Examining the association between real-world extended vs. standard pelvic lymph node dissection and early and late oncologic outcomes in men undergoing radical prostatectomy

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ABSTRACT

Introduction: In patients with prostate cancer (PCa), the impact of extended pelvic lymph node dissection (E-PLND) during radical prostatectomy (RP) on oncologic outcomes remains controversial. This study examined the association between extended vs. standard PLND (S-PLND) and biochemical recurrence (BCR), an early outcome, as well as metastatic PCa (mPCa), and castration-resistant PCa (CRPC) development, late outcomes, in a multi-institutional cohort.
Methods: High-risk post-RP patients from a Canadian PCa database were analyzed from

KEY MESSAGES

- Controversy exists surrounding the role of extended pelvic lymph node dissection (E-PLND) vs. standard pelvic lymph node dissection (S-PLND) during radical prostatectomy (RP) and its impact on oncologic outcomes.
- E-PLND was associated with higher complication rate and increased intraoperative blood loss when compared to S-PLND, with no statistically significant differences in biochemical recurrence, metastatic progression, or development of castration-resistant prostate cancer.
- Although E-PLND was not associated with clear oncologic benefits compared to S-PLND, E-PLND may offer more accurate staging in select high-risk patients who may benefit from further treatment.

January 1, 2005, to December 31, 2016. The association between PLND and BCR, mPCa, CRPC-development, and complication rate were examined using regression and correlation analysis.
Results: Data were collected on patients who underwent S-PLND (n=494) and E-PLND (n=107). The median followup was 40.1 months, and time to BCR, mPC, and CRPC-development was 9.8, 46.0, and 52.1 months, respectively. The median (interquartile range) number of lymph nodes extirpated was 7 (7) and 14 (11) for the S-PLND and E-PLND groups, respectively. E-PLND was associated with increased intraoperative blood loss and higher postoperative complication rate. There were no differences in BCR-free survival based on PLND approach, with 67.1% of S-PLND cases and 71.1% of E-PLND cases reaching BCR-free survival at the end of the followup period (hazard ratio [HR] 0.784 [0.506, 1.215], p=0.28). PLND extent was not a predictor for mPCa progression (p=0.963). Similarly, there were no differences in CRPC-free survival based on dissection type (S-PLND 90.9% vs. E-PLND 89.1%, p=0.561). LN positivity was predictive of BCR, mPCa, and CRPC progression.
Conclusions: E-PLND did not show significant differences in the rates of BCR, mPCa, or CRPC progression when compared to S-PLND. E-PLND was associated with higher complication rates. This study adds to the data exploring the association between PLND and PCa oncologic outcomes.

INTRODUCTION

For patients with prostate cancer (PC) undergoing radical prostatectomy (RP), pelvic lymph node dissection is commonly performed at the time of the procedure. Based on the probability of finding lymph nodes (LN) containing malignancy, urologists may opt to perform an extended pelvic lymph node dissection (E-PLND) or a standard (S-PLND) dissection.[1]

The role of E-PLND versus S-PLND remains controversial as the therapeutic benefit remains unclear.[1-5] Randomized controlled trials (RCTs) comparing E-PLND versus S-PLND in intermediate- and high-risk PC have demonstrated that E-PLND provides better pathological staging but no improvements in BCR-free survival or metastatic-free survival.[4,5] Despite this, high-quality systematic reviews and meta-analyses have demonstrated improved BCR-free survival with E-PLND.[1] Due to this controversy, E-PLND is often done at surgeon discretion for those with extensive local disease, with enlarged nodes on imaging, with high-risk preoperative clinical and/or pathologic features, and for those perceived to benefit the most from accurate nodal staging.[1] Most studies examining the outcomes of E-PLND versus S-PLND often examine very late oncological endpoints which tend to occur years later, resulting in missing data on the natural course of PC after RP due to loss of patient follow-up.[3,5-7] Few studies exist examining the role of PLND type on both early oncological outcomes such as biochemical recurrence (BCR) and late oncological outcomes such as the development of metastatic disease and castration-resistant prostate cancer (CRPC).[4] Furthermore, better understanding of the utility of E-PLND vs S-PLND can help inform the value of less invasive approaches to PLND.[8,9] Herein we examined the association between E-PLND versus S-PLND on the oncological outcomes of BCR, progression to metastatic PC (mPC), and the development of CRPC.

METHODS

Study and population

This study utilized a multicentre retrospective database created from seven high volume Canadian centres. This database contains demographic, pathologic, surgical, and post-operative data on patients undergoing RP at each site. Data was collected from January 1, 2005 until December 31, 2016 and was retrospectively reviewed. A total of 26 surgeons were included in this group. Choice of E-PLND versus S-PLND was non-standardized and decided upon by each surgeon individually. E-PLND (in general) was defined as PLND from the obturator nerve, external iliac artery, and internal iliac artery, whereas S-PLND was defined as PLND from the obturator nerve and external iliac artery.[5] Classification of S-PLND vs E-PLND was done through review of operative notes and the surgical boundaries used for PLND.

BCR was defined as an outcome determined when patient serum prostate specific antigen (PSA) level reached greater than or equal to 0.2 ng/mL with a second confirmatory level. Metastatic disease development was defined as any volume of new metastatic disease detected radiologically. Development of CRPC was defined as biochemical or clinical progression despite achieving castrate-level testosterone levels below 1.7 nmol/L.

Data collection

Data was collected from the study population through review of patient electronic medical records (EMR) at each site forming a database of patient information. Demographic information, pre-operative laboratory values, clinic visit information, operative reports, peri-operative and post-operative bloodwork, use of adjuvant or salvage therapy, and follow-up clinical reports and bloodwork were reviewed for clinical information and anonymized data was stored in a central database. Institutional research ethics approval was obtained prior to analysis.

Statistical analysis

Demographic, surgical factors, and outcomes were expressed using frequencies and percentages and were analyzed using chi-square and Mann-Whitney U tests. Spearman correlation analysis was used to analyze the correlation between E-PLND and S-PLND with patient and surgical factors. Cox regression analysis was used to model BCR, mPC development, and CRPC progression. Factors included for regression analysis were determined by review of literature and by strength of association between predictor and outcome variables after controlling for co-linearity. Variables in the regression analysis included: pathologic stage, pre-operative PSA, pathologic Gleason grade group, adjuvant systemic therapy, LN yield, LN positivity, margin status, and prostate volume. Statistical significance was set at p = 0.05 with a 95% confidence interval.

RESULTS

Patient population

Six hundred and one patients were included in the study with 494 undergoing S-PLND and 107 undergoing E-PLND. Patients in the E-PLND group were of younger age (mean ± standard deviation: 61.8 ± 7.18 years vs 63.8 ± 5.98 years, p = 0.008) and had slightly higher body mass index (BMI) (28.9 ± 4.3 vs 28.3 ± 4.04, p = 0.05) (Table 1). The majority of patients had Gleason grade ≥ 8 disease (S-PLND: 77.7%, n = 384/494, E-PLND: 73.8%, n = 79/107, p = 0.01). Salvage radiation was administered to 34.8% (n = 172/494) of S-PLND patients and 48.6% (n = 52/107) in the E-PLND group (p = 0.007). There was no difference between groups regarding the use of adjuvant androgen deprivation therapy (S-PLND: 9.9%, n = 49/494, E-PLND: 8.4%, n = 9/107, p = 0.632). There were no statistically significant differences in pre-operative PSA (S-PLND: 8.97 ng/mL [0.10, 250.0], E-PLND: 9.90 ng/mL [0.47, 300.0], p = 0.347), pathologic T stage (p = 0.738), or positive margin status (S-PLND: 37.2%, n = 184/494, E-PLND: 42.1%, n = 45/107).

