Sling surgery for stress urinary incontinence; the perfect solution?

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Risk of damage to the somatic innervation of the penis during the AdVance™ procedure: an anatomical study

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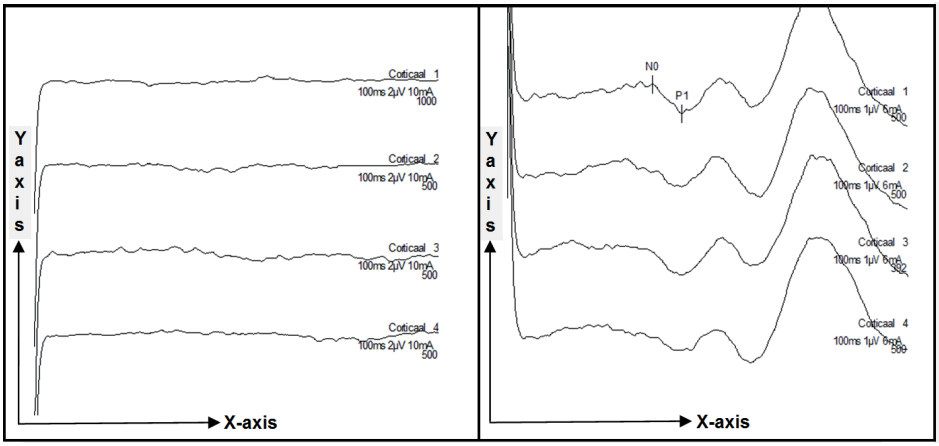
Case

A total of 32 AdVance™ male slings have been placed between 2007 and 2011 at the Leiden University Medical Center in patients suffering from SUI after a nerve sparing RP. Directly following an otherwise uncomplicated procedure, one patient complained of de-novo anesthesia of the right side of the penis. Since the anesthesia occurred directly post-surgery it could only be explained by neurological damage suffered during the placement of the sling. In the following period the sensory nerves of his penis were analysed using Somato Sensory Evoked Potentials (SSEP's), in order to identify the origin of the anesthesia. SSEP's are based on the electrical stimulation and response of individual somatic nerves that are reproduced as cortical curves with the SSEP's showing as evident peaks. The subsequent analysis showed complete interruption or neurotmesis of the right dorsal nerve of the penis (DNP), demonstrated by the lack of any response upon stimulation (figure).



Somatosensory evoked potential measurement of penis patient X
P: positive peaks represented by downward deflections, N: negative peaks represented by upward deflections. X-axis: time in milliseconds (ms), Y-axis: amplitude in in microvolts (µV).

The next chapter describes the anatomical relation between the AdVance™ male sling and penile nerves based on the dissection of 6 adult male pelves and investigating the sites of potential nerve damage during sling placement.

Introduction

One of the most popular treatment options for prostate cancer is the radical prostatectomy (RP). The two major complications following a RP are stress urinary incontinence (SUI) and erectile dysfunction (1). The post-RP SUI rates show a huge range throughout literature, but incontinence rates as high as 87% have been reported in the past (2). This divergence of reported SUI rates can be explained by the use of different surgical techniques as well as different definitions of continence. Despite an evolution in surgical techniques for RP following the introduction of (robot-assisted) laparoscopic prostatectomy over the past years, recently reported postoperative SUI rates are still between 5% and 48% (3). Moreover, the ever-growing number of radical prostatectomies worldwide entails increasing numbers of patients suffering postoperative SUI.

SUI due to sphincter incompetence is the most observed type of post-RP incontinence and initial therapy consists of lifestyle interventions, scheduled voiding and pelvic floor muscle training. After initial treatment has failed, invasive therapy should be considered. The recommended invasive treatment options for SUI due to sphincter incompetence are the placement of an artificial urinary sphincter or male sling (4).

