Abstract #325 **Safety of the use of peri-urethral bulking injection at the time of pelvic floor repair as surgical management of pelvic organ prolapse and stress urinary incontinence in women**

Lemmon B[1], Bray R[1], Cortes E[1]
1. Kingston Hospital NHS Foundation Trust

Kingston Hospital NHS Foundation Trust

Study Aims:

Pelvic organ prolapse (POP) and stress urinary incontinence (SUI) are common conditions that often co-exist. A combined surgical approach can be offered to women experiencing both POP and SUI, with a procedure for incontinence being conducted at the time of pelvic floor repair (PFR). There are several studies looking at the outcomes of mid-urethral slings (MUS) inserted at time of prolapse repair. The decision to opt for a one-step rather than a two-step operation is a combination of personal and clinical choice, however a single procedure does have the benefit of reducing hospital attendances, number of anaesthetics, and post-operative recovery time. Raised awareness of complications associated with the use of synthetic materials has led to a pause in performing any MUS procedures in the UK. As a result, peri-urethral bulking injections have become an increasingly attractive alternative. Our group previously presented the results of a pilot study looking at the continence performance of women undergoing peri-urethral bulking with polyacrylamide hydrogel (PAHG) performed at the time of pelvic floor repair. The current data looks at the safety profile of concomitant peri-urethral bulking and pelvic floor repair.

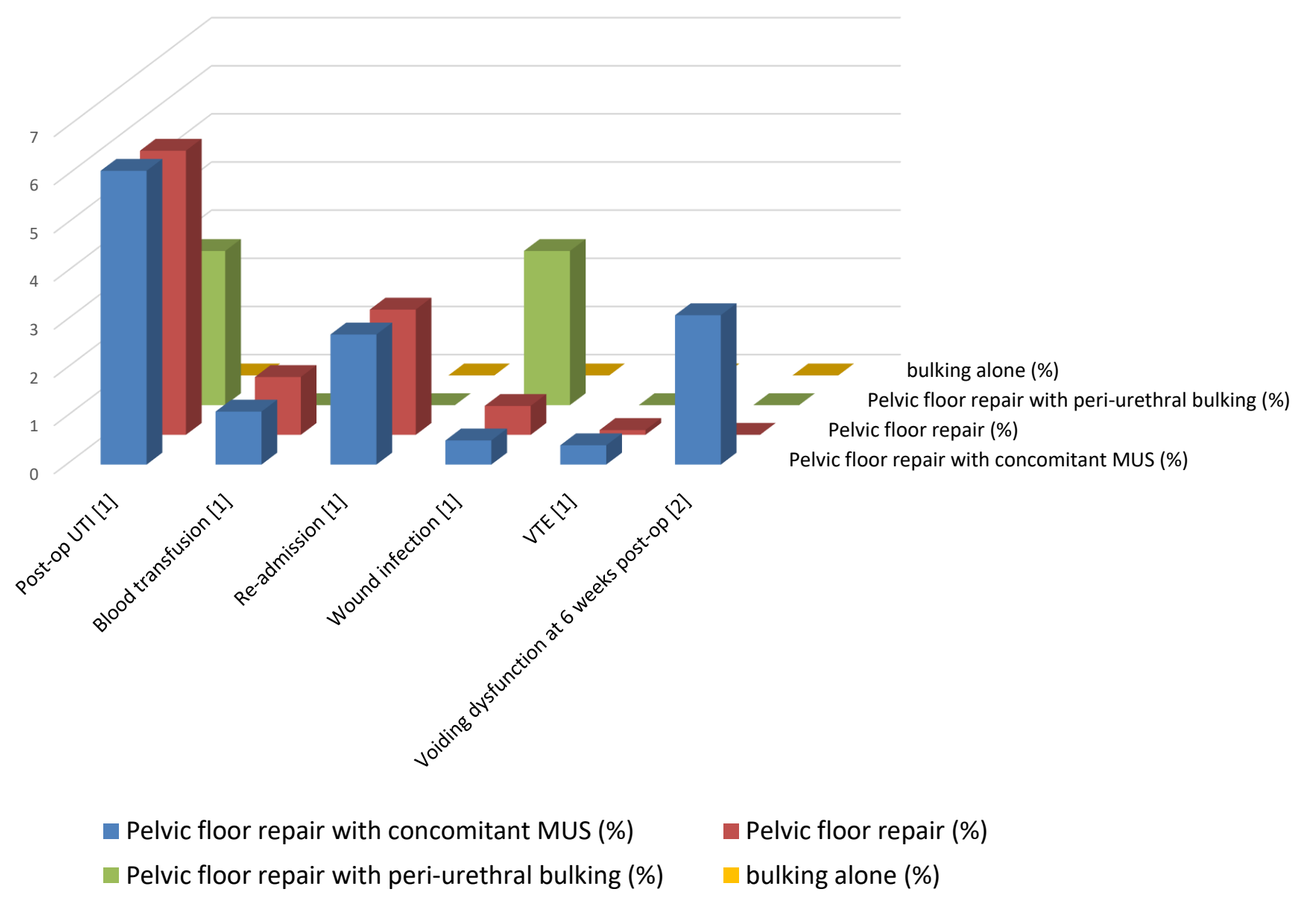

Figure: Comparison of operative complications of pelvic floor repair, pelvic floor repair with concomitant mid-urethral sling and pelvic floor repair with concomitant peri-urethral bulking , and peri-urethral bulking alone

Study design, materials and methods:

This was a retrospective analysis of all patients notes from 2017 to 2021 who underwent peri-urethral injection with PAHG at the time of PFR. We looked at the incidence of intra-operative complications, return to theatre within 72hours, immediate post-operative infection, urinary retention, haematoma, and any reasons for significant delay in discharge home. All patients were reviewed in an outpatient clinic setting 8-12 weeks following their procedure.

