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Research Article

A Qualitative Study on Patients' Decisions about Active Surveillance for Low Risk Prostate Cancer: Examining Patient and Provider Perspectives

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Abstract

Objective: Active Surveillance (AS) is recommended for patients diagnosed with low risk Prostate Cancer (PC) to minimize overtreatment and avoid potential decrease in patients' Health-Related Quality of Life (HRQoL). However, very few studies have examined barriers to and facilitators of the uptake of AS in eligible patients. The present study addresses this knowledge gap.

Methods: A total of 28 PC patients on AS and 3 providers were recruited from the Icahn School of Medicine at Mount Sinai (ISMMS) between January and May 2016 and interviewed to examine barriers to and facilitators of the uptake of AS. 3 Providers were interviewed to examine providers' challenges in PC care and recommendations for care improvement. Data was analyzed qualitatively using the Rapid Assessment Approach (RAA).

Results: Trust in the physician's expertise and good intentions, intimate partners' participation in the decision making, and a desire to avoid sexual dysfunction emerged as strong factors that influenced patients' decisions about choosing AS. Patients expressed no desire to discontinue AS or regret of their decisions. Insufficient information about follow-up care and missed or delayed follow-up surveillance appointments contributed to increased stress levels. Factors that could enhance patient decisions about and adherence to AS included family education, provision of AS care plans, and participation of family members in medical consultations and treatment decision making, as well as utility of supportive care services to improve patient outcomes (e.g, physical activities and nutrition programs).

Conclusions: Meeting patients' informational needs is imperative to ensure their adequate involvement in their PC management.

Practice Implications: A comprehensive follow-up care planning that address challenges of being AS enhance patient's adherence to AS and improve their health outcomes.

Keywords: Active Surveillance; Adherence to Cancer Surveillance; Lifestyle Changes; Localized Prostate Cancer; Patient-Provider Communication, Shared Decisions; Stress and Cancer Worries

Introduction

The number of PC survivors in the United States has approached 2.9 million with approximately 164,690 patients expected to be diagnosed in 2018 alone [1]. For patients diagnosed with localized disease (Gleason score 6 or less, cT1/T2a, prostate specific antigen less than 10 ng/ml), cancer care options include definitive treatment (e.g, prostatectomy) and Active Surveillance (AS) [2,3]. However, recent randomized-controlled trials in PC patients have showed a significant amount of overtreatment leading to a potentially avoidable decrease in Health-Related Quality of Life (HRQOL) [3]. AS delays definitive treatment until it is warranted on the basis of defined clinical indicators of disease progression [4]. Ideally, an AS protocol involves: a) identification of low-risk patients; b) rigorous monitoring for PC progression and c) providing appropriate therapy to those whose disease has progressed [5]. While the impact of AS on patients' HRQOL is less deleterious than for those who pursue definitive treatment, men on AS also experience substantial anxiety and distress [6,7]. Very few studies have examined barriers and facilitators of uptake of AS from the patient and provider perspectives [8,9]. These studies showed that patient factors affecting decisions about AS include younger age at diagnosis, higher educational level, desire for cancer control and cure, and avoidance of treatment side effects [2,8,9]. A national survey among 1,366 physicians showed that although the majority believe that AS is effective, only a minority would recommend it for eligible patients [10]. The present study aims to identify factors that influence patients' decisions and adherence to AS from both the patient and the provider perspectives with the goal to inform supportive care of patients and their family caregivers (e.g, psychosocial, educational, and communication interventions) [2,10].

Study Design

Selection and Recruitment of Participants

We used purposive sampling method [11] to recruit PC patients from the Icahn School of Medicine at Mount Sinai (ISMMS) between January and May 2016. Patients were eligible if they were 1) on AS protocol, able to communicate in English, and 2) between 18 and 85 years of age. Exclusion criteria included other cancer, metastasis, or cancer recurrence. This was done to reduce potential recall biases introduced by experiencing unmet informational needs unrelated to the AS experience. Patient data was collected though patient interviews, and via patient Electronic Health Records (EHR). Three ISMMS PC health care providers were interviewed to increase understanding of the challenges, barriers, and potential facilitators for the uptake of AS from their perspectives. This study was approved by the ISMMS Institutional Review Board.

Procedures

Eligible patients identified through EHR were sent invitation letters to participate in the study. Guided by literature reviews, our prior studies, and input from the research team [12,13], a semi-structured interview guide was developed to explore 3 major areas: 1) patients' needs at time of diagnosis, 2) patients' needs while on the AS protocol, and 3) patients' recommendations for health care improvements and follow-up care (Appendix A in Supplementary material). Of the 60 patients approached, 32 (53%) agreed to participate, and 28 (47%) completed an interview on phone (n=17) or in person (n = 11). The median time for the interviews was 60 minutes (range: 30–90 min). Consent forms were obtained prior to each interview. Reasons for non-participation or inability to complete the study included lack of interest or time and a poor health condition. The patient interviews were conducted by the same member of the research team (NM). Providers were asked by a second member of the research team (TB) about challenges patients have with AS and suggested strategies to enhance patients' decisions and adherence to AS (Appendix B in Supplementary material). All interviews were audio-taped and transcribed. Coding was conducted simultaneously with data collection and data collection ceased on reaching data saturation (i.e, when no new or relevant data emerged regarding the information/support needs categories) [14-16]. We used the Rapid Assessment Approach (RAA), to timely develop an understanding of AS patient experience and factors influencing adherence to AS. The RAA is an intensive qualitative inquiry using data triangulation [14] via conducting interviews, iterative qualitative data analysis via deductive coding, and utility of patient HER [14]. The utility of phone interviewing allowed inclusion of patients unable to participate in person due to geographical, medical or work-related restrictions to take part the study based on their time preferences. Alleviating these restrictions allowed us to increase the demographic (i.e, currently employed younger patients), and geographic heterogeneity of the study sample [17].

Data Analyses

Content analysis of participant responses included checking for representativeness of the data (i.e, checking interpretations against raw data), data triangulation (i.e, use of both interviews [14] and confirmation of clinical data using EHR), with an emphasis on contextually thick description (e.g, incorporating non-verbal responses and participants' emotional state) [15,16,18]. Patient recruitment continued until we reached data saturation with 28 patients (i.e, when adding more participants to the study did not result in additional codes of themes) [19]. Digitally recorded interviews of patients and health care providers were structured based on two interview guides; one for patients and one for stakeholders Following the RAA guidelines, two members of the research team (HC and JH) used the interview guides while listening to each recording to create case summaries capturing patients' and providers' responses to main codes or domains of interest [16,20-23]. Summary accuracy was facilitated by verifying details from recordings and identifying rich segments for in-depth analysis. Summary points were then transferred to a matrix display to systematically identify response trends. Differences in interpretations and summary points were resolved through entire research team discussions until all discrepancies were resolved.

Results

The majority of patients (N = 28; age range: 54-73 years) were married (78.6%), Caucasians (75%), and self-identified as heterosexual 89.3%; (Table 1).

Full Sample **N=28**	**N (%)**
Age	
Mean (Range)	64.9 (54-73)
SD	6.16
Gender	
Male	28 (100%)
Sexual Orientation	
Heterosexual	25 (89.3%)
Homosexual	1 (3.57%)
Unknown/Not stated	2 (7.14%)
Race	
Caucasian	21 (75.0%)
Asian	1 (3.57%)
Hispanic	1 (3.57%)
Unknown	5 (17.8%)
Marital Status	
Single	4 (14.3%)
Married/Living with Partner	22 (78.6%)
Divorced/ Separated	2 (7.14%)
Employment	
Employed	11 (39%)
Retired	6 (22%)
Unknown/Not stated	11 (39%)
Smoking Status	
Never Smoker	21 (75%)
Former Smoker	2 (7.14%)
Unknown/Not stated	5 (17.9%)
Comorbidities	
Hypertension	15 (53.6%)
Hyperlipidemia	15 (53.6%)
Diabetes Mellitus	3 (10.7%)
Erectile Dysfunction	2 (7.14%)
PSA level	
Mean (Range)	4.72 (0.78-12.54)
Score<10	27 (96.4%)
Score≥10	1 (3.57%)
Gleason Score	
3+3	26 (92.8%)
3+4	2 (7.14%)
Risk level based on D'Amico classification	
Low	25 (89.3)
Intermediate	3 (10.7)
High **Availability of social support**	0 (0)
Family caregivers involved in AS decision making	16 (57%)
Family caregivers not involved in AS decision making	1 (4%)
Unknown/Not stated	11 (39)

Table 1: Participants Demographic and Clinical Characteristics.

