356

Lobodasch K[1], Brosche T[1]
1. *Frauenklinik DRK-Krankenhaus Chemnitz*

LONG-TERM EFFECTIVENESS AND DURABILITY OF BULKAMID® AS PRIMARY TREATMENT OF STRESS URINARY INCONTINENCE – A LONGITUDINAL STUDY

Hypothesis / aims of study

Stress Urinary Incontinence (SUI) with its high socioeconomic burden and influence on women's quality of life is a serious problem with approximately 35% of women over 18 years of age suffering from involuntary loss of urine. At the age of 60, it increases to 45% in Europe (1). Urethral bulking agents are the least invasive procedure available and this study aims to demonstrate the long-term effect and durability of Bulkamid.

Study design, materials and methods

This longitudinal study on 352 women with SUI (N=255) or stress predominant mixed urinary incontinence (MUI; N=97) represents up to 7 years follow up data on patients treated with Bulkamid at our unit since 2005. All patients signed an informed consent form and baseline information, treatment details, post-operative complications and follow-up data were recorded in a database. We have records available on 687 patients. We have excluded from the current follow up women who had a previous incontinence operation (197), had died (18) or had dementia (8). Seventy patients were lost to follow up and forty two patients have not yet reached one year follow up. Mean age was 67.2 years (29-95) with a mean parity of 1.9 (0-8). Mean BMI was 29.5 (16.8-63.7). Many of the patients were elderly, obese and had significant co-morbidities.

Depending on patient preference, the procedure was performed either under local or short-acting i.v. anaesthesia. Two x 5 ml 1% Xylonest was used para-urethrally, and Instillagel was administered in the urethra. Prophylactic antibiotics (1.5 g Cefaloxin and 500 mg Metronidazol) were administered as a single dose prior to treatment.

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 ensure correct depth placement. Three deposits (0.2-1.0 ml each) were placed at 3, 6 and 9 o'clock, and after satisfactory urethral closure, the bladder was emptied via the endoscope. During the first 3½ years, the gel was injected at the bladder neck. From April 2008 to September 2011 21.1% of patients were bulked midurethrally, and after October 2011, all bulkings were performed with a blunt 22G x 120 mm needle with the opening on the side midurethrally. Objective data included a standing stress test with a comfortably full bladder. Subjectively, women were asked if they are "cured", "improved", "unchanged" or "worsened". Patients also evaluated the severity of their incontinence using a visual analogue scale (VAS) with one being "no symptoms" and 10 being the "most severe symptoms". The following classification was used to define the bulking efficacy: *Cured:* negative stress test and at least a 90% VAS improvement; *Improved:* losing only a few drops during stress test and improvement in VAS of at least 60%; or *Failed:* urine loss during stress test and a VAS of 50% or less.

Results

Results from the stress test combined with results from VAS demonstrate very consistent results over the years with an average 80% of patients cured or improved (Table 1). Mean use of pads was 4.1 pre-operatively and 1.76 post-operatively (last follow up visit).

At the most recent follow up visit 76% of patients described themselves as cured or improved while 22% were unchanged and only 2% were worse.

The re-injection rate decreased from 35% (injections given in the bladder neck) to 16% with midurethral bulking.

There were few complications, all peri-operative and included urinary tract infection (n=6), post-operative pain (n=13), prolonged voiding (n=112) and increased voiding frequency (n=24). There were no serious adverse events and no observed long-term adverse effects.

Interpretation of results

Our data shows the durability of the treatment of SUI with Bulkamid. We did not find a remarkable decrease in efficacy even after 7 years. The durability is most likely related to the properties of this homogenous non-particulate gel together with a well-practiced injection routine. Unlike other bulking agents, Bulkamid does not degrade and maintains shape and size years after injection (2). Failure may be related to natural tissue changes over time, as opposed to changes in the gel itself, and in some cases, failure may be due to the loss of gel during voiding in the first few days after treatment. The reason for this could be attributed to a suboptimal injection technique with deposits not being in the right place or layer or insufficient injection volume.

Concluding message

Bulkamid has proven to be an effective and safe long-term treatment for women with SUI or stress predominant MUI. With a low complication rate, an uncomplicated handling routine, bulking therapy has its obvious advantages.

The procedure can be recommended for first line therapy of SUI or stress predominant MUI. Further studies are required to determine the ideal patient population and the optimal treatment course.

Table 1: Bulking efficacy at the latest follow up.

Follow Up (years)	Patients (N)	Cured		Improved		Failed	
		N	%	N	%	N	%
1	74	26	35.1	37	50.0	11	14.9
2	69	28	40.6	23	33.3	18	26.1
3	59	19	32.2	30	50.8	10	16.9
4	54	18	33.3	23	42.6	13	24.1
5	49	17	34.7	19	38.8	13	26.5
6	24	8	33.3	12	50.0	4	16.7
7	23	9	39.1	12	52.2	2	8.7
(Σ) Mean	**352**	**125**	**35.5**	**156**	**44.3**	**71**	**20.2**

References

1. Hunskaar S, Lose G, Sykes D, Voss S. The prevalence of urinary incontinence in women in four European countries. BJU International 2004; 93(3):324-330.
2. Mouritsen L, Lose G, Møller-Bek K. Long-term follow-up after urethral injection with polyacrylamide hydrogel for female stress incontinence. Acta Obstet Gynecol Scand. 2014 Feb;93(2):209-12.

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** the presented data was compiled during routine patient visits **Helsinki:** Yes **Informed Consent:** Yes