



## Original article

## Early continence in patients with localized prostate cancer. A comparison between open retropubic (RRPE) and endoscopic extraperitoneal radical prostatectomy (EERPE)<sup>☆</sup>

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### Abstract

**Objective:** The study examined and compared continence rates in prostate cancer patients who had undergone either open retropubic prostatectomy (RRPE) or endoscopic extraperitoneal radical prostatectomy (EERPE). The core question was whether the surgical approach had an effect on the patients' continence status 3 months after surgery.

**Methods:** We conducted a multicentric, longitudinal study in 7 German hospitals. Three hundred fifty prostate cancer patients (166 EERPE, 184 RRPE) were asked to self-assess symptoms associated with urinary incontinence (UI) 1 day before and 3 months after prostatectomy. Symptoms of UI were assessed using the EORTC QLQ-PR25 questionnaire. Urinary continence was defined according to (1) the use of no protective pad, (2) the use of up to a single protective pad in a 24-hour period, and (3) according to the patient's self-assessment. A binary regression model was employed to predict early continence status.

**Results:** Three months after prostatectomy, 44% of patients who underwent EERPE and 40% of patients who underwent RRPE were completely continent. Patients who underwent nerve-sparing prostatectomy and patients younger than 65 years had a better chance of regaining urinary continence earlier. The surgical approach had no significant impact on the patients' continence status. Limitations of the study are a drop-out rate of 39% and sociodemographic and clinical differences between both treatment groups.

**Conclusions:** Three months after prostatectomy, there were no significant differences between both treatment groups regarding urinary continence. The surgical approach had no significant effect on the patients' continence status. Higher age and non-nerve-sparing surgery are associated with a longer period of convalescence. © 2011 Elsevier Inc. All rights reserved.

**Keywords:** Endoscopic; Health-related quality of life; Laparoscopic; Prostatectomy; Retropubic; Urinary continence

### 1. Introduction

With a yearly incidence of approximately 237,800 in Europe [1], prostate cancer is a major medical and socio-economic problem. In the USA, the 5-year survival rate of patients having localized prostate cancer is nearly 100% [2]. Thus, the focus of evaluation of new innovative treatment

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techniques has shifted from survival rates to health-related quality of life and functional outcome [3,4]. One critical dimension of functional outcome in the context of prostatectomy is urinary continence [5,6].

Patients with localized prostate carcinoma are offered several treatment options, including open retropubic prostatectomy (RRPE) and endoscopic extraperitoneal radical prostatectomy (EERPE). While RRPE has been established as a widespread treatment of localized prostate cancer since the 1980s [7], EERPE has recently become a first line therapy at specialized centers [8,9].

In fact, some studies show advantages of EERPE in clinical contexts, e.g., a shorter catheterization time and low intraoperative and postoperative complication rates [10], but the question of whether the 2 surgical techniques have a different impact on the patients' post-surgical continence status has not yet been addressed.

The current study is the first prospective multi-center study to compare functional results of patients who underwent open radical prostatectomy and minimally invasive radical prostatectomy where surgeons have not been involved in data evaluation and analysis. The analysis of data was conducted at the Department of Medical Psychology and Medical Sociology, University of Leipzig. In this paper, we report data related to urinary continence before (t0) and 3 months after (t1) prostatectomy. The core question of this paper is whether the kind of prostatectomy has a significant effect on post-surgical urinary continence. Since data from trials comparing RRPE with transperitoneal laparoscopic radical prostatectomy (LRPE) (a surgical approach similar to EERPE) suggest that there are no differences between both surgical techniques in terms of functional results [10], we do not expect significant differences between RRPE and EERPE regarding urinary incontinence either.

## 2. Materials and methods

We conducted a multicentric, longitudinal study in 7 German hospitals (located in the federal states of Saxony, Saxony-Anhalt, and North Rhine-Westphalia). Patients received a questionnaire 1 day before surgery in hospital and subsequently 3 months after surgery by mail. Presurgical data collection was carried out between February 2008 and May 2009, the subsequent data collection (3 months after surgery) was finished in September 2009.

