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Decision preparation, satisfaction and regret in a multi-center sample of men with newly diagnosed localized prostate cancer

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Abstract

Objective—To describe relationships between use of the Personal Patient Profile-Prostate (P3P) decision support system and patient characteristics, and perceived preparation for decision making (PrepDM), satisfaction and decisional regret in the context of prostate cancer treatment choice.

Methods—494 men with localized prostate cancer (LPC) were randomized to receive the P3P intervention or usual care and completed pre-treatment, 1-month and 6-month outcome measures. Multivariable linear regression models were fit for each outcome.

Results—Physician consult visits prior to enrollment, race/ethnicity, and use of clinic-provided books were significant predictors of perceived PrepDM at 1-month. Prior Internet use and PrepDM significantly predicted 6-month decision satisfaction. Decisional regret was significantly predicted by demographics, anxiety, PrepDM score, and EPIC bowel domain score at 6-months. Use of P3P did not predict any outcome.

Practice Implications—Information received and used between biopsy and the treatment options consult visit is likely to make a difference in decision satisfaction.

Conclusion—While the P3P intervention did not significantly affect the outcomes, pre-enrollment information and preparation were strong predictors of the 1 and 6-months outcomes. Decision regret was significantly influenced by personal characteristics and post-treatment symptoms/side effects.

Keywords

prostate cancer; randomized trial; Internet; decision making

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1. Introduction

Men with localized prostate cancer (LPC) face a treatment decision for which there are multiple options with varying side effect profiles, yet no demonstrable survival advantage for the majority of men diagnosed as low-risk. Despite a myriad of lay and professional patient education sources, direct clinician facilitation of such a treatment decision can be truncated or compromised due to shortened face-to-face clinic visits and the complexity of medical factors intertwined with patients' personal factors. Moreover, standard counseling, as studies across medical settings have shown [1], may focus more on information giving than elaboration and consideration of patient preferences and expectations,

At a 2011 National Cancer Institute, state-of-the-science conference addressing active surveillance for LPC, experts recommended research in "methods to support shared decision making, including participation of non-physician health care providers and the use of decision support tools" as well as "methods to improve patient satisfaction and reduce regret." [2, p.7] The authors of a 2009 Cochrane review[3] concluded that health care decision aids generally were effective with regard to patients' involvement in the decision and promoting informed, values-based decisions. In the Ottawa Decision Support Framework (ODSF)[4, 5] the goal of a decision support intervention is to prepare patients for decisions where there is uncertainty about the best approach, outcomes are unpredictable, and individual values, expectations and preferences are relevant. A high quality decision in this framework is one in which the patient has been informed, personal preferences and values honored and the patient is satisfied with the process. Common outcomes in trials of decision support interventions for LPC include the actual choice made, knowledge, decisional conflict, satisfaction with decision making, decisional regret and anxiety.[6, 7] Quality of life outcomes relevant to symptoms and side effects of LPC and its treatment are known to affect satisfaction and may have important relationships with other outcomes. [8]

The Personal Patient Profile-Prostate (P3P) intervention [9] was developed to provide tailored decision support to men recently diagnosed with LPC, addressing the complex scenario of medical and personal factors that influence a treatment decision. The Web-based P3P has been shown to significantly decrease decisional conflict over six months, measured at baseline, one- and six-months, in a multi-center randomized trial.[10] We now report additional outcomes of the P3P trial measured only at one or six months: preparation for decision making, satisfaction with decision, and decision regret. We hypothesized that use of the P3P decision support system would be associated with perceived preparation for decision making, satisfaction with the decision, and lower decisional regret.

2. Methods

A prospective, randomized clinical trial enrolled 494 of 724 (68%) eligible patients with recent diagnoses of LPC, pre-treatment, to test a decision support system for treatment decision making.[10] Eligible men had T1 or T2, histologically-proven LPC, spoke English or Spanish, were consulting with specialists who identified participants as candidates for at least two treatment options, and had not begun therapy. Participants were enrolled at six clinical sites in four American cities, with approval of respective institutional review boards and were invited to complete validated questionnaires comprising the P3P assessment component and research measures on touch-screen computers in clinic waiting rooms prior to the consult visit with a cancer specialist. Men who had home broadband Internet access could complete the P3P in advance. Control group participants then received links to established information websites about prostate cancer. Intervention group participants received education and coaching customized by race, ethnicity and age and specific to

influential personal factors identified in the P3P query. Participants completed baseline (all on-line) and 1-month and 6-month questionnaires (either online or paper). No difference in any baseline variable was found between study groups. Details of the sample and study procedures have been reported previously.[10]

2.1 Measures

Sociodemographic and clinical characteristics (weeks since biopsy, previous physician consultations) were self-reported at baseline and 6-months (treatment received). We also queried participants regarding information sources used and whether a treatment preference was already known.[11] Standard instruments were administered to assess prostate-specific symptoms, the Expanded Prostate Index Composite-26 (EPIC);[12] anxiety, the State-Trait Anxiety Inventory (STAI); [13] and decision control preferences, Control Preferences Scale (CPS).[14] The following outcome measures were deployed in follow-up assessments.

