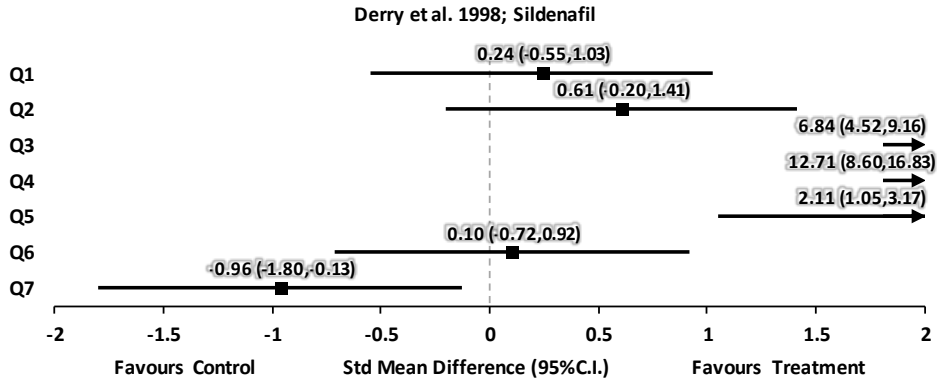
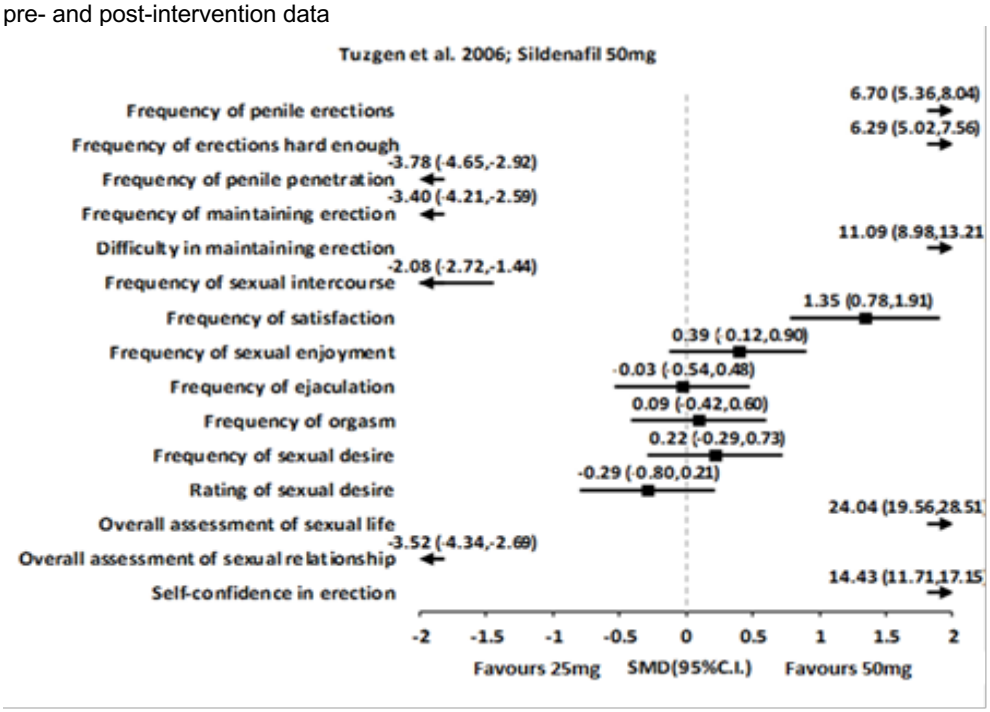
Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Khorrami et al. 2010; Iran RCT Level 1 PEDro=9 N=105	**Population:** 105 men with SCI who had neurogenic erectile dysfunction; all with paraplegia; mean age 47.6 (range 40-55); divided into those with upper motor neuron (UMN) injuries (n=72) and those with lower motor neuron (LMN) injuries (n=33). **Treatment:** Sildenafil 50mg 45min before start of sexual intercourse, increased to 100mg if not effective, for treatment group (n=45 from UMN and n=14 from LMN); placebo for control group (n=27 from UMN and n=19 from LMN). **Outcome Measures:** International Index of Erectile Function (IIEF5) questionnaire; if subject scored more than 15 points on the IIEF5, then treatment considered effective, if less than 15 then inadequate.	1. 37 (82%) of the 45 UMN participants who took sildenafil had a favourable response, compared to 7 (26%) of the 27 placebo UMN participants. 2. 4 (28.5%) of the 14 LMN participants who took sildenafil had a favourable response, compared to 5 (26%) of the 19 LMN participants who had placebo. 3. Side effects include headache (n=8), flushing (n=4) and gastro-intestinal discomfort (n=3).
