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The role of macroplastique implantation in the management of occult urinary stress incontinence

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ABSTRACT

Objective: Pelvic floor disorders, in particular pelvic organ prolapse (POP) and stress urinary incontinence (SUI), are common in women.
There is a described higher risk to develop postoperative SUI also in preoperatively continent women: this happens because in 30% of women the relief of the urethral obstruction caused by prolapse, unmasks a pre-existing compromised urethral function and thus an "occult" or potential SUI. The aims of this study were to evaluate the role of Macroplastique® implant, TVT-O or surgery alone in the management of occult urinary stress incontinence during prolapse surgery in terms of success rate and adverse events.
Study design: We enrolled 47 consecutive patients scheduled to vaginal prolapse surgery who did not report symptoms of stress incontinence. We collected surgical data, success and complication rates. Moreover we compared all the data with retrospective ones regarding surgery plus concomitant TVT-O (39 pts) and surgery alone (41 pts).
Results: At 12-months follow-up, we reported a success rate of 87,2% in the "macroplastique group", comparable to the "surgery plus TVT-O group", with a statistically significant difference in comparison to the "surgery alone" group. "Surgery + TVT-O" group reported a higher rate of major complications ($p<0,01$) in comparison to the other groups.
Conclusions: Postoperative SUI prevention at the time of prolapse repair remains a challenging issue. In selected patients, Macroplastique may play an interesting role having a good success rate and a low complication rate and for these reasons it may be proposed as A concomitant procedure during POP surgery.

Introduction

Pelvic floor disorders, in particular pelvic organ prolapse (POP) and stress urinary incontinence (SUI), are common in women.

Up to 50% of women with POP are incontinent. These women have a higher risk of SUI after a surgical procedure for prolapse repair, thus needing a concomitant anti-incontinence procedure [1]. On the other hand, there is a described higher risk to develop postoperative SUI also in preoperatively continent women: in 30% of women, the relief of the urethral obstruction caused by prolapse unmasks the so called "occult" or potential SUI [2–5].

For these reasons, in this setting of patients, some authors have recently proposed a concomitant anti-incontinence procedure at the time of prolapse surgery, reporting a lower incidence of postoperative SUI [5–8].

Risks and benefits of combination surgery are still unclear and there is still no consensus on the optimal prophylactic procedure regarding postoperative continence rates and morbidity.

In this scenario, some authors have proposed minimally invasive procedures in order to minimize adverse events. Urethral bulking agents have reemerged in the treatment of SUI and have also been proposed in critical setting of patients such as THE elder ones.

This prospective study aimed to evaluate the role of Macroplastique® implant in the management of occult urinary stress incontinence during prolapse surgery in terms of success rate and adverse events.

As secondary aim, we compared our results to retrospective data of surgery plus concomitant sling procedure and prolapse surgery alone.

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Material and methods

All consecutive patients undergoing vaginal prolapse surgery who did not report symptoms of stress incontinence were considered eligible for this prospective study. All patients referred to gynecologic Department of University Campus Bio-Medico of Rome.

Preoperative assessment included history and general assessment, urinalysis, urogynaecologic clinical examination and urodynamic evaluation (as recommended by the International Consultation on Incontinence (ICI) [9]. Baseline evaluation included the measurement of postvoiding residual volume, the preoperative prolapse-reduction stress test (at a bladder volume of 300 ml, with the prolapsed organ repositioned inside the vagina BY one or two large swabs, BY manual reduction or BY pessario); the test was considered negative if the woman had no leakage while coughing or straining in either the supine or standing position. Urethrovescical junction hypermobility was evaluated using the cotton swab test. Urodynamic evaluations were performed in accordance to the criteria established by the International Continence Society (ICS). Inclusions criteria were 1) urogenital prolapse greater than stage 1 using the pelvic organ prolapse quantification (POP-Q) system [10]; 2) positive preoperative prolapse-reduction test; 3) no contraindications to vaginal surgery 4) signed informed consent. Exclusion criteria were 1) detrusor overactivity, 2) symptoms of overactive bladder (OAB), 3) intrinsic urethral sphincter deficiency, 4) urinary retention, 5) previous anti-incontinence surgery, 6) neurologic bladder, 7) psychiatric disease and 8) planned pregnancy in the first year after surgery. The internal review board approved the study. All patients that met the inclusion and exclusion criteria were enrolled.

Intrinsic sphincter deficiency (ISD) was diagnosed when maximum urethral closure pressure is $<$20 cm H2O and VLPP $<$60 cm H2 O or less. All enrolled patients, at the time of vaginal prolapse surgery, were submitted to concomitant transurethral implantation using Macroplastique Implantation System (MIS) (Uroplasty, Minneapolis, Minnesota) as described in our previous studies.

