

Patient's choice of observational strategy for early-stage prostate cancer

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ABSTRACT

Active Surveillance (AS) may represent for selected patients with low risk, potentially indolent prostate cancer (PCa) a viable alternative to radical therapies, thus reducing the risk of over-treatment. Researchers and clinicians emphasized that the choice of AS may be a controversial one as patients have the chance to avoid the side effects of radical therapies but also the burden of living with an untreated PCa. The aim of our study is to focus on the decision-making process leading patients to elect AS amongst different therapeutic options. An observational, qualitative study was conducted. Between 2007 and 2009, 46 patients (mean age 67 years) were administered a semi-structured interview at enrolment in the Prostate Cancer Research International: Active Surveillance protocol. The focus of the interview was on the first question, i.e. "Why did you choose AS?". Interviews were audio-recorded and verbatim transcriptions were made. Content analyses were performed by using a text-driven, automatic software (T-lab). Four clusters of themes emerged. In cluster 1, the most meaningful theme was the ambivalence in front of different therapeutic options. In cluster 2, the focus was on patients' assessment of the aggressiveness of their PCa. In cluster 3, the topic was the collection of information from specialists. In cluster 4, the main theme was the collection of data through informal sources. Patients are motivated to opt for AS based on the subjective evaluation of medical information as well as characteristics of their psycho-social context. Understanding motivation for AS will help clinicians support patients in making the best choice for them.

Keywords: Choice; Prostate cancer; Active surveillance; Patient's engagement

1. INTRODUCTION

Prostate cancer (PCa) is the most common solid cancer in males and the second most common cause of cancer-related death among men in the Western World. Estimated incidence for 2008 was 186.000 in the United States (Jemal et al., 2008) and 382.000 in Europe (Ferlay, Parkin & Steliarova-Foucher, 2010). The incidence of PCa has been increasingly rising mainly due to aging population and widespread use of opportunistic screening of Prostate-Specific Antigen (PSA), together with increased clinicians', as well as patients', awareness of the disease (Associazione Italiana dei Registri Tumori & Associazione Italiana di Oncologia Medica, 2011).

Early diagnosed PCa can be radically treated with equally effective therapies, i.e., prostatectomy, external beam radiation therapy and brachytherapy (Heidenreich et al., 2011). Recent studies showed that early-diagnosed PCa, classified as low-risk and potentially indolent are likely to be often over-treated with no advantage in reducing mortality (Cooperberg, Carroll & Klotz, 2011; Klotz, 2012). Those patients could be offered an observational option, defined as Active Surveillance (AS), which implies a strict monitoring through repetition of PSA test, clinical examinations and repeated biopsies. Strict monitoring of potential cancer progression allows physicians to re-direct patients to active, radical treatments without losing the so-called opportunity window: patients whose cancer is re-classified as non-indolent will have the same survival chances as if they had chosen radical therapies right after diagnosis (Klotz, 2012).

Patients who choose AS may benefit from postponing, or even avoiding, the side effects of the therapeutic options. As a matter of fact, both surgery and radiation therapies may cause detrimental consequences such as sexual, urinary and bowel dysfunctions (Hamdy, 2011).

AS is receiving more and more consensus in the field of urologic oncology due to encouraging data that have been collected throughout Europe and Northern America above all (Bul et al., 2012; van den Bergh, Vasarainen et al., 2010; van den Bergh, Steyerberg et al., 2010).

A recent review emphasized that concerns about the quality of life of patients in AS are not supported by data (van den Bergh, Korfage & Bangma, 2012) and that patients do not show psychological distress related to the idea of living with an untreated cancer (Burnet, Parker, Dearnaley, Brewin &

Watson, 2007; van den Bergh, Essink-Bot et al., 2010; Vasarainen, Lokman, Ruutu, Taari & Rannikko, 2011).

The self-reported quality of life of patients who entered an AS protocol was likely to be influenced by a number of factors, including personality characteristics and the role of the physician recommending the observational strategy (van den Bergh et al., 2009). As a matter of fact, the influence of the physicians on patients' therapeutic/observational choice was highlighted in different studies (Cohen & Britten, 2003; Coulter, 2010; Davison, So & Goldenberg, 2007). Goh et al. (2011) reported that patients who had a positive approach to PCa and who perceived that they were receiving a regular medical support were more confident in bearing the uncertainty related to possible disease progression and reported they had a higher perception of control in the decision making process (Goh et al., 2011). Pickles et al. discussed potential psycho-social barriers to the acceptance of AS and reported physicians attitudes as one of the main obstacles that needed to be overcome in order to promote the adoption of AS (Pickles et al., 2007). Other barriers were lack of appropriate information and interventions to reduce potential anxiety related to the idea that cancer could spread.