Giuliano et al. 2008; USA RCT Level 1 PEDro=9 N=418	**Population:** 418 men with SCI over 18 yrs old with resulting erectile dysfunction for over 6 months, and in a stable heterosexual relationship for over 1 month, randomized to vardenafil (n=207) or placebo (n=211). **Treatment:** Vardenafil (placebo for controls) for 12 weeks; dosage for the first 4 weeks was 10mg, and subsequently adjusted individually to 20 or 5mg. **Outcome Measures:** Success of ejaculation; International Index of Erectile Function (IIEF) scores; Global Confidence Question (GCQ); Psychological General Well-Being Index (PGWBI); Centre for Epidemiological Studies – Depression (CES-D) score; Rosenberg Self-Esteem Score (RSES); Mental Health Summary of the SF-36 Health Survey.	1. Success rate of ejaculation was significantly higher in the vardenafil group compared to control (19% vs. 10%). 2. The IIEF orgasmic function domain score (questions 9 and 10) increased from 2.9 to 4.0 in vardenafil group, compared to 3.0 to 3.4 in control. 3. The GCQ score increased from 2.5 to 3.5 in the vardenafil group, compared to from 2.6 to 2.9 in control (significant difference). 4. No significant difference between vardenafil and control groups in the PGWBI, the CES-D, RSES, or SF-36 mental health domain scores before and after treatment.
Ergin et al. 2008; Turkey RCT with crossover Level 1 PEDro=8 N=50	**Population:** 50 men with SCI, over 19 yrs old, with associated erectile dysfunction but had some psychogenic or reflexogenic erectile function. **Treatment:** 50mg of sildenafil (placebo for controls) 1 hr before sexual activity, for 6 weeks; this was followed by a 2-week washout period, after which the patient was switched to the alternate treatment for another 6 weeks. **Outcome Measures:** International Index of Erectile Function (IIEF); Life-Satisfaction Check List (LISAT-8); Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS); Global Efficacy Assessment questionnaire.	1. Sildenafil produced greater improvements than placebo in following areas: satisfaction with sex life and sexual relationship (IIEF questions 13 and 14), EDITS score, erective function and overall sexual satisfaction. 2. No difference between the 2 groups with regard to total IIEF scores. 3. No difference between the 2 groups with regard to intercourse satisfaction or sexual desire. 4. No reports of AD symptoms in patients undergoing treatment. 5. Participants with incomplete injuries showed improvement in 7/11 measures whereas participants with complete injuries showed improvement in 3/11 measures.
Derry et al. 1998; UK RCT	**Population:** 27 men, treatment n=12, placebo n=14; Age: mean 32-34 yr; Injury level: T6-L5, AIS: A-D but must have partial	1. 75% on sildenafil and 7% on placebo reported that treatment improved erections. 2. Significant improved satisfaction with sex life

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
Level 1 PEDro=8 Initial N=27 Final N=26	reflexogenic erection to vibrostimulation. **Treatment:** Randomized to receive 50mg of sildenafil or placebo not more than 1/day, approx 1 hr before sexual activity. **Outcome Measures**: Efficacy and safety of sildenafil, sexual function questionnaire.	reported by sildenafil group. 3. Mean number of grade 3-4 erections was 1.8/wk for sildenafil group, 0.4/wk for placebo patients.
	Effect Sizes: Forest plot of standardized mean differences (SMD ± 95%C.I.) as calculated from pre- and post-intervention data  **Q1: frequency of sexual desire; Q2: rating of sexual desire; Q3: frequency of waking with erection; Q4: frequency of stimulated erections; Q5: frequency of erections hard enough for sex; Q6: frequency of erections lasting long enough; Q7: satisfaction with sex life**	
Giuliano et al. 2007; France RCT Level 1 PEDro=7 N=186	**Population:** 186 men with SCI; Age: mean 38 yrs, range 18-66; Level of injury: cervical 15.6%, thoracic 62.0%, lumbosacral 22.3%; Impairment grade: 69% AIS A; Erectile dysfunction (ED) at least 6 months. **Treatment:** Tadalafil 10-20mg for 12 wks or placebo, 1 tablet 1 hr before each attempt at intercourse, not more than 1 dose/day, at wks 4 and 8 dose maintained or titrated up/downwards (10 or 20mg). **Outcome measures:** International Index of Erectile Function (IIEF)/Erectile Function (EF) domain, Sexual Encounter Profile (SEP), adverse events.	1. IIEF/EF: Tadalafil group improved (13.5 to 22.6) compared to placebo group (13.0 to 13.6). 2. Tadalafil group compared to placebo reported greater mean per-patient percentage of successful penetration attempts (75.4% vs 41.1%), greater percentage improved erections (84.6% vs 19.5%), and greater ejaculatory frequency. 3. Adverse events: headache (8.5% vs 4.5%) and UTI (7.7% vs 6.8%).
Giuliano et al. 1999; UK RCT (cross-over) Level 1 PEDro=7 N=178	**Population: 178 men, Age: mean 38 yrs, Impairment: 53% complete.** **Treatment: Sildenafil 25, 50, or 100mg or placebo, 1hr before sexual activity for 6 weeks followed by a 2-week washout before cross-over.** **Outcome Measures:** Efficacy and safety of oral sildenafil, International Index of Erectile Function (IIEF), event log data.	1. IIEF: 83% reported improved erections with sildenafil vs. 12% on placebo. 2. Ability to achieve & maintain erection, satisfaction of sexual intercourse, & satisfaction of sexual relationship with partner significantly improved with sildenafil over placebo. 3. Ejaculation and orgasm frequency improved in sildenafil group over placebo.
Maytom et al. 1999; UK	**Population:** 27 men; Age: range 21-49 yrs; Impairment grade: AIS A (n=14), B (n=3), C	1. Part I: 65% had erections (defined as >60% rigidity) on sildenafil, 8% with placebo.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
RCT Level 1 PEDro=7 N=27	(n=5), D (n=5); Level of injury: T6-L5. **Treatment:** Single dose sildenafil 50mg or matching placebo (part I) in random order followed by at least a 3 day washout period before cross-over treatment (part II) for 28 days. **Outcome Measures**: Efficacy and safety of sildenafil, duration & rigidity of erections, self-report diary data.	2. Part II: 75% on sildenafil & 7% on placebo reported improved erections. 3. Sexual Satisfaction: the sildenafil group were more satisfied with their sex lives.
Potter et al. 1998; USA RCT Level 1 PEDro=7 Initial N=29 Final N=26	**Population:** 26 men; Age: mean 40.6 yrs; Injury level: C4-T12, tetraplegia (n=19), paraplegia (n=10), incomplete. **Treatment:** Fampridine-SR or placebo 12.5mg for first week, 17.5 mg for 7 days, 1 week washout before cross-over. **Outcome Measures:** Safety and efficacy of oral Fampridine-SR, patient satisfaction, quality of life, sensory and motor scores, Ashworth.	1. No significant results related to sexual function. 2. 5 fampridine-SR patients reported erection improvement; however 4 placebo patients also reported erection improvement.
Cardenas et al. 2014 US and Canada RCT PEDro=6 Study SCI-F301 N=213 Study SCI-F302 N=204	**Population:** Patients with incomplete chronic SCI from two identical double-blinded, placebo-controlled studies (SCI-F301 and SCI-F302), from 45 and 33 centres, respectively, in the US and Canada. Both patient populations were balanced at baseline rendering comparability of patient populations. SCI-F301: Placebo (n=98): Mean age: 40.1 yr; Gender: males=85, females=13. Fampridine-SR (n=114): Mean age: 41.6 yr, Gender: males=100, females=14. SCI-F301: Placebo (n=100): Mean age: 40.5 yr. Fampridine-SR (n=103): Mean age: 41.3 yr. **Intervention.** Patients were randomly assigned to either fampridine-SR 25 mg or placebo, twice daily for 2 wk in addition to a 2 wk titration, 12 wk of stable dosing, 2 wk of downward titration and 2 wk of untreated follow-up. Within treatment groups, patients were further stratified by concomitant antispasmodic medication within the two treatment groups. **Outcome Measures:** Ashworth Spasticity Scale (AS) scores for bilateral knee flexors and extensors, Subject Global Impression (SGI), Penn Spasm Frequency Scale (SFS), International Index of Erectile Function (IIEF), Bowel and Bladder assessments, Sexual function.	1. There were no significant between-treatment differences except for an improvement among men treated with fampridine-SR on two IIEF domains, erectile function (p=0.016) and orgasmic function (p=0.032) in SCI-F301.
