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Patient perceptions and preferences about prostate fiducial markers and ultrasound motion monitoring procedures in radiation therapy treatment

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Abstract

Introduction: Patient experiences and preferences of image-guidance procedures in prostate cancer radiotherapy are largely unknown. This study explored experiences and preferences of patients undergoing both fiducial marker (FM) insertion and Clarity ultrasound (US) procedures. **Methods:** A sequential explanatory mixed method approach was used. A questionnaire ($n = 40$) ranked experiences from 0 to 10 (worst) in the domains of invasiveness; pain; physical discomfort; and psychological discomfort. Responses were analysed with descriptive and inferential statistics. Semi-structured interviews ($n = 22$) obtained further insights into their perspectives and preferences and were thematically analysed. **Results:** Perceptions of invasiveness varied with 46% reporting FMs more invasive than US and 49% the same for the two procedures. The mean score for FM was 3.6 and 2.1 for US. Mean scores for pain, physical and psychological discomfort were higher for FMs with 3.3, 3.2 and 2.9, respectively, and 1.1, 1.2 and 1.7 respectively for US, only pain achieved significance ($P < 0.05$). Three themes emerged from the interviews: Expectations versus Experience; Preferences linked to Priorities; and Motivations. Eleven patients (50%) preferred US; however, 10 (45%) could not illicit a preference. **Conclusion:** Participants found both of the FM and US image-guidance procedures tolerable and acceptable. Men's preference was elusive, suggesting a more rigorous preference methodology is required to understand preferences in this population.

Introduction

Gaining perspectives from patients is important in healthcare provision and research and is gaining traction in the radiation oncology setting.[1–3] Rapid technological advancements in radiation oncology present an opportunity to gain patient perspective into different techniques and technologies to complement the clinical and technical data, particularly those with equipoise. For example, options for monitoring prostate motion during external beam radiation therapy treatment delivery include gold seed fiducial markers, Calypso beacons and Clarity ultrasound. However, a paucity of literature exists regarding patient perspectives on these technologies.

Gold seed fiducial markers (FMs) are commonly utilised in prostate radiotherapy to accurately locate the prostate on daily imaging. FMs are surgically implanted using transrectal ultrasound guidance, and patients are not routinely sedated for the insertion.[4,5] Three electromagnetic beacons are inserted into the prostate for Calypso technology using the same technique as FMs.[6]

In contrast, Clarity involves the placement of an external ultrasound probe against the patient's perineum every day for the duration of treatment delivery.[7] While non-invasive, the placement of the probe requires treating staff to ensure the patients' scrotum is out of the way and applying some pressure to gain a clear ultrasound image.[8] Thus, the procedure may be considered 'personally invasive'.

This study aimed to explore patient perceptions of the surgical procedure for FM insertion compared to the daily placement of the ultrasound probe using Clarity. Patients were asked for their preference of the two procedures. Additionally, we aimed to explore the factors patients considered when choosing between different technologies and procedures.

Methods

This sequential explanatory mixed methods study was completed as a subset of a larger randomised control trial [ACTRN12617001102369]. The study was approved through Townsville Hospital and Health Service HREC (HREC/17/QTHS/9) and James Cook University HREC (H6970), and all patients provided written informed consent. Patients were eligible if they had both FMs and Clarity ultrasound image-guidance performed during the study period.

Participants firstly completed a 'Procedures Experience' questionnaire. This questionnaire was developed by the investigators and included both open and closed questions, covering physical and psychological experiences. Closed questions used a 10-point Likert-type scale to assess patient perceptions of pain and invasiveness of both the FM insertion procedure and the Clarity procedure. Participants were provided with the questionnaire on the day of FM insertion and Clarity simulation. Five patients piloted the questionnaire to assess for comprehensibility prior to data collection which were not included in final analysis.

Semi-structured interviews were also conducted, with the aim of qualitatively exploring the patient's procedural experiences and preference. Purposive sampling was used to ensure a breadth of demographics, experiences and views based on the questionnaire responses. Interviews took place between the day of insertion and the first week of treatment to limit recall bias. It was, however, ascertained in the interviews that the participants understood that Clarity was a daily application as part of their treatment. The interviews were conducted by one investigator (AB), with the use of an interview guide. The interviewer was a clinician, but not directly involved in the treatment of participants.

