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A prospective cohort trial evaluating sexual function after urethral diverticulectomy

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ABSTRACT

Objective: Dyspareunia is a main symptom of urethral diverticulum in the female population, reported up to 60% of patients. Pain may cease after diverticulectomy as published in previous retrospective studies. To date scarce or no data exists on the postoperative outcome in terms of sexual function. The present study wants to quantify sexual function and evaluate lower urinary tract symptoms in sexually active patients after resection of urethral diverticulum.

Study Design: In this prospective cohort trial at a tertiary referral center, we evaluated 40 female patients who presented with symptomatic urethral diverticulum and were sexually active. All of them underwent a standardized surgical procedure with inverted U-shape colpotomy between 2008 and 2018. The patients completed the Female Sexual Function Index (FSFI), which is determined by the mean score of the different domains, and underwent urodynamic assessment both at baseline examination before surgery and 12 months postoperatively. For statistical analysis, we conducted a paired Wilcoxon rank sum test analyzing the non-normally distributed non-parametric variables of the female sexual function index.

Results: In two patients a malignancy was found in postoperative histology and received a different therapeutical approach. They have been excluded from statistical analysis. Sexual function improved in all domains (n = 38): total score (Z = -5.4, P < 0.000), satisfaction (Z = -5.3, P < 0.000), pain (Z = -5.4, P < 0.000), arousal (Z = -2.6, P = 0.010), lubrication (Z = -2.4, P = 0.020), desire (Z = -2.6, P = 0.009) and orgasm (Z = -2.2, P = 0.029). Maximum urethral closure pressure deteriorated from 39 to 36 cmH2O (P = 0.0008) and residual urine increased from 10 ml to 20 ml after surgery (P = 0.0019). No statistical significance is found for bladder capacity and free urinary flow.

Conclusions: All domains of the female sexual function index improved. Patients' bothersome symptoms, mainly pain may cease and sexual satisfaction increases, which is reassuring concerning patients' preoperative consent. We should be aware that occasionally an unexpected malignancy may be detected and it is mandatory to examine all excised tissue histologically. Lower urinary tract function remains clinically unchanged, although maximum urethral closure pressure deteriorated and postvoid residual increased though not being clinically significant.

Introduction

Urethral diverticula (UD) present as epithelial-lined outpouching of the urethral mucosal layer into the surrounding fascia [1–3], mostly located between the middle and distal third of the urethra and the vaginal wall [3]. The incidence in women ranges between 1.8 and 6% [1,4] in the age group of 30–60 years. Congenital and acquired etiological subtypes are postulated, the latter due to paraurethral gland inflammation resulting in urethral obstruction and secondary dilatation.

Detection and diagnosis of UD can be challenging. A post void MRI

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Abbreviations: UD, Urethral diverticula; MRI, Magnetic Resonance Imaging; LUTS, lower urinary tract symptoms; UTI, urinary tract infections; FSFI, Female Sexual Function Index; DSM V, Diagnostic and Statistical Manual of Mental Disorders V; MUCP, maximum urethral closure pressure; BMI, Body Mass Index; SUI, stress urinary incontinence.

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improves as gold standard the detection of UD by its proven specificity and sensitivity [5–6]. As the real volume of UD diverges from clinical examination, MRI supports additional information about the extent of the planned surgery and potential malignancy.

The symptoms resulting from UD are often indistinguishable from other lower urinary tract symptoms (LUTS) [7] like recurrent urinary tract infections (UTI) or vaginal discharge [8]. Previous studies have determined an incidence of dyspareunia in patients suffering from urethral diverticulum of 12–60% [1,5–6]. A retrospective study measuring patients' symptoms demonstrated that dyspareunia might improve after diverticulectomy [8]. Potential deleterious effects on patient's sexual function, caused by desensitation and scar tissue, could be expected as we are performing surgery in a very sensitive area of the anterior vaginal wall.

As UD are a rare entity and sexual dysfunction usually is reported as a secondary outcome measure, level of evidence is poor. With this study, evaluating sexual function and urodynamic changes in women after diverticulectomy, we intend to help creating data that help consenting patients.

Materials and methods

This prospective cohort trial was performed at the Department of Gynaecology, Women's Clinic, Inselspital Berne, Switzerland, a tertiary referral center.

The study was approved by the IRB/cantonal ethics committee (KEK 2020–00915).

