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Alimentary Tract

Perineal retraining improves conservative treatment for faecal incontinence: A multicentre randomized study

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ABSTRACT

Background: Anal incontinence is a frequent complaint that profoundly affects quality of life. Our aim was to determine whether perineal retraining gives additional benefits to standard medical treatment.
Methods: Patients with anal incontinence and a Wexner score >4 were randomly assigned to standard conservative treatment (control) or perineal retraining, including biofeedback, in addition to standard treatments (biofeedback). Diaries, self-administered questionnaires and satisfaction scores quantified the benefits. Self-evaluated improvement was the primary outcome measure. A score ≥3 (in an improvement scale from −5 to +5) defined success.
Results: Overall, 157 patients were included; 80 in the control group (75% females, mean age 60.1 ± 13.2 years) and 77 in the biofeedback group (79% females, mean age 61.9 ± 10.2 years). After a 4-month follow-up, the success rate was significantly higher in the biofeedback group (57% versus 37%; $p < 0.021$). In the biofeedback group, daily stool frequency, leakage, and faecal urgency significantly decreased, and daily non-urgent perception of stool increased. Conversely, symptomatic scores and quality of life scales did not significantly differ between groups. In a multivariate model, the adjusted odds ratio showed that perineal retraining was significantly associated with a higher chance of self-rated improvement (adjusted Odd Ratio [95%CI]: 2.34 [1.14–4.80]; $p = 0.021$).
Conclusions: Perineal retraining offers a moderate but significant benefit for patients suffering from anal incontinence.

1. Introduction

Anal incontinence (AI) is a frequent complaint with potentially devastating consequences for quality of life. A recent study confirmed the high prevalence of this symptom in the general population (8.3% of subjects complain of anal leaking at least once a month), which increases with age (affecting 15.3% of adults older than 70 years) [1]. It has been repeatedly shown that AI results in considerable embarrassment and anxiety [2,3]. Moreover, several studies showed a significant correlation between the severity of AI symptoms and decreased quality of life [2,4].

The non-surgical treatment of AI relies on both dietary counselling and drugs to modify stool consistency, and on behavioural interventions such as biofeedback [5,6]. The efficacy of behavioural management has been advocated in many retrospective or uncontrolled studies [5,7]. AI is not a well-defined pathology but a

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syndrome that groups common symptomatic features, such as faecal leakage and urgency. Bowel habits, stool consistency, cognitive functions, autonomy, locomotion, psychological status, and social considerations may impact AI as much as anorectal physiology [8]. Moreover, these events may induce daily variations of continence that make evaluation of treatment effect more difficult. Several clinical profiles have been defined that imperfectly correlate with anal physiology, such as faecal urgency (associated with decreased squeeze anal pressures) and passive incontinence or soiling (associated with low anal resting pressure) [9,10]. Both conditions may occur in association with each other, and perineal retraining might be more useful in the former condition than in the latter. Unfortunately, no previous study was able to identify specific profiles that might benefit from perineal retraining [9,11,12]. For all these points, there are inter-individual variations in the recorded items and, consequently, large dispersion around the mean values. This may have limited the demonstration of a significant effect of the treatment.

A Cochrane systematic review of all randomized trials evaluating biofeedback and/or anal sphincter exercises was recently published, and concluded that the limited number of trials and their methodological weaknesses did not allow the assessment of the efficacy of these treatments [13]. Recent randomized controlled studies showed discrepancies in the relative efficacy of biofeedback per se, pelvic floor exercises, and supplemental advice and education [12,14–16]. Furthermore, all trials were performed in single referral centres and did not take into account the variability of the biofeedback techniques used in clinical practice.

The goal of this study was thus to conduct a multicentre randomized controlled trial to determine whether a standard medical treatment associated with standardized perineal retraining (including biofeedback) was more effective than standard medical treatment alone.