Lymph node dissection

The median [interquartile range] number of lymph nodes dissected was 7 [7] and 14 [11] in S-PLND and E-PLND, respectively (p = 0.002). Positive lymph node involvement was more common with E-PLND (23.4%, n = 25/107) compared to S-PLND (12.3%, n = 60/489, p = 0.003). There were no significant increases in operative time noted between dissection type (p = 0.184). E-PLND was associated with increased intra-operative blood loss (ρ = 0.252, p < 0.001, E-PLND: 500 [100, 4000] mL, S-PLND: 300 [10, 3000] mL, p < 0.001).

Complications

Patients undergoing E-PLND (16.8%, n = 18/107) had higher complication rates compared to S-PLND (11.3%, n = 56/494, p = 0.01) (Table 2). Of patients who experienced post-operative complications, patients recovering from E-PLND were subjected to higher Clavien-Dindo grade complications compared to S-PLND patients, with 9 patients in the E-PLND group (50.0%) compared to 7 (12.5%) patients in the S-PLND group experiencing a Clavien-Dindo grade ≥ 3 complication (p = 0.01). The most common post-operative complications for E-PLND were anastomotic leaks (5.61%, n = 6/107) and symptomatic lymphocele development (4.67%, n =5/107) while S-PLND patients most commonly experienced wound infections/abscess development (3.24%, n = 16/494) and anastomotic leaks (2.83%, n = 14/494).

Oncological outcomes

The median follow-up was 40.1 [0.03, 137] months with a median time from operation to BCR, mPC progression, and CRPC development being 9.8 [0.6, 121.4], and 46.0 [1.2, 120.3], and 52.1 [12.0, 122.0] months, respectively. In the S-PLND group, 24.9% (n = 123/494) developed BCR with a median time of 9.3 [0.95, 94.75] months for BCR. In the E-PLND group, 22.4% (n = 24/107) of patients developed BCR with a median time to BCR of 11.84 [0.62, 67.46] months. Time to mPC progression was 58.8 [1.3, 111.5] and 44.5 [1.2, 120.3] months for S-PLND and E-PLND, respectively (p = 0.328). When examining CRPC development, 7.66% (n = 21/274) of patients who underwent S-PLND experienced CRPC progression with a median time to CRPC of 9.27 [0.95, 94.75] months. In the E-PLND group, 9.80% (n = 5/51) of patients progressed to CRPC with a median time to CRPC progression being 8.55 [0.62, 67.46] months.

In multivariable Cox regression analysis, there were no differences in BCR-free survival based on PLND extent (E-PLND: HR = 0.784 [0.506, 1.215], p = 0.28) (Figure 1). LN positivity was found to be a predictive factor for BCR in S-PLND (HR: 1.89 [1.77, 24.47], p = 0.005) and E-PLND (HR: 1.26 [1.12, 11.11], p = 0.03). For patients with positive LNs, BCR-free survival was 48.9% at 5 years compared to 68.9% for patients with negative LNs (X^2 = 33.3, p = 0.001)

Metastatic disease progression was seen in 12.1% (n = 13/107) of patients in the E-PLND group and 9.1% (n = 45/494) who underwent S-PLND (p = 0.229). Metastasis-free-survival was 91.2% at 5 years for patients who underwent S-PLND compared to 88.2% at 5 years for the E-PLND group (X^2 = 0.956, p = 0.328, Figure 2). On multivariable analysis, PLND extent was not found to be a predictor for progression to metastatic disease (p = 0.963). LN positivity (HR: 5.23 [1.19, 22.9], p = 0.028) was strongly predictive of metastatic disease progression, while older age at time of surgery (HR: 0.881 [0.777, 1.00], p = 0.049) was protective. Similarly, in multivariable Cox regression analysis, no differences in CRPC-free survival were seen based on PLND extent (E-PLND: HR = 1.34 [0.502, 3.567]. p = 0.561) (Figure 3). Positive LN disease was a factor influencing CRPC-free survival. Of patients with positive LNs, CRPC-free survival was found to be 68.3% at 5 years compared to 90.9% for those with negative LNs (X^2 = 11.2, p = 0.001). Therefore, patients with positive LN disease had a reduction in CRPC-free survival of approximately 22.6% at 5 years after surgery.

