Abstract #556: Urethral bulking agent (Bulkamid®) injection for the treatment of stress urinary incontinence. Analysis of a single-center experience.

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Introduction

Classically, mid-urethral slings have been the most widely used surgical treatment for female stress urinary incontinence (SUI).

However, in recent years, concern has been raised regarding the safety and long-term complications of such procedures, such as chronic pain, vaginal or bladder erosions or urethral obstruction.

In this scenario, urethral injection of bulking agents has raised interest as an alternative treatment for SUI, particularly in patients:

- Who prefer a low-risk surgical procedure
- Elderly patients
- Those who failed after a previous anti-incontinence procedure.

Although short-term efficacy has been demonstrated, current evidence does not establish long-term efficacy. The present study aims to evaluate the medium-term results and safety for Bulkamid® in patients with SUI or mixed UI (MUI) at a tertiary center.

Methods and Materials

This retrospective observational study included patients treated between January 2019 and May 2022.

Inclusion criteria:
Female patients 18 years or older who suffered from SUI or MUI with predominantly stress urinary incontinence treated with Bulkamid® injection.

Evaluation of results:

- Subjectively with the PGI-I (Patient Global Impression of Improvement) questionnaire and the Likert scale.
- Objectively in the physical examination (cough test).

Figure 1. Patient Global Impression of Improvement (PGI-I) questionnaire

The PGI-I consists of a single question that asks the patient to rate the relief obtained with the treatment he/she is following according to a seven-point Likert scale:		
Very much better	1	Responders
Much better	2	
A little better	3	
No change	4	Non responders
A little worse	5	
Much worse	6	
Very much worse	7	

A descriptive analysis of the data was performed using absolute frequency and percentage for qualitative variables and mean (standard deviation) or median (interquartile range) according to normality for quantitative variables. Shapiro-Wilk tests of normality were performed.

Results

Twenty-one patients were included in our study. Demographics data are shown in Table 1.

Table 1. Demographics

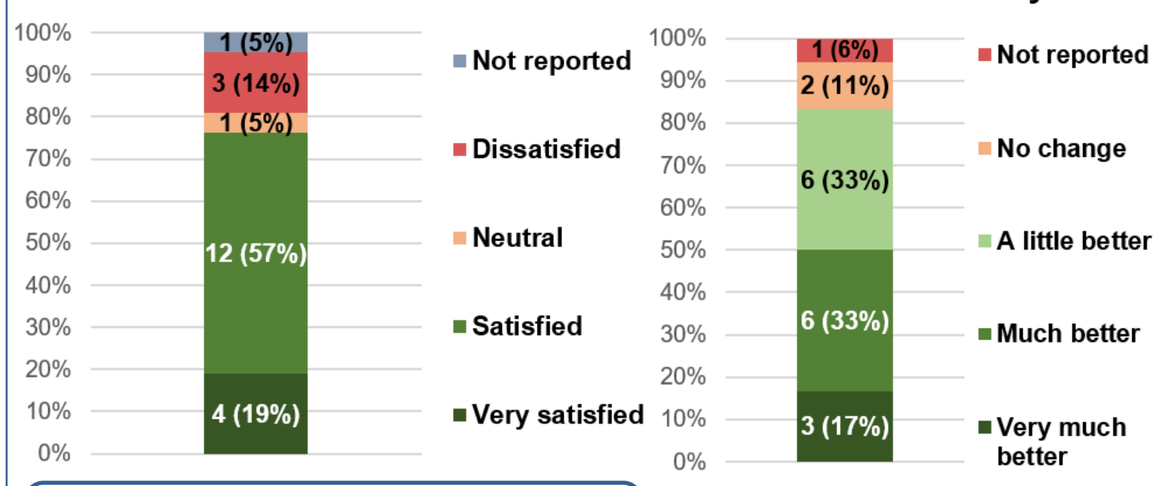
Overall	21		
Age (years)	69,7±14,4		
BMI (kg/m²)	30,7±6,2		
Personal background of pelvic radiotherapy	2 (9,5%)		
Previous incontinence surgery	8 (38,1%)	**TOT**	4 (19,05%)
		TOT + TVT	4 (19,05%)
Urge urinary incontinence	12 (57,1%)		
Procedures	24	**First procedures**	21
		Reinjections	3
Type of Anesthesia		**General Anesthesia**	2 (9,5%)
		Spinal Anesthesia	4 (19%)
		Sedation	7 (33,3%)
		Local Anesthesia	8 (38,1%)

No intraoperative or postoperative complications were reported.
After a median follow-up of 10 months (8-16.5), 8 (38.1%) patients showed no SUI, 100% being much/very much better (PGI-I). In 9 (42.9%) patients some degree of SUI persisted, of which 3 were dissatisfied, 5 satisfied and 1 neutral (Likert).

