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The Real Learning Curve for Open Radical Cystectomy

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Abstract

Introduction: Bladder cancer is a lethal disease, accounting for the fourth most common kind of cancer in America. This study evaluated, along one year, the evolution of second year urology residents, performing open radical cystectomy and urinary diversion to establish the learning curve for the surgery. Patients and Methods: It is a retrospective study of 132 patients undergoing open radical cystectomy with urinary diversion, performed in a high complexity public hospital in the state of São Paulo, in the period from the 16 January 2014 to the 30 December 2020. Results: In this study patients' mean age was 63.7, 78.7% were males. Mean surgical time was 281 minutes. Estimated mean blood loss was 783 ml. Whereas the mean amount of transfusion assessed by number of bags was 0.96. Median hospital stay was 10 days. Conclusion: The learning curve for urology residents is based on two pillars: quantity and periodicity. We noticed that after performing eight open radical cystectomies (ORC), the resident doctor starts presenting fewer postoperative complications and shorter surgical time. Other studies should be done with a larger number of cases to reinforce our results.

Keywords

Urinary Bladder Neoplasms, Cystectomy, Learning Curve, Medical Residency

1. Introduction

Bladder cancer is a lethal disease, accounting for the fourth most common kind of cancer in America, at a cost of approximately 3 billion dollars in annual spending [1] [2].

Muscle invasive bladder cancer and, in selected cases, high risk non muscle in-

vasive bladder cancer, have been classically treated by open radical cystectomy, a still currently gold standard approach in the treatment, despite its high morbi-mortality [3].

We have studied the learning curve for open radical prostatectomy surgery [4] for urology residents.

Thus, this study aims performing open radical cystectomy and urinary diversion to establish the learning curve for the surgery.

2. Material and Method

Retrospective study of 132 patients undergoing open radical cystectomy and urinary diversion, performed in a high complexity public hospital in São Paulo, from January/2014 to December/2020, approval by the institutional review board, number 1.014.385.

Second year urology, 15 residents performed the surgeries, supervised by the same assistant physician.

We assessed 1 to 10 surgeries were performed by each resident as well as the periodicity kept in regard to performance of the procedure during the year.

The patients eligible had either muscle invasive bladder cancer or recurrent high-grade bladder cancer, besides two patients with rectal adenocarcinoma and bladder invasion.

Demographic and epidemiologic data that could influence the postoperative and oncologic outcomes were assessed, such as age, comorbidities, and intraoperative data: surgery time, urinary diversion, estimated blood loss, need for blood transfusion, use of vasoactive drug, hospital stay (ICU and ward), postoperative complications (immediate, first thirty days and late), hospital readmissions and death.

All the patients underwent standard open radical cystectomy; 118 patients (89.39%, 118/132) had pelvic lymph nodes dissected, as some already were in an advanced stage and were referred for adjuvant therapy.

The surgical specimen and pathological data were also assessed, such as margins, status of the lymph nodes resected and the final pathologic stage, besides late urological complications and recurrences.

After total resection (radical cystectomy) the pathological data presented conclusive results for this study.

2.1. Surgical Procedure

The open radical cystectomy with extended pelvic lymph node dissection was performed through an infraumbilical midline incision.

For urinary reconstruction, a distal ileum segment was isolated for cutaneous ureteroileal anastomosis and orthotopic neobladder. Bowel transit was restored by means of mechanical latero-lateral entero-enteral anastomosis (linear stapler) in 59 cases and manual termino-terminal anastomosis in 65 cases.

Inclusion criteria were: Bladder urothelial carcinoma, histologically proven,

submitted to radical cystectomy; T1c-T4a, Nx, M0 stages; invasive rectal adenocarcinoma; and signing of the informed consent form. The impediment performance status was the criterion for exclusion.

2.2. Statistical Analysis

One way variance analysis (ANOVA-One Way) was carried out aiming to assess whether any differences were found in surgical times (min), estimated blood loss (mL), intraoperative transfusion (bags) and length of hospital stay (days) in regard to: number of surgeries performed; time from the first surgery (months); comorbidities; surgical margins; and application of the test for re-hospitalization (yes and no). All data was assessed normality by means of Kolmogorov-Smirande Shapiro-Wilk tests and are available within the text. Levene test was used to assess assumption of homogeneity of variance.

