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Biofeedback vs verbal feedback as learning tools for pelvic muscle exercises in the early management of urinary incontinence after radical prostatectomy

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Objective To evaluate the comparative effectiveness of electromyographic (EMG) biofeedback with verbal instructions as learning tools of pelvic muscle exercises (PMEs) in the early management of urinary incontinence after radical prostatectomy.

Patients and methods Forty-two consecutive patients (mean age 64 years, SD 4.2), with urinary incontinence after radical retropubic prostatectomy for localized prostate cancer, were randomized to receive biofeedback (group A, 28 men) or verbal feedback (group B, 14 men) as learning tools for PMEs immediately after catheter removal. Group A received 15 sessions of EMG biofeedback (three times weekly, 30 min each) and group B verbal instructions. Evaluation at baseline and 1, 2, 3 and 6 months included the 1-h pad-test and a questionnaire (number of pads/day and incontinence episodes).

Results By the last follow-up, 27 patients had received biofeedback and 15 verbal instructions. Data were analysed according to the intention-to-treat principle. Urine loss as assessed by the 1-h pad-test at baseline, 1, 2, 3 and 6 months was 39, 18, 7, 4 and 3 g for group A and 31, 11, 3, 1 and 0 g for group B, respectively ($P > 0.05$). The number of pads/day was 3.9, 3.4, 1.2, 0.8 and 0.4 for group A and 3.6, 1.8, 0.9, 0.4 and 0.2 for group B, respectively ($P > 0.05$). The overall continence rate at 6 months was objectively (urine loss >1 g) 91% and subjectively (0–1 pad/day) 95%.

Conclusion Intensive verbal instructions and biofeedback were both very effective behavioural methods and learning tools for PMEs in the early management of urinary incontinence after radical prostatectomy.

Keywords prostate carcinoma, radical prostatectomy, urinary incontinence, biofeedback, verbal feedback

Introduction

Prostate cancer is the most commonly detected malignancy in men in industrialized countries and represents the second commonest neoplastic cause of death after lung cancer. During 1996, 317 000 new cases were diagnosed in the USA, with a total mortality of 41 400 patients [1]. In the European Union, ≈ 35 000 deaths are recorded annually [2].

Radical prostatectomy is the oldest and possibly the most effective method of treating localized prostate cancer. However, this operation causes many complications, among which urinary incontinence is the most distressing [3,4]. The reported incidence of urinary incontinence varies, at 2–87% of patients, with significant leakage in 0.3–12.5% [5–9]. This wide discrepancy can be explained by differences in the definition of incontinence, in the duration of follow-up and the mode of assessment. The pathophysiology of urinary incontinence after radical prostatectomy is not completely defined, but it seems that several factors are implicated (sphincteric weakness, detrusor dysfunction, anastomotic stricture and central disturbance of the fine control of muscle function). In most cases incontinence is probably caused by sphincteric insufficiency [10–14].

Current therapeutic options for managing incontinence after prostatectomy (arising from sphincteric insufficiency) include the insertion of an AUS [15] and the endoscopic submucosal injection of bulking materials (Teflon, collagen, Macroplastique®) [16,17]. These methods are interventional, expensive and can fail [18]. An alternative and conservative treatment is behavioural training using pelvic floor muscle exercises (PMEs) to increase the strength and endurance of the pelvic floor [19]. The efficiency of PME has been well documented in women with genuine stress incontinence [20]. For the correct and isolated contraction of these muscles the patient must learn the technique by some method; behavioural methods include performing PMEs under verbal instructions, or using biofeedback. Several studies

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in women have shown that PMEs learned by biofeedback give better results in restoring continence than when learned by verbal instruction [21–23]. There are few published studies on the role of these behavioural methods in managing incontinence after prostatectomy [19,24–26]. Thus the aim of the present study was to compare the effectiveness of EMG biofeedback with verbal instructions as learning tools for PMEs in the early management of incontinence after radical prostatectomy.

Patients and methods

In a multicentre prospective randomized trial, patients incontinent after radical retropubic prostatectomy for localized prostate cancer were evaluated. All patients underwent prostatectomy by the Walsh technique, carried out by one of four experienced surgeons (G.A., C.D., C.C. or C.T.). Initially, 1 week after catheter removal, all patients were assessed by their surgeon and referred for further treatment. The inclusion criteria for the trial were: patients with objectively confirmed urinary incontinence, no significant perioperative complications (ureteric or rectal injury, urine leakage from anastomosis, thrombo-embolism), no history of preoperative incontinence and pelvic or lower urinary tract operations, no psychiatric history, a recognised ability to participate in a learning programme, good general condition and willingness to participate in the study.

