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## TREATMENT OF FAECAL INCONTINENCE AND CONSTIPATION IN PATIENTS WITH SPINAL CORD INJURY - A PROSPECTIVE, RANDOMISED, CONTROLLED, MULTICENTRE TRIAL OF TRANSANAL IRRIGATION VS. CONSERVATIVE BOWEL MANAGEMENT

### Hypothesis / aims of study

Bowel dysfunction in spinal cord injury patients often causes constipation, faecal incontinence or a combination of both with a high impact on quality of life. However, controlled trials comparing different bowel management regimes are lacking. This study aims to compare transanal irrigation using Peristeen Anal Irrigation (Coloplast A/S, Denmark) with conservative bowel management (best supportive bowel care without irrigation).

### Study design, materials and methods

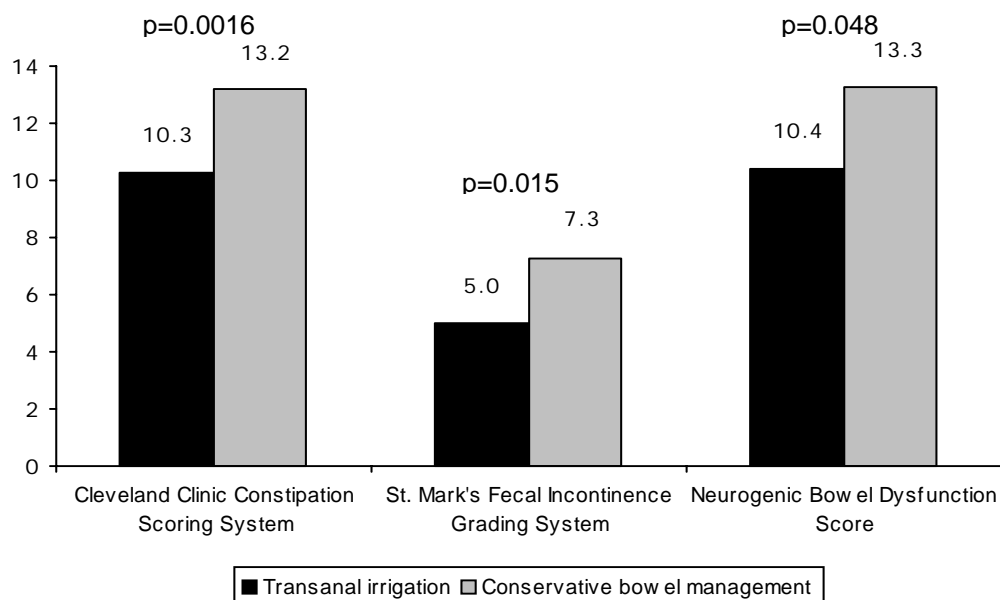
87 spinal cord injury patients with neurogenic bowel dysfunction were randomly assigned to ten weeks treatment with either transanal irrigation (42 patients) or conservative bowel management (45 patients) in this prospective, randomised, controlled, multicentre trial involving five specialized European spinal cord injury centres.

Bowel function was assessed at baseline and at termination using the Cleveland Clinic Constipation Scoring System (CCCSS) (0-30, 30 = severe symptoms), St. Mark's Faecal Incontinence Grading System (FIGS) (0-24, 24 = severe symptoms), and the Neurogenic Bowel Dysfunction Score (0-47, 47 = severe symptoms). Symptom-related quality of life was assessed using a modification of the American Society of Colorectal Surgeon Faecal Incontinence Score (for each domain, 0-5, high score = high quality of life).

