Original Article

Prospective evaluation of an intraoperative urodynamic stress test predicting urinary incontinence after robot-assisted laparoscopic radical prostatectomy

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Abstract

Introduction: Multiple factors influence postprostatectomy incontinence (PPI). This study evaluates the association between an intraoperative urodynamic stress test (IST) with PPI.

Materials and Methods: This is an observational, single-center, prospective evaluation of 109 robot-assisted laparoscopic radical prostatectomies (RALPs) performed between July 2020 and March 2021. All patients underwent an intraoperative urodynamic stress test (IST) in which the bladder is filled up to an intravesical pressure of 40 cm H_2O to evaluate whether the rhabdomyosphincter is capable of withstanding the pressure and ensure continence. Early PPI was evaluated using a standardized 1-h pad test performed the day after removal of the urinary catheter. The association of IST and PPI was evaluated using univariate and multivariable logistic regression models.

Results: Nearly 76.6% of the patients showed no urine loss during the IST ("sufficient" population group). There was no significant correlation between this group and PPI after catheter removal ($P = 0.5$). Subgroup analyses of the "sufficient" patient population showed a 3.1 higher risk of PPI when no nerve sparing was performed (95% confidence interval: 1.05–9.70, $P = 0.045$).

Conclusion: A sufficient IST, as a surrogate variable for a fully obtained rhabdomyosphincter, has no significant predictive value on its own but seems to be the optimal prerequisite for continence, since the data shows that the lack of neurovascular supply required for a functioning sphincter leads up to a 3.1 times higher risk for PPI.

Keywords: Intraoperative urodynamic stress test, nerve sparing, postprostatectomy incontinence, predictor, prostate cancer, robot-assisted radical prostatectomy

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INTRODUCTION

Postprostatectomy incontinence (PPI) as a side effect of radical prostatectomy (RPE) – a standard therapy of localized prostate cancer – is well known and feared as it is the most common type of urinary incontinence (UI) in men, but its pathogenesis is still not entirely understood. There are several proven patient- and surgery-related

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risk factors associated with the development of PPI after RPE.

Damage to the external sphincter is considered a surgical risk factor contributing to the development of PPI.[1,2] Studies have shown that the amount of striated muscle detected in prostatectomy specimens correlates with PPI. The more muscle tissue found in the specimen, the worse PPI was.[1]

Furthermore, the length of the membranous urethra (MUL) negatively correlates with PPI.[2] In preoperative cystoscopy, the MUL was measured. Mungovan *et al.* showed that the longer the urethra in the membranous part is the better the continence recovered after surgery.[3]

Schlomm *et al.* declared that preserving the functional urethra significantly contributes to a better outcome of postoperative continence in open surgery.[4] So far, these results have never been transferred to robot-assisted laparoscopic radical prostatectomy (RALP).

RALP allows a more detailed view of the surgical field in a narrowed space and could potentially offer the surgeon a more precise operation, although better functional outcomes compared to open surgery are yet to be proven.[5] Nevertheless, RALP is continuously becoming the more common surgical approach.

Proven, invariable patient-sited parameters that have a significant influence on PPI include older age,[2,6] a shorter (preoperative) MUL,[3] or a bigger prostate volume.[2,7]

In addition to these possible reasons for developing PPI, urodynamic changes after RPE have been observed.[8] The extent of their influence and the reason for their appearance is also not entirely understood.

In this study, we wanted to prospectively evaluate the specific influence of external sphincter function on PPI and whether a fully preserved external sphincter is able to avoid PPI. To collect data, we developed an intraoperative urodynamic stress test (IST) to evaluate sphincter function and to use this information as a surrogate marker for a fully preserved external sphincter.

If a fully preserved sphincter is present and PPI still occurs, we want to find cofactors that can help improve continence.

To our knowledge, this is the first study to examine the appearance of PPI prospectively by performing an IST.

MATERIALS AND METHODS

For this clinical, observational study, we prospectively included patients with biopsy-confirmed localized prostate cancer who underwent a RALP at the Department of Urology at the University Medical Center Goettingen (Germany) between July 2020 and March 2021. The Institutional Review Board of the University Medical Center Goettingen approved this study.