Cardenas et al. 2007; USA	**Population:** 72 men (19 female) with SCI; Injury level: C4-T10, AIS C-D; Age: mean 38-42 yrs, range 19-67; Time since injury at	1. IIEF: non-significantly improved scores for fampridine-SR 25mg and 40mg 2 times per day vs

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
RCT Level 1 PEDro=6 N=91	least 1 yr. **Treatment:** Fampridine-SR 25mg 2 times per day or fampridine-SR 40mg 2 times per day for 8 wks (2-wk dose titration, 4 wks at fixed target dose, 2-wk downward titration) or placebo. **Outcome Measures:** International Index of Erectile Function (IIEF), adverse events.	placebo. 2. Erection frequency: significantly improved for fampridine-SR 25mg group vs placebo. 3. Adverse events: fampridine-SR 40mg: increased incidence of abdominal pain, dizziness, insomnia, paresthesia, nervousness, and anxiety vs placebo; fampridine-SR 25mg: increased incidence of pain vs placebo.
Del Popolo et al. 2004; Italy RCT Level 1 PEDro=6 N=30	**Population:** 30 men, Age: range 21-60 yrs; Injury level: cervical (n=9), above T10 (n=6), below T10 (n=10); Time since injury: 6-12 months. **Treatment:** Randomized to sildenafil (4 doses 50mg) or tadalafil (4 doses 10 mg). To attempt intercourse on 4 separate occasions: within 4h of 1st tablet, 12h of 2nd tablet, 24h of 3rd and 24-36h after 4th tablet. Cross-over after 2 wk wash-out. **Outcome Measures**: Safety, time/duration effectiveness, Sexual Encounter Profile.	1. Tadalafil allowed normal sexual functioning up to 24hr post dosing compared to sildenafil.
Giuliano et al. 2006; USA RCT Level 1 PEDro=6 N=418	**Population:** 418 men, treatment n=207, placebo n=211; Age: range 18-80 yrs; Injury level: below T12 (n=94), at or above T12 (n=307). **Treatment:** Randomized to 12 wks of vardenafil (10mg for the first 4 wks) or placebo. 1 tablet 1 hr before each attempt at intercourse, not more than 1/day. At wks 4 and 8, dose maintained or titrated increasing or decreasing 1 step (to 5 or 20 mg). **Outcome Measures:** Efficacy and tolerability of vardenafil, Erectile Function Domain Scores (from International Index of Erectile Function), Sexual Encounter Profile.	1. EF domain scores in the vardenafil group improved significantly (22.0 from 11.6) compared to the placebo group (13.5 from 12.1). 2. Over 12 weeks of treatment, mean per-patient penetration (76% vs 41%), maintenance (55% vs 22%), and ejaculation success rates (19% vs 10%) on vardenafil were significantly greater vs the placebo group.
Hultling et al. 2000; Australia RCT (cross-over) Level 1 PEDro=6 N=178	**Population:** 178 men with SCI; Age: mean 38 yrs, range 19-63 yrs. **Treatment:** Sildenafil upward and downward titration with variable dose of 25mg 1hr pre-sexual activity to a maximum of 100mg. Doses adjusted by 25mg/wk during 6-wk period. Randomized to 6-wk flexible dosing, 2 wk washout, then 6-wk placebo or vice versa. **Outcome Measures:** Efficacy of sildenafil citrate, IIEF (Q13,14), Medical Outcomes Survey, SF-12, Psychological General Well-Being Index.	1. Increase in overall satisfaction with sex life (49% over baseline). 2. Sexual relationship with partner (increased 34% over baseline) with sildenafil. 3. "Impact of erectile problems" assessing emotional distress improved 23% above baseline.