Results:

A total of 31 women underwent concomitant peri-urethral bulking and PFR. The average length of stay for women having pelvic floor repair without sacrospinous ligament fixation and peri-urethral bulking injections was 1.5 days. Most women were discharged home after one night in hospital. There were no documented intra-operative complications such as visceral injury or need for blood transfusion and there were no cases of needing to return to theatre <72hours of the primary operation. The most common complication experienced was urinary retention which affected just under 26% of our women having concomitant peri-urethral bulking at time of PFR. Out of these women three of the eight passed a trial without catheter 24 hours after initial urinary retention in hospital and the other five women were discharged home with an indwelling catheter but passed a trial without catheter subsequently within five days. The incidence of other complications such as haematoma, urinary tract infection and wound infection was low (3.2%). None of the patients with initial urinary retention required further admission or intervention, with complete resolution of their symptoms.

	Pelvic floor repair with concomitant MUS (%)	Pelvic floor repair (%)	Pelvic floor repair with peri-urethral bulking (%)
Post-op UTI [1]	6.1	5.9	3.2
Blood transfusion [1]	1.1	1.2	0
Re-admission [1]	2.7	2.6	0
Wound infection [1]	0.5	0.6	3.2
VTE [1]	0.4	0.1	0
Voiding dysfunction at 6 weeks post-op [2]	3.1	0	0

Table: table showing percentage surgical complications or pelvic floor repair alone, concomitant pelvic floor repair and MUS, and pelvic floor repair with peri-urethral bulking

Interpretation of results:

Our results show that the incidence of adverse outcomes following peri-urethral bulking at time of PFR are low. As per the Clavien-Dindo scoring system of surgical complications, there were no documented grade II- V events. All post-operative complications were grade I and considered minor, “any deviation from the normal post-operative course not needing surgical, endoscopic or radiological intervention”. The most common experienced in less than 26% of our women was transient urinary retention, which we defined as a post-void residual of over 100ml on bladder scan following removal indwelling catheter. There are only a few studies exploring the complications of MUS at PFR, and most are comparing outcomes with PFR alone. These have reported complications including peri-operative blood transfusion, re-admission rate, post-operative urinary tract infection, post-operative wound infection, venous thromboembolism (VTE), bladder perforation, tape exposure, ureteral injury and long-term voiding dysfunction requiring sling revision. Consistently across several studies, the surgical complication rate of MUS at PFR is low with the most common risks being post-operative urinary tract infection and temporary voiding dysfunction [1, 2]. This is similar to what we have observed following peri-urethral bulking at PFR. However, more serious grade II and III complications related to synthetic material and tape placement are well documented and have led to the controversy surrounding these procedures, which are not seen in our study. The UK regulatory authorities estimate that 4% of the 100,000 MUS placed between 2005-2013 have required removal [3]. In French data from the VIGI-MESH registry there was a 7% risk of serious complications within the 6 months post insertion of MUS at prolapse surgery. In addition to our previous findings on the efficacy of PAHG at PFR, our results suggest that performing peri-urethral bulking as the continence procedure at PFR reduces any long-term risks associated directly with placement of any synthetic material. This pilot study shows that there are no serious risks associated with the use of PAHG at the time of PFR, although clinicians can expect a degree of transient voiding dysfunction.

Conclusions

We found increased incidence of urinary retention in our population following concomitant peri-urethral bulking at PFR. However, temporary voiding dysfunction resolving in under seven days is likely to be acceptable to many women when compared to a smaller risk of having a much more serious surgical complication seen with MUS insertion. Therefore, bulking injection at the time of PFR may be a suitable alternative to women who are being considered for one-step operations for POP and SUI and are reluctant to the placement of a mid-urethral sling.

References

1. Dominique Malacarne Pape & Christina M. Escobar & Surbhi Agrawal & Nirit Rosenblum & Benjamin Brucker, “The impact of concomitant mid-urethral sling surgery on patients undergoing vaginal prolapse repair”, International Urogynecology Journal, 2020. doi.org/10.1007/s00192-020-04544-6
2. Wei JT, et al. A midurethral sling to reduce incontinence after vaginal prolapse repair. N Engl J Med. 2012;366(25):2358–67
3. MRHA 2014. A summary of the evidence on the benefits and risks of vaginal mesh implants. Available from:https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/402162/Summary_of_the_evidence_on_the_benefits_and_risks_of_vaginal_mesh_implants.pdf.