The somatic peripheral nervous system is responsible for carrying motor and sensory information from (efferent) and to (afferent) the central nervous system. Standard anatomical literature shows that the somatic sensory information of the external male genital area is conducted to the sacral cord through the pudendal nerve (PN). The PN originates from sacral spinal segments 2–4 and travels through the Alcock's canal into the perineum. The PN has three major branches, namely the inferior rectal nerve, the perineal nerve, and the dorsal nerve of the penis (DNP). The DNP is the final branch of the PN and is considered the main somatic afferent nerve of the penis. It is responsible for the transfer of sensory input from the penis to the central nervous system and crucial for both erection and ejaculation (5). Damage to the DNP results in paresthesia or anesthesia of the innervated area and is highly invalidating in sexually active men (6;7).

The AdVance™ (American Medical Systems®, Minnetonka, MN, USA) male sling is a minimally invasive technique developed for the treatment of mild to moderate post-prostatectomy SUI. The AdVance™ repositions the urethral sphincter complex in the pelvis and is designed to minimize the risk of tissue damage during placement (8). In the initial study on the AdVance™, Rehder and Gozzi describe the anatomical effects of sling placement as well as the clinical outcome in men with SUI (8). In the results section, the authors state that "the penile vessels and nerves that lay in the 'shadow' of the inferior pubic ramus (IPR) were not injured by rotating the helical introducer needles" ((8) p. 863). Although the authors did not literally call the DNP by its name, it can be assumed that these were indeed the penile nerves described. The trajectory of the sling in relation to the pelvic neuro-anatomy was not pursued any further.

Following a complication in our clinic, in which the AdVance™ procedure resulted in a unilateral neurotmesis of the DNP, a literature search was performed via PubMed (using MeSH terms "neuroanatomy," "pudendal nerve," and "suburethral sling") to identify publications on the AdVance™. In this search, it became evident that there have been no studies up to present that analyse the trajectory and positioning of the AdVance™ in relation to the pelvic neuro-anatomy.

Aim

This study aimed to describe the anatomical relation between the AdVance™ male sling and penile nerves based on the dissection of 6 adult male pelves.

Methods

A total of 6 male donated Caucasian bodies from the Netherlands were used in this study. Bodies displaying any sign of surgery in the pelvic region were excluded. Preservation of the bodies was accomplished by injection of AnubiFIX™ (AnubiFIX, Gouda, the Netherlands) into the femoral artery followed by the embalming fluid, consisting of 36% formaldehyde with a mixture of ethanol, glycerin, phenol, K2SO4, Na 2SO4, NaHCO3, NaNO3, and Na2SO3. This particular fixation process ensures the flexibility of the pelvic structures such as muscles, nerves, arteries, and veins, and enables a realistic surgical procedure by retaining "lifelike" suppleness of the body. The bodies were all aged 70 years or older at the time of death and were donated according to the Dutch Burial and Cremation Act to the Department of Anatomy and Embryology at the Leiden University Medical Center for use in scientific research and medical education. As the bodies had been donated for medical research, no additional ethics approval was needed.

The procedures were conducted by the same urologist (HWE) who has extensive experience with the AdVance™ male sling and is experienced in placing mid-urethral slings in female cadavers for clinical research. The slings were placed using the same method and materials described by Rehder and Gozzi (8). After placement, the correct position of the mesh on the bulbar urethra was ascertained and the sling was fixated to the corpus spongiosum using two nonabsorbable sutures. The sling was then tensioned by pulling both arms of the sling, repositioning the urethral bulb.

After sling placement, the pelves were separated from the bodies, leaving the pelvic organs in place. First, the cutis and subcutaneous fat were removed from the dorsal side of the pelves, and the various muscle groups and cutaneous nerves were identified. Next, the consecutive tissue layers were dissected from the dorsolateral side of the pelvis, working in a ventral direction. After removal of the gluteal muscles, the ischial tuberosities were used as anatomical landmark to identify the ischial and PNs.

