Extended pelvic lymph node dissection at the time of robot-assisted radical prostatectomy: Impact of surgical volume on efficacy and complications in a single-surgeon series

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Abstract

Introduction: We assessed the impact of surgical volume on perioperative outcomes and complications of robotic extended pelvic lymph node dissection (ePLND).
Methods: From November 2008 to October 2012, a total of 233 consecutive patients with intermediate- or high-risk clinically localized prostate cancer underwent robot-assisted radical prostatectomy (RARP) and ePLND by a single, experienced open and laparoscopic surgeon. Data were prospectively collected. Complications were classified according to the Modified Clavien System. Complications potentially related to ePLND were documented. The minimum follow-up was 3 months. To evaluate the impact of surgical volume on the results, 4 patient subgroups (subgroup 1: cases 1–59; 2: 60–117; 3: 118–175; 4: 176–233) were compared using the Chi-squared and Kruskal-Wallis tests.
Results: The mean (range) operative time for ePLND was 79 minutes (range: 48–144), with a steady performance over time ($p = 0.784$). The count of resected lymph nodes plateaued after 60 procedures (mean [range]: 13 [range: 6–32], 15 [range: 7–34], 17 [range: 8–41], 16 [range: 8–42] in Groups 1 to 4, respectively, $p = 0.001$). Tumour lymph node involvement was 12% in Groups 1 and 2, 7% in Group 3 and 9% in Group 4 ($p = 0.075$). Overall, 115 complications were reported in 98/233 patients (42%), with a significant decrease after 175 cases ($p = 0.028$). In Group 4, 3 patients reported an ePLND-related bleeding requiring open revision. Lymphoceles were detected in 10/233 patients (4.2%) and 1 patient (1.7%) in each of the Groups 2 to 4 required a percutaneous drainage.
Conclusions: A surgeon with extensive experience is expected to achieve a safe learning curve for ePLND during RARP. A learning curve of 60 cases is suggested for optimal lymph node yield.

Introduction

Pelvic lymph node dissection (PLND) is the most effective method to detect lymph node metastases in prostate cancer patients undergoing radical prostatectomy.[1] PLND provides appropriate staging and prognostic information to guide postsurgical follow-up and therapy.[1] In addition, PLND has been shown to be curative, or at least beneficial, in patients with limited lymph node metastases.[2-5] Concerning the surgical approach, a recent systematic review of the literature clearly demonstrated that the PLND during robot-assisted radical prostatectomy(RARP) can be performed effectively and safely, providing similar outcomes compared to pure laparoscopic and open procedures.[6-9]

Moreover, several factors, including prior experience in open and/or laparoscopic surgery, type of training and surgical volume, may affect the results of PLND. On the other hand, learning curve may differ from surgeon to surgeon and may depend on patient characteristics. Overall, there is no definitive consensus about the caseload needed to achieve proficiency for PLND, and the lack of appropriate standardization in assessing the learning curve makes comparisons between series difficult and inaccurate.[10]

In the present study, we systematically evaluated the impact of surgical volume on efficacy and safety profiles of extended PLND (ePLND) at the time of RARP in a single-surgeon series.

Methods

Study cohort

We prospectively collected clinical and pathological data from 233 consecutive patients undergoing RARP and ePLND (encompassing obturator, internal iliac, external iliac and common iliac nodes up to ureteral crossing) for intermediate- or high-risk clinically localized prostate cancer at our institution from November 2008 to October 2012. All patients in the learning curve were included, and all procedures were performed by a single, experienced open and laparoscopic surgeon (AM). Patients underwent digital rectal examination, serum prostatic-specific antigen measurement, 10 to 12 biopsies for cancer detection and staging by computed tomography scans of the abdomen-pelvis and bone scan preoperatively. All patients provided written informed consent. Clinical parameters were assessed.

