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Original Article

Experience of one single surgeon with the first 500 robot-assisted laparoscopic prostatectomy cases in mainland China

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KEYWORDS
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Abstract *Objectives:* To summarize the experience of the first 500 robot-assisted laparoscopic radical prostatectomy (RALP) cases by one surgeon and analyze the influencing factors of functional and oncological outcomes.
Methods: Between April 2012 and October 2017, 500 patients who underwent RALP were included and divided sequentially into five equal groups. Patients' preoperative, perioperative and postoperative outcomes were analyzed and evaluated, and the Kruskal-Wallis test was used to analyze and compare the effect of surgeon experience by case.
Results: There is a statistically significant reduction in operative time, intraoperative estimated blood loss and postoperative hospital stay time (all $p<0.001$) with the increased experience. The results show that experience was the most important influencing factor in both operative time and blood loss. Pelvic lymph node dissection (PLND) might increase the operative time. The total positive surgical margin (PSM) rate was 21.8%. The PSM rate in pT3 tumors was significantly higher than that in pT2 tumors (12.0% *vs.* 37.1%, $p<0.001$). The 5-year biochemical recurrence (BCR)-free rate was 70.8%. The results of Cox regression showed that preoperative prostate-specific antigen (PSA), postoperative Gleason score (GS), and pathologic T stage were independent risk factors for BCR.
Conclusion: After approximately 200 cases, the surgeon reached a plateau for RALP, but the outcomes could still improve after more cases. The surgeon's experience was the most important influencing factor for both operative time and blood loss. PSM rate was mainly determined by tumor stage rather than by operation experience.

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1. Introduction

Prostate cancer (PCa) is the most generally diagnosed solid malignancy in men and the second leading cause of male cancer-related death in the United States [1]. The morbidity in China is also increasing rapidly [2]. With the development of the robotic platform, the new era has seen an exponential rise in robot-assisted radical prostatectomy (RALP). More than 80% of radical prostatectomies are performed with robot assistance in the United States today. Moreover, since the first da Vinci Surgical System was introduced to China in 2006, it had been widely applied in urinary operation, especially in PCa. To date, RALP has been performed at more than 60 centers in mainland China. Although many high-volume surgeons and institutions have introduced the excellent oncological and functional results abroad [3,4], there remains a lack of a sizable study regarding this procedure in China. We conducted this study to analyze changes in the learning curves and the influencing factors for its functional and oncological outcomes based on our sizable series of 500 RALP cases.

2. Patients and methods

2.1. Patients

A total of 507 consecutive PCa patients who underwent RALP in Changhai Hospital, Shanghai, China, performed by only one surgeon, from April 2012 to October 2017, were enrolled in the study. The surgeon has experienced open radical prostatectomy (ORP) skills without laparoscopic radical prostatectomy (LRP) experience. Patients whose postoperative pathology was not PCa and those who received preoperative neo-adjuvant radiotherapy or androgen-deprivation therapy (ADT) were excluded, leaving 500 patients to be included in the study. Preoperative data were collected, including age, body mass index (BMI), serum prostate-specific antigen (PSA), biopsy Gleason score (GS), and clinical stage. All intraoperative details (including operative time and blood loss), postoperative data (including pathologic stage, pathologic GS, and postoperative hospital stay) and pathologic results (such as surgical margin status) were also recorded.

2.2. RALP technique and data collection

We performed the RALP procedure as described previously [5—7]. A transperitoneal approach was performed, using six trocar ports of a conventional four-arm da Vinci Robotic System (Intuitive Surgical, Sunnyvale, CA, USA). Specimens were fixed, coated with Indian ink, and cut into systemic stepwise sections at 5 mm intervals. The positive surgical margin (PSM) was defined as the presence of malignant glandular cells on the inked surface of the specimen. Perioperative complication was recorded according to the Clavien-Dindo classification system.

Patients were followed up for clinical outcomes and PSA level every month in the first year after RALP, and then every 6 months during the next 5 years. Postoperative continence was defined as achieving the use of zero or one pad for "security" daily and was evaluated by the 1-year pad-free rate. Because of higher age, Chinese traditional ideology and greater risk of patients in the present study compared with Western patients, the number of patients who wanted to receive nerve-sparing RALP was relatively low. No potency information was recorded; most of the patients were impotent or had low sexual desire before surgery. Selective unilateral or bilateral interfascial nerve-sparing RALP was performed in 68 patients. Postoperative follow-up time was set to the last day of biochemical recurrence (BCR). BCR was defined as two consecutive confirmed PSA level of $>$0.2 ng/mL after RALP.

3. Data analysis

Normally and continuously distributed variables were presented as the mean $\pm$ standard deviation (SD); nonnormally distributed variables were presented as median with interquartile range. The learning curve of this study was analyzed from three aspects, including preoperative data, pathological results and functional outcomes. Measurement data that were normally distributed were analyzed using ANOVA tests among the five groups. Measurement data that were nonnormally distributed were analyzed using the Kruskal-Wallis test followed by stepwise step-down comparisons to compare the significant difference between two groups. Categorical data that were nonnormally distributed were analyzed by using the Kruskal-Wallis test. Learning curves were depicted by using locally weighted scatter plot smoothing regression analysis with EXCEL 2016. SPSS 22.0 for Windows (SPSS, Inc., Chicago, IL, USA) was used for all other statistical calculations and analyses. Statistical significance was regarded as a p-Value of less than 0.05.

4. Results

4.1. Baseline demographics

Table 1 shows the demographics and clinical summary statistics for the study cohort. The mean$\pm$SD age was 66.7$\pm$6.79 years, the mean BMI was 24.3$\pm$2.82 kg/m^2, and the median preoperative PSA was 14.0 ng/mL. In total, 129 (25.8%), 188 (37.6%), and 183 (36.6%) patients had biopsy GS $<$7, $=$7, and $>$7, respectively. The incidence of low-risk, intermediate-risk and high-risk patients was 11.8%, 28.4%, and 59.8%, respectively. Patient characteristics between groups regarding age, BMI, preoperative GS, preoperative PSA and risk stratification showed no statistical significance (all $p>0.05$).

4.2. Perioperative and pathologic outcomes

The operation parameters and pathological information for all of the cases are shown in Table 2. The total median (interquartile range, IQR) operative time, which was defined as the period from the separation of pelvic fascia to the completion of bladder and urethra anastomosis, was 120.0 (100.0—150.0) min, and the overall median (IQR) blood loss was 100.0 (100.0—200.0) mL. Using the learning curve, we can intuitively observe the significant changes in

Table 1 Preoperative characteristics for each group and overall.

Clinical data	Group 1	Group 2	Group 3	Group 4	Group 5	*p*-Value	Overall
	1–100	101–200	201–300	301–400	401–500		
Age, mean±SD, year	67.4±6.85	66.5±6.57	66.2±6.30	66.7±6.45	66.7±7.75	0.788[b]	66.7 (6.79)
BMI, mean±SD, kg/m^2	24.0±2.90	24.4±2.70	24.6±2.83	24.1±2.41	24.6±3.20	0.502[c]	24.3 (2.82)
Preoperative PSA, *n* (%)						0.342[d]	
<4.0	4 (4.0)	2 (2.0)	1 (1.0)	1 (1.0)	2 (2.0)		10 (2.0)
4.0–9.9	35 (35.0)	34 (34.0)	27 (27.0)	32 (32.0)	31 (31.0)		159 (31.8)
10.0–19.9	31 (31.0)	31 (31.0)	33 (33.0)	33 (33.0)	32 (32.0)		160 (32.0)
>19.9	30 (30.0)	33 (33.0)	39 (39.0)	34 (34.0)	35 (35.0)		171 (34.2)
Clinical stage, *n* (%)						0.005[d]	
T1	30 (30)	37 (37)	63 (63)	40 (40)	24 (24)		194 (38.8)
T2	61 (61)	54 (54)	23 (23)	41 (41)	54 (54)		23 (46.6)
T2a	31 (31.0)	32 (32.0)	12 (12.0)	19 (19.0)	13 (13.0)		107 (21.4)
T2b	30 (30.0)	21 (21.0)	2 (2.0)	6 (6.0)	11 (11.0)		70 (14.0)
T2c	0 (0.0)	1 (1.0)	9 (9.0)	16 (16.0)	30 (30.0)		56 (11.2)
T3 and T4[a]	9 (9.0)	9 (9.0)	14 (14.0)	19 (19.0)	22 (22.0)		73 (14.6)
GS, *n* (%)						0.633[d]	
<7	21 (21.0)	33 (33.0)	30 (30.0)	24 (24.0)	21 (21.0)		129 (25.8)
=7	45 (45.0)	38 (38.0)	26 (26.0)	35 (35.0)	44 (44.0)		188 (37.6)
>7	34 (34.0)	29 (29.0)	44 (44.0)	41 (41.0)	35 (35.0)		183 (36.6)
D'Amico risk group, *n*(%)						0.084[d]	
Low	12 (13.0)	10 (10.0)	14 (14.0)	12 (12.0)	10 (10.0)		58 (11.8)
Intermediate	31 (33.0)	38 (38.0)	22 (22.0)	26 (27.0)	22 (22.0)		139 (28.4)
High	57 (54.0)	52 (52.0)	64 (64.0)	62 (61.0)	68 (68.0)		303 (59.8)