The Preparation for Decision Making (PrepDM) scale[15] was administered in the 1-month follow-up to measure participants' perceptions of all actions taken to date while preparing for their decision. The questionnaire included 10 items about decision preparation, each with 5-point Likert-type responses from 1 (not at all) to 5 (a great deal); scores were transformed to a range of 0–100 according to the user manual [15] with higher scores indicating greater perception of preparedness. The instrument has been used to evaluate preparation for decision making in patients with breast and prostate cancer and in those seeking consultation in an orthopedic specialty clinic where PrepDM discriminated those participants who reported various levels of helpfulness of a concomitantly administered decision aid. Cronbach's alpha coefficient for the PrepDM in this trial was .92.

The Satisfaction with Decision (SWD) scale [16] measured decisional satisfaction at 6-months after study enrollment. The 6-item scale has been used in 10 randomized trials, none with men making a prostate cancer treatment decision, yet often has been included in descriptive studies of treatment decisions.[17] Cronbach's alpha coefficient for SWD scale in this trial was 0.97.

The 5-item Decisional Regret (DR) scale[18] was administered at 6-months. As reviewed by Joseph-Williams and colleagues, [7] the DR scale has been used in descriptive, treatment decision trials in prostate and breast cancer and one randomized trial conducted by Goel and colleagues [19] of a decision aid for breast cancer treatment decisions. Performance characteristics were reviewed as adequate. Cronbach's alpha coefficient for the DR scale in our trial was 0.90.

2.2 Analyses

Descriptive statistics were used to characterize patients at study entry. Analytic samples were defined individually for PrepDM (1-month), and SWD and DR (6-months) based on timing of the measures and the pre-requisite of having made a decision in order to report regret and satisfaction with that decision. Separate linear regression models were fit for each outcome. For analysis of the PrepDM scale, the study sample (N_{1mo}=393) was defined as those who reported knowing which treatment was preferred at 1 month after study entry. The same criteria was used to define the samples (N_{6mo}=401) at 6 months after study entry for both the SWD scale and DR Scale. Based on our previous work [11] and clinical experience, potential predictors included in the analyses for PrepDM were demographics at baseline and information sources used by 1-month (Table 2); for SWD and DR, variables included demographics and anxiety (baseline), PrepDM (1-month) and symptoms at 6-months (Tables 3 & 4).

Univariate associations were first assessed between each variable and the outcome measure using a linear model. Potential predictors with a significance level (p-value) less than 0.2 were then included in the multivariate model. Backward variable selection was used to identify a group of significant predictors. The significance level for a variable to stay in the model was .10; a p-value ≤ .05 was considered statistically significant. Possible two-way interactions among remaining predictors were examined, and no statistically significant interactions were found. All analyses were conducted using SAS (version 9.2). One extreme value of the EPIC urinary domain irritative subscale was considered an outlier using Inter-Quartile-Range (IQR) criteria and was removed from all analyses.

3. Results

At 1-month, 450 of 494 (91.1%) men returned questionnaires or submitted responses on line. Of these, 393 participants reported a treatment preference and/or decision. At 6-months, 436 (88.3%) responded, with 401 having expressed a treatment preference and/or decision. Table 1 displays the demographic characteristics of the sample for each time point. No significant differences in baseline characteristic were found between the participants included in the analyses for 1-month and 6-months and the 101 and 93, respectively, who had not reported a treatment preference (data not shown).

3.1 Preparation for Decision Making

Univariate analysis (Table 2) indicated that at least one prior physician visit for the purpose of discussing treatment options, baseline Internet information-seeking, and clinic-provided books were significantly associated with 1-month PrepDM scores. Results from multivariable analysis indicated that prior physician visits, race/ethnicity, baseline Internet information-seeking, and clinic-provided books were significant predictors of PrepDM.

3.2 Satisfaction with Decision

Significant univariate predictors for SWD (Table 3) were study site, prior physician visit, income, education, marital status, race/ethnicity, Internet use, and trait anxiety score at baseline, PrepDM at 1-month, and EPIC bowel function at 6-months. In the multivariable analysis, only Internet use and PrepDM were significantly associated with SWD.