The indications for surgery and the staging were made following the current guidelines (German S3 Guidelines and EAU Guidelines).[9,10]

Exclusion criterion was an interdisciplinary board decision to initiate a multimodal therapy before surgery.

The outcome of interest was the influence of the IST as a surrogate marker of the function of the external sphincter on PPI.

All patients were seen at least 1 day prior to surgery. After study inclusion, they underwent the standardized admission procedure including physical examination, sonography, and history taking. During the preoperative assessments, patients were asked if they performed pelvic floor training, instructed by physiotherapists, before surgery.

All RALPs were performed by three surgeons, with an experience of more than 450 RALPs, each, using the DaVinci SI system. The surgical techniques, such as preserving and reconstructing the pelvic floor, were executed in the same way (e.g., Rocco stitch,[11] etc.).

The neurovascular bundle was preserved whenever the oncological possibility with respect to the guidelines and the intraoperative findings was given and the patient asked for it. For oncological safety, we performed a whole-mount frozen section of the entire laterodorsal part of the gland surfacing the neurovascular bundle (from the urethra to the bladder neck) during RALP. When there was a cancer-positive area of the margin, the corresponding bundle was secondarily resected. The variable "nerve sparing (NS)" was defined as "no NS," "unilateral NS" and "bilateral NS."

The intraoperative urodynamic stress test

After suturing the vesicourethral anastomosis, an 18 Fr catheter was placed transurethrally into the bladder. The bladder was filled with 0.9% NaCl fluid at body temperature up to an intravesical pressure of 40 cm H_2O. This was done by standardized and measured placement of the NaCl fluid

40 cm above bladder level. Pressure level was reached when the infusion stopped dripping.

If the anastomosis was tight enough without showing extravasation, the transurethral catheter was removed. Possible urine leakage out of the urethra was measured standardized by catching all fluid extravasation in a bowl. The bowl weight was measured before and after placing it in front of the meatus. Afterwards, a new 18 Fr transurethral catheter was placed inside the bladder under visual control in all patients.

The postoperative course applied to the entire patient collective was standardized with regard to the use of analgesics, diet, and physiotherapy. The decision about the duration of the transurethral catheter was dictated by the surgeons on basis of the intraoperative course (planned for 5 or 7 days). Before removing the catheter, a radiological control (cystogram/retrograde urethrocystography) was performed. If there was no leakage of the contrast medium at the vesicourethral anastomosis, the tube was removed and the patient was immediately given standardized instructions by a physician to train the pelvic floor.

Patients stayed hospitalized for at least 24 h after catheter removal. During that time, they were trained again by physiotherapists within 5 h after catheter removal. The patients documented their micturition conditions using a standardized micturition protocol for 24 h (voiding rates, amount per fraction, pad usage, etc.). The next day they were asked to evaluate their urinary loss using a standardized 1-h pad test[12] [Appendix 1]. Before discharge, possible postvoid residual (PVR) urine volume was assessed by ultrasound.

During the pad test, the following parameters were documented: pad weight at the beginning and at the end of the test, urinary volume micturated, and PVR.

The loss of urine into the pad was dichotomized into "good continence" (<2 ml) and "unfavorable continence" (≥2 ml) ("dry" vs. "wet"). These cutoffs were chosen to distinguish the completely dry patients from the others. Because of the risk of measurement errors, 2 ml was chosen instead of 0–1 ml pad weight difference between the beginning and the end of the test. The same scale was consistently used to measure the pad weight.

Statistical analysis

Categorical variables are described with absolute number and its corresponding percentage, continuous variables with median and range. Categorical variables were compared between groups using the Chi-square test and continuous variables using the Wilcoxon rank-sum test based on the underlying distribution evaluated by the Shapiro–Wilk test.[13] Dichotomous outcomes were evaluated using univariate and multivariable logistic regression models. Variables were considered for inclusion in multivariable models based on their literature-based relevance as potential confounders and based on statistical significance ($P < 0.1$) from univariate logistic regression analysis and retained in the final multivariable model if $P < 0.05$. The final multivariable logistic regression models were assessed for goodness of fit (calibration) with the Hosmer–Lemeshow test[14] and for discrimination with the area under the curve (AUC) statistic. All statistical analyses were performed with R version 3.6.3 (R Core Development Team, Vienna, Austria) and RStudio version 1.1.463 (RStudio Inc., Boston, MA). Statistical tests with $P < 0.05$ were considered statistically significant. All P values are two-sided.

