Am J Clin Exp Urol 2021;9(5):378-383
www.ajceu.us /ISSN:2330-1910/AJCEU0136904

Original Article

Learning retrograde intrarenal surgery as a sheathless and radiation-free technique

Feyzi S Erdal[1], Oktay Özman[2,3]

[1]Haseki Training and Research Hospital, İstanbul, Turkey; [2]Urology Clinic, Gazismanpasa Training and Research Hospital, İstanbul, Turkey; [3]Department of Urology, Netherlands Cancer Institute, Antoni van Leeuwenhoek Hospital, Amsterdam, The Netherlands

Received July 1, 2021; Accepted September 8, 2021; Epub October 15, 2021; Published October 30, 2021

Abstract: The aim of this study was to evaluate the learning curve of inexperienced surgeon who can perform the operation on their own for access sheatless and radiation-free retrograde intrarenal surgery (RIRS) technique. Results of 70 consecutive patients who have renal stones and underwent RIRS which performed by a single surgeon were evaluated retrospectively. Cumulative stone free rates and fragmentation efficacy were taken as the primary outcomes for the learning curve analyses. Stone free rate was 74% (52/70). The learning curve constructed with moving average of cumulative stone free rates showed that learning curve of sheathless RIRS consisted of three phases; rapid ascent (0-15: phase 1), slight decline (16-35: phase 2) and plateau (36-70: phase 3). The number of case needed to obtain a final plateau in stone free rates was about 35. Fragmentation efficacy reached a plateau after 50 cases. The learning curve of access sheatless and radiation-free RIRS reached plateau phase after 35-50 cases. This steep learning curve points out that surgeons do not need to experience the classical RIRS technique before starting to perform access sheatless and radiation-free technique.

Keywords: Learning curve, minimally invasive surgery, retrograde intrarenal surgery, urinary calculi, urolithiasis

Introduction

Retrograde Intrarenal Surgery (RIRS) is an emerging minimally invasive method in the surgical treatment of kidney stones. It has rapidly become a preferred surgical technique owing minimally invasive surgical modality gap for small stones [1]. The technique requires the simultaneous and effective use of laser energy, fluoroscopy, access sheaths, fiberoptic and digital technologies. The increasing experience with RIRS has created a tendency to simplify this complex process. There are several studies revealing that RIRS can be performed safely and effectively without fluoroscopy or access sheath and the evidence is growing day by day [2, 3]. A recent systematic review and meta-analysis revealed that routine use of fluoroscopy doesn't influence the outcomes of RIRS [4].

Although RIRS is applied in a sheathless and fluoroless manner, there is no study in the literature examining the learning curve of this modified technique. It is not known if this simplified RIRS technique requires a regular RIRS experience just like laparoscopic surgical experience which required before robotic surgery. The aim of this study was to evaluate the learning curve of an inexperienced surgeon who can perform the operation on their own for access sheatless and radiation-free RIRS technique.

Materials and methods

Patients

After obtaining the ethical approval from local committee (Number: 59491012-604.01.02) the data of 70 patients underwent RIRS between 2017-2019 were included study retrospectively. All procedures was performed by a single surgeon (FSE) consecutively. All patients were primarily evaluated with non-contrast computed tomography (CT) (Toshiba Alexion®, 16 detectors, 3 millimeter slice thicknesses) and kidney, ureter, bladder x-ray (KUB) by the surgeon performing the operations. RIRS indication was given by the same surgeon.

The stone area was calculated by multiplying the two longest diameters (mm) measured on CT sections. Hounsfield units measured using CT bone windows [5]. Fragmentation efficacy was calculated area of removed stones (mm^2) divided by operating time (minute) [6]. Area of removed stones was same with stone burden of stone-free patients. In case of residual stones, the residual stone area detected on postoperative CT was subtracted from the stone area at the first evaluation. The operating time was calculated as the time from start of ureterorenoscopy to the end of insertion of ureteral stent.

Complications were rated according to the modified Satava and standardized Clavien-Dindo classifications for RIRS [7, 8]. The patients were followed up with KUB and CT in the postoperative period. 4 mm and larger or symptomatic fragments were considered as residual stones [9].

Surgical technique and equipment

Surgeon had no RIRS experience before these cases. But he had about 5 years of endourology experience before the first RIRS he performed. Informed consent for operation was obtained from patients. All patients received preoperative antibiotic prophylaxis with second generation cephalosporins. The operations were performed under spinal (42 patient) or general (25+3 patient) anesthesia. Spinal anesthesia was switched to general anesthesia in 3 patients because of anesthetic problems, anxiety or poor patient compliance.

All procedures were performed in the manner of the sheathless and fluoroless technique. Same side leg (with kidney which will being operated) was extended in the lithotomy position. First, ureteroscopy was performed with semirigid ureteroscope (9.5 Fr, Karl Storz®, Tuttlingen, Germany). Two hydrophilic nitinol sensor guidewires (0.035 inches, Boston Scientific®, Marlborough, MA, USA) were inserted into the ureter. One of the guidewires was selected as a safety guide. Second guidewire was used for back loading of flexible ureteroscope (Flex X2®, 7.5 Fr, Karl Storz®, Tuttlingen, Germany). In case of ureteral access failure, 4.8 Fr 28 cm double j stent was placed in the ureter and the procedure was postponed to the next session. Pelvicaliceal orientation was completed by entering all calixes. Lower calyx stones were relocated before starting the lithotripsy. Thus, perforations due to laser advancement through the deflected working channel were prevented by keeping the flexible ureteroscope as close to the neutral position as possible. Depending on the stone burden, 270 or 400 micron laser fiber was used (Dornier Smartflex®, Weßling, Germany). The laser was adjusted to the standard lithotripsy settings with 0.6-1.2 Joule energy levels and 5-15 Hertz rates according to the density of the stone (Dornier Medilas H Solvo®, Weßling, Germany). When the stones were completely fragmented or it was decided to terminate the procedure, the flexible scope was taken out and 4.8 Fr 28 cm ureteral double j stent (Plasti-Med®, İstanbul, Turkey) was inserted into the ureter via the guidewire. The double j stent was removed 4 weeks later.

Learning curve and statistical analyses

Cumulative stone free rates and fragmentation efficacy were taken as the primary outcomes for the learning curve, separately. Cumulative sum (CUSUM) analysis (for fragmentation efficacy) and moving average method (for cumulative stone free rates) used for learning curve assessments [6, 10].

Then, the patients were divided into three groups according to the phases of learning curve constructed with moving average of cumulative stone free rates (Group 1: phase 1, Group 2: phase 2 and Group 3: phase 3). The groups were compared in terms of demographic, stone related, perioperative and postoperative parameters. Continuous and categorical data were compared using Mann-Whitney U test for independent means and Chi-square tests, respectively. *P* value less than 0.05 was considered statistically significant. All analyses were carried out using SPSS, version 22 (SPSS Inc, Illinois, USA).

Results

Stone free rate was 74% (52/70). The learning curve constructed with moving average of cumulative stone free rates was shown in

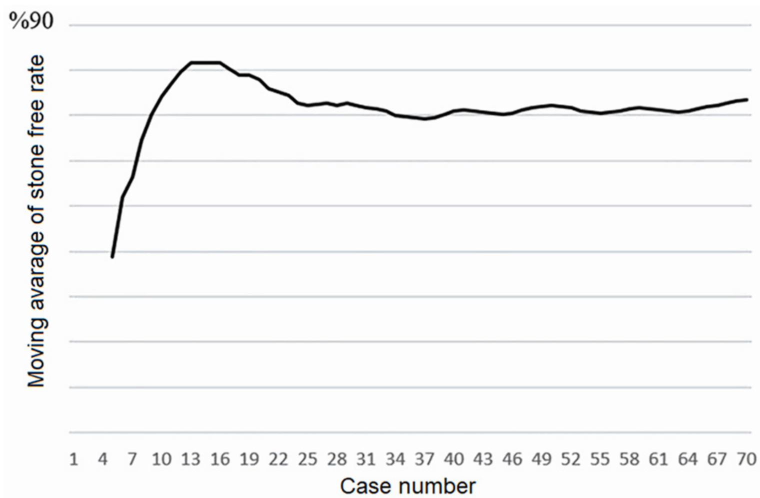

Figure 1. Learning curve constructed with moving average of cumulative stone free rates.

