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Extended Pelvic Lymph Node Dissection Does Not Affect Functional Outcomes during Bilateral Nerve-Sparing Radical Prostatectomy

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Keywords

Prostate cancer · Prostatectomy · Pelvic lymph node dissection · Potency · Continence

Abstract

Introduction: A possible association between extended pelvic lymph node dissection (ePLND) in radical prostatectomy (RPE) and functional outcomes such as erectile function (EF) and continence recovery has been previously considered. This association stems from the direct proximity of ePLND to the pelvic plexus. In this paper, we aimed to critically examine an association of ePLND with functional outcomes in patients who underwent bilateral nerve-sparing RPE. ***Methods:*** 272 out of 782 patients from a randomized, patient-blinded, multicenter trial were retrospectively classified into two groups based on the D'Amico criteria: 114 had no PLND and 158 had ePLND. Continence (no pad/safety pad) and EF (Index of Erectile Function-5 [IIEF-5] questionnaire ≥17; sufficient erection for sexual intercourse) were assessed at 3, 6, and 12 months as well as postsurgical complications (Clavien-Dindo Classification). ***Results:*** After 12 months of follow-up, no significant difference for potency could be found between men without and subjected to ePLND: IIEF-5 ≥17 (23.2% vs. 27.2%; $p = 0.55$) and sufficient erection for intercourse (44.1% vs. 45.6%; $p = 0.84$). A multiple linear regression analysis demonstrated that while preoperative EF ($p < 0.001$), pathological tumor stage ($p = 0.027$), and robot-assisted bilateral nerve-sparing RPE ($p < 0.001$) were independent predictors of EF recovery, the same did not apply to ePLND. No association was detected for continence recovery (94.2% vs. 89.7%; $p = 0.22$) and complications of any grade after surgery (11.4% vs. 16.5%; $p = 0.24$). ***Conclusion:*** ePLND is not associated with increased risk of erectile dysfunction, incontinence or complications after bilateral nerve-sparing RPE.

Introduction

Radical prostatectomy (RPE) plays a central role in treatment modalities for the majority of men with clinically localized prostate cancer and a life expectancy of at least 10 years [1]. Investigation of long-term results after surgery has been classically assessed under trifecta outcomes, including concomitant oncological, potency, and continence [2]. Pentafecta methodology also considers

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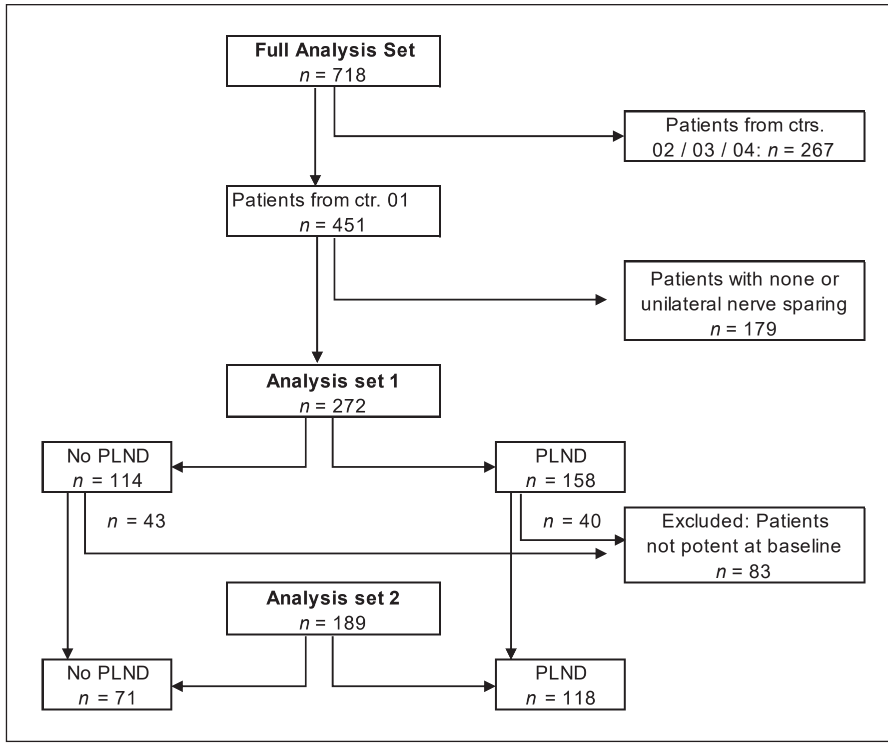

