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Nonabsorbable urethral bulking agent — clinical effectiveness and late complications rates in the treatment of recurrent stress urinary incontinence after 2 years of follow-up

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ABSTRACT

Objective: Those patients who failed to achieve continence after a procedure aimed to correct it, require a special attitude and precise management due to the sophisticated anatomical and functional field of interest. The purpose of the present study was to assess long-term clinical efficacy and evaluate the frequency and severity of any complications related to recurrent stress urinary incontinence treatment with a non-absorbable bulking agent periurethral injections.

Study design: Between February 2012–September 2013, 66 patients with recurrent stress urinary incontinence were treated with Urolastic in the tertiary referral gynecologic department. The efficacy of the procedure was assessed objectively at each follow-up visit, scheduled at two, six weeks and 3, 6, 12 and 24 months after primary procedure. Material was injected under local anesthesia according to the manufacturer's instructions, at 10, 2, 4 and 8 o'clock positions with 0.5–1.25 ccm per spot. Statistical analyses were performed with Statistica package version 8.0 (StatSoft Inc., Tulsa, OK, USA). A p value <0.05 was considered statistically significant.

Results: Objective success rate at 24 months was found in 32.7% of patients, including 22.4% patients who were completely dry. The efficacy of Urolastic, when considering the intention to treat, is 24.2% and 16.7%, respectively. In 4.5% patients an oval shaped material was found inside the bladder. Overall, complications were observed in 17 (25.8%) patients.

Conclusions: Although only 30% of patients will benefit from Urolastic injection on the long-term basis it seems to be a safe procedure in the treatment of recurrent stress urinary incontinence.

Introduction

That may be the impression that everything has been said about female stress urinary incontinence (SUI). The diagnosis, treatment methods and quality of life with SUI or after its successful resolution are widely discussed in the literature. On the other hand, little is known about patient adherence to repeated surgical treatment of recurrent stress urinary incontinence (RSUI) within the same method. There are some papers presenting the patients' adherence after repeated botulinum toxin injection due to overactive bladder symptoms (OAB), or neurogenic detrusor overactivity (DO), with promising results [1,2].

Interestingly, there are no clear algorithms of RSUI management indicating which treatment option would be the best rescue procedure in these cases. From one point of view, we might be proud of the fact that we have already the midurethral sling procedures, the golden standard in SUI treatment-naïve patients, with the cure rate as high as 95%, but on the other hand, the success achieved made us forget the failures [3]. Those patients who failed to achieve continence, although in the minority, require a special attitude and precise management due to the sophisticated anatomical and functional field of interest in the lower urinary tract system. In such cases, most surgeons rely on their own experience or opinion when counseling these women. One of the treatment options is therapy with bulking agents, injected either trans- or periurethraly. These procedures are safe and minimally invasive which means that they meet womens' expectations concerning the second stage mode of treatment [4–6]. Recurrent stress urinary incontinence is defined as a failure of anti-incontinence surgery after a period of time or persistence of SUI

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after a procedure aimed to correct it. We must remember that repeating procedures performed on the lower urinary tract markedly decreases subsequent vaginal procedures' efficacy, and dramatically increases the risk of early and late complications occurrence [7,8].

Urolastic is a urethral bulking agent (UBA) used in SUI treatment with success rate up to 68% after one year of follow-up and 30% of minor complications related to the injection [9,10]. It is composed of polydimethylsiloxane (PDMS) polymer, platinum divinyltetramethyl siloxane complex as the catalyst and titanium dioxide as a radio-pacifying component. It has been used since the 1970s as hysteroscopic tubal plugging in women seeking non-hormonal contraception [11]. Light microscopy of specimens showed that there was no significant difference between the ampullary region of the tube containing the silicone and the control and there was no evidence of inflammation as well [12]. Unfortunately, there are no histologic studies of Urolastic whilst injected periurethraly. Periurethral injection creates increased tissue bulk and subsequent coaptation and closure of the bladder neck and urethra, thus preventing urinary incontinence. The primary objective of the present study was to assess the long-term safety and clinical efficacy of RSUI treatment with Urolastic using the Stamey incontinence scale [13]. The secondary objective was to evaluate the frequency and severity of any foreseeable late complications related to Urolastic treatment.

