

Long-term function and oncologic outcomes following nerve-spare or wide resection during radical prostatectomy

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ABSTRACT

Introduction: Nerve-sparing during radical prostatectomy (RP) is associated with improved postoperative erectile function and urinary continence but may increase risk of positive surgical margins. This study sought to compare the long-term outcomes of patients treated with nerve-spare (NS) compared to wide resection (WR).

Methods: A historical cohort of consecutive patients was reviewed. A standardized surgical approach of lobe-specific NS or WR was performed. The primary outcome was treatment failure, defined as prostate-specific antigen (PSA) recurrence (PSA \geq 0.2 ng/mL) or receipt of postoperative radiation. Secondary outcomes included time to metastases, urinary continence, and erectile function.

KEY MESSAGES

- Oncologic and functional long-term outcomes of consecutive cohort of patients undergoing radical prostatectomy by a single surgeon were assessed in this study.
- Patients treated with nerve-sparing prostatectomy experienced more treatment failures compared to wide-resection prostatectomy.
- Patients treated with nerve-sparing prostatectomy experience better postoperative sexual function and earlier recovery of continence, though rate of continence is not statistically different than patients treated with wide-resection prostatectomy in long-term followup.
- These data can allow better counseling of patients preoperatively to incorporate patient values and preferences into treatment decisions.

Results: Of 193 consecutive patients, 121 (62%) received bilateral NS, 37 (19%) received unilateral NS, and 35 (18%) bilateral WR. Patients undergoing any NS had lower preoperative PSA, tumor stage, and grade group compared to WR (all $p < 0.05$). Adjusting for these variables, risk of treatment failure was increased in patients who underwent NS compared to WR (hazard ratio [HR] 3.08, 95% confidence interval [CI] 1.43–6.66). Continence recovered more quickly after NS, but by 24 months post-RP, this difference was not significant (relative risk [RR] 1.05, 95% CI 0.95–1.15). Postoperative erectile function was better in patients receiving unilateral or bilateral NS (unilateral: 21%, bilateral: 59%, WR: 0%).

Conclusions: NS during RP was associated with higher risk of treatment failure, but better functional outcomes compared to WR. These results indicate that NS presents a tradeoff of outcomes that must be matched to individual patient's values and preferences.

INTRODUCTION

Radical prostatectomy (RP) requires a balance between complete cancer removal and preservation of patient quality of life. While it may seem intuitive that the decision to pursue nerve-sparing during RP should be based on cancer risk, baseline sexual function, and patient preference, the evidence for a direct association between periprostatic dissection technique and outcomes such as positive surgical margins are often counterintuitive.^{1–7}

In multiple systematic reviews of nerve spare approach and positive surgical margin risk, no randomized trials of nerve spare have been conducted.^{1–3} In observational studies, nerve spare was counterintuitively associated with decreased risk of positive surgical margins (pT2 pooled RR 0.92, 95% CI 0.75–1.13; pT3 pooled RR 0.83, 95% CI 0.71–0.96).¹ This surprising result may reflect a selection bias beyond pathologic stage (i.e. volume of cancer) or because non-nerve spare surgery was not necessarily an extrafascial wide dissection (i.e. variations of lateral/extrafascial dissection). In fact, risk of bias assessment for all included studies in these systematic reviews were high, where majority of studies did not report or correct for clinical T stage, biopsy Gleason score, and initial PSA.³ Furthermore, the definition of nerve sparing was heterogenous or poorly defined within studies. Similar shortcomings may have also skewed patient-impactful outcomes such as treatment failure (cancer recurrence, metastases, or need for salvage treatment). Based on published literature, nerve sparing prostatectomy is associated with similar rates of biochemical recurrence as non-nerve sparing surgery, and even reduced risk of metastatic disease and decreased need for additional treatments.^{1,3–5} However, patients undergoing non-nerve sparing surgery had more aggressive disease in these cohorts,^{4,5} and these conclusions have been based on unadjusted analyses and prone to confounding by indication.³

It is also possible that wide dissection during radical prostatectomy does not achieve the desired oncologic outcomes theorized. To address this issue, we previously performed a consecutive patient cohort study of patients with preplanned surgical dissection. In that study,

adjusting for grade, stage, and PSA, wide resection was associated with a reduction in lobe-specific positive surgical margins (adjusted RR 0.43, 95% CI 0.26-0.71; $p=0.001$).⁸ The purpose of this study was to assess long-term patient-important functional and oncologic outcomes.

METHODS

This historical cohort study reviewed consecutive patients by a single surgeon (RHB) between August 2010 and November 2014 at one tertiary care centre (The Ottawa Hospital, Ottawa, ON, Canada). The surgical margin outcomes of these data were published in the Canadian Urological Association Journal in 2015 with the promise to update long-term patient-important outcomes when follow-up was mature. Baseline patient factors and disease characteristics were collected from clinical notes, radiology reports, and pathology reports in the electronic medical record using standardized abstraction. All patients completed baseline functional assessment using the expanded prostate cancer index (EPIC, EPIC 24 or EPIC-CP). Institutional ethics review board approval was obtained.

Surgical technique

The study included consecutive patients with prostate cancer treated with bilateral nerve spare, unilateral nerve spare, or wide resection during RP. The surgical techniques for nerve spare and wide resection have been previously described.⁸ Wide resection involved resection posterior to Denonvillier's fascia and incision on to the perirectal fat lateral to the neurovascular bundles. Indication for dissection technique was determined based on pre-operative cancer risk, erectile function, and patient values/preferences.

Followup

Patients were assessed 3, 6, 12 and 24 months, then annually post-operatively until discharged from follow up (usually between 5 and 10 years if disease-free and functionally well).

Outcomes

The primary outcome of this study was treatment failure, which was a composite outcome of PSA recurrence or receipt of postoperative radiation therapy. PSA recurrence was defined as at least one PSA concentration ≥ 0.2 ng/mL. Post-operative radiation could be either adjuvant (PSA < 0.02 ng/mL at the time of radiation) or salvage (PSA ≥ 0.02 ng/mL at the time of radiation). PSA recurrence and postoperative radiation were also examined individually as secondary outcomes. Secondary outcomes also included occurrence of distant metastases, which was determined by review of radiographic imaging and verified by clinical progress and response to systemic treatment to confirm accurate designation of metastatic prostate cancer. Radiographic imaging was only performed in the presence of PSA recurrence. Continence was defined as no pad usage over 24 hours (0 on the EPIC urinary continence domain). Erectile function was defined as erections sufficient for penetration (3 on the EPIC erectile function domain), with or without the use of PDE-5 inhibitors.

Statistical analyses

Descriptive analyses were used to compare baseline patient and disease characteristics. Student's t-tests were used for comparison of continuous values and chi-squared was used for categorical variables. For all time-to-event outcomes, date of RP was considered time-zero. Kaplan Meier curves were generated, censoring at last follow-up or death. Associations between nerve dissection technique (i.e. nerve sparing [either bilateral or unilateral] compared with wide resection) and oncologic outcomes were adjusted for pre-operative PSA, grade group, and pathologic T-stage. For functional outcomes, univariable and multivariable analyses were performed using log binomial regression at each time point (3, 6, 12, and 24 months). Statistical analyses were performed using SAS 9.2 (SAS Institute Inc., Cary, NC).

RESULTS

The cohort consisted of 193 patients, of which 34 (18%) underwent wide resection and 158 (82%) received unilateral (36; 19%) or bilateral (121; 63%) nerve-sparing. Patient and disease characteristics are summarized in Table 1 and Supplement Table 1. Patients who received wide resection had higher risk disease compared with those who underwent nerve-sparing surgery, with higher preoperative PSA, pathologic tumour stage, grade group, cancer volume, and lymph node metastases (all $p < 0.05$).

Median follow-up was 10.6 years (interquartile range 9.7-11.6 years). No patients were lost to follow up during the study period, but some patients were censored if discharged to primary care physician without biochemical recurrence. Figures 1 and 2 demonstrate unadjusted Kaplan-Meier survival curves for treatment failure and metastases, stratified by pathologic T stage. Time to PSA recurrence and radiation are presented in Supplementary Figures 1 and 2. In general, without adjusting for prognostic factors, patients undergoing nerve-sparing procedures had worse biochemical recurrence-free survival, radiation-free survival, and metastases-free survival, however not all the associations were statistically significant.