In patients under antiplatelet/anticoagulant therapy, the therapy was discontinued 10 days before surgery. All patients received 2 g of cefazolin before surgery as a single-shot antibiotic prophylaxis and subcutaneous low molecular weight heparin in the upper arm once daily from the day of admission to the day of discharge.

The ePLND was performed in a standardized manner, as previously described.[11] The operative time for ePLND was registered. The histologic investigation began with fat dissolution using an alcohol solution. The identified lymphatic structures and single nodes were fixed in paraffin and sectioned through the point of maximal diameter. Routinely, hematoxylin-eosin stain was used. In patients with unclear findings, an additional immunohistochemistry using pancytokeratin was performed.

Complications were classified according to the Modified Clavien System (Table 1).[12] In particular, ePLND-related complications (obturator nerve injury, bleeding, ureteral injury, deep venous thrombosis, pulmonary embolism, lymphocele) were documented. All patients underwent sonographic follow-up to identify lymphoceles on postoperative days 5 and 10, as well as at 3 and 12 months after surgery. All patients had a minimum of 3 months postoperative follow-up.

Statistical analysis

To evaluate the impact of the single-surgeon learning curve on the results, patients were divided into 4 subgroups (subgroup 1: cases 1–59; 2: cases 60–117; 3: cases 118–175; 4: cases 176–233). Data analysis was performed using the Chi-squared and Kruskal-Wallis tests. Multivariate tests relied on logistic regressions and mixed linear regression models using STATA 12.1 (StataCorp, College Station, TX). Statistical significance was set at $p \leq 0.05$.

Table 1. Modified Clavien classification of surgical complications

Grade	Definition
I	Any deviation from the normal postoperative course without the need for pharmacologic/surgical/radiological intervention
II	Complication requiring pharmacologic treatment
III	Requiring surgical/endoscopic/radiological intervention
IIIA	Intervention without general anesthesia
IIIB	Intervention under general anesthesia
IV	Life-threatening complication requiring intensive care unit management
IVA	Single organ dysfunction
IVB	Multiorgan dysfunction
V	Patient mortality

Results

Baseline demographic characteristics are listed in Table 2. There was a statistically significant difference among the groups with respect to age (Groups 1 and 3 vs. Groups 2 and 4; $p = 0.015$ for all). Additionally, in Group 4, a higher percentage of patients were under antiplatelet/anticoagulant therapy before surgery than in Groups 1 to 3 ($p = 0.014$). Surgical and pathological data are reported in Table 3.

The mean (range) operative time for ePLND was 79 minutes (range: 48–144), and the procedure duration did not significantly decrease with increasing surgical volume ($p = 0.784$) (Fig. 1). A significantly higher number of resected lymph nodes were found after 60 procedures (mean [range]: 13 [6–32], 15 [7–34], 17 [8–41], 16 [8–42] in Groups 1, 2, 3 and 4, respectively; Group 1 vs. Groups 2-4: $p = 0.001$).

Table 2. Baseline demographic characteristics

	Overall	Group 1	Group 2	Group 3	Group 4	*p* value
N	233	59 cases (1–59)	58 cases (60–117)	58 cases (118–175)	58 cases (176–233)	
Age, years, mean (range)	64 (46–76)	63 (46–73)	66 (53–76)	63 (49–74)	65 (53–73)	0.015
BMI (kg/m^2), mean (range)	27 (19–43)	26 (20–39)	26 (19–40)	27 (20–43)	27 (22–35)	0.431
CCI score, n. (%)						
≤1	44 (19)	13 (22)	11 (19)	16 (27)	4 (7)	
2	112 (48)	33 (56)	28 (49)	21 (36)	30 (52)	0.108
3	51 (22)	9 (15)	13 (22)	12 (21)	17 (29)	
≥4	26 (11)	4 (7)	6 (10)	9 (16)	7 (12)	
Antiplatelet/anticoagulant therapy before surgery, n (%)	53 (23)	8 (14)	8 (14)	17 (29)	20 (34)	0.014
PSA, ng/mL, mean (range)	7.7 (0.8–69)	8.2 (1.2–58.4)	8.1 (2.0–69)	6.5 (0.8–69)	9.3 (0.9–42.9)	0.069

Lorem ipsum PSA: prostate-specific antigen; BMI: body mass index; CCI: Charlson Comorbidity Index.

