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Anterior needle-guided mesh in advanced pelvic organ prolapse: apical fixation on sacrospinous ligaments☆

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ABSTRACT

Objective: To evaluate whether anterior–apical compartment mesh implants for pelvic floor reconstruction might be safely and effectively anchored to the sacro-spinous (SS) ligaments instead of the arcus tendineus fascia pelvis (ATFP). The SS ligaments as anchoring structures for centro-apical support mesh fixation are thought to be stronger than the ATFP and we presumed that anterior mesh fixation to the SS ligament might be feasible, safe and effective.

Study design: Patients with advanced anterior–apical pelvic floor prolapse, referred for mesh reconstruction and having poor ATFP were enrolled to this study. For these patients the posterior arms of the anterior mesh were fixed to the SS ligaments. Data regarding cure, complications and patient's satisfaction were collected prospectively: patients were interviewed and examined at the end of the first and third post-operative months, and interviewed again at the study conclusion.

Results: Of 72 patients who were asked to participate in this study, 44 had rather un-palpable ATFP, and SS ligament fixation was performed. The mean follow-up duration was 12 months (range: 10–43). No significant intra- or post-operative complications were recorded. The POP-Q points measurements showed marked improvements: the average delta for the Ba point was 7.4 cm, for the Bp point 4.7 cm, and for the C point 7.9 cm. These differences were all statistically significant. Bladder overactivity symptoms, namely urgency, frequency and nocturia, were all found to be reduced significantly, and so was the sexual discomfort rate. Fecal incontinence, pelvic pain and constipation rates were reduced as well, but these did not reach statistical significance.

Conclusions: This rather small study suggests that anterior pelvic floor meshes might be anchored safely and successfully to the SS ligament, aiming to achieve improved centro-apical support of the vaginal apex and the anterior wall by an anterior pelvic floor approach.

1. Introduction

Pelvic floor relaxation and pelvic organ prolapse are regarded by many as a pelvic floor herniation process caused by obstetrical trauma to the pelvic floor or/and pre-existing fascial weakness. As the classical reconstruction methods showed relatively high recurrence rate, mesh augmentation is advocated for pelvic floor reinforcement and proven to improve reconstruction [1,2]. Mesh implantation, however, is related to specific post-operative complications, such as exposure, pelvic and vaginal pain and dyspareunia, as well as a considerable rate of failure [1–3].

Posterior pelvic floor implants (meshes) are routinely fixed to the sacro-spinous (SS) ligaments, while anterior pelvic floor needle-guided meshes are attached to the arcus tendineus fascia pelvis (ATFP). For pelvic centro-apical support the ATFP is regarded as inferior to the SS ligament, as it is a relatively weak structure and provides a rather low level of support [4]. This makes the ATFP anchoring susceptible to breaking and potential prolapse recurrence. The use of ATFP mesh arms anchoring is also related to post-operative thigh pain, due to the operative needle passage through the obturator area and abductor triangle [5]. Recently, some manufacturers addressed this issue and launched anterior mesh

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kits, designed to be fixed to the SS ligaments rather than to the ATFP, but the efficacy and safety of these are still to be proven.

A cadaveric study designed to evaluate potential operative hazards related to anterior SS apical fixation of mesh implants was carried out recently, demonstrating safe distances to the ureters, uterine arteries or pelvic nerves [6]. Other authors shared the opinion that the deep anterior mesh arms should be fixed to the SS ligaments rather than the ATFP for better anchoring, and reported both feasibility and promising early results [7,8]. This study looks at the operative outcome in physically and sexually active patients suffering from advanced pelvic floor herniation of the anterior compartment of the pelvic floor. The augmented mesh was fixed to the SS ligaments when the ATFP was estimated by an experienced surgeon to be rather fragile and thus inappropriate for apical support.

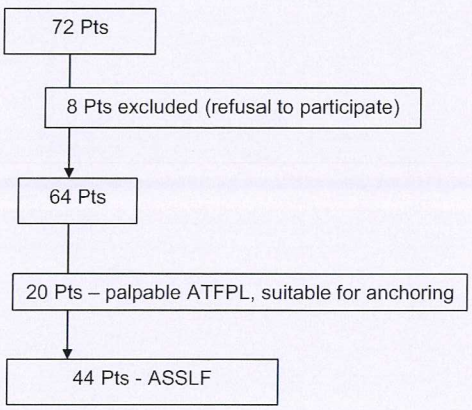
2. Patients and methods

This study, started on January 2009 and closed on October 2011, was designed to be open and prospective. We enrolled patients suffering from advanced prolapse of the anterior–apical pelvic floor compartments, with C points of more than +2 according to the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POP-Q) system. The mesh used here was Prolift + M® anterior (Gynecare, Summerville, USA). Apical SS ligament fixation was chosen whenever the ATFP was found by an experienced surgeon to be poor to the extent of being difficult to palpate, making it clearly inappropriate for mesh fixation. Informed consent was obtained after thorough information was presented. This was approved by the Institutional Board Committee (Helsinki Committee).

