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Learning Curve for Radical Retropubic Prostatectomy

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ABSTRACT

Purpose: The learning curve is a period in which the surgical procedure is performed with difficulty and slowness, leading to a higher risk of complications and reduced effectiveness due the surgeon's inexperience. We sought to analyze the residents' learning curve for open radical prostatectomy (RP) in a training program.
Materials and Methods: We conducted a prospective study from June 2006 to January 2008 in the academic environment of the University of São Paulo. Five residents operated on 184 patients during a four-month rotation in the urologic oncology division, mentored by the same physician assistants. We performed sequential analyses according to the number of surgeries, as follows: ≤ 10, 11 to 19, 20 to 28, and ≥ 29.
Results: The residents performed an average of 37 RP each. The average PSA was 9.3 ng/mL and clinical stage T1c in 71% of the patients. The pathological stage was pT2 (73%), pT3 (23%), pT4 (4%), and 46% of the patients had a Gleason score 7 or higher. In all surgeries, the average operative time and estimated blood loss was 140 minutes and 488 mL. Overall, 7.2% of patients required blood transfusion, and 23% had positive surgical margins.
Conclusion: During the initial RP learning curve, we found a significant reduction in the operative time; blood transfusion during the procedures and positive surgical margin rate were stable in our series.

Key words: *prostatic neoplasms; prostatectomy; learning; internship and residency; postoperative complications*
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INTRODUCTION

Prostate cancer (PCa) is currently the most common malignant tumor among men in Europe and the United States (US), except for malignant non-melanoma skin tumors. In the US, it is estimated that about 192,280 new cases are diagnosed per year, with 27,360 deaths a year due to PCa, which represents 9% of all cancer deaths in the country per year (1). In Europe, each year there are an estimated 190,000 new cases, with more than 50,000 deaths from the disease (2).

Radical prostatectomy (RP) was the first widely used standard treatment for localized PCa. The classic approach is the retropubic technique. RP was introduced in 1905 by Young and reviewed by Millin in 1946. However, it only became routinely and safely performed in 1982, when Walsh et al. published new technical aspects of the surgery, definitely setting the surgical standards for the treatment of PCa (3). Since then, new techniques and approaches have been developed, such as perineal (4), laparoscopic (5,6) and robotic-assisted RP (7). Throughout the first decade of the 21st century, the use of robotic-assisted surgery has rapidly increased in the U.S. (1), spanning the last three years to Europe (2) and finally to Brazil in 2008 (8).

Subsequently new technological elements have been incorporated into the surgical technique of RP, and increasingly high additional direct and indirect expenses have significantly added to the total cost of the procedure. Notwithstanding the problem of significantly elevated costs, technological complexity incorporated into new techniques may result in a longer or yet unclear learning curve (9).

High costs and a possibly longer learning curve prompted us to question the applicability of these new surgical modalities into clinical practice of our hospitals, especially those related to the public health system of our country. Furthermore, there still lacks a thorough discussion of their unclear benefits to oncologic outcomes and quality of life of patients who undergo minimally invasive procedures (10). To what extent have perineal, laparoscopic or robotic-assisted RP proved superior to the open retropubic approach?

The learning curve in surgery can be defined as the number of cases required to perform the procedure with reasonable operating time and an acceptable rate of complications, resulting in an adequate postoperative clinical outcome associated with a shorter hospital stay. Obviously, several key factors may impact the learning curve, not only such as those related to the surgeon, as attitude, confidence, experience with other surgical procedures, but also those related to the team members involved in the procedures. Undoubtedly, the number of cases performed by the surgeon and the volume of surgeries in a given center may certainly delineate the course of surgical outcomes (11).

RP is a particularly complex surgical procedure and it is assumed to be closely related to the surgical technique employed, depending in part on the surgeon's experience. Currently each RP technique, either open (retropubic and perineal), or minimally invasive (laparoscopic and robotic), present distinctive learning curves for the surgeon.

