〈Regular Article〉

Treatment outcomes of laparoscopic radical prostatectomy at Kawasaki Medical School Hospital

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ABSTRACT　 Laparoscopic radical prostatectomy (LRP) was carried out in 196 patients with prostate cancer between December 2009 and November 2017 at Kawasaki Medical School Hospital, and the therapeutic outcomes were assessed. An extraperitoneal approach was used in all cases except 1 and the median follow-up period was 55 months (range, 10-117 months). The median patient age was 69 years (range, 56-79 years), median body mass index was 23.3 kg/m^2 (range, 15.2-33.2 kg/m^2), and median prostate-specific antigen (PSA) level at diagnosis was 7.4 ng/mL (range, 2.2-42.0 ng/mL). Clinical stages of T1c, T2a, T2b, T2c, T3a, and T3b accounted for 63, 43, 31, 57, 1, and 1 case, respectively, while Gleason scores at biopsy of $\geq$ 6, 7, and $\geq$ 8 accounted for 26, 138, and 32 cases, respectively. The median prostate volume was 22.0 mL (range, 7.3-65.6 mL), median operating time was 266 minutes (range, 142-540 minutes), and median blood loss (including in urine) was 650 mL (range, 10-5,800 mL). During the initial induction period, 94 patients received autologous blood transfusion and 7 received allogeneic blood transfusion. Nerve-sparing prostatectomy was performed in 17 cases (bilateral in 3, unilateral in 14). Capsular invasion was observed in 57 cases (29.1%) and positive resection margins were observed in 51 cases (26.4%). The median indwelling catheter duration was 6 days (range, 4-26 days) and the median hospital stay after surgery was 11 days (range, 8-34 days). The main complications were intraoperative rectal injury in 7 cases (3.6%), postoperative inguinal hernia in 28 (14.3%), and urethral stenosis in 8 (4.1%). The rate of urinary incontinence at $\geq$ 1 year after surgery was 32.7% and the rate of PSA recurrence was 15.8%. The overall survival rate was 95.6% at 5 years and 94.7% at 10 years. In conclusion, the oncological outcomes were similar to that reported by previous reports, but postoperative stress urinary incontinence and complications were slightly worse. In the future, further improvement of the surgical technique was desired.　 doi：10.11482/KMJ-E202046001　 *(Accepted on December 3, 2019)*

Key words：Prostate cancer, Laparoscopic radical prostatectomy, Treatment outcomes

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INTRODUCTION

In the area of urology, laparoscopic surgery is minimally invasive and has achieved favorable outcomes in the treatment of various diseases of the urinary tract. Laparoscopic radical prostatectomy (LRP) was approved for insurance coverage in April 2006 and our hospital began performing LRP in December 2009. Since then, LRP has been carried out in 196 cases at our hospital by the end of November 2017. Reports on the mid- and long-term therapeutic outcomes of LRP in Japan are rare, which is why we carried out this clinical study.

SUBJECTS AND METHODS

This study was conducted in 196 patients who were diagnosed with localized prostate cancer and underwent LRP between December 2009 and November 2017. Patient characteristics, surgical and perioperative outcomes, pathological findings, and treatment outcomes were reviewed retrospectively. This study was approved by the Ethics Committee of Kawasaki Medical School and Kawasaki Medical School Hospital (approval number 3591). All authors have no conflict of interest which should be declared.

The median patient age was 69 years (range, 56-79 years), median body mass index was 23.3 kg/m^2 (range, 15.2-33.2 kg/m^2), and median prostate-specific antigen (PSA) level at diagnosis was 7.4 ng/mL (range, 2.2-42.0 ng/mL). As for clinical stage, T1c accounted for 63 cases, T2a 43 cases, T2b 31 cases, T2c 57 cases, T3a 1 case, and T3b 1 case. Gleason score at biopsy was $\geq$ 6 in 42 cases, 7 in 135, and $\geq$ 8 in 19. The median prostate volume was 22 mL (range, 7.3-65.6 mL). The National Comprehensive Cancer Network risk classification showed low risk in 26 cases, intermediate risk in 138, and high risk in 32. Patients' medical history included appendicitis in 19 cases, inguinal hernia in 8, holmium laser prostate enucleation in 5, gallstone surgery in 4, gastric cancer surgery in 3,

Table 1. Characteristics of patients (n=196)