Surgery was carried out according to the previously reported surgical method for anterior mesh implantation, except that the posterior pair of arms was introduced according to the reported method for insertion of the posterior mesh surgical needles. The deep arms needles were thus inserted through skin cuts, 3 cm posterolateral to the anus, passing through the gluteus muscle, via the para-rectal and ischio-rectal area, to penetrate the mid-SS ligament. An additional 3 cm manual medial dissection, starting at the ischial spine, was necessary to prepare the space for the needle SS passage.

All patients were given 1 g Monocef® (Cefonicid, Beecham Healthcare) intravenously one hour prior to surgery. They all underwent an iodine antiseptic vaginal wash before the surgery.

Table 1
Patients' flow-chart.



Pts, patients; ATFPL, arcus-tendineous fascia pelvis ligament; ASSLF, anterior sacro-spineous ligament fixation.

Table 2
Patients' personal details.

	ASSLF patient's group ($N=44$)
Centro-apical pelvic floor prolapse > Gr 2	44 Pts (100%)
Age (mean and standard deviation, years)	62.4 ± 7.75 SD (range 45–78)
Vaginal deliveries (mean and standard deviation)	2.89 ± 1.37 SD
Body mass index (mean and standard deviation)	25.67 ± 2.98 SD
Urgency	34 Pts (77%)
Frequency	37 Pts (84%)
Nocturia	34 Pts (78%)
Cystocele, Gr > 2	44 Pts (100%)
Rectocele, Gr > 1	40 Pts (91%)
Previous POP corrective surgery	12 Pts (27%)
Background chronic illness	23 Pts (52%)
Follow-up duration (mean and standard deviation, Mnts)	12 ± 6.52 SD (range 10–45)
Concomitant posterior wall mesh augmentation	22 Pts (50%)
Non-mesh posterior wall repair	18 Pts (41%)
Concomitant anti USI operation	26 Pts (59%)

POP, pelvic organ prolapse; USI, urinary stress incontinence; Pts, patients; Mnts, months; ASSLF, anterior sacro-spineous ligament fixation.

The mode of anesthesia, general or regional, depended on the patient's request. Urinary bladder catheterization or diagnostic cystoscopy was not carried out routinely. Patients presenting with additional posterior vaginal wall relaxation had either posterior colporrhaphy or posterior pelvic floor mesh augmentation reconstructive surgery (by Prosima® or Prolift + M®, Gynecare, Somerville, USA), depending on the severity of the herniation process. Mild degrees of prolapse were treated with native tissue colporrhaphy, moderate degrees with single incision small mesh, and advanced prolapse was treated with needle guided large mesh. Anti-incontinence surgery was added when indicated, using TVT-Obturator®, TVT-SECUR® or TVT-Abbrevo® (Gynecare, Somerville, USA), according with surgeon's preference. Patients were followed up at 1 and 3 months after the surgery and at study conclusion, with the last patient having 10 months of post-operative follow-up as well. All operations were carried out by a single surgeon at private and university hospitals.

The outcome measures were the anatomical and functional cure rates and the levels of post-operative pain and dyspareunia.

Table 3
Patients' operative details and outcome.

		ASSLF patient's group ($N=44$)
Operative bleeding > 100 ml		4 Pts (9%)
Bladder, bowel and/or urethral injury		0 Pts (0.0%)
Postoperative bladder outlet obstruction		0 Pts (0.0%)
Early postoperative pelvic pain		4 Pts (9%)
Early postoperative thigh pain		0 Pts (0.0%)
Operative field Infection		0 Pts (0.0%)
Post-operative UTI		1 Pt (2.2%)
Anatomical outcome		
POP cure ($C<-5$)		42 Pts (95.5%)
Operative failure ($C>0$)		2 Pts (4.5%)
Vaginal mesh protrusion		0 Pts (0.0%)
Functional outcome	Mild	Moderate
USI	0 Pts (0.0%)	4 Pts (9%)
Frequency	12 Pts (27%)	0 Pts (0.0%)
Urgency	12 Pts (27%)	0 Pts (0.0%)
Nocturia	12 Pts (27%)	0 Pts (0.0%)
Sexual discomfort	3 Pts (7%)	3 Pts (7%)
Constipation	0 Pts (0.0%)	1 Pt (2%)
Fecal incontinence	0 Pts (0.0%)	1 Pt (2%)

Pts, patients; POP, pelvic organ prolapse; ASSLF, anterior sacro-spineous ligament fixation; UTI, urinary tract infection; USI, urinary stress incontinence.