Due to the wide variation in training formats offered in the various surgical programs in urology, we sought to evaluate the learning curve for open RP among third-year urology residents (fifth year of residency in surgery overall) in a high volume tertiary referral center. We aimed at both defining a minimum number of procedures necessary to properly train the resident surgeon in urology for this procedure, as well as on determining the most sensitive key points of the learning process. As a result, we may be able to continuously improve the teaching process of the surgical technique and make it widely available to mentors and teaching centers, especially considering the social environment of growing ethical concerns with patient safety.

MATERIALS AND METHODS

We conducted a prospective study from June 2006 to January 2008 in the urologic oncology division of the University of São Paulo. Patients with clinically localized prostate adenocarcinoma (cT1-2 Nx M0) with medical conditions for surgical treatment were selected. Five residents operated on 184 patients during a four-month rotation in the urologic oncology division, mentored by the same physician assistants. Patients who had undergone other treatments such as chemotherapy, radiation therapy or biological agents prior or concomitant to surgery and patients with significant neurological, psychiatric disorders, including dementia or seizures, were excluded from the study.

Surgeries were performed following the same surgical technique for radical retropubic prostatectomy, as previously described (11,12). In all surgeries, the residents were assisted by 5 attending surgeons. Fifteen days after hospital discharge, the indwelling catheter and stitches were removed. The first functional evaluation (urinary incontinence) was 60 days after surgery, as well as laboratory tests (PSA value, blood count and serum creatinine).

The length of operative time was measured from skin incision until the completion of the wound dressing. The estimated blood loss was calculated by measuring the volume of the vacuum bottle minus the amount of saline used during surgery. No sponges were used during surgery.

We also assessed the surgical pathology stage and Gleason score, in all cases, as well as positive surgical margin for extracapsular extension. Statistical analysis was performed by using analysis of variance (ANOVA) and the number of surgeries in quartiles: up to 10, from 11 to 19, from 20 to 28 and more than 29 surgeries. Fisher's exact test was applied to evaluate the groups.

Table 1 – Distribution of the number of surgeries performed in accordance with month of training and residents.

	1st Month	2nd Month	3rd Month	4th Month	Total
Resident #1	7	3	12	6	28
Resident #2	12	8	11	10	41
Resident #3	17	9	11	1	38
Resident #4	11	4	6	22	43
Resident #5	12	9	4	9	34
Total	59	33	44	48	184

RESULTS

Each resident participated in the study during four consecutive months and, on average, each one of them performed 9 surgeries per month (Table-1).

The demographics of patients who underwent RP are summarized in Table-2.

The surgical pathology stage, prostate size, Gleason score and surgical margins are summarized in Table-3.

Table-4 presents surgical data. The median operative time was 140 minutes, and most patients did not require blood transfusion.

Table 2 – Clinical characteristics of all patients.

Age (years)	
Median (Q1 – Q3)	64 (58 – 70)
Range	42 – 79
PSA (ng/ml)	n = 181
Median (Q1 – Q3)	7.3 (4.7 – 11.5)
Range	0.6 – 44.0
Prostate weight	n = 182
Median (Q1 – Q3)	30 (30 – 40)
Range	20 – 100
Clinical Stage	
T_1	132 (71.7%)
T_2	52 (28.3%)
Gleason Score	
< 7	123 (66.8%)
7	42 (22.8%)
> 7	19 (10.4%)

A curve of decreasing operative time (p = 0.03) is shown in Figure-1, comparing the 19 initial RP to the following 9 RP performed (p = 0.01) and the remaining surgeries from 29 and more (p < 0.001). From the twentieth RP onwards, we found a significant decrease in the operative time.

There was a progressive decrease in estimated blood loss as the residents gained surgical experience with RP, as shown in Figure-2.

Table 3 – Surgical pathology features at radical prostatetectomy.

