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Original Article

Does robot-assisted laparoscopic radical prostatectomy enable to obtain adequate oncological and functional outcomes during the learning curve? From the Korean experience

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Abstract

To estimate the short-term results of robot-assisted laparoscopic radical prostatectomy (RALRP) during the learning curve, in terms of surgical, oncological and functional outcomes, we conducted a prospective survey on RALRP. From July 2007, a single surgeon performed 63 robotic prostatectomies using the same operative technique. Perioperative data, including pathological and early functional results of the patient, were collected prospectively and analyzed. Along with the accumulation of the cases, the total operative time, setup time, console time and blood loss were significantly decreased. No major complication was present in any patient. Transfusion was needed in six patients; all of them were within the initial 15 cases. The positive surgical margin rate was 9.8% (5/51) in pT2 disease. The most frequent location of positive margin in this stage was the lateral aspect (60%), but in pT3 disease multiple margins were the most frequent (41.7%). Overall, 53 (84.1%) patients had totally continent status and the median time to continence was 6.56 weeks. Among 17 patients who maintained preoperative sexual activity (Sexual Health Inventory for Men ≥ 17), stage below pT2, followed up for > 6 months with minimally one side of neurovascular bundle preservation procedure, 12 (70.6%) were capable of intercourse postoperatively, and the mean time for sexual intercourse after operation was 5.7 months. In this series, robotic prostatectomy was a feasible and reproducible technique, with a short learning curve and low perioperative complication rate. Even during the initial phase of the learning curve, satisfactory results were obtained with regard to functional and oncological outcome.

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Keywords: learning curve, outcomes assessment, radical prostatectomy, robotics

1 Introduction

Since the advent of testing for prostate-specific antigen (PSA), many prostate cancers have been detected in the initial stages of development, allowing for the potential use of curative resection [1]. However, the choice of which type of surgery to perform can be difficult. Among the current surgical modalities for radical prostatectomy, robot-assisted laparoscopic radical prostatectomy (RALRP) has gained worldwide popularity because of claims of superior 3-D magnified vision, easy surgical manipulation, and improved precision of
Outcome of RALRP in learning period
Young Hwii Ko et al.

168

Asian Journal of Andrology  |  http://www.asiaandro.com; aja@sibs.ac.cn

168

written informed consent was obtained for RALRP and for the use of the patient’s clinical data in the current study. In the case of local clinically advanced disease, all treatment options, including radiation therapy, open prostatectomy and cryoablation, with or without hormone therapy, were discussed with the patients, and the likelihood of adjuvant treatment was also explained. The clinical and pathological data from the patients were collected prospectively and analyzed.

2.2 Surgical technique
To minimize the effect of the operative procedure on the learning curve and the postoperative outcomes, we selected a single preferable procedure that was considered suitable for the characteristics of the patients and the aims of the operation. This method, originally described by Patel [10], was applied to almost all cases with a few modifications, as described below. If the accessory pudendal artery (APA) was encountered on adipose tissue overlying the endopelvic fascia and the prostate, the surgeon endeavored to preserve the situation as long as the procedure did not interrupt the surgical plane. The dorsal vein complex was ligated with a 1-0 Monocryl stitch (Ethicon Inc., Cornelia, GA, USA), and a second 1-0 Monocryl stitch was then placed in periurethral tissue and the periosteum of the posterior pubic symphysis for anterior reconstruction.

To optimize nerve sparing, all prostatic pedicles were clipped with Hem-o-lok polymer ligating clips (Weck Systems, Triangle Park, NC, USA) and then sharply divided. For the patient who met the preoperative criteria for nerve preservation, a neurovascular bundle (NVB) sparing procedure was performed using a method originally described by Patel [11]. After the NVB was released from the posterio-lateral aspect of the prostate, the dissection was extended distally toward the prostatic apex. Then, the attachment of the NVB and the prostate was dissected in a retrograde manner, using the endowrist of the da Vinci system toward the prostatic pedicle (an athermal early retrograde NVB release during an antegrade prostatectomy technique) and then divided after clipping. The urethrovésical anastomosis was performed in a running fashion using a double-arm 3-0 Monocryl suture. Pelvic lymphadenectomy was performed if clinically required (PSA over 20 ng mL⁻¹, Gleason score over 8 and stage beyond cT3) using a standard method. A pelvic drain was maintained in all cases and was typically removed on the second postoperative day.
2.3 Postoperative follow-up and data collection

