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A SINGLE-MASKED, RANDOMIZED, MULTI-CENTER, STUDY COMPARING THE SAFETY AND EFFECTIVENESS OF POLYACRYLAMIDE HYDROGEL AND COLLAGEN AS BULKING AGENTS FOR THE TREATMENT OF STRESS URINARY INCONTINENCE IN FEMALES

Hypothesis / aims of study

The primary purpose of this study was to demonstrate the safety and effectiveness of Bulkamid® in the treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) in adult women with stress incontinence (SUI) or stress predominant mixed incontinence.

Study design, materials and methods

The IRB approved study was performed at 37 investigational centers in the US and Canada with 345 subjects being randomized to treatment with either polyacrylamide hydrogel (Bulkamid®), or collagen (Contigen®) using a 2:1 ratio (229 Bulkamid® and 116 Contigen®). Subjects were masked to the treatment..

Screening/Baseline evaluations and skin testing were completed to determine eligible subjects and then subjects were randomized and treated with Bulkamid® or the comparator device.

Re-injection was offered at Evaluation Visit 1 and at Evaluation Visit 2 for subjects reporting stress incontinence in the subject diary or the self-assessment questions. A maximum of 3 injections (initial + 2 re-injections) were allowed. Only subjects re-injected at Evaluation Visit 1 attended and were eligible for re-injection at Evaluation Visit 2. Follow up was conducted at 3, 6, 9, and 12 months after the last injection.

The primary endpoint was non inferiority of Bulkamid® relative to collagen for a composite primary endpoint: the proportion of subjects with ≥50% reduction in leakage and incontinence episodes 12 months after the last treatment. The number of incontinence episodes, results of 24h pad test, the subject's perception of effectiveness, a quality of life assessment (ICIQ-UI) and safety data are also presented. The presented results are preliminary.

Table 1: Baseline Characteristics for the Bulkamid® and Collagen groups. Data is presented as median (min, max)

Baseline Characteristic	**Bulkamid®**	**Collagen**
Age	58.5 (23.3, 93.4)	56.7 (29.5, 85.4)
BMI (kg/m^2)	27.6 (17.0, 44.5)	26.8 (18.7, 34.8)
Duration of SUI (years)	6.6 (0.6, 51.5)	5.9 (0.7, 39.7)
Number of pregnancies	2.0 (0.0, 11.0)	2.0 (0.0, 8.0)
Valsalva Leak Point Pressure (cm H2O)	59.0 (8.0, 100.0)	54.0 (6.0, 102.0)
Maximum Cystometric Capacity (mL)	398.0 (244.0, 868.0)	375.0 (150.0, 838.0)
Maximum detrusor pressure (cm H2O)	5.0 (0.0, 23.0)	5.0 (0.0, 22.0)
Post-Void Residual urine (mL)	10.0 (0.0, 200.0)	10.0 (0.0, 100.0)
Leakage (mL)	44.2 (0.0, 908.0)	40.8 (0.2, 2211.4)
Incontinence Episodes	3.3 (0.0, 17.3)	3.0 (0.7, 13.7)

Results

Baseline data for the randomized subjects is shown in Table 1. All subjects had failed at least 2 other (non-invasive) therapies. The most frequent non-invasive therapies were pelvic muscle exercise and behavioural modification. Approximately 24% of subjects in either group had not undergone invasive therapy.

A summary of the efficacy data 12 months after last treatment is shown in Table 2. The composite primary endpoint criteria were achieved by 45.9% of Bulkamid® treated subjects and 41.4% of collagen treated subjects 12 months after last treatment (non-inferiority p-value=0.00003).

Leakage and incontinence episodes were reduced significantly from baseline to 3 months after last treatment and the reduced levels were maintained until 12 months after last treatment in both groups.

Subject assessment of their incontinence showed that 76.5% of Bulkamid® treated subjects and 70.6% of Collagen treated subjects felt that treatment had improved their incontinence.

Table 2: Efficacy data 12 months after last treatment

	Bulkamid®	Collagen
≥50% Reduction in leakage and incontinence episodes: n (%)	105 (45.9)	48 (41.4)
Leakage: median (min, max)	10.7 (0.0, 645.3)	10.9 (0.2, 778.8)
Incontinence episodes: median (min, max)	0.7 (0.0, 10.0)	0.7 (0.0, 7.7)
Subject Assessment (Cured/dry/much improved/improved): n (%)	166 (76.5)	77 (70.6)

Adverse events were reported in 59% of Bulkamid® treated subjects and 54% of Collagen treated subjects. The most common events were UTI, pain at the injection site and acute retention. Approximately 10% of events in Bulkamid® treated subjects and 20% of events in collagen treated subjects were possibly or probably related to the device. Twenty-seven serious adverse events were reported in the study, two of which was device (Bulkamid®) and procedure related.

Interpretation of results

The efficacy of Bulkamid® was similar to collagen up to 12 months after last treatment. A previous study with Bulkamid® showed that the efficacy and safety of Bulkamid® was maintained for at least 2 years (1).

Concluding message

This study demonstrated that Bulkamid® is a safe and effective treatment for SUI or stress predominant mixed incontinence.

References

1. (1) Toozs-Hobson P, Al-Singary W, Fynes M, Tegerstedt G, Lose G. Two-year follow-up of an open-label multicenter study of polyacrylamide hydrogel (Bulkamid®) for female stress and stress-predominant mixed incontinence. Int Urogynecol J. 2012; 23(10):1373-8.

Disclosures

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