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EFFICACY AND OUTCOME OF THE POLYACRYLAMIDE URETHRAL BULKING AGENT (BULKAMID®) IN THE TREATMENT OF STRESS URINARY INCONTINENCE IN AN AUSTRALIAN POPULATION.

Hypothesis / aims of study

Urethral bulking agents (UBA) are used primarily for the management of women with stress urinary incontinence (SUI) who have failed or are unsuitable for more invasive and efficacious measures such as the mid urethral sling (MUS) [1]. Studies have demonstrated that a primary Bulkamid® injection can improve SUI in up to 66% of women at twelve months post injection[2]. These results can be long lasting, however the percentage of responders tends to reduce the further from the time of injection.

This study aims to:
1. Evaluate the improvement in symptoms following Bulkamid® injection at 1, 6 and 12 months.
2. Determine the number that required further Bulkamid® injection or alternative SUI management after an initial Bulkamid® injection.

Study design, materials and methods

A retrospective analysis of prospectively collected data on patients from across three centres between 2007 and now, including the public and private practices of two urologists. Ethics approval was granted. Patient data was collated from paper and electronic medical records including prospectively collected questionnaires. Demographic, pre-operative symptoms, urodynamic parameters, co-morbidities and any other treatment modalities to treat stress urinary incontinence were documented. Complete response was defined as no incontinence episodes at the 1month review, whereas a partial response was defined as a reduction in the number of pads by 50% at this review. Patients were contacted by telephone and the PGI-I and ICIQ-FLUTS validated questionnaires were administered.[3] On the PGI-I, the patient would rank their satisfaction with their urinary symptoms post Bulkamid® from 1 to 7. Statistical analysis was performed using SPSS (Statistical Package for Social Sciences, version 22). Comparisons were made using the Wilcoxon test. P value <0.05 was considered significant.

Results

A total of 100 patients were studied. The median age of patients included in the study was 79 years and the mean BMI was 28kg/m^2. 40% had prior continence or prolapse operations. 90% had at least one pregnancy. The mean duration of urinary symptoms was 24 months prior to the time of injection, with 70% having at least moderate if not significant bother from their incontinence episodes. Eight patients (8%) were unable to be contacted by telephone. Pre-operatively, the mean number of pads used was 3 per day. Analysis of the urodynamic parameters, demonstrated a mean flow rate of 15 ml/sec, a mean residual of 46ml, a mean Maximum Cystometric Capacity of 366ml, mean Pdet (Detrusor pressure) at Qmax of 28, mean ALPP of 57cmH20. Two patients had poor compliance and 8 patients had detrusor overactivity. No patients had any evidence of bladder outlet obstruction.

At the one month, 75% of patients were completely dry and did not require pads. An additional 10% had a partial response. The improvement was sustained in 60% at the 3 month mark and 55% by the 6 months mark. At the 12 month mark, 50% sustained at least a partial response to Bulkamid. Of those whose symptoms recurred, only 5 proceeded to alternative surgery; 2 patients received a further Bulkamid® injection, 2 underwent a MUS. 80% of patients who were contacted, reported that they had a subjective improvement to their urinary symptoms with a mean scoring was 2 on the PGI-I. In terms of complications, only 1 patient had a Urinary Tract Infection and 5 had short lived urinary retention for no more than 3 weeks, where they performed self-catheterisation or remained in hospital with in/out catheters. The mean follow up time was 22 months.

Interpretation of results

Bulkamid® is an effective treatment option in women with urodynamic stress incontinence. In the majority, one injection was sufficient to achieve a complete response and render the patient dry. A sub-analysis of women with adverse urodynamic parameters defined as detrusor overactivity and poor compliance, had worse outcomes ($p = 0.03$). These women also had a mean score of 4 on the PGI-I Bulkamid®, as overall, they did not notice any significant difference following the Bulkamid® injection. Therefore, women who have evidence of detrusor overactivity or poor compliance, should be considered for alternative therapy or counselled that they may expect a poorer response.

Concluding message
The median age of participants in this study is older and the results demonstrate that it is a good option for this population. Bulkamid® can be used for those who prefer to or who are unsuitable for a more invasive procedure, without substantial compromise of outcome and with a sustained response and few complications.

References
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