Fig. 1. Flowchart.

complications and surgical margin status alongside the three main outcomes [3]. Recently, discussion has risen about the role of pelvic lymph node dissection (PLND) during RPE and its impact on functional outcomes. Since its establishment in rectal cancer surgery [4, 5], there has been much speculation about PLND and the consequent risk of injury to the pelvic plexus, especially during PLND in the internal iliac area. This area is particularly close to the neural fibers of the pelvic plexus, which is mainly responsible for potency and continence in men [6]. The topographic relationship of the pelvic plexus (also known as the inferior hypogastric plexus) as well as its neural pathways has been repeatedly examined. It comprises of ganglia and nerve fibers that come together forming a homogenous rhombic shaped nerve plate with a diameter of 4–5 cm. The plexus spreads bilaterally between the pelvic sidewalls and organs such as the rectum, seminal vesicles, prostate, and the posterior part of the bladder [7, 8]. The latest evidence suggests that it originates from three different sources: the hypogastric nerve running from the superior hypogastric plexus, the sacral splanchnic nerves from the sacral sympathetic trunk (mostly the S2 ganglion), and the pelvic splanchnic nerves, branching primarily from the third and fourth ventral rami of sacral spinal nerves, forming the parasympathetic cavernous nerves [9, 10]. These nerve branches provide autonomic innervation to the pelvis; therefore, damage to the sympathetic fibers results in ejaculatory dysfunction, whereas injury to the parasympathetic fibers causes urinary and erectile complications. Based on the aforementioned anatomy, the aim of this study was to assess whether ePLND during bilateral nerve-sparing RPE is associated with an increased risk of postoperative erectile dysfunction (ED), incontinence, or complications after surgery compared to patients without ePLND.

Methods

To prove an association between ePLND and functional outcomes as well as complications, we subclassified a study population of 782 patients from a multicenter, randomized, patient-blinded, controlled study (LAP-01) [11] and included all patients who underwent laparoscopic or robot-assisted bilateral nerve-sparing RPE at the University Hospital of Leipzig from November 2014 to April 2019 (shown in Fig. 1, analysis set 1, $N = 272$). The patients were classified into two groups. Low D'Amico risk patients had no PLND (114 from 272; 41.9%), whereas intermediate- and high-risk patients underwent ePLND (158 from 272; 58.1%). Assessment of functional outcomes was done by the patients themselves upon admission for surgery and at 3, 6, and 12 months postoperatively. All data were extracted from case report forms

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Table 1. Clinical characteristics and descriptive statistics of patients included in the study

