101

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THREE-DIMENSIONAL TRANSVAGINAL ULTRASONOGRAPHY TO ASSESS MACROPLASTIQUE OUTCOME IN WOMEN WITH STRESS URINARY INCONTINENCE

Hypothesis / aims of study

To evaluate short-term outcomes of Macroplastique™ (MPQ) in women with stress urinary incontinence (SUI) using a three-dimensional vaginal ultrasound (3DUS).

Study design, materials and methods

Following IRB approval, a chart review of non-neurogenic female patients that received MPQ for intrinsic sphincter deficiency (ISD) was extracted from a prospective database. Exclusion criteria included evidence of urethral hypermobility on examination and/or cystogram. Patients were divided into 3 groups: naïve (I), prior incontinence surgery (II), and both prior incontinence surgery and bulking agent (III). Baseline evaluation included history, physical examination confirming SUI, and questionnaires (Urinary Distress Inventory-6 (UDI-6), one QoL global score based on visual analog scale),and at times multichannel urodynamic studies and standing voiding cystogram. The first follow-up visit was 6-8 weeks after the MPQ injection procedure and included questionnaires and 3DUS imaging [1]. Further follow-up continued on an annual basis and included questionnaires with or without 3DUS. The 3DUS was performed by the same imaging team consisting of a senior ultrasound technician and a radiologist with a longstanding experience with collagen measurements by ultrasound [2]. MPQ is very echogenic and easy to identify (Figure 1) Success was defined as sufficiently improved after one injection such that subsequent reinjection/operation was not requested by the patient. Cure, meaning dry and not wearing any pads, was defined as a score of 0 on Question 3 of the Urinary Distress Inventory-6 (UDI-6) [3].It was hypothesized that group I would fare best. Descriptive statistics, Fisher's Exact test (categorical variables) and the Student t-test (continuous variables) were used to determine differences between the success and the failure groups. A mixed model was used to ascertain whether 3DUS volume after final injection decreased significantly over time after being controlled for by subgroup and number of injections. All statistics were completed using SAS 9.3 (SAS Institute Inc., Cary, NC).

Results

From a database of 72 patients from 7/11 to 12/13, 59 women met inclusion criteria (Table 1). Success rate was 83% for Group I, 70% for Group II, and 69% for Group III, at a mean follow-up of 8.5±0.9 months. Cure rate was 17% for Group I, 9% for Group II, and 38% for Group III. The mean age, parity, and BMI were comparable across the three groups as was the mean duration of follow-up (Table 1). For naïve patients, mean volume of MPQ injected was 4.43 ml (range 2,5-5), with mean volume measured on first 3 DUS after MPQ at 3.85 (range 1.77-5.91), for a retention rate of 87%. At this first 3DUS study, 72% of studies indicated a circumferential configuration for MPQ. Among the 15 failures, there was no significant difference between the groups, with 4 from Group I, 7 from Group II, and 4 from Group III (p=0.59) (Table 2). However, only 40% of those who failed had a circumferential configuration at their first 3D US. A VLLP greater than 60cm H2O was associated with a higher chance of success. 88% (15/17) of the patients who had VLLP ≥ 60 were in the success group, in comparison to 69% (11/16) of those with VLLP ≤ 60 (p = 0.22). The success group's UDI-6 scores for question 3 were generally more favorable pre-treatment than those of the failure group's. Among failures, 9 proceeded with reinjection, 4 with slings, and 2 with artificial urinary sphincters. Mean time between first and repeat injection was 10 months (3-19) whereas mean time between fist injection and a secondary sling was 8,5 months (2-16). Fifteen patients underwent a second 3DUS in follow-up (mean interval time of 9 months) with stable volume compared to first study (4.5±0.4 versus 4.4±0.4, p= 0.70). Four patients with prior collagen injection also underwent a second 3 D US with similar findings (5.3±0.6 versus 4.9±0.7, p=0.35). In a mixed model controlling for number of injections and their prior urological history, time since the last injection was not found to be a significant factor in ultrasound volume after the last injection (mean follow-up = 6.5 months; p = 0.46).

Interpretation of results

Even though absolute cure or strict dryness after MPQ is only achieved in a minority, MPQ provided durable SUI symptom improvement in the majority of our patient population. A VLPP over 60 cmH2O conferred a higher chance of success. No changes in question 5 of UDI-6 related to voiding, maximum flow, or post-void residual were noted, implying no effect on voiding function.

Concluding message

We report on our early experience with MPQ that indicates an overall success rate of nearly 70%, with a slightly higher rate of success in the naïve subgroup. In a subset of women who underwent repeat 3 D US testing over time, no significant loss of volume was noted. As confirmed by 3DUS, Macroplastique™ appears efficacious as both primary and salvage treatment for SUI due to ISD in the short-term.

