

Pelvic Floor

Endopelvic Free Anchorage Technique (EFA) surgical treatment of stress urinary incontinence due to urethral hypermobility in women. Eight years of experience

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ABSTRACT

Endopelvic free anchorage technique: surgical treatment of stress urinary incontinence due to urethral hypermobility in women. Eight years of experience.

We present a prospective study of a new tension free tape technique, called "endopelvic free anchorage", for the correction of stress urinary incontinence due to urethral hypermobility in women, from the results obtained in 312 patients with eight years follow up. All the patients included a clinical evaluation including swab test, quality of life test, ICIQ-SF questionnaire, mictional diary and a severity and improvement test; an urodynamic study was also carried out before and after the treatment. The technique involved the retropubic insertion of a polypropylene tape under the middle urethra through vaginal incision, creating a suburethral support as it passes through the musculotendinous structures of the urogenital diaphragm and the endopelvic fascia. There was a total cure in 298 cases (95.5%), reaching 97.74% if improvements were included. There was no intra or post operatory morbidity. The surgical intervention lasted for 10-15 minutes.

Key words: urinary incontinence, surgical treatment, endopelvic free anchorage.

ABSTRACT

Endopelvic free anchorage technique: surgical treatment in women for stress urinary incontinence urethral hypermobility. Eight years of experience.

We present a prospective study of a new tension free tape technique, called endopelvic free anchorage, for the treatment of stress urinary incontinence due to urethral hypermobility in women, from the results obtained in 312 patients' with eight years follow up. All the patients completed a clinical evaluation, including swab test, life quality test, ICIQ-SF questionnaire, mictional diary, overall impression of severity and improvement test, also an urodynamic previous and later treatment study The technique involves the retro pubic insertion of a polypropylene tape under the middle urethra, through vaginal incision, making a suburethral support going across the musculoligamentous structures of the urogenital diaphragm and the endopelvic fascia The total cure took place in 298 cases (95.5%), and reached a 97.74% adding improvement cases. No intraoperatory or post operatory complications. The duration of the surgery was of 10-15 minutes.

Keywords: urinary incontinence, surgical treatment, endopelvic free anchorage.

Introduction and objectives

Everyone is already aware of the good results obtained by free tape techniques, be they by the vaginal¹, suprapubic² or transobturator³ approach, in the surgical treatment of stress urinary incontinence. Basing ourselves on the "integral theory" on the urethral closure mechanism^{4,5}, we reinforce the function of the pubourethral ligament, inserting a polypropylene tape under the middle urethra via the vagina and behind the pubis, the ends of which, as they go through the musculoligamentous structures of the pelvic diaphragm

Pelvic Floor

and the endopelvic fascia become attached to it, serving as a reinforcement for the suburethral anterior vaginal wall and support for the urethra during effort³.

The effectiveness of this procedure is based on the characteristics of the edges of the ends of the mesh and on the capacity of the musculoligamentous structures of the urogenital diaphragm, the endopelvic fascia and the adjacent tissue to retain, fix and maintain in place the tape inserted in this area. This is due, on the one hand, to the points of the dentate edges of the distal thirds, which go towards the centre of the tape, becoming anchored in the retropubic tissue in the manner of a harpoon, taking advantage of the elasticity and firmness of this fibromuscular tissue, composed of collagen, elastin and smooth muscle. On the other, the healing of the endopelvic opening integrates the mesh and provokes positive changes in collagen metabolism, such as a considerable increase of the pepsin soluble fraction of collagen and a significant increase in collagen links, which determine the mechanical properties of the endopelvic connective tissue and causes the formation of a compact, firm and elastic scar tissue^{6,7}.

This does not happen when the patient's own fascia or some other organic material is used to restore support to the urethra⁸⁻¹⁰. The object of this prospective study is to demonstrate the efficiency of the new tension free vaginal tape technique, without needles and with a short mesh, denominated endopelvic free anchorage (EFA).