	Baseline characteristics (full analysis set)				
	all patients (*N* = 272)	no PLND (*N* = 114)	ePLND (*N* = 158)	*p* value	effect measure
Age at surgery, years					
Mean ± SD	62.4±7.0	62.3±7.2	62.5±6.8	0.34	D = −0.03
Range	[44, 75]	[44, 75]	[45, 75]		
BMI, kg/m^2					
Mean ± SD	27.4±3.2	27.2±3.3	27.6±3.1	0.55	D = −0.12
Range	[18.3, 41.0]	[18.3, 34.3]	[22.4, 41.0]		
PSA, preoperative, ng/mL					
Median	7.40	6.47	8.14	<0.001	D = −0.53
Range	[1.60, 54.9]	[1.60, 27.8]	[1.80, 54.9]		
Pathologic tumor stage, *n* (%)					
pT2	231 (85.3)	103 (92.1)	128 (80.9)	0.048	NA
pT3	39 (14.4)	10 (8.9)	29 (18.4)		
pT4	1 (0.4)	0 (0)	1 (0.6)		
Gleason score, *n* (%)					
6	71 (26.2)	59 (52.2)	12 (7.6)	<0.001	NA
7	186 (68.6)	53 (46.9)	133 (84.2)		
≥8	14 (5.3)	1 (0.9)	13 (8.2)		
Preoperative IIEF-5 score, *n* (%)					
≥17	157 (57.7)	58 (50.8)	99 (62.6)	0.083	OR = 0.62
<17	115 (42.3)	56 (49.1)	59 (37.3)		
Preoperative IIEF-5 score					
Mean ± SD	15.9±7.6	14.9±7.8	16.6±7.3	0.041	D = −0.22
Range	[1, 25]	[1, 25]	[1, 25]		
Estimated blood loss, mL					
Mean ± SD	264±150	249±120	275±168	0.015	D = −0.17
Prostate weight, g					
Mean ± SD	51±23	53±23	50±23	0.252	D = −0.11
Operation time, min					
Median	167	156	177	<0.001	Mdif = −27
Range	[86, 364]	[86, 236]	[107, 364]		
Pelvic LNs removed, *n*					
Median	NA	NA	15	NA	NA
Range	[0, 36]	NA	[6, 36]		
Positive LNs, *n* (%)					
No	264 (97.1)	114 (100)	150 (94.9)	NA	NA
≥1	8 (5.1)	0 (0)	8 (2.9)		
pT2	2 (1.3)	0 (0)	2 (0.7)		
pT3	6 (3.8)	0 (0)	6 (2.2)		
Surgical method					
RARP	196 (72.1)	84 (73.7)	112 (70.9)	0.68	OR = 0.87
LRP	76 (27.9)	30 (26.3)	46 (29.1)		

NA, not applicable; Mdif, median difference (Hodges-Lehman); OR, odds ratio; D, Cohen's D (for the logarithmized PSA value).

and medical records. During the follow-up period, participants received their questionnaires by mail and completed them independently at home. After completion, the questionnaires were sent to the study center for data entry into the eCRF [11]. Continence was defined as no use of pads or use of a single safety pad within 24 h. Investigation of complications during surgery was done using the Clavien-Dindo Classification. Regarding erectile function (EF) (shown in Fig. 1, analysis set 2, *N* = 189), only preoperative potent patients who reported sufficient erection for sexual intercourse were included in a subgroup: no PLND (*N* = 71; 37.6%) and ePLND (*N* = 118; 62.4%). To assess EF over the course of 1 year, the International Index of Erectile Function (IIEF-5) questionnaire was used. As recently proposed by Ficarra et al. [12] and used in a vast number of recent studies since [13–15], EF recovery was defined by an IIEF-5 score ≥17 in patients with or without erectile aids. Moreover, we used the single question "Would you describe your

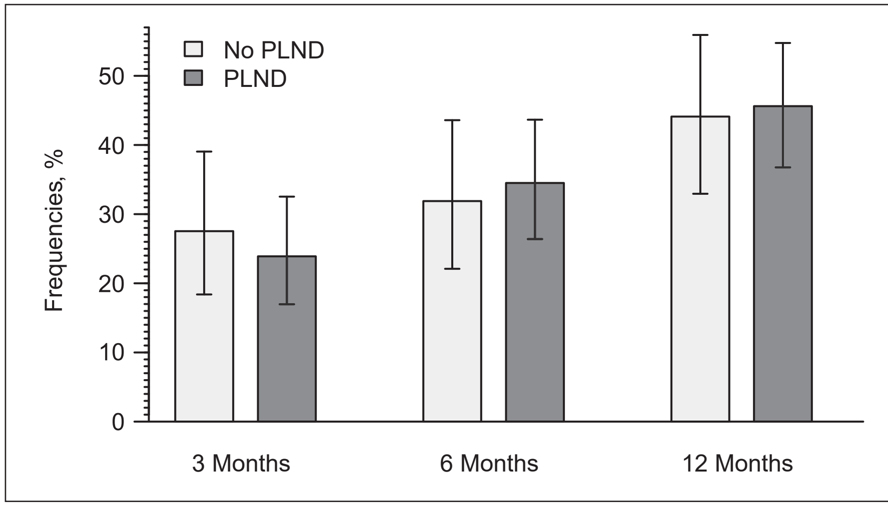

Fig. 2. Recovery of potency defined as "sufficient erection" over 12 months of follow-up. Patients who answered the question "Would you describe your erection as sufficient for sexual intercourse?" before surgery were classified baseline potent.

erection as sufficient for sexual intercourse?" to assess postoperative potency and compare the results of both potency assessment tools.

