Title

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Journal

Journal of Urology, 207(1)

ISSN

0021-0005

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Publication Date

2022

DOI

10.1097/ju.0000000000002176

Peer reviewed

Published in final edited form as:

J Urol. 2022 January ; 207(1): 127–136. doi:10.1097/JU.0000000000002176.

Prospective Multicenter Comparison of Open and Robotic Radical Prostatectomy: The PROST-QA/RP2 Consortium

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Conflicts of Interest/Disclosures:
Peter Chang: none
Andrew Wagner: none
Meredith Regan: none
Joseph Smith: none
Christopher Saigal: none
Mark Litwin: none
Jim Hu: supported by “The Frederick J. and Theresa Dow Wallace Fund of the New York Community Trust”, PCORI CER-2019C1–15682, PCORI CER-2019C2–17372, and NCI RO1 CA241758.
Matthew Cooperberg: none
Peter Carroll: none
Eric Klein: none
Adam Kibel consults for Dendreon and Sanofi.
Gerald Andriole: none
Misop Han: none
Alan Partin: none
David Wood: none
Catrina Crociani: none
Thomas Greenfield: none
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Daniel Spratt: none
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Abstract

Purpose: To evaluate the comparative effectiveness of robot-assisted laparoscopic prostatectomy (RALP) and open radical prostatectomy (ORP) in a multicenter study.

Materials and Methods: We evaluated men with localized prostate cancer at eleven high-volume academic medical centers in the United States from the PROST-QA (2003–2006) and the PROST-QA/RP2 cohorts (2010–2013) with a pre-specified goal of comparing RALP (N = 549) and ORP (N = 545). We measured longitudinal patient-reported health related quality of life (HRQOL) at pre-treatment, 2, 6, 12, and 24 months, and pathologic and peri-operative outcomes/complications.

Results: Demographics, cancer characteristics, and margin status were similar between surgical approaches. ORP subjects were more likely to undergo lymphadenectomy (89% vs 47%; p<0.01) and nerve sparing (94% vs 89%; p<0.01). RALP vs ORP subjects experienced less mean intraoperative blood loss (192 vs 805 mL, p<0.01), shorter mean hospital stay (1.6 vs 2.1 days; p<0.01), and fewer blood transfusions (1% vs 4%; p<0.01), wound infections (2% vs 4%; p=0.02), other infections (1% vs 4%; p<0.01), deep vein thromboses (0.5% vs 2%; p=0.04), and bladder neck contractures requiring dilation (1.6% vs 8.3%; p<0.01). RALP subjects reported less pain (p=0.04), less activity interference (p<0.01) and higher incision satisfaction (p<0.01). Surgical approach (RALP vs ORP) was not a significant predictor of longitudinal HRQOL change in any HRQOL domain.

Conclusions: In high-volume academic centers, RALP and ORP patients may expect similar long-term HRQOL outcomes. Overall, RALP patients have less pain, shorter hospital stays, and fewer post-surgical complications such as blood transfusions, infections, DVTs, and bladder neck contractures.

Trial Registration: NCT01325506: Effectiveness of Open and Robotic Prostatectomy (PROSTQA-RP2)

Keywords

prostatectomy; outcomes; quality of life

INTRODUCTION

While radical prostatectomy has remained a treatment mainstay for localized prostate cancer since the turn of the century, there has been a seismic shift from open radical prostatectomy

(ORP) to robot-assisted laparoscopic prostatectomy (RALP). Driven largely by market forces and patient preference, RALP utilization in the United States has increased from less than 5% in 2003 to 85% in 2013[1], outpacing evidence supporting its comparative effectiveness[2].

Most studies have suggested comparable cancer control and survival outcomes between surgical approaches, and an advantage for RALP regarding peri-operative outcomes such as blood loss and hospital stay[3]. Given generally favorable oncologic outcomes after radical prostatectomy, increasing emphasis has been placed on longer-term changes in urinary and sexual health-related quality of life (HRQOL). However, definitive conclusions regarding comparison of HRQOL between surgical approaches have been elusive. While longitudinal patient-reported outcome assessment has become the gold standard for evaluating HRQOL in prostate cancer[4], most reports comparing ORP and RALP have depended primarily on physician-reported outcomes or claims based data[5] or have been single center studies[6,7].

