

Utility of the HYBRID Method Incorporating the Advantages of Both Extracorporeal and Intracorporeal Urinary Diversion in Robotic-Assisted Radical Cystectomy

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ABSTRACT

Background Robotic-assisted radical cystectomy (RARC) is a well-known standard procedure for muscle-invasive bladder cancer. However, it remains controversial whether extracorporeal urinary diversion (ECUD) or intracorporeal urinary diversion (ICUD) is superior in this technique. We have developed a HYBRID method that combines ECUD and ICUD to retain the advantages of each. The purpose of this study was to compare perioperative outcomes between HYBRID and ECUD in RARC and to evaluate the usefulness of the HYBRID method.

Methods We retrospectively analyzed the perioperative outcomes of 36 consecutive bladder cancer patients who underwent RARC with ileal conduit at our institution between March 2013 and December 2021. Propensity-score matching was used to align patient backgrounds between the HYBRID and ECUD groups.

Results After matching, 12 cases were selected for each group. There was no significant difference in patient demographics between the groups except for the rate of neoadjuvant chemotherapy. Mean console time was significantly longer in the HYBRID group due to intracorporeal manipulation; however, a relatively favorable trend of mean blood loss was observed in this group. There was no significant difference between the groups in terms of positive surgical margin, mean number of lymph node removed, or positive lymph node. The incidences of complications associated and non-associated with the urinary tract and grade \geq III complications at postoperative day (POD) 0–30 and 31–90 were similar between the groups. In the HYBRID group, no complications non-associated with the urinary tract or grade \geq III complications were observed at POD 31–90.

Conclusion The HYBRID method takes advantage of the benefits of both ICUD and ECUD and is a highly applicable technique that can be used in a variety of patient backgrounds.

Key words extracorporeal urinary diversion; HYBRID method; intracorporeal urinary diversion; robotic-assisted radical cystectomy

Radical cystectomy with pelvic lymph node dissection (PLND) remains the gold standard treatment for muscle-invasive and high-risk superficial bladder cancer.¹ Since the publication in 2018 of the findings of the RAZOR study, a randomized phase 3 trial from 15 medical centers in the USA, robotic-assisted radical cystectomy (RARC) has become recognized worldwide as a standard procedure that is less invasive compared with open radical cystectomy (ORC).² In Japan, increasing numbers of patients have been treated with RARC since it became covered by health insurance in April 2018.

Urinary diversion (UD) is an essential procedure in RARC that requires high precision and delicacy in terms of preservation of urinary tract function and prevention of postoperative complications. Either extracorporeal UD (ECUD) or intracorporeal UD (ICUD) is selected for RARC, each method having its own advantages and disadvantages. The advantages of ECUD include gentle manipulation with tactile sensation, direct palpation of mesenteric blood flow, adequate cleansing of the conduit, and reduced head-down duration. In other words, the processes that have been considered essential in ORC can also be performed in ECUD, without omission. In comparison, the advantages of ICUD include shortening the duration of contact between the intestinal tract and the open air, avoiding excessive detachment of the ureter, fine anastomotic manipulation, allowing the ureter and intestinal tract to anastomose in a natural position and reducing third-space losses. However, we feel somewhat uncomfortable that in ICUD, we are forced to omit some of the essential procedures that we used to perform in ORC. In studies that have compared surgical outcomes, no consensus has been reached

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Abbreviations: BMI, body mass index; ECUD, extracorporeal urinary diversion; EBL, estimated blood loss; ICG, indocyanine green; IRCC, International Robotic Cystectomy Consortium; ICUD, intracorporeal urinary diversion; NAC, neoadjuvant chemotherapy; ORC, open radical cystectomy; PLND, pelvic lymph node dissection; POD, postoperative day; RARC, robotic-assisted radical cystectomy; RARP, robotic-assisted radical prostatectomy; TURBT, transurethral resection of bladder tumor

regarding the superiority of either method.^{3–8} Ahmed et al. analyzed 935 patients using the International Robotic Cystectomy Consortium (IRCC) database of 18 international centers, and reported that ICUD had significantly better outcomes in terms of 30- and 90-day postoperative readmission rates, postoperative gastrointestinal complications, and postoperative infections.⁹ Using the same IRCC database, however, an analysis with propensity-score matching of 972 patients by Hussein et al. reported that ICUD patients had significantly higher rates of overall complications and readmissions, but high-grade complications comparable to ECUD. More interestingly, the ICUD group had worse perioperative outcomes than the ECUD group, despite a significantly lower rate of neobladder implementation.¹⁰