Nerve-sparing was performed by intrafascial approach in all cases as described by Stolzenburg et al. [16]. According to the current EAU prostate cancer guidelines [17], no PLND was performed in low-risk patients, whereas lymph node (LN) dissection was carried out in all intermediate- and high-risk patients using the D'Amico criteria [18]. Controversy still exists regarding the anatomical limits of PLND. Currently, three variations of PLND exist: limited PLND, standard PLND, and extended PLND. Limited PLND includes only the obturator nodes, while standard PLND includes nodes from both the external and internal iliac artery as well as vein and extends up to the level of iliac vessel bifurcation. Extended PLND, which was performed in our study, additionally includes the presacral nodes as well as the obturator nodes and the common, external, and internal iliac nodes [7]. The statistical analysis is detailed in the supplementary Text (for all online suppl. material, see www.karger.com/doi/10.1159/000526113).

Results

Table 1 provides pathological and clinical characteristics of patients included in the study. Mean patient age was 62.4 years (SD: ±7.0). Men who underwent ePLND (158 from 272; 58.1%) had a significantly higher preoperative PSA level ($p < 0.001$) with a Cohen's D = −0.53 that proves medium association. Furthermore, they showed a higher postoperative Gleason Score ($p < 0.001$) as well as higher pathological T stage ($p = 0.048$), longer operation time ($p < 0.001$), and estimated blood loss ($p = 0.015$) compared to the no-PLND group (114 from 272; 41.9%). Effect measures of the remaining criteria showed weak correlation. The median number of LNs removed during surgery was 15 (range: 6–36). Positive LNs with nodal metastases were found in 2 (pT2) and 6 (pT3) patients out of 158 (5.1%).

Potency Recovery

At a mean follow-up of 12 months, no significant difference in EF recovery between both groups could be found (shown in Fig. 1, analysis set 2, $N = 189$). Potency was defined here by two different criteria, a subjectively sufficient erection and IIEF-5 ≥17. Regarding the mean change of potency defined as "sufficient erection" from baseline to 1 year after surgery (shown in Fig. 2), it decreases at 3 months and slowly improves afterward in both arms. Although at baseline all patients reported sufficient erection, at 3 months of follow-up, it was reported by only 23.9% of patients subjected to PLND, versus 27.5% of patients who did not receive PLND ($p = 0.58$). At 6 months of follow-up, EF was registered by 34.5% versus 31.9% ($p = 0.72$) and at 12 months by 45.6% versus 44.1% ($p = 0.84$) of the patients, respectively (shown in Table 2). Similarly, the course of potency defined by IIEF-5 ≥17 follows the previous one, only that the EF rates are much lower. At 3 months, potency is reported by 13% versus 16.2% ($p = 0.56$) of the patients in the PLND and no-PLND arm. The rates grow over 6 months to 21.2% versus 14.3% ($p = 0.24$) and at 12 months to 27.2% versus 23.2% ($p = 0.55$), respectively (shown in online supp. Table 1). Interestingly, patients who underwent ePLND show even better but not significant potency outcomes. Noteworthily, from 270 patients who answered to both scores pre-OP, the two potency assessment criteria coinced in 226 patients (84%). Following Landis and Koch

Table 2. Potency at 3, 6, and 12 months after surgery defined by the single question "sufficient erection for sexual intercourse"

	Sufficient erection	No PLND		PLND		Total		Difference of proportions, %	95% CI	*p* value
Baseline	No	42	37.2%	39	24.8%	81	30.0%	−12.4	[−23.5%, −1.2%]	0.029
	Yes	71	62.8%	118	75.2%	189	70.0%			
3 months	No	50	72.5%	86	76.1%	136	74.7%	3.6	[−9.5%, 17.0%]	0.58
	Yes	19	27.5%	27	23.9%	46	25.3%			
6 months	No	47	68.1%	74	65.5%	121	66.5%	−2.6	[−16.7%, 11.4%]	0.72
	Yes	22	31.9%	39	34.5%	61	33.5%			
12 months	No	38	55.9%	62	54.4%	100	54.9%	−1.5	[−16.4%, 13.4%]	0.84
	Yes	30	44.1%	52	45.6%	82	45.1%			