Table 3. Surgical and pathological data

	Overall	Group 1	Group 2	Group 3	Group 4	*p* value
N	233	59 cases (1–59)	58 cases (60–117)	58 cases (118–175)	58 cases (176–233)	
Operative time for RARP + ePLND, minutes, mean (range)	264 (150–475)	320 (200–475)	255 (150–465)	250 (165–400)	240 (169–400)	0.001
Operative time for ePLND, minutes, mean (range)	79 (48–144)	71 (52–132)	92 (70–130)	77 (49–144)	76 (48–120)	0.784
Attempted nerve sparing, n (%)						
All	161 (69)	42 (71)	50 (86)	38 (65)	31 (53)	0.034
Monolateral	95 (41)	23 (39)	37 (64)	17 (29)	18 (31)	
Bilateral	66 (28)	19 (32)	13 (22)	21 (36)	13 (22)	
Pathological stadium, n (%)						
T2	175 (75)	50 (85)	41 (71)	46 (79)	38 (66)	0.063
T3	56 (24)	8 (13)	16 (27)	12 (21)	20 (34)	
T4	2 (1)	1 (2)	1 (2)	—	—	
Dissected lymph nodes, n, mean (range)	15 (6–42)	13 (6–32)	15 (7–34)	17 (8–41)	16 (8–42)	0.001
Positive lymph nodes, n (%)	23 (10)	7 (12)	7 (12)	4 (7)	5 (9)	0.075
Positive margins, n (%)	44 (19)	13 (22)	9 (15)	10 (17)	12 (21)	0.485

RARP: robot-assisted radical prostatectomy; ePLND: extended pelvic lymph node dissection

In total, 115 complications were reported in 98/233 patients (42%), with a significant decrease after 175 cases ($p = 0.028$) (Table 4). Minor complications represented the most frequent events (86/115 complications; 75%) and were still significantly reduced in Group 4 compared to Groups 1 to 3 ($p = 0.011$). Specifically, ePLND-related complications were observed in 5%, 9%, 12% and 10% of patients in Groups 1, 2, 3 and 4, respectively ($p = 0.087$) (Table 5).

Among the 21 ePLND-related complications in 21 patients (9%), minor complications were the most frequent (14/21; 67%), showing a statistically significant improvement in Group 4 ($p = 0.031$). Lymphoceles represented the most common events (10/21 ePLND-related complications; 47%). They were detected in 10/233 patients (4%). Of note, only 1 patient (1.7%) in each of Groups 2 to 4 developed a symptomatic lymphocele requiring treatment by percutaneous drainage. Symptoms due to lymphoceles included infection/fever (Groups 2 and 3) and pelvic pain (Group 4). There was no difference between the right and left ePLND with respect to the occurrence of complications ($p = 0.542$).

Discussion

In prostate cancer patients treated with radical prostatectomy, PLND is considered the most accurate method to determine lymph node status, with a potential therapeutic role by removing metastases.[1-5] However, both surgeon- and patient-related factors may affect the outcomes of PLND. In particular, surgical experience plays a crucial role.[13]

To date, several methodological limitations remain when evaluating the learning curve for urological procedures, including PLND.[10] The most relevant gap is the absence of a shared definition of learning curve and of standardized methods to assess outcomes. Overall, despite the increasing number of trials focusing on robotic surgery,[10] there is little data on the impact of surgical volume on the efficacy and safety profiles of ePLND during RARP.

