

Does balloon dilatation and anal sphincter training improve ileoanal-pouch function?

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Abstract. Although patients' satisfaction may be high after restorative proctocolectomy the functional results are still far from perfect. Increased bowel frequency and imperfection in continence are common. Pouch volume and anal sphincter status are important determinants for the outcome. The aim of the present study was to evaluate if balloon dilatation of the pouch and sphincter biofeedback training might improve the results. Forty patients with an ileo-pouch anal anastomosis were randomized into a control and a treatment group. During the interval with a diverting ileostomy, patients in the latter group were subjected to balloon dilatation of the pouch and sphincter biofeedback training by using a manovolumetric technique. All patients were functionally assessed and anorectal manometry performed preoperatively and at regular intervals postoperatively. Follow-up time was at least 12 months. Immediately before ileostomy take down patients in the treatment group showed a significant initial increase in pouch compliance compared with controls. However, a rapid and pronounced increase in pouch volume occurring after ileostomy closure in the control group equalized this initial difference. Anal resting tone and maximum squeezing capacity were at all intervals similar in the two groups. Bowel frequency per 24 h was similar and mucus soiling occurred to a similar extent in both groups, and the overall functional result as assessed according to a scoring system was equal at each interval. Balloon dilatation of the pouch and sphincter exercises appear not to be essential measures in these patients.

ative proctocolitis and familial polyposis. An increasing number of surgical centres in the world have adopted the method and several modifications in design have been introduced in an attempt to improve results [1–6].

Frequent stooling and soiling is a distressing problem for many patients particularly during the first 2–3 months after operation, and the majority of patients have therefore to rely upon constipating drugs and need a perineal pad for protection during this period. Great care has also to be taken to protect perineal skin from soreness. Frequency of defaecation appears to be related to pouch volume and compliance [7, 8] and soiling at least partly due to sphincter insufficiency caused by the forceful and prolonged dilatation of the anus during the mucosal proctectomy [9, 10]. Improvement of function occurs gradually with time concomitant with increase of pouch capacity or compliance and recovery of anal sphincter tone and function [4].

Biofeedback training of the external sphincter has been demonstrated to improve anal incontinence [11] and anal sphincter exercises are often recommended after pelvic pouch surgery. The clinical importance of this measure remains controversial, however. Balloon dilatations of the terminal ileum in patients with straight ileoanal anastomosis have been employed to enhance the early development of the neorectal reservoir and improve the clinical result [12].

The aim of the present prospective randomized study was therefore to evaluate if in a similar way the combined use of graded balloon dilatation of the ileal pouch and sphincter biofeedback training, both measures instituted in the early postoperative period, could enhance pouch capacity and sphincter function, thereby improving the clinical result in patients with new constructed pelvic pouches.

Restorative proctocolectomy with ileal reservoir and ileoanal anastomosis has become a well-established method for curative treatment of ulcer-

Patients and methods

Forty consecutive patients with ulcerative proctocolitis were subjected to restorative proctocolectomy, i.e. abdominal colectomy, endocavitary mucosal proctectomy, and ileal pouch-anal anastomosis. The rectum was fully mobilized down to the anorectal ring. The distal mucosal proctectomy dissection was performed entirely from below, starting at the level of the pectinate line and carried out by endocavitary technique up to a centimetre or two above the levator plane where the rectal muscle tube was transected. A J-pouch was constructed by anastomosing side-to-side two limbs about 15 cm in length. The pouch was extended into the pelvis and its apex opened and sutured circumferentially to the pectinate line. A diverting loop ileostomy was routinely used and was closed after about 10 weeks when radiographic and endoscopic investigations had confirmed the integrity of the pouch and ileoanal anastomosis.

Assessment of sphincter status, pouch function and continence

All patients were investigated preoperatively and at regular intervals 4 weeks postoperatively, immediately before and 1, 3, 6 and 12 months after ileostomy closure. Anorectal manovolumetry was performed according to a method allowing for simultaneous recording of pouch volume to isobaric distension and sphincter pressure assessment [13].

The set up is shown in Fig. 1. A rectal balloon was connected to a system of reservoirs which provided a constant pressure and permitted continuous recording of pouch volume when distended at a preset pressure. A waterfilled cylindrical cuff (12 mm) was placed in the anal canal for simultaneous anal pressure recording.

Anal continence and bowel habits were evaluated qualitatively by history taken at each follow up visit. Particular attention was focussed on stool frequency and use of constipating drugs, and level of continence, as reflected by soiling, use of pad and perineal soreness. Patients were asked to fill in a protocol for daily recording of stooling pattern. To allow for comparison of the overall functional results a scoring system was worked out in which each patient scored points according to presence of functional defects (see Table 1). The lower the score the better the functional state.