Table 1. Baseline group comparison based on prior SUI surgical history			
	Naïve (n = 23)	**Prior Surgery (n = 23)**	**Prior Surgery + Collagen (n = 13)**
Age	64.1 ± 1.7	65.0 ± 2.4	70.1 ± 2.8
Parity	1.9 ± 0.2	2.8 ± 0.3	1.9 ± 0.4
BMI	26.0 ± 1.1	28.6 ± 1.3	27.2 ± 1.1
Duration of Follow-up (months)	7.2 ± 1.2	8.7 ± 1.5	10.3 ± 2.4
Pre-operative VLLP			
Mean ± standard error	53.6 ± 4.8	75.08 ± 11.20	65.4 ± 10.8
<60	4/13 (31%)	8/13 (62%)	4/7 (57%)
≥60	9/13 (69%)	5/13 (38%)	3/7 (43%)
Qmax (mean ± standard error)	15.5 ± 1.8	13.8 ± 2.0	20.1 ± 5.3
Post void residual			
No residual	16/19 (84%)	15/18 (83%)	6/9 (67%)
Residual (<50 mL)	3/19 (16%)	3/18 (17%)	3/9 (33%)
UDI6 Total (mean ± std. error) (0-18)	11.4 ± 1.1	10.4 ± 0.9	9.5 ± 1.5
UDI6 Q2 (0-3)			
0, 1	2/10 (20%)	5/18 (28%)	3/8 (38%)
2, 3	8/10 (80%)	13/18 (72%)	5/8 (63%)
UDI6 Q3 (0-3)			
0, 1	0/10 (0%)	1/19 (5 %)	2/8 (25%)
2, 3	10/10 (100%)	18/19 (95%)	6/8 (75%)
UDI6 Q5 (0-3)			
0, 1	5/10 (50%)	15/19 (79%)	6/8 (75%)
2, 3	5/10 (50%)	4/19 (21%)	2/8 (25%)

Table 2. Differences between the patients that only received one injection and had no other surgery versus patients that had another injection or reoperation			
	Success Group (n = 44)	**Failure Group (n = 15)**	**p-value**
Prior History			
Naïve	19/23 (83%)	4/23 (17 %)	0.59
Prior incontinence procedure	16/23 (70%)	7/23 (30%)	
Prior incontinence surgery + collagen	9/13 (69%)	4/13 (31%)	
Pre-operative VLLP			
Mean ± std. error	62.6 ± 6.2	71.9 ± 11.8	0.49
<60	11/16 (69%)	5/16 (31%)	0.22
≥60	15/17 (88%)	2/17 (12%)	
Qmax (mean ± std. error)	15.8 ± 1.7	15.5 ± 2.8	0.94
Post void residual			
No residual	29/37 (78%)	8/37 (22%)	1.00
Residual (<50 mL)	7/9 (78%)	2/9 (22%)	
UDI6 Total (mean ± std. error) (0-18)	10.2 ± 0.8	11.2 ± 1.0	0.44
UDI6 Q2 (0-3)			
0, 1	8/10 (80%)	2/10 (20%)	0.69
2, 3	18/26 (69%)	8/26 (31%)	
UDI6 Q3 (0-3)			
0, 1	3/3 (100%)	0/0 (0%)	0.54
2, 3	23/34 (68%)	11/34 (32%)	
UDI6 Q5 (0-3)			
0, 1	19/26 (73%)	7/26 (27%)	0.70
2, 3	7/11 (64%)	4/11 (36%)	

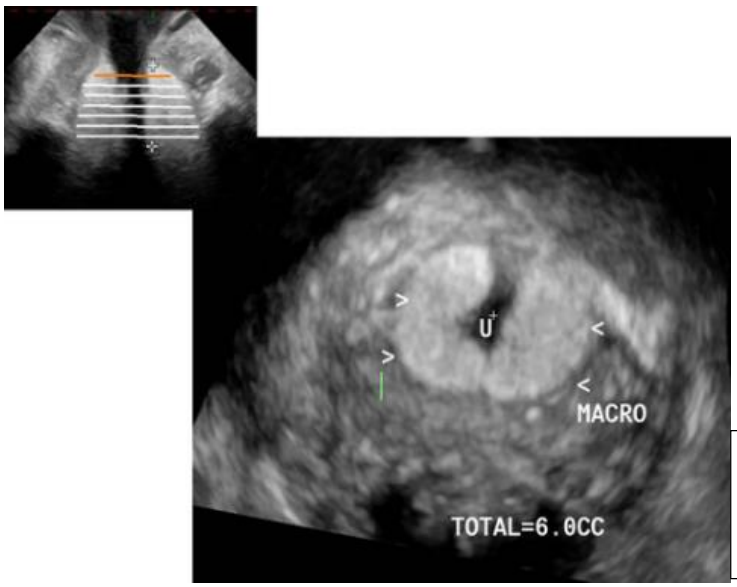

Figure 1: Macroplastique seen on 3DUS with very hyperechogenic appearance along the urethra (U) on longitudinal (A) and transversal (B) images in a naïve patient dry after one injection.

References

1. Curr Opin Obstet Gynecol 16(5):411-417, 2004
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Disclosures

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