Prospective Multicenter Evaluation of a Lightweight Polypropylene Transobturator Mid-Urethral Sling (GyneBand) for Stress Urinary Incontinence: 12-Month Outcomes

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Hypothesis / aims of study

The study aims to prospectively evaluate the 12-month effectiveness, safety, and patient-reported outcomes of a lightweight polypropylene transobturator mid-urethral sling (MUS) in women undergoing surgical treatment for stress urinary incontinence (SUI).

Study design, materials and methods

This prospective, multicenter, observational post-market clinical study was conducted at five hospitals in Catalonia, Spain. Women aged 18 years or older who had been diagnosed with SUI and were scheduled to have transobturator MUS were enrolled and followed for 12 months.

Device: A lightweight (43 g/m^2) polypropylene sling (GyneBand, Mallanets™)

Outcome assessment:

measured before the surgery and again at 1, 6, and 12 months after the surgery.

1. Objective continence (measured by cough stress test)
2. Symptom severity (measured by the International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF).
3. Quality of life and patient-reported measures assessed using the EQ-5D-5L,
4. Patient Global Impression of Improvement (PGI-I),
5. International Consultation on Incontinence Questionnaire–Overactive Bladder (ICIQ-OAB).

Within-patient comparisons were performed using paired statistical tests with 95% confidence intervals.

Safety

outcomes comprised systematic assessment of intraoperative, early, and late complications.

Results

75 women were included in the final analysis.
92% completing 12-month follow-up.
The proportion of patients with a positive cough stress test decreased significantly from 85.3% preoperatively to 8.8% at 12 months ($p < 0.001$).
Mean ICIQ-UI SF scores improved from 15.2 to 4.3 at 12 months, a mean reduction of −10.9 points (95% CI −12.5 to −9.3; $p < 0.001$)

Quality of life improved significantly, with EQ-5D-5L visual analog scale scores increasing by approximately 10 points at 12 months ($p<0.001$).
At final follow-up, 82.6% of patients reported feeling “better” or “much better” on the PGI-I, and more than 90% reported cure or improvement.
The safety profile was favorable. At 12 months, 95.7% of patients remained free of late complications.
One case of mesh extrusion was observed (1.5%), with no major intraoperative injuries, chronic pain, urinary retention, or thromboembolic events reported.

Interpretation of results

In this prospective multicenter post-market evaluation, a lightweight polypropylene transobturator MUS demonstrated sustained objective and subjective effectiveness, significant improvements in quality of life, and a favorable safety profile at 12 months.

Concluding message

These findings support the use of a lightweight polypropylene transobturator MUS as an effective and safe option for women with SUI