Tuzgen et al. 2006; Turkey RCT Level 1	**Population:** 60 Men with SCI; Age: mean 35.2 yrs, range 25-45; Impairment: AIS A (n=28), AIS B (n=8), AIS C (n=7), AIS D (n=17); Mean time since injury: 53.5 months.	1. Improved reflexogenic erectile response in both groups. 2. Significant improvement in erections, frequency of sexual intercourse, satisfaction, enjoyment,

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
PEDro=6 N=60	**Treatment:** Sildenafil 25mg or sildenafil 50mg for 4 wks, 1 hr before sexual activity. **Outcome measures:** International Index of Erectile Function (IIEF) - Erectile Function (EF), Intercourse Satisfaction (IS), Overall Satisfaction (OS), Orgasmic Function (OF), and Sexual Desire (SD); adverse events.	sexual desire, overall sex life, sexual relationship, and self-confidence in erections at both the low and the high dosage. 3. There were no significant differences between the low dose and the high dose groups. . 4. There were 13 and 16 adverse events recorded in the low dose and high does group respectively. Main adverse events: headache, dyspepsia and rash.
	Effect Sizes: Forest plot of standardized mean differences (SMD ± 95%C.I.) as calculated from pre- and post-intervention data 	
Hultling 1999; Sweden RCT Level 1 PEDro=5 N=178	**Population:** Men with SCI and partner; Age: mean 30 yrs, range 19-63 yrs. **Treatment:** Sildenafil flexible-dose 25-100mg (on demand) for 6 wks (cross-over with 4-wk washout period). **Outcome measures:** ability to have intercourse, partner perception of ability to achieve erection and ability to maintain erection.	1. Men: improved ability to achieve erections and to have intercourse was reported by 83% and 80% of men, respectively, compared to the placebo group with 10% reporting improvements. 2. The number of successful attempts at intercourse improved in the sildenafil group. 3. Partner perception: improved ability to achieve and maintain erections with sildenafil.
Yildiz et al. 2011; Turkey Prospective, one-way crossover, dose-controlled study Level 2	**Population:** Men with erectile dysfunction secondary to SCI. **Treatment:** Day 1- Group 1: visual and auditory sexual stimulus (VASS) Group 2: VASS with 25 mg of intracavernosal papaverine; Group 3: after a wash-out period	1. There was a statistically higher PSV with papaverine (45.31(11.37)) or with sildenafil (41.59(15.55)) compared to control (22.25(7.54)). 2. There was no statistically significant difference between the PSV and EDV values of the papverine and sildenafil groups.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
N=31	of papaverine on day 2, VASS with 50mg oral sildenafil on day 5. **Outcome Measures:** Peak (PSV) and end diastolic velocity (EDV) using penile color Doppler ultrasound.	
Lombardi et al. 2009a; Italy Pre-post Level 4 N=103	**Population:** 103 men with SCI and erectile dysfunction (mean age 39) **Treatment:** Tadalafil 10mg for 4 weeks; participants whose IIEF (ED) score were still less than 26 were treated with Tadalafil 20mg for 4 weeks; participants who responded well to the treatment (n=74) continued treatment and were included in a 6-month follow up. **Outcome Measures:** International Index of Erectile Function (IIEF15); Sexual Encounter Profile (SEP) question 2 and 3.	1. 38 out of 103 participants responded to 10mg of Tadalafil. 2. 36 participants subsequently responded to 20mg of Tadalafil. 3. 9 patients dropped out of the follow-up due to various reasons. 4. There was a statistically significant improvement in erectile function, sexual satisfaction, and SEP2-3 scores in the follow-up group. 5. There was no significant difference in ejaculatory function.
