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DEFINING A LEARNING CURVE IN LAPAROSCOPIC SIMPLE PROSTATECTOMY

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Resumo

Introduction: Achieving competency in laparoscopic simple prostatectomy (LSP) requires a thorough understanding of the learning curve associated with this minimally invasive procedure. In this study, we aimed to identify the point at which competency is achieved in LSP by analyzing outcomes from our first 101 LSP cases.

Methods: A total of 101 consecutive patients with symptomatic benign prostatic hyperplasia underwent LSP between January 2003 and January 2008. We analyzed prostate volume, International Prostate Symptom Score (IPSS), uroflowmetry, post void residual, mean operative time, estimated blood loss, duration of catheter use, length of hospital stay, and complication rates in this patient subset. The patients were divided into six groups based on the number of cases performed: Group I (cases 1-5), Group II (cases 6-10), Group III (cases 11-15), Group IV (cases 16-25), Group V (cases 26-40), and Group VI (cases >40).

Results: No significant differences were observed between the groups in terms of age, prostate volume, uroflow, or post void residual. However, IPSS scores were significantly different between the groups (p = 0.013). Mean operative time decreased significantly between Group I (115 minutes) versus Group VI (60 minutes) (p < 0.001).

Conclusion: Our study findings demonstrate that laparoscopic simple prostatectomy is a safe procedure with comparable outcomes to open prostatectomy series. The results suggest that the learning curve for this procedure can be achieved with practice, and we estimate that it requires 25 cases to reach competency. These findings can be useful in optimizing training of urologists in LSP.

Palavras-chave: Benign prostatic hyperplasia, adenomectomy, laparoscopic, learning curve

INTRODUCTION

The emergence of minimally invasive surgical techniques has revolutionized the field of urologic surgery, allowing for precise and efficient procedures that result in less pain and quicker recovery times for patients. The increasing popularity of pure laparoscopic and robotic-assisted procedures is a testament to the effectiveness of these techniques, and urologic surgery has been at the forefront of their development.

As with any new approach, the learning curve for minimally invasive procedures is an essential factor to consider when evaluating their efficacy. Experience is crucial in improving the performance of repetitive tasks, and the results of these procedures tend to improve over time (1). However, identifying the point at which the learning curve reaches a plateau is crucial for unbiased evaluation, as early assessments can lead to distorted interpretations that are biased against the new procedure (2).

The concept of the learning curve is, however, not without its limitations. The arbitrary definition of a learning curve as the number of procedures a surgeon must perform to achieve technical proficiency does not take into account the continuous evolution and refinement of surgical techniques. Moreover, the technical complexity of laparoscopic prostate surgeries, in particular, presents a unique challenge to the concept of a learning curve. Several authors have successfully related specific endpoints to surgical mastery (3-5).

Nonetheless, the benefits of minimally invasive techniques for the treatment of benign prostatic hyperplasia (BPH) are clear. Open simple prostatectomy have long been considered the conventional treatment of choice for large glands (>80 mL), according to the guidelines on benign prostatic hyperplasia from the European Association of Urology (6). However, less invasive alternatives, such as laparoscopic approaches and endoscopic anatomic enucleations, such as: holmium laser enucleation of the prostate (HoLEP), have demonstrated similar or better outcomes, highlighting the typical advantages of minimally invasive procedures.

Minimally invasive procedures have proven effective in the treatment of BPH, and their popularity continues to grow. While the concept of the learning curve presents limitations, identifying the point at which the curve reaches a plateau is essential for unbiased evaluation of these techniques.

METHODS

Patient Selection and Data Collection

In this study, we aimed to analyze our early experience with laparoscopic simple prostatectomy. Over a period of five years, from January 2003 to January 2008, data was prospectively collected from 101 consecutive patients who underwent laparoscopic adenomectomy at our institution. All procedures were performed by a team of highly skilled and experienced laparoscopic urologists.

Patient demographics, preoperative indicators including prostate volume measurements by transrectal ultrasonography, symptom score (IPSS scale), uroflowmetry (Qmax) and post-void residual volume (PVR), as well as intraoperative details such as surgical complications, blood loss and operative time were carefully recorded in our database. Postoperative data such as length of hospital stay, catheterization and irrigation times, transfusion rates, and minor and major complications were also collected for analysis.