The interviews were performed in-person or by telephone (by choice of participant), recorded and transcribed verbatim. Participants could choose to have a support person present for the interview.

Data and Analysis

Descriptive statistics and Fisher's exact test were used to analyse the questionnaire responses in R statistical software Version 3.6.1.[9]

The transcripts, interview recording and researcher notes were entered into NVivo (QSR) version 12 for analysis. The first five interviews were coded independently by two investigators (AB and TP), with the code list compared and ratified. Reflexive thematic analysis was performed, with both deductive and inductive coding.[10,11] The remainder of interviews were coded by one investigator (AB). Interviews and analysis were performed concurrently to maintain focus and develop analytical depth and integration of the data. Interviews were conducted until pragmatic saturation was reached.[12] To confirm trustworthiness, the findings were discussed with and reviewed by a third team member not involved in data collection and analysis (RP).[13] Excerpts of the transcripts are provided in the following results section to exemplify the identified themes, with all identifying information removed.

Setting

This study was conducted at a regional tertiary hospital and health service in Australia. The radiation oncology department services a large geographical catchment area, and patients may travel up to 800 kilometres from rural and remote regions for radiation therapy treatment. At our centre, both male and female health professionals perform the FM insertion and the Clarity set-up.

Results

Demographics

The demographics of participants in both the questionnaire ($n = 40$) and the interview ($n = 22$) are summarised in Table 1.

Questionnaire

A summary of the questionnaire results is presented in Table 2. The only domain which was statistically different between the two procedures was the pain median score (3 for FMs, 0 for Clarity). Perception of invasiveness varied with 46% reporting FMs more invasive than US and 49% considered the two procedures equivalent.

Interviews

The interviews ranged from 10 to 54 minutes (mean of 27) in length. The majority (18) were performed in person, with six choosing to have someone present (wife/partner = 4; daughter = 1; and sister = 1). An additional three participants were invited to interview, however, two

Table 1. Demographics of participants in the questionnaire and interviews

	Questionnaire	Interview
Number of participants*	40	22
Mean age in years (range)	73 (60 to 85)	72 (62 to 84)
Staging		
T1c	4 (10.0%)	2 (9.1%)
T2a	3 (7.5%)	2 (9.1%)
T2b	9 (22.5%)	7 (31.8%)
T2c	12 (30.0%)	7 (31.8%)
T3a	10 (25.0%)	4 (18.2%)
T3b	1 (2.5%)	0
T3c	1 (2.5%)	0
Androgen deprivation therapy		
Yes	35 (87.5%)	21 (95.5%)
No	5 (12.5%)	1 (4.5%)
Number of biopsies		
1	32	16
2	5	5
4	1	1

*Each participant had undergone both fiducial insertion and Clarity procedures at time of questionnaire and interview.

Table 2. Summary of questionnaire results – median (range)

	Fiducial markers (n = 40)	Clarity (n = 40)
Physical discomfort	3 (0–8)	1 (0–6)
Psychological Discomfort	3 (0–9)	1 (0–8)
Pain*	3 (0–8)	0 (0–8)
Invasiveness	3 (0–10)	1 (0–10)
Information (*count*)		
Not informed	1 (2.5%)	0
Somewhat	0	3 (7.5%)
Well Informed	37 (92.5%)	34 (85.0%)
Not recorded	2 (5.0%)	3 (7.5%)

*indicates statistically significant difference ($p < 0.05$)

did not wish to proceed, and one could not commit to several times suggested.

Analysis of the interviews revealed three major themes: Expectations Versus Experience; Preferences linked to Priorities; and Motivations (Table 3).

Expectations Versus Experience

Many men compared their biopsy experiences with the FM insertion and how the biopsy set-up expectations for the insertion. This was particularly evident in those who had experienced a painful or negative biopsy experience and those who had multiple biopsies.

