FULL TITLE: Qualitative analysis of interviews and focus groups exploring factors contributing to adherence to GnRH agonists in men with prostate cancer

RUNNING TITLE: Adherence to GnRH agonists in men with prostate cancer

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ABSTRACT

Objectives: Side effects from the prolonged use of gonadotropin-releasing hormone (GnRH) agonists may lead to nonadherence to the treatment in men with advanced prostate cancer (PCa). We investigated the reasons contributing to nonadherence to GnRH agonists through interviews with men with PCa and focus groups with their health care professionals.

Data Sources: The three stages of the study were validation of themes, interviews with men on GnRH agonists, and focus groups with oncology specialists and clinical nurse specialists. An experienced oncologist validated factors contributing to nonadherence identified from the literature. A total of 10 men with PCa were recruited from a large teaching hospital and were interviewed on a one-to-one basis using a topic guide. In

stage three, two separate focus groups were held with oncology specialists and clinical nurse specialists treating men with PCa. The interviews and focus groups were audio recorded and transcribed verbatim. Initial codes identified from stage three were grouped into themes and thematically analyzed.

Conclusion: Themes identified from the interviews and focus groups influencing adherence to treatment were side effects of treatment, patient belief system, benefits outweigh harm, quality of life over quantity of life, social support, and patient-clinician relationship. Although side effects such as hot flushes and loss of libido were sometimes overwhelming for many, these men felt that treatment benefits outweighed harm.

Implications for Nursing Practice: Reasons leading to non-adherence can be multi-factorial and unique to each patient. Employing different strategies by health care professionals may lead to the eventual acceptance of treatment, whilst also acknowledging their reasons for non-adherence.

KEY WORDS: Adherence, Interviews, Focus groups, GnRH agonists, Prostate cancer, Qualitative

BACKGROUND

A large proportion of men with locally advanced and metastatic prostate cancer (PCa) are on some form of androgen deprivation therapy (ADT) (1). Most men may remain on Gonadotrophin-releasing hormone (GnRH) agonists, a form of ADT, for the rest of their lives. In the United Kingdom (UK), it is recommended that men receiving Docetaxel chemotherapy (for a fixed period of time) continue with GnRH agonists even in castration-resistant PCa (NICE 1.5.12, NG131) (1). This is because GnRH agonists increases the expression of proteins that lead to re-sensitising castration-resistant PCa cells to the cytotoxic activity of Docetaxel, thus ensuring an ongoing castrate level of testosterone (2). Although adherence levels are high in men on ADT, there is still a small percentage of men with PCa who are non-adherent (3). It is therefore important to better understand factors contributing to adherence and non-adherence to GnRH agonists in this population.

A literature review conducted by Jin et al. identified factors contributing to non-adherence to medication, including research papers between 1970-2005 (4). Factors contributing to non-adherence were categorised into five categories: patient-centred factors, therapy-related factors, social and economic factors, healthcare system factors and disease factors. We used Jin et al.'s review as the basis for our study and combined the five factors into patient-related and clinician-related factors.

Patient-related factors influencing medication adherence can include a patient's demographic information such as age, ethnicity, education and marital status. Other factors such as forgetfulness, skipping medication and lack of drug dispensation can arise from a

patient. Non-adherence to a medication can also take the form of so-called ‘drug holidays’, where patients decide to take breaks for intervals of time from their routine medication, before resuming taking their medication. Often, such breaks can be due to no substantive reason (5). Medication adherence can also be positively associated with clinical appointments – a phenomenon called ‘white-coat compliance’ (5). Advice on general health, and reminders about medications from family members, may also contribute to an increased medication adherence in patients (4).

Side-effects associated with prolonged use of ADT was shown to be a major cause of non-adherence to medication in adherence studies on breast cancer (6). Side-effects reported by patients on ADT include: hot flushes, low bone density that may lead to increased risk of fractures, fatigue or extreme tiredness and other psychological issues (7, 8). Moreover, ethnicity was identified as a factor contributing to medication adherence by 16 studies in a literature review (4). The review suggested that language barriers and lower socio-economic statuses of the minorities in the included countries may have contributed to the decreased medication adherence observed in ethnic minorities compared to Caucasians.

Clinician-related factors detrimental to the adherence status of a patient can include the prescribing of complex treatment regimens, and a poor patient-provider relationship. It is important to establish a therapeutic alliance between a patient and their physician (9, 10). Building healthy relationships between a patient and their provider, by actively engaging the patient in their treatment plans from the beginning of their treatment regimens, can help patients to actively engage in their care (11).