Age (years) : 56 - 79 (median, 69)
BMI : 15.2 - 33.2 (median, 23.3)
PSA level at diagnosis (ng/ml) : 2.2 - 42.0 (median, 7.4) Clinical T stage : T1c 63, T2a 43, T2b 31, T2c 57, T3a 1, T3b 1 Gleason score at biopsy ($\leq$ 6/7/8 $\leq$) : 26/138/32
Prostate volume (ml) : 7.3 - 65.6 (median, 22)
NCCN risk classification : low, 26; intermediate, 138; high, 32

colonic diverticulitis in 1, transurethral resection of the prostate in 1, duodenal ulcer surgery in 1, intestinal injury in 1, and splenectomy for idiopathic thrombocytopenic purpura in 1. During the initial induction period, 63 patients received 4 units of autologous blood before surgery and 31 patients had 2 units of blood stored. The median follow-up period was 55 months (range, 10-117 months) (Table 1). Except for 1 patient who was treated using an intraperitoneal approach, all other patients were treated using an extraperitoneal anterior approach through the descending seminal vesicle. As for body posture, the supine position was used, while the legs were kept slightly open and the upper extremities were wrapped. The abdominal air pressure was maintained at 8 to 15 mmHg. Non-nerve-sparing radical prostatectomy was performed in 179 cases and nerve-sparing radical prostatectomy was performed in 17 cases (unilateral in 14, bilateral in 3).

Placement of the ports was as follows: First, the prevesical space (Retzius' space) was dilated using a PDB balloon (kidney-shaped distention balloon) from directly under the umbilicus. Then, a port for the optical viewing tube was placed at the same site and insufflation of the abdominal cavity was performed. A second port (5 mm) for the operator's left hand was placed at the halfway point between the umbilicus and left anterior superior iliac spine, while a third port (12 mm) for the operator's right hand was placed at a distance of 1 finger width to the right side of the halfway point between the umbilicus and pubic symphysis. As for ports for the assistant, the line connecting the umbilicus and
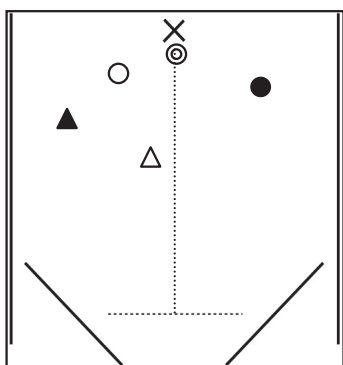
Trocar's site. ◎ : Laparoscope. ● : 5 mm (for operator).
○ : 12 mm (for operator). △ : 12 mm (for assistant).
▲ : 5 mm (for assistant).

Fig. 1. Trocar's site of LRP
LRP: laparoscopic radical prostatectomy

right anterior superior iliac spine was divided into 3 equal parts, and then a 12-mm port was placed on the medial side and a 5-mm port was placed on the lateral side (Fig. 1).

The surgical procedure was as follows: First, bilateral obturator lymphadenectomy was carried out. Then, an incision was made in the endopelvic fascia and the lateral surface of the prostate was detached while preserving the puboprostatic ligament. The dorsal vein complex was ligated using 2-0 Vicryl sutures and the area between the bladder and prostate was resected while making sure that the internal urethral orifice was preserved. Then, the vas deferens and seminal vesicle were detached and exposed, ligated using 3-0 Vicryl sutures, and removed from the body using an Endoclose device. Subsequently, Denonvilliers' fascia was incised, and the prostate vascular pedicle was treated using a sealing device while the posterior surface of the prostate was detached (in cases of nerve-sparing radical prostatectomy, the vascular pedicle was cut using a Hem-o-lok clip with an intrafascial approach). The dorsal vein complex, neurovascular bundle (in cases of nerve-sparing radical prostatectomy, the neurovascular bundle was

preserved), and urethra were cut and the prostate was removed. Next, posterior reconstruction of Denonvilliers' musculofascial plate was carried out using 3-0 Vicryl sutures, and urethrovesical anastomosis was performed by placing a running suture starting at 3 o'clock and turning clockwise using 3-0 monofilament absorbable sutures and a Lapra-Ty absorbable suture clip. A 20-Fr indwelling urethral catheter was placed and bladder irrigation was performed. Verifications were made to confirm that there was no leakage, and then the stump of the dorsal vein complex on the bladder side was ligated to the puboprostatic ligament using 3-0 Vicryl sutures (anterior suspension). Finally, an indwelling drainage tube was placed and the operation was complete. Operations were carried out by 3 operators; assistants and nurses were not always the same in all operations.