RESULTS

One hundred and nine patients were included in the statistical analysis.

Table 1 shows the patient cohort, dichotomized for "dry" versus "wet," with P values for the corresponding test of statistical comparison.

Besides the shown characteristics, no significance was reached regarding the histopathological findings (pT status [$P = 0.8$], pN status [$P = 0.57$], resection status [$P = 0.46$], or Gleason score [$P = 0.5$]). In addition, prostate volume, International Prostate Symptom Score (IPSS), and international consultation on incontinence questionnaire (ICIQ) test results test results were not significant ($P = 0.66$, $P = 0.1$, and $P = 0.77$, respectively).

Out of 107 patients, with a complete documented IST, 82 patients (76.6%) had <2 ml fluid loss through the urethra intraoperatively and therefore had a "sufficient IST." Twenty-five patients were categorized as having an "insufficient IST" with ≥2 ml loss in the IST.

There was a significant difference in age at the time of surgery between the patient collectives with a "sufficient IST" and those with an "insufficient IST" with overall younger patients yielding a "sufficient IST" (65 years [48:79] vs. 68 years [53; 78], $P < 0.01$).

In subgroup analysis of the "sufficient IST" patient population, we dichotomized the patients into "dry" and "wet" regarding the postoperative pad test ("dry" <2 ml and "wet" ≥2 ml).

Table 1: Patient characteristics between the "dry" and "wet" patient population (loss of urine in postoperative pad test after catheter removal)

	Total (*n*=109)	Dry (*n*=45) (<2 ml), *n* (%)	Wet (*n*=64) (≥2 ml), *n* (%)	*P*
Age (years), median (minimum–maximum)	65 (48–79)	64 (48–78)	66 (51–79)	0.11
BMI				
<24	11	3 (27.3)	8 (72.7)	0.55
24–<30	77	35 (45.5)	42 (54.5)	
≥30	21	7 (33.3)	14 (66.7)	
iPSA (ng/ml)				
<4	7	2 (28.6)	5 (71.4)	0.05
4–10	67	32 (47.8)	35 (52.2)	
10–<20	22	10 (45.5)	12 (54.5)	
≥20	13	1 (7.7)	12 (92.3)	
NS				
Bilateral NS	35	21 (60.0)	14 (40.0)	0.01
Unilateral NS	35	15 (42.9)	20 (57.1)	
No NS	39	9 (23.1)	30 (76.9)	
Preoperative pelvic floor training				
Yes	17	9 (52.9)	8 (47.1)	0.41
No	53	20 (37.7)	33 (62.3)	
IST (ml)				
Sufficient (<2 ml)	82	31 (37.8)	51 (62.2)	0.50
Insufficient (≥2 ml)	25	12 (48.0)	13 (52.0)	
Bladder volume (IST) (ml)				
<200	20	8 (40.0)	12 (60.0)	0.97
200–<400	37	16 (43.2)	21 (56.8)	
≥400	45	19 (42.2)	26 (57.8)	

BMI: Body mass index, iPSA: Initial prostate-specific antigen, NS: Nerve sparing, IST: Intraoperative urodynamic stress test

Table 2 shows the distribution of the patient characteristics in the "sufficient IST" patient subpopulation (n = 82).

Besides the shown characteristics, no significance was reached regarding the histopathological findings (T status [P = 1.0], N status [P = 0.94], resection status [P = 0.68], or Gleason score [P = 0.44]). In addition, prostate volume or ICIQ test results were not significant (P = 0.67 and P = 0.39, respectively).

The results of univariate and multivariable logistic regression analysis for the outcome PPI are presented in Table 3.