However, in Western high-volume centers belonging to the IRCC, the rate of ICUD surgeries has been increasing year by year. In particular, the rate of intracorporeal ileal conduit has increased dramatically from 5% to 81% between 2005 and 2016, and extracorporeal ileal conduit is now uncommon in real-world clinical practice.¹¹ Why is ICUD rapidly increasing in Western countries even though the usefulness of ICUD compared with ECUD has not been established? Direct reasons may include the importance of the advantages of ICUD mentioned above, and the fact that the institutions belonging to the IRCC are all high-volume centers with large numbers of cases, which make it easier to obtain the learning curve of ICUD. However, we can assume that an indirect reason is the additional influence of the background of patients undergoing RARC in these institutions. According to papers published by the IRCC, in both the ICUD and ECUD groups, mean age was the late 60s, mean body mass index (BMI) was just under 30 kg/m², and the proportion of obese patients (BMI > 30 kg/m²) was just less than 30%.⁹ In other words, many of the patients in the IRCC reports are relatively young and obese. In this situation, we can assume that technical difficulties would be encountered with ECUD in many of these patients, requiring open surgery to manipulate the ureter and bowel. Therefore, it can be inferred that surgeons tend to choose ICUD over ECUD in such patients, even if the surgical outcomes are comparable.

With the increasing number of RARC surgeries performed in Japan, numerous facilities have shifted from ECUD to ICUD, similar to the trend in Western countries. This shift is presumably based on the IRCC-based papers that highlighted the usefulness of ICUD. However, there are significant differences in the backgrounds of patients undergoing RARC between Western countries and Japan. In a nationwide

multi-institutional study conducted in 2018 in Japan for RARC cases before the introduction of insurance coverage, mean age in all 253 patients was 69.5 years, similar to the IRCC-based papers, but mean BMI was much lower at 24.2 kg/m², and only three patients (1.1%) had BMI ≥ 30 kg/m².¹² In addition, since coverage of RARC by insurance, the indications have been further expanded to include elderly patients, and in recent years, approximately 30% of patients have been aged ≥ 80 years. Accordingly, patients who undergo RARC in Japan are older and slimmer than those in Western countries. In other words, there is a low percentage of patients in Japan for whom ECUD is difficult due to the technicalities of the surgery. More to the point, although an increased risk of pulmonary edema and lower-leg compartment syndrome associated with prolonged Trendelenburg position has been reported in RARC,^{13, 14} in the Japanese patient background, which includes many elderly patients, ECUD may be more useful in reducing postoperative complications because the duration of the Trendelenburg position is shorter. Given these differences in patient backgrounds, is there merit in transitioning from ECUD to ICUD in Japan, as in Western countries?

In light of the above, the most efficient urinary diversion for Japanese patients (who are likely to be elderly and slim) would be a procedure that incorporates the advantages of both ECUD and ICUD. With this in mind, we developed the HYBRID method, which combines the ECUD and ICUD techniques. Similarly, Masumori et al. reported in 2019 a urinary diversion technique that combined ICUD and ECUD,¹⁵ but as yet there has been no reported comparison of its perioperative outcomes with other UD techniques (ECUD and ICUD). The purpose of this study was to evaluate the usefulness of the HYBRID method for UD in Japanese patients who underwent RARC. Our institution has not had any experience with ICUD, as we have performed ECUD continuously since the beginning of RARC until we developed the HYBRID method. Hence, in this study, we compared the perioperative results between the HYBRID method and ECUD alone. Furthermore, we included only patients who had UD by ileal conduit because a neobladder was implemented in only a small number of patients (ECUD, *n* = 7; HYBRID, *n* = 6).

