Oncology

Recovery of Social Continence and Sexual Function in Men With High-risk Prostate Cancer After Radical Prostatectomy: Results From a Statewide Collaborative

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OBJECTIVES	To examine post-operative urinary and sexual functional outcomes for men with high-risk
	prostate cancer (HRPCa) who underwent radical prostatectomy (RP) within the Michigan
	Urological Surgery Improvement Collaborative (MUSIC).
METHODS	We identified patients who underwent RP for HRPCa in MUSIC between 2014 and 2023.
	HRPCa was defined according to American Urological Association criteria. Patients completed
	Expanded Prostate Cancer Index Composite (EPIC-26) pre-RP and 3-, 6-, 12-, and 24-months
	postoperatively. Primary outcomes included social continence, defined as 0-1 pads used daily;
	and recovery of sexual function, defined as the ability to achieve erections firm enough for
	intercourse. Multivariable and bivariate analyses were performed to identify factors associated
	with recovery of social continence and sexual function.
RESULTS	Around 1323 patients were included in the post-RP urinary continence analysis and 422 men
	in the sexual function analysis. Fifty-eight percent and 86% of patients achieved social
	continence at 3- and 12-months post-RP, respectively. Continence recovery was associated
	with higher baseline EPIC-26 urinary continence scores (OR 1.10, per 5 points, 95% CI
	1.06-1.15, $P < .001$), and negatively associated with increasing age (OR 0.78 per 5-year
	increase, 95% CI 0.71-0.85 $P < .001$). Fifteen percent of patients had recovery of sexual function at 12-month post-RP. On bivariate analysis, recovery of sexual function was
	associated with nerve-sparing at time of RP, lower pre-operative PSA, and not receiving
	post-RP ADT/RT.
CONCLUSION	RP for HRPCa has acceptable rates of postoperative social continence. However, post-RP re-
	covery of sexual function remains a challenge. This information has important implications for
	pre-operative counseling and post-operative follow-up for patients with HRPCa. UROLOGY
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The prevalence of high-risk prostate cancer (HRPCa) at initial presentation of prostate cancer is increasing. Concomitantly, the use of radical prostatectomy (RP) for initial management of HRPCa is also increasing.^{1,2} Radical prostatectomy has acceptable long-term oncological outcomes in patients with clinically localized and non-metastatic high-risk disease with a 10-year cancer-specific survival as high as 85% and 10-year biochemical recurrence-free survival as high as 68%.^{3,4} Surgical treatment for HRPCa requires pre-operative counseling of both oncological control and functional outcomes (urinary continence and erectile

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function), particularly because functional outcomes are highly associated with patient post-RP dissatisfaction and regret.^{5,6}

Heterogeneity in post-RP functional outcomes is both patient and surgeon-dependent.⁷ In patients with HRPCa, surgeons may alter dissection planes or nervesparing technique to maintain oncological control which may affect functional outcomes. Additionally, HRPCa is associated with a higher rate of failure of local treatment with RP and many patients will eventually receive adjuvant or salvage androgen deprivation therapy (ADT) and/or radiation therapy (RT) which are associated with worse functional outcomes.⁸⁻¹⁰ Although several studies have examined longitudinal outcomes for men with prostate cancer, data on continence and sexual function specifically in patients with HRPCa after RP are limited despite increasing utilization of surgery in this patient population.¹¹ In this context, we sought to determine post-RP continence and erectile function rates in patients with HRPCa. Understanding contemporary post-RP functional outcomes for patients HRPCa should inform shared decision making prior to treatment.

METHODS

Michigan Urological Surgery Improvement Collaborative

MUSIC is a physician-led quality improvement collaborative, established in 2011, comprised a consortium of academic, private practice, and community urology practices across the state of Michigan. MUSIC was designed to evaluate and improve the quality of urology care. Currently, the collaborative includes greater than 90% of urologic practices in the state of Michigan. In each participating practice, trained abstractors prospectively enter standardized demographic and clinicopathologic data related to treatment and follow-up at fixed intervals in the patient disease course.