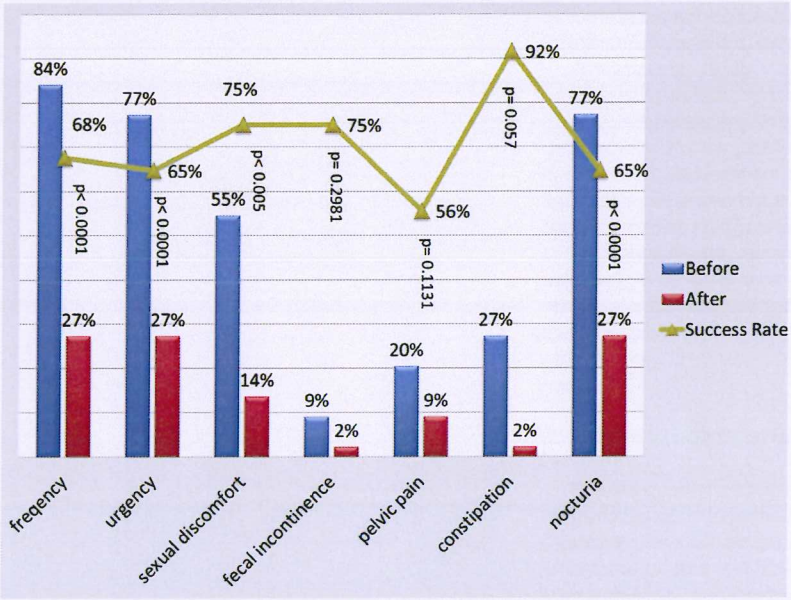


Fig. 1. Pelvic organs functional symptoms, before and after surgery.

Data were collected from patients' charts, including interviews and pelvic examinations, by researchers not involved with the patients' care. Subjective data regarding urinary and fecal urgency, frequency, stress and urge incontinence, impairment of sexual function, voiding habits, pelvic pain and bulging were obtained at the study conclusion interview by the uninvolved researchers and recorded on special forms and 0–10 Visual Analog Pain Scale (VAPS). Objective outcome was assessed by pelvic examination according to the POP-Q standard ICS-International Urogynecological Association (IUGA) terminology.

Statistical analysis with Vassar Stats Statistical Computation was performed. The Wilcoxon signed-ranks test was used to evaluate quantitative parameters data distribution among groups. The Mann–Whitney test was used to determine P value small number of groups. Point bi-serial correlation coefficient was used to calculate P values for changes from baseline to post-operative parameters. Significance has been set for a value of $P < .05$.

3. Results

Seventy-two patients suffering from anterior–apical pelvic floor compartment prolapse, either with uterine prolapse or with advanced post-hysterectomy vaginal vault prolapse (C point at (+)2 or below) were referred for corrective surgery with mesh implants. Eight patients were excluded from the study because of refusal, 20 had appropriate ATFP and 44 were enrolled in the study because of inferior quality or fragility of those ligaments (Table 1).

The patients' pre-operative personal characteristics are tabulated: 91% also had posterior pelvic floor reconstruction (50% with mesh implants) and 59% had a concomitant anti-incontinence sling procedure (Table 2). Operative details, operative and post-operative complications are shown in Table 3. No major complications were noticed, viscera were not injured, blood transfusion was not indicated, and pain and infection rates and severity were modest. Outcomes, tabulated in Table 3, were

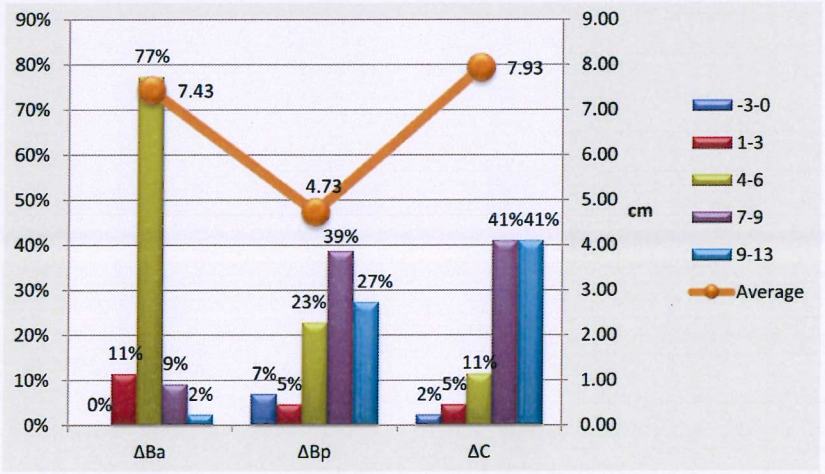


Fig. 2. Variety of changes with the POP-Q points, before versus after surgery.

