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Original Article

Robot-assisted versus three-dimensional laparoscopic radical prostatectomy: 12-month outcomes of a randomised controlled trial

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Objectives

To compare functional and oncological outcomes of robot-assisted laparoscopic prostatectomy (RALP) to three-dimensional laparoscopic radical prostatectomy (3D-LRP) at 12 months after surgery.

Patients and methods

Prospective randomised single-centre study of 145 consecutive men referred to radical prostatectomy in a tertiary referral centre in Finland. Patients were randomised 1:1 to the RALP (N = 75) and 3D-LRP (N = 70) groups. The primary outcome was urinary continence evaluated with the Expanded Prostate Cancer Index Composite 26-item version (EPIC-26) incontinence domain score at 12 months after surgery. Secondary outcomes included the use of protective pads at 12 months after surgery, EPIC-26 domain scores of irritative/obstructive, bowel, sexual and hormonal symptoms, positive surgical margin (PSM) rate, and biochemical recurrence (BCR). Complication frequency within the 3-month period after surgery was evaluated according to Clavien–Dindo classification. Statistical significance between groups was analysed using Mann–Whitney, chi-square and Fisher's exact tests. The trial was terminated after interim analysis based on no statistically significant difference in EPIC-26 urinary incontinence domain scores. Altogether 145 patients of the target accrual of 280 patients were recruited.

Results

Postoperative continence at 12 months after surgery according to the EPIC-26 incontinence domain was 79.25 in both groups (P = 0.4). Between group difference was −5.8 (95% confidence interval −15.2 to 3.6). There was no statistically significant difference in the rates of PSM or BCR between the two surgical modality groups.

Conclusion

We were unable to demonstrate a difference between the RALP and 3D-LRP groups for functional and oncological outcomes at 12 months after surgery.

Keywords

laparoscopic prostatectomy, robot-assisted laparoscopic prostatectomy, radical prostatectomy, prostate cancer, functional outcome

Introduction

Prostate cancer (PCa) is the second most common cancer among men globally [1]. Radical prostatectomy (RP) and radiation therapy are the standard treatment options for localised intermediate- to high-risk prostate cancer [2]. The aim of surgical treatment is to eradicate the PCa with as little functional harm as possible. Since its introduction, contemporary anatomical open RP (ORP) evolved with continuous technical improvements and showed good

oncological and functional outcomes [3]. However, ORP is associated with considerable perioperative morbidity, which was the driving force in the utilisation of minimally invasive techniques in PCa surgery [4]. While laparoscopic RP (LRP) was demonstrated to result in benefits of reduced perioperative blood loss and enhanced recovery, conventional LRP remained a technically demanding operation [4]. Improved ergonomics, magnified vision added with depth perception (three dimensional [3D]) and instruments with human wrist-like degrees of freedom, were the technical improvements that overcame the technical challenges of LRP and led to rapid popularisation of the robot-assisted laparoscopic prostatectomy (RALP) [5].

These advantages along with successful marketing and indisputably non-inferior oncological and functional outcomes has resulted in the adoption of RALP as the preferred method of RP in the Western countries [6]. However, this occurred without high-quality direct comparisons with ORP or LRP techniques, and it has also led to a net increase in treatment costs [7]. The outcomes of RALP and ORP have been compared in a large open population-based prospective [8] and in a randomised prospective study [6], both showing identical oncological results of RALP and ORP. Recently, the outcomes of RALP and LRP have been compared in a large randomised multicentre patient-blinded controlled study, which demonstrated better early urinary continence at 3 months and potency at 12 months after RALP [9,10]. The published differences of outcomes between LRP and RALP are likely to be caused by the 3D vision and articulated instruments associated with robot assistance.

Recently, several laparoscopic instrumentations with high-quality 3D vision have become available and the learning curve and functional and oncological outcomes of 3D-LRP have been published [11,12]. We undertook a randomised prospective study to compare the 12-month functional and oncological outcomes between 3D-LRP and RALP in an unselected patient cohort in a tertiary referral centre.

