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Mini Review

Superiority of the combination of electrostimulation and biofeedback on self-administered physical exercises for post radical prostatectomy urinary incontinence

Alessandro Sciarra[1*], Stefano Salciccia[1], Alessandro Gentiluccia[1], Susanna Cattarino[1], Paolo Casale[2], Francesco Del Giudice[1] and Gianna Mariotti[1]

[1]Department of Urology, Sapienza Rome University, Rome, Italy
[2]Department of Urology, Humanitas Hospital, Milan Italy

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Urinary incontinence (UI) after Radical Prostatectomy (RP) is a relevant side effect, able to early develop after catheter removal and to influence the quality of life of men. The determination of the number of pads it is not a valid tool to quantify urine leakage and its variation during treatments and it only consents to define a pad or no-pad status among patients. Pad tests are probably the most objective method to quantify leakage in UI, whereas questionnaires can describe the impact on patient's quality of life. There are several randomized prospective clinical trials evaluating the role of non-invasive rehabilitative methods in managing post-RP UI.

Key words: Biofeedback, electric stimulation, pad test, pelvic floor muscle training, radical prostatectomy, urinary incontinence

INTRODUCTION

How to evaluate urinary incontinence after radical prostatectomy

Urinary Incontinence (UI) after Radical Prostatectomy (RP) is a relevant side effect, able to early develop after catheter removal and to influence the quality of life of men. Although technical improvements in RP, this surgical procedure remains significantly associated to the development of UI. Rates significantly varied from 5% to 40%, depending on the characteristics of the populations and on the methods used (Burkhard et al., 2020, Dubbelman et al., 2010). The evaluation of UI in patients should always combine objective quantitative and individual subjective parameters. These two estimations often do not correspond, with patients that consider at low impact on their social life a significant quantitative leakage of urine and others that consider a significant symptom few drops. Pad tests are probably the most objective method to quantify leakage in UI, whereas questionnaires can describe the impact on patient's quality of life. These two tools should be homogeneously used in clinical trials on post RP UI so to have comparable results. The determination of the number of pads it is not a valid tool to quantify urine leakage and its variation during treatments and it only consents to define a pad or no-pad status among patients. It exists an extreme variability in the use of pad among patients in relation of few or relevant leakages that negatively influence quantification of UI.

Pad testing is a specific tool to quantify UI and to follow results during or after treatments for UI. A 1-hour pad test could be more standardized in the activities performed by the patient in a limited time but it does not represent a complete real world situation for a specific patient. A day (24-hour) pad test is a more reliable picture of a real world situation for the patient but it can be more influenced by variations in daily activities from different patients and different follow-up intervals.

Non-invasive rehabilitative treatments

Non-invasive therapies are often prescribed first and pelvic floor muscle exercises (PFME) can be used to improve strength of the pelvic floor. Several patients after RP are invited to start a non-guided program of pelvic floor muscle exercises, often the Keagel exercises. In particular, self-administered PFME programs are often not guided by a physiotherapist andtime of PFME session varied from 5 to 60 min, with intervals from seven days to just once per week.

European Association of Urology (EAU) guidelines

*Corresponding author. Georgi V. Petkov, E-mail: gp12kov@uthsc.edu.

(Eastham et al., 1996), underlines that PFME may speed the recovery of continence after surgery but aspecific biofeedback (BF) guided program, a pelvic floor electrical stimulation (PFES) or their combination can be alsoproposed. PFME guided with a BF program and PFES treatments are more homogeneously performed under the assistance of a physiotherapist and less variability in time of session and week intervals is present. A specific biofeedback (BF) guided program (under visual, tactile, or auditory stimuli) can better help patient to perform a correct contraction of PFM. An alternative non-invasive treatment is functional pelvic floor electrical stimulation (PFES). PFES artificially stimulates the pudendal nerve and its branches to cause direct and reflex responses of the urethral and periurethral striated muscles. Methods of delivery of ES vary considerably, and ES can also be combined with other conservative therapies, e.g., PFME and BF.