TNM	N = 184 (%)
pT_0, N_x, N_0	4 (2.2)
pT_1, N_x, N_0	4 (2.2)
pT_2, N_x, N_0, N_1	133 (72.6)
pT_3, N_x, N_0, N_1	42 (23.0)
Gleason score	
< 7	102 (55.4)
7	79 (32.1)
> 7	19 (10.3)
Positive surgical margin*	
Apical	28 (15.2)
Vesical	13 (7.1)
Lateral/Posterior	12 (6.5)
Prostate weight	
≤ 40g	101 (56.1)
41 – 80g	63 (35.0)
>80g	16 (8.9)

** positive margins may be concomitant. TNM = tumor node metastasis staging.*

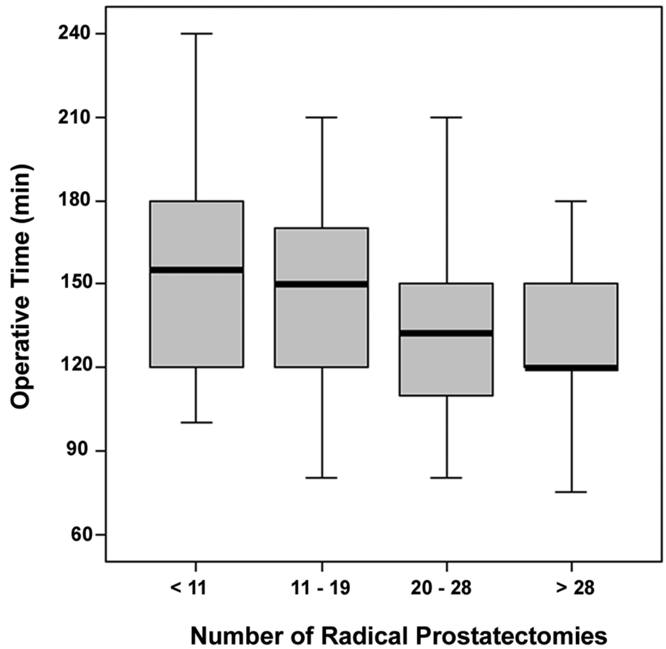

Figure 1 *– Box-plot of operative surgical time according to the number of surgeries.*

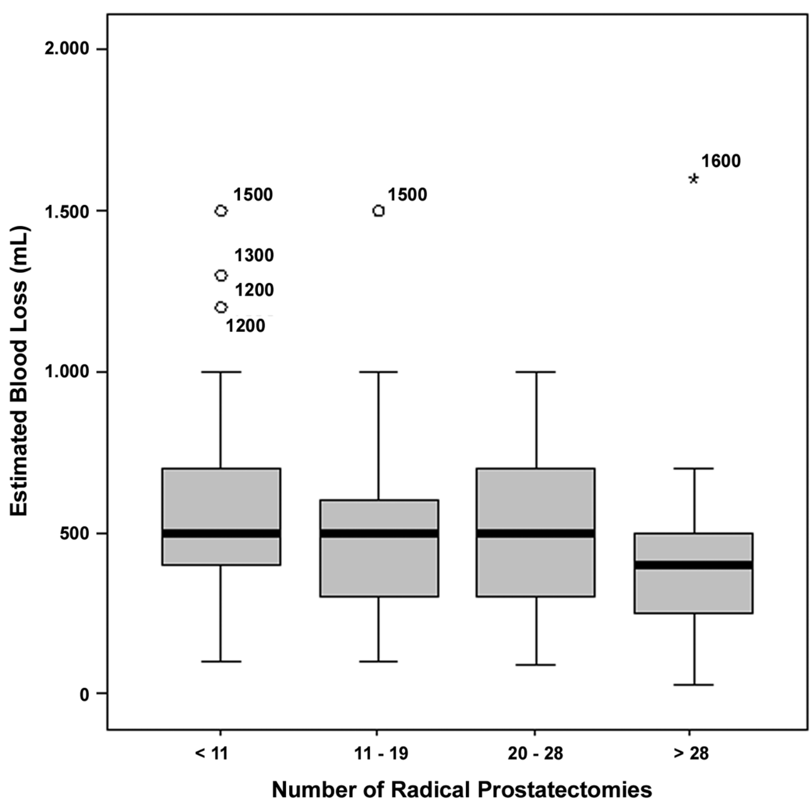

Figure 2 *– Box-plot of estimated blood loss according to the number of surgeries.*

Table 4 – Intraoperative data.