For the variables presenting homogeneity, Hochberg procedure was used for post-hoc analysis. For unequal variables, Welch correction and post-hoc assessment were applied by means of the Games-Howell test [4].

The variables did not show normality and for the application of the t test and one-way analysis of variance (ANOVA-One Way), so as the differences among the means presented a 95% confidence interval, bootstrapping procedures (1,000 re-samplings; 95% CI bootstrapping procedures) were used for more reliable results to be obtained [5].

In order to verify the independence among the variables, *i.e.*, whether or not a significant difference existed between the expected observations and the actual ones, the non-parametric G test [5] was used.

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

3. Results

From the patients selected for radical cystectomy 89.39% (11/132) were selected for pelvic lymphadenectomy, that some patients were already in an advanced stage and were referred for adjuvant therapy. In general, 1 pT1-2 (0.84%) patient and 11 pT3-4 (9.24%) patients had positive surgical margins (**Table 1**).

Table 1. Pathologic stage and histologic grade of patients undergoing to surgery.

Histology	Patients (n/%)
Transitional Cell Carcinoma	130 (95)
Squamous Cell Carcinoma	4 (3)
Neuroendocrine Tumor	1 (0.5)
Rectal Adenocarcinoma	2 (1.5)
Pathologic Stage	
Tis	1
Ta	26

Continued

T1	**42**
T2	51
T4	5
Lymph nodes	
Nx	14 (11)
N0	93 (70)
N1	15 (11)
N2	8 (6)
N3	2 (2)

Table 2 provides a summary of the demographic data. Patients' mean age was 63.7 and 78.7% were male.

Table 2. Demographic data.

Variables	Mean (SD)
Age (years)	63.77
Male	78.7%
Female	21.3%
Associated Comorbidities	
None	54
1	34
2	34
≥3	10
Surgery time (minutes)	281 (76.98)
Urinary diversion	
Bricker	99
Neobladder	25
Ureterostomy	3
Wet colostomy	3
Ureteral ligation	1
None	1
Estimated blood loss (ml)	783.41 (420.31)
Blood transfusion (blood bags)	0.96 (1.32)
Hospital stay (ward)	Mean 10
Hospital stay (ICU)	Mean 1
Immediate postoperative complications	
Clavien 1 - 2	97 (73.48%)
Clavien ≥3	35 (26.51%)

Continued

Postoperative complications first 30 days	**22 (16.66%)**
Late postoperative complications	101 (79.54%)
Incisional hernia	9
Parastomal hernia	4
Ureteroileal Stenosis	2
Neobladder lithiasis	1
Erectile dysfunction	10
No information	29
Hospital readmissions	22/132
Death (delay, due cancer)	46

The mean surgical time was 281 minutes. Mean estimated blood loss was 783 ml, with 43.9% of the patients requiring blood transfusion. Whereas the mean number of transfusions verified in number of bags was 0.96 (Table 3).

Table 3. Number of surgeries performed by the doctor.

	Number of surgeries performed by the doctor											
	1 to 4 surgeries (n = 86)				5 to 7 surgeries (n = 35)				8 to 10 surgeries (n = 10)			
	Mean	SD	LB CI	UB CI	Mean	SD	LB CI	UB CI	Mean	SD	LB CI	UB CI
Surgical times (min)	291.40[a]	85.18	273.93	311.22	265.00[ab]	60.23	244.30	285.43	249.50[b]	21.66	236.67	264.29
Estimated blood loss (ml)	839.07[a]	444.65	746.38	941.01	620.83[b]	315.18	529.47	723.46	890.00[ab]	412.18	630.92	1122.22
Intraoperative transfusion (bags)	0.98[a]	1.32	0.72	1.25	0.61[a]	1.05	0.29	0.97	2.10[b]	1.60	0.93	3.22
Length of hospital stay (days)	15.12[a]	12.38	12.78	17.49	12.92[a]	9.76	10.30	16.30	14.30[a]	15.01	8.32	25.63

CI = 95%; SD = Standard deviation; LB CI = Lower Bounds of confidence interval (LB CI); UB = Upper Bounds of confidence interval (UB CI); a = when there was no significant difference between the means at the 5% level, in relation to the letter "a" and "ab". b = when there was no significant difference between the means at the 5% level, in relation to the letter "b" and "ab". obs.: between the values marked with the letter "a" and "b", the means differed significantly at the 5% significance level (in relation to each dependent variable).