MUSIC began collecting patient-reported outcomes (PROs) data in 2014. From 2014 until September 2016, MUSIC collected functional PROs using the validated Prostate Quality of Life Survey. Since September 2016, MUSIC has used the 26-item Expanded Prostate Cancer Index Composite Short Form questionnaire (EPIC-26).¹² A crosswalk algorithm was developed to convert and standardize PROs to a 0-to-100-point scale which are reported in this manuscript as previously described.^{13,14} All PROs data will herein be referred to by EPIC-26 given the majority of PROs were collected in the EPIC-26 format. Not all MUSIC practice sites participate in the prostate PROs program.

Study Population

For this analysis, our study population included all patients who were treated with robotic RP for HRPCa in MUSIC from 2014-2023. We defined HRPCa consistent with the AUA guidelines which included men with presurgical prostate-specific antigen (PSA) \geq 20, pre-RP Gleason grade group (GG) \geq 4 and/or clinical stage \geq T3a (N = 4007). Men with pre-operative evidence of lymph node or distant metastases (N = 171) and men undergoing salvage prostatectomy after prior external beam radiation therapy, brachytherapy, or focal therapy were excluded (N = 20).

For the post-RP continence analyses, patients were further excluded if they had not completed pre-RP EPIC-26 survey (N = 2224). Social continence was defined as 0-1 pad required per day on EPIC-26 (answer of 0 or 1 on question #2) and patients with poor pre-RP social continence were excluded (N = 11). Men were also excluded if they had not completed at least 1 post-RP EPIC-26 with response to the pad use question (N = 258).

For the sexual function analyses, men were excluded if they had not completed pre-RP EPIC-26 with an answer to the erection quality question (N = 2573). Men were excluded if they had not met the sexual function criteria pre-operatively defined as the ability to achieve an erection firm enough for intercourse (N = 650). Men were further excluded if they did not complete at least 1 post-RP EPIC-26 with response to erection quality questions (N = 80). Men using pre-RP (N = 5) or post-RP (N = 86) erectile aids including intracavernosal pharmacologic injections, intra-urethral alprostadil suppository, or inflatable penile prosthetic devices were excluded in this cohort.

Outcomes

We evaluated the PROs of men with HRPCa who underwent RP. PROs questionnaires were administered preoperatively and post-operatively at defined intervals: 3-, 6-, 12-, and 24 months post-operatively. Social continence and good sexual function were outcomes of interest as defined above. Additionally, we examined patient-level factors associated with post-RP recovery of social continence and sexual function.

Statistical Analysis

A generalized estimating equation (GEE) with a first order autoregressive structure (AR1) to account for intra-subject was fitted to evaluate the association between longitudinal post-RP urinary continence at any survey point between 3- and 24 months post-RP and patient variables of interest, including age (continuous), race (White, African American, Other, Unknown), Charlson comorbidity index (CCI; 0, 1, \geq 2), highest Gleason grade group (GG1-3, 4, 5) on prostate biopsy, clinical T (cT) stage (T1, T2, T3/4), nerve-sparing (none, unilateral, bilateral, or unknown), pre-operative PSA (log transformed), pre-RP EPIC-26 urinary continence scores, and administration of post-RP adjuvant or salvage radiation therapy (RT) at any time point prior to survey response. Due to limitations from the sample size and small number of events for sexual function outcomes, we performed a bivariate analysis using Fisher's exact test for categorical variables with sparse classes (at least 1 expected cell count < 5), Pearson's chi-

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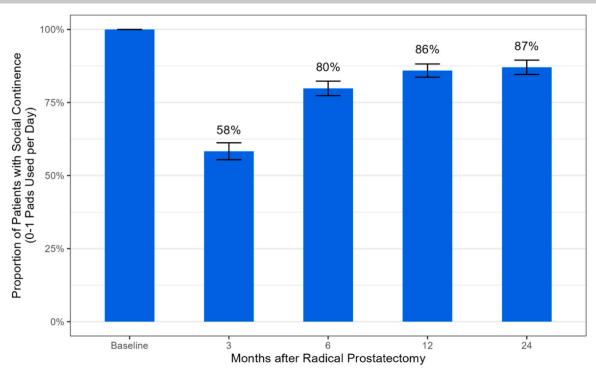


Figure 1. Proportion of patients with recovery of social continence after prostatectomy. (Error bars represent 95% CI). "Color version available online."

squared test for other categorical variables, and the Wilcoxon rank-sum test for continuous variables to identify factors associated with post-RP sexual function at 12-months post-RP. Variables of interest included age, race, CCI, pre-operative PSA, highest GG on pre-RP biopsy, clinical T (cT) stage, nerve-sparing (none, unilateral, bilateral, or unknown), surgical margins (positive vs negative), and administration of adjuvant or salvage RT and/or ADT within 12-months post-RP. For nerve-sparing, "unknown" status was treated as a separate category in all models. Statistical analysis was performed in SAS 9.4 and R version 4.3.1 with statistical testing at the 5% significance level.

RESULTS

From May 2014 to September 2023, a total of 1323 men with HRPCa who had undergone RP with pre-RP PRO data and post-RP social continence data were included in the urinary continence analysis. The clinicopathological characteristics of these patients are listed in Supplementary Table 1. Median age at RP was 65 (IQR 60-70) and 109 (8.2%) were African American. Median PSA at diagnosis was 8 ng/mL (IQR 5-15 ng/mL) and the positive surgical margin rate was 42%. The median pre-RP EPIC-26 urinary continence score was 94 (IQR 86-100). Importantly 252 (19%) and 557 (42%) underwent unilateral or bilateral nerve-sparing at the time of RP, respectively. In the social continence cohort, 370 (28%) patients received post-RP RT alone or in combination with ADT within the study period.

At 3-months post-RP, 58% (650/1115) of men in the urinary continence cohort had recovered social continence and at 6-months postoperatively, 80% (803/1006) of men had social continence. Twelve months after RP, social continence was 86% (787/916) and 87% (631/725) at 24 months (Fig. 1). In the multivariable model, recovery of social continence at any survey point post-RP was significantly associated with a higher pre-RP EPIC-26 urinary continence score (OR 1.10, per 5 points, 95% CI 1.06-1.15, P < .001), while increasing age was associated with lower odds of social continence (OR 0.78 per 5-year increase, 95% CI 0.71-0.85 P < .001, Table 1). There was no significant association of social continence recovery with race, comorbidities, clinical T-stage, pre-RP Gleason GG, nerve sparing at time of RP, pre-operative PSA, or administration of ADT/RT 3-months post-RP.

In the sexual function cohort, 422 patients with good pre-RP sexual function were included. The median age was 64 (IQR 59-68). In this cohort, 181 patients (43%) had bilateral nerve-sparing, 85 patients (20%) had unilateral nerve-sparing, and 85 patients (20%) had no nerve-sparing at the time of RP (71 patients had unknown nerve-sparing status). In this cohort, 129 (31%) received adjuvant or salvage ADT/RT. (Supplementary Table 2). Recovery of sexual function in this cohort was generally poor, with 15% (43/288) of men reporting erections satisfactory for intercourse 12-months after RP and 17% (35/209) of men at 24-months, (Fig. 2). In bivariate analysis, men with sexual function firm enough for penetration at 12 months had significantly higher rates of nerve sparing at time of RP (86% vs 60%, P = .010, lower pre-operative PSA (5 ng/mL vs 8 ng/mL, P = .038), and lower administration of adjuvant or salvage ADT/RT within 12 months post-RP (16% vs 34%,

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Table 1. Multivariable analysis of patient-leve	factors associated with recovery	of social continence after radical prosta-
tectomy.		

