

The First Pilot Comprehensive Evaluation of the Outcomes of Different Types of Robotic Surgeries in the Different Surgical Departments: The Penta, Tetra and Trifecta Achievements in Robotic Surgeries

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ABSTRACT

Background To ensure safe performance in robotic surgery, the Minimal Invasive Surgery Center (MISC) is composed of the anesthesiology department, five surgery departments and co-medical staff in our institution. The objective of this study was to evaluate the outcomes of different types of robotic surgeries for cancer treatment ($n = 326$) from different surgery departments in the MISC.

Methods The outcomes of robot-assisted radical prostatectomy (RARP), partial nephrectomy (RAPN), transoral robotic surgery (TORS) for pharyngeal cancer, and robotic surgery for lung, gastric and rectal cancer were evaluated using the similar concept of pentalectomy in RARP.

Results The pentalectomy rates of RARP and robotic surgery for rectal cancer were 33.3 and 56.5%, respectively. The tetralectomy rates of RARP (excluding potency evaluation from pentalectomy) and TORS were 48.4 and 57.1%, respectively. The trifecta rates of RAPN, robotic surgeries for lung and gastric cancer were 75.9, 74.2 and 84.2%, respectively. The failure of tetralectomy in RARP achievement was significantly associated with high risk than with low risk according to National Comprehensive Cancer Network classification.

Conclusion This is the world's first comprehensive evaluation of different types of robotic surgeries for

cancer treatment in the constitutional framework of an academic institution. MISC, which provides the constitutional framework of an academic institution, is providing immeasurable benefits in terms of robotic surgery quality, and it may ultimately lead to high penta-, tetra-, and trifecta rates for robotic surgeries for cancer treatment in all surgical departments.

Key words evaluation; outcome; robotic surgery

Robot-assisted radical prostatectomy (RARP) using the da Vinci surgical system started in 2000¹ and it has spread rapidly while retaining the concept of minimal invasive surgery. Although RARP was introduced in 2006 in Japan, the spread of RARP has been very slow because of the off-label application of Japanese health insurance over this time. However, the Japanese Ministry of Health, Labor and Welfare allowed the application of health insurance for RARP on April 2012; therefore, the rapid spread of RARP is ongoing. A concern with regard to the rapid spread of new surgical innovation is the issue of patient safety. Reduced patient safety occurs due to insufficient preparation and inadequate surgical techniques during the introduction of a new technology. To eliminate such concerns, the introduction and implementation of robotic surgeries in our institution were controlled by MISC, which performs robotic surgeries comprehensively not only in urology but also in other surgical departments. Recently, we reported our initial experience of 100 patients treated by RARP with a focus on constitutional introduction and implementation based on MISC.² Since the initial experience of all robotic surgeries from different surgical departments, the case numbers of robotic surgeries have been continuously growing. The next aim of MISC after completion of the safe introduction of robotic surgery is the evaluation of robotic surgical outcomes.

Trifecta was introduced by Bianco et al. to evaluate the outcomes of RARP, aiming for the coexistence of

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Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CD, Clavien-Dindo; CEA, carcinoembryonic antigen; eGFR, estimated glomerular filtration rate; LPN, laparoscopic partial nephrectomy; MISC, Minimal Invasive Surgery Center; MRI, magnetic resonance imaging; NCCN, National Comprehensive Cancer Network; PSA, prostate specific antigen; RAPN, robot-assisted partial nephrectomy; RARP, robot-assisted radical prostatectomy; RP, radical prostatectomy; TORS, transoral robotic surgery; WIT, warm ischemia time

cancer control and functional preservation.³ Along with increased patient demands and greater expectations of surgical interventions, a new and more comprehensive method for reporting outcomes in RARP, i.e., the penta-fecta, was proposed.⁴ Similarly, trifecta was advocated in robot-assisted partial nephrectomy (RAPN) for meeting high quality surgical goals, including cancer control, functional preservation and absence of complications.⁵ Despite the concrete surgical goals of robotic surgeries in the urological field, such goals seem to be obscure in robotic surgeries in other surgical departments. There is a concern with regard to the disappearance of sustained efforts by expert surgeons without concrete surgical goals. Therefore, we performed a comprehensive evaluation of the different types of robotic surgeries for cancer treatment in MISC, which provides the constitutional framework of our academic institution.