Out of the 58 patients (43.9%) that received transfusion, 38 (65.51%) had a complication (Clavien-Dindo >1) and 43 (74.13%) were hospitalized for more than eight days. Median hospital stay was 10 days (3-65) (Table 4).

Table 4. Description of dependent variables.

	Mean	Standard Deviation	LB CI 95%	UB CI 95%
Surgical time (min)	281.02	76.98	267.77	294.28
Estimated blood loss (ml)	783.41	420.31	711.04	855.78
Intraoperative transfusion (bags)	0.96	1.32	0.74	1.19

Although surgical time was inversely related to the number of surgeries, no significant difference was found between the number of procedures carried out and mean operative times.

A significant difference was found between the number of surgeries performed in group one (1 to 4 surgeries) and group three (8 to 10 surgeries), with signs of shorter operative times as of the 8th procedure. Besides, both significance and shorter time variability (smaller standard deviation) in the third group, which suggests greater surgical technique standardization or time standardization (**Figure 1**).

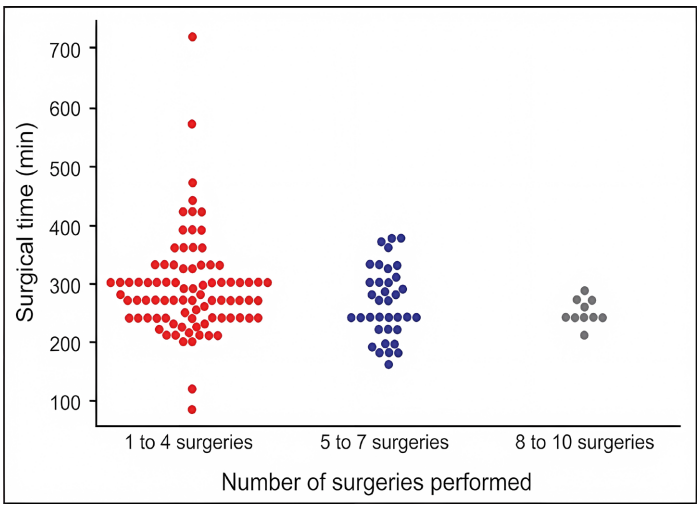

Figure 1. Surgical time vs. Number of surgeries.

We gave close attention to a significant difference between the number of surgeries performed and the intraoperative transfusion rate, particularly between groups one vs. three, and two vs. three. A higher transfusion rate was found in group 3, stressing that, in that group 18 pT3 or higher clinical stage cases underwent surgery.

No alteration was found in the patients' length of hospital stay associated with the number of surgeries performed by the doctor within a median 10-day hospital stay.

The residents were subdivided and allocating into 4 groups, relating the time (months) elapsed after the first surgery performed, aim at the outcome based on the periodicity of radical cystectomy (**Table 5**).

Table 5. Description of the dependent variables following the first surgery.

	Time after the first surgery															
	1 to 3 months (n = 62)				4 to 6 months (n = 35)				7 to 9 months (n = 19)				Over 9 months (n = 16)			
	Mean	SD	LB CI	UB CI	Mean	SD	LB CI	UB CI	Mean	SD	LB CI	UB CI	Mean	SD	LB CI	UB CI
Surgical times (min)	289.44	91.57	270.86	310.97	273.29	64.72	254.22	293.58	292.89	55.64	268.46	317.93	251.25	53.81	226.01	279.72
Estimated bleeding (ml)	801.77	468.1	685.84	928.07	777.14	396.6	656.13	909.75	836.84	359.3	682.3	1016.23	662.50	346.2	500	836.51
Intraoperative transfusion (bags)	1.06	1.32	0.75	1.41	0.60	1.01	0.31	0.92	0.95	1.51	0.33	1.68	1.38	1.59	0.62	2.16
Length of hospital stay (days)	13.79	11.01	11.16	16.52	15.14	11.98	11.55	19.11	16.53	14.85	11.2	24.11	13.06	11.85	9.4	18.68

CI = 95%; SD = Standard deviation; LB CI = Lower Bounds of confidence interval (LB CI); UB = Upper Bounds of confidence interval (UB CI).