Estimated blood loss	
Median (Q1 – Q3)	488 (300 – 600)
Range	90 – 1600
Blood transfusion	
No	168 (92.8%)
Yes	13 (7.2%)
Operative time (min)	
Median (Q1 – Q3)	140 (120 – 160)
Range	75 – 240

Figure-3 shows the association between the number of surgeries performed and need for blood transfusion, where a 3% transfusion rate was observed after the 29th surgery.

When the resident operated on smaller prostates, blood transfusion was rarely required, as highlighted in Tables 5 and 6, where prostates < 40g and > 40g required a blood transfusion in 3% and 13% of RP, respectively.

In reviewing the occurrence of positive surgical margins, we observed that it remained stable during the four phases, as shown in Table-7.

COMMENTS

The RP learning curve for residents showed that after twenty surgeries, there was a significant reduction in operative time from 150 to 120 minutes and, after the 29th surgery, the need for blood transfusion also decreased from 9% to 3%. Moreover, the percentage of compromised surgical margins remained stable during the learning curve.

The discussion regarding the learning curve in RP has not been frequently addressed in clinical studies and few series have reported clinical and pathologic data exclusively of residents in training instead of only experienced surgeons (13,14). Published evidence has demonstrated that the number of RP previously performed by the surgeon affects patient outcomes. It is believed that a learning curve of 200 cases would be necessary to achieve an “expert” status (13,15).

A recent prospective study evaluated surgeons after a urologic oncology fellowship program, after they had already completed an initial learning curve of an average of 47 cases during residency and another 87 RP performed during the fellowship (15). The mean operative time was 201 minutes, the estimated blood loss was 734 mL, with a 6% rate of blood transfusion.

The learning curve is a major problem in surgery, during which the surgical procedure is usually performed with more difficulty and slowness, associated with a higher risk of complications and low efficacy due to inexperience of the surgeon. If an initial assessment is made, the learning curve is primarily a theoretical concept, because this is a theme or line

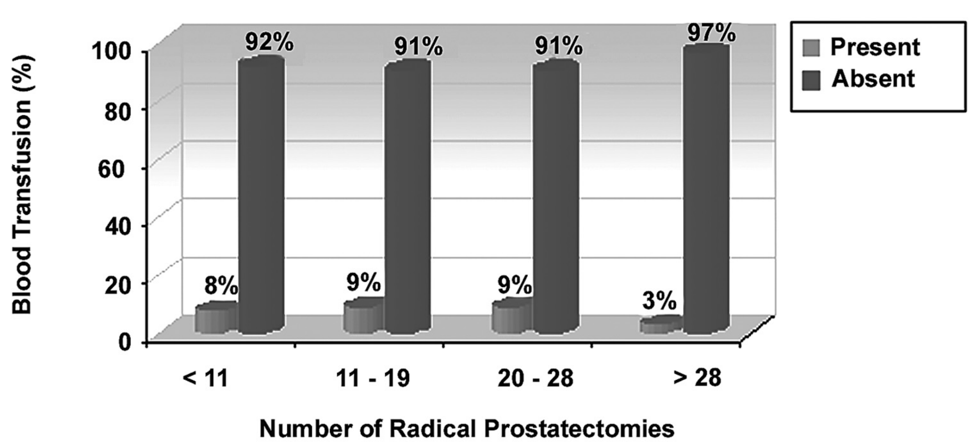

Figure 3 *– Distribution of the number of blood transfusions according to the number of surgeries.*