Material and methods

For this prospective study, carried out between January 2001 and January 2009, 312 women suffering from genuine SUI due to urethral hypermobility, proceeding from the Urodynamic and Pelvic Floor unit of the Department of Gynaecology and Obstetrics of the Valencia University General Hospital Consortium, who underwent surgery using the endopelvic free anchorage technique. The average age was 63 (range 39-88), with a median parity of 2.82 children per woman (range 0-7) and a body mass index (BMI) of 28.35 kg/m² (range 18-46). 85% of the patients were in the menopause. 68.63% (212 patients) had some type of pelvic organ prolapse, the evaluation was carried out in accordance with the classification described by Baden and Walker¹¹.

The study protocol includes a clinical and urodynamic evaluation prior to the treatment, and a urodynamic control was carried out 12 months after the intervention.

The clinical evaluation comprised a urogynaecological history including the completion of a questionnaire to evaluate quality of life, ICIQ-SF questionnaire, mictional diary and a severity and improvement test in patients with urinary incontinence (King's Health Questionnaire)¹². The severity of SUI was determined using the Ingelman-Sundberg scale¹³: 244 patients (78.21%) presented grade 2 SUI, 29 (9.29%) grade 3 SUI and 39 patients (12.5%) hidden SUI due to prolapse.

In order to assess urine leakage, residual urine was determined and a stress test was carried out (cough provocation test) in dorsal decubitus and standing position with a volume of some 300 ml. Urethral mobility was evaluated using the swab test, whose rotation angle at

Pelvic Floor

the woman's maximum effort reflects urethral displacement, which is considered normal up to 40 degrees^{14,15}. All of the patients presented urethral hypermobility.

The multichannel urodynamic investigation consisted of a cystometry, static and dynamic urethral profiles and uroflowmetry. The existence of uninhibited detrusor contractions (hyperactive bladder) was ruled out by cystometry, and the Valsalva leak point pressure was determined as long as there was no existing vesicular, uterine or rectal prolapse or hyperactive bladder, with the static urethral profile we measured the occlusive urethral strength, calculating the maximum urethral closure pressure (CP) and with the dynamic urethral profile during effort, such as coughing, we measured the percentage of transmission of abdominal pressure to the bladder and the proximal urethra. The absence of uninhibited detrusor contractions is a requisite in the criteria for genuine SUI of which there are two types:

- SUI due to urethral hypermobility: when the CP is over 20cm H₂O, the Valsalva leak point pressure is >60cm H₂O and the swab test is over 40 degrees¹⁶.
- SUI due to intrinsic sphincter deficiency, which can be:
 - With urethral hypermobility when the CP is equal to or lower than 20cm H₂O, the Valsalva leak point pressure is below de 60cm H₂O and the swab test is above 40 degrees.
 - With a fixed urethra if the swab test is below 40 degrees^{16,17}.

Only patients with SUI due to hypermobility urethral have been included in this study.

Description of the technique

Spinal anaesthesia and, occasionally, local anaesthesia with mepivacain 0.5% infiltrating the anterior vaginal mucosa on a level with the middle urethra, and the paraurethral spaces as far as the Retzius space, were used. A sagittal incision of about 2 cm in length is made in the suburethral vaginal wall at least 1 cm away from the external urethral meatus and a minimal bilateral paraurethral dissection is practised until the inferior edge of the pubis is reached. A suburethral support is created using a tape with dentate edges (figure 1), the ends of which are introduced through the dissected spaces and passed through the musculotendinous structures of the urogenital diaphragm and the endopelvic fascia behind the pubis with curved Pean type forceps as far as the retropubis where it is anchored tension free; the intervention finished by suturing the vaginal incision. In those cases where the patient had pelvic organ prolapse, reconstructive surgery was carried out at the same time.



