

ERECTILE DYSFUNCTION

A Retrospective Study of Erectile Function and Use of Erectile Aids in Prostate Cancer Patients After Radical Prostatectomy in Denmark



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ABSTRACT

Introduction: Radical prostatectomy (RP) offers a good long-term cancer control for clinically localized prostate cancer. However, complications such as erectile dysfunction and substantial decreases quality of life of the afflicted men and their sexual partners. Identification of pre-, per-, and postoperative factors that correlate with poor postoperative erectile status must be considered an important step to improving penile rehabilitation.

Aim: To describe postoperative erectile function after RP in a Danish cohort.

Methods: The medical records of 1,127 patients undergoing RP from March 2003 through September 2014 were reviewed retrospectively with a 12-month follow-up after surgery. In all, 704 patients fulfilling the inclusion criteria were included in the final analysis. Recovery was defined as self-reported erection sufficient for intercourse (ESI) with or without usage of erectile aids.

Main Outcome Measures: Subjective reporting of erectile function and usage erectile aids 12 months after RP.

Results: ESI with or without erectile aids was reported by 226 men (32.1%), among whom 109 (48.2%) required erectile aids. Erectile dysfunction (ED) was reported by 478 men (67.9%) and by 121 (25.3%) despite use of erectile aids. Of men with ED, 155 (22%) stated not being interested in penile rehabilitation, 26 (3.7%) stated not having resumed their sex life 12 months after RP, and 241 (34.2%) had ED and were unsatisfied with the condition. We found that 134 of 445 men (30.1%) who underwent non-nerve-sparing RP had ESI 12 months after RP. Age older than 60.5 years, a high body mass index, comorbidity, and a high American Society of Anesthesiologists score were negative predictors of erectile function 12 months after RP.

Conclusion: Twelve months after RP, 32.1% of men had ESI; half these men required the use of erectile aids. Age older than 60.5 years, a high body mass index, comorbidity, and a high American Society of Anesthesiologists score were negative predictors for ED 12 months after RP. **Haahr MK, Azawi NH, Andersen LG, et al. A Retrospective Study of Erectile Function and Use of Erectile Aids in Prostate Cancer Patients After Radical Prostatectomy in Denmark. Sex Med 2017;5:e156–e162.**

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Key Words: Erectile Aids; Erectile Dysfunction; Penile Rehabilitation; Prostate Cancer; Radical Prostatectomy

INTRODUCTION

Prostate cancer (PCa) is the most commonly detected cancer in men in developed countries, with nearly 800,000 new annual

cases, of which 325,000 occur in Europe.¹ PCa is the most common male malignancy in Denmark, with an incidence of 4,577 in 2014.² In Denmark, PCa has followed an increasing trend during the past decade, increasing by 35%, and the 2025 prevalence is expected to reach 90,000 cases.²

Radical prostatectomy (RP) or radiation therapy is the curative treatment option recommended for patients with localized disease. RP offers good long-term cancer control for clinically localized PCa,³ and the nerve-sparing technique is the treatment of choice for localized PCa in sexually active men.⁴ Complications such as erectile dysfunction (ED) are feared by all men undergoing RP because of its effects on the quality of life for the man and his partner.⁵

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Other side effects of RP include loss of ejaculate, penile shortening, change of orgasmic feeling, alterations in body image, stress incontinence, disturbances in partner relationships, and various types of anxiety.⁶ Managing penile rehabilitation should include sexual rehabilitation addressing these issues to help men cope with and accept a different sexual life. Evaluation and treatment should be informed by a patient's motivation, expectations, and physical and mental health.

Functional outcomes after RP reported in the literature vary widely with respect to sexual function depending on study design, extent of follow-up, choice of outcome, patient age, comorbidity, perioperative erectile status, type of surgery, high- vs low-volume centers, and the extent of appropriate penile rehabilitation.^{7–16}

The highest erectile function (EF) recovery rates are reported from single-center and single-surgeon series with a large number of patients. Many studies have reported on populations that are likely younger than what is seen in the community.¹⁷ This patient selection bias generally serves only to enrich the population and augment the data on EF recovery, and therefore it seems reasonable to question whether the results can be extrapolated to the general population.⁷

The objective of the present study was to describe postoperative EF after RP in a Danish cohort and to identify any predicative factors for EF.

METHODS

Settings and Patients

Data from 1,127 consecutive patients diagnosed with PCa who underwent RP from March 2003 through September 2014 at the Department of Urology in the Odense University Hospital (Odense, Denmark) were collected retrospectively from patient records and analyzed. The operations were classified according to the Nordic Medico-Statistical Committee Classification of Surgical Procedures. To obtain data on the number and type of RPs performed per year, a search was carried out for procedure codes KEC00 (radical retropubic prostatectomy), KEC01 (percutaneous endoscopic RP), KEC10 (perineal RP), and KEC20 (transsacral RP). KEC01 includes laparoscopic and robotic RPs, but they can be identified by the secondary code ZXC96 used for robot-assisted procedures. All procedures also were coded according to neurovascular bundle preservation. The department would be classified as a low-volume center (1–29 RPs) in 2003 to 2007, a medium-volume center (30–53 RPs) in 2008 to 2009, a high-volume center (54–105 RPs) in 2010, and a very high-volume center (>105 RPs per year) after 2010. Permission to conduct the study was obtained from the Danish Data Protection Agency (file number 2008-58-0035) and the Danish Health Authority (file number 3-3013-1347/1/) in accordance with Danish legislation.

Exclusion Criteria

We excluded men who were referred to their hometown hospital before a full 12-month postoperative check-up, who had

PCa relapse within a year, who died or were diagnosed with a serious illness that caused interruption of their routine follow-ups, and who reported ED before undergoing RP (Figure 1).

Medical Record Data

Pre- and postoperative variables were retrieved from the patient records. The following variables were recorded: age, prostate-specific antigen (PSA) level, smoking and intake of alcohol, medication, body mass index (BMI), spinal problems, comorbidity, American Society of Anesthesiologists (ASA) classification,¹⁸ type of surgery, Gleason score,¹⁹ pathologic tumor (pT) stage and surgical margin status, postoperative cancer control, and EF at 12 months. Information on preoperative status was assessed by the International Index of Erectile Function–5 or by direct questions. EF was categorized as unknown, EF sufficient for intercourse (ESI), and ED. The last group included men who had not resumed their sex life, men who were not interested in penile rehabilitation, and sexually active men who could not achieve ESI.

