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# DURABILITY OF POLYACRYLAMIDE HYDROGEL (BULKAMID®) INJECTION FOR FEMALE STRESS AND MIXED URINARY INCONTINENCE: 2-YEAR MULTICENTER STUDY RESULTS.

Hypothesis / aims of study

To report the 24-month follow-up outcome of the of patients treated with polyacrylamide hydrogel (PAHG) – a non-degradable bulking agent devoid of microparticles and optimal tissue integration characteristics which has provided promising clinical results in women with stress and mixed urinary incontinence. Efficacy and safety in women with stress and mixed incontinence treated with PAHG at 12 months has previously been reported [1].

Study design, materials and methods

A prospective multicenter (N=10) in a cohort of 135 women. Patients were aged ≥ 18 years with a history of urinary incontinence for ≥ 12 months, ≥ 1 incontinence episode per 24-h and invasive-therapy naïve. Treatment consisted of up to two treatments with PAHG under antibiotic coverage (cefuroxine (1.5 g i.v.), with a second treatment being offered within the first 3 months if required. Assessment of efficacy included patient's subjective perception (cured, improved, no change or worsen), 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

One hundred and thirty five women were recruited (67 with stress and 68 with mixed incontinence), 98 had completed the study with 12-month follow-up and 86 (64%) with the 24-month follow-up. Sixty-five percent of subjects were treated with a single injection and the remaining 35% with two injections. Efficacy calculations were based on ITT analysis set (n=135) where lack of clear information was categorized as failure. Twenty seven percent were totally cured for stress leakage and 24% for those treated for mixed incontinence. All secondary efficacy endpoints (Quality of life, Urine Leakage over 2 days, and Daily number of episodes) showed statistical significant improvements compared to baseline (ITT analysis, QoL $p<0.0001$, Urine leakage $p<0.0001$, Incontinence episodes $p<0.0001$) and were stable compared to 12-month results (Table 1).

**Table 1**

Summary of the main efficacy parameters, ITT analysis set (N=135)

| **Efficacy parameter** | **Baseline** | **12 months** | **24 months** |
|---|---|---|---|
| Subjective responder rate (%) | - | 67 | 64 |
| ICIQ-score (range 0-21) | 15 | 7 | 7 |
| Urine leakage (g/24h) | 29 | 4 | 3 |
| Incontinence episodes/24h | 3 | 0.7 | 0.5 |

Out of a total of 182 bulking procedures 33 treatment-related adverse events (AE's) had been registered, with urinary tract being the most frequent (n=11) (Table 2). No product-related AE's were observed, and no additional AE's were registered during the last 12 months.

**Table 2**

Summary of the treatment-related adverse events (n=33) reported at 12- and 24-month follow up.

| Adverse events | No. of occurrences 12-month | No. of occurrences Between 12- and 24- month |
|---|---|---|
| UTI | 11 | 0 |
| Injection site pain | 5 | 0 |
| Urinary retention | 2*) | 0 |
| Voiding difficulties | 2** | 0 |
| Past void residual > 100 ml | 2*** | 0 |
| Haematuria | 2 | 0 |
| Urine incontinence aggravated | 2 | 0 |
| De novo Urge incontinence | 2 | 0 |
| Injection site laceration | 1 | 0 |
| Headache | 4 | 0 |

*) classified as serious due to hospitalisation, recovered within 6 respectively 9 days
**) not catheterized
***) catheterized 2 respectively 4 times within 3 days

Interpretation of results

These results confirm the medium term (2 year) durability of PAHG. This study also demonstrates that approximately 3 out of 4 women with uncomplicated stress or mixed incontinence can be improved or cured by PAHG injection therapy. The procedure is easy and quick to perform, and the safety profile seems unique as no product specific adverse events were seen.

Concluding message

PAHG is an effective and safe bulking agent in women with uncomplicated stress or mixed incontinence.

References

1. ICS 2009 Abstract No 565



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|---|---|
| ***Specify source of funding or grant*** | **Contura** |
| ***Is this a clinical trial?*** | **Yes** |
| ***Is this study registered in a public clinical trials registry?*** | **No** |
| ***Is this a Randomised Controlled Trial (RCT)?*** | **No** |
| ***What were the subjects in the study?*** | **HUMAN** |
| ***Was this study approved by an ethics committee?*** | **Yes** |
| ***Specify Name of Ethics Committee*** | **All local ethics committees** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |