Health Services Research

Assessing the Impact of Decision Aid Use on Post Prostatectomy Patient Reported Outcomes

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OBJECTIVE	To evaluate whether completing a decision aid, Personal Patient Profile – Prostate (P3P), prior to
	prostatectomy, affects self-reported bother from post-prostatectomy urinary incontinence and erec-
	tile dysfunction.
MATERIALS AND	This retrospective analysis included data from men with newly diagnosed clinically localized, very
METHODS	low to intermediate risk prostate cancer who elected for prostatectomy within the Michigan Uro-
	logical Surgery Improvement Collaborative between 2018-2021. Multivariable logistic regression
	models were used to estimate the association between P3P use and bother from post prostatectomy
	erectile dysfunction and urinary incontinence as measured by the Expanded Prostate Cancer Index
	Composite (EPIC-26).
RESULTS	Among the 3987 patients included, 7% used P3P (n = 266). Men who used P3P reported signifi-
	cantly less bother from erectile dysfunction at 6 months vs non-users (aOR 0.42 95% CI 0.27-
	0.66]). At 12 months, the effect of P3P on bother from erectile dysfunction was not statistically
	significant (aOR 0.62 [95% CI 0.37-1.03]). Men who used P3P did not have a statistically signifi-
	cant difference in bother from urinary incontinence (3-month: aOR 0.56 [95% CI 0.30-1.06]; 6-
	month; aOR 0.79 [95% CI 0.31-1.97]).
CONCLUSION	Within the stated limitations of this study, we find that use of a decision aid for localized prostate
	cancer was associated with decreased odds of men being bothered from sexual dysfunction but not
	urinary incontinence at 6 months post prostatectomy. UROLOGY 00: 1–6, 2022. Published by
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In 2018, there were over 3 million men living with prostate cancer in the United States.¹ Men may live for decades with sequelae of prostate cancer treatment, which can include bothersome erectile dysfunction and urinary incontinence. Several therapies for localized prostate cancer exist which have comparable cancer and survival outcomes, necessitating men make decisions about treatment based on their individual preferences and values. As men face these preference-sensitive decisions, understanding and developing accurate expectations of downstream consequences of treatments is critical to supporting high-quality decision making. Decision aids are tools designed to help patients understand treatment options and their side effects, and to elicit patient preferences. One such tool, the Personal Patient Profile - Prostate (P3P) has been shown to reduce decisional conflict among men randomized to use it.^{2,3}

One understudied aspect of decision aid use is how it impacts downstream patient reported outcomes, particularly the bother men experience due to side effects from treatments. Bother within the context of patient reported outcomes can show how big of a problem the symptoms have been to the patient or how the symptoms disrupt social, emotional and role functioning.^{4,5} Using prospectively collected data as part of the Michigan Urological Surgery Improvement Collaborative (MUSIC), we aimed to explore how exposure to P3P modified men's bother from post-prostatectomy erectile dysfunction and urinary

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incontinence. We hypothesized that men who use P3P as part of a shared decision-making encounter would have increased awareness of potential risks of surgery and more accurate expectations of treatment outcomes and side effects. This will in turn lead to less self-reported bother from urinary incontinence and erectile dysfunction compared to men who did not use P3P and who had similar levels of urinary incontinence and erectile dysfunction.

METHODS

Data Source: This retrospective cohort study used data from the Michigan Urological Surgery Improvement Collaborative (MUSIC) between May 2018 through Feb 2021. MUSIC is a physician-led state-wide collaborative that includes about 90% of urologists within Michigan and captures data that represents the urologic practice (46 practices) and geographic variability within the state. From 2018-2021, MUSIC provided a validated, web-based decision aid (Personal Patient Profile-Prostate, P3P) to patients.^{2,3,6,7} MUSIC collects high quality data by using trained abstractors that submit data to the MUSIC registry and annual data audits are performed. To participate in MUSIC quality improvement efforts, each urology practice obtains regulatory exemption or approval from their local institutional review boards. This study was deemed IRB-exempt.

Study Population: Data from men with newly diagnosed clinically localized (T1-T2N0M0), very low, low or intermediate risk prostate cancer within the MUSIC registry and who underwent a prostatectomy were included in our analytic sample. We excluded patients younger than 40 and older than 90 years of age.

Patient Demographic and Health Status Data: We analyzed patient demographic, health status and clinical characteristics including age, race, ethnicity, family history of prostate cancer, prostatectomy date, clinical and pathologic staging.

Decision Aid Data: Personal Patient Profile-Prostate (P3P): P3P is a web-based decision aid tool designed to prepare newly diagnosed prostate cancer patients for conversations about their treatment options.^{2,3,6,7} P3P includes a baseline question set comprised of the Expanded Prostate Cancer Index Composite Short Form (EPIC-26) as well as questions about men's' readiness to make a decision, their decisional control preferences, and the degree to which their health status, physical function and relationships influence treatment decisions. Based on the answers to these questions, men are guided through video and text material that is tailored to their responses about prostate cancer care and survivorship. Statistics regarding cancer survival, bladder, sexual and bowel functional outcomes for treatment options are described. A report is generated for men to review with their physician and men are also provided with several coaching tips and tools to guide their treatment discussion with their physician.

MUSIC began implementation of P3P in May 2018. Practices that elected to join the P3P initiative received individual site-visit training from the Coordinating Center. Participating urologists selected which patients were appropriate for P3P use. These patients were then offered P3P enrollment by trained clinic employees, as previously described.^{8,9} Once enrolled, they accessed the P3P tool either via a web link or on an in-office tablet.

Patient Reported Outcomes: The EPIC-26 measures diseaserelated quality of life in localized prostate cancer and includes 5 domains of symptoms: Urinary Incontinence, Urinary Irritative/ Obstructive, Bowel, Sexual and Vitality.^{4,10} Each domain reports on both functional outcomes and patients' bother. Response options are listed in a Likert scale and transformed to a 0-100 scale during scoring, with higher scores representing better health related quality of life. EPIC-26 is measured at baseline and, for post-prostatectomy patients, at months 3, 6, 12 and 24 post-prostatectomy.

The 2 primary outcomes of interest were the patients' degree of bother from urinary incontinence and from sexual dysfunction. Men were asked "Overall, how big a problem has your urinary function been for you during the last 4 weeks?". Similarly, men were asked "Overall, how big a problem has your sexual function or lack of sexual function been for you during the last 4 weeks?". Response options for both items were a 5-point Likert scale as follows: "no problem, very small problem, small problem, moderate problem, big problem." We dichotomized patients' response to each item into "moderate or big problem" vs "no to small problem". Bother from urinary incontinence was assessed at 3- and 6-months post prostatectomy while bother from sexual function was assessed at 6- and 12-months post-prostatectomy. These time points allowed for an assessment of bother in an earlier and later portion of the recovery process for each of these conditions to allow for discrimination of bother between men experiencing differing degree of incontinence and erectile dysfunction.^{11,12} We did not evaluate the association between men's bother from UI or ED with completion of P3P past 12 months, since we hypothesized that effects of decision aids on patient's bother may decrease over time and there is increased risk of unmeasured confounders with increased time.

Analysis: Clinical and demographic characteristics of patients were summarized overall and compared by the usage of P3P using Student's *t* test for continuous measures and Chi-squared test for categorical variables. Baseline and postoperative urinary or sexual domain scores and bother were summarized and compared in the same fashion. Multivariable logistic regression models were used to assess the impact of P3P use on the bother men experienced from urinary incontinence at 3 and 6 months and from sexual dysfunction at 6 and 12 months. The models adjusted for race, age, ethnicity, family history of prostate cancer, prostate specific antigen level, Gleason score, clinical stage, baseline (preoperative) and postoperative overall urinary incontinence or sexual function domain scores, respectively. All calculations were performed in STATA version 16. The level of significance was pre-specified at *P* = .05.

RESULTS

A total of 3987 men with clinically localized (T1-T2N0M0), very low, low or intermediate risk prostate cancer underwent radical prostatectomy during the observation window (May 2018- Feb 2021), of which 266 (6.7%) used P3P. Men spent a median of 18 minutes (IQR 11, 36) on P3P, this included the time to complete the P3P and EPIC-26 questionnaires and review the decision aid and summary report.

Patient demographics and clinical staging are described in Table 1. Men who completed P3P had a lower rate of family history of prostate cancer (31% vs 37%, P = .02), and had a lower prostate specific antigen value (5.4 vs 5.9, P = .001) compared to men who did not complete P3P. There were racial and ethnic differences between the 2 groups, but this was in part due to

Table 1. Demographics & prostate cancer characteristics

	Did Not Use P3P N = 3,721	Used P3P N = 266	P-value
Age at CaP Diagnosis	63 (58-68)	64 (58-38)	.6
(median, IQR) Race (n, %)			<.001
African American	426 (11%)	26 (9.8%)	
Caucasian	2795 (75%)	173 (65%)	
Other	79 (2.1%)	2 (0.8%)	
Unknown/ Declined	421 (11%)	65 (24%)	
Ethnicity (n, %)			<.001
Non-	3162 (85%)	180 (68%)	(1001
Hispanic		200 (00/0)	
Hispanic	37 (1.0%)	5 (1.9%)	
Unknown/	522 (14%)	81 (31%)	
Declined			
Family History	1390 (37%)	81 (31%)	.02
of CaP (n, %)		(),	
PSA at CaP	5.9 (4.6-8.0)	5.4 (4.4-7.1)	.001
Diagnosis			
(median, IQR)			
NCCN risk			.1
group (n, %)			
Intermediate	3167 (85%)	217 (82%)	
Stage (TNM)			.9
(n, %)			
T1a-T1c, TX	2,975 (80%)	214 (81%)	
T2, T2x-T2c	743 (20%)	52 (20%)	
Total Gleason			.2
Score (n, %)			
7	3078 (82%)	211 (79%)	

Patients with newly diagnosed, clinically localized (T1-T2NOMO), very low, low, or intermediate risk prostate cancer undergoing prostatectomy within the MUSIC registry stratified based on use of Prostate Cancer Treatment Decision Aid.

CaP, prostate cancer; P3P, personal patient profile for prostate; PSA, prostate specific antigen; TNM, tumor nodes metastasis stage, only patients with T1-T2N0M0 disease included.

larger proportions of unknown/declined race (24% vs 11%, P < .001) and ethnicity (31% vs 14%, P < .001) data among P3P completers vs not completers.

EPIC-26 scores at 3-, 6-, and 12-months post prostatectomy were available for about 50%, 40%, 30% of both P3P users and non-users at each respective time point (Supplement). Baseline EPIC-26 urinary incontinence domain scores, sexual domain scores, and the proportion of men with moderate or severe bother from sexual symptoms or urinary incontinence did not differ between the 2 groups of patients (Table 2).

On multivariable analysis men who used P3P reported significantly less bother from erectile dysfunction at 6 months compared to non-users (aOR 0.42 [95% CI 0.27-0.66]) (Fig. 1). At 12 months, the difference in bother was not statistically significant (aOR 0.62 [95% CI 0.37-1.03]). As expected, men with "good or very good" self-reported rating of their ability to have an erection was associated with significantly lower odds of bother from sexual dysfunction (6-month aOR 0.02 [95% CI 0.004-0.05]; 12-month aOR 0.05 [95% CI 0.02-0.1]).

Though the effect size was large, there was no statistically significant impact of P3P on bother from urinary incontinence (3month aOR 0.56 [95% CI 0.3-1.1]; 6-month aOR 0.76 [95% CI 0.3-1.8]) (Fig. 1). Men with worse urinary function had greater odds of bother from UI; for each 1-point increase in UI domain score (less UI) was associated with a 10% decrease in odds of being bothered (3-month aOR: 0.89, [95% CI 0.89-0.9]; 6-month aOR 0.91 [95% CI 0.89-0.92]).

DISCUSSION

We find that use of the localized prostate cancer treatment decision aid, P3P, was associated with decreased adjusted odds of being bothered from post-prostatectomy sexual dysfunction but not from post-prostatectomy urinary incontinence. After adjusting for disease severity, sexual and urinary function, men who used P3P had a 58% decrease in being bothered by the same levels of sexual dysfunction than men who did not use P3P at 6 months post-prostatectomy.

The influence of decision aids on patient reported outcomes has not been well characterized in prostate cancer. A 1997 trial of 227 men facing treatments for benign prostatic hyperplasia randomized to a decision aid found improved general and physical health outcomes in the decision aid group but not statistically significant improvement in urinary symptoms.^{13,14} A meta-analysis of decision aids for people facing a variety of health treatment decisions, including prostatectomy, found no consistent differences in patient

Table 2. Baseline and follow-up EPIC-26 domain and item scores stratified by P3P use.

	Did Not Use P3P N = 3,721	Used P3P N = 266	P-value
Urinary Incontinence Domain (median, IQR)			
Baseline	100 (86-100)	100 (86-100)	.2
3-mo post RRP	52 (31-71)	52 (37-73)	.5 .2
6-mo post RRP	67 (46-88)	73 (52-92)	.2
Sexual Domain (median IQR)			
Baseline	71 (40-88)	70 (45-92)	.3
6-mo post RRP	21 (8.3-45)	22 (13-54)	.1
12 mo post RRP	26 (13-57)	24 (14-61)	.6
Erectile Function item response (median, IQR)			
Baseline	3 (2-4)	3 (2-5)	.5
6-mo post RRP	1 (1-2)	1 (1-3)	.5 .7
12 mo post RRP	1 (1-3)	1 (1-3)	.7
Proportion Bothered from Urinary Function (n, %)*			
Baseline	432 (20%)	65 (25%)	.1
3-mo post RRP	462 (25%)	25 (18%)	.08
6-mo post RRP	226 (14%)	11 (10%)	.2
Proportion Bothered from Sexual Function (n, %) ^{\dagger}			
Baseline	294 (15%)	32 (13%)	.42
6-mo post RRP	806 (52%)	35 (32%)	<.001
12 mo post RRP	507 (44%)	31 (37%)	.2

Patients with newly diagnosed, clinically localized (T1-T2N0M0), very low, low, or intermediate risk prostate cancer undergoing prostatectomy within the MUSIC registry stratified based on use of Prostate Cancer Treatment Decision Aid.

EPIC, expanded prostate cancer index composite; P3P, personal patient profile for prostate; PSA, prostate specific antigen. Domain scores range from 0-100 with higher numbers indicating worse function.

* Item Response to "How big a problem during the last 4 wk, if any, has your ability to have an erection" 5-point Likert with higher indicating worse function.

[†] Responded that Urinary or Sexual Function were moderate or severe problem.

reported health outcomes among people randomized to decision aids.¹⁴ To our knowledge, there is no literature on the impact of decision aids on patient reported outcome measures following prostatectomy. However, many of these outcome measures are routinely collected in prospective studies, and efforts to reproduce our findings from previously accrued data are needed.^{15,16}

We hypothesize that decision aids may decrease patients' bother from erectile dysfunction through improved expectation setting of physiologic recovery and may perhaps aid in psychosocial expectation setting. This hypothesis is supported by prior data showing that providing extensive preoperative counseling and written material on post-prostatectomy sexual outcomes led to high proportions of men who accurately predicted their future sexual function.¹⁷ And by a recent study evaluating preparedness for post-prostatectomy incontinence and sexual function found that low preparedness was associated with



Figure 1. Multivariable logistic regression models showing adjusted odds ratio (OR) of patients reporting bother from post prostatectomy erectile dysfunction (ED) at 6 mo and 12 mo and urinary incontinence (UI) at 3 mo and 6 mo. White markers and shaded regions represent urinary incontinence models. Adjusted for age, race, ethnicity, family history of prostate cancer, prostate specific antigen value, Gleason score, stage and erectile function at baseline and follow-up or urinary function at follow-up. P3P: Personal Patient Profile-Prostate. "Color version available online."

increased bother from urinary incontinence and erectile dysfunction.¹⁸ Taken together these data support the hypothesis that decision aids improve expectation setting, beyond traditional counseling methods, and decrease bother from post-prostatectomy erectile dysfunction.