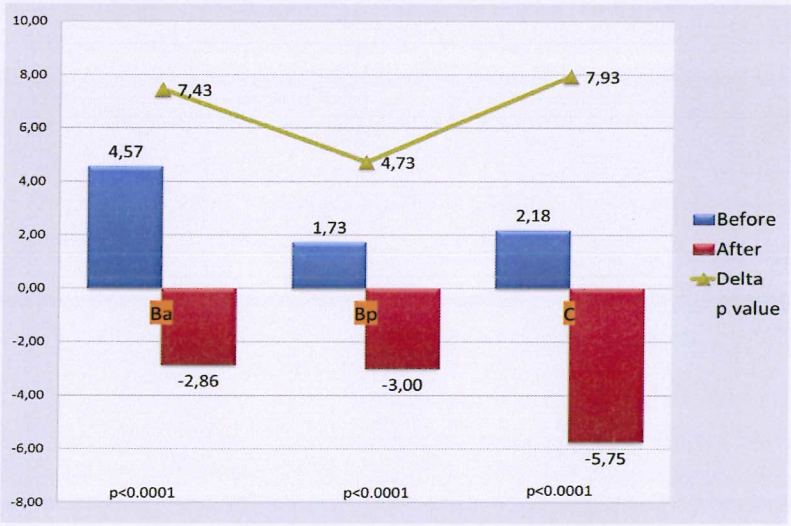


Fig. 3. POP-Q point changes, before versus after operation.

satisfactory, with both subjective and objective cure rates: there was anatomical improvement with the various POP-Q points as well as improvement in urinary, sexual and rectal functions, based upon patients' detailed satisfaction reports.

The POP-Q points measurements showed marked improvements: the average delta for the Ba point was 7.4 cm, for the Bp point it was 4.7 cm, and for the C point the delta was 7.9 cm. These measurements were all statistically significant. Bladder overactivity symptoms, namely urgency, frequency and nocturia, were all found to be reduced significantly, and so was the sexual discomfort rate. Fecal incontinence, pelvic pain and constipation rates were reduced as well, but these did not carry any statistical significance (Figs. 1–3).

4. Comment

There are few studies looking at the possibility of anchoring the anterior pelvic floor needle-guided mesh to the SS ligament, to create an utero-sacral-like level 1 supportive structure [9]. The SS ligament is usually firmer, stronger and located at a higher position when compared to the ATFP. Thus, the SS ligament might provide a superior fixation point for apical prolapse, replacing the ATFP. A previous cadaveric study proved this surgery to be safe regarding potential iatrogenic injury to the ureters and uterine vessels [6]. Nevertheless, the ATFP served long for anterior pelvic floor mesh implants. This was attributed to the fact that the surgical dissection required to create the proper axes for mesh placement and fixation is relatively simple and safe. Reaching the SS with the anterior approach seemed to be far more hazardous, and thus it was neglected even though regarded as superior to the ATFP for centro-apical pelvic floor supportive point and reconstruction.

The 44-patient cohort presented here shows that needle-guided mesh augmentation for reinforcement of the anterior pelvic floor and apical support anchoring to the SS ligaments provides safety and efficacy, and the improvements in anatomical and functional outcome are significant and reassuring. This technique is neither more complicated, nor more hazardous to perform, than the common one. The curative results are sustained for at least 10 months. Post-operative pain and dyspareunia levels are mild. These findings are in accordance with previously reported data regarding new single incision meshes.

Aiming for a high, medial, sustained and well-standardized repeatable centro-apical pelvic floor reconstruction, it might probably be better to prefer the SS as an anchoring point rather than the ATFP. This seems to be feasible and safe, and would probably entail better outcome for the patients. This concept, which is well accepted with posterior pelvic floor compartment reconstruction, might very well become an attractive option when anterior pelvic floor is to be reinforced as well.

This strength of this study is limited by being single armed and having rather short-term follow-up. Further studies should be designed and carried out to shed more light on this issue of optimal anchoring point for anterior apical support pelvic ligament, for single incision and needle-guided mesh augmentation.

Disclosure

Dr. Neuman is a consultant for J&J and ProAccess Medical. All other authors have no conflict of interests.

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