SUBJECTS AND METHODS

Patients

The study was approved by the Ethics Committee of Tottori University, Japan (No. 2555). Consent was obtained by opt-out in accordance with ethical guidelines for medical research involving human subjects. We

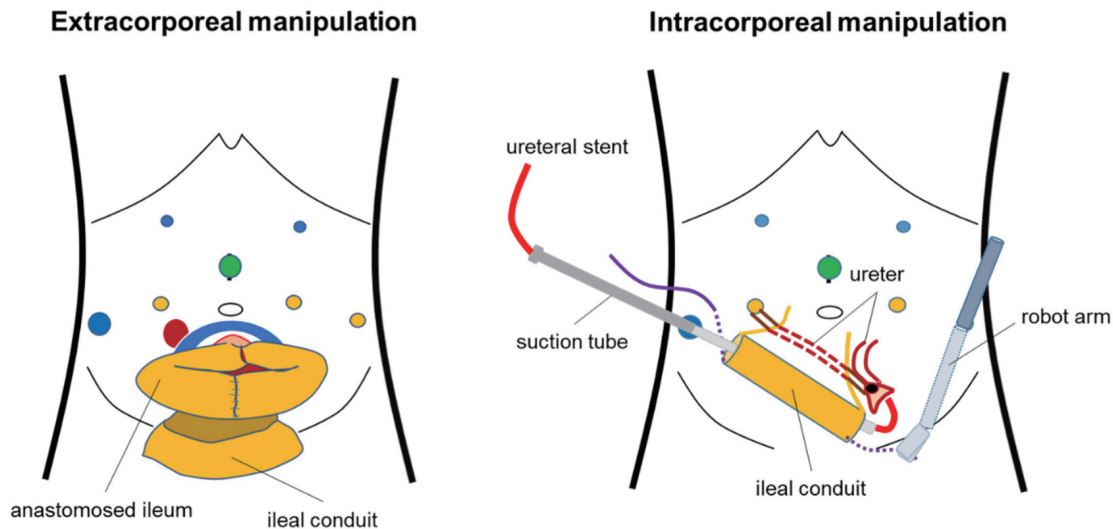


Fig. 1. Overview of the HYBRID method. (Left) Extracorporeal manipulation: After undocking the robot, ileal isolation and cleaning of the ileal conduit are performed by manipulation as for ECUD. (Right) Intracorporeal manipulation: See Fig. 2 for details of the technique.

retrospectively collected the clinical and laboratory data of 36 consecutive patients with bladder cancer who underwent RARC with ileal conduit at our institution between September 2010 and December 2021 and who were available for follow-up for at least 90 days after surgery. Bladder cancer was confirmed pathologically in all patients by transurethral resection of bladder tumor (TURBT) prior to RARC. All RARCs were performed with the da Vinci robotic system (Intuitive Surgical, Sunnyvale, CA). When comparing the HYBRID and ECUD groups, perioperative outcomes, complications evaluated by the Clavien–Dindo classification, and oncologic outcomes were evaluated after propensity-score matching. Four preoperative factors were used to align the patient backgrounds: ASA score, Charlson comorbidity index (CCI), history of previous abdominal surgery, and whether PLND was performed. Neoadjuvant chemotherapy (NAC) was not included as a factor for propensity-score matching in the present study because a number of recent papers have reported that NAC had no effect on perioperative safety in radical cystectomy.^{16, 17}

Operative technique of the HYBRID method

RARC and PLND were performed as follows. Seven ports were used: an additional assistant port at the left hypochondrium was added to the six ports used in our robotic-assisted radical prostatectomy (RARP) technique.¹⁸ The patients were placed in the Trendelenburg position (15 to 20 degrees), relatively less inclined than that for RARP. The 4th robotic arm was set up at the

left side of the patient. PLND usually included the external iliac, internal iliac, obturator, common iliac, and presacral lymph nodes. Each area of lymph nodes was dissected separately as a packet. Wallace anastomosis was used for the ileal conduit procedure.

ECUD was performed by the same procedure as for standard ORC, through a 5–7 cm subumbilical midline incision after the robot was undocked and the Trendelenburg position was released. In contrast, HYBRID combines intracorporeal and extracorporeal manipulation. An overview of the HYBRID method is shown in Fig. 1. In intracorporeal manipulation after bladder removal, the left ureter is moved to the right side through the dorsal aspect of the sigmoid colon, and the left and right ureters are fixed to the abdominal wall (Fig. 2A). After undocking the robot, the Trendelenburg position is released and extracorporeal manipulation is begun, which involves essentially the same procedures of ileal isolation and cleaning of the conduit as for ECUD. The anastomosed ileum and the free conduit are returned to the abdominal cavity, a wound retractor and its cap (Alexis Laparoscopic System, Applied Medical, CA) are attached to prevent air leakage of insufflation, and the technique returns to intracorporeal manipulation in the 15 degrees Trendelenburg position. A longitudinal incision (approximately 2.5 cm) appropriate for the diameter of the conduit is made in the bilateral ureters previously fixed in the abdominal cavity, and the ureters are united by continuous sutures with 5-0 Monocryl (Ethicon, Inc., Somerville, NJ) (Fig. 2B). After continuous suturing of the united ureter and

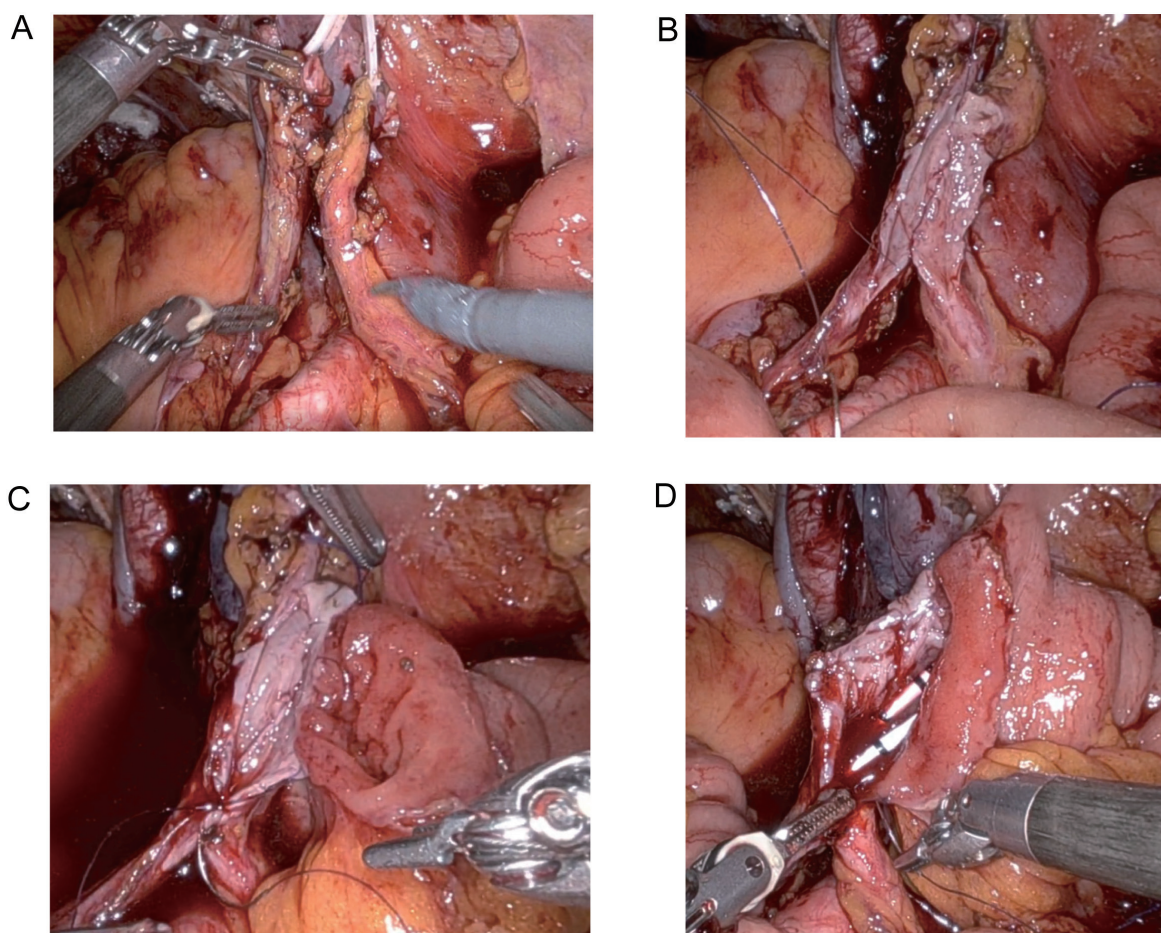


Fig. 2. Detailed technique of the HYBRID method. (A) The left and right ureters are fixed to the abdominal wall. (B) The ureters are united by continuous sutures. (C) Continuous suture of the united ureter and the posterior wall on the oral side of the conduit. (D) Anastomosis of the ureter and conduit is completed by closing the anterior wall of the ureter and conduit with a continuous suture.

the posterior wall on the conduit oral side with 4-0 Monocryl (Ethicon, Inc., Somerville, NJ) (Fig. 2C), a mono J stent is placed in each ureter. The anastomosis of the ureter and conduit is completed by closing the anterior wall of the ureter and conduit by continuous suturing with 4-0 Monocryl (Fig. 2D). After undocking the robot, the Trendelenburg position is released and a stoma is created using the same procedure as in ORC. At this time, retroperitonealization is performed by passing the conduit behind the detached peritoneum.