Figure 1. Tape Emerald Plus[®] Gallini

153 (49.04%) were carried out in association with classic plasties and the EFA technique, 66 (21.15%) plasty procedures with EFA and 93 (29.81%) isolated EPA techniques.

Pelvic Floor

The post surgical evaluation included the duration of the anti-incontinence intervention (EFA), the intra and post operatory surgical complications, duration of hospitalization and analysis of the results.

The criteria for cure were as follows: the patients were cured if the stress test was negative and if, subjectively, there was no urine loss due to effort, or if there was an improvement of 90% or more in quality of life test score. Improvement was defined as a significantly lower amount of episodes of urine loss while making occasional great efforts than before the intervention, to the patient's satisfaction, and if quality of life improved by 75%. Follow up was carried out 1, 3, 6, 9 and 12 months after the intervention and then twice a year up to a period of 8 years.

Results

312 patients, operated on in accordance with the protocol established by the Unit, were evaluated. The average follow up period was 4.5 years (range 1-8 years).

The average duration of the intervention was 10-15 minutes, and it was not necessary to use a cytoscope.

There were no intra or post operatory complications.

In 308 cases (98.71%) miction recommenced within the first 24 hours. All patients were discharged after between 24-96 hours. Those who only required EFA were discharged after 24hours. In those cases where another intervention was necessary (plasties or hysterectomy) discharge from hospital was after 48-72 hours.

There have been only two cases of urine retention, lasting 4 and 5 weeks, which were resolved in later controls up to the present day.

There have been nine cases (2.88%) of mesh extrusion; seven of them early (within 6 months of insertion) and two late cases, one of which took place 4 years after the mesh was implanted. Only one granuloma was documented in all the casuistic.

The de novo instability index was 1.92%, equivalent to six patients, but only one of them remains symptomatic after pharmacological treatment.

There was a total absence of late morbidity such as coitalgia, painful fibroses or retractions of the anterior vaginal mucosa.

The results of the clinical (swab test) and urodynamic evaluations are shown in table 1. The urodynamic parameters most modified were the functional length of the urethra, the continence zone and transmission.

There was a complete cure in 298 cases (95.51%), objectified with urodynamic criteria in 30.77% of all the patients. At the same time, an improvement in the symptoms of

Pelvic Floor

incontinence was obtained in 7 cases (2.23%) and another 2.24% were failures. Table 2 shows the details of the results and the complications.

Table 1. Values of the swab test and the urodynamic study before treatment and a year after free endopelvic anchorage

Variable	Pre operatory	Twelve months
Base line swab test	10 [-20-90]	0 [-30-80]
Swab Valsalva	70 [10*-90]	30 [-20-90]
Swab retention	10 [-20-90]	0 [-30-80]
CP	51 [22-161]	47 [15-158]
FL	21 [7-38]	24 [9-47]
CZ	11 [2-27]	13 [3-42]
TI	26 [1-100]	46 [2-100]

Values given as median [range].

* Represents two cases of a 10° pre operatory swab test during Valsalva and refers to patients with severe dystopia.

FL: functional length of the urethra; CP: maximum urethral closure pressure; TI: index or percentage of transmission; CZ: continence zone.

Table 2. Results and complications

	HY + PLS + EFA n(%)	PLS + EFA n(%)	EFA n(%)	Total n(%)
Cure	149 (97.39)	61 (92.42)	88 (94.62)	298 (95.51)
Improvement	1 (0.65)	3 (4.54)	3 (3.23)	7 (2.24)
Failure	3 (1.96)	2 (3.03)	2 (2.15)	7 (2.24)
Urine retention	0	1 (1.51)	1 (1.08)	2 (0.64)
Mesh extrusion	1 (0.65)	3 (4.54)	5 (5.38)	9 (2.88)
Granuloma	1 (0.65)	0	0	1 (0.32)
De novo urge	1 (0.65)	3 (4.54)	5 (5.38)	9 (2.88)

Data in number of patients and percentage in respect of their subgroup. EFA: endopelvic free anchorage, HY: vaginal hysterectomy; PLS: vaginal plasty.

