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# Back to Baseline: Erectile Function Recovery after Radical Prostatectomy from the Patients' Perspective

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## Abstract

**Introduction—**A variety of erectile function recovery (EFR) rates are reported post radical prostatectomy (RP), with some suggesting EFR rates over 90% [1]. Clinical experience suggests that patients view EFR as getting back to their baseline (BTB) erectile functioning (EF) without the use of medication.

**Aim—**This study explores EFR defined as BTB.

**Method—**Men pre-RP and 24 months post-RP completed the Erectile Function Domain (EFD) of the International Index of Erectile Function and one question on phosphodiesterase type 5 inhibitor (PDE5i) use. Men using a PDE5i at baseline were excluded.

**Main Outcome Measures—**At 24 m, "back to baseline" was defined as achieving the baseline EFD score (within 1 point or higher). Analyses included descriptive statistics, chi-square, and logistic regression.

**Results—**One hundred eighty men had an average age at RP of 59 (SD = 7) years. When including men who were using a PDE5i at 24 months, 43% (N = 78, 95% CI: 36–51%) returned BTB. When considering BTB without the use of a PDE5i, 22% (N = 39, 95% CI: 16% to 28%) returned BTB. When focusing on a subset of men with baseline EFD ≥ 24 (N = 132), 36% (N = 47, 95% CI: 28% to 44%) returned BTB at 24 months using a PDE5i and 16% (N = 21, 95% CI: 11% to 23%) without the use of aPDE5i. For this group, there was a significant difference by age (<60 years, 23% vs. ≥60 years, 4%, $P < 0.001$), which remained a significant predictor (OR = 6.25, 95% CI: 1.88 to 50, $P < 0.001$) in multivariable analysis.

**Conclusions—**Twenty-two percent of the entire sample and 16% of the men with functional (EFD ≥ 24) baseline erections returned to BTB EF without the use of medication. Only 4% of men who were ≥60 years old with functional erections pre-surgery achieved BTB EF. Although gaining

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partial EF is also important, men pre-RP should be educated on EFR and the chance of “back to baseline” EF.

**Keywords**

Prostate Cancer; Erectile Dysfunction; Sexual Function; Pre-operative Erectile Function

## Introduction

Prostate cancer is the most common type of cancer in men in the United States, with over 240,000 men expected to be diagnosed in 2012 [2]. Currently, 90% of men are diagnosed with early-stage disease and have excellent relative 5, 10, and 15-year survival rates of 99%, 95%, and 82%, respectively [2]. Over the past 20 years, prostate-specific antigen screening has resulted in an increasing number of men diagnosed with prostate cancer, who are younger and healthier than previous trends [3,4]. Radical prostatectomy (RP) is a gold standard treatment for early-stage prostate cancer with proven long-term benefit [5,6]. With the trend toward younger age of diagnosis, these younger men are choosing RP as the primary treatment modality, which has resulted in a three- to fourfold increase among men 45–59 years old, and a two to threefold increase in men 60 to 69 years old selecting RP [4].

With excellent cancer control, a primary focus for men following RP is the potential side effects associated with surgery. Erectile dysfunction (ED) is a common side effect of the surgery, and given the trend toward younger age at diagnosis and treatment with excellent survival rates, erectile function recovery (EFR) is a primary focus after RP for many men [7]. However, the literature reports a wide variation in EFR rate following RP. In a recent meta-analysis of EFR rates after RP by Tal et al., the reported EFR rates in the literature ranged from 25% to 78%, which is too wide a range to offer effective counseling to patients [7]. This wide range was found despite the fact that these authors used stringent selection criteria that identified the highest-quality studies in this area.

A primary reason for these wide rates is the multiple methodological variations in this literature [8]. These studies vary in a number of important considerations which include: degree to which patient selection was used, time of assessment post-RP, type of assessment of EF (validated instrument or physician assessment), lack of data on use of erectogenic medication, and the definition of EFR [8]. When focusing on defining EFR, the literature does not outline a clear and common definition. For example, the Tal et al. metaanalysis reviewed 22 studies in this area, and each study had a unique definition of EFR. In general, the studies have defined EFR as the ability to have intercourse at least a “few times,” “sometimes,” or “occasionally” [7]. From a surgeon’s perspective, this is a functional and practical definition that is easily assessed. However, patients may be able to occasionally have intercourse yet still report considerable loss of erection capacity in both rigidity and consistency.