We previously described a multicenter, longitudinal, prospective study evaluating HRQOL outcomes after localized prostate cancer treatment[8]. Accrued from 2003–2006, the PROST-QA (PQA) cohort defined the burden of prostate cancer treatment on HRQOL but was less well-equipped to evaluate comparative effectiveness between ORP and RALP given that adoption of robot-assisted surgery for radical prostatectomy was in its earlier stages. Building on our prior experience and research infrastructure, we accrued a second multicenter cohort – the PROSTQA-RP2 cohort (RP2) – between 2010–2013, after widespread dissemination of RALP. This study was specifically powered to evaluate whether surgical approach is a significant predictor of longitudinal differences in patient-reported HRQOL. Secondarily, we assessed for differences in peri-operative outcomes, including surgery-associated complications.

METHODS

Study Design

Study design and analytical plan were approved through a peer-reviewed funding process. Study subjects were participants in two prospective, longitudinal, multi-center cohorts, PROST-QA (PQA), and PROST-QA/RP2 (RP2) (Supplemental Table 1). The PQA consortium has been previously described[8], made up of nine university-affiliated hospitals, from which subjects were accrued between 2003–2006. From the 1,201 subjects who underwent prostate cancer treatment in PQA, 493 men fit the inclusion criteria in this study of having undergone open or robotic radical prostatectomy, with complete surgical data collected. Of these, 382 underwent ORP and 111 underwent RALP. The RP2 cohort, accrued between 2010–2013, and also made up of nine university-affiliated hospitals (Supplemental Table 1), consisted of 601 men with localized prostate cancer, of whom 163 underwent ORP and 438 underwent RALP. The final analytic cohort consisted of 545 ORP subjects and 549 RALP subjects (Figure 1).

Study subjects and outcome assessment

Subjects were men with previously untreated clinical stage T1 or T2 prostate cancer who elected to undergo either open or robot-assisted radical prostatectomy at a university-affiliated hospital and provided informed consent to enroll in an IRB-approved prospective, longitudinal study. The participating surgeon determined surgical approach and extent of nerve-sparing/lymphadenectomy.

Health-related quality of life outcome measures were collected using the Expanded Prostate Cancer Index Composite (EPIC-26)[9] and the Service Satisfaction for Cancer Care (SCA)[10] by a third-party phone survey facility at pre-treatment baseline, and at 2, 6, 12, and 24 months post-treatment for all analyzed subjects. Incisional and pain outcomes were collected two months post-treatment, while the post-operative complications encompassed the first six months following prostatectomy.

Statistical considerations

To assess the effect of surgical approach (ORP or RALP) on HRQOL over time, we used generalized estimating equations to model time profiles of each HRQOL domain. An all-inclusive base model was used that included, in addition to surgical approach, baseline HRQOL domain score, age, race, education, cohabitation, prostate size, Gleason score, tumor stage, baseline PSA, comorbidities, BMI, and nerve sparing. Lastly, the models also accounted for cohort (PQA or RP2) as a clustering factor for which the institutions and time periods of enrollment differed. Differences between ORP and RALP in distributions of categorical and continuous surgical outcomes and complications were compared using the Fisher's exact test and the Wilcoxon sum-rank test, respectively, with the Cochrane-Mantel-Haenszel test used to control for cohort. All statistical analyses were performed using SAS version 9.4 (Cary, NC).

RESULTS

Our analytic cohort consisted of 545 subjects who underwent ORP and 549 subjects who underwent RALP. At 2, 6, 12, and 24 months, 1036 (95%), 1019 (93%), 976 (89%), and 882 (81%) remained in both clinical and HRQOL follow-up (Figure 1). Mean age at treatment surgery was 60 for ORP and 61 for RALP. Subjects from the PQA cohort were more likely to have lower disease severity than those in the RP2 cohort (Supplemental Table 2). Still, observed significant differences in subjects between surgical approaches in categories such as clinical T-stage, Gleason score, and D'Amico risk group[11] (Table 1) were not statistically significant after controlling for cohort (Supplemental Table 2).

