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EFFICACY OF A SUPERVISED, AFFORDABLE PROGRAM OF PERIOPERATIVE PELVIC FLOOR MUSCLE TRAINING IN IMPROVING THE RECOVERY OF CONTINENCE AFTER RADICAL PROSTATECTOMY: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

Previous studies reported on the efficacy of preoperative or early postoperative assisted program of pelvic floor muscle training (PFMT) in hastening the recovery of urinary continence (ROC) after radical prostatectomy (RP) [1-3].

We aimed to evaluate the efficacy of a perioperative, supervised, nonintensive PFMT program in reducing the incidence, duration and severity of urinary incontinence (UI) and in improving the health-related quality of life (HRQL) in patients undergoing retropubic radical prostatectomy (RP).

Study design, materials and methods

A prospective, monocentric, randomized controlled trial was designed. The treatment group received the day before RP and after catheter removal a supervised training session with electromiographic biofeedback, oral and written instructions on Kegel exercises and a structured program of home PFMT, with a diary, to be performed three times a day for at least three days a week. The control group received after catheter removal only oral and written instructions on Kegel exercises to be performed at home. All patients were followed for a period of at least six months after catheter removal. Patients in the treatment group underwent also control visits at monthly intervals after removing the catheter with a session of PFMT with biofeedback at each visit . Patients in the control group were contacted by phone at 1, 3 and 6 months after catheter removal. At each visit / interview compliance with the exercises and urinary outcomes were assessed by a third person. All patients also received standardized self-administered questionnaires: ICIQ-UI, ICIQ-OAB, UCLA-PCI, IPSS-QoL. The primary outcome was the rate of self-reported ROC at six months. Continence was defined as ICIQ-UI score = 0. The secondary outcomes were number of incontinence episodes and diapers per week, scores of ICIQ-OAB, UCLA-PCI and IPSS-QoL. Post hoc power calculation showed that the study sample size was adequate to detect a difference of 31% in the rate of ROC, with a type I error of 0,05 and a type II error of 0,10. The variables considered in the study were analyzed and described as mean ± SD. The differences between groups were analyzed using the Student t-test and nonparametric Mann-Whitney test (threshold p= 0.05). Time to ROC was analyzed using the Kaplan-Meier survival curve. The software used was GraphPad Prism 5 for Windows. The Consolidated Standards of Reporting Trials (CONSORT) checklist and its indications were strictly followed in performing the study. Randomization was computer-generated, with allocation concealment by opaque sequentially numbered sealed envelopes.

Results

From November 2009 to March 2010, 32 out of 34 eligible patients (mean age 66±5.8 years) underwent RP and were randomly assigned to the treatment or control group. The two patients excluded refused the partecipation to the study. The two groups of patients were homogeneous for all pre and intra-operative parameters examined (age, BMI, prostate weight, preoperative PSA, LUTS, blood loss, pTNM, “nerve-sparing” procedures, pre/postoperative hormone therapy). In the treatment group, continence has been reached by 6/16 (37.5%), 8/16 (50%) and 10/16 (62.5%) patients at the first, third and sixth month after catheter removal, respectively. Six patients (37.5%) did not reach the ROC. In the control group only 1 patient (6.25%) reached ROC and it happened at the second month after catheter removal; this difference was statistically significant ($p < 0.000$).

At Kaplan-Meier analysis (Fig.1) a statistically significant difference has been observed in the probability to recover the continence status at 6 month ($p = 0.0007$; Hazard ratio = 12.9154; 95% CI = 2.5123-32.0673).

The analysis of UCLA-PCI and ICIQ-OAB scores showed statistically significant differences in favor of the treatment group at 3 (403.81 vs 272.44 with p=0.006 and 10.12 vs 13.19 with p=0.03 respectively) and 6 months (422.50 vs 274.25 with $p = 0.003$ and 9.06 vs 12.62 with p=0.01 respectively) follow-up. Also the number of incontinence episodes per week and the number of diapers per week was significantly lower for patients in the treatment group at both 3 (3.84 vs 14 and 1.50 vs 4.56 respectively) and 6 months (2.72 vs 13.06 and 1.31 vs 4.12 respectively).

The analysis of IPSS-QoL questionnaire mean values showed no statistically significant difference in favor of patients in the treatment group at 1 ($p = 0.08$), 3 ($p = 0.10$) and 6 months ($p = 0.06$).

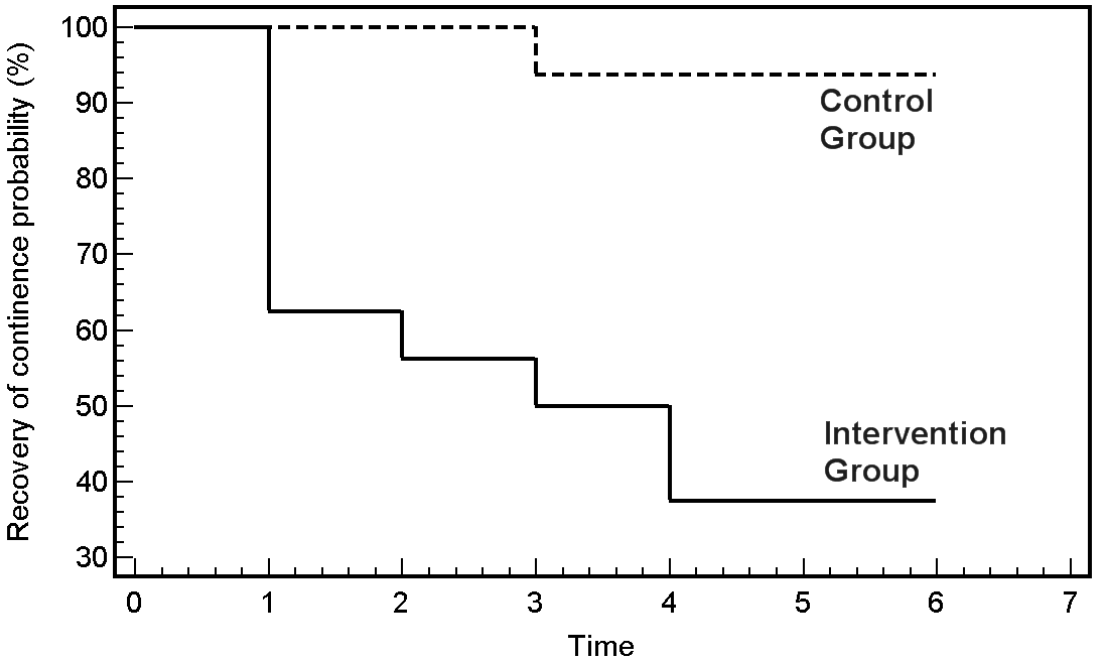
Interpretation of results

The present randomized controlled trial showed that the use of a structured and sustainable PFMT program, including a single preoperative biofeedback session combined with an early postoperative, supervised PFMT, significantly reduces the postoperative rate, duration and severity of urinary incontinence in patients undergoing RRP. The impact on HRQL appeared less evident, although a trend for a better HRQL was observed in the treatment group.

Concluding message

The adoption of an early periprostatectomy supervised PFMT is effective in improving the recovery of continence, even using a less intensive but more affordable program requiring only a monthly supervised session.

Fig.1 - Kaplan-Meier analysis of the probability to recover the continence status (ICIQ score=0) in the control and intervention group.



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Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**No invasive or harmful diagnostic tools or treatments were used. Control group received the standard of care. The work was anyway carried out in accordance with the ethical standards of the responsible institutional committee on human experimentation.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**