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AN OPEN MULTICENTER STUDY OF POLYACRYLAMIDE HYDROGEL (BULKAMID®) FOR THE TREATMENT OF STRESS AND MIXED URINARY INCONTINENCE.

Aims of study
Polyacrylamide hydrogel (PAHG) fulfils many requirements for an optimum urethral bulking agent and a pilot study has provided promising clinical results in women with stress and mixed urinary incontinence (1).
This open, 12-months multicenter (N=10) study was performed to evaluate the efficacy and the safety in a larger cohort of women with stress and mixed incontinence.
Study design, materials and methods
Patients were age ≥ 18 years with a history of urinary incontinence for ≥ 12 months, and ≥ 1 incontinence episode per 24-h. They were invasive-therapy naïve. Up to two treatments with Bulkamid gel were permissible (re-treatment was offered within 8 weeks after the first month follow-up visit). During injection the women received an i.v.dose of cefuroxine (1.5g).
The efficacy assessment included patient subjective perception (cured, improved, no change or worsen), number of incontinence episodes per 24-h, urinary leakage at the 24-h pad weighting test, ICIQ questionnaire score and Quality-of-Life (QoL) score based on a VAS scale.
Methods, definitions and units conform to the standards recommended by the International Continence Society, except where specifically noted.
Results
A total of 135 women were enrolled (67 with stress and 68 with mixed incontinence) and treated with PAHG. 98 completed the study while 36 withdrew for various reasons. Results were based on intention-to-treat.
The response rate was 72% at week 12 and 71% at 12 months. Fractions of totally cured patients were 27% and 24% respectively. The median number of incontinence episodes/24-h decrease from 3.0 at baseline to 0.7 at 12 months ($p< 0.001$ vs baseline). The median urine leakage/24-h was significantly reduced from 29g at baseline to 4g at 12 months ($p< 0.0001$ vs baseline). The median ICIQ score was reduced approximately 50% at 12 months ($p< 0.001$) and the overall QoL VAS score decreased significantly from a baseline median of 72 to 20 after 12 months. The results were very similar in the group of patients with stress compared to those with mixed incontinence.
The median total injected volume of PAHG per treatment was 1.5 ml (range 0.8-3 ml). The injection procedure took a median time of 7 min. (range 2-20 min.). Re-injection was carried out in 47 out of the 135 patients (35%).
Thirty-five treatments related adverse events (AE's) were registrated. Urinary tract infection (n=10) was the most frequent one. Transient urinary retention occurred in 4 patients. One injection site AE (mucosa rupture) was recorded but no product specific AE's were seen.
Interpretation of results
This study confirms that approximately 3 out of 4 women with uncomplicated stress or mixed incontinence can be improved or cured by PAHG injection therapy. The results appear to sustain at least one year postoperatively. The procedure is easy and quick to perform. The safety profile seems unique thus no product specific adverse events were seen.
Concluding message
Bulkamid is an effective and safe bulking agent in women with uncomplicated stress or mixed incontinence.
References
1. BJU 2006; 98: 100-4

Specify source of funding or grant	**Contura**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Den videnskabsetiske komité,Københavns amt,Glostrup,Denmark;De Videnskabsetiske Komitéer for Reg.Hovedstaden,Hillerød,Denmark;Ethics Committee for Gyn. and Obst.,Otology,Ophthalmology,Neurology and Neurosurgery,HYKS,NSK Hallinto, Helsinki, Finland;Etik-Kommission,Sächsische Landesärztekammer,Dresden,Germany; Ethikkommission der Charité-Hochschulmedizin Berlin,Geschäftsstelle,Germany;Regionala Etikprövningsnämnden i Stockholm,Sweden;Liverpool(Adult)Research Ethics Committee,Liverpool,UK.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**