



LAPAROSCOPIC RADICAL PROSTATECTOMY: SINGLE CENTER CASE SERIES

Luka Penezić, Tomislav Kuliš, Tvrtko Hudolin, Toni Zekulić, Hrvoje Saić and Željko Kaštelan

Department of Urology, University Hospital Center Zagreb
University of Zagreb School of Medicine, Zagreb, Croatia

ABSTRACT: Laparoscopic radical prostatectomy (LRP) is traditionally characterized as a technically difficult procedure with a long learning curve but it is successfully performed worldwide. The aim of this paper was to assess the initial learning curve and clinical outcomes for LRP in our center. We performed a retrospective study including 63 LRP cases, in the course of 22 months, performed by 2 urologists, with no previous LRP experience. All patients were previously assessed by a multidisciplinary team and were selected on the basis of low and intermediate risk disease attributes according to the classification of prostate cancer risk groups of the European Association of Urology. The main outcomes of follow-up are procedure duration, estimated blood loss, complications, positive surgical margins, biochemical relapse and urinary continence. The median follow-up was 19.6 months. The median procedure duration was 196.8 minutes and median blood loss 257.1 mL. Significant decrease in both outcomes was observed when comparing first and last cases in the series. There were 5 (7.9%) Clavien Dindo grade II complications. Undetectable prostate specific antigen (PSA) was observed in 59 (93.6%) patients, and fifty-five patients (87.3%) were continent. Following a methodical learning approach, LRP can be safely mastered with favorable outcomes.

Key words: Laparoscopy, Radical prostatectomy, Learning curve, Case series

Introduction

Robot-assisted radical prostatectomy (RARP) has almost reached the status of a gold standard in the treatment of localized prostate cancer^{1,2}, but only in developed countries. High purchase cost, expensive maintenance and single-use instruments discourage hospitals with lower budgets, as well as the developing countries to initiate such surgical programs, despite ever present aspirations for this technology. Laparoscopic radical prostatectomy (LRP) is a less expensive, minimally invasive approach, and there is

no conclusive clinical evidence supporting its inferiority to RARP³. LRP has traditionally been associated with a long learning curve and considered a lengthy and difficult procedure without major advantages compared to open prostatectomy⁴. Today, after two decades of technical refinements and technological advantages (high-definition cameras, 3D vision), LRP is performed in many urologic centers across the globe with excellent oncological and functional results⁵. Our center is a high-volume center for upper urinary tract laparoscopic surgery⁶, adrenalectomies⁷ and retroperitoneal lymphadenectomy⁸.

The aim of this paper is to report the oncological and functional outcomes and document the initial learning curve of a case series of LRP in our center where this procedure has not been routinely performed so far.

Corresponding author: *Tomislav Kuliš*
Department of urology, UHC Zagreb
Kišpatičeva 12, 10000 Zagreb, Croatia
e-mail: tkulis@kbc-zagreb.hr

Methods

We performed a retrospective study of LRP cases. The surgeries were performed by two urologists with proficient experience in laparoscopic urological surgery, however, with minimal LRP experience since the procedure hasn't been routinely performed so far in our center. The technique used was a standard extraperitoneal descending LRP using 5 ports⁹, and the vesicourethral anastomosis was formed using two running barbed sutures. The drainage tube was placed in the Retzius space and removed when the secretion was <100mL/24hours.

Every patient with prostate cancer at our center is discussed by a multidisciplinary tumor care team proposing the optimal treatment option for each individual. Clinical staging and treatment modalities are indicated according to the classification of prostate cancer risk groups³ given by the European Association of Urology. The risk of lymph node involvement is calculated using the Novel Briganti Nomogram¹⁰, and for the patients with the risk >7%, we performed laparoscopic limited pelvic lymphadenectomy.

The collected preoperative data included patient demographics, preoperative PSA, clinical stage, Gleason Score and grade according to the International Society of Urological Pathology (ISUP). The preoperative prostate volume was estimated using transabdominal ultrasound. Perioperative data included mean operative time and estimated blood loss (EBL), transfusion rate, addition of lymphadenectomy and nerve sparing (NS) procedures, and the length of hospital stay. Postoperative data included catheter removal time, final pathologic stage, positive surgical margin (PSM) status and Clavien Dindo complications during the postoperative period of 30 days.

The analyzed oncological outcomes were biochemical relapse (BCR), adjuvant and salvage radiotherapy rates. The analyzed functional outcomes were continence rate defined by a number of pads/day (continent: 0-1 pads/day and mild stress incontinence (SI): 2 pads/day), and erectile dysfunction (ED) rate based on the questionnaire¹¹ of Sexual Health Inventory for Men.