A shorter surgical time is clear as well as less blood loss and shorter hospital stay in the group performing surgery 9 months after the first one. However, statistical significance was not reached.

Although presenting no significance, as of the second group, shows no surgeries with highly isolated times, *i.e.*, after three months, fact that corroborates towards a time standardization trend.

Table 6. Number of comorbidities vs. variables.

	Number of patients' comorbidities															
	No comorbidity (n = 52)				1 comorbidity (n = 36)				2 comorbidities (n = 33)				3 and 4 comorbidities (n = 11)			
	Mean	SD	LB CI	UB CI	Mean	SD	LB CI	UB CI	Mean	SD	LB CI	UB CI	Mean	SD	LB CI	UB CI
Surgical times (min)	276.54	57.99	260.9	291.54	279.03	81.88	255.62	304.6	279.70	69.95	257.44	300.93	312.73	141.87	252.67	409.47
Estimated blood loss (ml)	776.15	430.62	665.67	896.01	763.89	397.96	643.77	887.07	746.97	403.1	620.86	885.07	990.91	490.82	714.29	1309.16
Intraoperative transfusion (bags)	0.94	1.29	0.61	1.29	1.03	1.28	0.64	1.47	0.76	1.23	0.39	1.18	1.45	1.81	0.56	2.67
Length of hospital stay (days)	14.96	13.59	11.73	18.65	11.94	8.3	9.78	14.75	16.48	13.17	12.4	21.14	14.18	8.61	9.59	20.39
ICU P. O. (days)	2.06	3.57	1.22	3.06	2.58	7.19	1.04	5	4.55	10.12	2.6	15.79	3.09	6.93	2.09	4.3

CI = 95%; SD = Standard deviation; LB CI = Lower Bounds of confidence interval; UB CI = Upper Bounds of confidence interval.

We also assessed whether the number of comorbidities would have influence on surgical time, estimated blood loss, intraoperative transfusion, length of hos-

pital stay and number of days in an Intensive Care Unit (Table 6). The patients were separated into 4 groups, namely: without comorbidities; with one, two and three or more comorbidities. Although not significant, patients with three of more comorbidities tend to have all further variable values increased.

Neither was any significant relation (p = 0.16) found between the readmission rate and the number of surgeries performed.

A reduction was found in the reoperation rate and need in regard to time elapsed from the first surgery. The group with periodicity greater than 9 months had the smallest rate of reoperation, however with no significance (p = 0.96) (Figure 2).

Analyzing the relation among the variables, we found that residents having operated eight or more radical cystectomies maintained a small standard deviation in surgical time.

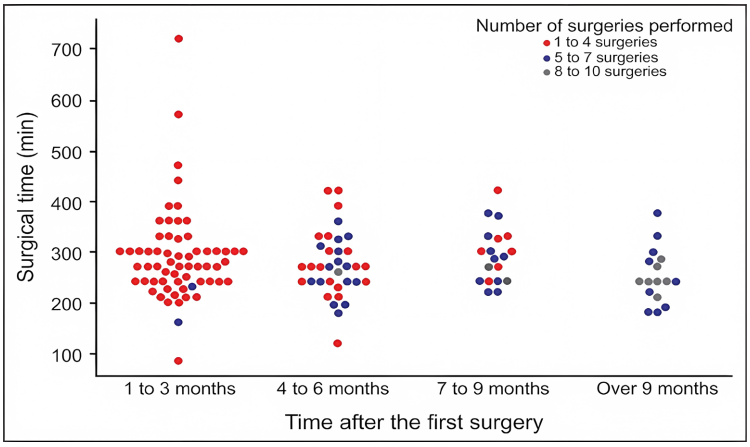

Figure 2. Surgical time vs. Time after the first surgery.

Although statistically showing no significance, there are signs that performing more than 5 surgeries within a greater than nine-month periodicity may be connected with less intraoperative blood loss, as per Figure 3.