> *I'd had two biopsies before so I reckon they were worse. It would be different if I didn't have them first. It was better than the biopsies.*
>
> (P32)

Table 3. Summary of themes and categories

Major theme	Subthemes
Expectations versus experience	Expectation based on past experiences
	Physical experiences
	Psychological experiences
Motivations	Desire to cure cancer
	Acceptance
	Resolve
	Resignation
Preferences linked to priorities	Doctor knows best
	Reasoning
	Understanding and Information

Physical sensations were for the most part downplayed by participants, particularly when comparing the FM insertion to the biopsy. Two main physical factors were reported by men when describing the FM procedure: the sensation of the internal US probe, and the feeling of the 5 needles (2 for local anaesthetic and 3 for FM insertion). This was reported mostly as discomfort, or in fewer cases, pain.

> *There was probably a little bit of pain [with insertion] ... But nothing, you know, nothing you couldn't put up with sort of thing.*
>
> (P03)

In describing the experience of Clarity, most men described being aware that the external probe was there, but not causing any discomfort or pain.

> *All I felt there was when they pushed it [the Clarity probe] up it touched me, you know, pushed up. And when they got it in position, they just left it. Pretty sure I didn't even know it was there.*
>
> (P01).

Many men reported on both the feeling of the cold ultrasound gel and the mess the gel made, requiring clean up.

> *The only other thing with the treatment, I've solved this myself actually, you've got so much gel down there right? Now when you stand up, to go and get changed, it runs down between your legs. So, I go to the toilet now and clean myself off.*
>
> (P32)

Psychological discomfort was expressed as anxiety, apprehension and embarrassment. Many reported a generalised anxiousness in the lead up to the procedures, attributed mostly to not knowing what to expect.

I was very apprehensive at first. I sort of had a rough idea of what to expect, because when they inserted the seeds, I had previously had a biopsy done, so I was assured that the biopsy was more painful than planting the seeds. I was still apprehensive.

(P19)

Most men stated that the desire to beat the cancer overcame any feelings of embarrassment.

I firmly believe that you leave your pride at the door and pick it up on your way out. So, I had no hassles.

(P09)

It was recognised that both procedures can be a personally confronting experience, requiring access to the pelvis.

Maybe some blokes would be embarrassed, things like that. You are lying on the table, getting the gold seeds in, you are naked sort of thing, and there are a lot of folk about you.

(P20)

Those who did report embarrassment indicated a willingness to endure the procedures in pursuit of cure.

There's no embarrassment. It's got to be done. I'm [. . .] lucky that they are doing it, that I can get it done, you know?

(P18)

Motivations (Including Acceptance, Resolve or Resignation)

The motivation to treat the cancer with the aim of cure was a strong theme amongst the men interviewed. 'You gotta do what you've gotta do [to treat the cancer]' was an overarching sentiment, expressed by most participants. This motivation for treatment manifested as two mindsets: Resignation and Resolve, underpinned by a desire for a cure. While many men identified as being of one of these mindsets, some described their mindsets to vary at different points during their cancer diagnosis and treatment experiences.

Then you have to set your mind to it – ok, I'm going to beat this thing. Use a lot of mind over matter.

(P12)

Resolve was expressed by over half of the participants, with a desire and determination to 'beat' the cancer and a proactive approach to their own health and treatment.

You know you are sick; you know you have to get it cured. [. . .] Aiming for a cure, so you take the best option, and to me, that is the best option at present.

(P10)

Resignation was expressed as an acceptance of the cancer and treatment requirements, with more of a submissive attitude to their treatment journey by six participants. These men were more likely to indicate a willingness to go along with health professional's recommendations.

I wasn't happy, well, it's got to be done, it's got to be done. [. . .] Yeah, leave to the professionals, and just do what you've got to do.

(P22)

Linked with these mindsets were expressions of Acceptance and Stoicism, implying a pragmatic approach to do whatever was required to treat the cancer.

But you just accept this, if you want to get this treatment, and get over this cancer. That's the way I look at it. It's just one of those things.

(P05)

Some reflected on the disruption to their life, usually in retirement. Despite this, a positive outlook was expressed by many.

My attitude is, I'm not going to die of it, I'm going to die with it, maybe, and when the treatment is finished, hopefully I'm going to be free and clear. [. . .] Once treatment is finished, I am going to live life to the fullest. I've got a second chance.

