

ANCHORSURE - ANCHORING SYSTEM: OUTCOMES AND SAFETY PROFILE IN VAGINAL RECONSTRUCTIVE SURGERY

Hypothesis / aims of study

Women with Levator Ani avulsion have higher incidence of pelvic organs prolapse (POP) as well as higher rate of recurrence of POP and failure of surgical native tissue repair of POP. Use of synthetic grafts have been suggested to improve outcomes of surgical correction of POP. Aim of the study is to evaluate results of AnchorSure – Tissue-anchoring system (Neomedic International) for repair of POP in women with Levator Ani avulsion.

Study design, materials and methods

Inclusion criteria for mesh-augmented repair was unilateral or bilateral avulsion of Levator Ani and/or ballooning of Levator Ani. All patients were evaluated by physical examination (PE) and vaginal 360° ultrasound prior to surgery and PE only thereafter. POP-Q stage, compartment failure and avulsion of Levator Ani were established. Monofilament Polypropylene mesh was used and tailored in trapezoid shape with 6 arms (3 on each side), just as SureLift pelvic repair system. 3 different meshes were used. Prolene-Soft™, Novasilk™ and Restorelle™. AnchorSure – Tissue-anchoring system was used to attach proximal arms to the sacro-spinous ligaments. Middle arms were brought through arcus tendineous at the level of ischial spines and distal arms at the insertion of arcus tendineous into inner portion of pubic bone. Both middle and distal arms were brought out through obturator foramen. Apical support was provided by utero-sacral ligaments colpopexy.

Results

Table 1: Failure of support prior and after surgery by compartment

All Compartments		Anterior and Apical		Anterior Only		Anterior and Posterior		Apical Only		Posterior and Apical		Posterior only	
Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome
39/13 %	0%	141/47 %	0	48/16 %	6/2%	27/9 %	0	15/5 %	0	21/7 %	0	9/3%	3/1%

Table 2: Prolapse stage prior and after surgery by compartment

Prolapse Stage	All Compartments		Anterior and Apical		Anterior Only		Anterior and Posterior		Apical Only		Posterior and Apical		Posterior only	
	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome	Prior to Surgery	Post-surgical outcome
Stage 2	20/6.6%	0/0	41/13.6%	0/0	8/2.6 %	0/0	7/3.3 %	0/0	20/6.6%	0/0	8/2.6 %	0/0	3/1%	1/0.3 %
Stage 3	10/3.3%	0/0	100/30%	0/0	40/13.3%	6/2%	20/6.6%	0/0	10/3.3%	0/0	13/4.3%	0/0	6/2%	2/0.6 %
Stage 4	9/3%	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0

Table 2: Complications

Blood Transfusions	Hematoma of Anterior Wall	Hematoma of Posterior Wall	Bladder Injury	Bowel Injury	Ureteral injury	Chronic Pelvic Pain	De-Novo DI	De-Novo SUI	De-Novo Obstructive Defecation	Post-op Dyspareunia	Early Mesh Erosion <8 weeks	Late Mesh Erosion >8 weeks	Infection/ Abscess
2/0.6%	3/1%	5/1.6%	0/0	0/0	0/0	1/0.3 %	0	5/1.6%	0/0	3/1%	2/0.6	1/0.3 %	2/0.6 %

Interpretation of results

Surgical outcomes were consistent with high cure rate for all types of POP (POP presented in different compartments) and for all stages of POP with very low complication rate.

Concluding message

AnchorSure – Tissue-anchoring system (Neomedic International) provides safe and effective repair of genital prolapse in patient population with very high risk of failure without use of graft augmentation. Versatility of the AnchorSure allow adjusting synthetic or biological graft according to the shape and size of the pelvis with very small risk to compromise anatomical or functional results.

References

1. Olsen et al, Obstet Gynecol 1997; 89: 501-506
2. Mirjam Weemhoff et al: Avulsion of puborectalis muscle and other risk factors for cystocele recurrence: a 2-year follow-up study; Int Urogynecol J. 2012 January; 23(1): 65–71
3. H. P. Dietz et al.; Levator avulsion is a risk factor for cystocele recurrence: Ultrasound Obstet Gynecol 2010; 36: 76–80

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** Follow up on results of approved surgical technique with use of FDA approved product. **Helsinki:** Yes **Informed Consent:** Yes