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Treatment preference and patient centered prostate cancer care: Design and rationale

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ABSTRACT

Prostate cancer is a slow progressing cancer that affects millions of men in the US. Due to uncertainties in outcomes and treatment complications, it is important that patients engage in informed decision making to choose the "optimal treatment". Patient centered care that encompasses informed decision-making can improve treatment choice and quality of care. Thus, assessing patient treatment preferences is critical for developing an effective decision support system. The objective of this patient-centered randomized clinical trial was to study the comparative effectiveness of a conjoint analysis intervention compared to usual care in improving subjective and objective outcomes in prostate cancer patients. We identified preferred attributes of alternative prostate cancer treatments that will aid in evaluating attributes of treatment options. In this two-phase study, in Phase 1 we used mixed methods to develop an adaptive conjoint task instrument. The conjoint task required the patients to trade-off attributes associated with treatments by assessing their relative importance. Phase 2 consisted of a randomized controlled trial of men with localized prostate cancer. We analyzed the effect of conjoint task intervention on the association between preferences, treatment and objective and subjective outcomes. Our conjoint task instrument can lead to a values-based patient-centered decision aid tool and help tailor treatment decision making to the values of prostate cancer patients. This will ultimately improve clinical decision making, clinical policy process, enhance patient centered care and improve prostate cancer outcomes.

1. Introduction

Prostate cancer accounts for 33% of all newly diagnosed malignancies in men in the US, with an estimated 220,800 new prostate cancer cases and 27,540 prostate cancer related deaths in 2015 [1]. Ethnicity, age and family history of prostate cancer are the only well-established risk factors for prostate cancer [2–13]. Overall mortality trends vary by age and ethnicity for all stages of prostate cancer [2,7,14,15]. Treatment decisions for prostate cancer patients are complicated. Men with early stage prostate cancer in particular face challenging treatment decisions since optimal treatment for prostate cancer remains unclear [2–13,16–50]. For patients with localized prostate cancer, treatment choices include active surveillance, watchful waiting, or aggressive, potentially curative therapies, such as radical prostatectomy (RP), including robotic-assisted laparoscopic prostatectomy (RALP), external-beam radiation therapy (EBRT), brachytherapy (BT) and proton therapy (PT), all with the potential for clinically significant side effects. Patient-centered care, a key component of high quality of care, involves the application of scientific knowledge to patient care, tailored to each individual's unique characteristics, circumstances, needs and preferences [11,27–36,42,46,51–56]. In patient-centered prostate cancer care, concordance between patient preferences and treatment attributes may help optimize outcomes of care [57–65].

Uncertainties confronted by healthcare providers and patients in the course of prostate cancer care call for improved measures to understand patient preferences [11,27–36,42,46,51–55]. This is particularly important because little is known about the optimal management strategies

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for prostate cancer and how best to advise patients regarding treatment choice [11,27–36,42,46,51–55]. Only few studies have assessed the patient treatment preferences, role desired by patients in decision-making, and the association of patient treatment preferences with outcomes, as we do in this study. Our study addresses the need for analyzing patients' values and their relationship to outcomes in order to determine if matching patients' values to attributes of treatment can improve quality of care and outcomes.

The objective of this patient-centered randomized clinical trial is to study the comparative effectiveness of a conjoint analysis intervention compared to usual care for improving subjective and objective outcomes in men with localized prostate cancer. We will also identify preferred attributes of alternative prostate cancer treatments (including active surveillance) that will aid in evaluating treatment options.

2. Theoretical framework

The Institute of Medicine defined patient-centered care as "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all decisions" [66–68]. Patient-centered care that encompasses informed decision- making is a process of decision-making by patient and physician where the patient: 1) understands the risk or seriousness of the disease or condition to be prevented; 2) understands the preventive service, including risks, benefits, alternatives and uncertainties; 3) has evaluated his/her values regarding the potential benefits and harms associated with treatment; and 4) has engaged in decision-making at a level he/she desires and feels comfortable with [32,54,60,66,67,69–72]. As seen in Fig. 1, a conceptual model of individual decision-making in the context of patient-centered care consists of multiple domains (patient and clinical characteristics, attributes and values; patient preferences; physician recommendation; treatment choice; concordance and outcomes) that influence treatment choice and outcomes [57,63,73–77]. Patients differ in the extent to which they wish to be involved in decision making for their medical care [69,78]. While some prefer active participation, others opt for a more passive role and defer decisions to their physician. Physicians are thus encouraged to tailor the care according to patient preferences [24,28,32,39,54,67,69,70,79–81].