Defining a surgeon's caseload for achieving proficiency in a new technique is important. To help define this caseload, we analysed the learning curve for robotic ePLND in prostate cancer patients. To the best of our knowledge, this is the first study to prospectively evaluate the association between surgical volume and results for ePLND in RARP using standardized criteria in a single-surgeon series. In fact, any novel approach presents a distinct learning curve for each individual surgeon that differs from the learning curve calculated by analyzing a group of surgeons.

When operative time was used as the outcome variable, the length of surgery did not significantly improve as the surgical volume increased (Table 3). Of note, the longest time (144 minutes) occurred in Group 3, whereas the shortest (48 minutes) in Group 4 (Fig. 1). The absence of a decrease in the ePLND time may indicate the performance of more challenging cases, which are taken on with increased surgeon competence. Indeed, stratifying patients based on risk features proved to be statistically significant, with higher risk cases undergoing ePLND from Group 1 to Group 4 ($p < 0.001$). On the other hand, the ePLND time cannot be very short provided the template is being properly dissected bilaterally.[11]

In contrast, the time for RARP plus ePLND showed a progressive decrease with an increase in the surgeon's experience ($p = 0.001$) (Table 3, Fig. 1). On the whole, this finding could imply the existence of a shorter time-related learning curve for RARP than for ePLND.

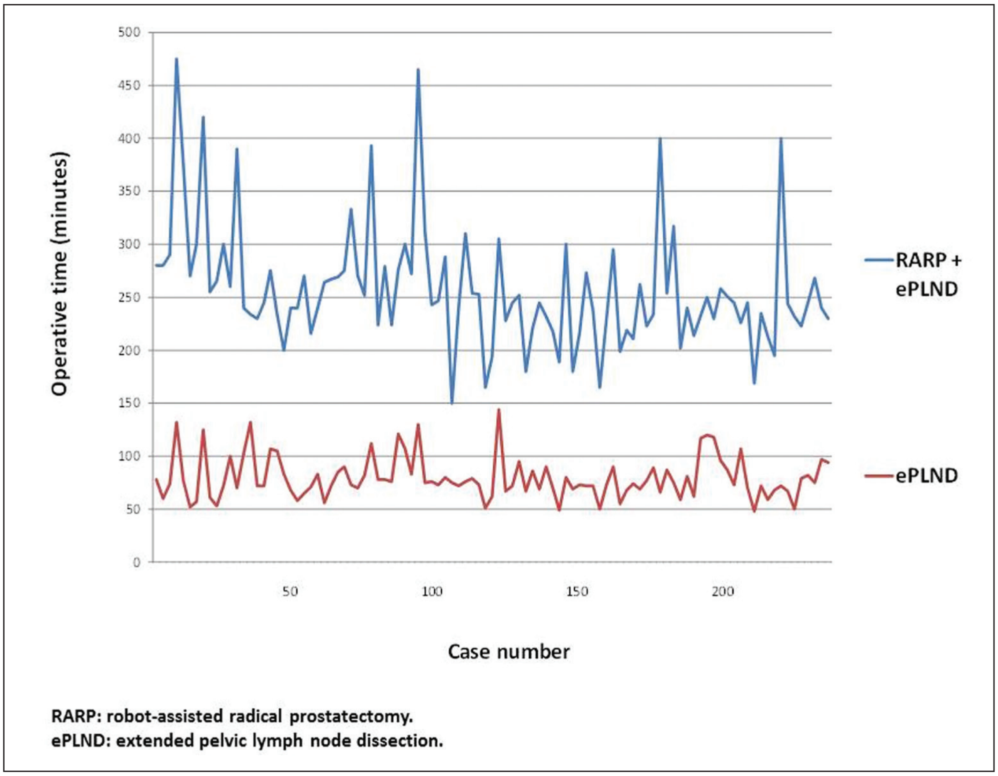

Fig. 1. Length of surgery for robot-assisted radical prostatectomy plus extended pelvic lymph node dissection (ePLND) and ePLND only over the learning curve.

van der Poel and colleagues studied 440 cases treated with ePLND during RARP, in 7 of these cases the console time improved during the first 150 procedures and remained stable thereafter. The number of removed nodes increased from a median 10 (interquartile range [IQR]: 5–30) in the initial 50 cases to a median of 18 (IQR: 6–22) in case numbers 351 to 400. However, they included ePLND procedures performed by 2 surgeons, and such cases did not equally contribute to the series (number of ePLND = 363 vs. n = 77).

