

## TRANSVAGINAL URETHRAL DIVERTICULECTOMY USING SMALL INTESTINAL SUBMUCOSA INTERPOSITION GRAFT

### Hypothesis / aims of study

Female urethral diverticula (UD) are a rare urological entity. Lately the incidence is increasing due to greater awareness and better imaging methods, although many urologists and gynaecologists are still not familiar with UD. Treatment modality of choice is transvaginal diverticulectomy with or without interposition of tissue between the vaginal and urethral wall. Multiple authors describe the use of an autologous tissue interposition graft (a Martius fat pad, bulbospongiosus muscle or a vaginal flap). However, to our knowledge, there are no reports of the use of biomaterial as interposition graft. Small intestinal submucosa (SIS) is an acellular biologic graft harvested from porcine small intestinal submucosa. It is commercially available (Surgisis<sup>®</sup>, Cook Biotech) and approved for human use. In this publication we like to report our four and a half year single-center experience in transvaginal diverticulectomy with interposition of SIS.

### Study design, materials and methods

We reviewed the records of all patients treated for UD at our center between September 2006 and December 2010. Collected data included demographic details, symptoms, diagnosis, treatment, follow-up and outcome. All patients underwent a transvaginal diverticulectomy by the same reconstructive urologist.

At the start of the operation a transurethral catheter is inserted. An inverted U-shaped incision is made in the anterior vaginal wall over the diverticulum. The diverticulum is dissected and resected and the urethral lesion is closed over the catheter. Subsequently the SIS graft is tailored and placed in the space between the urethral and the vaginal wall. In the first four patients of our series a four-layer SIS interposition graft was applied. In all subsequent patients single layer SIS was used as interposition graft. Next, the anterior vaginal wall is closed over the biomaterial. Finally a vaginal tampon with estrogen gel is inserted during 24 hours. Antibiotic prophylaxis is maintained during 48 hours after which the patient is discharged with the catheter in situ. All but two patients underwent a voiding cystourethrography before removing the catheter approximately 10 to 14 days postoperative. Antibiotic prophylaxis (fluoroquinolones) was administered when removing the catheter.

### Results

Twelve female patients underwent transvaginal urethral diverticulectomy at our center between September 2006 and December 2010. Mean age was 36 years (range 21-54 years). The presenting symptoms were in seven patients (58.3%) a combination of a urethral/vaginal mass, pain and discomfort. Five patients (41.7%) complained of recurrent urinary tract infection, four (33.3%) of urinary stress incontinence (SI). Three patients (25%) presented with urethral loss of old blood or pus and two patients (16.7%) had also complaints of dysuria, frequency and urgency. In one patient the diverticulum was incidentally found. At vaginal examination a mass in the anterior vaginal wall was seen or palpated in all patients. In five cases meatal loss of pus and urine occurred when palpating the mass. Further investigations were performed to reassure the diagnosis, identify the anatomy of the diverticulum and its relation to the external sphincter complex and urethra. Seven patients underwent a cystourethroscopy and ten magnetic resonance imaging (MRI) of the pelvis. In two patients the cystourethroscopy revealed the diverticular orifice, in the five others no abnormalities were found. In half the patients who underwent a MRI (5/10), the test was diagnostic and anatomical details were described. In all patients a transvaginal diverticulectomy was performed by the same reconstructive urologist. SIS biomaterial was used as interposition graft between the urethral and vaginal wall. One patient developed a postoperative bleeding that needed revision the same day. During the reoperation the SIS graft was removed and a piece of TachoSil<sup>®</sup> was used instead. Further postoperative course was uneventful. All other patients encountered no problems during the postoperative period. The mean time of follow-up after diverticulectomy was 127 days (range 10-539 days). No symptomatic diverticulum persistence or recurrence was seen; neither development of urethrovaginal fistula, urethral stricture or voiding difficulties. Two patients (16.7%) developed de novo urinary SI. An expectative approach was followed but since persistence of the incontinence and no benefit with physiotherapy, a suburethral sling procedure is planned in these patients.

### Interpretation of results

To our knowledge we are the first to report the use of SIS as interposition tissue in transvaginal urethral diverticulectomy. We started the use of SIS interposition in transvaginal diverticulectomy in 2006. This because we were never able to find the distinct peri-urethral tissue layer, in contrast to the surgical descriptions which describe the importance of this layer to prevent against complications such as urethrovaginal fistula. The first years the four-layer graft was used. In 2009 we switched to the one layer alternative. Since no postoperative problems were encountered, except for a minor postoperative bleeding, we do not know which material is superior. We can only conclude that a one-layer graft seems to be as effective as the four-layer alternative, although the duration of follow-up of the 1-layer-cases is still shorter. Two of our patients (16.7%) developed de novo urinary SI. In literature de novo SI is reported in 1.7 to 49% after transvaginal diverticulectomy [1, 2, 3]. This great variation is due to the different definitions used and the fact that preoperative urinary leakage and postvoid dribbling may be confused with SI making it very difficult to determine the rate of de novo postoperative SI correctly. Besides de novo SI, other postoperative complications reported in literature are persistence or recurrence of the diverticulum, development of urethrovaginal fistula and

urethral stricture, persistent irritative voiding symptoms, urethral pain and dyspareunie. None of these were encountered in our series. To our opinion this is due to the use of SIS interposition since it prevents bulging and development of urethrovaginal fistula. Moreover SIS is easy to handle and place because it can be cut, rolled or folded to accommodate the clinical requirements. This makes its use less time-consuming than harvesting an autologous tissue interposition graft. An extra advantage is that there are no associated comorbidities from harvesting techniques. The fact that there is no persistent foreign material makes it in addition very safe to use.

#### Concluding message

SIS biomaterial is efficacious and safe to use as interposition tissue in transvaginal urethral diverticulectomy. No difference in efficiency between single and four-layer material was found.

#### References

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<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 ethics committee approval because</i></b>	<b>It is not a clinical trial. It is a retrospective data analysis.</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>No</b>