MATERIALS AND METHODS

The role of MISC in robotic surgery; Constitutional framework of our institution

The urology staff started performing RARP in October 2010 as the first robotic surgery in our institution. MISC was organized six months after the first RARP, and it consisted of all of the departments related to robotic surgery including anesthesiology, urology, gynecology, respiratory and digestive surgery, otorhinolaryngology, operation room nurses, medical engineers and medical clerks. From the viewpoint of safe implementation of robotic surgery, each surgery was performed under the supervision of MISC. For instance, certification for surgery type and the console surgeon were authorized by MISC. Specifically, MISC has “termination order” authority, which is exercised when there is excessive bleeding or an extended surgical time (Fig. 1). Robotic surgery must be converted into another type of surgery, such as open conversion, once the order is given. Each robotic surgery case in all surgery departments is checked and discussed pre- and postoperatively at the regular meetings held by MISC twice per month.

<p>Department: <u>Urology</u></p> <p>Surgery type: <u>Robot-assisted radical prostatectomy</u> <u>(Limited lymphadenectomy)</u></p> <p>1) Standard operation time: <u>5</u> hours</p> <p>2) Basal condition of termination order</p> <p>a) Breakdown or malfunction of robotic surgical system</p> <p>b) Malfunction of robotic surgical equipment</p> <p>c) Excess bleeding: <u>more than 2000</u> mL</p> <p>d) Excess operating time: <u>more than 8</u> hours</p> <p>3) Other conditions of the termination order</p> <p>a) When operators recognize unexpected intra-operative findings of advanced cancer</p> <p>b) When it is obvious that other organ injuries occur</p> <p>c) When anesthetists recognize critical problem in the general care of the patient</p>	<p>Department: <u>Digestive Surgery</u></p> <p>Surgery type: <u>Robot-assisted low anterior resection</u></p> <p>1) Standard operation time: <u>6</u> hours</p> <p>2) Basal condition of termination order</p> <p>a) Breakdown or malfunction of robotic surgical system</p> <p>b) Malfunction of robotic surgical equipment</p> <p>c) Excess bleeding: <u>more than 500</u> mL</p> <p>d) Excess operating time: <u>more than 10</u> hours</p> <p>3) Other conditions of the termination order</p> <p>a) When operators recognize the difficulty of proceeding with the operation based on an anatomical abnormality or adhesion</p> <p>b) When anesthetists recognize a critical problem in the general care of the patient</p>
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Fig. 1. The termination order (English version) for RARP and robotic surgery for rectal cancer is shown. The original documents are described in Japanese. RARP, robot-assisted radical prostatectomy.

Patients

A total of 500 cases were treated by robotic surgeries from October 2010 to September 2015 in MISC. Among these cases, 326 cases were treated by robotic surgery for cancer therapy and followed for more than 12 months (according to the criteria of patients in the evaluation of pentalecta⁴) and were enrolled in the study. The median follow-up duration was 24.2 months (range: 12.5–54.2). The details of the 326 cases were RARP ($n = 217$), RAPN ($n = 29$), robotic surgery for lung ($n = 31$), gastric ($n = 19$) and rectal ($n = 23$) cancers, and transoral robotic surgery (TORS) for pharyngeal cancer ($n = 7$) (Table 1). The study was approved by the Ethics Committee of Tottori University Faculty of Medicine (Approved No. 1602A125).

Definition of penta and tetralecta in RARP and trifecta in RAPN

The definition of pentalecta in RARP complied with the robust previous literature,⁴ with some modifications only in the definition of potency. Because of the lower

incidence of preoperatively potent patients, compared with the incidence of patients in Western countries, and the small number of patients who underwent bilateral nerve sparing procedures, the definition of potency was modified as follows. The recovery of potency was defined in cases in which a preoperatively potent patient (International Index of Erectile Function erectile function domain > 21) underwent bi- or unilateral nerve sparing procedures and recovered to International Index of Erectile Function erectile function domain > 17, with and without the use of PDE5 inhibitors postoperatively. Because the patient cohort that the pentalecta rate was able to evaluate consisted of a small number of patients, tetralecta rate (excluding potency evaluation) was also evaluated in RARP. The most current use of the definition of trifecta in RAPN⁵ was employed in the study, i.e., warm ischemia time (WIT) less than 25 minutes, negative surgical margins and no perioperative complications.