BMI, body mass index; PSA, prostate-specific antigen; IQR, interquartile range; GS, Gleason score; SD, standard deviation.
[a] Only one T4a case in group 1.
[b] Comparison of age among five groups: ANOVA (analysis of variance).
[c] Comparison of BMI between five groups: Kruskal–Wallis test.
[d] Comparison of preoperative PSA, clinical stage, biopsy Gleason score, D'Amico risk group between five groups: Chi-square test.

operative time and intraoperative blood loss as the surgeon's surgical experience increases (Fig. 1A and 1B). These parameters reached a plateau after approximately the 200th case (group 1 *vs.* group 2, $p<0.001$ and $p<0.001$, respectively), whereas no obvious plateau was observed in the third and the fourth groups ($p=0.814$ and $p=0.613$, respectively) (Supplementary Table 1). After 400 cases, a second dramatic decline was observed (group 4 *vs.* group 5, $p<0.001$ and $p<0.001$, respectively). Further analysis showed that experience was the most important influencing factor in both operative time and blood loss (Supplementary Table 2 and Supplementary Table 3). And conducting pelvic lymph node dissection (PLND) was a significant factor for increasing operative time. The total median (IQR) postoperative hospital stay was 6.0 (5.0–8.0) days. A similar pattern was also observed in postoperative hospital stay (Fig. 1C), in which the plateaus were also observed after approximately the 200th case.

There were 300 patients (60%) with pT2 stage, 114 (22.8%) with pT3a stage, 83 (16.6%) with pT3b stage, and three (0.6%) with pT4 stage in all five groups. The PSM rate was 21.8% overall. No statistically significant difference was observed among these five groups in PSM rate. The percentage of patients with PSM in pT2 stage tumors was 12.0%, whereas patients with no nerve-sparing operation had a PSM rate of 12.2%, and patients with a nerve-sparing operation had a PSM rate of 11.1% ($p=0.926$). The PSM rate in pT3 stage tumors was 37.1%, which was significantly higher than that of the patients with pT2 stage tumors ($p<0.001$). The PSM rates of patients with pT3 stage were 26.1% and 38.5% for those who received nerve-sparing operation or not, respectively ($p=0.246$). The surgeon's increasing experience or the nerve-sparing operation did not seem to affect the PSM rate. The condition of the tumor itself was in key preventing PSM. No statistically significant difference was observed among each group for postoperative GS.

The median (IQR) follow-up time for all of the patients was 13 (5–24) months. Regarding continence, 390 cases were included. During the follow-up, only 3.8% of patients were constantly suffering postoperative urinary incontinence. The continence recovery rate was shown in Fig. 2A. The one-, three-, six- and the twelve-month recovery rates were 26.15%, 58.54%, 80.06%, and 92.08%, respectively.

Regarding the BCR-free survival rate, 295 patients were included in the series, excluding those who received adjuvant ADT or radiotherapy immediately after the operation. The BCR rate was 14.2% (71/500) at the median 13-month follow-up. The rate of BCR-free survival was showed in Fig. 2B.

Cox regression was used to analyse the possible risk factors for BCR. In univariate analysis, preoperative PSA, pathological T stage, PSM and postoperative GS were significant risk factors for BCR ($p<0.001$). However, in multivariate analysis, only preoperative PSA, pathological T stage and postoperative GS were independent risk factors

Table 2 Perioperative characteristics for each group and overall.

