

Research Communication

Long-term outcomes of polyacrylamide hydrogel treatment in women with stress urinary incontinence

Polyacrylamide hydrogel (PAHG; Bulkamid®, Contura International A/S, Søborg, Denmark) is a urethral bulking agent (UBA) commonly used in the treatment of stress urinary incontinence (SUI). However, long-term clinical data are limited. The aim of this study was to describe outcomes associated with PAHG injections in women with SUI. The primary outcome was treatment success. Secondary outcomes included incontinence impact, urinary distress, pain under local anaesthesia, willingness to refer PAHG treatment to a friend, and adverse events.

A total of 171 women underwent PAHG injections for the treatment of SUI by a single urologist at an Australian centre between January 2012 and December 2019. Clinical and fluoroscopic urodynamic assessments were used to confirm and define the subtype of SUI diagnosis. All injections were performed in a standardized fashion [1].

Study outcomes were assessed preoperatively (T1), 4 weeks postoperatively (T2) and 3–105 months postoperatively (T3). Information on the latter was gathered via a cross-sectional study conducted in July 2020. At T1, women completed the Incontinence Impact Questionnaire Short Form (IIQ-7) [2] and the Urinary Distress Inventory Short Form (UDI-6) [2]. At T2, women completed the UDI-6 as well as an 11-point numeric rating scale to assess pain associated with injections under local anaesthesia ('no pain to 'worst pain possible'), and indicated their willingness to recommend PAHG treatment to a friend. At T3, women completed the IIQ-7, the UDI-6, the International Consultation on Incontinence Questionnaire Short Form [3], and the Patient Global Impression of Improvement (PGI-I) [4].

Patients who did and did not complete T3 assessments were compared using Pearson's chi-squared test for previous treatment and independent-samples *t*-tests for age, and UDI-6 and IIQ-7 scores. All subsequent analyses were performed using data from women who completed the T3 assessments. Descriptive statistics were used to summarize sample characteristics and self-reported data, including changes between preoperative and follow-up assessments. Treatment success was defined as a PGI-I score of ≤ 2 ('very much better' or 'much better'). Treatment outcome was examined by time since initial injection: <1, 1–2, 3–4, 5–6 and 7–8 years. Outcomes were summarized using proportions and 95% CI. Kendall's tau was used to assess the association between self-reported scores at T3 and length of time from initial

PAHG injection. Analyses were performed in R (R Core Team, 2019) and *P* values <0.05 (two-sided) were taken to indicate statistical significance.

The study was approved by the institutional ethics committee (EH2020-621).

Of the 171 women, 107 completed the T3 assessment: 35 were lost to follow-up and 29 proceeded to alternative treatment following insufficient response to primary PAHG treatment. Responders and non-responders differed on incontinence impact (10-point difference, 95% CI 1–19; favouring responders) but not on age, previous treatment or urinary distress.

The median (range) age of responders was 65 (25–93) years. The median time between initial injection and T3 assessment was 51 months. A total of 64 women (60%) underwent repeat injection; the median time between injections was 3 months. Local anaesthesia was used in 83 women (78%); the median pain score associated with injections was 2 points (scale range 0–10).

Successful outcomes were reported by 60% of women <1 year after initial injection, and by 48% between 1 and 2 years, 46% between 3 and 4 years, 57% between 5 and 6 years and 53% between 7 and 8 years since initial injection (Table 1). Of those reporting a successful outcome, 42% had one injection and 58% had two injections.

Urinary distress and incontinence impact lessened following PAHG treatment, and associations between T3 scores and length of time since first injection were trivial and not statistically significant (Appendix S1). Differences between women reporting successful and unsuccessful outcomes on urinary distress and incontinence impact were trivial at T1 and T2. At T3, however, women reporting a successful outcome also reported lower (i.e. better) scores on all outcomes assessed (Appendix S2). Overall, 90% of women were willing to recommend this treatment to a friend.

Adverse events were infrequent. UTI within 30 days postoperatively occurred in five patients. Transient acute urinary retention (AUR) requiring urinary catheterization occurred in five patients, with four of these having a successful trial of void the following day; one patient, however, required deflation of a previously inserted adjustable continence therapy balloon for resolution. There was no case of erosion.

