80% of affected individuals (Krogh et al. 2002).

Five studies exploring the use of cisapride for neurogenic bowel management have been removed from this review as the drug is no longer available.

Table 16. Treatment Studies Using Prokinetic Agents for Neurogenic Bowel After SCI

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Rosman et al. 2008 USA RCT Level 1 (PEDro = 8) N=7	Objective: To evaluate the effect of neostigmine/ glycopyrrolate injections in patients with SCI and defecatory difficulties. Population: 7 SCI participants with defecatory problems (mean (SD) age: 46.9 (3.4) yrs, range 30 – 56 yrs); 4 cervical, 3 thoracic. Treatment: injections of neostigmine (2 mg) and glycopyrrolate (0.4 mg) for 1 week, wash-out period for 1 week, and placebo for 1 week, in random order Outcome Measures: Total bowel evacuation time; time to first flatus; time to beginning of stool flow; time to end of stool flow.	 Compared with placebo, neostigmine/glycopyrrolate significantly reduced the total bowel evacuation time (mean (SD)) from 98.1 (7.2) min to 74.8 (5.8) min (p<0.05). Neostigmine/glycopyrrolate significantly reduced the mean (SD) time to first flatus from 56.9 (5.4) min to 21.8 (4.5) min (p=0.001). Neostigmine/glycopyrrolate significantly reduced the mean (SD) time to beginning of stool flow from 69.8 (2.8) to 42.3 (6.4) min (p=0.01), and time to end of stool flow from 80.3 (4.0) to 53.3 (8.3) min (p<0.05).
Krogh et al. 2002 Denmark RCT Level 1 (PEDro = 7) N=22	Objective: To evaluate the tolerability and pilot efficacy of prucalopride in the treatment of CC due to SCL. Population: mean (SD) age: 34.7 (2.5) yrs (placebo), 36.5 (3.9) yrs (1mg group), 44.3 (3.1) yrs (2mg group). No information on level of injury was reported. Treatment: Participants randomized with double blind design to treatment with prucalopride 1mg or placebo,	 Compared with baseline, constipation severity decreased with prucalopride. The VAS score for treatment efficacy showed a clear dose response (medians 4, 52, and 73 for placebo, 1 and 2 mg, respectively). Self-report diary showed an improvement in average weekly frequency of all bowel movements over 4 wks within the 2 mg group (median 0.6). 3 participants (2 mg group) reported moderate/severe abdominal pain

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	taken once daily for 4 wks. A 2 nd group of participants was randomized to prucalopride 2mg or placebo for 4wks Outcome Measures: constipation; urinary habit; constipation severity and symptoms; colonic transit times	and 2 discontinued treatment. Adverse events (AEs) were reported by 6/7 in the placebo group, and by 7/8 and 6/8 in the 1 and 2mg groups. The most common AEs were gastrointestinal (flatulence, abdominal pain and diarrhea).
Korsten et al. 2005 USA RCT Level 1 (PEDro=6) N=13	Objective: To test the hypothesis that neostigmine, a medication that increases cholinergic tone by blocking the metabolism of acetylcholine, might promote bowel evacuation in people with SCI, in addition to whether neostigmine side effects such as bradycardia and bronchoconstriction could be prevented by coadministration of neostigmine with glycopyrrolate, an anticholinergic agent that has limited activity on the muscarinic receptors of the colon. Population: Level of injury: C4-T12 (5 tetraplegics, 8 paraplegics; 12/13 motor complete, 5/13 sensory incomplete); Age: mean (range) 46 (25-69)yrs; Duration of injury: mean (range) 14 (1-31) yrs Treatment: On different days, participants received, in a randomized, double-blinded design, one of three intravenous infusions (normal saline, 2 mg neostigmine, or 2 mg neostigmine and 0.4 mg glycopyrrolate) Outcome Measures: time to bowel evacuation using barium paste	 Neostigmine and the combination of neostigmine and glycopyrrolate both caused a similar expulsion of the stool, which was greater than with normal saline (median score 3 vs. 4 vs. 0, respectively) Mean time to expulsion was 11.5 min (range 5-20 min) after neostigmine and 13.5 min (range 4-23 min) after the combination. There was no correlation between the level of SCI and likelihood of bowel evacuation with any of the infusions

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Segal et al. 1987 USA Prospective controlled trial Level 2 N=28	Objective: To study the time-course of gastric emptying in people with SCI. Population: Il participants with tetraplegia, 9 participants with paraplegia (all complete SCI), 8 able-bodied controls; Age range: 20-55yrs Treatment: participants ingested a liquid meal, then within 2 weeks, ingested 2 nd liquid meal while metoclopramide (10mg) was administered intravenously; gastric emptying (GE) was evaluated after each liquid meal Outcome Measures: half time of gastric emptying, gastric emptying patterns in the early and later phases	 The mean GE half time for a liquid meal decreased in the participants with tetraplegia from 104.8 min to 18.8 min after treatment with metoclopramide. The pretreatment mean GE of 111.5 min decreased to 29.1 min among the participants with paraplegia.
Korsten et al. 2018 USA Prospective controlled trial Level 2 N=25	Objective: To investigate the effectiveness and safety of neostigmine/glycopyrrolate transdermal administration by iontophoresis in comparison to intravenous administration to elicit bowel movement in people with SCI Population: Age: 50 ± 15 y 15 paraplegia 10 tetraplegia Level: 11 cervical, 13 thoracic, 1 lumbar Severity: 12 A, 3 B, 7 C, 3 D Time since injury: 9.0 ± 9.0 y Treatment: Neostigmine and glycopyrrolate by lontophoresis versus by intravenous administration. Outcome Measures: Efficacy of transdermal Neo/Gly by	 No significant difference in bowel evacuation time between the three doses of drug (p=0.37) Of the original 25 people, the 40% response (combination of high-dose and low-dose findings) to the transdermal administration was significantly lower in comparison to the intravenous Neo/Gly response rate (72%) (p=0.083) Of the 21 people who responded to the intravenous administration, there was a 48% response to the transdermal-iontophoresis administration Individuals who received intravenous administration reported greater number of side effects compared to transdermal administration: eye/facial twitching (p<0.001); lightheadedness (p=0.029), headache (p=0.039); dry mouth (p=0.006) At the five minute interval the

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	iontophoresis to promote bowel movement, and safety/tolerability of this method, quantified through side effect monitoring	individuals who received intravenous administration showed greater change in mean arterial pressure in comparison to the transdermal groups (p=0.008), and significant changes in systolic blood pressure (p=0.021, which was also significant at the 15-minute interval (p=0.047).
Bauman et al. 2021 USA Pre-post Level 4 N=6	Objective: to investigate if a dual drug approach (neostigmine and glycopyrrolate) by transcutaneous route to standard of care (SOC) for the bowel management confers any clinical or patient-reported benefits over that of SOC alone Population: Mean age: 57 ± 10 years (range: 39–66 years) Time since injury: 18 ± 17 years (range: 3–47 years) Level: 3 complete motor lesion with partial sensory sparing; 3 motor-incomplete lesions with partial sensory; 5 above T6 Treatment: Neotstigmine and glycopyrrolate by transcutaneous route vs. standard care for bowel management. Outcome Measures: bowel evacuation time	 Average length of bowel care session was shortened with SOC neostigmine and glycopyrrolate to 41 ± 20 min from average of 107 ± 68 min at the end of the SOC control (p<0.001). Difference in length of time of bowel care between control and drugtreatment arms ranged from 42 to 88 min (CI:95%) No significant change in body weight after one-week of SOC or change in abdominal radiographic images of stool burden. Average loss by 2.8 +- 1.0 kg of body weight observed after 2-week SOC with dual drug-treatment (86 +- 25 kg vs. 83 +- 26 kg, P<0.0001) with initial 1.2 +- 1.2 kg loss at the end of the first week. Weight loss was due to reduction in retained stool, as confirmed by abdominal radiographs.

Prokinetic agents are presumed to promote transit through the GI tract, thereby decreasing the length of time needed for stool to pass through the intestines and increasing the amount of stool available for evacuation. Since constipation in patients with both acute and chronic SCI is considered primarily a consequence of prolonged colonic transit time, stimulating intestinal motility would appear to be a reasonable therapeutic approach.

There is little evidence on the use of metoclopramide and neostigmine in routine bowel management. <u>Segal et al. (1987)</u> investigated the use of metoclopramide (a potent <u>dopamine</u>

receptor antagonist with prokinetic properties) for enhancing gastric emptying in individuals with SCI. They found that impaired gastric emptying in patients with SCI can be significantly improved using metoclopramide. Korsten et al. (2005) found that neostigmine (a reversible cholinesterase inhibitor), or the combination of neostigmine and glycopyrrolate administered intravenously, improved stool expulsion compared to placebo. Rosman et al. (2008) reported similar findings for this combination over placebo, in which they reported significantly reduced total bowel evacuation time (p<0.05), mean time to first flatus (p=0.001), mean time to beginning of stool flow (p=0.01), and mean time to end of stool flow (p<0.05). Additionally, administration of this combination by transdermal iontophoresis has been examined in comparison to intravenous methods (Korsten et al. 2018; Bauman et al. 2021). Bauman et al. (2021) found a reduction in bowel evacuation time after transdermal iontophoresis when investigating this treatment in standard of care, indicating that both administration methods may be effective and safe for people with SCI.

Improvement in constipation and increased frequency of bowel movement were also seen with the use of prucalopride - a novel, highly selective serotonin receptor agonist with enterokinetic properties that facilitates cholinergic and excitatory non-adrenergic, non-cholinergic neurotransmission (Krogh et al. 2002; N=22).

Conclusion

Prucalopride

There is level 1b evidence (from one RCT; <u>Krogh et al. 2002</u>) that prucalopride increases stool frequency, improves stool consistency, and decreases gastrointestinal GI transit time; higher doses (2mg/day) were associated with moderate/severe abdominal pain.

Metoclopramide

There is level 2 evidence (from one prospective controlled trial; <u>Segal et al. 1987</u>) that intravenous administration of metoclopramide decreases time of gastric emptying.

Neostigmine

There is level 1b evidence (from one RCT; (Korsten et al. 2005) that neostigmine, administered with or without glycopyrrolate, leads to a greater expulsion of stool.

There is level 1 (Rosman et al. 2008) that neostigmine with glycopyrrolate decreases total bowel evacuation times and improves bowel evacuation.

There is level 2 evidence (<u>Korsten et al. 2018</u>) that transdermal administration of neostigmine/glycopyrrolate with iontophoresis can effectively and safely stimulate bowel movement in people with SCI and may have fewer side effects in comparison to intravenous administration.

There is level 4 evidence (<u>Bauman et al. 2021</u>) that using neostigmine/glycopyrrolate in bowel care regimens is a safe and effective way to reduce the time to bowel evacuation.

Key Points

In very small studies prucalopride, metoclopramide, neostigmine, and fampridine have been found to improve constipation in people with SCI.

More research is required on prokinetic agents prior to their regular use in neurogenic bowel dysfunction.

4.8.3 Central Potassium Channel Blockers

Potassium channel blockers are not currently used in bowel care management, but two randomized controlled trials demonstrate its potential benefits for bowel after SCI (<u>Cardenas et al. 2007</u>; <u>Cardenas et al. 2014</u>). 4-aminopyridine (fampridine) may improve excitability in damaged nerves but this mechanism requires further study.