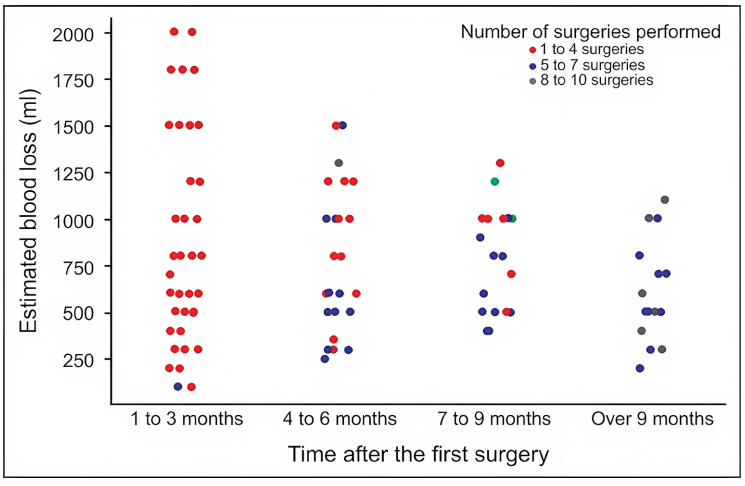

Figure 3. Blood loss vs. time after the first surgery and number of surgeries.

Significance was found in the analysis of complications (p = 0.01) by relating the number of surgeries performed to a smaller rate of complications in the group that had operated more than 8 radical cystectomies, as per Table 7.

We describe the complications emphasizing the high number of deaths that occurred during postoperative follow-up months, most of which due to progression of the disease or further minority causes such as sepsis, urinary or pulmonary source of infection, thromboembolic events or digestive hemorrhages. As the number of surgeries increased, the number of complications decreased (p = 0.01) in all Clavien categories (Table 8).

Table 7. Surgeries performed vs. complications.

Number of surgeries performed	Complications (G test = 25.8074; p = 0.0114)						
	I	II	IIIb	IVa	IVb	V	None
1 to 4 surgeries	6	13	13	2	1	11	40
5 to 7 surgeries	6	7	1 (3.8)	1	3 (1.1)	0 (3.5)	18
8 to 10 surgeries	0	3	0	1	0	2	4

Table 8. Complications.

Complications	Number/%
None	62 (46.96)
Vasoactive drug required	4 (3.03)
Blood transfusion	16 (12.12)
ARF with or without hemodialysis	14 (10.60)
DVT	1 (0.75)
Infection/Sepsis	5 (3.78)
Constipation	1 (0.75)
Dehiscence/Eventration	8 (6.06)
Intracavitary Collection	2 (1.51)
Acute abdominal obstruction	2 (1.51)
Intestinal fistula	2 (1.51)
Urinary fistula	2 (1.51)
Death	(9.84)

*ARF = Acute Renal failure; *DVT= Deep Venous Thrombosis.

4. Discussion

This unprecedented paper shows the initial behavior of the genuine learning curve for open radical cystectomy in a teaching hospital, demonstrating an acceptable level of proficiency as of the eighth surgery. Since it is an important study in regard to the surgical methodology of the new resident doctors' gener-

ation, it places our department as an educational and qualification center for such complex a surgery.

The surgical time of this work on the learning curve is compatible with the current literature on the subject. The data show better operative time as opposed to the first eight cases. However, according to Hayn *et al*., [6] such time may vary depending on the urinary diversion and type of lymphadenectomy.

Like Ng *et al.* [7] literature, our surgical time is within an expected mean, considering that the surgery is performed by second year residents guided by a uro-oncology specialist tutor. Time is clearly reduced after the eighth surgery, provided there is technical surgery standardization. As emphasized by Hayn *et al*., [6] surgical times in open radical cystectomy series have rarely been reported.

Like in the robotic radical cystectomies reported by Lawrence *et al*., [8] the blood loss estimated in this study is expected and accepted as we take into consideration an open technique procedure. We are aware that in this study there was a higher rate of transfusion in the group with the larger number of surgeries and more operations on patients in an advanced clinical stage (≥pT3)

The extensive blood loss and need for transfusion predict a higher probability of ileum and postoperative complication in open cystectomy series10; besides, previous studies have already set a relation between the ASA score and the rate of transfusions and complications [9].

Lymphadenectomy was performed in most patients and in 20% it was compromised by the disease. It is known that Herr recommends removal between 10 and 14 lymph nodes [10], and for Ghoneim 20 lymph nodes [11] should ideally be removed.

Herr *et al* recommended an acceptable global positive margin rate of < 10% with a < 15% for pT3-4 tumors [10].