Patients and Methods

A randomised controlled trial (RCT; Clinicaltrials.gov identifier: NCT03550040) was conducted at Tampere University Hospital in Finland between June 2018 and August 2022. The data collection was terminated in September 2022. The primary outcome in this RCT was urinary continence evaluated with the Expanded Prostate Cancer Index Composite 26-item version (EPIC-26) urinary incontinence domain score at 12 months after surgery. Secondary outcomes were oncological results (postive surgical margin [PSM] and biochemical recurrence [BCR] rate determined as a PSA level of ≥0.2 ng/mL), protective pad use, other EPIC-26 domain scores (urinary irritative/obstructive, bowel, sexual and hormonal) between surgical modalities at 12 months after surgery, and the complication frequency within the 3-month period after the surgery evaluated according to the Clavien–Dindo classification of surgical complications [13].

Patient recruitment was done at the Urology Outpatient Clinic by the investigators. Patients between the ages of 35–74 years, with clinically significant PCa in prostate biopsies and without documented metastasis, concomitant malignant illness, and life expectancy of >10 years were offered the possibility to participate in this study. After providing sufficient information, a written consent was obtained. Patients were randomised by using a computer-generated random sequence system. Even or odd randomisation number denoted selection between surgical modalities. All the 3D-LRP procedures in the study were performed by one surgeon (A.K.) with experience of >200 RALPs and >150 3D-LRPs. The RALPs were performed by three different surgeons, with no experience in 3D-LRP but one (J.R.) having performed >1000, one (J.K.) >500, and one (T.P.) >150 RALPs. No specific team for either of the surgical modalities was used. In the 3D-LRPs the Einstein Vision® 3D-system and Harmonic® ultrasonic scalpel was used. All operations in the RALP group were performed with DaVinci® XI surgical system. The operations were performed transperitoneally according to the Vattikuti institute prostatectomy method [5]. The vesicourethral anastomosis (VUA) was made using the Van Velthoven technique [14] in both groups. A Rocco suture [15] was used in the RALP group. The suture material used in creating the VUA was 3-0 poliglecaprone 25 (Monocryl®; Ethicon Inc., Somerville, NJ, USA) in RALP and 3-0 V-LOC® (Medtronic plc, Dublin, Ireland) in 3D-LRP. The decision to execute lymphadenectomy was based on Memorial Sloan Kettering pre-RP nomogram [16]. No drainage tubes were used. The indwelling catheter was kept in situ for 7 days after RALP and 12–14 days after 3D-LRP. If the urine in the catheter bag was bloody on the day of planned catheter removal, the catheterisation period was extended for 1 week, and cystography was performed to confirm integrity of the anastomosis before catheter removal.

Data collection was prospective. Intraoperative data such as total operative time and estimated blood loss (EBL) as well as the length of hospital stay was collected during the hospital stay. The patients had two regular control visits at the outpatient clinic. At 3 months, the immediate recovery, oncological results including PSM, PSA, and complications were evaluated. At the 12-month visit, the EPIC-26 and protective pad use survey were completed and serum PSA was measured. Any adjuvant/salvage treatment prior to a postoperative PSA <0.2 ng/mL was classified as a biochemical failure in both the RALP and 3D-LRP groups.

Urinary continence was chosen as the primary outcome because it is critically important in terms of quality of life

and its evaluation is rather straightforward. The widely used and validated EPIC-26 was utilised as the main outcome measure for other aspects of postoperative quality of life.

Evaluation of the functional results after surgery was based on the EPIC-26 and protective pad use questionnaires. The points for EPIC-26 were calculated using the university of Michigan scoring instructions [17].

Initially, we planned to recruit a total of 280 patients in order to detect a clinically meaningful difference of 10% of urinary continence rate between the surgical modalities at 12 months after surgery. An interim analysis was performed after 50% of the target accrual was recruited. However, as at interim analysis the continence rate of the study groups was identical, we decided to terminate the recruitment and report the results as shown. All patients had a minimum of 12 months follow-up after surgery. The results are presented as medians with interquartile ranges (IQRs) in the Tables. Statistical significance for differences between groups were analysed using Mann–Whitney, chi-square and Fisher's exact tests, all analyses were done using the IBM Statistical Package for the Social Sciences (SPSS®), version 27 (IBM Corp., Armonk, NY, USA).