Between January 2008 and December 2018 patients with a clinically manifested UD were prospectively enrolled. All patients were aged 18 years or older and were sexually active having penile-vaginal intercourse. After clinical examination, all patients received transperineal ultrasound and a postvoid Magnetic Resonance Imaging as imaging tools, because transvaginal ultrasound is investigator dependent and its standardization is difficult [3]. Prior to surgery and at the 12 months follow-up the patient completed the FSFI questionnaire and underwent urodynamic multichannel measurement. Inclusion criteria were the preoperative diagnosis of a urethral diverticulum and willingness to participate in this study, asymptomatic urethral diverticulum, age <18 years and sexual inactivity.

Urethral diverticulum excision was performed by a standardized surgical procedure:

Surgical procedure

Surgery was performed under general anaesthesia. A prophylactic single shot antibiotic (Amoxicillin 2.0 g i.v.) was administered. The patient was placed in lithotomy position.

After urethroscopy with a 0° urethroscope a transurethral indwelling catheter was inserted (Charrière 16). After performing an inverted U-shaped colpotomy, the diverticulum was identified, completely excised and sent for histological examination. Urethral closure was performed in a two-layered way using absorbable sutures (PDS® 5–0 and Vicryl® 2–0). The vaginal tissue was closed using Vicryl®2-0 interrupted sutures. Coagulation was limited to a minimum. The indwelling catheter was removed after ten days when urethral continuity was tested by double balloon urethrogram.

All study measurements were performed at baseline prior to surgery and 12 months postoperatively: the female sexual function index and urodynamic multichannel analyses.

Primary endpoint was sexual function as determined by the total score of the Female Sexual Function Index (FSFI). The FSFI is a highly regarded, multidimensional, self-reported questionnaire. Its six subscales encompasses all domains of sexual dysfunction by the DSM V: desire, arousal, lubrication, orgasm, satisfaction and pain. We used its validated German translation [9]. Response scores variate on a 6-point

scale from 0 to 5 with a total score range from 2 to 36. Results were obtained by summing individual items, that comprise the subscale and multiplying the sum by a factor. Lower scores on any of the subscales or on the overall FSFI indicate worse sexual function [10].

The FSFI takes approximately 15 min to administer and may be accessed on the web at https://www.fsfi-questionnaire.com.

A second goal were demographic data and multichannel urodynamic measurements.

Urodynamic multichannel measurement was performed as a basic investigational pre- and postoperative tool to assess free flow, bladder residual, bladder capacity and maximum urethral closure pressure (MUCP); SediaMedizintechnik, Givisiez, Switzerland). We focused on the before mentioned urodynamics to measure major findings in UD like obstruction, de novo stress urinary incontinence and voiding symptoms. Urodynamics were performed as recommended by the ICS/IUGA terminology group [11] using water perfused urethral pressure catheters.

We performed the first postoperative clinical follow-up in the outpatient department after six weeks. For the 12 months follow-up the patients received an invitation letter by mail containing the FSFI questionnaire and an appointment for the urodynamic multichannel assessment

Additionally we analyzed demographic data such as age, BMI, parity, duration of operation, days in hospital, postoperative complications, symptoms leading to urogynaecologic consultation, and administration of a MRI.

Sexual function measured by the FSFI questionnaire as primary outcome has been poorly studied. Considering the low incidence rate of UD, we aimed to enroll 25 participants over a period of 10 years.

All statistical analysis were performed using SPSS statistics version 25.0 (IBM SPSS, 191 Armonk, NY, IBM Corp, USA). We used descriptive statistics to present demographic variables. We determined significance of differences in continuous variables between groups by the two-tailed t-test and presented normally distributed data as median and 95% confidence interval. For non-parametric variables with non-normally distributed data, as in the FSFI questionnaire, we used the Wilcoxon rank sum test evaluating paired difference. We created Box-and-whisker plots (median, IQR, range) for each domain of the FSFI. A P < 0.05 was considered to be statistically significant.

Results

Sample description

A total of 40 patients were included in the study and completed the FSFI questionnaire. No asymptomatic patient with UD was detected. No patient was lost to follow-up. Demographic and perioperative data are summarized in Table 1. The cohort consisted of overweight (mean BMI 24.83 kg/m2) parous women in the middle age (mean 50.20 years). All follow-ups, except 4 outliers, took place after 12 months.