3.3 Decisional regret

Marital status, state and trait anxiety at baseline, PrepDM at 1-month, and all EPIC domains at 6-months were significantly associated with DR in univariate analysis. In multivariable analysis, predictors for DR were education, marital status, trait anxiety at baseline, PrepDM at 1-month, and EPIC bowel score at 6-months (Table 4).

4. Discussion and Conclusion

4.1 Discussion

While use of the P3P decision support intervention, in addition to usual preparatory conditions, did not predict significantly higher perceived preparation for decision making or satisfaction and did not significantly lower decisional regret, our findings reveal important associations among these outcomes, interesting baseline characteristics and several mutable variables that can be tested in future trials for enhancing the quality of a LPC treatment decision.

Men who perceived higher preparation for decision making were those who already had the benefit of at least one treatment option consultation with a physician prior to study enrollment and had used information from books and the Internet. This supports the

assumption of the ODSF that knowledge of the options and potential outcomes is necessary for a quality health care decision [5]. We also believe that the nearly two-thirds of the sample in both groups who were more than 4 weeks out from biopsy [10] at the time of enrollment may have been as informed as possible; in other words, the P3P was delivered too late in the decision making process for these men in the intervention group.

The finding that non-Hispanic, White ethnicity and race were associated with significantly lower perceived preparation for decision making than the Hispanic and racial minority men is counter-intuitive, since majority patients are often believed to be a more resourced group given differences in education and income. One possible hypothesis is that the ethnic and racial majority men valued a higher level of preparation for decision making than was achieved as compared to the minority men for whom preparation may have been perceived as adequate. This is a weak hypothesis, though, because the analysis incorporated preferred level of participation in the treatment decision, that did not predict perceived preparation. Our findings on predictors of the PrepDM scale scores are the only published data in a sample of individuals with cancer, precluding meaningful comparisons to any other study. The reliability performance of the instrument in our trial was equivalent to the results in a sample of orthopedic clinic patients.[15]

The findings indicate that satisfaction with the decision six months after study enrollment was predicted only by use of the Internet as an information source at baseline and higher perceived preparation for the decision at 1 month. Significant predictors of decision regret included education, marital status, baseline trait anxiety and 6-month bowel symptoms. Being married or partnered has been identified as a significant predictor of better prostate cancer treatment outcomes[20] and increased survival[21, 22, 23]. In a meta-analysis of 87 studies with cancer survival and social network and marital status variables, Pinquart and Duberstein[22] reported a positive effect of perceived social support, larger networks and marriage. Our findings and those of therapeutic outcome studies suggest that men with partners and socially supportive networks are best able to engage in a treatment decision process that best matches individual preferences and results in higher satisfaction and lower regret. The predictive ability of trait anxiety scores was demonstrated in our earlier work where satisfaction with decision was lower in men with higher trait anxiety at the time of the decision. [11]. Our current finding that trait anxiety significantly predicts 6-month regret may be related. No other longitudinal trials have used baseline anxiety as a predictive variable for decisional outcomes; more often anxiety has been evaluated as a response to an active surveillance treatment choice (e.g., van de Bergh et al.[24])

To evaluate treatment-decision regret, Hu and colleagues[25] used a 2-item measure in a telephone survey of 195 low-income, underinsured survivors of prostate cancer and reported that, as in our findings, regret was associated with bowel side effects. Likewise when Lin and colleagues [26] explored decision regret after radical prostatectomy in a sample of 100 Taiwanese patients, using a 3-item prostate cancer-specific regret measure and adding an item on regretting having the prostatectomy. In a stepwise regression analysis, bothersome bowel adverse effects also were found to predict regret, along with bothersome sexual adverse. Schroek and colleagues[27] conducted a retrospective study answered by 400 of 655 participants with LPC who had chosen one of two approaches to prostatectomy; correlates of decision satisfaction and regret were analyzed using multivariate analysis. The single item outcome measures asked the participant to assign a level of satisfaction and regret relevant to the previous surgical approach decision. While this measurement approach is different from our validated scale measures, and the median time since treatment was about 1.5 years, regret results are similar to our findings in that men with post-treatment bowel symptoms reported greater regret.