We were interested in evaluating more extensively the factors influencing the choice of AS and the decision making process that patients undergo when facing the opportunity to choose among different options including AS.

2. METHODS

Our sample consisted of 46 patients (mean age 63 years, range: 43-77) with a potentially indolent PCa who were enrolled in the Prostate Cancer Research International: Active Surveillance protocol (PRIAS). PRIAS is a multi-centre disease management and research protocol for men with localized, early-stage and potentially indolent PCa, aimed at limiting the amount of over-treatment. PRIAS is a prospective, observational study promoted by Erasmus Medical Centred based in Rotterdam which started in 2006 and was joined by the Prostate Cancer Program at Istituto Nazionale dei Tumori of Milan in September 2007. Twenty-six percent of the patients had a University degree, 51.2% had attended high school, 15% had vocational education, 3% had attended junior high school and 5% primary school. Ninety-two percent of the patients reported to have a partner. Patients who accepted to participate in the study signed a Informed Consent, which was endorsed by the local Committee of Ethics.

Patients were administered a semi-structured qualitative interview investigating the reasons for choosing AS. The interviews – conducted by a clinical psychologist and lasting about one hour – were recorded and integrally transcribed. All interview transcripts were analysed using T-LAB (a dedicated software for qualitative text analysis; for a detailed description of the software please see: Gilardi & Lozza, 2009). In particular an Elementary Context Analyses was performed on the set of responses to the first question of the interview, i.e., “Why did you choose AS?” (Gambetti & Graffigna, 2010) in order to enucleate and systematize the most frequent themes covered by patients stories.

3. RESULTS

The Elementary Context Analyses allowed us to obtain and explore a representation of corpus contents through few and significant thematic clusters.

This analysis identified 4 elementary thematic clusters (CE), as described in the following paragraphs.

1. The *Start* (which explained the 35.18% of the lexical variance of the textual corpus). The first CE was focused on the post-diagnosis events, on the first clinical consultation and on the patients’ ambivalence in front of different therapeutic options. The most recurrent words in this cluster were “Remove” and “But”. Patients highlight that prostatectomy, which in most cases is the first therapeutic option that they are recommended, seemed to be at the beginning the most suitable option: “You go for surgery, once you have everything removed, you do not have the problem anymore! But, if I understand right it’s not that surgery is going to completely eliminate the problem in the long run. That’s what I was told, it could come back. And radiotherapy, well, you never know how it is going to be later on”. Nonetheless, patients reported that they were not completely convinced mainly because of potential side effects of prostatectomy, and radiotherapy as well: “If there were no side effects may I would have gone for surgery, you know [...] you have everything removed and you do not think about it anymore. But, well, at the age of 43, remaining [...] it seems that the sexual complication is the more likely and also incontinence”, “Since prostatectomy it’s not like having one’s appendicitis removed but it has side effects” or “[...] the idea of having the prostate removed [...] let’s try to avoid that [...] and so was it. I discarded radiotherapy [...] there are side effects there as well”.

2. The *Crossroad* (which explained the 12.56% of the lexical variance). This EC emphasized the assessment of the situation from the patient's. The most significant words in this cluster were "To choose" and "Aggressive". Patients showed that they tried to find a meaning to their diagnosis and felt confident that their cancer had good chances of not being aggressive: "Let's say you convinced me by saying that, based on experience of situations like mine, you can't expect to develop in such a short time a very aggressive cancer. That's why I chose it", "I chose active surveillance because from what I understood, from what I was told, it's not a severe thing. It's something that needs to be kept under control. Not aggressive, I was told". The awareness of having a form of cancer that was not life-threatening allowed them to take into consideration the observational option thus avoiding the need for surgery: "I chose it because I do not want to have surgery and after I was told there is a very low percentage of risk, well there's always a small risk but very low, I chose this thing here that is the best option for the moment", "I came here the first time and I was provided the different options and I chose active surveillance because even a good surgeon would leave me with problems affecting my quality of life [...] and given that the risk in my head is minimum and that every three months I repeat the PSA".
3. The third EC, the *Map* (40.7% of the variance explained), was characterized mainly by the presence of the lexical units "To decide" and "Data". The topic of decision, which runs through the different clusters given the prompt question that was asked to the patients, was here related to the need for collecting official, certified information, supported by different physicians and, in some cases, available literature: "At this point, one says [...]. It sounds strange, I want to see things more clearly, reading, reading, reading. I look at the data of medical examination and it does not seem so relevant to me", "[The doctor said] You can do what you prefer but I can tell you that the side effects of each therapy that you will decide to undergo will make things worse compared to your actual state", "As such, if I had different parameters, they would be the first to tell We cannot propose this to you, we can propose other things. I have no reason to distrust someone presenting a situation like this one. It's obvious that I am the one choosing. It's my body that we are talking about, I am the one who decides", "And then I decided for this option! I am obviously very cautious, meaning that the examinations that they make me go through are what convince me to enter the program. The day I should see something different", "I decided because I followed this argument. If it's not an aggressive thing, an aggressive cancer, it will develop slowly and from a scientific point of view there will be other options apart from surgery".

