#511 PROSPECTIVE OBSERVATIONAL STUDY OF THE TREATMENT OF URINARY INCONTINENCE USING BULKAMID® URETHRAL INJECTION

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HYPOTHESIS / AIMS OF STUDY

Periurethral injection of the Bulkamid® agent, a polyacrylamide hydrogel, has been a breakthrough in the **treatment of Stress Urinary Incontinence (SUI)** in female patients.

The **aim of the study** is to analyze **our results** and evaluate the **quality of life** of patients treated with Bulkamid® agent.

STUDY DESIGN, MATERIALS AND METHODS

Prospective observational analysis of a serie of **27 female patients with SUI and 26 with stress-predominant Mixed Urinary Incontinence (MUI)** treated with Bulkamid® periurethral injection at our center between 2019 and 2022.

All patients had a previous urine culture. The procedure was performed by **2 - 3 periurethral injections** with a 23G x 120 mm needle with <0.8 mm per injection **at 0.5 - 1 cm from the bladder neck**.

Follow-up was performed with **flowmetry, 24-hour pad weight test (24h-Pad Test)** and the International Consultation on Incontinence Questionnaire Short Form **(ICIQ-UI SF) for a median of 10 months (1 - 40).**

RESULTS

Pre-treatment characteristics		Patients (N,%)
Physical examination		
Prolapse		20 (37.7%)
Narrow introitus		10 (18.9%)
Positive Q tip test		23 (43.4%)
Personal History		
Smoking		14 (26.4%)
Anticoagulation		7 (13.2%)
Delivery	Vaginal (median 2)	47. 88.7%)
	Caesarean section	6 (11.3%)
Delivery	Macrosomic	10 (18.9%)
	Instrumental delivery	9 (17%)
Previous gynecological surgery		14 (26.4%)
Previous devices	TOT	12 (22.6%)
	TVT	3 (5.7%)
Previous conservative Treatments	Anticholinergic drugs	16 (30.2%)
	β3adrenergic agonist	22 (41.5%)
Neurological disease		8 (15.1%)
Autoimmune disease		6 (11.3%)
Fibromyalgia		3 (5.7%)
SUI		27 (51%)
Stress-predominant MUI		26 (49%)
Complementary tests		
Pad Test	Mild (< 50 g/day)	31 (58.5%)
	Moderate (50-200 g/day)	18 (34%)
	Severe (> 200 g/day)	4 (7.5%)
Anesthetic risk		
ASA	I	8 (15.1%)
	II	30 (56.6%)
	III	13 (24.5%)
	IV	2 (3.8%)

Table 1. Pre-treatment characteristics.

We analyzed **53 patients** with a median age of **63 years (32 - 83)** and **BMI of 27 kg/m2 (19.23 - 35.6).**

The **immediate** postoperative adverse effects were **urinary tract infection (Clavien II, 1.9%)** and **acute urinary retention (Clavien II, 3.8%)**. Regarding the late ones, **11.3% presented de novo urgency UI** and **3.8% persistence of SUI.**

- Control **flowmetry** revealed a mean **Qmax 22 mL/s and post-void residual 24 mL.**
- **24h-Pad Test** showed a subjective satisfaction of **"being dry" of 77.6%**, with 30.2% of patients using 1 pad/day for security and 7.5% using 1 pad/day.
- **Average "dry time" is 12.5 months**.
- Quality of life was assessed with the **ICIQ-UI SF** questionnaire with a mean of **5**.

INTERPRETATION OF RESULTS

Our study shows that **this injectable agent presents low rate of complicationes** in the postoperative period. With regard to the persistence of SUI, **Bulkamid® injection was required in only two patients with a good response**.

A point to be highlighted is the average "dry time" after Bulkamid® injection is 14 months with mild urine leakage and the subjective satisfaction of "being dry" is high (4% of patients are dry at 3 years).

Bulkamid injection appears to be an alternative treatment for stress-predominant urinary incontinence in selected patients. However **further long-term studies and prospective trial comparing suburethral meshes with injectable agents are needed** to answer the question if there are clear factors favoring one of them in this distinct patient population.

CONCLUDING MESSAGE

Bulkamid® injection is a **minimally invasive, safe, and high satisfaction rate treatment** option for selected patients with **stress-predominant** urinary incontinence.

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