Table 1. Robotic surgery types for cancer treatment and their number of cases

Department	Surgery type	No. of cases
Urology	Robot-assisted radical prostatectomy (RARP)	217
	Robot-assisted partial nephrectomy (RAPN)	29
Respiratory surgery	Robotic surgery for lung cancer	31
Digestive surgery	Robotic surgery for gastric cancer	19
	Robotic surgery for rectal cancer	23
Otorhinolaryngology	Transoral robotic surgery (TORS) for pharyngeal cancer	7
Total		326

Table 2. Definition of penta, tetra and trifecta in each type of robotic surgery

Surgery type	Definition of penta, tetra or trifecta achievement
RARP (Pentalecta)	1) No biochemical recurrence, 2) Negative surgical margin, 3) Continence recovery (no pad), 4) Potency recovery, 5) No complication
RARP (Tetralecta)	1) No biochemical recurrence, 2) Negative surgical margin, 3) Continence recovery (no pad), 4) No complication
RAPN (Trifecta)	1) Negative surgical margin, 2) Warm ischemia time (WIT) ≤ 25 min., 3) No complication
Robotic surgery for rectal cancer (Pentalecta)	1) No recurrence, 2) Negative surgical margin, 3) Normal voiding, 4) Normal defecation, 5) No complication
TORS (Tetralecta)	1) No recurrence, 2) Negative surgical margin, 3) Normal swallowing, 4) No complication
Robotic surgery for lung and gastric cancer (Trifecta)	1) No recurrence, 2) Negative surgical margin, 3) No complication

RAPN, robot-assisted partial nephrectomy; RARP, robot-assisted radical prostatectomy; TORS, transoral robotic surgery; WIT, warm ischemia time.

Definition of pentafecta in robotic surgery for rectal cancer, tetrafecta in TORS, and trifecta in robotic surgeries for lung and gastric cancer

Because of the lack of evaluative measures for robotic surgical outcomes in the surgical departments other than urology, we originally defined penta, tetra and trifecta. Considering the transition from trifecta to pentafecta in RARP and the advocacy of trifecta in RAPN, three issues were included, if possible, in the study, i.e., “complete cancer control,” “functional preservation” and “no perioperative complications.” The issue of “complete cancer control” included both negative surgical margins and no postoperative relapse except for RAPN. Because the issue of “functional preservation” has not been established in robotic surgeries for lung and gastric cancer, it was excluded from these two types of surgery. With regard to the issue of “no perioperative complications,” complications occurring during the surgical procedure or within 90 d after surgery were documented and classified according to the Clavien-Dindo (CD) classification.⁶ The definitions of penta, tetra or trifecta in each type of robotic surgery in the MISC are summarized in Table 2.

Statistical analysis

Univariate and multivariate logistic regression analyses were used to analyze the factors predictive of achieving tri, tetra and pentafecta in each type of robotic surgery, with $P < 0.05$ considered statistically significant.

RESULTS

The types, case numbers, complications and open conversion rates of all robotic surgeries in the MISC

A total of 500 cases undergoing 14 types of robotic surgery were treated from the first case of robotic surgery until September 2015 in the MISC. Serious complications (CD grade \geq III) were recognized in 6 cases (1.2%). Open conversion was performed in only one case (0.2%), which was treated by robotic surgery for gastric cancer not because of an emergency reason but because of difficulty in the robotic procedure due to unexpected cancer progression.