When adjusted for pathologic T-stage, grade group, and pre-operative PSA, bilateral and unilateral nerve-sparing surgeries were associated with increased risk of treatment failure versus wide resection (RR 2.56, 95% CI 1.26-5.20; RR 2.32, 95% CI 1.10-4.93, respectively) (Table 2). These associations were also seen when assessing PSA recurrence and receipt of radiation independently. Nerve sparing procedures were associated with increased risk of biochemical recurrence compared with wide resection (bilateral NS RR 2.67, 95% CI 1.23-5.28; unilateral NS RR 1.57, 95% CI 1.13-5.84) (Table 2). Patients were more likely to receive adjuvant or salvage radiation therapy after bilateral and unilateral nerve spare compared to wide resection (RR 3.42, 95% CI 1.44-8.13; RR 3.23, 95% CI 1.38-7.54, respectively) (Table 2). Eighteen patients developed metastases during the study period (95.7% [95% CI 91.6-97.8] free from recurrence at 5 years; 91.1% [95% CI 85.9-94.4] free from recurrence at 10 years). Nerve spare patients had higher incidence of metastases compared to wide resection, but this was not statistically significant (RR 1.61, 95% CI 0.34-7.63; RR 3.83, 95% CI 0.79-18.5, respectively) (Table 2).

Patients who underwent nerve-sparing surgery, particularly bilateral nerve-sparing surgery, were more likely to be continent after surgery (Figure 3). This difference was more apparent closer to the time of surgery; by 24 months postoperatively, nerve spare patients had similar continence to those with wide resection. On multivariable analysis, no statistically significant differences in postoperative continence were observed between groups at 24 months postoperatively (bilateral NS: RR 1.10, 95%CI 0.95-1.30; unilateral NS: RR 1.01, 95%CI 0.82-1.24) (Figure 3).

At 12 months and 24 months post-RP, nerve-sparing procedures were associated with improved erectile function versus wide resection (associations not estimable; Figure 4). Patients who underwent bilateral nerve-sparing surgery had better erectile function postoperatively compared to unilateral nerve-sparing, with some improvement over time.

DISCUSSION

Radical prostatectomy can be performed using a wide resection or nerve sparing approach. Contrary to several previous publications, this study found that patients treated with wide resection were associated with fewer treatment failures, fewer biochemical recurrences, decreased need for adjuvant/salvage radiation, and lower risk of metastases compared to nerve-sparing approaches. Similar to previous publications, patients treated with wide resection experienced substantially worse post-operative sexual function and slightly worse urinary continence. Thus, these data highlight the careful considerations required when discussing and planning radical prostatectomy with patients.

Oncologic outcomes

Previous studies have reported nerve-sparing during RP did not increase the risk of positive surgical margins or biochemical recurrence compared with non-nerve sparing RP.^{1,3} However, important prognostic factors (e.g. biopsy grade group, clinical stage, and preoperative PSA) were lower in the nerve spare, compared to non-nerve spare groups.² In a large cohort of patients undergoing open radical prostatectomy, wide resection has been associated with higher risk of positive surgical margins and worse survival. However, with adjustment for clinical and pathologic variables, these differences are not statistically significant.⁹ Contemporary cohorts of high risk patients undergoing robotic prostatectomy also do not show an increased risk of biochemical recurrence, however no adjusted analyses were performed.^{5,10,11} This suggests that unadjusted confounding may partly explain the lack of association with outcomes reported in the literature.

In the current study, surgical approach was associated with clinically meaningful differences in biochemical recurrence and adjuvant/salvage radiation. Notably, patients undergoing wide resection had improved oncologic outcomes, even without adjusting for substantially higher baseline risk with higher preoperative PSA, tumour stage, and tumour grade. As more patients with higher risk disease are being offered, and are choosing surgical

intervention, these findings support the use of wide resection in appropriately selected, and informed, patients.¹²

Crude survival curves suggested worse oncologic outcomes in the unilateral nerve spare group in comparison to bilateral nerve spare, and wide resection groups, though this was not statistically significant. This finding may be due to chance, or may reflect the differences in patients between groups, where those undergoing bilateral nerve spare had more favorable pathology compared to those undergoing unilateral nerve spare and wide resection. Unilateral or intrafascial nerve spare may be requested by some patients with higher risk disease for the potential benefits of improved urinary continence and recovery of erectile function.