Discussion

In response to our objectives, these results indicate that the free endopelvic anchorage technique is reproducible, easy to carry out, minimally invasive and exempt from morbidity.

The results are excellent. Out of the 312 patients who underwent surgery, there was a complete cure in 298 cases (95.51%). Moreover, there was an improvement of the symptoms in another 7 patients (2.24%).

Pelvic Floor

This technique provides good reinforcement and adequate support for the urethra, correcting hypermobility 95.51% of the patients have are currently asymptomatic. This demonstrates that the healing and fibrosis over the mesh on the part of the urethropelvic or endopelvic opening and the adjacent tissue, will produce a firm, secure and lasting point of support for the urethra^{7,8}, ensuring continence during efforts, and it would not, therefore, be necessary to have recourse to a second anchorage in the anterior abdominal recti¹, or to practise an obturator hole³, avoiding the consequent risk of vesicular, nervous or vascular lesion entailed by going more deeply into other structures, or the risk of muscular tearing which would, moreover, lead to the failure of the technique, since insertion into the obturator muscle means an inefficient grip.

In our casuistic there have been no complications such vesicular and urethral, intestinal, vascular or nervous lesions during the intervention since the insertion depth of the tape did not reach these structures.

Nor have there been any cases or chronic urine retention, since the tape only comes into tension free contact with the suburethral tissue. When the tape is introduced, perforating the musculotendinous structures of the pelvic diaphragm and the endopelvic fascia, it is retained and fixed; remaining in the place where it is was positioned. This is due to the qualities of the edges of the mesh and to the elasticity and retraction of the endopelvic opening; moreover its posterior healing and fibrosis form an adequate urethral support, capable of maintaining urine continence during effort. This is because the retropubic insertion of EFA means that the ends of the tape pass through the insertion zone of the musculotendinous structures of the pelvic diaphragm and the endopelvic fascia, such as the pubococcygeus muscle insertion, the pubocervical fascia, the tendinous arch of the pelvic fascia and the pubourethral ligament, thus reinforcing physiological function.

As for the cases of mesh extrusion, those which took place during the first 6 months after insertion may be due to small, even subclinical, haematomas, seromas or infections around the mesh although, in our experience, the majority are due to lack of physical rest during the fibrosis and healing process which anchors the sling. Late extrusions, for example 4 years after insertion, are problems due to tissue intolerance or mucosal thinning due to hypoestrogenism resulting in genital atrophy. However, in the majority of patients who suffered extrusion, especially in the case of late extrusions, this phenomenon did not entail the persistence or reappearance of incontinence.

The absence of late morbidity, such as coitalgia, retractions and painful fibroses of the mucosa of the anterior vaginal wall, is due to the minimum amount of material implanted using the EFA technique.

In conclusion, we shall analyse the failures which have been observed. Amongst these, almost a third would be explained by proven situations of lack of post-surgical physical rest (one of the patients, for example, suffered from influenza), while the rest would be evenly explained by incontinences due to mixed phenomena in which , after surgery, the urge

Pelvic Floor

incontinence component predominates despite the improvement of the stress component. Those patients who only experienced "improvement" after endopelvic free anchorage -and not a cure- also respond to causes such as lack of rest, the association of mictional urge and, in two cases, mesh extrusion.

Conclusions

Based on the evidence of the results obtained, we can conclude by saying that endopelvic free anchorage is a very short, simple and easy to learn technique. It is minimally invasive, as there is no need to go too deeply into the tissue and, therefore, causes no complications and can be considered as "short stay major surgery", reducing surgical hospitalization costs. Moreover, the reduced amount of material implanted eliminates late morbidity. Lastly, the excellent results are endorsed by 8 years of experience and follow up of the technique.

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Pelvic Floor

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