Table 17. Treatment Studies Using Fampridine

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Cardenas et al. 2007 USA RCT Level 1 (PEDro = 6) N=91	Objective: Assess safety and efficacy of sustained-release fampridine in subjects with chronic spinal cord injury. Population: 91 participants with motorincomplete SCI randomized to three groups: (I) Fampridine, sustained release, 25 mg bid: Level of injury: 23 cervical, 7 thoracic; AIS grade: 14 C, 16 D; 22M:8F; Age: mean (range) 44 (23-66)yrs; Duration of injury: mean (range) 8.3 (1-30)yrs (II) 40 mg bid: Level of injury: 24 cervical, 6 thoracic; AIS grade: 12 C, 18 D 26M:,4F; Age: mean (range) 42 (21-67)yrs; Duration of injury: 10.8 years, range 1-35; (III) Placebo: Level of injury: 26 cervical, 5 thoracic; AIS grade: 18 C, 13 D; 24M:7F; Age: mean (range) 38 (19-61)yrs; Duration of injury: mean (range) 8.3 (1-37)yrs Treatment: Drug treatment (Fampridine orally 25mg bid or 40mg bid) or placebo for 8 weeks	 A significantly larger number of participants in the 25 mg bid (6/30 participants) and 40 mg bid (7/30 participants) groups had an increase in the number of days with bowel movements compared to participants in the placebo group (p=0.02 and p=0.01 respectively). Number of days increase not reported. In total 78% of participants completed the study. More (13/30) discontinued from Group II than Group I (4/30) and Group III (3/31). The most frequent AEs were hypertonia, generalized spasm, insomnia, dizziness, asthenia, pain, constipation, and headache. One

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Outcome Measures: Number of days with bowel movement, Participant Global Impression (PGI), Ashworth	participant in Group II suffered a seizure.
Cardenas et al. 2014 USA/Canada RCT Level 2 (PEDro = 2) N=213 in SCI-F301 N=204 in SCI-F302	Objective: To evaluate the efficacy and safety of fampridine sustained-release tablets (fampridine-SR) 25 mg twice daily for moderate-to-severe spasticity in patients with chronic spinal cord injury (SCI). Population: Men and women with chronic, incomplete, traumatic SCI between C3 and TIO, with injury occurring more than 18 months ago and ASIA B, C, or D, and stable neurological status for more than 6 months. SCI-F301 Placebo: Age: 40.1 ± 13.1; 13 % female, 28% ASIA B, 32% ASIA C, 38% ASIA D Fampridine-SR: Age: 41.6 ± 12.1; 14% female; 42% ASIA B, 29% ASIA C, 43% ASIA D SCI-F302 Placebo: Age: 40.5 ± 12.3; 14% female; 32% ASIA B, 30% ASIA C, 38% ASIA D Fampridine-SR: Age: 41.3 ± 11.8; 17% female; 32% ASIA B, 26% ASIA C, 45% ASIA D Treatment: 25 mg fampridine-SR twice a day vs. Placebo in two identical RCTs (SCI-F301 in the US and SCI-F302 in Canada) Outcome Measures: Bowel and bladder outcomes were measured by a daily diary questionnaire (including number of accidental leakage per day, number of bowel movements per days, and minutes per day for bowel routine). Penn Spasm Frequency Scale, International Standards for Neurological Classification for Spinal Cord Injury motor/sensory scores, and International Index of Erectile Function (IIEF) were used to measure secondary outcomes.	 In SCI-F301 there were no significant differences between treatments for bladder and bowel function. In SCI-F302 there was a significantly greater increase in number of bowel movement per day with fampridine-SR compared to placebo (p=0.006).

A study by <u>Cardenas et al. (2007)</u> examined fampridine dosages of 25 mg and 40 mg compared to placebo and reported higher efficacy and tolerability with the lower dosage for people with incomplete SCI. They also reported an increase in the number of days with bowel movements in approximately one-fifth of the participants given sustained-release fampridine (selective potassium channel blocker). Based on these findings, another trial investigated the use of a 25 mg dosage twice a week in two identical RCTs (SCI-F301 in the US and SCI-F302 in Canada) (<u>Cardenas et al. 2014</u>). Though, bowel was a secondary outcome in this study, findings showed an increased number of bowel movements per day only in one RCT (SCI-F302; p=0.006).

Conclusion

There is level 1 evidence from one RCT (<u>Cardenas et al. 2007</u>) that fampridine can increase the number of days with bowel movements in people with incomplete SCI.

There is level 2 evidence from one RCT (<u>Cardenas et al. 2014</u>) that fampridine can increase the number of bowel movements per day in people with incomplete SCI.

4.8.4 Other Pharmacological Agents

Table 18. Treatment Studies Using Other Pharmacological Agents

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Barak et al. 2019 Hungary RCT Level 1 (PEDro=6) N=19	Objective: to investigate the effect of the e α-agonist oxymetazoline 1.0% on fecal incontinence in patients with spinal cord injury versus a placebo gel. Population: N=19 Female: 15.8% Age: 42.6 (±9) years (range 23.7–57.2 years) Level and Severity: 2 cervical 11 thoracic 6 lumbar 9 complete 8 incomplete	 Change in mean fecal incontinence episodes per month (12 hours post drug application) favoured oxymetazoline over placebo: 26.3 (SD ±28.4) versus 36 (SD ±39.8) (p=0.021). When only non-gas episodes were included, the mean number of episodes decreased from 10.1 (+4.3) to 6.3 (±2.1) fecal incontinence episodes per month (p=0.022).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	2 unknown Treatment: Group I received topical treatment with oxymetazoline for 4 weeks followed by 2 weeks of washout period and then 4 weeks of topical treatment with placebo gel. Group 2 received topical treatment with placebo for 4 weeks followed by 2 weeks of washout period and then 4 weeks of topical treatment with oxymetazoline gel. Outcome Measures: number of fecal incontinence episodes in the 8 and 12 hours after drug administration using Fecal Incontinence Severity Index (FISI). Throughout the 10 weeks of the study, patients filled out a daily diary in which they recorded incontinence episodes and daily bowel practice.	
Lucci et al. 2020 Canada Prospective controlled trial Level 2 N=13	Objective: The objective of this study was to assess whether lidocaine lubricant (Xylocaine 2%) ameliorates AD during at-home bowel care compared with standard lubricant (placebo). Population: N=13 Age: 44.0 ± 3.3 years Time since injury: 13.9 ± 2.4 years Level: C3-T4 Severity: AIS A-C Treatment: 2% lidocaine topical anesthetic lubricant Outcome Measures: Difference in systolic arterial pressure between. Placebo and lidocaine conditions	 Participants displayed reduced autonomic function (LF SAP 3.02 ± 0.84 mmHg2), suggesting impaired autonomic control. Bowel care duration was increased with lidocaine (79.1 ± 10.0 min) compared to placebo (57.7 ± 6.3 min; p=0.018). All participants experienced AD on both days, but maximum SAP was higher with lidocaine (214.3 ± 10.5 mmHg) than placebo (196.7 ± 10.0 mmHg; p=0.046). Overall, SAP was higher for longer with lidocaine (6.5 × 105 ± 0.9 × 105 mmHg · beat) than placebo (4.4 × 105 ± 0.6 × 105 mmHg · beat; p=0.018) indicating a higher burden of AD.

For people with SCI, other pharmacological agents such as oxymetazoline and lidocaine have been examined in bowel care through little research. Oxymetazoline, an alpha agonist, increased resting anal pressure and decreased the number of fecal incontinence episodes in one small crossover RCT (Barak et al. 2019). Another small clinical trial found that lidocaine lubricant (xylocaine 2%) increased bowel care duration and worsened autonomic dysreflexia, so authors cautioned against this procedure unless people were under medical supervision (Lucci et al. 2020).

Conclusion

There is level 1 evidence from one crossover RCT that (Barak et al. 2019) that the α -agonist oxymetazoline 1.0% increases resting anal pressure and decreases fecal incontinence episodes.

There is level 2 evidence from one clinical trial (<u>Lucci et al. 2020</u>) that found lidocaine lubricant (xylocaine 2%) increases bowel care duration and worsened autonomic dysreflexia.

5 Bowel Preparation Pre-colonoscopy

Table 19. Bowel Preparation Pre-colonoscopy

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Korsten et al. 2015 USA RCT Level 1 (PEDro = 8) N=55	Objective: To determine whether the addition of neostigmine to MoviPrep before elective colonoscopy produced a higher percentage of acceptable bowel preparations in patients with SCI. Population: 27 people with SCI matched 28 people without SCI, all undergoing elective colonoscopy SCI mean (SD) age 61.9 (7.6) Mean (SD) time since SCI 24.3 (14.1) years Non-SCI mean (SD) age 58 (10) 9 paraplegia, 18 tetraplegia (11 tetraplegia in MoviPrep group) AIS-A to AIS-D	 Significantly lower percentage of individuals with acceptable OS (≤ 3) and mean±SD OS in SCI (7/14 and 3.4±1.6) vs. Non-SCI (25/28 and 1.8±1.9) in MoviPrep alone group Significantly higher percentage of individuals with acceptable OS in SCI MoviPrep + NG group (11/13) vs. SCI MoviPrep alone group (7/14) Significantly higher percentage reporting bloating/distension before evacuation in SCI MoviPrep + NG group) compared to other groups. All individuals receiving NG reported dry mouth or eye/mouth twitching for 1h after administration, but no serious

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Treatment: Bowel preparation using MoviPrep (N=14 SCI & N=28 Non-SCI) or MoviPrep + neostigmine (NG) (N=13) prior to colonoscopy. MoviPrep administered in 2x 1L doses, on the day before and of colonoscopy. NG (20mg) administered with glycopyrrolate (0.4mg) 2-3h before second dose of MoviPrep Outcome Measures: Ottawa Score for Bowel Evacuation (OS), complications, adenoma detection rate	adverse effects as a result of the study. 5. No significant changes in renal function before or after treatment
Ancha et al. 2009 USA RCT Level 1 (PEDro= 8) N=36	Objective: To assess the safety and efficacy of bowel cleansing regimens in people with SCI Population N=12 in the polyethylene glycol (PEG) group, N=11 in the oral sodium phosphosoda (OSPS) group, N=13 in the PEG+OSPS group. All participants were male. The mean time since injury was 20±15 years. N=21 had paraplegia (injury at or below thoracic level) and N=15 had tetraplegia (injury at cervical level) Treatment: PEG vs. OSPS vs. PEG+OSPS Outcome Measures: Phlebotomy was performed to assess renal function, the quality of the bowel preparing during colonoscopy was determined using the Ottawa scale	 Majority of people had unacceptable bowel preparations with Ottawa score > 3. Ottawa score did not significantly differ among the bowel preparations PEG, OSPS, or PEG+OSPS (4.8±2.6 (1-9), 6.3±4.3 (0-13), 6.8±2.5 (3-10 respectively) Between the three groups, the time to reach the caecum (if it could be intubated) (PEG 28 ± 19, OSPS 21 ± 7 and PEG+OSPS 27 ± 8 min) and the total time to complete the procedure were not significantly different. Number of polyps detected did not significantly differ between the groups Phlebotomy measures showed limited effects on renal function: No difference between bowel preparation groups in mean glomerular filtration rate (eGFR) post-preparation (PEG 132 ± 9, OSPS 158 ±21, PEG+OSPS 170 ± 16 mL/min)