RESULTS

The median operating time was 266 minutes (range, 142-540 minutes) and the median blood loss (including in urine) was 650 mL (range, 10-5,800 mL); allogeneic blood transfusion was performed in 7 cases. The median indwelling catheter duration was 6 days (range, 4-26 days) and the median hospital stay after surgery was 11 days (range, 8-34 days). In 3 cases, the procedure was converted to laparotomy due to adhesions to periprostatic structures. Intraoperative complications included rectal injury in 7 cases (3.6%), left ureteral injury in 1 (0.5%), and perforation of the small intestine in 1 (0.5%). Early postoperative complications included rupture of the suture at the urethrovesical anastomosis site in 3 cases (1.5%), lymphatic fistula in 3 (1.5%), subcutaneous abscess in 1 (0.5%), pelvic abscess in 1 (0.5%), and hematuria requiring blood transfusion in 1 (0.5%) (Table 2). Delayed complications included inguinal hernia in 28 cases (14.3%), urethral stenosis in 8 (4.1%), urethrorectal fistula in 1 (0.5%), and urethral lithiasis in 1 (0.5%).

Pathological findings from resected specimens revealed that Gleason score ≥ 6 accounted for 31 cases, score of 7 accounted for 156, and score ≥ 8 accounted for 9. As for pathological stage, pT2a accounted for 13 cases, pT2b 5 cases, pT2c 116 cases, pT3a 50 cases, and pT3b 12 cases. Capsular invasion was observed in 57 cases (29.1%) and positive surgical margins were observed in 51 cases (26.4%); the positive surgical margin rate was 20.1% in the 134 cases with pathological stage pT2 and 38.7% in the 62 cases with pathological stage pT3. Metastatic lymph node involvement was identified in only 1 case (0.5%) (Table 3).

The overall survival rate was 95.6% at 5 years and 94.7% at 10 years. Deaths due to prostate cancer accounted for 0 cases, while deaths from other causes accounted for 8 cases. Biochemical recurrence-free survival was 92.8% at 1 year, 85.9% at 5 years, and 79.5% at 10 years. Patients who showed PSA recurrence accounted for 31 cases (15.8%), while those who developed bone or lymph node metastasis accounted for 1 case each. As salvage therapy, hormone therapy was carried out in 8 cases, local radiation therapy in 6, and radiation

Table 2. Results (intra/perioperative) and complications (n=196)

Operation time (min) : 142 - 540 (median, 266)
Blood loss including urine (ml) : 10 - 5,800 (median, 650)
Transfusion: autotransfusion for 94 patients (of all, 7 patients underwent allogeneic transfusion concurrently)
Duration of catheterization (days) : 4 - 26 (median, 6)
Postoperative hospital stay (days) : 8 - 34 (median, 11)
Open conversion : 3 patient due to adhesion (1.5%)

Complications

Intraoperative :	rectal injury	7 (3.6%)
	ureteral injury	1 (0.5%)
	small intestine perforation	1 (0.5%)
Postoperative :	anastomotic leak	3 (1.5%)
	lymphocele	3 (1.5%)
	subcutaneous abscess	1 (0.5%)
	intrapelvic abscess	1 (0.5%)
	macrohematuria	1 (0.5%)

Table 3. Pathological results (n=196)

