

INTRODUCTION OF ROBOT-ASSISTED LAPAROSCOPIC RADICAL PROSTATECTOMY IN KAWASAKI MEDICAL SCHOOL HOSPITAL TREATMENT RESULTS OF INITIAL 100 PATIENTS

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Abstract:

Since November 2017, we have been conducting robot-assisted laparoscopic radical prostatectomy (RALP). As of August 2019, we have treated 100 patients using RALP and we herein examine the results of this treatment. As for the surgical method, the retroperitoneal approach was used in two cases with a history of abdominal surgery and the peritoneal approach was used for all other cases. The following data were collected: patient's age, 53–79 (median: 70) years; body mass index, 17.4–33.7 (median: 23.4) kg/m²; prostate-specific antigen (PSA) upon diagnosis, 1.3–144.3 (median: 7.1) ng/mL; clinical stage, T1c (n=29), T2a (n=28), T2b (n=5), T2c (n=29), T3a (n=8), and T3b (n=1); Gleason score upon biopsy, ≤6 for 18 cases, 7 for 71 cases, and ≥8 for 11 cases; prostate volume, 12.9–83 (median: 26) mL; operating time, 147–505 (median: 239) minutes; and blood loss and urine volume, 10–1,050 (median: 100) mL. Only one patient received blood transfusion after surgery. Nerve-sparing surgery was performed in 50 cases (bilateral = 33; unilateral = 17). Capsular infiltration was seen in 19 cases (19%), while a positive surgical margin was observed in 28 cases (28%). The duration of catheter insertion ranged from 5 to 59 (median: 6) days, and the duration of hospitalization after surgery ranged from 6 to 28 (median: 8) days. Some of the main post-surgical complications were inguinal hernia (n=5; 5%), abdominal incisional hernia (n=2; 2%), and uretero-cysto-anastomotic failure (n=2; 2%). The urinary incontinence rate one year after surgery was 11%. PSA recurrence was observed in five cases (5%). We concluded that RALP is a feasible surgical method.

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key words : Prostate cancer, robot-assisted laparoscopic radical prostatectomy, early treatment results

Introduction

In the field of urology, laparoscopic surgery has established good therapeutic results with minimal invasiveness in urinary tract diseases. Robot-assisted laparoscopic radical prostatectomy (RALP) has been an insured medical treatment since April 2012 in

Japan. At Kawasaki Medical School Hospital, we began performing RALP in November 2017, and by the end of August 2019, we had treated 100 cases. In this study, we aim to present the results of RALP at this hospital.

Methods

This clinical review included 100 patients diagnosed with localized prostate cancer who underwent RALP between November 2017 and August 2019. The study involved retrospectively analyzing patient background,

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surgical/perioperative results, pathological results, and treatment results of these patients based on their medical records.

Using da Vinci Xi surgical system, the transperitoneal surgical procedure was performed as follows: The patient was placed in a supine position. Under general anesthesia, an approximately 3-cm vertical skin incision was made on the navel. Next, an incision was made as an 8-mm port for the camera according to the open laparotomy approach, and three additional ports were made: an 8-mm port for the robotic arm, a 15-mm air-shield port for the assistant, and a 5-mm port for the assistant underneath the pneumoperitoneum (**Fig. 1**). The patient cart was rolled in and docked with a head-down tilt of 25°, and the surgery was started after forceps had been attached to the trocars. The assistant port and third arm port were located on the right and left sides of the patient, respectively. After severing the lateral and median umbilical ligament, the peritoneum was opened up to gain entry to the Retzius cavity. Thereafter, the dorsal veins of the penis were cut, periprostatic fat removed, inner pelvic fascia cut open, prostate wall peeled while preserving the puboprostatic ligament, and the dorsal vein complex ligated with 2-0 Vicryl before separating the bladder and prostate while preserving the internal urethral orifice. The vas deferens and seminal vesicle were then

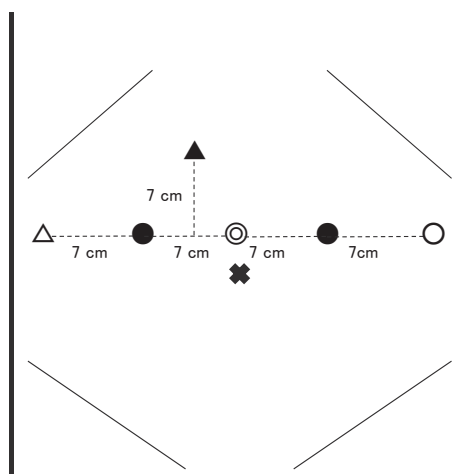
exposed and pulled out by end-close from the body using 3-0 Vicryl. After pulling the vas deferens and seminal vesicle upwards, the Denonvilliers fascia was cut open and treated while peeling the rear face of the prostate towards the apex and performing hemostasis on the prostatic vascular stem (for nerve preservation, the vascular stem was clipped with Hem-o-lok[®]), and the dorsal vein complex and urethra were cut before resecting the prostate and stored in a resection bag within the patient's body. Thereafter, posterior reconstruction of Denonvilliers' musculofascial plate was performed using the 3-0 V-Loc, and the ureterocysto-anastomosis was established with a 3-0 monofilament absorptive thread, through continuous suturing using a LAPRA-TY, clockwise from the 5 o'clock position. Subsequently, a 20-Fr urinary catheter was placed, and the bladder was flushed. If there was no leakage, the dorsal vein stump on the bladder side was ligated with the puboprostatic ligament using the 3-0 V-Loc (anterior suspension), and a drainage tube was placed before ending the surgery. Lymph node dissection was performed in 10 high-risk cases, and localized dissection of the obturator lymph nodes alone was performed in four cases. Meanwhile, extended dissection, which involves dissecting the internal and external iliac lymph nodes, common iliac lymph nodes, and obturator lymph nodes, was performed bilaterally in four cases and unilaterally in two cases. The surgeries were performed by three surgeons certified for laparoscopic surgery, and varying numbers of assistants and nurses were involved.

Postoperative urinary continence rate was calculated by Kaplan Meier method.

This study was approved by the Ethics Committee of Kawasaki Medical University and Kawasaki Medical University Hospital (Approval number 3633). The authors report no conflict of interest in the preparation of this paper.

Results

The median patient age was 70 (range 53–79) years old. The median body mass index was 23.4 (range 17.4–33.7) kg/m², and the median prostate-specific antigen (PSA) level upon diagnosis was 7.1 (range 1.3–144.3) ng/mL. The clinical stage was T1c in 29 cases, T2a in 28



◎ : Laparoscope. ● : 8 mm (for operator).
○ : 8 mm (for third arm). △ : 15 mm (for assistant).

Fig. 1 Port site of RALP

cases, T2b in 5 cases, T2c in 29 cases, T3a in 8 cases and T3b in one case. At the time of biopsy, the Gleason score was as follows: ≤ 6 in 18 cases, 7 in 71 cases, and ≥ 8 in 11 cases. The median prostate volume was 26 (range, 12.9–82) mL. The NCCN risk classification of cases was low risk in 13 cases, intermediate risk in 65 cases, and high risk in 22 cases. Five patients were on hormone therapy prior to surgery.

Surgical history included surgeries for appendicitis (9 cases), gallstones (4 cases), inguinal hernia (2 cases), stomach cancer (2 cases), colon cancer (2 cases), transurethral resection of the prostate cancer (one case), and vascular transplantation and bypass surgery (one case). Only in the two cases that followed surgery for colon cancer, we chose the retroperitoneal approach. The median observation period was 8 (range, 0–21) months (**Table 1**).

