

PATIENT SUMMARY

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Patient and caregiver benefit-risk preferences for non-metastatic castration-resistant prostate cancer treatment

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Introduction and background

This is a study by a group of American researchers (funded by the pharmaceutical company Bayer US). The men studied were being treated for non-metastatic castration-resistant prostate cancer. Non-metastatic castration-resistant prostate cancer (or nmCRPC) is a term used for prostate cancer that has not spread to other organs, but has been treated with hormone therapy injections which have become less effective. In this case, men will find their prostate specific antigen (or PSA) rising despite being on hormone therapy, but scans will not show any signs of cancer in the bones or in organs away from the prostate. Although most men living with nmCRPC will not experience symptoms from their cancer, a rising PSA can cause a lot of anxiety for men and their loved ones.

Traditionally there were no licensed treatments that could be used in this situation. Men were monitored and if the cancer showed signs of spreading, additional treatments such as chemotherapy or tablets would be used. More recently, it has been shown that tablets which block testosterone can be added to hormone therapy injections when it becomes less effective. These drugs (called second-generation androgen receptor inhibitors or SGARIs) can extend the length of time before prostate cancer spreads and help men live longer.

The aim of the study

These drugs have many benefits but also have side effects which may affect quality of life. This is an important consideration when choosing treatments. The researchers used an online survey to find out what men and their caregivers feel about the risks and benefits of these new treatments.

There were 14 questions, and each question compared two hypothetical drugs. A range of side effects with different severity was described for each hypothetical drug. The side effects included fatigue (tiredness), skin rash, cognitive problems (e.g. mental sharpness and memory), serious fall and serious bone fractures. The questions also described the benefits of the drugs (how many extra months men may live if they took the drug, and the length of time the drugs delayed progression of the cancer and resulting pain).

The researchers then used statistical models to estimate how important side effects were to responders. They also worked out how much survival benefit (amount of extra time that respondents could live) men and carers were willing to forego in order to experience less side effects.

What did the study find?

The survey analysed the responses of 143 men, and 149 caregivers. Unsurprisingly, both men and caregivers preferred treatments that worked well and offered less risk of side effects. The survey found that responders ranked side effects in the following order (most important to least important):

1. serious fracture (most important)
2. serious fall
3. cognitive problems
4. fatigue
5. skin rash (least important)

When it came to weighing up the benefits of the treatment against the side effects, both patients and caregivers were willing to trade extra months of life for reduction in risks that they viewed as more important, i.e. serious fracture, serious fall, and cognitive problems.

Limitations to the study

All studies have limitations and findings may not be applicable to all men. The study used hypothetical situations and respondents' preferences may not be truly reflective of their actual treatment choices. The number of responders was relatively small. The men who took part were young (the mean age was 53 years old) and the majority were white (84.6%), married (72.7%), had a college education or above (83.9%), and were employed full-time (60.1%). This may not reflect the typical characteristics of men with nmCRPC. The study used online recruitment and questionnaires which may have also meant that patients and caregivers who participated may have different characteristics than those who do not (e.g. younger, more educated, greater access to technology), which could affect their views on benefits and risks.

Why is this study important?

Previous research has shown that the majority of men want to be involved and consulted in treatment choices. Several studies have looked at treatment preferences of prostate cancer patients and caregivers but they did not specifically look at men living with nmCRPC.

Many of the new drugs for men with nmCRPC offer similar benefits in terms of controlling cancer and prolonging life but may also offer different risks in terms of side effects. The impact of these effects will depend on a man's individual situation, preferences and values.

For men living with nmCRPC, new side effects may be especially impactful given that their cancer is unlikely to be causing significant symptoms. Side effects such as falls, fractures and mental changes can be lifechanging and significantly affect quality of life. This study offers an insight on how patients and caregivers weigh the benefits and risks of these new treatments.

This study confirms that treatment-related side effects had a great influence on patients' and caregivers' treatment choices, and that they were prepared to sacrifice life expectancy for quality of life in some situations. For clinicians, this study highlights the importance of carefully balancing risks and benefits when selecting treatments and involving men and their caregivers in this decision.

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