In neobladder implementation, the pouch is made extracorporeally, but the front of the pouch is left open to facilitate ureteral stenting or balloon catheter placement intracorporeally. Intracorporeal manipulation is performed in the same 15 degrees Trendelenburg position as for the ileal conduit. The intracorporeal manipulation is completed by anastomosing the right and left ureters, anastomosing the united ureter with the chimney of the new bladder, anastomosing the urethral

opening of the neobladder with the urethra, and finally suturing the front of the pouch.

Statistical analysis

All statistical analyses were performed using PASW statistics 25 (SPSS, Chicago, IL). Statistical analysis was performed with the Mann–Whitney *U* test for non-parametric comparisons of continuous variables. Fisher's exact test was used to compare categorical variables. *P* values of < 0.05 were considered significant.

RESULTS

Patient demographics

Table 1 shows the patient demographics in the ECUD and HYBRID groups (*n* = 12 in each). Other than the four factors used for propensity-score matching, there was no significant difference between the groups in terms of age, sex, BMI, or preoperative Hb level. However, the rate of NAC induction was significantly

Table 1. Patient demographics

| | ECUD (<i>n</i> = 12) | HYBRID (<i>n</i> = 12) | <i>P</i> value |
|---|-----------------------|-------------------------|----------------|
| Median age, years (IQR) | 75.5 (50–82) | 74.5 (55–85) | 0.799 |
| Male / female | 9 / 3 | 8 / 4 | 1.000 |
| Median BMI, kg/m ² (IQR) | 24.3 (17.7–29.3) | 22.5 (18.0–28.8) | 0.219 |
| Median ASA score (IQR) | 2.0 (1–2) | 2.0(1–3) | 0.410 |
| Median CCS (IQR) | 1.0 (0–3) | 1 (0–3) | 0.932 |
| History of previous abdominal surgery (%) | 6 / 6 | 7 / 5 | 1.000 |
| Neoadjuvant chemotherapy (%) | 2 (17) | 8 (67) | 0.013 |
| Adjuvant chemotherapy (%) | 5 (42) | 4 (33) | 1.000 |
| Median pre-operative Hb levels, g/dL (IQR) | 12.5 (9.7–14.6) | 11.1 (9.2–14.9) | 0.128 |
| Median pre-operative Alb levels, g/dL (IQR) | 4.1 (3.5–4.7) | 3.9 (3.4–4.4) | 0.932 |
| cT3 or more (%) | 3 (25) | 6 (50) | 0.400 |
| cN0M0 (%) | 10 (83) | 11 (92) | 1.000 |
| PLND (%) | 11 (92) | 11 (92) | 1.000 |