This is an important concern for patients. The loss of erectile ability for those post-RP who can still achieve erections adequate for penetration has been associated with reduced sexual satisfaction and increased sexual bother (which includes reduced “general happiness in life”)

[9–11]. In addition, difficulty with erectile function is associated with increased depressive symptoms in men both with and without a history of prostate cancer treatments [12,13].

## Aim

When a surgeon states that a patient's EFR rate is in the range of 70–90%, it can be argued that the patient's understanding of this rate is that he will get back to his baseline erectile functioning (EF) without the use of an erectogenic medication if he was not using any of these medications prior to surgery. This argument is supported by the literature which suggests that patients' expectations are often not met following surgery [14], and that a percentage of men report regret related to their treatment choice [15]. Thus, this study focused on the percentage of men who are able to achieve back to their baseline (BTB) EF at 24 months post-RP. In two recent reviews of the literature, which assess quality studies in this area, no studies use BTB as their definition of recovery after RP [7,8]. As such this analysis will add a unique and important contribution to the literature. We hypothesize that the BTB results will be considerably lower than the EFR rates currently reported in the literature.

## Methods

### Patient Population

The data used in this analysis were collected as part of a larger quality of life study conducted in early-stage prostate cancer patients at our institution. The study was approved by the Institutional Review Board, complied with the ICH Good Clinical Practice Guidelines founded on the Declaration of Helsinki, and subjects provided informed consent. All subjects who were undergoing an RP (laparoscopic and open) and spoke English were eligible for the study and were consecutively recruited in prostate urology clinics. The subjects completed the Prostate-Health Related Quality-of-Life Questionnaire (PHR-QOLQ) [16,17] presurgery (study baseline) and then every 3 months for 2 years following surgery. This analysis will use data from the baseline and 24-month assessments. In addition, this analysis will exclude all subjects who underwent radiation or adjuvant hormone therapy after RP, and those men who were using a phosphodiesterase type 5 inhibitor (PDE5i) at baseline.

### Outcome Measures

The PHR-QOLQ is a psychometrically validated, patient self-report questionnaire which contains 63 disease-specific items that measure 11 domains: urinary, sexual, and bowel functions; associated bother and role limitation domains; and cancer worry, treatment satisfaction, and regret [16,17]. The PHR-QOLQ utilizes the Erectile Function Domain (EFD; maximum score 30) of the International Index of Erectile Function (IIEF) [18] to assess erectile function, and the EFD will be the focus of this analysis. The PHR-QOLQ also assesses the use of PDE5i at each time point with the following response regarding PDE5i use: "Never," "Sometimes," "Regularly".

In addition, demographic variables, a nervesparing score (NSS), and vascular risk factors (VRFs) were assessed for each patient. The NSS was graded intraoperatively by the surgeon,

using a four-point NSS assigned to each nerve where: 1 = fully preserved, 2 = partially preserved, 3 = minimally preserved, and 4 = resected. For this analysis, nerve-sparing surgery was defined as a score of 1 or 2 for both nerves. Unilateral resection was defined as a score of 3 or 4 for one nerve, and bilateral resection was defined as a 3 or 4 for both nerves. The VRFs assessed included: hypertension, hypercholesterolemia, diabetes mellitus, coronary artery disease, and cigarette smoking.

The primary outcome variable was the patient's ability to get back to his baseline erectile function at 24 months (i.e., BTB). BTB was defined as change from baseline to 24-month EFD score. As an example, in order to account for potential measurement error of ± 1 point on the EFD, a patient who had a presurgery EFD score of 26 was defined as achieving BTB if his 24-month EFD score was 25 or higher. The measurement error of ±1 was selected because the standard error of measurement for the change scores of the EFD in the original validation of the IIEF ranged from 0.8 to 1.2 [18].

### Statistical Analysis

Descriptive statistics were used to report the demographic variables and percent of patients achieving BTB. Logistic regression was used for multivariable analysis identifying predictors of BTB. In the subgroup analyses, chi-square was used to test significance, and Fisher's exact test was used when frequency in a cell fell below five. All significance testing used a *P* value of <0.05 to define significance. This is a secondary analysis of data from a quality of life study and the sample size was determined for the original study. As such, no formal power analysis was conducted for this current analysis nor were there any type of stratification procedures used to balance the number of variables for any specific subgroup.

