

What Is the Definition of a Satisfactory Erectile Function After Bilateral Nerve Sparing Radical Prostatectomy?

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DOI: 10.1111/j.1743-6109.2010.02179.x

ABSTRACT

Introduction. Different cut-offs of the erectile function (EF) domain of the International Index of Erectile Function (IIEF) have been used as definition of postoperative EF recovery.

Aim. To test the correlation between patient satisfaction and IIEF-EF domain score cut-offs.

Main Outcome Measure. The IIEF was used to evaluate EF and satisfaction before and after bilateral nerve sparing radical prostatectomy (BNSRP).

Methods. The study included 165 consecutive patients treated with retropubic BNSRP at a single institution. All patients had normal preoperative EF (IIEF-EF ≥ 26) and reached an IIEF-EF ≥ 17 following surgery. Complete data included EF, intercourse (IS), and overall satisfaction (OS) assessed by the corresponding domains of the IIEF administered prior and after surgery. Patients were divided into three groups according to the highest IIEF-EF score reached postoperatively, namely 17–21 (group 1), 22–25 (group 2), and ≥ 26 (group 3). One-way analysis of variance was used to compare IIEF-OS and IIEF-IS domain scores at the time the EF end point was reached. The same analyses were repeated separately in those patients with a complete EF recovery after surgery (group 3).

Results. Mean preoperative IIEF-OS and IIEF-IS domain score was 8.4, 8.8, 8.7 and 11.6, 11.8, 11.9 in group 1, 2, 3, respectively (all $P \geq 0.3$). After a mean follow-up of 26.7 months, mean postoperative IIEF-OS and IIEF-IS domain scores assessed at the time of EF recovery were comparable for patients reaching an IIEF-EF of 22–25 and for patients scoring postoperatively ≥ 26 (8.1, 8.1, and 10.6, 11.4; all $P \geq 0.3$). However, mean IIEF-OS and IIEF-IS domain scores of these patients were significantly higher as compared to patients reaching an IIEF-EF domain score < 22 (6.3 and 8.4, respectively; all $P \leq 0.006$). Similar results were achieved considering only those patients (group 3) who had complete EF recovery after surgery.

Conclusions. We demonstrated that in preoperatively fully potent patients treated with BNSRP a lower satisfaction is expected when an IIEF-EF cut-off of 17 is used. Conversely, no difference was found using a cut-off of 22 or 26. Therefore, our results support that a cut-off of IIEF-EF ≥ 22 might represent a reliable score for defining EF recovery after BNSRP. **Briganti A, Gallina A, Suardi N, Capitanio U, Tutolo M, Bianchi M, Salonia A, Colombo R, Di Girolamo V, Martinez-Salamanca JI, Guazzoni G, Rigatti P, and Montorsi F. What is the definition of a satisfactory erectile function after bilateral nerve sparing radical prostatectomy? J Sex Med 2011;8:1210–1217.**

Key Words. Prostate Cancer; Bilateral Nerve Sparing Radical Prostatectomy; Erectile Dysfunction; International Index of Erectile Function