11 patients participated in in person interviews and 17 patients participated in phone interviews. Although the majority were low risk (89.3%) based on D'Amico criteria [24], 3 patients were intermediate risk (10.7%). A physician, a physician assistant, and a nurse practitioner participated in the stakeholder interviews. The summary points that emerged from the data analyses are listed in (Tables 2-6).

	Full Sample (n = 28)	**Summary points**	**Examples**
Information believed to be useful but not offered or fully discussed by the physician	39%	● Treatment options and side effects	"I knew nothing about active surveillance I just wanted to understand what it was although it was a fairly easy concept to understand" Pt#7
		● Information received at the time of diagnosis about AS	"I knew nothing about it ……I mean nothing about it at the time my Gleason score came back at six and Dr. X just told me we were going to watch it" Pt#6
		● Frequency of follow up appointments	"I didn't receive anything at that time of diagnosis but as time went on there was clearly some information generated and I just got a whole pack of information" Pt#2
Searched for information about treatment options and treatment side effects	89%	● Searched the internet	"I searched the Internet high and low on everything I could find as well as I did speak to a couple of people who went to active surveillance or went through the surgery and had their prostate removed" Pt#13
		● Talked to other patients	
		● Second opinion	"I did research online and I spoke to a couple urologists along with the Doctor X" Pt#9
		● Read medical journals/ newsletter	
Discussion with physician	100%	● Pros/Cons of available treatment options	He just didn't think there was any necessity to do anything right now based on all the information he had and in being who he is, I have a lot of faith in him. I was gonna go along with it." Pt#1
		● Eligibility criteria for AS	"He seemed to be very open to the idea that while surgery was an option-not only was it not the only option, it might not be the best option-that there was a higher percentage of potential problem in surgery than there would be in a very effective active surveillance program" Pt#2
		● Follow up care plan	"He more or less outlined what to expect going forward as far as every 3 months or one sort of examination or test. He was very clear about it." Pt#2
Physicians, and family caregiver's involvement in the treatment decision making	79%	● Made their own personal choice of treatment	"I think the decision was a combination of both (Surgeon and patient's choice). Pt#1
		● Made their decision based on physicians' recommendation	"My son is a pathologist and he works with Surgeon so I guess you could say he influenced me as well when he said Surgeon is one of the leading authorities in the field of prostate cancer and whatever he says I should follow" Pt#3
		● Made treatment decision after considering family members recommendations	"Surgeon, Dr. X at the Cancer Foundation influenced my decision" Pt#11
		● Getting second opinion from colleagues	"Based on the potential impact on quality of life and basically the recuperation and going through the operation was something that we felt, between my wife and I, that we should explore the active surveillance" Pt#13
			-"I didn't like going to the internet because they overdo it...I saw another doctor. He was, based on all the initial stuff, he was pretty much in agreement with Dr. X. So i did get a second opinion... I did my own little reading and everything and I think that I got-I think I got-y'know- all the information that I needed-at least I believe I did" Pt#1

Choosing Active Surveillance	100%	● Better than the alternative (surgery, radiation, chemotherapy)	"Ultimately I was influenced by the fact that surgeon was a surgeon and thought that active surveillance was the right course. So that advice coming from a surgeon was significant for me." Pt#5
		● No symptomatology	"I think that most likely I'm going to die from something else at that point…Some of them (referring to the tests) are uncomfortable but it's something I'm resigned to…usually when I have a biopsy there's a lot of bleeding or soreness...I think that's just part of getting older and it's better than the alternative…" Pt#10
		● Tolerance for discomfort associated with surveillance tests	
		● Avoidance of side effects of surgery	"I prefer not to have any surgery with its side effects so if the cancer progressed then I'd deal with it...I chose to have AS." Pt#14
		● The belief that men live longer after prostate cancer compared to other cancers	
Worries about active surveillance management	96%	● Not removing a tumor that may potentially progress	"The major concern was by going on active surveillance your remove an opportunity for a cure prostate cancer if your symptoms accelerate and its determined later that you need surgery that the prognosis is not as good as it would have been if you had addressed it earlier on. "Pt#10
			"My concerns were about having something that didn't show up in the surveillance like a metastatic disease but the risk was so low" Pt#8
			"The negative is you have cancer in your body and the natural inclination is to get rid of that...you have to kind of accept your physician's advice that it's low grade...psychologically, at every quarter there is a heightened level of anxiety…"
			"Cancer is constantly in my mind. I think that if I had decided to have surgery I would have put that out of my mind. I probably would have had more peace of mind but there would still be worry" Pt#7

Table 2: Factors that affect patients' decisions about PC management at time of diagnosis.