All patients met the established indications for surgical management of BPH proposed by the European Association of Urology (EAU).

To analyze the learning curve the data was organized as follows: Group 1, first 5 cases; Group 2, cases 6 to 10; Group 3, cases 11 to 15; Group 4, cases 16 to 25; Group 5, cases 26 to 40; and Group 6, cases 40 and higher.

OPERATIVE TECHNIQUE

Several technique modifications have been made since original description in 2004. The laparoscopic extra-peritoneal approach is our preferred route for simple prostatectomy. For this procedure the patient is positioned in supine in the Trendelenburg position under general anesthesia; and to provide access to the rectum, the legs are abducted slightly. An 18Fr urethral catheter and oral gastric tube are placed during the procedure. A 10-mm longitudinal incision is made below the umbilicus and a digital preperitoneal space is performed, followed by further dissection with an 800 cm3 balloon (Autosuture™ Spacemaker™ Plus Dissector System, Tyco Healthcare Group LP, USA). A 10-mm port is inserted through the umbilical incision, and the preperitoneal space is expanded. Insufflation began with a pressure of 12 mmHg. Two 10-mm ports (right lower flank and suprapubic) and one 5-mm port (left lower flank) are placed under direct vision. The urethral catheter is removed and replaced by a Benique bougie to better identify the bladder neck. A transverse incision is made with electrocautery directly on the prostatic capsule. Bipolar electrocautery is used for hemostasis. The anterior and posterior planes between the adenoma and prostatic capsule are developed using blunt and sharp dissection. Once the plane between the prostatic capsule and adenoma is defined, the suprapubic trochar is removed and replaced with the right hand index finger. The double-gloved left hand is inserted in the rectum to elevate the prostate. Insufflation was restored and the suprapubic trochar replaced. Residual attachments at the prostatic apex and bladder neck are released using the laparoscopic shears and enucleation of the specimen is completed. The specimen is routinely placed in an extractor bag (Autosuture™ Endo Catch™, TycoHealthcare Group LP, Norwalk, CT, USA) and extracted through the suprapubic port incision, using morcelation when necessary. Control of bleeding from the prostatic pedicles is achieved with an insufflation pressure of 12 mmHg. Bipolar cautery was used to control any residual bleeding. The prostatic capsule is closed with a 2-0 absorbable continuous suture. A 22F Foley catheter is placed with continuous saline irrigation. A 5-mm tubular drain is placed through the 5-mm port incision and positioned in the space of Retzius and all port sites are then closed.

STATISTICAL ANALYSIS

Variables with normal distributions were described by their mean and standard deviation and compared among the groups using the test of analysis of variance (ANOVA).

The categorical variables were described by their absolute frequencies and percentile relative frequencies. The quantitative variables were described by their median, minimum, and maximum; and compared among the groups by the test of Krukal-Wallis. To determine significance among the multiple comparisons, a rank transformation and later a test of Turkey was used in the transformed variable. A level of significance of 5% was considered statistically significant.

Data were analyzed using SPSS 13.0 (SPSS 13 for Windows, Rel. 13.0 2004 SPSS Inc).

This study received Institutional Review Board approval.

RESULTS

During the study period, only one out of five surgeons performed laparoscopic simple prostatectomies. Of the surgeons who did perform the procedure, one high-volume surgeon (EB) conducted 52 out of 101 procedures, or 51%. All surgeons used a similar technique.

Patient characteristics and details of the six surgical groups are presented in Table 1. There were no significant differences between the groups in terms of age, prostate volume, uroflow, or post-void residual. However, there was a significant difference in terms of IPSS score.

