BMJ Open Factors that influence clinicians' decisions to decrease active surveillance monitoring frequency or transition to watchful waiting for localised prostate cancer: a qualitative study

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ABSTRACT

Objective Little is known about clinicians' decision-making about decreasing active surveillance (AS) testing/ converting patients to watchful waiting (WW), nor are there any guidelines. The objective of this study was to identify factors that clinicians consider when decreasing AS testing/ converting to WW for men with prostate cancer.

Design Exploratory qualitative study.

Setting All participants practiced in various institutions in the USA.

Participants Eligible clinicians had to provide clinical care for patients with prostate cancer in the USA and speak English. Clinicians could be either urologists or radiation oncologists. Of the 24 clinicians, 83% were urologists representing 11 states, 92% were men and 62% were white.

Methods This qualitative study used data from semi-structured interviews. Purposive sampling was used to ensure geographical variation in the USA. Data collection continued until thematic saturation was achieved. Framework analysis guided coding and identification of themes. Two researchers coded all transcripts independently, met to discuss and reached consensus.

Results Interviews with clinicians demonstrated that testing or monitoring for AS or transitioning to WW is happening in practice, whether intentionally or unintentionally. Decisions to decrease AS were personalised and tailored to patients' health status. Life expectancy was the dominant factor that influenced decision, but clinicians were generally hesitant to specify an age when they would decrease AS or transition to WW. Fear that poor adherence could lead to missed progression and concerns about the medico-legal issue of not doing enough were cited as barriers to decreasing AS.

Conclusions These findings suggest that in certain situations, AS frequency is reduced or transitioned to WW, yet decisions appear to be inconsistent and there are no significant barriers. These findings could inform further areas to explore when drafting recommendations that consider patients' values and preferences when making decisions about decreasing AS/ converting to WW.

Strengths and limitations of this study

- First study to explore clinician decision-making about decreasing active surveillance (AS) testing/ transitioning to watchful waiting (WW) for men with prostate cancer.
- Data from these semi-structured interviews with clinicians from different regions of the USA from academic centres and Veterans Affairs hospitals representing 11 states, may not represent all viewpoints or clinical practices regarding decreasing AS/ transitioning to WW for men with prostate cancer.
- Although clinical practice has evolved over the past several years for managing men with prostate cancer on AS, there is no clear consensus nor empirical studies on clinician attitudes on when or how to decrease AS testing/ transition to WW.

BACKGROUND

Many men diagnosed with prostate cancer are diagnosed with localised prostate cancer, which includes those who have low risk and intermediate risk disease.¹ For many of these men their prostate cancer is unlikely to cause symptoms or affect survival if left untreated.^{2,3} In contrast, unnecessary treatment may lead to treatment-induced urinary problems, rectal bleeding and sexual dysfunction.⁴ As a result, overtreatment remains a major concern, with estimates ranging between 6% and 64%.⁵ In response, clinical guidelines recommend active surveillance (AS) as the preferred management for patients with low-risk disease to minimise overtreatment.^{2,6}

The decision about AS or watchful waiting (WW) for prostate cancer includes consideration of clinical characteristics of the disease and life expectancy.³ The National Comprehensive Cancer Network recommends AS for men with at least 10 years of life expectancy if

they have low-risk disease; whereas, observation (WW) is recommended for those with life expectancy <10 years.⁶ The American Urological Association, American Society of Radiation Oncology and the Society of Urologic Oncology recommends AS for men when they have a life expectancy of 5 years or more.² There is some guidance on the frequency and modality of testing, but there is a significant amount of variability in practice.^{3,7}

In AS, men are typically monitored closely with prostate-specific antigen (PSA) test every 6 months, a digital rectal examination at least annually and repeat prostate biopsies and imaging every 1 to 3 years. If the cancer progresses, then curative treatment is delivered. In WW, men may have fewer tests and rely more on symptom-based monitoring. If the cancer progresses, then treatment would be started to help control the symptoms but not cure the cancer.

Although there is guidance about when to start AS, discussion or literature on what clinicians consider or have experienced when decreasing the frequency of testing for AS and/or transitioning to WW is largely absent. There is a commentary,⁸ few modelling studies^{9,10} and a narrative review.¹¹ These articles indicate that the decision to de-escalate AS and/or convert to WW is complex and needs to consider age, comorbidities and patient preferences. A consensus statement from the UK does state that the decision to convert to WW should consider men's preferences, clinical characteristics, comorbidities, functional impairment and life expectancy.¹² No currently published study reports on what clinicians think about decreasing AS and/or converting to WW. The purpose of this study was to identify factors clinicians consider when decreasing surveillance testing frequency or converting to WW for prostate cancer.