Table 5 – *Blood transfusion in radical prostatectomies of prostates ≤ 40g.*

Number of Surgeries	**Blood Transfusion**		
	Absent (%)	**Present** (%)	**Total** (%)
10 and under	26 (96.3)	1 (3.7)	27 (100)
11 - 19	23 (95.8)	1 (4.2)	24 (100)
20 - 28	22 (95.7)	1 (4.3)	23 (100)
29 or more	26 (100.0)	0	26 (100)
Total	97 (97.0)	3 (3.0)	100 (100)

Fisher's exact test: p = 0.796.

Table 6 – *Blood transfusion in radical prostatectomies of prostates > 40g.*

	Blood Transfusion		
Number of Surgeries	**Absent** (%)	**Present** (%)	**Total** (%)
10 and under	20 (87.0)	3 (13.0)	23 (100)
11 - 19	17 (85.0)	3 (15.0)	20 (100)
20 - 28	18 (85.7)	3 (14.3)	21 (100)
29 or more	13 (92.9)	1 (7.1)	14 (100)
Total	68 (87.2)	10 (12.8)	78 (100)

Fisher's exact test: p = 0.937.

of research rarely present in residency programs and urologic literature.

The surgeons gain much of the knowledge necessary for surgical procedures during medical residency programs. In the learning process, the urology resident trains in the areas of endourology, incontinence and reconstruction, erectile dysfunction and infertility, pediatric urology and kidney transplantation, laparoscopy and cryotherapy. Within the urologic oncology division, several surgeries are performed, such as transurethral resection of the prostate and bladder, cystectomy and urinary reconstruction, retroperitoneal lymphadenectomy and open and laparoscopic nephrectomy, fostering a growing field of surgical procedures and greater confidence to perform them. The American Urological Association reported that the number of RP performed by residents has declined in recent years, and overall 84% of surgeons have performed less than ten RP annually (8). Based on these data, we can infer that much of the surgical experience needed to acquire proficiency in complex procedures can only be acquired during residency. Eventually, according to local community demand or the volume of surgeries performed at the hospital, this development may never occur.

The percentage of compromised surgical margins varies with the surgeon's experience in this procedure. According to a landmark study by Vickers et al., the rate of positive margins was 36% before 50 RP performed, 29% with 50 to 99 RP, 23% with 100 to 249 RP, 22% with 250 to 999 RP, and 11% with 1000 RP or more (16). Overall, the surgical margin status was positive in 22.9% of surgeries.

Table 7 – Positive surgical margins during learning curve.

	Extracapsular Margin		
Number of Surgeries	**Negative** (%)	**Positive** (%)	**Total** (%)
10 or under	40 (80.0)	10 (20.0)	50 (100)
11 - 19	35 (77.8)	10 (22.2)	45 (100)
20 - 28	35 (76.1)	11 (23.9)	46 (100)
29 or more	32 (74.4)	11 (25.6)	43 (100)
Total	142 (77.2)	42 (22.8)	184 (100)

p = 0.929.

Regarding minimally invasive RP techniques, usually performed by surgeons in large centers with extensive surgical experience, data on robotic and laparoscopic was as follows, respectively: blood transfusion 3% and 9.8%, positive surgical margin of 15.8% and 19.5%, mean operative time was 166 and 160 minutes, and average hospital stay of 5.4 and 4.9 days (17). A study describing the learning curve of robotic RP showed that the robotic surgeon with up to 12 surgeries had an average operative time of 242 ± 64 minutes and 58% of cases with positive margins; with 13 to 188 robotic RP, the operative time was reduced to 165 ± 45 minutes and positive margins to 23%. Surgeons who performed more than 189 robotic RP had an average operative time of 134 ± 45 minutes and positive margins in 9% (18).