Patients were seen approximately 2 weeks after the operation for catheter removal. During the early learning curve, cystograms were routinely obtained before catheter removal. The patients were scheduled for follow-up starting at 4 weeks after the operation, and these visits were conducted every 3 months during the first year. For preoperative evaluation of erectile function, Sexual Health Inventory for Men (SHIM) score sheets were used for all patients. The early penile rehabilitation program consisted of the phosphodiesterase 5 inhibitor (100 mg sildenafil or 10 mg vardenafil, two times a week) starting 4 weeks after the operation, with or without a vacuum constriction device (two times a day) or an intracavernosal injection (two times a month). The program was conducted for patients who had enough erectile function before the operation (SHIM ≥ 17), was pathologically staged below pT2 and minimally maintained one side of NVB preservation during the RALRP. For continence evaluation, voiding symptoms, pad usage and duration of incontinence were examined. For the functional evaluation, patients requiring no urinary pads were considered continent and the use of even one pad per day for occasional stress urinary incontinence was not considered continence. The postoperative sexuality function was evaluated using questions 2 and 3 of the sexual encounter profile (SEP), with a mild modification of question 3 (Instead of ejaculation, maintenance of erection with satisfactory intercourse was examined). This evaluation was used at every visit for the patients who underwent the NVB preservation procedure. A minimum of 3 and 6 months of follow-up were utilized, respectively, to collect data on the patients’ continence and sexuality. These periods of time should be sufficient for the patient to regain functionality, while minimizing selection bias. All data were processed with SPSS version 12.0 (SPSS, Chicago, IL, USA) and $P < 0.05$ was considered significant.

3 Results

3.1 Surgical outcomes

Perioperative data from the patient population are summarized in Table 1. The mean age of patients was 62.9 years (range, 50–73 years), the mean initial PSA was 10.3 ng mL$^{-1}$ (range, 3.4–24.1 ng mL$^{-1}$) and the mean Gleason score was 6.7 (range, 6–10). The mean total operative time, the setup time and the console time were 280.5 min (range, 190–455 min), 18 min (range, 14–30 min) and 218 min (range 150–400 min), respectively. The mean estimated blood loss (EBL) was 377 mL (200–800 mL). With the addition of cases to the study, these parameters decreased (Spearman’s rank correlation coefficient = −0.49, −0.35, −0.54 and −0.32, respectively, $P < 0.05$, Figure 1). The NVB preservation procedure was conducted in 44 patients (69.8%; bilateral in 24 patients and unilateral in 20 patients) and a wide resection was conducted in the other 19 (30%) patients. However, there was no statistical difference between the degree of NVB preservation and operative time, console time and EBL ($P < 0.05$, $\chi^2$ test). Our study contained 13 patients who had an early transperitoneal abdominal surgery. However, compared with patients without history of previous abdominal surgery, the difference in the EBL, the complication rate and operative time, including setup and console time, was not statistically significant ($P < 0.05$, by Mann-Whitney test).
Table 1. Perioperative characteristics of the RALRP patients.

| Variable                                | Mean value (± SD) | Range       | P-value* |
|----------------------------------------|-------------------|-------------|----------|
| Age (years)                            | 62.9 ± 5.8        | 50–73       |          |
| BMI (kg m⁻²)                           | 23.7 ± 2.5        | 17.5–29.7   |          |
| Preoperative PSA (ng mL⁻¹)             | 10.3 ± 8.9        | 3.4–24.1    |          |
| Biopsy Gleason score                   | 6.7 ± 0.8         | 6–10        |          |
| Preoperative prostate volume (g)       | 29.3 ± 11.9       | 12–68       |          |
| Operation time (min)                   |                   |             |          |
| Overall                                | 281 ± 93          | 190–455     |          |
| Initial 30                             | 292 ± 122         | 190–455     | 0.002    |
| Late 33                                | 233 ± 23          | 190–320     |          |
| Setup time (min)                       |                   |             |          |
| Overall                                | 17.9 ± 4.6        | 14–30       |          |
| Initial 30                             | 20.1 ± 4.8        | 15–30       | 0.0003   |
| Late 33                                | 16.0 ± 3.4        | 14–24       |          |
| Console time (min)                     |                   |             |          |
| Overall                                | 219 ± 69          | 150–400     |          |
| Initial 30                             | 225 ± 92          | 170–400     | 0.014    |
| Late 33                                | 199 ± 24          | 150–275     |          |
| Estimated blood loss (mL)              |                   |             |          |
| Overall                                | 377 ± 93          | 200–800     |          |
| Initial 30                             | 421 ± 122         | 200–800     | 0.036    |
| Late 33                                | 325 ± 84          | 200–450     |          |
| Neurovascular bundle preservation (%)  |                   |             |          |
| None                                   | 19 (30.1)         |             |          |
| Unilateral                             | 20 (31.7)         |             |          |
| Bilateral                              | 24 (38.2)         |             |          |
| Hospital stay (days)                   | 8.8 ± 2.6         | 7–21        |          |
| Foley catheterization (days)           | 14.6 ± 3.3        | 14–21       |          |
| Postoperative complications            |                   |             |          |
| Intraoperative transfusion             | 3                 |             |          |
| Postoperative transfusion              | 3                 |             |          |
| Paralytic ileus                        | 3                 |             |          |
| Subcutaneous hematoma                  | 2                 |             |          |
| Rectal injury                          | 0                 |             |          |