## Results

### Patient Population

A sample size of 180 was used for this analysis. A total of 250 men completed the assessments at the two time points used in the larger QOL study (baseline and 24 months). Of these men, 70 were taking a PDE5i "sometimes" or "regularly" preoperatively and were eliminated from the analysis, leaving the final sample size of 180 subjects. The mean age was 59 (SD = 7) years. The mean EFD score at baseline was 24.3 (SD = 8.7), and declined significantly at the 24-month time point (17.4, SD = 9.8, *P*< 0.001). At baseline, 73% had an EFD score of ≥24 and this also was significantly reduced at 24 months (37%, *P* < 0.00l). The majority of the sample (82%) had nerve-sparing surgery. Of the 18% who had non-nerve sparing surgery, 12% had one nerve resected and 6% had two nerves resected. VRFs were relatively common, with 34% reporting one VRF, 18% reporting two VRFs, and 7% reporting three VREs (Table 1). A total of five surgeons contributed patients to this analysis, and the number of patients for each surgeon was: 68, 60, 44, 7, and 1. At the time of data collection, all of these surgeons operated at a well-respected academic cancer center. The first four surgeons were "high volume" surgeons (i.e., greatly exceeding more than 200 total RPs and more than 50 RPs per year). The last surgeon (one case), although an experienced surgeon, did not regularly perform RPs.

Another important subgroup for this analysis were those men reporting “functional” erections at baseline, for the purposes of this analysis defined as scoring ≥24 on the EFD at baseline (i.e., a score of 4 per question on the EFD, representing a “most of the time” response). Although a score of ≥26 is considered the cut-off for no ED, this cut-off was thought to be too restrictive for this analysis. Instead, a face valid cut-off was used for men with functional erections and included men who indicated an average response of “most of the time” on the EFD. There were 132 men in this subgroup, representing 73% of the entire study cohort. The mean age of these men was 58 (SD = 7) years. The mean EFD score at baseline was 29.2 (SD = 1.5), and decreased significantly at the 24-month time point (20.4, SD = 9.4 $P< 0.001$). At 24 months, 48% had an EFD ≥ 24,. The majority of this group (88%) had nerve-sparing surgery. Of the 12% who had onnerve-sparing surgery, l0% had one nerve resected and 2 % had two nerves resected. VRFs were also relatively common in this subgroup with 34% reporting one VRF, 19% reporting two VRFs, and 6% reporting three VRF’s (Table 1).

BTB EF at 24 months will be reported for two groups: (i) the total sample and (ii) a subgroup of men reporting functional erections (EFD ≥ 24) at baseline. For each group, two percentages will be reported representing BTB at 24 months. The first percentage will include men who achieved BTB EF either with or without the use of a PDE5i. The second percentage will be confined to only those men who were able to achieve BTB EF without the use of a PDE5i.

### Bock to Baseline (Total Sample)

When considering the total sample (N=180), 43% (N = 78, 95% CI: 36% to 51%) of these men returned BTB with or without the use of a PDE5i, and when considering only those men who returned BTB without taking a PDE5i at 24 months, the percentage was 22% (N = 39, 95% CI: 16% to 28%) (Table 2).

The following variables were used to predict the 22% of men who were able to achieve BTB erections without the use of medication: Baseline EFD scores (<24 vs. ≥24), age (<60 years vs. ≥60 years), nerve-sparing status (no resection vs. any resection), and VRF (0 VRF vs. ≥1 VRF). Of these variables, baseline EFD (odds ratio [OR] = 0.21, 95% CI: 0.08 to 0.52, $P$ = 0.001) was the only significant predictor. The value of the ORs indicates that those with non-functional erections (EFD < 24) presurgery were more likely to achieve BTB erections. This is most likely because men who have low EFD scores at baseline (e.g., EFD = 8) are likely to achieve BTB only because their baseline erectile function was so poor. Age, NSS, and number of VRFs were not significant predictors of BTB in this model. As baseline EFD was a significant predictor of men achieving BTB EF, an important focus (below) was on men with only functional erections at baseline.

