#439 Retrospective analysis of safety and efficacy of a bioresorbable polycaprolactone based injectable in female stress urinary incontinence

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Hypothesis / aims of study

A fully bioresorbable polycaprolactone-based bioresorbable bulking agent was evaluated for safety and efficacy in female patients with mild to moderate stress urinary incontinence (SUI) who attempted and failed prior pelvic floor muscle training.

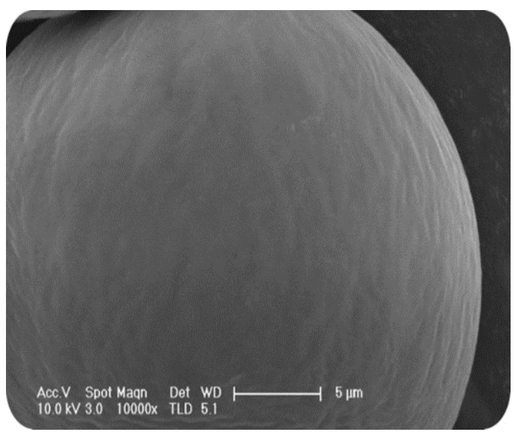
Study design, materials and methods

All patients in this retrospective case series were treated at the General Hospital in Šibenik (Croatia). Patients were suitable for treatment if there was an SUI SGS of 1 or 2. Patients with a SGS of 3 were excluded from the case series since the product is less effective for this category of patients. Patients with prior treatments for SUI were included in the study. Primary outcome measurements were the return of continence, the duration of the continence period using the SGS, as well as the complication rate. The outcome measurements were recorded in the patient's medical records. The data was collected retrospectively from the patients' medical records. Baseline characteristics are shown in table 1.

Urethral filler

The patients were treated using the medical polymer PCL-based bulking agent (Urolon®, AQLANE Medical B.V., Oisterwijk, Netherlands) because of its bioresorbability and neocollagenesis characteristics. The treatment procedure is described in our earlier publication (Mojsovic and Koldewijn, 2022). The PCL-based bulking agent consists of 30% PCL microspheres and 70% aqueous carboxymethylcellulose gel carrier.

The PCL microspheres are smooth and spherical-shaped and have optimal biocompatibility for use as a particle-based bulking agent. Moreover, the particles have previously been shown to stimulate (type I) collagen formation, potentially restoring lost collagen and supporting long-term effectiveness after the microspheres have been bioresorbed.



Follow-up

Data on the continence and complications experienced by the patients was collected during outpatient follow-up appointments. The continence level of patients was scored using the SGS, in which: grade 0 = continent; grade 1 = loss of urine with a sudden increase in abdominal pressure such as from coughing, sneezing, or laughing; grade 2 = leaks with lesser degrees of physical stress such as walking, standing erect from a sitting position, or sitting up in bed; grade 3 = total incontinence, urine is lost without any relation to physical activity or position.14 Patients were asked to evaluate their continence before treatment, at 6 months, 12 months, and 24 months post-procedure. The treatment was a success if the patients' continence improved to SGS 0. The duration of the continence period ended when patients scored >0 on the SGS. If patients opted for re-treatment using the PCL-based bulking agent due to loss of continence, the follow-up for this study would end, as these results would cloud the effectiveness of a single treatment.

Data analysis

Efficacy analysis was performed using a per-protocol (PP) approach on all subjects. Safety evaluations were recorded throughout the study via any reported adverse events (AE). Frequency statistics were calculated for all nominal results. The median and interquartile range (IQR) were calculated for the participants' age, and a Kaplan-Meijer survival curve was generated for the duration of continence post-intervention. Data analysis was performed using SPSS Statistics v28 (IBM, Armonk, NY, USA).

Tabel 1: Baseline characteristics

	Mild SUI (SGS 1) n=32	Moderate SUI (SGS 2) n=12
Age, median (IQR)	60 (20)	57 (23)
No of births (vaginal)		
1 (%)	2 (6.3)	1 (8.3)
2 (%)	20 (62.5)	8 (66.7)
3 (%)	6 (18.8)	3 (25.0)
4 (%)	3 (9.4)	0
5 (%)	1 (3.1)	0
Prior treatments		
Urodex (%)	2 (6.3)	0
Urolastic (%)	0	1 (8.3)
TVT (%)	2 (6.3)	1 (8.3)
Co-morbidities		
Urge incontinence (%)	4 (12.5)	0
Prior gynecological surgery (%)	6 (18.8)	1 (8.3)
Chronic cystitis (%)	5 (15.6)	0
Spinal hernia surgery (%)	2 (6.3)	2 (16.7
Diabetes mellitus (%)	2 (6.3)	0
Adipositas (BMI>30) (%)	2 (6.3)	0
Retreatment (%)	3 (9.4)	3 (25.0)

SUI, stress urinary incontinence; SGS, Stamey grading system; IQR, interquartile range; TVT, retropubic transobturator; BMI, body mass index.

