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TITLE PAGE

URETHRAL BULKING AGENTS: A RETROSPECTIVE REVIEW OF PRIMARY VERSUS SALVAGE PROCEDURE OUTCOMES

Authors

Ciara M. E. Daly[1], Jini Mathew[1], Judey Aloyscious[1], Suzanne Hagen[1], Veenu Tyagi[1], Karen L. Guerrero[1]

Affiliations

[1]Department of Urogynaecology Queen Elizabeth University Hospital, Glasgow

Corresponding Author

Dr Ciara M.E. Daly. Department of Urogynaecology, Queen Elizabeth University Hospital, Glasgow, Scotland. Tel – 0141 201 1100. cdaly22@qub.ac.uk

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Abstract

Purpose

Urethral Bulking Agents (UBA) have traditionally been offered as salvage procedures for recurrent Stress Urinary Incontinence (SUI). We compare the success of UBA in patients that had undergone a previous procedure for SUI (Salvage-UBA) to the SUI surgery naïve (Primary-UBA). We hypothesised a positive effect in both Primary and Salvage-UBA with potentially poorer rates of response in the salvage group.

Methods

Retrospective case-series of patients having their first UBA (2010–2018). Primary outcome was to assess any difference in patient reported success between groups. Patient reported improvement was assessed on a 4-point scale: 'cured, improved, no change, worse' and treatment 'success' defined as 'cured' or 'improved'.
A multivariate analysis, adjusting for plausible differences between groups was undertaken in IBM SPSS Statistics (2016).

Results

135 Primary-UBA and 38 Salvage-UBA were performed. Complete follow-up was obtained for 114 patients (66%): 86 Primary & 28 Salvage. Median follow-up time: 33-months. In 2012, 47% (8/17) of all UBA were Salvage-UBA, whilst in 2018 the majority were Primary-UBA (92%, 46/50).

Success was not significantly different between Salvage-UBA 75% (21/28) versus Primary-UBA 67% (58/86) (Wald χ^2= 0.687, df=1, p=0.407). Top-up rates were similar; 14% (n=4/28, Salvage-UBA) versus 15% (n=13/86, Primary-UBA) (χ^2= 0.011, df=1, p=0.914).

Conclusions

The number of women opting for UBA has increased substantially. No significant differences were noted for success with Salvage-UBA compared to Primary-UBA.

Keywords

Urethral, Bulking, Incontinence, Primary, Salvage

MAIN TEXT

Introduction and Purpose

Surgical management of Stress Urinary Incontinence (SUI) is under intense scrutiny. Mesh procedures for SUI were routine until recent years; a current pause is in place within the United Kingdom (UK) (1). Urethral Bulking Agents (UBA) are minimally invasive, non-mesh, day-case or office procedures for SUI. Traditionally, they have been offered as salvage procedures when surgical procedures (e.g. Colposuspension, Autologous Fascial Sling and Mid-Urethral Mesh-Tape) have failed to improve symptoms sufficiently, or when comorbidities make patients unsuitable for these procedures. A Cochrane review (2017) concluded UBA were inferior to surgery for SUI at one-year follow-up but had a better safety profile (2). Despite the inferior success, numbers are on the rise. National statistics from England show a doubling in the number of UBA performed in the last two years (3). For some, UBA may be a desirable first choice procedure for SUI especially if they wish a day–case, non-mesh procedure with a quicker recovery.

Our aim was to compare the success of UBA in patients that had undergone a previous surgical procedure for Stress Urinary Incontinence (Salvage-UBA) to the SUI surgery naïve (Primary-UBA). We hypothesised a positive effect in both Primary and Salvage-UBA with potentially poorer rates of response in the salvage group.

Methods and Materials

Patients having their first UBA treatment (2010–2018) were identified on departmental audit databases. Trakcare® electronic notes were then reviewed retrospectively and data collected

routinely during standard patient care recorded including: demographics, investigations, agent used, success rates and complications.

Diagnosis of SUI was with clinical assessment (positive cough-test with comfortably full bladder) or when clinically indicated, with cystometric finding of Urodynamic Stress Incontinence (USI). Symptomatic Voiding Dysfunction (VD) pre-procedure was defined as the patient complaining of: Slow or Intermittent stream / Hesitancy / Terminal Dribble / Straining. VD at Urodynamics was defined as: Flow rate <15mls/ second and/or signs of abdominal straining (with or without incomplete emptying). We have taken a Maximum Urethral Closure Pressure (MUCP) of $\leq$30cm H_20 as an indicator of Intrinsic Sphincter Deficiency (ISD) (4,5).

