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LONG TERM EFFICACY OF BULKAMID FOR THE TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Since October 2005 Bulkamid has been used for the treatment of female urinary stress incontinence in patients at our hospital. Baseline information, post-operative complications and follow-up data for these patients was recorded in our database.
We have examined the long term efficacy and safety of Bulkamid in 553 patients treated from 2005 until December 2011.

Study design, materials and methods

The patients average parity was 1.9 (range 0 to 7), the average age was 69.1 years (range 34 to 95 years). Body Mass Index (BMI) varied from 18.0 to 50.6. Many of the patients were elderly patients with obesity, significant co-morbidities or relapse after other treatments; however Bulkamid was used as the primary treatment in some patients.

On the day of admission, the results from the urogynaecological consultation were reviewed again, the residual urine was sonographically determined, and the required laboratory tests were conducted.

Depending on request from the patient, the procedure was done under local anaesthesia or with an i.v. short acting anaesthetic. 2 x 5 ml 1% Xylonest® local anaesthesia was used para-urethrally. Additionally Installagel® was administered in the urethra. Antibiotics (1.5g Cefazolin and 500mg Metronidazol) were administered prophylactically as single dosages.
Bulkamid was injected transurethrally into the submucosa under urethroscopic control (Bulkamid® rotatable sheath) using a 23G x 120 mm needle with 1 cm markings to enable correct placement of the injection. Two or three deposits (0.2-0.8 ml each) were placed, usually at 3, 6 and 9 o'clock. After satisfactory urethral occlusion, the bladder was emptied via the endoscope.
At each follow-up visit patients were asked how they perceived their incontinence compared to before the treatment: cured; improved; unchanged (same); or worsened. For the objective follow-up, patients performed a cough test and results were compared to the results of the cough test performed prior to treatment.

Results

The majority of patients (77%) only required a single Bulkamid treatment but 21% of patients received a single re-injection and 9 patients (1.6%) received 2 re-injections. Mean injection volume was 1.7ml (range 0.3 to 4ml) per treatment.

On average 67% of patients described themselves as cured or improved at their most recent follow-up visit while only 5 patients perceived their incontinence was worse after treatment (Table 1). There was no apparent change in patient satisfaction over time with 67% of patients treated more than 4 years prior to their latest follow-up visit describing themselves as cured or improved.

Very few complications have been observed following Bulkamid injection. Only 6 UTIs and 13 incidences of post-operative pain have been reported following injection. In addition 112 patients reported prolonged urination and 34 patients had increased frequency of urination after the procedure.

Table 1: Results of the most recent follow-up visit (n=462). Ninety-one patients have not yet attended a follow-up visit

Time Period (months)	Patients (n)	Patient Satisfaction			
		Cured	Improved	Same	Worse
		%	%	%	%
0-1 year	152	24	43	32	1.3
1-2 years	127	28	39	31	1.6
2-3 years	107	16	45	39	0.0
3-4 years	46	39	35	24	2.2
>4 years	30	27	40	33	0.0
avg	426	25	42	33	1.1

Interpretation of results

Patient satisfaction with the treatment remains largely unchanged beyond 4 years after treatment. This suggests that if the patient was satisfied with the treatment at the initial 6 month follow-up, they will continue to be satisfied with Bulkamid for the treatment of their stress urinary incontinence.
Some patients experienced peri-operative complications but no late-emergent complications have been recorded.

Concluding message

Treatments that were initially effective continue to be safe and effective for at least 4 years after treatment.

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** the presented data was compiled during routine patient visits and entered into an online databsae by the author. **Helsinki:** Yes **Informed Consent:** No