Introduction

Radical prostatectomy (RP) is the most widely performed procedure for patients with clinically localized prostate cancer (PCa) and a life expectancy of at least 10 years [1]. The introduction of Prostate Specific Antigen (PSA) and early detection programs for PCa has led to a significant migration toward earlier age and stage at diagnosis [2,3]. As a consequence, increasing attention has been focused on preservation of postoperative quality of life, which is based on a number of factors, including the maintenance of a satisfactory sexual function after RP. In 1998, Walsh et al. pioneered the understanding of pelvic neuroanatomy and the subsequent development of a surgical technique by which the entire prostate could be removed while preserving the anatomical integrity of the external urethral sphincter and the autonomic nerves surrounding the gland [4,5]. However, while an increasing number of studies have reported satisfactory postoperative rates of urinary continence, the preservation of erectile function (EF) after surgery clearly showed to be a major challenge for most urologists [6–12]. Research in post-RP recovery indicates that approximately 25–75% of men experience postoperative erectile dysfunction (ED) [6–16]. This broad range of postoperative EF impairment can be attributed to several study design factors, including differences in baseline tumor and sexual health characteristics as well as in the surgical and pharmacological approaches used [6–16]. More importantly, such discrepancies might be due to the lack of a standardized definition of postoperative EF recovery [14,15]. For this aim, several structured, multi-item, validated tools have been developed and validated [14–16]. Among these, the International Index of Erectile Function (IIEF) represents one of the most currently used questionnaire [17]. The IIEF is a cross-culturally and psychometrically validated measure of EF, containing five different domains. When scoring EF, the IIEF-EF domain is used. Based upon a classification tree analysis, Cappelleri et al. found that the optimal IIEF-EF cut-off was 25, with men scoring ≥ 26 classifying as having full EF [18]. However, no clear agreement exists with regards to the applicability of such cut-off in men treated with BNSRP. Some authors indeed consider an EF recovery after surgery as an IIEF-EF domain score ≥ 26 , while others utilize an IIEF EF domain scores cut-off of 21 or even 17 on a scale of 30 [19,20]. Such discrepancies are mainly due for two main reasons. First, not all patients

treated with BNSRP are fully potent prior to surgery [21,22]. Second, there is a lack of patient satisfaction assessment according to different degrees of EF after surgery. Patients treated for cancer might indeed lose sexual interest, thus lowering their threshold for a satisfactory sexual life as compared to the period prior to PCa diagnosis [14,16]. In order to address this void, we tested the level of patient satisfaction associated with different IIEF-EF cut-offs in fully potent patients undergoing BNSRP. Our aim was to find the ideal IIEF-EF domain score cut-off associated with highest level of patient satisfaction. This might help in patient counseling as well as in the standardization of EF recovery definition after BNSRP.

Materials and Methods

The study included 514 consecutive patients affected by clinically localized PCa and treated with retropubic BNSRP at our institution between January 2004 and July 2009. The indication to bilateral nerve sparing surgery was based on PCa characteristics at diagnosis (cT1-cT2a disease, biopsy Gleason score $\leq 3 + 4$, PSA < 10 ng/mL), regardless of preoperative erectile status. Of 514 patients, only 165 (32.1%) had full preoperative EF (defined as an IIEF-EF domain score ≥ 26) and reached an IIEF-EF ≥ 17 after surgery. These patient represented the study cohort. All patients had complete preoperative data including age at surgery, EF, intercourse (IS) and overall satisfaction (OS) assessed by means of the corresponding domains of the IIEF administered prior to surgery, at the time of hospital admission. Moreover, body mass index (BMI) was recorded prospectively prior to surgery in all patients and was calculated by dividing the weight (kg) by the square of the height (m^2) [23].

The nerve sparing technique described by Walsh was performed in 116 (70.3%) patients [4]. Conversely, in 49 (29.7%) patients, a modified nerve sparing approach was performed. This technique basically implies incising the levator and prostatic fasciae high anteriorly (1 and 11 o'clock positions) over the prostate, developing the plane between the prostatic capsule and the prostatic fascia, and displacing the neurovascular network localized between the two fasciae laterally [19]. None of the patients received any adjuvant or neoadjuvant treatment for PCa. Patients were encouraged to attempt sexual intercourse as soon as possible following catheter removal and were stimulated to use either a full dose of a phosphodi-

esterase type 5 inhibitor (PDE5-I) on demand or a low dose of PDE5-I every day for a period of 3 to 6 months. The decision on the type of ED treatment administered followed the surgeon and patient's discussion about possible treatment options and expectations. Moreover, all patients were postoperatively assessed every 3 months and were asked to complete the entire IIEF during each visit. Patients were then subdivided into three groups according to the highest IIEF-EF domain score cut-off achieved over time after surgery, namely IIEF-EF 17–21 (mild to moderate ED; group 1; N = 20, 12.1%), IIEF-EF domain score 22–25 (mild ED; group 2; N = 65, 39.4%), and IIEF-EF ≥ 26 (no ED; group 3; N = 80, 48.5%). Patients were censored at the time of the end point was reached. Corresponding IIEF-IS and IIEF-OS domain scores were available for all patients at the time the EF end point was reached.