Characteristics	Group 1	Group 2	Group 3	Group 4	Group 5	*p*-Value	Overall
	1–100	101–200	201–300	301–400	401–500		500
Operative time, median (IQR), min	165 (140–198.75)	130 (110–150)	110 (100–123.75)	105 (90–130)	90 (75–105)	<0.001[a]	120 (100–150)
Blood loss, median (IQR), mL	200 (105–300)	200 (100–200)	100 (70–187.5)	100 (100–200)	100 (50–128.75)	<0.001[a]	100 (100–200)
Postoperative hospital stays median (IQR), day	9 (7–11)	6 (5–8)	5 (5–7)	5 (4–7)	5 (4–6)	0.001[a]	6 (5–8)
NVB preserving, *n*	1	1	6	26	34		68
Unilateral	1	0	3	9	11		
Bilateral	0	1	3	17	23		
T2	1	1	6	26	32		
T3	0	0	0	0	2		
Pathologic stage, *n* (%)						0.001[b]	500
pT2	75 (75)	66 (66)	47 (47)	58 (58)	54 (54)		300 (60)
pT3	23 (23)	34 (34)	53 (53)	42 (42)	45 (45)		197 (39.4)
pT4	2 (2)	0 (0)	0 (0)	0 (0)	1 (1)		3 (0.6)
Gleason score, *n* (%)						0.201[b]	
<7	20 (20)	15 (15)	13 (13)	15 (15)	14 (14)		77 (15.4)
=7	54 (54)	64 (64)	54 (54)	58 (58)	51 (51)		281 (56.2)
>7	26 (26)	21 (21)	33 (33)	27 (27)	35 (35)		142 (28.4)
PSM^+ *n* (%)	23 (23.5)	24 (24.0)	29 (29.0)	18 (18.0)	15 (15.2)	0.143[b]	109 (21.8)
pT2	13 (17.3)	9 (13.6)	5 (10.6)	5 (8.6)	4 (7.4)	0.409[b]	36 (12.0)
pT3	10 (43.5)	15 (44.1)	24 (45.3)	13 (31.0)	11 (24.4)	0.170[b]	73 (37.1)

IQR, interquartile range; NVB, neurovascular bundle; PSM, positive surgical margin.

[a] Comparison of operative time, blood loss, and postoperative hospital stays between five groups: Kruskal-Wallis test followed by stepwise step-down comparisons.

[b] Comparison of pathologic stage, Gleason score, PSM between five groups: Chi-square test.

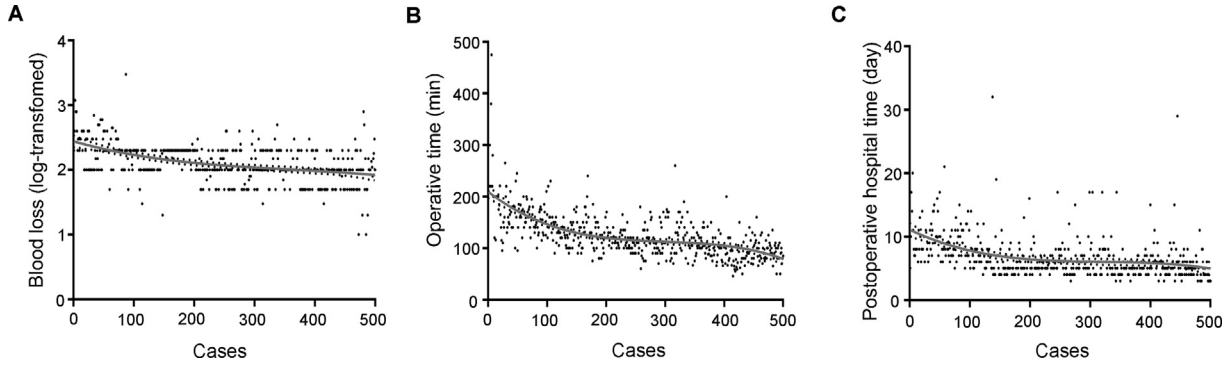

Figure 1 The learning curve of intraoperative blood loss (A), operative time (B) and postoperative hospital stays (C).

for BCR (Table 3). Due to the patients who had positive lymph nodes received ADT therapy immediately after operation and were excluded from the Cox regression, there was a lack of enough samples to investigate the relationship between lymph nodes and BCR.