Results

Functional Results

Postoperative continence at 12 months after surgery according to the EPIC-26 incontinence domain was 79.25 in both groups (P = 0.4). Between group difference was −5.8 (95% CI −15.2 to 3.6). At 12 months after surgery, complete EPIC-26 data were available for assessment for 62 and 64 patients in the RALP and 3D-LRP groups, respectively. The 12-month functional results are presented in Table 2 and in Fig. 1. The median values were in favour of RALP in the bowel and hormonal domains of the EPIC-26 whereas in the 3D-LRP group, the sexual domain values were better. Protective pad was used by 43.3% of the patients in the RALP and 41.7% of the patients in the 3D-LRP group. The degree of nerve sparing (NS) had no significant effect on the 12-month functional outcomes. Overall, there were no statistically significant differences between groups in any of the measured functional outcomes.

Preoperative Results

There were 75 patients randomised to RALP and 70 patients to 3D-LRP. One surgeon (A.K.) operated all the 3D-LRP patients. In the RALP group, the patients were operated in groups of 30, 22 and 23 patients by three surgeons (J.K., J.R., T.P.). Preoperative factors along with tumour International Society of Urological Pathology (ISUP) classifications based on needle biopsies are shown in Table 1. When patients were classified according to European Association of Urology (EAU) risk groups for BCR, 60% of patients in the RALP group had intermediate risk and 38.7% high-risk PCa. In the 3D-LRP group, the corresponding percentages where 61.4% and 34.3%.

Fig. 1 Boxplot of 12-month functional results (RALP vs 3D-LRP). Study population of 145 Finnish patients with PCa undergoing RP at Tampere University Hospital 2018–2021.

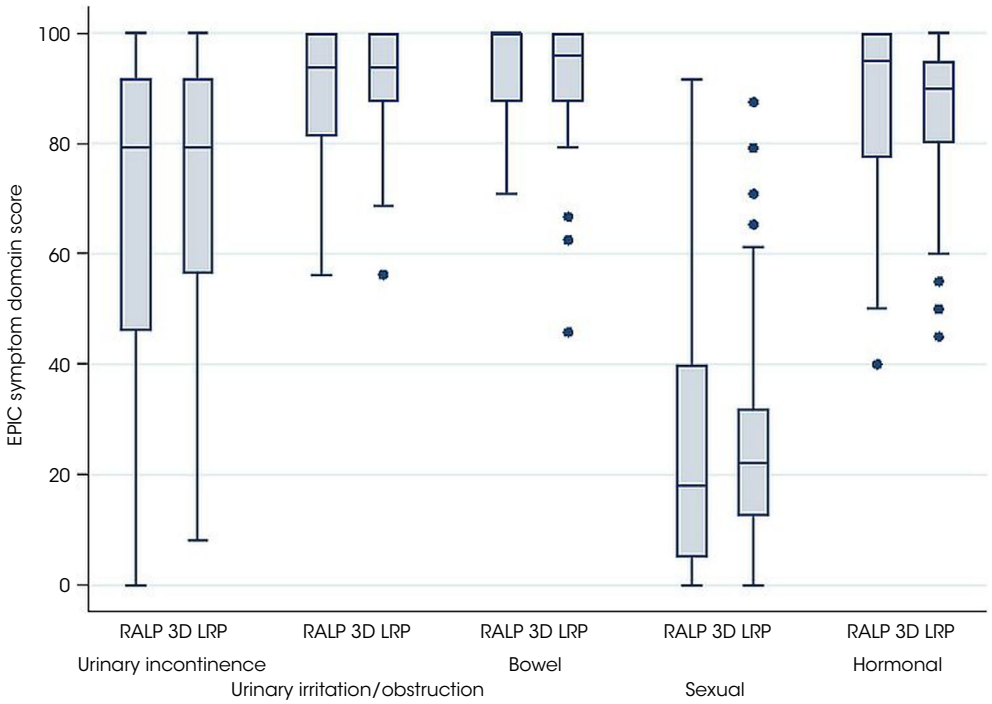

Table 1 Preoperative factors before RP (RALP vs 3D-LRP). Study population of 145 Finnish patients with PCa undergoing RP at Tampere University Hospital 2018–2021.

