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Prostate Cancer

Unexpected Long-term Improvements in Urinary and Erectile Function in a Large Cohort of Men with Self-reported Outcomes Following Radical Prostatectomy

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Abstract

Background: It is generally assumed that if a man does not regain urinary continence or erectile function within 12 mo of radical prostatectomy (RP), then the chance of subsequent recovery is low.
Objective: To determine the probability of achieving good urinary function (UF) or erectile function (EF) up to 48 mo postoperatively in men who reported poor UF or EF at 12 mo after RP.
Design, setting, and participants: We identified 3187 patients who underwent RP from 2007 through 2013 at a tertiary institution and had extended multidisciplinary follow-up with patient-reported UF and EF scores at ≥12 mo.
Intervention: Open or minimally invasive RP.
Outcome measurements and statistical analysis: Primary outcome was good UF as defined by a urinary score ≥17 (range: 0–21) or good EF as defined by a modified International Index of Erectile Function-6 score ≥22 (range: 1–30). The probability of functional recovery beyond 12 mo was determined by Kaplan-Meier analyses.
Results and limitations: Among patients incontinent at 12 mo, the probability of achieving good UF at 24, 36, and 48 mo was 30%, 49%, and 59%. In patients experiencing erectile dysfunction at 12 mo, the probability of recovering EF at 24, 36, and 48 mo was 22%, 32%, and 40%. On multivariable analyses, 12-mo functional score and age were associated with recovery, but only score was consistently significant.
Conclusions: Men with incontinence or erectile dysfunction at 12 mo have higher than anticipated rates of subsequent functional improvement. Probability of recovery is strongly influenced by score at 12 mo. Further research should address the impact of ongoing multidisciplinary follow-up care on our observed rates of recovery.
Patient summary: Many prostate cancer patients continue to recover urinary and erectile function after 12 mo. The level of functional recovery by 12 mo is associated with long-term recovery and should be discussed by the physician and patient when deciding on rehabilitative interventions.

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1. Introduction

An estimated 220 000 new prostate cancer (PCa) cases will be diagnosed in the United States in 2015 [1]. Radical prostatectomy (RP) remains the most common treatment option, with 52% of men ≤64 yr undergoing RP between 2009 and 2011 [2]. However, RP is associated with adverse effects [3–5], and both urinary incontinence and erectile dysfunction (ED) can impose a significant burden on patients [6–8].

The time course of improvement in urinary incontinence or ED is not fully understood. Physicians commonly tell patients based on published reports that there is little recovery in urinary function (UF) and erectile function (EF) beyond 12–24 mo after RP. While many studies characterize these outcomes, they provide average scores or recovery rates of all patients relative to baseline function and are more suitable for preoperative counseling [9,10]. There is a paucity of studies that consider how much postoperative function a patient has recovered when assessing long-term recovery, which makes it difficult to apply current evidence when counseling men with incontinence or ED following surgery.

The purpose of our study was to determine the long-term probability of achieving UF or EF for patients who reported urinary dysfunction or ED at 12 mo and to identify predictors for recovery. Based on previous studies, we hypothesized that there is very little functional recovery after 12 mo if function is not achieved by this time point.

2. Methods

2.1. Patient population

In 2007 our institution implemented routine collection of patient-reported outcomes at all follow-up visits for men treated surgically for PCa. After obtaining institutional review board approval, we retrospectively identified 3187 men who underwent open or minimally invasive RP for localized PCa from 2007 through 2013 with ≥12 mo of follow-up. We excluded patients who had previous hormonal therapy or pelvic irradiation. Our primary goal was to estimate the long-term functional recovery in patients who reported urinary dysfunction or ED at 12 mo as determined through a questionnaire completed between 10 mo and 14 mo. Therefore, our analysis further excluded patients who achieved function by 12 ± 2 mo (1825 and 553 patients for UF and EF, respectively), those with missing functional status (489 and 361 for UF and EF, respectively), and patients who had preoperative incontinence ($n = 73$) or ED ($n = 1270$) as assessed by their surgeon [11]. Our final urinary dysfunction and ED cohorts included 800 and 1003 patients, respectively.