Abbreviations: BMI, body mass index; PSA, prostate-specific antigen; RALRP, robot-assisted laparoscopic radical prostatectomy.

*Comparison of the first 30 cases with the last 33 cases in the study.

U-test). Our study also included five patients who had had neoadjuvant hormonal therapy before surgery for cT3 disease, and the mean duration of hormone treatment was 3.2 months (range, 2–4 months). When dividing the total number of cases into the initial 30 and the latter 33 patients, all parameters were found to be lower in the latter 33 patients. The mean hospitalization time was 8.8 days (range, 7–21 days). In one patient who had had an earlier panperitonitis operation for an appendiceal rupture, the hospital stay was lengthened, up to 21 days, because of a paralytic ileus after adhesinolysis. There was no deliberate effort for early Foley catheter removal, and thus the mean duration of the indwelling catheter after RALRP was 14.6 days (range, 14–21 days). The routinely performed cystogram at 14 days after operation showed no urine leaks, except in three patients. All of these patients were among the initial 20 cases, and the cystogram showed only mild leakage.
None of the patients had major complications, including open conversion, bowel injury, rectal fistula and thromboembolism. Three patients had postoperative ileus (transient in two, prolonged in one), and two patients had trocar insertion-related subcutaneous hematoma. All of these minor complications were resolved after conservative management. Three patients required a transfusion intraoperatively, and three patients required a transfusion postoperatively. All cases requiring transfusion were within the initial 15 cases.

### 3.2 Oncological outcomes

Table 2 outlines the postoperative pathology data across our cohort of patients. Organ-confined (OC; pT2) disease was present in 51/63 (80.9%) patients and extracapsular extension (ECE; pT3/T4) was present in 12/63 (19.1%). Although the other pre- and intraoperative parameters were similar, initial PSA was increased in ECE disease compared with OC disease (16.4 ± 11.1 ng dL⁻¹ vs. 9.2 ± 7.6 ng dL⁻¹, P = 0.048, by Mann-Whitney U-test). Seventeen patients (26.9%) had a positive surgical margin (PSM) on examination of the specimen, which decreased from 30% (9/30) in the initial 30 patients to 24.2% (8/33) in the latter 33 cases (P = 0.56). Compared with the PSM rate of OC disease (9.8%), patients with an ECE had a higher rate of PSM (100%, P = 0.001). The most frequent location of PSM in OC disease was the lateral aspect (60%), but in ECE disease multifocal PSM was the most frequent location (41.7%). As none of the patients with an ECE showed biochemical recurrence during the mean follow-up of 7.8 months, all patients were managed with close observation only. The exception to this finding was one pT4 patient who took hormone therapy with luteinizing hormone releasing hormone agonist injection. Between the PSM rate and the degree of NVB preservation, there was a statistical difference (P = 0.037, by χ² test). The percentages of positive margins for the bilateral sparing group, the unilateral sparing group and the wide resection group were 3/24 (12.5%), 5/20 (25%) and 9/19 (47.4%), respectively.

Pelvic lymphadenectomy was performed in 13 patients in our study. The average yield of lymph nodes was 8.6 ± 2.5 (range: 5–13). However, no positive nodes were detected in any case.