The data was obtained from hospital and outpatient records and from telephone interview with the patients during the follow-up period. The study was approved by the Ethical Review Board and conducted in compliance with the ethical principles of the Declaration of Helsinki. Data analysis and visualization was performed using descriptive statistics in Microsoft Excel.

Results

In the period from January 2020 to October 2021, we performed 63 laparoscopic radical prostatectomies. All patients had localized, low and intermediate risk prostate cancer and no contraindications for laparoscopic surgery. Demographic, preoperative and perioperative data are shown in Table 1.

Table 1. Patient demographic, preoperative and perioperative data

Demographic and preoperative data	
Age	Mean 62.6 years (IQR 59-68)
Preoperative PSA	Mean 6.75 ng/mL (IQR 4.76-7.97)
Prostate volume	Mean 37.8 cm ³ (IQR 30-42)
Preoperative clinical T stage	
cT1c	N=32 (50.8%)
cT2a	N=10 (15.9%)
cT2b	N=18 (28.6%)
cT2c	N=3 (4.8%)
Preoperative biopsy report	
ISUP I (GS 3+3)	N=35 (55.5%)
ISUP II (GS 3+4)	N=24 (38.1%)
ISUP III (GS 4+3)	N=4 (6.4%)
Perioperative data	
Operative time (minutes)	Median 196.8 (IQR 165-225)
Estimated blood loss (mL)	Median 257.1 (IQR 180-300)
Blood transfusions	0
Hospitalization length (days)	Median 5.8 (IQR 5-6)
Catheter removal (days)	Median 13 (IQR 12-13)

IQR = interquartile range; PSA = prostate specific antigen; N = number, ISUP = The International Society of Urological Pathology; GS = Gleason score

There were no conversions to open surgery, lymphadenectomy was performed in 2 (2.6%) cases, and we performed 2 (2.6%) NS procedures. Positive surgical

margin rate was 23.8% for the whole group (N=15), whereas 11 patients in the pT2 group (N=54) had PSM (20.3%), 4 patients in the pT3a group (N=8) had PSM (50%) and no PSM was reported in the pT3b group (N=1). During the first 30 postoperative days, we observed 5 (7.9%) Clavien Dindo grade I complications (prolonged drainage (N=3), fever (N=1), urinary retention after catheter removal (N=1)) and 5 (7.9%) Clavien Dindo grade II complications (epididymitis & UTI (N=4), hematoma (N=1)). The median follow-up period was 19.6 months (IQR 18-24).

Undetectable PSA (<0.1ng/mL) was observed in 59 (93.6%) patients, 4 (6.3%) patients had biochemical relapse (PSA >0.2ng/mL) and subsequent salvage radiotherapy, while one patient (1.5%) underwent adjuvant radiotherapy. Fifty-five patients (87.3%) were continent and 7 (11.1%) reported mild SI. An artificial urinary sphincter was implanted in one

(1.6%) case of severe SI. Mild ED was reported by 6 (9.6%) patients, mild to moderate ED by 2 (3.2%), moderate and severe ED by 51 (80.9%) patients, while ED data were unavailable for 4 (6.3%) patients. The operative time and estimated blood loss learning curves are displayed in Figure 1.

Discussion

The learning curve of LRP is considered challenging, and the procedure to be the pinnacle of urologic laparoscopy. Various authors report a range of learning curves, from 38 to 250 cases^{12,13}, but this depends on previous laparoscopic experience and measured outcome. The reasonable figure is proposed by Vallancien *et al.*¹⁴, suggesting at least 50 operations, minimally one case/week during the first year, in order to master urological laparoscopy. We decided to highlight the operative time and estimated blood loss as the primary