Table 3. Continence at 3, 6, and 12 months after surgery

	Continence (no or safety pad use)	No PLND		PLND		Total		Difference of proportions, %	95% CI	*p* value
3 months	No	28	31.8%	36	30.5%	64	31.1%	−1.3	[−14.1%, 11.5%]	0.84
	Yes	60	68.2%	82	69.5%	142	68.9%			
6 months	No	b9	9.7%	23	18.1%	32	14.5%	8.4	[−0.6%, 17.4%]	0.080
	Yes	84	90.3%	104	81.9%	188	85.5%			
12 months	No	6	5.8%	14	10.3%	20	8.4%	4.5	[−2.3%, 11.3%]	0.22
	Yes	97	94.2%	122	89.7%	219	91.6%			

[19], this results in a Cohens's kappa = 0.65 which is defined as "substantial agreement."

In a multiple linear regression analysis (shown in online supp. Table 2), we examined possible association of different variables with IIEF-sum at 12 months after surgery. Importantly, the analysis shows that IIEF-sum is neither associated with ePLND nor the number of removed LNs. These confounders were therefore excluded from further calculation. Nevertheless, the removal of one or more positive LNs was associated with a clinically important yet insignificant decrease of IIEF-sum by 4.9 points. Further analysis results show that patients with higher IIEF-sum at baseline were more likely to recover EF. The IIEF-sum was 0.47 higher per 1 point of the preoperative IIEF-sum. This corresponds to 2.4 for 5 points ($p < 0.001$). A significant decrease of 3.2 points ($p = 0.027$) could be proven for pathological T stage (pT3 vs. pT2) as well as a further decrease of 4.7 points when LRP is performed instead of RARP ($p < 0.001$). These findings are consistent with previous results of the LAP-01 study [11, 20].

Continence Recovery

No statistically significant difference in continence recovery can be demonstrated at any point of time (shown in Fig. 1, analysis set 1; $N = 272$). Noteworthy were the consistently worse continence outcomes in the PLND arm over a 12-month period. At 12 months of follow-up, no pad or safety pad use was reported by 94.2% who did not undergo ePLND versus 89.7% subjected to ePLND ($p = 0.22$) (shown in Table 3).

Complications after Surgery

The patients in the ePLND group had an increased rate of complications (Clavien-Dindo classification): 13 (11.4%) in the no-PLND arm versus 26 (16.5%) patients in the ePLND arm developed complications of any grade ($p = 0.24$) (shown in Fig. 1, analysis set 1; $N = 272$). Most complications were low-grade (grade I) (shown in online supp. Table 3).

Discussion

Aside from being one of the most essential steps in RPE, PLND also provides correct clinical staging to guide treatment after surgery and – though still controversial – could possibly improve the prognosis of patients by eradicating micro metastases [21]. Despite the several advantages offered by PLND, its necessity and the extent of its benefits in patients undergoing RPE remain a widely debated topic in the urological community [22]. The concept that PLND and its extent might negatively impact functional outcomes such as EF or continence occurred first in a review of Heidenreich et al. 2007 [23]. The authors assumed that LN dissection around the iliac area might cause nerve fiber injuries to the pelvic plexus, which was shown to carry both sympathetic and cholinergic nerves controlling erectile, ejaculatory, and bladder neck functions [24].