Figure 1. According to this graphic learning curve of sheathless and radiation-free RIRS consisted of three phases; rapid ascent (0-15: phase 1), slight decline (16-35: phase 2) and plateau (36-70: phase 3). The number of case needed to obtain a final plateau in the cumulative stone free rates was about 35. Median stone burdens were 72, 90 and 110 mm^2 for phase 1, 2 and 3, respectively. Although stone burden increased with progressing of phases this relation was not statistically significant (P=0.33). Lower calyx stone presence rate increased as the phases progressed (13%: phase 1, 35%: phase 2, 54%: phase 3, P=0.02). There was no significant differences between phases according to other factors (**Table 1**). Fragmentation efficacy reached a plateau after 50 cases in CUSUM analysis (**Figure 2**).

Overall complication rate was 15.7% (11/70). Details of perioperative and postoperative complications according to modified Satava and standardized Clavien-Dindo classifications for RIRS were shown in **Table 2**. Bleeding developed in two patients during the procedure (not required blood transfusion or additional intervention, as Grade 1 complication). The ureter was perforated in one patient and the procedure was terminated after insertion of a double j stent (Grade 2b). Two patients had fever (Grade 1) and four patients had urinary tract infection as Grade 2 complication and two patients had urosepsis (as Grade 2 complication).

Discussion

Our study is the first report in the literature investigating the learning curve of sheathless and radiation-free RIRS. The learning curve reached plateau phase after 35-50 cases. There are many studies investigating robotic surgical learning curves in urology [11-13]. However, there are a limited number of studies examining the effect of experience on RIRS outcomes. Cho et al. reported that 56 cases were required to reach the plateau phase according to the learning curve obtained from the results of the first 100 cases performed by a single surgeon [6]. In this study, CUSUM analysis was performed to obtain learning curve. We also used CUSUM analysis with same methodology. Plateau phase was required about 50 cases. da Cruz et al. showed that there was no more improvement in operation times of particular steps of RIRS after 60 cases [14]. Apparently and surprisingly the sheathless and fluoroless RIRS is not requiring more experience than classical technique to reach proficiency. Furthermore we found similar complication rates with surgeons at the early phase of learning curve for classical technique (15.7%). Komori et al. reported complication rate of 13.6% in first 44 consecutive cases of a single surgeon [15].

The learning curve was first described in 1936 by Wright in an article investigating factors affecting cost of airplanes [16]. Since its initial discovery, many geometric alternatives have been proposed for the learning curve [17]. The plateau model often provide the best fit in surgical learning process. In other words, the nature of surgical learning is best explained by the plateau model. In our study, we obtained one of the learning curves by using the moving average method. The learning curve reached plateau phase after 35 cases. There was a decline phase (phase 2) after the rapid ascent (phase 1). The second phase of the learning curve can be explained by the patient selection attitude of the surgeon. The good results obtained in the first phase with relatively small

Table 1. Characteristics of all patients and comparisons of the learning curve phases

Characteristic	All patients	Phase 1	Phase 2	Phase 3	*P* value
Number	70	15	20	35	
Age (median, range)	45.5 (21-70)	44 (22-64)	42 (21-62)	46 (26-70)	0.47
Stone Burden (mm^2)	100 (15-800)	72 (32-225)	90 (15-700)	110 (18-800)	0.33
Hunsfield Unit (median, range)	911 (430-1700)	1150 (620-1600)	875 (430-1600)	900 (450-1700)	0.50
Lower Calyx Localisation	40% (28/70)	13.3% (2/15)	35% (7/20)	54.3% (19/35)	0.02
Hydronephrosis	48.6% (34/70)	66.7% (10/15)	35% (7/20)	48.6% (17/35)	0.18
Previous Stone Surgery	67.1% (47/70)	60% (9/15)	75% (15/20)	65.7% (23/35)	0.63
Preoperative Double J Stent	35.7% (25/70)	20% (3/15)	40% (8/20)	40% (14/35)	0.36
Operation Time (minute)	71 (30-170)	80 (50-155)	80 (45-130)	60 (30-170)	0.06
Length of Hospitality (day, median, range)	1 (1-11)	1 (1-3)	1 (1-2)	1 (1-11)	0.43
Complication Rate	15.7% (11/70)	6.7% (1/15)	15% (3/20)	20% (7/35)	0.49
Auxilliary Procedure	27.1% (19/70)	26.7% (4/15)	40% (8/20)	20% (7/35)	0.28