Lombardi et al. 2009b; Italy Pre-post Level 4 N=113	**Population:** 113 participants with SCI and with erectile dysfunction (ED), median age 39 (range 21-67), mean time since injury 39 months (range 6-74 months); 74 participants had injury level above T12, and 70 were AIS A. **Treatment:** Sildenafil 50mg, increased to sildenafil 100mg for non-responsive participants. **Outcome Measures:** Sexual Encounter Profile Questions 2 and 3 (SEP2 and SEP3); International Index of Erectile Function (IIEF15) erectile domain score; both scales were used for Phase 1, and only IIEF15 was administered for Phase 2 (follow-up every 6 months for 10 years).	1. 75 participants reached an erectile domain score of at least 26 and answered "yes" for 75% of the time or more for SEP2 and 3; of these participants 48 responded to 50mg of sildenafil while the rest had increased to 100mg. 2. In responsive participants, the IIEF15 erectile domain score increased from 16-18 to above 25. 3. 34 of the 75 responsive participants stayed for Phase 2 of the study; erectile domain scores remained stable at above 25 for the duration of the 10-year follow-up.
Soler et al. 2009; France Pre-post Level 4 N=14	**Population:** Men who sustained an abnormal prolonged erection or priapism following an intracavernous injection of prostaglandin E1 to induce erection. **Treatment:** Oral midodrine following the failure of 30 minutes of cooling procedures using ice or ether, or penile vibrator stimulation. **Outcome measures:** evaluation of penile rigidity at 30 minutes, and 1, 3 and 6 hours post treatment.	1. All patients returned to flaccid penile state within 30-45 min after midodrine administration. 2. Oral midodrine well tolerated with few side effects and without increasing incidence of AD. 3. Complete erection could be induced again 6 months later by intracavernous injection in all treated patients.
Moemen et al. 2008; Egypt Pre-post Level 4 N=60	**Population:** 60 men with SCI and erectile dysfunction, at least 6 months post-injury, randomized into 3 groups of 20 (A, B, C). **Treatment:** Group A took sildenafil 50mg before sexual activity for 1 month; Group B were given intracorporal injection (ICI, 10 mg/ml prostaglandin E1 or 0.5 ml trimix) for 1 month and then took sildenafil for 1 month;	1. The improvement in the IIEF-EF score was 90% in all groups after sildenafil, 90% in Group B after ICI, and 70% in Group C after VCD. 2. Improvement in erection reached 100% in all groups according to the GAQ, but ability to penetrate reached 90% after sildenafil, 90% after ICI, and 70% after VCD.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Group C used vacuum constriction device (VCD) for 1 month and sildenafil for 1 month. **Outcome Measures:** International Index of Erectile Function – erectile function domain (IIEF-EF); Global Efficacy Assessment Questionnaire (GAQ); Hormonal Profile.	3. There was a significant increase in testosterone in all groups after sildenafil treatment. 4. Participants in Group B reported that ICI resulted in more rigid erections than sildenafil, but 14 of the 20 participants preferred sildenafil due to easier administration; no participants in Group C was satisfied with VCD and preferred either ICI or sildenafil.
Soler et al. 2007; France Pre-post Level 4 N=240	**Population:** Men with SCI; Age: mean 32.6-36.2 yrs; tetraplegia (n=78), paraplegia (n=145), cauda equine (n=17); Impairment: AIS A (n=197), AIS B (n=19), AIS C (n=18), AIS D (n=6); Mean time since injury 91.5-112.4 months. **Treatment:** Sildenafil (50-100mg, n=120), tadalafil (10-20mg, n=66), and vardenafil (10-20mg, n=54) depending on efficacy/tolerability, follow-up at 3 months. **Outcome measures:** Quality of erection; duration of erection; International Index of Erectile Function (IIEF) - Erectile Function (EF), Intercourse Satisfaction (IS), Overall Satisfaction (OS), Orgasmic Function (OF), and Sexual Desire (SD); adverse events.	1. Good rigidity reported by 85% (sildenafil), 74% (vardenafil), and 72% (tadalafil) of the patients. 2. Mean duration of erection: 34 min (sildenafil), 28 min (vardenafil), 26 min (tadalafil). 3. IIEF: improved global and domain (EF, IS, and OS) scores for all groups; improved orgasmic function and ejaculation for sildenafil group. 4. Initial dose sildenafil (50mg) effective in 55%, whereas vardenafil and tadalafil (10mg) ineffective in over 70%. 5. Adverse events: mild; 15% on sildenafil (headache, flushing, dizziness, dyspepsia); 14% on vardenafil (headache, dizziness); 6% on tadalafil (headache, back pain).