Table 2. Perioperative surgical and oncological outcomes

| | ECUD (<i>n</i> = 12) | HYBRID (<i>n</i> = 12) | <i>P</i> value |
|--|-----------------------|-------------------------|----------------|
| Median total operative time, min (IQR) | 584 (476–872) | 562 (469–645) | 0.347 |
| Median console time, min (IQR) | 242 (152–513) | 309 (262–368) | 0.039 |
| Median EBL, mL (IQR) | 357 (50–1145) | 190 (30–580) | 0.114 |
| Blood transfusion (%) | 2 (16) | 2 (16) | 1.000 |
| Interval to resumption of a regular diet, days (IQR) | 12 (7–24) | 11 (7–18) | 1.000 |
| Degree of elevation of serum CRP, mg/dL (IQR) | 14.7 (6.1–23.1) | 14.7 (5.6–24.2) | 0.977 |
| Lowest post-operative serum Alb, g/dL (IQR) | 2.3 (2.0–2.9) | 2.2 (2.0–2.5) | 0.843 |
| pT3 or more (%) | 3 (25) | 2 (16) | 1.000 |
| PSM (%) | 0 (0) | 0 (0) | 1.000 |
| Median number of LNs removed | 23 (11–58) | 30 (13–47) | 0.093 |
| Positive LNs (%) | 2 (16) | 1 (8) | 1.000 |

higher in the HYBRID group, which was attributed to the higher number of recent cases in that group.

Perioperative surgical and oncological outcomes

Table 2 shows the perioperative surgical and oncological outcomes. With regard to surgical outcomes, mean total operative time was similar between the groups, whereas mean console time was significantly longer in the HYBRID group due to the intracorporeal manipulation. Although not statistically significant, a relatively favorable trend was observed in the HYBRID group in terms of mean blood loss. For oncological outcomes, there was no significant difference in terms of extravesical disease (pT3/pT4), positive surgical margin, mean number of LNs removed, or positive LNs. However,

the trend toward more lymph nodes removed in the HYBRID group was due to the more recent cases and the higher rate of extended PLND compared with the ECUD group.

Complications

Table 3 shows postoperative complications at postoperative day (POD) 0–30 and 31–90. The incidence of complications associated and non-associated with the urinary tract, ileus, and grade \geq III complications at POD 0–30 were similar between the groups. Similarly, there was no significant difference in complications at POD 31–90, with no cases of complications non-associated with the urinary tract, ileus, or grade \geq III complications in the HYBRID group.

Table 3. Postoperative complications

| | ECUD (n = 12) | HYBRID (n = 12) | P value |
|---------------------------------------|---------------|-----------------|---------|
| POD 0–30 | | | |
| Associated with urinary tract (%) | 1 (8.3) | 2 (16.7) | 1.000 |
| Non-associated with urinary tract (%) | 5 (41.7) | 4 (33.3) | 1.000 |
| Post-operative ileus (%) | 3 (25.0) | 3 (25.0) | 1.000 |
| Grade III or greater (%) | 1 (8.3) | 2 (16.7) | 1.000 |
| POD 31–90 | | | |
| Associated with urinary tract (%) | 1 (8.3) | 1 (8.3) | 1.000 |
| Non-associated with urinary tract (%) | 1 (8.3) | 0 (0) | 1.000 |
| Post-operative ileus (%) | 1 (8.3) | 0 (0) | 1.000 |
| Grade III or greater (%) | 1 (8.3) | 0 (0) | 1.000 |

DISCUSSION

Our institution began performing RARC before it was covered by insurance in Japan and it was one of the earliest in Japan to introduce RARC. Prior to introduction of the HYBRID method, we had continued with ECUD while other institutions were transitioning to ICUD.¹⁹ The main reason why we continued with ECUD was that it could be performed without omitting any of the techniques we had developed in open surgery. We particularly appreciate its usefulness in that it enables palpation of mesenteric blood flow and adequate cleaning of the ileal conduit. Some institutions that perform ICUD have devised ways to confirm blood flow in the mesentery by using indocyanine green (ICG) or a light from a flexible cystoscope,^{20, 21} but it is impossible to confirm pulsation by directly touching the blood vessels in either method. We had previously experienced a case in which the gastrointestinal surgeon recommended a change to a uretero-cutaneostomy due to the risk of conduit necrosis in a patient scheduled for an ileal conduit, because although the mesenteric vessels were visible, the palpable pulsation was faint. Also, bowel cleansing is almost impossible with ICUDs. When watching videos of ICUD performed in the U.S. and Europe, there is a sense that no consideration has been given to this point. However, fecal peritonitis is a serious complication and there have been reports of deaths when it occurs.²² It is highly questionable for preventive measures not to be taken simply because it occurs infrequently. In contrast, it is also true that ICUD has the advantage of being less affected by obesity than is ECUD. Ahmadi et al. examined the impact of BMI on complications in ICUD and reported that as BMI increased, blood loss and operative time also increased, but there was no effect on complications or prognosis.²³ Accordingly, it makes sense that there would be high rates of ICUD