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
		- No differences in serum creatine concentration or serum sodium between groups - The OSPS group had significantly decreased serum potassium concentration (4.3± 0.17 vs. 3.8 ± 0.15 mEq/L, P < 0.005), and serum calcium (9.2 ±0.13 vs 8.4 ± 0.13 mg/dL; p=0.001), and a significant increase in serum phosphate ((OSPS: 3.8 ±0.5 vs. 5.8 ± 0.4 mg/dL; p<0.005) - The PEG+OSPS combination group had a significant decrease in serum potassium (4.3 ± 0.17 vs. 3.7 ± 0.16 mEq/L, P < 0.0005) and serum calcium (PEG + OSPS: 8.9±0.15 vs 8.3 ±0.13 mg/dL; p<0.005), and a significant increase in serum phosphate (PEG+OSPS: 3.2 ±0.3 vs 4.8 ±0.3 mg/dL; p<0.0005).
Lyons et al 2015 USA Prospective controlled trial Level 2 N=24	Objective: To determine the most effective preparation for elective colonoscopy applying a novel and traditional approach to bowel cleansing. Population: N=24 veterans with SCI undergoing elective colonoscopy Mean (SD) age 25 (14) Mean (SD) time since SCI 25.5 (14.0) years 13 paraplegia, 11 tetraplegia Cervical to lumbar SCI AIS-A to AIS-D Treatment: N=12 Pulsed Irrigation Enhanced Evacuation (PIEE): standard splitdose magnesium citrate for 2 days	 No difference between percentage of individuals with acceptable OS in either group. No serious adverse effects as a result of the study. No changes in renal function before or after treatment. Significant but not clinically relevant increase in serum magnesium in PIEE group

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	prior to colonoscopy & PIEE on the day of colonoscopy N=12 Polyethylene glycol-electrolyte lavage solution (PEG): split-dose over 2 days	
	Outcome Measures: Ottawa Score for Bowel Evacuation (OS), complications, polyp detection rate	

Table 20. Colonoscopy Preparation – Retrospective Reviews

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Teng et al. 2018 USA Case-control Level 3 N=255	Objective: To compare adequacy of colonoscopy bowel preparation and diagnostic findings between persons with SCI receiving an extended inpatient bowel preparation and the general population. Population: N=255 N: 85 with SCI, 170 control SCI group: Female: 0% Age: 63.3 (7.2) Time since injury: 20.6 (14.6) y Level: Cervical 53 (62%), thoracic 29 (34%), Lumbar 3 (4%) Severity: AIS A 35 (41%); AIS B 7 (8%); AIS C 7 (8%); AIS D 36 (42%) Control population: Age: 61.2 (10.7) Female: 8% Treatment: N/A Outcome Measures: Reviewed an electronic database of all colonoscopies performed at a tertiary Veterans Affairs medical center	 The SCI patient group was more likely to receive a colonoscopy for average risk screening (25 vs. 14%) (p=0.03). There was no difference in adequacy of bowel preparation (87 vs. 85%, p=0.73) or adenoma detection rate (55 vs. 51%, p=0.59) when comparing patients with SCI with the control population.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	between 7/12/13 and 15/10/15. Patients with SCI received a multi-day bowel preparation with magnesium citrate, and 8-10 liters of polyethylene glycol-3350 and electrolyte colonic lavage solution (PEG-ELS) over two and one half days. The control population received a standard bowel preparation consisting of magnesium citrate and 4 liters of PEG-ELS over 1 day.	
Hayman et al. 2013 USA Case series Level 4 N=311	Objective: To determine the safety of colonoscopy. Population: Veterans with SCI and disorders undergoing colonscopy N=306 Male, N=5 Female Median age: 61 y (IQR 53-69 y) SCI level: 149 cervical, 50 upper thoracic (T6 and above), 78 lower thoracic (T7 and below), 31 lumbar/sacral, 3 missing. 89 complete, 156 incomplete, 66 missing 151 tetraplegia, 159 paraplegia Treatment: N/A Outcome Measures: Medical record review for patient demographics, procedure indications, pathological findings, rates of bowel preparation adequacy, and indicdence of post-procedural complications	 40% of the 368 colonoscopies had a polypectomy performed. Diagnostic colonoscopies were less likely to require polypectomy (31 v 48%) but were more likely to be positive for neoplasm (76 vs. 69%, p=0.0005). There was a significant increase in the proportion of colonoscopies with adequate bowel preparation over time (12.5% in quartile 1 to 58.6% in quartile 4, p=0.001) Quality of preparation was not associated with SCI level or completeness. There was a high percentage of procedures that did not document quality of bowel preparation, but this percentage significantly decreased from quartile 1 to quartile 4 (70% to 6%, p<0.001).
Song et al. 2018 USA Case series Level 4	Objective: To assess the safety, tolerability, and efficacy of a multi-day inpatient bowel preparation regimen in a population of patients with SCI. Population:	 Bowel preparation was tolerated by 91% 89% had adequate quality of bowel preparation at colonoscopy (no actual

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
N=53	N=56 Female: 0% Age: mean 64.1 ± 7.3 years Time since injury: mean 20.0 ± 13.8 years. Level: 68% cervical, 30% thoracic, 2% lumbar Severity: 41% AIS A, 7% AIS B, 9% AIS C 43% AIS D Treatment: Day 1: clear liquid diet starts in the evening with 480 mL of magnesium citrate after dinner Day 2: continue clear liquid diet, and PEG- ELS 4L over 2 hours in the morning Day 3: continue clear liquid diet until midnight and then Nothing by mouth. PEG- ELS 4 over 2 hours in the morning Day 4: if rectal colostomy output is still not clear then PEG-ELS 2L prior to colonoscopy Outcome Measures: Adequacy of colonic cleansing was based on either the Aronchick or the Boston Bowel Preparation Scale, people demonstrated adequate bowel cleansing if they graded "excellent" or "good" on the Aronchick scale OR if they had Boston score of greater than or equal to 2 in all three bowel segments; serum chemistry testing	values of Aronchick or Boston Bowel Preparation scores were provided). No significant differences between people who had inadequate and adequate quality bowel preparations regarding the completing of full bowel preparation, AIS, level of injury, frequency of bowel care, or bowel care method 3. Results of serum chemistry testing: - Calcium decreased by 0.25 mg/dL (p=0.00) - Phosphate decreased by 0.45mg/dL (p=0.00) - BUN decreased by 7.46 mg/dL (p=0.00) - Creatinine decreased by 0.05 mg/dL (p=0.00) - No significant changes in sodium, potassium, chloride, bicarbonate, glucose, or magnesium levels
Deroche et al. 2017 USA Case-control Level 3 N=17,842 with 35,036 controls; N=7,126 SCI	Objective: Investigate whether adults, aged 50-75 years, with one of three disabilities (blind/low vision [BLV], intellectual disability [ID], spinal cord injury [SCI]) receive CRC screening at rates equivalent to adults without the three disabilities, by accounting for combinations of recommended CRC screenings during a 10-year period (colonoscopy, sigmoidoscopy, fecal occult blood test). Population: Adults aged 50-75 years with one of three disabilities (blind/low vision (BLV), intellectual disability (ID), or spinal cord injury (SCI)	1. Colonoscopy was the most prevalent screening test-for people with SCI at least one colonoscopy was received by 41.67% of people vs. 41.5% in the comparison group.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Treatment: Colorectal cancer (CRC) screening Outcome Measures: Proportion of adherence to and adjusted odds of CRC screening over time	

Studies that investigate the effect of bowel preparation before colonoscopy for people with and without SCI showed mixed results. Ancha et al. (2009) found that 75% of people with SCI had suboptimal preparation prior to elective colonoscopy whereas Song et al. (2018) found 89% of people with SCI had adequate quality of bowel preparation. Ancha et al. (2009) investigated preparation methods for people with SCI using polyethylene glycol (PEG), oral sodium phosphosoda (OSPS), or a combination of both. Between these groups, the quality of bowel preparation based on Ottawa scores did not significantly differ. The authors suggested the use of a prokinetic agent to induce gut motility prior to surgery (Ancha et al. 2009). Further study demonstrated how the injection of neostigmine added to standard bowel preparation routines (MoviPrep low volume polyethylene glycol-electrolyte lavage with ascorbic acid) had some beneficial results for surgical preparation (Korsten et al. 2015). Between the SCI groups (those who received MoviPrep and those who received MoviPrep + neostigmine/glycopyrrolate), people who received the prokinetic combination had a greater percentage of acceptable preparation (p=0.05). Although, the numbers recruited did not reach the authors power calculations and they also noted that neostigmine needs to be administered in a monitored, controlled setting.

Lyons et al. (2015) compared 24 people with chronic SCI, 12 in each group, one who received standard split dose of magnesium citrate for 2 days before the procedure and Pulsed Irrigation Enhanced Evacuation (PIEE) the day of the procedure and the other received the oral lavage solution with polyethylene glycol split-dose over 2 days. There was no statistical difference in the quality of bowel preparation although the groups may have been too small to detect a difference. Regardless, PIEE requires specialized equipment and training and is not currently available in most centres. No serious adverse events were reported in this study.

Conclusion

There is level 1 evidence from one RCT (Korsten et al. 2015) that adding neostigimine/glyocpyrrolate to Moviprep before elective colonoscopy for people with SCI improves the quality of preparation in comparison to Moviprep alone. However, the addition of injection of neostigmine to standard bowel preparation needs to be administered in a controlled setting due to potential side effects.

There is level 1 evidence from one randomized controlled trial (<u>Ancha et al. 2009</u>) that oral sodium, phosphosoda and polyethylene glycol either alone or in combination are not sufficient in bowel preparation for visualization prior to a colonoscopy, although they are safe to use.

There is level 3 evidence (<u>Teng et al. 2018</u>) that bowel preparation and adenoma detection rate was similar between people with SCI and non-SCI controls undergoing colonoscopy.

There is level 4 evidence (<u>Hayman et al. 2013</u>) that the adequacy of bowel preparation prior to colonoscopy increased over time for Veterans with SCI, which was not associated with SCI level or completeness.

There is level 4 evidence (Song et al. 2018) that a multi-day inpatient bowel preparation is tolerable and safe for people with SCI prior to colonoscopy.

Key Points

Further research is needed to determine how effective bowel preparations are for people with SCI, as well as which specific bowel preparation products are most effective, prior to colonoscopy.

People with SCI might experience additional discomfort and hardship when undergoing bowel preparation.

6 Surgical Interventions for Bowel Management

Both colostomy and ileostomy are surgical procedures. Essentially, a hole is created in the colon for colostomy or ileum for ileostomy. Another hole created in the abdomen allows a tube to be inserted. It is through this tube that stool flows out to a collection bag. Colostomy and Ileostomy are generally considered after conservative methods fail. Other motives for choosing surgical interventions may be because they are less time consuming, are appropriate for severe constipation or fecal impaction, decrease cases of autonomic dysreflexia or pain, and avoid diseases or pressure ulcers near the anus.

6.1 Colostomy and Ileostomy

A stoma is a surgically formed opening between a body cavity, such as the colon or ileum, and the external body environment, such as the outer abdominal wall. After formation of a colostomy or ileostomy, stool flows through the stoma from the colon or intestines respectively, into a collecting device attached to the abdominal wall, thereby bypassing the rectum and anus. SCI individuals who undergo elective colostomy or ileostomy have usually exhausted all other appropriate bowel management options. The most common reasons for undergoing stoma surgery include prolonged bowel management episodes, unmanageable fecal incontinence, and constipation. Autonomic dysreflexia and pain associated with bowel evacuation, difficulties

finding appropriate care, perianal disease and pressure injuries close to the anus may also be reasons to choose a stoma for bowel management. Stoma for bowel management remains uncommon; one study suggested prevalence in the UK of around 2.5% (Coggrave et al. 2009). There is no general consensus as to when colostomy should be performed in people with SCI. Aging and increased duration of SCI may contribute to bowel management difficulties (Faaborg et al. 2008) and with increasing life expectancy amongst people with SCI, stoma may become a more common management choice in the future.

One systematic review examined studies that directly compared clinical, functional, QOL outcomes or satisfaction among individuals with a stoma to individuals using conservative means. The second focused on studies that investigated quality of life after colostomy formation.

