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Rectal Balloon Training as Add-On Therapy to Pelvic Floor Muscle Training in Adults With Fecal Incontinence: A Randomized Controlled Trial

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Aims: Fecal incontinence (FI) is embarrassing, resulting in poor quality of life. Rectal sensation may be more important than sphincter strength to relieve symptoms. A single-blind, randomized controlled trial among adults with FI compared the effectiveness of rectal balloon training (RBT) and pelvic floor muscle training (PFMT) versus PFMT alone. **Methods:** We randomized 80 patients, recruited from the Maastricht University Medical Centre. Primary outcome was based on the Vaizey score. Secondary outcomes were the Fecal Incontinence Quality of Life Scale (FIQL), 9-point global perceived effect (GPE) score, anorectal manometry, rectal distension volumes, and thresholds of anorectal sensation. Analyses were by intention-to-treat. **Results:** Forty patients were assigned to combined RBT with PFMT and 40 to PFMT alone. Adding RBT did not result in a significant improvement in the Vaizey score [mean difference: −1.19; 95% confidence interval (CI): −3.79 to 1.42; $P = 0.37$]. Secondary outcomes favoring RBT were: Lifestyle subscale of the FIQL (0.37; 95% CI: 0.02–0.73; $P = 0.04$), GPE (−1.01; 95% CI: −1.75 to −0.27; $P = 0.008$), maximum tolerable volume (49.35; 95% CI: 13.26–85.44; $P = 0.009$), and external anal sphincter fatigue (0.65; 95% CI: 0.26–1.04; $P = 0.001$). Overall, 50% of patients were considered improved according to the estimated minimally important change (Vaizey change ≥ -5). **Conclusions:** RBT with PFMT was equally effective as PFMT alone. Secondary outcomes show beneficial effects of RBT on urgency control, GPE, and lifestyle adaptations. Characteristics of patients who benefit most from RBT remain to be confirmed. *Neurourol. Urodynam. 31:132–138, 2012.* © 2011 Wiley Periodicals, Inc.

Key words: biofeedback; fecal incontinence; pelvic floor; physical therapy; Vaizey score

INTRODUCTION

Fecal incontinence (FI) is defined as "the complaint of involuntary loss of feces" and affects 2–24% of community-dwelling adults.[1,2] It is astonishing that patients regularly accept having FI, with only 5–27% seeking medical help.[3] This may result from embarrassment, the erroneous belief that FI is a normal part of aging, or the perception that no treatment is available. However, established interventions for FI are available, such as dietary changes, medication, and physiotherapy.[4] If medication or dietary adaptations offer no relief, physiotherapy intervention is an attractive alternative to surgery, because it is inexpensive, non-invasive, and without any adverse effects.[5]

Biofeedback, including rectal balloon training (RBT) and pelvic floor muscle training (PFMT) are elements of physiotherapy treatment. PFMT is recommended as an early intervention in FI treatment and is accepted as an effective intervention for urinary incontinence.[6] The multifactorial nature of FI symptoms means that not every patient will benefit from PFMT to the same extent. Moreover, changes in sphincter strength are not necessarily linked to changes in symptoms. It is reported that rectal sensation may be more important than sphincter strength in attempts to relieve symptoms.[7–9] RBT is used to improve rectal sensitivity by stepwise reductions in rectal balloon distension, in order to distinguish smaller rectal volumes, or resist urgency by using progressive distension, or use a voluntary anal squeeze to counteract the recto-anal inhibitory reflex in response to rectal filling. Even though precise mechanisms responsible for improvement after PFMT or biofeedback interventions remain unclear, some have argued that rectal sensitivity training is the most important element of biofeedback.[7–9]

Lack of reliable, well-controlled research in the field of physiotherapy has hampered recommendations for pelvic physiotherapy interventions.[5] Knowledge of effective physiotherapy elements enables guidance and improves referral patterns to pelvic physiotherapists, thereby preventing surgical treatment or wasting of other healthcare resources, and improving cooperation between physicians and physiotherapists. We

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hypothesized that a combined physiotherapy program with RBT and PFMT, aimed at treating the multifactorial origin of FI, would show more symptom relief. The purpose of this study was therefore to assess the effectiveness of RBT as an add-on therapy to PFMT in adults with FI.

