Received: 27 January 2020 | Revised: 28 February 2020 | Accepted: 31 March 2020

DOI: 10.1002/ags3.12341

ORIGINAL ARTICLE

AGSurg Annals of Gastroenterological Surgery Open Access | WILEY

# Preliminary results of robotic inguinal hernia repair following its introduction in a single-center trial

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## Abstract

**Aim:** Robotic surgery using the da Vinci system has markedly increased worldwide. However, robotic inguinal hernia repair remains unpopular outside the United States. We introduced and evaluated a robotic transabdominal preperitoneal repair (R-TAPP) technique for inguinal hernia in our hospital.

**Methods:** First, we designed a task protocol according to the surgical results of 388 laparoscopic TAPP (L-TAPP) procedures performed during the 4 years prior to introducing R-TAPP. Our task protocol included several time limitations during a step-wise procedure: creating the peritoneal flap (<60 minutes), mesh placement with fixation (<30 minutes), and peritoneal suture closure (<30 minutes) under experienced supervision. We investigated the preliminary clinical results of R-TAPP performed by a single operator between December 2018 and January 2020.

**Results:** We identified 27 lesions in 20 patients (unilateral in 13 and bilateral in seven). According to the Japan Hernia Society Classification, our cohort included eight type I, five type II, and seven bilateral hernias (nine type I, four type II, and one type IV). The median operation time was 124 minutes (range, 81-164 minutes), and the median console operation time was 85 minutes (range, 50-132). The median time required for the peritoneal incision was 30 minutes (range, 18-54 minutes), that for mesh placement (including tucking) was 13 minutes (range, 7-27 minutes), and that for peritoneal suturing was 9 minutes (range, 3-20 minutes).

**Conclusion:** Our preliminary results suggest that our task protocol for R-TAPP is feasible. However, refinement of our task protocol is essential for standardization.

KEYWORDS

inguinal hernia, laparoscopy, robotic surgical procedures, safety management, treatment protocols

# 1 | INTRODUCTION

A striking increase in robotic surgery has been documented, and Intuitive Surgical Inc. (ISJ National Sales Meeting 2019)[1] reported that more than 1 million da Vinci procedures were performed worldwide in 2018. Additionally, more than 350 000 robotic general surgeries were performed in 2018, which exceeded the number in gynecology and urology.[1] Robotic ventral and inguinal hernia repair contributed to the greatest incremental growth in the United States (US); consequently, reports regarding robotic inguinal hernia repair are mainly from the US.[2,3]

In contrast, the Japanese public health insurance system has approved robotic surgery only for gastric, esophageal, and rectal cancers, and the number of these robotic surgeries is increasing because of their delicate manipulation.[4,5] A questionnaire survey by the Japanese Society for Endoscopic Surgery (14th report) reported 320 cases of gastrectomy and 223 cases of rectal resection in 2017, and continuous increases in these numbers are predicted.[6]

In Japan, surgical inguinal hernia repair is performed mainly by an open approach (inguinal incision)[7,8] or laparoscopic approach.[9,10] We recently began performing robotic transabdominal preperitoneal repair (R-TAPP) as an alternative for patients with inguinal hernia. There have been many reports on R-TAPP from the US,[2,3] but no reports have described approaches for its safe introduction with a task protocol and double bipolar dissection techniques. The prime concern when introducing a new and/or naïve technique must be patient safety. Our approach for introducing R-TAPP described in this paper may have a significant impact on both domestic and international surgeons regarding the proper use of robotic surgery.