TABLE 1. Patient Characteristics

Characteristics	Group I (1-5)	Group II (6-10)	Group III (11-15)	Group IV (16-25)	Group V (26-40)	Group VI (>40)	Total	p
No. pts.	25	21	16	13	15	12	101	
Mean age (SD)	68.2 (6.7)	69.8 (6.0)	65.9 (6.0)	68.0 (6.7)	67.9 (6.4)	68.0 (4.7)	67.9 (6.0)	.292
Mean cc US prostate vol (SD)	104.7 (47.9)	108.4 (40.3)	107.0 (23.7)	119.5 (26.6)	110.3 (25.4)	111.1 (35.8)	109.3 (35.8)	.866
No. IPSS scale (%)								
mild	1 (5.0)	2 (11.8)	1 (16.7)	4 (36.4)	4 (44.4)	1 (20.0)	13 (19.1)	.013
moderate	8 (40.0)	12 (70.6)	4 (66.7)	6 (54.5)	3 (33.3)	2 (40.0)	35 (51.5)	
severe	11 (55.0)	3 (17.6)	1 (16.7)	1 (9.1)	2 (22.2)	2 (40.0)	20 (29.4)	
No. Urofluxogram (%)								
<10cc/sec	17 (89.5)	15 (93.8)	8 (80.0)	9 (90.0)	8 (88.9)	7 (100)	64 (90.1)	.778
10-15cc/sec	2 (10.5)	1 (6.3)	1 (10.0)	1 (10.0)	1 (11.1)	0 (.0)	6 (8.5)	
>15cc/sec	0 (.0)	0 (.0)	1 (10.0)	0 (.0)	0 (.0)	0 (.0)	1 (1.4)	
No. post-void residual volume (%)								
less than 50 cc	0 (.0)	2 (13.3)	0 (.0)	2 (22.2)	1 (7.7)	2 (20.0)	7 (10.4)	.246
50 - 100 cc	4 (30.8)	4 (26.7)	3 (42.9)	3 (33.3)	4 (30.8)	3 (30.0)	21 (31.3)	
more than 100 cc	9 69.2)	9 (60.0)	4 (57.1)	4 (44.4)	8 (61.5)	5 (50.0)	39 (58.2)	

The study included 101 consecutive patients, with a mean age of 67.9 years (standard deviation [SD], 6.0) and a range of 53 to 80 years. The average prostate volume was 109.3 cm3 (SD 35.8), calculated using trans--rectal ultrasonography. The prevalence of degree symptoms was statistically significant (p=0.013), possibly due to the small number of patients in each subgroup.

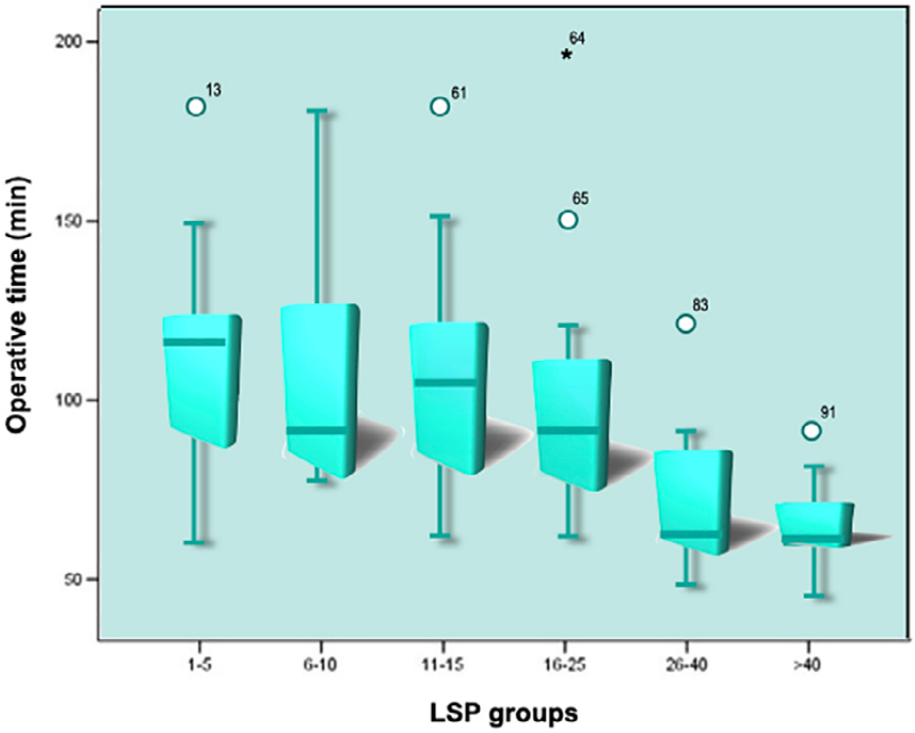
The first group of surgeries was performed in 2003, the second group between 2003 and 2004, the third and fourth groups between 2004 and 2005, the fifth group between 2005 and 2006, and the sixth group between 2006 and 2007.

