Long- term Safety and Efficacy of Polydimethylsiloxane (Macroplastique®) in Female Patients with Stress Urinary Incontinence: Analysis of Patients Who Completed 3- Years of Treatment

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Abstract 616

Introduction

Macroplastique (MPQ) is a urethral bulking agent (UBA) used in the treatment of stress urinary incontinence (SUI) in women with intrinsic sphincter deficiency (ISD). UBA of various materials have been studied as early as the 1930s. MPQ has been shown to have a good safety profile with no carcinogenic effects. It is constructed of a silicone elastomer with a large diameter of 140 ųm suspended in a lower molecular weight gel. The elastomer has a rough configuration that interlock. These are unique properties of the material that do not allow for migration once implanted under the mucosa of the urethra [1]. The durability of MPQ has been shown in patients who were successful at one year and followed up to 2 years in a previous study. They maintained high success rate and demonstrated up to a 67% dry rate but even higher improvement rates of incontinence in the short term, 75% [1, 2]. The purpose of this study is to evaluate the safety and efficacy of MPQ in women with SUI due to ISD who completed 3-year follow-up in this post market study.

Methods and Materials

- Retrospective review of prospectively collected data
- Muticenter* study between October 2008-August 2017
- 276 subjects enrolled
- 70 subjects completed 3 year follow up
- Subjects were treated with up to two MPQ injections
- Stamey grade (0= continent, 1= incontinence with vigorous activity, 2= incontinence with minimal activity and 3= total incontinence) and I-QoL questionnaire divided into 3 subscales assessed at baseline, 12, 24, and 36 months post injection
- Patient Global Impression of Satisfaction (PGI-S) assessed at 36 months
- Success defined as improvement to Stamey grade 0 or 1 at 36 months
- Safety assessment reported on serious and non-serious adverse events (AE)
- Two-sided binomial test for overall success rate
- Linear mixed effect model with patient-level random effect to examine longitudinal trends over the 3-year study period

Acknowledgement to centers involved

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12. University of Michigan Health Center
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14. Western Carolina Women's Specialty Center
15. Urology of Virginia
16. Urology Associates, PC
17. Carolina Urology Partners
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Results

- Majority white n= 67
- Mean age 63.3 years
- 36 months
  - 21/70 (30%) Stamey grade 0
  - 28/70 (40%) Stamey grade 1
  - Overall satisfaction 68%
  - 27/70 (38.5%) very satisfied on PGI-S
- Composite success rate 51.4% (QoL, PGI-S and Stamey grade improvement)
- Most common AE within first 3 months
  - Transient dysuria 3.2%
  - Hematuria 6%
  - Pain at the injection site 1.6%
  - Urinary tract infection 2%
- No serious AE reported

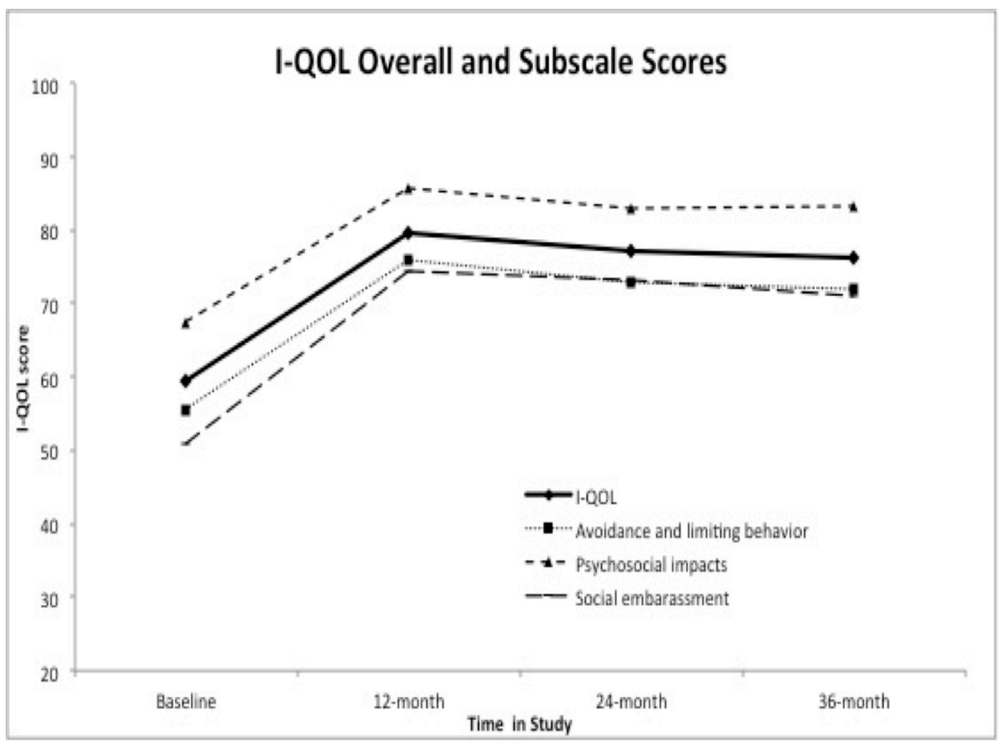

Table 1: I-QoL scores and subscales significantly improved at 12, 24 and 36 months from baseline (p <0.0001) and remained stable

Discussion

Composite outcome was determined by combining the subject reported outcomes based on the questionnaires and some degree of objective improvement as based on Stamey grade. Using a standardized questionnaire allows for longitudinal follow up that has shown the sustainability of satisfaction over the years even if some subjects required repeat injection. Subjects may have improved within their own Stamey grade therefore accounting for a higher overall satisfaction when compared to the composite success rate. One could argue that measures such as pad weight or urodynamic testing could be used to evaluate the success of UBAs, validated questionnaires such as the I-QoL and PGI-S are sufficient to evaluate subjective outcomes. This subjective improvement is significant when it comes to treating conditions that effect quality of life such as SUI. The injection is also safe seeing that non-serious AE resolved in a short period of time and no patient deaths or serious AE occurred in this cohort. A recent publication demonstrated that surgeon skill level and pelvic radiation history was correlated with failure of MPQ [3]. While the surgeon experience was not captured in this study, the ease of administration of the implant by a minimally invasive, endoscopic route can account for the low risk and assuring complication profile in this study.

Conclusions

At 3 years, MPQ is safe and efficacious for the treatment of SUI secondary to ISD in women. The overall satisfaction is sustained from baseline to 3 years post injection.

References

1. Ghoniem G, Corcos J, Comiter C, Westney OL, Herschorn S: Durability of urethral bulking agent injection for female stress urinary incontinence: 2-year multicenter study results. *J Urol* 2010, 183(4):1444-1449.