Of the available 500 patients, two patients (0.4%) were converted to open surgery due to severe adhesions between the prostate and the rectum or blood loss. During the perioperative period (0—30 days), one patient had prolonged pelvic drainage output; the rate of blood transfusion was 0.4% (2/500). One patient experienced slipping of the urethral catheter that required bedside insertion, and one patient had urinary retention after catheter removal, which was relieved after oral administration of alpha blockers. One of the patients had urethral stricture and one had a pulmonary embolism. All patients have recovered well to date (Supplementary Table 4).

5. Discussion

Compared with their use in Western countries, the use of robotics in mainland China is relatively new. Our research analyzed the learning curve for PCa control after RALP, based on the analysis of the first 500 surgeries performed by a single surgeon at a high-volume center in China. No routine PSA screening is performed in the Chinese mainland, which is why our surgical population has higher PSA results (14.0 ng/mL) than other studies (4.9—7.2 ng/mL), and high-risk patients account for 59.8% of the total

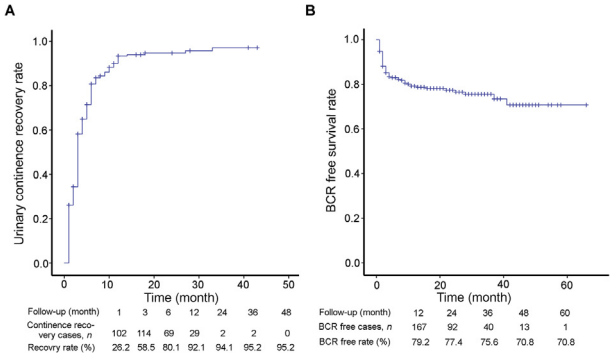

Figure 2 The continence recovery rate (A) and the biochemical recurrence-free survival rate (B). BCR, biochemical recurrence.

compared to other series (6.5%—13.25%). The situation is relatively similar to the background reported by Ou et al. in Taiwan, China [7], with an average PSA of 18.5 ng/mL for all the patients and 48.4% of the patients are high-risk.

Perioperative outcomes, such as operating time and blood loss, are at least comparable to or even better than the results obtained in other larger published series of RALP [8—11]. The analysis conducted in the present research revealed a statistically significant improvement in these variables throughout the series. In contrast to our general hypothesis, the results of multivariate linear regression analysis showed that neurovascular bundle (NVB) preservation did not increase operation time. The results may also vary with the increasing number of NVB preservation operations. The operation experience and conducting PLND were significant factors for operative time. However, the PLND rate had no statistical difference among the five groups, so extensive surgical experience can significantly shorten operation time.

Oncologic prognosis is the dominant endpoint for patients with PCa receiving RP. BCR is an important point to indicate the prognosis. Without further radiotherapy or ADT therapy, about 34% patients will develop into distant metastasis after BCR. Based on previous research, many factors may affect the BCR rate, such as preoperative PSA, GS, pathological stage, surgical margin status and so on [12]. However, all of the factors above, except PSM, cannot be avoided by surgeons, but whether the PSM could predict biochemical recurrence was still controversial [12,13]. The study of Evren et al. [13] showed PSM was not a risk factor for BCR. In our study PSM was not a significant factor for BCR in multivariate COX regression either, which might be caused by the short follow-up time. However, prevention of PSM is still a crucial point for RP. Multiple studies have evaluated the PSM based on pathologic stages. According to the results, PSM rates are highly variable [14,15]. Vickers et al. [16] reported an overall PSM rate of 27% in a retrospective analysis of 7 765 patients treated with RRP in four major American academic medical centers. They also showed that PSM are strongly influenced by surgical experience.

Generally, comparing surgical margin rates between series is difficult because of the variations in a large population of patients. However, the positive surgical margin rates for patients with organ-confined disease (Stage pT2) should be comparable. On our further analysis, although

Table 3 The association of possible risk factors of BCR.