Gleason score (6 ≥ /7/8 ≤) : 31/156/9
Pathological T stage : pT2a 13, pT2b 5, pT2c 116, pT3a 50, pT3b 12
Infiltration into prostate capsule : 57 (29.1%)
Positive surgical margin :
Overall, 51 patients (26.4%)
Rate of positive surgical margin in pT2 patients: 27 /134 (20.1%)
Rate of positive surgical margin in pT3 patients: 24/62 (38.7%)
Seminal vesicle invasion : 12 (6.1%)
Lymph node metastasis：1 (0.5%)
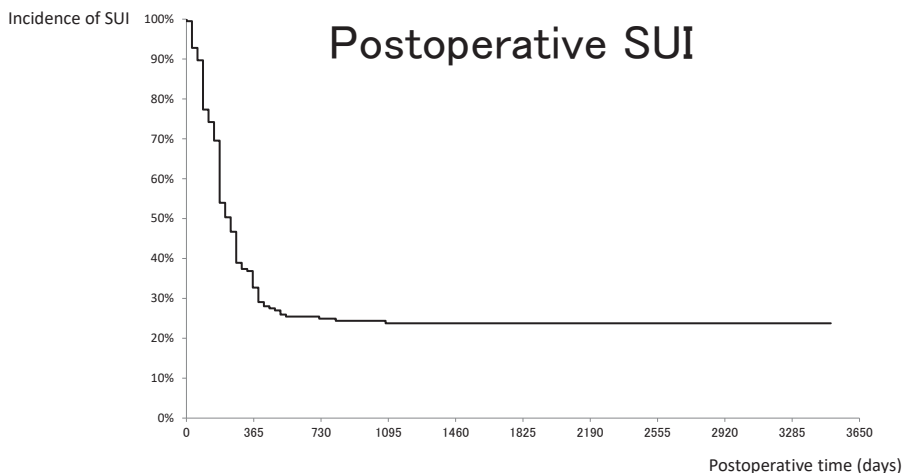
Postoperative day	0	182.5	365	730	1095	1460	1825	2190	2555	2920	3285	3650
Incidence of SUI	100	54	32.7	24.9	23.8	23.8	23.8	23.8	23.8	23.8	23.8	23.8
at risk	194	103	63	48	46	45	36	34	28	23	21	16

Fig. 2. Postoperative SUI
SUI: stress urinary incontinence

therapy followed by hormone therapy in 3. The rate of urinary incontinence, defined as the use of ≥ 2 urinary pads per day, was 54% at 6 months, 32.7% at 1 year, and 24.9% at 2 years (Fig. 2).

DISCUSSION

After Walsh et al reported nerve-sparing retropubic radical prostatectomy in 1979[1], radical prostatectomy has been established as the standard treatment for localized prostate cancer. LRP was first reported in 1998 by Guillonneau et al[2], and initially, using a transperitoneal approach was the mainstream tendency. However, due to the high frequency of gastrointestinal complications[3], the procedure is currently performed mainly using a retroperitoneal approach. Our institution has been an LRP-certified facility since December 2009, and because it is minimally invasive and allows for sharing a large field of view, LRP has been carried out as a replacement for retropubic radical prostatectomy in all patients except those predicted to develop adhesions to the surrounding tissue and those requiring extensive lymphadenectomy. In November 2017, our hospital started using the DaVinci XI Surgical System, and thus far, LRP for the treatment of localized prostate cancer has been performed using a robot-assisted procedure except when it is impossible to keep the patient's head low, such as in cases of glaucoma or cerebral aneurysm. In cases of LRP requiring sutures and ligatures inside the body, it initially took a considerable amount of time to perform urethrovesical anastomosis, but according to reports from various authors, the operating times seem to have gradually decreased[4-6]. If possible, the operation should be performed by a fixed team, including the nurses. In our cases, the operators consisted of 3 surgeons and the assistants varied. However, in cases treated in the latter period, the operating time was approximately 200 minutes, clearly indicating that the duration of surgery had decreased. The median operation time was 266 minutes, and the median blood loss was 650 ml, which was similar to that reported by the previous studies[7, 8]. Compared with open radical prostatectomy, it is reported that the operation time is longer but the amount of bleeding is less[9].

In terms of surgical outcomes, the rate of urinary incontinence at 6 months to 1 year after surgery has been reported to be approximately 20%[5, 10, 11]. In our experience, the rate was 32.7% at 1 year, which is slightly higher than previous reports. This may be due to the fact that many cases were in the early stages of prostate cancer, some cases were halfway through the learning curve, in some cases it was difficult to ensure a good field of view due to bleeding near the bladder apex, in some cases energy devices were used in order to stop the bleeding, and in some cases failure of the urethrovesical anastomosis occurred. As a preventive method against postoperative stress urinary incontinence, Chen et al emphasized the importance of maintaining a long urethral stump whenever possible[12]. Furthermore, a significant correlation has been reported between functional urethral length and postoperative urinary incontinence[13], and early recovery from urinary incontinence can be achieved by using a urethra-sparing technique that maintains sufficient length of the urethral sphincter[14, 15]. Preserving the urethra as much as possible, carrying out the surgical procedure in a protective manner, and endeavoring to preserve the urethral sphincter are believed to lead to good urinary continence. Other techniques have also been reported to be useful for recovery from postoperative urinary incontinence. Rocco et al reported the importance of reinforcing the posterior wall at the vesicourethral anastomosis site[16], Gacci et al reported the importance of preserving the bladder neck[17], and Stolzenburg et al reported the importance of preserving the puboprostatic ligament[18]. In addition, a report has also shown that