Table 1 Characteristics of patients (n=100)

Age (years) : 53 – 79 (median, 70)
BMI : 17.4 – 33.7 (median, 23.4)
PSA level at diagnosis (ng/mL) : 1.3 – 144.3 (median, 7.1)
Clinical T stage : T1c 29, T2a 28, T2b 5, T2c 29, T3a 8, T3b 1
Gleason score at biopsy ($\leq 6/7/\geq 8$) : 18/71/11
Prostate volume (mL) : 12.9 – 82 (median, 26)
NCCN risk classification : low, 13; intermediate, 65; high, 22

The median operating time was 239 (range 147–505) minutes, the median blood loss and urine volume was 100 mL (range 10–1,050 mL), and none of the cases needed blood transfusion during surgery. The median duration of urethral catheter placement was 6 (range 5–59) days, and the median duration of hospitalization after surgery was 8 (range 6–28) days. None of the cases were transitioned into open surgery. No rectal injuries were reported in any of the cases. Postoperative complications included five cases of inguinal hernia, two cases of abdominal incisional hernia at the camera port site, two cases of uretero-cysto-anastomotic failure, two cases of macrohematuria (one of the cases received blood transfusion), one case of urethral stenosis, one case of pelvic hematoma, and one case of paralytic ileus (**Table 2**).

The pathological results were based on the Gleason score of the resected specimen: ≤ 6 in 8 cases, 7 in

Table 2 Results (intra/perioperative) and complications (n=100)

Operating time (min) : 147 – 505 (median, 239)
Console time (min) : 101 – 431 (median, 172)
Blood loss including urine (mL) : 10 – 1,050 (median, 100)
Duration of catheterization (days) : 5 – 59 (median, 6)
Postoperative hospital stay (days) : 6 – 28 (median, 8)
Complications
Intraoperative : small intestinal injury
Postoperative : anastomotic leak
paralytic ileus
intrapelvic hematoma
urethral stricture
macrohematuria
inguinal hernia
abdominal incisional hernia

78 cases, and ≥ 8 in 14 cases. The pathological stage was pT2a in 9 cases, pT2b in 2 cases, pT2c in 67 cases, pT3a in 16 cases, and pT3b in 6 cases. Capsular infiltration was observed in 19 cases (19%), and a positive surgical margin was observed in 28 cases (28%), comprising 16 of the 78 pT2 cases (20.5%) and 12 of the 22 pT3 cases (54.5%). No metastasis was observed in any of the patients who underwent lymph-node dissection (**Table 3**).

Table 3 Pathological results (n=100)

Gleason score ($\leq 6/7/\geq 8$) : 8/78/14
Pathological T stage : pT2a 9, pT2b 2, pT2c 67, pT3a 16, pT3b 6
Infiltration into prostate capsule : 19 (19%)
Positive surgical margin :
Overall, 28 patients (28%)
Rate of positive surgical margin in pT2 patients: 16 /78 (20.5%)
Rate of positive surgical margin in pT3 patients: 12/22 (54.5%)
Seminal vesicle invasion : 6 (6%)

The biochemical recurrence-free survival rate over 1 year was 92.3%. Moreover, there were five cases (5%) of PSA recurrence and one case of bone metastasis; three patients underwent radiation therapy and two patients received hormone therapy as salvage therapy for the excision site.

Urinary incontinence was defined as the use of >2 pads/day, and the postoperative urinary continence

rate was 18% over 1 month, 54% over 3 months, 73% over 6 months, and 89% over 12 months (Fig. 2).

Discussion

In this study, we examined the surgical results of our initial 100 patients in the early years following RALP introduction. We found that there was no inferiority with regard to operating time and console time, and as all three surgeons had experience with LRP, the transition to robot-assisted surgery was smooth¹⁾.

Since the report of Walsh et al.²⁾ in 1979 about nerve-sparing retropubic radical prostatectomy, radical prostatectomy has become established as the standard treatment for localized prostate cancer. Thereafter, since the report of Guillonneau et al.³⁾ on laparoscopic radical prostatectomy (LRP), robot-assisted laparoscopic radical prostatectomy received approval from the United States Food and Drug Administration in July 2000 and it became listed under insurance medical care in Japan in April 2012 because of its rapid progression.

In terms of the pathological positive surgical margin rate, the literature suggests that the positive surgical margin rate in pT2 cases ranges from 9.6% to 15.5%, while that of pT3 cases ranges from 39% to 52.1%. In our study, pT2 cases had a positive surgical margin rate of 20.5%, while pT3 cases had a rate of 54.5%,

suggesting that our results were slightly higher than those in previous reports⁴⁾⁻⁶⁾. The biochemical recurrence-free survival over 1 year was 92.3%, which appeared comparable to that of previous reports⁴⁾⁻⁶⁾.

