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Original article

Psychological and functional effect of different primary treatments for prostate cancer: A comparative prospective analysis

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Abstract

Objectives: The aim of the study was to comparatively evaluate the psychological and functional effect of different primary treatments in patients with prostate cancer.

Methods and materials: We conducted a single-center prospective non randomized study in a real-life setting using functional and psychological questionnaires in prostate cancer cases submitted to radical prostatectomy, external radiotherapy, or active surveillance. Totally, 220 cases were evaluated at baseline and during the follow-up at 1-, 3-, 6-, and 12-month interval after therapy. Patients self-completed questionnaires on urinary symptoms and incontinence, erectile and bowel function, psychological distress (PD), anxiety, and depression.

Results: Several significant differences among the three groups of treatment were found regarding the total score of the functional questionnaires. Regarding PD, cases submitted to radical prostatectomy showed stable scores during all the 12 months of follow-up whereas cases submitted to radiotherapy showed a rapid significant worsening of scores at 1-month interval and persistent also at 6- and 12-month interval. Cases submitted to active surveillance showed a slight and slow worsening of scores only at 12-month interval. PD and depression resulted to be more associated with urinary symptoms than sexual function worsening whereas anxiety resulted to be associated either with urinary symptoms or sexual function worsening.

Conclusions: The results of our comparative and prospective analysis could be used to better inform treatment decision-making. Patients and their teams might wish to know how functional and psychological aspects may differently be influenced by treatment choice.

Keywords: Prostate neoplasm; Radical prostatectomy; Active surveillance; Radiotherapy; Psychological distress

1. Introduction

Cancer diagnosis represents a potential challenge for patients' psychological adjustment [1]. Psychological distress (PD) is a well-recognized phenomenon connected with cancer diagnosis and the most common forms of PD are anxiety and depression [2–6].

The aim of the study was to comparatively and prospectively evaluate in a real-life setting the psychological and functional effect of different primary treatments in patients with prostate cancer (PC) and no evidence of

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disease progression after therapy during the first year of follow-up.

2. Materials and methods

We conducted a single-centre prospective non randomized study from January 2014 to June 2017 using functional and psychological questionnaires in PC cases submitted to radical prostatectomy (RP), external beam radiotherapy (EBRT), or active surveillance (AS). All cases were referred and homogeneously and consecutively treated in the department of Urology and Radiotherapy of our university, by the same multidisciplinary team of clinicians, as part of our clinical practice.

2.1. Patient characteristics

In total 350 consecutive patients with a histological confirmed diagnosis of PC, suitable for primary treatments, were included in the initial analysis. Inclusion criteria were clinical or pathological staging for localized or locally advanced PC (T1–T3, N0, and M0); primary treatment such as RP, EBRT, or AS as discussed options between the patient and a multidisciplinary team of clinicians; no evidence of disease progression during the follow-up. Thus we enrolled 280 cases from the initial population. Written informed consent was obtained from all patients before their participation. The study was approved by the internal ethics committee of the department and has, therefore, been performed in accordance with ethical standards. Exclusion criteria included a history of neurological or psychological diseases or therapies, other oncologic diseases, low compliance to questionnaire compilation, other diseases or therapies that could interact with the results of our analysis. Therefore, a final population of 220 cases who responded to inclusion and exclusion criteria was analyzed. Table 1 shows the baseline socio-demographic and clinical characteristics of the population. According to European Urological Association risk classification for PC, all our cases were in the low or intermediate classes.

2.2. Study design

The final population of 220 cases was evaluated at baseline, one week before the beginning of the primary treatment, and during the follow-up at 1-, 3-, 6-, and 12-month interval after therapy. All cases submitted to RP were treated with a retropubic laparoscopic RP, and at 1-month interval after surgery they started a penile rehabilitation with phosphodiesterase-5 (PDE-5) inhibitors. All cases treated with RT were submitted to 3D conformal irradiation or intensity-modulated radiation therapy with a dose of 75 Gy to the prostate field and a (neo)adjuvant hormonal treatment of 6 months (all 102 cases were in the intermediate risk group). All cases managed with AS were followed using a standard protocol for AS and no cases shifted to an active treatment during the first 12 months. All 220 cases were followed with biochemical and radiological controls as part of our clinical practice and none showed tumor progression during the first 12 months of analysis. Figure 1 shows the flow chart of our study.

2.3. Measures

Our evaluation was mainly based on self-administered and validated questionnaires on functional and psychological parameters. Patients self-completed questionnaires at baseline and thereafter during the follow-up visit at 1-, 3-, 6-, and 12-month interval. All our patients were Italian and questionnaires were provided in the validated patients native language.

Urinary symptoms and incontinence were evaluated using the international continence society (ICS) male short-form (SF) and the International Prostate Symptom Score (IPSS) questionnaire. The ICS male SF was considered as a total score but also dividing in 9 items for lower urinary tract symptoms (LUTS) and 5 items specific for urinary incontinence [7]. Each item scored from 0 (lowest) to 5 (highest).

The IPSS consists in 7 items on LUTS (scored from 0–5) and 1 on quality of life [8]. On the basis of the total score, patients were divided in 3 classes: 0 to 7 low, 8 to 19 moderate, and 20 to 35 severe symptoms.

Erectile function was assessed using the International Index of Erectile Function-5 (IIEF-5) [9]. The total score ranged from 0 to 25, and cases were divided in 5 classes: 22 to 25 normal; 17 to 21 low; 12 to 16 low-moderate; 8 to 11 moderate; and 5 to 7 severe erectile dysfunction.

Health-related quality of life was evaluated using the SF-12 standard questionnaire [10]. The UCLA-Prostate Cancer Index was used to analyze separately the effect of treatment on urinary function (5 items), bowel function (4 items), and sexual function (5 items) [11].

PD was evaluated using three validated questionnaires. Anxiety, depression, and PD were assessed using the Hospital Anxiety and Depression scale (HADS) [1,12]. The HADS is a widely used and validated screening tool which consists of 7 anxiety and 7 depression items, each scored from 0 to 3. It produces 2subscales, 1 measuring anxiety and the other measuring depression, which range from 0 to 21, with a cut-off >8 and <11 indicating "suspicious" and a cut-off >11 indicate "definite" cases. The HADS total score, used to measure for PD, has a theoretical range between 0 and 42 with a cut-off >15 indicating PD (with higher values indicating more severe psychological distress).

Depression was evaluated using the Patient Health Questionnaire (PHQ-9), a reliable 9-item instrument developed to screen for the presence and severity of depression [13]. Items range from 0 ("not at all") to 3 ("nearly every day"). Thus the total score (range from 0–27) indicates varying levels of depression with 5 classes (1–4 minimal,