UBA were offered under local anaesthesia (LA), in an ambulatory setting.
Anaesthesia consisted of topical Instillagel® 20ml. A further 10ml of Lidocaine 1% injected peri-urethrally, at 3 and 9 o'clock positions, was at the discretion of the operating surgeon. Two agents were used within the department over this time period: Polydimethylsiloxane (Trade name: Macroplastique®, Manufacturer: Cogentix Medical) was the bulking agent used from 2010-2017. Polyacrylamide Hydrogel (PAHG) (Trade name: Bulkamid®, Manufacturer: Contura) was introduced in 2016.
PAHG was injected trans-urethrally under urethroscopic vision using a 23G x120mm needle surrounded by a rotatable sheath (Bulkamid® system). 1cm markings on the needle aided placement of PAHG blebs 1cm from the urethral orifice. x4 deposits at 2, 5, 7 and 10 o'clock positions were performed (2ml maximum volume), with needle repositioning undertaken to keep sites at the same level/plane to achieve coaptation of the urethra.

Polydimethylsiloxane was administered using an administration device (Macroplastique® - MIS system). Three deposits (5ml maximum volume) were placed at 2, 6 and 10 o'clock positions, trans-urethrally. Trial of void was performed and if residual bladder volumes were less than 150ml (on bladder scan) women were discharged. If there were concerns about VD, patients were taught Clean Intermittent Self Catheterisation (CISC) and discharged. Patients were admitted for intermittent drainage if they were unable to perform CISC.

Post-treatment review was conducted by nurse specialists at approximately 3-months. Top-up injections were administered within 3-6 months after the 1st UBA if the patient was not cured of symptoms and 2nd UBA treatments were defined as those occurring >6months from the 1st UBA.

Primary outcome was the difference in patient-reported success between groups, defined according to patient-reported outcomes on a 4-point scale: cured (defined as no SUI symptoms), improved (defined as sufficiently improved to not wish any alternative surgical treatment), no change (defined as no change or minimal change in symptoms +/- further alternative treatment requested), worse- adapted from the British Society of Urogynaecology (BSUG) audit database (6). Treatment 'success' was defined as cured or improved, assessed at the first clinic follow-up appointment (at approximately 3-months).

Secondary Outcomes included: 'top-up' injection requirement, complications (post-procedure VD, Urinary Tract Infection (UTI) and urethral pain rates), change in Overactive Bladder (OAB) symptoms (cured, improved, no change, worse, new onset), change in the 'International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form' (ICIQ-UI SF) scores, duration of treatment success and further management for SUI post UBA therapy.

IBM SPSS version 24 (2016) was used to perform multivariable binary logistic regression modelling to examine the effect of patient type (Primary versus Salvage-UBA) on the outcome of cure or improved (combined to assess 'success') versus no change. The model adjusted for age, bladder symptom type (SUI/ MUI), method of diagnosis (clinical versus urodynamics), operator grade (consultant versus trainee supervised procedure), time to follow-up, and agent used (PAHG versus Polydimethylsiloxane). Variables with a high proportion of missing data (BMI, MUCP and baseline ICIQ-UI SF score) were excluded to maintain analysis validity however none of these variables was individually associated with the outcome in a univariate analysis (see Online Resource 1). Graphpad Prism 8.1.2 was used to assess any differences in secondary outcomes (paired t-test for change in ICIQ-UI SF score, Chi-squared/ Fisher's Exact for categorical data and Mann-Whitney U for data which were not normally distributed.

A significance level of 5% was used throughout.

Results

We identified 173 women over this time period (n=170 with documented type of agent). 135 Primary-UBA and 38 Salvage-UBA were performed. Mean age was 60 years and mean BMI=30. 89% of procedures were performed under local anaesthesia (2 with concurrent sedation).

There has been a greater than four-fold rise in the number of UBA performed on an average of 11 per year between 2010 and 2016 to 48 per year between 2017 and 2018. Furthermore, in

2012 almost half (47%) of all UBA were salvage-type, whilst in 2018 the majority are Primary-UBA (92%).

In the salvage group, patients had undergone a wide range of surgical treatments for SUI (Fig1.docx), including some with multiple previous operations.

Patients awaiting follow-up and those who did not attend for follow-up were excluded. Complete follow-up was therefore obtained for 114 patients (n=86 Primary, n= 28 Salvage). Median follow-up time from date of injection to date of study (October 2018) was 33 months (Interquartile range: 46 months). Median follow-up time for Primary-UBA: 24 months, Salvage-UBA: 56 months.

Primary Outcome

Initial success at follow-up was 75% versus 67% in the Salvage-UBA and Primary-UBA groups respectively. Additional data are given in Online Resource 2. In the logistic regression analysis there was no significant association between type of patient (Primary or Salvage-UBA) and the success (cured or improved versus no change) (Wald $\chi 2= 0.687$, df=1, p=0.407) (Table 1).