Variable	OR	95 % CI	Р
Survey time period			< .001
6 mo vs 3 mo Post-RP	2.85	2.45, 3.31	
12 mo vs 3 mo Post-RP	5.24	4.26, 6.44	
24 mo vs 3 mo Post-RP	5.14	4.11, 6.43	
Age (in 5 years)	0.78	0.71, 0.85	< .001
Race			.2
African American vs White	0.72	0.47, 1.12	
Other vs White	0.59	0.28, 1.25	
Unknown vs White	0.78	0.52, 1.16	
Charlson Score (CCI)		.12	
CCI= 1 vs 0	0.76	0.56, 1.02	
CCI > = 2 vs 0	1.14	0.75, 1.73	
Baseline EPIC UIN score (in 5 points)	1.10	1.06, 1.15	< .001
Pre-Operative PSA (log)	0.99	0.84, 1.16	.9
Gleason Grade Group (GG)			.057
GG4 vs GG1-3	0.86	0.57, 1.28	
GG5 vs GG1-3	0.67	0.45, 1.00	
Clinical T-Stage (cT)			.2
cT2 vs cT1	0.91	0.71, 1.17	
cT3/4 vs cT1	0.68	0.44, 1.05	
Nerve Sparing			.4
Unilateral vs None	0.92	0.64, 1.31	
Bilateral vs None	1.17	0.87, 1.57	
Unknown vs None	0.99	0.68, 1.45	
Receipt of RT before survey response	1.14	0.85, 1.52	.4

Bolded values represent statistically significant variables.

P = .019) (Table 2). Men with recovery of sexual function tended to be younger (64 vs 61 years old), however, this did not reach statistical significance (P = .067).

For patients who underwent bilateral nerve-sparing, only 23/127 (18%) reported sexual function recovery at 12

months post-RP. In this subgroup of patients, the positive surgical margins rate was 34.6% (44/127) and 21/127 patients had received adjuvant/salvage ADT or RT within 12 months post-RP (7 RT, 6 ADT, 8 ADT + RT). We found that increasing age (65 vs 59 years old, P = .007) and

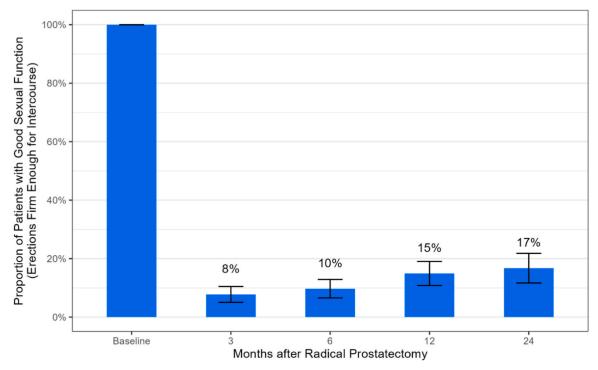


Figure 2. Proportion of patients with recovery of sexual function after prostatectomy. (Error bars represent 95% CI). "Color version available online."

Characteristic	Erections not Firm Enough for Intercourse at 12 mo, N = 245 ^a	Erections Firm Enough for Intercourse at 12 mo, $N = 43^{a}$	<i>P</i> -Value ^b
Age	64 (59, 69)	61 (58, 67)	.067
Race			.5
White	192 (78%)	38 (88%)	
African American	20 (8.2%)	2 (4.7%)	
Other	7 (2.9%)	1 (2.3%)	
Unknown	26 (11%)	2 (4.7%)	
Charlson Score			.5
0	178 (73%)	35 (83%)	
1	50 (21%)	6 (14%)	
> =2	15 (6.2%)	1 (2.4%)	
Missing	2	1	
Pre-operative PSA	8 (5, 15)	5 (4, 11)	.038
Missing	10	4	
Biopsy GG			.4
GG1-3	40 (16%)	5 (12%)	
GG4	126 (51%)	20 (47%)	
GG5	79 (32%)	18 (42%)	
Clinical T-Stage			.8
T1	135 (56%)	25 (63%)	
T2	90 (38%)	13 (33%)	
T3/4	15 (6.3%)	2 (5.0%)	
Missing	5	3	
Nerve Sparing			.010
None	56 (23%)	3 (7.0%)	
Unilateral	45 (18%)	14 (33%)	
Bilateral	104 (42%)	23 (53%)	
Unknown	40 (16%)	3 (7.0%)	
Positive surgical margins	96 (39%)	17 (40%)	>.9
RT and/or ADT 12 mo Post-RP	84 (34%)	7 (16%)	.019

Table 2. Bivariate analysis of patient-level factors associated with recovery of good sexual function at 12 months after radical prostatectomy.