Materials and methods

The study was conducted in accordance with the Helsinki Declaration, local laws and regulations relevant to the use of therapeutic agents. Prior to start of the study the protocol was approved by the Medical Ethics Committee. The present study is a single center follow-up of a previous multicenter study [10]. Between February 2012–September 2013, 66 patients with RSUI were treated with Urolastic (Urogyn BV, Nijmegen, The Netherlands) in the tertiary referral gynecologic department. Inclusion criteria for the study were as follows: women with RSUI confirmed by medical history and cough test, with at least second grade of incontinence according to the Stamey scale, bladder capacity at least 300 ml or more and preoperative post-void residual urine of less than 100 ml. Exclusion criteria were: detrusor overactivity (DO) or predominately urgency incontinence, pelvic organ prolapse (POP), suspicion of neurogenic bladder. Characteristics of the study group are shown in Table 1. Previous anti-incontinence procedures are shown in Table 2. Mean time from previous surgery was 12 months. Eligible patients were fully informed about the study. All patients signed informed consent before commencement of the treatment. Urolastic was injected midurethrally through a 18G needle under local anesthesia with 1% lignocaine according to the manufacturer's instructions, at 10, 2, 4 and 8 o'clock positions with 0.5–1.25 ccm per spot. All injections were performed only by one investigator (KF). Immediately after the injection, cough test was performed with the bladder filled with 200 ccm. Routinely, ciprofloxacin 500 mg bid for 5 days in order to minimize the risk of infection was prescribed. Follow-up visits were scheduled two, six weeks and 3, 6, 12 and 24 months after primary procedure. If the patient required a second injection was administered 6 weeks after the primary procedure and Urolastic was injected only at 4 and 8 o'clock with 0.75 ccm per spot. The efficacy was assessed objectively at each follow-up visit by means of cough test in the supine and standing positions, with a comfortably full bladder and a standard 1-h pad test. A pad weight increase or decrease, when compared to baseline, was then calculated for each patient. Patients were considered completely cured when they were free of all objective SUI symptoms, cough tests, as well as a pad test being negative. The procedure was considered a failure if the patient still reported urine leakage during increases of intra-abdominal pressure, or if the cough tests or pad test were positive. In the improvement group, the cough test was negative but patients still reported occasional urinary leakage or the pad test was negative, although the increase in pad weight was minimal: approximately less than 1 g. Additionally, subjective cure rate was assessed by means of a visual analog scale (VAS). Patients had to indicate their satisfaction on a scaled line with 0–100 endpoints. Stamey incontinence scale was evaluated according to a description of the symptoms severity. Statistical analyses were performed with Statistica package version 8.0 (StatSoft Inc., Tulsa, OK, USA). A p value <0.05 was considered statistically significant. Wilcoxon Rank test was carried out to test the difference between outcomes of follow-up visits versus baseline characteristics. Chi square test was used to calculate significance of SUI severity. Also the intention to treat (ITT) analysis was taken into account when calculating the final results of Urolastic efficacy.

Table 1
RSUI patients' baseline demographic and clinical data divided into two groups A – all patients enrolled in the study, B – patients who were available for 24 months follow-up.

Parameter	A RSUI baseline (n = 66)	B RSUI 24 months (n = 49)
Age at surgery (years ± SD)	65.5 ± 9.2	64.1 ± 7.4
Parity n (range)	2.8 (0–6)	2.7 (0–6)
BMI (kg/m^2 ± SD)	28.8 ± 5.7	28.0 ± 5.7
Stamey Score 2° n (%)	32 (48.5)	19 (38.8)
Stamey Score 3° n (%)	34 (51.5)	30 (61.2)

Results

Forty-nine out of 66 patients were available for 24 months follow-up. Eleven patients were re-injected 6 weeks after primary procedure. Objective success rate (cured and improved) at 24 months was found in 16 patients (32.7%) including 11 patients completely dry (22.4%) out of 49 patients. The detailed outcome is shown in Table 2. When considering the intention to treat (ITT), Urolastic efficacy is 24.2% and 16.7%, respectively. In 4 (6.1%) patients, bladder outlet obstruction (BOO) was observed after procedure, and catheterization for a maximum of 7 days was required. In three of these, partial removal of the bulking material

Table 2
Outcome after 2 years according to previous type of surgery.

Type of surgery	Baseline n = 66 (%)	Failures after 24 months of follow-up n = 33 (% of baseline)	Lost to follow-up n = 17 (% of baseline)
Burch colposuspension	2 (3%)	2 (100%)	0 (0%)
Retropubic sling (TVT)	4 (6.1%)	3 (75%)	1 (25%)
Transobturator sling (TOT)	56 (84.8%)	28 (50%)	16 (28%)
TOT and TVT	4 (6.1%)	0 (%)	0 (0%)