Statistical Analyses

One-way analysis of variance (ANOVA) was used to compare patient satisfaction (assessed by the IIEF-OS and IIEF-IS domain scores) between the three groups at the time of the end point was reached (namely, IIEF-EF domain score of 17–21 for group 1, 22–25 for group 2 and ≥ 26 for group 3, respectively). The same analyses were repeated separately for those patients who maintained full potency after surgery (IIEF-EF ≥ 26 ; group 3; N = 80). In this group, mean IIEF-OS and IIEF-IS domain scores assessed at the time of different IIEF-EF domain cut-offs were reached (namely, IIEF-EF ≥ 17 , ≥ 22 , or ≥ 26) was compared using ANOVA test. Differences in categorical variables among the three groups were tested using chi-square test.

Results

Patient clinical characteristics are shown in Table 1. Despite all patients receiving a recommendation to initiate a treatment for ED after surgery, only 112/165 (67.8%) decided to be treated. Of these, 82 (73.2%) used PDE5-I on demand, while 30 (26.8%) used PDE5-I on a daily basis for a period of up to 6 months. After a mean follow-up of 26.7 months (median 24; range 2–73), 20 (12.1%), 65 (39.4%), and 80 (48.5%) patients achieved an IIEF-EF domain score 17–21, 22–25, and ≥ 26 , respectively (group 1, 2, and 3, respectively). Mean and median time to EF recovery was 17.6 and 11, 6.7 and 4, 8.6 and 7 months for group 1, 2, 3, respectively. Mean preoperative IIEF-OS

Table 1 Preoperative patient characteristics and descriptive statistics

	All patients (N = 165) No (%)	Group 1* (N = 20) No (%)	Group 2† (N = 65) No (%)	Group 3‡ (N = 80) No (%)	P value
Age at surgery					
Mean (median)	58.6 (58.9)	60.5 (59.7)	59.5 (60)	57.3 (57.5)	0.047
Range	40–74	47–72	42–74	40–68	
Preoperative BMI (Kg/m ²)					
Mean (median)	25.8 (25.6)	25.6 (25.3)	25.6 (25.4)	26.1 (26)	0.25
Range	17.3–37.4	20.3–35.4	20.3–35.4	18.4–37.4	
Preoperative IIEF-OS					
Mean (median)	8.7 (9)	8.4 (8)	8.8 (9)	8.7 (9)	0.38
Range	4–10	7–10	6–10	4–10	
Preoperative IIEF-IS					
Mean (median)	11.8 (12)	11.6 (12)	11.8 (12)	11.9 (12)	0.84
Range	7–15	9–15	8–15	7–15	
Type of nerve sparing technique					
Standard	116 (70.3%)	16 (80%)	45 (69.2%)	55 (68.7%)	0.14
Intrafascial	49 (29.7%)	4 (20%)	20 (30.8%)	25 (31.3%)	
Postoperative use of PDE5-I	112 (67.8%)	13 (65%)	47 (72.3%)	52 (65%)	0.16

*Group 1: patients reaching a postoperative IIEF-EF domain score ≥ 17 and < 22 .

†Group 2: patients reaching a postoperative IIEF-EF domain score ≥ 22 and < 26 .

‡Group 3: patients reaching a postoperative IIEF-EF domain score ≥ 26 .

IIEF-OS = overall satisfaction domain of the International Index of Erectile Function; IIEF-IS = intercourse satisfaction domain of the International Index of Erectile Function; BMI = body mass index.

and IIEF-IS domain score was 8.4, 8.8, 8.7 and 11.6, 11.8, 11.9 in group 1, 2, 3, respectively ($P = 0.38$ and $P = 0.84$, respectively; Table 1).

Overall, mean postoperative IIEF-OS and IIEF-IS domain score was 8.0 (median 8.0; range 4–10) and 10.8 (median 11; range 3–15). No significant differences in terms of mean postoperative IIEF-OS and IIEF-IS domain score were found between patients treated and those not treated with PDE5-I (all $P \geq 0.3$).

