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# **Original Article**

# Laparoscopic radical prostatectomy: oncological and functional results of 126 patients with a minimum 3-year follow-up at a single Chinese institute

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#### Abstract

In this study we evaluate the oncological and functional results of the largest cohort of patients in China treated by laparoscopic radical prostatectomy (LRP) and with at least 3 years of follow-up. 126 inconsecutive patients (range 56–78 years, median 62.5) who had an LRP were retrospectively analyzed. The mean prostate specific antigen level and Gleason score was 13.4 ng mL<sup>-1</sup> and 6.4, respectively. Twenty-seven patients had unilateral or bilateral nerve preservation and 29 had pelvic lymphadenectomy. Multivariate analysis was used to adjust for differences in clinical and pathological features when comparing the risk for biochemical progression-free survival (bPFS). Urinary continence was assessed by incontinence questionnaire and erectile function by the Sexual Health Inventory for Men score. The mean operative duration was 250 min and blood loss 354 mL. Five patients received blood transfusion and nine had complications, including rectal injury (two), ureteral injury (one), active bleeding (one), bladder neck stenosis (two), paralytic ileus (one), subcutaneous hematoma (one) and port-site hernia (one). The overall positive surgical margin rate was 20.6% and correlated with pathological stage and Gleason score respectively (P = 0.03, P < 0.001 respectively). All patients had  $\geq 3$  years of follow-up (range 3–6.75 years, mean 4.6, median 4.75). At 3 years of follow-up, the overall survival rate was 100% and the bPFS was 81.0% in all patients; 124 patients (98.4%) were continent; 22 of 27 patients (81.5%) who underwent nerve preservation retained erectile function. Our series confirms that LRP is an effective, safe and precise technique at Chinese institution.

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Keywords: complication, follow-up, laparoscopic surgery, prostate cancer, prostatectomy, survival

#### 1 Introduction

Prostate cancer (PCa) is one of the most common malignancies in Western countries, but it is relatively

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rare in China. In an epidemiological study, Yu *et al.* [1] reported a 26-fold higher rate of PCa in American than in Chinese men, with an intermediate rate in Chinese-American men. Such differences may be due to genetic and/or environmental factors [1].

Although PCa is uncommon in China, some recent reports indicate that its incidence is increasing rapidly [2]. Gu [3] evaluated the incidence of PCa at 187 hospitals based in 26 Chinese provinces. The overall incidence rate of PCa in 1997 was 1.5% (1 389/95 749). Between 1951 and 1960 the incidence rate of PCa at the Institute of Urology, Beijing University was 0.6%.

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From 1991 to 1997 this rate increased to 3.4%.

Despite numerous treatment options being currently available, open radical prostatectomy (ORP) remains the standard treatment for patients with clinically localized PCa (cT1–2) and a life expectancy of > 10 years [4]. However, during the last decade laparoscopic radical prostatectomy (LRP) techniques have developed dramatically in urology, particularly in Europe. The first LRP was performed in 1997 by Schuessler *et al.* [5]. Since then, LRP has been reported widely and it has gained popularity as a PCa treatment [6].

Many comparative studies have confirmed the advantages of laparoscopic surgery in terms of blood loss, transfusion rates, postoperative pain scores, and the duration of both catheterization and hospitalization, with similar peri-operative complication rates to those of open prostatectomy [7, 8]. Some of these perioperative advantages could be correlated with the reduced invasiveness of the laparoscopic procedure. However, the limited duration of follow-up reported in these comparative studies does not allow a longterm evaluation of biochemical disease-free survival probabilities [9]. As for the functional results, at present it is difficult to compare the laparoscopic and open approaches, because of variability in the end points used to evaluate the outcome, and owing to the different lengths of follow-up [7, 9].

In 2000, we performed the first LRP for clinically localized PCa in China. Based on our previous experiences [10–12], in this study, we evaluated the medium-term oncological and functional results after LRP at our institute.

# 2 Materials and methods

# 2.1 Patients selection

From October 2000 to May 2004, 126 patients diagnosed with clinically localized PCa (cT1–2) underwent LRP at our institute. Their medical records were reviewed retrospectively. In principle, indications for LRP were the same as those for open prostatectomy, and patients with clinical stage T1c–2c PCa with a life expectancy of more than 10 years were candidates [4]. The selection of LRP was based on a joint decision by surgeons and patients, who were appropriately informed about the surgical procedures and possible complications and provided written informed consent to the surgery and to the use of their clinical data for this study.

# 2.2 Inclusion and exclusion criteria

The study included patients with stage T1c– 2cN0M0 localized PCa; those who had had previous hormone therapy, chemotherapy, radiotherapy or surgery for PCa were excluded. Patients suspected of having metastases on CT or MRI of the abdomen and pelvis, or radionuclide bone scan were also excluded. The Human Ethics Review Committee of the Third Affiliated Hospital, Sun Yat-Sen University approved the study protocol.

# 2.3 Pre-operative data

The median (range) age of the 126 patients was 62.5 (56–78) years. The mean prostate-specific antigen (PSA) level and Gleason score were 13.4 ng mL<sup>-1</sup> and 6.4, respectively (Table 1). All patients had a negative radionuclide bone scan and CT or MRI. All had undergone LRP alone without any kind of neoadjuvant or adjuvant therapy for managing their PCa.

Table 1. Patient demographics and pathological data.

Characteristic	Mean (range) or $n$ (%)
No. of patients	126
Age, years	62.5 (56–78)
PSA level, ng mL <sup>-1</sup>	
< 10	67 (53.2)
10–20	38 (30.2)
> 20	21 (16.6)
Clinical stage	
T1c	22 (17.5)
T2a	61 (48.4)
T2b	30 (23.8)
T2c	13 (10.3)
Biopsy Gleason score	
2–6	80 (63.5)
7	26 (20.6)
8–10	20 (15.9)
Pathological stage	
T2a	57 (45.2)
T2b	26 (20.1)
T2c	28 (22.2)
T3a	9 (7.1)
T3b	6 (4.4)
Pathological Gleason score	
2-6	59 (46.8)
7	31 (24.6)
8-10	36 (28.6)

Abbreviation: PSA, prostate-specific antigen.

# 2.4 Surgical procedure

LRP was performed using the Montsouris technique, with some modifications by us [10-13]. In brief, after the puboprostatic space is developed, the bilateral endopelvic fascia of the prostate is dissected longitudinally toward the apex and puboprostatic ligament section. The dorsal vein complex is divided and sutured with 2–0 Vicryl. When the bladder neck is transected and its posterior wall opened, the vas deferens and seminal vesicles are dissected carefully to avoid injury to the pelvic plexus. The Denonvilliers' fascia is exposed and opened, and the posterior plane of the prostate is created and extended to the apex of the prostate. The lateral vascular pedicle of the prostate is then dissected using a harmonic scissors. A sharp scissor is used to cut the anterior aspect of the urethra close to the prostate apex. The specimen is entrapped in an extraction bag. The vesicourethral anastomosis is performed using a monofilament 3:0 absorbable suture in a continuous manner. All operations were performed by a single experienced surgeon (XG).

A modified pelvic lymphadenectomy, as described by Stone *et al.* [14], was used in patients with a PSA level of > 20 ng mL<sup>-1</sup> or biopsy Gleason score of > 7. Preservation of the neurovascular bundle was attempted in patients with a PSA level of < 10 ng mL<sup>-1</sup> and a primary Gleason score of 3. During LRP the consistency of the local tissue was examined, and if induration was present the ipsilateral neurovascular bundle was excised.

# 2.5 Intra- and peri-operative data acquisition

The operative duration (the time from first incision to closure of the last wound) was recorded. Oral fluids and diet were introduced as tolerated. The drain was removed when the drainage was < 100 mL per 24 h. Patients were discharged home when comfortable.

For the purposes of histopathological analysis specimens were inked, apical and basal shaves taken, and the prostate then sliced in entirety. Whole-mount sections were cut and examined after routine hematoxylin and eosin staining. Positive surgical margins (PSMs) were defined as any cancer cells in contact with ink. All specimens were examined by a single pathologist.

# 2.6 Follow-up

Patients were assessed at 4 weeks after surgery, then at 3-month intervals during the first year and at every 6 months subsequently. Each visit except for the first was preceded by serum PSA measurement, and functional results prospectively recorded by the same reviewing clinician. An interview at the outpatient clinic or a telephone questionnaire was used to evaluate the urinary continence and erectile function.

Biochemical progression was defined as a PSA level of > 0.2 ng mL<sup>-1</sup> after LRP. Urinary continence after surgery was defined as being pad-free, according to a validated symptom questionnaire. Erectile function was considered normal after LRP if the Sexual Health Inventory for Men (SHIM) score was > 22 in patients whose previous score was > 22 [15].

# 2.7 Statistical analysis

Fisher's exact test was used to compare PSM rates among different pathological stages and Gleason grade groups. Biochemical progression-free survival (bPFS) was analyzed using the Cox proportional hazard model, with multivariate survival analyzed using the stepwise backward procedure to identify whether the variables (including pretreatment PSA, PSM, pathological stage, pathological Gleason grade, seminal vesicle involvement, invasion of the prostate capsule, a nervesparing procedure, tumor volume, *etc.*) had significant independent relationships with survival. The Kaplan– Meier method with the log-rank test was then used to compare the bPFS among different groups. In all analyses, P < 0.05 was considered to indicate statistical significance.

#### 3 Results

The patient characteristics are summarized in Table 1. All of the 126 LRPs were successfully performed, and there was no conversion to open surgery. Patients were hospitalized for a mean (range) of 6.7 (5-19) days after LRP. Five patients received a blood transfusion and twelve had a fever ( $\geq 38.5^{\circ}$ C). Drains were removed in all patients before discharge. Catheters were removed after a mean (range) of 6.1 (3–15) days, all with no previous cystogram. Twenty-nine patients had a modified pelvic lymphadenectomy. The mean count of removed lymph nodes was 9.2 and none had metastatic nodal disease on final histology. In 27 patients, preservation of the neurovascular bundle was accomplished. A comparison between the first 63 and second 63 cases of the series was made, highlighting the impact of surgical experience. The operative duration decreased significantly with experience (P < 0.05), but



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the mean blood loss was similar in the first and second cohorts of 63 cases (Table 2).

There were four major complications, all occurring in the first 30 cases of the series. These included rectal injuries in two cases, ureteral injury in one and active bleeding from retropubic vessel complex in one patient. The rectal and ureteral injuries were recognized immediately and repaired laparoscopically during the operation with no sequelae. One continued to be hemodynamically unstable during the surgery, which was controlled by retropubic compression with a balloon catheter through the urethra after the gland had been removed. Minor complications were evenly distributed across the series, and consisted of two patients requiring transurethral incision of bladder neck stenoses, one who developed a paralytic ileus, which resolved spontaneously, one with subcutaneous hematoma, which was cured by conservative treatments, and one who required repair of a port-site hernia (Table 2).

The overall PSM rate was 20.6% and was related to pathological stage and pathological Gleason grade (P = 0.03, P < 0.001, respectively, Table 3). All patients had  $\geq$  3 years of follow-up (range 3–6.75 years, mean 4.6, median 4.75). The PSA level was < 0.2 ng mL<sup>-1</sup> at 6 months after surgery in all patients. The total bPFS decreased with the follow-up time (Figure 1). Figure 2 showed bPFS according to pretreatment PSA value (Figure 2A), PSM (Figure 2B), pathological stage (Figure 2C) and pathological Gleason score (Figure 2D), respectively. Although numerous factors were identified as predictive for bPFS, only pretreatment PSA value, PSM, pathological stage and Gleason score were identified as independent prognostic factors for bPFS in multivariate analysis. At 3 years of follow-up, the overall survival rate was 100% and the bPFS was 81% in all patients, 90% for pT2, 61% for pT3a and 43% for pT3b, respectively. Twenty-four (19%) patients had a biochemical progression at a mean duration of 3.2(1-5)years after LRP. In one patient, the sign of recurrence was PSA relapse and bone metastasis. In the other 23 patients, PSA relapse was the only sign of recurrence and these 23 patients were started on hormonal therapy.

Ninety-nine patients (78.6%) were continent after removal of the catheter, 117 patients (92.8%) at 6-month follow-up, 123 patients (97.6%) at 1-year follow-up and 124 patients (98.4%) at  $\geq$  3-year follow-up. Two patients needed pads when abdominal pressure increased. However, no more than 1 pad/ 24 h was needed. Of those

Table 2. Peri-operative outcomes, with a comparison between the first and second group of 63 patients.

Outcome	First 63	Second 63	Overall, mean
Outcome	11150 05	Second 05	(range)
Operative duration, min	274	221*	250 (110-660)
Blood loss, mL	362	349	354 (150-1 100)
Blood transfusion, n	3	2	5
Complications, n			
Rectal injury	2	0	2
Ureteral injury	1	0	1
Active bleeding	1	0	1
Bladder neck stenosis	1	1	2
Paralytic ileus	1	0	1
Subcutaneous hematom	na O	1	1
Port-site hernia	1	0	1

 $^*P < 0.05$ , compared with the first group of 63 patients.

Table 3. PSM rate according to pathological stage and Gleason score.

score.	$\mathbf{DCM} = \{0, \ell\}$	D 1 .
Characteristic	PSM rate (%)	P value
Pathological stage		0.03
T2a	3/57 (5.3)	
T2b	7/26 (26.9)	
T2c	9/28 (32.1)	
T3a	4/9 (44.4)	
T3b	3/6 (50.0)	
Pathological Gleason score		< 0.001
2-6	4/59 (6.8)	
7	6/31 (19.4)	
8–10	16/36 (44.4)	
Total	26/126 (20.6)	

Abbreviation: PSM, positive surgical margin.

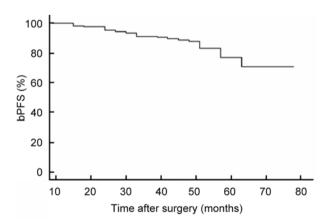


Figure 1. The overall biochemical progression-free survival (bPFS).

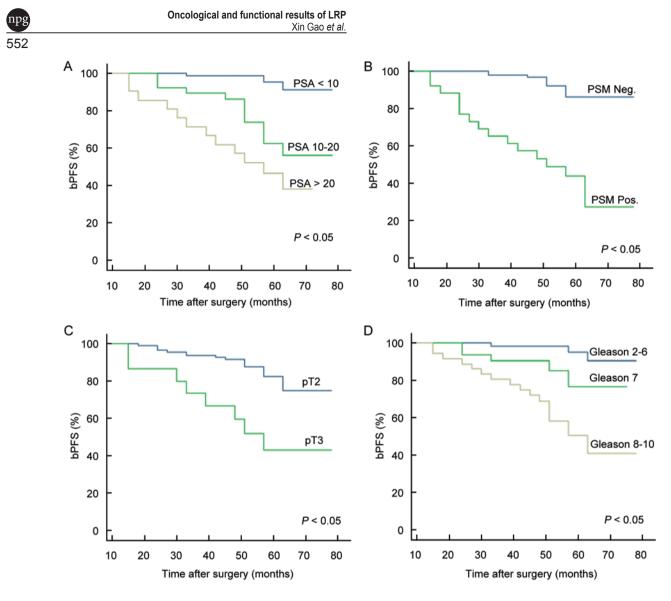


Figure 2. Correlation between biochemical progression-free survival (bPFS) and preoperative PSA level (A), PSM (B), pathological stage (C) and pathological Gleason score (D) (log-rank test, P < 0.05).

patients undergoing nerve preservation, 51.9% (14/27) had satisfactory penile erectile function at 1-year follow-up. At 3-year follow-up, 81.5% (22/27) retained penile erection, and 10 patients were able to have sexual intercourse with the help of phosphodiesterase-5 inhibitor (sildenafil citrate).

#### 4 Discussion

In Western countries PCa has emerged as one of the most common malignancies after the age of 50 years [16]. The wide use of screening programs based on PSA has led to the detection of asymptomatic and early-stage PCa. Indeed, in the United States and Europe PCa is usually asymptomatic at diagnosis, DRE is normal and PCa is diagnosed on the sole basis of increased PSA in more than 60% of cases [17]. Conversely, in China, screening for PCa using DRE and PSA is not done in routine practice. Most newly diagnosed PCa cases are symptomatic and at late stage. In a retrospective analysis of 431 consecutive Chinese patients treated for PCa, PCa was suspected because of increased PSA in only 6.2% of cases. Moreover, only 26% of patients had normal DRE [2]. These results differ markedly from those in Western reports. Hence, the present series of 126 cases with clinically localized PCa at a single institute is a relatively large series in China, which can provide comprehensive information regarding LRP only for Chinese people.

Laparoscopy provides a much magnified and close-up view of the structures deep within the pelvis, which is usually impossible in conventional open surgery, particularly in Chinese men who have a narrower pelvis than Western men. However, the paucity of medium and longer-term results for LRP, as well as training issues, still prevents the wider acceptance and dissemination of this technique, especially in Asian countries with less workload of PCa.

To our knowledge, this is the largest study to date that represents the longest follow-up of LRP in China. The effectiveness of our technique in removing all prostate tissue was confirmed by the PSA level at 6 months of < 0.2 ng mL<sup>-1</sup> in all patients. The malignant potential of organ-confined PCa is usually low and secondary treatments are available for patients with recurrence. As a result, bPFS is frequently used as a surrogate end point. Another surrogate end point for surgical outcome is the margin status.

The oncological data available from comparative studies show that LRP apparently gives results of similar percentages of PSM to those of ORP [18–30] (Table 4). The PSM rates for LRP in pT2 and pT3 disease were 7.4%–27.5% and 17.2%–77.3%, respectively, and for ORP in pT2 and pT3 disease were 3.3%–18.8% and 19.3%–53%, respectively. Our PSM rates (pT2, 17.1%; pT3a, 44.4%; pT3b, 50.0%) were comparable, although we acknowledge the fact that the patients in our series were of better preoperative stage and the follow-up so far has been a brief period of time. Fromont *et al.* [31] reported a significant reduction of PSM in LRP, and LRP was also reported to have lower PSM rates at apex and multiple sites [32].

However, a comparison of the PSM rates between institutes is often difficult because the margin status of the prostate is influenced by factors such as disease extent, surgical skill, preparation of specimen and pathological evaluation. bPFS might offer a better index of oncological outcome. Previous series of LRP reporting bPFS are shown in Table 5 and are compared with large ORP series [18, 22–24, 27–29]. The bPFS rates in the present series at 3-year followup, of 90% for pT2, 61% for pT3a and 43.0% for pT3b, respectively, are comparable with both open and laparoscopic series with a similar duration of follow-up. It is not surprising to find that both PSM and bPFS rates were similar for open and laparoscopic procedures, as

Table 4. PSM rates of prostatectomy techniques in previous reports.

St. t.	No. of		PSM rate (%)			
Study	patients	pT2	pT3a	pT3b		
LRP						
Guillonneau et al.[18]	1 000	15.5	30.0	34.0		
Stolzenburg et al. [19]	700	10.8	31.2	_		
Rozet et al. [20]	600	14.6	26.9	22.6		
Touijer and Guillonneau [21	] 500	8.2	17.2			
Rassweiler et al. [22]	500	7.4	25.2	42.0		
Salomon et al. [23]	137	21.9	40.8			
Hara et al. [24]	136	27.5	77.3	53.8		
Soderdahl et al. [25]	110	13.5	50.0	_		
El-Feel et al. [26]	100	18.1	45.0	50.0		
Present series	126	17.1	44.4	50.0		
ORP						
Catalona and Smith [27]	1 778		20.9			
Swindle et al. [28]	1 209	6.8	19.3	_		
Hull et al. [29]	1 000		12.8			
Pettus et al. [30]	800	3.3	53.0	_		
Salomon et al. [23]	145	18.8	52.7	_		

Abbreviations: LRP, laparoscopic radical prostatectomy; ORP, open radical prostatectomy; PSM, positive surgical margin.

they essentially used the same approach in removing the organ.

In this study, bPFS was statistically significantly correlated with PSM, pathological stage, final Gleason grade and preoperative PSA level. This is in accordance with the results reported by Eden *et al.* [33]. They also drew a similar conclusion in their series, but the correlation between PSM and bPFS did not attain statistically significant difference.

Urinary continence was second only to tumor control as an evaluation indicator of the effectiveness of LRP. The reported rates of urinary continence after LRP compare favorably with those in large series of ORP, which have been reported to be 80%–95%. Although the definition of urinary continence varies among the reported series, the incidence of requiring no pads after LRP was 83%–100% at 1 year [22–25]. In a prospective comparison of 70 patients with ORP and 230 with LRP, there was no significant difference in continence at 1 year, but patients undergoing LRP had an earlier return to continence [23]. Many investigators have proved the importance of the external urethral sphincter and its related structures to postoperative urinary continence. Based on our initial experience, we

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Table 5. bPFS	rates of p	rostatectomy	techniques	ın	previous rep	orts.

Study No. of patients		t	bPFS at 3 years (%)			bPFS at 5 years (%)		
	pT2	pT3a	pT3b	pT2	pT3a	pT3b		
LRP								
Guillonneau et al.[18]	1 000	90.4	77.1	44.1	—		_	
Rassweiler et al. [22]	500	95.2	74.1	69.0	89.5	81.2	54.5	
Salomon et al. [23]	137	90.4	56.8		—		_	
Hara et al. [24]	136	91.8	66.8	44.9	—		_	
Present series	126	90.0	61.0	43.0	—			
ORP								
Catalona and Smith [27]	1 778	92.5	78.0	47.5	87.5	65.9	30.0	
Swindle et al. [28]	1 209		—	—	93.7	80.0	_	
Hull et al. [29]	1 000	_	—		94.9	76.3	37.4	

Abbreviations: bPFS, biochemical progression-free survival; LRP, laparoscopic radical prostatectomy; ORP, open radical prostatectomy.

discovered that the posterior urethra contributes to the function of the sphincter, and so the posterior urethral stump and its posterior walls should be preserved for as long as possible. Besides, all patients in our study practiced urinary continence training, such as the Kegel exercises or biofeedback therapy, 1 week after catheter removal. The urinary continence rate was 97.6% at 1 year when using these techniques.

When neurovascular bundles were preserved during LRP, the reported penile erectile rates were 33%–85% [18–23]. In this study, it was 51.9% at 1 year and 81.5% at 3 years after surgery. These results are similar to those of Guillonneau [18]. In order to decrease the risk of thermal nerve injury, we used titanium clips or Ham-lock instead of bipolar diathermy during the seminal vesicle and neurovascular bundles dissection. In addition, sildenafil citrate given in small dosages during the early recovery stages can stimulate the function of the sexual nerves and prevent sexual neural dystrophy [34].

Notably, the functional outcomes in this study seem to be better than those of several previous reports [22–25]. Although wide disparity exists in the reported continence and erectile function after LRP, which could result from differing definitions of continence and erectile function, surgical techniques and qualityof-life instruments used, there is possible observer– receiver bias when evaluating the functional results by outpatient or telephone interviews. Response rate, which is difficult to determine in outpatient or telephone interviews, is important to estimate the significance of continence or erectile function for patients after LRP [35, 36]. All functional results of our patients were prospectively recorded by the same reviewing clinician to minimize the interobserver bias; however, the survey results were probably affected by the observerexpectancy effect. A prospective evaluation with validated quality-of-life questionnaires using mailin or web survey is the optimal method for evaluating functional outcomes and could be the focus of a future study.

The major obstacle in adopting the laparoscopic procedure is the long operation time. Indeed, laparoscopic surgery in the pelvic cavity is difficult to perform for a surgeon with limited LRP experiences at the beginning. To overcome these difficulties, we learned the laparoscopic technique from other types of laparoscopic surgery, such as laparoscopic ureterolithotomy and nephrectomy, by watching the operations done by experienced surgeons and practicing the skills on experimental pigs. All of these methods help us to shorten the learning curve and accumulate the experience of LRP quickly. For the first case, our operative duration was 660 min. The operative duration decreased significantly with experience. Although there is still much room for improvement, our average operative time of 250 min and blood loss of 354 mL compared favorably with the average operative time of 403 min and blood loss of 856 mL in a larger Asian series [24]. The four major complications seen in the first 30 patients of our series are a testament to the technical difficulty of this procedure.

In summary, our series confirms the reproducibility of the results of other centers using LRP for safety and efficacy at the present Chinese institution. This will help to make LRP a more appealing option to the patients. However, our study also confirms that LRP is technically demanding and requires extensive initial experience.

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