There are several randomized prospective clinical trials evaluating the role of these non-invasive methods in managing post-RP UI. However, as stated by Cochrane reviews (Franke et al., 2000) and EAU guidelines [Eastham et al., 1996], the data is still controversial, and the level of evidence remains uncertain. Therefore, we performed a systematic review and meta-analysis (Filocamo et al., 2005) on the role of non-invasive treatments, such as PFME without and with BF and PFES in patients with post-RP UI (Table 1). We analyzed studies (Floratos et al., 2002, Glazener et al., 2011, Gomes et al., 2018, Hunter et al., 2004, Laurienzo et al., 2018, Mathewson-Chapman 1997, Moore et al., 2008, Mariotti et al., 2015, Mariotti et al., 2009, Manassero et al., 2007, Moore et al., 1999, Nitti 2001, Nilssen et al., 2012, Overgård et al., 2008, Pedriali et al., 2016, Pan et al., 2019, Park et al., 2012, Ribeiro et al., 2010, Sciarra et al., 2021, Simeit et al., 2010, Tienforti et al., 2012, Tantawy et al., 2019, Van Kampen et al., 2000, Wille et al., 2003, Yamanishi et al., 2010, Yokoyama et al., 2004) including post-operative non-invasive programs for the treatment of post-RP UI, trying to define whether the use of guided programs using BF or PFES may improve results obtained with only PFME. Homogeneously studies on these rehabilitative programs used a 24-h pad weight analysis to quantify UI after surgery and improvement after the end of programs.

Table 1. Main data from the 26 studies considered in the meta-analysis.

Study Author	Study design	Treatments analyzed	Cases for treatment group, n	Outcomes measurements	Follow-up (months)
Laurienzo CE et al.	RCT	- PFME not assisted - PFES	- 41 - 42	IPSS, Pad test	3, 6
Mathewson-Chapman M et al.	RCT	- BF - PFME not assisted	- 27 - 24	Bladder diary, Pad test	1, 3
Moore KN et al.	RCT	- PFME not assisted - BF	- 77 - 89	IPSS, Pad test	3, 6, 12
Ribeiro LH et al.	RCT	- BF - PFME not assisted	- 26 - 28	ICSI, ICST, Pad test	1, 3, 6, 12
Tienforti D et al.	RCT	- BF - PFME not assisted	- 16 - 16	ICIQ-UI, IP-SS-QoL, Pad test	1, 3, 6
Van Kampen M et al.	RCT	- BF - PFES	- 48 - 50	Pad test	1, 3, 6, 12
Dubbelman Y et al.	RCT	- PFME (assisted) - PFME not assisted	- 33 - 33	Pad test	6
Floratos DL et al.	RCT	- BF - PFME not assisted	- 28 - 14	Pad test	1, 3, 6
Franke JJ et al.	RCT	- BF - PFME not assisted	- 15 - 15	Pad test	1, 3, 6
Mariotti G et al.	RCT	BF+PFES	60	ICS-male, Pad test	1, 3, 6
Gomes CS et al.	RCT	- PFME assisted - PFES	- 34 - 35	Pad test	3
Moore KN et al.	RCT	- PFME assisted - PFES	- 18 - 19	Pad test	3, 6
Pedriali FR et al.	RCT	- PFME assisted - PFES	- 26 - 28	Pad test	3
Yokoyama T et al.	RCT	- PFES - PFME not assisted	- 12 - 12	Pad test	1, 3, 6
Wille S et al.	RCT	- PFME assisted - PFES - PFES+BF	- 47 - 46 - 46	Pad test	3, 12
Yamanishi T et al.	RCT	- PFES - PFME not assisted	- 26 - 30	Pad test	1, 3, 6, 12

Mariotti G et al.	RCT	- BF+PFES - PFME not assisted	- 30 - 30	Pad test	1, 3, 6
Tantawy SA et al.	RCT	- PFME not assisted - PFMS not assisted+ whole body vibrations	- 31 - 30	ICIQ-UI, Pad test	1, 3
Manassero F et al.	RCT	- PFME not assisted - Life style advices	- 54 - 54	Pad test	1, 3, 6, 12
Nilssen SR et al.	RCT	- PFME not assisted - PFME assisted	- 42 - 43	UCLA-PCI, Pad test	3, 6, 12
Glazener C et al.	RCT	- PFME not assisted - Life style advises	- 205 - 206	ICIQ-UI SF, Pad test	3, 6, 9, 12
Simeit R et al.	RCT	- PFME assisted - BF	- 87 - 72	SGUIS	1, 3, 6
Park SV et al.	RCT	- PFME not assisted - PFME not assisted	- 33 - 33	Pad test	3
Filocamo MT et al.	RCT	- PFME not assisted - control group	- 150 - 150	ICS, Pad test	1, 3, 6, 12
Overgård M et al.	RCT	- PFME assisted - PFME not assisted	- 42 - 43	Pad Test	1, 3, 6, 12

