

A NEW BULKING AGENT (AQUAMID) IN TREATING FEMALE STRESS URINARY INCONTINENCE

Aims of study

Aquamid represents a new generation of soft-tissue fillers that fulfils the requirements of an ideal injectable agent (1) since it is non-immunogenic, atoxic, biocompatible, diffusion/migration resistant and technically easy to inject. The Aquamid gel contains 2.5% polyacrylamide and 97.5% water. It is homogenous, perfectly stable and nonbiodegradable and has favorable viscosity and elasticity. The gel has been used in plastic and aesthetic surgery for more than a decade and is being used in the production of soft contact lenses and in ophthalmic surgery. Aquamid has been authorized for sale in Europe since March 2001 as a new medical device (CE-mark 0543).

The aim of the study was to investigate the efficacy and safety of transurethral injection of Aquamid in female patients with the condition stress urinary incontinence.

Materials and methods

This was a two-center study with 3 investigators. Between November 2001 and November 2003 25 women (median age 64.9 years, range 35-84) with urodynamically proven stress urinary incontinence (SUI) were recruited. Eligible patients had a predominant symptom of SUI, urin leakage > 20g/24 h, no detrusor overactivity during filling cystometry at a volume <300 ml, residual urine volume <50 ml and no significant pelvic organ prolapse (i.e. < grade 1). Urodynamic work-up included spontaneous uroflowmetry, residual urine measurement, urethral pressure profilometry (water perfusion), sitting water cystometry and a pressure-flow study.

Efficacy was assessed by means of Stamey score, incontinens episode frequency (IEF), 24h pad weighing test and The King's Health Questionnaire (KHQ). All patients were seen in the outpatient clinic 1, 3 and 12 months after (latest) injection. Urodynamic work-up was repeated 3 months after treatment. Safety analysis was comprehensive including blood tests before 1, 3 and 12 months after injection.

Following administration of 2 x 10 ml local anaesthetic (3 and 9 o'clock) 2-3 deposits of Aquamid (1.5 – 2.5 ml) was injected transurethally into the submucosa via a 23 G needle about 1cm distal to the bladder neck under endoscopic control. Peroperatively all patients recieved a single i.v. 1.5 mg dose of Cefuroxim.

Patients who did not achieve satisfactorily benefit after the first injection were offered a second treatment after 3 months.

Statistical analyses were performed using Friedman's ANOVA test.

Results

A total of 21 patients completed the study. Four were dropouts because of various reasons. Twelve women were satisfied after one treatment, 9 wanted another injection.

"Dry" Stamey Scores (=0) were achieved in 38.1% (8/21) while 42.8% (9/21) of the patients improved at least one degree on the Stamey scale at one year.

Statistical significant improvements were found in limitation and severity KHQ domains.

A statistical significant reduction in median urine leakage (per 24 hour) was observed from 56g at baseline to 6g at 1 month and 4 g at 12 months posttreatment respectively.

IEF decreased similarly from a median value of 4.6/24h at baseline to 0.6 /24h at 1 month and 0.6/24h at one year. The results in women who had reinjection versus those who did not are seen in table 1. There were no significant changes in the urodynamic variables after therapy.

The material proved easy to inject. No patients developed acute retention after injection while 5 cases of acute urinary tract infection were found. No complications at the injection site were seen in the follow up period. There were no cases of de novo urgency or voiding difficulties after therapy. All blood tests were unchanged.

Table 1

	Baseline	1 month	12 months
<u>Median urine leakage (g)</u>			
Re-injected (n = 9)	57	13	2
Not re-injected (n = 12)	52	6	4
<u>IEF/24 h</u>			
Re-injected (n = 9)	4.3	2	2
Not re-injected (n = 12)	4.6	0.4	0

Interpretation of results

Aquamid bulking is an effective and well-tolerated treatment for stress incontinence with efficacy sustained for at least one year.

Concluding message

Aquamid seems to be a promising new bulking agent for treatment of SUI.

Reference

Pichard R, Reaper J, Wyness L, Cody DJ, McClinton S, N'Dow J. Periurethral injection therapy for urinary incontinence in women. The Cochrane Library, Issue 2, 2003.

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