Results and interpretation

Results

SGS improvement was shown in both the mild and moderate SUI groups. At 12 months, 96.9% of the patients with mild SUI were still continent (n=31) versus 100% of patients with moderate SUI (n=12).
At 24 months, most participants continued to be continent; 78.1% in the mild SUI group (n=25) and 66.7% in the moderate SUI group (n=8).
Moreover, all participants in the moderate SUI group showed an improvement of the SGS grade versus baseline.
Tabel 2 shows the cure rates (Stamey grade 0) over the 2 groups and time points.

Tabel 2: Cure Rates per group and over time

Stamey Grade	Continence (Cure Rate %)	
	12 months	24 months
1 - mild SUI (n=32)	96,9%	75,0%
2 - moderate SUI (n=12)	78,2%	66,7%
Total (n=44)	87,2%	70,2%

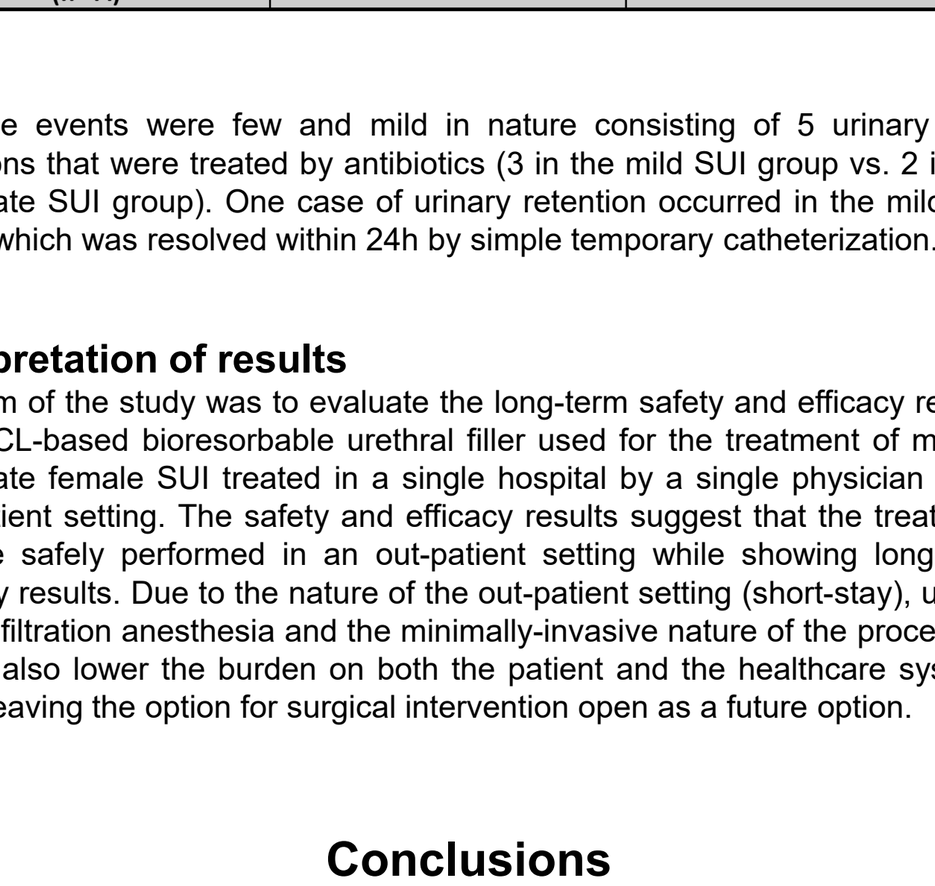
Adverse events were few and mild in nature consisting of 5 urinary tract infections that were treated by antibiotics (3 in the mild SUI group vs. 2 in the moderate SUI group). One case of urinary retention occurred in the mild SUI group which was resolved within 24h by simple temporary catheterization.

Interpretation of results

The aim of the study was to evaluate the long-term safety and efficacy results of a PCL-based bioresorbable urethral filler used for the treatment of mild to moderate female SUI treated in a single hospital by a single physician in an out-patient setting. The safety and efficacy results suggest that the treatment can be safely performed in an out-patient setting while showing long-term efficacy results. Due to the nature of the out-patient setting (short-stay), use of local infiltration anesthesia and the minimally-invasive nature of the procedure, it may also lower the burden on both the patient and the healthcare system, while leaving the option for surgical intervention open as a future option.

Conclusions

The study shows that the polycaprolactone-based bioresorbable bulking agent treatment seems to be a safe and effective treatment option for women with mild to moderate stress urinary incontinence who attempted and failed prior pelvic floor exercises.



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