

Embarking with laparoscopic radical prostatectomy and dealing with the complications and collateral problems: A single-center experience

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ABSTRACT

Objective: The aim of the present study was to report our single-center initial experience in laparoscopic radical prostatectomy (LRP) with special emphasis on the complications and collateral problems and their management.

Material and methods: A total of 48 patients (mean age 64 years) underwent LRP in our institution between August 2014 and July 2018. Two surgeons completed a fellowship training program for LRP before. Mentored operations started after the first 10 cases. The patients were divided in two groups of 30 (group I) and 18 (group II) patients. Demographic, preoperative, peroperative, and postoperative data were collected prospectively. Anesthesiology and nurses' team performances, as well as problems and their management, were reviewed.

Results: The demographic data for both groups (group I vs. group II) were similar. Estimated blood loss (695.5 ± 139.23 vs. 398 ± 339.39 mL) and intraoperative complication rates (36.66% vs. 5.55%) were significantly ($p < 0.05$) higher in group I. Conversion to open surgery occurred in 7 (20%) patients in group I and in 1 (5.55%) patient in group II. Continence rates at 12 (83%) months were similar in both groups. Positive surgical margins were 8.33% for pT2 and 27.1% for pT3 stages.

Conclusion: A validated fellowship program before starting LRP and performing the first cases under mentorship are helpful. The complication and conversion rates decrease after 30 cases in addition to the improved experience also with improved cooperation with the anesthesiologist and scrub nurse.

Keywords: Complications; conversion rate; laparoscopic radical prostatectomy; laparoscopy team; surgeons experience.

Introduction

Radical prostatectomy (RP) is the gold standard treatment for organ confined prostate cancer (PCa) with respect to cancer control, complication rates, and functional outcomes.^[1]

Laparoscopic radical prostatectomy (LRP) aims to combine the optimal functional and oncologic results with the renown benefits of minimally invasive laparoscopic surgery.^[2] Extraperitoneal ascending LRP (ELRP) is a technique that combines the laparoscopic approach and open retropubic RP for surgical PCa therapy and was initially described by Raboy et al.^[3] in 1997. The first ELRP series were published

in 2001, with results comparable to those of open RP.^[4] Rassweiler et al.^[5] described their ascending Heilbronn technique for LRP. This technique included dissecting the prostate antegradely starting from the apex of the prostate, as in the open technique.^[5] It has been shown that the learning curve of LRP can be reduced with validated fellowship training programs.^[6]

The Heilbronn Laparoscopy Training Program (HLTP) is a validated well-constructed training program for LRP. Its construct and predictive validity have been described previously.^[7] Two surgeons from our clinic completed in Heilbronn, Germany, a 3 months fellowship program in 2014. After their fellowship, they

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started with their first laparoscopic ascending radical prostatectomies in 2014 in Trakya University Urology Department, where today the approach is established.

Laparoscopic radical prostatectomy is a demanding procedure with a steep learning curve that requires extensive knowledge of prostate anatomy and mastery of laparoscopic skills. The publications about the LRP experiences report higher complication rates in the first series.^[8] The objective of the present study was to report our experience, including complications and their management, along the learning curve.

Material and methods

The study was approved by the ethics committee (Trakya University School of Medicine, 22nd April 2019, TUTF-BAEK-2019-186) in accordance with the Declaration of Helsinki. Written consent was obtained from all of the patients. A total of 48 patients underwent ELP between August 2014 and July 2018 in Trakya University Urology Department. The two surgeons who were involved as first operators (HA and TA) have completed a 3-month HLTP in a high-volume center before the study. The HLTP consists of two steps: (1) hands-on experience on pelvic trainer, simulating different steps of the LRP, such as dorsal vein stitch, and performing urethrovesical anastomosis and (2) a step-by-step mentored training phase in the operation theater.