It was not surprising that adverse symptom experiences predicted 6-month outcomes, though it is notable that the EPIC bowel domain was the only significant symptom predictor in the multivariate model of regret for the entire sample. More men in our sample had reported lower quality of life relevant to sexual and bladder function outcomes, similar to other studies of post-prostate cancer therapies.[8] Possibly sexual and bladder symptoms are well-known by the lay community of men with LPC, so subsequent experience with these two outcomes were not unexpected by men in the study. Bowel and rectal symptoms are known to clinicians, particularly radiation oncologists, yet may not have the same reputation in the lay community as the other adverse outcomes. In a cross-sectional study of 349 respondents of 540 men with LPC invited in 1999 to answer a questionnaire set, Clark et al.[28] found that decision regret was significantly associated only with lower sexual intimacy scores. The discrepant results may indicate the collective increased knowledge over the last decade in the lay community regarding adverse outcomes of LPC treatment. In a more recent cross-sectional questionnaire study of LPC treatment decision making, reasons for choosing non-surgical options (hormonal, brachytherapy and external radiotherapy) all included a self-reported belief that these options would result in fewer side effects.[29] Joseph-Williams et al.[7] presented a useful conceptual model for the further development of regret measures and research on regret. The authors distinguished anticipated from experienced regret, and within the latter, immediate from delayed, with the implication that regret may usefully be measured longitudinally; they also differentiate regret about the process of decision making, the option chosen, and the outcome. In their review, the DR scale used in this study measures regret about the option chosen and outcome. Our study measured regret at 6-months, which may be considered delayed regret. Again, not surprisingly, regret was predicted by 6-month symptom outcomes. In future research, measuring regret at multiple time points throughout the decision process and longitudinally may yield additional predictors and a more dynamic picture of decision regret. Likewise, including a measure targeted at regret regarding the process (e.g., the role the man took with his doctor in the decision, information-seeking he did or failed to do), will provide greater understanding of opportunities for intervention.

Our study and analyses are limited primarily by the effect of unmeasured variables. Despite knowing the type of information source and relative frequency of use, the quality and exact nature of how each man prepared for making his treatment decision remains unknown. For example, we know that reading books provided by the clinic after the biopsy was an important predictor of feeling prepared for the decision, but we have no data at this time regarding which books were used. Also, we were not able to collect consistent medical record data on tumor outcomes due to low numbers of men returning to the enrolling clinic at 6-months. While our study was conducted in a sample representing a similar percent of Black men as reside in the United States,[30] because of the higher incidence of prostate cancer in Black men, this number may not have been adequate to draw definitive conclusions about the effect of race/ethnicity on the outcomes. Finally, the outcome measures had limited use in randomized trials with samples of men with LPC prior to our study, and while internally consistent, may not have been the best approach to evaluating the quality of a cancer treatment decision.

4.2 Practice Implications

Clinicians who support men with new diagnoses of LPC may find assessment of baseline characteristics helpful in identifying those men who need more or less support to make a quality decision. The anxious, single man with less than a college education and no Internet access may be the archetype of the patient for whom more time and resources are best targeted prior to a final treatment decision. And for all men, books received and used between biopsy and the treatment options consult visit are likely to make a difference in

perceived preparation and, subsequently, decision satisfaction and regret. Clinics in which books are provided to men prior to decision making may use these findings to justify costs, and clinics without such resources may find rationale to implement the practice.

4.3 Conclusions

The P3P intervention did not result in higher, self-reported preparation for decision making one month after study enrollment. This preparation outcome was more related to resources obtained prior to study enrollment and minority race/ethnicity. Satisfaction with the decision at 6 months was not significantly related to intervention use, but again, predicted by a baseline behavior, use of the Internet and feeling prepared for the decision at one month. Decision regret was not an outcome significantly predicted by use of the intervention, but was significantly influenced by baseline characteristics, feeling prepared for the decision at one month, and adverse bowel symptoms at six months. Taken together, we conclude that these outcomes of a quality decision are heavily influenced by factors both known and previously unknown to impact decisional outcomes. Future exploration and intervention testing for LPC decision making is warranted with appropriate measures of these factors.

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Table 1

Demographic characteristics of participants with a treatment preference at 1 and 6 months after study enrollment.