During the first visit patients were informed about the aims and perspectives of the study. Eligible patients consented to random (2 : 1) assignment to either biofeedback (group A) or verbal instructions (group B), as a learning tool for PMEs, with randomization based on order of reference. All patients were familiarized with the anatomy and physiology of the pelvis, using appropriate photographs and anatomical models. For the initial evaluation of incontinence, all patients underwent the 1-h pad test, as recommended by the ICS [27].

Patients randomized to group A were referred to a specialist in physical therapy and rehabilitation (C.A.R.). These patients had 15 sessions of EMG biofeedback (three times weekly) of 30 min duration each. For the purpose of the study, a two-channel EMG biofeedback apparatus (Totem Biofeedback, BEAC, Italy), was used, with one channel for perineal and the other for abdominal muscles, and the signal received through surface electrodes. During the initial two to three sessions, a strong emphasis was placed on the specificity of muscle contraction (isolated contraction of the pelvic muscles with the minimum possible activity of the abdominal muscles). During the following sessions, the exercises were designed to increase the power, endurance and coordination of the pelvic floor muscles. In parallel, patients in group A practised 50–100 exercises daily at home.

Patients in group B were taught in detail about the methods of constricting their pelvic muscles, with special emphasis on avoiding constricting the abdominal muscles simultaneously. The patient was placed in the lateral decubitus position and the index finger of the instructor inserted in the patient's rectum. The patient then contracted the anal sphincter around the index finger while the instructor's left hand palpated the abdominal muscles, checking for simultaneous contraction. Verbal guidance and feedback of the contractions were used to instruct the patient how to correctly and selectively contract the anal sphincter while relaxing the abdominal muscles. In addition, these patients received an informative leaflet with these instructions (Appendix) and a telephone number for further explanations. Home practice comprised 80–100 exercises daily, divided in four sessions of 20–25 exercises each. The duration of each constriction was 3–5 s with submaximal strength (70%) and a relaxation period of 6–10 s between the exercises. Initially, patients practised these exercises while supine but later when sitting and standing. After the first month patients were encouraged to practise the exercises during normal daily activities, including movements that provoked incontinence.

Patients in both groups were evaluated at 1, 2, 3 and 6 months of treatment, objectively using the 1-h pad test and subjectively with a questionnaire (to determine the number and extent of incontinence episodes, number of pads used per day, and any LUTS). For the best intra- and inter-patient estimates in the pad test, a special type of 'pocket pad' was used which covered only the penis, thus reducing the interference from sweat on the pad weight gained during the test.

Because urodynamic studies are invasive they were abandoned during the early part of the study and used only in patients with incontinence after the 6-month follow-up. During the study patients with irritative symptoms and a negative urine culture received empirical anticholinergic medication (oxybutynin).

To account for patients who might not adhere to the treatment schedule, the results were analysed using the intention-to-treat approach [28]. At 1, 2, 3 and 6 months the difference between the groups in urine loss and pad use were assessed. Student's *t*-test was used with normally distributed variables, or otherwise Wilcoxon's nonparametric test. Finally, an analysis of the repeated measurements at 1, 2, 3 and 6 months was used to test differences between groups in the improvement. Such analysis optimally uses the longitudinal design of the study, while accounting for possible differences in baseline characteristics.

Results

Forty-two patients fulfilled the eligibility criteria of the trial and agreed to participate; 28 (mean age 63.1 years, SD 4) were allocated to group A while the remaining 14 (mean age 65.8 years, SD 4.3) received verbal training. One of the patients initially randomized to group A could not follow the programme (for personal reasons) but performed PMEs under verbal instruction. The duration of hospitalization of the patients was 1–2 weeks; the mean (SD) duration of catheterization was 19 (4) days. There was full compliance by the patients with the study protocol.

Of the 42 patients, three in group A and two in group B reported irritative symptoms during the first month. All had negative urine cultures and receive oxybutynin 2.5–5 mg three times daily, with some reduction in the irritative symptoms.