The following strengths can be highlighted in the present study: a homogeneous group of residents in training who had never performed a RP was included; the prospective design of the study allowed us to perform the same surgical technique and mentored by the same group of physician assistants; and the sample size accrued was reasonable. Therefore, we believe that these results may generate important information on surgical training and education in urologic oncology.

The fact that the surgeon is inexperienced, starting the learning curve with this procedure, may be of benefit by rapidly improving the performance in the short term, considering that a homogenous and standardized teaching methodology is applied. As our data suggests, it renders the possibility to generate less intraoperative morbidity and lower rate of positive surgical margins, improving the clinical course of patients.

CONCLUSIONS

Open radical prostatectomy is a safe and effective procedure that can be done on a large scale in teaching institutions, as long as a structured training program provides adequate teaching methods. During the initial training experience of a surgeon, a steep reduction in blood transfusions and a quick stabilization of the learning curve after twenty procedures can be expected.

CONFLICT OF INTEREST

None declared.

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EDITORIAL COMMENT

Open radical prostatectomy is the gold standard and most widespread treatment for clinically localized prostate cancer.

About thirty years ago the first purposeful nerve sparing radical prostatectomies were performed by Dr. Patrick Walsh. Since then, a better understanding of the periprostatic anatomical results with continued improvement in functional outcomes and oncological control for patients undergoing radical prostatectomy, whether by open or minimally-invasive surgery.

The oncologic results of author's paper in an important center of high volume treatment of prostate cancer are in line with those reported with the use of the retropubic approach. With a "homogenous and standardized teaching methodology", the residents can achieve good data as regards less intraoperative morbidity and lower rate of positive surgical margins, improving the clinical course of patients.

The learning curve in surgery can be defined as the number of cases required to perform the procedure with reasonable operating time and an acceptable rate of complications, resulting in an adequate post-operative clinical outcome associated with a shorter hospital stay (1).

A paper was published about the learning curve for surgery for prostate cancer recurrence after radical prostatectomy. The study cohort included 7765 prostate cancer patients who were treated with radical prostatectomy by one of 72 surgeons at four major US academic medical centers between 1987 and 2003. The learning curve for prostate cancer recurrence after radical prostatectomy was steep and did not start to plateau until a surgeon had completed approximately 250 prior operations (2). As a surgeon's experience increases, cancer control after radical prostatectomy improves.

These results may generate important information on surgical training, improve the teaching process of the surgical technique and make it widely available to mentors and teaching centers, especially considering the social environment of growing ethical concerns with patient safety. Further research is needed to examine the specific techniques used by experienced surgeons that are associated with improved outcomes.

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EDITORIAL COMMENT

The learning curve plateau comes with training and experience. Surgeons have always recognized a structured way to introduce new procedures: learning a new technique requires dedication.

If we try to define a learning curve, we should look back at the work of Dr. Donald Ross - a pioneer in cardiac surgery in the United Kingdom - who proposed the Ross procedure in 1962 (1). The Ross procedure, first performed in 1967, is a challenging operation for patients with aortic valve disease. The principle is to remove the patient's normal pulmonary valve and used it to replace the patient's diseased aortic valve. In Dr. Ross's own series, 23% of the patients died during the first year of the operation and 18% in the second year. The following 10 years, surgical mortality in a series of 188 patients dropped to 9%. This is a learning curve. The message: it requires time and hard work.

How many cases do we need to become expert surgeons in the technique we perform on an everyday basis? The latter remain a controversial question for the field of radical prostatectomy. The arrival of both, laparoscopy and later robotic surgery has put on stage the term learning curve. In fact, laparoscopic series brought with them a tremendous enthusiasm in terms of validation of the technique and therefore extensive work in the procedure's learning curve.

In our experience at the Institut Montsouris in Paris, it was hard to keep in mind Dr. Walsh's concepts on radical prostatectomy and simultaneously comply with the demanding endoscopic surgical environment, but a step-by-step structured training brought us through the task.