As shown in Table 2, the overall median operative time was 90 minutes (range, 60-195 min). However, the median operative time and variance of the duration decreased with experience. There was a statistically significant difference in operative times between the groups (p<0.001). In particular, a plateau was reached in terms of surgical duration between groups V and VI (more than 25 cases) compared to the previous four groups (first 25 cases), as shown in Figure 1. The di-

TABLE 2. Operative and Postoperative results

	Group I (n=25)	Group II (n=21)	Group III (n=16)	Group IV (n=13)	Group V (n=15)	Group VI (n=12)	Total	p
Median min. operative time (minimum-maximum)	115 (60-180)	90 (75-180)	102 (60-180)	90 (60-195)	60 (45-120)	60 (45-90)	90 (45-195)	.001
Median mL blood loss (minimum-maximum)	300 (150-2200)	375 (150-2700)	400 (100-1000)	400 (200-2000)	450 (200-1000)	300 (200-500)	400 (100-2700)	.493
Median days irrigation time (minimum-maximum)	2 (1-12)	2 (0-5)	2 (0-6)	2 (0-5)	2 (2-2)	2 (2-5)	2 (0-12)	.423
Median duration (days) of urethral catheter (minimum-maximum)	4 (3-26)	4 (3-10)	5 (3-8)	5 (4-6)	5 (4-7)	5 (4-6)	5 (3-26)	.056
Median days hospital length (minimum-maximum)	5 (3-15)	5 (3-11)	6 (4-9)	7 (5-8)	6 (5-9)	6 (5-8)	6 (3-15)	.271
No. cases convertion (case mumber)	1 (13)	1 (41)	0	1 (64)	0	0		.443
No. transfusion patients (%)	4 (16.0)	3 (15.0)	3 (20.0)	2 (15.4)	1 (6.7)	2 (16.7)	15 (15.0)	.705
No. complications								
minor	5	3	6	8	5	5	32	
major	4	3	2	2	1	0	12	

Figura 1: Operative time. (The box contains the values between the 25th and 75th percentiles. The line across the box indicates the median. The whiskers are lines that extend from the box to the highest and lowest values, excluding unusually high or low values. An outlier case (denoted by a circle) lies between 1.5 and 3 box-lengths from the box edge, and an extreme value lies beyond three box-lengths (denoted by an asterisk).



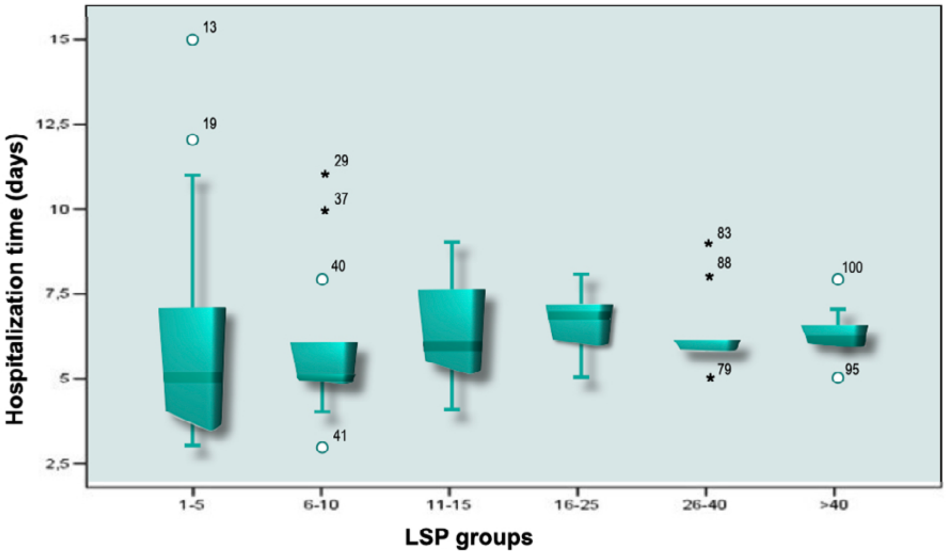
fference between the groups was tested by the Kruskal-Wallis and Turkey tests after a rank transformation.