Per preference assessment theory, prostate cancer patients will be aided in deciding their treatment strategy based on information about the choices. The healthcare provider, as the patient's agent, will support the patient in this process, rather than deciding the treatment for him. As physicians are more likely to recommend treatments related to their specialty [82], patient-centered care with the addition of uniform preference assessment can help minimize the physician decision bias and help better inform the patients. Patient-centered care requires knowledge of how patients' preferences and reasoning affects choice of alternative therapeutic options. This study has direct relevance to patient-centered care as we will identify patient preferences, and how the concordance between preferences and attributes of treatment received affects the outcomes of prostate cancer treatment.

3. Materials and methods

3.1. Design overview

Our study has two phases (Fig. 2). In Phase 1, we adopted a mixed methods approach to determine the attributes and levels for the conjoint task instrument. First, we recruited 49 prostate cancer survivors for Phase 1. Participants engaged in a one-on-one, in-depth interview taking an average 2 h to discuss experiences with prostate cancer and treatment decision making.

At the end of the interview, each participant completed a structured survey that asked about resources that were helpful in learning about prostate cancer treatment options and in making treatment decisions. Patients talked about the attributes of treatment that were most important in choosing the treatment. Participants were offered a $20 gift as a token of appreciation. Next, we conducted three provider focus groups and an extensive literature review to identify more attributes. The results of patient interviews, focus groups and the literature review were used to develop the attributes and levels of the conjoint instrument used in Phase 2 of the study. We used Sawtooth Software for development of the computer based adaptive conjoint instrument. The conjoint instrument has three main parts. In Part 1, general instructions about using the instrument are provided. Part 2 shows some of the different features of prostate cancer treatments. The participant is asked to indicate which attributes are most desirable to him. This information

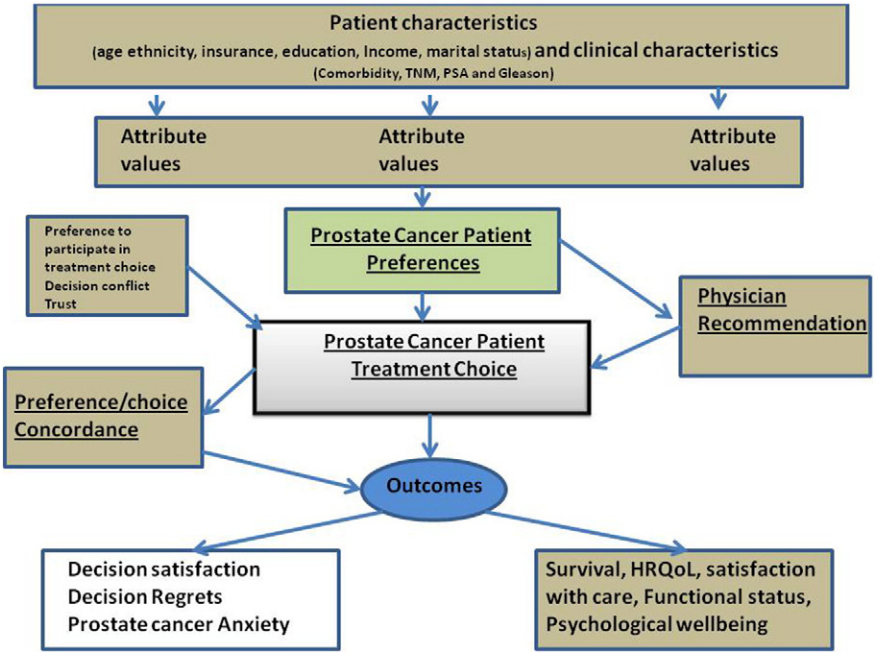

Fig. 1. Patient centered prostate cancer care.

