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A DOUBLE-BLIND, RANDOMIZED CONTROLLED TRIAL COMPARING SOLVENT-DEHYDRATED CADAVERIC FASCIA LATA AND POLYPROPYLENE MESH FOR SACRAL COLPOPEXY

Hypothesis / aims of study

To compare the surgical outcomes after sacral colpopexy performed with solvent-dehydrated cadaveric fascia lata and polypropylene mesh.

Study design, materials and methods

From July 2001 through June 2003, patients scheduled for sacral colpopexy in our institution were offered enrollment. Eligible patients were randomized to receive either fascia lata (Tutoplast® processed Suspend® fascia lata, Mentor Corp, Santa Barbara, CA) or polypropylene mesh (Trelex®, Boston Scientific, Boston, MA). A computer-generated random assignment technique was used to determine the allocation sequence, and opaque sealed envelopes were used to conceal the group assignments until the time of surgery. Only the surgical team was aware of the patients' group assignments. All outcome measures were obtained by a single independent observer who was blinded as to which material was used. Likewise, patients were not told which material was used until they had completed the study. Data was collected at 6 weeks, 3 months, 6 months and 1 year postoperatively. The main outcome measures were POP-Q stage and individual POP-Q points over time. Objective surgical failure was defined as POP-Q stage ≥ 2 at any point during the follow-up period. Our study design called for 30 patients in each arm to have 90% power ($\alpha = .05$) to detect a 30% difference in mean POP-Q stage over a 1 year period using a repeated measures analysis of variance test. Also, mean POP-Q points and stage at 1 year were compared using the independent samples t-test. Baseline group characteristics were compared using Chi-square for proportions and either Mann-Whitney U tests or t-tests for numerical data as appropriate.

Results

One hundred patients were randomized to receive either fascia (n=46) or mesh (n=54). Currently, 67 patients have completed their 1 year follow-up period. Data on the entire 100 patients will be accrued prior to the ICS/IUGA meeting. As expected, there were no significant differences between the groups with respect to pre-operative POP-Q points, age, BMI, gravity, parity, race, prior prolapse or incontinence surgery, or hormone use. Mean pre-operative POP-Q stage was 2.3 ± .7(fascia) and 2.6 ± .6 (mesh) p = 0.1. For the group of 67 at one year, mean point C measurements were -8.1±3.1 (fascia) and -9.1±1.2 (mesh) p=0.1; mean Aa measurements were -2.0±1.4 (fascia) and -2.6±.9 (mesh) p=0.06; and mean Ba measurements were -2.0±1.3 (fascia) and -2.5±0.9 p=0.07. POP-Q stage at 1 year was 0.9±0.9 (fascia) and 0.6±0.7 (mesh) p=0.08. Results from the repeated measures analysis of variance will be calculated when the entire group has completed the study.

Interpretation of results

In the group with available data so far, there were no statistical differences in objective surgical outcomes at one year for sacral colpopexies performed with either Tutoplast® processed fascia lata or Trelex® polypropylene mesh.

Concluding message

By the time this abstract is presented, the entire 1-year data analysis will be included.

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