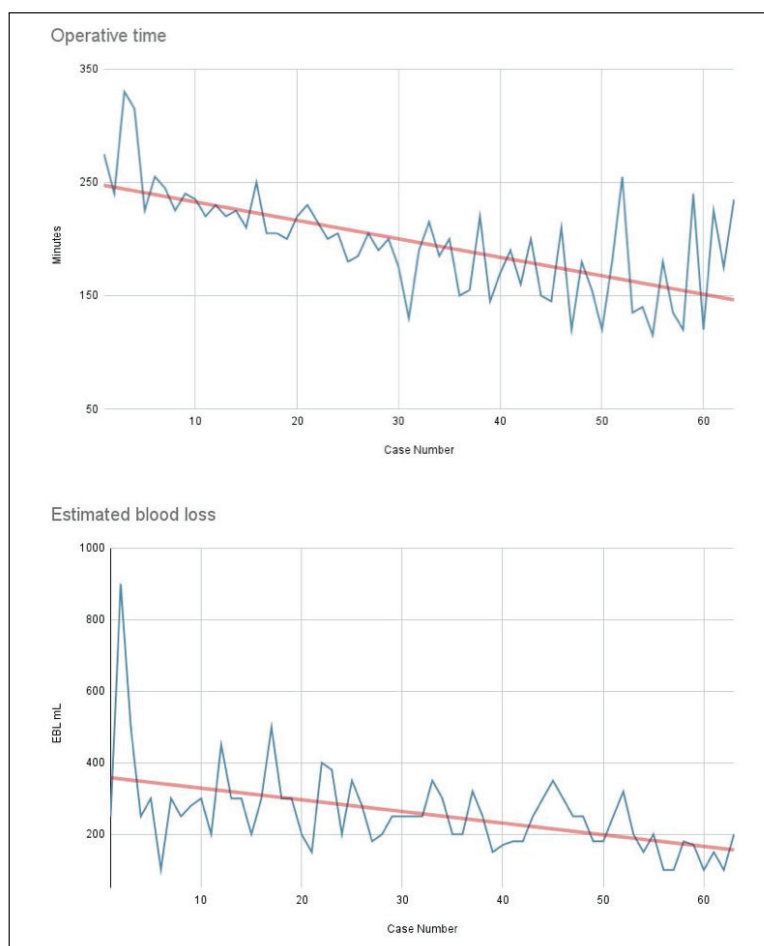


Figure 1. Operative time and estimate blood loss learning curve (EBL = estimated blood loss).

learning curves because this is an initial series of LRP in our center, and the proper analysis of oncological and functional learning curves requires a larger number of cases and longer follow-up period. Our operative time learning curve represents the collective curve of the whole team engaged in the procedure, including surgeons, assistants, scrub nurses and supporting staff, because such a complex procedure is definitely a team effort. Two senior urologists with >10 years of experience in urology spent two weeks observing and assisting LRP in a high-volume center in Slovenj Gradec, Slovenia, prior to starting the programme in our center. There was a significant reduction in operative time from around 250 minutes in initial cases to around 150 minutes in the last few cases in the series. Handmer *et al.*¹⁵ report a decrease in mean operative time needed by the Australian urologists from 193 minutes in the first 100 cases to 163 minutes in the second 100 cases. Since we achieved a similar trend in operative time decrease after a few cases, further reduction of time can be expected with more cases. The median operative time was 196.8 minutes, which is between other reported results, such as 235 minutes by Guazzoni *et al.*¹⁶ and 180 minutes by Jurczok *et al.*¹⁷, but they both included lymphadenectomies more frequently.

Although LRP compared to open radical prostatectomy requires more operative time, LRP has significantly smaller EBL and transfusion rates¹. We report a median EBL of 257.1 mL and no transfusions, compared favorably to international series - EBL from 200mL¹⁷ to 378mL¹⁵ and transfusion rate from 0.8%¹⁵ to 13.3%¹⁶. The EBL learning curve depicts a clear decrease of intraoperative blood loss for the first few cases compared to the last cases. This fact, combined with a low complication rate of 15.8% (and only five (7.9%) Clavien Dindo grade II complications), allows us to state that we have established a safe LRP programme with a minimal risk of serious complications. Jurczok *et al.* report 9.2%¹⁷ and Stolzenburg *et al.* 21%² of overall complications, the latter being mostly low grade.

Positive surgical margins are mostly emphasized as the oncological measure of the quality of the LRP because they are considered an adverse oncological outcome. However, they should be compared and analyzed only on the basis of a subset analysis of the pathological T2 stage and should be minimal, but in reality, the PSM rate of 15% is considered respectable¹⁸. The rate of PSM in our series for pT2 was 20.3

% (11/54), which is comparable to international series - Handmer *et al.* report 9.5%¹⁵, Guillonneau *et al.* 15.4% (120/775)¹⁹, Magheli *et al.* 17.5% (21/120)²⁰, and Jurczok *et al.* 22.9% (16/70)¹⁷. The PSM learning curve is described to plateau after 200 cases²¹.

Biochemical relapse occurred in 6.3% patients, similar to Dahl *et al.* 6.9%²², but this depends on the length of the follow-up and the definition of BCR. Since we report a low incidence of salvage radiotherapy in our cohort, even though the follow-up period was relatively short, this proves the statement that “the impact of PSM on long term survival is highly variable and dependent on other risk modifiers”²³.