In terms of lymph node dissection, Touijer et al.⁷⁾ reported that extended dissection, i.e., from dissecting only the obturator lymph nodes during LRP to dissecting the external iliac lymph nodes, internal iliac lymph nodes, and obturator lymph nodes, increased the percentage of cases positive for lymph node metastasis from 3% to 10%. Furthermore, Heidenreich et al.⁸⁾ reported that compared to localized lymph node dissection, which only involves dissection of the obturator lymph node, extended lymph-node dissection doubled the number of lymph nodes resected, which increased the rate of diagnosis of lymph node metastasis by 2.8 times. In other words, localized lymph-node dissection is not recommended, as it leads to understaging⁸⁾. Our study showed that extended lymph- node dissection was performed on high-risk patients and none of them exhibited metastasis. Going forward, we hope to carry our more extended lymph node dissections proactively following a careful selection of cases.

Tewari et al.⁹⁾ published a review on intraoperative and perioperative complications. The most common complication was anastomotic leakage, which occurred at 3.5% on average. In the present study, two patients

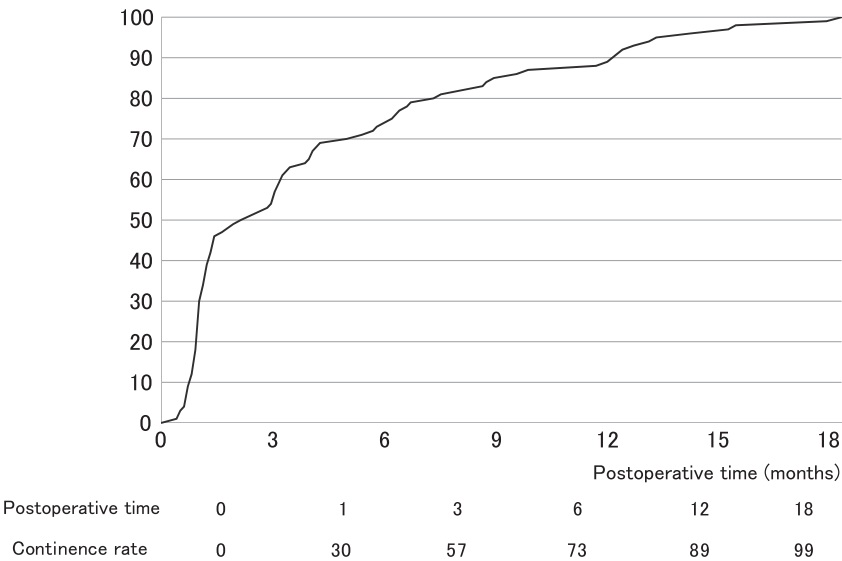


Fig. 2 Postoperative continence rate

developed this complication. Additionally, two patients had macrohematuria, one patient had urethral stenosis, one patient had pelvic hematoma, and one patient had paralytic ileus, but these findings were the same as has been reported previously. Although inguinal hernia was reported to occur in 3%–19.4% of cases after RALP¹⁰⁾, in the present study, five cases were observed, which was a permissible result. As this condition is said to manifest increasingly over time, we plan to monitor patients more carefully for this complication. Although abdominal incisional hernia at the camera port site is known to occur very rarely after RALP surgery, we observed two patients with the same condition, and restoration surgery was performed using mesh sheets. Inadequate suturing of the peritoneum and fascia is thought to be the cause of this complication, and we are now engaged in efforts to ensure greater care during the suturing process.