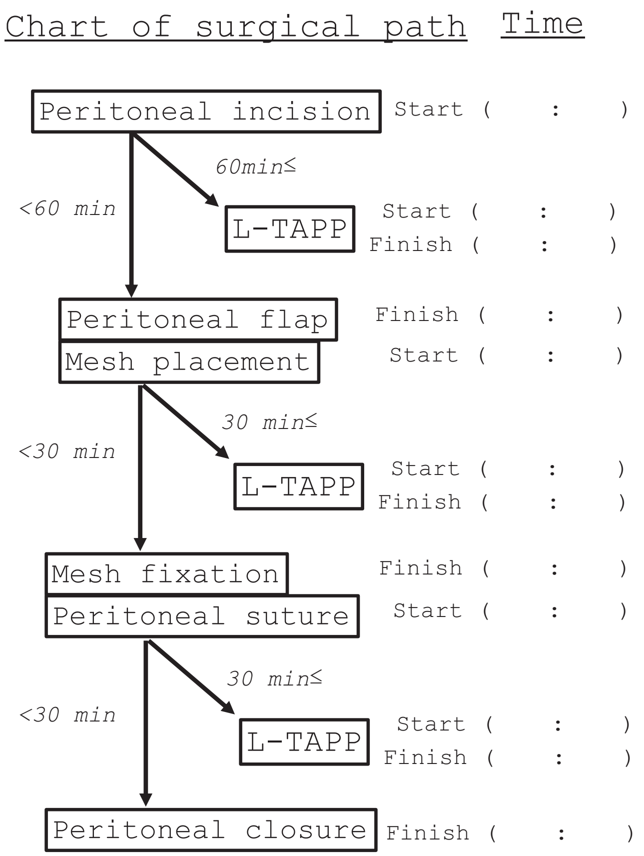


**FIGURE 1** The practical descriptive task protocol (AMU protocol). The times required for each surgical phase are recordable, and decision making regarding the transition to the next step is easily recognizable during R-TAPP

# 2 | MATERIALS AND METHODS

## 2.1 | Introduction of R-TAPP in our department

Robotic surgery using the da Vinci® Xi surgical system (Intuitive Surgical Inc.) has been a standard treatment of choice for gastric and rectal cancer at Aichi Medical University (AMU) Hospital since July 2018. We evaluated this robot-assisted system and recognized its reported operability and consistency.[11–13] We therefore considered R-TAPP as a potential alternative to laparoscopic TAPP (L-TAPP) for patients with inguinal hernias. In December 2018, we introduced R-TAPP as a treatment option after obtaining approval from AMU Hospital for this new and highly difficult medical technology. We nominated a surgeon who was board-certified in L-TAPP by the Japan Society for Endoscopic Surgery and who routinely performed robotic gastrectomy as the main operating surgeon for R-TAPP in our department. This surgeon was also qualified as a specialist by the Japan Robotic Surgery Society.

## 2.2 | Task protocol

We designed a task protocol (AMU Protocol) (Figure 1) lasting 60 minutes from the start to the end of the peritoneal incision (opening phase), 30 minutes from the beginning of mesh placement to the end of mesh fixation (dissecting phase), and 30 minutes from the start to the end of peritoneal suturing (suturing phase). We reviewed the data of 43 consecutive men who underwent treatment for unilateral, uncomplicated, and recurrence-free inguinal hernias from April 2015 to March 2016, corresponding to our introduction phase of L-TAPP. The operation time and the 75th percentile of the three phases were used as the time limitations, and 1.5 times the 75th percentile was used as the limitation of the dissecting phase in terms of the change in mesh size.

When the time limit was exceeded, the procedure was converted from robotic surgery to a standard laparoscopic approach. After discharging the patient, we created a report describing the patient's summary profile from admission to discharge, including the surgical record, and sent this report to the Medical Safety Management office of AMU to ensure the patient's safety.

## 2.3 | Patients

The inclusion criteria were an age of ≥18 years, the ability to undergo R-TAPP, and a current plan to undergo R-TAPP. The exclusion criteria were an age of <18 years, pregnancy, a body mass index of >35 kg/

m[2], and lack of written informed consent. All patients were followed up by the operative surgeon at our outpatient clinic for 12 weeks postoperatively.

## 2.4 | Surgical technique for R-TAPP

Under general anesthesia, the patient was placed in the Trendelenburg position, and the da Vinci® Xi platform was docked with the patient from the left side (Figure 2). The robotic trocar was usually placed at the level of the umbilicus. In patients with small body size, we placed the trocar cranial to the umbilicus to provide adequate space for intra-abdominal manipulations. The left and right trocars were placed at least 3 cm from the costal arch and anterior superior iliac spine on each side. We used Cadiere forceps with the left hand and Maryland bipolar forceps (Intuitive Surgical Inc.) with the right hand (Figure 3). The Maryland bipolar forceps were connected to a VIO 300D electrosurgical generator (Erbe USA, Inc.) in the forced coagulation mode.[14,15]

