Sling surgery for stress urinary incontinence; the perfect solution?

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Summary (abstracts)

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Chapter 1 provides an insight into the pathophysiology and history of surgical treatment of urinary incontinence in both male and female patients. Next (the rise of) sling surgery in urological and uro-gynecological practice is described and an overview is given of the methods of introduction of a new sling device on the commercial market. In the following section the relation between sling surgery, neurovascular damage and sexual functioning is discussed and the shortcomings of current literature are pointed out.

Finally the question is raised whether slings, old and new, for either male and female, can live up to the expectations of both patients and physicians by being both safe and effective in curing urinary incontinence. Secondly, we speculate whether sling surgery is anatomically safe with regard to those nervous systems which are essential for the sexual function or may actually be responsible for iatrogenic neurological damage during placement.

Chapter 2.1; The Introduction of mid-urethral slings: an evaluation of literature

Introduction and hypothesis

The objective of this study was to evaluate the degree and reliability of evidence used by manufacturers before the introduction of mid-urethral slings (MUS) onto the commercial market. Furthermore, minimum standards for marketed slings are recommended by evaluating recent suggestions for the introduction of gynecological meshes.

Methods

A systematic literature search was conducted using PubMed and commercial internet search engines in order to identify slings introduced by the industry over the last decade. Moreover, manufacturers were contacted by email, mail, and phone to provide data from before the introduction of the slings onto the commercial market. Once contact had been initiated, a 6-month deadline was set for data collection.

Results

Forty-one slings introduced between 1996 and 2012 were identified. Ten slings were described in a total of 20 studies with sample sizes varying from 10 to 368. The 41 MUS were produced by a total of 19 different companies. Seven companies never responded to recurrent emails, phone calls or other means of attempted contact. Thirty-one slings (76 %) remained without any comparative pre-launch data.

Conclusions

Mid-urethral slings were often introduced without any scientifically proven basis or pre-launch research. The US Food and Drug Administration and the European authorities should undertake immediate action by imposing strict rules before the launch of new MUS comparable with those recently suggested for meshes used in vaginal prolapse surgery.

Chapter 2.2; Erratum to: The Introduction of mid-urethral slings: an evaluation of literature presents relevant new information that became available on two slings after the publication of chapter 2.1.

Chapter 3; The MiniArc sling for female stress urinary incontinence: clinical results after 1-year follow-up

Introduction and hypothesis

The objective of this study was the assessment of the efficacy of the MiniArc for curing stress urinary incontinence.

Methods

Seventy-seven patients, operated on from March 2008 to November 2009, were evaluated in this study. One year postoperative data are presented. All patients suffered from predominant stress urinary incontinence. After 1 year, response was 74%. Evaluation was performed using a questionnaire consisting of the EuroQol-5 Dimensions, the Patient Global Impression of Improvement, the Incontinence Impact Questionnaire, the Urinary Distress Inventory, the Prolapse/Urinary Incontinence Sexual Questionnaire, short form, and the Defecation Distress Inventory.

Results

One year after surgery, 68% of the patients stated an improvement in their incontinence status, while only 44% stated to be completely dry.

Conclusion

The 1-year follow-up suggests that the MiniArc is less effective in the treatment of stress urinary incontinence than the TVT.

Chapter 4; Results of sling surgery in a non-selected population

Objective

To evaluate sling surgery in terms of effectiveness and quality of life, and describe the effects of confounding variables on outcomes.

Methods

A retrospective cohort study using multiple validated questionnaires was conducted in a specialized pelvic floor center in the Netherlands. Women were enrolled after undergoing sling surgery between January 1, 2010, and January 31, 2012. In addition to the preoperative questionnaire, participants completed a questionnaire a minimum of 6 weeks after surgery to assess outcomes.

Results

Of 255 eligible participants, 228 (89.4%) returned the postoperative questionnaire after a mean follow-up of 14.9 months (range 2–32). At the time of follow-up, 158 (69.3%) patients considered themselves cured and an improvement was observed in 155 (68.9%) patients. Seventy (31.1%) patients rated their postoperative situation as little

improved, unchanged or deteriorated. Compared to patients who had no history of previous related surgery, patients with prior sling surgery benefited significantly less from surgery, whereas those with concomitant vaginal surgery showed similar scores in all outcome parameters. A high body mass index was found to have a negative effect on the results of surgery.

Conclusion

Mid-urethral sling surgery is both efficient and effective in curing stress urinary incontinence. However, patient characteristics and confounding variables can influence the outcome of surgery and should therefore always be discussed with the patient.

Chapter 5; Results of collagen sling placement following the partial removal of a synthetic mid-urethral sling

Objective

To assess results of placement of the Pelvilace collagen sling following partial removal of a primary synthetic sling because of late complications.

Methods

A retrospective study was undertaken of patients with late complications after mid-urethral sling surgery who underwent placement of a Pelvilace sling at a center in the Netherlands between January 2006 and January 2011. A postoperative questionnaire was used to evaluate the continence status and continence-related quality of life. Patients scoring 0 in the Urogenital Distress Inventory stress symptoms section were considered cured. The subjective improvement or deterioration in symptoms was scored using the Patient Global Impression of Improvement (PGI-I).