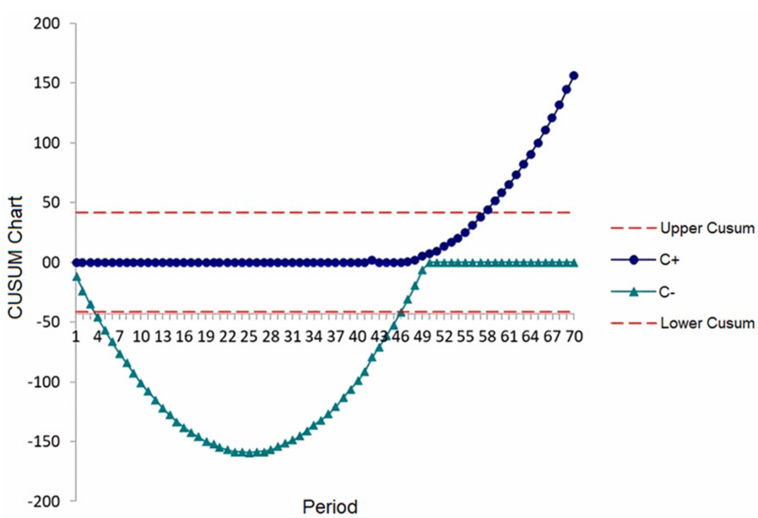

Figure 2. CUSUM analysis for fragmentation efficacy.

stones encouraged the surgeon to engage in larger stones. However, there was no statistically significant difference between the mean stone areas of the patients operated on all three phases. In addition, the rate of lower calyceal stones was lower in the first phase than in following phases. Patients with lower calyceal stones are more likely to have residual stone after RIRS than patients have stones in other calyces [18, 19]. In the light of these findings and evidences, we could match the cases from each phase in terms of factors influencing outcome measurements such as stone area and localization. But in this case, we would have ignored the surgeon's experience with more challenging cases (large and lower calyx stones). A natural curve with trends that change as experience is gained reflects the surgeon's learning process more accurately as a human rather than a machine.

The plateau phase of stone free outcome was reached earlier than of fragmentation efficacy. This finding was fitted with surgeons goals that change as the experience was gained. In early cases, the surgeon's priority was to provide a stone free status regardless of operation time and total laser energy being used. Then his awareness regarding the sustainability of the surgical instruments and the management of time was increased.

Main limitation of our study was the retrospective design. The fragmentation efficacy could have been calculated with variables such as laser duration, total laser energy, stone density or more accurately calculated stone volume. Also, patient-reported surgical outcomes (improvement in symptoms, evaluation of quality of life etc.) could have provided domains to learning curve analysis from patients point of view.

Conclusions

It seems that the learning curve of access sheatless and radiation-free RIRS reached plateau phase after 35-50 cases. This steep learning curve points out that surgeons have endourological experience do not need to experience

Table 2. Complication characteristics

Variable	Grade	
Postoperative complications according to the Clavien Classification	1	2 (25%)
	2	6 (75%)
	3	0 (0%)
	4	0 (0%)
Postoperative complications		8 (11%)
Perioperative complications according to Satava Classification	1	2 (66%)
	2A	0 (0%)
	2B	1 (34%)
	3	0 (0%)
Perioperative complications		3 (4%)
Overall complications (patients)		11 (15%)

the classical technique before starting to perform access sheatless and radiation-free technique.

Disclosure of conflict of interest

None.

Address correspondence to: Oktay Özman, Department of Urology, Netherlands Cancer Institute, Antoni van Leeuwenhoek Hospital, Plesmanlaan 121, CX, Amsterdam, The Netherlands. Tel: 05545012312; E-mail: ozmanoktay@hotmail.com

References

[1] Inoue T, Okada S, Hamamoto S and Fujisawa M. Retrograde intrarenal surgery: past, present, and future. Investig Clin Urol 2021; 62: 121-135.

[2] Emiliani E, Motta GL, Llorens E, Quiróz Y, Kanashiro AK, Angerri O, Palou J and Bujons A. Totally fluoroless retrograde intrarenal surgery technique in prestented patients: tips and tricks. J Pediatr Urol 2019; 15: 570-573.

[3] Mahmood SN, Toffeq H and Fakhralddin S. Sheathless and fluoroscopy-free retrograde intrarenal surgery: an attractive way of renal stone management in high-volume stone centers. Asian J Urol 2020; 7: 309-317.

