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## Research Summary - Neurogenic Bowel Dysfunction Score (NBD) - Other Physiological Systems / Quality of Life

| Author Year<br>Country<br>Research<br>Design<br>Setting  | Demographics and<br>Injury Characteristics<br>of Sample  | Validity  | Reliability   | Responsiveness<br>Interpretability  |
|--|--|---|---|---|
| Van Doorn et al. 2022  Prospective validation study for a Dutch- version  Patients with SCI visiting the urology department or general practitioner in Rotterdam, the Netherlands. | 55 patients with SCI Mean ± SD age 54 ± 15.8 years Gender: 36 male and 19 female Level of injury: Cervical (n = 14), Thoracic (n = 29), Lumbar (n = 9), and unknown (n = 3) AIS A (n = 15), AIS B (n = 7), AIS C (n = 10), AIS D (n = 9), AIS E (n = 1), and unknown (n = 13) Time since injury 13.6 ± 8.4 years  Reference group: 50 patients with multiple sclerosis Mean ± SD age 38.4 ± 14.4 years Gender: 11 male and 39 female | Content validity (n = 17 patients): The questions were found to be relevant, clear, and easy to fill in; content validity was confirmed without the necessity of adjustments.  Criterion validity: Moderate significant correlations were found between total scores of the NBD score and total scores of the FIQL, FISI, and EQ-5D-3L.  Please see Table 1 below.  Construct validity: Good construct validity was found because references had significant lower scores in the NBD score than patients. | Internal consistency: Moderate to low for the total scores of the NBD score, Cronbach's alpha was measured to be 0.56 for the test and 0.30 for the retest.  Reproducibility: The mean change between total scores of the NBD score of the test and retest was -0.5 ± 3.46. For the total score of the questionnaire, the ICC was 0.87, indicating adequate reliability. The LOA ranges of the total scores were -7.28 to 6.78. | effects: There were no floor and ceilings effects present in the patient group; one patient (1.8%) had the lowest score possible, no patient had the highest score possible. Floor effects were seen in the reference group, 52% of the participants had the lowest score (0) possible, indicating they experience no neurogenic bowel symptoms. Ceiling effects were not present in the reference group; no one scored the highest score possible. |

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|---|--|--------------|----------------------------|--------------------------------|-----------------------------------|--|------------------------------------|
|   |  | FIQI         | -                          | FISI                           |                                   | EQ-5D-3L index score   | EQ-5D-3L VAS score                 |
|   | Test, NBD total score  | -0.6<br>0.00 | 48 <sup>a</sup> (p <<br>1) | 0.367 <sup>a</sup> (p < 0.001) |                                   | -0.589 <sup>a</sup> (p < 0.001)  | -0.428 <sup>a</sup> (p < 0.001)    |
|   | Retest, NBD total score  | -0.4<br>0.00 | 91 <sup>a</sup> (p <<br>1) | 0.301 <sup>b</sup> (p = 0.042) |                                   | -0.394 <sup>a</sup> (p = 0.007)  | -0.499 <sup>a</sup> (p = 0.001)    |
|   | <sup>a</sup> Criterion validity tested by Spearman correlation coefficient. <sup>b</sup> Criterion validity tested by Pearson's correlation coefficient. |              |                            |                                |                                   |  |                                    |
| <u>Conzález Viejo et</u><br><u>al.</u> 2021                 | 59 patients in total: 3 patients with disabili due to SCI and 29 patients with disabili due to cerebral vascu accident.                                  | ty<br>ty     |                            |                                | of posts                          | e construct<br>ability in the group<br>patients with SCI<br>lows a Cronbach's<br>re of 0.897 for all<br>iables.              |                                    |
| Validation of the<br>Spanish-version<br>of the NBD<br>Spain | SCI: 24M, 6F Mean age of 43.6 year (SD 11.7) Mean disability progression time of 1 years (SD 8.4)  |              |                            |                                | the<br>SCI<br>rete<br>the<br>0.88 | e <b>reliability</b> result of NBD score for the group in the testest using the ICC on total score was 86 (95% CI 64-0.946). |                                    |

