TREATMENT OF CONSTIPATION AND FECAL INCONTINENCE IN STROKE PATIENTS
RANDOMIZED CONTROLLED TRIAL

Danielle Harari, FRCP; Christine Norton, PhD, RN; Linda Lockwood, RN; Cameron Swift, PhD, FRCP

BACKGROUND AND PURPOSE—Despite its high prevalence in stroke survivors, there is little clinical research on bowel dysfunction in this population. This is the first randomized controlled trial to evaluate treatment of constipation and fecal incontinence in stroke survivors.

METHODS—Stroke patients with constipation or fecal incontinence were identified by screening questionnaire (122 community, 24 stroke rehabilitation inpatients) and randomized to intervention or routine care (73 per group). The intervention consisted of a 1-off structured nurse assessment (history and rectal examination), leading to targeted patient/carer education with booklet and provision of diagnostic summary and treatment recommendations (after consultation with geriatrician) to patient’s general practitioner (GP)/ward physician.

RESULTS—Percentage of bowel movements (BMs) per week graded as “normal” by participants in a prospective 1-week stool diary was significantly higher in intervention versus control patients at 6 months (72% versus 55%; P=0.027), as was mean number of BMs per week (5.2 versus 3.6; P=0.005). There was no significant reduction in fecal incontinence, although numbers were small. At 12 months, intervention patients were more likely to be modifying their diets (odds ratio [OR], 3.1 [1.2 to 8.0]) and fluid intake (OR, 4.2 [1.4 to 12.2]) to control their bowels and to have visited their GP for their bowel problem (OR, 5.0 [1.4 to 17.5]). GP prescribing of laxatives and suppositories was significantly influenced at 12 months.

CONCLUSIONS—A single clinical/educational nurse intervention in stroke patients effectively improved symptoms of bowel dysfunction up to 6 months later, changed bowel-modifying lifestyle behaviors up to 12 months later, and influenced patient–GP interaction and physician prescribing patterns. (Stroke. 2004;35:2549-2555.)

Key Words: constipation ■ fecal incontinence ■ randomized controlled trial ■ stroke

Bowel dysfunction is a common and distressing condition after stroke, but there are virtually no intervention studies in this important clinical area.1 Fecal incontinence (FI) affects ≥56% of individuals acutely after stroke, 11% at 3 months, and ≥22% at 12 months.2,3 Constipation is recognized as a serious problem in clinical practice, affecting 60% of those in stroke rehabilitation wards.2 FI may develop months after acute stroke and can be transient, consistent with constipation overflow as a possible cause.2,6 We identified only 2 published clinical studies of constipation in stroke. Munchiando found that daily versus alternate day bowel care with digital stimulation achieved regular evacuation sooner after acute stroke in an uncontrolled trial,7 whereas Venn found no difference in efficacy between morning versus evening inpatient bowel care, with or without a suppository.8

There are no published trials examining treatment of FI in stroke patients. However, epidemiological data suggest FI is associated more with modifiable disability-related factors (eg, toilet access and anticholinergic medications) than stroke-related factors (eg, severity and lesion location).2,3 Similarly, constipation in older people is related more to modifiable lifestyle factors such as diet,9–11 fluid intake,10,12,13 physical activity,14 and toileting habits15,16 than to aging gut pathophysiology. Therefore, we hypothesized that an educational intervention targeting lifestyle factors combined with structured clinical assessment and treatment would significantly improve bowel function in stroke patients with constipation or FI compared with “usual care.” Our secondary hypothesis was that intervention patients would benefit regarding quality of life and self-management of their bowel problem through lifestyle changes.

MATERIALS AND METHODS
We recruited participants from 3 stroke rehabilitation units and local communities in London who had experienced a stroke beyond 1 month...
and within 4 years. Patients were screened by questionnaire to identify bowel dysfunction according to standardized definitions:9,16,17

- Constipation (≤2 bowel movements [BMs] per week or ≥2 of the following on more than 1 in 4 occasions: straining, hard stools, feeling of incomplete evacuation);
- Rectal outlet delay (need for self-digitation or feeling of anal blockage or prolonged defecation [≥10 minutes] on ≥1 in 4 occasions);
- FI (any degree of bowel leakage).

