291

Jacquetin B[1], Cosson M[2], Lucente V[3], Miller D[4], Robinson D[5], Berrocal J[6], Clavé H [7], Debodinance P[8], Garbin O[9], Rosenthal C[10], Salet-Lizée D[11], Villet R[11]

1. Maternité Hotel-Dieu, CHU, 2. Hôpital Jeanne de Flandre, CHRU de Lille , 3. Institute for Female Pelvic Medicine and Reconstructive Surgery, Allentown , 4. Milwaukee Urogynecology, Milwaukee, WI, 5. Lincoln Center OB/GYN, P.A., Topeka, KS, 6. Clinique de l'Europe, Rouen, 7. Clinique Saint George, Nice, 8. Maternité Les Bazennes, CH de Dunkerque, 9. SIHCUS- CMCO, Schiltigheim, 10. Clinique Saint Germain, Brive-La Gaillarde, 11. Groupe Hospitalier Des Diaconesses, Paris

PROSPECTIVE CLINICAL ASSESSMENT OF THE TRANS VAGINAL MESH (TVM) TECHNIQUE FOR TREATMENT OF PELVIC ORGAN PROLAPSE – ONE YEAR RESULTS OF 175 PATIENTS.

Hypothesis / aims of study

The TVM technique involves a polypropylene mesh of specific size and shape that is secured tension free by extension arms that pass through the arcus tendineous via a transobturator approach anteriorly and through or fixed to the sacrospinous ligament via a transgluteal approach posteriorly. The aim of this presentation is to report results combined from two prospective studies, set up to evaluate the effectiveness and complications at one-year post-TVM.

Study design, materials and methods

Women from 8 French centers and 3 US centers with symptomatic POP (POP-Q Stage II-IV) were invited to participate in these prospective studies. The studies were similar in terms of patient population, and assessments. There were two differences between the 2 studies: 1) in the French study, patients were to have either prior or concurrent hysterectomy, whereas in the US study, there were no specified requirements regarding hysterectomy; 2) in the French study, total mesh was to be used in all patients, whilst in the US study, mesh could be placed as anterior or posterior only, or as total. In both studies, follow-up visits were planned at 6 weeks, 6 months, and 1, 3 and 5 years post-TVM. Assessments included: POP-Q, Quality of Life (QOL) and Prolapse Symptom Inventory (PSI). The primary endpoint was prolapse recurrence rate at 12 months post-TVM. Procedural success was defined as POP-Q Stage < II, without further re-intervention.

Results

In total, 175 patients were enrolled (90 French and 85 US). Anterior mesh only was placed in 27 women, posterior only in 8 and combined in 140 women. Mean age was 63.5; 14.9% had previous prolapse repair, 11.4% had previous SUI surgery, 50.9% had concurrent hysterectomy and concurrent incontinence procedure in 46.3%. Mean duration of procedure was 98.2 minutes with return to full activity in 19.7 days. At one-year post-TVM, the overall recurrence rate (POP-Q≥Stage II) was observed in 14.8% (90% CI 10.5 to 20.0%), with 1 subject at Stage III and none at Stage IV. Of the 26 women with Stage ≥ II at 12 months, the leading edge was inside the introitus in 17 of the anatomical failures (most of them were asymptomatic) ; in 8 patients, the leading edge was at the introitus and beyond the hymen in only 1 patient.

For PSI, improvement from baseline to 1 year was observed (mean change -11.6; SD 6.6, n=148, p<0.0001, Wilcoxon-signed-rank test). For QOL, mean change from baseline to 1 year was -3.7 (SD 3.8, n=86, p<0.0001). 26.9% had vaginal pain at baseline, with 7.1% reported at 1 year. Of the 58.3% patients who were sexually active at baseline, 20.6% reported dyspareunia, and by 1 year, this had reduced to 3.9%. New onset dyspareunia was 2.9% at 1 year. Mesh exposure was 2.4% at 1 year. 11 women required brief outpatient intervention for mesh exposure. 3 women required fistula repair for 2 vesico-vaginal fistulas and 1 recto-vaginal fistula.

Interpretation of results

Combining the results from these two studies demonstrates reasonable 12-month success rates with low mesh exposure and complication rates. Substantial improvements to QOL were observed.

Concluding message

Longer term follow-up is required to determine if the failure rate remains stable over time.

FUNDING: Gynecare (Ethicon)

DISCLOSURES: B. Jacquetin is consultant for Gynecare

CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the CCCPRB Lille University Hospital (2003,July 1st) and followed the Declaration of Helsinki Informed consent was obtained from the patients.