MATERIALS AND METHODS

Study Design and Patients

In a two-armed parallel randomized, single-blind controlled trial patients were included from August 2006 to May 2009 at the Maastricht University Medical Centre, the Netherlands. An experienced colorectal surgeon consecutively included adult patients who reported having had FI for more than 6 months, with a Vaizey incontinence score $\geq$12 (range: 0–24), and failure of dietary measures and medication. Patients diagnosed with an anorectal tumor within the past 2 years, absent squeeze pressure of the anal sphincter, chronic diarrhea (always fluid stool 3 or more times a day), overflow incontinence, proctitis, ulcerative colitis, Crohn's disease, soiling (defined as leakage of a minimal amount of watery feces from the anal canal), previous ileo-anal or colo-anal anastomosis, and/or rectal prolapse in situ were excluded. Participants who had received physiotherapy during the previous 6 months or who were considered unable to comply with therapy were also excluded. Many patients appeared to have minor day- or night-time soiling. Patients with minor soiling were included as long as it was not due to overflow incontinence. The total Vaizey score was exclusive of soiling.

After signing informed consent, participants received either PFMT combined with RBT or PFMT alone. The Medical Ethics Committee of the Maastricht University Medical Centre approved the study. A more detailed overview of this trial was published elsewhere.[10]

Randomization and Masking

Patients were assigned in a 1:1 ratio with a random permuted block size of 4. To conceal treatment allocation, an independent research assistant prepared a computer-generated randomization list and treatment allocation. An independent physician performed enrolment. It was impossible to mask patients and therapists. To minimize bias, we ensured no involvement of therapists in the diagnostic and follow-up measurements, blinded double-data entry of baseline data, and blinded primary outcome assessment.

Outcome Measures

The primary outcome measure was the Vaizey grading system for FI severity, ranging from 0 (complete continence) to 24 (complete incontinence).[11] Secondary outcome measures were the Fecal Incontinence Quality of Life Scale (FIQL),[12] a 9-point global perceived effect score (GPE; 1 = very much improved, 9 = very much worse), anorectal manometry (resting pressure and squeeze pressure of the anal canal), rectal capacity measurement (sensory threshold, urge sensation, maximum tolerable volume), and thresholds of anorectal sensation.

All outcomes were measured at baseline and as soon as possible after completion of physiotherapy treatment. Baseline diagnostic work-up also included medical history taking, physical examination, endoanal ultrasound, and defecography.

Physiotherapy Program

Nationwide, 90 physiotherapists working in private practices, meeting the requirements for registration as a specialized physiotherapist in the field of pelvic floor disorders, were trained to provide supervised physiotherapy close to the patients' home.[10] Physiotherapy treatment was standardized by organizing a briefing meeting for all therapists. Furthermore, physiotherapists received a DVD film, illustrating the intended RBT, and used the same provided rectal balloons. Individual treatment was administered according to a standardized protocol, developed by clinicians and physiotherapists specialized in the field of pelvic floor disorders. Patients attended a maximum of 12 sessions within 9 weeks. Sessions lasted 35 min and about 45 min in the group with rectal sensitivity training. Protocol deviations were registered for every session. Pelvic floor muscle assessment following the PERFECT scheme was evaluated at baseline and at the final session.[13] The assessment involved "Power," evaluated by means of the modified Oxford grading scheme (0 = no discernible muscle contraction, 5 = strong muscle contraction), "Endurance," defined as seconds (maximum 30) sustaining submaximum contraction, and "Repetitions," as number (maximum 5) of maximum contractions. Exercise regimens were patient-tailored due to differences in tolerance of workload and planned according to baseline assessments. To increase the chance of successful outcome, patients were instructed to practice the training program three times daily at home. In the Netherlands, PFMT and RBT is incorporated as part of other conservative management, that is, providing information and advice. This was done according to a checking off list and included information about the anatomy and function of the pelvic floor muscles and bowels, the continence mechanism, incontinence material and advice on defecation mechanisms, and toilet behavior.