Interestingly, mean postoperative IIEF-OS and IIEF-IS domain scores assessed at the time of EF recovery was reached were comparable for patients reaching IIEF-EF ≥ 22 and for patients scoring postoperatively ≥ 26 (8.1, 8.1, and 10.6, 11.4; $P = 0.9$ and $P = 0.3$, respectively; Table 2). However, the mean IIEF-OS and IIEF-IS domain scores of patients scoring ≥ 22 and ≥ 26 were significantly higher as compared to patients reaching a score < 22 (8.1 and 8.1 vs. 6.3, and 10.6 and 11.4 vs. 8.4; $P = 0.001$ and $P \leq 0.006$, respectively; Table 2). A significant reduction of postoperative satisfaction as compared to the preoperative period was evident only for those patients who had a postoperative IIEF-EF domain score < 22 ($P < 0.001$). Similar results were achieved considering only those 80 patients (group 3) who had complete baseline EF recovery (IIEF-EF ≥ 26) after surgery (Table 3). Mean IIEF-OS and IIEF-IS domain scores at the time of reaching an IIEF-EF domain score of 17 were lower as compared to mean IIEF-OS and IIEF-IS domain scores when the same patients achieved over time at least 22 or 26 (6.4 vs. 7.8 and 8.1, and 9.4 vs. 11 and 11.4; all $P \leq 0.01$). Conversely, no difference was found in the IIEF-OS and IIEF-IS domain scores when patients achieved an IIEF-EF 22–25 and an IIEF-EF ≥ 26 (7.8 vs. 8.1 and 11 vs. 11.4; $P = 0.4$ and $P = 0.5$, respectively; Table 3).

Discussion

Radical prostatectomy represents an effective approach for the treatment of patients with clinically localized PCa [1]. This procedure may be associated with treatment-specific sequelae affecting health-related quality of life [6–16]. Preservation of optimal functioning after surgery is becoming increasingly important since the diagnosis of PCa is currently more frequent in younger patients with localized disease [2,3]. In this context, EF impairment represents one of the most significant disorders that negatively affects postoperative quality of life of patients treated

Table 2 Comparisons of postoperative overall and intercourse satisfaction domains of the International Index of Erectile Function (IIEF-OS and IIEF-IS) according to the use of phosphodiesterase type-5 inhibitor (PDE5-I) and to the highest erectile function score achieved after surgery in the entire patient population (N = 165)

	All patients (N = 165) No (%)	Patients receiving PDE5-I (N = 112)	Patients not receiving PDE5-I (N = 53)	P value	Group 1* (N = 20) No (%)		Group 2† (N = 65) No (%)		Group 3‡ (N = 80) No (%)		P value
					Mean (median) Range	No (%)	Mean (median) Range	No (%)	Mean (median) Range	No (%)	
Postoperative IIEF-OS											
Mean (median)	8.0 (8)	8.0 (8)	7.9 (8)	0.5	6.3 (6.5)	8.1 (8)	8.1 (8)	8.1 (8)	8.1 (8)	8.1 (8)	0.001 [§]
Range	4–10	5–10	4–10		4–10	6–10	6–10	6–10	6–10	6–10	0.9 [¶]
Postoperative IIEF-IS											
Mean (median)	10.8 (11)	10.5 (11)	10 (11)	0.3	8.4 (7)	10.6 (10)	10.6 (10)	11.4 (11)	11.4 (11)	11.4 (11)	$\leq 0.006^{\S}$
Range	3–15	4–15	3–15		3–15	8–15	8–15	7–15	7–15	7–15	0.3 [¶]

*Group 1: patients reaching a postoperative IIEF-EF domain score ≥ 17 and < 22 .

†Group 2: patients reaching a postoperative IIEF-EF domain score ≥ 22 and < 26 .

‡Group 3: patients reaching a postoperative IIEF-EF domain score ≥ 26 .