DISCUSSION

The role of E-PLND versus S-PLND during RP remains controversial with limited evidence on the benefits of more extensive resection.[1-3,5] Previous comparative studies have shown no significant improvements in metastasis-free survival with more extensive dissection but the impact of E-PLND on earlier and later oncological outcomes remains understudied.[4] To address this knowledge gap, this study used a retrospective multi-centre approach to examine BCR, mPC progression, and CRPC development based on PLND type.

In our study, patients in the E-PLND group were slightly younger and had greater BMI when compared to the S-PLND group, but otherwise were similar in demographics and disease characteristics such as clinical and pathologic T stage and pre-operative PSA. This similarity exemplifies that urologists do not have a unified approach or consensus on which patients should undergo E-PLND, but the decision is often influenced by Gleason grade and tumor and nodal characteristics.[1] E-PLND demonstrated double the LN yield compared to S-PLND with an increased positive LN yield. This finding supports current literature suggesting E-PLND has higher staging accuracy which may influence treatment options and allow for improved risk stratification.[4,10] This improved staging accuracy has to be considered alongside the potential increased complication risk associated with E-PLND.[11] E-PLND has been shown to have higher complication risks which was supported by our findings of E-PLND having increased intra-operative blood loss and complication rate.[11,12] Of note, patients in our study undergoing E-PLND not only had higher complication rates, but also higher average Clavien-Dindo complication grades.

When analyzing PLND type on BCR, there was no statistically significant reduction in BCR in the E-PLND group compared to S-PLND. Some studies have suggested that E-PLND may be associated with improved BCR-free survival compared to S-PLND, although this evidence is not consistent.[13-18] When analyzing predictors for development of BCR, in both patients undergoing S-PLND and E-PLND, LN positivity was a significant predictive factor. This is consistent with the current literature, citing Gleason score >7, pre-operative PSA, pathologic T stage, positive surgical margins, and LN positivity being predictors of 5-year BCR-free survival.[5,19,20] LN positivity demonstrated a reduction in BCR-free survival by 20% at 5 years which is consistent with timelines in the current literature.[19] Metastasis-free survival was worse for patients in the E-PLND group with higher rates and earlier progression when compared to S-PLND, although this was not statistically significant. Furthermore, metastasis-free survival was significantly worse for patients with positive LN disease which likely reflects the more aggressive disease characteristics of PC which has invaded regional nodes.

Although E-PLND was mildly associated with increased positive LN yield compared to S-PLND, this did not translate to statistical significance when analyzing BCR-free survival, metastasis-free survival, or CRPC-free survival. Similar to BCR, limited data exists on the utility of E-PLND on improving CRPC-free survival.[21] Theoretically, E-PLND may confer improved CRPC-free survival as potential cancer that has spread to the LNs will be fully resected, and staging is superior which may allow for additional – and earlier – treatment for node-positive disease. Additionally, patients in the E-PLND group were more likely to undergo salvage radiation treatment compared to the S-PLND group which may have influenced oncological outcomes despite controlling for salvage treatment in the multivariate analyses. With respect to node positivity, in our study, patients with positive LNs had reduced CRPC-free survival compared to patients with negative node status by approximately 23%. Positive LN disease was associated with worse BCR-free survival, metastasis-free survival, and CRPC-free survival highlighting that positive LN disease is a poor prognostic factor in PC.[22,23] Despite this finding with node-positive disease, dissection type was not a significant predictor. Furthermore, although more accurate staging of disease may be accomplished with E-PLND when compared to S-PLND, E-PLND may aid simply in identifying patients at higher risk for disease progression rather than offer a direct therapeutic effect.[17,22,23]