In contrast, we find that despite a large effect size, decision aid use was not statistically associated with men's bother from urinary incontinence.^{17,18} Smaller betweengroup difference observed for bother from urinary incontinence compared to sexual function may account for the lack of statistically significant difference in post prostatectomy UI bother between P3P users and non-users (Table 2). Another reason for the lack of difference may be because the physiologic implications of urinary incontinence and erectile dysfunction impact men's bother and coping through different mechanisms. While decision aids may improve expectation setting for urinary incontinence, the awareness may not overcome the bother men experience from urinary incontinence. In support of this hypothesis, prior research has found that worsening urinary symptoms were predictive of psychological distress, but there was no association between erectile dysfunction and psychological distress.¹⁹ Future efforts to evaluate how decision aids impact expectation setting for post prostatectomy incontinence and association between expectations and realized urinary incontinence and bother from UI are needed next steps to understanding the mechanisms by which decision aids may impact men's bother.

While our findings provide some of the most robust data on the impact of decision aid use on patient reported outcomes following prostatectomy, its limitations should be considered. Our study provides prospectively collected outcome data from a statewide initiative to use P3P, a prostate cancer decision aid. Participation was voluntary and at the practice level, as such only a small portion of men who underwent prostatectomy used the P3P tool. The reason for this is 2-fold, first we have previously described factors that influence P3P enrollment and found that urologists account for a significant effect on patient enrollment, while no clinically meaningful patient factors were associated with use.⁸ Qualitative work has pointed to "lack of awareness, personal habit, or organizational inertia" as barriers to physician uptake of P3P.⁹ Addressing these barriers is necessary for implementation of decision aids in the future. Another reason for the low use of P3P in this study includes only men who underwent prostatectomy, which represent only 22% of all P3P users during the same period. We evaluated for differences between P3P users and non-users and used multilevel logistic regression, adjusting for both patient factors and the effect of clustering under urologists, to mitigate any differences. Despite the small proportion of men who used P3P, we noted a strong effect size in our models of P3P on patient bother. Finally, bother from sexual and urinary function is multifaceted and our model may not include measured or unmeasured factors that may contribute to bother. We did not evaluate for the impact of disease recurrence or the treatments for UI or ED following

prostatectomy. Yet, based on *a priori* discussions, we adjusted for factors strongly correlated with bother in other studies of urinary and sexual symptoms, specifically symptom severity and racial and ethnic differences.^{20–22} Finally, our findings are specific to the P3P tool which has been rigorously created and tested by a multidisciplinary team of researchers and physicians to provide men with decisional support and to minimize bias. Further research is required to understand whether our results are generalizable to other validated prostate cancer decision aids.

Our finding that decision aids may help patients experience decreased bother from side effects of prostate cancer surgery has broad significance. It suggests that policies that support development and use of decision aids may improve patient reported outcomes after prostatectomy. For clinicians, it implies that offering patients a decision aid may help decrease their distress from decreased sexual function following prostatectomy. This is particularly salient in the context of our prior work showing that clinicians are a key facilitator in patients' enrollment to use a decision aid.^{8,9} Finally, for patients and patient advocates, it suggests that use of a decision aid is a meaningful step in prostate cancer survival. We hypothesize that men exposed to the decision aid experienced decreased bother from erectile dysfunction; they set more accurate expectations and were able to better cope with their outcomes. However, future research is warranted to reproduce our findings in other populations and to better elucidate the mechanism by which decision aids can modify a men's bother from post-prostatectomy erectile and urinary dysfunction.

CONCLUSION

Within the stated limitations of this study, we find that use of a decision aid for localized prostate cancer is associated with decreased odds of men being bothered from sexual dysfunction at 6-month post-prostatectomy. Attempts to reproduce these findings in cohorts of men undergoing differing treatments will be a necessary and important next step.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2022.02.008.

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