The use of polyacrylamide hydrogel in the setting of failed female stress incontinence surgery

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Introduction

Approximately one in five women will develop stress urinary incontinence (SUI),[1] and of those undergoing surgical management, up to 50% will experience recurrent stress incontinence over time.[2,3] In Ontario, approximately 5% of women will undergo a repeat stress incontinence procedures in the 10 years after a midurethral sling (the primary SUI procedure used over the last decade).[4] Management of patients with recurrent incontinence after the failure of prior procedures is challenging. A recent Cochrane review failed to identify any high-quality studies to direct patient management for this situation.[5] In a subset of women with recurrent incontinence, repeat operative procedures are not feasible, and therefore urethral bulking agents are an attractive option. They are minimally invasive, and well-suited for intrinsic sphincter deficiency, which is common after multiple incontinence procedures; however, the substantial cost associated with them limits their utilization in Canada. There are very few contemporary reports of the efficacy of bulking agents for recurrent urinary incontinence; a recent systematic review of bulking agents primarily identified patients with mild untreated stress incontinence.[6] The objective of our study was to report our results of a series of patients treated with polyacrylamide hydrogel (Bulkamid™) after failed stress incontinence surgeries.

Methods

We conducted a chart review of all women who underwent treatment with polyacrylamide hydrogel for demonstrated stress incontinence at our institution between July 2013-March 2017. We excluded individuals who underwent these procedures as primary treatment for stress incontinence (n=3). Standard clinical evaluation of patients included a history, physical exam, completion of the ICIQ-UI questionnaire[7], and in select cases urodynamics and cystoscopy. A bulking procedure was offered when alternative surgical options were not felt to be appropriate. Two mL of Polyacrylamide hydrogel was injected under neurolept sedation in all women using a specialised sheath and rigid pediatric cystoscopy into 3 to 4 sites in the proximal urethra as

previously described; we utilised the standard technique of periurethral injection with the goal of creating "mounds" that increased the coaptation of the urethra[8]. Followup was performed at 6 weeks, and then every 6 to 12 months. A second injection procedure was offered only to women with a good response to the first injection. Our primary outcome was the overall success of the bulking agent. Failure of the bulking agent was defined either as a subjective return to their baseline level of incontinence or initiation of an alternative treatment for stress incontinence. Ethics approval was obtained from Western University.

Results

We identified a total of 17 women who met our inclusion criteria. The median age of participants at the first bulking agent injection was 70 years (IQR 59-78). Four participants (24%) used diapers and the rest of participants (n=13, 76%) used a median of 5 (IQR 3-6) light to heavy pads per day. The significant degree of bother associated the urinary incontinence was represented with the answers to the ICIQ-UI questions (Table 1). Mixed incontinence was present in 12/17 (71%), and all of these patients were trialed on various oral overactive bladder medications prior to bulking agents. The previous stress incontinence procedure history, (and complicating factors such as mesh complications, pelvic radiation, pelvic fracture or neurogenic disease) for the patients included in this study are listed in Table 2.

In total there were 22 peri-urethral injections of 2 ml of polyacrylamide hydrogel (representing 17 primary injections, and 5 repeat injections). One patient required catheterization for 48 hrs for post injection urinary retention. Success of the bulking procedure over time is shown in Figure 1. Of the 12/17 (71%) patients who experienced benefit at the end of followup, 5/12 (42%) required a second injection (at 10, 13, 24, 29 and 46 months after the initial injection).

Discussion

While the use of bulking agents at our institution was associated with a good early response, as expected durability was limited, and often required a second injection. In these women, due to medical comorbidities, patient choice, or multiple failed prior operative procedures, bulking agents were the best therapeutic option, and overall there was acceptable clinical efficacy. Given the current funding challenges in Canadian healthcare, this study provides important evidence supporting the role of bulking agents for selected patients with recurrent stress urinary incontinence. Overall our results are consistent with a recent systematic review of periurethral polyacrylamide hydrogel, which primarily included patients with mild primary stress incontinence; the included studies reported good clinical success, minimal morbidity, and an approximately 25% reinjection rate[8].