The adherence factors discussed previously were used as a basis to better understand factors contributing to adherence and non-adherence to GnRH agonists in men with PCa. Recently, we identified increased age, being on a longer injection intervals and being diagnosed with a higher risk PCa at diagnosis as factors influencing adherence to GnRH agonists in a quantitative study using national database from Sweden (12). To our knowledge this is the first study to qualitatively assess factors contributing to adherence and non-adherence to GnRH agonists from both a patient and clinician perspectives. An understanding of these factors can help develop ways to support men who are prescribed GnRH agonists.

METHODS

This study was divided into three stages: 1) validation of themes in study protocol; 2) interviews with men with PCa on GnRH agonists; and 3) focus groups with healthcare professionals. The consolidated criteria for reporting qualitative research (COREQ), which is a 32-item checklist for reporting the results of qualitative research was used as a guide to report important aspects of the research team, study methods, context of the study, findings, analysis and interpretations in this study (Appendix A) (13).

Validation

The concept of validation was developed in qualitative research to ensure that the research question is valid for the desired outcome, that the methodology chosen is appropriate for

answering the research question, and that the study design is suitable for the methodology applied (14). We modified this to validate the methodology and reasons contributing to medication non-adherence highlighted by Jin et al. in their review (4). An oncology specialist with more than 10 years of experience treating men on GnRH agonists validated the study protocol by reading the draft protocol and highlighted additional reasons for non-adherence specific to the study population. Because limited qualitative research has been conducted specifically in PCa, it was important that a specialist working in the area provided his or her perspective on the reasons for medication adherence as highlighted in the study protocol. The purpose of the validation process was also to make sure that the issues highlighted in the study protocol were relevant in the real-world setting. The topic guides for the interviews and focus groups were then developed based on the full breadth of issues contained in the validated study protocol.

Interviews

A total of 10 men with advanced PCa who were on the treatment pathway for GnRH agonists were identified from the uro-oncology clinic in a large teaching hospital in London. Clinicians at the hospital determined whether a participant was adherent or non-adherent before study entry. All adherent men were on GnRH agonists for at least 6 months. Non-adherence was defined as men with PCa who were on the treatment pathway for GnRH agonists but refused treatment, with or without trial. No further exclusion criteria were applied. Once the participants had read the study participant information sheet and signed an informed consent form, they were interviewed one-to-one basis by a female PhD student (GG) with prior clinical coordination experience, using a semi-structured format. The topic

guide for the interviews (Appendix B) included open-ended questions, and participants were encouraged to initiate topics that they deemed important. No prior relationship was established between the interviewer and the participants. Before each interview, GG introduced her research interests and the purpose of the study. Each interview lasted for a maximum of 45 minutes and interviews continued until no new themes emerged in three successive participant interviews. A total of 10 men were interviewed.

Focus groups

Two focus groups were held: one with oncology specialists and one with clinical nurse specialists (CNS). A topic guide (Appendix B) was used to direct discussion, with specific emphasis on themes provisionally identified from the interview stage with men with PCa. As the minimum number of members required for a focus group is between three and five participants, three clinicians per focus groups were recruited (15). The focus groups lasted for a maximum of 1.5 hours.

Data analysis

The interviews and focus groups were audio recorded, transcribed verbatim and anonymised. Audio recordings were each given a unique study ID during transcription and were analysed using thematic analysis (16). Thematic analysis is a flexible approach which allows for in-depth exploration of participant's experiences and perceptions. Initial codes were generated by GG by working systematically through the transcripts from interviews and focus groups. The language used by the participant was used to determine each code. The initial codes were then grouped into themes using the software NVIVO v. 12. The

themes were then refined following discussions with the research team and by examining them alongside the raw data to ensure coherence of each theme and adequate representation of participants' voices.

Ethical approval

Ethical approval was obtained from the Health Research Authority using the Integrated Research Application System before the start of the study (Research Ethics Committee reference: 18/EM/0370).

RESULTS

In the validation stage of the study, feedback was given on the study protocol by an oncology specialist with more than 10 years of experience in the field. The oncology specialist signed off the study protocol and highlighted two further reasons that influenced medication adherence that they observed in clinic: the mixed health beliefs of patients on GnRH agonists and major life events (for example, a partner being diagnosed with cancer or other chronic conditions) in the patients' lives that may contribute to non-adherence.