Variable	Overall study population	RALP	3D-LRP
Patient age, years, *n*	145	75	70
Median (IQR)	66 (61–70)	66 (60–70)	65 (61.8–69)
BMI, kg/m^2, *n*	134	69	65
Median (IQR)	26.9 (24.8–28.9)	27 (24.7–28.9)	26.6 (25–29.9)
Prostate size, mL, *n*	138	71	67
Median (IQR)	34 (29–45)	38 (29–47)	33 (29–45)
PSA level, ng/mL, *n*	145	75	70
Median (IQR)	7.4 (5.7–12.4)	7.4 (5.6–12.6)	7.6 (5.9–12.4)
ISUP classification, *n* (%)	145	75	70
1	7 (4.8)	3 (4.0)	4 (5.7)
2	62 (42.8)	35 (46.6)	27 (38.6)
3	29 (20)	11 (14.7)	18 (25.8)
4	22 (15.2)	11 (14.7)	11 (15.7)
5	25 (17.2)	15 (20)	10 (14.2)

Table 2 Functional results at 12 months after surgery (RALP vs 3D-LRP). Study population of 145 Finnish patients with PCa undergoing RP at Tampere University Hospital 2018–2021.

Variable	RALP	3D-LRP	*P*
EPIC-26 domain			
Urinary incontinence			
N	62	64	
score , median (IQR)	79.25 (44.4–91.75)	79.25 (55.31–91.75)	0.4
Urinary irritative/obstructive			
N	61	63	
score, median (IQR)	93.75 (81.25–100)	93.75 (87.5–100)	0.3
Bowel			
N	61	63	
score, median (IQR)	100 (87.5–100)	95.83 (87.5–100)	0.4
Sexual			
N	61	63	
score, median (IQR)	18 (5–40.17)	22.17 (12.5–32)	0.5
Hormonal			
N	60	61	
score, median (IQR)	95 (76.25–100)	90 (80–95)	0.3
Protective pad 12 months after surgery, *n* (%)	60 (43.3)	60 (41.7)	0.9

Intra- and Perioperative Results

The intraoperative results between groups are presented in Table 3. The difference in EBL (100 mL) and in surgical time (10.5 min) was in favour of RALP with the former being statistically significant. In the RALP group 54.3% and in the 3D-LRP group 45.7% of the patients underwent lymphadenectomy. NS was done bilaterally in 34.7% and unilaterally in 48% in the RALP group and in 35.7% and 35.7% in the LPR group, respectively.

Antithrombotic medication such as acetylsalicylic acid, dipyridamole, clopidogrel, warfarin, apixaban or rivaroxaban was used before surgery by 13 patients in the RALP group and by 10 patients in the 3D-LRP group. There were two patients in the RALP group and three patients in the 3D-LRP group who were taking omega-3 fatty acids. The assistant surgeon was a senior urologist in 33.7%/37.1% and resident in 66.6%/62.9% of the RALP/3D-LRP cases.

After surgery, all the patients in the RALP group and 94.3% of the patients in the 3D-LRP group were discharged from hospital within 2 days. Clavien–Dindo Grade ≥IIIa complications occurred in two patients in the RALP group and four patients in the 3D-LRP group. Among the RALP patients, one patient required treatment in intensive care unit because of acute kidney failure and abscess, and one patient required endoscopic intervention under spinal anaesthesia in the RALP group. In the 3D-LRP group, two patients required endoscopic re-operation because of haematoma and abscess. One patient had urinary catheter changed under spinal anaesthesia and one patient had an abscess drained by an intervention radiologist.