Secondary Outcomes

Similar top-up rates (second injection) were seen; 14% (n=4/28) versus 15% (n=13/86) respectively ($\chi^2= 0.011$, df=1, p=0.914). Outcomes from top-ups in Primary-UBA: success n=5, no change n=3, awaiting FU n=5 and Salvage UBA: success=1, no change n=2, awaiting FU n=1. No patient's symptoms worsened following top-up.

Transient post-procedure VD was higher in the Salvage-UBA group (21% versus 13%) but was not statistically significantly different (χ^2= 1.384, df=1, p=0.239). Median duration of CISC use was 2.5 days (range 1-14 days) and differed by one day between groups (Primary-UBA: 2 days, Salvage-UBA: 3.5 days).

The incidence of VD was highest overall for those who had symptomatic VD pre-operatively (n=12/68; incidence with Primary-UBA 22%, n=11/50 and Salvage-UBA 11%, n=2/18). In those who were asymptomatic pre-operatively, VD still occurred in 12% (n=13/105) and was higher for those in the salvage group (30%, n=6/20) compared to the Primary-UBA group (8%, n=7/85). In women with urodynamic VD, the risk of transient post-operative VD was lower overall at 10%, n=2/21 (Incidence with Primary-UBA: 7%, n=1/14 and Salvage-UBA: 14%, n=1/7). Post-procedure VD was not seen in the top-up groups.

Following a 2nd treatment course, post-procedure VD overall was 32% (n=10/32); 30% (n=3/10) in Salvage-UBA and 32% (n=7/22) in Primary-UBA cases.

Other complications rates were low, namely: UTI (n=1) treated with an oral antibiotic course and transient urethral pain (n=2) at the time of administration was seen in both groups and settled with expectant management rapidly post procedure.

No patient reported new or worsening overactive bladder (OAB) symptoms in either group. 7 patients did undergo OAB treatment at follow-up; all had prior stress-predominant, mixed urinary incontinence (MUI) and wished to address the OAB component following treatment for SUI and after trying conservative measures.

ICIQ-UI SF questionnaires were poorly completed at 3-month follow-up, allowing only 13 pre and post treatment pairs. Statistically significant reductions in pre and post-treatment ICIQ-UI SF scores were seen overall (Paired t-test t=4.107, df=12, p=0.0015*), although this needs to be interpreted with caution due to the small numbers.

Despite any initial success, 36% (n=10) of Salvage-UBA versus 26% (n=22) of Primary-UBA ultimately underwent a 2nd treatment course (χ^2= 1.074, df=1, p=0.300). Median time to 2nd treatment course was 11 months: Salvage-UBAs median time was 10 months (interquartile range 7-20 months) and 11 months with Primary-UBAs (interquartile range 8-14 months), p=0.635 (Mann-Whitney test). 21 completed 3-month follow-up after a 2nd treatment course; overall success was slightly poorer at 62% (n=13/21), 88% (n=7/8) success with Salvage-UBA versus 46% (n=6/13) with Primary-UBA. 20 patients proceeded to alternative SUI surgery during the study follow-up: Salvage-UBA (n=8/28, 29%), Primary-UBA (n=12/86, 14%) (Fishers Exact, p=0.908). Alternative procedures in the Primary-UBA group included: 4 mid-urethral tapes, 5 autologous fascial slings and 3 colposuspension procedures. In the Salvage-UBA group: 3 underwent mid-urethral tapes, 4 autologous fascial slings and 1 patient had colposuspension.

Discussion

We have seen an accelerated use of UBAs which may be due to current government restrictions on transvaginal mesh in this country (1). A UK review into surgical practice highlighted certain criteria to be met prior to lifting restrictions (7). Furthermore, the National Institute for Clinical Excellence (NICE) guidelines (8) advises offering all surgical options and multidisciplinary team

approach. These aspects and the medicolegal environment may have resulted in a shift in treatment preferences.

Literature reviews (9–12), of UBAs suggest short-term efficacy is encouraging, however, overall success rates wane over time with repeat injections required. Retrospective studies have shown subjective short-term response with UBA to be 71-84% for those who have had prior SUI surgery (13,14). This is comparable to rates reported in primary SUI cases (71-82% at 6 months and 3 months respectively) (15,16). Reported success is similar to our cases with comparable success for Primary and Salvage-UBA procedures (67-75%) but with slightly lower success for Primary-UBA. Cure rates in our study (8%) are lower than published studies however ≥2/3 of women were significantly improved to decline further management. Lower cure rate may be due to differences in the populations studied with lower BMI (mean= 25, range 22-27) and younger women (mean= 49 years, range 42-60) in one randomised trial (17). This is in contrast to mean BMI=30 and mean age = 60 years in our study.

