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Information support on the role of high intensity focused ultrasound and cryotherapy for the treatment of localised prostate cancer

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Abstract

Aim: Patients diagnosed with localised prostate cancer have a choice between comparable standard treatments, and developing focal therapy, high intensity focused ultrasound (HIFU) and cryotherapy. Growing numbers of men are attracted to focal therapy due to the minimal invasive, and lesser side-effect, profile. Our knowledge about information support for standard treatments is well established, but there is a lack of evidence on information support for focal therapy. The aim of this study is to examine the information support received by men who select focal therapy with HIFU and cryotherapy, for the treatment of localised prostate cancer, to help identify the source of information support, and the conditions that influence choice of treatment.

Method: Convenient sampling was used to recruit eight participants who received treatment with either HIFU or cryotherapy. Data were collected through semi-structured telephone interviews, and analysed by thematic approach.

Findings: There is a lack of information support on focal therapy during clinical consultations with urologists and oncologists, choice of treatment is influenced by information on minimal-invasive, and lesser side-effect, profiles, and there is a desire for quality information support at treatment centres, to enable informed decision-making.

Conclusion: It is vital to provide greater public access to quality information to support patients to make an informed choice between standard and developing prostate cancer treatments. Support from urology clinical nurse specialists, and access to reputable websites, and other information material, will contribute to quality information.

cancer nursing practice, cryotherapy, focal therapy, high intensity focused ultrasound (HIFU), information support, prostate cancer

Introduction

Prostate cancer is the second highest male malignancy in the UK, with new cases of 43,700, and mortality of 10,800, annually (Office for National Statistics 2014). There is a gradual rise in new diagnoses, partly due to increasing life expectancy, and awareness of the disease, but prognosis is generally good due to earlier presentation, and improved interventions (Schröder et al 2014). Several treatments are offered to men whose disease is confined to the prostate, or localised, including active surveillance, prostatectomy, External Beam Radiotherapy (EBRT), and brachytherapy. Some units also offer clinical trials, and clinical practice, with high intensity focused ultrasound (HIFU) and cryotherapy (National Institute for Health and Care Excellence (NICE) 2014).

Different treatments are offered based on their comparable overall mortality, and functional benefits (Mottet et al 2014, Xiong et al 2014), and this requires men to process complex information about treatment techniques, side-effect profiles, and curative outcomes. Inadequate knowledge about these issues can result in unrealistic expectations, therefore patients require individualised evidenced-based information support to enable them to make an informed choice about treatment (van Tol-Geerdink et al 2008).

Information support is often provided by urologists, oncologists, urology specialist nurses, and charities like Prostate Cancer United Kingdom. There is a body of evidence on information support for standard treatments, but a lack of investigation into information support for developing treatments like HIFU and cryotherapy.

Focal therapy with HIFU and cryotherapy

HIFU and cryotherapy offer localised treatment for prostate cancer, that reduces the risk of damage to normal surrounding tissues, and anatomical structures. The rationale is to treat clinically significant cancer that is likely to confer harm if left untreated (Gravas et al 2012). Dickinson et al (2013) likened the treatment to the success of conservative approaches of lumpectomy in breast care, and nephrectomy in renal care. The benefits of focal therapy include better prostate cancer detection, through improved radiological and histological characterisation, avoidance of overtreatment of low-risk cases, favourable alteration of the natural history of cancer, permitting safe retreatment, and causing minimal quality of life problems (Onik et al 2008, Sommers et al 2008, Mowatt et al 2013). Challenges associated with focal therapy include the limited availability of characterisation tests, like multi-parametric magnetic resonance imaging, trans-perineum template, or targeted, biopsies, and lack of agreed suitable salvage or retreatment protocols (Dindo et al 2004, Eggener et al 2007).

HIFU is a high precision technology that involves focusing ultrasound waves at specific tissue sites to generate intense heat, and is used in the treatment of prostate, breast, uterine fibroid, liver, renal, pancreas, and bone tumours or cancers (Zhou 2011). In prostate cancer treatment, it is ultrasound waves above 45°c enables prostate tissue vibration and ablation (Uchida et al 2009). Treatment is undertaken with real-time visual monitoring of the effect of the heat on prostate tissue.