	Full Sample (n = 28)	Summary points	Examples
Caregivers' influences on follow-up care	79%	● Spouses' and other family caregivers' involvement in patients' follow-up care ● Colleagues/ Neighbors	- "My wife was involved with me the entire time, she went with me in all the appointments, shared all the reading with her, and she was with me with Surgeon …" Pt#9 -"She (wife) probably was a negative influence. She probably had more worries about recurrences than I had"Pt#8

Difficulties and challenges during the active surveillance protocol	100%	● Keeping up with frequent appointments ● Uncertainty of living with tumor ● Side effects from biopsies and MRIs ● Other existing health issues	- "Urinary problems, not sure if the problems are associated with prostate cancer or just simply with age. "Pt#11 -"I live in southern Jersey, so sometimes it's a pain in the butt getting over to New York City."Pt#6 -"Cancer is constantly in my mind. I think that if I had decided to have surgery I would have put that out of my mind. I probably would have had more peace of mind but there would still be worry" Pt#8
Coping with the possibility of tumor progression	93%	● Adherence to follow-up appointments every few months will ensure cancer would be watched carefully ● Side effects of surgery and chemotherapy would be avoided with Active Surveillance ● Patient's beliefs about symptom and symptom management	- "Surgeon and the staff there have been very good. As long as I'm diligent with my appointments and just monitoring things and reassuring that as things stay the same there's no need to go a further step at this point and it's just more of a personal decision-if you're more comfortable or not. It's a judgement call and different people react in variety of ways"Pt#13 - "I did have concerns about that. (possibility of tumor progression) I know there is still one there but...the fact that we're watching it every 3 months gives me confidence that if something changes, we'll know about it pretty quickly" Pt#1 -"I coped with it fine...I have been living my life to the fullest and I have been very vigilant with it."Pt#2 -" …usually when I have a biopsy there's a lot of bleeding or soreness...I think that's just part of getting older and it's better than the alternative…"Pt#10
Symptom management	18%	● Urinary problems ● Side effects of follow-up tests	- "Urinary problems, not sure if the problems are associated with prostate cancer or just simply with age. "Pt#11 - "Usually when I have a biopsy there's a lot of bleeding or soreness.."Pt#10 -"The thing that was hard was the biopsy. That was difficult and Surgeon did it...so I guess that was the hardest thing and the MRI" Pt#4

Emotional distress	82%	● Fear of cancer progression ● Anxiety and stress ● Stress because of the difficulty keeping up with the follow-up appointments	-"I wouldn't say that I'm completely stress free right now but considering the alternative, I'm happy to be doing this" Pt#2 -Initially, there was a little bit of disappointment and surprise because I'm healthy and very athletic. Still, it's just a part of me and all sorts of things that are normal. " Pt#2 -"I'm out on Long Island and I have to come into the city every three months and see Surgeon and along the way, next week he recommended I see an oncologist. It's the so-called inconvenience taking a trip into Manhattan every 3 months" Pt#5 -"I'm kind of in the midst of getting a high PSA score and that creates anxiety...but the good news is I was diagnosed in 2014 and here I am in 16 and I haven't needed a radical procedure and I think I'm still relatively healthy…" Pt#7

Table 3: Factors that affect patients' adherence to active surveillance protocol**.**

	Full Sample (n = 28)	**Summary points**	**Examples**
Recommendations for health care improvements_	100%	● Follow up care plan ● Brochure (Internet and Web Based) ● Spanish translation of educational materials and follow-up care information ● Utility of Patient Portal ● Personal testimonials from AS patients	- "Provide information about the various tests like the ultrasound and biopsies." Pt#10 - "I think a hard copy of a care plan would be the best way, mailed to my home" Pt#13 - "I think it would be helpful to get a report without asking- what's my running PSA, what are the results of the MRI, things like that. I just think it would be helpful for people to have those type of reports periodically" Pt#3 -"Either email or hard copy but something. Just showing your history [results of DRE, PSA, MRI]...I think something like that would be very helpful and I think patients would appreciate that really, rather than having to remember on their own every 3 months I gotta make an appointment."Pt#3 -"Ideally it would be great if it was just web based but for elderly it would be easier on paper…"Pt#7

Additional Health Services needed	61%	● Dietician/ nutritionist ● Session with the navigator, nurse, and social worker etc. to discuss AS ● Physical Activity Program ● Smoking cessation program ● Receiving reminders for future appointments	-“He (physician) gave me some stuff about nutrition, and stuff like that. And he had wanted me to go to a nutritionist that he had on staff but for some reason i never was able to get back to it. I sent her a few emails and she never responded back.” -“I had a service meeting; I know you (referring to patients) have a nutritionist... Surgeon had given me (the dietician).“ Pt#9 -- “I’ve spoken with her (the dietician)...I think she’s terrific.” Pt#11 -“When Surgeon made that drawing, I swear it was like magic...but that meant a lot more to me, just showing me it visually, than all the forms in the world.” Pt#20
Recommendations for Future AS Patients	100%	● Patients should choose AS only if they are completely confident and committed to what this process entails (i.e. annual biopsy, serial PSAs and DREs and regular appointments) ● Keeping track of all appointments ● Keeping track of the history of the results ● Finding a doctor you can trust and are comfortable with ● Maintaining a good exercise and diet ● Ask your physician questions	- “My advice is go to the best surgeon you can find and the best radiologist...if they tell you, you don’t need radiation or surgery, then that should be the source of your comfort...then I think that’s a lot more important than what your friend tells you or what you hear on the radio…” Pt#11 - “Try to be as comfortable as possible with the situation and we really have to figure it out on an individual basis” Pt#13 -“Find a good doctor, stay in good physical shape, don’t gain weight, eat properly...keep a close eye on your condition.”Pt#1 -“If you’re going to consider AS, you have to be committed. It’s not always going to be convenient but you have to make sure to see a doctor every 3 months...the DREs, annual MRIs, and just the interaction with the doctor...I get a lot out of my conversations with the doctor. I bring questions, and he always has solid, good, scientific answers for me...By embracing the visits, I do better because I walk out with more confidence.” Pt#9
Connect with other patients on AS	79%	● Connect with other PrCa survivors via support groups ● Medical care team to match the patient with r patient currently on AS	-“If you know somebody else who has gone through the disease talk to them about what they went through and whether it was a good experience, a bad experience…”Pt#5 -“I think probably the experiences of other people might be helpful, sharing their ideas of what they think is helpful, about leaving yourself the opportunity to have the denial set in…”Pt#8

Educational Intervention - the care plan - Pamphlets - EHR - Mt. Sinai patient portal	100%	● Being provided with a hard copy/brochure of information would be helpful. ● Having access to lab results (MRI, DRE, etc.) and info about active surveillance.	-"Information about the various tests like the ultrasound and biopsies." Pt#10 -"I think a hard copy would be the best way, mailed to my home." Pt#13

Table 4: Patients' recommendations for health care improvements and follow-up care.

	Summary points	Examples
Challenges prostate cancer patients face when making decisions about active surveillance, in your opinion	● Difficulty of decision making ● Disease progression	- "If they proceed with active surveillance, is their disease going to progress, you know, to the point where it's inoperable?"
	● Eventual need for surgery	- "Being concerned about the timeline of things going forward and am I just putting off something that I will ultimately have to do any way and would I be a better surgical candidate younger and healthier?"
	● The word "cancer" causing anxiety	- "One, is the actual anxiety of being diagnosed with a cancer, and I think the "cancer" word is the big problem and then not doing anything about it."
Challenges prostate cancer patients who are on active surveillance face	● PSA fluctuations lead to worry of disease progression	- "The PSA fluctuations…….. Because it's not that specific, so a slight increase, you know, which isn't that significant but to them (patients) they think their cancer is progressing."
	● Recommending diagnostic testing	- "… I feel like using MRI versus biopsy there's always, patients prefer one versus the other. Not having the data to support one or the other makes it difficult because patients actually have opinions on what they want."
Challenges with managing uncertainty, anxiety, and worries and dealing with anxiety	● Uncertainty due to lack of universal standards/protocol ● Dealing with patients' anxiety, worries, and concerns	- " I think, one of the big problems that we have as providers, because we still don't have a consensus on who should be on active surveillance and who should not be on active surveillance. Every program, every person, everybody has their own, sort of, inclusion criteria. There's not a universal protocol so I think that's difficult for patients. "
		- "I think the biggest thing about active surveillance is having a universal protocol, so whether it's institutional, whether it's national, um I think basically, making it a language that we all understand, and it's sort of, doesn't diverge from person to person or place to place would make it a lot easier for patients to understand."
		- "That's the biggest challenge we face for active surveillance patients, is how do we treat their anxiety. I think that we have tools that we can use: genomic tools, MRIs, biopsies, PSAs, and a variety of other tools that can help us decrease anxiety levels by showing patients that look, we've done four to five different tests. They all show that you're low-risk, they all show that you have favorable pathology."

Patient referral to other resources including resources for mental health support	● Opting not to see mental health professional	- "I do have people to refer to for[]mental health services], but many patients choose not to take the referrals or anything to that extent."
	● Support groups	- " But I do think that support groups are key for these patients to be able to see other patients who are on active surveillance and who are doing well, is key."
Challenges in adherence to active surveillance protocol	● Adherence to follow up appointments	- "You know, you have patients who are just very… who say they would just rather get treated because this is becoming a little bit too cumbersome."
	● Medical Insurance	- "I think one of [the reasons for opting out is there might be a possibility of a change in Gleason score, on a repeat biopsy or surveillance biopsy."
	● Reasons why patients drop-off active surveillance	"I don't know about resources but just maybe the follow up plan, some patients forget that PSA every three months, they forget the yearly MRI. One patient specifically was confused about his follow up, and I said ok, I'm going to write it down for you."
		Some guidelines are a little bit different. Where a lot of times you can say this is our recommendation to do the annual MRI for surveillance but some insurances may not cover it because it's not in like a certain guideline. It would be nice for them to see what our ideal plan would be."
Helping patients stay on active surveillance when there is no sign of clinical progression	● Offering multiple modalities of testing	"I think it's the reinforcement of having multiple modalities and multiple tools to show patients that they're low-risk. And by actually piling on the data and information with patients, they understand a little bit more, and of course keeping it in laymen's terms."
	● Discussion of HRQoL	- "By showing them the data that's out there for patients who been on active surveillance for ten, or twelve or fifteen years and showing that not many patients fall off. Or that when they do fall, and they get treatment, they have the same survival as the patients who got treated right away."
	● Ultimately patient's decision	- "But, it's ultimately their decision because it's their body, it's their health, and we can help to guide them, but I try not to be very… not that I try not to take a side, but I try not to be overly encouraging one way or the other."
Other clinic or hospital resources that could be uses to address informational or supportive care needs of patients	● Referral to urologists for second opinion	- "I usually refer them to another physician. So another urologist. A second opinion with one of the other prostate guys to be able to sort of hear the same, hear it from somebody else."
	● List of cancer resources (non specific).	- "I think outside resources it's been more like a list of cancer resources. Maybe not necessarily as specific as they could be."
Utility of support groups and access to mental health resources	● Support group system	- "I think a more robust support group system would definitely help patients. You know, having like an organized place where they can go and meet and speak with people would definitely be beneficial to Sinai. "
	● A list of resources/different psychologists and social workers.	- "I wish there was a list. Resources, or different psychologists and social workers."
	● Connections with other patients	- "There was a patient recently who asked if there was any other patients on active surveillance who had volunteered to talk to the patients to try and make that decision. And that wasn't something that we had as far as I know."

Table 5: Challenges in PC management and patient care: Provider perspective.

• Information about AS protocol
• Information about benefits and risks of AS compared to other PC management options (e.g, surgery, radiation, and watchful waiting)
• Combating stress triggered by cancer screening and worries about cancer progression and metastasis
• Involvement of family caregivers and social partners in AS decisions and PC management
• Follow-up reminders about cancer screening and timely access to clinical information for patients and their caregivers
• Lifestyle changes to maintain a sense of control and improve patients' outcomes (e.g, smoking cessation, diet and nutrition, physical activities)

Table 6: Summary of the patients' prominent challenges in decisions and adherence to AS.

Factors that Influenced Patients' Decisions about AS: Patient Perspective

39% of the patients reported unmet informational needs at time of diagnosis. These needs revolved around understanding AS; follow-up tests and frequency of testing; and side effects of frequent biopsies. 89% searched the internet, talked to other PC patients on AS, or read medical journals about AS. The information searched included comparing AS to PC definitive treatments, potential changes in sexual function, and AS selection criteria. Over three quarters (79%) of participants followed the physician's recommendation for AS. Trust in the physician's expertise and good intentions, spouses' participation in the decision making, spouses' age, and the desire to avoid sexual dysfunction associated with other PC treatments strongly influenced patients' decisions. All but one reported feeling stressed about the possibility of PC progression and more than two-thirds (68%) felt that the major challenge with AS is losing the chance for a definitive treatment in the future.

Challenges Encountered During the AS protocol: Patient Perspective

Patients expressed no desire to discontinue AS or regret for their decisions. Patients, however, stated that felt more stressed around the time of repeat prostate specific antigen testing and prostate biopsies. Insufficient information about follow-up care and care management plans as well as missed or delayed follow-up appointments also contributed to patients' stress levels. Moreover, financial and insurance barriers were reported as reasons for potential AS discontinuation in the future.

Factors that Could Enhance Patients' Decisions About and Adherence to AS: Patient and Provider Perspective

Patients' and providers' input revealed several strategies that could enhance patient decision and facilitate adherence to AS. Patients' suggestions included using different informational tools (e.g, brochures, Websites, patient portals) presented in different languages and formats; sending reminders to patients of follow-up appointments; and improving access to programs to help patients with lifestyle changes (e.g, physical activities, and dietary changes). Providers' suggestions included matching patients with other survivors who are currently on AS based on patient demographic characteristics (e.g, age, race) and sexual orientation; improving the utility of mental health and social support resources within the health system and in the community to enhance patients' self-regulation and control beliefs; increasing family caregivers' involvement in PC treatment decision-making and follow-up care; and providing caregivers with access to the patient's clinical test results and care plans (e.g, patient-and-caregiver portals).

Discussion

Despite the uncertainty associated with AS, this management option remains a viable option for men with early stage, localized disease. Examining patient and provider factors that influence patients' decisions about AS and their adherence to a life-long surveillance protocol are crucial steps in improving shared treatment decision making and follow-up care. However, data on factors that may hinder or increase the uptake of AS in eligible patients is limited. We have conducted personal interviews with PC patients on AS and their health care providers to identify salient issues and significant challenges associated with treatment decision making and adherence to AS protocols. In general, our study results mirror research findings in unmet informational needs among other cancer populations including AS patients (e.g, information on cancer prognosis, information on AS, information on alternative management options, lifestyle modification, access to support resources and interaction with other survivors, and financial and medical system information) [24-26]. Providers' input confirmed unmet needs reported by AS patients and described several areas for care enhancement (e.g, utility of follow-up care plans, shared treatment decision and educational tools, and support resources).

Our study results indicated that although the majority of patients followed their physician's recommendation, they were dissatisfied with the information they received about AS and the follow-up protocol. Because patient engagement in AS decisions and follow-up care is imperative given the intensive follow-up surveillance plans and the uncertainty associated with AS outcomes, patients need to be fully informed about all aspects related to AS compared to other PC management options. There is evidence that informed PC patients are likely to make treatment decisions that reflect their values and preferences, adhere to treatment regimen, and experience improved outcomes (e.g, HRQOL, satisfaction) [27,28]. However, a major challenge for physicians that could influence their treatment recommendation and communication with patients about AS is the absence of a standardized criteria identifying patients best suited for this option. Due to the ambiguity of AS protocols, clinicians are often uncomfortable with the lack of a universal protocol and do not have a strict understanding of which patients are best a fit for AS.

In our current work, we have categorized patient input according to 3 major areas: 1) unmet informational needs at time of diagnosis and during treatment decision making, 2) unmet needs during the AS protocol, and 3) patient input on strategies to facilitate both patients' decisions and adherence to AS protocol. Several critical issues came to light, which, if addressed, could enhance patients' experience and engagement in their health care. These issues include the need for full information about AS compared to other PC management options, the need for information about risk for PC progression while on AS protocol, and increased stress and worries specifically around the time of follow-up screening test. Patients and care providers in our study suggested several care enhancement strategies that could reduce the difficulties experienced by patients in treatment decision making and challenges experienced during follow-up care. These suggestions include greater involvement of family and caregivers in PC management and treatment, communication with physicians about PC management options; utilization of a variety of informational materials on AS (e.g, brochures, websites, patient portals presented in different languages); and follow-up reminders using phone calls, Emails, or text message. Prior research in cancer patients showed that the utility of similar tools and reminders has increased patients' satisfaction with care, adherence to cancer screening, and reduced decisional regret [29-31]. Thus, it is likely that these tools, if implemented in AS standard care, may improve patient outcomes and reduce physicians' burden of care.

Additionally, both patients and care providers in our study suggested improving supportive care resources and programs to help patients with their emotional adjustment and lifestyle changes (e.g, physical activities, diet and nutrition, participating in support groups). The descriptive information of our sample showed that half of the study sample had other disease or health conditions for whom interventions and support may improve management of both PC and of other conditions comorbid with PC. Increasing evidence from recent cancer research points to the significant positive impact of lifestyle changes and social support on survival, cancer progression, and patient-centered reported outcomes (e.g, HRQOL, stress, fatigue) [32,33]. Engaging patients in positive lifestyle changes is likely to increase their control and self-efficacy beliefs, which will, in turn, boost their coping and emotional adjustment [34,35]. This is particularly relevant in circumstances where there is uncertainty regarding cancer progression and patient outcomes. Involvement of informal caregivers, particularly spouses and intimate partners, in treatment decision-making and follow-up care emerged as a significant theme confirming other research findings [36,37] Spouses and intimate partners play a significant role in cancer treatment decision making, adherence to follow-up recommendations, and provision of emotional, financial, and instrumental support [38]. A previous study in PC patients and their partners showed that decisions for AS were built on couples' evaluation of the man's health condition, desire to avoid side effects (e.g, sexual dysfunction), and trust in the ability and accuracy of the AS protocol in identifying negative changes for a successful definitive treatment whereas couples' decision for surgery was motivated by their desire to remove the cancer at all costs [39]. Thus, understanding the spouse/partner's attitudes, beliefs, and expectations about AS is needed to facilitate dyadic (patient-spouse/partner) and triadic (patient-physician-spouse/partner) AS decision-making and adherence to AS. Furthermore, because of their caregiving roles and involvement in AS decision making, family caregivers could benefit from strategies that maximize their provision of support while reducing their stress levels and burden of care. Such strategies may include education about AS, increasing their participation in medical consultations, and utilization of medical supportive care services including access to patient's lab results and care plans. The goal of these strategies is to help caregivers assume more active roles in patient disease management and reduce the emotional impact of both PC and patient care on their physical and emotional well-beings.

Limitations and Recommendations

Our study has several limitations. Patients were recruited from a single institution. The majority of our study population was Caucasian; well-educated, married/with partners, and heterosexual. Thus, our sample is unlikely to reflect the general characteristics of all prostate cancer patients. In order to maximize participation rate and to minimize recall biases, we used purposive sampling and targeted PC survivors currently participating in AS. As a result, there was an absence of data with patients who discontinued AS based on personal preferences and without evidence for clinical cancer progression. Future research should explore the challenges and unmet needs of these patients to further shed light on their beliefs and concerns that led to their decisions to discontinue AS. It is apparent from patient reports that family caregivers significantly influenced the patients' decisions. Therefore, evidence of information and support needs obtained from caregivers will further enhance our understanding of both patient and caregiver factors that affect shared treatment decision making, dyadic communication, and patients' disease management.

Conclusions

Meeting patients' and their family caregivers' informational needs is imperative to ensure their adequate involvement in PC management, and to enhance their emotional coping and adjustment to cancer. The relative paucity of research in this population and their caregivers strongly suggests the need for research to further improve understanding of factors that affect patients' decision making and adherence to AS protocol. Such research should take into account the patient's background and the involvement of family caregivers in decision-making processes and disease management.

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