#329 A retrospective evaluation of 47 procedures using a bioresorbable polycaprolactone based injectable for the treatment of mild to moderate stress urinary incontinence in adult females

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Aim of the study

The treatment armamentarium for female stress urinary incontinence (SUI) consists of a variety of options ranging from conservative to invasive surgical intervention. Many women, however, find a conservative approach does not yield satisfying results but, for various reasons, are also unwilling or unable to undergo surgical intervention. When asking for expectations or preferences from their SUI treatment, patients are often prefer minimally invasive, preferably non-permanent procedures, providing relief and reduce the impact on their quality of life [1]. Women suffering from SUI are often left in a gap between conservative and surgical intervention and are therefore untreated for too long. We undertook a retrospective evaluation of using a novel bioresorbable and collagen-stimulating procedure for the treatment of mild-to-moderate female SUI. If successful, this has the potential to bridge the gap between conservative treatment and more invasive surgical intervention with permanent materials, while leaving the latter option available.

Study Design, materials and methods

A retrospective evaluation of safety and effectiveness was performed of a bioresorbable transurethral female SUI procedure introduced in our hospital. This injectable is based on non-permanent and biostimulatory polycaprolactone microspheres (Urolon, AQLANE Medical BV, The Netherlands). The product consists of 30% polycaprolactone microspheres suspended in a carrier-gel of carboxymethyl cellulose. Primary outcome parameter were return of continence using the Stamey incontinence grading scale (SGS) and complication rate.
The initial 6 patients were treated in the operating theatre using propofol sedation. However, as the procedure is relatively simple and can be performed within 15 minutes, we changed to an out-patient setting using a periurethral block using 2% lidocaine and ketoprofen. This eliminated the need for an anesthesiologist and reduced procedural cost. Single-dose gentamycin was used for periprocedural prophylaxis.
Procedures were performed using a transurethral cystoscopy-guided approach, providing visual confirmation of correct product placement. Injection was done with available cystoscopes having a ≥5 Fr working channel and a standard cystoscopic injection needle (Williams Cystoscopic Needle 23G, 35cm, Cook Medical, Ireland).

The needle was introduced into the mid-urethral submucosal tissue at a depth of 3-5mm. In general, three injections were done (2, 6 and 10 o'clock) using an average of 1.5 - 2.0 ml of product for SGS-1 (mild SUI), 2.0 - 2.5 ml for SGS-2 (moderate SUI) and up to 3.0 ml for SGS-3 (severe SUI). Contrary to the standard recommendation, we used our initial injection site as the main bulking area by injecting the largest volume of the three sites. This leads to maximum coaptation from the initial injection site, using the other 2 sites for support and optimization. After treatment patients are discharged from the hospital on the same day after having spontaneous voiding.

Results

We report the finding of the initial 47 female patients suffering from SUI in different levels of severity. All patients were dry immediately following treatment. In the follow-up period, 46 remained continent or had significant improvement of their incontinence 6 to 12 months post-treatment (table 1). Although incontinence returned in 4 patients at 6 months post treatment (8.5%) and 6 patients at 12 months post treatment (12.8%), these patients were still improved versus baseline. Moreover, these patients also described their condition as improved and indicated to be satisfied with the result. In 1 patient with severe SUI a re-treatment was performed after 3 months due to insufficient results. However, this did not result in an improvement, likely caused by an anatomically very short urethra (<3 cm). It is noteworthy, however, that none of the other patients received a re-treatment regardless of the SUI severity or initial result.

After 6 months, 43 patients (91,5%) are still continent. Per severity group this result was achieved in 93.9% (mild; 31/33), 91.7% (moderate; 11/12) and 33.3% (severe; 1/3), respectively. After 12 months the results showed an over effectiveness to continence of 87.2%. Per severity group achieved in 93.9% (mild; 31/33), 75.0% (moderate; 9/12) and 33.3% (severe; 1/3), respectively.

The treatment was generally well tolerated, both in the operating theatre as well as in the out-patient setting. No serious complications occurred and few mild and transient complication were observed that all resolved within 48 hours. A total of 5 cases of procedure related UTI occurred and were treated with antibiotics.

Interpretation of results

In our hospital there was a need for an innovative injectable procedure for the treatment of SUI that could be used as a first-choice treatment option in different patient types and SUI severities. Although the results described here are limited, it is suggested this complies with most to all of our needs for such first-option treatment. The procedure has to-date shown to be safe, effective and well tolerated in both naïve patients as in patients who previously had other interventions.

In our experience it is preferred to maximize bulking to the point of urinary retention, followed by insertion of a 12Fr catheter for several minutes to allow the product to settle. Maximal bulking improves efficacy and may prevent the need for re-treatment with bulking agents in general, as described in literature.
In line with the international recommendation for bulking agents [2], this procedure is suited for women suffering from SUI but a) are planning pregnancy, b) unwilling or unable to undergo surgery, c) are looking for a procedure with a low complication rate rather than a high efficacy rate, d) had unsatisfactory results from surgical intervention.

In addition, if the treatment does not provide satisfactory results, it leaves the option for surgical intervention as it is bioresorbed, reducing potential interaction-induced complications.

Tables

Mild SUI (SGS1)			
	baseline	6Mo	12Mo
continent	0	31 (93,9%)	31 (93,9%)
mild	33	2 (6,1%)	2 (6.1%)
moderate	0	0	0
severe	0	0	0

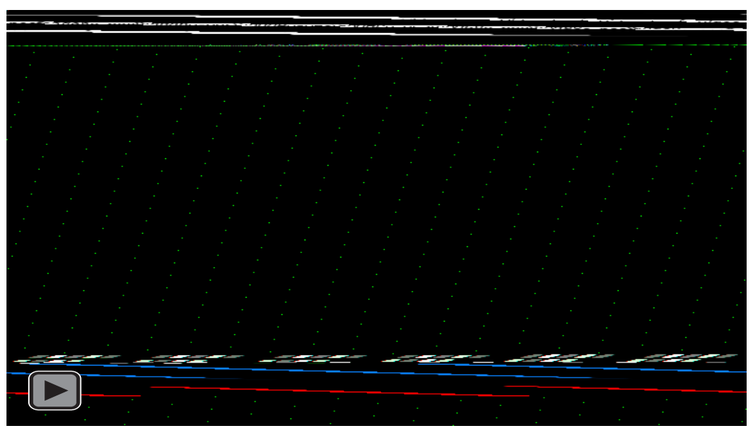
Table 1: Effectiveness results 6 and 12 months post treatment shown per baseline severity group. Percentage of total patient group between brackets.

Moderate SUI (SGS2)			
	baseline	6Mo	12Mo
continent	0	11 (91.7%)	9 (75%)
mild	0	1 (8,3%)	3 (25%)
moderate	12	0	0
severe	0	0	0

Severe SUI (SGS3)			
	baseline	6Mo	12Mo
continent	0	1 (33,3%)	1 (33,3%)
mild	0	1 (33,3%)	1 (33,3%)
moderate	0	0	0
severe	3	1 (33,3%)	1 (33,3%)

Interpretation of results

More data is needed to further determine the position of this product within the range of treatment options. The bioresorption and neocollagenesis characteristics of this specific product give it the potential to become the first-choice interventional treatment after pelvic floor muscle training. If successful, the product may show to bridge the treatment-gap between a conservative approach and surgical intervention.



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