[§]Group 1 vs. group 2 and 3.

[¶]Group 2 vs. group 3.

Table 3 Postoperative overall and intercourse satisfaction domains of the International Index of Erectile Function (IIEF-OS and IIEF-IS) only in patients who recovered full potency after surgery (IIEF-EF \geq 26; group 3; N = 80)

	IIEF-EF \geq 17 and <22	IIEF-EF 22–25	IIEF-EF \geq 26	P value
Postoperative IIEF-OS				\leq 0.01*
Mean (median)	6.4 (6)	7.8 (7)	8.1 (8)	0.4 [†]
Range	4–10	5–10	6–10	
Postoperative IIEF-IS				\leq 0.01*
Mean (median)	9.4 (9)	11 (11)	11.4 (11)	0.5 [†]
Range	4–15	7–15	7–15	

Comparisons of mean IIEF-OS and IIEF-IS domains evaluated when the corresponding IIEF-EF cut-offs were reached.

*Mean IIEF-OS domain score at IIEF \geq 17 vs. mean IIEF-OS at IIEF-EF 22–25.

[†]Mean IIEF-OS domain score at IIEF 22–25 vs. mean IIEF-OS at IIEF-EF \geq 26.

with RP [15]. However, when assessment of postoperative EF is often limited by several confounding variables, such as inadequate preoperative EF evaluation, poor postoperative data collection, lack of consensus related to optimal timing of EF assessment after surgery, nonuniform agreement of what constitutes ED post RP [14,15]. For the latter, several multi-items, structured questionnaires have been developed and validated [14–16]. Among these, the IIEF represents one of the most currently used in the every day clinical practice [17]. This questionnaire is based on five different domains addressing not only EF, but also IS, OS, orgasmic function, and sexual desire. Evaluating all domains of this questionnaire is key for patients with sexual dysfunction, since ED is not “per se” associated with the same degree of sexual bother and dissatisfaction in all patients [24]. Previous studies have indeed shown a wide range of sexual satisfaction in patients with ED [24,25]. This issue is even more important in oncological patients where psychogenic issues related to the presence of cancer might decrease the postoperative interest in sexual life, and subsequently, ED-related sexual bother [26].

Despite these considerations, no study has ever addressed the association between EF impairment and sexual satisfaction in patients treated with RP. In order to address this void, we assessed the association of patient satisfaction with different IIEF-EF domain scores cut-offs. Such analysis is aimed at finding the IIEF-EF domain score cut-off associated with highest level of patient satisfaction. The importance of such approach resides on the need of standardizing postoperative patient evaluation. We performed our analysis in a large cohort of prospectively assessed preoperatively fully potent patients (IIEF-EF domain score \geq 26) treated with BNSRRP at a single high-volume tertiary referral center. Patients were prospectively followed and divided into three groups according

to the maximum IIEF-EF domain score reached over time after surgery. Data on patient satisfaction (evaluated by means of the OS and IS domains of the IIEF) at the time of the end point was reached (namely, the highest IIEF-EF domain score reached after surgery) was available for all patients.

Our results showed that patient satisfaction was equal for patients reaching a maximum IIEF-EF domain score of 22–25 and for those recovering baseline EF after surgery (IIEF-EF \geq 26; all $P \geq$ 0.3). Conversely, mean IIEF-OS and IS domain scores were significantly lower for men scoring < 22 as compared to the other two groups of patients (all $P \leq$ 0.006). Similar results were achieved when the analyses were repeated separately in patients regaining full potency after surgery (group 3). A comparable satisfaction was indeed shown when these patients reached an IIEF-EF domain score of either 22–25 or >25 (all $P \geq$ 0.4). Conversely, lower level of satisfaction was reported by the same patients when a postoperative IIEF-EF < 22 was achieved (all $P \leq$ 0.01).