The first step in R-TAPP is to reverse the hernia sac into the abdominal cavity. When reversal of the hernia sac into the abdominal cavity is difficult, we progress directly to the next process. The next manipulation is critical to determine the incisional point in the peritoneum. This site is the lateral side of the hernia sac corresponding to the slightly dorsal site of the iliopubic tract (Figure 4). Loose connective tissue is present between the peritoneum and the areolar layer of the extraperitoneal fascia (transversalis fascia).[16,17] The peritoneum is incised around the periphery, leaving the areolar fascia (transversalis fascia), which includes the spermatic cord and vas deferens. In our approach, the umbilical ligament is preserved to avoid the risk of injuring the urinary bladder, and traction on this ligament both inside and outside provides an adequate operative view. The spermatic cord and vas deferens are carefully confirmed and preserved, and an incision is made on the inside of the peritoneum and areolar fascia (transversalis fascia) simultaneously to open the Retzius space. Finally, Cooper's ligament is identified. A ventral peritoneal incision is then made to create a peritoneal flap, and the annular incision in the hernia sac is completed. After mesh placement and fixation for reinforcement, the peritoneum is sutured closed. We use either a self-fixating mesh (Parietex ProGrip™; Medtronic) (Figure 5) or a partially absorbable lightweight mesh (ULTRAPRO®; Ethicon Inc). When we use the ULTRAPRO® mesh, the assistant fixes the mesh with a strap fixation device (SECURESTRAP®; Ethicon Inc) in conjunction with the robot's right arm from the left-side port.

Finally, we close the opened peritoneum with continuous sutures under low pneumoperitoneal pressure to reduce the tension for suturing.

## 2.5 | Statistical analysis

Continuous data are expressed as median (range). The statistical analyses were performed using the chi-square test, the Mann-Whitney U test, or Fisher's exact probability test, as appropriate. All $P$ values are two-sided, and $P < .05$ was considered to indicate a statistically significant difference. All statistical calculations were performed using the IBM SPSS Statistics 21 software package (IBM Japan Inc.).

# 3 | RESULTS

## 3.1 | Patients' characteristics

From December 2018 to January 2020, 198 patients underwent inguinal hernia repair in our department [L-TAPP, 146 (74%);

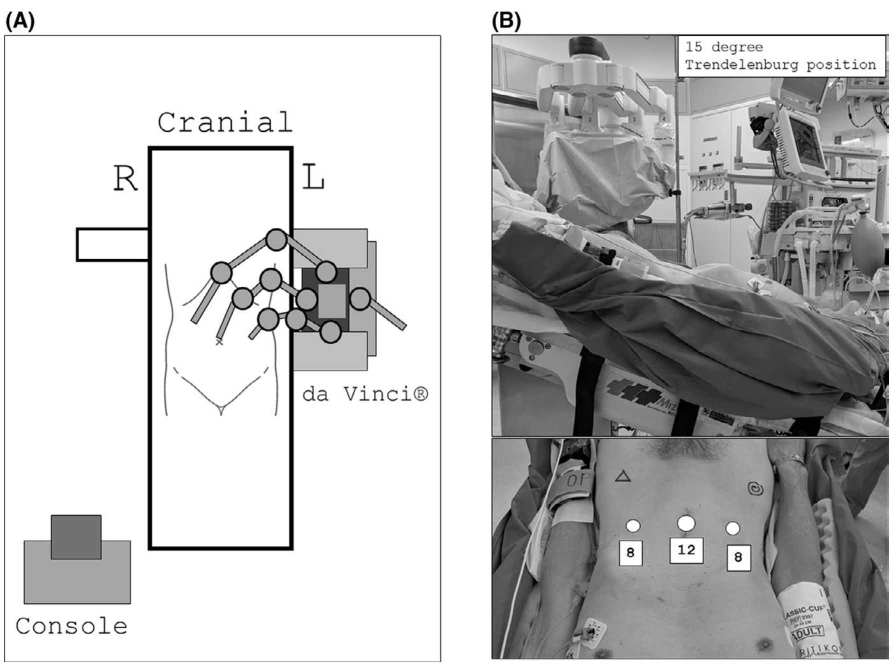


**FIGURE 2** A, Schematic illustration of the arrangement of the operative instruments in the operating room. B, Intraoperative photograph showing the positioning of the patient in the Trendelenburg position and markings of the port sites