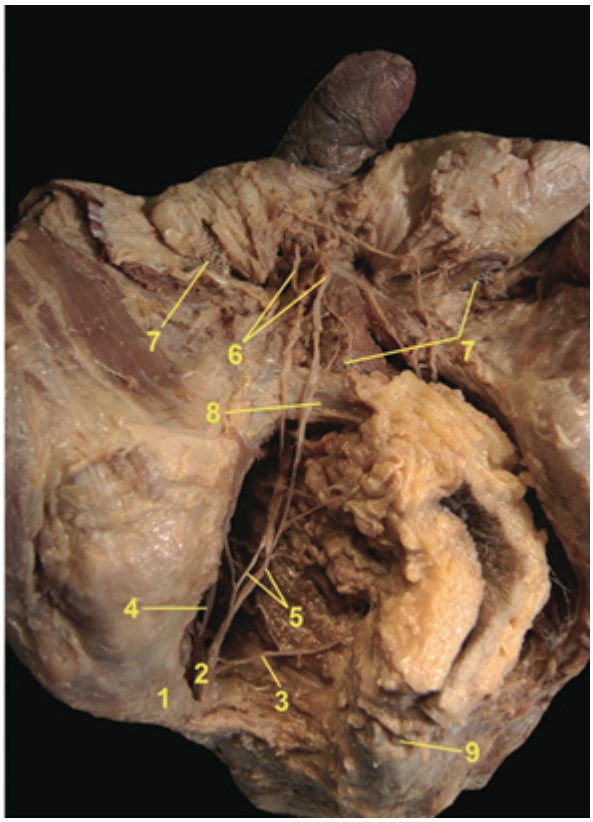


Figure 1 Course of pudendal nerve through the male pelvis. 1, sacrotuberous ligament; 2, pudendal nerve; 3, inferior rectal nerve; 4, dorsal nerve of penis; 5, perineal nerves; 6, posterior scrotal nerves; 7, AdVance™; 8, transverse perineal muscle; 9, coccyx

The PN arises from the sacral spinal segments 2–4 and travels though the Alcock's canal before entering the perineum. The course of the PN around the ischial spine was approached posteriorly by removal of the superficial fascia between the anterior inferior iliac spine, the ischial tuberosity and the posterior superior iliac spine. The sacrotuberous ligament was identified and the trajectory of the PN subjacent to the sacrotuberous ligament around the ischial spine of the pelvis was uncovered. The entrance of the PN into Alcock's canal was identified and dissected to reveal the PN and its three main branches (Figure 1). The DNP was then followed all the way through the perineum to its termination at the base of the penis.

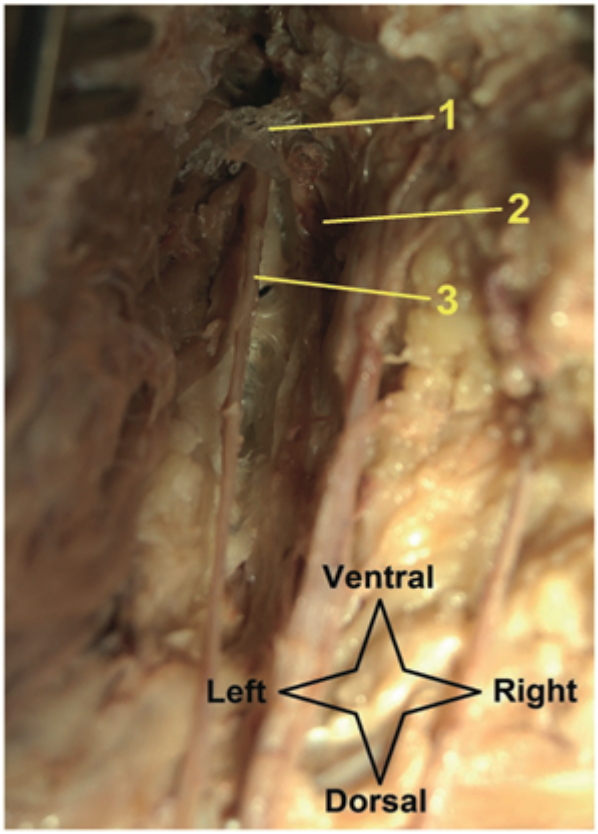


Figure 2 Close-up inferior view of the AdVance™ sling situated directly next to the dorsal nerve of the penis (DNP) in the right hemipelvis. 1, AdVance™ sling; 2, inferior pubic ramus; 3, DNP