Kimoto et al. 2006; Japan Pre-post Level 4 N=32	**Population:** 32 men with SCI; Age: mean 37.5 yrs, range 20-64; Level of injury: T12-lumbar (n=10), cervical-T11 (n=22); Time since injury at least 6 months. **Treatment:** Vardenafil 10mg for 12 wks or vardenafil 10mg for 4 wks and then 20mg for 8 wks. **Outcome measure:** International Index of Erectile Function (IIEF)/Erectile Function (EF), success in penetration, success in maintaining erection during intercourse.	1. IIEF/EF: Improved in both the 10/10mg group (12.2 to 25.0) and the 10/20mg group (10.3 to 22.5); the 10/20mg group increased 5.0 points following up-titration. 2. Success in penetration: 10/20mg group: 56% at 4 wks, 76% at 8 wks, 83% at 12 wks; 10/10mg group: 88% at 4-12 wks. 3. Success in maintaining erection: 10/20mg group: 43% at 4 wks, 62% at 8 wks, 69% at 12 wks; 10/10mg group: 81% at 4-12 wks.
Gans et al. 2001; USA Pre-post Level 4 N=17	**Population:** 17 men with SCI; Age: mean 40.3 yrs, range 25-58; Injury level: cervical (n=4), thoracic (n=12), lumbar (n=1). **Treatment:** Sildenafil 25mg (dose increased in 25mg increments as needed), mean(SD) follow up of 5.3(2.2) months. **Outcome measures:** International Index of Erectile Function (IIEF) (abridged version), questions on aspects of sexual function.	1. IIEF scores improved significantly compared with baseline or previous therapies. 2. Of the 17 men, 94% recommended sildenafil to others. 3. One patient discontinued treatment due to hypotension.
Schmid et al. 2000; Switzerland Pre-post Level 4 N=41	**Population:** 41 men with SCI; Age: mean 36.5 yrs, range 20-63; Injury level: paraplegia (n=33, 23 incomplete, 10 complete), tetraplegia (n=8, 7 incomplete, 1 complete); Time since injury: mean 5.9 yrs, range 0.5-26. **Treatment:** Sildenafil 25-100mg as needed.	1. Improved erections (grade 3-4) permitting sexual intercourse reported by 38 (93%) men. 2. 58% of men achieved good erectile function with sildenafil 50mg, 37% required 75-100mg, and 5% required only 25mg. 3. EF (9.2 to 25.5) and IS (4.5 to 10.5) significantly improved after sildenafil therapy.

Author Year; Country Score Research Design Total Sample Size	Methods	Outcome
	Outcome measures: International Index of Erectile Function (IIEF) – Erectile Function (EF) and Intercourse Satisfaction (IS), response rate, ideal dose, adverse events.	4. Men with preserved reflexive or psychogenic erection responded well to sildenafil, while men without integrity of either sacral or thoraco-lumbar segments due to ischemic damage did not have a successful response. 5. Adverse events: 10% suffered side effects such as headache, dizziness or flushing.
Ohl et al. 2015; USA Retrospective Analysis Level 5 N=248	**Population**: 248 men (≥ 18 years, mean age=37.7 years) with traumatic spinal cord injuries (≥ 6 months duration, 136/248 complete SCI) and erectile dysfunction attributed to SCI and in a stable heterosexual relationship (≥ 6 months). **Treatment**: Participants were randomized and treated sequentially with sildenafil and placebo in two treatment phases. The starting dose was 50 mg, taken one hour before sexual activity. Subsequent dose adjustments to 100 mg or 25 mg based on patients' tolerability during the 6 week treatment phase. **Outcome Measures:** The International Index of Erectile Function (IIEF) questions and percent successful attempts at intercourse were analyzed for sildenafil vs. placebo using analysis of covariance (ANCOVA) models.	1. Average changes from baseline to week 6 in the IIEF Q3 (frequency of penetration), Q4 (maintaining erection after penetration), and Q9 (frequency of ejaculation) scores significantly improved with sildenafil vs. placebo (all $P<0.01$). 2. Treatment preference for sildenafil vs placebo was 96% vs 4% in the overall population ($P<0.001$). 3. The most common all-cause adverse events with sildenafil were headache (16.1%) and urinary tract infection (UTI) (11.6%)