Patients with ≥1 of the above met the inclusion criteria. People reporting acute diarrhea or colonic disease other than diverticular disease were excluded (Figure 1). Of the 1715 people screened, 521 (30%) responded, 189 had no bowel dysfunction, and 146 gave written consent (24 stroke rehabilitation inpatients, 122 community). Randomization was by external process using computer-generated numbers and closed envelopes. Baseline data included Barthel Index (physical function),18 SF-12,19 Geriatric Depression Scale,20 abbreviated mental test score (AMTS),21 and clinical data and stroke characteristics.

Intervention
Patients were seen in the outpatient or ward setting or at home. Figure 2 outlines the evidence-based assessment and treatment protocol.1,9,16,22–26 The intervention consisted of a 1-off assessment by a nurse22 leading to (1) targeted patient and carer education; (2) provision of booklet; and (3) diagnostic summary and treatment recommendations sent to the patient’s general practitioner (GP), and ward physician if in hospital. The nonspecialist study nurse received simple practice-based training in bowel management. History taking focused on medications, bowel symptoms, and toilet access. Examination consisted of abdominal palpation, perineal inspection (fecal soiling, pelvic floor descent, rectal prolapse), and rectal examination. Internal sphincter tone was evaluated by ease of entry into the anal canal and external sphincter tone by asking the patient to “squeeze and pull up” around the examining finger.27 Patients with FI but without rectal impaction had an abdominal x-ray to look for obstructive colonic impaction.

This assessment identified the often multifactorial causes for bowel symptoms, and after discussion with the geriatrician (D.H.), the nurse communicated treatment recommendations with the patient, carer, and provider. Providers were alerted when medications (eg, opiates) were possibly causing bowel problems. Generic education was provided by the study booklet28 (contents listed in Figure 2), with instructions on regular toilet habits,15,16 pelvic floor and sphincter-strengthening exercises, suppository insertion, and laxative and loperamide dose titration. Control subjects received routine care with no study nurse assessment, but their providers were notified of their enrollment, thus identifying them as having bowel problems.
Outcome Measures
The primary outcome was BMs per week on the basis of published data enabling the power calculation and demonstrating clinical importance. Secondary outcomes were percentage of BM graded as normal by the patient and number of FI episodes, all measured by postal prospective 7-day stool diary at 1, 3, 6, and 12 months. Other outcomes included bowel-related symptoms, visual analogue scores for severity rating, quality of life (bowel-related and SF-12), and self-reported treatment and resource use.

Statistical Analysis
Studies of bran supplementation versus placebo show an increase of 1.3 BMs per week, representing a 54% increment from baseline mean of 2.4 BMs per week (SD=2.0) derived from laxative trials in older people. Assuming 90% power and a 20% drop out rate, we aimed to randomize 120 patients. Continuous outcome data were compared using t tests if normally distributed, Mann–Whitney U test if skewed, and χ² if dichotomous. All outcomes were adjusted for baseline AMTS (Table 1) and time since stroke (linear regression for continuous data, multiple logistic regression for categorical data). Resource use was additionally adjusted for baseline Barthel score. Individual bowel characteristics were adjusted for baseline level in view of some baseline discrepancy between randomized groups. The data were analyzed on an intention-to-treat basis using SPSS software.

Results
Drop-Outs
Drop-out rates were 17% at 1 month, 19% at 3 months, 24% at 6 months, and 27% at 12 months (Figure 1). Comparison of baseline data (including bowel function) showed that nonrespondents at 12 months (n=40) compared with respondents (n=106) had worse physical function (Barthel Index <16 of 20, 33% versus 18%; P=0.007) but no other differences. Furthermore, no baseline differences were found between drop-outs in intervention versus control group.

Baseline Characteristics
Table 1 shows baseline comparisons between randomized groups. Prestroke rates of self-reported constipation and FI were comparable to those in similarly aged populations.