A challenge when comparing studies is that the extent of resection in non-nerve sparing surgery is not commonly described.¹ A small retrospective study detailing fascial dissection showed intra-fascial nerve spare is associated with shorter recurrence-free survival than other variations of lateral/extra-fascial dissections in pT2 tumors.¹³ Here, the results show a wide resection technique involving resection posterior to Denonvillier's fascia onto the perirectal fat lateral to the neurovascular bundles is associated with better oncologic outcomes compared with nerve-sparing prostatectomy.

Urinary continence

In wide resection prostatectomy, urinary continence is significantly worse in the early months of recovery, however continence improves with time. By 2 years following surgery, continence in wide resection patients approach that of the nerve spare patients (wide resection: 84%; unilateral NS: 85%; bilateral NS: 94%). A similar urinary continence recovery trend stratified by nerve-sparing procedures has been demonstrated in other studies.¹⁴ In a large cohort of men undergoing RP in a tertiary care center (38% non-nerve spare RP), patients undergoing non-nerve spare surgery were less likely to achieve early postoperative continence but by 17 months post-operative, 94% of the entire cohort were fully continent.¹⁵ Even in older longitudinal cohort studies, meta-analysis demonstrated nerve spare RP was associated with early (< 6 week post operative) urinary continence, but no differences were observed at 12 or 24 months from surgery.¹⁶

The mechanisms by which nerve sparing prostatectomy better preserve urinary continence are likely multifactorial. Closer dissection around the prostate likely allows for better preservation of the bladder neck and peri-urethral tissues. Urodynamic evaluation of patients following prostatectomy have shown better preservation of urethral closing pressures in patients who had nerve-sparing surgery compared to non-nerve sparing surgery.¹⁷

Erectile function

The major perceived benefit of nerve spare prostatectomy is postoperative erectile function. In this cohort 48% of patients undergoing unilateral or bilateral nerve spare surgery were potent following surgery, consistent with other published cohorts where good post-operative erectile function ranges from 32%-82%.^{9-11,18-20} As expected, bilateral nerve spare surgery has improved

outcomes at all time points compared with unilateral nerve sparing, (60% and 21% recovery of erectile function at 2 years, respectively). Intraoperative electrostimulation of the posterior prostate and medial aspect of the prostate pedicles elicits similar cavernosal pressures as the typical posterolateral neurovascular bundle, demonstrating a more complex periprostatic nerve network contributes to erectile function.²¹ It is possible that unilateral dissection posterior to Denonvillier's fascia results in the significant decrease in erectile function in unilateral wide resection patients compared to bilateral nerve spare patients. In addition to neurovascular bundle sparing, greater preservation of posterior tissues may further improve potency outcomes in patients for whom erectile function is a priority.

Strengths and limitations

This study has several strengths. Surgeries were performed by a single surgeon, allowing for a consistent surgical approach to wide resection and nerve spare. Additionally, nearly all patients in this center undergo prostate biopsy with dedicated radiologists at our center, allowing for standardization in biopsy technique and preoperative pathology findings. The use of a consecutive cohort of patients in all prostate cancer risk categories limits the risk of selection bias. Finally, the models created in this study adjust for important patient and disease factors.

The generalizability of this study is unknown as wide resection/non-nerve spare techniques may differ between surgeons and institutions. This cohort predominantly underwent robotic prostatectomy, therefore may not be applicable to smaller volume centers without access to robotic approaches. There were also no predetermined, defined criteria for which patients underwent nerve spare or wide resection which can introduce unknown confounders and limits reproducibility in other populations.

CONCLUSIONS

From this single-surgeon experience, nerve spare RP is associated with increased risk of PSA recurrence and adjuvant/salvage treatment compared to patients undergoing wide resection RP. However, nerve spare was also associated with earlier recovery of continence and better long-term erectile function. These results indicate that a nerve spare technique presents a trade-off of patient outcomes that must be matched to an individual patient's values and preferences.