The evaluation of robotic surgical outcomes for cancer treatment according to penta, tetra and trifecta in the MISC

Only patients who successfully met all of the aforementioned criteria in each type of robotic surgery were considered to achieve penta, tetra or trifecta. The penta, tetra and trifecta rate (percentage) are the rates of cases in which surgical outcome has met successfully all

of the criteria. For instance, the trifecta rate in robotic surgery for gastric cancer is the rate of cases against total cases in which surgical outcome has met successfully “no recurrence,” “negative surgical margin” and “no complication.” The pentafecta rates of RARP ($n = 24$) and robotic surgery for rectal cancer were 33.3 and 56.5%, respectively. The tetrafecta rates of RARP ($n = 217$) and TORS were 48.4 and 57.1%, respectively. The trifecta rates of RAPN, robotic surgeries for lung and gastric cancer were 75.9, 74.2 and 84.2%, respectively. The penta and tetrafecta rates of RARP, robotic surgery for rectal cancer and TORS are shown with their radar graphs (Fig. 2). Similarly, the trifecta rates of RAPN and robotic surgery for lung and gastric cancer are shown with their radar graphs (Fig. 3).

The predictive factors for achieving tri, tetra and pentafecta in each type of robotic surgery for cancer treatment

TORS was excluded from the analyses because of the small number of cases. The factors analyzed were patient and tumor backgrounds, which reflected patients generally and tumors specifically. Moreover, the analyzed factors were chosen based on the concept of easy use for clinical practice. Age, body mass index (BMI), and the American Society of Anesthesiologists (ASA) risk classification system score were analyzed in each type of robotic surgery. Other than these data, the following factors were analyzed. For RARP (penta and tetrafecta achievement), preoperative prostate specific antigen (PSA), risk stratification in the National Comprehensive Cancer Network (NCCN), T stage, Gleason score and existence of lymph node metastasis in final pathology were considered; for robotic surgery for rectal (pentafecta achievement), gastric (trifecta achievement) and lung cancers (trifecta achievement), sex, preoperative carcinoembryonic antigen (CEA) and T stage in final pathology were considered; and for RAPN (trifecta achievement), sex, renal nephrometry score and whether malignant or benign in final pathology were considered. From all of the analyses, only one independent factor was revealed that was predictive of tetrafecta achievement in RARP (Table 3), which indicated that the failure of tetrafecta achievement was significantly associated with high risk than with low risk according to NCCN classification.

DISCUSSION

Almost 10 years have passed since the introduction of trifecta in RARP, but only 11 original articles have reported trifecta rates, with a mean value of 58% (range 20–83%).⁷ Although the surgical goal in RARP has been

