

IMPROVED OUTCOMES IN PATIENTS WITH TRANSIENT URINARY RETENTION AFTER MACROPLASTIQUE URETHRAL BULKING PROCEDURE

Hypothesis / aims of study

A variety of urethral bulking agents (UBA) have been incorporated into the treatment algorithm for stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD). This minimally-invasive therapy works by increasing the urethral closing pressure and increasing the resistance to urinary flow. Macroplastique® (MPQ), a silicone elastomer, was first introduced in 1991. In the largest published series studying the use of Macroplastique for female SUI, an intent-to-treat RCT, 36.9% of subjects were cured with 61.5% improved at 1 year, and a transient urinary retention (UR) rate of 6.9% was observed [1]. In our series, we have found a higher rate of UR than previously reported. The aim is to compare overall improvement/cure rates between patients with and without UR after urethral injection of MPQ in a single-institution series.

Study design, materials and methods

This single institution series included 29 female subjects, each of whom had undergone an in-office urethral bulking procedure with Macroplastique from 8/2007 through 5/2009. All subjects had a peri-urethral block with 10cc of buffered 1% lidocaine and were injected

trans-urethrally with a total of 5cc Macroplastique at the mid-urethra as described by the manufacturer. Injections were all performed by a single investigator. The subjects were divided into two groups based on whether they experienced transient urinary retention or voided immediately post-procedure. The two groups were matched for age, length of follow-up and percentage of subjects with prior stress and/or urge incontinence procedures. Data was collected from telephone questionnaires and chart review. Global Improvement (GI)

in stress incontinence was assessed for both subsets, including assessment of IIQ-7 and IQOL scores.

Results

14/29 subjects (48%) experienced UR requiring intermittent catheterization/indwelling catheter, while 15/29 (52%) were able to void spontaneously post-procedure.

The mean length of UR was 4.7 days. After excluding 3 outliers with confounding factors such as post-procedure UTI or previous botox therapy, the mean UR length was 2.14 days. A larger percentage of patients in the transient UR subset had a global improvement in stress incontinence of greater than 75% (see Table 1). Follow-up data on global improvement scores ranged from 1.5 to 24 months.

Table 1: Global Improvement

Subset	<50% GI	50-75% GI	>75% GI	100% GI
Retention	4 (28.6%)	2 (14.3%)	8 (57.1%)	4(28.6%)
No Retention	7 (46.7%)	2 (13.3%)	6 (40%)	2(13.3%)

Additionally, those with transient urinary retention had an overall improvement in IQOL scores by 4.6 versus 4.3 for those without retention. A trend towards statistical significance was seen, however, significance was not achieved due to the small size of the study cohort.

Interpretation of results

Almost fifty percent of the study population experienced transient urinary retention, a rate that far exceeds published rates of UR after Macroplastique. Though the exact mechanism behind the high rate of retention is unknown, the authors hypothesize that the effect is likely the result of an aggressive peri-urethral block in combination with a marked and evenly-distributed bulking effect. In those subjects who experienced transient UR, higher overall GI scores were reported and the effect was sustained for up to one year post-procedure.

The distribution of the bulking agent is thought to be responsible for both the retention and the higher GI scores. Further research is focused on elucidating the cause of high UR rates with concomitant improved GI scores. All of the subjects, except one in the transient UR subset, were able to perform intermittent catheterization without difficulty and noted no adverse effect on their QOL outcomes or willingness to proceed with repeat injection, if necessary. The study was limited by the small cohort of patients and retrospective examination of outcomes.

Concluding message

Macroplastique is an effective treatment for SUI. In our series, there was a high rate of UR, possibly associated with the peri-urethral block and the distribution of the bulking agent. The UR subset reported higher Global Improvement scores, and many maintained benefit for > 1 year. These findings impact our patient counseling and merit further investigation.

References

1. Ghoniem, G., Corcos, J., Comiter, C., Bernhard, P., Westney, O.L., & Herschorn, S. (2009). Cross-linked polydimethylsiloxane injection for female stress urinary incontinence: Results of a multicenter, randomized, controlled, single-blind study. *J Urol*, 181, 204-210.

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<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Health East IRB
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes