A Prospective, Single-Arm, Single-Center, Case Series to Determine the Feasibility of Safe Skill Transfer for Transabdominal Preperitoneal (TAPP) Repair Utilizing a Hands-On Mentorship Model

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Objectives: It is difficult to introduce laparoscopic surgery in institutions with a small number of patients, and surgical training relies heavily on mentors to produce well-trained surgeons. The aim of this study was to determine whether implementation of a hands-on mentorship model could provide safe skill transfer for transabdominal preperitoneal (TAPP) repair.

Methods: A trainee who had no experience with TAPP repair underwent operative tutorials until the mentor judged that the trainee could carry out the operation independently. Ten patients who underwent an elective TAPP repair were prospectively enrolled in this study.

Results: No cases had over 5 mL of bleeding, intraoperative/postoperative complications, or recurrence. There were significant differences in operation times between the first 4 cases and the later 5 cases, except for a bilateral inguinal hernia case.

Conclusion: A prospective, single-arm, single-center, case series showed the feasibility of safe skill transfer for TAPP repair using a hands-on mentorship model.

Key words: Inguinal hernia, Mentorship, Transabdominal preperitoneal (TAPP) repair

INTRODUCTION

Laparoscopic surgery, including cholecystectomy and many other operations, is thought to be a less invasive procedure that has become prevalent in Japan since the 1990s [1, 2]. After the operative procedures and associated medical devices were developed, many clinical studies provided evidence that laparoscopic surgery is a useful procedure [3]. As a result, the indications for laparoscopic surgery increased to include various diseases, and a fixed operative procedure has been developed. On the other hand, inguinal hernia repair is one of the most common surgical procedures performed worldwide [4]. The standard method for inguinal hernia repair has changed dramatically [5]. Recently, the procedure of laparoscopic hernia repair has been adopted for patients with inguinal hernia [6, 7]. Furthermore, many patients have begun to request the procedure, because of some advantages, including less postoperative pain, a shorter recovery period, earlier return to daily activities and work, and better cosmetic results [8, 9]. When we began to introduce this procedure, the educational system and technology transfer of laparoscopic surgery were discussed avidly, and a few reports concerning this area were published. Some researchers reported that using the Objective Structured Assessment of Technical Skills (OSATS) to

assess the surgical skills of trainees in the operating room was feasible and effective [10]. Because the numbers of inguinal hernia patients differed among institutions, it became clear that the introduction of laparoscopic surgery is difficult in institutions with a small number of patients. Surgical training relies heavily on mentors to produce well-trained surgeons [11]. As we introduced the technique of laparoscopic inguinal hernia repair (LIHR) to our institute, we tried to determine whether implementation of a handson mentorship model could provide safe skill transfer of the techniques required. In addition, mentorship involves operative tutorials by especially experienced surgeons. In this study, the usefulness of mentorship for skill transfer was prospectively investigated.

PATIENTS AND METHODS

A surgeon with 10 years of postgraduate experience was selected as the trainee. He had performed laparoscopic gastrointestinal and colorectal surgery, as well as open inguinal hernia repair, but had neither seen nor performed LIHR. As an expert in LIHR, a mentor who had 10 years of experience as a surgeon, especially transabdominal preperitoneal (TAPP) repair, was selected.

In our institute, the trainee underwent operative tutorials until the mentor judged that the trainee could

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carry out TAPP repair independently. Specifically, the trainee was involved in 10 TAPP repairs, observing the first 5 cases and carefully performing the remaining 5 cases under the mentor's supervision, taking between 90 minutes and 120 minutes for the procedures. The number of cases to reach the plateau of the learning curve was reported to be 10-50 for LIHR [12, 13], 10 cases which was the smallest number of patients were selected either during or after tutorial. The proportion of the first cases under observation and the remaining cases under performance during this tutorial was decided on the basis of the mentor's experiences in accordance with the trainee's ability. After this tutorial, a total 10 of patients who underwent an elective LIHR in the Department of Tokai University Hachioji Hospital since January through April in 2014 were prospectively enrolled independent of the mentor in this study. Namely, 5 cases were done as demonstrations by the mentor, 5 cases were done by the trainee under the mentor's supervision, and 10 cases were later done by the trainee alone.

At the time of study enrollment, the patients were required to fulfill the following criteria: age ≥ 20 years; written, informed consent; clinically diagnosed unilateral or bilateral inguinal hernia; and operation under general anesthesia was considered possible by the anesthetist. Because a case of bilateral inguinal hernia was accurately diagnosed through the laparoscopic field of view at the time of initial examination, the bilateral inguinal hernia was included. Exclusion criteria were BMI >30 kg/m², previous lower abdominal surgery, recurrent inguinal hernia, or the doctor in charge judged the patient inappropriate for this study.