Results

4 (19%) patients had recurrent SUI, one of them during current pregnancy; two other patients reported being satisfied with occasional leakage. 83% of the patients were considered responders.

Figure 2. Results after first inyection



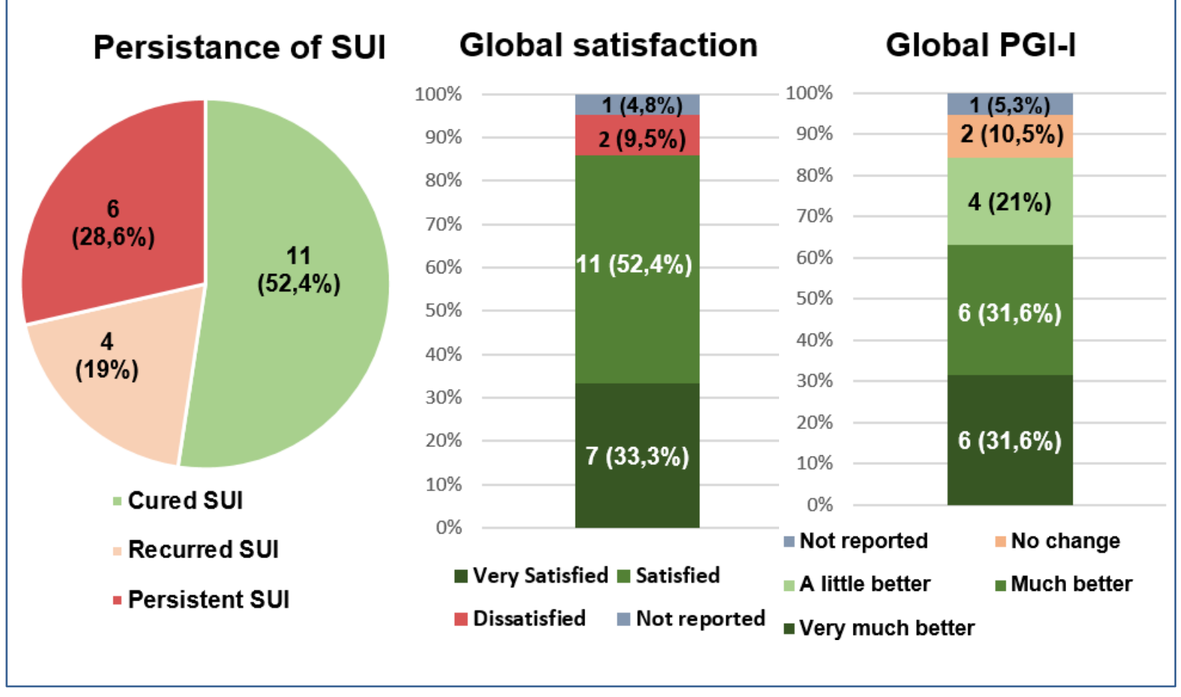
16 patients satisfied / very satisfied (76%)

15 patients responders (83%)

3 patients (14.2%) underwent a second injection of Bulkamid®; 100% of them are dry and very much/much better (PGI-I).

Considering the total number of patients after 1 or 2 Bulkamid® injections, 11 (52.4%) patients have no SUI, and 18 (85.7%) patients are satisfied or very satisfied. According to PGI-I (19 patients), and considering reinjections, 89.5% of the patients were responders.

Figure 3. Global results



Discussion

The results of the present study show that, although most patients are not completely dry, more than 80% respond to the therapy and are satisfied with the treatment (1, 2).

According to EAU guidelines, urethral bulking agents are grated a strong recommendation to women with SUI who request a low-risk procedure (3). Although our sample is small (21 patients) compared to other studies, the patients who underwent urethral injection of bulking agent in our study showed no intraoperative or perioperative complications, being a safe procedure as indicated by current evidence and a good alternative in groups of patients who do not want complex surgery, such as elderly patients, young women with unfulfilled reproductive desire or patients with high BMI.

This therapy allows re-injection of bulking agent in case of non-efficacy or persistence of variable degrees of stress urinary incontinence after the procedure without producing an increase in side effects. All the reinjected patients in the present study presented persistent moderate-severe incontinence after the first injection of Bulkamid®, and after the second procedure they presented a very occasional grade of incontinence, and were very satisfied with the intervention.

As limitations of the study, we can point out its retrospective methodology with a small sample size. Even so, and although it has a limited follow-up, the results shown are promising.

Conclusions

Bulkamid® urethral injection shows adequate objective and subjective success rates in the medium term, being a good alternative for patients with SUI seeking a minimally invasive treatment with minimal complications.

References

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