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| 3  | Cerebral Vascular Accident: 12M, 17F Mean age of 59.2 years (SD 14.2) Mean disability progression time for was 4.51 years (SD 7.2)  |   | •  |                                    |
| Erdem et al. 2017  Psychometrics study.  Dokuz Eylül University Faculty of Medicine, Turkey. | SCI N: 42 Level: 12 cervical, 24 thoracic 24,6 lumbar; AIS 23 A, 4 B, 11 C, 4 D Etiology: traffic accident 21, 4 firearm injury, 11 falling down, 3 crushing underweight, 1 diving into shallow water, 2 Others Age: Mean 39 years, SD 16 years Duration: | Correlations between total NBD score & SF-36 subscales, a statistically significant negative correlation was detected between:  • bodily pain (r=-0.382, P=0.013)  • general health (r=-0.560, P<0.001)  • vitality (r=-0.626, P<0.001)  • social role functioning (SF) (r=-0.741, P<0.001)  • emotional role functioning (r=-0.604, P<0.001) and | Internal consistency:  NBD score is not a  Likert type scale, but the additivity of the total score was tested with Tukey's nonadditivity test and the additivity characteristic was demonstrated. Due to the presence of additivity characteristic of the test and ordinal characteristic of the answers, Cronbach alpha coefficient was calculated to determine the reliability of internal consistency. |                                    |

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|   |   | <ul><li>mental health<br/>(r=- 0.687,<br/>P&lt;0.001)<br/>subscales,</li></ul>  | Cronbach's alpha<br>coefficient for internal<br>consistency was 0.547  |                                    |
|   |   | No significant correlation was found with the following subscales of SF-36:  • physical functioning (PF) (r=- 0.233, P=0.138) and • physical role functioning (RP) (r=0.067, P=0.674)  The highest correlation among these was found in the social function subscale.  • Significant negative correlation with the mental component summary score (MCS) (r=- 0.872, P< 0.001) | Test-retest, Interrater, Intra-rater: Test-retest answers of each question r=1.000, P<0.001 Consistency of frequency distribution r=1.000, P<0.001 |                                    |

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|   |   | <ul> <li>No significant correlation with the physical component summary score (PCS) (r=- 0.187, P=0.235).</li> <li>Significant positive correlation between NBD total score and PGA (r=0.91, P&lt;0.001).</li> <li>Significant positive correlation was found between NBD total score and positive correlation was found between NBD total score and patients' assessment of impact of NBD on QoL (r=0.92, P&lt;0.001).</li> </ul> |             |                                    |
|   |   | The patients were divided into 2 groups according to their NBD scores:   |             |                                    |

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|   |   | <ul> <li>NBD scores<br/>between 0 and 9<br/>were classified as<br/>mild and</li> <li>NBD scores &gt;10<br/>were classified as<br/>significant NBD.</li> </ul>   |             |                                    |
|   |   | According to this, a statistically significant difference was detected in all SF-36 subscales and MCS score (P<0.05), except PF and RP subscales and PCS score in both groups (P>0.05).   |             |                                    |
|   |   | When total NBD score before and after treatment was compared with Wilcoxon test, it was demonstrated that improvement in NBD score at the end of 2 months was significant (P=0.011). Also, there was a statistically significant positive correlation |             |                                    |

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|   |   | of Change scale and the<br>change in total NBD<br>score at the end of 2<br>months (r=0.821,<br>P=0.007)     |  |   |
| Kelly et al. 2017  Development, Reliability and Validation Study  University of California Irvine, Urology Center, CHOC Children's Hospital, Orange, California | Spina Bifida N: 34 children Control N: 18 patients Level: 4 thoracic (12%), 16 lumbar (46%), 12 sacral (35%), 2 unknown (6%) Ambulatory status: 16 fully ambulatory (47%), 18 wheelchair or walker (53%) Etiology: spina bifida Age: Mean 5.3yo Ethnicity: Caucasian 14 (27%) Hispanic 31 (60%) Asian 7 (13%) % Female: 50% | Construct Validity A Spearman's rank-order correlation (r <sub>s</sub> ): r <sub>s</sub> = 0.943 (P<0.0005) | Test-Retest Reliability B/w each answer on the two questionnaires: 53% was found (k>0.8) 32% had k b/w 0.6 and 0.8  Difference b/w mean score of 1st and 2nd questionnaire not statistically significant.  Inter-Rater Reliability B/w each answer on the two questionnaires: 79% with k>0.8 18% had k b/w 0.6 and 0.8 | Interpretability: Mean Scores: Bowel subjects: 15.18 (SD ± 5.77) Control subjects: 4.68 (SD ± 2.98) |
| Krogh et al. 2006   | <b>SCI N:</b> 589 (424/72%responded)  | Reproducibility & validity of questions describing colorectal   |  |   |