To examine this hypothesis, we included only preoperative potent patients with sufficient erection for intercourse in a subgroup analysis of 189 out of 782 men from a randomized, multicenter, patient-blinded study [11] and investigated EF for 1 year after surgery. For this consideration, we used the IIEF-5 score ≥17, which is a validated simplified 5-item version of the original IIEF-15 score, consisting of 4 questions concerning EF and 1 addressing sexual intercourse satisfaction. This score aims to clearly discriminate between men with and without ED in a simple way [25]. It has become one of the most commonly used patient-reported diagnostic tools in studies evaluating potency, especially in epidemiological studies with a large number of individuals [26–28]. Based on NIHs definition of potency [29], we further assessed the ability of patients to maintain sufficient erection for sexual intercourse by an according question posed to patients. One year after surgery only 27.2% versus 23.2% ($p = 0.55$) of the patients with and without ePLND recovered potency, whereas for 45.6% versus 44.1% ($p = 0.84$) erection sufficiency for sexual intercourse was registered, respectively. Considering each potency assessment tool, the main curve progression seems to be equal for both categories, whereas the IIEF-5 score outcomes show much lower EF rates in comparison to the data obtained from the single question surrounding erectile sufficiency. This might be since the IIEF-5 score consists of more domains regarding potency which are all counted equally. Therefore, questions that might play a negligible role in patients' lives might have a larger impact. Furthermore, it must be emphasized that the IIEF-5 score is subjective and could be easily influenced by cultural differences in the review and interpretation of the specific terms. A low score could also be the consequence of a patient having an absence of chance or a scarcity of interest in sex rather than ED by itself [28]. With this in mind, our EF rates are much lower when compared to other studies. Nevertheless, a meta-analysis of 21 independent studies from different countries showed ED prevalence in the general population in 32–52%. This prevalence is associated with diabetes, depression, vascular disease, hypertension, and increased age [28]. Moreover, a recent study found potency rates ranging from 31% to 86% after bilateral nerve-sparing RPE even in younger sexually active men with organ-confined disease without preoperative ED [30]. After performing multiple linear regression analysis, our study could not prove any association of potency with ePLND nor the number of dissected or positive LNs.

Contradictory results were carried out by Sagalovich et al. [13] who proved significant difference in potency rates in a subgroup analysis including 29 patients with ≥20 LNs and <20 LNs dissected (55.2% vs. 70%, $p = 0.02$). Limitations of these findings might be the small sample size as well as the difficulties comparing findings as no anatomical location of dissected LNs was specified. Importantly, the definition of potency during the study of Sagalovich et al. [13] has been changed. Patients were seen as preoperative potent with an IIEF-5 score ≥17, whereas the postoperative definition maintained only question 2 and 3 of the IIEF-5 questionnaire which may lead to bias [15]. Furthermore, the EF results were reported after 6 months, but some authors suggest that potency might take longer to recover [6]. No difference in continence outcomes between both groups could be proven (90% vs. 90.2%; $p = 0.845$). The findings fit our numbers of continent patients without and subjected to ePLND (94.2% vs. 89.7%; $p = 0.22$).

Noteworthy, a study of van der Poel et al. [31] reported that patients undergoing ePLND (>10 LNs) were twice as likely to experience ED compared to men with 1–10 removed LNs after 6 months (4.3% vs. 17.8%). Further subgroup analysis with extensive fascia preservation however did not yield a difference in the incidence of ED between the groups. No association with continence has been reported at 6 and 12 months, respectively (98.8% vs. 98.5%; $p = 0.501$). Referring to these results, Gandaglia et al. [6] conclude that while preserving profound nerves, PLND does not affect EF. In their detailed examination of 396 patients undergoing bilateral nerve-sparing RPE no significant association between ePLND and potency could be provided after 2 years of follow-up (46.6% vs. 49.7%, $p = 0.33$), though the association of PLND with continence outcomes was regrettably not assessed. In contrast to our study that adhered to D'Amico criteria, the choice to carry out PLND was left to the surgeons' subjective judgment that may lead to bias. Additionally, the retrospective study design without dissection of the internal iliac vessels might be a limiting fact.

Further multiple regression results of our study showed that independent predictors of potency at 1 year after surgery included preoperative EF with a significant increase of 2.4 points ($p < 0.001$) in IIEF-sum every 5 points at baseline, pathological tumor stage (pT3 vs. pT2) with a decrease of 3.2 points ($p = 0.027$) and operation method with a decrease of 4.7 points for LRP compared to RARP ($p < 0.001$). These results match previous studies, which demonstrated preoperative EF and tumor stage as independent predictors as well as patient age, which we could not prove to be independent [6, 15, 32]. The superiority of RARP for potency outcomes confirms earlier results of the LAP-01 study [11, 20].