Pelvic Floor Muscle Training

PFMT consisted of selective voluntary contractions and relaxations of the pelvic floor muscles and the anal sphincter, practiced in different starting positions.[10] Training aimed to maximize strength, improve duration of strength, and improve timing and coordination of contractions. Digital rectal examination was used to measure the ability of pelvic floor muscles to achieve maximum contraction, concurrent complete relaxation, and to quantify the strength. A contraction was only considered sufficient if the pelvic floor and anal sphincter lifted inward and upward.

Change in neuromuscular function was promoted by basing PFMT on principles of overload and specificity, maintenance, and reversibility, similar to previously established recommendations for PFMT training dosage.[14]

Rectal Balloon Training

A rectal balloon attached to a syringe was introduced into the rectum and slowly inflated with air. Sensory threshold, urge sensation, and maximum tolerated volume were assessed. Patients with an insensitive rectum were trained to distinguish and respond to smaller rectal volumes of distension until a normal level of sensory threshold was achieved. In addition, patients with a hypersensitive rectum were trained to tolerate larger volumes by means of progressive distension and urge resistance, until a normal level of urge sensation was achieved. Coordination training tried to enhance the voluntary anal contraction in response to rectal filling, thereby

counteracting the recto-anal inhibitory reflex, combined with reinforcement of rectal sensitivity and sustained external anal sphincter contractions to improve sphincter strength.

Statistical Analyses

Missing values were checked prior to the analyses. A precalculated sample size of 106 participants was deemed sufficient to detect a 4.33 point difference in our primary outcome variable between groups ($\alpha = 0.05$, $\beta = 0.20$, one-sided).[10]

Statistical analyses were performed using SPSS software, version 17.0 (IBM Corporation, Somers, NY). First, observed group differences were analyzed using the independent samples *t*-test. Adjusted group differences were analyzed using ANCOVA with post-intervention measurements as dependent variable and baseline measures as covariates. Baseline to post-intervention comparisons were based on intention-to-treat analysis. Potential confounders were considered, such as presence of urinary incontinence and medication use, however, they did not influence the results.

In case of missing values, data were completed using the multiple imputation procedure, in which each missing value was replaced by a set of multiple values, estimated from regression models and available data. We identified 15 core factors, which were used as predictors for the missing values in each imputation model. We generated five multiple imputed datasets for each intervention group.[15,16] The pooled results are presented, with a *P*-value of 0.05 indicating statistical significance.

RESULTS

Patients

The flow chart (Fig. 1) shows the study flow after 101 patients had been assessed for eligibility. Eighty patients (79%) gave informed consent and were randomly assigned to either group 1 (PFMT + RBT, n = 40) or group 2 (PFMT, n = 40). Baseline and clinical characteristics were available for most non-participants. Table I shows baseline demographic and clinical characteristics of the participants (n = 80) versus non-participants (n = 20), only showing a difference between the groups in time since onset of FI symptoms ($P = 0.04$). After randomization, groups did not differ significantly in terms of baseline demographic and clinical characteristics (Table II). Ultimately, 25 out of the 90 trained physiotherapists treated all included patients. No adverse events were reported for the subjects in each group. Ten patients (12.5%) dropped out during or after physiotherapy treatment. Completion rates did not differ between groups ($P = 0.31$).

Patients were evaluated at a mean of 6.8 weeks (SD 5.8) after completing physiotherapy, which was comparable for both groups ($P = 0.41$). Moreover, the mean therapy period for both groups was similar [11.5 weeks (SD 3.6), $P = 0.21$].