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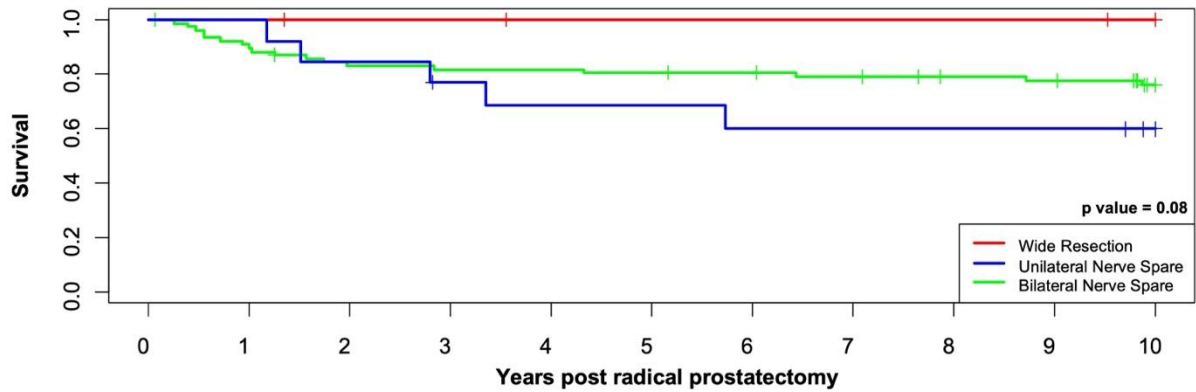
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FIGURES AND TABLES

Figure 1. Treatment failure-free survival (prostate-specific antigen and radiation-free) after radical prostatectomy, stratified by pathologic T-stage: A) pathologic stage T2; B) pathologic stage T3.

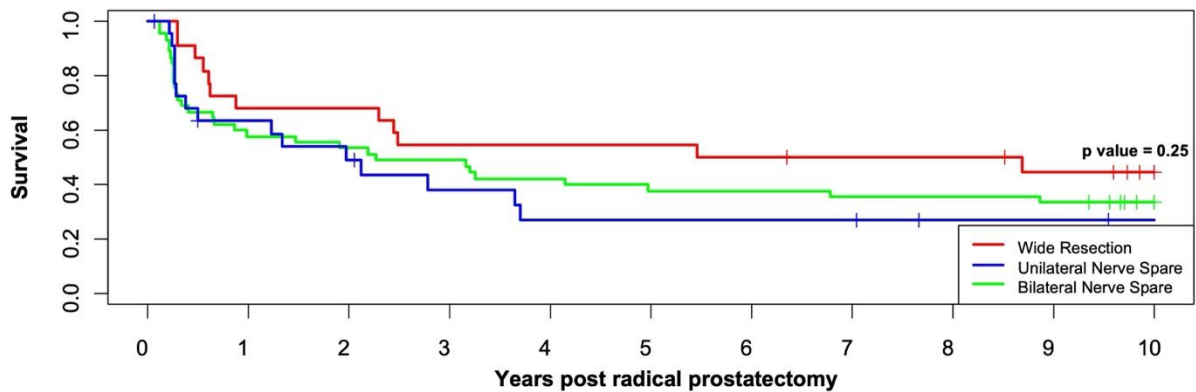
A) Pathologic stage T2



Number at risk

Full Nerve Resection	12	12	11	11	10	10	10	10	10	10	9
Unilateral Nerve Spare	13	13	11	9	8	8	7	7	7	7	5
Bilateral Nerve Spare	78	69	63	62	62	61	60	58	55	54	46