Table 21a. Systematic Review on Colostomy

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Waddell et al. 2020 Systematic Review N=15 studies	Objective: To determine whether colostomy formation improves QoL in patients with SCI. Methods: Literature search was conducted on March 23 and 30, 2019, and again on January 31, 2020, for clinical trials that included SCI and QOL, time spent on bowel care, or patient satisfaction with stoma. Databases: The Cochrane register, Medline, Embase and CINAHL	 Nine out of 11 studies reported that people's QOL was improved by the stoma Two out of 11 studies found no difference Thirteen studies found that time spent on bowel care was reduced for individuals with a stoma. The average time was reduced from 1 hour to less than 15 minutes a day All studies that assessed individual satisfaction with stoma reported higher satisfaction.
Hocevar and Gray 2008 USA Reviewed published articles from January 1960 to November 2007 N=6 studies n=203 SCI Types of Articles: 2 case-control AMSTAR: 3	Objective: 1. To compare clinical, functional, or quality of life outcomes in spinal cord injured patients with gastro-intestinal symptoms managed by conservative measures versus intestinal diversion (colostomy or ileostomy). 2. To identify complications associated with ostomy surgery in patients with bowel dysfunction and SCI. Methods: literature search for prospective and retrospective	 Creation of an ostomy in selected patients provides equivocal or superior quality of life outcomes when compared to conservative bowel management. Both colostomy and ileostomy surgery significantly reduces the amount of time required for bowel management (Level of Evidence: 3). Patients who undergo ostomy surgery tend to be satisfied with their surgery, and a significant portion report a

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	studies that directly compared clinical, functional, quality of life outcomes or satisfaction among patients with intestinal diversions to patients managed by conservative means. Databases: MEDLINE, CINAHL, Cochrane Database for Systematic Reviews, Google Scholar	desire to be counselled about this option earlier. 4. There are no clear advantages when functional, clinical, or quality of life outcomes associated with colostomy are compared to those seen in SCI patients undergoing ileostomy (Level of evidence: 4).

Table 21b. Colostomy After a Spinal Cord Injury – Cross-Sectional

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Boucher et al. 2019 England Retrospective Level 3 N=83	Objective: to discover the reasons behind individuals choosing to have a colostomy early following SCI, rather than later. And establish whether early colostomy is safe and advisable Population: N=83 Female: 18% Age: 49 years range (15-90y) Early colostomy: mean 58 years Mean time from SCI to colostomy: 6.5 months for early group and 214.6 months for later group Treatment: N/A Outcome Measures: survey asking reasons for having colostomy	 Most frequent reason for having a colostomy in the later group were localized bowel care complications. Approximately half of those choosing a colostomy had cervical spine injuries. For the early colostomy group, reliance on caregiver and increased independence and to improve QOL were also frequent reasons. 40% of the early group experienced no later complications, compared to 69,2% for the later group (p=0.0005). No significant difference between groups requiring further surgery (p=0.28).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Randell et al. 2001 New Zealand Case-control Level 3 N=52	Objective: To determine whether a colostomy changes quality of life in patients with a spinal cord injury. Population: 26 participants with colostomy: 10 with cervical SCI, 16 with lumbar/lower thoracic SCI; age: 22-87yrs, matched with 26 participants without colostomy. Treatment: Colostomy (with vs. without) Outcome Measures: Burwood Quality of Life Questionnaire: 5 areas: systemic symptoms, and emotional, social, work and bowel function.	No significant difference in the group with a colostomy compared to the group without a colostomy in regard to their general well-being, emotional, social or work functioning.
Safadi et al. 2003 USA Case-control Level 3 N=45	Objective: Assess the quality of life (QOL), health status, and time to bowel care before and after stoma formation. Population: 21 tetraplegics, 24 paraplegics; 44M 1F; Mean age 55.9yrs, Treatment: 20 right side colostomies (RC), 21 left side colostomies (LC), 7 ileostomies (IL) Outcome Measures: quality of life, colonic transit time, bowel care time	 Colonic transit time was significantly longer in the right side colostomy compared to the left side colostomy and the ileostomy. In all groups, quality of life increased (RC: 49 to 79, LC: 50 to 86, IL: 60 to 82 min) and bowel care time decreased (RC: 102 to 11 min, LC: 123 to 18 min, IL: 73 to 13 min).
Negosanti et al. 2020 Italy Case series Level 4 N=19	Objective: to explore how a colostomy may be considered to improve bowel management in SCI patients when other conservative treatments fail Population: N=19 Age: 55.21 years old (range 19–73) Female: 15.8% Level: 13 paraplegia 5 tetraplegia	 No major complications were reported after the surgical procedure. In two cases, we observed small dehiscences of the abdominal incision which were treated conservatively during hospital stay. In two other cases, mucorrhoea was observed. Reported a high degree of patient satisfaction with an improved quality of life, but further studies

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Kelly et al. 1999 UK Case-control Level 3 N=14	I spina bifida Time since injury: mean 25.68 years (range 1–56) Treatment: subtotal colectomy Outcome Measures: surgery outcomes, including complications and patient satisfaction. Objective: To investigate the role of intestinal stomas in alleviating physical and psychological problems associated with bowel dysfunction. Population: Level of injury: C4-L2 (3 cervical, 10 thoracic, 1 lumbar); 12M 2F; Age at time of operation: mean (range) 54.8 (20-65) yrs; time from injury to stoma formation: mean (range)15 (2-37) yrs Treatment: 12 participants underwent left iliac fossa end colostomy and 2 participants right iliac fossa end ileostomy Outcome Measures: Time spent on bowel care per week; independence in bowel care; quality of life	vith appropriate tools are necessary to assess this finding. 1. Colostomy participants (N=12): mean time spent on bowel care per week before stoma formation was 8.8 h (0.6-12.2) compared with 1.4 h (0.3-3.5) after; 50% of these patients were independent in bowel care before, 92% independent after; 10 patients claimed that the colostomy had a beneficial effect on their quality of life. 2. Illeostomy patients (N=2): mean time spent on bowel care per week before ileostomy was 17.5 h and this was unchanged after ileostomy formation. 1 participant decreased the time he spent on bowel care from 28 h to 14 h; the other developed complications and his time increased from 7 h to 21 h.
Branagan et al. 2003 UK Case series Level 4 N=32	Objective: To evaluate the effect of colostomy formation on both quality of life and time taken for bowel care. Population: 10 participants with cervical SCI, 18 with thoracic, and 3 lumbar; Age at injury: average 28.9 yrs; Duration of injury: mean 17.1 years Treatment: Medical records were reviewed for participants who had a previous colostomy.	 The average time spent on bowel care per week decreased significantly from 10.3 hours to 1.9 hours after the colostomy. 18/31 participants felt the colostomy gave them greater independence. 25 participants wished they had been offered a stoma earlier. No participants wanted a stoma reversal.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Outcome Measures: Results of surgery	
Rosito et al. 2002 USA Case series Level 4 N=27	Objective: To evaluate the effects of colostomy on the quality of life (QOL) in patients with spinal cord injury (SCI). Population: Level of injury: C4-L3 (17 complete, 10 incomplete); mean age: 62.9 yrs; 26M 1F; Duration of injury: 25.8yrs Treatment: Colostomy Outcome Measures: Quality of life questionnaire with 5 domains: physical health, psychosocial adjustment, body image, self-efficacy, and recreation/leisure	 Quality of life improved significantly after colostomy. All 27 patients were satisfied, 16 very satisfied Colostomy reduced the number of hospitalizations caused by chronic bowel dysfunction by 70.4%. After colostomy, the average amount of time spent on bowel care was reduced significantly from 117.0 min/day to 12.8 min/day. Significant improvements were recorded in the areas of physical health, psychosocial adjustment, and self-efficacy.
Munck et al. 2008 Belgium Case-series Level 4 N=23	Objective: To determine the effect of constipation and fecal incontinence on the quality life of patients with spinal cord injury (SCI). Population: 23 SCI participants who had a colostomy in the digestive surgery department of Brugmann Hospital between Jan 1996 and Dec 2005 (age range 22-72). Level of injury: 13 dorsal, 7 cervical, 3 lumbar. Treatment: Colostomy Outcome Measures: Demographic information and medical information on the stoma formation and complications, collected from participants' medical records; quality of life questionnaire.	 1. 10 participants had a stoma for perineal wounds 2. Average time spent on bowel care per week decreased from 5.95 hr prior to stoma formation to 1.5 hr after 3. Of the 10 patients, 3 reported cutaneous irritations and 1 reported detachment of the pocket 4. Of the 10 patients, 9 reported having much easier bowel care since the stoma formation, and 6 felt that the stoma had given them greater independence.
<u>Stone et al.</u> <u>1990b</u>	Objective: To determine the effectiveness and safety of	All seven participants who had colostomy performed as an adjunct to the treatment of

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
USA Case Series Level 4 N=7	colostomy when it is performed for a late complication of SCI. Population: Level of injury: C4-T10; Age: mean 51.6yrs; Duration of injury: mean 15.7 years Treatment: Medical records were reviewed for participants who had undergone a colostomy Outcome Measures: Efficacy of colostomy.	perianal pressure ulcers successfully healed their ulcers. 2. The amount of time spent on bowel care decreased dramatically in the patients with prolonged bowel care.
Luther et al. 2005 USA Cross-sectional Level 5 N=370	Objective: To compare patient outcomes and quality of life for people with neurogenic bowel using either a standard bowel care program or colostomy. Population: SCI participants in 6 centers that were selected to be representative of the 23 Veteran Affairs SCI centers. Survey respondents with colostomies were matched to controls based on age, year of injury, classification of paralysis and marital status by calculating propensity scores. Comparison of 74 patients with a sample of 296 matched controls without colostomies. Treatment: Colostomy Outcome Measures: Bowel carerelated items; quality of life.	 No statistically significance differences were found in the demographic distributions for cases and controls. No statistically signifi-cant differences were reported between the cases and the matched controls for any of the bowel care outcomes or bowel-related quality of life. Both groups reported low incidence of accidental/unplanned bowel movements and falls related to bowel care. Mean responses to the quality of life items were generally very high; however, a large number of respondents continue to express dissatisfaction with bowel care. The cases had a much higher percentage of responses (55.7%) in the "very dissatisfied" category than did the controls (41.7%).
Coggrave et al. 2012 UK Retrospective self- report survey Level 5 N=92	Objective: To characterise spinal cord injured (SCI) individuals with a stoma, their stoma management and outcomes, to identify sources of information and support for decision making and to explore the impact of a stoma on life satisfaction.	1. Participants reported experiencing bowel difficulties for a mean (SD) time of 10 (10) years before surgery. 11% would've preferred surgery a year earlier, 28% up to 5 years earlier, 30% up to 10 years earlier and 32% earlier still. None suggested stoma formation was too early.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Population: 26 cervical (15 complete, 10 incomplete, 1 unknown), 61 thoracic (49 complete, 10 incomplete, 2 unknown), 1 missing data on level of injury; 64M:28F; Age: mean (SD) 56(9)yrs; duration of injury: mean (SD) 26(13)yrs; 91% colostomy, 9% ileostomy. Treatment: Retrospective analysis of a self-report postal survey of individuals with SCI who had a stoma for bowel management issues (five UK spinal centres) Outcome Measures: Tennessee Self-Concept Scale, Satisfaction with Life Scale, Hospital Anxiety and Depression Scale, 3 simple rating scales for satisfaction, ability to live with bowel dysfunction, and how much bowel care restricts life.	 Participants reporting an ileostomy were significantly more likely to need assistance than those with a colostomy. Laxative use was reduced from 58 to 31% and dietary manipulation to assist bowel care was reduced significantly. 83 (70%) reported they felt very positive about their stoma, whereas 2 participants felt others avoided them due to the stoma. For 23%, there was impact on personal relationships; 9 reported positive impact, 6 negative and 3 neutral.
Cooper et al. 2019 Australia Observational Level 5 N=43	Objective: to examine surgical outcomes and the effect on an individual's health-related quality of life Population: N=43 Female: 27% Age at injury: median 41 y, mean 44.8 (13-80) y Level: 42.3% cervical 50% thoracic 7.7% lumbar 0% sacral Treatment: N/A Outcome Measures: 10-point Likert scale asked patients their level of satisfaction with stoma	 Reasons for stoma formation included sacral pressure ulcer (50%) prolonged bowel care (35%) fecal incontinence (19%) constipation (8%), autonomic dysreflexia (8%), carer difficulties (8%) and hemorrhoids (4%) 76% reported improvement in health-related quality of life. 72% scored satisfaction with a stoma as 8/10 or more.
Van Ginkel et al.	Objective: To explore individual	1. 22 (96%) participants were satisfied