### 2.1. Recruitment

In 2 participating centers, patients were recruited by interviewers, in 5 centers patients received the questionnaires from physicians. The two hospitals where EERPE was performed had a mean bed size of 1,457; the 5 hospitals where RRPE was performed had a mean bed size of 650 (1 hospital performed both EERPE and RRPE). Medical data

were gathered from (electronic) patient records. Three months after surgery, patients received a telephone call before the questionnaire was sent asking them to continue their participation in the study. Patients who had still failed to respond 2 weeks after reception were once again contacted by telephone and asked to complete the questionnaire.

The study was restricted to men with a first-time diagnosis of localized prostate cancer. To prevent different surgeons' experience from biasing results, both EERPE and RRPE were performed respectively by 2 surgeons per center with a personal experience of more than 200 cases in the last 5 years.

Written informed consent was obtained from all patients prior to their participation. The study was approved by the Ethics Committee of the University of Leipzig, Faculty of Medicine (approval no. 219–2007) and has therefore been performed in accordance with ethical standards.

### 2.2. Patient characteristics

About 50% of patients were aged between 61 and 70 years (range 45–81 years). EERPE patients were significantly younger than RRPE patients (1.6 years), had a better school education, and more often a private health insurance. The proportion of pensioners was significantly larger among RRPE patients.

The proportion of patients undergoing nerve-sparing surgery and lymph node dissection was significantly larger among RRPE patients. RRPE patients were at a more advanced pathologic stage and had a higher Gleason score than EERPE patients.

Between respondents (study participants) and non-respondents (patients who refused participation or were excluded from the study) there were no statistically significant differences regarding age, nerve-sparing status, and pelvic lymph node dissection. Participation rates of EERPE patients and RRPE patients were rather similar.

### 2.3. Variables

For the assessment of urinary incontinence, 3 different criteria were used:

1. The use of protective pads, with 0 pads being equivalent to urinary continence;
2. The use of protective pads, with up to 1 pad being equivalent to urinary continence;
3. The self-assessment of the patients, in answer to the question "Do you suffer from urinary incontinence?"

The symptoms of urge incontinence were assessed by the question "Do you feel sudden urges to urinate and subsequently lose urine without being able to avoid it?" Patients who answered this question with "occasionally," "frequently," or "always" were considered urge-incontinent.

Stress incontinence was assessed using the question: "In what situations do you involuntarily lose urine?" According to Stamey [11], patients who specified "when coughing" or "when sneezing" were ascribed a stress incontinence of grade of 1, patients who specified "when getting up" or "when sitting" were considered to have a stress incontinence of grade of 2, and patients who specified "when lying" or "always" were ascribed a stress incontinence of grade of 3.

The EORTC QLQ-PR25 is a multidimensional questionnaire of the "European Organization for Research and Treatment of Cancer" (EORTC) for the evaluation of prostate related quality of life [12]. Amongst others, this questionnaire comprises 3 symptom scales for the assessment of urinary symptoms, bowel symptoms, and the burden of symptoms caused by incontinence aids. A high score on these 0–100 scales indicates a high burden of symptoms.

### 2.4. Analysis

Statistical analysis was conducted with PASW 18 and MS Excel 2003. Cross-sectional differences between the 2 treatment groups were assessed using unpaired *t*-tests and  $\chi^2$  tests. Longitudinal differences were calculated using paired *t*-tests and  $\chi^2$  tests. Because this study has explorative status, no correction for multiple testing was applied. A binary logistic regression model (method: enter) was employed to test the influence of patient age, the kind of surgery, Gleason score, and presurgical PSA and urinary incontinence symptoms on the patients' postsurgical continence status.

Limitations of the present study were statistically significant differences between EERPE patients and RRPE patients both in sociodemographic (age, school education, health insurance, and employment status) and in clinical parameters (preservation of neurovascular bundles, pelvic lymph node dissection), which hampered the comparison between the 2 surgical techniques.

## 3. Results

### 3.1. Patients

In total, 576 patients underwent radical prostatectomy, of whom 89 patients had to be excluded from the study; 15 because of insufficient German language comprehension and 19 because they could not be met by the recruiters. In order to avoid biased results, patients who had a pathologic cancer stage of pT4 ( $n = 4$ ) and patients who answered the first questionnaire *after* surgery ( $n = 51$ ) were also excluded from the study.