B) Pathologic stage T3

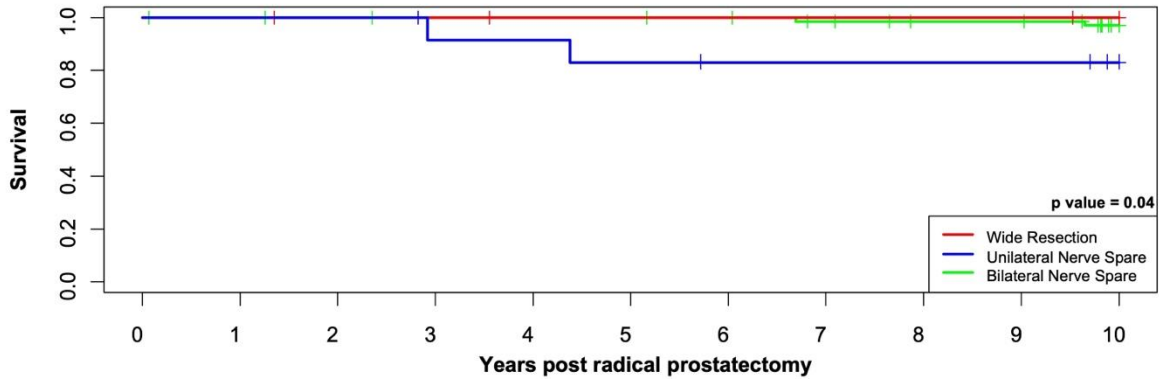


Number at risk

Full Nerve Resection	22	15	15	12	12	12	11	10	10	8	5
Unilateral Nerve Spare	23	13	10	7	5	5	5	5	3	3	2
Bilateral Nerve Spare	45	26	24	22	19	17	17	16	16	15	10

Figure 2. Metastases-free survival after radical prostatectomy, stratified by pathologic T-stage: A) pathologic stage T2; B) pathologic stage T3.

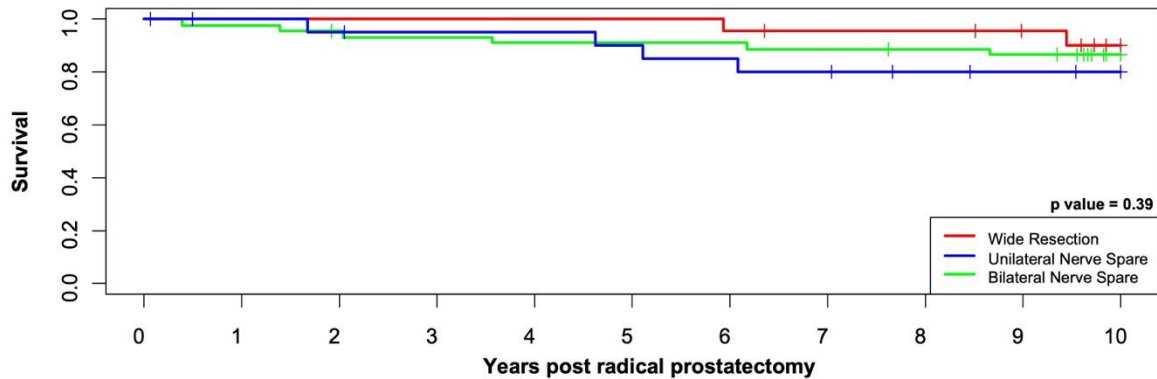
A) Pathologic stage T2



Number at risk

Full Nerve Resection	12	12	11	11	10	10	10	10	10	10	9
Unilateral Nerve Spare	13	13	13	11	11	10	9	9	9	9	7
Bilateral Nerve Spare	78	77	76	75	75	75	74	71	68	68	59

B) Pathologic stage T3



Number at risk

Full Nerve Resection	22	22	22	22	22	22	21	20	20	18	14
Unilateral Nerve Spare	23	21	20	19	19	18	17	16	14	13	12
Bilateral Nerve Spare	45	44	42	41	40	40	40	39	38	37	30



Figure 3. Recovery of urinary continence after radical prostatectomy.