	Sample for PrepDM ($N_{1\text{-mo}}$=393)		Sample for SWD and DR ($N_{2\text{-mo}}$=401)	
Age (median and range)	63	40–86	63	40–86
	n	%	n	%
Income				
≤ $35,000/year	81	20.6	84	20.9
>$35,000/year	296	75.3	300	74.8
Missing	16	4.1	17	4.2
Education				
High school or less	170	43.3	170	42.4
College or higher	223	56.7	231	57.6
Marital status				
Single	84	21.4	87	21.7
Married	308	78.4	313	78.1
Missing	1	0.3	1	0.2
Race/ethnicity				
White & non-Hispanic	327	83.2	334	83.3
Minority	61	15.5	61	15.2
Missing	5	1.3	6	1.5

Table 2

Preparation for decision making one month after study enrollment: univariate and multivariable regression model results

Preparation for decision making ($N_{1\text{-}mo}$=393)				
	Univariate		**Multivariable**	
Variable	**Estimate**	**p-value**	**Estimate**	**p-value**
Physician visit prior to enrollment	5.91	0.001	5.67	0.002
Married/partnered	2.71	0.17	--	--
Minority race/ethnicity	3.87	0.09	7.31	0.002
Baseline Internet information-seeking	4.27	0.02	4.51	0.012
Information sources used between baseline and 1-month				
Clinic-provided books	5.24	0.01	5.57	0.004
Books from elsewhere	3.03	0.08	--	--
The Internet	3.52	0.10	--	--
Television/videos	2.42	0.14	--	--
Family members' experiences with cancer	2.32	0.19	--	--
Friends' experiences with cancer	4.19	0.09	--	--

Note: Other potential predictors examined, but not displayed, were weeks since prostate biopsy, income, education, study group, role played in the treatment decision, study site, and other information sources (pamphlets provided by clinic, pamphlets from outside the clinic, magazines/ newspaper).

Table 3

Satisfaction with decision six months after study enrollment: univariate and multivariable regression model results

Satisfaction With Decision ($N_{6\text{-}mo}$=401)				
	Univariate		Multivariable	
Variable	**Estimate**	**p-value**	**Estimate**	**p-value**
Physician visit prior to enrollment	1.41	0.01	--	--
Income: >$35,000/year	1.35	0.03	--	--
Education: College or higher	1.22	0.02	--	--
Married/partnered	1.71	0.005	--	--
Race/ethnicity: minority	−1.04	0.14	--	--
Baseline Internet information-seeking	1.69	0.002	1.25	0.02
Baseline trait anxiety	−0.06	0.01	--	--
1-month Preparation for Decision Making	0.08	<.0001	0.07	<.0001
6-month EPIC Urinary irritative subscale *	0.02	0.15	--	--
6-month EPIC Bowel domain	0.03	0.05	--	--
6-month EPIC Sexual domain	0.01	0.13	--	--
6-month EPIC Hormonal domain	0.03	0.06	--	--
Study site (reference group - Seattle VA)		0.01		
Augusta, Georgia VA	0.71	0.48	--	--
Fox Chase Cancer Center, Philadelphia, PA	2.31	0.02	--	--
San Antonio, TX VA	0.50	0.74	--	--
Seattle Prostate Institute, Seattle, WA	2.93	0.04	--	--
UWMC & SCCA, Seattle, WA	2.56	0.005	--	--

Note: Other potential predictors examined, but not included in the tables, were study group, weeks since prostate biopsy, state anxiety score at baseline, decisional control preference at baseline, Internet use at 1-month, , EPIC urinary incontinence at 6-months, number of doctors consulted by 6-months, , and treatment preferred or received at 6-months.

VA= Veterans Administration; UWMC=University of Washington Medical Center; SCCA=Seattle Cancer Care Alliance

* Extreme value removed from the analysis

Table 4

Decisional regret six months after study enrollment: univariate and multivariable regression model results

Decisional Regret ($N_{6\text{-mo}}$=401)				
	Univariate		Multivariable	
Variable	**Estimate**	**p-value**	**Estimate**	**p-value**
Income: >35,000	−3.07	0.14	--	--
Education: College or higher	−3.06	0.07	−3.56	0.05
Married/partnered	−4.87	0.02	−4.08	0.04
Baseline Internet information-seeking	−2.88	0.11	--	--
Baseline state anxiety	0.21	0.0008	--	--
Baseline trait anxiety	0.42	<.0001	0.32	0.0001
Baseline to 1-month, Internet as information source	−3.60	0.13	--	--
1-month Preparation for Decision Making	−0.20	0.0002	−0.16	0.001
6-month EPIC urinary irritative subscale *	−0.09	0.05	--	--
6-month EPIC urinary incontinence subscale	−0.06	0.04	--	--
6-month EPIC bowel domain	−0.30	<.0001	−0.31	<.0001
6-month EPIC sexual domain	−0.06	0.04	--	--
6-month EPIC hormonal domain	−0.21	<.0001	--	--

Note: Other potential predictors examined, but not included in the table, were study group, weeks since prostate biopsy, physician visit prior to enrollment, baseline decisional control preference, race/ethnicity, number of doctors consulted by 6-months, and treatment preferred or received at 6-months.

* Extreme value removed from the analysis