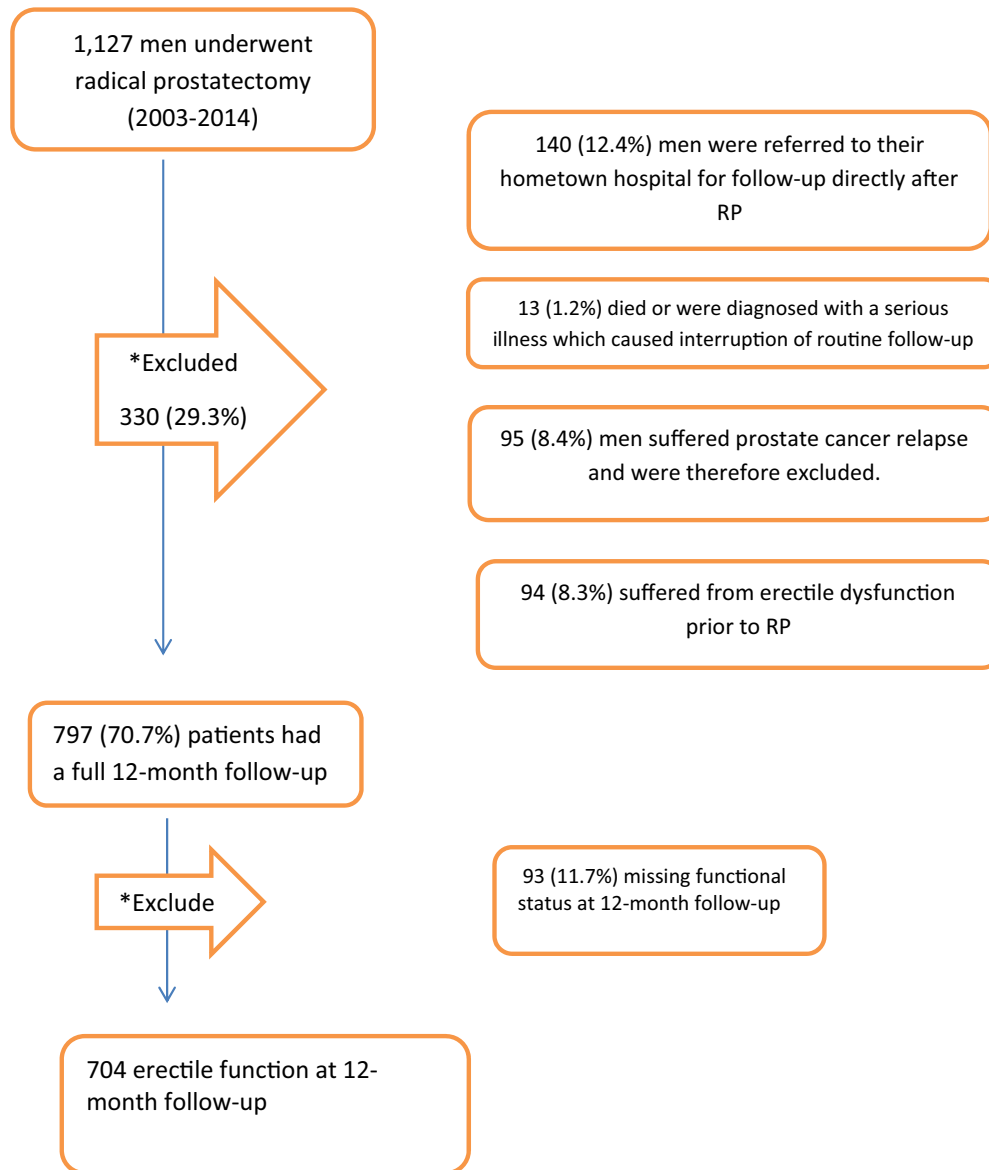
Statistical Methods

Descriptive data were analyzed using the χ^2 test and Fisher exact test, and continuous variables were analyzed by t-test and analysis of variance. Multivariate analysis was performed using logistic regression in which ED and urinary incontinence were the dependent variables and age, BMI, PSA, comorbidity, surgical technique, pT stage, and Gleason score were the independent variables. A *P* value less than .05 was considered statistically significant. To select the threshold point of age related to EF, the receiver-operating characteristics curve analysis was used. Data are presented as mean and SD. Statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

A total of 704 men with a median age of 62 years (SD = 5.8) and a median BMI of 26.7 kg/m² (SD = 3.2) were enrolled in the study. Postoperative ED was seen in 478 men (67.9%) and ESI was reported by 226 (32.1%). A normal BMI (<24.9 kg/m²) was seen in 127 men (18.0%), 220 men (31.3%) were overweight (BMI < 29.9), and 64 (9.9%) were obese (BMI > 30). In the ED group, 345 men (72.2%) had a comorbidity of whom 208 (43.5%) had hypertension; in the ESI group, only 117 (51.8%) had a comorbidity of whom 66 (29.2%) had hypertension (Table 1). We found a significant difference between ASA scores of the ED and ESI groups (*P* < .01; Table 1). In all, there were 119 smokers (16.9%), and 105 men (18.7%) had an alcohol problem (Table 1). Men in the ESI group were significantly younger (mean age = 60 years; *P* < .01), had a lower prevalence of hypertension (*P* < .05), and had a lower ASA score (*P* < .01) than men who reported ED (Table 1).