Table 3 Intraoperative and oncological results (RALP vs 3D-LRP). Study population of 145 Finnish patients with PCa undergoing RP at Tampere University Hospital 2018–2021.

Variable	RALP	3D-LRP	*P*
N	75	70	
Operation time, min, median (IQR)	148 (131–186)	158.5 (135–179)	0.5
EBL, mL, median (IQR)	100 (100–200)	200 (100–350)[†]	0.02
Lymphadenectomy, *n* (%)	41 (54.7)	32 (45.7)	
pT Stage, *n* (%)			0.4
T2a	3 (4.0)	1 (1.4)	
T2b	0 (0)	2 (2.9)	
T2c	33 (44)	28 (40)	
T3a	32 (42.7)	28 (40)	
T3b	7 (9.3)	11 (15.7)	
ISUP classification, *n* (%)			0.5
1	5 (6.7)	6 (8.6)	
2	35 (46.7)	34 (48.6)	
3	13 (17.3)	10 (14.3)	
4	5 (6.6)	6 (8.5)	
5	17 (22.7)	14 (20.1)	
pN(+), *n* (%)	5 (6.7)	7 (10)	0.2
PSM, %	29.3	35.7	0.4
pT2	16.7	16.1	
pT3	41.0	51.3	
PSA level <0.2 ng/mL, %			
3 months	90.7	91.4	0.9
12 months	88.0	88.2*	1

*$N = 66$. [†]$N = 68$.

Oncological Results

Oncological results are shown in Table 3. In the 3D-LRP group there were more locally advanced PCas with extraprostatic extension or seminal vesicle invasion. Lymph node involvement was more common in the 3D-LRP group. The PSM rate was higher in the 3D-LRP group, but no statistically significant differences between groups were observed.

Four patients in the 3D-LRP group and two patients in the RALP group had measurable PSA at 3 months with PSM of ISUP ≥2 and/or lymph node involvement of the cancer. With these patients, treatment with salvage radiotherapy, LHRH-analogue or antiandrogen was started with PSA <0.2. At 3 months, 9.3% of the patients in the RALP group and 8.6% in the 3D-LRP group had a PSA of ≥0.2 ng/mL and at 12 months the corresponding percentages were 12% and 11.8%. The difference in BCR proportions between groups at 3 and 12 months was not statistically significant.

Discussion

While RALP has been adopted as the predominant surgical modality of PCa treatment in Western countries, solid evidence of its superiority over other surgical modalities is still scarce. In this study we show that conventional LRP with the aid of 3D vision leads to similar functional and oncological outcomes as RALP.

A recent large prospective study by Stolzenburg et al. [9] compared the functional results of RALP and conventional LRP. The differences in the functional outcomes between surgical modalities were rather modest, which was the case also in the present investigation. However, the return of continence was faster with the robot-assisted technique as was the return of potency [10]. Due to the relatively small size of the present study, we chose not to investigate the rate of continence recovery, but rather the final continence outcomes. As in the Stolzenburg et al. [9] study, no differences in the continence at 12 months were seen. Our study is also consistent with investigations by Rechtman et al. [18] and Chien et al. [19], which showed EPIC-26 outcome scores comparable with our findings at 12 months after RALP.

The determinants of quality of life and satisfaction on the care are subjective measures. As a reflection of this complexity, even the definitions of urinary continence vary [20]. After RP, protective pad use has most often been the measurement method for evaluating continence. In contrast to studies that define urinary continence after RP as use of ≤1 pad/day, we defined continence more strictly as being entirely pad free. While critical, this measure is less prone to subjective interpretations and error. Our figures for pad-free patients at 12 months after surgery were 56.7% in the RALP group and 58.3% in 3D-LRP group. The strict definition of continence in this study makes direct comparison with other investigations difficult, but our previous investigations [11,12]

do indicate that our continence after RALP/3D-LRP data are similar to the data published in other series in Scandinavia [20,21].