Table 1 Descriptive statistics for treatment outcome and number of injections, stratified by time since first polyacrylamide hydrogel injection

First surgery to follow-up	n	Successful outcome			Number of injections	
		n	%	95% CI	1	2
<1 year	10	6	60%	31–83	1	5
1–2 years	29	14	48%	31–66	5	9
3–4 years	26	12	46%	29–65	5	9
5–6 years	23	13	57%	37–74	6	7
7–8 years	19	10	53%	32–73	5	5

First surgery to follow-up	n	Unsuccessful outcome			Number of injections	
		n	%	95% CI	1	2
<1 year	10	4	40%	17–69	3	1
1–2 years	29	15	52%	34–69	6	9
3–4 years	26	14	54%	35–71	4	10
5–6 years	23	10	43%	26–63	6	4
7–8 years	19	9	47%	27–68	1	8

There are few studies on the durability and long-term safety of this agent, with only three having reported on longer-term (>24 months) outcomes of PAHG treatment [5–7]. In a study of 24 patients, Mouritsen et al. reported seven patients (29%) having undergone subsequent mid-urethral sling placement [5]. All patients were then interviewed on their continence outcomes at 8-year follow-up. The overall cured/much improved rate of 44% reported [6] therefore reflects not only PAHG outcomes but also subsequent mid-urethral sling therapy. Pai et al. reported an 83% subjective cure/significant improvement rate in a study of 256 patients at 3 months, with a non-statistically significant reduction in efficacy in a remaining cohort of 60 patients assessed at 5 years [6]. There was no mention of the number of patients who progressed to alternative SUI surgery. Brosche et al. assessed 7-year outcomes of PAHG treatment in 388 patients. Of these, 74 patients (19%) had undergone an alternate SUI procedure, with 253 patients (65%) found to have a subjective cure/improved rate when surveyed using a four-point scale: 'cured', 'improved', 'unchanged' or 'worse' [7].

Transient minor complications such as UTI, AUR and haematuria are not uncommon after UBA injections. The median reported pain score of 2 indicates that PAHG injections were generally well tolerated under local anaesthesia. The 5% UTI and 5% AUR rates in this study are comparable to the 1.6–40% UTI and 0.4–20% AUR rates reported by other studies [8]. No serious adverse event such as erosion or migration of product was noted in our study or in the literature, which is important when making comparisons with other UBAs in the long term.

The strength of this study lies in it being the largest Australasian series on PAHG treatment outcomes performed by a single urologist. Although intervention for SUI is

generally focused on minimizing urinary leakage, it is ultimately a procedure aimed at improving a patient's quality of life. Therefore, subjective satisfaction with symptom improvement is important. The use of validated patient-reported outcome measures is valuable in assessing patients' perceptions of how interventions have affected their symptom severity, quality of life, and daily functioning over time.

Nevertheless, the study has several limitations. Firstly, it was a cross-sectional study, with all the limitations inherent to this design. Patients who did not respond to primary PAHG treatment and proceeded to alternative SUI treatment were excluded from the final assessment. Clinicians should take this into consideration when interpreting the results of this study. A statistically significantly lower baseline IIQ-7 score was seen in the responder group. This was not unexpected, as patients with more severe incontinence at baseline were more likely to proceed to sling surgery and therefore be classified as non-responders. Lastly, the final assessment was administered at a single point in time rather than at standard, prespecified times.


Overall, 21% of women did not respond sufficiently to treatment with PAHG injection. As opposed to the common perception about UBAs being a short-term therapy requiring frequent repeat injection, a 53% success rate was achieved in those 7–8 years since initial injection. Short-term adverse events were infrequent and mild and there was no serious long-term adverse event. Larger prospective comparative studies are warranted.

Disclosure of Interests

The authors declare no conflicts of interests.

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Abbreviations: AUR, acute urinary retention; IIQ-7, Incontinence Impact Questionnaire Short Form; PAHG, polyacrylamide hydrogel; PGI-I, Patient Global Impression of Improvement; SUI, stress urinary incontinence; UBA, urethral bulking agent; UDI-6, Urinary Distress Inventory Short Form.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Descriptive statistics for patient-reported outcome measures (PROMs) and the association between time since first injection and final assessment.

Appendix S2. Patient-reported outcome measures by PGI-I classification (successful vs unsuccessful) and estimate of difference between means.