

Outpatient periurethral injections of polyacrylamide hydrogel (Bulkamid) under local anesthesia in the office: a prospective single-center series #25917

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Introduction

Polyacrylamide hydrogel (Bulkamid®) is a relatively recent bulking agent which may have a better safety profile than previous generations. The objective of this study was to report our experience of outpatient peri-urethral injections of Bulkamid® under local anesthesia in the office in female patients for stress urinary incontinence (SUI).

Aim

The objective of the present study was to report the results of the injections of PAHG in a single center

Methods and Materials

- The data of all women who underwent outpatient peri-urethral Bulkamid® injections under local anesthesia in the office at a single academic center were collected prospectively between November 2019 and August 2023.
- This therapeutic option was offered to patients who had SUI if > 80-year-old and/or had multiple comorbidities or if they declined all other therapeutic options.

Results

- Ninety-two patients were included and one hundred and three injections were performed.
- The mean age was 78 years (30-97).
- Twenty-two patients experienced postoperative complications (21%), nineteen were Clavien 1 complication, two were Clavien 2 and only one complication was Clavien = 4.
- Sixty-two injections yielded patients ‘satisfaction at 3 months according to the predefined primary endpoint, i.e. PGI-I ≤ 2.
- The USP SUI and OAB subscores and the ICIQ-SF were all significantly improved at 3 months (p<0.001).
- The VAS for urethral coaptation self-assessed by the surgeon at the end of the procedure was the strongest predictor of postoperative outcomes.

Conclusions

- Peri-urethral Bulkamid injections are feasible in an outpatient setting in the office using a simplified local anesthesia protocol with a great tolerance and with similar functional outcomes than previously reported.
- The injections have a low rate of complications.
- These options may be of great value in frail patients and those looking for a minimally invasive treatment. Other studies are needed to confirm these findings.

Results

Table 1: Patients' characteristics

Number of patients	92
Age	78 (30-97)
Number of injections (per patient) :	
• 1 :	80 (87%)
• 2 :	9 (10%)
• 3 :	2 (2%)
• Stopped due to unbearable pain :	1 (1%)
ASA score:	
• 1 :	16 (17.5%)
• 2 :	52 (57%)
• 3 :	22 (24%)
• 4 :	1 (1%)
Anticoagulant	15 (16.5%)
Antiplatelet	25 (27.5%)
Previous pelvic radiotherapy :	2 (2%)
Previous pelvic surgery :	45 (49.5%)
Previous SUI surgery :	37 (40.5%)
• TVT :	9 (10%)
• TOT :	14 (15%)
• Burch :	7 (7.5%)
• Peri-urethral ACT balloons :	6 (6.5%)
• Artificial urinary Sphincter	1 (1%)
Mean maximum urethral cloture pressure(cmH2O):	28 (7-62)
Detrusor overactivity	15 (18.8%) Missing data N=12
Ileal neobladder	1 (1.1%)
Median number of pads per day	3 (1-15)
Neurological condition	8 (8.7%)

	Baseline (N=103)	At 3 months (N=103)	p-value
Maximum urinary flow rate (ml/s)	18.9 (+/-10.3)	16.1 (+/-8.5)	0.008
Post-void residual (ml)	11.8 (+/-35.4)	6 (+/-19.6)	0.12
USP			
Mean OAB subscore (/21)	11 (+/-4.6)	8.2(+/-5)	<0.0001
Mean SUI subscore (/9)	6.8 (+/-2.1)	3.5 (+/-3)	<0.0001
Mean Voiding symptoms subscore (/21)	1.2 (+/-1.7)	0.9 (+/-1.6)	0.04
ICIQ-SF (/21)	15.2 (+/-4.1)	8.1 (+/-6.7)	<0.0001
PGII at last follow-up			
Very much better		33 (32%)	
Much Better	NA	29 (28.2%)	NA
Slightly better		14 (13.6%)	
Unchanged		25 (24.3%)	
Worsened		2 (1.9%)	