Technique of balloon dilatation and sphincter muscle exercises

Twenty patients were randomized to balloon dilatation and sphincter training, both procedures starting 4 weeks after the original operation and continuing for 2–8 weeks period until closure of ileostomy. By using the laboratory set up described above the ileal pouch was distended using step-wise increasing pressure (5–80 cm water; each step: 5 cm water). Each distension lasted 60 s. Moreover each session included 4–6 shortlasting distensions using maximal tolerable volume. The patients were also carefully instructed to perform maximal and sub-maximal squeezing manoeuvres, visually controlled on the recording equipment (Grass Polygraph) according to a detailed programme, and were even subsequently after closure of the loop ileostomy instructed to practise contracting the anal sphincter muscles several times each day, particularly when they sensed urge or pouch distension.

The number of supervised sphincter training and pouch dilatation sessions averaged eight (range 5–10), and each session amounted to 50–60 min. The treated group and the control group are characterized in Table 2.

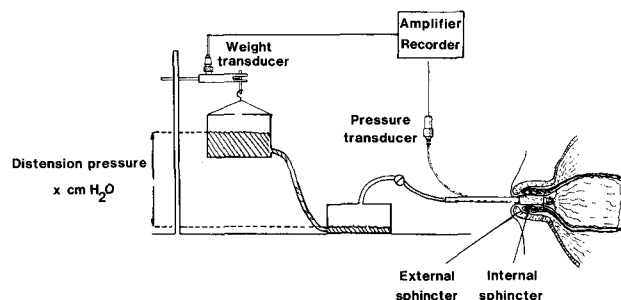


Fig. 1. Schematic illustration of the method used for manovolumetry

Table 1. The functional scoring system. The lower the score the better the functional state. Score range 0–15

| | Score | | |
|-------------------------|-------|------|-----|
| | 0 | 1 | 2 |
| Bowel movements | | | |
| daytime | ≤ 4 | 5 | ≥ 6 |
| at night | 0 | 1 | ≥ 2 |
| Medication | no | yes | |
| Urgency | no | yes | |
| Evacuation difficulties | no | yes | |
| Leaks | | | |
| daytime | no | yes | |
| at night | no | yes | |
| Perianal soreness | no | occ. | yes |
| Protective pad | | | |
| daytime | no | yes | |
| at night | no | yes | |
| Dietary restrictions | no | yes | |
| Social handicap | no | yes | |

Table 2. Details of patients in the two groups

| | Patients | |
|---------------------------------|---------------|-------------------------------|
| | Control group | Training and dilatation group |
| <i>n</i> | 20 | 18 |
| Females/males | 10/10 | 10/8 |
| Age, years | 38 (18–51) | 36 (19–58) |
| Time with loop ileostomy, weeks | 11 (7–30) | 10 (6–30) |

Results

Two patients both randomized to the training group had to be withdrawn from the study due to postoperative complications that prevented them from completing the training programme.

Pouch volume

As can be seen in Fig. 2 the pouch volume at 4 weeks after construction, i.e. before patients were allotted to balloon dilatation, was similar in both groups, measuring about 75 ml when distended at a pressure of 80 cm water, corresponding to maximal tolerable volume. When measured immediately before ileostomy take down maximal pouch volume in the treated group was 136 ± 34 ml (SD) as compared to 108 ± 57 ml in the control group, an increase of 84 and 40%, respectively. The difference did not reach statistical significance. However, when looking at volume increase per cm water pressure increase in the physiological pressure interval between 20 and 40 cm water there was a statistically significant difference between the two groups (trained 1.04 ± 0.47 (SD) ml/cm water, controls 0.70 ± 0.33 ml/cm water, $p < 0.02$).

At 1 month after ileostomy closure and cessation of the balloon dilatations pouch volume had increased considerably, but the mean volume at this stage was almost equal in the two groups of patients amounting to about 220 ml, implying that the mean percentage volume increase in the pretreated group was 63% compared to 107% in the control group (n.s.). There was a slow and gradual expansion of the pouches over the ensuing year but the volumes measured at each interval differed insignificantly and at the end of 1 year pouch volume averaged 265 ml in both groups of patients.

Maximal squeezing capacity and resting anal pressure (Fig. 3)

At 4 weeks postoperative maximal squeeze pressure had decreased from about 200 mm Hg to 170 mm Hg and resting anal pressure from about 72 mm Hg to 50 mm Hg corresponding to a mean reduction of 15 and 40 per cent respectively. At the time for ileostomy closure squeeze pressure had increased somewhat (8%) but there was in this respect no statistical difference between the trained and the control group. Squeeze pressure had reached preoperative level in both groups of patients at 3 months.