Bolded values represent statistically significant variables.

^a Median (IQR); n (%).

^b Wilcoxon rank sum test; Fisher's exact test; Pearson's Chi-squared test.

receipt of adjuvant or salvage ADT/RT (21% vs 0%, P = .013) were significantly associated with poor recovery of erectile function in patients undergoing bilateral nerve-sparing (Supplementary Table 3).

DISCUSSION

The proportion of patients being diagnosed with HRPCa at initial diagnosis is increasing.^{2,15} This has been met with a parallel increase in RP for these patients. Understanding and counseling on post-operative functional outcomes and rates of recovery of social continence and sexual function is an essential part of shared treatment decision making for all men with HRPCa. However, expected rates of post-RP recovery of continence have not been well described in men with high-risk disease. We analyzed post-RP social continence and erectile function after prostatectomy in HRPCa men across a diverse, prospective registry of patients treated by academic, community, and private practice urologists. We found that while 12- and 24-month post-RP rates of continence were adequate, there is poor recovery of erectile function post-RP.

While others have reported on urinary function after RP for men with prostate cancer, few groups have

specifically evaluated urinary function recover in men undergoing RP for HR disease. A prior meta-analysis by Ficarra et al, reported social continence rates after RP, defined as utilizing 0 or 1 pad per day, as 89%-92% with a mean of 91%.¹⁶ The authors of this meta-analysis did not stratify continence rates by prostate cancer risk group. Prior studies examining HRPCa patients specifically have shown continence rates from 81%-92%.¹⁷⁻¹⁹ However, many of these prior studies are single institution or single surgeon and limited to men \geq 70 years old. Our reported continence rates are in a similar range of the above studies; 86% and 87% at 12- and 24 months, respectively, with a large and diverse sample size. Additionally, our study included a large number of surgeons (109) and practice types which contributed to our cohort of patients, suggesting these results may be more applicable to most men with HRPCa undergoing RP.

Recovery of post-RP continence is multifactorial. In our cohort, poor recovery of continence was highly associated with increasing age, which has been independently associated with post-RP continence recovery in several studies.^{20,21} Additionally, patients with high-risk disease and poor pre-RP urinary symptoms according to EPIC-26 scores had worse post-RP continence in multivariable analysis. This is consistent with a prior retrospective single-institution study of 1436 men with PCa undergoing robotic RP, in which, Shikanov et al, found worse pre-operative urinary symptoms were independently associated with worse post-RP continence.²² These data reaffirm the use of preoperative validated questionnaires to determine baseline voiding symptoms as part of patient evaluation and counseling.

The role of nerve-sparing on post-RP incontinence is not clearly defined, but recent literature supports an association of nerve-sparing with continence.^{23,24} The anatomical basis of this relationship may relate to preserved autonomic innervation of the membranous urethra in addition to preserved circulation to the external urethral sphincter.²⁵ One prior study showed that bilateral nerve-sparing is superior to unilateral nervesparing with improved post-RP preservation of continence, but only 4% of all patients in their study received unilateral nerve-spare.²⁶ Interestingly, our study did not show a significant association of post-RP continence recovery with nerve-sparing. These data likely reflect the complex nature of post-RP continence, particularly in patients with high-risk disease. It is possible that high-risk disease affects tissue dissection planes and quality of nerve-spare or nerve-sparing techniques or that the wide range of surgical techniques used across the state of Michigan prevented observation of an association of 'nerve-sparing' with continence.