There were no significant differences among perioperative variables. The median blood loss was 400 mL (mean 503 mL, SD 438 mL, P25th-P75th percentiles, 300-575 mL). The overall average transfusion rate was 15% (15/101). Although not statistically significant, the period of indwelling catheter after LSP tended to vary less after the first 46 patients (P=0.056).

Initially, postoperative care was based on open prostatectomy protocols. However, with experience, a postoperative standardization care and discharge plan was developed that reflected a shorter hospitalization for LSP patients, as shown in Figure 2.

The complications were classified as minor when they fit in the Clavien-Dindo's criteria for Grade I (any deviation from the normal postoperative course without any need for treatment) and Grade II (requiring pharmacological treatment with drugs, such as antibiotics and blood transfusions). Thirty-two minor complications were reported, including 16 Grade I cases of postoperative bleeding treated with electrolytes, and 15 Grade II cases requiring blood transfusions or antibiotics for a urinary tract infection. Major complications were classified as Grade III (requiring surgical, endoscopic or radiological intervention) and Grade IV (life-threatening complications). Twelve major complications occurred, including three episodes of clot retention requiring operative intervention, three patients requiring recatheterization for urinary fistula, one patient needing endoscopic intervention for urinary retention, and two surgical reinterventions for bleeding. Two Grade IV injuries

Figura 2: Length of hospital stay.



occurred, both of which were cardiac arrests that were successfully revived. The patients were admitted to the intensive care unit and discharged home on days 10 and 15, respectively, without further complications.

Three laparoscopic procedures were converted to open procedures. All conversions were necessary to control bleeding [2 transoperative, (cases no. 13 and 64 denoted by asterisks in Figure 4); and 1 immediately after extubation with cardiopulmonary resuscitation (C.P.R.) (case no. 41)]. In case no. 13 C.P.R. was also necessary. There was no mortality, readmissions or incontinence reported in this series.

DISCUSSION

Open prostatectomy is a long-accepted method of treating patients with large hyperplasic glands. Anatomic endoscopic enucleations have demonstrated efficiency and safety for high volume BPH (6). Minimally invasive laparoscopic and endourological enucleations have reproduced similar results to open simple prostatectomy with some clinical advantages (6). The overall success of the laparoscopic simple prostatectomies performed in this study, in terms of low rates of mortality and serious complications, supports the growing evidence that laparoscopic techniques can be a safe and effective alternative to open prostatectomy.

In 1894, Eugene Fuller was the pioneer in suprapubic adenomectomy. However, such procedures were only popularized by Freyer one decade later (7, 8). The retropubic area was not explored during the next forty years until a retropubic simple prostatectomy was first described by Millin in 1947 (9). In 2002, Mariano et al proposed a transperitoneal laparoscopic approach.(10) The same author published their 6-year experience, demonstrating the clinical benefits of minimally invasive surgery. Extraperitoneal access was first described by Van Velthoven et al. (11). They reported their initial experience performing a transcapsular adenomectomy using a harmonic hook scalpel to enucleate the adenoma. In 2003, Njinou et al described a digitally-assisted laparoscopic simple prostatectomy, resulting in shorter operative times.(12) More recently, Sotelo et al reported their initial series treated with robot-assisted transperitoneal simple prostatectomy (13). Since our first description,(10) our technique has been modified to four ports to perform the LSP with the addi-

Figura 3: Surgical complications.

