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Randomized controlled trial of EndoWrist-enabled robotic versus human laparoendoscopic single-site access surgery (LESS) in the porcine model

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Abstract

Introduction A robotic laparoendoscopic single-site access surgery (R-LESS) platform that incorporates the EndoWrist function of robotic instruments may provide better triangulation and retraction during LESS. The aim of the study is to assess if R-LESS is feasible with standard robotic instruments via a single incision and whether the approach could reduce the difficulty of the procedure and confer additional benefits over conventional LESS.

Methods This was a prospective randomized controlled study investigating the workload performance, efficacy, and risks of performing R-LESS when compared with human LESS (H-LESS) in a survival porcine model for cholecystectomy and gastrojejunostomy. The primary outcome is the NASA task load index. Secondary outcomes included the difficulty of the procedures, procedural time, morbidities, and mortalities.

Results Twenty-four cholecystectomies and gastrojejunostomies using the R-LESS or H-LESS approach (12:12) were performed. None of the swine suffered from procedural adverse events and none of the procedures required conversion. In both the cholecystectomy and gastrojejunostomy groups, R-LESS was associated with significantly lower NASA task load index ($P < 0.001$) and reduced difficulties in various steps of the procedures. No differences in the overall procedure times of the two procedures were observed ($P = 0.315$).

Conclusion The R-LESS approach significantly reduced the workload and difficulties of LESS cholecystectomies and gastrojejunostomies. A dedicated single-site platform that could reduce instrument clashing while retaining the EndoWrist function is eagerly awaited.

Keywords Laparoendoscopic single-site access surgery · Single-port surgery · Robotic surgical procedures · Cholecystectomy · Gastrojejunostomy

Minimally invasive surgery is now the gold standard approach for performing many abdominal operations worldwide [1, 2]. With the ongoing pursuit to reduce surgical trauma and minimize wounds, the feasibility of performing laparoendoscopic single-site access surgery (LESS) for a variety of surgical procedures was investigated [3–6]. LESS offers the potential of improving cosmesis, decreasing wound pain, and shortening postoperative recovery. Randomized studies have demonstrated lower pain scores and better cosmesis in LESS cholecystectomy as compared to conventional laparoscopic cholecystectomy [7, 8].

However, there are a number of limitations to the LESS approach. Firstly, LESS complicates surgery by limiting the movements and dexterity of the instruments since multiple laparoscopic instruments are inserted through a single transumbilical wound. Furthermore, the loss of retraction and triangulation renders a seemingly simple operation more intricate. Articulating or curved instruments are often used to reduce instrument collision increasing the technical difficulties of the procedures [9]. This may lead to a longer operative time and also create a window of danger for developing major complications.

Recently, the robotic platform for performing LESS has become available [10–12]. The system allows insertion of a multichannel port and curved robotic instruments through a

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single 3.5-cm transumbilical incision. However, the EndoWrist function that provides 7° of freedom is not available in this system and the platform still suffers from the constraints of the LESS approach on triangulation and retraction. A robotic LESS platform that incorporates the EndoWrist function of robotic instruments may, on the other hand, provide better triangulation and retraction during LESS procedures. Furthermore, it may also reduce the difficulty of performing LESS procedures and improve the operative outcomes.

Hence, the aim of the current study is to assess if robotic LESS (R-LESS) could be performed with standard robotic instruments with EndoWrist functions via a single incision and whether such an approach could reduce the difficulties of the procedures and confer additional benefits over conventional human LESS (H-LESS). We hypothesize that R-LESS could reduce the workload for the surgeon as compared to H-LESS.

Methods

This was a prospective randomized controlled study investigating the workload performance, efficacy, and risks of performing R-LESS when compared with H-LESS in a survival porcine model for 2 benchmark procedures: cholecystectomy and gastrojejunostomy. The study protocol was approved by the animal experiment ethics committee of The Chinese University of Hong Kong.

Study interventions

All the procedures were performed in the animal laboratory of the Prince of Wales Hospital, The Chinese University of Hong Kong. Two designated surgeons with experience of more than 100 LESS laparoscopic and robotic surgeries performed all the procedures. Two procedures (cholecystectomy and gastrojejunostomy) were used to evaluate the differences between the R-LESS and H-LESS approaches. The choice of the approach was randomized to either R-LESS or H-LESS approach. Randomization was done immediately before the procedures by opening sealed envelopes containing a sequence of computer-generated numbers in blocks of ten.