The univariate analyses showed a 3.1 (95% confidence interval: 1.05–9.70, P = 0.045) times higher risk of suffering PPI in patients who received no NS compared to patients with bilateral NS [Table 3].

Upon multivariable analyses, with adjustment for IPSS, NS did not appear to be a significant predictor of PPI.

Model diagnostics of the multivariable model revealed adequate model calibration and an acceptable discrimination (AUC = 0.796).

DISCUSSION

Since male UI is not as well scientifically investigated as female UI, the pathomechanisms of this undesirable burden are not entirely understood. PPI is the most common type of UI in men. Dramatic changes in the anatomy of the pelvis occur due to RPE/RALP. Besides the obvious anatomical changes, functional "disorders" are observed as well.[15]

The perfect outcome for patients undergoing RPE/RALP would encompass oncological control over the disease, return to full urinary continence and erectile function, as well as a satisfactory quality of life (QoL).

The occurrence of decision regret in patients for consenting to RPE/RALP depends on the mentioned "trifecta" above,[15] especially on the factors affecting daily life.

Recent studies postulate that the external sphincter (combination of smooth and striated muscle) seems to have a significant influence on postprostatectomy continence.[1] Skeldon *et al.* correlated the amount of striated muscle on histopathological specimens of the prostate gland after RPE with the appearance of PPI on corresponding patients. They proposed a so-called "SM score" (striated muscle score) which can predict the occurrence of PPI with a specificity of 98% and sensitivity of 19%.[1]

In 2017, Good *et al.* retrospectively evaluated the extraprostatic tissue in the apex and proposed that the more tissue that can be found in this area, the less continence can be achieved postoperatively.[16] Thirty-eight out of a total of 80 patients were considered continent (0 pads) 12 months after

Table 2: Characteristics in the "sufficient intraoperative urodynamic stress test" group - Distribution into dry and wet regarding their postoperative pad test

	Total (*n*=82)	Dry (*n*=31) (<2 ml), *n* (%)	Wet (*n*=51) (≥2 ml), *n* (%)	*P*
Age (years), median (minimum–maximum)	65 (48–79)	64 (48–75)	65 (51–79)	0.10
BMI				
<24	8	3 (37.5)	5 (62.5)	0.87
24–<30	57	23 (40.4)	34 (59.6)	
≥30	17	5 (29.4)	12 (70.6)	
iPSA (ng/ml)				
<4	6	2 (33.3)	4 (66.7)	0.33
4–<10	51	22 (43.1)	29 (56.9)	
10–<20	16	6 (37.5)	10 (62.5)	
≥20	9	1 (11.1)	8 (88.9)	
IPSS (preoperative)				
<8	45	23 (51.1)	22 (48.9)	0.04
8–19	29	7 (24.1)	22 (75.9)	
20–35	5	1 (20.0)	4 (80.0)	
NS				
Bilateral NS	27	14 (51.9)	13 (48.1)	0.12
Unilateral NS	24	9 (37.5)	15 (62.5)	
No NS	31	8 (25.8)	23 (74.2)	
Preoperative pelvic floor training				
Yes	14	7 (50.0)	7 (50.0)	0.31
No	40	12 (30.0)	28 (70.0)	
Bladder volume (IST) (ml)				
<200	19	8 (42.1)	11 (57.9)	0.97
200–<400	26	10 (38.5)	16 (61.5)	
≥400	33	13 (39.4)	20 (60.6)	

BMI: Body mass index, iPSA: Initial prostate-specific antigen, NS: Nerve sparing, IST: Intraoperative stress urodynamic test, IPSS: International Prostate Symptom Score

Table 3: Univariate and multivariable logistic regression analysis for the outcome postprostatectomy incontinence in the "sufficient intraoperative urodynamic stress test" subgroup of patients