Thus, 487 (237 and 250) patients were eligible to participate in the study, of whom 97 patients refused study participation at baseline. Reasons for patients not participating in the study were general refusal of study participation ( $n = 11$ ) and high psychic burden ( $n = 11$ ), 75 patients did not specify a reason for refusing to participate in the study. Thus, the baseline

participation rate was 80%. Three months after baseline, a further 40 patients did not answer the questionnaire.

In consequence, the total number of valid questionnaires returned was 390 (183 and 207), and 350 (166 and 184) at baseline and 3 months after baseline (for EERPE and RRPE patients), respectively (Tables 1 and 2).

### 3.2. Urinary incontinence

Three months after baseline, 44% of EERPE patients and 40% of RRPE patients had no need for any pad (complete continence), about 66% of EERPE patients and 63% of RRPE patients had no need for more than a single protective pad in a 24-hour period, and 39% of EERPE patients and 46% of RRPE patients assessed themselves as continent (see Table 3). There were no statistically significant differences between the 2 treatment groups for either definition of continence. On the other hand, the continence rate with continence being defined as no need for more than 1 pad was significantly higher than the rates of complete continence and the continence rate according to the patients' self-assessment (Table 4).

Fifty-two percent and 53% had symptoms of urge and 61% and 66% (EERPE patients/RRPE patients) had symptoms of stress incontinence with no significant differences between the treatment groups. Overall, 43% of patients had symptoms of both urge and stress incontinence (not in table). Ten percent and 13% had symptoms of high-grade urge incontinence, 2% and 6% had symptoms of high-grade stress incontinence (EERPE patients/RRPE patients).

### 3.3. The burden of symptoms

The EORTC QLQ-PR25 symptom scales give information about the burden of urinary and bowel symptoms and symptoms caused by incontinence aids (pads).

According to Osoba et al., longitudinal changes of more than 5 points on a 0–100 EORTC QLQ-PR25 scale must be considered clinically meaningful. Moreover, changes of 5–10 points can be classified as "little," changes of 10–20 points as "moderate," and >20 points as "very much" change [13].

Three months after baseline, the burden of urinary symptoms had significantly increased for both treatment groups irrespective of the nerve-sparing status.

According to Osoba's classification, the changes in EERPE patients and RRPE patients who underwent nerve-sparing surgery were "little" and the changes in EERPE patients and RRPE patients not eligible for nerve-sparing surgery were "moderate." The burden of bowel symptoms was generally very low. Longitudinal differences were not statistically significant.

Since only 14 patients used incontinence aids at baseline, it was pointless to assess longitudinal differences of the burden of symptoms associated with incontinence aids. Three months after baseline, 55% of EERPE patients and 51% of RRPE patients were using incontinence aids.

Table 1  
Sociodemographic and clinical baseline characteristics of the study population

	EERPE		RRPE		P value
Age (Mean $\pm$ SD)	166	64.2 $\pm$ 6.8	184	65.8 $\pm$ 6.2	0.022*
$\leq$ 65 years	85	51%	78	42%	0.099
>65 years	81	49%	106	58%	0.099
Family status: married	137	83%	164	90%	0.055
Partnership: yes	155	94%	178	97%	0.127
School education: higher level	80	49%	63	35%	0.008**
University education	78	48%	54	30%	0.001**
Health insurance: private	50	30%	23	13%	0.001**
Employment status					
Pensioner	99	60%	138	75%	0.002**
Employed	59	36%	42	23%	0.009**
Therapy	166	47%	184	53%	n/a
Nerve-sparing of which	89	54%	132	72%	0.001**
bilateral nerve-sparing	63	71%	96	73%	0.753
Pelvic lymph node dissection	92	56%	167	92%	0.001**
Positive surgical margins	23	14%	31	17%	0.453
PSA ng/ml (mean $\pm$ SD)	166	8.7 $\pm$ 6.7	184	8.5 $\pm$ 6.4	0.709
Pathologic stage					
pT1a–pT1c	1	1%	3	2%	n/a
pT2a–pT2c	128	77%	123	67%	0.033*
pT3a–pT3b	37	22%	58	32%	0.052
Gleason score					
Gleason 4	0	0%	1	1%	n/a
Gleason 5–6	78	47%	61	33%	0.008**
Gleason 7	67	40%	98	53%	0.016*
Gleason 8–10	21	13%	23	13%	0.966
Grading					
Grading 1–2	72	43%	63	34%	0.080
Grading 3	93	56%	113	61%	0.306

n/a = not applicable.