Preparation of animals

Domestic farm swine (sus domestica) weighing between 25 and 30 kg were used (12 per each group). The swine were sedated with 15 mg/kg ketamine, 1 mg/kg xylazine, and 0.05 mg/kg atropine. Intravenous thiopental 10 mg/kg was then administered and the animals were intubated with a 7-mm endotracheal tube in the supine position. Anesthesia was maintained with 2% isoflurane with equal parts of oxygen and nitrous oxide at a flow rate of 5L/min within a closed circuit. All procedures were performed with the swine in supine position.

LESS access and instruments

LESS access was obtained with a single skin incision and multiple fascial punctures by trocars through the same incision in both H-LESS and R-LESS procedures. Under direct visualization, a 2-cm incision was performed 2 cm cranial to the umbilicus. In R-LESS procedures, one 12-mm port and two 5-mm ports were inserted through this incision. The robotic platform is originally intended for multi-port laparoscopic surgery and not labeled for use with single-site access surgery. The robotic cart (DaVinci-Si surgical system, Intuitive Surgical, CA, USA) was docked from the head of the swine. The procedures were performed with a 30°-angulated 12-mm laparoscope. Two 5-mm robotic instruments were used. The surgeon's control of the robotic arms was inverted when using the console, so that the left hand controlled the right-sided instrument and vice versa (Fig. 1A, B). This was required as the instruments were crossed inside the abdomen and the arrangement allowed handling of the crossed instruments by the ipsilateral hand.

For H-LESS procedures, one 10-mm and two 5-mm ports were inserted through this incision. Dissection was performed using a 10-mm 30-° laparoscope (Endoeye, Olympus Medical Ltd, Tokyo, Japan) and straight 5-mm laparoscopic instruments.

Cholecystectomy

Cholecystectomy was performed in a manner similar to traditional four-port laparoscopic cholecystectomy [2]. The gallbladder was retracted at the fundus by a 2-*O* prolene suture introduced percutaneously (Fig. 2A). With the gallbladder retracted upwards and laterally, critical view of the Calot's triangle was obtained. The cystic artery and duct were exposed, controlled, and divided between metal clips. The gallbladder was then dissected off the liver using diathermy (Fig. 2B) and the specimen retrieved through the incision.

Gastrojejunostomy

The gastrojejunostomy was performed over the anterior surface of the greater curvature at the body of the stomach. A loop of proximal jejunum adjacent to the stomach was selected for anastomosis and anchored to the stomach with 3-*O* vicryl sutures. An enterotomy was made on each organ to allow for introduction of a 60-mm laparoscopic linear stapler cutter (EndoGIA, Covidien Co Ltd, USA) (Fig. 2C). An additional 13-mm port was inserted at the

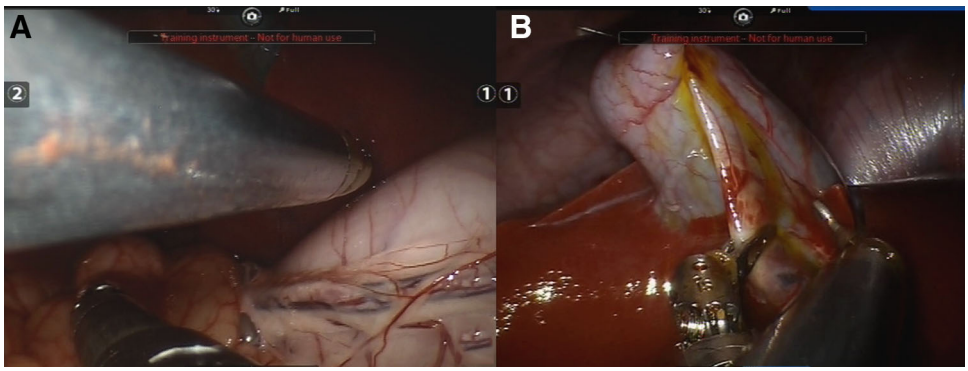

Fig. 1 **A** Crossing the instruments inside the abdomen. **B** Inversion of the control of the instruments when using the console, so that the *left hand* controlled the *right-sided* instrument and vice versa

