ONCOLOGY

Exploring the Optimal Erectile Function Domain Score Cutoff That Defines Sexual Satisfaction After Radical Prostatectomy

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ABSTRACT

Introduction: The International Index of Erectile Function (IIEF) is the gold standard validated instrument for defining erectile function (EF) and its response to treatment. The EF domain (EFD) contains six questions and is a sensitive and specific measurement of treatment-related changes in EF. The EFD score has been widely used as a primary assessment end point for clinical trials of EF recovery after radical prostatectomy (RP). Various EFD scores have been used to define functional erections. Recently, an EFD score of at least 22 has been used as a threshold in major post-RP penile rehabilitation studies.

Aim: To define the EFD score that optimally defines "functional" erections after RP.

Methods: We assessed men 24 months after RP using the IIEF and specifically analyzed the scores of the EFD and intercourse satisfaction domain (ISD).

Main Outcome Measures: We used two questions on satisfaction (score = 0−5) and enjoyment (score = 0−5) from the ISD to classify IS (score = 0−10). We tested the following intercourse satisfaction classifications: ISD score equal to 10, ISD score of at least 8, and a score of at least 4 for the ISD questions on satisfaction and enjoyment. We used the classification that produced the largest area under the curve (AUC) using a receiver operating characteristic (ROC) curve. Then, we used a three-step process to determine the optimal EFD score cutoff using sensitivity and specificity analysis.

Results: One hundred seventy-eight men had an average age at RP of 58 ± 7 years and a 24-month EFD score of 20 ± 9. Sixty-four percent had complete nerve-sparing surgery, 35% had partial nerve-sparing surgery, and 1% had the nerves fully resected. Thirty-three percent had laparoscopic RP and 67% had open RP. The ROC curves produced AUCs of 0.80 (ISD score = 10), 0.85 (ISD score ≥ 8), and 0.86 (ISD scores for satisfaction and enjoyment ≥ 4; $P < .001$ for all comparisons). Using the IS criterion of ISD scores for satisfaction and enjoyment of at least 4 (largest AUC), the sensitivity and specificity values were 0.89 and 0.66 for an ESD score equal to 22, 0.78 and 0.71 for a score equal to 23, 0.78 and 0.80 for a score equal to 24, 0.77 and 0.82 for a score equal to 25, and 0.73 and 0.85 for a score equal to 26. The scores of 24 and 25 met the criteria outlined in the first two steps of analysis. The score of 24 was selected as the cutoff using face valid judgment and the previous literature.

Conclusion: These data support an EFD score of 24 as a valid cutoff defining "functional" erection in men with erectile dysfunction after RP. These data are important for clinicians in counseling patients and to researchers to define inclusion criteria and treatment end points for trials of erectile dysfunction after RP. **Terrier JE, Muhall JP, Nelson CJ. Exploring the Optimal Erectile Function Domain Score Cutoff That Defines Sexual Satisfaction After Radical Prostatectomy. J Sex Med 2017;14:804−809.**

INTRODUCTION

Prostate cancer is the most frequently diagnosed solid tumor and the second most common cause of death from malignancy in men in the United States.[1] Radical prostatectomy (RP) is a gold standard curative treatment for early and localized prostate cancer. RP has been found to decrease the risk of prostate cancer death vs watchful waiting in men younger than 65 years at

10 years of follow-up.[2] Erectile dysfunction (ED) is a common side effect of RP. Despite the development of nerve-sparing RP, only 16% of men undergoing RP will regain their presurgery level of erectile functioning.[3,4] This is important because ED can have a negative effect on quality of life and can cause significant distress in men and their partners. The burden of sexual bother after RP persists at significantly high levels for at least 2 years after surgery[5] and the link between ED and depressive symptoms is well established.[6]

