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Original Article

Dilemmas in gaining consent for radical radiotherapy from patients with early stage prostate cancer

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Abstract

Prostate cancer is a common male cancer, and arguably the form of cancer with least certainties about most appropriate form of treatment, leading to a greater freedom of choice among patients as to which treatment they wish to undertake.

Department of Health guidelines state that to be valid, consent to treatment must be fully informed, and professional bodies demand that consent should be ongoing throughout a course of treatment. It is recognised that in spite of the wealth of information available, prostate cancer patients generally feel less well informed about their disease and treatment than those with any other form of cancer.

Information about treatment efficacy and outcome is available from a wide variety of sources, of varying reliability, and patients can as easily receive too much information as they can too little. Bias from those imparting information cannot be excluded, and patient choices could be made on the basis of inaccurate or misleading information.

Practitioners have a duty of care to ensure that patients receive a level of information appropriate to their level of understanding and ability to absorb knowledge, and longstanding legal precedents are established to ensure that risks as well as benefits of treatment are discussed with patients.

Keywords

Prostate cancer; informed consent

INTRODUCTION

Prostate cancer is the second commonest cancer in men, with approximately 10,000 deaths per annum, and around 27,500 new cases diagnosed in England and Wales each year.[1] With the advent of testing for prostate specific antigen (PSA) serum, there has been a rise in the incidence of prostate cancer in comparatively young men, and there is evidence to suggest that clinics now see greater number of patients aged 55–70 years.[2] Patients identified by means of "routine" PSA testing are often asymptomatic, have early stage disease and frequently there is no "right" or "wrong" treatment. The traditional approach of diagnosis, discussion of treatment and its outcomes followed by patient consent is modified as this category of patients has arguably greatest patient input in deciding which treatment, if any, is appropriate.

Because there is no evidence base to suggest one is demonstrably superior to another, patients are given four options and asked to choose which treatment they prefer. A choice must be made

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between radical prostatectomy, external beam radiotherapy, brachytherapy, or active monitoring. None is without side effects – patients who opt for "active monitoring" may suffer an elevated level of concern for their health and life expectancy, the other three options are invasive and have well-documented side effects.[3–7]

Patients are given information as to risks and benefits of each treatment option, they make a choice and sign a consent form, even though it frequently cannot be proved that the choice made is the optimum for their individual circumstances. Conventionally, this has been the responsibility of the urologist or oncologist: with the advent of role extension and advanced practise, gaining informed consent for a form of radiotherapy, either external beam or brachytherapy may now fall within the remit of the radiographer.

Uncertainties around treatment cause anxieties for patients and their families. NICE (National Institute for health and Clinical Excellence) has recognised this and guidelines it has issued[8] require that healthcare professionals take account of individual needs and preferences ensuring that patients and their families (or carers where appropriate) can make informed decisions about care and treatment. NICE recommends that there should be easy access to a wide variety of free information, and that help should be available to interpret information if needed.

While this is a sound principle, in reality in busy departments such information is not always present: budget constraints may mean that at certain times of year supplies are limited. Staff shortages can reduce opportunities to participate in lengthy discussions, and in many departments space is at a premium, reducing the chance of creating the ideal environment. This can be a real dilemma for healthcare professionals; knowing what is needed does not always match resources to provide it.

Information can be obtained from many sources including national newspapers which print a bewildering array of information of varying degrees of accuracy. A "Google" internet search requesting information on prostate radiotherapy offered the choice of >541,000 sites and while publications such as Cancerbacup booklets are reliable, others are less so. Because such a huge choice of information and potential misinformation is available, it is important that healthcare staff are able to provide clear unambiguous impartial advice to patients. Patients report in clinic that they have read of miracle cures, while in May 2006 BBC news reported on the study by Parker et al.[9] recommending no active treatment (or miracle cure) but solely active monitoring for some patients. The "Cancer Information Maze"[10] report issued in 2005 has recognised that of all patients with cancer, prostate cancer patients are the most likely to feel they are not well informed about side effects, and "were significantly less well informed than other patients". The reason for this is not made clear, but should be a cause for concern for all those involved with gaining consent for prostate cancer treatments, including radiotherapy.

Following histological confirmation of diagnosis, details of disease are usually given to patients by a urologist who will inform the patient of his treatment options. This can later cause a dilemma to the oncology team as a urologist and an oncologist may have differing opinions as to what is the optimum treatment, and it cannot be guaranteed that information and/or advice patients receive at the time of diagnosis or in subsequent consultations are free from prejudice or bias.

Differing opinions as to best treatment are widely recognised within the medical profession and are found acceptable in the eyes of the law. Legal precedent which is still accepted as being current was established in *Bolam v Friern Hospital Management Committee*[11] when the "Bolam standard of care" was established. This sets that the standard of care required in all aspects of medical treatment should be "that of the ordinary skilled man exercising and professing to have that special skill." While judgement as to what constitutes the required level of skill will be made by a responsible body of medical opinion, it is recognised that a different body of competent medical opinion may adopt a different approach. If an oncologist disagrees with the urologist's opinion, providing both have equal levels of skill as recognised by the relevant professional bodies, and appropriate evidence for the two opinions is available, both opinions should be held to be of equal value.

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Unfortunately, opinions may not be entirely founded on evidence alone, and personal bias, with little supporting evidence can occur. The Royal College of Radiologists and British Association of Urological Surgeons jointly produced guidelines on the management of prostate cancer in 1999.[12] In this they state that "Prostatectomy remains the modality of choice for many urologists for the treatment of men with organ-confined prostate cancer. It has to be stressed however that this preference is not based on scientific data". Following on from this statement it would be logical to assume that as it is normally a urologist who first discusses treatment, it could be suggested that there is no guarantee that the patient will be given full unbiased information as to alternative forms of treatment available. While it would be wrong to suggest that any urologist would deliberately mislead or misinform a patient, a predisposition to favour surgery may allow unwitting prejudice to be introduced into the conversation about treatment options. If this does occur and a patient is then informed that he will also be seeing the oncology team to discuss radiotherapy, he may feel that this is merely a formality.

Anecdotal evidence in new patient Radiotherapy clinics suggests that some patients feel that they have been sent to clinic for no discernible reason – having surgery will take away the cancer, so why is radiotherapy needed? A dilemma facing the practitioner then unfolds. If for some reason the Oncology team has a strong belief that radiotherapy is the best choice for treatment, (e.g. results of investigations not available at the time the patient saw the surgeon suggest extra capsular spread) the patient may feel he is being offered less than optimum treatment and even being coerced into consenting to a form of treatment with which he is less than comfortable.

Conversely, if a wealth of information concerning all potential treatment options is given by a team of professionals at the time of diagnosis, potential bias may be reduced. However, the patient may then receive a lot of detail about all available options, possibly from an expert from each field, and could be so overwhelmed that he is unable to absorb all the information being presented.

Patient overload is a recognised problem[13] and it is well known that some patients find an excess of information to be as counter productive as not enough. This can be further compounded by patients experiencing difficulty retaining levels of information that could be considered excessive. Information overload can interfere with optimal decision making, and patients unused to interpreting numbers (you have x% probability of toxicity y) may have difficulty understanding what is being said, and a lack of understanding precludes consent being fully informed.

The problem that information imparted may not be fully received or completely understood by the patient is well known,[13,14] but it is difficult to establish how accurately health care practitioners are able to monitor their own information giving skills. A study by Keating et al.[15] showed a significant discrepancy in doctor/patient recollection of information imparted to patients with breast cancer when treatment choices were being offered. Patients' choice was between mastectomy or breast conservation: 213 patients who were eligible for either option reported that they had been told of only 1 option, but doctors reported that both options were discussed with 75% of these patients.

There are similarities between patients in this study and prostate patients. Both are being offered a choice of treatments which are equally beneficial, both are being offered by a surgeon at around the time the diagnosis is given to the patient. Keating et al. suggest that there is no definite conclusion to be reached as to why there is a mismatch in recollection of information, but comment that "discussions may be incomplete or that communication may be inadequate", and also suggest that there is not equal information about both choices imparted by surgeons. They also report that if a patient already has a preferred choice, the alternative may be less well discussed. But should this be the case? The possibility exists that a patient's decision has been made on inaccurate information or misinterpretation of data through inadequate understanding of medical jargon.

If a patient arrives in the oncology clinic with preconceived ideas as to which treatment option is preferred, it is appropriate to explore the reason

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why one particular option has already been chosen. A patient may be reluctant to follow this course of action, but it should nevertheless be pursued to ensure that the patient has full, accurate and comprehensible information about radiotherapy, and treatment consent is indeed fully informed.

O'Neill[16] suggests that "Genuine consent is not a matter of overwhelming patients with information, arrays of boxes to tick or propositions for signature", rather that information should be presented in a more structured manner appropriate to the individual's level of understanding. This will enable patients who wish to do so to delve more deeply (or less deeply as the individual requires), ideally supported by counselling if wanted, and time should be allowed to absorb further information. Department of Health (DOH) guidelines to patients[17] stress that patients (other than in emergency situations) have the right to take as much time as needed to make decisions, and this should be observed when obtaining consent even in a busy clinic with tight time constraints.

Imparting information about treatment outcomes, both in terms of toxicity and benefits is an important part of the consent process. While mention of some side effects may cause distress to some patients (e.g. potential impotence), DOH guiding principles consider that potential patient upset does not justify omitting information.[18] Patients frequently have the choice of treatments and it would be preferable to be able to give direct comparison of outcomes between treatment options. Unfortunately more evidence from clinical trials needs to be available before this can truly be done. Until such data are available, information comparing outcomes of treatment modalities is not available and the patient still makes a choice as much on information concerning side effects as on potential cure.

A further dilemma while obtaining consent for radiotherapy is that it is impossible to say with absolute certainty exactly how an individual will respond to treatment, as there are always variations in response between patients. While statistical evidence on toxicity is readily available,[3–5] reasons for variation between individual responses are not yet fully understood, nor is it possible to predict the extent of the individual's side effects.

Another quandary facing the clinician when deciding how much information should be given is deciding how large a risk needs to be before it is mentioned. If a side effect occurs in 50% of patients, it will automatically be discussed: if it occurs in 0.5% of patients, should it automatically be included in discussions about potential risks? Smith[19] quotes the Medical Defence Union when he tells us that "Informed consent requires an explanation to the patient in non-technical language about the nature, purpose and material risks of the proposed procedure". Furthermore, it is important to remember that the patient must understand the explanation, and that "material risk" should be seen as being one which a reasonable person would consider significant. *Sidway v Board of Governors of the Bethlem Royal Hospital*[20] established that it is appropriate for doctors to make decisions as to what level of risk need be disclosed to patients, but this can be somewhat problematical as different patients have different priorities, and there can be no "one size fits all" approach.

Kagan[21] is aware of this when speaking of different patients with seemingly identical disease choosing different options – a valid observation, but then goes on to say that patients with cancer are told by various people including nurses and other patients that doctors are not necessarily trustworthy. While this is clearly a disturbing comment the source is not revealed, and with no evidence presented to support the claim it appears to be unsubstantiated, which must cause veracity to be questioned. Kagan also reports that peer review of informed consent is rare in oncology: an interesting proposition, but one which again is difficult to prove or disprove. If peer review is conducted internally in a large department by oncologists and/or radiographers it could be undertaken frequently and regularly as part of normal internal audit/quality assurance procedures. Such a review would not necessarily be published, but lack of publication does not reduce validity or efficacy. Conversely, the lack of published data means it is difficult to establish how true this assertion is.

It remains necessary for practitioners to elicit from patients how much information they need, and which information should be available to all patients.

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Side effects that are frequently seen with IMRT or conformal radiotherapy and which may be regarded as normal such as bowel disruption or increased frequency of micturation[22] can be discussed with patients as part of the consent process, but decisions concerning information on other side effects can be more difficult. Neugut et al.[23] discuss an elevation in the risk of bladder cancer following prostate radiotherapy as being "not dramatic", and report that there is no increased risk of rectal carcinoma. Baxter et al.[24] disagree, noting a significant increase in the development of rectal cancer, with no effect on the remainder of the colon following radiotherapy. Hanfmann et al.[25] meanwhile mention a reduction in bladder capacity during radiotherapy to the prostate, without drawing conclusions as to long-term implications or subsequent potential risk of bladder cancer.