The feasibility of mentorship was evaluated by the following items: operation time, bleeding, operative procedure, spermatic cord injury, and vascular injury during operation, and complications, length of hospitalization, recurrence, reoperation, and readmission between the day of surgery and the 30th postoperative day. Because the most important aspect of efficacy was thought to be the safe transfer of skills, absence of adverse events was considered particularly important. Namely, the occurrence, reoperation, and readmission was considered evidence of failure of safe transfer of skills. Other items were evaluated for reference purposes.

Statistical analysis was performed using the unpaired Student's *t*-test. P < 0.05 was interpreted as being significant. Values for all continuous variables are expressed as means \pm standard deviation (SD).

This study was sponsored by Covidien Japan, and a contract was made involving Covidien Japan, Tokai University, and Kazunori Uchida, MD. This study protocol was approved by the Human Ethics Review Committee of Tokai University School of Medicine. Written, informed consent was obtained from each enrolled patient before study entry in accordance with the Declaration of Helsinki.

Surgical procedure

Under general anesthesia in the supine position, a transumbilical skin incision was made to enter the peritoneal cavity, and a 12-mm port was inserted. The pre-peritoneal space was expanded with carbon dioxide (CO_2) gas, and a flexible camera was inserted through the 12-mm port. Then, a 5-mm port was inserted into the left flank region, and a 12-mm port was inserted into the right flank region of the abdomen. The intra-abdominal pressure was maintained at 10 mmHg. The peritoneum was incised over the hernia and extended laterally using an ultrasonically activated device (USAD). The hernia sac was reduced meticulously, carefully preserving the epigastric vessels and vas deferens using a combination of squareshaped gauze and the USAD. Cooper's ligament next to the pubic tubercle was then clearly defined. Once the dissection was complete, a 15 cm x 11 cm polypropylene mesh (ParietexTM Anatomical Mesh, Covidien, Mansfield, MA, USA) was inserted into the abdominal cavity. The mesh was fixed medially over Cooper's ligament next to the pubic tubercle and superiorly to the abdominal wall using AbsorbaTackTM (Covidien). The peritoneum was closed over the mesh by hand sewing. The pneumoperitoneum was then released under vision to ensure that the repair remained firm. The fascial and skin incisions were closed.

RESULTS

The perioperative data are summarized in Table. Operation times are listed in Figure (case A to case J). Case F, an 83-year-old male, had an incarcerated left inguinal hernia and had been on oral anticoagulant therapy for a deep venous thrombus for 1 month prior to the procedure. He was given a short-acting anticoagulant intravenously for 7 days before the operation. Thus, his hospital stay was 12 days, and the operation time was relatively long because of adhesions after incarceration. Most of the elderly patients had many complications, and the presence of intra-abdominal adhesions was accurately diagnosed through the laparoscopic field of view at the time of the initial examination. Therefore, this case was included in this study. There were no cases with more than 5 mL of bleeding, intraoperative/postoperative complications, or recurrence after 30 postoperative days. The mean operation time was 94.8 ± 18.9 minutes. There was a significant difference in the operation times between the first 4 cases and the last 5 cases, except for the bilateral inguinal hernia case (J) (109.8 \pm 6.6 minutes vs. 82.8 \pm 16.6 minutes, P = 0.019). Although the mentor's operation time during which the trainee only observed (the first 5 cases) was not included in the examination items in this study, it was 60.0 ± 6.1 minutes and there was a significant difference between the mentor's and the trainee's operation times for the last 5 cases (60.0 ± 6.1 vs. 82.8 ± 16.6 , P = 0.034). When the mean operation time of the trainee's last 4 cases, excluding case F who had adhesions after incarceration, was compared with that of the mentor, there was no significant difference $(77.5 \pm 13.4 \text{ vs. } 60.0 \pm 6.1, P = 0.073).$

DISCUSSION

Laparoscopic surgery has been gaining increasing popularity worldwide. Inguinal hernia surgery is one of the most common surgical procedures performed worldwide, and the standard method for inguinal hernia repair has changed with the introduction of synthetic mesh and laparoscopic technique [4, 5].