\*  $P < 0.05$ .

\*\*  $P < 0.001$ .

EERPE patients not eligible for nerve-sparing surgery had a significantly higher burden of symptoms than EERPE patients who underwent nerve-sparing surgery (+14.9 points). In RRPE patients, this difference was not statistically significant (+3.2 points).

### 3.4. Predictors of early continence

A binary logistic regression model was employed to test the influence of several factors on the patients' post-surgical continence status. In this model, continence was defined as no need for any pad. As potential factors, we considered the kind of prostatectomy (EERPE vs. RRPE), nerve-sparing status, patient age, presurgical PSA, Gleason score, and the burden of

urinary symptoms before surgery. Gleason score and urinary symptoms before surgery were excluded from the model because both variables significantly correlate with patient age (the older the patient, the higher/more pronounced the Gleason score/urinary symptoms). The age stratification ( $\leq$ 65 vs. >65) was chosen to make the results of the current study comparable to others studies dealing with EERPE [9].

Patients who underwent nerve-sparing surgery had an 87% (OR = 1.87; 95% CI: 1.14–3.07; SE = 0.25;  $P < 0.05$ ) higher chance of regaining urinary continence 3 months after surgery. In patients younger than 65, this chance was about 58% higher than in patients older than 65 years of age (OR = 1.58; 95% CI: 1.01–2.46; SE = 0.23;  $P < 0.05$ ).

Table 2  
Sociodemographic and clinical baseline characteristics of respondents vs. non-respondents

	Respondents		Non-respondents		P value
Age (Mean $\pm$ SD)	350	65.1 $\pm$ 6.5	226	65.1 $\pm$ 6.7	0.955
Nerve-sparing of which	220	63%	123	55%	0.058
bilateral nerve-sparing	159	72%	94	78%	0.247
Pelvic lymph node dissection	259	75%	167	76%	0.707

Table 3  
Urinary Continence 3 months after surgery and additional therapies

Urinary continence	EERPE		RRPE		P
	n	%	n	%	
Use of pads per day					
0 pads	73	44%	73	40%	0.44
1 pad	37	22%	42	23%	0.904
2–3 pads	38	23%	39	21%	0.702
≥4 pads	18	11%	29	16%	0.178
Patients' self-assessment	65	39%	85	46%	0.169
Urge incontinence					
Never	79	48%	86	47%	0.873
Occasionally	70	42%	73	40%	0.635
Frequently/always	17	10%	24	13%	0.662
Stress incontinence					
None	65	39%	62	34%	0.289
Grade 1	45	27%	54	29%	0.642
Grade 2	53	32%	57	31%	0.848
Grade 3	3	2%	11	6%	0.047*
Inpatient rehabilitation	100	60%	125	69%	0.1
Perineal floor exercises	120	73%	144	80%	0.136
Medication against urine loss	7	4%	13	7%	0.449
Surgery against urine loss	0	0%	0	0%	n/a

\*  $P < 0.05$ . n/a = not applicable.

Forty-eight percent of patients who underwent nerve-sparing surgery vs. 31% of patients who underwent non-nerve-sparing surgery were completely continent 3 months after surgery ( $P = 0.002$ ). Regarding age, 49% of patients up to 65 years vs. 35% of patients older than 65 years were completely continent ( $P = 0.01$ ).

The kind of surgery (EERPE vs. RRPE) and presurgical PSA had no significant influence on the patients' continence status 3 months after baseline.

### 3.5. Rehabilitation and additional therapies

About two-thirds of the patients (60% EERPE patients; 69% RRPE patients) attended inpatient rehabilitation hospitals after surgery and about three-fourths of patients (73%

EERPE patients; 80% RRPE patients) did pelvic floor exercises in order to regain urinary continence. Patients who were incontinent attended rehabilitation and did pelvic floor exercises significantly more often ( $P < 0.001$ ) than continent patients.

No patient underwent additional surgery against urine loss but about 6% of patients (4% EERPE patients; 7% RRPE patients) took medication (above all urologic spasmolytics) against urine loss.