Assessment Findings in Intervention Group (n=73)
Most participants had >1 finding on assessment. Forty-eight (66%) had constipation, 41 (56%) rectal outlet delay, and 16 (22%) rectal impaction. Twenty-two (30%) reported FI, of whom 12 had constipation with overflow. Thirty (41%) had reduced internal sphincter tone, 40 (55%) weak external sphincter tone, and 27 (37%) excessive pelvic floor descent. Thirty-four (47%) had difficulties with toilet access.

Effect of Intervention
The intervention group were significantly more likely to be modifying their dietary and fluid intake to control their bowel problem, even at 12 months after intervention (Table 2). Prescribing and use of suppositories and ≥2 types of laxatives was
higher in intervention patients throughout the 12 months, although overall laxative use was higher initially only (Table 2). Enema and antidiarrhoeal use did not differ significantly, although numbers were small. Percentage of self-rated normal BMs per week was significantly higher in intervention patients at 1 and 6 months, as was mean number of BMs per week with a persisting trend at 12 months (Table 3). The number of uncomfortable BMs per week was significantly reduced in the intervention group at 1 month. There was a trend in reduction in FI episodes at 1 month, but numbers were small. At baseline, the intervention group rated the severity of their bowel problem and loss of bowel control as being worse than the control group (Table 4). However, at 1 month follow-up, this finding was reversed, with the intervention group having a significantly lower severity rating. There was a significant intervention effect on straining at 1 month and prolonged evacuation at 12 months. Intervention patients showed no benefit in specific (“bowel problems affect physical or emotional health”) or SF-12 quality of life measures.

During the last 6 months of follow-up, intervention subjects were more likely to have visited their GP (15 [20.6%] versus 5 [6.9%], odds ratio, 4.96 [1.4 to 17.5]), or hospital (13 [17.8%] versus 0) for their bowel problem. There were no differences in number of barium enemas or colonoscopies performed or number of district nurse and personal carer visits.

**Discussion**

In this first randomized controlled trial of constipation and FI management in stroke patients, we found that 1 year after intervention, active subjects were more likely to be altering their diet and fluid intake to control their bowel problem and were receiving different GP-prescribed patterns of bowel agents.
subjects reported an improvement in bowel function at 6 months in terms of number and normality of weekly BMs, although the effect was no longer significant at 12 months. Although 32% of intervention and 26% of control subjects reported FI at baseline, the small number of documented episodes during follow-up made underestimation of treatment effect a possibility. The study assessment findings demonstrated that bowel problems in stroke patients are often multifactorial, thereby needing structured broad-based management. Therefore, this is a multi-component intervention (per Medical Research Council guidelines), but this study design cannot define which single action had most effect. However, more important, it does test a

TABLE 2.

