A Randomized, Controlled Trial of Transanal Irrigation Versus Conservative Bowel Management in Spinal Cord–Injured Patients

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Background & Aims: Bowel dysfunction in patients with spinal cord injury often causes constipation, fecal incontinence, or a combination of both with a significant impact on quality of life. Transanal irrigation improves bowel function in selected patients. However, controlled trials of different bowel management regimens are lacking. The aim of the present study was to compare transanal irrigation with conservative bowel management (best supportive bowel care without irrigation). **Methods:** In a prospective, randomized, controlled, multicenter trial involving 5 specialized European spinal cord injury centers, 87 patients with spinal cord injury with neurogenic bowel dysfunction were randomly assigned to either transanal irrigation (42 patients) or conservative bowel management (45 patients) for a 10-week trial period. **Results:** Comparing transanal irrigation with conservative bowel management at termination of the study, the mean (SD) scores were as follows: Cleveland Clinic constipation scoring system (range, 0–30, 30 = severe symptoms) was 10.3 (4.4) versus 13.2 (3.4) ($P = .0016$), St. Mark's fecal incontinence grading system (range, 0–24, 24 = severe symptoms) was 5.0 (4.6) versus 7.3 (4.0) ($P = .015$), and the Neurogenic Bowel Dysfunction Score (range, 0–47, 47 = severe symptoms) was 10.4 (6.8) versus 13.3 (6.4) ($P = .048$). The modified American Society of Colorectal Surgeon fecal incontinence scores (for each subscale, range is 0–4, 4 = high quality of life) were: lifestyle 3.0 (0.7) versus 2.8 (0.8) ($P = .13$), coping/behavior 2.8 (0.8) versus 2.4 (0.7) ($P = .013$), depression/self perception 3.0 (0.8) versus 2.7 (0.8) ($P = .055$), and embarrassment 3.2 (0.8) versus 2.8 (0.9) ($P = .024$). **Conclusions:** Compared with conservative bowel management, transanal irrigation improves constipation, fecal incontinence, and symptom-related quality of life.

During the past decade, the magnitude of bowel dysfunction in patients with spinal cord injury has been documented in several studies.[1–6] Spinal cord injury affects colorectal motility,[7] transit times,[8–10] and bowel emptying,[11,12] often leading to constipation, fecal incontinence, or a combination of both.[1–5] Although these symptoms are not life-threatening, they may have a severe impact on quality of life[1,2,6] and increase levels of anxiety and depression.[2,4]

Various bowel management programs have been empirical, and individual solutions have been sought on a trial-and-error basis. The Paralyzed Veterans of America organization has proposed clinical practical guidelines regarding bowel management for patients with spinal cord injury,[13] including the use of dietary plans, oral laxatives, rectal suppositories, and digital stimulation or digital evacuation.

Transanal irrigation has been known since 1500 BC.[14] Throughout medical history, transanal irrigation has been performed for various indications, such as cleaning of "toxic substances" from the bowel to prevent "autointoxication," treatment of ileus, and ritual purification.[15] In 1987, transanal irrigation was reinvented with the introduction of the enema continence catheter[16] for children with bowel dysfunction due to spina bifida. The more pragmatic aims of this treatment were to prevent fecal incontinence and treat constipation. Since then, several studies have documented the efficacy and safety of the treatment in children.[17–21] Transanal irrigation has also been used in selected adults with constipation or fecal incontinence.[22–28] In spinal cord–injured patients, treatment with transanal irrigation is often difficult to manage due to immobility or impaired hand function and due to pathologic reflex contractions of the rectum and anal sphincters[7,29] when performing transanal irrigation. However, the majority of spinal cord–injured patients in a recent study benefited from the treatment.[23]

There is limited evidence in the literature supporting any bowel management program in spinal cord injury in favor of another, and well-designed controlled trials are still lacking.[30] Therefore, the present study aims to compare transanal irrigation with conservative bowel management, defined as best supportive bowel care without irrigation, in a prospective, randomized, controlled, multicenter study among spinal cord–injured patients with neurogenic bowel dysfunction.

Patients and Methods

Patients

Between December 2003 and June 2005, 87 patients (Figure 1 and Table 1) with spinal cord injury and neurogenic colorectal dysfunction were randomly assigned to either transanal irrigation or conservative bowel management. Patients were recruited from 5 spinal cord injury centers in 5 European countries (Spinalis, Karolinska Sjukhuset, Stockholm, Sweden; Montecatone Rehabilitation Institute, Bologna, Italy; Orthopädische Universitätsklinik, Heidelberg, Germany; National Spinal Injuries Centre, Stoke Mandeville Hospital, Buckinghamshire, England; and Centre for Para-