There are only a few published studies where the EPIC-26 sexual domain score at 12 months after RP has been used to measure return of sexual function [18,19]. While the domain scores shown here are comparable to previously published results, it is worth noting that previous studies involved more low-risk diseases, where bilateral NS was more often feasible. Indeed, in our study, many patients had high-risk PCas where NS surgery was not indicated. Presumably due to the small size of the subgroups in this investigation, the degree of NS had no significant effect on the 12-month functional outcomes.

The PSM rate in our data was higher than reported by centres of excellence of RALP [22,23], which may to be due our patient cohort consisting of mainly intermediate- and high-risk patients. However, it should be noted that similar PSM rates among pT2 cancers were also reported in the study by Porpiglia et al. [24], which also compared outcomes of LRP and RALP. Similarly, BCR incidence at 12 months after surgery in this series was comparable to previously published results on operated intermediate- and high-risk patients [10,25]. The complication frequency in our study was 5.7% in the 3D-LRP group and 2.67% in the RALP group. With 3D-LRP these figures are higher than those presented in a meta-analysis comparing RALP and LRP, where Clavien–Dindo Grade ≥III varied between 0% and 5.3% [26]. On the other hand, similar frequencies of Clavien–Dindo Grade ≥III complications of 5.25% and 8.5% after RALP have also been reported, which is comparable to our findings [27,28]. Perioperative parameters, such as operation time and EBL of our series is comparable to what has been reported by others [9,29].

The strength of this study is the randomised study design of comparison of outcomes between RALP and 3D-LRP. According to our results, the articulated instruments give no remarkable benefit if most of patients do not undergo a NS operation. However, it must be stated that the lack of articulated instruments is a challenge that the surgeon has to overcome during the learning curve of 3D-LRP [11]. Our patient series reflects the current situation in Finland, where most patients with low-risk cancers undergo active surveillance and those with localised intermediate- or high-risk PCa choose between radiotherapy and RP. In the light of this study, LRP with 3D vision is a good alternative to RALP, at least when NS surgery is not necessary. Indeed, this notion is supported by a recent larger study, where the advantages of robot assistance were shown to lie in the early return of continence and return of potency, both of which are considered to benefit from delicate dissection of the neurovascular bundles [9]. However, it must be remembered that conventional 2D laparoscopy was used in that study and no comparison between 3D-LRP and RALP in this matter is available.

Our study also has limitations. While this study suggests similar functional results between RALP and 3D-LRP, the result must be weighed against the study population, which mostly comprised intermediate- and high-risk PCas not ideally suited for NS surgery. As this study had a smaller accrual than initially planned, we did not present recovery rate of continence. It is therefore possible that the rate of continence recovery of these surgical modalities may vary. In addition, the relatively small size of this study does not allow to state non-inferiority of 3D-LRP when comparing with RALP in terms of surgical outcomes. Blinding of the study subjects to surgical modality was not undertaken, because the Finnish MyKanta website allows patients to see their health data including description of surgical procedures. Even with these limitations, according to our best knowledge, this is the first prospective RCT to compare RALP and 3D-LRP and suggests that LRP is still a valid option in the treatment of localised PCa.

Conclusion

The 3D-LRP and RALP showed similar functional and oncological outcomes at 12 months postoperatively in men with intermediate- to high-risk PCa.

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Disclosure of Interests

Teemu J. Murtola is paid consultant to Astellas, Amgen, Janssen-Cilag, Novartis, Sanofi, Recordati, Pfizer And Ferring. He reports receiving speakers bureau honoraria from Astellas, Amgen, Janssen-Cilag, Merck and Pfizer. He reports congress participation at expense of Sanofi, Orion, and Pfizer. The other authors have no conflicts of interest.

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Abbreviations: BCR, biochemical recurrence; 3D, three-dimensional; EPIC-26, Expanded Prostate Cancer Index Composite 26-item version; IQR, interquartile range; ISUP, International Society of Urological Pathology; NS, nerve sparing; PCa, prostate cancer; PSM, positive surgical margin; RALP, robot-assisted laparoscopic prostatectomy; RCT, randomised controlled trial; (L)(O)RP, (laparoscopic) (open) radical prostatectomy; VUA, vesicourethral anastomosis.