All these patients were included in “POP surgery plus macroplastique” group.

Operative time and adverse events were all recorded/noted.

During surgery an indwelling catheter was placed for 24 h.

A voiding trial will take place on post-operative day 1. A successful voiding trial is defined as a post residual volume (PVR) of $\leq$100cc (combined with a minimum void of at least 100 cc) documented by a catheterized residual. Subjects with inadequate voiding trials carried out intermittent self-catheterization at home until a PVR less than 80 ml on 2 consecutive measurements was obtained and reassessed after 10 days. Satisfactory self-catheterization voiding was defined as temporary bladder outlet obstruction. Otherwise, the condition was defined as permanent bladder outlet obstruction and, after 30 days, all these patients were submitted to urodynamic evaluation where a pressure–flow study according to the Blaivas and Groutz nomogram was performed. If the permanent bladder outlet obstruction was confirmed, the patient was submitted to surgery and excluded from the follow-up. However, all THE excluded patients were considered as failure and excluded from follow-up visits. However, they were included in the final data analysis.

A postoperative evaluation with urodynamic assessment was performed at the 12-mo follow-up. At this time, success rate was assessed.

Cure of occult SUI was defined as no leakage of urine during the stress test at urodynamic testing. Urinary frequency was defined as a repeated voiding of a small volume of urine ($>$8 times/d) in short intervals. Urgency was defined as a strong desire to void accompanied by fear of leakage or fear of pain; nocturia was defined as the need to awake more than twice a night to void. Urinary tract infection was defined as at least 1 positive urine culture ($>$100 K CFU/mL). Severe pain was defined as THE presence of pain requiring analgesic therapy lasting 1 weak after surgery.

We retrospectively reviewed our database and included all patients who underwent prolapse surgery and met our criteria from 1 January 2011 through 31 December 2013.

They were divided into two groups according to their surgical treatment: patients who underwent POP surgery were enrolled in the group “POP surgery alone”, while patients submitted to POP surgery and concomitant TVT-O were enrolled in the group named “POP surgery plus TVT-O”.

We recorded also demographic, preoperative, operative data and adverse events. We recorded data from postoperative evaluation at 12-mo follow-up and compared them with those of the prospective group. Absolute risk reduction (ARR) and number needed to treat (NNT) for the combined procedure compared with prolapse repair alone were derived at 12 months follow-up.

ARR was defined as the number of patients would be prevented from developing bad outcomes.

On the other hand, NNT was the average number of patients who need to be treated to prevent one additional bad outcome. The Wilcoxon signed rank sum test was used for comparison among groups. The Mann-Whitney *U* test was used for comparison between the two groups. The changes of urinary symptoms from baseline were analyzed using the McNemar test, with the Fisher exact test being used for analysis among groups. Statistical significance was set at $p < .05$.

Results

From January 2014 to October 2015, 104 patients IN our department were considered eligible for the study. After the preoperative assessment, 47 patients were enrolled according to our inclusion and exclusion criteria (Fig. 1).

All patients were submitted to prolapse surgery and Macroplastique implantation (prolapse surgery + macroplastique group). Characteristics of patients are reported in Table 1.

Mean operative time was 125,6 $\pm$ 23,4 min and mean hospital stay was 4,84 $\pm$ 0,80 days. Mean operative time of Macroplastique implantation was 12,3 $\pm$ 3,2 min.

Only one patient was excluded from follow-up visits due to permanent bladder obstruction.

Median follow up was 16 months (range 12–23 months). At 12-months after surgery, during urogynecological examination and urodymanic assessement, a positive stress test was reported in 5 patients, showing an objective failure rate of 12,7%, requiring in 3 (6,3%) patients an anti-incontinence surgery (Table 2).

Regarding minor adverse events, the most common was de novo urgency which was reported in 7 patients (14,8%), while only 1 patient (2,1%) reported major adverse events (Table 3).

As mentioned, we reviewed our surgical database and retrospectively enrolled 39 and 41 patients in the “prolapse surgery plus TVT-O” group and “prolapse surgery alone” group respectively, according to the surgical procedure performed previously. Characteristics of patients were also reported in Table 1 and compared with prospective group. No statistically significant differences were noted.

At 12-months follow-up, in “prolapse surgery plus TVT-O” group we recorded an objective cure rate of 89,7% while in “prolapse surgery alone” group it was 78% (Table 2). A report of adverse events was also collected in the retrospective group at 12-months evaluation after surgery. Data resulted comparable among groups as showed in Table 3.