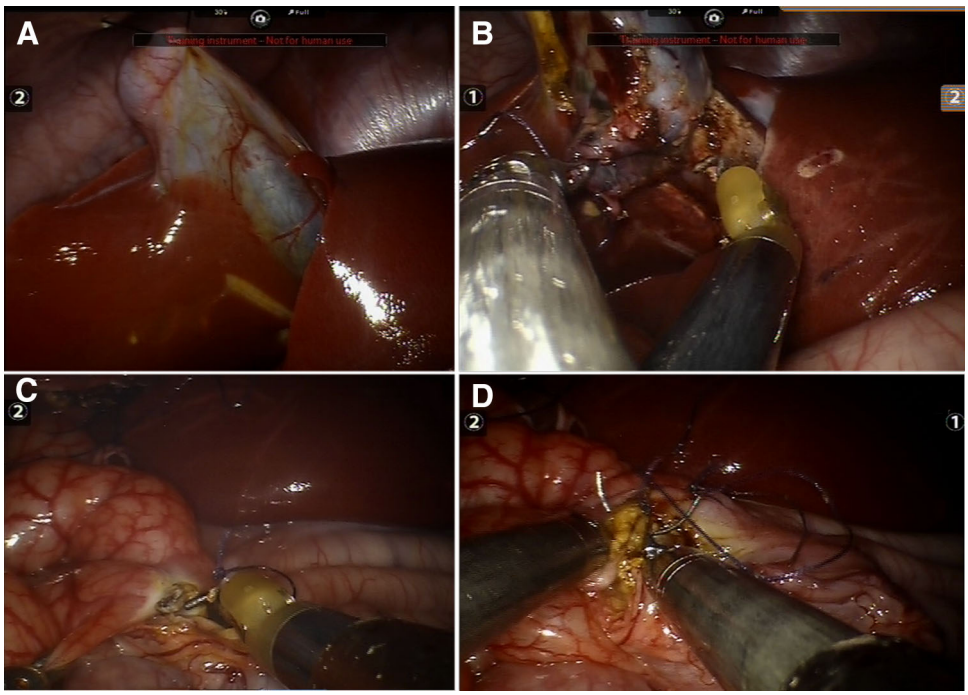

Fig. 2 **A** Retraction of the gallbladder by a 2-*O* prolene suture introduced percutaneously. **B** Dissection of the gallbladder from the liver bed. **C** Opening of the enterotomy on the jejunum. **D** Closure of the enterotomy after laparoscopic stapling

right upper quadrant for insertion of the laparoscopic stapler. After completion of the stapling, the enterotomy was then closed with interrupted 3-*O* vicryl sutures (Fig. 2D).

Indications of conversion

The procedures were converted if the safety of the procedure was compromised or if the LESS approach hindered adequate movements of the arms. When conversion is required, additional ports were first inserted to aid dissection. If this was still inadequate, conversion to open surgery was performed.

Post-procedural management

Diets were resumed the next day after the procedure. The swine were observed for signs of adverse events including poor oral intake, decreased mobility, and signs of sepsis in the week after the procedure.

Follow-up assessment

The swine were scheduled for a gastroscopy 2 weeks after the procedure for assessment of the patency of the gastrojejunostomy (Fig. 3). The procedure was performed under general anesthesia; the endoscope was inserted into the stomach, the afferent and efferent limbs of the gastrojejunostomy. Contrast was also injected to confirm patency of the lumens. After the procedure, the swine were then sacrificed. A post-mortem examination was performed to inspect for evidence of adverse events and healing of the gastrojejunostomy.

Outcome measurements

The primary outcome was the workload score measured by the NASA task load index. It is a tool that rates perceived workload in order to assess a task, system, or team's effectiveness or other aspects of performance. It was

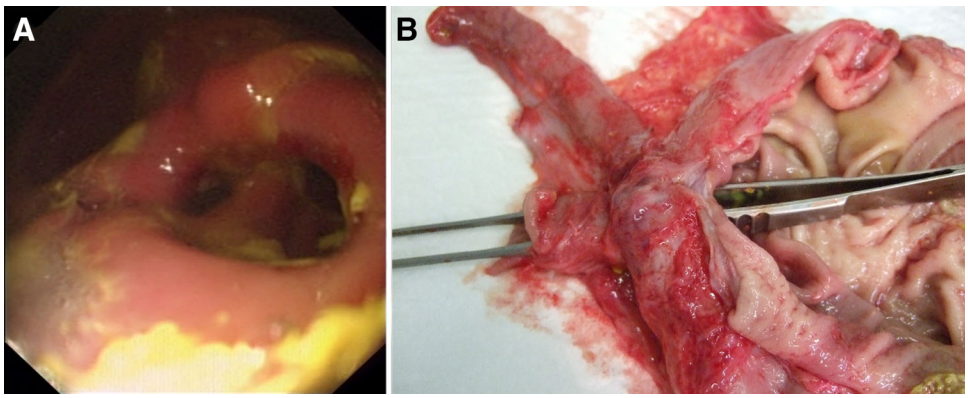

Fig. 3 **A** A patent gastrojejunostomy as noted during endoscopy. **B** Post-mortem showing a patent gastrojejunostomy