There was no significant difference (*P* < .13) in PSA between the ED group (mean = 10.6, SD = 8.1) and the ESI group



* Some patients were excluded based on several criteria

Figure 1. Flowchart showing the inclusion process. RP = radical prostatectomy.

(mean = 9.8, SD = 6.2). Nerve-sparing RP (NSRP) was performed in 259 patients (36.8%), among whom 74 (10.5%) had unilateral nerve-sparing RP (UNSRP). The number of UNSRPs performed was small, and we found no significant difference in ESI between UNSRP (36.5%) and bilateral NSRP (35.2%; Table 2). All NSRPs were performed after 2010 and 92 men (35.5%) in the NSRP group reported ESI 12 months after surgery. We found that 134 of the 445 men (30.1%) who underwent non-NSRP (NNSRP) had ESI 12 months after RP (Table 2). Men in the ESI group had a lower Gleason score ($P < .02$) and had undergone more extensive NSRP ($P < .04$; Table 2) than men in the ED group. There was no significant difference in positive surgical margin between the two groups ($P > .56$).

Preoperative sexual function was stated in the patient record in only 27 cases (3.9%), and 10 men (1.4%) used erectile aids before RP. Overall, postoperative ED was reported by 478 men (67.9%).

The group of men reporting ED included 155 (22%) who were not interested in penile rehabilitation and 26 (3.7%) who stated that they had not resumed their sex life 12 months after RP (Table 3). One third of men (241) stated being sexually active but could not achieve ESI despite using erectile aids or having tried erectile aids. Of these men, 36 (14.9%) reported ED despite continuously using erectile aids (injection therapy in 2.5%, phosphodiesterase type 5 inhibitor [PDE-5i] in 12.5%); 91 (37.8%) had tried PDE-5i and 4 (1.7%) had

Table 1. Demographics and clinical data of the cohort*

Characteristics	Total	Erectile dysfunction	Erectile function sufficient for intercourse	P value
Subjects	704	478 (67.9)	226 (32.1)	
Patient age (y)	62 ± 5.8	63.2 ± 5.5	60 ± 5.9	<.01
Age < 63 y	387	230	157	<.0001
Age > 63 y	317	248	69	
Body mass index (kg/m ²)	26.7 ± 3.2	26.7 ± 3.2	27.0 ± 3.2	<.02
Not stated	293 (41.6)	189 (39.5)	104 (46)	
Normal > 19	127 (30.9)	99 (34.3)	28 (23)	
Overweight > 25	220 (53.5)	146 (50.5)	74 (60.7)	
Obese > 30	64 (15.6)	44 (15.2)	20 (16.4)	
Smoker	119 (19.3)	77 (18)	42 (22.1)	.27
Alcohol overuse	105 (18.7)	70 (18)	35 (20.4)	.07
Diabetes	27 (3.8)	22 (4.6)	5 (2.2)	.15
Hypercholesterolemia	161 (22.9)	115 (24.1)	46 (20.4)	.28
Hypertension	274 (38.9)	208 (43.5)	66 (29.2)	<.05
ASA PS 1	273 (40.1)	166	107 (48.9)	<.01
ASA PS 2	387 (56.9)	278	109 (49.8)	
ASA PS 3	20 (2.9)	17	3 (1.4)	
ASA PS not stated	24 (3.5)	17 (3.6)	7 (3.1)	

ASA PS = American Society of Anesthesiologists Physical Status.

*Data are presented as mean ± SD or number (percentage).

tried injection therapy (Table 3). Of men who reported being sexually active but unable to achieve ESI, 117 (48.5%) were referred for further sexual rehabilitation at their 12-month

follow-up (Table 3). Of men who reported erectile recovery, 108 (47.8%) used erectile aids (90 men [39.8%] used PDE-5i and 18 men [8.4%] used injection therapy). Of men who