Post-Intervention Follow-Up

Table III shows the outcomes of post-intervention group comparisons. The adjusted mean difference on the Vaizey score was 1.19 point larger in group 1 than in group 2 (−5.58 vs. −4.39); this difference was not significant ($P = 0.37$). Secondary outcome measures that improved in favor of group 1 were the mean GPE score [mean difference −1.01; 95% confidence interval (CI) −1.75 to −0.27; $P = 0.008$], the Lifestyle subscale of the FIQL (mean difference 0.37; 95% CI: 0.02–0.73; $P = 0.04$), maximum tolerable volume (mean difference 49.35 ml; 95% CI: 13.26–85.44; $P = 0.009$), and fatigue of the external anal sphincter (mean difference 0.65; 95% CI: 0.26–1.04; $P = 0.001$). No significant differences were found in the total FIQL score and its Coping/Behavior, Depression/Self perception, or Embarrassment subscales, resting pressure, squeeze pressure, thresholds of anorectal sensation, the rectal distension volumes of sensory threshold and urge sensation, Oxford score of the external anal sphincter and pelvic floor, endurance of the external anal sphincter, or endurance and fatigue of the pelvic floor.

Figure 2 illustrates the change in Vaizey score in both groups after the intervention. Improvement rates (reduction in Vaizey change score $\geq$1) were 82.5% and 76% for groups 1 and 2, respectively ($P < 0.78$, χ^2); 7.5% and 8.5% remained stable (Vaizey change score = 0; $P < 1.00$, χ^2), and 10% and 15.5% deteriorated (increase in Vaizey change score $\geq$1; $P < 0.74$, χ^2). Fifty-one percent and 48% of patients were considered importantly improved based on the minimally important change, as determined before[17,18] (reduction in Vaizey change score $\geq$5; $P < 1.00$, χ^2). Six patients in group 1 and 2 in group 2 reported complete continence for gas, liquid, and solid stools, whereas 11 patients in group 1 and 5 in group 2 reported complete continence for liquid and solid stools.

DISCUSSION

This study assessed the effect of adding RBT to PFMT in patients with FI of mixed etiology. We hypothesized that both groups would show symptom reduction, with group 1 having additional benefits from supplementary attention to rectal sensitivity training. Although this study provided no evidence for an add-on effect of RBT to PFMT, some of the secondary outcomes show beneficial effects of RBT on the control of urgency, external anal sphincter function, subjective rating of improvement, and lifestyle adaptations. Half of the patients demonstrated clinically important improvement on the Vaizey score, based on the minimally important change.[17,18]

Several aspects should be taken into account when interpreting our results. Firstly, various outcome measures have been used to evaluate pelvic physiotherapy studies,[11,19] and no outcome measures have a high level of scientific rigor, due to the lack of a criterion standard.[20] We decided to use the Vaizey score as the primary outcome since it incorporates several items regarding severity of incontinence, correlates with patients' subjective perception of relief[21] and has a significant relation with frequency of reported problems in general health domains.[22]

Secondly, the number of included patients was lower than anticipated, resulting in a power of 73.2%. Given the few colorectal surgeons in the Netherlands specializing in FI, patients sometimes had to travel far to visit our specialized center for a diagnostic work-up. In addition, 90 physiotherapists were trained nationwide to facilitate attendance of physiotherapy care sessions, nevertheless this implied additional travel time in certain areas of the Netherlands. Practical and financial issues thus might have resulted in non-participants.

Furthermore, it was impossible to blind therapists or patients, which may have introduced bias. However, the questionnaires that asked participants for subjective judgments were completed at home, minimizing interaction between patients and healthcare professionals.