In the present series of patients treated by a single surgeon, a mean of 15 (range: 6–42) lymph nodes were removed, with a significantly higher count occurring after 60 procedures ($p = 0.001$). Considering that our patients underwent extended PLND, the count of resected nodes may appear low when compared to other series reporting on ePLND.[8,9,14] However, it must be noted that the number and positivity of the dissected lymph nodes depend on the extent of PLND (as well as individual features of the patient and cancer), and these variables can also be influenced by pathological examination due to inter-institutional differences in lymphatic tissue dissection, collection and pathological processing procedures as recently demonstrated by Meijer and colleagues.[15] Several contiguous lymph nodes, for example, may be counted as a single node in some histological institutes and as more than one in others. Moreover, a large study of PLND for bladder cancer found that if lymph nodes are resected and analyzed en block, rather than as several separate tissue fragments, there is (1) no difference in the overall incidence of lymph node-positive disease and (2) a significant decrease of the total number of nodes counted, even though the same template was used.[16-18] This is probably also true for ePLND in cases of prostate cancer, but no data are available. This could also help explain the difference in lymph node yield between our robot-assisted monoblock technique and the open approach or similar mini-invasive approaches not using a monoblock technique. On the other hand, adherence to the anatomic boundaries of the ePLND template is likely more important than the number of removed nodes, which depends on various factors that often are not controlled.[19]

Conversely, the number of nodal metastases did not increase with accumulating experience (Table 3). In this context, as mentioned above, other variables, such as pathologic evaluation, may contribute to the detection of lymph node invasion. In addition, our percentage of positive lymph nodes (10%) may appear low. However, according to a recent literature review by Ploussard and colleagues,[6] our positivity rate was within the ranges (0–22%) reported in other series.

A potential pathologic bias is not applicable to our study because all of the specimens were analyzed by a single institution using a standardized procedure.