Cryotherapy, on the other hand, involve freezing and thawing cycles that aim to destroy targeted prostate tissues through a process of dehydration, protein denaturation, rupture of cell membranes, vascular stasis, endothelial injury, platelet aggregation, and ischaemia from thrombi formation and apoptosis (Marberger et al 2008, Siomos and Barqawi 2011). Third-generation cryotherapy uses liquid nitrogen argon and helium circulation in cryo-needles, which are deployed under trans-rectal ultrasound guidance. The precision of HIFU and cryotherapy enable focal and whole-gland treatments. These non-invasive out-patient treatments involve bowel preparation, and one to three hours of spinal or general anaesthesia.

Clinical outcome of focal therapy with HIFU, and cryotherapy, fit between the extremes of standard radical treatments and active surveillance. While radical treatments have good chance of whole-gland cure, they are associated with significant urogenital toxicity. On the other hand, though active surveillance has good medium-term survival, the practice is associated with potential psychological morbidity. Focal therapy has good chance of partial or whole-gland cure, and psychological relief from improved test reports. They are increasingly available in clinical practice, and are recommended treatments in men with localised prostate cancer, in the context of controlled clinical trials comparing their use with established interventions (NICE 2014). At present, they are geographically limited on the NHS.

Information support and urology specialist nurses

A multidisciplinary (MDT) team approach should be taken to information provision, to support men faced with making decisions about prostate cancer treatments. Urology nurse specialists (UNSs) liaise between the MDT and patients (Tarrant et al 2008). NICE (2014) recommends that men with prostate cancer should be offered information by health practitioners, including clinical nurse specialists. This information should be individualised, and can be provided in written, spoken, and audio-visual form (Hiley 2006). UNSs are key workers, who use their specialist knowledge to provide invaluable information to patients and their families or carers (Ling et al 2013). A crucial aspect of this information support is to understand individual preferences about the various treatments offered by clinicians. Therefore, to provide effective support, UNSs should have wide-ranging experience and knowledge of developing treatments like HIFU and cryotherapy, as well as standard treatments. This is particularly significant in this internet-era, which offers instant, and up-to-date, information.

Aims

The aim of this study is to explore the information support received by men who select focal therapy with HIFU, and cryotherapy, for treatment of localised prostate cancer, to help identify the sources of the information support, and conditions that influence choice of treatment.

Method

Participants and sampling

Following study approval from the hospital, and national ethics and research departments, the author was given access to the focal therapy (HIFU and cryotherapy) clinical trial registers to identify potential participants. Convenient sampling was used to recruit participants from a cohort of 35 men who received HIFU and cryotherapy between July and September 2014 at an NHS hospital in London. All participants were referred by their GPs and received treatments as NHS patients.

The age range of the eight participants selected was between 51 and 73, with mean age of 65. Six were white Caucasians, one was Afro Caribbean, and one was of Asian background. Five participants were graduates, and the other three had diploma level education. Three were employed in senior management positions, and of the five retirees, three were self-employed.

Their diagnosis or risk classifications ranged from low risk (Gleason grade 3+3=6) to intermediate risk (Gleason grade 3+4 or 4+3=7). Four participants received HIFU, and the other four received cryotherapy. The eight men who consented to participate were provided with full details of the study objectives. Inclusion criteria were diagnosis with localised prostate cancer, able to speak and understand English, able to participate in a telephone interview, primary treatment with HIFU or cryotherapy within six weeks at time of recruitment, and able to provide informed consent to participate in a telephone interview. The first eight patients who met the eligibility criteria were approached, and recruited on a first come first served basis.