The erectile function domain (EFD) of the International Index of Erectile Function (IIEF) has been widely used as a primary assessment end point for clinical trials of EF recovery after RP. Various EFD scores have been used to define functional erections. Normally, absence of ED is defined by an EFD score of at least 26[7]; however, this cutoff was developed in men with general ED as opposed to men with ED after prostate cancer treatment. Briganti et al[8] presented data on an EFD cutoff score in men after RP and demonstrated that patient sexual satisfaction after RP was equivalent for patients with mild ED (EFD score = 22–25) and those men with no ED (EFD score ≥ 26). They concluded that an EFD score cutoff of 22 could be used to define postoperative EF recovery. Subsequently, this cutoff has been used as the threshold in a major erectile rehabilitation study (REINVENT and REACCT) after RP.[9,10]

Although the study by Briganti et al[8] helped provide the first data quantitatively defining EF recovery with the EFD score after RP, this has never been replicated. There is concern that a score of 22 might be too low to represent "true" EF recovery and this low score might overestimate the percentage of men with "recovered" EF. Also, the method of dividing EFD scores into specific severity groups and comparing those groups raises some methodologic questions.[11] For example, if different group ranges were selected (eg, mild ED score = 20–25), then the investigators might have easily defined a different cutoff score.

The aim of this study was to define an optimal EFD cutoff score after RP to define "functional" erections.

METHODS

Patient Population

This study is part of a larger prospective quality-of-life (QOL) study conducted in patients with early-stage prostate cancer at our institution. The study was approved by the institutional review board and complied with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice Guidelines founded on the Declaration of Helsinki. The subjects eligible for this study were men diagnosed with localized prostate cancer who were undergoing an RP and could speak English. Patients were recruited consecutively in our clinics before RP and, after consent, completed the Prostate-Health Related Quality-of-Life Questionnaire.[12] The subjects completed this questionnaire before surgery and then every 3 months for 2 years after surgery.

Because nerve healing and recovery are considered complete by 24 months after RP,[13] the analysis in this article uses data from the men who completed the 24-month assessments.

Outcome Measurements

The Prostate-Health Related Quality-of-Life Questionnaire is a psychometrically validated, patient self-report questionnaire that contains 63 disease-specific items that measure 8 domains: urinary, sexual, and bowel function; associated bother and role limitations domains; and cancer worry, treatment satisfaction, and regret.[12] This study used the sexual function subscale from this QOL instrument, which is represented by the IIEF.[14] The IIEF contains five domains, and this study analyzed the six questions that compose the EFD (maximum score = 30) and two of the three questions of the intercourse satisfaction domain (ISD; maximum score = 10). The EFD is considered the gold standard assessment of EF and is a sensitive and specific measurement of treatment-related changes in EF.[15] We included only those men who were sexually active (EFD score ≥ 6) at 24 months after RP. The ISD asks about frequency, satisfaction, and enjoyment of sexual intercourse. We used only the satisfaction and enjoyment questions of the ISD. We removed the intercourse frequency question from the ISD for this analysis because physical and psychological factors related to sexual functioning after RP can affect sexual frequency and confound ISD results. Higher scores indicated better functioning in these domains.

Statistical Analysis

All analyses were conducted using IBM SPSS 24 (IBM Corp, Armonk, NY, USA). Descriptive statistics are provided to characterize the sample. We used a receiver operating characteristic (ROC) curve to determine the optimal EFD score cutoff that would identify intercourse satisfaction (IS). The ISD as used in the analysis has two questions that have response options that range from 1 to 5 on a Likert scale. Because there is no standard or defined cutoff for the ISD score, we defined a priori three "face valid" classifications of IS based on subjects' scores on the ISD. The three classifications were an ISD score equal to 10 (very highly satisfying, highest score possible), an ISD score of at least 8 (fairly to very highly satisfying), and an ISD score of at least 4 for the ISD questions on satisfaction and enjoyment (highly to very highly satisfying). We ran a separate ROC curve for each of these three definitions of IS and used the one that produced the largest area under the curve (AUC) as primary definition for the analysis. An AUC equal to 1 represents perfect classification, and an AUC equal to 0.5 indicates no better than chance. Once we determined the ISD criterion that produced the largest AUC, we analyzed the sensitivity and specificity for each EFD score based on this criterion. Sensitivity is the measurement of the proportion of "positives" who are correctly identified by the cutoff score (ie, the proportion of men correctly identified who met the ISD criterion of sexual satisfaction). Specificity measures the proportion of