

## RECTAL BALLOON TRAINING AS ADD-ON THERAPY TO PELVIC FLOOR MUSCLE TRAINING IN ADULTS WITH FAECAL INCONTINENCE: A RANDOMISED CONTROLLED TRIAL

### Hypothesis / aims of study

Faecal incontinence (FI) is embarrassing and socially restricting, resulting in poor quality of life. No definitive assessment can be made of the potential role of rectal balloon training (RBT) and/or pelvic floor muscle training (PFMT) in the management of patients with FI (1). It is reported that rectal sensation may be more important than sphincter strength to relieve symptoms. We hypothesised that RBT as an add-on to PFMT would improve outcomes.

### Study design, materials and methods

A single-blind, randomised controlled trial among adults with FI compared the effectiveness of RBT and PFMT versus PFMT alone from August 2006 to May 2009 (2). Inclusion criteria were a Vaizey score of at least 12, FI complaints lasting at least six months, and failure of dietary measures and medication. Eighty patients, recruited from the Maastricht University Medical Centre, were block-randomised by means of a computer-generated list. Treatment was administered by specialised and trained physiotherapists according to a standardised protocol and consisted of 12 sessions within nine weeks. PFMT aimed to maximise strength, improve duration of strength, and improve timing and coordination of contractions of the pelvic floor muscles and anal sphincter. RBT was based on retraining the sensory threshold and coordination training. Primary outcome was based on the Vaizey score, ranging from 0 (complete continence) to 24 (complete incontinence). Secondary outcomes were the Fecal Incontinence Quality of Life Scale (FIQL, a higher score indicates better quality of life), nine-point global perceived effect score (1=very much improved, 9=very much worse), anorectal manometry, rectal distension volumes, thresholds of anorectal sensation, and pelvic floor muscle assessment following the PERFECT scheme (3). Researchers were blinded to treatment assignment. A pre-calculated 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). Adjusted group differences were analysed using ANCOVA with post-intervention measurements as dependent variable and baseline measures as covariates. Analyses were by intention to treat with a P-value indicating statistical significance. Missing values were completed using the multiple imputation procedure.

### Results

Forty patients were assigned to combined RBT with PFMT and 40 to PFMT alone. Groups were comparable in terms of baseline demographic and clinical characteristics. Ten patients (12.5%) dropped out during or after treatment. Completion rates did not differ between groups ( $P=0.31$ ). Patients were evaluated at a mean of 6.8 weeks ( $SD=5.3$ ) after completing treatment. Adding RBT did not result in a significant improvement in the Vaizey score (mean difference -1.19; 95% confidence interval (CI) -3.79–1.42;  $P=0.37$ ). Secondary outcomes favouring RBT were: Lifestyle subscale of the FIQL (0.37; 95% CI 0.02–0.73;  $P=0.039$ ), global perceived effect (-1.01; 95% CI -1.75– -0.27;  $P=0.008$ ), maximum tolerable volume (49.35; 95% CI 13.26–85.44;  $P=0.009$ ), and fatigue (repetitions of maximum contractions) of the external anal sphincter (0.65; 95% CI 0.26–1.04;  $P=0.001$ ). Overall, 50% of patients were considered improved according to the minimally important change (Vaizey change  $\geq 5$  points).

### Interpretation of results

RBT with PFMT was equally effective as PFMT alone. Secondary outcomes show beneficial effects of RBT on urgency control, global perceived effect and lifestyle adaptations. Our findings suggest that selected categories of patients may benefit from RBT as an add-on to PFMT. Selection of patients benefitting most from RBT remains to be confirmed. Fifty percent of patients with moderate to severe FI had a clinically relevant improvement, so referral for conservative management, with no adverse effects and relatively low costs, should be considered before surgery.

### Concluding message

The limited evidence from previous studies, combined with the results of our trial, suggests opportunities for RBT, but will not change the existing recommendations as yet, which is relevant for the development of practice guidelines.

### References

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3. Laycock J, Jerwood D. Pelvic floor assessment: The PERFECT scheme. *Physiotherapy* 2001;87(12):631-642

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**Is this a clinical trial?**

Yes

**Is this study registered in a public clinical trials registry?**

Yes

<i>Specify Name of Public Registry, Registration Number</i>	ISRCTN 8640169
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Medical ethics committee of the University Hospital Maastricht/Maastricht University
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes