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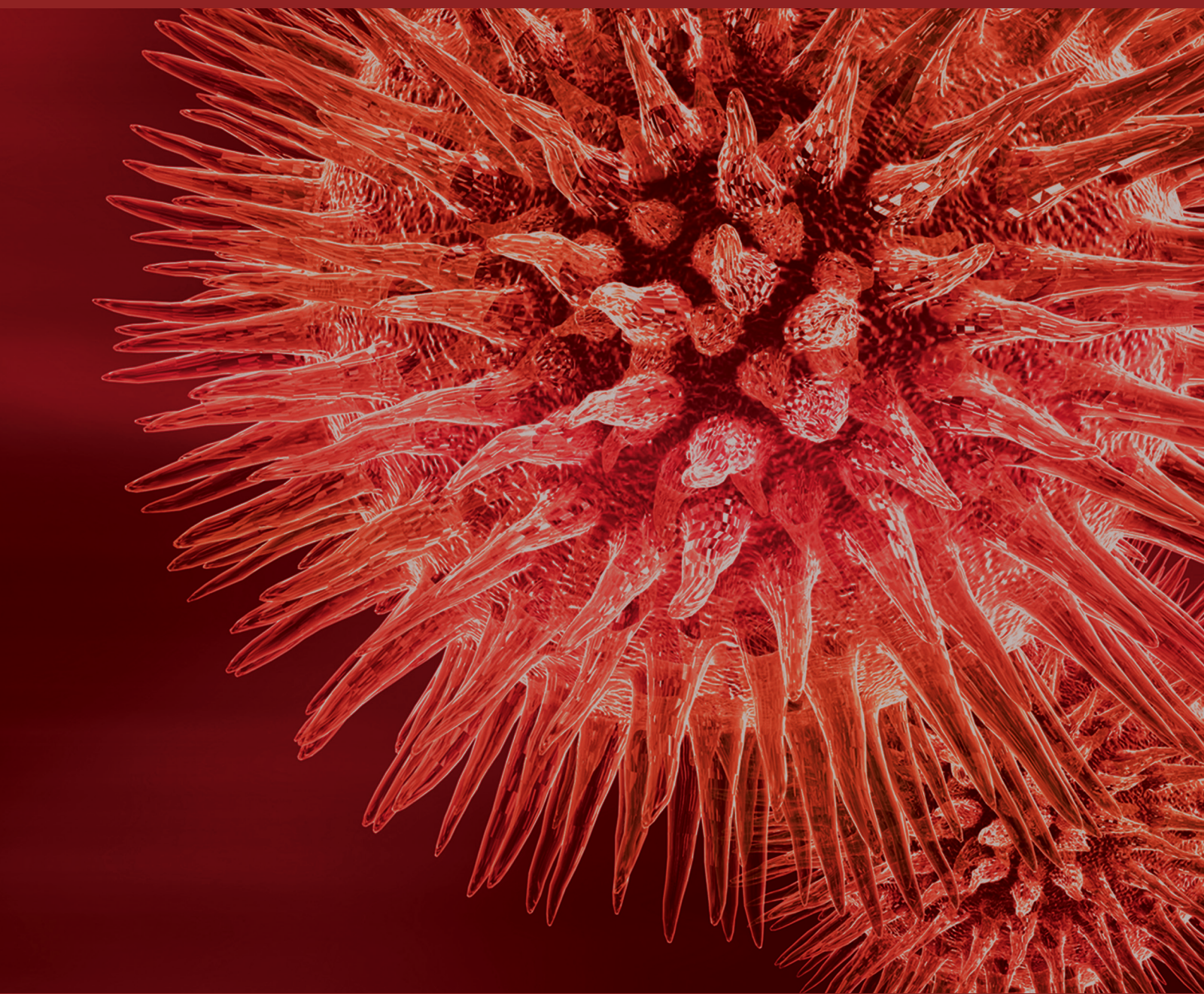
Evidence in Urologic- and Pelvic-Surgery Research: Finding the IDEAL Way of Reporting

Guest Editors: H. Gerullis, D. Barski, P. U. Malmström, X. Sun, and T. H. Ecke



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Editorial

Evidence in Urologic- and Pelvic-Surgery Research: Finding the IDEAL Way of Reporting

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In 2009, the Idea, Development, Exploration, Assessment, Long-Term Follow-Up (IDEAL) Collaboration, an international, Oxford-based group of surgeons and methodologists, suggested a template of clear recommendations to define the fundamental stages of surgical innovations and related research [1–3]. IDEAL provides a framework for the evaluation of surgical innovations comparable to the existing standards for drug development. Ever since, the IDEAL recommendations have increasingly been applied in surgical research and reporting.

This special issue has been introduced with the aim of offering the possibility of publishing research results and particularly discuss them according to IDEAL to urologists and researchers connected to the field of urosurgery, urogynecology, surgery, and pelvic surgery.

While editing this special issue we have learned that the awareness towards the IDEAL recommendations is not as developed as one could hope. Although IDEAL has been applied in several prospective research projects and even shown applicable when retrospectively reporting the status of a surgical method or innovation it has not been used by the majority of submissions to this special issue. However, not labelling an innovative surgical or diagnostic method does not diminish its value as the recommendations have existed for 7 years only. This special issue aimed to contribute in divulging IDEAL and in encouraging surgeons and scientists to use these recommendations when reporting their innovations. As a conclusion it can be stated that the awareness of IDEAL needs to increase among both researchers and reviewers.

Acknowledgments

The editors thank all submitting authors for their efforts and time spent for each manuscript. The lead editor would like to thank all editors for the time spent in reviewing, assigning reviews, and commenting on submitted manuscripts. As editorial team, we hope that this special issue will prove useful to surgeons and researchers involved in the field of pelvic surgery, urology and urogynecology. We hope that it would help to better apply and integrate the IDEAL recommendations into planning, conducting, and reporting of surgical research.

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X. Sun
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Research Article

Challenges of Longevity: Safety of Vaginal and Laparoscopic Urogynecological Procedures in Septuagenarians and Older Patients

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Introduction. Pelvic organ prolapse (POP) and urinary incontinence (UI) have increasing prevalence in the elderly population. The aim of this study was to compare the comorbidities of these procedures between <70 y/o and ≥70 y/o patients. *Materials and Methods*. In our retrospective study over a period of 2.5 years, 407 patients had received an urogynecological procedure. All patients with POP were treated by reconstructive surgery. Complications were reported using the standardized classification of Clavien-Dindo (CD). The study can be assigned to stage 2b Exploration IDEAL (Idea, Development, Exploration, Assessment, Long-term study)-system of surgical innovation. *Results*. Operation time, blood loss, and intraoperative complications have not been more frequent in the elderly, whereas hospital stay was significantly longer in ≥70 y/o patients. Regarding postoperative complications, we noticed that ≥70 y/o patients had an almost threefold risk to develop mild early postoperative complications compared to younger patients (OR: 2.86; 95% CI: 1.76–4.66). On the contrary, major complications were not more frequent. No case of life-threatening complication or the need for blood transfusion was reported. *Conclusion*. After urogynecological procedures, septuagenarians and older patients are more likely to develop mild postoperative complications but not more intraoperative or severe postoperative complications compared to younger patients.

1. Introduction

Both UI and POP are pelvic floor dysfunctions frequently encountered in older women [1]. Recent data revealed high prevalence of both entities with a peak at the age of 70-71 years for UI and a progressively increasing age-specific annual risk for POP [2].

Taking demographic trends into account, it is clear that there is a global significant increase in longevity, which is also to be noticed in Germany [3, 4]. The greater life expectancy for women leads to a sex ratio increase with age. This trend underpins the inexorably expected growing need for treatment modalities in this population [5].

There seems to be a very negative impact of POP and urinary incontinence on women's quality of life, social behavior, and even their mental status [6, 7]. It is estimated in Germany that up to 50% of admissions to nursing homes take place for burdens related to urinary incontinence [8].

Although pessaries are not a causal treatment and are often associated with discomfort, their use is still frequent in the elderly [9, 10]. In many cases, however, surgical correction is the only way to restore anatomy and function. Yet, the elderly are often regarded as unfavorable clientele and are denied access to surgical intervention due to their higher age.

When surgery is performed, obliterative procedures remain more frequently applied [11, 12]. Yet, evidence suggests the equality and even superiority of reconstructive procedures [13, 14].

Although urogynecological surgery in the elderly seems a pressing public health issue, age-related perioperative

comorbidity especially in reconstructive prolapse surgery is underreported. Our aim was to compare perioperative morbidity in septuagenarians and older patients undergoing surgery with that of younger ones in a retrospective single-center study and to estimate the safety of applying reconstructive procedures in the elderly.

2. Materials and Methods

2.1. Study Design. We conducted a single-center retrospective study at the University Hospital of Saarland in Homburg, Germany, which is a tertiary referral center for both gynecologic laparoscopy and urogynecology to compare the perioperative morbidities associated with urogynecological procedures regarding the age of patients. Data were collected by reviewing the electronic patient's charts.

All patients who had undergone an operative procedure for treatment of POP or UI between July 2012 and December 2014 were continuously enrolled in this study. In this period of 2.5 years, overall 407 patients were surgically treated. We chose an age cutoff of 70 years and regarded patients ≤70 years as younger, while those aged ≥70 years were regarded as older patients.

Our presented study can be assigned to stage 2b Exploration IDEAL (Idea, Development, Exploration, Assessment, Long-term study)-system of surgical innovation. This stage focuses on adverse effects and potential benefits.

2.2. Collected Data. In addition to demographic data, we collected detailed obstetric and surgical history. In order to assess the effect of comorbidities, we chose the American Society of Anesthesiologists' (ASA) risk classification system as an index for the general condition of elderly patients.

We further collected intraoperative data regarding duration of surgery and intraoperative complications as well as postoperative data including hemoglobin (Hb) decline, hospital stay, and the occurrence and type of postoperative complications. We defined Hb decline as the difference between preoperative Hb and the lowest Hb measured during postoperative hospital stay. Details to the evaluation of postoperative complications are presented in Section 2.4.

As for laparoscopies, we regarded the conversion to laparotomy for any reason an intraoperative complication and documented it as such.

2.3. Applied Procedures and Materials. Cases of UI were surgically treated using retropubic and transobturator slings as well as laparoscopic Burch colposuspension. Although technically more challenging, all patients suffering from POP were offered reconstructive procedures. Applied POP surgery can be further subdivided into native tissue repair and mesh-assisted repair.

There was no need to perform obliterative vaginal surgery or abdominal procedures on the patients enrolled in this study, as they could all be treated with reconstructive vaginal and laparoscopic procedures, which indicates the high standard of treatment.

Vaginal native tissue repair offered included anterior and/or posterior colporrhaphy, McCall culdoplasty procedure, transvaginal sacrospinous fixation, or a combination of these procedures as indicated. Mesh-assisted repair mainly included laparoscopic sacropexy in addition to anterior, posterior, or total vaginal mesh in some selected cases.

Applied mesh material consisted of macroporous type-1 meshes made of polypropylene in most cases and polyvinylidenfluorid (PVDF) in some cases.

2.4. Presentation of Postoperative Complications. Postoperative complications were subdivided into early and intermediate depending on the time of occurrence. Those taking place from leaving the operation room (OR) to 72 h after discharge were regarded as early complications and those occurring from 72 h to 30 days after discharge were regarded as intermediate ones. The minimum follow-up time was 30 days after discharge.

We applied the standardized CD classification to record the postoperative complications in this study. This classification provides uniform definitions for the existence and severity of a surgical complication.

Since complications grades CD-I and CD-II represent those managed nonoperatively and only differ in the type of management required, we regarded the sum of both as mild complications. On the other hand, we regarded the sum of complications grade CD-IIIa (complications that required operative management under local anesthesia) and grade CD-IIIb (complications that required operative management under general anesthesia) as severe complications.

We compared the occurrences of postoperative complications for both the early and intermediate time intervals. In each of these intervals, the comparison was undertaken regarding each complication grade on its own (CD-I, CD-II, CD-IIIa, and CD-IIIb), as well as regarding the sum of mild (CD-I + CD-II) and that of severe (CD-IIIa + CD-IIIb) complications.

2.5. Statistics. According to the intent-to-treat principle, all patients with evaluable data were analyzed using descriptive statistics. Missing data were not imputed. The null hypothesis of no difference between those younger than 70 years and septuagenarians or older patients receiving urogynecological procedure was exploratively tested against its alternative of any difference.

Categorical variables were tested using chi-square test and Fisher's exact test. Continuous variables were tested using either Student's t-test under the assumption of equal variances or Mann–Whitney U test. p values were adjusted on the basis of multiple testing corrections via false discovery rate (FDR) using R© Version 3.2.0. Statistical significance was defined as adjusted p value of ≤0.05. The statistical analyses were performed using the program IBM SAS (Version 2.2.; SAS Inc., Cary, NC, USA; http://www.sas.com/). Details are described in Tables 1–6.

Additionally, following predictors were analyzed by logistic regression to assess their impact on postoperative complications: affiliation to the group of ≥70 y/o patients, obesity (Body Mass Index (BMI) > 30), multiparity (≥3 births), and ASA score III or IV. All predictors staying significant

Table 1: Patient's characteristics.

Age group (y/o)	<70		≥70		
Parameter		[*n*]		[*n*]	*p* value
Age (y/o)	55.60 ± 8.94	[278]	75.41 ± 4.05	[129]	
BMI (kg/m^2)	27.20 ± 4.72	[278]	26.97 ± 4.05	[129]	0.658^t
ASA score		[278]		[128]	
I	31 (11.2%)		1 (0.8%)		0.001^c
II	215 (77.3%)		78 (60.9%)		0.003^c
III	32 (11.5%)		48 (37.5%)		<0.001^c
IV	0 (0.0%)		1 (0.8%)		0.401^f
Birth	2 [1-2]	[277]	2 [2-3]	[125]	0.032^m
Vaginal delivery	2 [1-2]	[277]	2 [2-3]	[125]	0.005^m
C-section	0 [0-0]	[277]	0 [0-0]	[125]	0.006^m
Vac. extraction	0 [0-0]	[277]	0 [0-0]	[125]	0.098^m
BW ≥ 4000 g	0 [0-0]	[277]	0 [0-0]	[125]	0.628^m
BW ≥ 4500 g	0 [0-0]	[277]	0 [0-0]	[125]	0.717^m
Multiparity (≥3)	68 (24.5%)	[277]	46 (36.8%)	[125]	0.029^c
Grade IV prolapse (Baden-Walker) for each compartment					
Anterior	30 (15.6)	[192]	34 (28.8)	[118]	0.033^c
Middle	11 (5.7)	[192]	28 (23.7)	[118]	<0.001^c
Posterior	7 (3.6)	[192]	9 (7.6)	[118]	0.328^c

Data are presented as average ± standard deviation or median and [IQR].
Statistical test: t = *t*-test; m = Mann–Whitney *U* test; c = chi-squared test; f = Fischer's exact test.
Vac. extraction: vacuum extraction; BW: birth weight.

Table 2: Intraoperative data.

Age group (y/o)	<70		≥70		
		[*n*]		[*n*]	*p* value
Duration of surgery (min)					
All procedures	91.06 ± 65.57	[278]	96.64 ± 64.35	[129]	0.643^t
POP procedures	109.32 ± 59.75	[167]	101.24 ± 60.93	[110]	0.643^t
UI procedures	39.84 ± 35.09	[86]	33.09 ± 21.05	[11]	0.634^t
Combined procedures	140 [67.50–219.50]	[25]	60.50 [40.75–233.75]	[8]	0.643^m
Intraoperative complications	7 (2.5%)	[278]	3 (2.3%)	[129]	1^f
Bladder injury	4 (57.1%)	[7]	2 (66.7%)	[3]	
Rectal injury	1 (14.3%)	[7]	0 (0.0%)	[3]	
Uterine perforation	0 (0.0%)	[7]	1 (33.3%)	[3]	
Emphysema	1 (14.3%)	[7]	0 (0.0%)	[3]	
High ventilation pressure	1 (14.3%)	[7]	0 (0.0%)	[3]	

Data are presented as average ± standard deviation or median and [IQR].
Statistical test: t = *t*-test; m = Mann–Whitney *U* test; f = Fischer's exact test.

Table 3: Postoperative data.

Age group (y/o)	<70		≥70		
		[*n*]		[*n*]	*p* value
Hb decline (g/dL)	1.13 ± 0.77	[247]	1.24 ± 0.89	[125]	0.343^t
Hospital stay (day)	5 [3.50–7.00]	[278]	6 [2.25–8.75]	[129]	<0.001^m

Hb: hemoglobin. Data are presented as average ± standard deviation or median and [IQR].
statistical test: t = *t*-Test; m = Mann-Whitney-*U* test.

Table 4: Detailed presentation of the postoperative complications.

Grade of complication	Age < 70	Age ≥ 70
	Early complications, classified according to CD	
I	(i) Higher need for analgesics: 14 (ii) Prolonged urinary catheterization: 3 (iii) Requiring iv. fluids: 2 (iv) Requiring vaginal tamponade: 1 (v) Prolonged hospital stay: 1 (vi) Requiring observation in ICU: 3 (vii) Requiring drugs for temporary symptomatic treatment: 3	(i) Higher need for analgesics: 3 (ii) Prolonged urinary catheterization: 4 (iii) Requiring iv. fluids: 1 (iv) Requiring vaginal tamponade: 2 (v) Prolonged hospital stay: 2 (vi) Transient paresthesia: 1 (vii) Requiring drugs for temporary symptomatic treatment: 3
II	(i) Requiring antibiotics: 21 (ii) Requiring antihypertensives: 6 (iii) Requiring other drugs for temporary symptomatic treatment: 10	(i) Requiring antibiotics: 21 (ii) Requiring antihypertensives: 21 (iii) Requiring other drugs for temporary symptomatic treatment: 8
IIIa	*Performed under local anesthesia* (i) Loosening a tight TVT sling: 6 (ii) Revision of a vaginal hematoma: 1	*Performed under local anesthesia* (i) Loosening a tight TVT sling: 3 (ii) Revision of a vaginal hematoma: 1 (iii) Suture of a scar dehiscence: 1
IIIb	*Performed under general anesthesia* (i) Revision of a colporrhaphy scar: 4 (ii) Loosening a colposuspension suture: 1 (iii) Loosening a sacropexy mesh: 1 (iv) Revision of a rectal suture: 1	*Performed under general anesthesia* (i) Revision of a colporrhaphy scar: 1 (ii) Revision of a vaginal suture: 1
	Intermediate complications, classified according to CD	
I	(i) Higher need for analgesics: 1 (ii) Observation/minor scar dehiscence: 1 (iii) Observation/minor urinary retention: 1	(i) Observation/minor scar dehiscence: 1
II	(i) Requiring antibiotics: 8 (ii) Requiring drugs for temporary symptomatic treatment: 4	(i) Requiring antibiotics: 9 (ii) Requiring drugs for temporary symptomatic treatment: 3
IIIa	*Procedures performed under local anesthesia* (i) Draining a labial boil: 1 (ii) Loosening a tight TVT sling: 3	
IIIb	*Performed under general anesthesia* (i) Revision of a hematoma: 1 (ii) Laparoscopic ureterolysis: 1 (iii) Loosening a colposuspension suture: 1	*Procedures performed under general anesthesia* (i) Revision of a hematoma: 1

($p < 0.05$) after adjusting for multiple testing have been additionally analyzed in a multivariate model.

3. Results

3.1. Patient's Characteristics. Out of 407 patients who had undergone a surgical treatment for POP, urinary incontinence, or both, 278 (68.3%) were younger than 70 y/o, whereas 129 (31.7%) were aged 70 years or older.

The preoperative general health condition of septuagenarians and older patients was significantly worse compared with younger patients. Older patients more frequently were classified ASA-III (37.5% versus 11.5%; $p < 0.001$) (Table 1).

There were no significant differences regarding BMI. Differences regarding obstetrical history are presented in detail in Table 1.

3.2. Intraoperative Data. No significant differences could be found between both age groups regarding duration of surgery or the occurrence of intraoperative complications (Table 2).

Overall intraoperative complications occurred in 2.5% of the younger patients and in 2.3% of the septuagenarians and older patients. Most of these complications seemed to be occurring sporadically without any tendency for repetition except for the bladder injury which was the most common intraoperative complication in both groups (Table 2).

Table 5: Postoperative complications classified according to Clavien-Dindo.

	Minor complications			Major complications		
Grade	I	II	(I + II)	IIIa	IIIb	(IIIa + IIIb)
Early compl.						
Age < 70	27 (9.7%)	34 (12.2%)	61 (21.9%)	7 (2.5%)	7 (2.5%)	14 (5.0%)
Age ≥ 70	16 (12.4%)	47 (36.4%)	63 (48.8%)	5 (3.9%)	2 (1.6%)	7 (5.4%)
p value	*0.796*[c]	*<0.001*[c]	*<0.001*[c]	*0.796*[f]	*0.967*[f]	*1*[c]
Late compl.						
Age < 70	3 (1.1%)	12 (4.3%)	15 (5.4%)	4 (1.4%)	3 (1.1%)	7 (2.5%)
Age ≥ 70	1 (0.8%)	12 (9.3%)	13 (10.1%)	0 (0.0%)	1 (0.8%)	1 (0.8%)
p value	*1*[f]	*0.272*[c]	*0.281*[c]	*0.749*[f]	*1*[f]	*0.796*[f]

Early compl.: early complications from leaving the OR until 72 hrs after discharge from hospital; late compl.: late complications occurring from 72 hrs until 30 days after discharge from hospital.
Statistical test: c = chi-squared test; f = Fischer's exact test.

Table 6: Postoperative complications: logistic regression and multivariate analysis.

	p value Univariate analysis	*p* value Multivariate analysis	OR	95% CI
		Early postoperative complications		
Age group[1]	<0.001	<0.001	2.953	1.893–4.607
BMI	0.543		1.014	0.970–1.060
Multiparity[2]	0.005	0.035	1.746	1.102–2.769
ASA score[3]	0.002	0.140	1.560	0.912–2.669
		Mild early complications		
Age group[1]	<0.001	<0.001	2.862	1.757–4.661
BMI	0.388		1.021	0.974–1.070
Multiparity[2]	0.005	0.046	1.765	1.082–2.880
ASA score[3]	<0.001	0.064	1.748	1.004–3.043
		Severe early complications		
Age group[1]	0.627		1.720	0.664–4.459
BMI	0.782		0.971	0.873–1.079
Multiparity[2]	0.627		1.631	0.630–4.224
ASA score[3]	0.935		0.949	0.267–3.374
		Intermediate postoperative complications		
Age group[1]	0.666		1.417	0.700–2.868
BMI	0.674		1.025	0.953–1.103
Multiparity[2]	0.799		0.902	0.407–1.996
ASA score[3]	0.666		0.476	0.163–1.386
		Mild intermediate complications		
Age group[1]	0.385		1.929	0.889–4.186
BMI	0.784		1.023	0.942–1.112
Multiparity[2]	0.086		0.923	0.377–2.260
ASA score[3]	0.784		0.634	0.214–1.882
		Severe intermediate complications		
Age group[1]	0.997		0.318	0.039–2.615
BMI	0.997		1.033	0.891–1.198
Multiparity[2]	0.997		0.835	0.166–4.203
ASA score[3]	0.997		0.000	

OR: odds ratio; CI: Confidence Interval.
ASA score: for the logistic regression we summed up ASA I + II as well as ASA III + IV.
1 = Reference: age < 70 y/o; 2 = Reference: <3 births; 3 = Reference: ASA I + II.
p value was adjusted to "FDR."

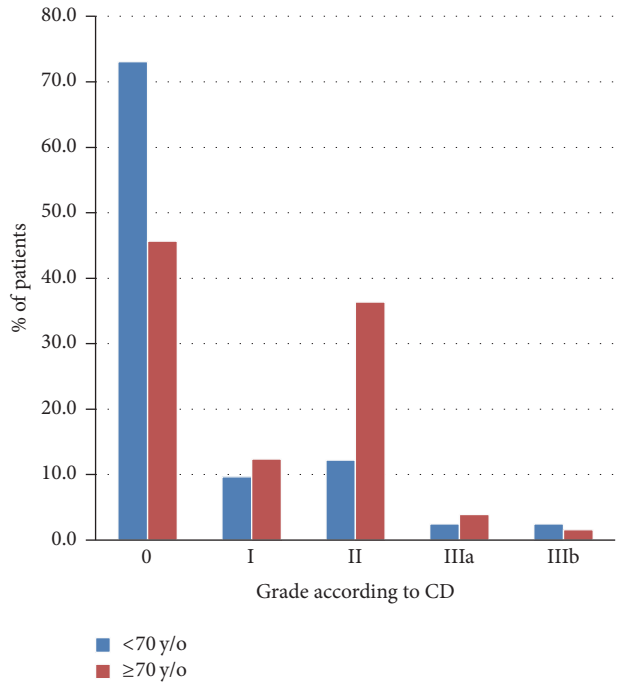

Figure 1: Early postoperative complications.

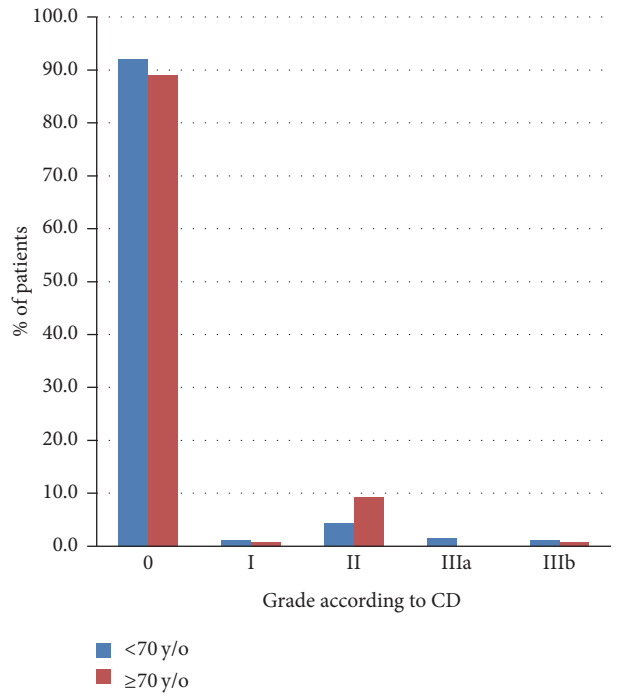

Figure 2: Late postoperative complications.

3.3. Postoperative Data. Regarding Hb decline, there was no significant difference between both age groups, whereas hospital stay was significantly longer in septuagenarians and older patients (Table 3).

3.4. Postoperative Complications. The postoperative complications were recorded using the CD classification and categorized into CD-I, CD-II, CD-IIIa, and CD-IIIb. No complication severity in this study reached higher than stage CD-IIIb. A detailed presentation of the postoperative complications can be found in Table 4.

We found that ≥70 y/o patients suffered significantly more frequently from mild postoperative complications, which was mainly attributed to the occurrence of grade CD-II. No significant differences, however, could be found concerning severe complications.

The incidence of early complications grade CD-II in ≥70 y/o patients was higher compared with younger patients (36.4% versus 12.2%; $p < 0.001$). Further significant differences were found regarding the sum of early mild complications (48.8% versus 21.9%; $p < 0.001$) (Table 5) (Figure 1).

On the contrary, we found that neither mild nor severe intermediate postoperative complications were more frequent in septuagenarians and older patients (Table 5) (Figure 2).

Four parameters have further been analyzed by a logistic regression to assess their impact on postoperative complications. Of those four, the following three showed significant results: affiliation to the group of ≥70 y/o patients, multiparity (≥3 births), and having an ASA score III or IV ($p < 0.05$). With regard to the resulting odds ratio, the group of ≥70 y/o patients had an almost threefold risk to develop early postoperative complications as compared to the group of younger patients (OR: 2.95; 95% CI: 1.89–4.61). However, the influence of multiparity was slightly less (OR: 1.75; 95% CI: 1.11–2.77) (Table 6).

Further differentiating the early complications into the two subgroups, mild and severe early postoperative complications revealed the fact that both affiliation to the elderly group (OR: 2.86; 95% CI: 1.76–4.66) and multiparity (OR: 1.77; 95% CI: 1.08–2.88) were significant predictors for the mild early postoperative complications.

None of the predictors showed a significant correlation to the occurrence of intraoperative complications, mild intermediate postoperative complications, or any severe postoperative complication (Table 6).

4. Discussion

Demographic data from Germany show that the proportion of people ≥65 y/o will rise from 21% in 2015 to an estimated 33% in 2060. Along with rising life expectancy, these trends are expected to increase the future need for urogynecological surgery [4].

Our contemporary data analysis shows that UI and POP in the elderly patients aged ≥70 years can be safely managed surgically and that, even in cases of total prolapse, reconstructive procedures can be applied with good outcome. Our choice of the age cutoff is based on the definition of geriatric patients in Germany, which is acknowledged to be a patient aged ≥70 y/o in addition to suffering from defined health burdens [15].

The percentage of ≥70 y/o patients in our study was impressively high compared with other studies with the same age cutoff (31.7% versus 21%, 18.8%, and 20.6%, resp.), which further underpins the study results [16–18].

Septuagenarians and older patients suffered significantly more often from a reduced general condition than the younger ones. Up to 38% of the elderly in our study had an ASA score of III-IV, yet they were offered the same surgical options as younger patients including reconstructive POP procedures.

We did not find significant differences concerning duration of surgery between both age groups, which was in consistence with data from previous studies [19, 20]. The occurrence of intraoperative complications also did not significantly differ between the age groups. This also seemed to agree with other studies [17, 19, 20].

The intraoperative complications in our study seemed to be sporadic occurring only once except for bladder injury which occurred in 6 patients of whom all had received a laparoscopic sacropexy. The incidence of bladder injury during laparoscopic sacropexy in our study was 6/104 (5.7%), which lays within the upper accepted range when compared with other studies [21, 22]. Amongst overall low incidence of complications in our study, this may be explained by the very low rate of conversion to laparotomy for technical difficulty in our study in comparison with reported rates in other studies (0% versus 1.9–4.6%) [21–23].

In order to evaluate surgical blood loss during surgery, we chose Hb decline rather than estimated blood loss for comparison, since it is less observer-dependent. Our data show low Hb decline in both age groups and no difference between them.

Hospital stay was significantly longer in ≥70 y/o patients than in the younger ones, which was in consistence with other studies [16, 18, 19]. Yet, a possible confounder in discharging elderly patients is one of logistic nature, like waiting for discharge solutions or assistance from social workers [24].

Age-dependent occurrence of postoperative complications after urogynecological procedures is controversially discussed in literature. Although fairly consistent in that a comparable anatomical outcome can be achieved, studies seem controversial with regard to postoperative complications. Whereas some showed no differences [16, 17, 25, 26], others had proven that elderly patients suffered significantly from more postoperative complications than the younger ones [18–20, 27].

In an effort to clarify this issue, we applied a very strict protocol for recording complications in which we defined a complication as any deviation whatsoever from the ideal perioperative course without judging the causality. Classifying complications according to CD is acknowledged in urogynecology and even recommended by medical societies [28–32].

The most prevalent complications grade CD-I were higher need for analgesics and prolonged urinary catheterization due to temporary urinary retention. Both occurred mainly as early complication. Since registration of higher need for analgesics requires a standardized postoperative pain management, it was not reported as a complication in most studies [18–20].

Regarding complications grade CD-II, the most prevalent ones were requirement of antibiotics and requirement of antihypertensives. The requirement of antibiotics in our study resulted in most cases from urinary tract infections (UTIs) which were detected postoperatively in 10% of ≥70 y/o patients and in 6.5% of the younger ones. This high prevalence of postoperative UTIs in urogynecological patients is in consistence with data from other studies [33].

Nevertheless, it has to be mentioned that we had performed a urinalysis in each operated patient on the first postoperative day during the removing of the indwelling catheter. Thus, the detection rate was very accurate even in asymptomatic patients. In their study, Sze at al. came to similar results [17].

The requirement of antihypertensives, which made up for the most obvious difference between both age groups, was solely underreported in most studies [17–20]. In a further evaluation of our clientele, we found that all the ≥70 y/o patients who had required antihypertensives postoperatively were known to suffer from hypertension preoperatively. These patients were already taking antihypertensive medication and experienced a rising need postoperatively, so that either the dosage of the patient's home medication had to be increased or an additional pharmacological substance is added.

Most of the mild complications in the elderly seem to be attributed to the preoperative comorbidity and reduced patient's mobility.

Comparing previously published data with our results is hampered by the lack of uniform methodology. Just to mention the age cutoff set for comparison, the definition of complications, and their classification, the follow-up time and the vast differences concerning the applied surgical procedures are only some differences that cannot be overcome.

The strengths of this study include the high percentage of ≥70 y/o patients compared with other studies, which further reaffirms the study results [16–18].

Another strength is the high ratio of reconstructive surgery of POP, which is technically more challenging but has anatomical and functional advantages towards obliterative procedures, which are more frequently applied in the elderly [11–14]. Thus, the data from our study encourage offering reconstructive procedures to elderly patients.

A further strength is that the study concerns the assignment to stage 2b Exploration IDEAL-system of surgical innovation. According to the definitions of the stages that were further explained on the website of the "IDEAL collaboration," this stage involves data from studies with an output concerning measurement and comparison and focuses on adverse effects and potential benefits. Regarding the number of patients, it is stated that this stage has to involve many rather than few, and the number of surgeons is defined as many, too. In our study, we had involved more than 400 patients who were treated surgically by 4 surgeons.

The type of patients in the studies assigned to this stage 2b should be a mixed type with broadening of the indication. Our study seems to fulfill this requirement too, as the

complete spectrum of accepted and standardized vaginal and laparoscopic reconstructive surgery was applied in our study. Our innovation concerned the application in a highly aged group of patients who are routinely denied access to these procedures because of lack of experience in the outcome in this age group [34, 35].

Concerning follow-up, stage 2b Exploration only requires short-term or patient-reported outcomes in opposition to stage 3 Assessment which requires middle-term and stage 4 which requires long-term outcomes. Although our study presents middle-term outcomes, it cannot be assigned to stage 3 Assessment, since either randomized clinical trials or multicenter data are required for this stage, which our data do not fulfil [34, 35].

Lastly, the study had continuously enrolled all performed procedures in this tertiary center without any exclusion criteria and the complications were recorded following a very strict and standardized protocol, leaving very little room for observer's interpretation.

But our study also had several limitations. The character of a monocentric case-control study implements a bias in the retrospective nature of data acquisition from possibly inhomogeneous documentation.

Another limitation is that patients were not randomized to the different procedures. It has rather to be said that the selection of the procedure for each patient was based on many criteria including age, which, in addition to the extent of the disease, patient's surgical history, and weight, was an important factor in decision making.

Lastly, there is a limitation regarding follow-up. All patients in whom an alloplastic material was applied during surgery were offered a follow-up at 3–6 months after discharge. This group of patients comprised 74.7% of whom almost 95% participated in follow-up. The remaining 5% were inquired by telephone. As for patients who had undergone native tissue repair, we assume that they would have sought treatment in our center in case of postoperative complications, since the hospital was the only regional tertiary center for urogynecology. Yet we can only be sure that the vast majority but not all possible complications are known to us.

In order to gain more valuable information about applying urogynecological surgery in the very aged, efforts should be undertaken to perform multicenter studies or randomized controlled studies to fulfil the requirements for assignment to stage 3 Assessment of IDEAL-system of surgical innovation. One further necessity seems to be constructing registries for further structured long-term follow-up and subgroup analysis according to IDEAL stage 5.

5. Conclusion

Even though the general health condition was significantly worse and the extent of prolapse was significantly higher in septuagenarians and older compared with younger patients, they were offered the same therapeutic options and treated using reconstructive POP surgery. Neither operation time nor blood loss or intraoperative complications were more frequent in ≥70 y/o patients, whereas hospital stay was significantly longer.

Regarding postoperative complications, we noticed that minor complications had occurred more frequently in ≥70 y/o patients who had an almost threefold risk to develop mild early postoperative complications compared with younger patients (OR: 2.86; 95% CI: 1.76–4.66). On the contrary, major complications were not more frequent. No case of life-threatening complication or the need for intensive care or blood transfusion was reported.

We advise that elderly patients with the need for urogynecological procedures should be offered all surgical options and counseled about a higher risk to develop minor but not major complications.

We advise to perform multicenter studies and to build up registries for further structured long-term follow-up and subgroup analysis.

Abbreviations

ASA: American Society of Anesthesiologists
BMI: Body Mass Index
CD: Clavien-Dindo
FDR: False discovery rate
Hb: Hemoglobin
IDEAL: Idea, Development, Exploration, Assessment, Long-term study
OR: Operation room
POP: Pelvic organ prolapse
UI: Urinary incontinence
UTI: Urinary tract infection.

Competing Interests

The authors declare that there are no competing interests regarding the publication of this paper.

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Research Article

The Outcome of Repeated Mid Urethral Sling in SUI Treatment after Vaginal Excisions of Primary Failed Sling: Preliminary Study

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Mid urethral sling is the standard in SUI treatment. Nevertheless, the risk of reoperation reaches 9%. There is no consensus as to the best treatment option for complications. A question is raised: what is the optimal way to achieve the best result in patients after primary failure? The aim of the study was to evaluate the outcomes of repeat MUS surgery in patients after excision of the sling with recurrent SUI. We compared its effectiveness with uncomplicated cases treated with TVT. 27 patients who underwent the repeated MUS and 50 consecutive patients after primary TVT were enrolled in the study. After 6 months, we have found that 24 (88.46%) patients from repeat sling group and 48 (96%) patients after primary sling were dry (1-hour pad test, 2 g or less). The difference between groups was not significant. We showed statistically significant improvement of quality of life in both groups. In conclusion, we showed that repeated sling after MUS excision is almost as effective as primary MUS. We postulate that sling excision and repeated MUS may be the best option for persistent SUI and/or complications after MUS procedures. Further multicenter observations are ongoing as to provide results on bigger group of cases.

1. Introduction

Mid urethral sling is the gold standard in stress urinary incontinence treatment [1]. The effectiveness of the procedure is estimated for 70–95%; nevertheless, the risk of reoperation reaches even 9% [2]. Indications for reoperations are usually lack of effectiveness, voiding dysfunctions, OAB de novo, pain, or recurrent infections [3].

There is no consensus as to the best treatment option for complications. In the armamentarium, there is implantation of second sling without removal of the first one in case of failure, sling incision in case of voiding dysfunctions [4], and vaginal excision of the sling in case of voiding dysfunction, OAB de novo, pain, and so forth [5]. A question of major importance is raised: what is the optimal way to achieve resolving of complications and at the same time to achieve the best result in SUI treatment in patients with primary failure?

The vaginal excision of the sling is a safe procedure that resolves most of complications such as voiding dysfunctions, OAB de novo, and pain; nevertheless, in over 60% of patients SUI recurrence is present [5].

The aim of the present study was to evaluate the outcomes of repeat MUS surgery in patients after excision of vaginal portion of the failed sling with persistent or recurrent SUI. We compared the effectiveness of the repeated sling procedure with uncomplicated cases of pure stress incontinences treated with TVT. The outcome of the surgery was evaluated as objective and subjective cure rate after at least six months after the surgery.

2. Materials and Methods

27 patients who underwent the repeated MUS implantation after first sling vaginal excision in 1st Department of

Table 1: Results of 1-hour pad test and IIQ7 in the group of patients after sling excision and in control group.

	1-hour pad test [g]		IIQ7 score [0–100]	
	After sling excision	Control group before TVT	After sling excision	Control group before TVT
Mean	121.52	81.14	85.90	77.54
Median	115	44.50	85.71	76.19
Std. dev.	65.87	97.84	12.88	16.21

Obstetrics and Gynecology of Medical University of Warsaw between 2013 and 2015 were enrolled in the study.

The excisions of the first sling were performed mainly because of the failure of the surgery (85%) and in other cases because of other complications (32%) (such as OAB or urinary retention). Some of the patients suffered from more than one symptom (i.e., persistent SUI and OAB). All the patients who underwent repeated sling implantation presented pure stress urinary incontinence without other symptoms (they were resolved by first sling excision). The degree of SUI after first surgery (first sling implantation) before its excision was determined using 1-hour pad test, cough test, and IIQ7 scoring. The time of repeated tape implantation after excision of the failed one was from 80 to 100 days.

One surgeon using the same technique performed the sling excisions. After localization of the tape in ultrasound examination, the vagina was incised beneath the sling. The Hegar maneuver was used to facilitate the tape preparation. Then the sling was grasped with two Peans and incised beneath the urethra. The arms of the sling were then prepared from the surrounding tissues in their vaginal part and then excised.

In control group, we analyzed 50 consecutive patients after the TVT implantation from 1 January to 30 June in 2015.

Preoperative assessment in both groups consisted of detailed medical and surgical history, urogynecologic examination, a 1-hour pad test, cough stress test, urine analysis, multichannel urodynamic evaluation, and pelvic floor ultrasonography [6] and additionally all patients completed the Incontinence Impact Questionnaire (IIQ7).

Patients after sling excision were operated by only one surgeon using the standard TVT procedure (Gynecare; Ethicon Inc., Somerville, NJ). In all cases, surgical procedures were performed as previously described according to 1/3 rule after PF ultrasound evaluation of urethra length [7]. Tensioning of the tapes for TVT was achieved by cough test. 3 trained gynecologists performed surgeries in control group.

All patients were followed up at 1 day, 1 month, 6 months postoperatively, and every second year thereafter. Pelvic floor ultrasound, 1-hour pad test, cough test, IIQ7, and pelvic examinations were completed within 6 months and every second year of follow-up.

The tape location after sling implantation was assessed using pelvic floor ultrasound examination as it was described previously [7]. In summary, the distance from proximal edge of the tape to the echolucent urethral lumen and the distance from the middle part of the tape to the bladder neck were measured.

Statistical analysis was performed using Chi-square and Mann–Whitney U tests.

3. Results

Between 2013 and 2015, 116 patients with complications after MUS procedure were diagnosed in the department. 71 of them underwent vaginal sling removal, and 40 underwent repeated sling implantation. Till now, 27 patients (62.4 ± 8.4 years) completed 6-month observation period and were included in the study. Patients after third or fourth sling procedure as well as after bladder or urethral injury were excluded from the study.

In the group of patients with complications, the main reason of sling removal was persistent SUI (14 patients), OAB de novo after the surgery (1 patient), and persistent SUI with OAB (12 patients). In the group with unsuccessful treatment in general sling was located in proximal part of urethra.

In 16 cases (59.3%), a primary sling was TOT, there was a retropubic sling in 4 cases (14.8%), and in 2 cases there were mini slings (7.4%). In 5 patients, we did not obtain information about first procedure.

The average time between primary sling excision and repeat TVT was 3 months.

Mean age of patients from control group was 58.3 ± 9.4.

In Table 1, the results of 1-hour pad test and IIQ7 in analyzed patients after first sling excision and from control group (initial examination before TVT implantation) were summarized. The differences between two groups in 1-hour pad test and IIQ7 score were not statistically significant.

After 6 months of observation, we have found that 24 (88.46%) patients from the group after repeated sling group and 48 (96%) patients after primary sling implantation were dry (1-hour pad test, 2 g or less). The difference in percentage of negative pad test after primary and repeated procedure was not statistically significant. There were statistically significant differences ($p < 0.01$) in IIQ7 score in analyzed groups.

In Table 2, results in 1-hour pad test and IIQ7 score performed after 6 months after repeated sling implantation and primary sling implantation were summarized.

In successfully treated patients after repeated sling ($n = 24$), IIQ7 score did not defer significantly from the control group's results.

Analysis of failure of the TVT surgery showed that in 5 cases of unsuccessfully treated patients in both groups the sling was implanted in proximal part of urethra.

In patients who remained dry 6 months after the surgery, the location of the sling was in distal 1/3 part of urethra,

Table 2: Results in 1-hour pad test and IIQ7 score performed 6 months after repeated sling implantation and primary sling implantation.

	1-hour pad test [g]		IIQ7 score [0–100]	
	Repeated MUS	Primary MUS	Repeated MUS	Primary MUS
N	27	50	27	50
Mean	10.92	0.92	19.05	4.10
Median	0	0	4.76	0
Std. dev.	41.32	5.26	30.21	11.18

Table 3: Tape location 6 months after repeated sling implantation.

($N = 24$)	Distance from the bladder neck		Distance from the echolucent urethral lumen
	[mm]	% of urethral length	[mm]
Mean	19.43	64.9%	3.13
Median	19.00	64.5%	3.30
Std. dev.	3.19	6.9%	0.94

approximately 3.3 mm from echolucent urethral lumen in ultrasound examination (Table 3).

4. Discussion

The primary aim of the study was to evaluate the results of repeated MUS procedure after vaginal sling excision in unsuccessfully or complicated patients with SUI.

The most common reason for sling excision was persistent incontinence and in half cases persistent incontinence with concomitant OAB de novo. In patients treated with repeated sling, we showed that the objective cure (negative cough and 1-hour pad test) was achieved in 89% of patients after repeated sling as compared to 96% in primary sling cases. The difference between repeated sling and primary sling in our group was not statistically significant.

We also obtained great improvement in quality of life (measured as IIQ7 score) in both groups; nevertheless, the improvement was more pronounced in primary sling patients.

Nowadays, there is a worldwide discussion regarding the best way of unsatisfactory results after MUS procedures as there are a lot of treatment options.

The first step in the attempt to provide the best way of treatment for the complicated patients is the proper diagnosis of failure and indications for sling revision.

In analysis of Unger et al., the main purposes for sling revision (incision or partial or complete excision) were urinary retention, LUTS, and recurrent infections. The percentage of LUTS was similar to that in our group; nevertheless, the authors did not analyze cases of persistent SUI in their center [8]. In complicated cases, another important reason for sling excision is the sling exposure that results in recurrence of SUI [9].

In case of LUTS (urinary retention, OAB, and voiding difficulties), different treatment approaches are discussed.

One option is sling release. The technique of releasing differs according to the time in which complications are diagnosed. In Rautenberg et al.'s analysis, authors showed that early tape mobilization provides resolution of symptoms in almost all patients [10].

What is important is that such procedure is possible during first week after the sling implantation. In case of later diagnosis, there is no possibility of sling mobilization. In such case, the sling release (incision or partial or complete excision) must be taken into consideration. Sling incision is one of the options. In analysis of 100 cases from Mayo Clinic, global improvement and satisfaction were reported by 41% of patients after the procedure [11]. The main purpose of low satisfaction after sling incision is the recurrence of SUI which occurs in over 60% of patients after sling incision [4]. Another approach is complete sling excision that is even more accurate in LUTS resolution but naturally causes recurrent SUI in similar percentage of cases as after sling incision [5].

According to literature data and our experience, complete sling excision in case of urinary retention, OAB, sling exposure, infections, and so forth is the most effective procedure as far as the resolution of above complications is concerned.

On the other hand, there is a group of patients with persistent SUI after MUS procedure. Therapeutic option for them is second sling implantation, sling shortening, and repeated sling after sling excision. Meyer et al. showed 77% of successfully treated patients after second sling in the group of patients with persistent SUI with persistent urethral hypermobility [12]. In analysis of subjective cure rate after repeated sling, the significant lower satisfaction was shown after second sling as compared to the primary sling implanted (62% versus 86%) [13]. In another observation, cure rate after repeated sling reached 79% [14]. In case of persistent SUI, the tape shortening is another option for patients. In comparison of cure rates in patients after repeated sling and after sling shortening, it was shown that repeated sling was much more effective than the other option (72% versus 46%) [15].

In many cases of unsuccessful treatment of SUI, we have to deal with complex problems such as persistent SUI with OAB, retention, pain, or sling exposure. Taking the above into account, we should choose the option that allows obtaining the complications resolution and on the other hand

provides the best conditions for secondary treatment. As it was previously shown, the complete sling excision is more efficient in OAB and pain treatment; we would like to show the effectiveness of the repeated sling after sling excision as well as the results of that procedure in cases with persistent SUI.

We showed that repeated sling after MUS excision had the same effectiveness (as far as the continence is considered in objective tests: negative cough test and negative 1-hour pad test) as the primary implanted sling (89 versus 96%; ns). As far as the subjective cure rate is considered, the results were slightly worse than those after the first sling, something that was connected mainly with emotional status of the patients (anxiety and depression). What is worth mentioning is that we observed lower IIQ7 score after 2 years of observation (as patients reported that they started to believe in success).

The main limitation of the study is small patients group. It also should be stressed that not in all cases of failed sling the repeated one will be the best option because the most important inclusion criterion was pure stress incontinence after first sling excision.

In conclusion, we showed that repeated sling after MUS complete excision is probably almost as effective as primary MUS. We postulate that vaginal sling excision and repeated MUS may be the best option for persistent SUI and/or complications after mid urethral sling procedures. Further multicenter observations are ongoing to provide the result based on bigger group of cases.

Competing Interests

The authors declare that there are no competing interests regarding the publication of this paper.

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Research Article

Size Does Not Make the Difference: 3D/4D Transperineal Sonographic Measurements of the Female Urethra in the Assessment of Urinary Incontinence Subtypes

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Purpose. The objective was to evaluate the usefulness of transperineal ultrasound in the assessment of the urethral length and urethral lumen by 3D/4D transperineal sonography to discriminate between female patients with subtypes of urinary incontinence. *Methods.* A total of 150 female patients underwent an examination because of urinary incontinence. 41 patients were diagnosed with urgency urinary incontinence (OAB), 67 patients were diagnosed with stress urinary incontinence (SUI), and 42 patients were in the control group (CTRL). Three diameters of the urethral lumen (proximal (U1), medial (U2), and distal (U3)) and the urethral length were measured. By the assessment of the urethral lumen, the presence of the urethral funneling was evaluated. *Results.* We found a significant difference in the urethral length and urethral lumen U2 of OAB and SUI versus CTRL. The urethral length was significantly greater ($P < 0.05$) and the urethral lumen was significantly wider ($P < 0.05$) in the patients with urinary incontinence. The incidence of the urethral funneling was significantly higher ($P < 0.05$) in the study groups with urinary incontinence than in the control group. *Conclusions.* Our results have shown the urethral changes obtained by ultrasound in patients with urinary incontinence, but they are still insufficient to distinguish between subtypes of urinary incontinence.

1. Introduction

The female urethra is functionally and anatomically a complex tubular organ extending below the bladder. Its crucial functional role is to maintain continence during bladder filling and to allow emptying during the voiding phase. One of the mechanisms involved in controlling continence is the urethral tonus. The urethral tonus is provided by the urethral smooth muscles, the urethral striated muscle, and the vascular elements within the submucosa [1]. Striated external urethral sphincter (rhabdosphincter) encircles the urethra in its middle part. It is responsible for increasing intraurethral pressure during times of need and contributes by about one-third of the resting tone of the urethra. The urethral smooth muscle blockade additionally reduces resting urethral closure pressure by about one-third. Lastly, the urethral submucosa with its prominent vasculature is partly responsible for the urethral closure. Occlusion of arterial flow to the urethra decreases resting urethral closure pressure [2].

It is possible to visualise the parts of the urethra with different echogenicity by the performance of transperineal ultrasound: the outer layer with external striated muscle, the middle layer with smooth muscle, the inner layer, which corresponds to the connective tissue with the vessels and submucosa, and the central part which represents the urethral lumen and the mucosa. Ultrasound based clinical examination became increasingly important. New generation high-resolution ultrasound offers the advantages of visualising anatomical structures and in the same time allows for functional assessment. Moreover, it is a noninvasive and cheap technique without any ionising radiation. 3D/4D ultrasound additionally allows virtual reconstruction of the urethra for precise evaluation and hence offers a technique with excellent intra- and interobserver repeatability [3, 4].

Changes in anatomical structures which provide urethral tonus can be assessed by ultrasound and were described for patients with stress urinary incontinence in previous studies. This includes a thinner striated external urethral sphincter as well as thinner urethral smooth muscle [5] and changes in the urethral vasculature [6, 7]. As a general doctrine, it has been proposed repeatedly that urethral length is shorter in patients with stress urinary incontinence [8, 9] though evidence from properly structured clinical trials is low. However, as stress urinary incontinence is a result of relaxation of the periurethral encircling connective tissue, elongation or enlargement of the urethra rather than shortening is the more likely consequence. Hence, we hypothesized that urethral length is greater and urethral lumen is wider in patients with stress urinary incontinence than in healthy controls or patients with urgency urinary incontinence.

The aim of this study was to evaluate the usefulness of transperineal ultrasound in the assessment of the urethral length and urethral lumen by 3D/4D sonography to discriminate between patients with subtypes of urinary incontinence. We aimed, by this new diagnostic approach, at providing a basis for future selection of patients that may benefit from specific treatment strategies. We assigned this study to the development stage of the IDEAL method (Stage 2a) [10].

2. Materials and Methods

A total of 150 female patients were included in our retrospective study. The women underwent an examination in the outpatient department of the urogynaecology centre at the University Hospital RWTH Aachen, because of urinary incontinence. The data were collected between 2009 and 2015. The diagnosis was based on anamnesis, including ICIQ-SF (International Consultation on Incontinence Questionnaire-Short Form), gynaecological examination, stress test, transperineal ultrasound, and urodynamic testing.

A single experienced senior physician performed the urodynamic testing. The examination was based on the ICS criteria [11].

Transperineal ultrasound was performed by a single experienced senior physician qualified according to the DEGUM level II standard (German Society for Ultrasound in Medicine). The ultrasound examination was performed under the same standard condition. Briefly, the patient was lying during the examination on the exam chair in the supine position. Bladder filling volume was approximately 300 mL. The ultrasound system (GE Medical Systems, Zipf, Austria; Voluson 730 Expert, E8) with a perineal ultrasound transducer (frequency range: 3.5–5 MHz) was used for all examinations. The ultrasound transducer was placed on the perineum with a beam angle of 70°. To avoid the compression of the urethra, the pressure on the transducer was produced as low as possible. A 3D/4D simultaneous view of multiple parallel slices in real time (Figure 1) was used for better assessment of the position and mobility of the urethra. The acquisition time for one volume data set was 5–7 s. During this period of time, we were imaging the bladder with bladder neck and bladder base in the longitudinal plane, the urethra in the largest diameter, and the transverse plane of the pubic symphysis with ligamentum arcuatum, pubic bone, and interpubic disc. The examination was performed in a state of relaxation, by contraction of the pelvic floor, by Valsalva manoeuvre, and during coughing. The process of the examination was recorded and saved on hard disk.

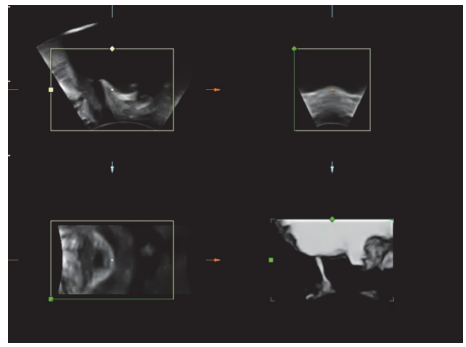

Figure 1: 3D/4D transperineal ultrasound image.

For analysis, the clinic database was searched for patients with the diagnosis of de novo urgency urinary incontinence (OAB) and stress urinary incontinence (SUI). The diagnosis was based on the IUGA/ICS criteria [12]. All patients with SUI complained of activity related incontinence, which was also presented by evaluation of ICIQ-SF. Stress test was positive and urodynamic testing confirmed the diagnosis of SUI. All patients with OAB complained of involuntary loss of urine associated with urgency, which was confirmed by filling of ICIQ-SF. Stress test was negative and the urodynamic testing confirmed the diagnosis of OAB. Exclusion criteria in the group of patients with urinary incontinence were the diagnosis of mixed urinary incontinence, previous urogynaecological surgery or other invasive urogynaecological therapies, pelvic radiation, and descent of the anterior vaginal wall, posterior vaginal wall, the uterus, or the apex of the vagina (POP-Q II or more).

Control group (CTRL) was chosen from patients, who were examined in our department during the same time period without symptoms of urinary incontinence. The CTRL did not suffer on pelvic organ prolapse (POP-Q II or more) and did not undergo previous urogynaecological surgery or other invasive urogynaecological therapies and pelvic radiation.

Transperineal ultrasound data were edited in the computer program 4D-View (GE Medical Systems). Measurements taken in a state of relaxation were used for further analysis. Three diameters of the urethral lumen in the sagittal plane were measured as shown in Figure 2: the diameter located at the ostium urethrae internum (U1), the diameter located in the middle of the urethra (U2), and the distal diameter (U3). The common problem in the transperineal ultrasound examination is the definition of the ostium urethrae externum [13]. To define the distal part of the urethra, we used a reference line according to Hennemann et al. [13]. This line is being fixed between two hyperechogenic contours of symphysis pubis. The ventral and dorsal points of the diameter were defined as a transition zone between echogenic and anechogenic parts of the urethra. The length of the urethra

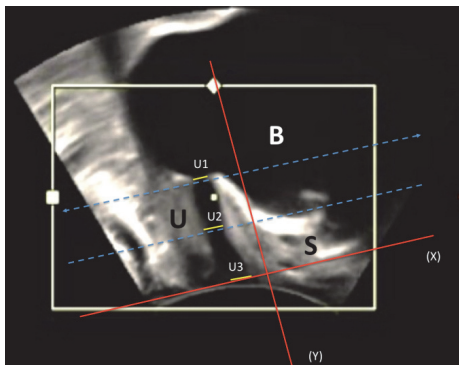

Figure 2: Perineal ultrasound image on midsagittal plane from a patient at rest. The positions of symphysis (S), urethra (U), bladder (B), reference line (X), the line orthogonal to reference line (Y), and urethral lumen (proximal (U1), medial (U2), and distal (U3)) are indicated.

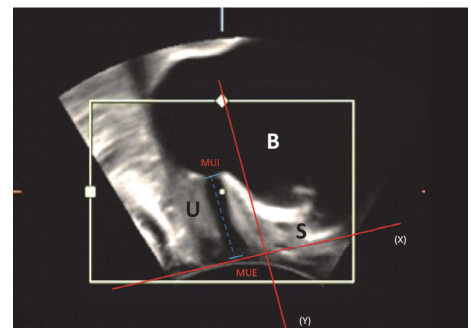

Figure 3: Perineal ultrasound image on midsagittal plane from a patient at rest. The positions of symphysis (S), urethra (U), bladder (B), ostium urethrae externum (MUE), meatus urethrae internum (MUI), reference line (X), and the line orthogonal to reference line (Y) are indicated. The urethral length is defined as a distance between MUE and MUI.

was measured between ostium urethrae internum and the reference line as shown in Figure 3. The urethral length (SUL) was defined as a curve between ostium urethrae internum and ostium urethrae externum, which was presented by the reference line.

The statistic program SAS Version 9.2 and Microsoft Office Excel 2007 were used for analysis. The Kruskal-Wallis test with Dunn's multiple comparisons was used. Fisher's exact test was applied for the evaluation of the urethral funneling. The results are described as statistically significant by P value < 0.05.

This study was performed according to the Declaration of Helsinki and approved by the local ethics committee.

3. Results

The 150 examined patients had a mean age of 60.4 years (range: 19–89). After examination in our outpatient urogynaecology centre, there were 41 patients with mean age of 66 years (range: 45–89) diagnosed with OAB, 67 patients with mean age 56.5 years (range: 19–80) with a diagnosis of SUI, and 42 patients in the CTRL with mean age of 61.2 years (range: 40–80).

Funneling of the bladder neck was demonstrated in 11% of the patients with the diagnosis of incontinence (Table 1) but was not found in the control group ($P < 0.05$). As presented in Table 2, we did not find any significant difference in the presence of funneling of the bladder neck between SUI and OAB (9.7% of patients with OAB and 11.9% of patients with SUI).

Mean urethral lumen U1 (Table 3) was 5.19 mm in OAB (95% CI: 4.54–5.83), 4.99 mm in SUI (95% CI: 4.47–5.52), and 4.88 mm in CTRL (95% CI: 4.46–5.30). There were no significant differences between the study groups (Table 4).

Urethral lumen U2 (Table 3) differed significantly between OAB (mean: 5.49 mm, 95% CI: 4.94–6.05) and SUI (mean: 5.17 mm, 95% CI: 4.85–5.49) when compared to CTRL (mean: 4.47 mm, 95% CI: 4.10–4.85) ($P < 0.05$). There was no significant difference in the urethral lumen U2 between OAB und SUI (Table 4).

Table 1: Comparison of the presence of urethral funneling between women with urinary incontinence and CTRL.

Parameter	Urinary incontinence ($n = 108$)	CTRL ($n = 42$)	P value*
Urethral funneling	12	0	0,02

*Fisher's exact test, P value < 0.05 as significant.

Table 2: Comparison of the presence of urethral funneling between women with OAB and SUI.

Parameter	OAB ($n = 41$)	SUI ($n = 67$)	P value*
Urethral funneling	4	8	ns

*Fisher's exact test, P value < 0.05 as significant.

Mean urethral lumen U3 (Table 3) did not differ significantly between the study groups (Table 4) and was 4.95 mm in OAB (95% CI: 4.21–5.69), 4.98 mm in SUI (95% CI: 4.38–5.58), and 4.96 mm in CTRL (95% CI: 4.34–5.58).

Mean urethral length (Table 3) was 2.85 cm in OAB (95% CI: 2.72–2.98), 2.82 cm in SUI (95% CI: 2.72–2.91), and 2.63 cm in CTRL (95% CI: 2.53–2.73). We have observed significant differences ($P < 0.05$) of the urethral length for OAB versus CTRL and SUI versus CTRL. There was no significant difference in the mean urethral length between OAB and SUI (Table 4).

4. Discussion

Transperineal ultrasound is increasingly used in the diagnostic evaluation of female urinary incontinence. Part of the ultrasound examination is to assess the urethral lumen as well as the measurement of the urethral length. The knowledge of both parameters is important for planning of incontinence surgery and for selecting an appropriate implant. In the evaluation of the urethral lumen, presence or absence

Table 3: Measurements of the urethral lumen (U1, U2, and U3) and the urethral length (SUL).

Parameter	U1 (mm)	U1 (95% CI)	U2 (mm)	U2 (95% CI)	U3 (mm)	U3 (95% CI)	SUL (cm)	SUL (95% CI)
OAB	5,19	4,54–5,83	5,49	4,94–6,05	4,95	4,21–5,69	2,85	2,72–2,98
SUI	4,99	4,47–5,52	5,17	4,85–5,49	4,98	4,38–5,58	2,82	2,72–2,91
CTRL	4,88	4,46–5,30	4,47	4,10–4,85	4,96	4,34–5,58	2,63	2,53–2,73

The results are given as mean, 95% confidence interval (CI).

Table 4: Comparison of the measurements of the urethral lumen (U1, U2, and U3) and urethral length (SUL) between patients with SUI and OAB and CTRL.

Parameter	P value (OAB versus SUI)*	P value (OAB versus CTRL)*	P value (SUI versus CTRL)*
U1	ns	ns	ns
U2	ns	<0.05	<0.05
U3	ns	ns	ns
SUL	ns	<0.05	<0.05

*Kruskal-Wallis test with Dunn's multiple comparisons, P value < 0.05 as significant.

of urethral funneling is the only established parameter in patients with urinary incontinence. However, no study has been done to the best of our knowledge for the evaluation of sonographically measured urethral length as well as for changes of the diameter of urethral lumen.

In contrast to current doctrines, in which it is generally believed that a shorter urethra leads to SUI, we here show for the first time by the use of 3D/4D transperineal ultrasound that the urethral length was significantly greater and the midurethral lumen was significantly wider in patients with urinary incontinence. This is best explained by structural relaxation of supportive periurethral tissue which ensures urethral tonus. However, we missed our aim to discriminate subtypes of incontinence by ultrasound assessment. Of note, we did not observe significant differences in urethral length or urethral lumen or in the presence of urethral funneling between patients with SUI and OAB. The incidence of urethral funneling, however, was significantly higher in the study groups with urinary incontinence than in the CTRL group even when mixed incontinence was excluded suggesting common pathomechanisms in both entities. This finding is interesting and merits further investigations.

Depending on the method used for assessment, mean urethral length varies from 2.78 cm to 4.1 cm [4, 14, 15]. Mitterberger et al. [15] measured urethral length by transurethral ultrasound with 3D-sonographic reconstruction and did not find any significant differences between patients with SUI and CTRL. The reason for the difference from our study could be the different ultrasound technique and small number of patients used in their study. However, together, these findings emphasize that the current doctrine of a short urethral length leading to SUI is not valid.

Our finding of a wider urethral lumen U2, actually in the middle of the urethra, in patients with SUI is in concert with observations obtained by incontinence surgery. Surgical insertion of tension-free vaginal tape (TVT) aims to stabilize the midthird of the urethra. The ideal position for TVT placement is estimated to be between 50% and 70% of the urethral length [16]. We expect that the lower urethral tonus in the middle of the urethra, according to our findings, provides the ideal function for passive support of the TVT at that part of the urethra.

The difference in the movements of the anterior and posterior walls of the proximal urethra during increase of the intraabdominal pressure causes the urethral funneling. The incidence of urethral funneling observed in women with stress urinary incontinence is reported to range from 18.6% to 97.4% [17]. A reason for the enormous variation in incidence of the urethral funneling between studies is the use of different ultrasound techniques. On the one hand, in some patients with stress urinary incontinence, urethral funneling was seen only with straining; on the other hand, some degree of urethral funneling could be already present at rest, increasing then with straining [17, 18]. Ultrasound evaluation of urethral funneling can improve diagnostics. It is one of the important qualitative parameters that can confirm the diagnosis of urinary incontinence. It is also an important parameter in the pre- and postoperative diagnostics and its presence is associated with an increased probability of therapeutic failure or recurrence [18–20].

As compared to the continent patients, the urethral lumen U2 in patients with OAB and SUI was significantly wider. The wider urethral lumen U2 can best be explained by lower urethral tonus in patients with SUI. The reason for the lower urethral tonus in SUI is a decreased volume of the rhabdosphincter as well as decreased volume of urethral smooth muscle [21]. Athanasiou et al. [22] evaluated the urethra and the urethra sphincter in women with stress urinary incontinence with 3D ultrasound and reported that urethral sphincter is thinner, smaller, and shorter in volume compared to controls. The reports on urethral vasculature are controversial. Different Doppler parameters have been studied to evaluate the vascular elements within the urethra in patients with stress urinary incontinence. Some authors [6] reported fewer periurethral vessels and Doppler flow parameters of the urethral vasculature in patients with stress urinary incontinence whereas others [7] could not find any difference in the appearance of the urethral vasculature in women with or without stress urinary incontinence. The other factors which could affect the urethral lumen are changes in the detachment of the pubourethral ligaments. Disruption of the pubourethral ligaments is significantly associated with stress urinary incontinence and has been observed in most patients with SUI by MRI studies [23, 24].

The present study reports on a new approach to guide urogynaecologists selecting patients for planned surgical

strategies. Following the IDEAL recommendations [10], this refers to Stage 2a, the development level on a small collective of patients. Future prospective studies will address the therapeutic outcome in relation to the sonographic findings in a larger number of patients.

A limitation of the present study is the limited number of patients in each study group. Moreover, the CTRL consists of patients visiting our outpatient centre because of urogynaecological problems other than urinary incontinence or pelvic organ prolapse (POP-Q II or more) and hence they are not necessarily healthy women.

Strength of our study is the use of a well established and robust ultrasound technique [13, 25] that allows exact evaluation of the anatomical urethral structures with excellent repeatability and intra- or interobserver variability [3].

In conclusion, following the IDEAL recommendations [10], the reported study aimed at challenging the potential of 3D/4D sonography in the urethral morphology to provide guidance for urogynaecologists in choosing the right patient for the right procedure. According to our hypothesis, we expected differences in the urethral length as well as in the urethral lumen by patients with SUI versus CTRL. Our results have shown structural urethral changes in patients with incontinence, yet with no difference between both subtypes of urinary incontinence, SUI and OAB. Hence, anatomical findings obtained by ultrasound are still insufficient to distinguish between subtypes of urinary incontinence and cannot replace the conventional diagnostics.

Competing Interests

The authors declare that there are no competing interests regarding the publication of this paper.

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Research Article

Comparison of Perineal Sonographically Measured and Functional Urodynamic Urethral Length in Female Urinary Incontinence

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Objectives. To detect the anatomical insufficiency of the urethra and to propose perineal ultrasound as a useful, noninvasive tool for the evaluation of incontinence, we compared the anatomical length of the urethra with the urodynamic functional urethral length. We also compared the urethral length between continent and incontinent females. *Methods*. 149 female patients were enrolled and divided into four groups (stress, urge, or mixed incontinence; control). Sonographically measured urethral length (SUL) and urodynamic functional urethral length (FUL) were analyzed statistically. Standardized and internationally validated incontinence questionnaire ICIQ-SF results were compared between each patient group. *Results*. Perineal SUL was significantly longer in incontinent compared to continent patients ($p < 0.0001$). Pairwise comparison of each incontinent type (stress, urge, or mixed incontinence) with the control group showed also a significant difference ($p < 0.05$). FUL was significantly shorter in incontinent patients than in the control group ($p = 0.0112$). But pairwise comparison showed only a significant difference for the stress incontinence group compared with the control group ($p = 0.0084$) and not for the urge or mixed incontinent group. No clear correlation between SUL, FUL, and ICIQ-SF score was found. *Conclusions*. SUL measured by noninvasive perineal ultrasound is a suitable parameter in the assessment of female incontinence, since incontinent women show a significantly elongated urethra as a sign of tissue insufficiency, independent of the type of incontinence.

1. Introduction

Urinary incontinence in females has an increasing prevalence [1, 2]. Its diagnosis is mostly possible with a thorough history taking and clinical evaluation. But additional invasive urodynamic investigations are often necessary and help to further classify the type of incontinence and to facilitate the preoperative planning [3, 4]. One relevant parameter of the urodynamic investigation is the functional urethral length (FUL). There are a huge number of publications from the eighties on the FUL all showing that the mean length was lower in incontinent (especially stress incontinent) versus continent women [5, 6]. But still, up until now, its usefulness for establishing a precise diagnosis of urinary incontinence is debated, since measurements are often affected by artefacts and the overlap of values between continent and incontinent women was huge.

Besides urodynamic measurements, other modalities like magnetic resonance imaging (MRI) or dynamic cystocolpoproctography (DCP) are used for further examination of incontinence, especially giving further objective anatomical information like bladder position. But these techniques are either partly invasive, laborious and embarrassing for the patient, or expensive diagnostic tools with long waiting periods.

In contrast, perineal ultrasound (PUS) is gaining importance in urogynecological diagnostics. Good availability, easy handling, low cost, and good patient acceptance are some of

the conveniences which have already made PUS a popular diagnostic tool, for example, in the assessment of pelvic organ prolapse, the detection of paraurethral pathologies, and the postoperative sonographic control of tension-free vaginal tape (TVT) slings [7]. But even with these benefits, the use of PUS is not as widespread as it could be and especially the role of PUS in the diagnostic of incontinence is still unclear, although it may contribute great advantages. Therefore, the present study was intended to investigate the potentials of PUS as a noninvasive diagnostic tool in incontinence. For this, it was analyzed whether the anatomical urethral length measured by PUS is a good diagnostic parameter to assess female urinary incontinence.

2. Materials and Methods

The present study was performed according to the Declaration of Helsinki and with approval of the local ethics committee (reference number EK085/11).

As a new approach to diagnosing incontinence, we assigned this study to the development stage of the IDEAL method (Stage 2a) [8]. Therefore, to investigate the potential of PUS, we chose to perform PUS on a small collective of patients with only one examiner in our center.

2.1. Patients. All 149 women who presented at our continence center between 2008 and 2012 were retrospectively included. Data acquisition was performed using an electronically data program which continuously documented all patients. Patient data included patients' history and results of clinical examinations, complete urodynamic investigations, and perineal ultrasonography. Study patients (Table 1) were divided into three groups: Patients in group I suffered from stress urinary incontinence (SUI), patients in group II from urgency urinary incontinence (UUI), and patients in group III from both stress and urgency urinary incontinence (SUI/UUI). A control group (group IV) consisted of patients who clinically and urodynamically showed no criteria of urinary incontinence.

2.2. Urodynamic Investigation: FUL. All urodynamic investigations were performed according to the description by Schaefer et al. 2002 [4]. For urodynamic investigation of the FUL, the urethra pressure profile was evaluated with a 40 cm long three-lumen catheter CAT307 (Laborie, Mississauga, Canada) and the pressure sensor (Transducer) MX960XP1 (Smith Medical International LTC, St. Paul, USA). While retracting (0.7 cm/s) the catheter mechanically under a constant saline perfusion rate (2–10 mL/min), intravesical and intraurethral pressure were measured simultaneously. FUL then is defined as the distance in which the intraurethral pressure exceeds the intravesical pressure.

2.3. Perineal Ultrasonography: SUL. PUS was performed by an experienced board qualified gynecologist according to the DEGUM Level II standard (Deutsche Gesellschaft für Ultraschall in der Medizin) [9]. Patients were asked to drink two glasses of water half an hour prior to the examination to reach a bladder filling of approximately 300 mL. Ultrasonography was performed with the patient in the lithotomy position using a Voluson 730 Expert (GE Health Care, Wauwatosa, USA) with a 3.5 to 5 MHz transperineal probe (GE Medical Systems, Zipf, Austria) [10]. After covering the transducer with a condom, the examiner parted the labia and placed the transducer on the perineum [10]. Sagittal pictures were obtained according to a standard protocol as shown in Figures 1(a) and 1(b). Patients were asked to rest and then to perform the following maneuvers: pelvic floor muscle contraction, Valsalva maneuver, and coughing. A four-dimensional video volume of the ultrasound evaluation was recorded for each patient. Analysis of the data was performed later, using the software 4DView (GE Medical Systems, Systems, Zipf, Austria) and the sonographic urethral length at rest (SUL-R), during contraction (SUL-C) and under pressure (SUL-P), was determined. Figure 1(b) demonstrates a measurement of the urethra length as shown by the punctuated linear line from the intraurethral opening to the external opening of the urethra.

Table 1: FUL for incontinent patient groups (SUI, UUI, and SUI/UUI) and the control group given as mean, standard deviation (SD), and median (a). p values of pairwise statistical comparison of different patient groups (b).

(a)

Group	Mean (mm)	SD	Median (mm)
SUI	22.44	7.48	20
UUI	21.95	6.32	21.5
SUI/UUI	22.61	6.13	22
Control	24.22	6.47	25

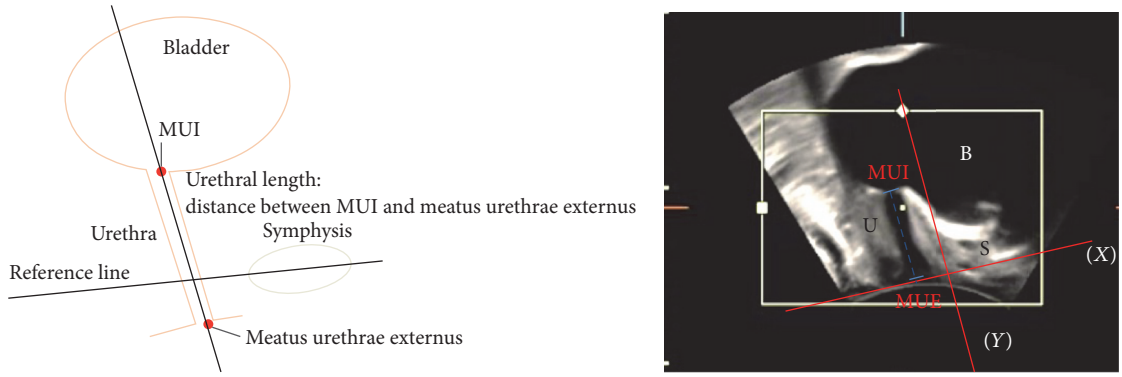
(b)

Groups	p
SUI versus control	0.0084
SUI versus UUI	0.6265
SUI versus SUI/UUI	0.4980
UUI versus control	0.1369
UUI versus SUI/UUI	0.9186
SUI/UUI versus control	0.1246

2.4. Clinical Questionnaire: ICIQ Score. The standardized and internationally validated incontinence questionnaire ICIQ-SF (International Consultation on Incontinence Questionnaire-Short Form) as a measure for the psychological strain of incontinent was obtained from the patients during the first visit. The score ranges from zero to 21, with zero being no strain at all.

2.5. Statistical Analysis. An explorative data analysis was performed with the significance level at $p \leq 0.05$. Statistical analysis was performed with Med Calc version 9.2.0.1 (Ostend, Belgium).

SUL and FUL values for all patient groups were given as median, mean, maximum, and minimum as well as quartiles and interquartile distance and standard deviation.



(a) (b)

Figure 1: (a) Schematic illustration of bladder and measurement of urethral length (MUI: meatus urethrae internus). (b) Ultrasound image showing bladder (B), symphysis (S), meatus urethrae internus (MUI), and transperineal measurement of the sonographic urethral length (SUL).

Comparison of the FUL was performed by Mann–Whitney U test. Analysis of the SUL values was performed by t-test and Welch-Test. For the correlation of SUL-R, FUL, and ICIQ scores, Spearman's rank correlation coefficient r was calculated. The higher the correlation between parameters, the closer the correlation coefficient r to −1 (antiproportional correlation) or +1 (proportional correlation).

3. Results

3.1. Patients. 149 women were included in the study. 117 of the patients were diagnosed with incontinence: 72/117 (61.5%) with stress urinary incontinence (SUI), 22/117 (18.8%) with urgency urinary incontinence (UUI), and 23/117 (19.65%) with both, called mixed urinary incontinence (SUI/UUI). Median age of the incontinent women was 62 ± 11 (35–83), 67 ± 10 (49–82), and 65 ± 12 (41–90) years for the stress, urge, and mixed incontinent patients groups, respectively. The female control group consisted of 32 patients with a mean age of 62 ± 12 years (range 41–80 years).

3.2. FUL. FUL values for the three incontinent patient groups (SUI, UUI, and SUI/UUI) and the control group are given in Table 1(a). Mean and median value of the incontinent women were shorter compared to the control group. Statistical significance was reached between incontinent patients and the control group ($p = 0.0112$). Subsequent pairwise t-tests between each incontinent group with the control group showed only a significant difference for the SUI group compared with the control group ($p = 0.0084$). No significant difference was found comparing the incontinent patients groups UUI and SUI/UUI with the continent group (Table 1(b)). Furthermore, pairwise comparison of the three types of incontinence (SUI, UUI, and SUI/UUI) showed no significant difference (Table 1(b)).

3.3. SUL. SUL values for the three incontinent patient groups (SUI, UUI, and SUI/UUI) and the control group under the three conditions (rest, contraction, and pressure) are given in Tables 2(a)–4(a).

Table 2: FUL for incontinent patient groups (SUI, UUI, and SUI/UUI) and the control group given as mean, standard deviation (SD), and median (a). p values of pairwise statistical comparison of different patient groups (b).

(a) FUL

Group	Mean (cm)	SD	Median (cm)
SUI	3.85	0.68	3.91
UUI	3.63	0.72	3.68
SUI/UUI	3.82	0.65	3.76
Control	2.87	0.38	2.84

(b)

Groups	p
SUI versus control	0.0001
SUI versus UUI	0.1960
SUI versus SUI/UUI	0.8562
UUI versus control	0.0001
UUI versus SUI/UUI	0.3560
SUI/UUI versus control	0.0001

SUL-R was statistically highly significantly longer in all incontinent patients compared to the continent control patients ($p < 0.0001$). Subsequent pairwise comparison of each incontinent type (SUI, UUI, and SUI/UUI) with the control group showed also a statistically significant difference (Table 2(b)).

SUL-P values were statistically highly significantly longer in all incontinent patients compared to the continent control patients ($p < 0.0001$). Subsequent pairwise comparison of the incontinent patients with the control group showed also a statistically significant difference independent of the type of urinary incontinence (Table 3(b)).

Similar results were seen comparing the SUL-C results. Values were statistically significantly longer in all incontinent patients compared to the continent control patients ($p < 0.003$). Pairwise comparison of the incontinent patients with

Table 3: FUL for incontinent patient groups (SUI, UUI, and SUI/UUI) and the control group given as mean, standard deviation (SD), and median (a). p values of pairwise statistical comparison of different patient groups (b).

(a) FUL

Group	Mean (cm)	SD	Median (cm)
SUI	3.18	0.85	3.18
UUI	3.05	0.87	2.92
SUI/UUI	3.37	0.77	3.45
Control	2.13	0.57	2.17

(b)

Groups	p
SUI versus control	0.017
SUI versus UUI	0.5278
SUI versus SUI/UUI	0.3536
UUI versus control	0.0001
UUI versus SUI/UUI	0.2005
SUI/UUI versus control	<0.0001

Table 4: FUL for incontinent patient groups (SUI, UUI, and SUI/UUI) and the control group given as mean, standard deviation (SD), and median (a). p values of pairwise statistical comparison of different patient groups (b).

(a) FUL

Group	Mean (cm)	SD	Median (cm)
SUI	3.45	0.55	3.34
UUI	3.35	0.55	3.31
SUI/UUI	3.62	0.54	3.56
Control	3.20	0.40	3.23

(b)

Groups	p
SUI versus control	0.0093
SUI versus UUI	0.4221
SUI versus SUI/UUI	0.2094
UUI versus control	0.2618
UUI versus SUI/UUI	0.0988
SUI/UUI versus control	0.0016

the control group showed also a statistically significant longer SUL-C for the SUI and the SUI/UUI groups. Comparison of the UUI with the control group revealed no statistically significant difference ($p = 0.2618$) (Table 4(b)).

Spearman's rank correlation in incontinent patients between the FUL and the SUL-R, SUL-P, and SUL-C showed only a very weak correlation with a coefficient of $r = -0.064$, $r = 0.05$, and $r = 0.077$, respectively.

3.4. ICIQ Score. The ICIQ score was obtained in 110 of the incontinent patients with a mean score of 13.8±4.5. The mean ICIQ score of the SUI ($n = 69$), UUI ($n = 21$), and SUI/UUI ($n = 20$) group was 14.4 ± 3.7 (range 4–21), 11.8 ± 6.2 (range 0–21), and 14 ± 4.5 (range 6–21), respectively.

Analysis of Spearman's rank correlation between the ICIQ score and the FUL, the SUL-R, SUL-P, and SUL-C showed a coefficient of $r = -0.124$, $r = 0.026$, $r = 0.356$, and $r = 0.182$, respectively.

In summary, no clear correlation between ICIQ data and FUL or SUL was found.

4. Discussion

The prevalence of female urinary incontinence is up to 25% depending on age [11]. The diagnosis of urinary incontinence follows an accurate case-history collection including standardized questionnaires. There is an ongoing effort to correlate clinical symptoms with objective measurements, for example, the urethral pressure profile established by urodynamic investigations [12]. Measurement parameters include maximum urethral closure pressure, active and passive pressure transmission, and the functional urethra length [4, 12]. Still, their clinical relevance is debatable and the investigations are partly invasive, laborious, and embarrassing for the patient. In contrast, perineal ultrasound has gained importance in urogynecological diagnostics for it is easy to handle, good, available, and of low cost. Furthermore, it easily provides additional diagnostic information, for example, about pelvic organ prolapse or paraurethral pathologies [10, 13]. This clinical study aimed to evaluate whether the anatomical urethral length measured by perineal ultrasound can serve as a useful diagnostic tool in assessing urinary incontinence in women.

Our study clearly demonstrates that the perineal sonographically measured urethral length differs statistically significantly between continent and incontinent females with a statistically significant longer SUL value in incontinent patients. The difference is best seen in the examinations at rest and under pressure and least during pelvic muscle contraction. Under these two conditions, the SUL was statistically significantly longer for the stress, urge, and mixed incontinence group. Urinary incontinence has multifactorial causes such as age, child birth, and insufficiency of the connective tissue. As urinary incontinence is often associated with a genital prolapse [14], we assume that insufficiency of the urethral tissue itself may be the reason for the longer anatomical urethral length. Up until now, there have been quite a few reports about the association of urethral hypermobility with urinary incontinence [15, 16]. However, there is hardly any literature about a possible association between urethral elongation and urinary incontinence. It has to be assumed that the reproducibility is best in an examination at rest because investigations under pressure or during contraction are influenced and potentially falsified by patient related factors and thus hardly to reproduce precisely. Furthermore, the FUL is only evaluated at rest and thus a direct comparison of FUL and SUL under the same conditions is ensured. Therefore, we recommend measuring the sonographic urethral length at rest. SUL could be shorter in continent women due to compression by the examiner, better contractility of intact pelvic muscles, or unconscious tension.

Results show that there is no statistical significant difference of SUL between the three types of incontinence;

therefore, PUS cannot help to clearly differentiate between the three different types of incontinence. However, the longest average SUL at rest is observed in patients with stress urinary incontinence (3.85 cm ± 0.68 cm) compared to the shortest urethral length in patients with urgency urinary incontinence (3.63 cm ± 0.72 cm). The average urethral length in continent patients is 2.87 cm ± 0.38 cm. Reasons for the elongated urethra especially in females with stress urinary incontinence are anatomical changes with generalized pelvic floor insufficiency, vaginal deliveries, and age [17, 18]. Future larger studies have to show at what cut-off value SUL can serve as a reliable diagnostic tool in the assessment of incontinence.

In contrast to the noninvasive SUL measurements, results from the urodynamic FUL showed only a statistically significant difference for the stress incontinent compared to the control group. These findings are in accordance with previous studies reporting from a reduced FUL in stress incontinent patients [5, 6, 19]. Analysis for the urge and mixed incontinent patients revealed no statistically significant shorter FUL and consequently these two types of incontinence cannot be detected by FUL measurement. In addition, FUL cannot differentiate between the different types of urinary incontinence, for there was no statistically significant difference between the different incontinent patient groups.

The comparison of the SUL at rest with the urodynamically measured FUL showed no correlation and even no antiproportional correlation as one might expect. But FUL and SUL are completely different parameters, as FUL describes a urodynamic functional finding and SUL an anatomical finding. Thus, taking this into account, these findings seem to be comprehensible.

The degree of urinary incontinence is difficult to determine but can be estimated, for example, with the subjective questionnaire tool of the ICIQ. According to Karantanis et al., the score correlates with the degree of urinary incontinence and is recommended as measurement tool [20]. In our study, correlation between the ICIQ values and SUL indicates a correlation of high ICIQ values and longer anatomical urethral length, but values show quite a lot scattering around the regression line and statistically there was no correlation found. The same phenomenon was seen when correlating the objectively measured FUL with the ICIQ results: results only show a tendency of increased ICIQ values with shortened functional urethra length. In summary, no statistically significant correlation is seen neither with functional nor with anatomical length and ICIQ scores.

Our study has quite a few limitations. As we only have a small number of patients, we cannot make definite conclusions concerning the statistical differences between both groups. However, we have statistically significant results. This can encourage further studies with the possibility of establishing a larger control group of healthy population, which is needed to obtain results referring to a normal distribution. As this is a stage 2a study, we were limited to the patients in our hospital who came to us with the diagnosis of urinary incontinence. Because of the limitation of only being able to perform urodynamics with our patients, we have an inhomogeneous age distribution. Also, only one examiner performed one examination; therefore, the repeatability cannot be assessed. Further, probable causes for a lack of correlation might be the limited number of patients, and therefore it is possible that larger scale studies may find a correlation between ICIQ and SUL or FUL. Another limitation might be that the control group was recruited from our gynecological clinic and some women, though incontinence was excluded by clinical and urodynamic evaluation, showed minor signs of pelvic insufficiency. This may also have influenced both the questionnaire and the objective measurements.

5. Conclusions

We believe to have obtained interesting results which should be pursued further in order to gain a better insight into the pathophysiology of urinary incontinence, as well as gaining a new parameter in the assessment of female incontinence. In this study, SUL measured by perineal ultrasound was a suitable parameter to differentiate between continent and incontinent females independently of the three types: stress, urge, and mixed incontinence. In incontinent females, a statistically significant elongated urethra was found. In contrast, the parameter FUL was only statistically significant altered in stress but not in urge or mixed incontinent patients compared to the control group. Furthermore, perineal ultrasound provides the advantage of a noninvasive tool compared to the invasive urodynamic investigations and additionally facilitates the evaluation of comorbidities such as urethral kinking or funneling, obstruction, or paraurethral pathologies [21–23]. Thus, further studies with focus on perineal SUL measurement should be considered in patients with presumed incontinence.

Competing Interests

The authors declare that they have no competing interests.

Authors' Contributions

Laila Najjari participated in protocol/project development, data collection, and editing. Nadine Janetzki performed data collection and data analysis. Lieven Kennes participated in data analysis. Elmar Stickeler and Julia Serno contributed to project development. Julia Behrendt participated in manuscript writing, project development, and editing.

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