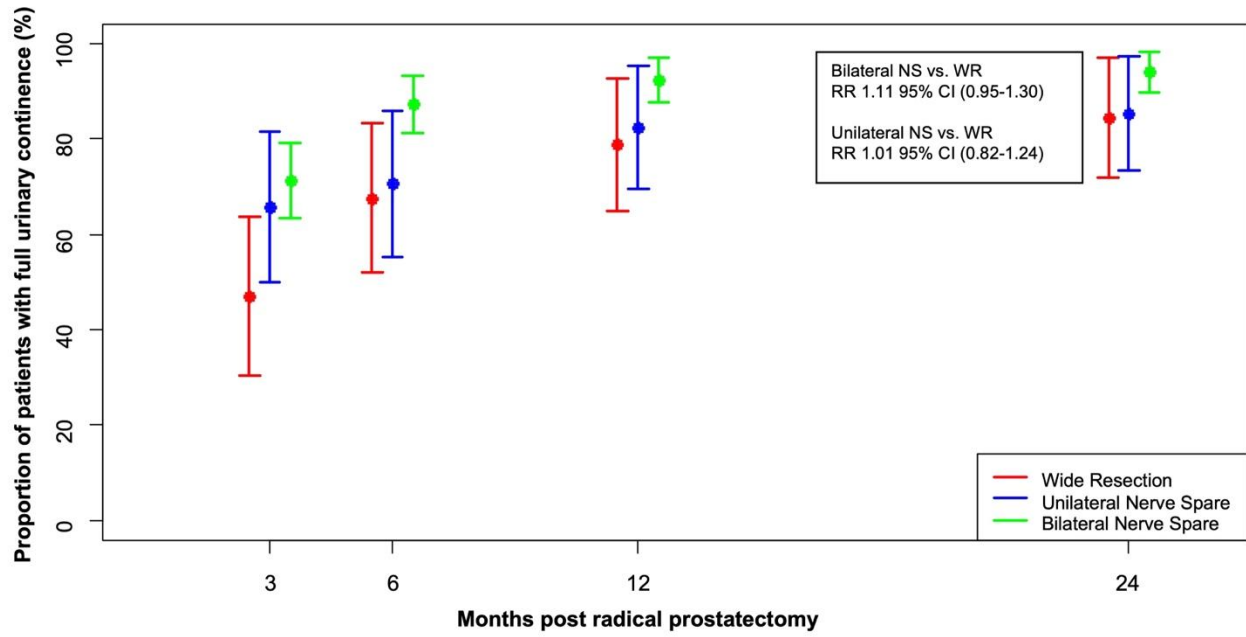
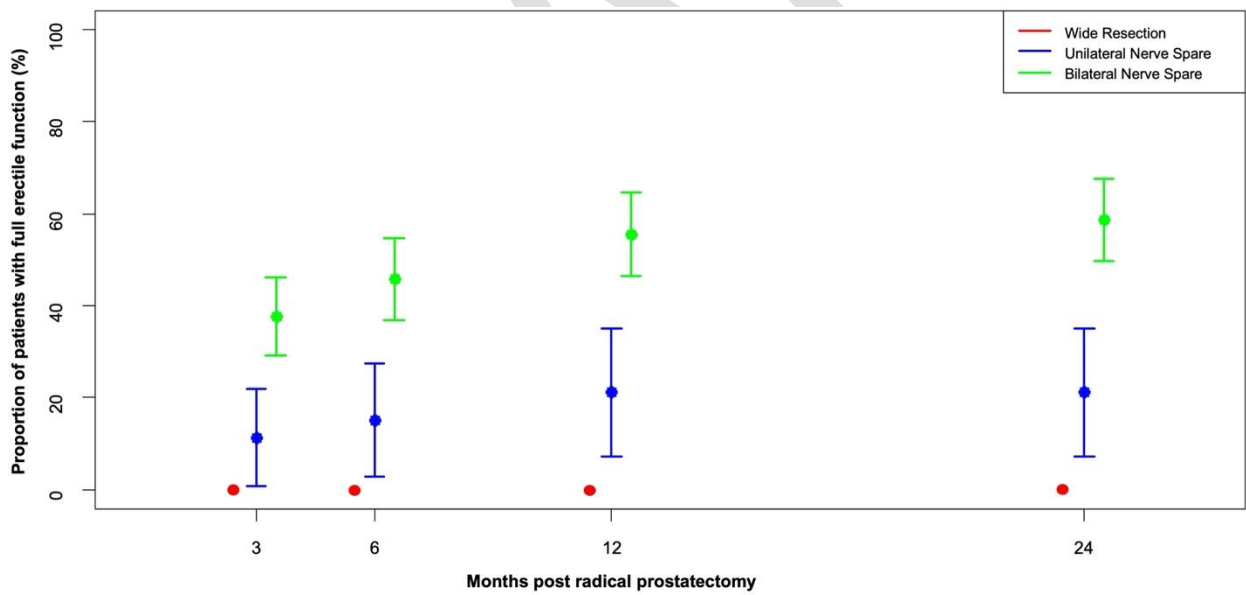


Figure 4. Recovery of erectile function after radical prostatectomy.