(P14)

For others, the prostate cancer coincided with retirement and other health issues, leading to feelings of frustration.

I must admit it was a bit of a surprise. . . I had a stroke 5 years ago, so I'm thinking, why are all of these things rearing their head now, just as I'm retiring now, sort of thing.

(P07)

Preferences linked to Priorities

With the motivation of actively seeking treatment and a cure for the prostate cancer, many men discussed their priority was to be cured. This then influenced perceptions and preferences for image guidance.

When asked to identify a preference, 11 participants preferred Clarity, one preferred FMs, and the remainder could not define a preference, even when presented with a vignette of describing the procedures to a friend and identifying their preferred procedure in the process. In those who could not define a preference, three said that they were ambivalent with both procedures, while seven indicated confusion about the need for both procedures, that is 'Gold seeds and the Clarity Probe. They are tied

up together aren't they?' (P20) and 'I thought they were both to do with the whole procedure'. (P03).

The interviewer clarified they were receiving both methods only because of department policy but that clinically one or the other was necessary. Nevertheless, six still could not elicit a preference.

> *I think it just comes down to perception really. I don't think that any guy likes to be laid down and have things inserted in them. [. . .] It's just if. . . you've got some thoughts about invasive procedures, as a lot of guys do, then go for the Clarity. But if you're quite happy to go for the gold seeds, well. . . do it!*
>
> (P06)

Those who could identify Clarity as their preference in interview gave a variety of reasons, including it was less painful/most comfortable, and less embarrassing as it did not require an internal probe.

> *The internal thing is just not pleasant.*
>
> (P17)

The one participant who identified FMs as their preference did so by relating it back to lived experience of increased accuracy.

> *I did a navigation course years ago and to pinpoint your exact position on the earth, you had to have. . . to be more accurate, you had to have 3 . . . sightings of something and then you can pinpoint. And that's why I think that gold seeding is really accurate.*
>
> (P03)

A subtheme of 'following health professionals' recommendations', or 'doctor knows best' arose. This subtheme was particularly evident when preference was discussed, with many participants expressing they will follow the recommendations of the doctors and health professionals, regardless of own personal preference: 'I'll do what I'm told [by the health care staff]' (P17).

> *Main thing is to listen to those who are actually treating you, like the staff, and the doctor.*
>
> (P19)

The need for information and understanding about the procedures varied between the men.

> *Too much information is too much problem. . . it's a problem for some people. And not enough is another problem for other people. So, you have to pick that balance.*
>
> (P05)

> *And because it doesn't matter how much you read, you've still gotta go through with it. (P04)*

Discussion

Overall, low scores across the questionnaire domains (physical discomfort, psychological discomfort, pain and invasiveness) were supported by the 'gotta do' attitude in the interviews. There was a statistically significant difference in the median pain score of the FMs and the Clarity procedures; however, it is noted that both procedures scored low overall. The low scores indicated the resolve of this patient population to treat and 'beat' the cancer. Robins et al (2018) similarly found low pain scores reported by patients who had undergone transrectal ultrasound-guided biopsies, with an overall median pain score of 3 (0-9).[14] The main themes emerging from interviews illustrated the variety of ways the men faced and processed their prostate cancer treatment.

Results from the questionnaire showed no statistically significant difference in physical discomfort between the procedures. However, during interviews, most men only reported FM discomfort, with little mention of Clarity discomfort. Pang et al reported that patients found the Clarity positioning was acceptable.[15] However, this was a cohort of patients who only experienced the Clarity set-up, with no other literature on the patient perspective of FMs and Clarity.

Reports of lack of embarrassment was at odds with clinical staff anecdotal observations of many patients expressing a fair degree of both verbal and non-verbal embarrassment during the FM procedure. Low embarrassment levels were also evident in the questionnaire's psychological discomfort score. It is possible that embarrassment is acutely felt at the time of the FM procedure, but quickly forgotten or brushed aside by the men, particularly with the pragmatic approach of getting the procedures 'over and done with' to achieve cure. Chapple et al (2007) reported similar findings of downplaying of pain, discomfort and embarrassment in their qualitative study of patient experiences of prostate biopsies, a procedure similar to FMs.[16] Similarly, the participants accepted any embarrassment associated with the Clarity procedure in the pursuit of cure, although the reports of this embarrassment were low in both the questionnaires and interviews. Future studies in this population may benefit from data collection closer to the procedure to validate whether there is acute embarrassment, or incorporating field observations into future studies.