At the time for ileostomy closure resting anal pressure remained low in both groups of patients. Although resting anal pressure showed a slight increase at 1 and 3 months there was in each interval no statistical significance between groups. At 1 year resting anal pressure averaged $56 \pm$

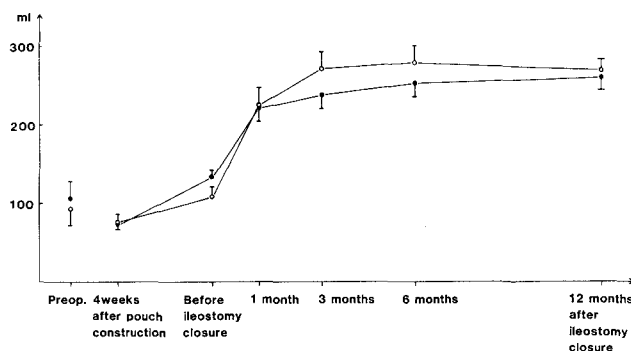


Fig. 2. Pouch volumes at maximal distending pressure (80 cm water); ● training anal dilatation group ($n = 18$); ○ control group ($n = 20$); mean \pm SEM

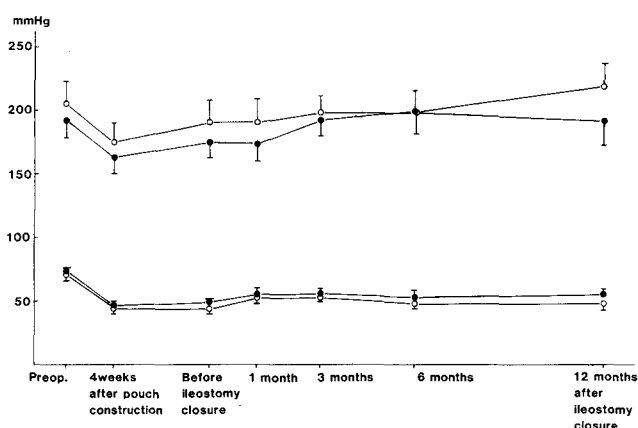


Fig. 3. Anal pressure at rest (lower curves) and maximal squeezing capacity (upper curves); ● training and dilatation group ($n = 18$); ○ control group ($n = 20$); mean \pm SEM

17 mm Hg in the trained group and 50 ± 15 mm Hg in the control group (n.s.), which was still about 25% below preoperative level, however.

Defaecation frequency and defects in continence function

Once intestinal continuity was restored all patients suffered from a high stooling frequency. At 1 week after ileostomy closure the average number of bowel evacuations per 24 hours was 7.3 ± 2.5 (SD) in the balloon dilated group and 7.5 ± 2.5 in the control group (Fig. 4) and at one month 7.1 ± 1.7 and 7.0 ± 2.3 respectively. The number of night evacuations averaged 1.3 and 1.7 respectively.

At the 6 months interval bowel frequency had decreased further amounting to 4.9 ± 1.6 in the treated group and 5.4 ± 1.8 in the control group,

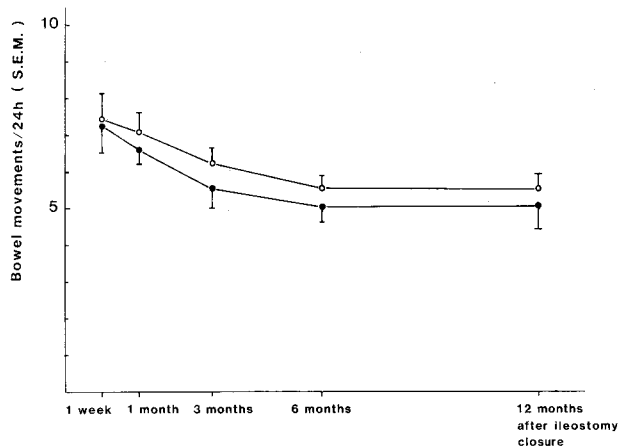


Fig. 4. Defaecation frequency; ● training and dilatation group; ○ control group, mean \pm SEM

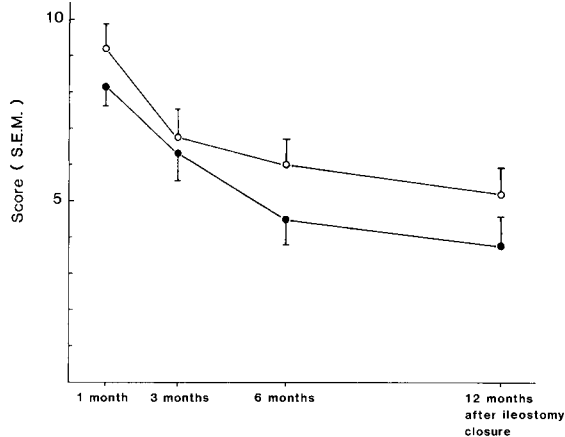


Fig. 5. Overall function as reflected in the functional score (Table 1); ● training and dilatation group; ○ control group, mean \pm SEM

and a similar stooling pattern was noted at one year. Although stooling frequency appeared to be less at each interval in the treated group, these differences failed to reach statistical significance. The need for constipating drugs and dosage used was similar.