We assessed HRQOL outcomes using EPIC-26 at baseline, 2, 6, 12, and 24 months. As expected, significant HRQOL changes after both ORP and RALP, stratified by whether nerve-sparing was performed, were observed in the urinary incontinence and sexual domains, similarly to previously described[8] (Figure 2). All statistically or clinically significant HRQOL changes from baseline observed in ORP subjects were also observed in RALP subjects. Satisfaction with cancer outcome did not vary significantly by surgical approach. On multivariable longitudinal analysis, age, baseline HRQOL domain score,

and having more than 2 comorbid conditions were factors most frequently associated with a significant change in HRQOL (Supplemental Table 3). Nerve-sparing and larger prostate size predicted improved post-surgical HRQOL in the urinary irritation-obstruction domain. Surgical approach (ORP vs RALP) was not found to be a significant predictor of longitudinal patient-reported HRQOL change in any domain.

Pathologic outcomes were similar between groups (Table 2). The rate of positive margins trended towards being higher in RALP subjects ($p = 0.080$), although a higher proportion of RALP subjects had extraprostatic disease than ORP subjects (23% vs 19%, respectively, $p = 0.05$). Subjects who underwent RALP were far less likely to undergo lymphadenectomy (47% vs 89% in ORP; $p < 0.001$). RALP subjects were also more likely to undergo bilateral non-nerve sparing surgery (11% vs 6%, $p = 0.008$). Mean length of stay and estimated blood loss were lower in RALP subjects (1.6 days, 192 cc, respectively) than in ORP subjects (2.1 days, 805 cc, respectively). Two months post-operatively, subjects who underwent RALP reported lower pain scores (56% of RALP subjects with no pain vs 45% of ORP subjects; $p = 0.009$), were less likely to have pain-related moderate to extreme interference with activity (7% for RALP vs 12% for ORP; $p = 0.004$), and were more likely to be mostly to completely satisfied with the appearance of their surgical incisions (95% for RALP vs 89% for ORP; $p < 0.001$).

Post-surgical complications were uncommon across both surgical approaches (Table 3). Blood transfusions were more common in subjects who underwent ORP (6.2% vs 1.3% in RALP; $p = 0.006$), as were post-operative infections. The rate of bladder neck contracture (BNC) requiring dilation/treatment was significantly higher in men undergoing ORP (8.3% vs 1.6% in RALP; $p < 0.001$). Thromboembolic events were rare in both approaches, but the incidence of deep venous thrombosis (DVT) was higher in men undergoing ORP (1.9% vs 0.5% in RALP; $p = 0.04$). Cohort factors (other than type of surgical approach) may have contributed to some of the observed differences (although BNC remained significantly higher after ORP regardless of cohort), though such post-hoc analysis was further limited by reduction in sample power (Supplemental Table 4).

DISCUSSION

The rapid adoption and eventual predominance of robot-assisted radical prostatectomy in the last decade has presented unique challenges to researchers seeking to supplement the dearth of high-quality evidence evaluating the comparative effectiveness of ORP and RALP. Most early reports were single-surgeon series from high-volume centers that either lacked or featured a retrospective ORP comparator group[6,7] and often featured surgeons at various stages of the substantial RALP learning curve[12].

Since the first reported robotic prostatectomy in 2001[13], only one trial has successfully randomized subjects to ORP and RALP. This single-center Australian study randomized 326 patients by surgical approach and found no significant differences between ORP and RALP in patient-reported EPIC urinary or sexual function domain scores 6 and 12 weeks as well as 24 months post-operatively[14,15]. However, RALP subjects had superior physical function scores six weeks post-operatively, corroborating our findings in which RALP subjects had

less pain-induced interference with physical activity. Despite the rigor of its randomized approach, its generalizability is limited by it being a single center comparison of one open surgeon to one robotic surgeon with a significant surgeon experience differential. Attempts at a multi-center randomized controlled trial have been unsuccessful[16].

Efforts at comparing RALP and ORP have used different methods to tackle the analytical moving target in which the proportion of radical prostatectomies performed robotically in the United States changed from 15% to 85% within 10 years[1]. A population-based analysis compared RALP subjects from the Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) study group (2011–2012) to ORP subjects primarily from the historical Prostate Cancer Outcomes Study (PCOS) (1994–1995) and found RALP subjects to have a small but statistically significant advantage in patient-reported sexual function 6 and 12 months post-operatively[17]. While this analysis did control for baseline HRQOL, it could not control for the almost 20 year between-group time period differences in surgical technique and the availability of sexual function recovery aids including PDE-5 inhibitors. A multi-center prospective Swedish trial (2008–2011), the Laparoscopic Prostatectomy Robot Open (LAPPRO) study, compared 778 subjects from seven centers that exclusively performed ORP to 1847 subjects from a second group of seven centers performing RALP and found no significant difference in urinary outcomes between surgical approaches, but a modest advantage in erectile dysfunction rates in favor of RALP over ORP; however, this analysis did not control for baseline sexual HRQOL, a strong predictor of post-operative outcome[18].