Hospital stay proved to be a little longer as compared to the mean in the literature, however, given a few occasional cases with more severe complications. But it is known that in the literature the mean time for hospitalization is of approximately 6 - 8 days, depending on the technique used [12].

In a prospective study of senior surgeons comparing open radical cystectomy vs. robotic, the positive margin was 5% for both groups, 23 and 11 lymph nodes removed, 800 ml and 400 ml blood loss, 50% and 40%, transfusions, 3.5 h and 4.2 h surgical time, 6- and 5.1-days hospital stay, respectively [12].

Another randomized prospective study [13] of senior surgeons, comparing open radical cystectomy vs. robotic showed respectively estimated blood loss 676 ml and 516 ml, hospital stay time eight days for both groups, positive margin 16% and 12% for > T3, surgical time 330 min and 464 min, estimated blood loss 681 and 500 ml, standard lymphadenectomy outcome 18.9 and 19.5 lymph nodes, complications according to Clavien-Dindo classified as 2 - 5, 65%, and classified as 3 - 5, 21%, in both groups.

A further relevant factor noticed in all surgeries and was the shorter surgical time, less blood loss and shorter hospital stay upon periodicity in the surgery per-

formance, with improved results after 9 months of evolution.

Like in other papers, we also identified that with the increased comorbidities (≥3), the following variables also increase: surgical time, blood loss, transfusion rate and ICU admission [9].

Lauridsen *et al*., [14] evidenced that robot-assisted RC is not superior to open RC as far as complications and hospital stay are concerned; however, in this systematic review of 239 patients, all urinary diversions were extra corporeal.

Despite the growing increase of minimally invasive surgeries and non-inferiority of robotic surgery, [15] the Gold Standard remains open surgery [16] [17]. It is worth pointing out that this surgery is an option for urologists in their surgical clinic and that they will not become efficient unless they develop such confidence and autonomy during training. Furthermore, when discussed if there should be reference hospitals and departments for referral of those patients, a trend exists towards privileging certain centers, which is unfair. Much better it would be if we provided solid surgical training, since it will be up to the labor market to give everyone an opportunity.

This study showed that statistical data indicate a trend towards significant outcomes in the performance of large surgeries. We were unable to provide a definitive response, except that a smaller number of postoperative complications are presented after nine months, *i.e*., in the last quarter of training.

An additional accompaniment is required to assess oncologic and survival outcomes in the long term.

5. Weaknesses

We are aware of the limitations in our current study. The size of the sample is limited, but it could be the embryo for multicentric studies in our country, pointing out all the difficulty in year 2020 during the Coronavirus pandemic.

As in our service, second-year urology residents perform radical cystectomies and prostatectomies, we would have more robust data if they also did it in the last year of medical residency, without the proctor. This is a future project aiming to explore that work methodology and also to provide definitive data.

A further limitation is the analysis of the oncologic outcome that was short, as well as in regard to data connected with quality of life. And lastly, we had a high number of follow-up losses, 21.9%, as many patients went back to their origins since we are a high surgical complexity reference service.

6. Strengths

This study provides the actual learning curve for open radical cystectomy, not found before in the literature, covering from the first surgery to the number of cases operated by each resident. Surgeries performed under the guidance of a single Proctor tutoring residents since 2000, with experience in Teaching hospitals, using the same methodology and standardized surgical approach. In addition to a rigid postoperative control with specific routine and ambulatory follow-up.

Although being a learning curve we already have results that can be compared to prospective studies of senior surgeons.

7. Conclusions

It should be noted that it is not before eight ORC performed that the resident doctor starts presenting a smaller number of postoperative complications. Such finding can be justified through greater standardization of the technique, since the standard deviation of procedure time is reduced as of eight surgeries.

The relevance of periodicity in the performance of cystectomies should also be emphasized, suggesting shorter operative time, less blood loss and shorter hospital stay in the group performing surgeries nine months from the first one.

Therefore, it can be concluded that the learning curve for the Urology resident is based on two pillars: quantity and periodicity. Both are extremely relevant in the operative improvement and standardization, as well as in the reduction of comorbidities and reoperations. In addition to a good tutoring with an experienced proctor.

Other studies should be done with a larger number of cases to reinforce our results.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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