### 3.3 Functional outcomes

Fifty-three (84.1%) patients were totally continent and the median time to continence was 6.6 weeks (range: 2–20 weeks). Of the 36 patients who were followed up over 6 months, 94.4% (34/36) of the patients were continent. Upon catheter removal, 15% of continent patients showed immediate, total continence. For sexuality issues, more follow-up would be necessary for adequate evaluation. However, among pT2 patients who had, at a minimum, one side of the NVB preserved and who maintained enough erectile function before

| Pathological stage | No. of points | Location of PSM | Total No. of PSM |
|--------------------|---------------|-----------------|-----------------|
| ≤ T2               |               | Apex Lateral Base Multifocal |                  |
| T2a                | 15            | 0 0 0 0 | 0 0 |
| T2b                | 5             | 0 0 0 0 | 0 0 |
| T2c                | 31            | 1 3 0 1 | 5 5 |
| Total              | 51            | 1 3 0 1 | 5 (9.8%) |
| ≥ T3               |               | Apex Lateral Base Multifocal |                  |
| T3a                | 4             | 1 1 0 2 | 4 4 |
| T3b                | 3             | 0 1 0 2 | 3 3 |
| T3c                | 4             | 2 0 2 0 | 4 4 |
| T4a                | 1             | 0 0 0 1 | 1 1 |
| Total              | 12            | 3 2 0 5 | 12 (100%) |
| Sum                | 63            | 4 (23.5%) 5 (29.4%) 2 (11.8%) 6 (35.3%) | 17 (26.9%) |

Abbreviations: PSM, positive surgical margin; RWALRP, robot-assisted laparoscopic radical prostatectomy.

1Apex and lateral (3); base and lateral (1); apex and lateral (1); vas deference and bladder neck (1).
Outcome of RALRP in learning period

Young Hwi Ko et al.

Asian Journal of Andrology  |  http://www.asiaandro.com; aja@sibs.ac.cn

172

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the operation (SHIM ≥ 17), with a minimal follow-up of 6 months (range: 6–14 months), 12 of 17 (70.6%) were capable of satisfactory postoperative intercourse. Additionally, all of the patients with normal preoperative erectile function (SHIM ≥ 22) regained erections (Table 3).

For those patients, the mean time for return of erection was 3 months (range: 1–6 months), and it took 5.7 months (3–12) for sexual intercourse.

4 Discussion

The goal of a radical prostatectomy is to remove the entire prostate with negative surgical margins, preferably with minimal intra- or perioperative complications, with no blood transfusions and with a full recovery of baseline urinary continence and erectile function [12]. Although more improvements are still required to achieve this ideal, RALRP is currently one of the most promising, minimally invasive treatment options. Over 50% of prostatectomies in the United States were performed with RALRP in 2007 [13], and it has now become a part of mainstream urology. Many urologists are struggling to incorporate this technique into their therapeutic arsenal. The success of RALRP is mainly based on evidence that the characteristics of robotics contribute to shortening the learning curve and facilitating the transition from a standard open radical prostatectomy to a laparoscopic radical prostatectomy (LRP) without the time-intensive training necessary to gain the skills for laparoscopy [14–16]. For surgeons with no experience in laparoscopy, the learning period of LRP amounted to as many as 80–100 consecutive cases, extending over several years [3]. In contrast, for RALRP, Patel et al. [17] estimated that 20–25 cases were required to achieve technical proficiency, and Ahlering et al. [3] observed that their RALRP operative times declined continually until case 19, after which they essentially maintained a nadir level. Our experience confirms such data in the literature. The total operation time, setup time, console time and EBL decreased with accumulation of cases. Of great interest to our study, no patient needed a blood transfusion after the initial 15 cases, and no radiological evidence of urine leakage occurred after 20 cases. Our results, as well as the data in the literature, would suggest that 15–20 cases might be the number of procedures needed for a surgeon with experience in open prostatectomies to overcome the learning curve. However, considering that the learning curve varies according to surgeon-related factors, such as earlier surgical experience, surgeon-declared perception of expertise, definition of expertise and workload [18], these results might be affected by earlier experience with surgical prostatectomies. Although patients who have had a previous abdominal operation are best suited for the extraperitoneal route, the surgeon’s open surgical experience is integral in performing transperitoneal RALRP in patients with a history of previous abdominal surgery. Thirteen patients had a history of various open transperitoneal abdominal surgeries, including herniorrhaphy (4), appendectomy (4), gastrectomy (3), cholecystectomy (2), ureterolithotomy (1) and repair of small bowel rupture (1). Two patients with