Table 4. Overall intra- and postoperative complications*

	Overall	Group 1	Group 2	Group 3	Group 4	*p* value
N	233	59 cases (1–59)	58 cases (60–117)	58 cases (118–175)	58 cases (176–233)	
Total	**115 in 98 patients (42%)**	**31 in 27 patients (46%)**	**32 in 29 patients (50%)**	**34 in 26 patients (45%)**	**18 in 16 patients (27%)**	0.028
MINOR	**86 in 77 patients (33%)**	**22 in 20 patients (34%)**	**25 in 23 patients (40%)**	**28 in 24 patients (41%)**	**11 in 10 patients (17%)**	
I	55 in 49 patients (21%) Pressure skin redness (47) Lymphocele (7) Sciatic nerve deficit (1)	17 in 16 patients (27%) Pressure skin redness (14) Lymphocele (2) Sciatic nerve deficit (1)	17 in 16 patients (28%) Pressure skin redness (14) Lymphocele (3)	18 in 14 patients (29%) Pressure skin redness (16) Lymphocele (2)	3 in 3 patients (5%) Pressure skin redness (3)	
II	31 in 26 patients (11%) UTI (11) Pressure skin ulcer (6) Obturator nerve deficit (4) Transfusion (3) Humeral nerve deficit (1) Femoralis nerve deficit (1) Addison crisis (1) Sciatic nerve deficit (1) Paralytic ileus (1) Malignant hyperthermia (1) Vein thrombosis (1)	5 in 4 patients (7%) Femoralis nerve deficit (1) Addison crisis (1) Transfusion (1) UTI** (1) Pressure skin ulcer (1)	8 in 6 patients (10%) Pressure skin ulcer (3) UTI** (2) Paralytic ileus (1) Malignant hyperthermia (1) Vein thrombosis (1)	10 in 9 patients (16%) UTI** (5) Obturator nerve deficit (3) Humeral nerve deficit (1) Pressure skin redness (1)	8 in 7 patients (12%) UTI** (3) Transfusion (2) Pressure skin redness (1) Sciatic nerve deficit (1) Obturator nerve deficit (1)	0.011
MAJOR	**29 in 25 patients (11%)**	**9 in 9 patients (15%)**	**7 in 7 patients (12%)**	**6 in 3 patients (5%)**	**7 in 6 patients (10%)**	
IIIa	19 in 15 patients (6%) Urinary retention (6) Pressure skin ulcer (3) Lymphocele (3) Anastomosis stricture (2) Bladder tamponade (2) Postop. hydronephrosis (1) Ureteral injury (1) Myocardial infarction (1)	7 in 7 patients (12%) Pressure skin ulcer (3) Anastomosis stricture (2) Urinary retention (1) Postop. hydronephrosis (1)	6 in 5 patients (10%) Urinary retention (3) Ureteral injury (1) Bladder tamponade (1) Lymphocele (1)	2 in 2 patients (3%) Urinary retention (1) Lymphocele (1)	4 in 3 patients (5%) Bladder tamponade (1) Urinary retention (1) Lymphocele (1) Myocardial infarction (1)	0.375
IIIb	8 in 8 patients (4%) Postoperative bleeding (4) Ureteral injury (1) Port hernia (1) Rectovesical fistula (1) Anastomosis stricture (1)	2 in 2 patients (3%) Ureteral injury (1) Port hernia (1)	1 in 1 patients (2%) Rectovesical fistula (1)	2 in 2 patients (3%) Postoperative bleeding (1) Anastomosis stricture (1)	3 in 3 patients (5%) Postoperative bleeding (3)	
IV	2 in 2 patients (1%) Urinary sepsis (2)	—	—	2 in 2 patients (4%) Urinary sepsis (2)	—	
V	—	—	—	—	—	

*See Table 5 for a listing of the Clavien grades. UTI: urinary tract infection.

Overall, ePLND provides an advantage in terms of cancer cure in selected patients.[2-5] This benefit, however, must be weighed against potential complications.

According to the Modified Clavien System, we identified ePLND-related complications in 21/233 patients (9%) (Table 5). Lymphoceles represented the most common events (10/21 ePLND-related complications; 47%). In particular, as already demonstrated,[20-22] the learning curve for RARP with ePLND is safe also at the beginning of experience and only a limited number (3/10; 30%) of lymphoceles were symptomatic and required treatment by percutaneous drainage. Also, in 4 (2%) patients we observed an obturator nerve deficit, with a full functional recovery during the follow-up. Although the number of neural injuries may seem unusual, this figure can be explained by the strict follow-up we carried on. In fact, we aimed to actively identify every single ePLND-related complication postoperatively. On the other hand, in other series these adverse events are likely not to be reported at all.

On the whole, our incidence of ePLND-related complications fell within the range reported by similar studies (3%–12%).[7-9,23,24] In addition, it must be noted that we included all patients in the learning curve and reported any deviation from the intra- and postoperative standard course