Brief description of the surgical technique

The patients were operated using the ascending Heilbronn technique.^[5] The patient was positioned in Trendelenburg decline and lithotomy position, with his arms parallel to the body and legs adducted. A rectal balloon catheter was placed, and the patient was prepped and draped. An 18-French Foley catheter was inserted. The first trocar was placed following the Hasson open technique in periumbilical position. The extraperitoneal space was created by a standard space-maker balloon. The first five trocars were placed in a W shape (13 mm umbilical port, 2×10 mm medial, and 2×5 mm lateral ports), and the sixth trocar was placed in the suprapubic region. When indicated, pelvic lymphadenectomy was performed after dissecting the Retzius space. The Briganti score was used for pelvic lymphadenectomy indications.^[9] Then, the dorsal vein complex (DVC) was controlled with a stitch. After a careful apex preparation, the urethra was transected, and the distal pedicles of the prostate were prepared. The cases have been operated by a non-nerve sparing technique. The bladder neck was incised, and the vas deferens and seminal vesicles were accessed. After completing the prostatectomy, urethrovesical anastomosis was performed with two running 3/0 v-loc sutures, according to the van Velthoven technique. A drain was left in the Retzius space,

and the specimen was removed via optic port umbilical incision in an endobag.

Demographic data, including age, preoperative prostate-specific antigen (PSA), clinical staging, prostate volume, Gleason score, American Society of Anesthesiologists score, and Briganti score were documented prospectively (Table 1). Surgical parameters, including the mean operation time, estimated blood loss, intraoperative blood transfusions, and days of hospitalization, were also collected. Pathological staging, postoperative complications, and continence grade during follow-up were reviewed (Table 2). Intraoperative and postoperative complications and their managements were documented separately. Postoperative complications were classified in accordance with Clavien modified by Dindo et al.^[10] and recorded during a close follow-up regarding applied additional therapies and recovery period. We have additionally followed the workflow and initial collateral issues in the operation theater.

It has been reported in the literature that after a validated fellowship program or performing the operations under a mentorship, the surgical experience is improved after the first 30-50

Table 1. Preoperative data

	LRP	Overall	
Preoperative data	1-30	31-48	1-48
Number of patients (n)	30	18	48
Age (years)	64	63.5	64
ASA Score	1.9	1.88	1.89
BMI (kg/m ²)	24.97	27.04	25.75
PSA (ng/mL)	10.26	9.47	9.96
PV(cc)	40.8	43.3	41.75
Biopsy Gleason score (n)			
6	13 (43.3%)	11 (61.1%)	24 (50%)
7a	12 (40%)	5 (27.7%)	17 (35.4%)
7b	4 (13.3%)	2 (11.1%)	6 (12.5%)
8	1 (3.3%)	-	1 (2.1%)
9	-	-	-
10	-	-	-
Clinical stage (n)			
T1c	9 (30%)	1 (5.55%)	10 (21%)
T2a	18 (60%)	6 (33.3%)	24 (50%)
T2c	3 (10%)	11 (61.1%)	14 (29.1%)
Briganti Score	6.17	4.56	5.56

LRP: laparoscopic radical prostatectomy; ASA: American Society of Anesthesiologists; BMI: body mass index; PSA: prostate-specific antigen; PV: prostate volume

cases.^[2,8,11] For this reason, the patients have been divided in two groups with 30 cases in group I and 18 cases in group II. Demographic and surgical data were compared in both groups.

Statistical analysis

Statistical analysis was performed using IBM Statistical Package for Social Sciences for Windows 21.0 package program (IBM SPSS Corp.; Armonk, NY, USA). Continuous data were expressed as mean±standard deviation/median (minimum-max-

imum), and categorical variables were expressed as number (n) and percentage (%). Mann-Whitney U test was used to compare the means between the two groups. Fisher's exact test was used to compare categorical data. A p value <0.05 was considered statistically significant.

Results

A total of 48 patients have been operated using the ELRP Heilbronn technique. The mean age of the patients was 64±5.87 years. The intraoperative and postoperative data of the two groups are shown in Table 2. Estimated blood loss (695.5±139.23 vs. 398±339.39 mL, p<0.01) and intraoperative complication rates (36.66% vs. 5.55%, p=0.018) in groups I and II (Table 3) showed a statistically significant difference. Mean operation times were 241.1±34.13 versus 215.2±55.69 min, p=0.110 in both groups. Conversion to open surgery was required in 7 patients (20% vs. 5.55%, p=0.23) because of uncontrollable bleeding. Postoperative complication rates were 23.33% versus 27.7%. The distribution according to Clavien classification is given in Figure 1. The most frequent postoperative complication was anemia requiring transfusion, occurring in 12.5% of our cases, and was classified as Clavien 2. Additionally, two epididymo-orchitis cases and one wound infection case were observed and classified as Clavien 2. Urethrorectal fistula occurred once and required post-operative reintervention with anesthesia. This was classified as Clavien 3b. Detailed information on each category of complications and their management is provided in Table 4.