E-PLND has consistently shown inconclusive evidence from a BCR-free survival, metastasis-free survival, and CRPC-free survival perspective, but provides increased nodal staging accuracy.[17] Therefore, for select patient groups with intermediate and high-risk PC who may benefit from the improved nodal staging, E-PLND may be considered. This decision must be patient-specific and made in the context of increased risk for intra-operative complications and blood loss. Additionally, with the recent advent and adoption of prostate specific membrane antigen-positron emission tomography (PSMA-PET), high-risk patients may be further assessed for nodal involvement in a non-invasive manner rather than receive upfront E-PLND.[24-26] With this potential option for non-invasive nodal staging through PSMA-PET, the benefits of E-PLND over S-PLND may potentially be further diminished, favoring S-PLND or node sparing approaches.[25,27] Another promising alternative to E-PLND is location-based sentinel node dissection using magnetic-fluorescent hybrid tracers.[8,9] Through pre-operative injection of these tracers, surgeons can identify involved lymph nodes for extirpation with the goal of avoiding extensive PLND.[8,9] This approach has shown early success and serves as a potential way of extending PLND beyond S-PLND templates to resect suspicious LNs while minimizing the increased morbidity of extended dissection.[8,9] Preliminary studies have shown comparable BCR-free survival rates in patients who received sentinel node dissection of LNs outside of the standard template with patients who underwent E-PLND – further minimizing the benefits of E-PLND.[8]

It is important to acknowledge the limitations of this study. This study is retrospective in nature and decision to pursue E-PLND was based on surgeon preference which may impact the strength of the findings. Despite this, the proportion of patients undergoing E-PLND vs S-PLND is consistent with practice patterns.[11] As well, a standardized template-based definition of E-PLND or S-PLND was not used. Although this reflects a real-world practical example of PLND, it is possible that surgeons performing E-PLND may be under-resecting and diminishing any potential advantages of E-PLND. For categorization of PLND in this study, E-PLND boundaries were defined based on large-scale studies with similar patient populations and outcomes.[4,5] Variations in extent of PLND and templates used must be considered when interpreting results among similar studies which may have differing boundaries. Additionally, whether dissected LNs are sent for pathologic evaluation in a cluster vs individually may impact LN yield and outcomes in this study and understate the benefits of increased nodal extirpation. Of important consideration, although data was collected from a Canadian database featuring 26 surgeons, certain participating centres collected and reported more cases which may bias the results of this study to align more with practices and outcomes from certain participating surgeons/centres. The sample size examined was large but unbalanced with more patients undergoing S-PLND than E-PLND, although measures were taken to account for this through analysis, the ability of statistical analysis to detect group differences is more limited. Additionally, patients in the E-PLND group were more likely to undergo salvage radiation treatment compared to the S-PLND group which may have influenced oncological outcomes despite controlling for salvage treatment in multivariate analyses. Despite this, this may influence the results of this study. There were also instances where care deviated from standard of care, with 9.9% of S-PLND and

8.4% of E-PLND patients receiving adjuvant hormonal therapy and 0.9% of E-PLND receiving neoadjuvant chemotherapy which is not standard of care for localized PC. This may bias outcomes. Nonetheless, the lack of benefit with regards to BCR, mPC progression, and CRPC development is consistent with similar studies.[1,4] Furthermore, limitations exist due to the nature of this study. A formal RCT or a large volume matched-analysis study would improve generalizability of results to provide stronger recommendations on the benefits of more extensive PLND. Although this study provides a meaningful perspective on real-world PLND for PC, generalizability to larger populations may be limited. As this study utilized a database approach, there is a chance that patient interventions and data collected may not reflect current practices which may bias results further.

CONCLUSIONS

In our study comparing E-PLND and S-PLND in patients undergoing RP, there was no significant differences in BCR, metastatic development, or CRPC progression between patient groups. Despite this, E-PLND was shown to have increased LN yield and positivity, which may provide benefit to patient groups who benefit the most from more accurate nodal staging. Further research is needed to refine patient selection criteria for patients who may benefit from E-PLND.

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FIUGURES AND TABLES

Figure 1. BCR-free survival based on pelvic lymph node dissection (PLND) type.