<table>
<thead>
<tr>
<th>Self-Reported Treatment and Health Care Resource Use</th>
<th>Intervention n=73</th>
<th>Control n=73</th>
<th>OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alters diet to control bowel problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>28 (38.4)</td>
<td>19 (26.0)</td>
<td>1.80 (0.8–4.0)</td>
<td>0.158</td>
</tr>
<tr>
<td>6 months*</td>
<td>27 (37.0)</td>
<td>15 (20.6)</td>
<td>2.31 (1.0–5.4)</td>
<td>0.052</td>
</tr>
<tr>
<td>12 months*</td>
<td>24 (32.9)</td>
<td>13 (17.8)</td>
<td>3.13 (1.2–8.0)</td>
<td>0.017</td>
</tr>
<tr>
<td>Alters amount or type of fluids to control bowel problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month*</td>
<td>27 (37.0)</td>
<td>11 (15.1)</td>
<td>3.57 (1.5–8.6)</td>
<td>0.005</td>
</tr>
<tr>
<td>6 months*</td>
<td>24 (32.9)</td>
<td>10 (13.7)</td>
<td>3.76 (1.4–9.8)</td>
<td>0.007</td>
</tr>
<tr>
<td>12 months*</td>
<td>18 (24.7)</td>
<td>8 (11.0)</td>
<td>4.15 (1.4–12.2)</td>
<td>0.010</td>
</tr>
<tr>
<td>Laxative taken over previous week</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month*</td>
<td>44 (60.3)</td>
<td>19 (26.0)</td>
<td>4.19 (1.5–11.8)</td>
<td>0.007</td>
</tr>
<tr>
<td>6 months</td>
<td>28 (38.4)</td>
<td>18 (24.7)</td>
<td>1.62 (0.6–2.6)</td>
<td>0.323</td>
</tr>
<tr>
<td>12 months</td>
<td>29 (39.7)</td>
<td>20 (27.4)</td>
<td>1.21 (0.5–3.2)</td>
<td>0.692</td>
</tr>
<tr>
<td>Taking ≥2 types of laxatives</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month*</td>
<td>16 (21.9)</td>
<td>5 (6.9)</td>
<td>3.32 (1.0–11.5)</td>
<td>0.059</td>
</tr>
<tr>
<td>6 months</td>
<td>13 (17.8)</td>
<td>4 (5.5)</td>
<td>2.00 (0.6–6.8)</td>
<td>0.270</td>
</tr>
<tr>
<td>12 months*</td>
<td>15 (20.6)</td>
<td>4 (9.6)</td>
<td>6.57 (1.3–33.1)</td>
<td>0.023</td>
</tr>
<tr>
<td>Suppository use over previous week</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month*</td>
<td>13 (17.8)</td>
<td>4 (5.5)</td>
<td>3.82 (1.1–15.0)</td>
<td>0.020</td>
</tr>
<tr>
<td>6 months</td>
<td>6 (8.2)</td>
<td>2 (2.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>8 (11.0)</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Favorable intervention effect at a significance level of P<0.05 (OR >1).
All analyzed outcomes adjusted for baseline laxative use, baseline AMTS, and time since stroke.

TABLE 3.

<table>
<thead>
<tr>
<th>Bowel Function (Prospective 7-Day Stool Diary)</th>
<th>Intervention (n=73)</th>
<th>Control (n=73)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of BMs per week</td>
<td>Mean±SD</td>
<td>Mean±SD</td>
<td></td>
</tr>
<tr>
<td>1 month*</td>
<td>5.55±3.4</td>
<td>4.10±4.0</td>
<td>0.011</td>
</tr>
<tr>
<td>6 months*</td>
<td>5.22±3.0</td>
<td>3.56±3.3</td>
<td>0.005</td>
</tr>
<tr>
<td>12 months</td>
<td>5.57±3.2</td>
<td>4.81±2.3</td>
<td>0.209</td>
</tr>
<tr>
<td>Percentage of normal BMs per week</td>
<td>Mean±SD</td>
<td>Mean±SD</td>
<td></td>
</tr>
<tr>
<td>1 month*</td>
<td>75.1±35.9</td>
<td>55.3±40.9</td>
<td>0.030</td>
</tr>
<tr>
<td>6 months*</td>
<td>72.1±32.3</td>
<td>55.0±39.0</td>
<td>0.027</td>
</tr>
<tr>
<td>12 months</td>
<td>74.9±28.9</td>
<td>67.7±33.6</td>
<td>0.277</td>
</tr>
<tr>
<td>No. of uncomfortable BMs per week</td>
<td>Median (25–75%)</td>
<td>Median (25–75%)</td>
<td></td>
</tr>
<tr>
<td>1 month*</td>
<td>1.0 (0.0–2.25)</td>
<td>1.0 (0.0–3.75)</td>
<td>0.031</td>
</tr>
<tr>
<td>6 months*</td>
<td>1.0 (0.0–3.0)</td>
<td>2.0 (0.0–4.0)</td>
<td>0.185</td>
</tr>
<tr>
<td>12 months</td>
<td>1.0 (0.0–3.0)</td>
<td>1.0 (0.0–3.0)</td>
<td>0.934</td>
</tr>
<tr>
<td>One or more episodes of FI per week</td>
<td>n (%)</td>
<td>n (%)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>1 month</td>
<td>5 (6.9)</td>
<td>12 (16.4)</td>
<td>0.36 (0.1–1.2)</td>
</tr>
<tr>
<td>6 months</td>
<td>5 (6.9)</td>
<td>6 (8.2)</td>
<td>0.85 (0.2–3.7)</td>
</tr>
<tr>
<td>12 months</td>
<td>3 (4.1)</td>
<td>3 (4.1)</td>
<td>1.13 (0.1–8.9)</td>
</tr>
</tbody>
</table>