METHODS

Study design

This study used data from a previously published qualitative study of clinicians that care for patients with prostate cancer, which reported on physician decision-making regarding general AS practices such as, protocol selection, comfort with AS, impact of patient selection for AS.¹³ Eligible clinicians had to provide clinical care for patients with prostate cancer in the USA and speak English. Clinicians could be either urologists or radiation oncologists. All participants provided written informed consent and completed an intake questionnaire prior to their interview.

Recruitment

Loeb and colleagues used a combination of purposive sampling to select urologists from both the American Urological Association and the American Society of Clinical Oncology memberships and snowball sampling.¹³ Clinicians were enrolled onto the study until data saturation was reached. Purposive sampling is a non-probability sampling strategy to obtain information for a pre-specified population and ensured that each clinician provided care for men with localised prostate cancer on

AS and were from geographically diverse settings across the USA. Eligible clinicians who were informed about the study were allowed to nominate other colleagues as potential participants as long as they also met eligibility criteria. Participants were contacted by email and were given the choice to have their interview either in person, or over the phone.

Data collection and management

All interviews were conducted from July to December of 2015 either over the phone or in person by a female urologist or a female research assistant. Data collection procedures were described previously.¹³ In brief, that study initially conducted 17 interviews, and then conducted 7 more interviews to reach thematic saturation. Thematic saturation is commonly used to determine when enough interviews have been conducted and when no new insights are identified.¹⁴ Interviews were conducted with the study participants only and lasted between 22 and 51 min. Atlas.ti was used to facilitate data management and analysis.

Interview

The interviewers used a semi-structured interview guide that was developed from a literature review and previous AS research.^{15–18} The guide was pilot tested with two clinicians and was edited for improved clarity. The guide consisted of 15 questions, including 'What are your triggers to stop active surveillance and convert to watchful waiting?' and 'What are your main concerns about active surveillance?' All interviews were audio recorded and anonymously transcribed by a third-party service.

Analysis

For this study, framework analysis guided our analytical approach.^{19,20} Two researchers independently reviewed each full transcript and coded any discussion relevant to de-escalating AS or transitioning to WW. Researchers met to discuss their coding and how to organise and conceptualise the coded text (refine code definitions) until all transcripts were discussed. After all transcripts were coded, we charted the coded text into matrices, where rows represented codes and columns represented participants, to facilitate identification of themes. For each participant, we summarised when and how the code was applied and an example quote from the coded transcript. We determined that data saturation was reached when the coded interviews did not generate additional codes or themes or further our understanding.

Patient and public involvement

No patient involvement.

RESULTS

Sample characteristics

A total of 48 invitations were sent with enrolment on a rolling basis. Enrolment was stopped after 24 clinicians because data saturation was achieved. The characteristics of the participants were published previously.¹³ Majority

of the clinicians were urologists (n=20), men (n=22) and white (n=15) and represented 11 states.

Overview of qualitative findings

These interviews suggested that some clinicians are reducing the frequency of surveillance testing and transitioning patients to WW, whether intentionally (eg, clinician and patient discussed de-escalating surveillance testing and/or converting to WW) or unintentionally (eg, patient stopped following up for visits at preset intervals, every 6 months for PSA testing). Life expectancy considering age and existing comorbidities was the dominant factor influencing these decisions. However, there were some barriers to decreasing test frequency and transitioning to WW. One barrier is the concern of poor adherence leading to missed disease progression. They also discussed the fear of being potentially sued.

Patient preferences may be leading to reduced testing and converting to WW

Patients and/or clinicians are reducing the frequency of surveillance testing, whether unintentionally or intentionally. The surveillance testing frequency may be spread out due to patients missing or cancelling appointments. Reasons could include the general discomfort with the biopsy procedure and/or issues with transportation. They also noted that the appointments take time, which interferes with their work.

Because not just with these patients but every patient has to come to the office every three months, take time off work or you know, wait in the office. I think that really bugs them. Clinician 19

One clinician mentioned how there is not really a trigger to switch to WW, unless patients stops showing up.

Yes if you mean by watchful waiting we don't see the people or the individuals anymore or perform any other tests on them then I would say we don't ever convert someone to watchful waiting unless they can't make it back for a visit. Clinician 14

Clinicians discussed situations where the patients have wanted to switch to WW because they have not progressed for many years.