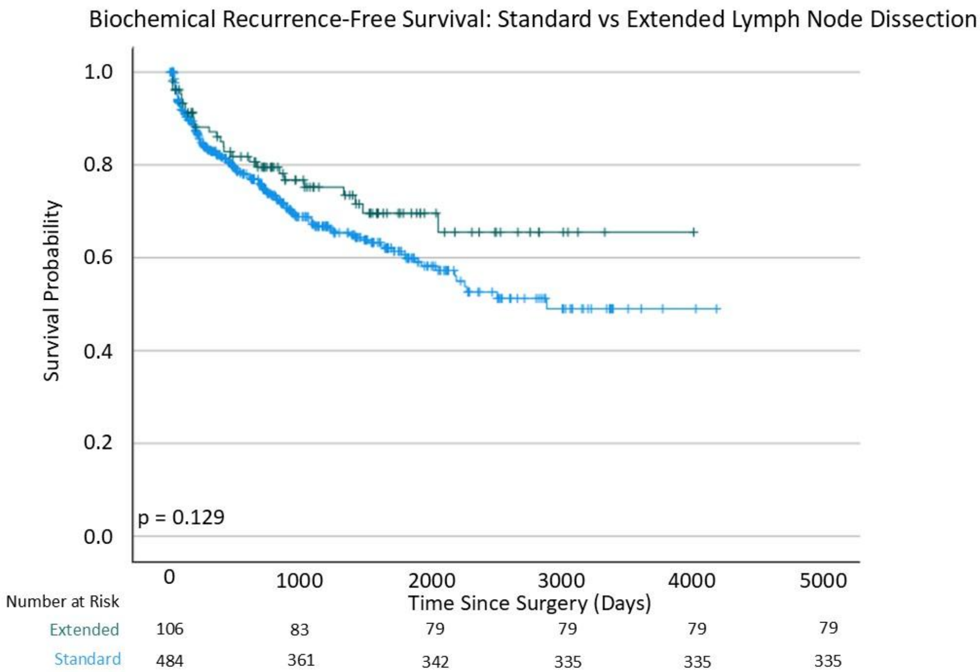

Figure 2. Metastasis-free survival based on pelvic lymph node dissection (PLND) type.

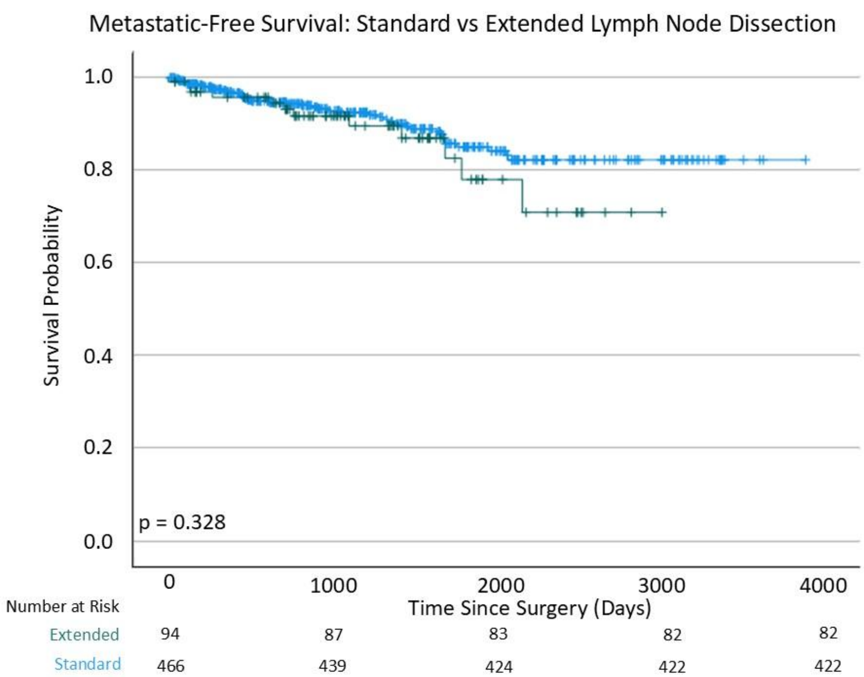

Figure 3. CRPC-free survival based on pelvic lymph node dissection (PLND) type.