Particulate UBAs are made from solid microparticles in an absorbable liquid/gel carrier whereas non-particulate UBAs rely on host cells entering the hydrogel to form a network of fibers for anchorage (18). With a constant exchange of water molecules from surrounding tissues, non-particulate UBAs mechanistically resist absorption (18), staying in place over time.

Two agents were used in our study. The first, PAHG (Bulkamid ®) is non-particulate, made of 97.5% water and 2.5% cross-linked polyacrylamide. Studies vary in short term (3-6 month) subjective responder rate when used as a Primary-UBA, ranging from 71% (16), (19), to 82% (15). In a study by Sokol et al (20) 12-month follow-up had a 77% subjective cure/ improvement rate and a 17% acute urinary retention event rate affecting 5.7% of patients.

The 2nd agent, Polydimethylysiloxone (Macroplastique ®) has a silicone particulate (2). In a systematic review and meta-analysis by Ghoniem success was 75% (<6 months) and 64% (> 18months). Typical reinjection rate was 30% and high reinjection rates were associated with better long-term success (21). In our study, the use of PAHG was more common in the Primary-UBA group (~2/3 of cases) than the Salvage-UBA (~1/2 of cases), reflecting the rise in Primary-UBA over the last 2 years. The change of agent in 2016 was based on a previous department review (22), showing high reinjection rates due to early recurrence of symptoms (30%). Notably, agent type did not contribute to any significant differences in outcomes between groups in the logistic regression analysis.

Studies have varied in timing of and the terms used in reporting repeat injections. Pai and Al-Singury (15) reported 'no *booster* was offered when there was no improvement but good coaptation at surgery'. The Standard Operating Procedure for PAHG suggests if a '*top-up'* is required to improve treatment efficacy, this can be carried out at 4-6 weeks following 1st injection. Other studies ((19,20) have reported *2nd and 3rd reinjection* requirement rates (not using 'top-up'), with a 2nd injection rate of 35% at 6-8 weeks following 1st UBA (19) and a 3rd injection rate of 35.8% if not dry after 1st+/- 2nd bulking (repeat injections administered at a mean 35 days after previous injections) (20). Standardisation of follow-up assessment points and reporting would allow better comparisons of outcomes across studies.

In this study salvage-UBA tended to lose more effect over time with 36% vs 26% of Primary-UBA proceeding to have a 2nd treatment course. These were repeated at about one year and results did not reach statistical significance between groups.

The rate of voiding dysfunction in this study (15%) is higher than previously reported. Most of our procedures are performed under LA in ambulatory care. A strict local policy with early recourse to CISC (PVR >150ml), may have impacted on our results.

This was a single-institution, retrospective study which did not have a control group. Additionally, primary outcome was assessed at 3 months (short-term). We do acknowledge that these are sources of potential bias and limitations of our study. ICIQ-UI SF was poorly completed post-procedure, which is being addressed locally.

Objective assessment with urodynamics post-procedure has been used when reporting outcomes for UBA, however, has tended to show more favourable success. Subjective patient responses capture the crucial impact on quality of life for the patient which we have used in this study - this is arguably more important (12).

Overall, this study reports a moderate subjective success (67-75%) for both Primary and Salvage-UBAs with no significant differences in success between these groups, however, further work is needed. The number of women opting for UBA has increased substantially with 92% of procedures performed as primary SUI procedures in 2018. With the uptake in UBA as a primary choice, follow-up of any impact on future SUI surgical procedures has not been established. More than ever, long-term outcomes should be a priority for all UBA research. These will inform patient safety with UBA and aid counselling on the success longevity for these agents.

DECLARATIONS

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Nil received

Availability of data and material

Not available

Consent to participate

Not applicable given study design

Consent for publication:

Not applicable

Code availability

Not available

Conflicts of interest

Authors JM and JA have no conflicts of interest. Authors CMED, VT and KLG have received funding/sponsorship from Contura Ltd. for attendances at educational conferences & meetings.

Ethics approval

In view of the retrospective nature of the study and all the procedures being performed were part of the routine care, this study did not meet requirements for ethical approval according to the Health Research Authority decision tool.

Authors' contributions

Daly C. M. E: Project development, Analysis of Results, Manuscript writing/ editing.

Aloyscious J: Data collection, Manuscript editing.

Mathews J: Data collection, Manuscript editing.

Hagen S: Data Analysis, Manuscript editing.

Tyagi V: Project Development & Manuscript editing.

Guerrero K. L: Project development, Manuscript writing/ editing.

CAPTIONS

Fig.1 Type of Previous Stress Urinary Incontinence Procedure in the Salvage-UBA group

Table 1. Multivariable Logistic Regression Analysis

Online Resource 1. Univariate analysis of BMI, MUCP and ICIQ-UI SF variables on primary outcome

Online Resource 2. Primary Outcome for Primary and Salvage-UBA groups

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