With regard to the control of urinary incontinence, during the early stage of the introduction of RALP, the reported urinary continence rates at 1, 3, 6 and 12 months after surgery were 29.4%–75%, 64.2%–82.5%, 79%–95% and 84%–91.1%^{11)–13)}, respectively; however, in the present study, the urinary continence rates at those time points were 18%, 54%, 73% and 89%, respectively, which suggests that the urinary continence rate is slightly worse during the early stages. Chen et al. emphasized the importance of keeping the urethral stump as long as possible in order to improve postoperative urinary continence¹⁴⁾. A previous study also reported that functional urethra length and urinary continence are significantly correlated¹⁵⁾ and that urinary continence can be recovered during the early stages through urethra-preserving surgical approaches that leave a sufficient length of the urethral sphincter^{16)–18)}. We believe that leaving as much of the urethra as possible and engaging in protective surgical approaches that preserve the urethral sphincter would lead to improved urinary continence. Other techniques that have been reported in relation to their usefulness for recovery of postoperative urinary continence are the rear wall reinforcement of uretero-cysto-anastomosis as suggested by Rocco et al.¹⁹⁾, bladder neck preservation as proposed by Gacci et al.²⁰⁾, and

the report by Hurles et al.²¹⁾ which suggested that anterior suspension and posterior reconstruction are useful for urinary continence during the early stages after surgery, based on the results of a randomized controlled trial. Furthermore, the nerve-sparing technique was reported to help improve postoperative urinary incontinence^{18) 22) 23)}. However, as there are reports suggesting that bilateral nerve preservation in pT2 cases increases the rate of the positive surgical margin²⁴⁾, that the presence of posterolateral cancer lesions increases the rate of positive surgical margin²⁵⁾, but it has been reported that the study in Japan is not relevant²⁶⁾, further studies are needed in the future.

Retzius-sparing robot-assisted radical prostatectomy has been reported as a new surgical approach that seeks to preserve the Retzius cavity²⁷⁾, and it was reported to be useful for improvement of urinary continence in even earlier stages^{28) 29)}. Going forward, we intend to carry out better surgery while improving the surgical method further.

Abboudi et al.³⁰⁾ examined the learning curve of RALP. With respect to operating time, volume of blood loss, complications, and recovery of urinary continence, they reported that the results were stable with 40 cases, discussed improvements with every 50 cases, and indicated a plateau after 200 cases. In the present study, the results from the early stage of RALP introduction at our hospital have been tolerable. Each surgeon has experienced about 30 cases and we intend to continue studying through an increased case-load experience in the future.

Summary

We examined the results from early stage of RALP introduction at our hospital. Surgical procedures, postoperative continence rate and biochemical free survival were comparable to rates in other institutions. This technique was otherwise safe without any other serious complications. We conclude that RALP is a feasible surgical method.

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川崎医科大学におけるロボット支援腹腔鏡下前立腺全摘除術初期導入 100 例の治療成績

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抄録:

2017年11月よりロボット支援腹腔鏡下前立腺全摘除術(Robot-assisted Laparoscopic Radical Prostatectomy: RALP)を開始し、2019年8月で100例に行い、その治療成績について検討した。手術法は腹部手術歴のある2例のみ経後腹膜アプローチ、その他は経腹膜アプローチにて行った。年齢は53~79(中央値70)歳、BMIは17.4~33.7(中央値23.4)、診断時PSA値1.3~144.3(中央値7.1)ng/ml、臨床病期はT1c/T2a/T2b/T2c/T3a/T3b:29/28/5/29/8/1例、生検時のGleason scoreは6以下/7/8以上:18/71/11例、前立腺体積は12.9~82(中央値26)mlであった。手術時間は147~505(中央値

239)分、出血量は尿込み10~1,050(中央値100)mlで術後に1例のみ輸血を行った。神経温存は50例(両側33例、片側17例)に対して行った。被膜浸潤は19例(19%)、切除断端陽性は28例(28%)に認めた。カテーテル留置期間は5~59(中央値6)日、術後入院日数は中央値6~28(中央値8)日であった。主な合併症として、術後に鼠径ヘルニアを5例(5%)、腹壁癒着ヘルニアを2例(2%)、尿道膀胱吻合不全を2例(2%)に認めた。術後1年での尿失禁率は11%であった。PSA再発をきたした症例は5例(5%)に認めた。RALPは有用な術式であると考えられた。

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キーワード: 前立腺癌, ロボット支援腹腔鏡下前立腺全摘除術, 初期治療成績