Item elevated	Data (n = 10)
Affected side (right/left/both)	6/3/1
Age (years)	$68.3 \pm 14.2 \ (43-83)$
Patient height (cm)	163.8 ± 4.5
Patient weight (kg)	59.7 ± 8.4
Performance status (0/1)	4/6
Type of hernia (external/internal)	4/7
Operation time (minutes)	$94.8 \pm 18.9 \ (60\mathchar`-137)$
Amount of bleeding (>5ml)	0
Intraoperative complications (%)	0
Hospital Stay (days)	$5.9 \pm 2.3 \ (4-12)$
Postoperative complications (%)	0
Recurrence (%)	0

Table Summary of perioperative data

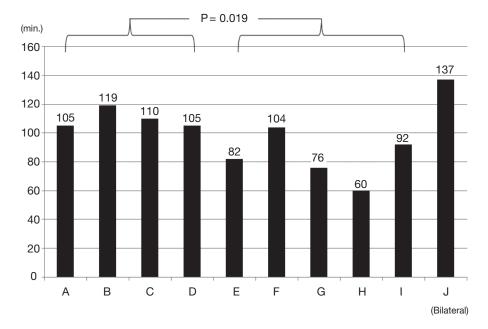


Figure Changes in operation times There are significant differences in the operation times between the first 4 cases and the last 5 cases, except for the case of bilateral inguinal hernia (J).

Compared with open repairs, LIHR has some advantages, including less postoperative pain, a shorter recovery period, earlier return to daily activities and work, and better cosmetic results [8, 9]. On the other hand, in the beginning of the 1990s, laparoscopic hernia repair was controversial because various studies reported early recurrence rates and various medical misadventures [7]. For the performance of safe laparoscopic surgery, various efforts have been made in the field of surgical education and instruction. Nevertheless, even though training with a simulator and/or in a dry laboratory has been done, many cases of actual operative experience are needed to learn the surgical procedures. Furthermore, in order to estimate the status of learning, times to reach the plateau of the learning curve were studied, and operation time, blood loss, conversion rate, complication rate, and various

rating scales were found to be indicators [14–16]. The number of cases to reach the plateau of the learning curve was reported to be 9–35 for laparoscopic cholecystectomy [14–16] and 10–50 for LIHR [12, 13]. Because the somatotype of the patients easily affects the results, one can only conclude that making an estimate is difficult.

In actual operative situations, the operations are often carried out under the mentor's direct supervision [17]. If the trainee has the abilities to perform fundamental procedures and the mentor's advice is appropriate, the trainee himself could perform the operation following the mentor's advice without developing an understanding of the anatomy and achieving adequate comprehension and judgment for accurate operative procedures. Because there may be discrepancies between the mentor's appreciation of the trainee's comprehension and the trainee's actual understanding, these discrepancies are important. It is important that the mentor understand the trainee's attainment level as it provides a good opportunity for the mentor to devise the contents and methods of his approach to advising the trainee. This concept is called mentorship, and it means continuous guidance or counseling for the trainee (protégé) by the mentor [18]. Mentorship is thought to be a concept that provides the trainee with an opportunity for quick and effective learning of knowledge and skills, and it provides the mentor with the chance to reconfirm his own knowledge and skills, as well as the possibility of discovering a new perspective and new ways of thinking. In recent years, mentorship has been studied in various fields. This study was carried out to clarify the possibility of the safe introduction of LIHR. At least 10 patients had to be enrolled to undergo LIHR based on the numbers needed to master the technique [12].

In the present study, the following points were considered crucial: 1) careful preservation of the epigastric vessels and vas deferens using a combination of dissection by the square-shaped gauze and the USAD; 2) clarifying the confluence portion between the inguinal ligament and Cooper's ligament; 3) paying attention to the corona mortis as important knowledge; 4) fixation of the mesh medially over the pubic tubercle next to Cooper's ligament and superiorly to the abdominal wall using ProTackTM (CovidienTM); and 5) a sufficient field of view provided by adequate direction and traction as a meaningful skill. In this way, the trainee was thought to be able to reach a technical level close to that of the mentor.

Because the numbers of inguinal hernia patients differ among institutions, it became clear that the introduction of laparoscopic surgery is difficult in institutions with a small number of patients. With handson mentorship, the possibility of more effective and safer skill transfer appears possible. Although only 10 cases were included in the present study, the operation times decreased significantly, and the learning curve might be observed if time were one of the indicators. However, the relationship between the mentorship and the learning curve was not sufficiently evaluated. Apart from the investigated items, there were no significant differences between the operation time for the 5 cases done by the mentor and that for the last 4 cases, excluding case F, done by the trainee. Although this was an investigation of a small number of cases and the first operation by the mentor was performed without haste to maximize its educational value, the acquisition of sufficient understanding by the trainee through the mentorship might have significantly decreased the operation time. A mentor with higher skills in the specific field is more likely to effectively and safely transfer skills promptly.

In conclusion, a prospective, single-arm, single-center, case series showed the feasibility of safe skill transfer for TAPP repair using a hands-on mentorship model. Training for other kinds of operations should be similarly examined in order to determine the efficacy of mentorship.

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