	Outcome	Univariate OR	Multivariate OR
IPSS	<8	1 (reference)	-
	8–19	3.29 (1.21–9.74, *P*=0.024)	2.98 (1.07–8.95, *P*=0.042)
	20–35	4.18 (0.56–85.27, *P*=0.216)	2.91 (0.36–61.70, *P*=0.371)
NS (cat)	Bilateral NS	1 (reference)	-
	Unilateral NS	1.79 (0.59–5.64, *P*=0.306)	1.56 (0.49–5.12, *P*=0.455)
	No NS	3.10 (1.05–9.70, *P*=0.045)	2.19 (0.68–7.35, *P*=0.193)

OR: Odds ratio, IPSS: International Prostate Symptom Score, NS: Nerve sparing

laparoscopic RPE. In their study, the extraprostatic tissue was an independent predictor of UI at 12 months ($P = 0.002$). With more than 10% of extraprostatic tissue in cruciate sections, they achieved a 71% sensitivity and an 82% specificity to predict UI at 12 months.[16]

Our goal was to investigate the individual value of an external sphincter, which is potentially fully capable of providing continence. To do so, we decided not to focus on anatomical conditions but on "real" intraoperative function of the sphincter. If the external sphincter was able to provide a sufficient urethral pressure to withstand physiological intravesical pressure, we wanted to detect synergistic parameters which lead to PPI. To our knowledge, this is the first study to provide a prospective intraoperative urodynamic examination thus far. That urodynamic changes occur after RPE/RALP has already been proven.[2]

Hammerer and Huland discussed the urodynamic changes found after open RPE.[8] They showed that the functional urethral length decreased from 61 mm preoperatively to 25.9 mm postoperatively. Between continent versus incontinent patients, a significant difference was found in regard to the maximal urethral closure pressure (68.1 vs. 53.1 cm H_2O) as well as the functional urethral length (27.6 vs. 20.5 mm). They postulated that urethral closure pressure as well as the functional urethral length and bladder stability are significant urodynamic factors that influence PPI.

The functionality and the correct coordination of smooth and striated muscle fibers, in combination with an appropriate MUL, can provide a return to continence after RPE/RALP.[3] Since the amount of these muscle fibers is associated with the MUL, the preoperative MUL and its intraoperative correct preservation correlate significantly with urethral pressure.[17]

In 2013, Dubbelman and Bosch published a systematic review of the urethral function before and after RPE and highlighted the importance of the urethral closure pressure

regarding the recovery time to continence after RPE.[18] The closure pressure of the urethral sphincter does not only influence the time to recovery but also correlates significantly with the extent of PPI.[19] In combination with the functional changes, anatomical changes can be observed that can possibly lead to PPI. They demonstrated this via magnetic resonance imaging after surgery.

Since normally, the maximal voiding detrusor pressure is defined at 40 cm H_2O and a higher pressure increases the risk of damage in the upper urinary tract,[20] we decided to fill up the bladder with fluid to this pressure level.

Romano *et al*. intraoperatively adjusted their implanted male slings by measuring retrograde urethral pressure.[21] In a multicenter trial, they proved that the urethral pressure within muscle-relaxed patients should range between 45 and 55 cm H_2O to achieve a social continence rate of 80% in patients that were completely incontinent before.

Interestingly, Cameron *et al*. showed a 2.6 times higher contraction of the urethral sphincter during the Kegel maneuver in continent men in comparison to incontinent men after RPE.[19] However, the Kegel maneuver is a voluntary pelvic floor contraction. We intraoperatively observed the loss of urine in potentially muscle-relaxed patients.

In our population (n = 107 patients), 82 patients had < 2 ml loss of fluid in the IST and 25 patients had ≥2 ml loss of fluid. Interestingly, there was no significant difference between these groups regarding their postoperative pad test (<2 ml: 37.8% vs. 48.0% and ≥2 ml: 62.2% vs. 52.0%, respectively, P = 0.5). This result shows that preserving muscle does not seem to be the only factor leading to continence. Damage to the neurovascular supply of the membranous urethra can occur because of the surgical intervention,[2] leading to sphincter dysfunction. Different surgical strategies were investigated to minimize those damages, but the evidence of a better sphincter function because of these strategies is still pending. Previous studies showed the significance of NS procedures, which seem to improve postprostatectomy continence or at least shorten the time to recovery.[2,22]

We analyzed the subpopulation of patients who performed "sufficiently" in the IST to evaluate potential predictors for PPI, even in those patients with a fully anatomically preserved and functioning sphincter.