Seemingly negative (Resignation) and positive (Resolve) mindsets were presented during interviews. Both mindsets led to the same outcome in this group of participants – the active pursuit of treatment with the desire to cure the cancer. The notion of proactivity in curing cancer was also identified in Saigal et al as an important attribute in prostate cancer treatment where undergoing treatment validated a proactive approach.[17]

The stoicism expressed by many participants is in keeping with hegemonic masculinity, reported in the broader male population and the prostate cancer-specific population.[18–20] Kannan et al described the 'Australian masculinity' stereotype of stoicism, silent endurance and a reluctance for help-seeking behaviour.[19] Stoicism was also reflected in the overall low scores of the questionnaire domains. A number of strategies employed by prostate cancer patients have been identified in the literature, including positive mindsets, using humour to diffuse the emotional situation and believing the cancer was non-invasive and non-aggressive.[21]

The desire to beat the cancer was reported by most interviewees as their priority. To this end, they were willing to be guided to the most appropriate treatment choices recommended by their treating team of health professionals. This finding is consistent with Smith et al demonstrating trust in the radiation oncology professionals was such that that patients would agree with their treatment recommendations without much questioning.[22] Likewise, Scherr et al also found urology professionals opinions influenced prostate cancer patients treatment decisions.[23] Literature about prostate cancer preferences is currently focussed on prostate cancer screening and treatment modality decision-making, rather than specificities of a treatment modality such as image-guidance.[24–27]

The inability of many participants to separate the two procedures may have influenced the viewpoints expressed. In particular, the 7 participants who could not give a preference could not do so because they could not separate the two procedures in the interview. As participants received both procedures, asking them to hypothetically choose one over the other departed from their lived experience making the choice difficult. Indeed, many participants were surprised to be asked, suggesting patients are unfamiliar with health professionals asking them about their health preferences.

Of note, most participants indicated they were well informed about both procedures. However, this was not evident in the interviews where many could not separate the necessity of the two procedures suggesting the educational information about the reasoning of the two procedures was not understood or retained by participants, or indeed may not have been adequately given by the health professionals. Disparate information needs of participants were noted with some wanting to know everything, while others were satisfied to know only the basics. This dichotomy of information needs was also found by Kannan et al amongst undiagnosed men.[19] It is recognised that understanding the patient's health literacy level, their preference for both information and treatment decision-making should not be overlooked by the healthcare community.[28–30]

Strengths and Limitations

This study was able to gain perspectives from patients who had undergone two image-guidance procedures. Our centre was in the unique position of using both procedures in routine care at the time of the study, giving the opportunity to directly compare both, which strengthens this study.

As the interviewer was a younger female, the male participants may have been reticent when discussing their prostate cancer experiences and preferences. To limit this influence and put them at ease as much as possible, the participants could choose to have a support person present. This may reflect the low reporting of embarrassment in interview, compared with clinical observations. Another limitation is ethnic homogeneity, with all participants of Caucasian decent.

Future Directions

With a large proportion of participants (45%) unable to initially identify a preference at interview, a discrete choice experiment (DCE) will be undertaken. This qualitative work will inform the DCE development. The importance of patient perspectives in health technology assessments is recognised, and this body of work will contribute to the assessment of the Clarity system.

Conclusion

Overall, both image-guidance procedures were well tolerated by patients, with low rates of pain, discomfort and embarrassment reported. Interviews revealed the majority were willing to follow the clinician's recommendations regardless of their own personal preference, with a large percentage (45%) not able to express a personal preference.

These results could potentially be extrapolated to insertion of other markers such as electromagnetic beacons done in the same procedure as FMs. For radiation oncology departments considering the implementation of either of these two procedures, these results will be reassuring that patients find both of the image-guidance procedures tolerable and patient reflections could be considered along with the clinical and technical data.

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