using a nerve-sparing technique is advantageous, not only for postoperative erectile dysfunction, but also for urinary incontinence[19]. In our experience, the surgical procedure has been gradually improved by using the above as references until the current technique was established, and recent cases tend to exhibit less postoperative urinary incontinence. Thus, in the future, nerve-sparing techniques will be actively carried out and efforts will be made to improve postoperative stress urinary incontinence. Furthermore, preoperative pelvic floor muscle exercises have been reported to accelerate recovery from urinary incontinence[20] and have been adopted by our hospital.

The rate of positive resection margins was 20.1% in patients with stage pT2 and 38.7% in those with stage pT3, which are nearly the same as those reported by other authors[21]. The overall survival rate was 95.6% at 5 years and 94.7% at 10 years (in all cases, death was due to other causes), while the biochemical recurrence-free survival rate was 92.8% at 1 year and 85.9% at 5 years, which are comparable to those reported by various authors[22, 23].

Regarding lymphadenectomy, only bilateral obturator lymphadenectomy was performed in our cases, and metastasis was observed in only 1 case (0.5%). Touijer et al previously reported that when the obturator lymph nodes alone were resected during LRP, patients with lymph node metastasis increased from 3% to 10%, which was higher than in cases subjected to extensive lymphadenectomy comprising the external iliac, internal iliac, and obturator lymph nodes[24]. In addition, Heidenreich et al previously stated that compared with local lymphadenectomy comprising only the obturator lymph nodes, twice as many lymph nodes were resected in extensive lymphadenectomy and lymph node metastasis was diagnosed at a 2.8-times higher rate. Thus, local lymphadenectomy may lead to underdiagnosis and therefore should not be performed[25]. In our study, some of the patients may have demonstrated false negativity with regard to lymph node metastasis, and thus careful follow-up of the clinical course may be required. Our institution is also considering to actively conduct extensive lymphadenectomy in the future.

As for intraoperative complications, rectal injury is believed to occur at a rate of approximately 1%[26, 27], but in the cases we experienced, it accounted for 3.6%, which is slightly higher. Rectal injury occurred in patients we treated at the time we got acquainted to the procedure; it occurred as the rectum was not fully detached during detachment of adhesions to the posterior surface of the prostate and during incision of the lateral pedicle. In all cases, the injury was confirmed intraoperatively, repair was carried out by performing a double-layer suture using resorbable suture thread, and the postoperative course was good. In addition, perforation of the small intestine was found in 1 case. The patient had a history of abdominal surgery and perforation occurred during detachment of intestinal adhesions, but repair was performed laparoscopically during surgery. Left ureteral injury occurred in 1 case, which was repaired on another day using laparotomy. The injury occurred during resection of the lymph nodes on the central side as the surgical tools entered the area around the bladder while visibility was poor. In the early postoperative period, rupture of the suture at the urethrovesical anastomosis site, lymphatic fistula, subcutaneous abscess at the site of the port, pelvic abscess, and hematuria requiring blood transfusion were observed in a small number of cases, but all improved after being treated conservatively. Our findings suggest that surgical manipulations may need to be done more carefully in the future.

As a postoperative complication, inguinal hernia has been reported to occur in 4.3% to 8.3% of cases[27], but in the cases we experienced, it accounted for 14.3%, which is quite higher. Low

body mass index and voiding impairment have been reported to be involved in its occurrence[28], but in our cases, the causes were unclear and will be the topic of future studies. In addition, urethral stenosis was observed in 8 cases (4.1%) and was often found in patients who had urine leakage due to rupture of the suture at the urethrovesical anastomosis site. Thus, more careful vesicourethral anastomosis will be desired in the future.

CONCLUSIONS

The treatment outcomes of LRP for localized prostate cancer at our hospital were examined. The oncological outcomes were comparable to those reported in previous studies. However, the outcomes in terms of postoperative urinary incontinence were slightly less favorable. In the future, further improvement of the surgical technique was desired.

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