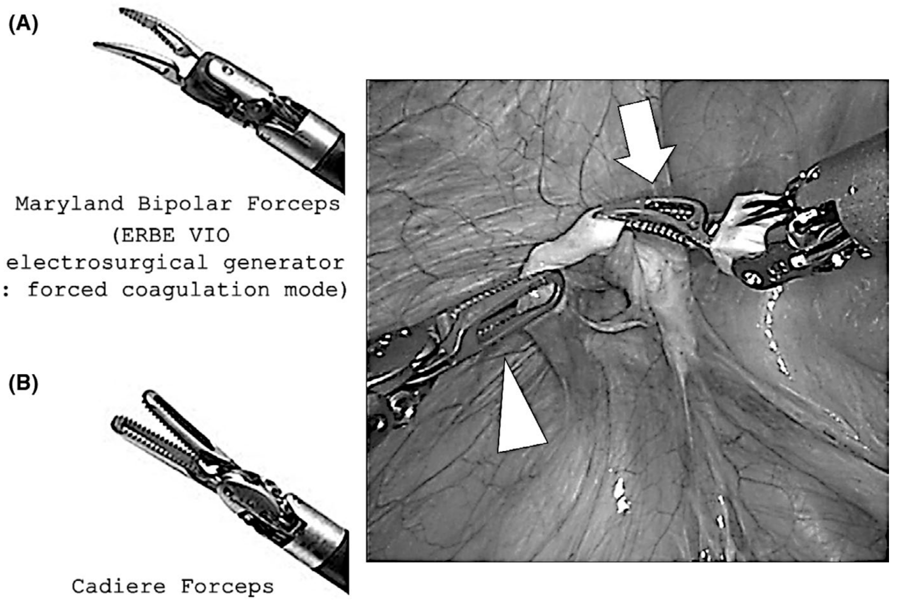


**FIGURE 3** Both hands are used to grasp the hernia sac at the same time. A, The right hand shows the Maryland bipolar forceps (arrow), and (B) the left hand shows the Cadiere forceps (arrowhead)

standard anterior approach, 35 (18%)]. Of these patients, 20/198 (10%) underwent R-TAPP: 19 men and one woman with a median age of 69 years (range, 56-76 years). Eleven patients underwent the operations on the right side, two on the left side, and seven bilaterally. According to the Japan Hernia Society classification, eight patients had unilateral type I hernias, five had unilateral type II hernias, and seven had bilateral hernias (nine type I, four type II, and one type IV) (Table 1).[18,19]

### 3.2 | Perioperative outcomes following L-TAPP

Table 2 shows the patients' perioperative variables. The median operation time was 83 minutes (range, 38-197 minutes). For the unilateral inguinal hernias, the median operation time was 81 minutes (range, 38-137 minutes). For the bilateral inguinal hernias, the median operation time was 145 minutes (range, 99-197 minutes). The median time required for the peritoneal incision was 36 minutes (range, 15-79 minutes), the median time required for mesh placement (including tucking) was 11 minutes (range, 4-25 minutes), and the median time required for peritoneal suturing was 13 minutes (range, 5-40 minutes).

### 3.3 | Perioperative outcomes following R-TAPP

Table 2 shows the patients' perioperative variables. The median operation time was 124 minutes (range, 81-164 minutes), and the median console operation time was 85 minutes (range, 50-132 minutes). For the unilateral inguinal hernias, the median operation time was 111 minutes (range, 81-146 minutes), and the median console operation time was 72 minutes (range, 50-100 minutes). For the bilateral inguinal hernias, the median operation time was 150 minutes (range, 130-164 minutes), and the median console operation time was 125 minutes (range, 110-132 minutes). The median time required for the peritoneal incision was 30 minutes (range, 18-54 minutes), and the median time required for mesh placement (including tucking) was 13 minutes (range, 7-27 minutes). The median time required for peritoneal suturing was significantly shorter in the R-TAPP than L-TAPP group (9 vs 13 minutes, respectively; $P < .001$).