## 4. Discussion

The purpose of this paper was to test whether the kind of prostatectomy chosen (EERPE vs. RRPE) had an effect on the patients' continence status 3 months after surgery.

Urinary continence was defined according to 3 criteria. Concordant continence rates were obtained according to continence defined as no need for any pad and according to patient self-assessment. However, the continence rate defined as no need for more than a single protective pad in a 24-hour period was significantly higher and not concordant with patient self-assessment. Thus, use of no pad seems to be a more precise measure for urinary continence than use of one pad.

Generally, reported continence rates (with 0 pads) vary greatly [14]. Three months after retropubic and laparoscopic prostatectomy, continence rates range between 17% [15] and 76% [16,17]. Continence rates reported for EERPE are within this range [8,9,18]. The reason for the discrepancy between reported continence rates may have something to do with different clinical and sociodemographic characteristics of patients. However, according to Herrmann et al., it is the heterogeneity of methodology having the largest impact on the results. Trials using questionnaires for the evaluation of postoperative incontinence report lower continence rates than trials merely relying on the physicians' assessment [19]. Furthermore, there are some publications including patients using 1 single pad per day in the complete continence group [19]. In the current study, the strict definition of complete continence (no pads) was used. Thus,

Table 4  
Symptom scales of the EORTC QLQ-PR25 at baseline and 3 months after surgery

Domain	EERPE			RRPR		
	t0	t1	P	t0	t1	P
Nerve-sparing	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
Urinary symptoms	18.1 ± 14.3	27.2 ± 17.4	0.001*	21.7 ± 15.3	29.4 ± 18.6	0.001
Bowel symptoms	2.9 ± 6.2	4 ± 7.4	0.339	3.5 ± 6.3	4.3 ± 9.2	0.253
Incontinence aid	n/a	32.6 ± 35.6	n/a	n/a	37.4 ± 34	n/a
Non-nerve-sparing	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
Urinary symptoms	22.5 ± 17.7	36.5 ± 20.2	0.001*	26.1 ± 20	38.8 ± 21.5	0.001*
Bowel symptoms	4.7 ± 11.6	6.1 ± 10.5	0.266	6.4 ± 11.9	5.6 ± 9.1	0.589
Incontinence aid	n/a	47.5 ± 33.1	n/a	n/a	41.4 ± 37.2	n/a

n/a = not applicable.

\*  $P < 0.001$ .

only 44% and 40% of patients (EERPE, RRPE) were completely continent 3 months after prostatectomy. If we included patients wearing up to 1 pad per day, the continence rates were 66% and 63% (EERPE, RRPE).

Regarding factors predicting early return of continence, our findings differ from those of Lepor and Kaci [20], who found that age and nerve-sparing status did not predict early return of continence. This discrepancy may be due to the different statistical models (GLM vs. binary logistic regression) used to analyze the data. However, our results are broadly consistent with those of Burkhard [21], who found that neurovascular bundle preservation improves the chance of remaining continence. The relatively low burden of bowel symptoms in patients after prostatectomy accords with the findings of Schmeller [22].

Our data show that EERPE and RRPE offer similar outcome in terms of urinary continence 3 months after surgery. Rather than the kind of prostatectomy, it is the preservation of neurovascular bundles and a younger age ( $\leq 65$  years) that significantly improve the probability of patients regaining urinary continence 3 months after surgery. Patients older than 65 years and patients not eligible for nerve-sparing surgery suffered most strongly from urinary incontinence and must reckon with a longer convalescence period. Physicians should address this impairment when advising patients.

In future trials, the patients' continence status should be defined and evaluated using validated questionnaires and not by clinicians. Generally, uniform standards and instruments to measure postoperative incontinence are needed [23]. In order to receive a more comprehensive overview on the patients' continence status, further information is required, e.g., the patients' self-assessment and knowledge about the type of incontinence (urge and stress incontinence).

In fact, an assessment of long-term differences in urinary continence between the 2 treatment groups would be interesting. Yet, according to Anastasiadis et al., long-term differences between retropubic and laparoscopic surgery regarding urinary continence are even less likely than short-term differences [17].

Thus, subsequent trials should assess whether there are more short-term differences between the 2 patient groups in regaining continence. Since a quicker return of complete continence could save costs for rehabilitation and health insurance, such differences could be economically meaningful.

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