### Bock to Baseline (Men with Baseline EFD ≥ 24)

Of the 132 men who had full erections (EFD ≥ 24) at baseline, 36% (N = 47, 95% CI: 28% to 44%) achieved BTB erections with or without the use of a PDE5i and only 16% (N = 21, 95% CI: 11% to 23%) of the sample achieved BTB EF without the use of a PDE5i at 24 months (Table 2).

When examining differences on important baseline variables for those who could achieve BTB EF with or without the use of a PDE5i, there were differences related to age (<60 years, 48% vs. ≥60 years, 16%, $P < 0.001$). The percent who reached BTB EF as a function of NSS was: nerves spared, 35%; one nerve resected, 21%; both nerves resected, 0%. The comparison of the percent who had their nerves spared vs. those who had either one or both nerves resected did not reach significance (35% vs. 21%, $P = 0.16$). There were also differences in the percentage of patients who achieved BTB EF by VRF (0 VRF, 44% vs. ≥1 VRF, 30%, P = 0.08, Table 3), which demonstrated a trend toward significance.

When considering those able to retain BTB EF without the use of a PDE5i, there were also differences by age (<60, 23% vs. ≥60 years, 4%, $P = 0.003$). The percent who reached BTB EF as a function of NSS was: nerves spared, 16%, one nerve resected, 7%, both nerves resected, 0%. The comparison of the percent who had their nerves spared vs. those who had either one or both nerves resected did not reach significance (16% vs. 7%, $P = 0.2$). There were also differences in the percentage of patients who achieved BTB EF by VRF (0 VRF, 22% vs. ≥1 VRF, 12%, $P = 0.10$, Table 3), which demonstrated a trend toward significance.

In a multivariable model, the following variables were used to predict the 16% of men who returned BTB without the use of a PDE5i: age (<60 years vs. ≥60 years), NSS (no resection vs. any resection), and VRF (0 VRF vs. ≥1 VRF). The results are displayed in Table 4. The only significant variable in this analysis was age (OR = 6.68, 95% CI: 2.10 to 21.29, $P = 0.001$), indicating that those who were under 60 years old were more likely to achieve BTB erections. Nerve-sparing status was not a significant predictor in the analysis. This may be due to the low number of men who had nerves resected, leaving the analysis with low power.

## Discussion

This study presents data using the criteria of EFR after RP as a patient returning to his baseline EF. Men who were using a PDE5i presurgery were excluded from this analysis. When considering the total sample (without criteria for functional erections at baseline), 22% of men returned to their baseline EF without the use of a PDE5i at 24 months postsurgery. When considering only those men who reported good erections at baseline (EFD ≥ 24), the percentage of men who report BTB EF at 24 months without the use of PDE5i dropped to 16%. For these men (baseline EFD ≥ 24), age was an important predictor, with men younger than 60 years old more likely to report BTB EF (23%) compared with men ≥:60 years of age, where the percentage was only 4%. Nerve-sparing status also impacted the ability to achieve BTB EF. For those men who had nerve-sparing surgery, 16% achieved BTB EF without a PDE5i, and for those who had unilateral nerve-sparing surgery, 7% achieved BTB EF without a PDE5i For those who had bilateral resection of their nerves at surgery, none achieved BTB EF, with or without a PDE5i. It is important to note that the aging process may have an impact on these percentages with a possible decline in EF over a 2-year period however it is not likely a significant decline would occur over only a two year period.

When comparing the rates of EFR in this analysis to rates previously reported in the literature, it is not surprising that the rates reported here are lower than what is typically published. In the aforementioned Tal et al. meta-analysis, the authors identified 22 manuscripts that met important inclusion criteria and were selected as the highest full publications that reported EFR rates following RP. In this meta-analysis, they found that the overall EFR was 58%. The rates of EFR differed on a number of variables including single center vs. multicenter report (60% vs. 33%), and patient age, <60 years old vs. ≥60 years old (77% vs. 61%) [7]. The rates reported in our analysis are clearly and appreciably lower than these rates. The difference lies, of course, in the definition of EFR. In the manuscripts included in the Tal et al. [7] meta-analysis, although there was not a uniform definition of EFR, they generally considered EFR as the ability to maintain an erection hard enough for penetration about 50% of the time (i.e., “few times,” “sometimes,” or “occasionally”). Although regaining some erectile function capacity can be important and meaningful for patients, our clinical experience suggests that men who had good erections prior to surgery view themselves as having significant “problems” with erections following surgery if they only achieve penetration hardness about half the time. The results in the literature that most closely mirror the figures reported in this analysis are those reported by Schover et al. [19] and support our clinical observations. Schover and colleagues assessed over 1,200 early-stage prostate cancer patients who were, on average, 4.2 years posttreatment. In this analysis, 85% of the men reported having “problems” with their erections [19]. Our results, in combination with the data reported by Schover et al. [19], suggest that surgeons should clearly explain their definition of “recovery” to their patients and possibly provide a spectrum of figures which range from the likelihood of patients achieving their baseline erections to the percent of patients who “sometimes” have erections hard enough for penetration.