Our study used the existing rigorous PQA core infrastructure – prospective third-party administration of patient-report HRQOL surveys, centralized data coordinating center, and high-volume university-affiliated member institutions – to accrue the RP2 cohort and form the only American multi-center prospective trial designed and powered to detect a longitudinal difference in patient-reported HRQOL outcomes between RALP and ORP. In contrast to the PCOS/CEASAR and LAPPRO studies, we found no significant effect of surgical approach on longitudinal HRQOL change (in all domains) from pre-treatment baseline to two years post-treatment after adjusting for other factors, including baseline HRQOL. The most likely explanation for our difference in results from the above two studies, in addition to the already mentioned differences in confounding adjustment, is that PCOS/CEASAR and LAPPRO were population-based cohorts, while PQA/RP2 subjects received their care at high-volume academic institutions[19].

The rate of positive surgical margins varies widely both within series and between series[20,21], and is influenced by many factors, especially cancer severity, which is readily subject to selection bias between groups. Similar to the Australian RCT[14] and the LAPPRO study[18], we did not find a significant difference in positive surgical margin rates between ORP and RALP for organ-confined disease, a metric considered to be an oncologic care quality measure in radical prostatectomy. In our study, the rate of lymphadenectomy in ORP subjects was disproportionately high (89%) considering the number of subjects with low-risk disease, while lymphadenectomy utilization in RALP subjects (47%) was more appropriately matched with disease severity, a commonly observed finding in other registry-based series[22]. This overutilization of lymphadenectomy in our ORP subjects, especially

considering the proportion of subjects with low-risk disease, may be related to the tradition of considering routine lymphadenectomy as a pedagogical opportunity during ORP in our participating academic medical centers.

While prior single center reports have suggested a lower incidence of bladder neck contracture in RALP compared to ORP[23], to our knowledge this is the first multicenter prospective study that has shown this finding, which was demonstrated independent of cohort (PQA vs RP2) despite RALP being performed relatively early in its evolution compared to ORP in the PQA cohort. While this finding did not translate into a significant overall difference in longitudinal urinary HRQOL between surgical approaches, it did represent an additional burden of post-surgical intervention in men undergoing ORP.

We found that ORP subjects had a higher incidence of post-surgical DVT than RALP subjects. While the magnitude of this finding was more pronounced in PQA than RP2 subjects, suggesting cohort effects, the trend was maintained across cohorts. Possible explanations include further evolution of DVT prophylaxis over time, a higher surgeon/institutional heterogeneity in the PQA cohort, or that this increased thrombotic risk is conferred by the disproportionately high incidence of lymphadenectomy in the ORP group. Indeed, 10/13 (77%) of men who experienced DVT underwent lymphadenectomy; however, the overall incidence of DVT was small enough in our study that we cannot rigorously test these hypotheses. A separate analysis of thromboembolic events in the LAPPRO study suggested that both open surgery (RR 12.67, 95% CI 5.05–31.77) and lymphadenectomy (7.80, 95% CI 3.51–17.32) were independent predictors of thromboembolic events[24].

Peri-operatively, RALP subjects had a shorter hospital stay, less blood loss, fewer blood transfusions, reported less pain, and were more satisfied with the appearance of their incisions than ORP subjects. These advantages, commonly associated with a minimally invasive surgical approach, were also observed by Yaxley et al. While the differences in post-operative pain between groups are limited to the initial weeks after surgery[14], the nationwide opioid crisis has illustrated that the societal impact of post-surgical pain and its potential downstream effects should not be underestimated[25].

Our study has several limitations. Subjects were accrued from academic, university-affiliated institutions, which may limit the generalizability of our results. However, with growing regionalization and centralization of cancer care[26], and multiple studies suggesting that higher-volume radical prostatectomy centers provide superior outcomes independent of surgical approach[1,27,28], our results gathered from eleven of the highest-volume academic centers in the United States represents an idealized comparison of ORP and RALP in settings of high care quality.