Preoperative symptoms (Fig. 1) were postmictional dribbling n=26 (67,5%), recurrent urinary tract infections (UTI) n=7 (17.5%), dyspareunia n=2 (5%), feeling of residual (n=2) 5%, hematuria (n=1), spraying stream (n=1), and pain (n=1).

Postoperative problems (Fig. 1) occurred in 10% and were as

Table 1Demographic and perioperative Data.

Variable (n = 40)	mean, SD
Age (years)	50.20 (17.983)
Parity BMI kg/m ²	2.03 (1.819) 24.83 (3.954)
Operation time (minutes)	66.08 (21.288
Days in Hospital Follow Up (month)	3.72 (2.253) 11.83 (1.999)

Table 1 shows demographic data as mean and SD.

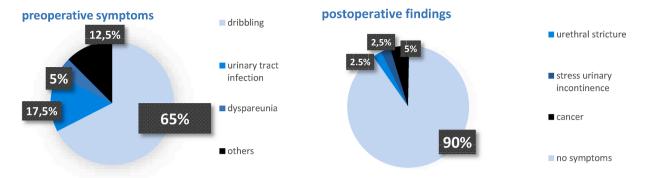


Fig. 1. Presents the preoperative and postoperative findings.

follows: stress urinary incontinence (n = 1), urothelial carcinoma requiring pelvic exenteration (n = 1), neuroendocrinologic tumor requiring radio-chemotherapy (n = 1), and urethral stricture requiring autodilatation (n = 1). Histology confirmed in two patients an unexpected malignancy. In both cases, preoperative MRI suspected a simple urethral diverticulum. We have not included these patients from further statistical evaluation as we considered it because of different surgical approach. 90% of patient reported to be asymptomatic after the surgery. Recurrent UTI's decreased significantly from 17.5% preoperatively to postoperatively 0%. Detrusor overactivity was present, but irritative aspects have not changed (n = 3).

Scattered missing data were found in the FSFI domains orgasm (n=4), desire (n=1), lubrication (n=2) and pain (n=1). The domain satisfaction was full completed.

In one case urodynamics was not performed at follow-up due to patient's reluctance.

Sexual function - FSFI

The calculation of the FSFI is summarized in Figs. 2 and 3 and the statistical significance of the Wilcoxon rank sum test is visible in Table 2. Fig. 4 visualizes the comparison of pre-and postoperative status of each patient.

Only 5% of patients reported dyspareunia as their main symptom. But we noticed appallingly low scores in the domain pain preoperatively, with most patients did not give any information about their disability in sexual function.

Urodynamic multichannel assessment

Urodynamic changes are shown (Table 3) as median values with the 95% confidence interval. Maximum urethral closure pressure deteriorated from 39 to 36 cmH2O (P = 0.002) and residual urine increased from 10 ml (maximum 40 ml) to 20 ml (maximum 40 ml) after surgery (P = 0.002). Free flow (P = 0.972) and bladder capacity (P = 0.704) remained unchanged.

Only one patient (2.5%) developed postoperative de novo stress urinary incontinence, which was treated by physiotherapy and local estrogen sufficiently and did not require further surgery.

Discussion

The study herein focused to determine sexual function twelve months after vaginal resection of urethral diverticulum in sexually active patients. Our findings of the sexual function show an improvement of all aspects of sexual function, in particular satisfaction and pain

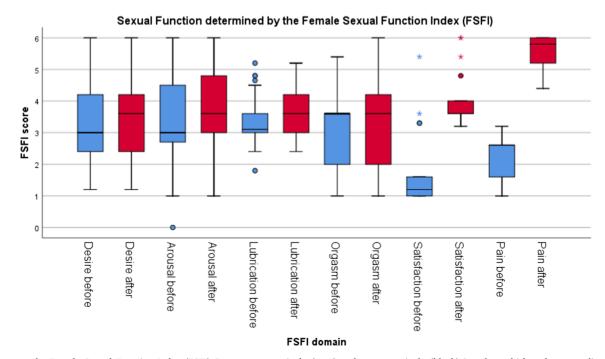
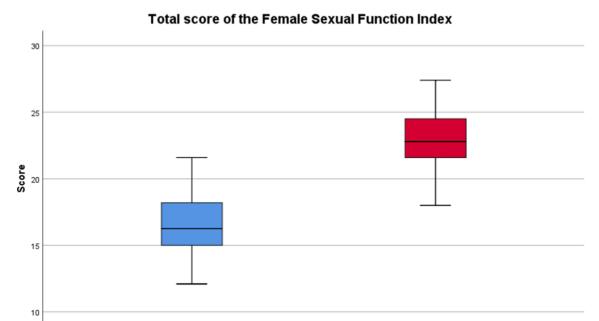


Fig. 2. Presents the Female Sexual Function Index (FSFI) Scores preoperatively (grey) and postoperatively (black) in a box-whisker-plot as median and IQR o outliners * extreme outliners Wilcoxon rank sum test, paired difference.



Female Sexual Function Index

Fig. 3. Presents the Female Sexual Function Index (FSFI) Total Scores (minimum 2 to maximum 36) preoperatively (grey) and postoperatively (black) in a box-whisker-plot as median and IQR Score 36: no disturbance of sexual function Wilcoxon rank sum test, paired difference.

 Table 2

 Female Sexual Function Index (FSFI) - Significance.

	desire after- before	arousal after - before	lubrication after - before	orgasm after - before	satisfaction after - before	pain after - before	total score after - before
Z	-2.6	-2.6	-2.4	-2.2	-5.3	-5.4	-5.4
Significance two-sided	0.009	0.010	0.020	0.029	0.000	0.000	0.000

Z base on negative ranks.

Table 2 shows the statistical results of the several domains and the total score of sexual function described by the FSFI (Wilcoxon rank sum test).

Total score before

of the domains as determined by the FSFI – arousal, desire, lubrication, orgasm, satisfaction and pain. The results of our study support the assumption, that there is a causal link between sexual dysfunction and urethral diverticula.

Dyspareunia is a commonly symptom in UD [1,12–13]. There is substantial evidence, that UD is compromitting sexual function in women disturbing quality of life. Indeed Handa et al. [14] measured that pelvic floor symptoms are associated with low sexual arousal, infrequent orgasms and dyspareunia and another study investigated, that sexual dysfunction can occur in up to 45% of women with lower urinary tract symptoms (LUTS) [15].

Paquet et al. showed that the presence of pain evokes anxiety and has deleterious effects on sexual function because of distress of both partners [16]. It is likely that sexual satisfaction improves when the reason for the patient's pain is gone.

Probably the cause of pain in UD is diverse. We hypothesize that UD bulging in the vaginal wall could mimic pelvic organ prolapse in terms of impact on sexual function. Just as a pelvic organ prolapse has negative effects on sexual function [17] and is related to the body image that women themselves perceive [18], an improvement in general sexual function after diverticulectomy can be expected.

Surgery is indicated in symptomatic UD leading to cure rates over 70% [19]. Complete resection of a UD is recommended to prevent recurrence. Hence specialized surgeons are to be favored, as the first operation shows best results and post-operative sequela increase with repeated surgery [20]. Complications after urethral diverticulum resection include urethrovaginal fistula, strictures, diverticula

recurrence and de novo stress urinary incontinence (SUI) [20-21].

Total score after

Additionally to the clinical examination, urodynamic assessment and transvaginal ultrasound, we preferred a postvoid MRI, because transvaginal ultrasound is investigator dependent and its standardization is difficult [22]. Ultrasound could yield more information in trained hands than MRI, especially with the use of 3D/4D techniques, unfortunately there is no standardization or evidence to date. Although MRI scans can achieve 100% sensitivity, surgeons need to be aware of their limitations. A discrepancy between MRI and surgical findings occurs in 24.4%, so malignancy may not be detected [23].

In our study, two malignancies were detected histologically despite the preoperative MRI showing a simple diverticulum. Histology confirmed urethral carcinoma and a neuroendocrinologic tumor. Despite preoperative benign findings, all excised material needs to be examined histologically.

Chronic irritation and stress of the epithelial-lined (squamous 41,9%, columnar 31,8%) [24] mucosa can progress the cells into a malignant transformation. The risk of an unexpected tumor in an UD is 2–6%. [25–26] and predominates in women 3:1 in the 6th to 7th decade of age [27]. Clear cell adenocarcinomas are the most frequently histological type (70%) [28–29] rising from UD following by serous carcinoma [29], squamous cell carcinoma [4], transitional cell carcinoma in situ, nephrogenic adenoma and mesonephric carcinoma. Cancer in UD can lead to irritative voiding symptoms, hematuria and dyspareunia. These were the same findings in our patients.