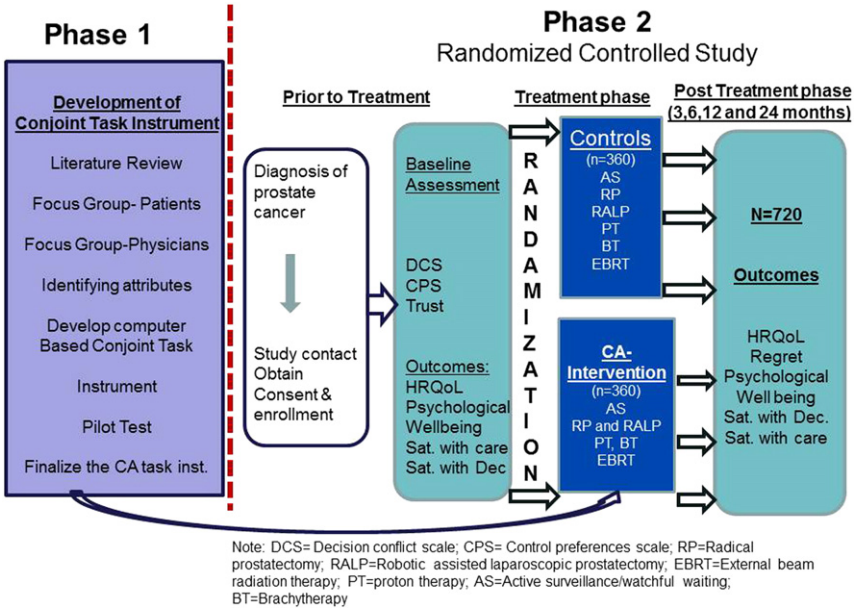

Fig. 2. Summary of the research design.

is used to refine the conjoint attributes displayed in Part 3. Part 3 shows bundles of features and the participant simply selects the treatment bundles that are most desirable to him. After completing the instrument, the participant receives a summary of features of prostate cancer treatment that are most important to him based on his answers. Participant is able to share conjoint results with his provider.

In Phase 2, we analyze the comparative effectiveness of the patient centered conjoint analysis intervention and assess the relationships among attributes of treatment received, profiles of valued treatment attributes, and patient outcomes using a two-arm randomized controlled trial. We test if the concordance between values markers and treatment received is predictive of subjective and objective outcomes in prostate cancer patients.

3.2. Eligibility criteria for Phase 2

The criteria for eligibility for Phase 2 of the study are as follows: (1) treated for prostate cancer at University of Pennsylvania Health System (UPHS), Fox Chase Cancer Center (FCCC), Temple Health System, or Corporal Michael J. Crescenz VA Medical Center (CMCVAMC); (2) aged ≥18 years; (3) newly diagnosed with localized prostate cancer (diagnosed within last one year and haven't received curative intent treatment for prostate cancer); (4) low risk (PSA ≤10 ng/ml, and Gleason ≤6, and stage T1c–T2a), intermediate risk (PSA >10–≤20 ng/ml, or Gleason 7, or stage T2b), and high risk (PSA > 20 ng/ml, or Gleason score 8–10, or stage T2c) group [36,83] and (5) provide informed consent. The exclusion criteria are as follows: (1) distant, metastatic or un-staged prostate cancer at diagnosis; (2) unable to communicate in English; and (3) has received treatment for prostate cancer.

3.3. Recruitment

Participants were recruited from urology and radiation oncology practices of UPHS, CMCVAMC, FCCC and Temple Health System. Recruitment occurred in following steps: 1) obtaining consent from patient's urologist/physician for reviewing medical records; 2) determining potential eligibility by reviewing medical records; 3) screening via phone or in practice to assess willingness to participate; and 4) obtaining informed consent and HIPAA permissions. The study and consent form comply with HIPAA Standards for Privacy of Individually Identifiable Health Information. This study was approved by the local Institutional Review Board at all sites. The study was registered with the Clinicaltrials.gov (NCT02032550).

3.4. Randomization

The study biostatistician created randomization sequences for each site using a pseudo-random number generator with random blocking varying sizes from 2 to 6. The treatment assignments were placed in sealed, opaque envelopes. All investigators, staff and referring physicians were masked to the treatment assignment, except the research assistant who opened the envelope and notified participants of group assignment.

3.5. Intervention

Arm 1: Participants in the intervention arm completed the computer based adaptive conjoint instrument to assess their preferences at baseline. This instrument has three parts. In the first part, brief overview of the instrument is provided. In the second part, the participants ranked (ranging from 'not important' to 'extremely important') the attributes of various treatments. In the third part, choice scenarios consisting of combinations of attributes are presented based on the ranking of the attributes. The participants are asked to select the combination that they preferred most (five choices ranged from 'strongly prefer treatment A' to 'strongly prefer treatment B'). At the end of the task, a graph and a list of the top five attributes most preferred by the participant is generated. The participants are offered an option to have a printout of this list and graph and share it with their providers. On average, this instrument required 30–40 min to complete. The participant could complete the instrument on a laptop in the practice or could choose to complete it from home. Arm 2: Participants from this group received usual care that consisted of standard educational material from the provider about prostate cancer treatment options.