Two prior studies are particularly relevant to our results. Gaddi et al performed a retrospective cohort study of patients who had undergone midurethral sling placement and compared bulking agent to repeat sling for recurrent SUI. They found no difference in perioperative complications or adverse events, but they did show that risk of failure was higher

in those undergoing bulking agents compared to those with repeat midurethral sling (OR: 3.49 95% CI: 1.24-9.09)[9]. Altman et al performed a prospective observational study of individuals with SUI deemed ineligible for midurethral sling who underwent treatment with polyacrylamide gel, (12 of the 81 patients had previously undergone stress incontinence surgery). Contrary to our study, they found minimal improvements at 6 months, and no significant improvement after repeat injections[10]. The paucity of data and increasing clinical need for recurrent incontinence treatment highlights the need for further research within this area.

Limitations of our study include the small and heterogeneous patient population, and the fact that repeat injections (often used in patients treated with bulking procedures) were only offered if the initial procedure had some success due to limited hospital funding for these procedures. Finally, our outcome was based on subjective improvement as opposed to an objective measure such as pad weights or incontinence diaries.

In conclusion, polyacrylamide hydrogel has reasonable clinical efficacy in a population of women with stress incontinence who otherwise have few treatment options.

References

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Figures and Tables

Fig. 1. Kaplan-Meier survival curve showing failure of the bulking procedure over time (months). Five of the 17 patients included required repeat injections, and they are counted as a success from the initial injection to the end of followup, or failure of the procedure.

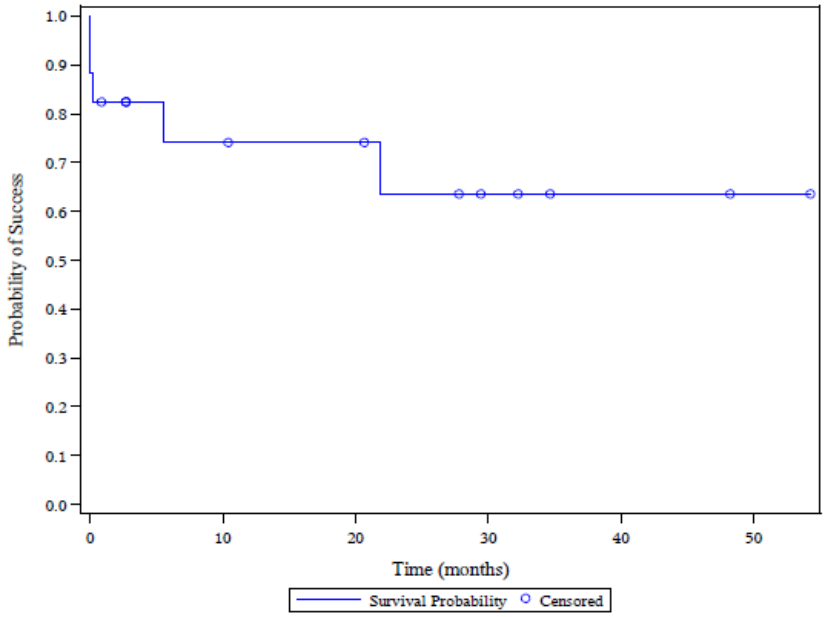

Table 1. ICIQ-UI responses at baseline

Question	Scale	Median response (IQR)
ICIQ-UI item 1, How often do you leak?	Never (0) – All the time (5)	5 (4–5)
ICIQ-UI item 2, How much urine do you leak?	None (0) – A large amount (6)	4 (3–5)
ICIQ-UI item 3, How much does this interfere with daily life?	Not at all (0) – A great deal (10)	10 (9–10)

ICIQ-UI: International Consultation on Incontinence Questionnaire-Urinary Incontinence; IQR: interquartile range.

Table 2. Relevant stress incontinence complications factors and prior procedures

Patient	Other relevant conditions	SUI complications	Prior SUI procedures
1	SCI		AFPVS
2	Pelvic Fracture		AFPVS
3		Mesh erosion	TVTO, BC
4		Mesh incision	MMK x2, BC, TVTO, TVT
5		Mesh incision	TVT
6	Morbid obesity		TVTO x2
7			BC x 2, AFPVS, Marlex BNS, collagen
8			TVTO, PVS
9	Prior bladder neck injury during hysterectomy		AFPVS
10			TVT
11	Spina bifida with prior ileocystoplasty		AFPVS
12	Pelvic radiation		TVT
13			TVT, collagen X2
14			BC, TVTO
15	Pelvic radiation		BC
16			AFPVS
17			AFPVS, collagen x2

AFPVS: autologous fascial pubovaginal sling; BC: Burch colposuspension; BNS: bladder neck sling; MMK: Marshall-Marchetti-Krantz; TVT/O: tension free vaginal tape/obturator.