2. Materials and methods

2.1. Patients

The ORALIA Trial was conducted between September 2006 and March 2010 (recruitment period), and all data were gathered by March 2011. Candidates for inclusion in the trial were patients referred for AI to 8 centres in France (Lyon, Rennes, Nice, Grenoble, and 4 centres in Paris). All patients aged between 18 and 85 years who attended the outpatient clinics of these departments for AI were invited to participate in the trial. AI was defined as involuntary and/or uncontrolled gas and/or stools through the anus. Symptoms had to have been present for at least the last 6 months (i.e. at least a gas or liquid leak once a week for at least 6 months with impact on quality of life), and patients had to have a Cleveland Clinic Faecal Incontinence score (CCFI, Jorge & Wexner score) $\geq$5 [17]. Exclusion criteria were past perineal retraining sessions, vaginal delivery or perineal surgery within the last 6 months, active inflammatory bowel disease, indication of a surgical treatment for AI (e.g. rectal prolapse), and ongoing sacral nerve stimulation. All patients underwent an initial examination to determine eligibility for the study, and recto-anal manometry and endo-anal ultrasound (EUS) were performed before all eligible patients were randomized into treatment groups.

2.2. Ethics

An Ethics Committee (CPP Sud-Est III on August 6th, 2006) approved the study, which was declared on ClinicalTrials.gov (NCT00387439). Written informed consent was obtained from all patients. All authors had access to the study data and reviewed and approved the final manuscript.

2.3. Therapeutic interventions

Before the start of the study, a preliminary meeting brought together all the investigators in order to standardize diagnostic procedures and therapeutic options. These options were based on the French Guidelines for therapeutic management of faecal incontinence [18]. The investigators' group proposed to adapt bowel management with dietary counselling (dietary book support) and stool transit-modifying drugs according to the quality of bowel transit (normal, constipation, or diarrhoea). Osmotic laxatives, bulking agents, and loperamide were the main options [18]. The physiotherapists involved in the trial were part of a national network and could be either hospital-based or in private practice. Thus, a preliminary step also included the agreement on and the writing of a standardized perineal retraining protocol and the formal training of the physiotherapists. The standardized protocol was based on 20 sessions of 30 min with the physiotherapist, all performed within a 4-month period at an initial rate of 2–3 sessions per week for the first 4 weeks, and 1–2 sessions per week thereafter. These 20 sessions included 5 initial sessions dealing with education, optimization of rectal evacuation (anal relaxation, body position, and gentle squeezing pressure), and rectal sensitivity (rectal isovolumic distension testing in order to decrease the first sensation threshold into normal ranges). The retraining of anal voluntary squeeze and abdominal and pelvic coordination completed them. The following 15 sessions aimed at acquiring competence at anal voluntary squeeze and at abdominal and pelvic coordination (manual techniques, BFB with anal device, and abdominal breathing). The squeezing exercises combined long-duration contractions and short-duration contractions using a biofeedback device. Each series of contractions was separated from the other by a resting period of which the duration was twice as long as the squeezing period. These sessions were completed by daily home-based anal exercises combining short and long contractions [14,19].

2.4. Standardized measurements

Standardized interviews and self-administered questionnaires were based on the CCFI, and a validated constipation score (KESS) [17,20]. Quality of life was assessed by a specific Faecal Incontinence Quality of Life scale (FIQL) and by a non-specific Quality of Life scale (SF12) [21,22]. At home, patients filled out daily diaries of stool, gas or liquid leaking events, and the number of pads used. A diary of the home-based rehabilitation training was also completed. To independently quantify their own clinical improvement, patients were invited to evaluate the evolution of their AI symptoms using a scale ranging from −5 (significant aggravation) to +5 (significant improvement), with 0 meaning no significant change [14]. This assessment was obtained before the follow-up visit with the physician in order to minimize the impact of the patient–doctor relationship.

2.5. Randomization

Patients were randomly assigned to 1 of the 2 groups: standard medical conservative treatment alone (SC group) or perineal retraining treatment including biofeedback (BFB group). Both groups received counselling with the delivery of dietary recommendations and adapted treatments to control their bowel movements. For all patients, modification of laxative dose and/or loperamide dose was continued throughout the study. Randomization was centralized at the public health department of the University Hospital of Lyon and was stratified by centre in blocks of 6.