Additionally, the percentage of missing post-intervention data was 12.5. We aimed to ensure valid imputation by generating five imputation datasets based on a comprehensive set of predictors. It is unlikely that this approach greatly

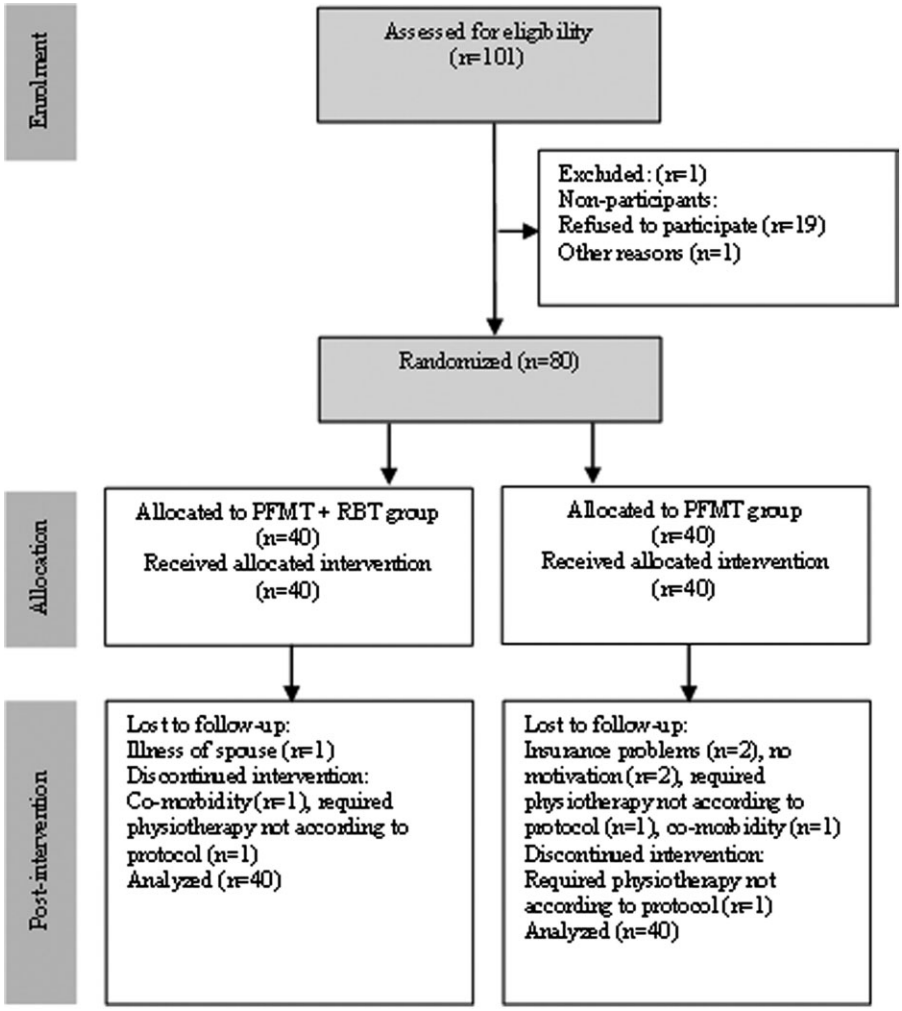

Fig. 1. Flow chart describing enrolment, allocation, number of drop-outs, and lost to follow-up.

influenced our results, as a sensitivity analysis for the primary outcome (complete cases) showed the same result.

Some of the presumed mechanisms by which RBT reduces symptoms are inconsistent with our results and hypothesis, which may be explained by several factors. Our goal was to perform a pragmatic trial which aimed to assess the add-on effect of RBT in all patients with FI referred to a secondary care setting. In practice, this means that patients have different FI complaints in terms of type, severity, and amenability to symptom relief when treated with pelvic physiotherapy. In this cohort, representing hyper- and hyposensitive patients, we aimed to normalize the rectal capacity thresholds. Patients

TABLE I. Baseline Demographic and Clinical Characteristics of Participants and Non-Participants: % (n) Unless Otherwise Stated