Proper expectations for men following surgery are important as problems with erections and can have negative psychological and relationship implications for men. Men who frequently fail to achieve erections hard enough for penetration tend to lose confidence in their ability to perform sexually, become frustrated and distressed, and avoid sexual situations. To illustrate, as described by men in recent focus groups, patients reported fear, anxiety, and a tendency to give up when asked about entering into a sexual situation when they were not fully confident in their erections [20]. There is also consistent evidence that hardness of erections is associated with sexual satisfaction and psychosexual variables [9,13]. Additionally, in a recent report by Nelson et al., sexual bother remained elevated in men following RP, even for those men who were able to achieve functional erections (EFD ≥ 24) [10]. Nelson and colleagues also demonstrated that EF was an independent predictor of depressive symptoms in men following prostate cancer treatment [13], and this is supported by the consistent findings that EF is associated with depressive symptoms for nonprostate cancer patients [12].

Our clinical experience suggests that when most patients hear, “You will recover,” they believe that they will be back to where they were prior to surgery. This is again supported by recent focus groups of men (who were at least 1 year postprostatectomy) who reported that their expectations prior to surgery were that their erections would eventually achieve the same full as before surgery [20]. It is unclear if surgeons do not provide proper expectations

for patients, or if the surgeons do provide the proper information, but patients cannot digest the information because they are focusing on treatment and eliminating their cancer. Despite the reason, distress may be higher for patients who are not given realistic expectations [14]. In a survey of 400 patients post-RP, Schroeck et al. reported that patients who underwent a robotic prostatectomy were more dissatisfied and had higher regret compared with men who underwent an open procedure. The authors suggest that this is most likely due to unrealistic expectations for recovery after a robotic surgery [14].

Of significance, in our data only 4% of men who are 60 years old or older with functional erections prior to surgery will "recover" BTB EF without the use of a PDE5i. In this age group, only 16% of men achieved BTB EF with or without PDE5i, so the hope of getting back to baseline erections with a PDE5i also seems to be poor. Although there has been a shift toward a greater percentage of younger men receiving a diagnosis of prostate cancer, and the average age of this sample was under 60 years (i.e., mean age of men with functional erections prior to surgery was 58 years), prostate cancer continues to impact a large number of older men. The American Cancer Society estimates that 62% of men diagnosed with prostate cancer are over the age of 65, and 39% of our sample was 60 years old or older. Thus, there is a high percentage of men opting for surgery who are over the age of 60 years. We believe it is important to communicate realistic expectations to these men.

We believe this analysis has a number of strengths. First, we believe it is the first quality report that rigorously assesses BTB data. The study used a well-validated and widely used assessment of EF, and assessed EF prior to surgery and 24 months postsurgery. The data on erectogenic medication is also unique and an aspect we consider to be an important strength of the data. Despite these strengths, there are some limitations to this study. First, the data do not include rates from robotic RP. Initial reports on the ERF rates of robotic surgery were higher than open or laparoscopic RPs. However, this initial data have been widely criticized and suffers from serious methodological limitations [20,21]. More recent and methodologically sound data indicate that erectile function may actually be worse after robotic prostatectomy as compared with open prostatectomy [22,23]. Another limitation in the data is the low number of men who had nonnerve-sparing surgery, which may explain the nonsignificant results for the nerve-sparing surgery in the multivariable models. Third, the PHR-QOLQ only assessed if patients were taking a PDE5i, and did not assess other types of erectile aids (intracavernous injections, vacuum devices). This allowed for the inclusion of patients who were using these other types of aids prior to surgery. Lastly, this study did not include a control group to compare these results against the natural aging process over 2 years. It is reasonable to assume that there would be some men who would not get BTB EF due to age or other medical factors.