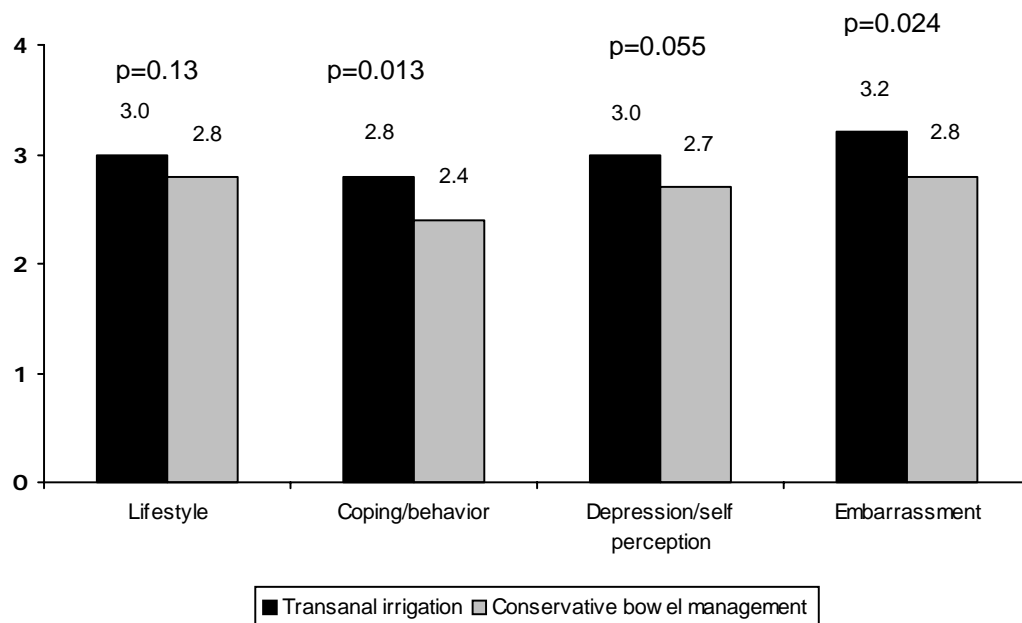
A sample size of 33 in each group should have an 80% power to detect a difference of 6 between the groups in the added CCCSS and FIGS scores, assuming a common within group standard deviation of 8.5 and using the Student's t-test with a 0.05 two-tailed significance level. To compensate for dropouts, it was planned to include 80 patients.

### Results

The severity of symptoms at termination was significantly decreased in the transanal irrigation group compared to the conservative bowel management group for all three bowel-function scoring systems (Figure 1). Furthermore, the symptom-related quality of life at termination was significantly higher for two out of four sub-scales in the transanal irrigation group and tended to be higher in the other two sub-scales (Figure 2).



**Figure 1. Bowel function scores at termination.** Bowel function was assessed using three different scores: Cleveland Clinic Constipation Score System (range 0-30, 30 = severe symptoms), St. Mark's Faecal Incontinence Grading System (range 0-24, 24 = severe symptoms), and Neurogenic Bowel Dysfunction Score (range 0-47, 47 = severe symptoms). Comparison at termination with Student's t-test.



**Figure 2. Symptom-related quality of life at termination.** Symptom-related quality of life was assessed using a modification of the American Society of Colorectal Surgeon Fecal Incontinence Score from which four subscales can be extracted (lifestyle (range 1-4, 4 = high quality of life), coping behavior (range 1-4, 4 = high quality of life), depression / self perception (range 1-5, 5 = high quality of life), and embarrassment (range 1-4, 4 = high quality of life)). Comparison at termination with Student's t-test.

Interpretation of results

For all outcome measures, significant results in favour of transanal irrigation were found. Transanal irrigation aims to ensure emptying of the left colon. This prevents faecal leakage between washouts and re-establishes control over time and place for defecation. A regular evacuation of the rectosigmoid furthermore prevents constipation. Colorectal dysfunction is regarded by spinal cord injured patients to be among the three greatest problems after loss of mobility. The improvement in faecal continence and constipation-related symptoms provides the spinal cord injured patient with better control over their bowels and increases some aspects of their quality of life.

Concluding message

Transanal irrigation in spinal cord injured patients with neurogenic bowel dysfunction improves constipation, faecal incontinence and symptom-related quality of life.

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**HUMAN SUBJECTS:** This study was approved by the Den videnskabetiske komité for Aarhus Amt, Regionala etikprovningnsnamnden i Stockholm, Mid & South Buckinghamshire Local Research Ethics Committee, Comitato Etico dell'Azienda Ospedaliera di Bologna Policlinico S.Orsola-Malpighi and followed the Declaration of Helsinki Informed consent was obtained from the patients.