	Participants (n = 80)		Non-participants (n = 20)	
	%	n	%	n
Age (years) (mean; SD)	59 3 (11.9)		60.6 (10.2)	20
Gender (female)	90.0	72	95.0	19
Time since onset of FI symptoms (months) (mean; SD)	78.4 (99.5)	80	114.2 (90.5)	18[a]
Vaizey score (mean; SD)	17.8 (2.8)	80	17.4 (3.1)	19[b]
Nature of incontinence		8O		19[b]
Passive FI	10.0	8	5.3	1
Urge FI	33.8	27	47.4	9
Mixed FI	56 3	45	47.4	9

SD, standard deviation; FI, fecal incontinence.
[a]Missing: n = 2.
[b]Missing: n = 1.

TABLE II. Baseline Demographic and Clinical Characteristics: % (n) Unless Otherwise Stated

	RBT + PFMT group (n = 40)		PFMT group (n = 40)	
	%	n	%	n
Age (years) (mean; SD)	58.3 (10.8)		60.2 (12.9)	
<45	10.0	4	10.0	4
45–54	17.5	7	17.5	7
>54	72.5	29	72.5	29
Gender (female)	90.0	36	90.0	36
BMI (mean; SD)	25.3 (4.6)		24.8 (3.4)	
Time since onset of FI symptoms (months) (mean; SD)	78.5 (104.9)		78.3 (95.1)	
Parity (mean number; SD)	2.1 (1.1)		2.3 (1.1)	
0	13.9	5	8.3	3
1	5.6	2	5.6	2
2	47.2	17	47.2	17
>3	33.3	12	38.9	14
Vaizey score (mean; SD)	17.4 (3.0)		18.2 (2.6)	
Nature of incontinence				
Passive FI	10.0	4	10.0	4
Urge FI	32.5	13	35.0	14
Mixed FI	57.5	23	55.0	22
Stool consistency				
Thin	5.0	2	5.0	2
Soft mushy	50.0	20	45.0	18
Solid	22.5	9	37.5	15
Firm	2.5	1	0.0	0
Varying	20.0	8	12.5	5
Origin				
Surgery	12.5	5	17.5	7
Delivery	10.0	4	7.5	3
Spontaneous	17.5	7	12.5	5
Gradually	7.5	3	7.5	3
Other	15.0	6	10.0	4
Unclear	37.5	15	45.0	18
Previous gynecological surgery	58.3	21	41.7	15
Hysterectomy	47.2	17	41.7	15
Current constipating medication (yes)	20.0	8	15.0	6
IAS/EAS deficiency (yes)	52.5	21	42.5	17
IAS deficiency (yes)	27.5	11	25.0	10
EAS deficiency (yes)	42.5	17	30.0	12
Urinary incontinence (yes)	37.5	15	55.0	22
Co-morbid conditions (yes)				
Cardiovascular problems	22.5	9	25.0	10
Diabetes mellitus	7.5	3	10.0	4
Lung problems	12.5	5	5.0	2

RBT, rectal balloon training; PFMT, pelvic floor muscle training; SD, standard deviation; BMI, body mass index; FI, fecal incontinence; IAS, internal anal sphincter defect; EAS, external anal sphincter defect.

received all elements of RBT, although emphasis was placed on those elements appropriate for each type of FI. The interpretation of changes in rectal distension volumes is complicated, since no consensus exists on standards of normal ranges, so conclusions about improvement at the individual level should be interpreted with caution. This was why we analyzed at group level, which may have averaged and diluted the effect of RBT. Subgroup analyses (e.g., hyposensitivity vs. hypersensitivity, passive FI vs. urgency FI) are required to assess the true effect of RBT. Rectal distension volumes may also have been influenced by the potential presence of rectal contents. Finally, the outcomes may indicate loosely related proxy measures of symptom relief or lack of precise knowledge on putative mechanisms of RBT. The only mechanisms explaining the effect of RBT for which our results show evidence is that of control of urge resistance and forceful external anal sphincter contraction to counteract the recto-anal inhibitory reflex. Fatigue reduction of the external anal sphincter was significantly greater in group 1. This may be explained by the additional coordination training in group 1, consisting of a forceful contraction of the external anal sphincter following rectal distension. The remaining outcomes of pelvic floor muscle assessment did not differ between the groups, confirming our expectations.