	Wide resection	Unilateral NS	Bilateral NS	p
Total, n (%)	34 (17.6)	36 (18.7)	123 (63.7)	
Age, mean \pm SD (yrs)	66.8 \pm 5.1	62.5 \pm 5.2	60.6 \pm 6.5	<0.0001
Preoperative PSA (μ g/L)	11.5 \pm 10.8	10.2 \pm 8.6	7.7 \pm 5.1	0.01
Preoperative erectile function, n (%)				<0.0001
EPIC = 0/1 (None at all)	12 (35.2)	1 (2.8)	5 (4.1)	
EPIC = 2 (Firm enough for masturbation only)	11 (32.4)	7 (19.4)	11 (8.9)	
EPIC = 3 (Firm enough for intercourse)	11 (32.4)	28 (77.8)	107 (87.0)	
Biopsy grade group, n (%)				<0.0001
1	2 (5.9)	2 (5.6)	41 (33.3)	
2	13 (38.2)	11 (30.6)	59 (48.0)	
3	5 (14.7)	11 (30.6)	15 (12.2)	
4	6 (17.7)	7 (19.4)	6 (4.9)	
5	8 (23.5)	5 (13.8)	2 (1.6)	
Clinical T-stage, n (%)				<0.0001
T1c	10 (29.4)	6 (16.7)	58 (47.2)	
T2	16 (47.1)	16 (44.4)	63 (51.2)	
T3	8 (23.5)	14 (38.9)	2 (1.6)	
Pathologic T-stage, n (%)				0.002
pT2	12 (35.3)	13 (36.1)	78 (63.4)	
pT3a	17 (50.0)	17 (47.2)	39 (31.7)	
pT3b	5 (14.7)	6 (16.7)	6 (4.9)	
Pathologic N-stage, n (%)	5 (14.7)	2 (5.6)	2 (1.6)	0.04
RP grade group, n (%)				<0.0001
1	1 (2.9)	0 (0)	12 (9.8)	
2	17 (50.0)	9 (25.0)	78 (63.4)	
3	6 (17.7)	22 (61.1)	28 (22.8)	
4	1 (2.9)	1 (2.8)	2 (1.6)	
5	9 (26.5)	4 (11.1)	3 (2.4)	
Cancer volume, mean \pm SD (cc)	8.2 \pm 9.8	7.1 \pm 5.8	4.7 \pm 4.8	0.006
Prostate volume, mean \pm SD (cc)	50.0 \pm 21.6	42.6 \pm 20.9	38.3 \pm 21.9	0.02

Surgical margin, n (%)				0.04
Negative	29 (85.3)	30 (83.3)	83 (67.5)	
Positive	5 (14.7)	6 (16.7)	40 (32.5)	
RP Modality, n (%)				0.03
Open	11 (32.4)	10 (27.8)	18 (14.6)	
Robotic	23 (67.6)	26 (72.2)	105 (85.4)	

NS: nerve spare; PSA: prostate specific antigen; RP: radical prostatectomy; SD: standard deviation.

Table 2. Oncologic outcomes after radical prostatectomy adjusted for pathologic tumor stage, Gleason grade group, and pre-operative PSA.

Comparison	Adjusted HR (95% CI)			
	Treatment failure ^a	PSA recurrence ^b	Radiation ^c	Metastases
Bilateral NS vs. WR	2.56 (1.26–5.20)*	2.67 (1.23–5.82)*	3.42 (1.44–8.13)*	1.61 (0.34–7.63)
Unilateral NS vs. WR	2.32 (1.10–4.93)*	2.57 (1.13–5.84)*	3.23 (1.38–7.54)*	3.83 (0.79–18.5)
Any NS vs. WR	2.46 (1.25–4.83)*	2.63 (1.25–5.54)*	3.32 (1.49–7.38)*	2.23 (0.51–9.85)

*p<0.05. ^aDefined as biochemical recurrence or receipt of adjuvant/salvage radiation. ^bAt least one PSA value \geq 0.2 ng/ml after prostatectomy. ^cReceipt of adjuvant or salvage radiation after prostatectomy. NS: nerve spare; PSA: prostate-specific antigen; WR: wide resection.