

## PUBO-VAGINAL SLING USING CADAVERIC FASCIA LATA IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE DUE TO A SPHINCTERIC DEFICIENCY: OUR EXPERIENCE WITH A 10-YEAR FOLLOW-UP.

### Hypothesis / aims of study

Pubo-vaginal sling procedures still represent the gold standard treatment in the management of female stress urinary incontinence (FSUI) due to a sphincteric deficiency. Often they are performed as a saving treatment in case of recurrent FSUI following pelvic surgery. Among the several materials used to manufacture a sling, cadaveric fascia lata may represent an alternative to both synthetic and autologous slings. The aim of our study was to report the long term results of pubovaginal sling procedures using cadaveric fascia lata carried out in our Institute from 1998 to 2000.

### Study design, materials and methods

From December 1998 to July 2000 23 patients underwent a pubo-vaginal sling implant using cadaveric fascia lata alone or in combination with pelvic organ prolapse repair. All patients had FSUI with or without defects of pelvic statics. A complete urogynaecologic work up was performed (i.e. clinical history, physical examination, bladder diary, pad test, urodynamics). The evaluation of the associated pelvic organ prolapse was made using the Half-way system (HWS) classification. Patients mean age was 65.3 years (range 44 to 76 years). Mean parity was 1.8 (range 0 to 4). Twenty out of 23 patients were in menopause and none was in substitutive hormone therapy. Two patients were in treatment with tamoxifene for breast cancer. Table 1 shows the number of patients previously undergone pelvic surgery.

**Table 1. Previous pelvic surgery in the study population.**

Intervention	N° of cases (%)
Hysterectomy	3/23 (13%)
Burch colposuspension	2/23 (9%)
Anterior vaginal wall prolapse repair	2/23 (9%)
Posterior vaginal wall prolapse repair	1/23 (4%)
Ovaric cyst excision	1/23 (4%)

Urogynaecological physical examination documented a pelvic organ prolapse in 16 patients (see table 2).

**Table 2. Pelvic organ prolapse in the study population according to the HWS classification.**

Vaginal wall prolapse	Grade I	Grade II	Grade III	Grade IV
Anterior	2	11	4	1
Cervix/cuff	8	3	1	0
Posterior	3	1	0	1

Preoperatively urinary sediment was negative in all cases. An urethral hyper-mobility was present in 10 patients. In all patients FSUI was confirmed by urodynamics. All patients showed either a urethral maximal closure pressure <20 cmH<sub>2</sub>O or an Abdominal Leak Point Pressure <60 cmH<sub>2</sub>O or both. Two cases showed a detrusor overactivity. The follow-up included urine analysis, physical examination, uroflowmetry, pad test and telephonically administered questionnaire on the overall satisfaction after treatment.

The intervention is performed transvaginally with a U inverted incision on the anterior vaginal wall, at the vesico-urethral junction level. The vaginal wall is separated from the bladder; the endopelvic fascia is incised penetrating into the Retzius space. Two sutures are located on each edge of the cadaveric fascia sling. A 3-cm long soprapubic incision is made, detaching recta muscles fascia. Using a Pereyra needle introduced soprapubically and guided through the Retzius space by the operator finger, the above mentioned sutures are put above the recta muscles fascia and then knotted each other. A cystoscopy may be useful to avoid bladder wall and neck injuries and to observe the physiological ejaculation of the ureters.

### Results

Fifteen patients underwent a combined procedure for the correction of both FSUI and pelvic organ prolapse (table 3 and 4). At a mean follow-up of 31 months (range 22-41 months) 2 out of 23 were lost at follow up and 1 died because of causes not related to surgery; 15 out of 20 patients were continent (75%) and 2 (10%) showed a significant decrease in urine leakage. In 3 cases, after a short period of clinical improvement, FSUI relapsed (15%); one of them underwent a tension free vaginal tape procedure 10 months after the previous surgery. Two patients developed a "de novo" urge incontinence. Other 2 patients showed voiding symptoms and underwent the urethral calibration and the sling dissection 7 and 21 months after the previous surgery, respectively. Concerning the questionnaire on the overall satisfaction, 75% of patients were satisfied of their urinary condition (table 5).

**Table 3. Surgical interventions associated to cadaveric fascia lata sling implant**

Kind of pelvic organ prolapse surgery	N° of patients
Anterior vaginal wall repair using a Marlex mesh	12
Posterior vaginal wall repair	7
Anterior vaginal wall repair	4
Transvaginally hysterectomy	4
Colpoperineoplasty	3

**Table 4. Outcomes of pelvic organ prolapse surgery**

Pelvic organ prolapse	Grade I	Grade II	Grade III	Grade IV
Anterior vaginal wall	10	0	0	0

Cervix/cuff	4	0	0	0
Posterior vaginal wall	0	0	0	0

**Table 5. Results from the overall satisfaction questionnaire**

Question	Yes	No
Would you undergo the surgery again?	18	2
Do you advise the intervention to a friend with the same problem as you are ?	19	1
Are you satisfy of your urinary condition ?	15	5

At a mean follow-up of 9 years (range 8-10 years) 6 patients were lost at follow-up; 9 out of 14 were still completely dry (64%), but two of them underwent further surgery to improve their continence status over the years. A further patient developed a "de novo urge incontinence". Concerning the questionnaire on the overall satisfaction, 57% of patients were still satisfied of their urinary condition.

#### Interpretation of results

At a long term follow-up pubo-vaginal sling procedure using cadaveric fascia lata may offer an overall success rate of 70%. It represents an effective intervention to manage FSIU due to sphincteric deficiency, but its effectiveness seems to be unstable over the time. Although only 57% of patients declared a complete satisfaction of their urinary condition after surgery, 78.5% were ready to undergo that surgery again recommending it.

#### Concluding message

Following cadaveric pubovaginal sling incontinence surgery the overall success rate at a medium term follow-up is satisfied. Nevertheless at a longer term follow-up although the results in terms of continence are disappointing, patient satisfaction would seem to be still reasonable.

<b><i>Specify source of funding or grant</i></b>	<b>NONE</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require eithics committee approval because</i></b>	<b>The subjects were enrollend within a standard set of surgery for stress urinary incontinence</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>