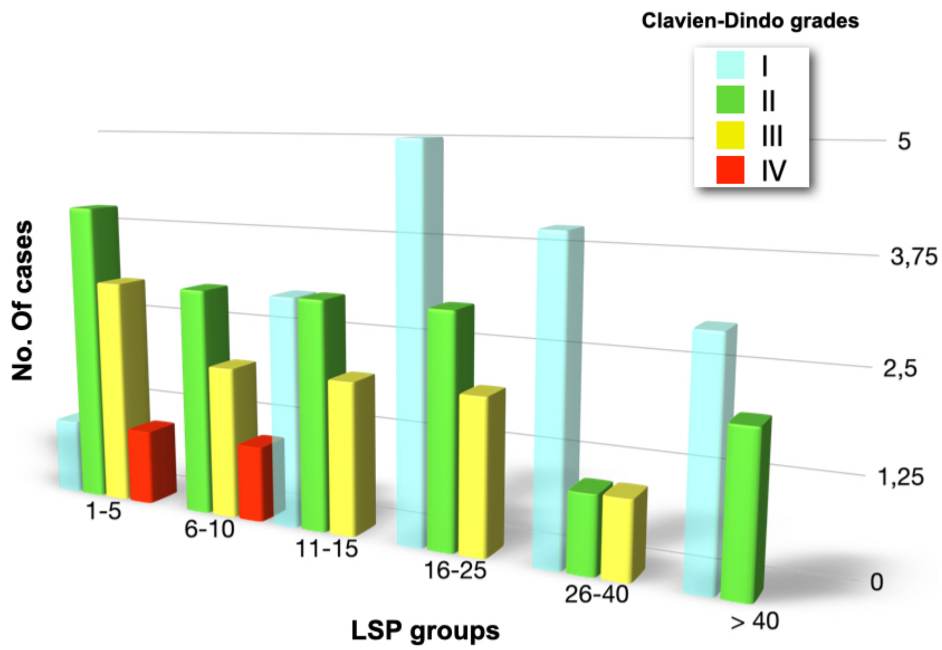
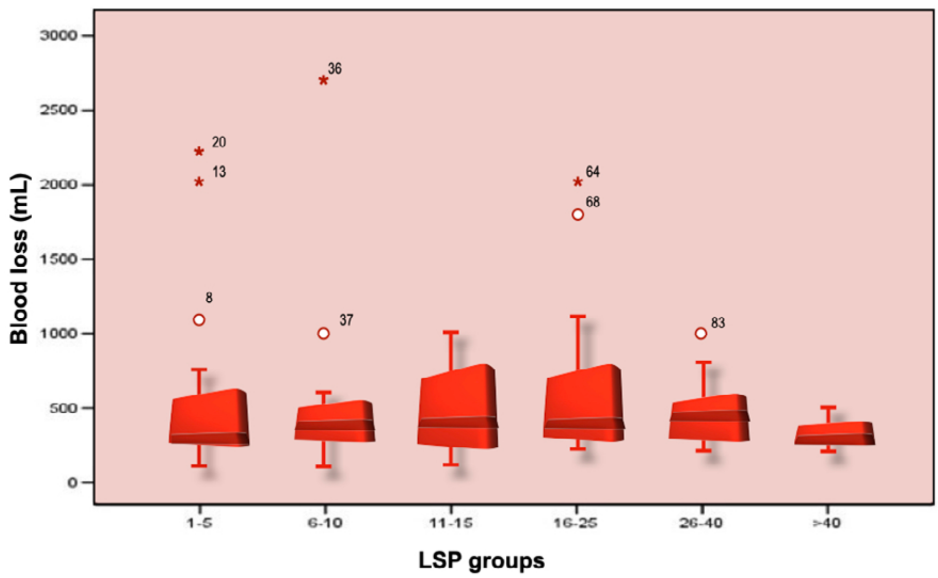


Figura 4: Estimated Blood Loss (mL).



tion of an index finger to assist in the dissection the adenoma.