Preservation of sexual function after RP remains a challenge. Recovery rates of sexual function in men undergoing RP are influenced by several factors such as baseline sexual function and nerve-sparing.²⁷ Short-term sexual function recovery rates are highly variable in the literature. The number of men recovering erectile function firm enough for penetrative intercourse meagerly increased during our collection period with 17% of men regaining sexual function at 24 months. Interestingly, while there was an association with nerve-sparing at the time of surgery and sexual function recovery, only 18% of patients who underwent bilateral nerve-sparing reported sexual function recovery at 12 months. In this subgroup, those who recovered sexual function were younger and zero patients had post-RP ADT/RT exposure.

Our sexual function recovery findings are similar to a prospective analysis performed by Sridhar et al, who evaluated erectile function outcomes in a multi-institutional cohort of men undergoing RP for HRPCa. They found that 16.7% of men achieved an erection with mild dysfunction or no dysfunction based on the international index of erectile function (IIEF) questionnaire, and only 23.5% of patients regained erectile function at their baseline level 18 months after surgery.²⁸ In the Prostate Cancer Outcomes Study adjusted post-RP erectile dysfunction was 82% at 2 years.²⁹

Adjuvant and salvage ADT/RT are associated with worse functional outcomes in post-RP patients.⁸ We observed that 31% of respondents in the sexual function cohort had received adjuvant/salvage treatment by 12-months post-RP. This was also associated with worse

recovery of sexual function consistent with previous studies. Thirty percent of patients in the social continence cohort had received post-RP adjuvant or salvage RT within the study period which was not associated with worse continence. It is possible that RT exposure may affect longer-term continence in this cohort.

There are few studies directly comparing post-RP sexual outcomes when stratified by prostate cancer risk group. In a small series, Pierorazio et al, have previously shown post-RP sexual potency rates in D'Amico HRPCa patients were lower but not statistically different than D'Amico low-risk patients, where potency was defined as erections firm enough for intercourse.³⁰ A multi-in-stitutional Canadian and European retrospective review found National Comprehensive Cancer Network (NCCN) high-risk and very-high-risk patients had no significant difference in post-RP potency.³¹

LIMITATIONS

Our findings should be considered in the context of several limitations. These data are impacted by the limitations of a retrospective study. In this study, a high proportion of patients did not complete the pre-RP EPIC-26 and were excluded from the analysis which has potential for responder bias. Our data are limited to MUSIC practices which participate in the prostate PROs program which excludes a proportion of patients from the analyses. MUSIC does not currently collect data on rates of pelvic floor physical therapy utilization which may affect continence outcomes. For patients receiving post-RP ADT, MUSIC does not collect data on type of ADT, duration, or dosing. For patients using adjunctive erectile aids, we do not know if these patients had erections sufficient for intercourse and are only intermittently using other aids. An additional limitation is that not all patients completed the EPIC-26 at the established intervals. Furthermore, the followup period for our PRO outcome data is 24 months post-RP and longer-term outcomes are not well established in MUSIC. However, it is unclear if further follow-up in this cohort is likely to generate clinically significant outcomes.

CONCLUSION

Our findings have important implications for patients and providers. Pre-operatively, providers must counsel patients regarding expected post-operative continence and sexual function rates, which are crucial components of shared decision making. For providers, our study provides a real-world basis for shaping post-RP expectations for men with HRPCa: across a wide variety of Michigan practices, RP for HRPCa has acceptable continence outcomes and potency rates on par with previous reports. For patients, these data provide concrete numbers to anchor their understanding of likely surgical outcomes: at 24 months after surgery, 87% of men achieved social continence and 17% of men with good baseline sexual function had recovery of sexual function.

Ethical Approval

Each MUSIC practice has obtained an exemption or approval by the local institutional review board for participation in the collaborative.

Disclaimer: Although Blue Cross Blue Shield of Michigan and MUSIC work collaboratively, the opinions, beliefs, and viewpoints expressed by the authors do not necessarily reflect the opinions, beliefs, and viewpoints of BCBSM or any of its employees.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.urology. 2024.06.018.

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