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Netherlands Cross-sectional survey Level 5 N=23	satisfaction with bowel stoma and timing of stoma formation. Also, to explore reports of diversion colitis and QOL changes after the stoma formation. Population: N=23 Age: 45.2 ± 11.3 y Time since injury: 25.6 ± 15.9 y Level: 7 tetraplegia 16 paraplegia 15 complete 8 incomplete Female: 52% Treatment: N/A Outcome Measures: Stoma-modified version of NBD score (Stoma-Modified Neurogenic Bowel Dysfunction questionnaire" measured severity of bowel symptoms. Questions asked regarding experiencing loss of blood, moisture, and mucus to obtain insight in diversion colitis. Satisfaction was classified in five categories (5-item scale), from very dissatisfied to very satisfied. Four domains of QOL (life as a whole, physical health, social life and psychological health) were used to indicate QOL alterations	 with their bowel stoma 2. 83% felt their stoma was placed too late 3. >80% reported improvements in the four QOL domains after bowel stoma procedure 4. 9 participants reported stomarelated problems in the last month 5. 7 participants reported diversion colitis in the last three months. 4 of these 7 participants experienced this once a week or more. 2 reported this had moderate influence on daily activities
Frisbie et al. 1986; USA Cross-sectional Level 5 N=20	Objective: To determine the difference in the bowel care of spinal cord injury patients before and after enterostomy. Population: Level of injury: 9 cervical, 11 thoracic; 19M 1F; Age: median (range) 55 (27-75) yrs. Duration of the enterostomies at	 Bowel care frequency increased from a median 3 times/week (range 2-7) before enterostomy to a median 7 times/week (range 4-14) after enterostomy. Bowel care duration diminished from a median 6 hours/week (range 0.7-14 hours) before

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	time of interview was, median (range): 11 months (3 months to 14 yrs). Treatment: A total of 24 enterostomies were carried out in 20 participants: 17 sigmoid colostomies, 5 transverse colostomies, and 2 ileostomies. Outcome Measures: Bowel care time, bowel care frequency, bowel care related complaints, quality of life.	enterostomy to a median 1 hour/week (range 1.3-7 hours) after enterostomy. 3. The number of patients affected by bowel care related complaints pre- vs. post-operatively, respectively, were as follows: abdominal pain in 10 vs. 2, fecal leakage in 8 vs. 0, anorexia in 7 vs. 2, flatus in 9 vs. 4, sweating in 4 vs. 2 and odour in 4 vs. 5.
Bølling Hansen et al. 2016 Denmark Cross-sectional Level 5 N=18	Objective: To evaluate the effect of colostomy on bowel function and quality of life (QoL) in individuals with spinal cord injury (SCI). Population: N=18 (12M, 6F) with SCI and post-SCI colostomy Mean (range) age 49.9 (37-72) Mean (range) time post SCI 20.9 (3-56) years Mean (range) time since colostomy 6.9 (0.5-20) years 8 tetraplegia, 10 paraplegia 8 cervical, 10 thoracic AIS-A/C/D: 15/2/1 17 had sigmoidostomy, 1 had transverse colostomy Treatment: N/A Outcome Measures: Gastrointestinal transit time (GITT), SF-36, bowel management questionnaire	 39% reported one or more problems related to the colostomy 13/18 reported significant reduction of time required for bowel management, none reported increase of time 17/18 reported better bowel management after colostomy, and would prefer not to reverse the colostomy if given the choice. 15/18 are not concerned about bowel management after colostomy when they travel long distances 16/18 are not dependent on easy access to toilets after colostomy when not at home 9/18 reported positive social influence; 8 reported no change 12/18 had GITT within normal range after colostomy, 2 had GITT over normal range by less than 12h 2/18 reported both leakage & skin issues post colostomy. One reported odor problems, the other reported cosmetic issues & pain Disregarding the physical component, QOL was not

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
		significantly lower in the study group compared to a Danish norm group. However, QOL was significantly lower when compared to the subgroup of people with tetraplegia
Tate et al. 2023 USA Cross-sectional survey plus interviews Level 5 N=18	Objective: to investigate factors influencing surgical decision-making to treat neurogenic bladder and bowel (NBB) dysfunction for veterans and civilians with SCI in the USA Population: Age: 54.72 (11.87) y Time since injury: 27.06 (16.02) y Level: 22.2% incomplete tetraplegia 27.8 % complete tetraplegia 11.1% incomplete paraplegia 38.9% complete paraplegia Female: 22% Treatment: N/A Outcome Measures: Semi-structured interviews to reflect factors, decision-making enactment and outcomes such as surgery satisfaction and QOL. Also, COMRADE, Ways of Coping Questionnaire, Bladder and Bowel Treatment Inventory, PROMIS Global Health and Cognitive Abilities scales and SCI-QOL Bladder and Bowel short form.	 Factors influencing decision making (DM) included recurrent symptoms and complications; balancing dissatisfaction with NBB management against surgery risks; achieving independence and lifestyle adjustments; participant's driven solutions; support and guidance and trust in doctors; and access and barriers to DM. For bowel, colostomy (42.8%) followed by ileostomy (28.5%) and hemorrhoidectomy (28.5%) were the main surgeries. bowel surgeries were performed mainly on those with complete paraplegia (87.5% compared to only 10% for those with bladder surgeries, P<.01). For decisions about colostomies, satisfaction ratings averaged 5.62. Those with ileostomies rated satisfaction with decisions higher (9.75) and QOL (8.25) accordingly. Those who had hemorrhoidectomies reported the highest satisfaction, with both providing ratings of 10 for satisfaction and 9 for QOL.

Stoma formation is a relatively safe, effective and well-accepted method of managing significant neurogenic bowel management problems in individuals with SCI. Studies report that a stoma reliably reduces the number of hours spent on bowel care (Munck et al. 2008; Branagan et al.

2003; Rosito et al. 2002; Kelly et al. 1999; Stone et al. 1990b; Frisbie et al. 1986; Bolling Hansen et al 2016; Waddel et al. 2020; Cooper et al. 2019), reduces the number of hospitalizations caused by GI problems (Rosito et al. 2002) and bowel care-related complaints (Frisbie et al. 1986), simplifies bowel care routine (Frisbie et al. 1986), may be associated with normal gastrointestinal transit times (Bolling Hansen et al. 2016), and reduces fecal incontinence.

Majority of people with SCI also report QOL improvements after a stoma formation (Coggrave et al. 2012; Munck et al. 2008; Safadi et al. 2003; Rosito et al. 2002; Kelly et al. 1999; Waddel et al. 2020; Van Ginkel et al. 2021; Cooper et al. 2019). Stomas were well-received by people and either met or exceeded their expectations (Rosito et al. 2002; Coggrave et al. 2012; Bolling Hansen et al. 2016; Van Ginkel et al. 2021). Tate et al. (2023) describes the large interplay of factors that contribute to surgery decision making, in which bleeding hemorrhoids, bowel incontinence, wounds, and ineffective management methods were the most common reasons to choose bowel-related surgeries such as colostomies, ileostomies or hemorrhoidectomies. Many SCI participants wished to have the stoma done earlier, or to have had it done earlier (Coggrave et al. 2012; Branagan et al. 2003; Bolling Hansen et al. 2016). Overall, current evidence supports the earlier education of stomas for bowel management for individuals with SCI.

Stoma increases independence, facilitates travel, elevates feelings of self-efficacy, and does not negatively affect body image (<u>Branagan et al. 2003</u>; <u>Rosito et al. 2002</u>; <u>Bolling Hansen et al. 2016</u>). Therefore, while research findings suggest that stoma formation be used to relieve bowel complications it may also be used to facilitate independence, and acceptance toward bowel care following SCI (<u>Boucher et al. 2019</u>; <u>Waddel et al. 2020</u>; <u>Van Ginkel et al. 2021</u>; <u>Cooper et al. 2019</u>; <u>Tate et al. 2023</u>).

There have been a few complications including increase in bowel times in one participant receiving an ileostomy (<u>Kelly et al. 1999</u>) and leakage and increased odor (<u>Frisbie et al. 1986</u>; <u>Bolling Hansen et al. 2016</u>), one participant with sigmoidoscopy reported noise as an issue, one reported cosmetic issues and pain (<u>Bolling Hansen et al. 2016</u>).

Conclusion

There is level 3 evidence (<u>Boucher et al. 2019</u>; <u>Negosanti et al. 2020</u>) that colostomy for people with SCI is a safe and effective option that is frequently used to treat localized bowel care complications, in which earlier surgery results in fewer later complications.

There is level 4 evidence (from seven studies; <u>Frisbie et al. 1986</u>; <u>Stone et al. 1990b</u>; <u>Kelly et al. 1999</u>; <u>Rosito et al. 2002</u>; <u>Branagan et al. 2003</u>, <u>Munck et al. 2008</u>; <u>Bolling Hansen et al. 2016</u>) that colostomy reduces the number of hours spent on bowel care.

There is level 4 evidence (from one retrospective pre-post study; <u>Frisbie et al. 1986</u>) that colostomy greatly simplifies bowel care routines and one study (<u>Bolling Hansen et al. 2016</u>) that this facilitated travel.

There is level 4 evidence (from one case study; <u>Rosito et al. 2002</u>) that colostomy reduces the number of hospitalizations caused by gastrointestinal problems and improves physical health, psychosocial adjustment, and self-efficacy areas within quality of life.

There is level 4 evidence (from one cross-sectional study; <u>Coggrave et al. 2012</u>) that colostomy reduces need for laxative use and dietary manipulation to assist bowel care.

There is level 5 evidence (<u>Tate et al. 2023</u>) that colostomy, ileostomy and hemorrhoidectomy are the main surgeries used to treat NBD in people with SCI. Surgical decision-making is influenced by multiple health, personal and social factors.

There is level 5 evidence (<u>Bolling Hansen et al. 2016</u>) that majority of people with SCI who undergo a colostomy require less time for bowel management and have a gastrointestinal transit time within the normal range afterwards.

Key Points

Elective stoma formation is a safe and effective treatment for significant neurogenic bowel management problems and perianal pressure injuries in persons with SCI, and greatly improves their quality of life.

7 Assistive Devices and Exercise

In addition to standard bowel protocols and pharmacological modalities, numerous devices and activity-based therapies were evaluated as means to improve bowel evacuation in individuals with SCI. These include standing and ambulation protocols, biofeedback, a wooden toothbrush, and a modified toilet seat.