All R-TAPP were completed within the time limit specified in the task protocol (AMU protocol). No patients required conversion to a laparoscopic approach or anterior open approach. All patients underwent R-TAPP using the bipolar forceps dissection. To reinforce the inguinal region, 11 lesions were fixed with ULTRAPRO® mesh plus a SECURESTRAP® and 16 lesions were treated with the Parietex ProGrip™ mesh. In the latter half, we used Parietex ProGrip™, which is tackerless from the viewpoint of dependence on tacking assistance and the risk of postoperative pain. Peritoneal closure was accomplished with 4-0 PDS monofilament suture (Ethicon Inc.) with sequential running sutures. No patients experienced postoperative complications or chronic pain according to the Clavien–Dindo classification.[20]

## 4 | DISCUSSION

The prime concern in introducing R-TAPP as a new approach and strategy based on L-TAPP techniques must be ensuring patient safety. We carefully created three essential tenets to address this concern and designed a task protocol that included time limitations and changes to the approach during the procedure if such changes were necessary. We then obtained approval of our task protocol from the AMU Ethics Committee and Medical Safety Management Office as a highly advanced and difficult new medical technology. Finally, we selected one main operating surgeon familiar with both L-TAPP and robotic gastrectomy during the introduction phase of R-TAPP in our department.