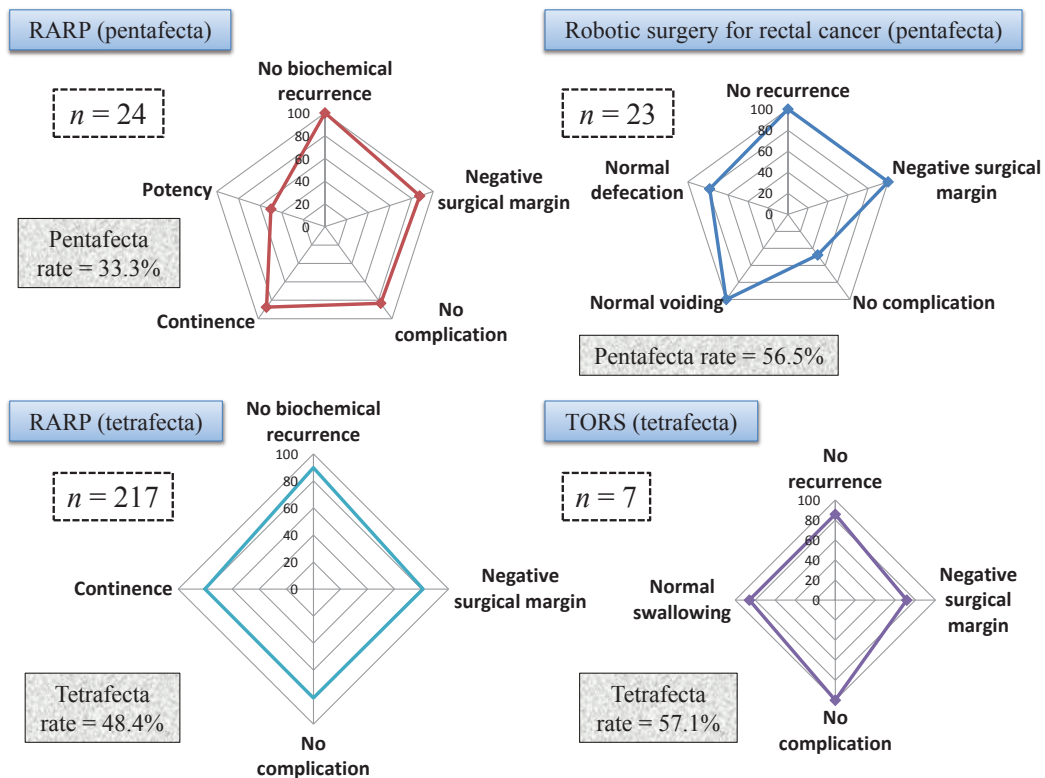


Fig. 2. The radar graphs of penta and tetrafecta achievements in RARP and of robotic surgery for rectal cancer and TORS are shown. In each radar graph, single components and their successful rates are also shown. RARP, robot-assisted radical prostatectomy; TORS, transoral robotic surgery.

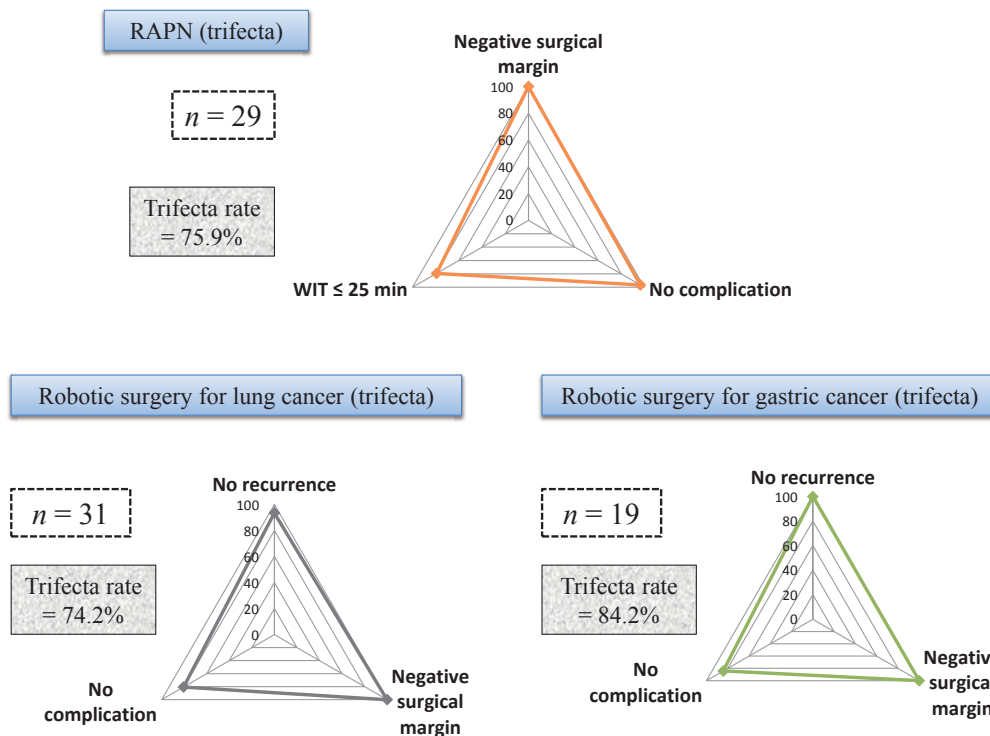


Fig. 3. The radar graphs of trifecta achievements in RAPN and robotic surgeries for lung and gastric cancer are shown. In each radar graph, single components and their successful rates are also shown. RAPN, robot-assisted partial nephrectomy, WIT, warm ischemia time.