We can only speculate whether the number of sessions and total treatment period were sufficient to show a dose–response relation. This relation has already been established in patients with stress or mixed urinary incontinence, in that at least 3 months of supervised PFMT should be offered as a first-line approach.[23] Future research should elucidate whether increasing the number of sessions results in further improvement. This would provide stronger evidence for a dose–response relation and biological plausibility of physiotherapy treatment.

Our results are difficult to compare with other studies, due to differences in methodology and outcomes. A meta-analysis

TABLE III. Outcomes of Group Comparisons After Intervention (Intention-to-Treat)*

	Mean (SD) change from baseline				
	PFMT + RBT group (n = 40)	PFMT group (n = 40)	Mean difference (95% CI) in change from baseline as observed	Adjusted mean difference (95% CI) in change from baseline[a]	*P*-value
Vaizey score (range: 0–24)	−5.50 (5.8)	−4.47 (5.0)	−1.03 (−3.59, 1.54)	−1.19 (−3.79, 1.42)	0.37
FIQL total (range: 4–16)	1.67 (2.3)	0.79 (2.3)	0.88 (−0.28, 2.03)	1.01 (−0.07, 2.08)	0.07
Lifestyle subscale (range: 1–4)	0.45 (0.8)	0.21 (0.8)	0.24 (−0.16, 0.63)	0.37 (0.02, 0.73)	0.04
Coping/Behavior subscale (range: 1–4)	0.52 (0.7)	0.20 (0.6)	0.32 (−0.03, 0.66)	0.32 (−0.02, 0.66)	0.06
Depression/Self perception subscale (range: 1–4)	0.23 (0.6)	0.04 (0.7)	0.19 (−0.14, 0.52)	0.24 (−0.04, 0.53)	0.09
Embarrassment subscale (range: 1–4)	0.47 (1.0)	0.34 (0.8)	0.13 (−0.35, 0.62)	0.14 (−0.32, 0.59)	0.55
Post-intervention GPE (range: 1–9)	2.91 (1.4)	3.92 (1.7)	−1.01 (−1.75, −0.27)	—	0.008
Resting pressure (mmHg)	7.86 (22.1)	6.05 (23.3)	1.82 (−9.31, 12.95)	5.46 (−4.73, 15.64)	0.29
Squeeze pressure (mmHg)	6.26 (46.6)	10.20 (33.7)	−3.95 (−24.77, 16.88)	2.85 (−18.96, 24.65)	0.79
Threshold rectal sensation (mAmp)	1.94 (9.5)	1.23 (4.9)	0.70 (−5.03, 6.44)	1.65 (−3.12, 6.42)	0.48
Threshold anal sensation (mAmp)	−0.78 (6.8)	0.87 (7.4)	−1.65 (−5.90, 2.60)	−0.72 (−4.28, 2.84)	0.68
Sensory threshold (ml)	6.68 (39.6)	−0.13 (42.9)	6.80 (−17.12, 30.72)	8.57 (−16.26, 33.39)	0.48
Urge sensation (ml)	29.08 (60.3)	−0.93 (48.0)	30.00 (−6.77, 66.77)	32.37 (−8.85, 73.59)	0.11
Maximum tolerable volume (ml)	39.80 (77.8)	−3.28 (54.0)	43.08 (6.43, 79.72)	49.35 (13.26, 85.44)	0.009
Oxford score EAS (range: 0–5)	0.52 (1.2)	0.93 (1.3)	−0.42 (−0.99, 0.16)	−0.25 (−0.78, 0.28)	0.36
Endurance EAS (range: 0–30 sec)	10.47 (12.7)	7.34 (12.0)	3.13 (−3.71, 9.97)	1.40 (−5.14, 7.94)	0.66
Fatigue EAS (range: 0–5)	1.39 (1.8)	0.24 (1.3)	1.15 (0.42, 1.88)	0.65 (0.26, 1.04)	0.001
Oxford score PF (range: 0–5)	0.48 (1.2)	1.16 (1.4)	−0.68 (−1.31, −0.04)	−0.52 (−1.13, 0.09)	0.09
Endurance PF (range: 0–30 sec)	12.14 (12.0)	11.48 (11.2)	0.67 (−5.39, 6.72)	−3.24 (−7.33, 0.86)	0.12
Fatigue PF (range: 0–5)	1.44 (1.9)	1.10 (2.2)	0.34 (−0.74, 1.41)	−0.28 (−1.12, 0.57)	0.51