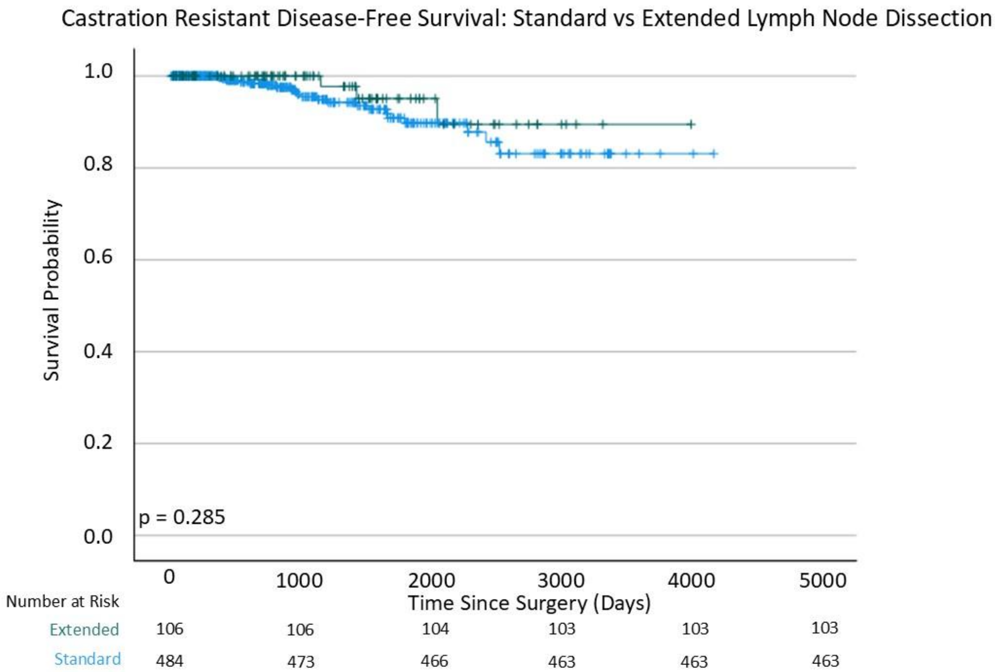

Table 1. Demographic factors			
	Standard (n = 494)	**Extended (n = 107)**	
Patient demographics	**Frequency (%)**		**p**
Clinical T stage			0.90
T1			
T1a	1 (0.2)	1 (0.9)	
T1b	114 (23.1)	13 (12.1)	
T1c	208 (42.1)	44 (44.1)	
T2			
T2a	56 (11.3)	18 (16.8)	
T2b	43 (8.7)	9 (8.4)	
T2c	44 (8.9)	14 (13.1)	
T3			
T3a	8 (1.6)	4 (3.7)	
T3b	–	–	
Missing	19 (3.8)	4 (3.7)	
Pathologic T stage			0.738
T1			
T1a	–	–	
T1b	–	–	
T1c	–	–	
T2			
T2a	35 (7.1)	6 (5.6)	
T2b	10 (2.0)	2 (1.9)	
T2c	95 (19.2)	16 (15.0)	
T3			
T3a	216 (43.7)	53 (49.5)	
T3b	131 (26.5)	30 (28.0)	
T4	4 (0.8)	–	
Missing	3 (0.6)	–	
Pathologic N stage			0.004
N0	429 (86.8)	81 (75.7)	
N1	53 (11.3)	25 (23.4)	
Missing	9 (1.8)	1 (0.9)	
Gleason grade (preoperative)			0.012
Gleason 6	21 (4.3)	3 (2.8)	
Gleason 7 (3+4)	43 (8.7)	9 (8.4)	