Table 22a. Assistive Devices and Exercise – Interventions

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Gorman et al. 2021 USA RCT Level 1 N=50	Objective: To determine the amount of sessions needed to achieve adequate exoskeletal-assisted walking skills and velocity milestones. The secondary aim was to investigate whether this intervention would improve bowel function in comparison to usual activity. Population: Female: 24%	 From the 10Q Bowel Function survey, 12% reported reduced need for external help, 24% reported reduced evacuation time during a session and for a full week following EAW sessions. The BSS showed greater improvements in stool consistency after EAW (loose stool changed from 19.1% pre-

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	72% paraplegic Time since injury: 52% greater than two years, 48% six months to two years 62% AIS A and B, 38% AIS C and D Treatment: Exoskeletal-assisted walking (EAW) vs. usual activity in a crossover RCT design – all participants appeared in both groups, and were randomized which condition they did first or second. Outcome Measures: 10 Question Bowel Function Survey, the BSS, and the short-form item bank for Bowel Management Difficulties from the SCI-Quality of Life instrument	EAW to 9.3% post-EAW) more so than after usual activity (19% pre-UA to 15.2% post-UA). 3. Between men and women, the percentage of men with loose stool decreased with EAW (22.2 to 9.1%) whereas the percentage of women changed from 9.1% to 10%. 4. The BSS showed people with a motor complete injury had improvements in stool consistency (23.3% pre-EAW to 6.9% post-EAW) whereas people with incomplete injuries had worsening (11.8% pre-EAW to 14.3% post-EAW). 5. For the Bowel Management Item Bank components of the SCI-QOL, there was a statistically significant improvement regarding bowel management difficulties during the EAW phase for those who started in the UA-first group (improvement in satisfaction from 49.5 ± 9.2 to 46.5 ± 9.8 (p=0.028)).
Kwok et al. 2015 Australia and UK RCT Level 1 (<u>PEDro</u> =8) N=20	Objective: To determine the effects of a 6-week standing programme on bowel function in people with spinal cord injury. Population: N=20 (15M, 5F) wheelchair dependent SCI community members Median (IQR) age: Treatment first group: 46 (39-55) Control first group: 46 (42-51) Median (IQR) time since SCI: Treatment first group: 4 (3-11) Control first group: 9 (6-20) 15 cervical, 5 thoracic	 No significant mean between-intervention difference for any outcome measure. Median (IQR) of perceived change in bowel function is 0/10 (0-3). Median (IQR) of inconvenience is 5/10 (0-7).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	AIS-A/B: 13/7 Treatment: Standing phase: participants stood on tilt table for 30min, 5 times/week No-stand phase: participants did not stand Crossover with: 6 weeks of standing/no-stand phase + 4 weeks of washout phase + 6 weeks of no-stand/standing phase Outcome Measures: time to first stool, time to complete bowel care, Neurogenic Bowel Dysfunction Score, Cleveland Clinic Constipation Score, St. Mark's Incontinence Score, SCI-SET	
Huang et al. 2015 China RCT Level 2 (<u>PEDro</u> =5) N=24	Objective: To compare the effects of body weight-supported treadmill training (BWSTT) and robot-assisted rehabilitation (RAT) on bowel function in patients with spinal cord injury with respect to defecation time and defecation drug dose (enema). Population: N=24 incomplete SCI from T8 to L2, less than 6 months post-SCI Body weight supported treadmill training (BWSTT) group: N=12 (7M, 5F) Mean (SD) age 38.4 (2.25) RAT group: N=12 (9M, 3F) Mean (SD) age 41.7 (2.25) Treatment: 20min BWSTT or robot-assisted training (RAT) sessions 4 times per week for 1 month Outcome Measures: defecation time, glycerine enema dose	 Significant interactions in defecation time and enema dose between both groups. Significant within-group decrease in enema dose (68.1±10.7mL to 38.8±12.4mL) and defecation time (93.0±14.7min to 64.5±11.6min) in RAT group (p<0.01). No significant within-group change in enema dose and defecation time in BWSTT group.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Hubscher et al. 2021 USA Prospective controlled trial Level 2 N=22	Objective: To investigate whether the urogenital and bowel functional gains previously demonstrated post-locomotor step training after chronic spinal cord injury could have been derived due to weight-bearing alone or from exercise in general. Population: Female: 9% Age: mean 32.6 y Time since injury: 5.3 y Level: 12 cervical, 10 thoracic Severity: 11 AIS A 7 AIS B 3 AIS C 1 AIS D Treatment: Approximately eighty daily one-hour sessions of either stand training or nonweight bearing arm crank ergometry. Comparisons are made with previously published locomotor training data (step; N=7). Outcome Measures: Assessments at both pre-and post-training time-points included cystometry for bladder function and International Data Set Questionnaires for bowel and sexual functions	 The overall NBD score did not change pre-/post-training for any of the three training groups examined. The results indicate that most of the scores fall within the ranges clinically interpreted as moderate to severe levels of dysfunction. Although we have previously found a significant decrease in time required for defecation after LT20, no significant pre-/post-training differences (p>0.05) for either stand or arm crank were found.
Mazor et al. 2016 Australia Prospective controlled trial Level 2 N=21	Objective: to compare anorectal biofeedback (BF) outcomes in patients with incomplete motor spinal cord injury and neurogenic bowel dysfunction with a group of functional anorectal disordermatched control patients Population: N=42 controls Age: 51 (17) y Female: 81% N=21 SCI with NBD	 Following anorectal biofeedback therapy, symptom scores significantly improved in both groups, as did effect of bowel disorder on QOL. The SCI group had larger improvements in constipation score compared with the control group (40% vs 27%, respectively, P=0.04) whereas the reduction in FI weekly episodes was not

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Age: 50 (17) y Female: 81% Level: 10 lumbosacral, 4 thoracic, 2 cervical, 3 cauda equina, 2 unknown Severity: 13 ASIA D, 3 ASIA C, 3 Cauda equina syndrome Etiology: 17 traumatic 8 UMN 13 LMN Treatment: Anorectal biofeedback 30-60 min/session, once a week for 6 weeks Outcome Measures: The Knowles Constipation Questionnaire and the Fecal Incontinence Severity Index were calculated before and after treatment for constipated and FI patients, respectively. A 10cm visual analogue scale was also used before and after treatment for impact of bowel dysfunction on quality of life, patient satisfaction with bowel movement, and feeling of control over bowel function. Physician assessment and follow-up questionnaires	significant between the two groups (p>0.05) 3. Both the SCI and control groups had a significant improvement in bowel function control (p<0.05 for both groups) 4. Within-group decrease in first sensation threshold (75±53 to 64±65mL) and max anal resting pressure (62±19 to 53±21mmHg) in SCI group, but not in controls. 5. Within-group increase in sustained squeeze duration (23±9 to 31±14s) in controls, but not in SCI group. 6. Individuals with SCI and NBD improved sensory and motor anorectal function, including lowering of first sensation threshold and more effective balloon expulsion. Improvement in balloon expulsion time was correlated to Faecal Incontinence Severity Index and constipation score improvements (p<0.05). 7. The improvement in Faecal Incontinence Severity Index score was correlated with improved feelings of bowel movement control (p=0.003) 8. 10/11 SCI group reported stable or improved bowel symptoms at long-term follow-up.
Hubscher et al. 2018 USA Prospective controlled trial Level 2 N=12	Objective: Locomotor training (LT) as a therapeutic intervention following spinal cord injury (SCI) is an effective rehabilitation strategy for improving motor outcomes, but its impact on non-locomotor functions is unknown. Given recent results of our labs' preclinical animal SCI LT studies and existing overlap of lumbosacral spinal circuitries controlling pelvic-visceral	 Within the activity-based training group, time required for defecation significantly decreased from 57.9 minutes to 35.7 minutes (p=0.022). Within the activity-based training group, medication usage for bowel, and bowel emptying method remained unchanged. Frequency of fecal incontinence,

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	and locomotor functions, we addressed whether LT can improve bladder, bowel and sexual function in humans at chronic SCI time-points (> two years post-injury). Population: SCI Locomotor Training (LT) Group N=8 Level: 4 AIS A, 1 AIS B, 2 AIS C, 1 AIS D Age: Mean 27.4 years, SD 6 years old Duration: Mean 4.3 years, SD 3.8 years % Female: 38% SCI Usual Care (Non-Trained) Group N=4 Level: 2 AIS A, 1 AIS B, 1 AIS C Age: Mean 30.3 years, SD 5.2 years Duration: Mean 6.7 years, SD 2.6 years % Female: 0% Treatment: 80 daily sessions of bodyweight support treadmill training (BWSTT) (1 hour per session) or locomotor training plus weight bearing standing (1 hour each day). One trainer assisted the pelvis and hips while each leg was assisted by a trainer. Locomotor training vs nontrained group Outcome Measures: The International Spinal Cord Injury Data Sets Questionnaires for Urodynamics and Lower Urinary Tract Function (adapted by C.H. Hubscher to include average number of nightly bladder emptying/day) and for Bowel Function (adapted by C.H. Hubscher to include an expansion of the average time required for defecation).	frequency of defecation, and oral laxative usage changed although these findings were not significant.

Table 22b. Assistive Devices and Exercise – Case Series/Cross-Sectional studies

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome Measures
Esfandiari et al. 2017 Israel Pre-Post Level 4 N=61	Objective: The aim of this study was to investigate the therapeutic effect of traditional wooden toothbrush usage on most severe constipation, which usually occurs in spinal cord injury (SCI) patients. Population: N=61 Level: 6 cervical, 32 thoracic, 14 lumbar, 8 thoracolumbar (classification not defined) Age: Mean 41 years, SD 12.35 years Duration: >2 years % female: 18% Timeline: Jan- Feb 2013 Treatment: 6 weeks of using of a wooden toothbrush for brushing teeth after breakfast and dinner for at least 5 minutes comparing: before vs. after, gender, level of injury Outcome Measures: NBD and Constipation Assessment Scale (CAS; lower score better)	 CAS mean score decreased (from 3.34 to 1.73; p<0.001) with the following symptoms decreased significantly: abdominal distension/bloating, flatulence, bowel movement infrequency, liquid stool, rectal pain with bowel movement, small volume of stool, and inability to pass stool. NBD scores improved (from 8.95 to 3.03; p<0.0001). NBD score improved for individuals with thoracic (p<0.0001), or thoracolumbar injuries (p=0.031), but not individuals with cervical or lumbar injuries CAS score significantly improved for individuals with thoracic (p=0.0001), or lumbar (p=0.019) but not individuals with cervical or thoracolumbar. NBD scores improved for individuals with cervical or thoracolumbar. NBD scores improved for individuals who were 30-40 years old, but not other age demographics. No difference in results between woman and men.
Juszczak et al. 2018 USA Pre-post Level 4 N=45	Objective: To explore changes in secondary health conditions that may result from using a powered exoskeleton as well as their potential impact on QoL. Population: N=45 Female: 19% Age: 35 y (SD= 12.65) Time since injury: 3.9 y (SD= 5.13, range, 0.25-23.75 y)	 No negative changes in bowel and bladder were reported; positive changes were reported by 20% and 9% of participants with respect to bowel and bladder management. There were no statistically significant changes in SWLS sum score from baseline to conclusion of study (20.4 +/- 8.0 to 21.3 +/- 7.6; p>.05).