Table 2. Surgical and pathologic characteristics of cohort*

Characteristics	Total	Erectile dysfunction	Erectile function sufficient for intercourse	P value
Subjects	704	478 (67.9)	226 (32.1)	
Preoperative PSA (ng/mL)	10.0 ± 5.6	10.6 ± 8.1	9.8 ± 6.2	.13
Surgical approach				
Open	524 (74.4)	353 (73.8)	171 (75.7)	
RALP	180 (25.6)	125 (26.2)	55 (24.3)	.64
Nerve-sparing status				
None	445 (63.2)	346 (72.4)	134 (59.3)	
Unilateral	74 (10.5)	35 (7.3)	27 (11.9)	<.04
Bilateral	185 (26.3)	97 (20.3)	65 (28.8)	
Pathologic tumor stage				
T1–T2a	48 (6.8)	25 (5.24)	23 (10.2)	
T2b	17 (2.4)	11 (2.3)	6 (2.7)	.17
T2c	552 (78.4)	379 (79.3)	173 (76.5)	
pT3a + b	60 (8.5)	44 (9.2)	16 (7.1)	
T3b	27 (3.8)	19 (4)	8 (3.5)	
Gleason score				
≤6	121 (17.1)	68 (14.3)	53 (23.5)	<.02
3 + 4	392 (55.7)	270 (56.5)	122 (54)	
4 + 3	148 (21.1)	111 (23.4)	37 (16.4)	
8	28 (4)	18 (3.8)	10 (4.4)	
≥9	15 (2.2)	11 (2.3)	4 (1.8)	
Positive surgical margins	109 (15.5)	76 (10.8)	33 (14.6)	.56

PSA = prostate-specific antigen; RALP = robot-assisted laparoscopic prostatectomy.

*Data are presented as mean ± SD or number (percentage).

Table 3. Results of erectile function 12 months after radical prostatectomy

ED	478 (67.9%)
1. Lack of interest in penile rehabilitation	155 (22%)
2. Did not resume sex life	26 (3.7%)
3. No further elaborated ED	56 (8.0%)
4. Sexually active but could not achieve ESI	241 (34.2%)
Using PDE-5i	30 (12.5%)
Using injection therapy	6 (2.5%)
Tried PDE-5i*	91 (37.8%)
Tried injection therapy*	4 (1.7%)
Referred for further sexual rehabilitation*	117 (48.5%)
ESI	226 (32.1%)
PDE-5i	90 (39.8%)
Injection therapy	18 (8.4%)
Using vacuum erect device	1 (0.4%)
Not stated	40 (17.7%)

ED = erectile dysfunction; ESI = self-reported erection sufficient for intercourse; injection therapy = intracavernous injections of alprostadil; PDE-5i = phosphodiesterase type 5 inhibitor.

*Some patients might be in more than one group. No patient had been using intraurethral agents and none had been offered penile prosthesis placement.

reported erectile recovery, 117 (51.8%) did not use erectile aids (Table 3).

In univariate analysis, older age ($P < .3$) and PSA ($P < .1$) showed no association with erectile outcome. In bivariate analysis, hypertension ($P < .0003$), ASA score ($P < .01$), NNSRP ($P < .05$), and Gleason score ($P > .02$) were significant predictors of a poor outcome for EF. Smoking, alcohol overuse, pT stage, preoperative PSA, and surgical techniques (robot-assisted vs open procedure) were not confirmed as significant predictors of ED ($P < .05$). ESI showed a trend ($P < .09$) toward improvement after 2010, when NNSRP was implemented. Patients no older than 60.5 years showed better EF in the receiver-operating characteristics curve analysis.

In the multivariable analysis, age older than 60.5 years ($P < .01$, 95% confidence interval [CI] = 0.14–1.08), a high BMI ($P < .01$, 95% CI = –0.79 to 0.08), a high ASA score ($P < .15$, 95% CI = 0.15–1.12), and NNSRP ($P < .05$, 95% CI = 0.006–0.52) remained predictors of a poor outcome for EF.