Gleason 7 (4+3)	41 (8.3)	16 (15.0)	
Gleason 8	265 (53.6)	41 (38.3)	
Gleason 9/10	119 (24.1)	38 (35.3)	
Missing	5 (1.0)	–	
Gleason grade (postoperative)			0.03
Gleason 6	4 (0.8)	–	
Gleason 7 (3+4)	104 (21.1)	14 (13.1)	
Gleason 7 (4+3)	178 (36.0)	32 (29.9)	
Gleason 8	77 (15.6)	17 (15.9)	
Gleason 9/10	122 (24.7)	41 (38.3)	
Missing	9 (1.8)	3 (2.8)	
Extra-prostatic extension			0.107
Yes	344 (69.6)	83 (77.6)	
No	149 (30.2)	24 (22.4)	
Missing	1 (0.2)	–	
Lymphovascular invasion			0.010
Yes	118 (23.9)	39 (36.4)	
No	367 (74.3)	68 (63.6)	
Missing	9 (1.8)	–	
Active surveillance			0.656
Yes	45 (9.1)	11 (10.5)	
No	436 (88.3)	91 (85.0)	
Missing	13 (2.6)	5 (4.7)	
Neoadjuvant chemotherapy			0.222
Yes	-	1 (0.9)	
No	471 (95.3)	89 (83.2)	
Missing	23 (4.7)	17 (15.9)	
Adjuvant androgen deprivation therapy			0.632
yes	49 (9.9)	9 (8.4)	
No	445 (90.1)	98 (91.6)	
Surgical approach			0.001
Open	211 (42.7)	79 (73.8)	
Robotic-assisted laparoscopic	261 (52.8)	26 (24.3)	
Missing	22 (4.5)	2 (1.9)	
Positive lymph node involvement			0.003
Yes	60 (12.2)	25 (23.4)	
No	429 (86.8)	82 (76.6)	
Missing	5 (1.0)	–	

Margin status			0.361
Positive	184 (37.2)	45 (42.1)	
Negative	309 (62.6)	62 (57.9)	
Missing	1 (0.2)	–	
*Chi-squared test			
	Mean (standard deviation) / Median [minimum, maximum]		
Age	63.8 (5.98)	61.8 (7.18)	0.008
Body mass index	28.3 (4.04)	28.9 (4.3)	0.049
Preoperative PSA	8.97 [0.10, 250.0]	9.90 [0.47, 300.0]	0.347
Prostate volume (CC's)	31.0 [10.0, 150.0]	37.5 [15.0, 180.0]	0.137
Operating room time	153.0 [61.0, 534.0]	153.0 [66.0, 445.0]	0.184
Number of lymph nodes dissected	7.00 [1, 29]	14.0 [1,48]	0.0001
Number of positive lymph nodes dissected	0.19 (0.67)	0.58 (1.17)	0.002
*Mann-Whitney U test			

PSA: prostate-specific antigen.

Table 2. Postoperative complications and complication rate

Complication	**Standard (n=494) n (%)**	**Extended (n=107) n (%)**
Anastomotic urine leak	14 (2.83)	6 (5.61)
Bladder neck dehiscence	1 (0.20)	1 (0.93)
Wound infection/abscess	16 (3.24)	2 (1.87)
Lymphocele	8 (1.62)	5 (4.67)
Surgical bleed	8 (1.62)	2 (1.87)
Hernia	3 (0.61)	0 (0)
Hematuria requiring intervention	5 (1.01)	0 (0)
Venous thromboembolism	1 (0.20)	2 (1.87)
Complication rate	S-PLND: 11.3%	E-PLND: 16.8%
Highest Clavien-Dindo		
Grade 1	18 (32.1)	7 (38.9)
Grade 2	10 (17.9)	2 (11.1)
Grade 3	7 (12.5)	8 (44.4)
Grade 4	–	1 (5.56)

E: extended; PLND: pelvic lymph node dissection; S: standard.