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome Measures
	Level: 60.1% Upper paraplegia (TI-T8) 39.9% lower paraplegia (T9-L2) Severity: 67% A complete 11% B incomplete 22% C incomplete Treatment: this study was to explore changes in secondary health conditions that may result from using a powered exoskeleton for independent walking for 26 sessions, as well as their potential impact on QoL. Outcome Measures: self-reported assessments of pain, spasticity, bladder/bowel function, Satisfaction with Life Scale (SWLS), and Modified Ashworth Scale (MAS).	
Chun et al. 2020 USA Pre-post Level 4 N=10	Objective: To explore the effects of exoskeletal-assisted walking (EAW) on bowel function in persons with spinal cord injury (SCI). Population: N=10, (one participant was lost due to early withdrawal) Female: 9% Age: 31-45 yrs – 4 participants; 46-60 yrs – 4 participants; 61-65 yrs – 2 participants Level: 100% Thoracic, T1-T11 Severity: All motor complete paraplegia 82% AIS A, 18% AIS B Time since injury: 1- 5 yrs – 6 participants; 6-10 yrs – 2 participants; 11-15 yrs – 2 participants Treatment: To explore the effects of exoskeleton-assisted walking (EAW) on bowel function in persons with spinal cord injury (SCI) Participants were asked to attend 3–4 Exoskeleton Assisted Walking (EAW) sessions weekly with a goal of completing at least 25 sessions in 12–14 weeks. Each session consisted of donning the device, checking vitals, performing sit to stand, then walking for	 5/10 reported improved frequency of bowel evacuations over the past week, 5/10 reported reduced time in minutes spent on having a bowel movement per bowel day, 6/10 reported fewer bowel accidents over the past month, and 7/10 reported decreased frequency of laxative and/or stool softener use over the past week post-EAW training. 6/10 participants reported improved overall satisfaction with their bowel programs over the past month and, in 8/10 participants, ratings of stool consistency changed from either too hard or too watery to "ideal" (4–5) post-EAW training. Seven participants reported a ≥10% improvement on the SCI-QOL Bowel Management and one participant who reported

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome Measures
	30–90 minutes in the device, with occasional rest periods as required. Outcome Measures: The International Standards for Neurological Classification of SCI (ISNCSCI) Exam was used to classify participants as complete (AIS A) or motor complete/sensory incomplete (AIS B) as well as to determine their neurological level of injury. Modified Lynch Gastrointestinal (GI) Survey, Bristol Stool Scale (BSS), SCI-QOL Bowel Management Difficulties (Short Form)	worsening score. This individual also reported increased bowel accidents and medication use post-EAQ training without changes in frequency of bowel evacuations, time spent on bowel management per bowel day, or overall satisfaction with regards to bowel program post-EAW training. Also a slight softening in stool consistency on the BSS
Brinkemper et al. 2023 Germany Cross-sectional Level 5 N=35	Objective: To explore whether bowel and bladder management can be influenced by locomotion therapy with HAL Robot Suit. Population: N=35 Level: Incomplete paraplegia 1 AIS B, 22 AIS C, 7 AIS D Complete paraplegia 5 AIS 5 Group was divided into two subgroups of acute and chronic SCI patients Time since injury: 13 participants less than 1 year since injury, average 3.85 ± 2.58 months, 46.85 ± 13.98 years 22 participants more than one year since injury, average 71.73 ± 60.71 months, average age of 48.95 ± 13.81 years Treatment: to explore whether bowel and bladder management can be influenced by locomotion therapy with HAL Robot Suit Outcome Measures: Bowel incontinence measured using the Wexner Score, constipation by the Cleveland Clinic Constipation Scoring System and bladder function using a self-developed questionnaire before and after completion of a 12-week training period with HAL	 Wexner Score- Bowel Incontinence Over all patients (N=35), there was a significant change from 8.89 ± 4.62 points to 6.51 ± 4.92 points (P=.008) For acute injury participants, average Wexner score of 7.77 ± 5.56 points before training reduced to 5.62 ± 3.52 points after exoskeleton training (p=0.109) (ns) 6/13 acute injury patients showed significant decrease in Wexner Score from 12.83 ± 3.06 points before training to 7.5 ± 2.74 points after training (P=.016) For chronically paraplegic patients (N=22), score significantly improved from average of 9.55 ± 3.96 points to 7.05 ± 5.59 points (P=.039) Analysis of 7 participants with a baseline score > 7 (N=16) showed significant improvement in scores from 11.44 ± 2.53 points to 7.94 ± 5.64 points after locomotion

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome Measures
		training (P=.013) Cleveland Clinic Constipation Scoring System- Constipation Overall (N=35) CCCS decreased from 6.86 ± 4.28 points to 5.69 ± 4.95 points (P=0.212) (ns)
Forchheimer et al. 2016 USA Cross-sectional Level 5 N=246	Objective: To describe management of neurogenic bowel in individuals with chronic SCI and to explore associations between behaviors and outcomes. Population: N=246 Level: 14.2% incomplete paraplegic, 31.3% complete paraplegic, 26.8% incomplete tetraplegic, 27.6% complete tetraplegic Age: Mean 49.73 years, SD 12.8 years Duration: Mean 18.73 years, SD 10.2 years % Female: 26% Treatment: N/A Outcome Measures: Bladder and Bowel Behavioral Management Questionnaire, and Bowel and Bladder Treatment Index, SF-36, Qualiveen	1. Most individuals who exercised less than 30 minutes per week reported often or always spending time on bowel management, while most individuals who exercise at least 1 hour per week reported never or rarely spending time on bowel management (p=0.02)
Uchikawa et al. 2007 Japan Cross-sectional Level 5 N=20	Objective: To study the effectiveness of a modified washing toilet seat equipped with a CCD camera monitor and an electronic bidet to facilitate precise hitting of the anal area with water streams to stimulate bowel movement in patients with spinal cord injury (SCI). Population: 11 participants with cervical, 7 with thoracic, and 2 with lumbar SCI; AIS level: 8 A, 4 B, 4 C, and 4 D; all male; Age: mean (range) 46.3 (18-73) yrs; all were at least 5 months post injury Treatment: Newly developed procedure to induce bowel movement involving a toilet seat equipped with an electronic bidet (provides water flow), a charge-coupled device (CCD) camera monitor and a light (facilitates location of	 Time needed for bowel management was shorter with the intervention than that with participants' usual manner of bowel care. 35% (n=7) of participants originally spent less than 30 minutes for usual defecation compared to 75% (n=15) with modified device. Residual stools found in 8/15 participants who successfully defecated within 30 minutes with the device. Success of defecation not related significantly with injury level or AIS

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome Measures
	anorectal area). Outcome Measures: Time required for successful bowel movement, amount of residual stool in rectum	impairment scale.

Discussion

Johns et al. (2021) recommend regular physical activity for people with SCI, as it may have positive effects on bowel function with other health benefits. One cross-sectional study found that majority of people with SCI who exercised less than 30 minutes each week report more time spent on bowel management in comparison to people who exercise at least one hour a week (Forchheimer et al. 2016). Standing programs, aerobic arm ergometers, and assisted walking (with bodyweight support or exoskeletons) may be used to facilitate exercise (Johns et al. 2021). Most studies report the effects of activity-based therapies on bowel-related outcomes for people with SCI as a secondary measure.

<u>Kwok et al. (2015)</u> tried to replicate these results with 20 participants with SCI in a crossover trial with regular use of a standing frame (30 min, 5 times per week for 6 weeks) and found no difference in time to first stool or time to complete bowel care between the treatment and control phase.

Gorman et al. (2021) investigated exoskeletal-assisted walking (using ReWalk and Ekso powered exoskeleton devices) and bowel management/function as a secondary outcome measure. For people in the intervention group, there was some reduction in bowel evacuation time and normalization in stool consistency reported after 36 sessions of exoskeleton-assisted walking. Chun et al. (2020) reported similar findings with exoskeleton-assisted walking 3-4 sessions per week within 12-14 weeks. Brinkemper et al. (2021) also reported improvements in bowel incontinence and constipation after locomotion therapy/exoskeleton training with a HAL Robot Suit.

In two small studies, Hubscher et al. (2018 and 2021) found that most variables of bowel dysfunction were not different between arm crank erg, BWSTT, or standing groups. Medication usage, bowel emptying method, frequency of fecal incontinence, frequency of defecation, oral laxative usage, and NBD score changes were not statistically significant. The only significant difference between groups was time required for defecation; participants in locomotor training on a BWSTT for 80 daily one-hour sessions had significantly decreased (p=0.022) time required for defecation vs. those in weight-bearing standing for one hour every day. Similarly, Huang et al. (2015) found reductions for those doing RAT vs. those doing BWSTT on defecation time ((93.0±14.7 to 64.5±11.6 min) and reduction in enema dose (68.1±10.7 to 38.8±12.4 mL; p<0.01). Unfortunately, the study was also small, the study took place within 6 months of injury, and

there were no data on level or completeness of injury for participants, we cannot attribute differences clearly to any one factor at this time.

Other assistive devices that may help improve bowel management and function include wooden toothbrush and toilet seat modifications. Esfandiari et al. (2017) investigated the effect of wooden toothbrush usage (5 minutes after breakfast and dinner over 6 weeks), on constipation for people with SCI. (They hypothesized that stimulation of the trigeminal sensory nerve would stimulate the vagus motor nerve responsible for gut activity through the medial longitudinal fasiculus (MLF) and therefore lead to GI reflexes). Esfandiari et al. 2017 reported a significant decrease in many constipation symptoms and increase in NBD scores. However, NBD scores only improved for individuals with thoracic or thoracolumbar injuries, and not cervical or lumbar. Additionally, this improvement was only observed for those between 30-40 years old. There were no differences in results between men and women. Results suggest the wooden toothbrush at least 5 minutes twice daily can be considered to assist in management constipation in SCI, but further research with control group is needed.

One prospective controlled study investigating anorectal biofeedback therapy found changes in anorectal parameters after the intervention along with larger improvements in constipation compared to the control group (40% vs. 27%; p=0.04; Mazor et al. 2016).

<u>Uchikawa et al. (2007)</u> developed a new procedure to induce bowel movements using a toilet seat equipped with an electronic bidet that provides water flow to the anorectal area. A CCD camera and light are included to facilitate location of the anorectal area. The authors report that a reduction in the time needed for bowel management, with an additional 8 (40%) participants who can complete defecation in less than 30 minutes. <u>Mazor et al. (2016)</u> trialed biofeedback once a week for 6 weeks in a matched controlled trial with 21 patients with motor incomplete SCI. There was improvement in constipation scores, first sensation threshold and maximum anal resting pressures. Ten of eleven SCI participants reported stable or improved bowel function at long term follow up.

Utilizing these programs and assistive devices to improve bowel management and function requires further research.

Conclusion

There is level 1 evidence from one RCT (<u>Gorman et al. 2021</u>) that some improvements in average bowel evacuation time and stool consistency occur with an exoskeletal-assisted walking intervention in comparison to usual activity for people with SCI.

There is level 1 evidence (<u>Kwok et al. 2015</u>) that a regular standing program did not change neurogenic bowel function.

There is level 2 evidence (<u>Huang et al. 2015</u>) that ambulation training programs may improve some aspects of neurogenic bowel function (enema dose and defecation time).

There is level 2 evidence (<u>Hubscher et al. 2021</u>) that after stand and arm crank training there were no significant differences in bowel dysfunction.

There is level 2 evidence (<u>Hubscher et al. 2018</u>) that people in the weight-supported treadmill training, locomotor training, or weight-bearing standing groups required less time for defecation.

There is level 2 evidence (<u>Mazor et al. 2016</u>) that anorectal biofeedback therapy improves anorectal function and neurogenic bowel constipation symptoms in motor incomplete participants.

There is level 4 evidence (<u>Esfandiari et al. 2017</u>) that a wooden toothbrush for 5 minutes twice daily has therapeutic effects and improves neurogenic bowel dysfunction symptoms.

There is level 4 evidence (<u>Chun et al. 2020</u>) that exoskeleton-assisted walking improves bowel evacuations, reduced time of bowel movements, decreased bowel accidents and frequency of laxative use.

There is level 4 evidence (<u>Juszczak et al. 2018</u>) that exo-skeleton walking is beneficial for bowel management although no increase in quality of life was reported.

Assistive Devices and Exercise- Case Series/Cross-sectional studies
There is level 5 evidence (Forchheimer et al. 2016) that people with SCI who exercise at least one hour per week will spend less time on bowel management.

There is level 5 evidence (<u>Uchikawa et al. 2007</u>) that a washing toilet seat with a CCD camera monitor for visual feedback reduces time spent on bowel care.

There is level 5 evidence (<u>Brinkemper et al. 2021</u>) that SCI bowel incontinence and constipation scores improve after locomotion therapy with a HAL Robot suit.