3.6. Study outcomes and assessments

All participants complete self-administered surveys at baseline within 1–2 weeks after enrollment (prior to treatment initiation) and at 3, 6, 12 and 24 months post-enrollment. Non-respondents are contacted via telephone after 10 days. Table 1 presents the subjective and objectives outcomes, corresponding assessment tool and testing

Table 1
Study outcomes and assessments.

Outcome	Assessment tool	Time
Subjective outcomes		
Urologic symptoms	American Urological Association Symptom Index (AUA-SI) [85]	Baseline, 3,6, 12, and 24 m
Regret	Regret scale [24,65,86–88]	Baseline, 3,6, 12, and 24 m
Generic HRQoL	SF-36 [89,90]	Baseline, 3,6, 12, and 24 m
Prostate specific HRQoL	EPIC [91–93]	Baseline, 3,6, 12, and 24 m
Satisfaction with decision	Satisfaction with decision (SWD) [94]	Baseline, 3,6, 12, and 24 m
Patient satisfaction	Patient satisfaction questionnaire (PSQ-18) [95]	Baseline, 3,6, 12, and 24 m
Control preferences	Control preferences scale (CPS) [96]	Baseline
Decision conflict	Decision conflict scale (DCS) [97]	Baseline
Anxiety	Memorial anxiety scale for prostate cancer (MAX-PC) [98]	Baseline, 3,6, 12, and 24 m
Patient trust	Patient trust-wake forest physician trust scale [99–101]	Baseline
Depression	The Center for Epidemiologic Studies Depression (CES-D) scale [102]	Baseline, 3,6, 12, and 24 m
Objective outcomes		
Treatment choice	Self-report and verified from medical chart review	3 m, 6 m, 12 m, and 24 m
Biochemical recurrence	Medical chart review [11,35,36,46,103,104]	3 m, 6 m, 12 m, and 24 m
Medical complications	Medical chart review [105]	3 m, 6 m, 12 m, and 24 m

schedule. Participants receive $20 gift card as a token of appreciation for completing the baseline and for each follow-up assessment.

Data on following potential confounding variables are collected: *Disease severity*: Prostate cancer stage or TNM stage, grade and histology obtained from electronic medical records. *Gleason score*: The Gleason score is a sum of the predominant pattern and the second most common pattern of the Gleason grade. Gleason score ranges from 2 to 10 classified as low (2–4), intermediate (5–7) or high-grade (8–10). *Charlson comorbidity index*: This index is a medical record-based metric designed to predict death in longitudinal studies, with an integer score representing increasing burden of illness [84]. We will use diagnostic information from administrative databases regarding inpatient encounters in 180 days prior to the month of prostate cancer diagnosis and will develop comorbidity index score. *Demographic variables*: We will gather via standard self-report baseline data on patient age, income, race, ethnicity, education, health insurance, occupation, marital status, smoking status, height, weight and family history of prostate cancer.

3.7. Sample size

Our sample size is based on the observed differences in outcomes such as HRQoL (SF-36 and prostate cancer index, PCI) and psychological wellbeing across groups. The primary outcome is HRQoL as measured by the SF-36 and prostate cancer index sub-scales. A change of 5 to 9 points on prostate cancer index is clinically meaningful [91]. Similarly, a difference of 7 points or more on the SF-36 subscales is considered clinically meaningful [90,91,95]. Based on our prior research and that of Litwin et al. [91,106], the standard deviations for the prostate cancer index and SF-36 scales in samples of men with prostate cancer mostly range from 8 to 14; hence standardized differences (SDs) of $7/14 = 0.5$ to $7/8 = 0.87$ will be clinically relevant. The power calculations for specific aims assume availability of 720 participants who are eligible for randomization into one of the two intervention groups. We assume a conservative intra-class correlation of 0.3 and 4 follow-up measures per subject. The sample size is adjusted to accommodate a 10% missing or dropout rate by 24 months based on rates over a similar period of time in previous studies [90,91,95]. We assume 80% power and two-sided level of significance of $\alpha = 0.05$. We have 80% power to detect a 1.2 point difference in prostate cancer index or SF-36 sub-scale.