in Western countries where there are large numbers of obese patients. In Japan, the number of obese patients has been increasing in recent years due to the westernization of food culture, and although it is a rare occurrence, we do encounter cases in which ECUD is difficult due to obesity. Even in such cases, however, the HYBRID method is still an easier operation compared to ECUD and appears to be an appropriate technique for the Japanese patient background.

In addition to those mentioned above, the HYBRID method has the following advantages. During manipulation of the neobladder by ICUD, in some patients the pouch created does not reach the urethra and it is difficult to achieve anastomosis between the neobladder and the urethra. However, as the pouch is created extracorporeally with the HYBRID method, it is possible to manually pull the intestinal tract to find a location that will reliably reach the urethra. We also experienced a very rare case of incomplete duplicated left ureter that was not detected on preoperative imaging and was discovered intraoperatively. We passed a guidewire from outside the body through the thinner of the two left ureters, which were separated near the bladder. Patency was checked fluoroscopically with contrast medium, which confirmed that there was no urine flow because of a blind end on the central side. We then resumed intracorporeal manipulation. If the smaller of the two left ureters had functioned as a urinary tract, a complex urinary diversion would have been required that is extremely difficult to accomplish with an ICUD. However, with the HYBRID method, even if such an unforeseen situation occurs, it is possible to immediately perform extracorporeal manipulation simply by removing the cap of the lower abdominal wound, which is a great advantage.

Although RARC is now recognized as a standard

| | ECUD | ICUD | HYBRID |
|---|------|------|--------|
| Direct palpation of mesenteric blood flow | | × | |
| shortening head-down duration | | × | |
| adequate cleansing of the ileal conduit | | × | |
| shortening the contact duration between the intestinal tract and the open air | × | | △ |
| avoiding excessive detachment of the ureter | × | | |
| Anastomosis of ureter and intestinal tract in natural position | × | | |

Fig. 3. Advantages of the HYBRID method. The HYBRID method takes advantage of the features of both ICUD and ECUD and is a highly applicable technique.

procedure, it is worthwhile to consider its primary benefit: that it has enabled total cystectomy to be performed in patients with locally advanced disease or high risk of complications, which was previously considered impossible with ORC.¹⁹ In other words, ICUD is not essential to this procedure, and it is therefore not meaningful to discuss the superiority or inferiority of ICUD and ECUD. Rather, it is important to use each method appropriately according to the patient's condition. In this sense, the HYBRID method that we are working on takes advantage of the benefits of both ICUD and ECUD, and we consider that it is a highly applicable technique (Fig. 3).

There are several limitations to this study. First, this is a small, single-center, retrospective study. Propensity-score matching enabled us to align the patient backgrounds to some extent, but the number of cases was small. Second, there are differences in the patients' historical backgrounds, with the majority of ECUD cases treated early after the introduction of RARC at our institution and the majority of HYBRID cases being more recent. Therefore, compared to the early cases, the recent cases have a different proportion of elderly patients, those who underwent extended lymph node dissection, and those who received neoadjuvant chemotherapy. In addition, the influence of the learning curve cannot be ignored. Finally, the observation period of the study was short and we presented no

data regarding long-term cancer control.

In conclusion, the present study could not statistically prove the usefulness of the HYBRID method compared with ECUD. However, the HYBRID method takes advantage of the features of both ICUD and ECUD and has the potential benefit of being a highly applicable technique that can be used in a variety of patient backgrounds without omitting any processes similar to those in ORC. Future prospective studies with a larger number of patients are needed to evaluate its usefulness.

The authors declare no conflict of interest.

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