Table 3. Restoration of sexual activities in patients who had preoperative sexual intercourse, tumor stage below pT2 and follow-up for more than 6 months with the NVB preservation procedure.

| Total | Vaginal penetration (SEP Q2) | Complete intercourse (SEP Q3) |
|-------|-----------------------------|-------------------------------|
|       | n | n (%) | n (%) |
| No preoperative ED | 10 | 10 (100) | 8 (80) |
| Bilateral NVB preservation | 4 | 4 (100) | 3 (75) |
| Unilateral NVN preservation | 6 | 6 (100) | 5 (83.3) |
| Mild ED | 7 | 4 (57.1) | 4 (57.1) |
| Bilateral NVB preservation | 5 | 3 (60) | 3 (60) |
| Unilateral NVN preservation | 2 | 1 (50) | 1 (50) |
| Total | 17 | 14 (82.4) | 12 (70.6) |

Abbreviations: ED, erectile dysfunction; NVB, neurovascular bundle; SEP, sexual encounter profile.

SEP question 2 asks, ‘Were you able to insert your penis into your partner’s vagina?’.

SEP question 3 was modified and asks, ‘Did your erection last long enough for you to have satisfactory intercourse?’.

Sexual Health Inventory for Men (SHIM) over 22.

SHIM between 17 and 21.
herniorrhaphy had multiple transperitoneal operations (one with cholecystectomy, one with gastrectomy). Although the mean total operation time (301 ± 127 min vs. 278 ± 89 min, \(P = 0.293\)), setup time (19.4 ± 5.5 min vs. 17.9 ± 3.8 min, \(P = 0.053\)), console time (227 ± 137 min vs. 214 ± 456 min, \(P = 0.317\)) and EBL (391 ± 212 mL vs. 372 ± 200 mL, \(P = 0.473\)) were mildly increased in patients with earlier abdominal surgery compared with the remaining patients, the difference was not statistically significant. Therefore, to overcome the learning curve, we surmise that open surgical experience and an understanding of the pelvic anatomy are pivotal.

Although the decreased morbidity associated with RALRP is likely attributable to the minimally invasive characteristics, the key benefit of RALRP has been the improvement of oncological outcomes in patients. Although the ultimate measure of any intervention is the ability to prolong long-term survival, modifications in surgical technique can be assessed in the short term by analyzing pertinent oncological principles. One such variable is the pathology of the tumor margins, and the incidence of PSM in OC prostate cancer is directly related to the quality of surgery [19]. In a recent systemic review, including 22 robotic prostatectomy reports, the weighted means of PSM for robotic, laparoscopic and open radical prostatectomies were 10.3%, 20.2% and 18.3%, respectively [4]. In patients with pathologically OC prostate cancer, our PSM rate of 9.8% was similar to that reported in the main published study, and these data emphasize that a high standard of quality was achieved, even during the learning curve. In addition, the PSM rate, as with other surgical parameters, was affected by surgical experience. In a review of open radical prostatectomies, Vickers et al. [20] reported that cancer control after a radical prostatectomy improves as a surgeon’s experience increases, which is presumably due to improved surgical technique. Similarly, in an open study by Ahlering et al. [21], the reported PSM rate was 14.8% for OC disease in an initial report of 45 robotic cases, but this decreased to 6.5% after experience with 200 cases. Additionally, Patel et al. [22] reported a PSM rate of 5.7% for OC disease in the initial 200 cases, but this number decreased to 2.5% after 500 consecutive cases. In our study, the PSM rate of OC disease was decreased from 12.5% (3/24) among the initial 30 cases to 7.4% (2/27) among the latter 33 cases. Furthermore, no difference existed in the pathological distribution of tumors between our initial 30 patients and the latter 33 patients (six vs. six cases of ECE). Collectively, these data suggest that the decline in the PSM rate is mostly attributed to improved surgical skill with the robotic technique, rather than a decrease in the number of biologically aggressive tumors.