The results at 1, 2, 3 and 6 months after initiating the trial are essentially as shown in Fig. 1a,b. In general, the level of incontinence in patients using PMEs, in both groups, declined over 6 months; patients in group B appeared to regain continence earlier than those in group A but the difference was not statistically significant. Using a repeated-measurement design, accounting for the differences in baseline characteristics between the groups, the conclusions of the univariate analysis did not change (Fig. 1a,b). Group B had less urine loss at assessment, with correspondingly fewer pads used. However, again the differences were not statistically significant. By the end of the study, only four of the 42 patients remained incontinent, as shown by the results of pad test (urine loss >1 g). Thus, the objective continence rate 7 months after surgery was 91%. Only 11 of 42 patients were regularly using one or more pads/day, so the percentage of pad-free patients at 7 months was 74%, with only two patients using two or more pads/day, giving a 95% socially acceptable continence rate.

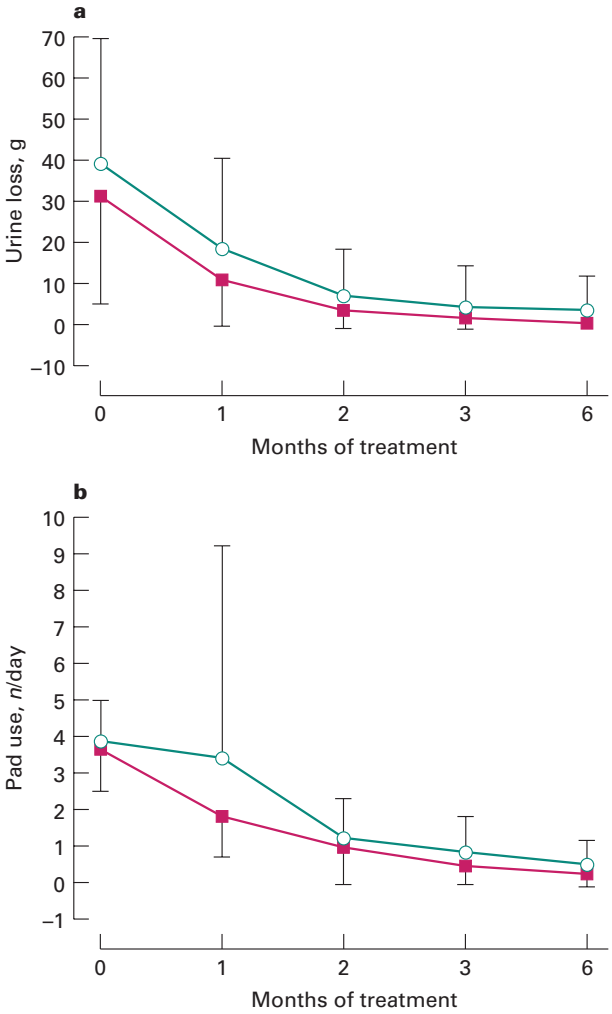

Fig. 1. Estimated mean (with error bars showing the SD) **a,** urine loss and **b,** number of pads used daily, for group A (green open circles) and B (red closed squares), with the means corrected for age (64.0 years), catheter use (19.3) and urine loss (**a**) and number of pads (**b**) at the start of treatment. The uncorrected values were similar and the differences between groups were not significant.

Discussion

Urinary incontinence is defined by the ICS as the involuntary loss of urine that is a social or hygienic problem and which is objectively demonstrable [27]. Because currently there are more newly diagnosed cases of prostate adenocarcinoma, especially in early stages where curative treatment is feasible, the number of radical prostatectomies has also increased. Consequently, there are increasingly more relatively young and socially active men with some form of urinary incontinence.

The application of PMEs (Kegel exercises) has been extensively studied in women with genuine stress incontinence. The treatment is easy to apply, has few side-effects and is very acceptable to patients. For female incontinence it is well documented that the effect of PMEs is better when they have been learned using some form of feedback (verbal or biofeedback). Indeed, several studies have shown the advantages of biofeedback in regaining of continence [21,22]. Although incontinence after radical prostatectomy has many causes the main factor seems to be insufficiency of the sphincteric mechanism [10–12], caused by the anatomical and functional changes during surgery (direct surgical trauma, neural injury, decreased elasticity of the bladder neck). Therefore, strengthening the distal sphincteric mechanism by PMEs seems a logical and promising approach. However, there are few studies in which PMEs with or without biofeedback have been used for managing such incontinence [19,24–26]. Possible limitations of these studies are the few patients

included, the subjective method of evaluating incontinence and the wide range in interval between surgery and initiating treatment.