At this stage the AdVance™ sling and its trajectory through the obturator foramen were fully exposed by opening of the perineal membrane (Figures 1 and 2). Next the pelvis was turned and the obturator foramen was exposed by removal of the adductor muscles of the hip and the external obturator muscle. The AdVance™ sling and obturator vessels and nerves were identified and followed through the internal obturator muscle. Finally, the distance of the AdVance™ sling to the DNP and obturator vessels and nerves was measured in all pelves. All stages of the dissection were recorded photographically using a high resolution digital camera with additional macro lens (Nikon™ D70, Nikon Corporation, Tokyo, Japan). Statistical analysis was performed using SPSS release 20.0 for Windows (SPSS Inc., Chicago, IL, USA). Outcomes were considered statistically significant at the 95% level.

Main Outcome Measures

The main outcome measures werethe distance between the AdVance™ male sling, the DNP and the obturator neurovascular bundle.

Results

In all pelves, the DNP was found running in between the superior and inferior borders of the perineal membrane (or urogenital diaphragm), medial to the inferior border of the IPR, without signs of an aberrant course. The mean distance of the sling to the DNP was 4.1 mm and found situated directly next to the DNP (distance: 0 mm) in 4 out of the 12 hemipelves (33%, Table 1, Figure 2). No signs of direct nerve damage caused by the passage of either trochar or sling was found in any of the 6 pelves. The distance of the AdVance™ to the DNP did not show a significant difference between left and right. In 2 pelves (bodies 3 and 4, see Table 1), the tape was situated significantly further away from the DNP than in the other 4 pelves. The distance of the sling to the obturator neurovascular bundle was 30 mm or more in all 6 pelves.

Table 1 Distance of AdVance™ male sling to dorsal nerve of the penis

Distance to tape (mm)	Body 1	Body 2	Body 3	Body 4	Body 5	Body 6
Dorsal nerve of penis	L R	L R	L R	L R	L R	L R
AdVance™ male sling	0 2	4 5	10 7	10 9	0 2	0 0
Mean	4.1 mm.					

Discussion

This study aimed to visualize the anatomical relation between the DNP and the AdVance™ male sling.

Post-RP SUI because of sphincter incompetence is a well-known complication of the surgical treatment of prostate cancer. One of the recommended invasive treatment options for this type of SUI is the male sling procedure (4). During these past years, there has been an enormous rise in male sling surgery because of its minimally invasiveness and promising success rate (9).

The male sexual function is a complex combination of external and internal stimuli in which the sensory nerves of the penis play a vital role (6).The main sensory nerve of the penis, the DNP, is the final branch of the PN and runs medially to the inferior border of the IPR through the perineum (Figure 1). Damage to the DNP can cause both erectile

and orgasmic dysfunction and is therefore considered highly invalidating in sexually active men (7).

Damage to the DNP caused by the AdVance™ male sling procedure has not been noted or described in current literature. This anatomical study was performed following an AdVance™ procedure in our clinic that resulted in a unilateral neurotmesis of the DNP. Results showed a mean distance of the AdVance™ sling to the DNP of 4.1 mm (Table 1). Although the sling was found directly situated next to the DNP in 4out of12 (33%) hemipelves, none of the DNP showed any sign of direct damage by the trochar or sling (Table 1, Figure 2).

A literature search on anatomical studies describing the course of male slings produced one recent article by Pereira-Correia et al. that analysed the course of the Argus T™ (Promedon SA, Cordoba, Argentina) needles and sling in relation to the pelvic neuroanatomy. Although the authors extensively elaborate on the anatomical relation of the sling and the obturator neurovascular bundle, the proximity of the tape to the PN and DNP was not discussed (10).