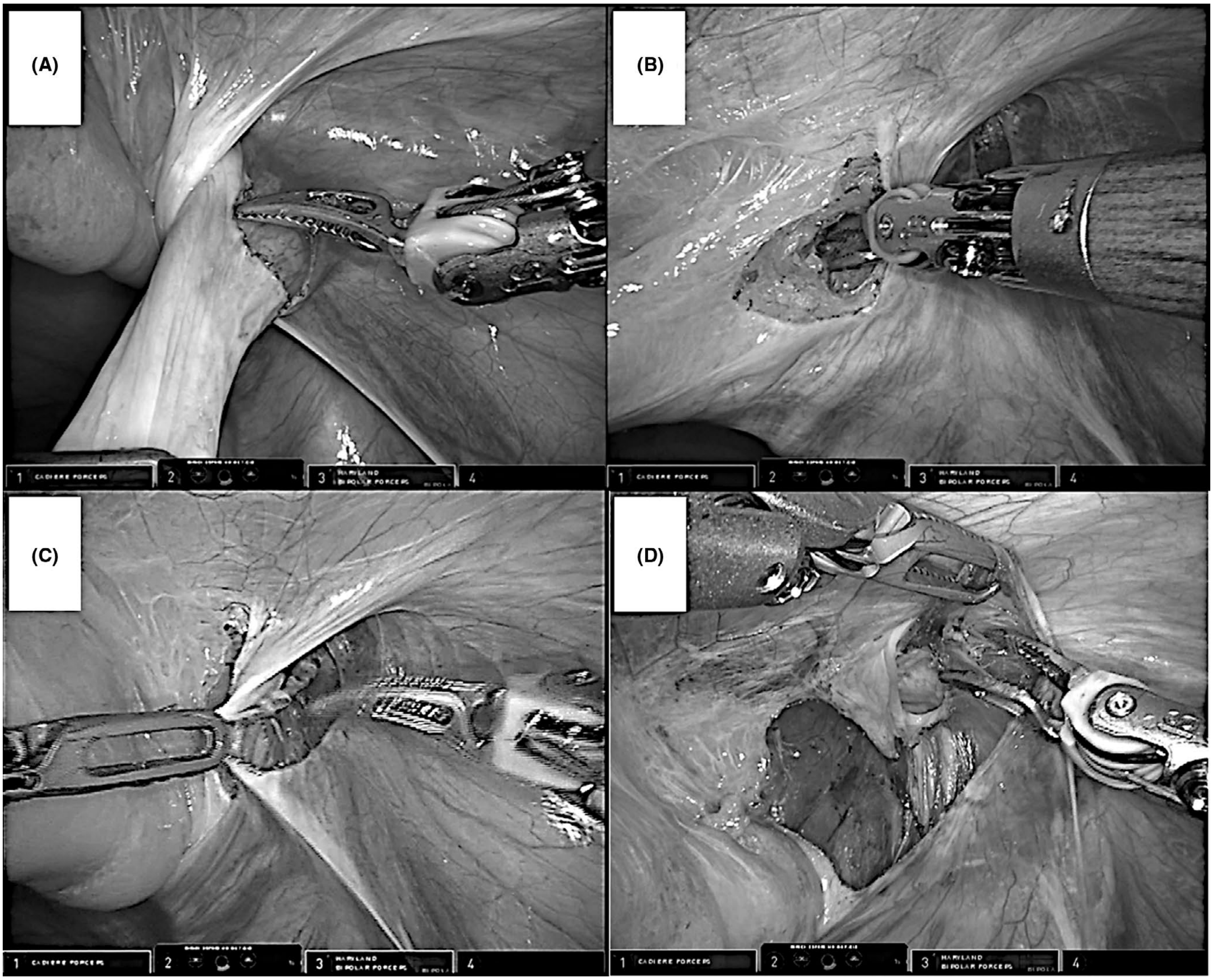


**FIGURE 4** A, The peritoneum is inverted in the abdominal cavity, and (B) the hernia sac is dissected circularly. Careful attention is needed to avoid injury to the (C) inferior epigastric vessels and (D) spermatic cord, including the testicular vessels

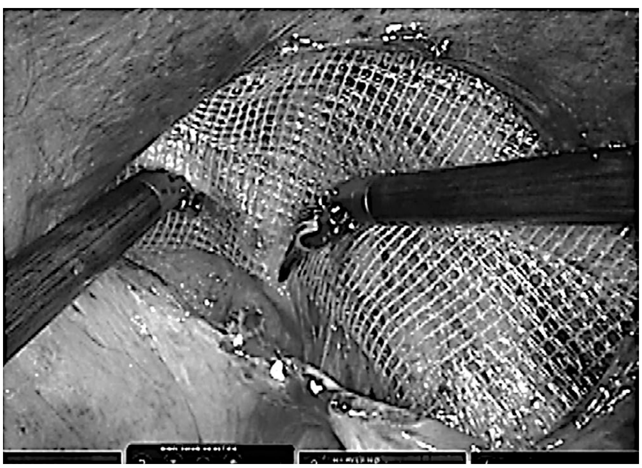

**FIGURE 5** Creation of the peritoneal flap is completed, and the Parietex ProGrip™ self-fixating mesh (Medtronic) is placed and fixed using a Maryland forceps.

It is important to note that patients must pay the costs of R-TAPP in Japan, and the costs are high. This is a heavy burden for many patients with inguinal hernia and makes patient recruitment for R-TAPP difficult.

Regarding the design of our task protocol for R-TAPP, we divided the surgical process into three phases (opening, dissecting, and suturing) according to our experience performing 388 L-TAPP procedures during the most recent 4 years. Inexperience with robotic surgery carries the risk of prolonging the surgical time. Our task protocol defined 30-minute limits for each surgical phase, which was estimated according to the median surgical time (106 minutes; range, 81-165 minutes) in the 20 patients in the initial stage of introducing L-TAPP in our department. Compliance with the task protocol ensures patient safety. When changing to R-TAPP procedures, operator skill and in-depth knowledge of the anatomical variations in hernia operations are mandatory. Our selected surgeon had experience performing 388 L-TAPP procedures as an operator and/

**TABLE 1** Patient characteristics

| | Laparoscopic (n = 146) | Robotic (n = 20) | *P* |
|---|---|---|---|
| Age (year) | 70 (24-94) | 69 (56-76) | .827 |
| Sex (male/female) | 137/9 | 19/1 | 1.000 |
| Bilateral inguinal hernia | 12 (8%) | 7 (35%) | .003 |
| Unilateral inguinal hernia | 134 (92%) | 13 (65%) | |
| Left side | 56 (42%) | 2 (15%) | .001 |
| Right side | 78 (58%) | 11 (85%) | |
| Hernia type | | | |
| Direct | 39 (27%) | 5 (25%) | .018 |
| Indirect | 90 (62%) | 8 (40%) | |
| Both or Others | 17 (12%) | 7 (35%)[a] | |

*Note:* Expressed as N (%) or median (range).
[a]Direct type/ Indirect type/ Other type: 4 hernias/ 9 hernias/ 1 hernia.