[...] he actually went through like five years of yearly consecutive biopsies where his PSA didn't change much, his DRE is the same. The pathology was nothing or one or two cores. And, you know, alternating, nothing or a little something. And after year five he was like I'm done, no more we're done. I'm like you know what if I were you I would do the same thing. Clinician 07

The role of life expectancy, age and comorbidities

Life expectancy, considering age and comorbidities, was the primary factor that influenced decisions to reduce surveillance testing and/or transition to WW.

The decision to space out testing required clinicians to balance a patient's risk of dying from prostate cancer compared with their other comorbidities, and how the patient values its impact on quality of life and potential for benefit.

Well, whenever I see a patient, we're always thinking about based on what we know about this patient now, what's their risk of dying of prostate cancer, and then what's their risk of dying of other disease? And finally, how do they value their quality of life? Clinician 18

It was clear that clinicians tailor their decisions about transitioning to WW based on patients' health status.

I mean, there's two different scenarios. One scenario is you've watched someone for a while; maybe you've gotten biopsies on them. Their PSA has remained stable, and now you know, instead of being in the early seventies, now they're in their late seventies or early eighties, and so I think it's reasonable to convert that person to an observation... On the other hand, I think that there are some patients that you can look at very quickly and see this is a patient who's not going to benefit from repeat biopsy or close monitoring because they have too many other medical issues that they're dealing with. Clinician 03

In general, clinicians were reticent to specify an exact age where they would consistently transition to WW. One clinician noted the need for a guideline to guide this decision.

But I would think like after the age of 80, you know, we could probably just stop because you know, you and I know that you know, most men already are going to have prostate cancer. Most men over 70 will have some cancer cells in them. But I would need some kind of guideline or something somewhere. Clinician 19

However, one clinician felt that 75 years should be the cut-off and will only keep patients on AS if they insist.

I would say if someone is on it for 6 years, has gone through our protocol and now they're over 75 years of age then I'll move to, I'll go to watchful waiting... I tell them if you came to me with a normal PSA and a normal rectal exam since age 75 I would stop following you at age 75. Sometimes I'll go to 80 if they're really healthy and they're insisting on it but most patients I try to encourage them to say listen we've made it to 75 without a problem it's reasonable to just not check it. Clinician 09

Barriers to decrease testing and transitioning to WW Concerns about poor adherence leading to missed disease progression

One barrier to decreasing test frequency or transitioning to WW was clinicians' concern about poor adherence, resulting in missing disease progression. One clinician

had a patient who did not adhere to the AS schedule and came back and had progressed.

Cause if you've got a patient that should come back in six months and they kind of fall off the radar, then there's a chance that there are patients out there—by the way, this happened a couple times where patients come back a year and a half later and they've had progression... that if patients aren't compliant, then active surveillance doesn't work. Clinician 06

The experience of having missed a progression due to poor adherence could perpetuate clinicians fear of missed progression and deter them from wanting to de-escalate AS or transition to WW because they do not know which patients will have cancer progression.

Fear of litigation/retribution

Clinicians expressed that fear of legal action is in the back of their mind, but acknowledged that it is rare that they are sued.

The third barrier is worry over legal stuff although I've never heard of someone being sued because of surveillance or not but I think that's in the back of people's minds. When I talk to private practice guys they say that. Clinician 12

The fear of litigation is further amplified by the misalignment of AS and the natural context of the field and purpose of their work.

Well there is misalignment of how should I say let's say perverse incentives for managing people with low grade disease. In other words, physicians get reimbursed for doing something not for doing nothing. Clinician 14

DISCUSSION

Our qualitative analysis suggest that surveillance testing for prostate cancer is being decreased and/or transitioned to WW in clinical practice. Intentional decisions to decrease surveillance testing/transition to WW may consider patients' age, health and life expectancy. These decisions may also take into consideration patients' values and preferences. Unintentional decisions to decrease surveillance testing/transition to WW may be due to missed or cancelled appointments. These missed appointments may be an indicator that patients are prioritising their quality of life or ability to work over the management of their prostate cancer.