Data collection

Semi-structured telephone interviews were conducted using an interview schedule which described the purpose of the research. This approach encouraged honest disclosure, convenient access to participants, and efficient use of research resources (Davison et al 2007). Pre-interview telephone contact with participants clarified the clinical and academic background of the author, and the study aims. These contacts also helped develop rapport between the participants and the author. Careful set-up arrangements for successful interviews included firm agreement of interview dates, time, and duration, pre-booking of a quiet room, and use of two, high-quality digital voice recorders.

The eight interviews were conducted on separate days, and lasted between 20 and 90 minutes. A combination of questioning approaches guided extraction of information from participants about their experiences of information support on the role of HIFU and cryotherapy treatment for prostate cancer. Interview questions focused on:

* The treatments they were offered during initial consultations with urologists, oncologists, UNSs, and GPs.
* Sources of information about HIFU and cryotherapy.
* Information that influenced their choice of treatment.
* The information support they required at the centre where they received their treatment.

An example of an open-ended question is ‘Would you like to share with me the discussion you had with your clinicians about treatments that were suitable for your type of prostate cancer?’ This question revealed information about their diagnosis, clinicians with whom they had consultations, treatments they were offered, and whether HIFU and cryotherapy were considered. Another open-ended question was ‘What information did you receive that made you consider HIFU or cryotherapy treatment for your type of prostate cancer?’ This question revealed information about their perspectives on how various treatments compare, in terms of technique, efficacy, and side effects.

An example of a closed question is ‘Which clinician did you get your initial consultation with following your diagnosis?’, which provided specific information relevant to the aim of the study. Participants were also encouraged to provide additional information, some of which was useful for the study.

Data analysis

Thematic analysis was used for the systematic organisation and preparation of the interview data. First, the author listened to the recorded digital devices to ensure they were of excellent quality, and to develop familiarity with the content. The recorded interviews varied between 20 and 90 minutes. Transcripts were carefully prepared by the author for each interview, and varied in length between two and six double-spaced A4 pages. The author repeatedly listened to the recorded interviews, and read the transcripts to establish concordance and accuracy. This created familiarisation with words, and helped identify themes significant to the study objectives. Transcripts were peer reviewed by two clinicians not involved with the research, who were asked to identify significant themes. The peer reviewers, and the author, then discussed and agreed on themes.

Credibility was established by asking questions about issues relevant to the study objectives, transferability was achieved through logical processing of the descriptive data, and dependability was ensured by collaboration with peer reviewers about themes relevant to the study (Creswell 2014).

Findings

The following four themes were identified:

* Lack of information support on the role of HIFU and/or cryotherapy, at initial consultations with urologists and oncologists.
* Significant information is available on both treatments on the internet, especially specialist cancer websites.
* Choice of treatments was influenced by their minimal invasive, and lesser side effect, profiles.
* There is a desire for quality information support at the treatment centre, about the techniques and outcomes, to enable decision making.

Lack of information support during initial consultations

All eight participants had their initial clinical consultation with urological surgeons and oncologists, who therefore served as the primary source of information support about treatments. Each of the participants expected to be provided with information on all available standard, and non-standard or developing, treatments, including clinical trials, at their initial consultation. Their responses, some of which can be seen below, indicate there was a lack of information at their initial consultations on the role focal therapy with HIFU and cryotherapy in prostate cancer treatment: ‘The consultant (urology consultant) suggested robotic surgery and radiotherapy as the only two treatments for my cancer’ (respondent 3), ‘Down here they only do surgery and radical radiotherapy. They didn’t tell me anything about any alternatives. In fact, there was no alternative’ (respondent 4), ‘My local hospital surgeon offered radical surgery, and my local physician offered me radical radiotherapy’ (respondent 6), and ‘It was after I asked my surgeon about other treatments that he arranged for me to see the radiotherapist at another hospital’ (respondent 3).