A longer duration of surgery has been reported in the laparoscopic arm in many other series. Baumert et al compared 30 consecutive laparoscopic adenomectomies versus a retrospective series of 30 open adenomectomies (14, 15). The authors reported a longer operative time in the laparoscopic group (115±30 minutes). However, after an experience with 350 cases, Lufuma et al reported a cohort with 100 patients undergoing LSP with a mean operative time of 66.3 ± 12.3 minutes with a finger-assisted technique.(16) In the present study, after the initial experience, our operative time was similar to the mean operative time in our series for OSP previously presented (15). We observed a mean operative time of 64.1 ± 14.8 minutes after the 25th case. In fact, this difference was statistically significant and this operative time plateau was evident in the final two groups. Therefore, concerning this endpoint, an expertise in laparoscopic simple prostatectomy is achieved after 25 cases.

In general, our results confirm the results presented in previous laparoscopic simple prostatectomy series (16). Major complications tended to decrease with time. The current study reiterates that laparoscopic adenomectomy can be performed safely with minimal risks. We did not observe a decrease in overall morbidity and minor Grade I complications such as blood transfusions and postoperative bleeding.

A potential bias in the present study is the fact that all five urologists are high volume laparoscopic surgeons. Recently, Lombardo et al, also investigate the learning curve of LSP in well-trained laparoscopic surgeons (3).

Mean blood loss in LSP series has been reported to be less than OSP. Porpiglia et al reported a significant difference in blood loss comparing these two approaches (LSP, mean blood loss for laparoscopic group 411mL versus 687mL in open group, P<0.001) (17). However, this was not observed in our hands (P=0.387).(15) A potential explanation is that in our technique there is no pre-emptive vascular control, coupled with blunt finger dissection of the adenoma replicating the open technique—accounting for the increased bleeding and transfusion rates in our series.

This study reported a standardization of postoperative care with experience, evident when examining the length of hospital stay curve. Mean hospital stay tends to have less variation with time. Urethral catheter management and duration of continuous bladder irrigation did not differ with added experience, probably due to uniform care in our department. Nonetheless, both times were shorter than our OSP data (15).

Ideally, surgeons should achieve expertise during residency or fellowship training. Unfortunately, the learning curve of several procedures has been described as too extensive (18-20). Furthermore, the development of new technologies and time constraints for urologists can make the task of achieving expertise even more difficult. In several studies a steep learning curve for laparoscopic radical prostatectomy has been demonstrated (18).

Except for operative time, none of the other parameters have shown changes over time. This fact associated with the laparoscopic approach demonstrates its safety in comparison to open approaches. Our technique combines laparoscopic skills, including transforming the extraperitoneal space and intracorporeal suturing in a restricted field. The successful implementation of LSP in urological residencies hospitals and fellowship programs could help decrease the learning curves for other advanced procedures such as laparoscopic radical prostatectomy. However, the safety of Laparoscopic Millin prostatectomy when performed by urologists with limited experience in laparoscopic procedures during their residency training program, in comparison to the open approach, has not yet been definitively established.

There were no major complication, such as: deaths, readmissions, or cases of incontinence reported in this series of laparoscopic simple prostatectomies. While there were a significant number of minor complications, the majority of these were successfully managed with pharmacological treatments and did not require further intervention. Major complications were relatively rare, with the most common being episodes of clot retention requiring surgical intervention. The overall success of the laparoscopic simple prostatectomies performed in this study, in terms of low rates of mortality and serious complications, supports the growing evidence that laparoscopic techniques can be a safe and effective alternative to open prostatectomy.

This study had limitations, including the small number of patients, single center and surgeries performed by surgeons well trained in pelvic laparoscopic surgeries.

CONCLUSION

In summary, this study suggests that the learning curve for Laparoscopic Simple Prostatectomy (LSP) by experienced laparoscopic urologists may require a minimum of 25 procedures, as evidenced by a marked decrease in operative time. However, it should be noted that other critical parameters such as blood loss, length of stay, urethral catheter duration, and complication rate did not display significant differences with increasing experience. These findings indicate that LSP may serve as a secure steppingstone for surgeons with limited exposure to extraperitoneal space surgeries.

CONFLICT OF INTERESTS

None declared.

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