The patients in both groups suffered from day and/or night time soiling of a similar severity and to a similar extent at each time interval, and the need for wearing a protective pad appeared to be virtually the same.

When incorporating the functional indices into a scoring system (Fig. 5) it appeared that the overall functional score at 1 and 3 months differed but little, and the differences noted at 3 and 6 months were also not significant.

Discussion

The results of the present study confirm the observations made by other authors [3–5, 7, 8] that ileoanal pouch patients suffer from a high evacuation frequency initially, with imperfections in continence, disturbances which appear to diminish with time concomitant with a gradual expansion of the ileal reservoir and with improvement in anal sphincter function. Telander et al. [12] demonstrated that balloon dilatations of the neorectum during the early postoperative phase enhanced neorectal enlargement corresponding to a 40% volume increase at the time of ileostomy closure, and that frequency of stooling both at 3 and 6 months after ileostomy take down was significantly less in these patients. Balloon dilatation also enhanced pouch enlargement to a similar extent in the present series of patients. Due to the pronounced and rapid volume expansion even in the untreated patients occurring after ileostomy closure these differences disappeared, however, and at 1 month pouch volume in the two groups were similar amounting to about 220 ml or 90% of the maximum volume reached at 1 year. A gradual decrease in the mean number of stools was seen along with the volume expansion of the pouches, but no statistical differences between the two groups of patients could be observed in this respect, either at the 1 or 3 months interval, or at 1 year.

Anal manometry 4 weeks postoperatively demonstrated a marked reduction both in maximal squeeze pressure and resting anal pressure in all patients of the present study. The voluntary component recovered and had reached preoperative level at the 3 month interval. This recovery appeared uninfluenced by the biofeedback sphincter training. The improvement in resting anal pressure was incomplete in both groups of patients and the differences favouring the trained patients failed to reach statistical significance at each interval.

The benefit of sphincter exercises is poorly reflected in these data and each functional marker when compared separately appeared to be qualitatively and quantitatively equal in the two groups. Incorporation of the indices into a scoring system showed no evidence that the trained group fared better than the controls.

The results of the present study show that despite an initial increment of pouch volume, balloon dilatation of the newly constructed pelvic pouch does not influence the functional result, either in the short or long term. It is sometimes

stated that these patients should be encouraged to begin anal sphincter exercises early in the postoperative course [6] in the belief that this measure might enhance recovery of sphincter function and improve clinical results, as it has also been demonstrated to do in selected patients after other kinds of anorectal surgery [11]. The results in our study where patients were specifically instructed and supervised according to "a biofeedback system" do not support these statements.

Anal sphincter continence which is predominantly neuromuscular in origin, and reservoir continence, depending on the ability of the ileal pouch to distend and accommodate contents without increasing its tone or contract, appear to be two important components that determine the clinical result in these patients. Imperfection in continence, particularly the excess incidence of day and/or night time faecal soiling or mucus seepage, might partly or entirely be due to anal sphincter insufficiency caused by forceful and prolonged sphincter dilatation during the endoanal mucosal dissection. In fact even moderate sphincter stretch such as that employed for treatment of haemorrhoid or anal fissure, appears to be associated with such defects in continence [9, 14]. Reduction of the incidence of soiling by performing the mucosal proctectomy entirely by an abdominal approach [10] demonstrates the importance of the sphincter component. Apart from the role of the anal sphincters other authors [15, 16] emphasize the importance of the epithelial lining of the distal anal canal suggesting that 1–2 cm of the mucosa above the dentate line should be preserved to provide better continence and avoid mucus leakage. However, whether or not soiling in patients with a pelvic pouch is entirely related to sphincter function or may even be dependent on the reservoir design is unclear. There is experimental and clinical evidence that a pouch constructed to prevent the development of the pressure waves that may overcome anal sphincter resistance will be associated with less soiling and better overall functional result [2, 8, 17], implying that the ultimate volume should be more satisfactory if the reservoir was constructed initially with a larger capacity. The results of the present investigation imply that neither balloon dilatation of the new constructed pouch nor anal sphincter exercises appear to be essential measures and do not influence the early or late functional outcome in pelvic pouch patients.

Acknowledgement. This work was supported by Assar Gabrielson's foundation, Skandia 100-års fond and Swedish Medical Research Council (MFR: 17X-03117).

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Accepted: 20 January 1988

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