This study suggests that the issues of age, health and life expectancy may also play a role in decisions to decrease surveillance testing or transitioning to WW, similar to the decisions to start AS.^{21 22} In contrast, a study where clinicians were presented with scenarios and rank ordered factors that influenced their decision-making about starting AS, found that clinicians used 10-year survival probability, stage and PSA.²³

A modelling study demonstrated that generally AS had greater quality adjusted life years than WW, except among patients diagnosed older than 65 years.²⁴ Another study found that for men older than 65 years, one biopsy round resulted in a loss of one quality adjusted life year, likely due to other quality of life outcomes and potential biopsy-related complications.⁹ The University of Toronto stops serial biopsies once a man is 80 years old and has a life expectancy of less-than 5 years.²⁵ However, the consensus statement from the UK does state that age as well as other factors need to be considered, including frailty.¹²

As time on AS increases, clinicians' and patients' comfort with AS and acceptance of the low probability of progression may support them in making the decision to decrease the frequency of surveillance testing/transition to WW. This finding is consistent with the literature around men who select AS. Patients and their families who may be more anxious are less likely to choose AS initially or stop AS for immediate treatment.^{21 26} One qualitative study found that men on AS understood their disease was low risk and were confident there would be time for curative treatment if they progressed. These men also had to convince family members that they were not crazy for having a cancer and not treating it immediately.²⁷ In a study that followed men on AS for 3 years found that over time, men adopted coping mechanisms and became less anxious about their prostate cancer.²⁸

The issue of adherence may be associated with the fear of missing the window of curability, which then in turn may serve as a barrier to decreasing surveillance testing or transitioning to WW. Clinicians noted that AS only works if patients show up for the appointments. However, they recognised that there are practical barriers (eg, transportation issues and time off from work) that may contribute to non-adherence to the AS protocol. In a large cohort of men with grade group 1 prostate cancer, about 24% were lost to follow-up among men who were not reclassified.²⁹ However, the increased use of telemedicine due to the COVID-19 pandemic may help with some of the practical barriers in the future. It may also help to explore the goals of care at the start of AS and during AS, so that the clinicians can be aware of what is important to the patient. Another would be to set the expectation that surveillance testing may decrease over time and that they may transition to WW in the future. The Michigan Urological Surgery Improvement Collaborative (MUSIC) is taking this approach to their AS patients.³⁰

Finally, the fear of litigation may be a barrier to decreasing testing for disease progression and transitioning to WW. The fear of litigation is likely related to the fear of missing a cancer that will become metastatic and its downstream consequences, such as patients and family members being upset and wanting to sue or submit a complaint. The qualitative study by Loeb and colleagues found that there are medico-legal considerations when starting AS because the clinicians felt the need to protect themselves.¹³

Although this study provides new information regarding what clinicians consider when making the decision to decrease the frequency of surveillance monitoring or to transition to WW, limitations need to be considered when interpreting the results. The interviews focused on a variety of issues about AS, such as testing frequency and modality and decreasing surveillance testing frequency or converting to WW were only one area of focus. The sample consisted of clinicians at academic and Veterans Affairs hospitals representing 11 states. Their perspectives and the patients they treat may not represent the wider group of clinicians who see and treat men with prostate cancer, such as general urologists and primary care providers outside of the institutions in this study. Additionally, clinicians who practice outside the USA may have different experiences because of the differences in the healthcare system. Some of the interviews were conducted by a female urologist who is well known among the medical community, which may have introduced response bias. However, this interviewer used open-ended and non-judgmental questioning to facilitate an open dialogue. The interviewers did not participate in the analysis process for this study, limiting the ability to incorporate the insights of the interviewers in the analysis process. The results and interpretation of this analysis was shared and discussed with the primary study lead and interviewer.

Since the time of the interviews, it is possible that clinical practices regarding de-escalation of AS and transitioning to WW have changed. However, the American Urological Association guidelines on the management of localised prostate cancer does not address the issue of when or how to de-escalate AS and transition to WW.² The authors aware of one formal group that has a staged approach to AS, the Michigan Urological Surgery Initiative.³⁰

These findings suggested that decreasing surveillance testing frequency or transitioning to WW may be happening in certain situations. More research is needed to explore all the scenarios when clinicians and patients may be amenable to decreasing AS testing or transitioning to WW and communication strategies to facilitate this difficult conversation. These decisions are preference-sensitive and patients' values and priorities in addition to their health status needs to be considered. Interventions to support shared decision-making, such as patient facing decision aids and encounter-based decision aids, may be helpful to identify patients' values and goals of care in making the decision to transition to WW. Clinicians and men need guidance to make thoughtful decisions to decrease surveillance testing or transition to WW. These guidelines could also emphasise the need to consider men's preferences in addition to clinical characteristics and encourage shared decision-making.

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Patient consent for publication Not applicable.

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