Until now, we did not know the outcome and effect on sexual function after diverticulectomy. To point our results herein out, we can

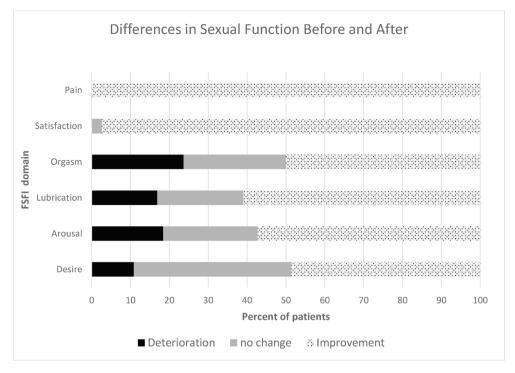


Fig. 4. Shows changes in percent (%) of the several FSFI domains postoperatively for each patient: improvement, no change, deterioration.

Table 3
Urodynamic multichannel results.

urodynamic variable	Preoperative score (median, SD)	Postoperative score (median, SD)	P values
MUCP (cmH2O) Bladder Capacity (ml) Free flow (ml/s) Urine residual (ml)	41.16cmH20 (12.7)	35.74 (9.9)	0.002
	423.6 ml (109.5)	422.2 ml (105.2)	0.704
	25.4 ml/s (4.5)	25.4 ml/s (6.0)	0.972
	15.4 ml (6.5)	22.9 ml (9.7)	0.002

Table 3 Results of the urodynamic measurement as median, 95% confidence interval and P values before and after surgery two-tailed t-test

predict an amelioration of patients' sexual function after surgery. Patients rarely talk about sexual dysfunction which is a considerable obstacle in consultations. Even if patients feel embarrassed, surgeons are responsible to communicate these reassuring information when consenting to operation.

Our results contradict the effect of surgery on the continence mechanism as published in previous studies. Differences may be explained either by demographic characteristics (age, BMI), anatomy, follow up measures of UD or surgical technique which leads to a sufficient urethral support.

MUCP decreased statistically significant but without clinical implication. We explain the deterioration of the MUCP as the consequence due to potential denervation by diverticulectomy. Location and competence of urethral sphincter have important implications when considering surgical repair of UD due to close anatomic overlap [13].

Size (>30 mm) and proximal urethral location promote SUI [8]. End-to-end urethral anastomosis leads, more often in circumferential than in simple UD, to stress urinary incontinence, but urinary tract infection (UTI) [30] resolves after surgery. So do urgency-frequency symptoms and dyspareunia [8,31], as also shown in the current study, but long-term results are inconsistent [30]. Lee et al. [21] showed in 20% of patients a bothersome SUI after diverticulectomy and 10% of these had a subsequent anti-incontinence procedure. Another previous study confirmed that SUI findings will resolve in 60.6% after conservative management [32]. We prefer a two-time anti-incontinence surgery to avoid overtreatment for the majority of the patients suffering from SUI.

As expected, an increased residual (from 10 ml to 20 ml) is no source of recurrent UTI and does not need further treatment. It is likely that preoperatively a small amount of urine remained in the diverticulum causing recurrent UTI.

As sexually inactive patients were excluded from the study, a potential bias is possible. We have no information on how many of those who were sexually inactive became active again after diverticulectomy. Another weakness of the study is that we did not analyze the patients' hormonal status as this may affect sexual function as well.

We consider it possible that patients expected an improvement in sexual function after diverticulectomy and that this expectation may have influenced their FSFI questionnaire responses, which is another potential weak aspect of the current study. However, a strong aspect of this study is the rather large number of patients presenting with a rare entity and underwent the same surgical method. Additionally, we used validated tools as the FSFI and standardized urodynamics, which adds strength to our study.

Further research including prospective trials are needed, as well as long-term follow-up data [33] to increase level of evidence mainly on the urethral continence mechanism.

Conclusion

Dyspareunia is a main symptom the patient is suffering from urethral diverticula. Our results of the FSFI show a significant improvement considering pain and satisfaction after surgery. This information is crucial and reassuring in the preoperative consent of patients predicting postoperative symptom relief.

We should be aware that occasionally an unexpected malignancy may be detected.

Clinically bothersome symptoms improve and recurrent urinary tract infections may disappear after diverticulum resection.

Urodynamic measurements change, but without relevant clinical deterioration.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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