Contradictory or inconsistent information could confuse patients, so should the practitioner take a "paternal" attitude and not discuss second malignancies? If a patient appears to be better informed at the outset of a consultation than most new patients are, should he be given a fuller account of potential side effects – in effect is he no longer to be regarded as Bowen's "man on the Clapham omnibus",[26] i.e. "Mr. Average", another still current, long established legal precedent. Could it be considered a case of neglect if a better informed patient, or one expressing a need to know all the minutia of radiotherapy is not given a fuller level of information so he could make his own decisions retreatment and potential side effects? Do we have the right to decide which patient is given which information?

Obtaining consent by the oncology team can have another dilemma – because it is ultimately the patient who chooses whether or not to have treatment, he may opt for a course of radiotherapy which the oncologist feels is not entirely necessary. Smith[19] discusses patient rights to health care, and comments on the "corresponding obligation on other people to supply what the right holder makes a claim for". Some older patients who have very early stage disease, and less aggressive tumours are believed to have no clinical need for radiotherapy.[9,27,28] A well-differentiated tumour may be so slow growing as to pose little threat to an elderly patient who is more likely to die of unrelated illness. This being the case, offering radiotherapy as a treatment option may be done with some reluctance, with a corresponding reluctance to ask for consent. The practitioner may judge treatment is not clinically necessary, although the patient feels it is vital because of something he read in a newspaper. A different bias may then occur. In order to dissuade the patient from undertaking a course of treatment, side effects may be given greater emphasis in discussions than would be given to a young fit patient with a more aggressive tumour.

The College of Radiographers professional code of conduct defines informed consent as a process rather than an individual event, and points out that unless patients understand exactly what the treatment process entails, and are aware that they have a right to refuse, consent cannot be held to be informed. This poses a dilemma for radiographers – how fully informed has the patient been before attending for simulation or treatment? If a consent form is present with a patient signature, and all potential side effects are clearly annotated, it is a good starting point. It is, however, still necessary to confirm that the patient knew what he was signing, fully understood his commitment to several weeks treatment and has not since changed his mind. Before administering radiotherapy therefore, it is essential that the radiographer is confident that for all fractions, the patient continues to consent to undergo treatment, and is fully aware of potential risks as well as benefits.

Consent can be given in a number of ways: a signed consent form is useful as readily available evidence that consent has been discussed, but equally valid is verbal consent, confirming at each treatment that the patient continues to consent. Prior to beginning a course of treatment "first day chat" between radiographer and patient about the treatment process and management of side effects is standard practise. This can and should include confirmation of consent, and can be recorded by the radiographer on the consent form – a useful reminder to radiographers of their "gatekeeper" role. Implied consent is recognised by Royal Colleges as being equally valid, and can be seen regularly when a patient who is familiar with

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treatment routines removes the requisite clothing and lies unbidden on the treatment couch.

Gaining informed consent can be problematical for a number of reasons, not least because newly diagnosed patients or those who are given unwelcome news about extent of disease are frequently upset, and not in a position to think clearly or make rational decisions which can have a major impact on their life.[10] For such patients it is especially important that information is presented in a clear manner, in understandable language, and geared to the individual's requirements. As information for treatment may be given at the start of a relationship with a patient, there may have been little if any time available to develop a rapport between staff and patient. Practitioners are not always aware of patients' current level of understanding of their disease, or what preconceived ideas of treatment they may have. Time may be needed to allay groundless fears, or explain misunderstandings.

In order for consent to radiotherapy to be fully informed, it is essential that the patient is aware of all treatment options, as well as risks and benefits of the treatment he is about to undergo and having given consent during consultation prior to starting treatment, he then continues to consent to the ongoing course of radiotherapy. Consent should be taken at a pace to suit the patient, not the practitioner: anecdotal evidence suggests that a patient who has been allowed time to think over things and discuss his fears before committing himself to a course of action will have fewer fears and concerns during treatment than one who feels he has been rushed ill prepared into a decision, and may then add to the burden of side effects a fear that he has consented to treatment which he neither wants nor understands.

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