3.8. Data analysis plan

First, we will check the data quality and carry out descriptive analyses of demographics and key outcome variables. We will also test for differences in patient demographic variables in those who completed the study in comparison to patients who were lost to follow-up. The primary and secondary outcomes are measured up to four times after baseline (3 m, 6 m, 12 m and 24 m). Using an intent-to-treat approach, we will apply mixed effects models for binary, continuous and count outcomes as appropriate to estimate changes over time for satisfaction with decision, complications, HRQoL, urologic symptoms, psychological wellbeing and satisfaction with care. The mixed effects models properly account for correlation among repeated measures. The models will include fixed effects for group, time and the group-by-time interaction. The interaction term allows the comparison of the change in outcome over time between the intervention groups. Additionally, the models will include patient demographics that are not balanced by randomization or are associated with loss to follow-up. Both unadjusted and adjusted results will be reported in terms of the Wald test, point estimates, and 95% confidence intervals. We will apply survival analyses (Kaplan–Meier, logrank and Cox model) to model effects of intervention and covariates on time to PSA recurrence

For the intervention group only, to develop values markers, we will assess individual level utilities, followed by latent profile analysis based on these individual level utilities. We will carry out additional analyses of individual-level utilities to classify patients according to profiles or patterns of utilities using latent profile analysis. Next, we will test if prostate cancer patients whose treatment is more concordant with their values markers experience improved subjective and objective outcomes. We will analyze the association of the concordance between stated individual preferences and actual treatment received with objective and subjective outcomes, using Kappa statistics, adjusting for covariates. We operationalized concordance as agreement between a patient's value markers and the attributes of the treatment that the patient receives (choice). The degree of concordance will be used as an independent variable to test its association with outcomes. Additionally, 'concordant group' will be defined as at least 75% agreement between values markers and treatment related attributes. We will perform sensitivity analysis to test robustness of results. For objective outcomes, we will test the hypothesis that degree of concordance is associated with prostate cancer recurrence (measured by PSA doubling time). We will apply survival analyses (Kaplan–Meier, logrank and Cox model) to model effect of concordance on time to PSA recurrence. For subjective outcomes, we will first perform inferential analysis with ANOVA, chi-squared and non-parametric tests. Next, we will apply mixed effects models for binary, continuous and count outcomes as appropriate to estimate the association between degree of concordance and changes over time for satisfaction with decision, complications, HRQoL, urologic symptoms, psychological wellbeing and satisfaction with care.

4. Summary

Informed decision-making is at the core of patient-centered care and is a process that implies that a physician's unbiased knowledge is transferred to the patient, who then has the knowledge and preferences necessary to make a decision. Studies have discussed the non-systematic process of decision making in prostate cancer care. Many patients with localized prostate cancer choose surgery instead of other treatments thinking that surgery is the best way to cure prostate cancer [107–110]. Prostate cancer treatments frequently are complex and unfamiliar to many patients. A majority of prostate cancer patients report that their physician's recommendation was the most important factor in their treatment choice [11,12,28–37,42,46,47,51–55]. This is appropriate if the physician is an efficient agent for the patient, i.e., making the decision the patient would if the patient had physician's medical knowledge. The physician agency model presupposes that the physician knows and understands the patient's attitudes, beliefs, preferences and values. However, patient and physician beliefs differ in many respects, such as prioritizing outcomes, conceptualization of the illness, and ranking available options [11,12,16,28–37,42,46,47,51–55,59,111–113]. Thus, a physician's opinion as a credible source may inappropriately bias a patient's systematic decision process. Preferences cannot be based on misinformation or missing information, so physicians need to ascertain that they and their patients have sufficient knowledge to tailor treatment in concordance with the patient's values. Respecting and responding to patient preferences - the hallmark of patient centered care – requires accurately eliciting preferences and aiding patients in constructing them.

Currently, little is understood about how a patient's personal values align with the treatments they receive, if this has an impact on outcomes, and the role of trust in treatment choice and outcomes. It is important to understand the process of discovering what patient-centered care will mean and what clinicians and researchers must do to transform the concept into a safe and effective reality [114]. Our study will provide important information related to patient preferences. We focus on the attributes of prostate cancer treatment that are most valued by patients to determine if specific valued treatment profiles or "values markers" are associated with treatments received and if concordance between values markers and treatment received is associated with subjective and objective outcomes among prostate cancer patients.

Conflict of interest

There are no conflicts of interest to disclose.

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