Table 1 shows the patient characteristics of men with PCa who were interviewed. We interviewed seven adherent men and three non-adherent men identified in clinic by their clinicians. None of the men approached refused to participate or dropped out of the study. The two focus groups included three clinical nurse specialists (CNS-001, CNS-002 and CNS-003) and three oncologists (ONC-001, ONC-002 and ONC-003). One researcher (GG)

transcribed the audio recorded interviews and focus groups verbatim and used the NVIVO software to draw initial codes from the transcribed scripts. These initial codes were then grouped into themes which were refined into key themes following discussions with the research team (which included epidemiologists, oncology consultants and qualitative researchers).

A substantial overlap was found in themes identified by the interviews (stage 2) and focus groups (stage 3). The key themes were: side-effects of treatment, patient belief system, benefits outweigh harm, quality of life over quantity of life, social support and patient-clinician relationship (Figure 1 – summary of themes and Tables 2 and 3 for quotes to support these themes).

Interviews

Side-effects mentioned by the men interviewed included: hot flushes (n = 9), loss of libido n = 6), weight gain (n = 6), mood swings (n = 1), fatigue (n = 4), gynaecomastia (n = 4), impotence (n = 2), loss of muscle strength (n = 2), memory loss (n = 1) and painful injection site (n = 1). 90% of men in this study reported hot flushes which they found challenging and embarrassing. For one individual, sleeping patterns were disrupted due to hot flushes that occurred at night (side-effects of treatment, ADT-003; Table 2). 60% of men interviewed voiced loss of libido as a huge concern and many found this the most difficult side-effect to cope with. Loss of libido was a concern even among men in a committed relationship with

men feeling that they were letting their partners down sexually (side-effects of treatment, ADT-008; Table 2).

Adherence status was influenced by particular beliefs held by many men, with some men believing that they were being injected with “female hormones” (patient belief system, ADT-007; Table 2). Patient belief system also included religious beliefs that seemed to play an integral role in some men’s adherence status, whereby they believed that the outcome of their illness would be dictated by a higher deity, more so than the actions of the medication (patient belief system, ADT-007; Table 2). For some men, side-effects were a price to pay for the benefits of having treatment and viewed treatment regimens as a necessity to stop their PCa from progressing (benefits outweigh harm, ADT-001; Table 2).

Some men discontinued GnRH agonists due to severe side-effects that limited their quality of life (quality of life over quantity of life, ADT-005; Table 2). However, other men were willing to make the compromise in their quality of life to prevent PCa progression and spend more time with their family (quality of life over quantity of life, ADT-003; Table 2).

Social support in the form of a spouse or a family member was important for some men, especially when it came to reminders on medications (social support, ADT-003; Table 2). Side-effects such as loss of libido were worsened in men who did not have an understanding or stable partner, which in turn, influenced their decision to not have the treatment. Additionally, understanding treatment regimens (patient-clinician relationship, ADT-002;

Table 2) and misinterpretations of prescribed treatments (patient-clinician relationship, ADT-005; Table 2) were also highlighted as patient-clinician factors influencing non-adherence to GnRH agonists.

Focus groups

Based on routine assessments made by clinicians, loss of libido was also highlighted by clinicians who took part in the focus groups (side-effects of treatment, CNS-001; Table 3). Moreover, clinicians agreed that a strong belief system, especially held among men from certain ethnicities, influenced the adherence status of men on GnRH agonists (patient-belief system, CNS-001, ONC-003; Table 3). Some men preferred to have a "short-term life with quality" rather than a long-term life with side-effects from treatment (quality of life over quantity of life, CNS-001; Table 3). Reminders in the form of an "efficient family" also helped some men to adhere to their injection regimen (social support, CNS-001, CNS-002; Table 3).

From a clinician's perspective, some men failed to understand the importance of their medication despite the vast amount of information given to them (patient-clinician relationship, CNS-002, CNS-003; Table 3). The focus groups also highlighted the role differences between doctors and nurses in this class of patients (patient-clinician relationship, ONC-001; Table 3). Whereas oncological and treatment outcomes formed the focus of doctors' consultations with patients, functional issues and side-effects such as sexual dysfunction formed the focus of consultations with nurses. Both clinician groups agreed that men attending these clinics were aware of what issues to discuss with different

healthcare professionals. The most important point highlighted by all clinicians in the focus groups was to keep non-adherent men engaged with the healthcare system (patient-clinician relationship, CNS-001, ONC-002; Table 3).

DISCUSSION

This is the first qualitative study to provide patient and clinician perspectives on factors contributing to adherence and non-adherence to GnRH agonists in men with PCa. Men who were non-adherent had struggled to cope with their side-effects, and wanted a better quality of life than quantity of life. Of particular concern to these men was experiencing a loss of libido, which was strongly implicated by patients as a reason for non-adherence. Adherent men were often those who had found ways to cope with the side-effects, and perceived the benefits of the treatment as outweighing the harms. Strong cultural or religious views that some men held also influenced their non-adherence (or complete refusal) of initiating GnRH agonists. Other factors contributing to adherence in men on GnRH agonists were the amount of social support they experienced, and a positive patient-clinician relationship.