Our study is non-randomized and accrued subjects from two cohorts – PQA and RP2 – separated by time, institution composition, and surgical approach distribution, which introduces confounding that cannot be completely accounted for by statistical adjustment. The temporal difference may introduce between-cohort subject variability (overall cancer severity was higher in RP2, likely because active surveillance was not as prevalent in 2003–2006), surgeons' experiential learning curve, and technical[29] or peri-operative

advancements[30]. Institutional variability between cohorts was small (5/8 institutions in PQA and RP2 were in both cohorts) but also contributes to unadjusted confounding. While confounding cannot be fully eliminated, given how this is a highly controlled prospective study in which extensive pre-treatment baseline characteristics, including cohort, were known and controlled for, significant unadjusted confounding is less likely.

CONCLUSIONS

In this multicenter, prospective, longitudinal study, we found that RALP subjects had superior incisional/pain outcomes, shorter hospital stays, and fewer post-surgical complications such as blood transfusions, infections, DVTs, and bladder neck contractures. Long-term post-operative patient-reported HRQOL outcomes were similar between open and robotic surgical approaches. These results should help guide treatment counseling and be integrated into future cost analyses.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGEMENTS

Acknowledgments: The PROSTQA and PROSTQA-RP2 Consortium includes contributions in cohort design, patient accrual and follow-up from the following investigators: Meredith Regan (Dana Farber Cancer Institute, Boston, MA); Matthew Cooperberg, Peter Carroll, and Leslie Wilson (University of California San Francisco, San Francisco, CA); Larry Hembroff and Douglas Roberts (Michigan State University, East Lansing, MI); John T. Wei, Dan Hamstra, Daniel Spratt, Rodney Dunn, Laurel Northouse and David Wood (University of Michigan, Ann Arbor, MI); Eric A Klein and Jay Ciezki (Cleveland Clinic, Cleveland, OH); Misop Han and Alan Partin (Johns Hopkins Medical Institutions, Baltimore, MD); Joseph Smith (Vanderbilt University Medical Center, Nashville, TN); Jeff Michalski and Gerald Andriole (Washington University, St. Louis, MO); Mark Litwin and Chris Saigal (University of California, Los Angeles Medical Center, Los Angeles, CA); Thomas Greenfield, PhD (Emeryville, CA), Louis Pisters and Deborah Kuban (MD Anderson Cancer Center, Houston, TX); Howard Sandler (Cedars Sinai Medical Center, Los Angeles, CA); Jim Hu and Adam Kibel (Brigham and Women's Hospital, Boston, MA); Douglas Dahl and Anthony Zietman (Massachusetts General Hospital, Boston, MA); Peter Chang, Andrew Wagner, and Irving Kaplan (Beth Israel Deaconess Medical Center, Boston, MA) and Martin G. Sanda (Emory, Atlanta, GA).

We acknowledge PROSTQA Data Coordinating Center Project Management by Catrina Crociani, MPH (Beth Israel Deaconess Medical Center, Boston, MA), Kyle Davis and Jill Hardy, MS (Michigan State University, East Lansing, MI), Erin Najuch and Jonathan Chipman (Dana Farber Cancer Institute, Boston, MA), Dattatraya Patil, MBBS, MPH and Mersiha Torlak (Emory, Atlanta, GA) and the Research Coordinators at each clinical site. We would like to thank the study participants. Without them this study would not be possible.

Attestation: Dr. Chang had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

4. Funding:

PROST-QA and PROST-QA/RP2 Consortium Funded by National Institutes of Health Grants R01 CA95662, RC1 CA146596, and RC1 EB011001, as well as the Winship Cancer Institute Fund-a-Cure Initiative from the Dunwoody Country Club. Dr. Chang is supported by a Urology Care Foundation Research Scholar Award, the Martin and Diane Trust Career Development Chair in Surgery, and the Movember Foundation.