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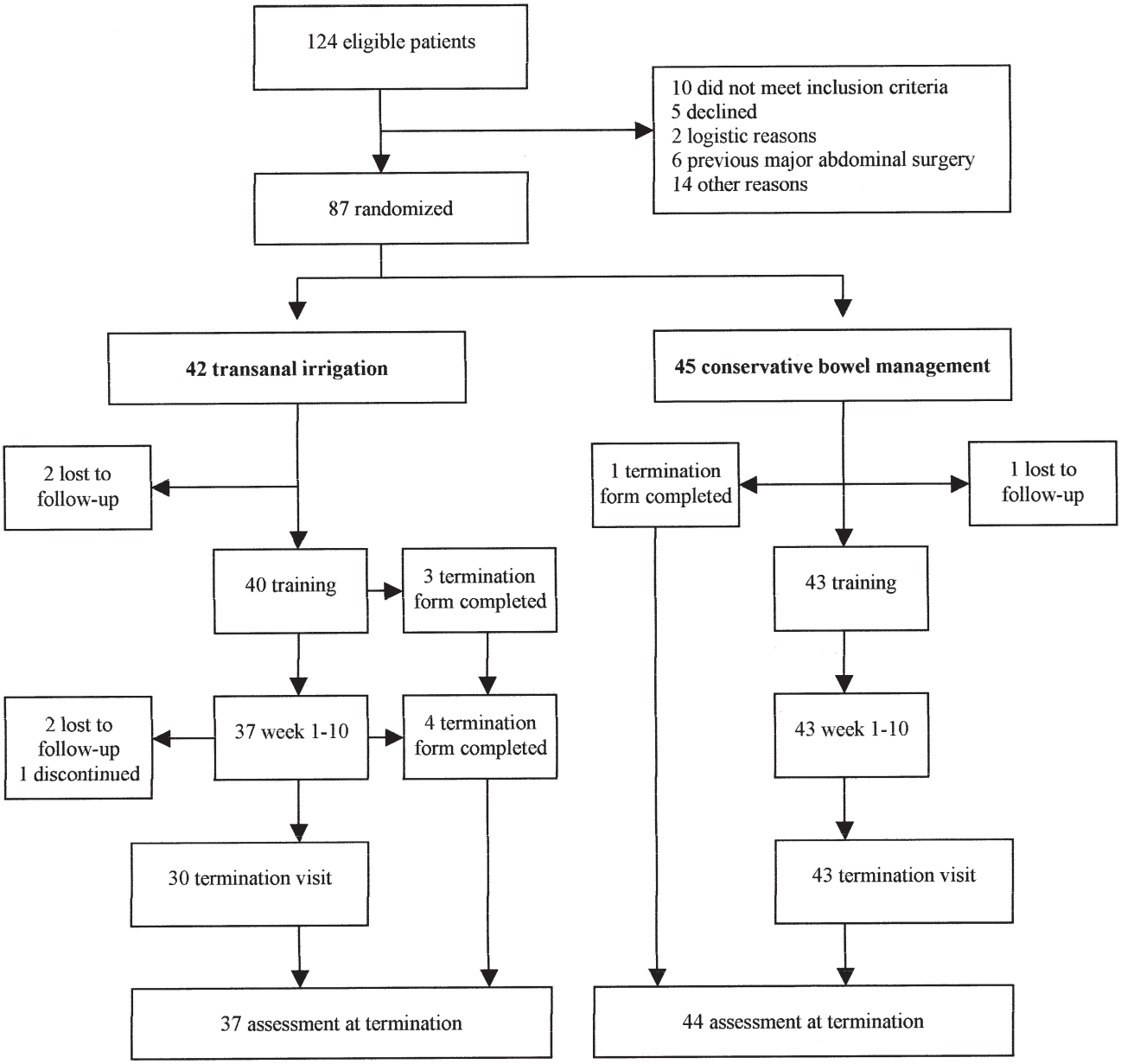

Figure 1. Trial profile.

plegia, Viborg Hospital/Surgical Research Unit, Aarhus University Hospital, Aarhus, Denmark).

Each patient was classified according to the international standards for classification of spinal cord injuries based on the spinal segment damaged.[31] Patients were then divided into 4 groups according to the effect of the injury on the complex innervations of the colon and rectum[32]: (1) high supraconal injury (T9 and above), above the level of the sympathetic outflow to the bowel causing loss of supraconal control of sympathetic innervation and loss of supraspinal control of parasympathetic innervation of the left colon and rectum; (2) intermediate supraconal injury (T10–L2), affecting sympathetic outflow to the bowel and causing loss of supraspinal control of parasympathetic innervation of the left colon and rectum; (3) low supraconal injury (L3–S1), intact sympathetic outflow to the bowel but loss of supraspinal control of parasympathetic innervation of the left colon and rectum; and (4) conal or cauda equina lesion (S2–S4), causing damage to the sacral defecation center and to the sacral reflex arc, interrupting parasympathetic innervation of the left colon and rectum. Each group was then subdivided into complete or incomplete injuries. Patient baseline demographic data are shown in Table 1.

Inclusion criteria were age 18 years or older with a spinal cord injury at any level at least 3 months after injury and at least one of the following symptoms: (1) spending a half hour or more attempting to defecate each day or every second day, (2) episodes of fecal incontinence once or more per month, (3) symptoms reflecting autonomic dysreflexia before or during defecation, and (4) abdominal discomfort before or during defecation. Exclusion criteria were as follows: coexisting major unsolved physical problems due to the injury, performance of