Table 3. Multivariate analysis for predictive factors of achieving tetrafacta in RARP

Factor		OR (95% CI)	P value
Age at surgery (ys)		1.040 (0.993–1.090)	0.0949
BMI (kg/m ²)		1.000 (0.899–1.111)	0.9933
ASA score	Class I	1.000 (referent)	
	Class II	0.865 (0.483–1.549)	0.6246
Initial PSA (ng/mL)		1.009 (0.957–1.065)	0.7272
NCCN risk	Low	1.000 (referent)	
	Intermediate	0.627 (0.239–1.641)	0.3411
	High	0.346 (0.125–0.955)	0.0405
T stage (final pathology)	0, 2a	1.000 (referent)	
	2b	1.377 (0.345–5.505)	0.6506
	2c	0.824 (0.396–1.713)	0.6032
	≥ 3a	1.186 (0.432–3.257)	0.7403
Gleason score (final pathology)	6	1.000 (referent)	
	7	1.675 (0.643–4.364)	0.2913
	≥ 8	1.332 (0.425–4.171)	0.6227
Lymph node metastasis (final pathology)	Absent	1.000 (referent)	
	Present	0.188 (0.020–1.797)	0.1466

ASA, American Society of Anesthesiologists; BMI, body mass index; CI, confidence interval; NCCN, National Comprehensive Cancer Network; OR, odds ratio; PSA, prostate specific antigen; RARP, robot-assisted radical prostatectomy; ys, years.

changed from trifecta to pentaefacta, the number of studies indicating pentaefacta rates has been limited. Three major studies, in which more than one hundred patients were treated by RARP, demonstrated pentaefacta rates of 70.8, 60.4 and 45.6%, respectively.^{4, 8, 9} There have been criticisms that trifecta and pentaefacta systems are not appropriate reporting tools for the majority of patients undergoing radical prostatectomy (RP) because they are only applicable in preoperatively continent and potent patients who receive bilateral nerve-sparing procedures. Recently, the survival, continence, and potency, so called SCP classification, has been advocated to classify appropriately all patients who undergo RP according to the oncologic and functional outcomes of relevance to them on an individual basis.⁷ The diverse sexual activity and desire of patients treated by RP worldwide definitely affects the usefulness of the pentaefacta system. In Asian patient cohorts, only one study demonstrated a pentaefacta rate of 72.9% in 170 patients treated by laparoscopic RP.¹⁰ It is presumed that patients' sexual activity and desire in Japan are lower than those of patients from Western countries. Moreover, the relatively high incidence of patients in Japan who underwent plain localization of cancer foci in the prostate by frequent use of magnetic resonance imaging (MRI) indicated

unilateral rather than bilateral nerve-sparing procedures. Therefore, we investigated for the first time worldwide the tetrafacta rate, excluding the potency term from pentaefacta, in patients treated by RARP. Because there have been no studies indicating tetrafacta rates, our result of 48.4% should be considered a pilot value. Our study demonstrated that the failure of tetrafacta achievement was significantly associated with high risk than with low risk according to NCCN classification. Because we performed extended lymphadenectomy and wide dissection of the prostate in high risk patients, it seemed to be the necessary consequence that high risk according to NCCN classification was revealed as factor predictive of the failure of tetrafacta.

There has been a debate over the definition of functional preservation in trifecta for RAPN. Hung et al. demonstrated the outcomes of 534 patients treated by laparoscopic partial nephrectomy (LPN) and RAPN based on the trifecta concept, with failure of renal functional preservation defined as a greater than 10% reduction in the actual estimated glomerular filtration rate (eGFR), compared with that of the volume predicted postoperative eGFR rate.¹¹ In contrast, Buffi et al. proposed an evaluation measure called "MIC" (margin, ischemia and complications) in nephron spar-

ing surgery.¹² Hung et al. argued that ischemia was not necessarily the most important surgical factor affecting postoperative renal function. However, the majority of studies have defined WIT < 25 min. as an indicator of functional preservation, based on a study indicating a cut-off time for warm ischemia in solitary kidney cases treated by partial nephrectomy.¹³ Trifecta rates of RAPN have been demonstrated, in the setting of retrospective comparison between LPN and RAPN, as 58.7 and 70% derived from 251 and 1185 cases treated by RAPN, respectively.^{5, 14} If having complications with \leq CD grade II was defined as a successful criterion, the trifecta rate increased to 81.8 % in 44 cases treated by RAPN.¹⁵ Although the number of cases in our cohort was lower than those in the aforementioned studies, our trifecta rate of 75.9% in RAPN seemed to be excellent. This result might have three causes. The first is the expert skill of the surgeon (Co-author; A.T.), who had sufficient experience in LRP and RARP. Unlike RARP, all cases of RAPN were performed by him. The second cause was the MISC management, especially the regular conferences at which all robotic cases were assessed pre- and postoperatively. The third was the intraoperative navigation system used, with SYNAPSE VINCENT (Fujifilm, Tokyo, Japan) film technology, which could draw renal vascular images precisely.

