Sexual Health and Relationship Enhancement of patients with Prostate Cancer and their partners

Published: 02-06-2015
Last updated: 16-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON43789

Source
ToetsingOnline

Brief title
SHaRE-PC

Condition

- Reproductive neoplasms male malignant and unspecified
- Sexual function and fertility disorders

Synonym
prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Astra

Zeneca,Bayer,Bontius Stichting Doelfonds Urologie. Bedrijven; Bayer;AstraZeneca.

Intervention

Keyword: communication, prostate cancer, relationship, sexual function

Outcome measures

Primary outcome

The patient*s and if applicable the partner's experiences and satisfaction

regarding current care for sexual issues following prostate cancer treatment.

The timing and type of intervention and by which health care provider would be

the best approach for sexual rehabilitation after prostate cancer diagnosis and

treatment. Also, the relationship quality will be measured.

Secondary outcome

Not applicable.

Study description

Background summary

Prostate cancer is the most common male cancer in the Western world. In the Netherlands, on an annual basis 11100 men are diagnosed on average with prostate cancer (2010-2013, IKNL. The majority of men diagnosed with prostate cancer survive for many years, but they may experience adverse effects of the disease or its treatments. Many effective treatment options are available to men with prostate cancer, including surgery, hormonal therapy, external-beam radiotherapy (EBRT), and brachytherapy. Most of these currently available treatments carry the risk of a number of treatment-related side-effects, including urinary incontinence, erectile dysfunction (ED), decreased libido and others that vary, depending on the treatment received. Some men select treatment based on perceived side effect profiles, frequently focusing on urinary incontinence and ED. One of the main complications associated with treatment for prostate cancer is ED. The significance of ED as a complication following prostate cancer treatment, especially laparoscopic radical prostatectomy (LRP), lies in the negative impact that it has on patients* sexual and overall life. In the literature, rates of ED following LRP range

from 25% to 100%. Such variety is associated with pelvic dissection and conservation of neurovascular structures. Following nerve-sparing LRP, the impotence rate at academic centers has been shown to be as high as 32% to 38% and is even greater (60% to 70%) in community-based surgical series. Likewise, there is a significant incidence of erectile dysfunction (ED) following external beam radiotherapy and interstitial brachytherapy when patients are followed for at least 2 years after treatment (23% to 56% and 27% to 53%, respectively). All forms of prostate cancer therapy carry significant risk of ED, but patients value sexual function so highly that they are often willing to choose a therapy that offers a shorter life expectancy but better potency following treatment. Although the precise estimations of ED secondary to prostate cancer treatment vary from study to study, more than 50% of men experience it and consider it upsetting. Many men affected by prostate cancer and erectile dysfunction experience symptoms of anxiety and depression, with reduced quality of life directly associated with urinary and sexual body-image changes that occur after surgery. Partners of these men also experience considerable psychological distress, with partners reporting anxiety and depression more often than patients. The difficulties experienced after surgery can also impact on the couple relationship itself; for instance, erectile dysfunction is associated with reduced wellbeing and lower levels of dyadic adjustment in the first year after surgery. Prostate cancer has been described as a *relationship disease* and it has been established that couples affected by prostate cancer often have significant unmet psychosexual supportive care needs around sexual recovery and rehabilitation.
Alongside the pre-treatment informed consent, it is important for physicians to address post-treatment sexual concerns and supply support and advice on how to deal with the treatment consequences. Little is known of the patients* point of view concerning type and timing of sexual counseling.

Study objective

This study is designed in order to determine the type and timing of sexual rehabilitation after prostate cancer treatment according to the patient*s and the patient*s partner*s point of view. Furthermore, it will assess which health care provider the patient desires for this specific support. Outcome of this survey will be used to design a quality care improvement based on patient*s experiences and suggestions.

Study design

We will perform a multicenter, cross-sectional study among prostate cancer patients diagnosed in the past two years or treated in the past two years after active surveillance at four Dutch centers; Leiden University Medical Centre in Leiden, Reinier de Graaf Gasthuis in Delft, Diakonessenhuis in Utrecht and Zuwe Hofpoort hospital in Woerden and of which Leiden University Medical Centre will be the coordinating center and Reinier de Graaf Gasthuis, Zuwe Hofpoort and

Diakonessenhuis the participating centers. Patients will receive a postal letter on writing paper from the medical center where treated, explaining the objectives of the study and a consent form with post-paid return envelope.(Appendix 1,2) If consent is provided, the patient will receive the questionnaire, which can be filled out at home. In addition to the specific questionnaire regarding post-treatment care for sexual concerns, there is the PQN-R in order to inventory the disease and treatment*s effect on the relationship. A copy will be provided for the partner (if applicable). Given our data indicate certain type of intervention regarding sexual counseling for prostate cancer patients after diagnosis and/or treatment is needed, we will implement this into the our department of Urology on short notice.

