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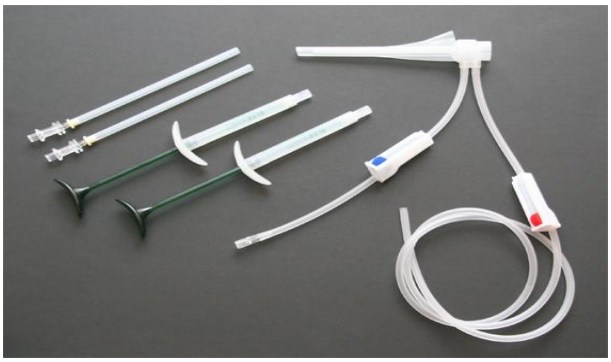
PRIMARY MANAGEMENT OF STRESS AND MIXED URINARY INCONTINENCE WITH URETHRAL BULKING -POLYACRYLAMIDE HYDROGEL (BULKAMID®) OUTCOME MEASURES.

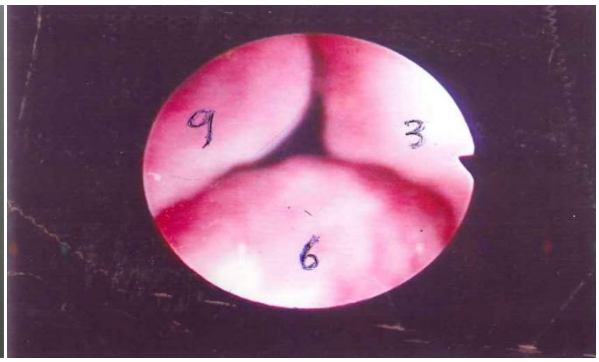
From June 2006 to October 2008, 72 selected patients who underwent Bulkamid injection as a primary procedure were retrospectively enrolled in this study. 56 (77.7%) patients completed the study, the remaining 16 patients did not respond to the postal questionnaires at 20months (12-26months) after their Bulkamid injection, and were therefore excluded from this study. All patients were evaluated at 3 and 12 months with history, physical examination, urine analysis, urodynamic, and quality-of-life questionnaires (international consultation on continence questionnaires/female lower urinary tract symptoms, ICIQ-FLITS). All patients included in this study had Urodynamic proven stress incontinence, 22 patients were diagnosed with urethral hypermobility.
All patients had Bulkamid injection as a primary single procedure. Symptomatically stress incontinence was pure in 48 patients (85.7%), while 8 (14.3%) had mixed incontinence (stress and urge). The median age was 59.8 years (31-93 years) with 34% being pre-menopausal.
A total of 42 (75%) patients had Bulkamid performed under local anaesthesia (2% lignocaine), 12(21%) had local anaesthesia in addition to intravenous sedation and 2 had general anaesthesia (patients choice). Intra venous Gentamicin 120mg was given before the procedure to all patients.

The patient is positioned on the operating table with slight hip flexion and the patient prepared following standard procedure at the hospital unit. Anaesthetic gel is placed inside the urethra and bladder is emptied of urine first with small catheter followed by slowly trans-urethral injection of 2% lignocaine. The Bulkamid injection is performed under endoscopic control using a single use Bulkamid cystoscope (11cm long) connected to 0 degree optic with X 5 magnification to make sub –mucosal injection of Bulkamid precise and accurate (**picture 1**). The rotating sheath over the cystoscope, allow the working channel of the needle (23G x12cm needle) to rotate 360 degree to provide optimal access and visual control of the injection sites without moving the whole cystoscope.

Continuous saline flow is important to open the proximal urethra, by turning the in and out flow taps, to be able to identify the injections site. The Bulkamid syringe is inserted into the scope working channel. The needle is advanced very slowly avoiding accidental injury the urethral mucosa. The bifid end of the needle should face the urethral lumen and the cystoscope angulation is no more than 5 degree (0-5 degree) to avoid deep injection. The ideal sub-mucosal injection site is 3, 6, 9 O'clock and within 1 cm distal to the bladder neck (proximal urethra). Slow speed Bulkamid injection is mandatory to avoid over injection at that site which subsequently results in tissue necrosis and expulsion of the Bulkamid 2-3 weeks later. To achieve good coaptation of the urethral wall, 1-2mls of Bulkamid are injected at 3 sites with no more than 0.5ml at each site (**picture 2**).
All patients were discharged home after spontaneous voiding with residual volume less than 100mls, except one who went into acute urinary retention. Patients were assessed at 3 and 12 months post operatively, including urine analysis, objective assessment with bladder scan for residual volume. Patient Subjective satisfaction was assessed using patient- completed questionnaires (ICIQ-FLUTS) for evaluation of lower urinary tract symptoms and their impact on quality -of-life (QOL). Operative success was defined as a total bother score of 4 or less with no adverse outcome and urine leaks either never (cure) or about once a week or less often (improvement).