Abbreviations:

PCa	prostate cancer

RALP	robot-assisted laparoscopic prostatectomy
ORP	open radical prostatectomy
PQA	PROST-QA
HRQOL	health related quality of life
DVT	deep venous thrombosis
LAPPRO	the Laparoscopic Prostatectomy Robot Open study

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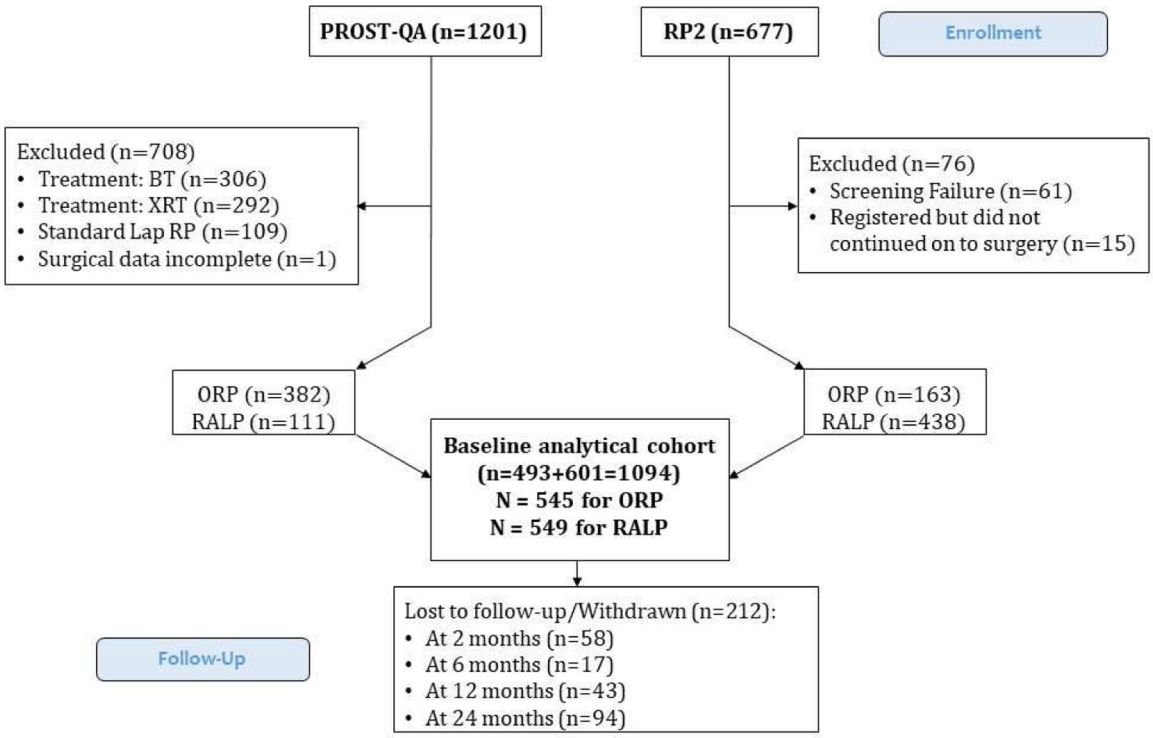