The paper on the learning curve of retropubic radical prostatectomy presented by Dall'Oglio et al. in this issue of IBJU, represents a comprehensive analysis of the initial experience of a group of residents with retropubic prostatectomy, perhaps missing in the literature. The paper offers real information gained by surgical experience and presents a sincere vision of a proctored prostatic surgical approach in the everyday world.

Dall'Oglio et al. found in their interesting analysis, that improvement of clinical outcomes can be seen after 20 to 30 cases. We could say that these findings are far from those presented by Vickers et al in their timely publication assessing surgical learning curve for prostate cancer control (2). Vickers et al. found statistical significance related to surgeon's experience and cancer control after radical prostatectomy in an analysis of highly dedicated surgeons. This study brought back to reality the definition of learning curve in radical prostatectomy, reflecting a real link between surgical technique and cancer control, and establishing the concept of a dramatic improvement in cancer control with increasing surgeon experience up to 250 previous treated cases. That said, we must agree with Dr. Stuart Howards in the fact that it is somewhat arbitrary to assert that it is necessary to perform 250 procedures to become competent and provide good cancer control (3). Therefore, establishing solid bases for radical prostatectomy performed in a Urology program, is an important challenge to any institution and it requires hard dedication and a focused operating room team; but as presented in the Dall'Oglio et al. study this is a feasible task and it might get the future urologists ready to finish their training and be able to offer a surgical procedure of the highest quality.

The future seems difficult for the young urologist, because as presented by Ficarra et al., positive surgical margin rates decreased with the surgeon's experience and technique improvement, reaching similar percentages for retropubic, laparoscopic and robotic series (4); but perhaps the positive surgical margins are not so secure as oncological endpoint (5) and even our current definitions for biochemical recurrences do not substantially impact prognostic factor estimates. This situation implies that the training period should provide solid concepts to build a professional career, and because knowledge and concepts might and will change; an academic way to learn, and eventually teach, is the way that it ought to be in order to assure the adequate surgical treatment of patients, in years to come.

With a structured methodical system, it is possible to implement radical prostatectomy safely and effectively without compromising morbidity, oncological and functional outcomes. A team-based approach helps to reduce the learning curve of the procedure for individual surgeons. This was our initial approach for laparoscopic and robotic prostatectomy at our institution.

The fruit you harvest from the three in this interesting publication is that we must be sure to teach the philosophy of how to adequately treat localized prostate cancer and then, we must get in the operating room with the urologists-in-training to provide them with the basic tools that will hopefully sustain future reliable operators.

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REPLY BY THE AUTHORS

Both editorial comments reassured the importance of a structured learning methodology in the surgical field and pointed out the feasibility of safely teaching complex procedures, such as radical prostatectomy. In our study, we sought to demonstrate a real learning curve of inexperienced surgeons, on which we could evaluate both an increasing growth in surgical skills from an early starting point, combined with the radical prostatectomy training itself. This was possible due to a homogeneous group of mentors, all of them with more than 200 prostatectomies performed.

As mentioned in the editorial, the landmark paper by Dr. Vickers demonstrated a long learning curve, on which improvements were observed to 250 cases performed (1). This study differed significantly from ours, since not only no standardized surgical methodology was applied by all 72 surgeons, but also several very experienced surgeons after urology training were included in the study.

Although our learning curve demonstrated an initial experience with radical prostatectomy, the standardized technique had been extensively improved and validated by Prof. Miguel Srougi, throughout his 4,000 cases (2,3). Currently, two participating residents in the study are now mentors of the residents at our institution.

A further study is now being finalized and will focus on the initial 100 consecutive cases operated with this same standardized technique, with a larger number of surgeons, due to the expansion of our program. Therefore, we expect to generate a stronger evidence to support the use of our teaching methodology, which may help to create a gold standard approach for urology training programs throughout the country.

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