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| Development/vali dation study  University Hospital of Aarhus, Denmark. | Level: cervical 174, thoracic 155, 79 lumbar; 254 sensory complete, 166 incomplete in 166 Etiology: trauma (75%), spinal surgery (8%), myelomeningocele (4%), infection (4%), spinal thrombosis or hemorrhage (3%), or other causes (6%). Age: Mean 41 years, Range8-88 years Duration: Mean 14 years, Range 0 to 59 years % Female: 29% | problems in patients with spinal cord lesions Item & Validity (k coefficient):  • Frequency of bowel movements k = 0.92  • Desire for defaecation (any) k = 0.89  • Normal desire for defaecation k = 1.00  • Abdominal discomfort k = 0.83  • Perspiration, headache, or general discomfort during defecation k = 0.82  • Oral laxatives k = 1.00  • Enemas k = 0.77  • Average time for defecation k = 0.79  • Use of Clysma k = 0.90  • Frequency of digital stimulation k = 0.77  • Need helpfrom others for defecation k = 0.73 |             |                                    |

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|   |   | <ul> <li>How much does<br/>disturbed defecation<br/>restrict social<br/>activities? k = 0.63</li> </ul> |             |                                    |
|   |   | How much does<br>disturbed defecation<br>restrict quality of<br>life? k = 0.83                          |             |                                    |
|   |   | • Frequency of faecal incontinence k = 0.79   |             |                                    |
|   |   | • Flatus incontinence k = 0.53  |             |                                    |
|   |   | Medication against<br>faecal incontinence k = 1.00  |             |                                    |
|   |   | Perianal skin     problems k = 0.60   |             |                                    |
|   |   | How much does<br>faecal incontinence<br>restrict social<br>activities? k = 0.62                         |             |                                    |
|   |   | How much does<br>faecal incontinence<br>restrict quality of<br>life? k = 0.52                           |             |                                    |
|   |   | OR, level of significance and points in the NBD score   |             |                                    |

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|   |   | for items significantly associated with impact on quality of life   |             |                                    |
|   |   | <ul> <li>Frequency of bowel<br/>movements OR = 6.1,<br/>p &lt; 0.0001, points in<br/>NBD score = 6</li> </ul>                                       |             |                                    |
|   |   | <ul> <li>Headache,<br/>perspiration or<br/>dyscomfort before or<br/>at defecation OR =<br/>2.4, p &lt; 0.01, points in<br/>NBD score = 2</li> </ul> |             |                                    |
|   |   | <ul> <li>Tablets against<br/>constipation OR = 1.9,<br/>p &lt; 0.001, points in<br/>NBD score = 2</li> </ul>  |             |                                    |
|   |   | Drops against<br>constipation OR = 2.3,<br>p < 0.0001, points in<br>NBD score = 2   |             |                                    |
|   |   | Time used for defecation OR = 6.8, p < 0.0001, points in NBD score = 7  |             |                                    |
|   |   | Digital stimulation or<br>evacuation OR = 5.0<br>p < 0.01, points in<br>NBD score = 6   |             |                                    |

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|   |   | • Frequency of faecal incontinence OR = 13.1, p < 0.0001, points in NBD score = 13                                |             |                                    |
|   |   | Medication against<br>faecal incontinence<br>OR = 3.6, p < 0.01,<br>points in NBD score<br>= 4                    |             |                                    |
|   |   | <ul> <li>Flatus incontinence</li> <li>OR = 1.8, p &lt; 0.05,</li> <li>points in NBD score</li> <li>= 2</li> </ul> |             |                                    |
|   |   | Perianal skin problems<br>OR = 2.6, p < 0.01, points<br>in NBD score = 3  |             |                                    |

|                               | FIQL                            | FISI                           | EQ-5D-3L index score            | EQ-5D-3L VAS score              |
|-------------------------------|---------------------------------|--------------------------------|---------------------------------|---------------------------------|
| Test, NBD<br>total score      | -0.648 <sup>a</sup> (p < 0.001) | 0.367 <sup>a</sup> (p < 0.001) | -0.589 <sup>a</sup> (p < 0.001) | -0.428 <sup>a</sup> (p < 0.001) |
| Retest,<br>NBD total<br>score | -0.491 <sup>a</sup> (p < 0.001) | 0.301 <sup>b</sup> (p = 0.042) | -0.394 <sup>a</sup> (p = 0.007) | -0.499 <sup>a</sup> (p = 0.001) |