We could not prove a significant increase of complications according to Clavien-Dindo scale (no PLND 11.4% vs. ePLND 16.5%; $p = 0.24$). The complication rates match the latest studies that report difficulties in 18.7% versus 12.8% of the patients with and without PLND, respectively [33]. However, Fossati et al. [34] showed conflicting results in a meta-analysis of 15 retrospective studies in which 5 proved that PLND and its extent were associated with a higher rate of intra- and perioperative complications (8.2% vs. 19.8%), such as a rise in blood loss, surgery time, lymphoceles, lymphedema, or morbidity. Further, the authors could not prove any direct therapeutic benefit for patients who underwent PLND. These findings certainly require further examination that allows critical and constructive discussion about the use and need of PLND in the future.

Strengths of our study reside in the fact that we performed subgroup analyses from a multicenter, patient-blinded, randomized trial and assessed data of potency and continence as well as complications. This may lead to a more profound image of already existing study results. We also regarded only patients who underwent bilateral nerve-sparing surgery and included only preoperative potent patients in our subgroup analysis of potency to eliminate any bias on functional outcomes. Another advantage is the implementation of multiple patient-reported assessment tools [11], particularly the use of two different potency assessment tools which enabled us to compare potency outcomes and to examine existing differences. However, our study is not without limitations, which must be acknowledged. By its nature, our study is primarily an explorative one. Thus, it cannot prove any statement according to statistical evidence. However, it may create some hypotheses and support them, respectively. Although our study included a larger patient group in comparison with previous investigations, more data could be provided through recruiting an even more extensive group. Moreover, our results do not apply to patients who did not undergo a bilateral nerve-sparing approach. It must be emphasized that the power of the initial study design of LAP-01 [11] was calculated based on continence and not on potency, and randomization was not stratified based on preoperative potency status.

Conclusion

EPLND is not associated with worse postoperative EF recovery and continence outcomes after bilateral nerve-sparing RPE. Independent predictors of potency are presented by preoperative EF, pathological tumor stage as well as robot assisted RPE. Hence, when an oncological indication is present, PLND can be performed without compromising functional outcomes.

Statement of Ethics

This study protocol was reviewed and approved by Ethik-Kommission Leipzig, Faculty of Medicine Leipzig, approval number 219-2007. We state that written informed consent was obtained from all participants to participate in the study.

Conflict of Interest Statement

The material is original research and has not been previously published or submitted for publication elsewhere. None of the authors have any conflicts of interest to declare, and all of them have read the final version of the manuscript and approved the submission.

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Author Contributions

Jens-Uwe Stolzenburg was the coordinating investigator of the study; Sigrun Holze was the study coordinator, and Meinhard Mende was the biometrician. Sigrun Holze, Jens-Uwe Stolzenburg, and Luise Krieger created the concept and design of the study with the contribution of Meinhard Mende. Supported by the team, Sigrun Holze acquired the scientific data. Statistical data analysis was carried out by Meinhard Mende with the support of Luise Krieger and Sigrun Holze. Literature research was conducted by Luise Krieger, Meinhard Mende, Sigrun Holze, and Jens-Uwe Stolzenburg. Data interpretation was carried out by Meinhard Mende, Luise Krieger, Sigrun Holze, and Jens-Uwe Stolzenburg. Luise Krieger, Jens-Uwe Stolzenburg, Sigrun Holze, and Meinhard Mende prepared the manuscript with support of Hoang Minh Do, Anja Dietel, Toni Franz, and Vinodh-Kumar-Adithyaa Arthanareeswaran. Luise Krieger, Jens-Uwe Stolzenburg, Sigrun Holze, Meinhard Mende, Hoang Minh Do, Anja Dietel, Toni Franz, and Vinodh-Kumar-Adithyaa Arthanareeswaran reviewed and edited the manuscript.

Data Availability Statement

The data that support the findings of this study are stored in the database of the Clinical Trial Centre of the University of Leipzig. They will be made available for meta-analyses on well-founded request to the corresponding author.

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