Covariate	Univariate analysis		Multivariate analysis	
	HR (95% CI)	*p*-Value	HR (95% CI)	*p*-Value
Postoperative GS				
=6[a]	1		1	
>7	24.717 (5.827−100.272)	<0.0001	11.325 (2.590−49.520)	0.0013
Preoperative PSA				
<10[a]	1		1	
>20	7.004 (3.672−13.359)	<0.0001	4.174 (2.077−8.391)	<0.0001
Age				
≤59[a]	1			
74	1.475 (0.638−3.411)	0.3631		
BMI				
<24[a]	1			
≥24	1.100 (0.671−1.802)	0.7065		
Pathologic T stage				
<T3a[a]	1		1	
≥T3a	5.802 (3.457−9.739)	<0.0001	2.344 (1.226−4.341)	0.0067
Pathologic N stage				
N0[a]	1		1	
N1	6.366 (3.390−11.952)	<0.0001	1.756 (0.880−3.502)	0.1102
PSM				
Negative[a]			1	
Positive	3.967 (2.410−6.528)	<0.0001	1.837 (1.052−3.207)	0.0325

GS, Gleason score; PSA, prostate-specific antigen; BMI, body mass index; PSM, positive surgical margins; BCR, biochemical recurrence; HR, hazard rate; CI, confidence interal.

[a] Reference group.

the incidence of PSM gradually decreased by cases in pT2 tumors and pT3 tumors, the incidence of PSM did not significantly decrease with the surgeon's experience. The condition of the tumor itself perhaps is more related to PSM. It may be controversial that the experience simply conduces to the improvement in PSM rates. Several studies have reported PSM rates in a surgeon's early experience [16,17] and showed a "learning curve" of 20−50 cases [18,19]. Some studies suggested that surgeons' surgical experience is closely related to the PSM [20,25,26]. However, if enhanced experience was the influencing factor, one would expect to see a steady reduction in PSM. After comprehensive analysis, we found no dramatic reduction in PSM rates with increased experience in our study. The ability to accomplish negative surgical margins depends on both the disease itself and the preservation of the tissues. Surgeons must accomplish a balance between preservation of the neurovascular bundles, functional tissues and sufficient resections of tumors in situations suspected of having extracapsular extension. Some authors found that a dramatic reduction in PSM rates coincided with a change in technique [17,21]. Others compared their own open experiences to robotic experiences. Ahlering et al. [22] found no significantly significant difference between open results versus RALP results within a single institution regarding PSM. Menon et al. [23] conducted a prospective comparison of 30 consecutive patients undergoing RRP and 30 initial patients undergoing RALP evaluating baseline patient and tumor characteristics. They found that surgical margin statuses were comparable for both techniques [23]. We agree with Ahlering et al. [22] that in spite of the technique used, a key factor in reducing the PSM rate during RALP is an elaborate dissection of the prostatic apex and the removal of peri-prostatic fat. It is reported in the literature that to minimize the PSM rates in laparoscopic RP, surgeons should complete at least 200 to 250 cases of surgery and 1 000 to 1 500 RALP cases [24,25]. In particular, there is a widespread shortage of surgical cases and inadequate experience among surgeons in the Chinese mainland, which contributes to the risk of PSM. This fact could be another reason why no significant difference was observed in our study.

This research had only one single surgeon, which reduces bias when compared with other research that had two or three surgeons. In addition, our research applied the appropriate statistical methods, not only to confirm that these preoperative data were not the same in the five groups, but also to determine the exact difference between the groups. Over time, our study may provide a reference for other surgeons.

Our study has limitations, particularly the relatively short follow-up. RALP is a relatively new procedure that is not commonly performed in China until 2007. With longer follow-up, our results may be different.

6. Conclusion

In conclusion, our findings demonstrate that RALP is a safe, minimally invasive procedure that is technically feasible with good intermediate-term pathological and oncological outcomes and desirable functional results. After approximately 200 cases, the surgeon reached a plateau for RALP, but the outcomes could still improve after more cases. The

surgeon's experience was the most important influencing factor in both operative time and blood loss. The PSM rate was mainly determined by tumor stage rather than operation experience.

Author contributions

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Critical revision of the manuscript: Yinghao Sun, Xu Gao.

Conflicts of interest

The authors declare no conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajur.2019.12.004.

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