## Conclusion

Studies generally considered EFR as the ability to maintain an erection hard enough for penetration about 50% of the time (i.e., "few times," "sometimes," or "occasionally"). Although regaining some erectile function capacity can be important and meaningful for patients, when a surgeon tells a patient he will recover erections following a radical prostatectomy, it can be argued the patient assumes he will get back to the EF he had prior to

surgery. However, no quality studies have used “back to baseline” erections as the definition of “recovery of erections.” In the data presented in this manuscript, using back to baseline erections as the definition of recovery and excluding men using a PDE5i presurgery, only 22% of the entire sample and 16% of the men with functional erections presurgery returned to their baseline EF without the use of medication. Of note, only 4% of men who were ≥60 years of age with functional erections presurgery achieved their baseline EF without the use of medication. These data suggest that men who are considering undergoing an RP should be educated on the meaning of erectile function recovery.

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## Table 1

Patient characteristics

| | Total sample | Baseline EFD ≥ 24 |
|---|---|---|
| N | 180 | 132 |
| Mean age (years) | 59 (SD = 7) | 58 (SD = 7) |
| EFD Mean | | |
| Presurgery | 24.3 (SD = 8.7) | 29.2 (SD = 1.5) |
| 24 months postsurgery | 17.5 (SD = 9.8) | 20.4 (SD = 9.4) |
| EFD ≥ 24 | | |
| Presurgery (%) | 73 | 100 |
| 24 months postsurgery (%) | 37 | 48 |
| Nerves resected | | |
| Unilateral (%) | 12 | 10 |
| Bilateral (%) | 6 | 2 |
| Vascular risk factors | | |
| 1 (%) | 34 | 34 |
| 2 (%) | 18 | 19 |
| 3 (%) | 7 | 6 |

EFD = erectile function domain

**Table 2**

Percent achieving back to baseline erectile function recovery

| | | With/without PDE5i at 24 months | 95% CI | Not using PDE5i at 24 months | 95% CI |
|---|---|---|---|---|---|
| Total sample | N = 180 | 43% | 36–51% | 22% | 16–24% |
| Baseline EFD ≥ 24 | N = 132 | 36% | 28–44% | 16% | 11–23% |

EFD = Erectile Function Domain; PDE5i = phosphodiesterase type 5 inhibitor

## Table 3

Back to baseline figures for men with functional erections at baseline (Erectile Function Domain ≥ 24)

| Variable | With/Without PDE5i at 24 months (%) | *P* | Not Using PDE5i at 24 months (%) | *P* |
|---|---|---|---|---|
| Age | | | | |
| <60(N = 81) | 48 | | 23 | |
| ≥60(N = 51) | 16 | *P*< 0.001 | 4 | *P*< 0.001 |
| Nerve-sparing status* | | | | |
| Nerves spared (N = 100) | 35 | | 16 | |
| Unilateral resection (14)† | 21 | *P* = 0.16 | 7 | *P*=0.20 |
| Bilateral resection (N = 3)‡ | 0 | | 0 | |
| Vascular risk factor | | | | |
| No VRF (N = 54) | 44 | | 22 | |
| ≥1 VRF (N = 78) | 30 | *P* = 0.08 | 12 | *P* = 0.10 |

Note:

*Fifteen subjects in this group did not have nerve-sparing status recorded.

†Nine men were ≥60, 1 BTB with PDE5i.

‡Two men were ≥60.

BTB = back to their baseline; PDE5i = phosphodiesterase type 5 inhibitor; VRF = vascular risk factor

## Table 4

Logistic regression for men with functional erections at baseline: Predicting back to baseline erectile function recovery at 24 months

| Variable | OR | 95% CI | *P* |
|---|---|---|---|
| Age: <60 years vs. ≥60 years | 6.68 | 2.10–21.29 | 0.001 |
| NSS: No resection vs. Any resection | 1.45 | 0.35–6.05 | 0.6 |
| VRF: 0 VRF vs. ≥1 VRF | 1.28 | 0.55–3.00 | 0.6 |

*Note:* Total sample size for this analysis was 117; 15 subjects were missing nerve-sparing status data.

NSS = nerve-sparing score; VRF = vascular risk factor