developed by the Human Performance Group at NASA's Ames Research Center over a three-year development cycle that included more than 40 laboratory simulations [13–16]. The instrument is a validated multidimensional rating procedure that provides an overall workload score based on a weighted average of ratings on six subscales: Mental Demands, Physical Demands, Temporal Demands, Own Performance, Effort, and Frustration. These subscales were rated on a 100-point range within 5-point steps. Descriptions for each measurement of the subscales are shown in Table 1. The ratings were then combined to formulate the task load index. The weighting of the subscales was determined by the subject's responses to pairwise comparisons among the six factors. Ratings of factors deemed most important in creating workload of a task are given more weight in computing the overall workload score. Calculation of the score was performed on smart phone-based application (https://humansystems.arc.nasa.gov/groups/tlx/tlxapp.php). Secondary outcomes include the difficulties of the procedures (measured by visual analogue scale), overall procedure times, time to completion of each step of the procedures, morbidities, and mortalities.

Sample size, statistical analyses, and duration of study

Assuming 50% reduction in the task load index, a power of 80% and a two-tailed P value of 0.05, 12 procedures would be required in each group. Statistical analyses were performed using SPSS 22.0 statistical software (SPSS, Chicago, Illinois, USA). Comparisons are to be made by Chi square test or Fisher exact test for categorical data and Mann–Whitney *U* and Wilcoxon test for continuous data.

Results

Twenty-four swine were operated between June 2013 and April 2014. Twenty-four cholecystectomies and gastrojejunostomies using the R-LESS or H-LESS approach (12:12) were performed. None of the swine suffered from procedural adverse events and none of the procedures required conversion.

In the cholecystectomy group, R-LESS was associated with significantly lower NASA task load index ($P < 0.001$), reduced difficulty in exposing the gallbladder ($P = 0.037$),

Table 1 NASA task load index subscales and descriptions for each measurement of the subscales

Subscales	Descriptions for each measurement
Mental demand	How much mental and perceptual activity was required? Was the task easy or demanding, simple or complex?
Physical demand	How much physical activity was required? Was the task easy or demanding, slack or strenuous?
Temporal demand	How much time pressure did you feel due to the pace at which the tasks or task elements occurred? Was the pace slow or rapid?
Overall performance	How successful were you in performing the task? How satisfied were you with your performance?
Frustration level	How irritated, stressed, and annoyed versus content, relaxed, and complacent did you feel during the task?
Effort	How hard did you have to work (mentally and physically) to accomplish your level of performance?

Table 2 Comparison between R-LESS and H-LESS cholecystectomies

	R-LESS $N = 12$	H-LESS $N = 12$	P value
NASA task load index	23.4 (15.6)	61.7 (19.6)	< 0.001
Exposure of Calot's triangle (VAS)	2.6 (1.4)	3.8 (1.3)	0.037
Dissection of Calot's triangle (VAS)	2.4 (1.3)	4.3 (1.2)	0.003
Ligation of the cystic duct and artery (VAS)	2.1 (0.9)	4.8 (1.8)	<0.001
Removal of the gallbladder from the liver bed (VAS)	2.9 (1.8)	4 (1.2)	0.016
Overall procedure time (seconds)	1345.3 (655.6)	1004.6 (309.4)	0.356
Time to isolation of the cystic duct and artery (seconds)	684.8 (435.0)	347.9 (159.2)	0.017
Time to ligation of the cystic duct and artery (seconds)	336.9 (216.8)	229.8 (208.1)	0.278
Time to removal of the gallbladder (seconds)	323.6 (359.8)	426.9 (291.2)	0.211

Table 3 Comparison between R-LESS and H-LESS gastrojejunostomies

	R-LESS $N = 12$	H-LESS $N = 12$	P value
NASA task load index	55.3 (23.9)	68.7 (15.8)	< 0.001
Difficulty of exposure for gastrojejunostomy (VAS)	2.7 (1.8)	3.4 (1.4)	0.051
Difficulty of anastomosis (VAS)	2.6 (1.0)	4.9 (1.9)	<0.001
Difficulty of closing the enterotomy (VAS)	2.9 (0.7)	6.4 (.16)	0.002
Overall procedural time (seconds)	2791.4 (721.9)	2258.8 (761.7)	0.315
Time required for enterotomy (seconds)	571.9 (214.7)	496.4 (209.4)	0.447
Time required for anastomosis (seconds)	1552.4 (569.3)	1495.1 (765.2)	0.905

dissection of the Calot's triangle ($P = 0.003$), ligation of the cystic artery and duct ($P < 0.001$), and removal of the gallbladder from the liver bed ($P = 0.016$) (Table 2). No difference in the overall procedure time ($P = 0.315$), the time required for ligation of the cystic duct and artery (0.278), and removal of the gallbladder from the liver bed were detected.