Gleason scores were 6 in 39.5%, 7a in 37.5%, 7b in 4.16%, 8 in 10.4%, and 9 in 8.33% of the cases. Tumor stages, according to the TNM 2017 classification system^[12], are summarized in Table 2. The overall positive margin rate was 35.4% (stage pT2a, 2.1%; pT2c, 6.25%; pT3a, 25%; pT3b, 2.1%). Median catheterization time was 12.9±1.2 days, and continence rate at 12 months was 83%.

Table 2. Intraoperative and postoperative data			
Intraoperative and postoperative data	LRP	Overall	
	1-30	31-48	48
Blood loss (cc)	695.5	398	583.9
Operation time (min)	241.1	215.2	231.45
Hospital stay (days)	3.43	5.33	4.14
Remove catheter (days)	7-14	7-14	7-14
Pathology stage (n)			
T2a	2 (6.66%)	6 (33.33%)	8 (16.6%)
T2b	-	-	-
T2c	10 (33.33%)	5 (27.77%)	15 (31.25%)
T3a	14 (46.66%)	5 (27.77%)	19 (39.5%)
T3b	4 (13.33%)	2 (11.11%)	6 (12.5%)
T4a	-	-	-
Gleason score			
6	10 (33.33%)	9 (50%)	19 (39.5%)
7a	11 (36.66%)	7 (38.88%)	18 (37.5%)
7b	2 (6.66%)	-	2 (4.16%)
8	5 (16.66%)	-	5 (10.4%)
9	2 (6.66%)	2 (11.11%)	4 (8.33%)
10	-	-	-
Lymph node dissection(n)			
N0	7 (23.33%)	10 (5.55%)	17 (35.4%)
N1	23 (76.6%)	1 (5.55%)	24 (50%)
PSM* by stage (n)			
T2a	-	1 (5.55%)	1 (2.1%)
T2b	-	-	-
T2c	2 (6.66%)	1 (5.55%)	3 (6.25%)
T3a	7(23.33%)	5 (27.77%)	12(25%)
T3b	-	1 (5.55%)	1(2.1%)
T4a	-	-	-
All stages	9(30%)	8 (44.44%)	17(35.4%)
Continenence rate (n)	25(83%)	15(83.3%)	40(83.3%)

LRP: laparoscopic radical prostatectomy; PSM: positive surgical margin

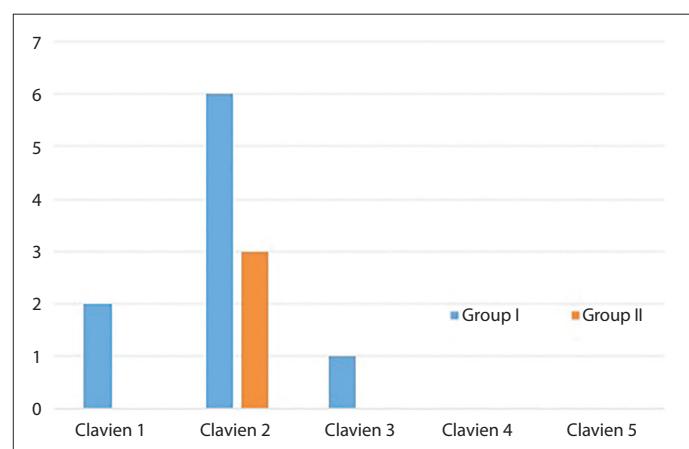


Figure 1. Complication rates by grade in the first and second groups

Table 3. Intraoperative complications and their management

Intraoperative complications	1-30	31-48	Overall	Management
Bleeding	9 (30%)	-	9 (18.75%)	6/9 conversion
			6/9 transfusion	
Rectum injury	1 (3.3%)	-	1 (2.1%)	Primary repair
Obturator nerve injury (5.55%)	-	1		
	1 (2.1%)			Conversion to open, neurolysis by neurosurgery and postoperative physiotherapy
Urether injury	1 (3.3%)	-	1 (2.1%)	Intraoperative DJ catheter