Significant information on the internet

All the participants said that their secondary source of information about treatment for localised prostate cancer was mainly the internet. Some participants said they accessed specialist websites, such as Prostate Cancer UK, and Cancer Research UK. The common view was that these secondary sources provided a significant amount of information about the role of HIFU and cryotherapy for prostate cancer. Some of the participants’ responses are follows:

* ‘While on holiday, I visited the BBC website to look for information about prostate cancer. I found a report about HIFU concept study in April 2011 with 41 patients with promising result. This was my first ever information about treatments for prostate cancer other than surgery and radiotherapy’ (respondent 1).
* ‘Because I wanted to know a bit more about other possible treatments for prostate cancer, I did some research on the web, like Google, the EEC directive, NICE, and other international guidelines. I was particularly interested in clinical trials. It was during the course of searching on the internet that I found some information about HIFU, and other clinical trials at the X (name withheld) hospital’ (respondent 2).
* ‘At that point, I have already done some research on the internet, and heard about work with HIFU treatment for prostate cancer’ (respondent 6).
* ‘I also contacted the Prostate Cancer UK charity and spoke to their nurses on the information support line. They were very helpful. They informed me about various treatments for prostate cancer, and advised me to contact the X (name withheld) hospital for information about clinical trials’ (respondent 3).
* ‘I spoke to a nurse on the Prostate Cancer UK charity telephone line, and she gave me some information about the ultrasonic (HIFU) clinical trial. That was very useful’ (respondent 8).

Choice of treatment influenced by minimal-invasive and lesser side-effect profiles

All the participants said they were attracted to HIFU or cryotherapy because of their minimal-invasive techniques, and lesser side-effect profiles. Participants reported on how focal therapy techniques and outcomes compare with standard radical treatments such as surgery and radiotherapy. Some of their responses are given below:

* ‘I knew that the chances of collateral damage to the nerves system by doing surgery are higher than these new treatments’ (respondent 3).
* ‘I am concerned, and always wanted to avoid losing control of urinary control and sexual function, which I know there is a good chance of them happening with surgery and radiation (radiotherapy) treatments’ (respondent 7).
* ‘For me it was simply the idea of reducing the likelihood of various side effects of radiation treatment and surgery, like my urine control and potency, as these are very important to me’ (respondent 4).
* ‘There was no way I was going to have surgery for my type of cancer, because it just felt that the total obliteration of the prostate sounds a bit of a sedge-hammer to crack a nut…There is less chance of incontinence. For me it was really good, and seems better than radiotherapy and surgery and radiotherapy, which causes erectile problems, which I was concerned about’ (respondent 1).
* ‘The chance of collateral damage to the erection nerves system is probably reduced. In fact, I did not have any problems with my erections after the treatment, which was a major concern for me’ (respondent 5).
* ‘I wanted a treatment that will not affect my continence and quality of life, that were the decisive factors and focal therapy offered me that’ (respondent 6).
* ‘With HIFU they will just treat cancer cells. In my case they only treated the left-side, and they left some cancer, as I was told it was not significant. There was no cut in the skin, which I wanted to avoid as done in surgery’ (respondent 6).
* ‘The treatment is not destructive as surgery or radiotherapy, a lot more concentrating on the area that was affected by the cancer, and that was demonstrated by the MRI. There was no cut into the skin and no blood loss. I understand they pointed the sound waves from the ultrasound on the area they treated, so no cutting into my skin’ (respondent 2).

Need for quality information support at treatment centre

The eight participants reported that they required quality information support, about standard and developing treatments, at their treatment centre, to enable informed choice. Their experiences of information support at the centre where they received their HIFU and cryotherapy treatments are shown in the following comments:

* ‘I would have liked to receive more information about outcomes, and helpful to have information on work done to date, and how it compares for example with surgery, all the people so far, age, general health, type of tumour, Gleason score, prostate size, position of tumour, outcomes - erectile dysfunction, incontinence, and how that move over time… There should be more detailed information about range, normal distribution, erectile dysfunction, percentages, tumour in relation to nerve damage, compare percentages with other treatments’ (respondent 1).
* ‘There should be information prior to decision-making about outcomes, it’s about side effects, it’s about what’s gonna be there afterwards. Some sort of webpage or something like that, some sort of moderation webpage… because when you go on the forums or stuff you don’t know what you’re dealing with’ (respondent 3).
* ‘There should be sources of information with FAQs that gave links to answers, or the relevant sites’ (respondent 2).
* ‘It would have been great to receive some information about these new treatments (focal therapy) from my surgeon, or even my GP, but they did not mention it during our conversation’ (respondent 6).