*Favorable intervention effect at significance level P<0.05.
Normally distributed data presented as mean±SD, adjusted for AMTS and time since stroke.
Skewed data presented as median (percentiles).
Dichotomous data presented as n (%) with ORs (95% CI).
Exact confidence limits used for small numbers.
structured practical approach that nonspecialist doctors and nurses may feasibly apply in various settings. Further applied research would aid in assessing effective ways of delivering this type of intervention within health services.

Although there are no comparable intervention trials, there are epidemiological data in older people with constipation and FI to support our lifestyle measures intervention.11–13,16,23,32 Although our study does not specifically demonstrate the effectiveness of nonpharmacological measures in stroke patients, we have shown that a simple targeted educational approach including written materials may have clarified this. Older patients often do not report FI to talk to their GPs about their condition; qualitative evaluation which may imply that they were empowered through education rather than stool softener to avoid anal leakage).

Our findings show that although dietary and prescribing pattern changes persisted, the benefits on bowel symptoms were not maintained beyond 6 months. Health care visits for bowel problems among the active group increased in the last 6 months, which may imply that they were empowered through education to talk to their GPs about their condition; qualitative evaluation may have clarified this. Older patients often do not report FI to providers,10 and structured assessment in stroke patients would make it less of a “hidden problem.” One practical implication is

Our intervention design was of a simple but structured nurse-led assessment leading to targeted treatment of bowel dysfunction. For instance, where rectal outlet delay (a common constipation subtype associated with rectal impaction with overflow)9,17 was identified, suppositories rather than increased doses of laxatives were recommended,1,9 and suppository use was demonstrably higher in the intervention group. Our overall treatment approach moved away from empirical laxative prescribing (common in neurologically disabled people)1,16,26 toward individualized recommendations (eg, patients with constipation plus weak anal sphincters were advised to use a bulking agent rather than stool softener to avoid anal leakage).
that this intervention should be repeated periodically and long term in stroke patients with bowel dysfunction.

Quality of life scores were unchanged in the context of improved bowel function in intervention patients. Similar to these findings, studies of secondary prevention through education in stroke patients show that although knowledge and adherence to lifestyle changes improves, perceived health status and quality of life measures remain unaltered.33

Limitations
The drop-out rate was high, reflecting the frailty of this population, but comparative analysis showed that randomization was uncompromised. The study had sufficient power to demonstrate intervention effect on bowel pattern, but a larger sample would have permitted evaluation of impact on FI and constipation subgroups (eg, rectal outlet delay). Baseline stool diary data were not collected, although statistical adjustment for other baseline bowel symptom measures (Table 4) showed that significant treatment effects remained significant. The study was nonblinded by nature of the intervention. The study nurse was involved in collecting outcome data, but potential bias was minimized through use of postal self-completed questionnaires. By recruiting mainly community patients, the possible Hawthorne effect of having control and intervention patients on the same ward was reduced. The intervention effect may have been weakened through ethical requirement to notify GPs and ward physicians of control group enrollment; there was a trend toward improved bowel symptoms in controls over 12 months.

Conclusions
A single encounter nurse-led intervention in stroke patients significantly improved measures of bowel dysfunction ≤6 months later and changed bowel-modifying lifestyle behavior and GP-prescribing patterns throughout the ensuing 12 months. Although further trials are needed, these findings may promote structured management of bowel problems in stroke patients and encourage targeted health education (including provision of booklets) to this population.

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References
3. Baztan JJ, Domenech JR, Gonzalez M. New-onset fecal incontinence after stroke: risk factor or consequence of poor outcomes after rehabilitation?
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