Table 4. Details of Clavien-Dindo complication grades

Complication grade	Management of complications	Rate-n (%)
Clavien 1		2 (4.16)
Lymphorrhea	Long-term drainage	1 (2.1)
Pelvic hematoma	No special therapy	1 (2.1)
Clavien 2		9 (18.75)
Anemia without other reasons	Transfusion	6 (12.5)
Wound infection	Local therapy, Parenteral antibiotics	1 (2.1)
Epididymoorchitis	Parenteral antibiotics	2 (4.16)
Clavien 3a	-	-
Clavien 3b		1 (2.1)
Urethrorectal fistula	Open fistul repair	1 (2.1)
Clavien 4a	-	-
Clavien 4b	-	-
Clavien 5	-	-

Discussion

According to LRP series reported in the literature regarding the early learning curve, intraoperative complication rates are between 1.6% and 6.2%, and early postoperative complication rates are between 5% and 23.7%.^[13,14] Our median intraoperative complication rate was 25% (36.6% in the first group and 5.55% in the second group). Surgical results improved after 30 cases in the second group along with the growing experience of surgeons, as well as of anesthetist and nurses. We have also achieved reduced complication rates in the second group, which is in line with the published literature.

The conversion rates reported for LRP range from 1.2% to 12% in the early cases. The main reasons were bleeding, access injury, and rectum injury.^[15,16] Conversions were mostly reported during the early cases.^[15,17] Bleeding is mainly caused by the

DVC or the neurovascular bundle (NVB).^[15] We have converted 6 (20%) cases of the first group and 1 (5.5%) case of the second group to open surgery (total conversion rate: 14.5%). The reason was uncontrolled bleeding in 4 cases from DVC and in 2 cases from NVB. These 6 patients received blood transfusion intraoperatively and 4 of them also postoperatively. Controlling the DVC with an endoscopic stitch is one of the important steps of LRP. Endoscopic stitching is requiring training before LRP and dedicated skills that can be acquired along specific training events.^[18] We have not experienced any bleeding from DVC in the second group, since the surgeons started to master endoscopic stitching of the DVC. The last conversion occurred because of a misplaced lockable synthetic clip on the obturator nerve during pelvic lymph node dissection which could not be removed laparoscopically.

The obturator nerve injury has been reported in 0.1%-0.8% of LRP cases in the literature.^[2,19] A possible solution is to remove the clip and perform a neurolysis. We have asked neurosurgeons for an intraoperative consultation. We have removed the clip carefully, and the neurosurgeons have performed a neurolysis. The case has been completed uneventful using an open approach.

Rectum injury is one of the feared complications of LRP and reported in 1%-2% of the cases.^[14,20] The reason is mostly due to advanced PCa cases or adhesions after antiandrogen therapy.^[17,20] The intraoperative repair is the best therapy if the injury is identified during the operation.^[21] We had only one case of rectum injury, where the 2 cm lesion was repaired by Vicryl 3/0 sutures in two layers. However, the patient has developed a urethro-rectal fistula after the surgery. We successfully re-operated the patient after 11 months in open fashion in collaboration with the general surgery department.

Ureteral injury is another rare complication during LRP, and its incidence has been reported to be 0.13%-0.5%.^[15,22] The reported injuries mostly have been produced during the posterior bladder neck dissection. Ureter injuries, such as transections, can be treated with end-to-end anastomosis or ureteroneocystostomy.

Cases with small injuries, such as ureter tearing, can be treated also via Double J (DJ) placement.^[15] In our series, we registered one case of ureteral injury (tearing) during the bladder neck dissection, managed during the same operation with a DJ catheter placement through a 5 mm suprapubic trocar, before performing the anastomosis. The DJ catheter has been removed uneventfully after 2 months.

Postoperative complications of LRP are well classified by the Clavien system. In one of the first studies using this system to assess the complications associated with urological laparoscopic surgery, the authors reported a total complication rate of 22.1% after <2700 laparoscopic procedures. Permpongkosol et al.^[23] reported 15% complications following LRP. We have identified a total of 12 (25%) postoperative complications, and our complication rate was similar to the published literature about early LRP series.^[5,11,13]

Lymphorrhea typically occurs in LRP after pelvic lymphadenectomy. The lymphorrhea rate after lymph node dissection during LRP is 0.2%-2.2%.^[15,24] We have observed one patient with lymphocele. Persistent lymphorrhea after the surgery was related to extended lymphadenectomy (Briganti score 12%) for T2a case with Gleason score 8 (4+4) and PSA 22 ng/dL. The lymphorrhea required long-term drainage and persisted after 12 days.