DISCUSSION

Our study showed that ESI was reported by 226 men (32.1%) after RP, 117 (51.7%) of whom did not use erectile aids. Age, BMI, NNSRP, and ASA score were the most important factors predicting a positive outcome. Another factor likely contributing to the observed improvement was the volume of operations; the number of patients receiving surgery increased from more than 50 per year before 2010 to more than 150 per year after 2010; this trend has been reported in the literature.⁷ In April 2012, a three-armed da Vinci Robotic System (Intuitive Surgical, Sunnyvale,

CA, USA) was installed in our department. Before the introduction of this system, all RPs were performed as open RPs.

Our data show that men undergoing RP in Odense have approximately the same erectile outcome as men reported in other similar studies. Østby-Deglum et al²⁰ reported erectile recovery in 25% of men 1 to 6 years after robot-assisted laparoscopic prostatectomy (RALP), Riikonen et al²¹ found that 25.7% could have intercourse with or without the use of PDE-5i at 1 year after RALP, and Haglund et al²² reported 30% erectile recovery 12 months after RALP and 25% recovery after open RP irrespective of the surgical technique used. Our study compares well with these studies in geographic area, flow of operations, age, preoperative PSA, BMI, and proportion with cardiovascular comorbidity. Mandel et al²³ reported a 33% recovery rate regardless of surgical technique. A similar Danish study of 418 patients comparing RALP with open RP showed a 12-month recovery rate of 28.9% among men after open RP and 36.3% after RALP.²⁴ The ideal follow-up is not 12 months, because there are indications that the median time to return of intercourse is 340 days.¹⁵

Our study showed that patients with a normal BMI, who were younger than 60.5 years old, who had no cardiac disease, and who underwent NSRP showed the greatest improvement in EF during the first 12 months. These features also were reported as important predictors of EF after RP in other studies.¹⁵

We found that 30.1% of men who underwent NNSRP and 35.5% who underwent NSRP had ESI 12 months after RP. There is no obvious explanation for this. However, because focus on sexuality has been limited, preoperative EF has not been systematically assessed. Therefore, we speculate that the most suitable patients might not have been selected for NSRP. The preoperative assessment of an RP candidate is the first compulsory step in managing postoperative ED. This allows for correct assessment of the potential risk of postsurgical ED, allowing the surgeon to properly counsel the patient regarding the optimal treatment, taking into account the patient's wishes and expectations, and performing an oncologically safe procedure.

In general, patients who undergo NNSRP are not considered candidates for penile rehabilitation. In this cohort, we found a larger proportion with ESI than anticipated among those who underwent NNSRP. We recommend that a penile rehabilitation program be offered to all patients who have EF before surgery, regardless of the surgical technique used.

In the present study, postoperative care involved routine follow-up. All patients had an outpatient appointment with their surgeon 8 to 10 days after the operation to have their catheter removed and to receive their histologic results. The patients visited our clinic at 3, 6, 9, and 12 months after surgery. The follow-up program included pelvic floor exercises for all patients to promote urine continence recovery. Penile rehabilitation was not provided by standard instructions although this has been recommended by an international expert panel.²⁵

Recommendations regarding the use of erectile aids were individually determined depending on the surgeon's assessment and the patient's choice. Since October 2013, we have offered sexual counseling to all men with ED, including medical history, risk factors, sexual history, sexual habits, and relationships. Because there is no clear benefit of one rehabilitation strategy over another,²⁶ the appropriate rehabilitation strategy is chosen based on the patient's choice and the surgeon's objective information.

The limitations of our study include its retrospective design, the mode of assessment used, and inadequate information about preoperative sexual function. The strength of the study is the number of patients and the fact that we implemented a full 12-month follow-up. Mulhall⁷ described 10 methodologic requirements for studies reporting outcomes after RP. The present study fulfilled seven of them. We did not use validated questionnaires, had only 12 months of follow-up data, and baseline data on EF were insufficient for calculation of the rates of men returning to their normal function after RP.

CONCLUSION

We found that 32.1% of men who underwent RP subsequently had ESI and that half these men needed erectile aids. Age older than 60.5 years, a high BMI, more comorbidities, and a high ASA score predicted poor EF 12 months after RP. We recommend counseling before surgery and a penile rehabilitation program for this group of men.

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