One of the most common side-effects that both adherent and non-adherent men discussed during the interviews was loss of libido. In one participant, it was viewed as the single most important factor contributing to his non-adherence because it was affecting his chances of finding a partner. Reviews of studies investigating adverse effects of ADT also showed that this was a concern in majority of men on GnRH agonists, regardless of their civil status (17). More than 50% of married men experienced some form of marital erosion following ADT

administration (18). However, social support was the reason why married patients were more adherent to medication compared to single patients (4), which was reported by men in our study.

Loss of libido was also the biggest concern raised by the nurses and doctors in the focus groups, as this was highlighted in holistic needs assessments forms completed regularly in clinics by men with PCa. Loss of libido can also be accompanied by other factors such as effects on body image and self-perceived masculinity in these men. It has been reported that over 60% of men on ADT feel a loss of their masculinity (19). A meta-synthesis of qualitative reports by Alexis and Worsley, 2018 described how side-effects of PCa treatment are inconsistent with cultural ideals about masculinity, which can have a profound psychological impact post-treatment (20). These observations, taken together with the findings of the present study, suggest that self-identity and self-perception could be linked with non-adherence to ADT.

Whereas some non-adherent men struggled with their side-effects and wanted a better quality of life than quantity of life, adherent men were determined to cope with their side-effects and believed that the benefits of their treatment outweighed the side-effects of the treatment. This was also observed in Moon et al.'s (2017) study on adherence in women with breast cancer (21).

Strong personal views or beliefs held by some men in this study also appeared to influence their decision to be non-adherent to treatment. Being treated with GnRH agonists were believed to be emasculating because some men believed that they were being injected with "female hormones". After only three months on ADT, 50% of the participants reported feeling less masculine. Moreover, patients' religious, personal and cultural beliefs, negative attitude towards their treatments, and a lack of motivation were found to be some psychological factors influencing non-adherence to treatment in other studies (4). Although it is difficult to approach patients' deep-rooted beliefs, it is important to acknowledge these beliefs in order to keep non-adherent men engaged with the healthcare system.

An increased confidence in herbal and natural remedies was heightened by a negative attitude towards "Western" medicine in men of certain cultures (e.g. men of Afro-Caribbean ethnicities, refer to quotes by ADT-005 and ADT-006), which was also reported in other studies (22). Addressing non-adherence to GnRH agonists in this ethnic group is particularly important because men of Afro-Caribbean ethnicities are often diagnosed with more aggressive PCa which can affect treatment-outcomes (23). The review by Jin et al. review showed that adherence was higher in Caucasian men compared to other ethnicities, which was attributed to language barriers and lower socio-economic statuses of the minorities included in the study countries (4).

According to clinicians who attended the focus groups, education seemed of less relevance in non-adherent men. Although clinicians can attempt to educate men on the importance of adherence, in this study they reported that some men simply fail to retain the information

that they were given. Senior et al. showed that patients without a formal education had better adherence to medication compared to those who held higher qualifications (24).

A good patient-clinician relationship also influenced the adherence status of men on GnRH agonists because it contributed to understanding treatment regimen and differences in roles of healthcare professionals. Whereas some men found treatment regimens too complicated to understand, other men had a good understanding of their treatment regimen and even tailored their discussions with clinicians according to the clinicians' roles. It was particularly important in non-adherent men to have a good patient-clinician relationship because it would keep them engaged with the healthcare system that may lead to eventual acceptance of treatment in these men while also acknowledging their reasons for non-adherence.

Although employing thematic analysis to qualitative data collected from one-to-one interviews with men with PCa and focus groups with clinicians from a hospital setting provided further insight into adherence and non-adherence, further multi-centre studies including larger sample sizes and general practitioners' perspectives are required to fully understand adherence to GnRH agonists in men with PCa.

CONCLUSION

This single-centre study identified a positive patient-clinician relationship and side-effects of treatments to be the major factors influencing adherence to GnRH agonists in men with

PCa. Because reasons contributing to non-adherence can be multifactorial and unique to each patient, keeping them engaged with the healthcare system by employing different strategies and acknowledging their reasons for non-adherence may lead to the eventual acceptance of treatment.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest with regard to the content of this paper.

DATA AVAILABILITY

Anonymised data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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FIGURES

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TABLES

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APPENDIX A, B

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