Deep vein thrombosis (DVT) is one of the major postoperative complications of pelvic surgeries. Its incidence was reported in the literature to be 0.3%-0.5% in LRP series.^[15,24] We have seen one patient in our series with DVT who received anticoagulant therapy with low molecular heparin (Clexane 6000 IU/0.6 mL subcutaneous injection, once a day) for 3 months. The patient suffered no further events during and after the therapy.

Blood transfusion in LRP has been reported to be 3%-31% in the literature.^[13,16] The higher rates were from the studies about learning curve. Our overall intraoperative and postoperative transfusion rates were 14.5% and 12.5%, respectively, which is in line with data from the literature. Moreover, the intraoperative transfusion rates are significantly influenced by the indication of the treating surgeon, as well as by the anesthesiologist.^[25] Our anesthesiologists were not specially trained for laparoscopic anesthesia, therefore had a low threshold for a transfusion.

Surgical margin rates were reported as higher during early experience and reaching a plateau after 200-250 cases.^[26] Gregori et al.^[13] published the first 80 LRP cases in 2003 and reported that the rates of positive margins are 5.5% in stage pT2a, 71.4% in stage pT3a, and 70% in stage pT3b. Although our results were similar for T2 tumors compared with their study, we have lower rates of surgical margins for T3 tumors. In the study that presented the oncological parameters of the first 500 cases of ELRP,

it was reported that positive margins rates reached 7.4% for pT2 and 31.8% for pT3 tumors.^[27] Our surgical margin positivity rates are 30% in the first 30 cases and 44.4% in our last cases. In our series, the positive surgical margin ratios were 8.33% for T2 tumors and 27.1% for T3 tumors. We feel that the higher rate of positive surgical margins is also depending on the high number of T2 and T3 cases in our late series.

The reported continence rates after 1 year of the LRP are between 90% and 97%.^[14,16] The continence rate 1 year after the surgery was 83.3% for both the analyzed groups in our series.

Performing a successful LRP has a steep learning curve, and >30 cases are required for qualification. For laparoscopic naive surgeons, the learning curve might be as many as 80-100 cases, extending literally for years.^[28] Validated laparoscopy training programs with modular training has been shown to be effective to get confident with full surgical procedures^[29] and is today an established methodology in surgical education.

We have started with our LRP cases without a mentor in our institution and could manage to organize the presence of a laparoscopic mentor who is experienced in LRP, after our first 10 cases. The guidance of a mentor during the operations has reduced our complication rate drastically. Today, we feel that the first cases should be performed only under a mentorship to contextualize the lessons learned in the simulation laboratory.

We have seen that performing an endoscopic stitch is a critical step during the LRP. Despite our training in a high-volume center, our experience was initially not enough. However, endoscopic stitching can be trained also in the training box in the own institution, and the hands-on training has to be part of the learning pathway for LRP, as suggested internationally.^[18]

Laparoscopy is a team work, and the anesthesiologist and nurses are natural members of this team. We have experienced difficulties in cooperation and related to the missing education and experience in laparoscopy. The communication among the surgeons, anesthesiologists, and nurses during the operation is of utmost importance, and it has been reported that the missing communication can lead to adverse events during the surgery.^[30] We think that the team members should undergo dedicated training sessions before starting with the laparoscopic cases to overcome the problems during the first cases. Creating a team before starting with training would be even better to cover the deficit of theoretical knowledge and optimize the communication between the team members.

In conclusion, LRP is a complicated operation and has a steep learning curve. A validated fellowship program is helpful be-

fore starting with LRP. However, a shorter learning curve can be achieved by performing the first cases under mentored supervision. The complication and conversion rates decrease after 30 cases with growing experience and with improved cooperation with the anesthesiology and nurses' team. Our series confirm also the reproducibility of an established LRP technique with acceptable perioperative morbidity in the initial series.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Trakya University School of Medicine (TUTF-BAEK-2019-186/ 22nd April 2019).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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