Mid-urethral sling surgery in women is currently considered the preferred invasive treatment for curing SUI (4). The second generation midurethral slings (the Tension-free Vaginal Tape-Obturator and the Trans Obturator Tape) are placed through the foramen obturatorium using techniques similar to the one used in the AdVance™ male sling procedure (11–13). The dorsal nerve of the clitoris (DNC) in women is the anatomical equivalent of the DNP in men. A literature search using MeSH terms [pudendal neuralgia] and [suburethral sling] produced several articles on pudendal neuralgia following a trans-obturator sling procedure (14–16). However, none of these studies described incidents in which neurotmesis of the DNC occurred. Anatomical studies on the risk of injury to the DNC after mid-urethral sling placement through the foramen obturatorium in women showed that, hypothetically, the trochar and sling could come into contact with the DNC. Although these studies did not describe direct damage to the DNC; they clearly described the proximity of the trochars and sling to the DNC (17,18).

As the complication in our clinic could not be explained by precedents (male or female) in the current literature, and only partly by the anatomical study performed at this center, other explanations should be considered.

Firstly, there is the possibility that the complication of neurotmesis of the DNP was indeed encountered in other clinics as well, but has not been reported by either patients or physicians. Being a rare complication in a predominantly elder (and sexually inactive) population, this could at least partly explain the absence of any current literature on the subject.

Secondly, there is a chance that in our patient, the DNP had an aberrant course through the pelvis. Assuming this, the damage to the DNP could then have been suffered either during the surgical mobilization of the bulbar urethra or the placement of the

AdVance™. A recent study on the course of the PN and DNP does indeed show a high variability in different pelves (19). Unfortunately, as there is no way to ascertain the actual course of the DNP in our patient, this theory is purely hypothetical.

Thirdly, the DNP could have been damaged not during, but directly following the actual placement of the sling. After introduction, the AdVance™ is tensioned in order to reposition the urethral sphincter complex in the pelvis (8). During this process, the sling is in the close proximity or sometimes even directly adjacent to the DNP, as was described in the anatomical part of this study. After the sling has been tensioned, the plastic cover is removed from the mesh arms, uncovering the serrated edges that help secure the sling in the neighboring tissue (Figure 2). In theory, these serrated edges situated directly next to the DNP could potentially be responsible for nerve damage. Finally, the sling itself could have been placed incorrectly by the urologist, resulting in an abnormal route of either trochar or tape, and thus causing damage to the DNP. Although the specialist in our clinic was trained and educated in the placement of the AdVance™ by AMS, human error should always be taken into consideration when surgery is performed.

There are certain limitations to this study that have to be taken into consideration as well. The first limitation is that there were only 6 bodies used in this study, which makes it difficult to reproduce rare complications and draw conclusions concerning these complications. Moreover, the small number of bodies used limits the authors to present a logical explanation for the fact that in 2 pelves, the tape was situated significantly further away from the DNP than in the other 4 pelves (Table 1). In order to prove if diverging trajectories of the AdVance™ male sling are indeed encountered in the clinic as well, an in vivo study should be conducted on a larger scale.

The second limitation is the fact that the bodies used had no history of RP, whereas patients opting for the AdVance™ sling procedure usually do have a RP in their medical history. This difference could hypothetically result in an altered course of the AdVance™ sling in the dissected pelves and potentially bias results. On the other hand, a standard RP does not change the position of the DNP, as it lies in a different part of the pelvis. Second, the AdVance™ procedure uses the "outside–in" method, which ensures the initial course of trochar and sling is independent of the prostate. When introducing the trochar through the adductor muscles of the thigh, it first passes the obturator foramen (and the IPR) before it reaches the urethral bulb. The use of the outside-in method strengthens our opinion that these findings are independent of the fact whether or not a RP was performed.

Conclusions

The proximity of the AdVance™ to the DNP could potentially pose a risk that should be taken into consideration by physicians and patients when opting for surgery. Moreover, when introducing a new mid-urethral sling, an anatomical study should always include a description of the distal part of the neuro-anatomy in relation to the anatomical position of the sling.

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