Results

The questionnaire was completed and returned by 32 (84%) of 38 patients with a mean follow-up of 54.3 months. Nine (28%) patients were deemed cured. Among 29 patients who had not undergone a third surgery, the PGI-I showed a postoperative improvement in 14 (48%). The other 15 patients rated their postoperative situation as little improved, unchanged or deteriorated. Further sub-analysis showed clear differences in postoperative results between the different types of late complications (erosion and/or displacement).

Conclusion

The concomitant placement of a collagen sling following partial removal of a primary polypropylene sling shows reasonable results for specific complications.

Chapter 6; Sling surgery for the treatment of urinary incontinence after transurethral resection of the prostate: evaluation of literature and new data on the Virtue® male sling

Objective

To provide a review of literature regarding the role of male slings in the treatment of stress urinary incontinence (SUI) following a transurethral resection of the prostate (TURP) and to evaluate the effects of the Virtue® male sling in patients suffering from post-TURP SUI.

Materials and methods

A systematic review of literature was performed to identify all papers on the use of male slings in patients suffering from Post-TURP SUI. Secondly, a prospective cohort study was conducted on 8 patients who received the Virtue® as surgical treatment of post-TURP SUI. Questionnaires were collected preoperatively and 1, 3, 6 and 12 months postoperatively. Success and improvement were defined as pad usage (0 pads: success, pad reduction of ≥50%: improvement). The primary endpoint was the continence rate 1 year postoperatively. Data was analysed using the paired two-tailed *t*-test.

Results

Sling surgery appears to be significantly less successful in the treatment of SUI post-TURP when compared to other types of prostate surgery. The clinical trial on the Virtue® sling observed continence in 4 of 8 patients, with another 2 patients with improved continence after 1 year follow-up. No difference in success was observed between patients with mild and patients with severe SUI.

Conclusions

Little is currently known about the effects of sling surgery in patients with mild to severe SUI following a TURP. Although the Virtue® male sling seems to be an efficient and safe device in the treatment of this complication, longer follow-up and larger cohorts will be needed to further confirm these results.

Chapter 7; The somatic and autonomic innervation of the clitoris; preliminary evidence of sexual dysfunction after minimally invasive slings

Introduction

Vaginal sling procedures may have a negative effect on sexual function due to damage to vascular and/or neural genital structures. Even though autonomic innervation of the clitoris plays an important role in female sexual function, most studies on the neuroanatomy of the clitoris focus on the sensory function of the dorsal nerve of the clitoris (DNC). As of present, the autonomic and somatic pathways in relationship to sling surgery have not been described in detail.

Aim

The aim of this study is to reinvestigate and describe the neuroanatomy of the clitoris, both somatic and autonomic, in relation to vaginal sling procedures for stress urinary incontinence.

Methods

Serially sectioned and histochemically stained pelves from 11 female fetuses (10–27 weeks of gestation) were studied, and three-dimensional reconstructions of the neuroanatomy of the clitoris were prepared. Fourteen adult female hemipelves were dissected, after a tension-free vaginal tape (TVT) (7) or tension-free vaginal tape-obturator (TVT-O) (7) procedure had been performed.

Main Outcome Measures

Three-dimensional (3-D) reconstruction and measured distance between the clitoral nerve systems and TVT/TVT-O.

Results

The DNC originates from the pudendal nerve in the Alcock's canal and ascends to the clitoral bodies. In the dissected adult pelves, the distance of the TVT-O to the DNC had a mean of 9 mm. The cavernous nerves originate from the vaginal nervous plexus and travel at the 5 and 7 o'clock positions alongside the urethra. There, the autonomic nerves were found to be pierced by the TVT needle. At the hilum of the clitoris the branches of the cavernous nerves medially pass/cross the DNC and travel further alongside it. Just before hooking over the glans of the clitoris, they merge with the DNC.

Conclusion

The DNC is located inferiorly to the pubic ramus and was not disturbed during the placement of the TVT-O. However, the autonomic innervation of the vaginal wall was disrupted by the TVT procedure, which could lead to an altered lubrication-swelling response.

Chapter 8; Risk of damage to the somatic innervation of the penis during the AdVance™ male sling procedure; an anatomical study

Introduction

One of the methods to treat post radical prostatectomy stress urinary incontinence is the AdVance™ (American Medical Systems®, Minnetonka, MN, USA) male sling procedure. During this procedure, the somatic innervation of the penis may be at risk for injury. Six AdVance™ procedures were performed in 6 donated bodies at the Anatomy and Embryology Department of the Leiden University Medical Center. The pelves were dissected and the shortest distance between the sling and the dorsal nerve of the penis (DNP) was documented.

Aim

The aim of this study was to describe the anatomical relation between the AdVance™ male sling and penile nerves based on the dissection of 6 adult male pelves.

Methods

The AdVance™ male sling procedure was conducted in 6 donated male bodies. After placement, the pelves were dissected and the shortest distance between sling and the DNP was documented.

Main Outcome Measure

The main outcome measure was the distance between the AdVance™ male sling and the DNP

Results

The mean distance of the sling to the DNP was 4.1 mm and was found situated directly next to the nerve (distance 0 mm) in 4 out of 12 (33%) hemipelves. The distance of the sling to the obturator neurovascular bundle was 30 mm or more in all 6 bodies.

Conclusions

Damage to the DNP caused by the AdVance™ male sling procedure appears to be an extremely rare complication, which has not been described in current literature. The proximity of the AdVance™ to the DNP could, however, pose a risk that should be taken into consideration by physicians and patients when opting for surgery.