Key Points

There is no convincing evidence that a standing table reduces constipation.

There is limited evidence that ambulation training programs may improve some aspects of neurogenic bowel function.

There is limited evidence that a washing toilet seat with visual feedback may assist bowel care.

There is limited evidence that biofeedback may improve constipation in motor incomplete patients.

8 Experimental Studies

Epidural spinal cord stimulation (SCS) was originally investigated by researchers looking to recover voluntary motor function in case-studies of people with SCI (e.g., <u>Harkema et al. 2011</u>). Based on positive results in voluntary neural function other than motor below the level of injury,

researchers have reasoned that bladder, bowel, and sexual dysfunction would be most logical to study in parallel (<u>Pettigrew et al. 2017</u>).

Epidural Stimulation

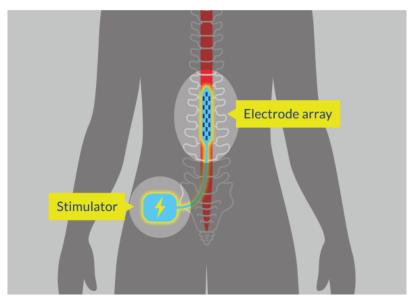


Figure 2: Epidural Spinal Cord Stimulation (SCS)

Other experimental treatments for neurogenic bowel after SCI include type A-botulinum toxin (BTX-A), Wharton jelly mesenchymal stromal cell intrathecal infusion, and osteopathic manipulative treatment.

Table 23. Experimental Studies

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Valles et al. 2021 Spain RCT Level 1 (PEDro=) N=16	Objective: To study the efficacy of external anal sphincter (EAS) infiltration with type-A botulinum toxin (BTX-A) in motor incomplete SCI patients with outlet constipation. Population: motor-incomplete SCI ASIA grade C or D; more than 1 year since injury; 4 female; mean age 49 (29-68) y. Treatment: EAS infiltration with BTX-A vs. placebo infiltration Outcome Measures: Rome III criteria evaluated constipation, Wexner score	 People in the BTX-A group reported an improved level of satisfaction related to bowel function at 1-month post infiltration (p=0.02) and in the ODSS at 3-months post infiltration (p=0.03) compared to baseline levels. Constipation severity at 1 month (p=0.02) and 3 months (p=0.02) post

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	evaluated fecal incontinence, Obstructed Defecation Scoring System assessed outlet (obstructed) defecation, NBDS measured severity of NBD, CVE-20 questionnaire assessed QOL, numerical rating scale assessed level of satisfaction related to bowel function.	infiltration was improved compared to baseline. 3. NBS at 3-months post infiltration (p=0.02) significantly improved compared to baseline. 4. Fecal incontinence, colonic transit time and QOL did not significantly change after BTX-A infiltration. 5. EAS voluntary contraction pressure decreased 3-months post BTX-A infiltration compared to baseline (p=0.02) and in comparison to the placebo group (p=0.01).
Tamburella et al. 2022 Italy RCT Level 1 (PEDro=) N=13	Objective: To explore OMT effects on NBD in individuals with SCI compared with Manual Placebo Treatment (MPT). Population: OMT Group: mean age 37.5 (11,1) y; time since injury 8.16 months, 3 AIS A, 0 AIS B, 2 AIS C, 2 AIS D; 71% traumatic etiology; 14% female MPT Group: mean age 52.6 (22, 5) years, time since injury 7.66 months, 2 AIS A, 1 AIS B, 1 SIS C, 2 AIS D; 33% traumatic etiology; 17% female Treatment: Osteopathic manipulative treatment once a week for four weeks. Included myofascial techniques, balanced ligamentous tension, visceral manipulations and osteopathy in the cranial field vs. Manual placebo treatment (MPT) once a week for four weeks. Included passive mobilizations of the pelvis, upper and lower limbs, cervical spine and light manual touch of the abdomen and thoracic region Outcome Measures: Neurogenic Bowel Dysfunction Scale (NBDS). Secondary	 There was a more positive trend in the OMT group for the NBDS general satisfaction question regarding the bowel management. KESS score improved more in the OMT group between E1 and E2 compared to the MPT group but was not significantly different. PAC-QOL worries score improved within the OMT group between E1 and E2 (p=0.0029), between E0 and E2 (p=0.0031) and E0 and E3 (p=0.041). VAS daily score significantly improved after treatments in the OMT group (sense of constipation; p=0.031, swelling; p=0.006; pain; not statistically significant) compared to E1, whereas there were no changes in the MPT group.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	outcome measures include Knowles Eccersley Scott Symptom Scale (KESS) and patient Assessment of Constipation Quality of Life (PAC-QOL) measuring constipation. Visual Analogue Scale was used. Evaluation at enrollment (E0), 30 days after enrollment (E1), at the end of 4 treatments (E2), and 30 days after last treatment (E3).	5. Within the OMT group, NBDS score improved from E0 to E3 (p=0.0011) and from E1-E3 (p=0.040) whereas NBDS in the MPT group did not significantly improve.
Albu et al. 2021 Spain RCT Level 1 (PEDro=) N=10	Objective: Investigate the safety and clinical recovery effects of intrathecal infusion of expanded Wharton jelly mesenchymal stromal cells (WJ-MSCs) in chronic complete SCI patients. Population: 10 people with complete, thoracic SCI. 3 females, age range 25-47 years Treatment: WJ-MSC intrathecal infusion compared with placebo infusion in crossover design Outcome Measures: AIS motor and sensory score, lower limb spasticity, neuropathic pain and electrical perception and pain thresholds, SCIM III, WHOQOL-BREF were assessed at baseline, 1 month, 3 months, and 6 months after each intervention. Anorectal manometry, urodynamic studies, Qualiveen questionnaire, Wexner score and Rome III diagnostic questionnaire were conducted at baseline and 6 months after each intervention	 Bowel constipation did not significantly change after MSC or placebo intervention (p>0.05) as measured by Rome III criteria. Wexner score at baseline indicated low severity of fecal incontinence for all participants, which did not significantly change after MSC or placebo interventions (p>0.05). Anorectal manometry parameters (anal resting pressure, voluntary anal contraction, change in rectal pressure during squeeze, rectoanal inhibitory reflex, excitatory reflex) did not significantly change after MSC or placebo intervention (p>0.05).
DiMarco et al. 2021 USA Cohort Level 2 N=5	Objective: To systematically determine whether use of the spinal cord stimulation (SCS) system to restore cough may improve bowel management (BM) in individuals with spinal cord injury (SCI). Population: Age: Mean 37 years Level/Severity: 1 C4-C6,1 C3-C6, 1 C6, 1 C3, 1 C7/T1; 5 AIS A, motor complete cervical SCI Female: 0%	 Bowel management (BM) time fell by 84% at week 21. Largest changes in bowel management time occurred by week 4 (28.7% and 17.7% of control values by weeks 4 and 21 respectively). Gradual reduction in BM time was related to increase in maximum airway

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Etiology: 4 trauma, 1 abscess Time of injury: All ranged between 2-4 years Treatment: Implanted spinal cord stimulation (SCS) cough system was chronically applied at home 2-3 times a day when the bowel regimen was performed Outcome Measures: Airway pressure generation with SCS, weekly completion of Bowel Routine Log including B< time, mechanical measures and medications employed	pressure generation with SCS over the reconditioning period.
Darrow et al. 2019 Canada/USA Case series Level 4 N=2	Objective: Key questions include whether epidural spinal cord stimulation can meaningfully restore function to radiographically severe injuries, whether the intervention can improve function in people with long-term chronic SCI, how consistent and predictable recovery may be when comparing individuals, and whether epidural spinal cord stimulation can restore autonomic control of cardiovascular, bowel, bladder and sexual function. Population: 2 female participants with chronic thoracic AIS A SCI. Participant 1 was 52y and 10y from injury (T8). Participant 2 was 48 y and 5 y from injury (T4). Participant 1 had no type of rehabilitation 6 months prior to the study whereas participant 2 had 60 h of outpatient rehabilitation in the 6 months prior. Treatment: Epidural spinal cord stimulation (eSCS) Outcome Measures: Neurogenic Bowel Dysfunction Score (NBDS) for bowel function	 Participant 1 had no change in bowel function after eSCS. Participant 2 had NBDS severity rating change from Moderate to Severe after eSCS, although reported bowel care regimen time decreased from 90 mins to less than 30 minutes.

Discussion

There are several innovations that have been developed to treat people with SCI, but they are still considered "experimental" as there is little to no evidence supporting their use, their safety and efficacy have not yet been fully established, and/or they have not yet been approved for widespread use.

For example, epidural spinal cord stimulation (eSCS) is currently being investigated to restore volitional movement and autonomic function in people with SCI. Darrow et al. (2019) presented findings from the Epidural Stimulation After Neurologic Damage clinical trial (E-STAND). One objective was to determine whether eSCS could restore autonomic control of bowel function. Both participants who received the implantation had no bowel function improvements observed with the epidural SCS, and participant 2 had a worsening of NBD severity. However, participant 2 did report that time required for bowel care decreased from 90 minutes to less than 30 minutes. Further studies are required to confirm changes in bowel function and management with epidural spinal cord stimulation.

Botox (BTX-A) infiltration of the external anal sphincter resulted in significant constipation symptom improvements in one clinical trial (p=0.02; <u>Valles et al. 2021</u>). Another clinical trial investigating Wharton jelly cell intrathecal infusion at the L3-4 intervertebral level found no significant changes in constipation, fecal incontinence, or anorectal manometry parameters (Albu et al. 2021).

<u>DiMarco et al. (2021)</u> investigated an experimental, airway suppression secretion management using electrical stimulation. Electrodes were inserted on the upper lumbar, dorsal surface of the spinal cord and the intervention resulted in increased airway pressure generation as well as reduced bowel management time (mean BM 118 ± 34 min to 18 ± 2 min at week 21 (p<0.05) (<u>DiMarco et al. 2021</u>).

Conclusion

There is level 1 evidence from a pilot RCT (Valles et al. 2021) that type A-botulinum toxin infiltration in the external anal sphincter improved constipation symptoms (p=0.02) by decreasing anal canal pressure and EAS contraction. Fecal incontinence, colonic transit time, and quality of life did not significantly change after the intervention.

There is level 1 evidence from one double blinded RCT (<u>Tamburella et al. 2022</u>) that osteopathic manipulative treatment which had focus on the abdominal region may have a positive effect on neurogenic bowel function symptoms and perceptions in comparison to a manual placebo treatment for people with SCI and NBD.

There is level 1 evidence from a randomized controlled trial (<u>Albu et al. 2021</u>) that while wharton jelly mesenchymal stromal cell intrathecal infusion demonstrated a positive effect on sensory perception below level of injury compared to a placebo infusion, the treatment did not significantly improve bowel function in people with complete, thoracic SCI.

There is level 2 evidence (<u>DiMarco et al. 2021</u>) that using spinal cord stimulation to activate muscles that induce a cough improves bowel management time and quality of life for select individuals with cervical SCI.

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Abbreviations

ACE antegrade colonic enema

BWSTT Body Weight Supported Treadmill Training

DIE difficult intestinal evacuation

DGN dorsal genital nerve
DRS digital rectal stimulation

FES Functional Electrical Stimulation FMS Functional Magnetic Stimulation

GE gastric emptying
GI gastrointestinal

HVB hydrogenated vegetable-oil base

LMN lower motor neuron

Bowel Dysfunction and Management Following Spinal Cord Injury

MACE Malone Antegrade Continence Enema

NBD neurogenic bowel dysfunction

PGB polyethylene glycol base

SARS sacral anterior root stimulator

SNM sacral nerve modulator SNS sacral nerve stimulation

TAI transanal irrigation
UMN upper motor neuron