

# #709 Surgical treatment for women with urodynamic stress urinary incontinence and sonographic fixed urethra. Are bulking agents an alternative?

Ros C, Escura S, Anglès S, Bataller E, Espuña M

Gynecology, ICGON, Hospital Clínic of Barcelona. University of Barcelona

## Hypothesis / aims of study

**Urethral bulking agents (UBA)** are injections of an agent into the submucosal tissues of the urethra to increase the coaptation of the urethral walls, increasing urethral resistance. Due to its efficacy and safety, UBA could be an alternative treatment to women with primary or recurrent stress urinary incontinence (SUI), especially with intrinsic sphincter deficiency (ISD) and/or fixed urethra, and to older women with comorbidities.

The **main objective** of the present study was to evaluate the results of UBA injection (Bulkamid®) in women with urodynamic SUI (USUI) and sonographic fixed urethra at 1 year follow-up.

## Study design, materials and methods

A prospective study was designed including **women with USUI** who ask for **surgical treatment**, in a cohort of women with **sonographic fixed urethra** (bladder neck descent <5 mm).

**Demographic variables** (age, body mass index, parity and previous SUI surgeries) were collected.

Urinary incontinence **symptoms** were evaluated subjectively by the International Consultation on Incontinence Questionnaire (ICIQ-UI-SF) validated questionnaire, and objectively, by a **24h-pad-test** and **urodynamics** tests, including measurement of the **maximal urethral closure pressure (MUCP)**.

A **transperineal ultrasound** was performed to all women to evaluate **bladder neck descent** at baseline.

ICIQ-UI-SF were repeated at **3 months** after UBA and at **1 year follow-up**, including a **postsurgical urodynamics and pad-test**. Satisfaction after surgery was evaluated by the Patient Global Impression of Improvement (PGI-1) questionnaire.

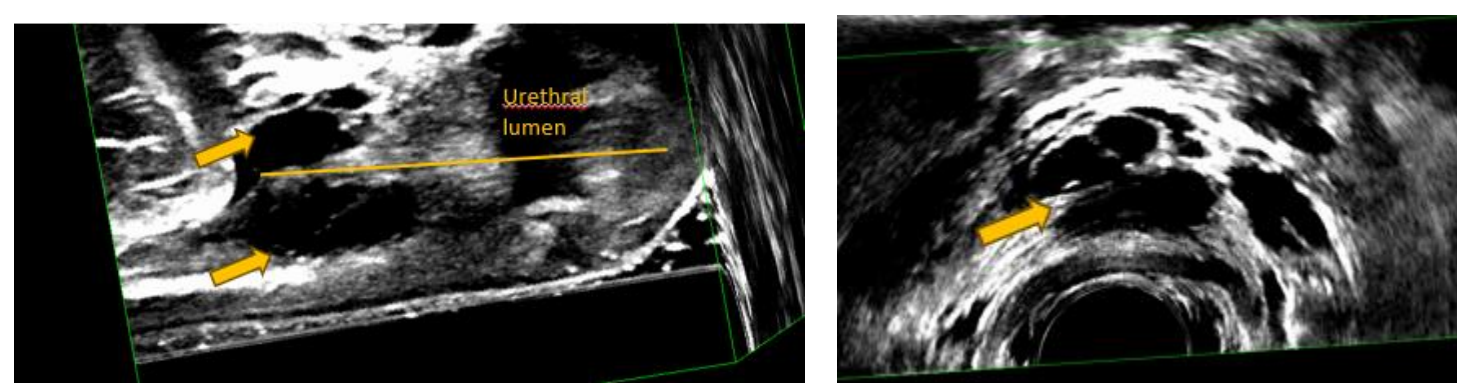


Figure 1. Mid-sagittal plane of the urethra (above) and transverse plane (below), obtained with a high-frequency three-dimensional transvaginal probe (type 9038, BK Medical). UBA wheals are identified in the proximal urethra, coapting the bladder neck.

## Results and interpretation

Up to **44 women with fixed urethra who underwent a UBA injection (Bulkamid®)** were included in the study, with a median age of 73.5 (62.3 – 78.8) and median body mass index 27.6 (25.1 – 32.3).

Only 4.5% were nullipara and up to **88.6%** had history of **previous SUI surgery** (11 patients underwent 2 SUI surgeries and 2 women, 3 previous SUI surgeries). Comparison of the baseline study variables versus 3 months and 1 year follow-up is showed in Table 1 (17 women have not yet completed 1 year follow-up).

The **prevalence of symptoms of SUI decreased significantly, with some worsening between 3- and 12-months follow-up.**

Leakage measured by the **pad-test decreased and MUCP increased.**

More than **70%** of women felt **much better after UBA** at 3 months, although the degree of satisfaction decreased when evaluated at 1 year follow-up.

**No adverse effects** have been reported, even in patients with presurgical voiding dysfunction confirmed by urodynamics.

Table 1. Comparison of the baseline study variables versus 3 months and 1 year follow-up.

	Baseline (n=44)	3 months (n=43)	1 year (n=27)	p-value
ICIQ-UI-SF, median (IQR)	17.0 (14.8 – 18.0)	8.0 (0.0 – 12.0)	15.0 (3.0 – 18.0)	<0.001
SUI severity, n (%)				
no UI	0 (0)	12 (27.9)	6 (22.2)	0.004
mild (1-5)	0 (0)	6 (14.0)	1 (3.7)	0.076
moderate (6-12)	1 (2.3)	16 (37.2)	5 (18.5)	<0.001
severe (13-18)	34 (77.3)	9 (20.9)	12 (44.4)	<0.001
very severe (19-21)	9 (20.5)	0 (0)	3 (11.1)	<0.001
SUI symptoms, n (%)	44 (100)	20 (46.5)	19 (67.9)#	<0.001
UII symptoms, n (%)	37 (84.1)	22 (51.2)	18 (64.3)#	0.005
Pad-test (g), median (IQR)	116.0 (54.5 – 231)*		34.0 (13.0 – 126.5)##	0.039
Urodynamic diagnosis, n (%)				
Hypersensibility	6 (14.0)**		2 (9.1)###	0.869
Hypoaccommodation	3 (4.7)**		3 (13.6)###	0.671
Detrusor overactivity	7 (16.3)**		8 (36.4)###	0.069
Voiding dysfunction	9 (20.9)**		4 (18.2)###	0.948
MUCP (cm H <sub>2</sub> O), median (IQR)	28.0 (21.0 – 43.3)***		32.5 (22.3 – 36.8)####	0.769
PGI, n (%)				
Very much better		13 (30.2)	7 (25.0)#	0.632
Much better		18 (41.9)	2 (7.1)#	0.004
A little better		7 (16.3)	10 (35.7)#	0.061
No change		5 (11.6)	9 (32.1)#	0.034

## Conclusions

**For patients with a severe USUI and fixed urethra, UBA are an effective and safe treatment with an acceptable degree of patient's satisfaction.**

## References

- Zheng Y, Rovner E. Update on Urethral Bulking for Stress Urinary Incontinence in Women. Curr Urol Rep. 2022 Oct;23(10):203-209. doi: 10.1007/s11934-022-01099-5
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