**TABLE 2** Surgical outcome

| | Laparoscopic (n = 146) | Robotic (n = 20) | *P* |
|---|---|---|---|
| Operation time (min) | 83 (38-197) | 124 (81-164) | <.001 |
| Unilateral | 81 (38-137) | 111 (81-146) | <.001 |
| Bilateral | 145 (99-197) | 150 (130-164) | .902 |
| Console time (min) | — | 85 (50-132) | — |
| Unilateral | — | 72 (50-100) | — |
| Bilateral | — | 125 (110-132) | — |
| Phase (min) | | | |
| Opening (min) | 36 (15-79) | 30 (18-54) | .111 |
| Dissecting (min) | 11 (4-25) | 13 (7-27) | .010 |
| Suturing (min) | 13 (5-40) | 9 (3-20) | <.001 |
| Complications | | | |
| Serous fluid collection[a] | 10 (7%) | 0 | .611 |
| SSI[a] | 1 (1%) | 0 | 1.000 |
| Recurrence | 0 | 0 | — |

*Note:* Expressed as N (%) or median (range).
[a]Clavien Dindo grade I.

or supervisor during the 4 years prior to introducing R-TAPP in our department.

In Japan, a proctor system for robot-assisted surgery has been introduced for prostatic, gastric, and rectal cancers[21]; however, there is currently no proctor for R-TAPP. Several risks may be associated with the performance of R-TAPP by a laparoscopic surgeon in the absence of a proctor, even if the surgeon is familiar with L-TAPP. The learning curve for robot-assisted gastrectomy is reported to be approximately 20 cases.[22] We carefully considered that the surgeon performing R-TAPP required experience performing 20 cases of robot-assisted surgery. Our selected surgeon had performed more than 20 robotic gastrectomies and was considered an appropriate operator who was qualified to perform R-TAPP.

We incorporated the double-bipolar method performed in robotic gastrectomy into R-TAPP.[14,15] Robotic surgery has the advantage of easy-to-fine operative manipulation, eliminating fine hand tremors and small restrictions related to polyarticulated equipment. During hernia operations, the peritoneal incision, mesh placement, and peritoneal suturing must be performed with the goal of minimizing postoperative recurrence or complications. Placing a self-fixating mesh is not indicated in L-TAPP because of the technical difficulties. However, this procedure is smooth and can be performed without tacking in R-TAPP, avoiding the potential risk of postoperative pain. Suturing is also easy to perform, as described by Chandra et al.[23] The bipolar forceps dissection method has merit, especially regarding the peritoneal incision. Creating the peritoneal flap is of prime importance to minimize the recurrence of inguinal hernias. Appropriate mesh placement depends largely on the size of the peritoneal flap; however, our method may allow for easier and more reliable creation of an appropriately sized peritoneal flap without injury while preserving the dissection layer.

Additionally, no report has precisely described the procedure for robotic surgery with a focus on separating the hernia sac. We performed the bipolar forceps dissection method using Maryland bipolar forceps as previously reported for robotic gastric cancer surgery.[14,15] This method is reportedly appropriate for precise dissection and is considered to be at least as effective as that performed with other energy devices.[15,24] R-TAPP repair using this technology may be superior for maintaining the dissection layer and facilitates easy dissection of the hernia sac and creation of a peritoneal flap. We consider that the most clinically significant benefit of R-TAPP for inguinal hernia repair is the ability to easily perform effective, accurate procedures using the multiarticular function during mesh placement and peritoneal suturing. This will contribute to the prevention of complications and hernia recurrence. R-TAPP includes fundamental surgical manipulations; therefore, it is suitable as an initial step for complex robotic surgery under the guidance of a skilled supervisor.

In conclusion, we safely introduced R-TAPP in our institution, and this safe introduction was related largely to our task protocol. The AMU protocol will be revised in the future according to our preliminary results. Our management strategy in introducing R-TAPP will play a significant role in the evolution of this procedure in Japanese hospitals after approval by the Japanese public health insurance system and in R-TAPP-naïve countries outside the US.

## ACKNOWLEDGEMENT

We thank Jane Charbonneau, DVM and Angela Morben, DVM, ELS, from Edanz Group (www.edanzediting.com/ac) for editing a draft of this manuscript.

## DISCLOSURE

Conflict of Interest: The authors declare no conflicts of interest for this article.

Ethical Approval: The protocol for this research project was approved by the Ethics Committee of our institution and conforms to the provisions of the Declaration of Helsinki. The AMU Ethics Committee and Medical Safety Management Office approved this study (Approval No. 2019-086). Informed consent was obtained from all participants in this study.

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**How to cite this article:** Saito T, Fukami Y, Uchino T, et al. Preliminary results of robotic inguinal hernia repair following its introduction in a single-center trial. *Ann Gastroenterol Surg*. 2020;4:441–447. https://doi.org/10.1002/ags3.12341