[4] Subiela JD, Kanashiro A, Emiliani E, Villegas S, Sánchez-Martín FM, Millán F, Palou J and Angerri O. Systematic review and meta-analysis comparing fluoroless ureteroscopy and conventional ureteroscopy in the management of ureteral and renal stones. J Endourol 2021; 35: 417-428.

[5] Perks AE, Schuler TD, Lee J, Ghiculete D, Chung DG, D'A Honey RJ and Pace KT. Stone attenuation and skin-to-stone distance on computed tomography predicts for stone fragmentation by shock wave lithotripsy. Urology 2008; 72: 765-769.

[6] Cho SY, Choo MS, Jung JH, Jeong CW, Oh S, Lee SB, Son H and Jeong H. Cumulative sum analysis for experiences of a single-session retrograde intrarenal stone surgery and analysis of predictors for stone-free status. PLoS One 2014; 9: e84878.

[7] Berardinelli F, De Francesco P, Marchioni M, Cera N, Proietti S, Hennessey D, Dalpiaz O, Cracco C, Scoffone C, Schips L, Giusti G and Cindolo L. Infective complications after retrograde intrarenal surgery: a new standardized classification system. Int Urol Nephrol 2016; 48: 1757-1762.

[8] Tepeler A, Resorlu B, Sahin T, Sarikaya S, Bayindir M, Oguz U, Armagan A and Unsal A. Categorization of intraoperative ureteroscopy complications using modified Satava classification system. World J Urol 2014; 32: 131-6.

[9] Osman MM, Alfano Y, Kamp S, Haecker A, Alken P, Michel MS and Knoll T. 5-year-follow-up of patients with clinically insignificant residual fragments after extracorporeal shockwave lithotripsy. Eur Urol 2005; 47: 860-4.

[10] Ucar M, Varol AT, Gülkesen KH, Ceylan AE, Kutlu Ö and Güntekin E. Does the learning curve affect the surgical, functional, and oncologic outcomes in bilateral nerve-sparing robot assisted laparoscopic prostatectomy? Cureus 2019; 11: e5274.

[11] Islamoglu E, Karamik K, Ozsoy C, Tokgoz H, Ates M and Savas M. The learning curve does not affect positive surgical margin status in robot-assisted laparoscopic prostatectomy. Urol J 2018; 15: 333-338.

[12] Zorn KC, Gofrit ON, Orvieto MA, Mikhail AA, Zagaja GP and Shalhav AL. Robotic-assisted laparoscopic prostatectomy: functional and pathologic outcomes with interfascial nerve preservation. Eur Urol 2007; 51: 755-62.

[13] Artibani W, Fracalanza S, Cavalleri S, Iafrate M, Aragona M, Novara G, Gardiman M and Ficarra V. Learning curve and preliminary experience with da Vinci-assisted laparoscopic radical prostatectomy. Urol Int 2008; 80: 237-44.
[14] da Cruz JA, Thiago C, de Queiros Barros U, de la Roca RL, Lima JP and Di Migueli R. MP33-17 the learning curve for retrograde intra-renal surgery (RIRS): how many cases are necessary? J Urol 2016; 195: e443.
[15] Komori M, Izaki H, Daizumoto K, Tsuda M, Kusuhara Y, Mori H, Kagawa J, Yamaguchi K, Yamamoto Y, Fukumori T, Takahashi M, Kanayama HO, Sakaki M, Nakatsuji H, Hamao T and Miura H. Complications of flexible ureteroscopic treatment for renal and ureteral calculi during the learning curve. Urol Int 2015; 95: 26-32.
[16] Wright TP. Factors affecting the cost of airplanes. J Aeronaut Sci 1936; 3: 122-128.
[17] Yelle LE. The learning curve: historical review and comprehensive survey. Decis Sci 1979; 10: 302-328.
[18] Tonyalı Ş, Yılmaz M, Karaaslan M, Ceylan C and Işıkay L. Prediction of stone-free status after single-session retrograde intrarenal surgery for renal stones. Turk J Urol 2018; 44: 473-477.
[19] Jeong CW, Jung JW, Cha WH, Lee BK, Lee S, Jeong SJ, Hong SK, Byun SS and Lee SE. Seoul National University renal stone complexity score for predicting stone-free rate after percutaneous nephrolithotomy. PLoS One 2013; 8: e65888.