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TRANSURETHRAL INJECTION THERAPY FOR FEMALE STRESS INCONTINENCE: CAN WE PREDICT RESPONSE AND LIKELIHOOD OF REPEAT TREATMENTS?

Hypothesis / aims of study

The objective of this study was to identify prognostic indicators for treatment response and the need for reinjections in stress-incontinent women undergoing transurethral bulking with silicone microimplants.

Study design, materials and methods

This was a retrospective longitudinal study of stress incontinent women who underwent transurethral bulking with silicone particles (Macroplastique®**,** Uroplasty, Minnetonka, MN) between July 2007 and September 2009. Analysis was performed to determine risk factors for treatment response in women undergoing single and multiple treatments of Macroplastique (MP).

To determine treatment failure, a self-reported incontinence severity scale was used (0: continence; 1: 1-2 incontinent events/day; 2: 3-4 incontinent events/day; 3: ≥ 5 incontinent events/day). Treatment response was defined as a decrease by at least one in their incontinence severity score; treatment failure was no change or an increase in severity score. Secondary analysis was performed to identify risk factors associated with retreatment.

Statistical analysis was performed using Wilcoxon rank sums test, Fisher exact and Chi square tests, and binary logistic regression. Variables tested are listed in Table 1.

Results

124 women underwent transurethral bulking with MP during the study period. Median demographics were age 74 (66-80), BMI 28 (24-31), and parity 2 (2-3). 66% (82/124) had previous anti-incontinence surgery, 15% (18/124) previous bulking therapy, and 78% (97/124) previous pelvic reconstructive surgery including hysterectomy.

61% (76/124) patients responded to treatment with improved incontinence severity scores following therapy; 39% (48/124) were unchanged or worsened. Of the responders, 66% (50/76) were treated with a single injection and 34% (26/76) underwent multiple injections (range 2-6). Of the non-responders, 32 /48 (67%) had one injection and 16/48 (33%) had multiple injections (range 2-3). The treatment response was equal in the single and multiple injection arms [61% (50/82) vs 62% (26/42)] respectively. The cure/dry rate was 32% (40/124).

Variables associated with treatment response compared with failure are displayed in Table 1. Mixed incontinence symptoms (p=0.02, OR 2.4, CI 1.1-5.0), ≥ 3 pads per day (p=0.05, OR 2.1, CI 1.0-4.5), ≥ 5 incontinent events/day (p=0.05, OR 2.1, CI 1.0-4.5), previous anterior colporrhaphy (p=<0.01, OR 2.8, CI 1.3-6.1), 1st leak ≤ 50ml on CMG (p=0.01, OR 2.0, CI 1.2-7,5), and MUCP≤40 (p=0.03, OR 2.6, CI 1.1-5.9) were strongly associated to treatment response.

The repeat injection cohort was studied secondarily. They included 34% (42/124) of the total study population. Repeat MP injection was associated with history of urethrolysis (p=<0.01, OR 6.2 CI 1.5-24.7), MUCP≤40 (p=0.02; OR 3.5, CI 1.2-10.0), LPP≤60 at 150ml (p<0.01, OR 3.5, CI 1.3-9.3), LPP ≤60 at capacity (p<0.01, OR 7.3, CI 1.6-33.2), ≥ 5 incontinent events/day (p≤0.01; OR 3.0, CI 1.4-6.4), and positive empty supine stress test (ESST) (p=0.02; OR 2.7, CI 1.1-6.3). Positive ESST (p=0.02), 1st leak ≤ 50ml on CMG (p=0.02), 3+ pads per day (p=0.04), LPP at 150ml (p=0.05) were predictors for treatment response in the multiple treatment arm but not in the single treatment group. Increased incontinent events per day were a predictor of treatment response in both arms (p≤0.01).

Interpretation of results

61% of patients had improved incontinence severity scores following Macroplastique® injection; approximately 1/3 required repeat injection to achieve this response. Clinical and urodynamic parameters may be used to predict response to treatment and the likelihood of retreatment in patients undergoing transurethral bulking with Macroplastique®.

Concluding message

Patients with clinical and urodynamic indicators of more severe incontinence require repeat injections; however these at-risk patients are more likely to respond to treatment.

Table 1: Factors associated with Macroplastique treatment response

Variable	Responders (n=76)	Nonresponders (n=48)	p-value

Clinical parameters			
Age	74 (66-79)	74 (65-80)	0.66
Parity	2 (2-3)	3 (2-3)	0.08
BMI	27 (24-31)	28 (25-31)	0.34
Incontinence type[a]			
SUI	25 (33)	22 (46)	0.15
MUI	43 (57)	9 (19)	**0.02**
UUI	8 (11)	17 (35)	0.19
3+Pads per day[a]	53 (70)	25 (52)	**0.05**
Hypermobility [a]	54 (71)	32 (67)	0.69
Empty stress test [a]	21 (28)	8 (17)	0.16
Prolapse > Stage 3 [a]	4 (5)	4 (8)	0.50
Incont Events/Day	5 (4-5)	2 (2-5)	**<0.01**
Anti-incontinence surgery [a]			
Sling	50 (66)	26 (54)	0.20
Burch/MMK	10 (13)	4 (8)	0.41
PUB	16 (21)	7	0.37
Pelvic surgery [a]			
Urethrolysis	8	3	0.41
Anterior colporraphy	41	14	**0.01**
Vault suspension	23	53	0.70
Hysterectomy	49	30	0.82
Urodynamic parameters			
1st leak ≤ 50ml, CMG [a]	29 (38)	8 (17)	**0.01**
LPP 150	53 (27-70)	60 (45-89)	0.08
LPP capacity	41 (25-60)	46 (32-60)	0.32
MUCP≤40 [a]	59	28	**0.03**
Detrusor overactivity [a]	11	10	0.32
MP injections	1 (1-2)	1 (1-2)	0.16
Total MP ml	5 (2.5-7.5)	5 (2.5-7.5)	0.34
FU (wks)	10 (3-22)	13 (4-26)	0.78

Median (interquartile range) unless otherwise stated
[a] n (%)

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Institutional Review Board (Cleveland Clinic Florida)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**