Picture 1 : Bulkamid system



Picture 2 : central filling with coaptation effect

Results
A total of 46 patients (82.6%) expressed significant improvement in their stress incontinence symptoms, with 30 patients (53.6%) being cured (complete resolution of their symptoms in absence of any post-operative complications). In this group, incontinence episodes per 24h reduced by 92%, and 82% were not wearing pads after the procedure. The remaining 10 patients (17.8%) had persistant stress and or urge urinary incontinence with a high bother score or developed an adverse outcome, which is considered as a post operative failure. Only one patient (1.78%) was unable to void post operative and failed 2 trial without catheter. The Bulkamid was aspirated from the 6 O'clock position, 4weeks later under general anaesthesia and

subsequantly, the patient void successfully and remained dry. Three patients (5.3%) had recurrent stress incontinence, 3-8 weeks after the Bulkamid injection which was confirmed on video-urodynamic study. Of these patients with recurrent incontinence, one had a re-injection of Bulkamid and the other two underwent Trans-obturator tape insertion. No patient reported worsening symptoms or developed de novo frequency/ urgency symptoms. In our study non developed infection/abscess or allergic reaction at site of the injection. All patients had Bulkamid performed as a day case surgery with an average operative time of 9 minutes (6-17minutes).

Discussion

Stress incontinence is the involuntary leakage of urine during exercise or movements such as coughing, sneezing or laughing. It results from weakness or damage to muscle and supportive connective tissue of the pelvic floor, or weakness of urethral muscle itself. We always recommend pelvic floor exercise, electric stimulation and biofeedback for at least 3-6months. Patients who fail conservative measures, are offered surgical treatments as an alternative options (colposuspension or sub urethral sling/ TVT or TOT).

Bulking agents are rarely offered as the first line treatment because of the uncertainties about their efficacy and the perception that the benefits of the procedure diminish overtime. Most bulking agent are used in women who have persistant or recurrent stress incontinence following other surgical repair. However Bulkamid may be offered as first line treatment in patients who are not suitable for surgical procedures due to anaesthetic risk or fixed hip/hips, gross obesity, young women of childbearing age and those who prefere minimally invasive procedure compared to the standard conventional surgery

❑ **Internal sphincter deficiency (ISD)**
❑ **Women prefer minimally invasive surgery**
❑ **Young women (childbearing age)**
❑ **Patients not suitable to surgical intervention: Elderly, severe vaginal stenosis, fixed hips, risk for Spinal or general anaesthesia**
❑ **Gross obesity**
❑ **Recurrent stress incontinence**
❑ **Detrusor hypo-activity (Low flow, low voiding pressure <15cmH20)**

Table 1 : Indications of Bulkamid injection

Most of our patients returned to work the next day with no restriction of lifting heavy weights.

The Bulkamid (polyacrylamide hydrogel) is easy to adminster, provided full visual control and can produce precise bulging with good coaptation. Its unique chemical composition make it well tolerated by the adjacent tissues with minimal fibrous reaction and they are non-resorbable and migration resistant

- **Biocompatibility**
- **No immunogenicity**
- **Non carcinogenic**
- **Maintain elasticity**
- **Adequate viscosity**
- **Minimal fibrosis & Little inflammatory response**
- **Volume should be retained after injection**
- **No re-injections needed over time**
- **Total incorporation in the tissue**

Table 2 : Bulkamid characteristics

Lose G et al (14) presented encouraging results data in 2006 for 17 patients with 12 months follow up. 81 % were cured/improved and urine leakage per 24hrs was reduced by 93% and the number of incontinence episodes reduced by 87%.

Conclusion

Bulkamid is a new bulking agent for women with stress urinary incontinence., It is safe, easily adminstered under local anaesthesia with a success rate of over 80%. Bulkamid injection can be used as a primary procedure in a carefully selected group of patients.

References

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Specify source of funding or grant	**NONE**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**This is an audit and we reporting our experience**
Was the Declaration of Helsinki followed?	**No**
This study did not follow the Declaration of Helsinki in the sense that	**This was an audit of our clinical practice all patients signed informed consent prior to surgery**
Was informed consent obtained from the patients?	**Yes**