Postoperative care via our multidisciplinary survivorship program involves routine follow-up and includes teaching Kegel exercises to all patients to promote continence recovery. Patients are recommended to start daily or on-demand phosphodiesterase type 5 inhibitors as soon as possible following surgery. Physical rehabilitative therapy for incontinence or ED is typically initiated after 12 mo for continued impairment.

2.2. Primary outcome

Patient-reported recovery of good UF or EF was determined through the urinary and erectile domains of the validated Prostate Quality of Life Survey (Supplement 1), which is electronically captured through our Web-based platform [12]. The urinary domain of the Prostate Quality of Life Survey scale ranges from 0 to 21; achievement of good UF is ≥17 points. As a secondary analysis, we used complete pad-free status, a more conservative alternative measure for good UF. This accounted for patients possibly adapting to urinary symptoms.

Good EF recovery was determined with a score ≥22 points on the validated International Index of Erectile Function (IIEF-6) scale ranging from 1 to 30 [13,14]. Three questions pertain to sexual intercourse and therefore depend on men having a sexual partner. Accordingly, we attempted to capture men reporting no sexual intercourse by calculating a modified score in patients who had a sum score ≥12 from the first three questions with a sum score of zero from the last three questions of the IIEF-6 and then scaling the total score to a possible 30 points. The percentage of surveys for which the modified score was calculated was 2.8%.

2.3. Statistical analysis

We used Kaplan-Meier survival analyses to determine the probabilities of regaining function at 24, 36, and 48 mo postoperatively in patients who had not achieved function by 12 mo. Survival time started at 12 mo after RP. Patients were considered to have an event if they reached our primary outcome. We censored patients receiving hormonal therapy during their follow-up course. Because androgen-deprivation or radiation therapy is common in patients who recur, patients were censored at the date of biochemical recurrence. Interval censoring was accounted for according to patients' response to two survey questions: "When did you first achieve an erection sufficient for penetration?" and "When did you stop needing pads for urinary leakage?" Patients could answer "within the last month," "between 1 and 2 months," "between 2 and 3 months," or "greater than 3 months," and the questionnaire completion date was subtracted by 0.5, 1.5, 2.5, or 3.5 mo, respectively.

We conducted sensitivity analyses to investigate factors that may affect recovery rates. We compared Kaplan-Meier estimates before and after censoring for secondary procedures including artificial urinary sphincters, slings, or penile prostheses. Furthermore, we accounted for reporting bias by studying whether a patient's functional status would affect subsequent survey completion. We anticipated that a 12-mo score would be associated with the probability of subsequent recovery; hence we determined whether a 12-mo score was correlated with the number of surveys completed.

Multivariable Cox proportional hazards regression models were used to identify predictors of recovery. Predictors were selected a priori and included UF or EF scores at 12 mo post-RP, age, number of comorbidities, body mass index, preoperative prostate-specific antigen (PSA), nerve-sparing status (none, unilateral, bilateral), pathologic Gleason score(≤6, 7, ≥8), and pathologic T stage. Statistical analyses were performed using Stata v.13.1 (StataCorp, College Station, TX, USA). Tests with p values <0.05 were considered significant.

3. Results

Table 1 lists the clinical characteristics of the UF and EF. Among men who reported good preoperative UF and EF, 800 patients (26%) had not reported recovery of continence, and 1003 patients (52%) had not achieved good EF by 12 mo after RP.

For patients who did not achieve UF by 12 mo, the probabilities of recovering UF were 30% (95% confidence interval [CI], 27–34%), 49% (95% CI, 45–54%), and 59% (95% CI, 55–65%) at 24, 36, and 48 mo, respectively (Fig. 1;

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