There is still room for technical improvement in the NVB preservation procedure. Among 51 OC diseases, 44 had NVB preservation procedures in our study, and among PSM cases, the lateral side of the prostate was the most frequent location (60%). These numbers are similar to the 56% observed by Patel et al. [22], who introduced the NVB preservation procedure used in our study. Owing to penetrating vessels and a concern for erectile dysfunction, the lateral aspect of the prostate is one of the most frequent locations of PSM. Therefore, initiation of NVB preservation from the lateral aspect of the prostate by blunt dissection has the possibility of increasing PSM on the lateral side of the prostate. Recently, Shah et al. [23] introduced a unique technique of NVB preservation and reported a PSM rate of 3.2%. Instead of a sharp dissection at the posterior lateral side of the prostate, they initiated NVB release at the base of the prostate and carried it to the apex. Although more data are required to validate the advantage of this novel approach, identification of the plane between the prostate capsule and the NVB would be the key process in decreasing lateral PSM.

The high PSM rate of ECE disease in our study warrants discussion. One of the plausible explanations for the high incidence would be the characteristics of the tumor. The initial PSA was significantly increased in ECE disease compared with that of OC disease, which differed from other variables. This finding correlates well with the results of Liss et al. [24], who reported that the most important risk factor for a PSM after RALRP was the preoperative PSA level. Their study analyzed 216 consecutive patients who had undergone RALRP. In addition, our study included five patients who had neoadjuvant therapy before the operation, and their final stage was shown as pT3b (1), pT3c (3) and T4 (1). In those patients, the operative time and EBL were significantly increased to 314 ± 29 min and 443 ± 87 mL, respectively, compared with those of OC patients (\(P < 0.05\) by Kruskal-Wallis test). These results indicate that the characteristics of a tumor with higher PSA and adhesion to the local structure at the time of operation may affect the high PSM of the ECE disease. However, we also recognize the effect of a surgeon’s learning curve on this high PSM rate. In our
cases of ECE disease, although multifocal PSM was the most frequent, most of the PSMs occurred in the initial 30 cases, with only one occurring in the latter 33 patients. This result implies that inadequate resection of advanced disease decreased as the surgeon accumulated cases of RALRP.

Despite the importance of cancer control, patients are often equally concerned with any negative effects on urinary continence and sexual potency in the period immediately after surgery. Attempts to eliminate these two functional side effects are critical during treatment innovations. Whereas the current study was limited by the minimal follow-up of 3 months, 84.1% of the patients were totally continent, and the mean time to continence was 6.56 weeks. These results are comparable to the results of a high-volume center [4, 25]. Conclusions regarding sexual function are pending. Sexual potency generally requires more time to return to normal. Thus, this study presents the results of restrictive patients who had OC disease with preoperative active sexual intercourse, minimally one side of the NVB preserved and more than 6 months of follow-up. In SEP, which was used in our study to evaluate potency postoperatively because of its simplicity and convenience, 70.6% of patients were capable of satisfactory intercourse postoperatively. Besides efforts to preserve the NVB, if indicated, and to aid in early penile rehabilitation, we tried to protect every possible APA during the procedure, which would help to improve the early potency rate. Among the 63 cases, we encountered nine cases of APA, including two cases of multiple APAs, which were successfully preserved in seven cases. Although no unequivocal role has been established on APA preservation and postsurgical functional outcomes [26], recent reports [27, 28] indicate that the preservation of APA during a radical prostatectomy increases the likelihood of potency more than twofold, and these patients show a significantly shorter median time to regain potency.

In our study, the prolonged patient hospitalization of 8.7 days, compared with that of other published RALRP reports, requires explanation. Korean Health Care is national and mandatory, and the entire cancer population is covered. Because of this national coverage, the hospital admission cost can be maintained at a minimum compared with the costs of other nations. Therefore, the patients and doctors alike were not aggressive in scheduling an early discharge. Most patients expected to be discharged after the stitches were completely removed, which was routinely performed 7 days after operation. As per foreign standards, many patients in our study would have been discharged 3 or 4 days earlier.

In conclusion, the RALRP in our study was a reproducible technique with a relatively short surgeon learning curve and excellent postoperative outcomes. The low rate of PSMs reported in pathologically localized prostate cancer, as well as early functional recovery, showed that high standards of surgery could be reached even in the relatively early stages of the learning curve. However, urologists should acknowledge the fact that the outcome of a radical prostatectomy is significantly more dependent on the surgeon’s technique, experience and regular practice than on the particular approach used.

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Young Hwii Ko et al.

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