The continence affects the quality of life and is an important outcome but it was not reported for LRP in the recent systematic review¹. The most common method of reporting is pad usage¹. In our series with a median follow-up of 19.6 months, the continence rate was 87.3%, which is as good as 88% at 12 months reported by Good *et al.*²¹, 85.5% at 12 months by Guillonneau *et al.*²⁴ and 90% one year after surgery reported by Salomon *et al.*²⁵, but all these reports included more patients (550, 235 and 350, respectively), and NS procedures.

The least successful outcome in our series was the erectile function, but since we performed only 2 NS procedures, it was expected. Post-prostatectomy erectile function depends on various factors that have not been investigated in this report, one of them being the ED before surgery. Every outcome has its own learning curve, and it increases with the complexity of the outcome, with the most complex outcome being erectile function. The pentafecta outcome measure includes: the biochemical recurrence, erectile function, continence, positive surgical margins and complications²⁶. Good *et al.* analyzed the combined learning curve of the pentafecta for NS LRP and concluded that the curve follows the pattern of the most complex outcome (erectile function) which continues to improve even after 250 cases²¹. The erectile function at 3 and 12 months after the procedure is reported at 6.7%² and 52%²¹, respectively, for bilateral NS procedure.

Although RARP is reported to facilitate a shorter learning curve¹, the availability has been its downside since the Da Vinci has been the only robotic system available on the market until recently. Novel robotic systems are emerging, and the one with most RARP reports is the Senhace^{27,28}, with the learning curve reported for 40 procedures²⁸. Laparoscopic surgery isn't a prerequisite for the DaVinci RARP, but can be a major

advantage for Senhance RARP, facilitating a fast and intuitive transition from LRP to RARP²⁸.

Step-wise teaching protocols and formal training, as described in Brazil²⁹ and Australia¹⁵, can be used to optimize and abbreviate the learning curve and effectively teach safe and successful LRP with regard to oncology. Along with the growth of the capacity of surgical technique, the perioperative outcomes are upgrading and the hospital stay getting shorter. The most advanced form of LRP today is day case surgery³⁰, but this approach needs specific organizational requirements regarding patient education and accommodation.

The limitations of our study are related to its design, mainly the lack of control group and randomization, and to a limited number of cases and a relatively short follow-up period, resulting in a low level of clinical evidence for reported results. Nevertheless, this case series represents a real-life initiation of a novel operative technique with favorable and safe surgical results, comparable oncological and functional outcomes. The effort behind such a project must be made at all levels: the patronage of the hospital and department leadership, the enthusiasm of surgeons and assistants, and the support of the operative room staff.

Laparoscopic radical prostatectomy has a traditional reputation of being a difficult procedure with a challenging learning curve, however, with a methodical and diligent approach, the technique can be learned appropriately to benefit the patients with prostate cancer.

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Sažetak

LAPAROSKOPSKA RADIKALNA PROSTATEKTOMIJA: SERIJA SLUČAJEVA JEDNOG CENTRA

L. Penezić, T. Kuliš, T. Hudolin, T. Zekulić, H. Saić i Ž. Kaštelan

Laparoskopska radikalna prostatektomija (LRP) tradicionalno se smatra tehnički zahtjevnom operacijom s dugom krivuljom učenja, ali se uspješno primjenjuje u cijelome svijetu. Cilj rada je prikazati krivulju učenja i ishode liječenja za LRP u našem centru. Proveli smo retrospektivnu studiju koja je uključila 63 pacijenta tijekom 22 mjeseca. Sve zahvate izvela su 2 specijalista urologa bez iskustva u LRP. Uključene pacijente prethodno je procijenio multidisciplinarni tim te su imali karakteristike nisko i srednje rizičnog bolesti prema klasifikaciji karcinoma prostate Europskog urološkog udruženja. Glavni ishodi praćenja bili su trajanje operacije, procijenjen gubitak krvi, učestalost komplikacija, prisutnost pozitivnog kirurškog ruba, biokemijski povrat bolesti i kontinencija mokraćne. Medijan praćenja bio je 19.6 mjeseci. Medijani trajanja operacije i procijenjenog gubitka krvi bili su 196.8 minuta i 257.1 mL. Značajno smanjenje oba parametra zabilježeno je uspoređujući zadnje s prvim slučajevima u seriji. Zabilježeno je 5 (7.9%) Clavien Dindo stupanj II komplikacija. Nemjerljiv post-operacijski prostata specifični antigen (PSA) imalo je 59 (93.6%) pacijenata, a pedeset i pet pacijenata (87.3%) bilo je kontinentno. Prateći metodičan sustav učenja, moguće je na siguran način savladati LRP u zadovoljavajuće ishode liječenja.

Ključne riječi: *Laparoskopija, radikalna prostatektomija, krivulja učenja, serija slučajeva*