Materials; Questionnaire
The questionnaire was designed by the authors, based on study aim and a review of the literature in the area. The validated Psy Questionnaire Netherlands-Relationship Quality (PQN-R) was incorporated for inventory of the relationship quality, for the use of both patients and partners.(Appendix 3) A multidisciplinary expert panel, with experience in developing surveys, checked the questionnaire for comprehensiveness and quality. A patient panel piloted the questionnaire afterwards.
The questionnaire focuses on the patient*s experiences and satisfaction regarding current care for sexual issues following prostate cancer treatment. Moreover, it assesses the timing and type of intervention and by which health care provider would be the best approach for sexual rehabilitation after prostate cancer diagnosis and treatment.

Data management:
We will approach every patient that was treated with laparoscopic radical prostatectomy, brachytherapy, external beam radiotherapy and hormonal therapy in the past two years with the ability to understand the questionnaire in Dutch. Furthermore, patients who have been treated for prostate cancer in the past two years after a period of active surveillance or watchful waiting will be approached. If applicable, partners of the approached patients will also be asked to fill out a questionnaire regarding the relationship. Other inclusion criteria are willingness and informed consent to participate in the study. Sexual active as well as sexual inactive patients will be enrolled. The frequency or kind of sexual activity was not part of the inclusion or exclusion criteria, nor will be the sexual orientation.
Additional data which we will obtain from the status will include age, prostate cancer staging, PSA level, Gleason score, treatment type and comorbidities.

Sample size:
For the study, we intent to approach 2250 patients and their partners (600 patients from Leiden University Medical Centre in Leiden, around 550 patients

from Reinier de Graaf Gasthuis, 600 patients from Diakonessenhuis and around 500 patients from Zuwe Hofpoort hospital. Patients will be approached who are or have been under treatment of the outpatient clinic of the Urology department of the Leiden University Medical Centre in Leiden, Reinier de Graaf Gasthuis, Diakonessenhuis and Zuwe Hofpoort with clinical, biochemical, radiological or pathological confirmed prostate cancer, diagnosed within the past 2 years (accounting back from the last possible oncology registration date of the LUMC, which is July 2014) or started with treatment in the past 2 years after an earlier diagnose with initial watchful waiting or active surveillance. We will exclude patients who passed away or moved abroad. The number of partners who will provide permission for participation is not predictable.

Statistical analysis:
Quantitative data were analyzed by SPSS release 18 (SPSS Inc., Chicago, IL, USA). Means of numerical demographic values and the answers to the questions will be analyzed with frequencies. Bivariate associations between demographic information and the categorical data will be calculated using the Pearson chi-square procedure. Associations between numerical data and demographics of the respondents will be analyzed with the independent sample t-tests. Two-sided P values < 0.05 were considered statistically significant.

Ethics:
Ethical approval was asked and obtained in June 2015 by local medical ethical committee at Leiden University Medical Centre, since it concerns a survey with sensitive questions. For inclusion of patients of other medical centers, Reinier de Graaf Gasthuis, Diakonessenhuis and Zuwe Hofpoort ethical approval is required to perform a multicenter study. For the inclusion of the patients, a letter explaining the study and an informed consent form will be provided before sending the questionnaire.

Study burden and risks

Questions from the questionnaire may be confrontational and / or sensitive, depending entirely on the attitude towards sexuality of the patient. This risk is mitigated by providing comprehensive information in advance, so the patient and the partner itself may decide to participate before he / she gets to see the questionnaire.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients who are or have been under treatment of the outpatient clinic of the Urology department of the LUMC with clinical, biochemical, radiological or pathological confirmed prostate cancer, diagnosed within the past 2 years (accounting back from the last possible oncology registration date of the LUMC, which is July 2014) or started with hormonal treatment in the past 2 years after an earlier diagnose with initial watchful waiting or active surveillance. ;Partners of the above mentioned persons.

Exclusion criteria

Patients who passed away or moved abroad are excluded.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2015
Enrollment:	2250
Type:	Actual

Ethics review

Approved WMO

Date:	02-06-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	23-03-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL52385.058.15