In the present study, patients with varied grades of incontinence after retropubic radical prostatectomy were evaluated soon after surgery. To minimize the possible influence of other contributing factors strict inclusion criteria were used. The careful selection of participants and the initiation of the training programme soon after surgery, when patients have not become accustomed to the idea of wearing a pad and thus desire to remain free of them, might explain their complete compliance with the programme.

An accurate estimate of the severity of urine loss is not only necessary for an appropriate follow-up of incontinent patients, but also for interpreting the results of a study. Classically, useable methods are divided in objective and subjective [29]; the former include the amount of urine loss estimated by different pad tests and various urodynamic investigations, and the latter include questionnaires about the patient's perception of his continence status, especially the number of pads used daily. Subjective data are less reliable, with possible under- or over-estimation of the severity of incontinence, but they represent the patients' perception, and for the patient, perception is reality.

To objectively assess the grade of incontinence [30] and the progress during treatment, the ICS 1-h pad test was used. This test was preferred because it is simple, cheap and has acceptable reproducibility. Patients were considered continent when the weight gain of the pad during the test was $\leqslant 1$ g. A more objective evaluation of incontinence would be urodynamic investigations, i.e. filling cystometry and pressure/flow study, urethral closure pressure profilometry, abdominal and retrograde leak-point pressures [31] at baseline. However, these investigations are invasive, especially soon after surgery, and although they provide important information about the cause of incontinence, they do not correlate with subjective rates (overestimating clinically important incontinence rates) [6]. Thus such investigations were postponed and used only in refractory cases.

The usage of pads/day correlates better with the actual leakage than does the patient's quantification of his urine loss [32]. For a better intra- and inter-patient comparison, but also for their convenience, patients were encouraged to use the smallest pad that could protect them adequately.

The present results suggest that neither the severity of incontinence initially nor the age of the patient was correlated with treatment outcome, although the sample size is small for such generalization. The results were excellent in both groups, giving an objective continence rate at 7 months after surgery of $\approx 90\%$. This success is explained partly by the effect of treatment and by the initial selection of patients. An important and unmeasurable factor that seems to influence the final outcome is surgical skill [33]. In the present study, four experienced surgeons referred patients and this might have contributed to the results. There was no significant difference in outcome between the groups; the absolute values favoured group B, but this might be a result of the coincidental randomization of the four patients who remained incontinent (pad test >1 g) to group A. The similarity in results is also explained by the intensity of learning in group B; exercises were not only described but supported by an explanation of the control of the appropriate muscular response.

The two patients who were using two or more pads/day at the 6-month follow-up were contracting their pelvic muscles early and had a stable grade of incontinence during the study. They were assessed urodynamically at 6 months but had no abnormality, except for a positive stress test. During cystoscopic evaluation with no anaesthesia they had a normally appearing vesicourethral anastomosis and could voluntarily contract the external sphincter. Both of them requested a better solution and had an AUS implanted.

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Abbreviation: **PME**, pelvic muscle exercise.

Appendix

Dear Mr.....
You have recently undergone an operation (radical prostatectomy) for the treatment of the malignant growth of your prostate gland. A common complication of this operation is some degree of involuntary urine loss (urinary incontinence), which in most cases can be managed adequately.

For the management of your urinary loss, it is recommended to regularly perform exercises of the muscles of the pelvic floor, which are commonly called Kegel's exercises. They do not involve any simultaneous medication and pose little risk of side-effects. An important point during the performance of these exercises is the relaxation of other muscle groups, namely abdominal and gluteal muscles, so try to keep your stomach and buttocks relaxed.

To identify and correctly contract the pelvic muscles, imagine that you try to 'hold back bowel movements or passing gas'. During this action you should feel the opening of the rectum contract. Tighten the muscles for 3–5 s and then relax for 6–10 s. Repeat this sequence 20–25 times. Do the set of 20–25 contractions 3–4 times daily. During the first week of the programme, perform the exercises while supine, but later while sitting and standing. After the initial 'learning' period, perform the exercises when you need them, i.e. just before sneezing, coughing or straining.

Please keep in mind: be patient, you are going to see good results after a few weeks' training! Try to comply with the above schedule. Your dedication to the programme is going to be the biggest part of your success!