Figure 1. CONSORT Diagram

ORP = Open radical prostatectomy

RALP = Robot-assisted laparoscopic prostatectomy

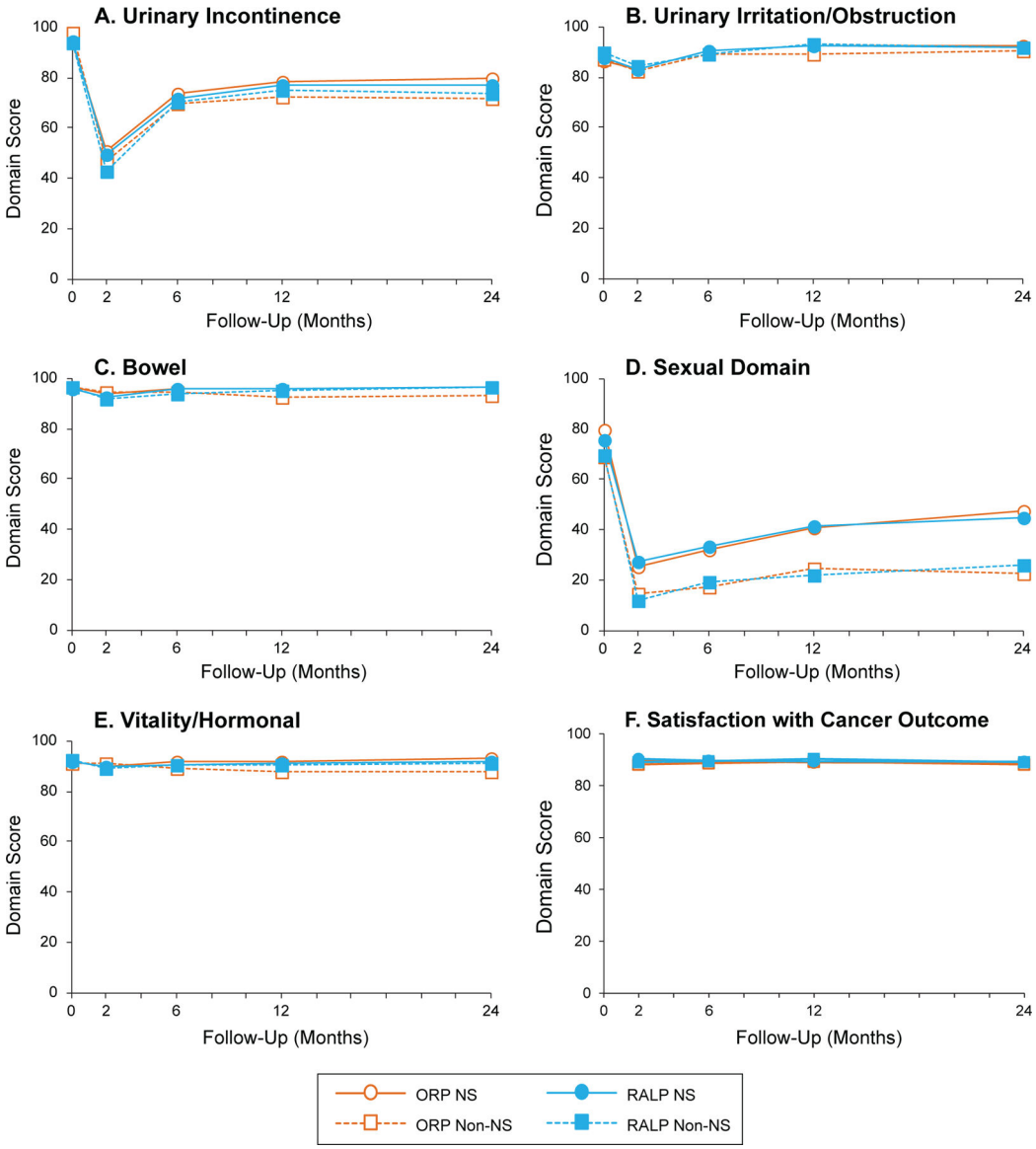

Figure 2. Longitudinal patient-reported HRQOL and satisfaction with cancer outcome after radical prostatectomy, stratified by surgical approach and nerve-sparing status

ORP = Open radical prostatectomy

RALP = Robot-assisted laparoscopic prostatectomy

Panels A-E are health domains of the EPIC-26 HRQOL instrument[9]

Panel F describes satisfaction with cancer outcome, a domain of the Service Satisfaction Scale for Cancer Care (SCA) instrument[10]

Surgical approach (ORP vs RALP) was not found to be a significant predictor of longitudinal patient-reported HRQOL change in any domain.

Table 1:

Pre-treatment subject characteristics, by surgical approach

	ORP (n=545)	RALP (n = 549)	Total (n=1094)	p-value
Age – no. (%)				
<60	276 (51)	242 (44)	518 (47)	0.08
60 – 69	229 (42)	256 (47)	485 (44)	
70+	40 (7)	51 (9)	91 (8)	
Race – no. (%)				
White	475 (91)	496 (91)	971 (91)	0.97
African-American	35 (7)	36 (7)	71 (7)	
Other	10 (2)	9 (2)	19 (2)	
College or post-graduate education - no. (%)	365 (67)	351 (64)	716 (65)	0.31
Married/Cohabitating– no. (%)	478 (88)	481 (88)	959 (88)	0.93
BMI (kg/m2) – median (IQR)				
<35	515 (95)	515 (94)	1030 (94)	0.79
35+	30 (5)	33 (6)	63 (6)	
Number of comorbidities – no. (%)				
0–2	511 (94)	508 (93)	1019 (93)	0.47
3+	34 (6)	41 (7)	75 (7)	
Prostate volume (mL) – no. (%)				
<30 cc	123 (27)	143 (31)	266 (29)	**0.005**
30–53 cc	226 (50)	248 (55)	474 (52)	
>53 cc	100 (22)	64 (14)	164 (18)	
PSA (ng/mL) – no. (%)				
<4	126 (23)	107 (20)	233 (21)	0.14
4 – 10	341 (63)	375 (68)	716 (65)	
>10	78 (14)	67 (12)	145 (13)	
Clinical T-stage – no. (%)				
cT1	405 (74)	445 (81)	850 (78)	**0.006**
cT2	140 (26)	102 (19)	242 (22)	
Gleason Score on initial biopsy– no. (%)				
6 or less (grade group 1)	299 (55)	234 (43)	533 (49)	**<.001**
7 (grade group 2–3)	214 (39)	272 (50)	486 (44)	
8–10 (grade group 4–5)	32 (6)	43 (8)	75 (7)	
D'Amico risk group – no. (%)				
Low	255 (47)	211 (39)	466 (43)	
Intermediate – High	290 (53)	336 (61)	626 (57)	**0.007**

p-value is calculated by the Fisher's exact test

Table 2:

Peri-operative and Incisional Outcomes

	ORP (n=545)	RALP (n = 549)	Total (n=1094)	p-value
Pathologic stage – no. (%)				
pT2 (gland-confined disease)	436 (81)	419 (77)	855 (79)	0.05
pT3+ (locally-advanced disease)	99 (19)	128 (23)	227 (21)	
Positive margins – no. (%)	83 (16)	109 (20)	192 (18)	0.08
pT2 (gland-confined disease)	47 (11)	53 (13)	100 (12)	0.46
pT3+ (locally-advanced disease)	36 (36)	56 (43)	92 (40)	0.28
Lymphadenectomy performed – no. (%)	478 (89)	260 (47)	738 (68)	**<0.001**
Non-nerve-sparing - no. (%)	35 (6)	60 (11)	95 (9)	**0.008**
Length of stay in days – Mean (SD)	2.1 (7.7)	1.6 (7.8)	1.9 (7.7)	**<0.001**
Estimated blood loss – Mean (SD)	805 (525)	192 (142)	498 (491)	**<0.001**
Pain at surgical site * - no. (%)				
0	232 (45)	287 (56)	519 (50)	**0.009**
1–3	233 (45)	189 (37)	422 (41)	
4–6	37 (7)	30 (6)	67 (7)	
7–10	12 (2)	9 (2)	21 (2)	
Pain interfered with activity * - no. (%)				
None/Slightly	449 (88)	478 (93)	927 (90)	**0.004**
Moderately – Extremely	64 (12)	37 (7)	101 (10)	
Appearance of surgical incision * – no. (%)				
Completely satisfied – mostly satisfied	455 (89)	485 (95)	940 (92)	**<0.001**
Mixed – Completely unsatisfied	55 (11)	26 (5)	81 (8)	

* assessed two months post-operatively

Table 3:

Post-surgical complications

	ORP (n=545)	RALP (n = 549)	Total (n=1094)	p-value
Blood transfusion	21 (4.0)	7 (1.3)	28 (2.6)	**0.006**
Urinary tract infection requiring treatment	33 (6.2)	23 (4.2)	56 (5.2)	0.14
Unplanned urinary catheterization	35 (6.6)	17 (3.1)	52 (4.8)	**0.007**
Bladder neck contracture requiring dilation	45 (8.3)	9 (1.6)	54 (4.9)	**<0.001**
Wound infection	23 (4.3)	10 (1.8)	33 (3.1)	**0.02**
Other infection	23 (4.3)	6 (1.1)	29 (2.7)	**0.001**
Deep venous thrombosis*	10 (1.9)	3 (0.5)	13 (1.2)	**0.04**
Pulmonary embolism	3 (0.6)	4 (0.7)	7 (0.7)	0.74
Rectal bleeding requiring treatment	3 (0.6)	2 (0.4)	5 (0.5)	0.63
Hematuria requiring treatment	13 (2.5)	12 (2.2)	25 (2.3)	0.78
Unplanned hospital admission	27 (5.1)	24 (4.4)	51 (4.8)	0.59

*Routine imaging assessment for deep vein thrombosis was not protocol-mandated in the absence of symptoms