Rectal balloon training as add-on therapy to pelvic floor muscle training in adults with faecal incontinence: a randomised controlled trial

Esther MJ Bolsa, Bary CM Berghmans, Rob A de Bie, Bas Govaert, Bart van Wunnik, Martijn W Heijmans, Erik JM Hendriks, Cor GMI Baeten

Department of Epidemiology, School for Public Health and Primary Care (CAPHRI), Maastricht University Medical Centre (MUMC+), Maastricht, the Netherlands

CAPHRI School for Public Health and Primary Care, MUMC+, Maastricht, the Netherlands

Centre for Evidence Based Physiotherapy, MUMC+, Maastricht, the Netherlands

Pelvic care Center Maastricht, MUMC+, Maastricht, the Netherlands

Department of Surgery, MUMC+, Maastricht, the Netherlands

Department of Epidemiology and Biostatistics, VU University Medical Centre Amsterdam, the Netherlands

Background
Rectal sensation may be more important than sphincter strength to relieve faecal incontinence (FI) symptoms. Hypothesis: a combined physiotherapy program with rectal balloon training (RBT) and pelvic floor muscle training (PFMT) shows more symptom relief compared to PFMT alone.

Objective
To assess the effectiveness of RBT as add-on therapy to PFMT in adults with FI referred to a secondary care setting.

Methods
Design: pragmatic single-blind, randomised controlled trial.
Patients: (1) adults with FI complaints ≥ months, (2) failure medication and dietary adaptations.
Primary outcome: Vaizey score (range 0-24).
Secondary outcomes: Fecal Incontinence Quality of Life Scale (FIQL), nine-point global perceived effect (1=very much improved, 9=very much worse), anorectal manometry, rectal distension volumes, thresholds of anorectal sensation and PFM coordination.

Treatment: standardised programme, 12 sessions during 9 weeks. Specialised and trained physiotherapists nationwide. PFMT: education, advice, awareness, endurance, peak force, coordination and home exercises. RBT: sensory and coordination protocol (see photograph). Analyses: ANCOVA, intention to treat (multiple imputation).

Results
Patients: 101 assessed for eligibility, 80 randomised (Table 1). Drop-out: n=10 (12.5%). Group completion rates equal (P=0.31). Follow-up: 6.8 weeks (SD 5.8) after completing physiotherapy, comparable for both groups (P=0.41).
Primary outcome: adding RBT resulted in a small, but not significant improvement in Vaizey score (Table 2).
Secondary outcomes: no significant differences between groups.

Overall: 50% of patients considered improved according to estimated minimally important change (Vaizey change ≥5).

Table 2. Outcomes of group comparisons after intervention

| Table 1. Patient characteristics: % (n) unless otherwise stated |
|------------|-------|-------|-------|

<table>
<thead>
<tr>
<th></th>
<th>RBT+PFMT (n=40)</th>
<th>PFMT (n=40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) (mean; SD)</td>
<td>58.3 (10.8) 60.2 (12.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender (female)</td>
<td>90.0 36 90.0 36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (mean; SD)</td>
<td>25.3 (4.6) 24.8 (3.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time since onset FI (m) (mean; SD)</td>
<td>78.5 (104.9) 78.3 (95.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parity (mean number; SD)</td>
<td>2.1 (1.1) 2.3 (1.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaizey score (mean; SD)</td>
<td>17.4 (3.0) 18.2 (2.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Passive FI</td>
<td>10.0 4 10.0 4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urgency FI</td>
<td>32.5 13 35.0 14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixed FI</td>
<td>57.5 23 55.0 22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IAS/EAS deficiency (yes)</td>
<td>52.5 21 42.5 17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary incontinence (yes)</td>
<td>37.5 15 55.0 22</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*No significant differences between groups.
Note: RBT, rectal balloon training; PFMT, pelvic floor muscle training; SD, standard deviation; BMI, Body Mass Index; FI, faecal incontinence; m, months; IAS/EAS, internal/external anal sphincter.

Discussion
Effectiveness RBT possibly influenced by:
* Heterogeneity study population.
* Decreased power.

Conclusions
* RBT with PFMT is equally effective as PFMT alone.
* Selection of patients benefitting most from RBT needs confirmation.

References