Discussion

The study shows that there was a lack of information support provided by the urological surgeons and oncologists, about the role of focal therapy for prostate cancer, and that participants discovered the therapy as an alternative treatment during their quest for additional information on the internet. Information about the minimal-invasive, and lesser side effect, profiles of the therapy influenced participants’ selection of focal therapy. Their overwhelming desire was quality information support to enable them to make an informed choice between standard and developing prostate cancer treatments.

A crucial stage of information support is at initial outpatient clinical consultations. The main role of urological surgeons is to arrange diagnostic tests, chair MDT meetings, give diagnosis and treatment options, and make referrals (Guest et al 2012). However, findings from this study suggest that focal therapy with HIFU and cryotherapy was not discussed during the initial consultations, although it is not clear if referrals to centres that offer these treatments were made following the consultations.

Focal therapy guidelines in the UK recommend not to ‘offer high-intensity focused ultrasound and cryotherapy to men with localised prostate cancer other than in the context of controlled clinical trials comparing their use with established interventions’, because of the ‘insufficient evidence of the clinical and cost effectiveness of cryotherapy and HIFU in comparison to established interventions to recommend their routine use’ (NICE 2014).

Clinical discussions about the role of these treatments should be guided by the NICE recommendations, and by the growing evidence of their efficacy as minimally invasive procedures with the potential to ablate well-characterised, significant, localised prostate cancers, with lesser side effects, and better quality of life profiles (Ahmed et al 2012, Gravas et al 2012). These factors are worth considering when providing information that would enable men to make informed decisions between standard and developing treatments for localised prostate cancer.

**Limitations**

 Two limitations of this study are the use of small number of participants and single-site to collect data. Views of eight participants cannot be used to generalise the experience of the greater number of patients who have received these treatments. Similarly, it is unsound to extrapolate the experience of patients at a single centre to other focal therapy treatment centres. However, the understanding that has developed from in-depth exploration of the experience of these participants can be significant in designing future studies, involving larger numbers of service users at multi-sites.

Conclusion and implications for practice

The data collected from a relatively small number of participants demonstrate the need for quality information support to enable patients to make an informed choice about focal therapy with HIFU and cryotherapy. It also suggests there is a need for wide-ranging information support from health practitioners, who engage with patients through the decision-making phases. This is particularly relevant to UNSs, who are keyworkers with responsibility for coordinating health care, and information support, for men with prostate cancer (Ream et al 2009). Information support about HIFU and cryotherapy should include guidelines, treatment techniques, functional and oncological outcomes, follow-up protocols, and units that offer these developing treatments.

 Clinical nurse specialists, and research nurses, can fill the information gap by providing information about clinical trials, which could be discussed routinely in MDT meetings, at nurse-led clinics, and during contact with men and their families. Discussions about new or developing treatments should incorporate information about unknown medium to long-term side effects.

Although there is little control over the content of internet sources, clinicians, and members of the public, seeking information about existing and developing prostate cancer treatments could access websites such as Prostate Cancer UK (<https://prostatecanceruk.org/>), Cancer Research UK (<https://www.cancerresearchuk.org/>), and NICE (<https://www.nice.org.uk/guidance/cg175>). These are reputable websites that provide unbiased, and evidenced-based information on focal therapy with HIFU and cryotherapy.

The participants talked about the role of treatment centres and information provision, therefore practical, easily-accessible, materials should be available in clinics, and on the wards, in the form of factsheets, or digital resources such as computer discs, and USB flash drives. A combination of support from UNSs, access to reputable websites, and other information materials, will contribute to improving quality information support, to enable patients to make an informed choice about focal therapy with HIFU and cryotherapy for localised prostate cancer.

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