SD, standard deviation; RBT, rectal balloon training; PFMT, pelvic floor muscle training; CI, confidence interval; FIQL, Fecal Incontinence Quality of Life Scale; GPE, global perceived effect; EAS, external anal sphincter; PF, pelvic floor.
*Pooled results are presented.
[a]Adjusted for the baseline value of the parameter.

of 11 trials of biofeedback therapy in FI found no differences comparing biofeedback with non-biofeedback therapy (odds ratio, 1.19; 95% CI: 0.69–2.05; $P = 0.54$) or comparing various modes of biofeedback (odds ratio, 1.28; 95% CI: 0.74–2.22; $P = 0.38$).[24] Similar conclusions were reported by Norton et al.,[25] who found that hospital-based computer-assisted sphincter pressure biofeedback yielded no greater benefit than advice or advice combined with instructions on sphincter exercises, for all outcomes. Contrary to our findings, Heymen et al.[26] found that a program combining PFMT and biofeedback was more effective than PFMT alone.

Since the primary outcome did not differ between the groups, we also conducted combined group analyses. The results show that PFMT with or without RBT reduced the Vaizey score by a mean of 5.0 points (95% CI: −6.25 to −3.72; $P = 0.00$), equal to the estimated minimally important change.[17] Secondary outcomes also changed significantly from baseline ($P = 0.00$), except for the physiological variables of squeeze pressure, anorectal sensation, and rectal distension volumes. Our physiotherapy program resulted in 50.5% of the patients being importantly improved. It is not certain whether the observed improvement was solely due to the physiotherapy program, as we did not include a true control group reflecting patient expectations or the natural course of FI.[25] However, given the nature of our patient group in a secondary care setting, with a long history of moderate-to-severe FI symptoms, it seems unlikely that untreated patients would improve to the same extent. Based on this observation, we recommend physiotherapy first before proceeding to surgery.

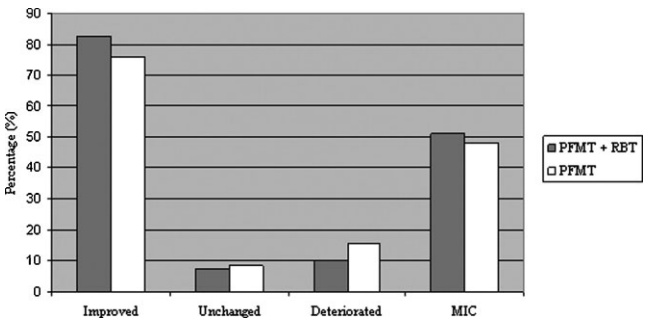

Fig. 2. Change in Vaizey score in both groups after the intervention. PFMT, pelvic floor muscle training; RBT, rectal balloon training; MIC, minimally important change.

CONCLUSIONS

Our study provides no evidence for an add-on effect of RBT to PFMT, although some of the secondary outcomes show beneficial effects of RBT on the control of urgency, external anal sphincter function, subjective rating of improvement, and lifestyle adaptations. Selection of patients benefitting most from RBT remains to be confirmed in studies allowing subgroup analyses.

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