Original Article

Patient-reported outcomes after robot-assisted radical prostatectomy and institutional learning curve for functional outcomes

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Abstract

Purpose: The study was performed to examine patient-reported outcomes (PROs) in the 1st year after surgery and the institutional learning curve after the introduction of robot-assisted radical prostatectomy (RARP).

Materials and Methods: The subjects were 320 consecutive patients who underwent RARP from 2014 to 2018. These cases were divided into three groups treated in the early, middle, and late periods, with about 100 cases in each. PROs were recorded using the Expanded Prostate Cancer Index Composite (EPIC).

Results: There were no significant differences among the early, middle, and late periods based on EPIC scores. Urinary function and bother decreased in the 1st month after surgery, and gradually recovered thereafter. However, urinary function was significantly worse in the 1st year after surgery than at baseline. Urinary function and bother were better in patients treated with nerve-sparing surgery, and in nerve-sparing cases, urinary function and bother were best in the early period and worst in the late period. These cases also had the best score for sexual function in the early period, but sexual bother was worst in the early period. In contrast, in cases treated without nerve-sparing surgery, urinary function and bother were best in the late period and worst in the early period, although without significant differences.

Conclusion: The functional results of this study based on PROs are useful for providing information for patients. Interestingly, the institutional learning curves for RARP differed in cases that did and did not undergo a nerve-sparing procedure.

Keywords: Expanded Prostate Cancer Index Composite, nerve sparing, sexual function, urinary function

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Received: 07.05.2022, **Revised:** 26.06.2022, **Accepted:** 18.07.2022, **Published:** 08.11.2022.

INTRODUCTION

Prostate cancer is increasing in Japan and may now be the second most common malignancy in males.[1] Almost all patients without metastasis undergo radical treatment such as radical prostatectomy (RP) or radiotherapy (RT), and these treatments have recently changed markedly. In particular, surgery has undergone a major transformation from open to endoscopic surgery. RP was performed by open RP (ORP) until the late 1990s, but is now achieved using minimal invasive surgery, such as laparoscopic RP (LRP) and robot-assisted RP (RARP). We have performed LRP from 2011 and RARP since 2014.

Access this article online	
Quick Response Code:	Website: www.urologyannals.com
	DOI: 10.4103/ua.ua_75_22

How to cite this article: Hashine K, Tada K, Minato R, Sawada Y, Matsumura M. Patient-reported outcomes after robot-assisted radical prostatectomy and institutional learning curve for functional outcomes. Urol Ann 2023;15:60-7.

RARP is equal to or better than ORP and LRP for oncological outcomes[2] and for functional outcomes.[3,4] Patient-reported outcomes (PROs) are increasingly used for functional evaluation since they assess the quality of life accurately. However, Sonn *et al.* found that physician ratings of symptoms do not correlate well with PROs, and that disagreement between physician and patient ratings did not decrease over time.[5] We have reported PROs for ORP compared to LRP,[6,7] with the finding that ORP was better for urinary incontinence. However, we have not examined the outcomes of RARP, and there are few reports on this surgery using PROs in Japan.[8] Here, we examined PROs in the 1st year after RARP and we consider the problems encountered during the introduction of this procedure.

MATERIALS AND METHODS

Ethical approval

This study was carried out following the ethical standards of the Declaration of Helsinki, and was approved by the Institutional Review Board of National Hospital Organization Shikoku Cancer Center (Reference Number: SCC2014-62). Written informed consent was obtained from all patients.

Selection of patients

Performance of RARP started in December 2014 at our hospital and was used for 320 patients up to December 2018. The subjects in this study start from the first patient treated with RARP, with only one case excluded due to the performance of salvage surgery after radiation therapy. The surgical indications and procedures were the same as those for LRP, as described previously.[6] An antegrade surgical technique was used with an intraperitoneal or retroperitoneal approach, with the choice of approach dependent on the patient's condition.[9] All patients underwent posterior and anterior wall reconstruction.[10,11] The indications for nerve sparing were primary Gleason pattern 3 and patient preference, and bilateral or unilateral nerve sparing was performed based on the characteristics of the tumor. The 319 cases were divided into three periods with about 100 cases each: an early period from November 2014 to April 2016, the middle period from May 2016 to July 2017, and a late period from August 2017 to December 2018. Seven surgeons performed RARP over the whole period of the study. The number of cases differed among these surgeons, and thus, we divided the surgeons into those with <40 and >40 cases. The initial two surgeons had the same operator or first assistant for up to 40 cases, and were classified as expert surgeons with >40 cases. At the start of RARP, there was guidance from a proctor, but all the surgeons at our hospital completed the surgery on their own.

Survey of patient-reported outcomes

PROs were evaluated using the Expanded Prostate Cancer Index Composite (EPIC).[12] The survey was performed as a self-assessment (without an interview) before surgery (baseline = 0 months) and at 1, 3, 6, and 12 months after surgery. EPIC was used for the assessment of disease-specific PROs. EPIC scores were calculated using a scoring program and linearly transformed to a scale of 0 (lowest) to 100 (highest) points in each domain. The domains of hormone function and bother were omitted because only a few patients received neoadjuvant androgen deprivation therapy (ADT). PRO surveys were returned by 89.3%, 90.3%, 93.1%, 94.0%, and 93.4% of the patients at 0, 1, 3, 6, and 12 months after surgery.

Statistical analysis

Each factor was compared using average values. Group comparisons were performed by Kruskal–Wallis test for continuous variables and by Chi-square test for categorical variables, with a two-tailed $P < 0.05$ considered significant. Differences in PROs between treatment groups were tested by one-way analysis of variance with continuous variables. The Bonferroni method was used to adjust for multiple comparisons. SPSS version 20.0J (IBM, Armonk, NY, USA) was used for all statistical analyses.

RESULTS

During the study period, RARP was performed for 319 patients and PROs were returned in 318 cases. The median age and prostate-specific antigen (PSA) level were 68.0 years old and 6.84 ng/ml, respectively. Most cases were in clinical Stage T1c, and most had a Gleason score of 7. However, significantly more patients had a lower Gleason score in the early period compared to those in the middle and late periods. There were no significant differences in clinical stage and PSA, and the rate of nerve-sparing cases was the same in each period. Positive resection margins (PRMs) were observed in 105 patients (32.9%), and there was PSA recurrence (PSA >0.2 ng/ml) in the 1st year after surgery in 32 patients (10.0%), with no differences among the periods. Of these patients, 5 were treated with salvage RT, 2 with salvage RT plus ADT, 10 with ADT, 12 with anti-androgen therapy, and 3 received no treatment in the 1st year after surgery. Fewer cases were operated on by expert surgeons in the middle and late periods [Table 1]. The PRM rate was the same in each period in all patients and in pT2, pT3, and nerve-sparing

cases. PSA recurrence also showed no significant differences among the three periods [Table 2].

Functional outcomes

On EPIC, there were also no significant differences among the three periods. Urinary function and bother decreased at 1 month after surgery, and gradually recovered thereafter. However, urinary function was significantly worse than at baseline in the 1st year after surgery, whereas urinary bother recovered to the baseline level at 6 months after surgery. Urinary irritative/obstruction also recovered at 6 months after surgery, but urinary incontinence was still worse than at baseline at 1 year after surgery [Figure 1]. Bowel function and bother had similar scores in the three periods, with a slight decline at 1 month and recovery at 3 months after surgery. Bowel bother did not change significantly within 1 year after surgery. Sexual function was similar in the three periods, and the score remained low and did not recover after 1 month. Sexual bother was worse in the early period, but with no significant differences among the periods, except at baseline.

In cases that received nerve-sparing surgery, urinary function and bother were better than in nonnerve-sparing cases. Moreover, urinary function recovered to baseline after 6 months and urinary bother recovered after 3 months. Sexual function was also better in nerve-sparing cases, but did not recover to baseline, while sexual bother was worse in nerve-sparing cases [Figure 2].

Learning curves

Urinary function and bother were best in the early period and worst in the late period among nerve-sparing cases, although without significant differences. A similar result was found for sexual function, but sexual bother was worst in the early period [Figure 3]. In contrast, in cases treated without nerve sparing, urinary function and bother were best in the late period and worst in the early period, and there were significant differences at 1 and 3 months. Urinary irritative/obstruction and incontinence were also worst in the early period, with significant differences after 1 month [Figure 4].

Table 1: Characteristics of cases treated with robot-assisted radical prostatectomy in the early, middle, and late periods

Item	Total	Early	Middle	Late	*P*
n	319	106	107	105	
Age (years)					
Median	68.0	67.0	69.0	69.0	0.053
Range	45-82	52-77	54-82	45-82	
Clinical stage					
T1	231	84	75	71	0.203
T2	79	18	29	32	
T3	9	4	3	2	
PSA (ng/ml)					
Median	6.85	5.88	7.49	7.27	0.663
Range	1.93-171.90	2.30-160.90	1.94-171.90	2.32-78.90	
Gleason score					
≤6	71	33	19	18	0.033
7	140	46	44	50	
≥8	108	27	44	37	
Nerve sparing					
None	253	83	80	90	0.041
Unilateral	18	5	5	8	
Bilateral	48	18	23	7	
NADT	28	11	8	9	0.753
Surgeons (*n*)	7	2	5	6	<0.001
Cases with an expert surgeon, *n* (%)	216 (67.9)	106 (100)	68 (63.6)	42 (40.0)	<0.001

NADT: Neoadjuvant androgen deprivation therapy, PSA: Prostate-specific antigen

Table 2: Resection margin in cases treated with robot-assisted radical prostatectomy in the early, middle, and late periods

Item	Total	Early	Middle	Late	*P*
n	318	106	107	105	
Positive resection margin, *n* (%)	105 (33.0)	32 (30.2)	41 (38.3)	32 (30.5)	0.359
pT2	227	78	76	73	0.804
pT2 with PRM, *n* (%)	63 (27.8)	20 (25.6)	28 (36.8)	15 (20.5)	
pT3	91	28	31	32	0.616
pT3 with PRM, *n* (%)	42 (46.2)	12 (42.9)	13 (41.9)	17 (53.1)	
Nerve sparing	64	22	27	15	0.363
Nerve sparing with PRM, *n* (%)	29 (45.3)	8 (36.4)	15 (55.6)	6 (40.0)	
PSA recurrence in the 1st year	32	11	10	11	0.992

PRM: Positive resection margin, PSA: Prostate-specific antigen

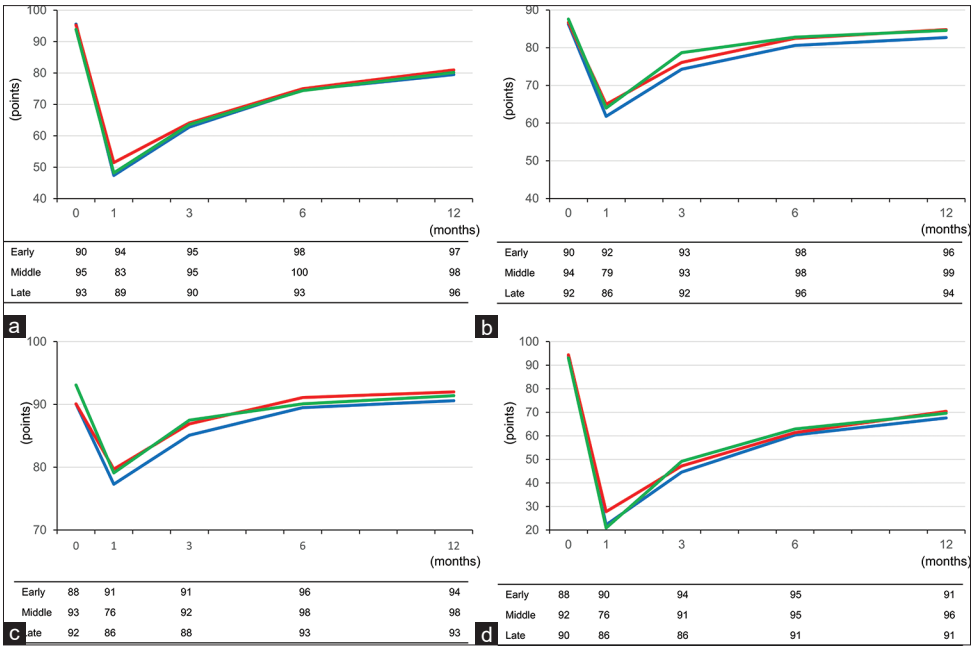

Figure 1: Changes in EPIC scores in all cases in the early (blue), middle (red), and late (green) periods. (a) urinary function, (b) urinary bother, (c) urinary irritation/obstruction, (d) urinary incontinence. There were also no significant differences among the three periods. EPIC: Expanded Prostate Cancer Index Composite

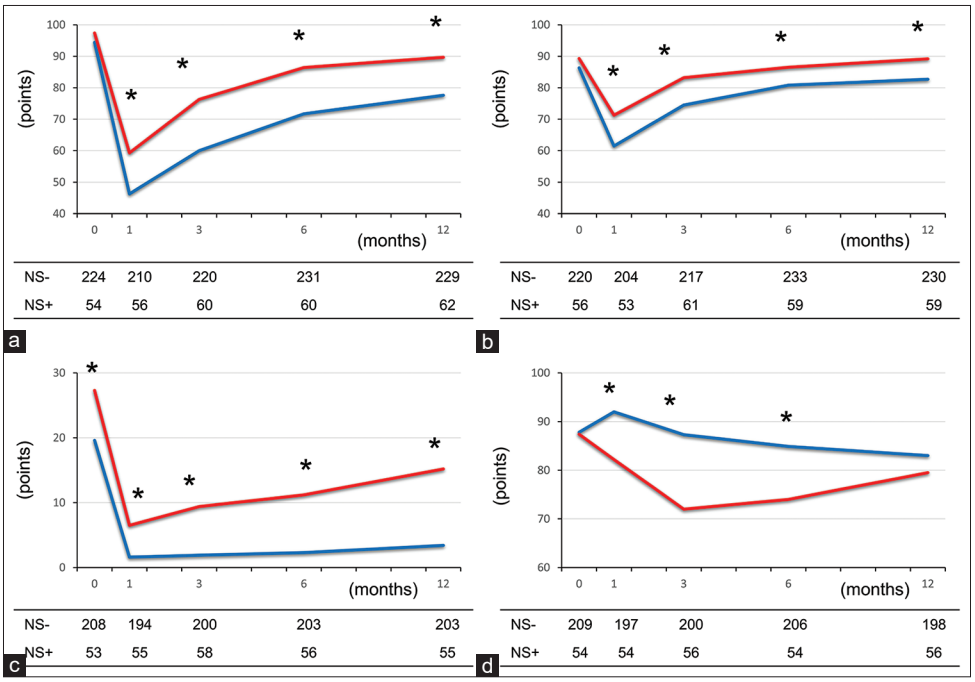

Figure 2: Changes in urinary function (a), urinary bother (b), sexual function (c), and sexual bother (d) in procedures without (blue) and with (red) nerve sparing. *P < 0.05. In cases that received nerve-sparing surgery, urinary and sexual functions and urinary bother were better than in nonnerve-sparing cases

DISCUSSION

In this study, we examined functional outcomes after the introduction of robotic surgery using PROs and we examined the learning curve for these outcomes at our hospital. It is clear that urinary and sexual functions are major problems in PROs based on EPIC scores, with no recovery of urinary function and urinary incontinence at even 1 year postoperatively. However, recovery of these factors was better in nerve-sparing cases than in nonnerve-sparing cases. In nerve-sparing cases, sexual function did not recover to that before surgery, and sexual bother was worse in these cases. However, few patients

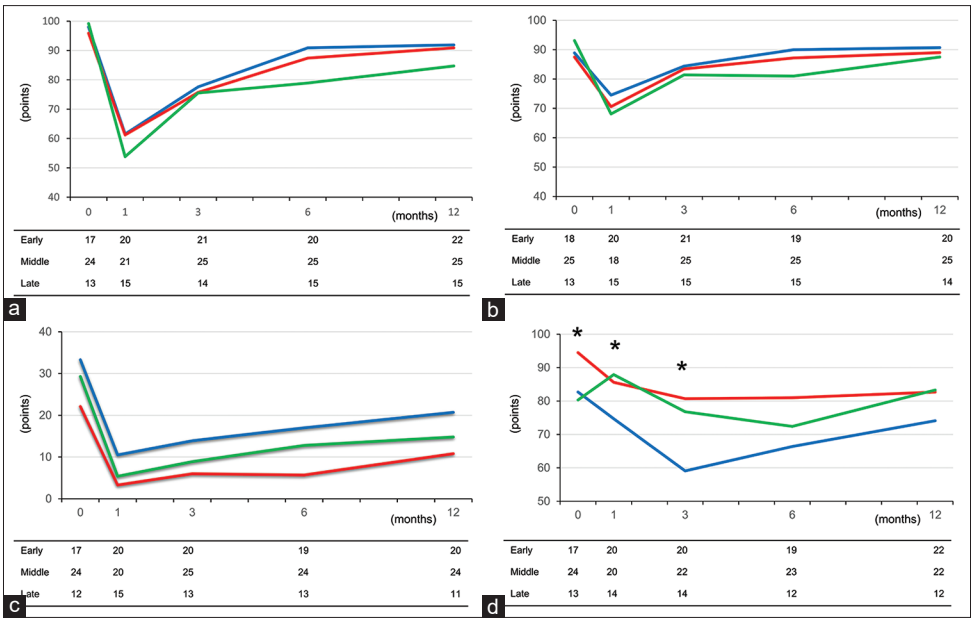

Figure 3: Changes in urinary function (a), bother (b), sexual function (c), and bother (d) in procedures with nerve sparing in the early (blue), middle (red), and late (green) periods. **P* < 0.05. Urinary and sexual functions and urinary bother were best in the early period and worst in the late period among nerve-sparing cases

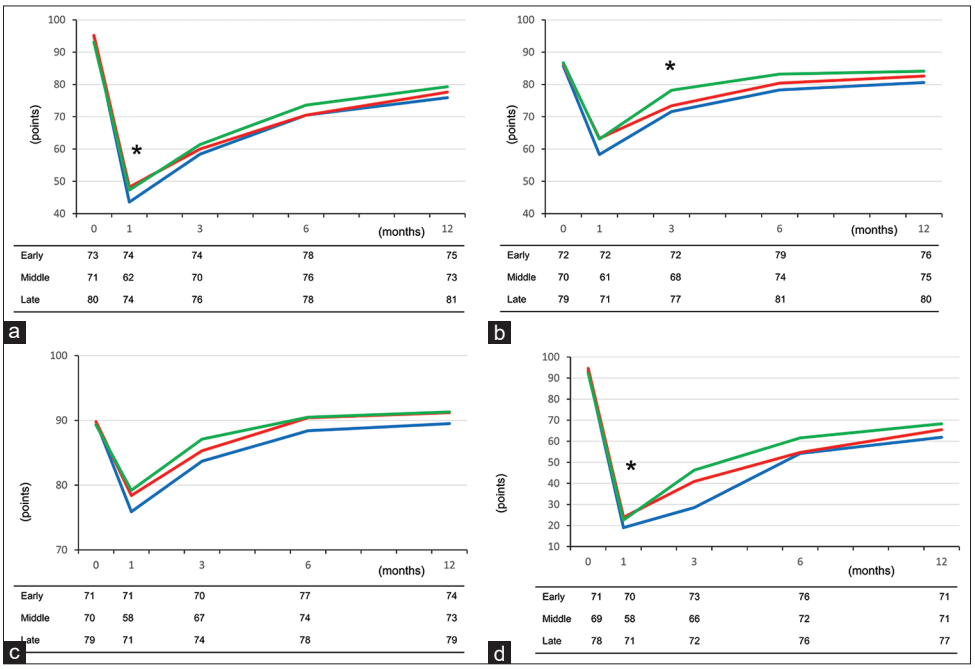

Figure 4: Changes in urinary function (a), urinary bother (b), urinary irritation/obstruction (c), and urinary incontinence (d) in procedures without nerve sparing in the early (blue), middle (red), and late (green) periods. **P* < 0.05. Urinary function and bother were best in the late period and worst in the early period, and there were significant differences at one and 3 months in cases treated without nerve sparing

wanted nerve preservation and preoperative sexual function was poor. Patients who wish to preserve sexual function often prefer brachytherapy rather than surgery, and sexual function does not seem to be a major concern in this study.

Many functional results of RARP have been described using PROs.[13,14] Among recent randomized controlled trials of RARP, two were performed as comparisons with open surgery and a third compared RARP with LRP. Porpiglia *et al*.[15] found that the continence rate was higher after RARP at all time points compared to LRP, whereas Asimakopoulos *et al*.[16] found no significant difference in continence between RARP and LRP, but the rate of incontinence at each point was lower after LRP. Yaxley *et al*.[17] found that urinary and sexual functions did not differ after ORP and RARP in the 2nd year after surgery.[18]

Collectively, these results suggest that RARP has similar functional results to open surgery[13,14] and is good for sexual function compared to LRP. It is difficult to compare our results directly with these findings, but it seems that our recovery of continence after 6 months was poor and that the surgical technique should be considered further.

Surgical techniques have improved with increased understanding of the pelvic anatomy, and this has clearly led to the improvement of PROs. Indeed, robotic surgery is expected to improve functional results due to anatomy advances and the ease of the operation. The flexibility of forceps movement may particularly contribute to improved functional outcomes. However, urinary incontinence and sexual function remain as major problems, even in robotic surgery, and various reconstruction methods have been devised to improve urinary incontinence. For example, in addition to conventional posterior musculofacial reconstruction, total anatomical reconstruction has recently been proposed.[10,11,19] We have added both posterior and anterior reconstruction, but verification of these procedures is needed.

The learning curve is another factor that influences the functional results. To examine the learning curve in this study, PROs were evaluated by dividing the study period into groups of about 100 cases. No learning curve was examined for the entire cohort, but interesting results were obtained for cases divided into those treated with and without nerve-sparing surgery. In nerve-sparing cases, sexual function was significantly better in the early period, and urinary function and urinary incontinence were also better in this period. In contrast, in nonnerve-sparing cases, urinary function and bother were better in the late period, although without significant differences.

The learning curve for urinary function may require more than 400–600 cases in robotic surgery before reaching a plateau,[20,21] although other reports have suggested that a plateau is reached after about 100 cases.[22,23] In general, a plateau for functional outcomes requires more cases than for oncological results.[20,24,25] Since this study includes only 300 cases, we cannot state with certainty that the functional results have reached a plateau. However, it is interesting that the learning curves differed depending on whether nerves were preserved in surgery. In nerve-sparing cases, the early group had better results than the middle and late groups, whereas in nonnerve-sparing cases, the late group had the best results. This finding may be due to the difficulty of the nerve-sparing procedure itself. There was no significant difference in PRM among the three periods, but PRM was highest in the middle period in nerve-sparing and pT2 cases. All nerve-sparing surgery was performed by a single surgeon (KH) in the early period. From the middle to the late period, the procedures gradually shifted to other surgeons. Since the results of PRM were similar, this shift may have influenced the results for sexual function. Two surgeons performed the procedures in the early period, but many surgeons started to perform RARP from the middle period. Therefore, the quality of surgery may have temporarily declined for nerve-sparing cases. However, in cases without nerve sparing, functional results improved as the number of operations increased and a normal learning curve was observed. These results reflect the difficulty of the nerve-sparing procedure.

Our results show the importance of establishing an educational system to shorten the RARP learning curve.[26-29] No LRP experience is thought to be required to perform RARP, and we did not find that a lack of experience had a negative effect. The first two surgeons had considerable experience with LRP, but the surgeons from the middle period had little or no experience. The importance of bedside assistants has also been pointed out. Ultimately, RARP is a team operation and it is necessary to educate the entire team.[30]

There were some limitations in the study. First, even though we examined about 300 cases, it is unclear if a plateau was reached. The PRM rate was still higher than in other reports,[26-29] which suggests that the learning curve is still in the midrange of the slope. Second, an expert was defined as a surgeon with experience of more than 40 RARP cases. One of the criteria for instructors (proctors) at the Japanese Society of Endourology is performance of RARP as an operator in more than 40 cases, and this criterion was used as a reference. Although 40 cases are far from a learning curve, this number of cases is thought to be sufficient for understanding the surgical techniques. In the early period, <40 cases were performed by experts, but these surgeons had experience of more than 300 LRP procedures as surgeons or assistants and clearly differed from all other surgeons. Therefore, cases from the first case performed by these surgeons were examined as cases performed by experts. The results in the early period were the best among nerve-sparing cases, which indicates that this analysis was appropriate, and we believe that it gave an interesting result.

Finally, it is difficult to evaluate the outcomes for individual surgeons, since a nonexpert surgeon may be replaced by an expert surgeon during surgery. The learning curve in such cases cannot be evaluated, and there are many such cases that were initially assigned to nonexpert surgeons. However, we believe that the learning curve can be evaluated based

on the results for the team, rather than the individual. For the team, the results improved as the number of operations increased, except for nerve-sparing cases, and a normal learning curve formed for nonnerve-sparing cases. Therefore, an educational system including nerve-sparing surgery should lead to shortening of the learning curve in the entire cohort. The functional results based on PROs are also useful for providing information to patients regarding treatment selection.

CONCLUSION

The functional results of this study based on PROs are useful for providing information for patients on treatment selection. Interestingly, the learning curves for RARP differed in cases that did and did not undergo a nerve-sparing procedure.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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