Several aspects of our study are noteworthy. First, this is the first study addressing sexual satisfaction according to postoperative EF after BNSRRP. Although previous trials have indeed studied the association between patient satisfaction and degree of EF [27,28], only few focused on patients treated for PCa [16,24,25]. Recently, Nelson et al. found a significant increase in sexual bother after surgery in patients treated with RP [25]. Interestingly, a direct association between levels of sexual bother after RP and the degree in EF change between the preoperative and postoperative period was reported. However, change in patient satisfaction according different IIEF-EF domain score was not reported. Quantifying patient satisfaction according to postoperative EF is key for patient assessment and counseling as well as for the standardization of EF recovery defini-

tion after surgery. The issue of which IIEF-EF cut-off represents the optimal definition of EF recovery has been also debated during the last International Consensus of Sexual Medicine [29]. The Committee on Erectile Function Rehabilitation on the Radical Prostatectomy Patient recommended the use of a cut-off of 26 to define postoperative normal EF (grade A recommendation). However, a cut-off of 22 as a definition of EF recovery was also discussed. The lack on clear data on patient satisfaction has brought to the conclusion on the need on further studies to address the validity of such a cut-off in clinical practice. This issue was addressed in our study where we demonstrated that a cut-off of 22 can be safely used for the definition of complete EF recovery in preoperatively fully potent patients undergoing BNSRP. Our results seem to support the methodological approach of a previous prospective randomized trial where a cut-off of 22 was used to define postoperative EF recovery in fully potent men prior to BNSRP [19]. Such approach was based on the clinical assumption that a virtually equal satisfaction could be expected for patients with mild ED and those with no ED after surgery. However, no clear data supporting such approach was available at the time of this trial.

Second, we included in this study only preoperatively fully potent patients (IIEF-EF ≥ 26) in order to exclude the potential effect of a preexisting sexual dysfunction already before surgery. As a matter of fact, no difference in the preoperative satisfaction (IIEF-OS and IIEF-IS) was evident in the preoperative period among the three groups of patients (all $P \geq 0.4$). Finally, our results are strengthened by the standardized prospective protocol of patient assessment.

Despite several strengths, our study is not devoid of limitations. First, all patients were preoperatively fully potent and were treated at a major tertiary academic center. Results obtained in high-volume centers might differ from those derived from other clinical settings, where patient selection might be less rigorous. Moreover, no patient with partial or poor response to PDE5-I has been switched to intracavernosal injection (ICI) during the study period. This might not replicate the everyday clinical practice where patients are often managed with ICI immediately after PDE5-I failure. Second, a bias in EF assessment might have been introduced. Indeed, all patients were asked to fill out the IIEF at the time of hospital admission, well after the diagnosis of PCa. The timing of questionnaire administration might underestimate

preoperative EF due to potential changes in sexual life related to psychogenic issues after PCa diagnosis. Third, despite extensive patient counseling, not all men received treatment for ED. Therefore, our study is limited by the lack of a standardized protocol for the treatment of postoperative ED. However, the aim of our study was not to address the impact of a given pharmacological approach on EF after surgery. Our aim was instead to evaluate the degree of patient satisfaction when either unassisted or medically assisted EF recovery (defined using different IIEF-EF domain score cut-offs) was achieved. Finally, despite previous studies have reported a significant association between EF and patient satisfaction [27,30], it is possible that other outcomes not considered in this study (i.e., improvement in couple relationship and in ED-related distress, bother, and anxiety) might represent more accurate end points to be associated with EF recovery after surgery.

Despite these limitations, our study represents the first attempt to define the best IIEF-EF cut-off score to define EF recovery in a large population of preoperatively fully potent patients treated with BNSRP.

Conclusions

This is the first analysis investigating patient satisfaction according to different postoperative IIEF-EF domain score cut-offs in preoperatively fully potent patients treated with BNSRP. We demonstrated a lower satisfaction when an IIEF-EF cut-off of 17 is used as compared to 22 or 26. Conversely, no difference was found using a cut-off of either 22 or 26. Therefore, our results support that an IIEF-EF domain score ≥ 22 might represent a reliable cut-off for the definition of EF recovery after BNSRP in preoperatively fully potent patients. However, this data need to be confirmed in an external validation setting.

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Conflict of Interest: None.

Statement of Authorship

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