Note: RCT: randomized controlled trial; PFME: pelvic floor muscle exercises; BF: biofeedback; PFES: pelvic floor electrical stimulation; NR: not reported; IPSS: International Prostate Symptom Score; QoL: quality of life; ICSI: Interstitial Cystitis Symptom Index; ICIQ-UI SF: International Consultation on Incontinence-Urinary Incontinence Short Form; ICS: International Continence Society; UISRP: Urinary Incontinence Scale after Radical Prostatectomy; UCLA-PCI: UCLA Prostate Cancer Index; SGUIS: St George Urinary Incontinence Score.

Our meta-analysis suggests that a specific BF guided program or the addition of PFES to PFME significantly ($p<0.01$) improve short-term (1- and 3-mo intervals) results, either in terms of pad weight reduction or continent rate (pad-free) recovery, when compared to the use of post-operative simple PFME. On the contrary, this advantage is not significant ($p>0.1$) in long-term (6- and 12-mo) follow-up. Of note, event rate of continence recovery significantly increased up to 66% and 75%, at 1- and 3-mo intervals, respectively when a PFES was added to PFME and BF, compared to an event rate of 16% and 40% at 1- and 3-mo interval, respectively when using PFME alone. At 6- and 12-mo intervals, event rate of continence recovery, although differences were not statistically significant ($p>0.1$) reached 96% and 91%, respectively adding a PFES and BF program compared to 59% and 76%, respectively using PFME alone (Filocamo et al., 2005). However, our meta-analysis found a significant heterogeneity of results ($I2 >80\%$).

Which factors can predict results from rehabilitative programs?

Several pre-operative or intra-operative variables may condition UI after RP such as continence recovery results after treatments. However, most of the clinical trials published in the literaturedid not consider these variables (Floratos et al., 2002, Glazener et al., 2011, Gomes et al., 2018, Hunter et al., 2004, Laurienzo et al., 2018, Mathewson-Chapman 1997, Moore et al., 2008, Mariotti et al., 2015, Mariotti et al., 2009, Manassero et al., 2007, Moore et al., 1999, Nitti 2001, Nilssen et al., 2012, Overgård et al., 2008, Pedriali et al., 2016, Pan et al., 2019, Park et al., 2012, Ribeiro et al., 2010, Sciarra et al., 2021, Simeit et al.,. 2010, Tienforti et al., 2012, Tantawy et al., 2019, Van Kampen et al., 2000, Wille et al., 2003, Yamanishi et al., 2010, Yokoyama et al., 2004), such aspre-operative conditions, co-morbidities, prostate volume, and surgical techniques at RP. The heterogeneity of UI levels (pad weight) detected in the meta-analysis at baseline after RP, is likely condition by some of these variables. In the studies considered in our meta-analysis (Filocamo et al., 2005) at baseline after RP and catheter removal, mean pad weight extremely varied from 7.0±56.3 to 738.5±380.6 g. Baseline pad weight is a variable able to condition the heterogeneity of results in terms of mean difference of pad weight improvement at different follow-up intervals. We found a consistently positive association between higher baseline mean pad weight and subsequent improved recovery over the follow-up. Prostate volume (PV) is the main variable significantly correlated with pad weight results, and an increased PV is able to significantly and independently increase the risk of higher baseline postoperative pad weights as well as the risk of residual pad weight >10 g after the rehabilitative program. A significantly ($p<0.01$) higher percentage of cases with a PV <40 cc (55.2%) and a baseline pad weight <100 g (76.2%) reaches a pad-free status at 3-month interval of follow-up.

CONCLUSION

A guided rehabilitative program combining BF with ES can significantly speed continence recovery in patients with UI after RP when compared with a self-administered program of PFME. In our experience, most of clinical, pathological and surgical variables are not able to significantly condition results of a BF+PFES program for UI after RP, whereas stratification on the basis of prostate volume and baseline pad weight should be always consider.

CONFLICT OF INTEREST

None declared.

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