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USE OF BOVINE PERICARDIUM IN PELVIC RECONSTRUCTIVE SURGERY

Hypothesis / aims of study

With an estimated 30% of women needing additional surgery for pelvic organ prolapse recurrence, there has been a significant increase in the use of synthetic and biologic grafts. Our aim was to evaluate our experience with bovine pericardium (Veritas®, Synovis Surgical Innovations, Minneapolis, MN) in pelvic reconstructive surgery. Veritas® is a non-cross linked bovine pericardium implant that acts as a temporary scaffolding to allow ingrowth of deficient fascia by surrounding host tissues.

Study design, materials and methods

All patients at our institution who had urogynecologic surgery utilizing bovine pericardium graft were reviewed. The decision to use bovine pericardium was based on the surgeon's intraoperative assessment of endopelvic fascial quality. For anterior repairs the graft was secured from apex to bladder neck and from arcus to arcus as an overlay to reinforce traditional midline plication. In vaginal enterocele repairs, a 4x7 piece of graft was utilized when the rectovaginal septum could not be successfully reattached to the vaginal apex. Data analyzed included demographics, prior urogynecologic surgery, postoperative POP-Q values, prolapse recurrence rates, complications, and healing abnormalities. The primary outcome was prolapse recurrence in the same compartment defined as POP-Q values ≥-1.

Results

From 2003 – 2009, 135 urogynecology procedures incorporated a bovine pericardium graft. Mean patient age was 62.2 ± 11.7.

There were 53 anterior repairs reinforced with a bovine pericardium graft. Preoperative POP-Q values Aa and Ba were 1.21 and 1.77 cm respectively. At a median follow-up of 54 weeks (24-142.5), anatomical results were satisfactory with measurements of Aa and Ba at
-2.33 and -2.28 cm respectively ($p<0.0001$). For patients with previous anterior repairs (6/53) there was also a statistically significant improvement in postoperative POP-Q values Aa and Ba. 10 patients had cystocele recurrence. None of these patients were symptomatic or required repeat surgery.

There were 77 posterior enterocele repairs utilizing a bovine pericardium graft. Preoperative POP-Q values Ap and Bp were -0.18 and 0.31 cm respectively. At a median follow-up of 56 weeks (41-105), anatomical results were satisfactory with measurements of Ap and Bp at -2.66 and -2.68 cm respectively ($p<0.0001$). For patients with previous posterior repairs (13/77) there was also a statistically significant improvement in postoperative POP-Q values Ap and Bp. 5 patients had posterior wall recurrence. There were no significant differences between preoperative and postoperative rates of dyspareunia or bowel complaints.

5 patients underwent urethral diverticulum excision with reinforcement with bovine pericardium. All patients had concomitant suburethral sling and Veritas® was used for tissue reinforcement prior to placement of the sling. Postoperatively, all patients reported themselves as "cured/greatly improved" with no diverticula recurrence or graft erosion.

Overall, patients were satisfied with surgical outcomes with 76% reporting themselves as either "cured" or "greatly improved". Alterations in healing were evaluated by presence of granulation tissue at 6 weeks postoperatively and beyond. At 6 weeks, granulation tissue was present in 18.5% of anterior repairs and 16.9% of posterior repairs. The majority of these healing abnormalities were related to suture sites and resolved by 12 weeks postoperatively. There were no graft exposures/erosions and no patients required repeat surgery for graft related complications.

Interpretation of results

At one year follow up, bovine pericardium used in vaginal prolapse repair results in acceptable anatomical and functional outcomes without significant graft related complications.

Concluding message

Bovine pericardium is useful for tissue augmentation in pelvic organ prolapse surgery.

Specify source of funding or grant	**Synovis Surgical Innovations; Minneapolis, MN**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Cleveland Clinic Florida Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**