Table 5. Extended pelvic lymph node dissection-related complications*

	Overall	Group 1	Group 2	Group 3	Group 4	*p* value
N	233	59 cases (1–59)	58 cases (60–117)	58 cases (118–175)	58 cases (176–233)	
Total	**21 in 21 patients (9%)**	**3 in 3 patients (5.1%)**	**5 in 5 patients (8.7%)**	**7 in 7 patients (12.1%)**	**6 in 6 patients (10.4%)**	**0.087**
MINOR	**14 in 14 patients (6%)**	**3 in 3 patients (5.1%)**	**4 in 4 patients (7%)**	**5 in 5 patients (8.7%)**	**2 in 2 patients (3.4%)**	
I	7 in 7 patients (3%) Lymphocele (7)	2 in 2 patients (3.4%) Lymphocele (2)	3 in 3 patients (5.3%) Lymphocele (3)	2 in 2 pts (3.4%) Lymphocele (2)	—	
II	7 in 7 patients (3%) Obturator nerve deficit (4) Postoperative bleeding (2) Vein thrombosis (1)	1 in 1 patient (1.7%) Postoperative bleeding (1)	1 in 1 patient (1.7%) Vein thrombosis (1)	3 in 3 patients (5.3%) Obturator nerve deficit (3)	2 in 2 patients (3.4%) Postoperative bleeding (1) Obturator nerve deficit (1)	0.375
MAJOR	**Obturator nerve deficit (4)**	**–**	**1 in 1 patient (1.7%)**	**2 in 2 patients (3.4%)**	**4 in 4 patients (7%)**	
IIIa	Postoperative bleeding (2)	—	1 in 1 patient (1.7%) Lymphocele (1)	1 in 1 patient (1.7%) Lymphocele (1)	1 in 1 patient (1.7%) Lymphocele (1)	
IIIb	Vein thrombosis (1)	—	—	1 in 1 patient (1.7%) Postoperative bleeding (1)	3 in 3 patients (5.3%) Postoperative bleeding (3)	0.015

*See Table 5 for a listing of the Clavien grades.

as complications (including clinically insignificant events, such as asymptomatic lymphoceles not requiring therapy). Without considering those occurrences, our complication rate would drop to 6% (14 adverse events in 14/233 patients).

Not surprisingly, the ePLND-related complication rate did not significantly decrease over time (Table 5). In fact, after the first 60 cases (5% of patients experienced complications), the complication rate skyrocketed to 9% in Group 2 and to 12% in Group 3, whereas it decreased to 10% in Group 4 ($p = 0.087$). Groups 3 and 4 (the latter half of learning curve) were associated with a higher percentage of major complications compared to Groups 1 and 2 (3.4% and 7% vs. 0% and 1.7%; $p = 0.015$), indicating an apparent worsening of the surgeons' performance. In particular, the highest rate of bleeding complications occurred in the latest Group (Table 5) and was associated with the introduction of a new patient-side surgeon.

For these reasons, as suggested by the trend toward higher risk cases undergoing ePLND from Group 1 to Group 4 ($p < 0.001$), more complex cases are being performed over time. In addition, an increasing number of patients on antiplatelet/anticoagulant therapy prior to surgery were observed in the last two Groups ($p = 0.014$). These findings are confirmed by the gradually lowered percentage of nerve-sparing procedures and no significant decrease in positive surgical margin rates due to the inclusion of higher risk cases over time.

This study has its limitations. The specific intraoperative estimated blood loss for ePLND was not available. Our ePLND technique did not provide the exact anatomic location of possible metastatic nodes. Long-term follow-up is required to draw definitive oncological conclusions. One of the major strengths of this study is that all of the procedures were performed by a single surgeon in a consecutive series. This stipulation prevents variability in the outcomes due to including a group of surgeons with different surgical training levels and proficiencies. Therefore, we believe that the results of this study could assist and guide trainers and trainees when introducing ePLND for prostate cancer in similar clinical settings.

Conclusion

Defining the learning curve for any given procedure is required to improve outcomes and to reduce complications when introducing a surgical training program. Our study suggests that a surgeon with extensive open and laparoscopic experience can be expected to demonstrate a safe learning curve for ePLND at the time of RARP. A learning curve of 60 procedures is suggested for lymph node yield. However, long-term follow-up is required to draw definitive oncological conclusions.

Competing interests: Authors declare no competing financial or personal interests.

This paper has been peer-reviewed.

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