As mentioned above, damage to the neurovascular supply of the membranous urethra can lead to dysfunction. If this is a voluntary function, damage will not be observed in muscle-relaxed and anesthetized patients. This could explain why, with higher abdominal pressure, the solitary function of the sphincter is not sufficient enough and needs its neurovascular supply to be capable of withstanding the pressure load.

Alongside the IPSS, we could demonstrate that the preservation of the neurovascular bundle (bilateral vs. no NS) might be predictive of a better continence result. If the sphincter is preserved well enough to withstand 40 cm H_2O in the IST and a NS was performed, there is a 3.1 higher chance to be continent in the early phase after RPE compared to patients with an equally functional sphincter but no NS.

Studies so far showed surrogate parameters to explain why sphincter malfunction occurs by measuring the urethral length or investigating urodynamics before and after RPE. The combination of a good functioning rhabdomyosphincter and its neurovascular control seems to be key. This issue completes the studies so far, which showed significant differences in continence rates in regard to the extent of resected external sphincter.

In our population, 62.2% (n = 51) of patients with sufficient IST still suffer from PPI. The control over a well-functioning sphincter seems to be as important as the well-preserved sphincter itself. This study can be the next step to understanding the etiology of PPI, since is the first study to use an IST, thereby underlining its relevance. The sufficient intraoperative closure pressure of the rhabdomyosphincter can be used as a surrogate parameter for a fully functioning external sphincter after prostate resection. According to the results of this study, the importance of the functional control of the external sphincter is high.

Another advantage of our study is that we defined PPI as any loss of urine (≥2 ml in postoperative pad test), since even these little amounts can have an impact on patients' QoL.

There are some limitations to this study, as well: the limited size of this experimental study might have caused underpowered statistical tests, especially for the logistic regression models.

Moreover, the results only refer to very early incontinence rates. Chances of recovering continence, even if there is an insufficient urethral closure pressure after RPE, seem feasible.[8,19] Continence recovery can last up to 2 years after

surgery,[23] although the main improvement is observed during the first 12 months. Therefore, a 1-year follow-up is crucial. Finally, it would have been very interesting to see whether there are risk factors that work synergistically to an insufficient sphincter function intraoperatively or vice versa. This has to be considered in future studies.

CONCLUSION

IST, as a surrogate marker for a well-functioning external sphincter, seems not to be a significant predictor for PPI. However, a fully obtained rhabdomyosphincter seems to be the optimal prerequisite for continence, since data show that an existing neurovascular supply of a functioning sphincter might be associated with a lower risk for PPI.

This study can be the next step to understanding the etiology of PPI, since is the first study to use an IST, thereby underlining its relevance.

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Conflicts of interest
The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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APPENDIX 1

Pad Test: [12]

The pad test was performed as follows:

- Documentation of the pad weight
- Emptying the bladder prior to test begin
- Placement of the pad in front of the meatus
- Asking the patient to:
    - Drink 500 ml water or tea in 20 min,
    - Go for a walk including taking the stairs for 30 min,
    - Cough hard 10 times,
    - Step on the spot for 10 min,
    - Do ten deep squats,
    - Wash their hands with warm water for 1 min, and
    - Micturate and measure the urine volume
        - Ultrasound analysis to evaluate the residual urine volume
        - Weighing of the used pad.

After the pad test, the following parameters were documented:

Pad weight at the beginning of the test, pad weight at the end of the test, urinary volume micturated, and residual urine volume after emptying the bladder.

The loss of urine into the pad was distinguished binarily into the categories "good continence" (<2 ml) and "bad continence" (≥2 ml) ("dry" vs. "wet"). These cutoffs were chosen to distinguish the completely "dry" patients from the rest. Because of the risk of measurement errors, 2 ml was chosen instead of 0–1 ml pad weight difference between the beginning and the end of the test. The same scale was consistently used to measure the pad weight.