First, there was no other way to recognize our results of penta, tetra and trifecta in robotic surgeries other than using the urological field for pilot values because no studies have been conducted previously. However, it is universal to use the items of “complete cancer control” and “no perioperative complication” in the evaluation of the surgical outcome for various kinds of cancer treatment. To unify the matter of complete cancer control in the study, negative surgical margins and no postoperative relapse were employed in all of the robotic surgery types except for RAPN. However, there were no studies investigating surgical margin status in robotic surgeries for lung or gastric cancer. Complete cancer control should be evaluated in the future employing other factors in these two types of robotic surgery because there are some potent prognostic indicators, such as lymph node pathology, especially in gastric cancer. In the comparison of cancer control between robotic and laparoscopic surgeries for rectal cancer, circumferential and distal resected margin positive rates were demonstrated as being equivalent between the two approaches.^{16–19} In contrast, the positive surgical margin rate of 4.3% in TORS, which was indicated from a prospective, multicenter study, was suggested not to be inferior to other types of transoral minimally invasive surgeries.²⁰ In our study, the positive surgical margin rates with robotic surgery

for rectal cancer and TORS were 0% and 28.6%, respectively. However, the evaluation of TORS was difficult because of the small number of cases in our study ($n = 7$).

With regard to evaluation of visceral functional preservation in robotic surgeries with penta, tetra and trifecta other than in urological field, we chose some appropriate and established items. “Normal defecation” and “normal voiding” have been established in the evaluation of robotic surgery for rectal cancer as well as “normal swallowing” in the evaluation of TORS. Voiding and sexual function were demonstrated to be better after robotic surgery than after laparoscopic surgery for rectal cancer using uroflowmetry and questionnaires.^{21, 22} The functional preservation of voiding and defecation, rather than sexual function, based on the collectable data in our study, was generally satisfactory (18 of 23 cases; 78.3%). Percutaneous endoscopic gastrostomy dependency after TORS which was defined as the surrogate factor for swallowing evaluation reported in 5% of cases, and the rate was equivalent to those in other treatment modalities for oropharyngeal malignancy.²⁰ Finally, the complication rates in all types of robotic surgery, except RARP and RAPN, were demonstrated to be better than or equivalent to those in open or other minimally invasive surgeries.^{23–26} Although complications occurred in 12 of 23 cases (52.2%) in robotic surgery for rectal cancer, most of them (11 of 12 cases) were minor (CD grade \leq II). In other types of robotic surgery, the complication rates were generally low in our study.

Our study has certain limitations. The first is that there were no data with regard to penta, tetra or trifecta rates in robotic surgeries other than from the urological field. Even the concept of these surgical goals was not present. Therefore, our data were only pilot values. However, the first trial of the evaluation of robotic surgical outcomes, based on the concept of penta, tetra and trifecta, in surgical departments other than urology should be initiated in urology because urologists are the pioneers of robotic surgery. Other limitations include the retrospective nature of the study, as well as its single-center trial design and the small sample size. External validation of the penta, tetra and trifecta rates in all types of robotic surgery for cancer treatment will facilitate the comprehensive evaluation of robotic surgical outcomes not only in urology but also in other surgical fields.

In conclusion, the world’s first comprehensive evaluation of different types of robotic surgeries for cancer treatment in the constitutional framework of an academic institution could result in the safer implementation of robotic surgeries with higher quality. MISC is a useful construction that can evaluate robotic surgical outcomes

based on the same measures that extend across the boundaries among different surgical departments. Although penta, tetra and trifecta rates in surgical departments other than urology are only pilot values, it is valid to initiate a comprehensive evaluation of robotic surgical outcomes using data from urologists, who are the pioneers of robotic surgery.

The authors declare no conflict of interest.

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