4. The fourth EC – *Encounters* – explained 11.56% of the lexical variance and highlighted patients' collection process of informal data mainly through friends. The most significant words in this cluster were "To talk" and "Friend" ("This friend of mine, friend of a friend, younger than me, he was diagnosed with prostate cancer [...] by chance", "I signed up for the surgery waiting list before a friend of mine told me Wait, if you are not convinced you talk to the oncologist, it's still at the beginning, do not hasten, wait, in the meanwhile whether it should develop you gained some years, one, two", "Then I got in contact with two friends of mine who had already undergone these interventions"). In many cases, informal data collection was carried on by different acquaintances in the medical environment: "I know the oncologist, she's a friend of ours and she told me, I'll have you talk to the radiotherapist", "And then I promised myself I was going to hear another opinion. As such, I had a contact with the Prostate Cancer Program. I changed my mind also because in the meanwhile I talked to a friend of mine, an aesthetician, who told me something very odd", "I got in contact with this friend who told me, Look, you can come over here".

4. DISCUSSION

The analyses of the interviews showed that the choice of active surveillance involves a complex decision-making process which can be characterized by ambivalence, conflicts and extensive need for adequate information. Patients could experience decisional conflict as each of the therapeutic/observational option presented risks and benefits that were not always straightforward and was associated with a certain degree of uncertainty.

The interviews provided a structured representation of what was discussed in previous literature (see for instance Mauri et al., 2009; Graffigna et al., 2011) and provided a more detailed picture of the decision making process that patients go through when called to face the double-edged responsibility of choosing an observational strategy.

The choice of AS is influenced by different people and events: patients are motivated to opt for AS, rather than radical therapies, based on the subjective evaluation of a number of factors that include medical information as well as contributes from their psycho-social context. The research underlines that patients try to get as much information as possible about their illness: the choice of AS could be compared to a journey that patients, and their families, undertake to find a meaning to their diagnosis of cancer before they can feel ready to make a decision.

The role of the physicians they met and their attitude toward AS was reported as crucial by all the interviewed patients. This result was similar to what reported by other authors (Davison, Oliffe, Pickles & Mroz, 2009; Gorin, Soloway, Eldefrawy & Soloway, 2011), who highlighted that the specialists' description of the PCa was the most influential factor on men who chose AS.

The above-discussed results suggest that patient-physicians communication and patients' engagement are crucial factors in overcoming the barriers to the acceptance of AS. As other studies already underlined (Hibbard et al., 2004; Gruman et al., 2010) the engagement of patient is a crucial ingredient for the clinical success of a healthcare intervention. From this perspective more and more attention is claimed to the organizational characteristics of the intervention (in terms of relational, communicative, structural and technical ones) that can contribute to enhance patients' engagement and activation toward the clinical process (Barello, Graffigna & Vegni, 2012). In the case of AS this appear particularly crucial in order to improve patients' empowerment and to make them feel able to muster and lead their own process of care. We thus suggest that physicians should be involving patients in a process of shared decision-making and adopt decision aid tools (O'Connor et al., 2009), which may support patients in reaching a well-informed choice based on their personal values and psycho-social priorities. Multidisciplinary teams could provide the most adequate setting for facilitating the exchange of information about therapeutic/observational options between the physicians and the patient (Bellardita, Donegani, Spatuzzi & Valdagni, 2011; Magnani et al., 2012; Valdagni, 2011)

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