On the other hand, R-LESS gastrojejunostomies were also associated with significantly lower NASA task load index ($P < 0.001$), reduced difficulty for performing the anastomosis ($P < 0.001$), and closure of the enterotomy ($P = 0.002$), whereas no significant differences in the overall procedural time ($P = 0.315$), time required for opening the enterotomy ($P = 0.447$), and completion of the anastomosis ($P = 0.905$) were present (Table 3).

Follow-up gastroscopies performed at 2 weeks showed all gastrojejunostomies to be patent with free drainage of contrast (Fig. 3A). None of the swine suffered from anastomotic leakage. Post-mortem reviewed no evidence of adverse events. All explanted gastrojejunostomies were patent (Fig. 3B).

Discussion

In the current study, the R-LESS approach significantly reduced the NASA task load index and the difficulties in performing LESS cholecystectomies and gastrojejunostomies. The overall procedural time and the procedural times of various steps of R-LESS cholecystectomies and gastrojejunostomies, on the other hand, were comparable to those of the H-LESS counterpart. Furthermore, no differences in adverse events and the need for conversions were present.

The use of robotics with the EndoWrist function to perform LESS was first described in 2009 [16]. In this feasibility study, the robotic instruments were crossed at the "abdominal wall" of a trainer box. By switching the left–right control at the console, the reversed handedness of the instruments was corrected. Compared with standard parallel setup, this configuration was shown to decrease procedural times, instrumental collisions, camera manipulations, clutching maneuvers, and errors when performing various tasks. In another study, R-LESS fundoplication was compared with H-LESS fundoplication in porcine model [17]. The R-LESS procedure was also associated with shorter procedure times and less instrument conflicts. These studies demonstrated the feasibility of performing R-LESS in a single incision. However, they do not provide information on whether the approach could reduce the workload or difficulties of the LESS approach and for what types of procedure the approach confers the most benefit. Since then, several small reports had reported the successful use of this technique in humans performing a cholecystectomy with hepatectomy, right hemicolectomies, adrenalectomies, pyeloplasties, and radical and partial nephrectomies [18–21].

Recently, a dedicated the robotic single-site platform (RSSP) has become available [22]. The system incorporates a multichannel single port that accommodates two curved robotic cannulas. These cannulas transmit interchangeable semi-rigid instruments that cross each other within the trocar such that the left entering instrument becomes the right-sided operative instrument and vice versa. The controls of the instruments could then be switched in a manner as described above. These robotic instruments, however, lack the EndoWrist function and behave in a manner similar to conventional laparoscopic instruments.

In an ex vivo study comparing the suturing capabilities of the RSSP versus H-LESS approach in experienced surgeons, the time to completion using RSSP was significantly shorter than that of H-LESS. There were no leaks after closure with the RSSP, while the leak rate following the H-LESS was 90% [23]. In the largest robotic single-site cholecystectomy (RSSC) series, 97.8% of the 465 cholecystectomies were successful [24]. None of the procedures required conversion and the complication rate was 2.6%. The operative time showed a decreasing trend after 55–85 cases. Other series also reported feasibility of the RSSP for adrenalectomies and inguinal hernia repair [25, 26].

When compared to RSSC, H-LESS cholecystectomies were associated with significantly longer operative times (83.2 vs. 62.7 min, $P < 0.001$) [27], while no significant differences in the hospital stay and morbidities were present. Interestingly, in another study, RSSC was reported to be associated with lower costs as compared to H-LESS cholecystectomies [28]. This was driven by operating room, supplies, and anesthesiology costs. Whether the results of this study could be reproduced in other centers is doubtful.

The current study has a number of strengths and limitations. Firstly, the current study involved 2 experienced surgeons in both robotic and LESS procedures performing 2 procedures in a randomized setting. Hence, it provided an accurate representation on how R-LESS compared to H-LESS in 2 procedures of different complexities for the experienced surgeon. Furthermore, in order to measure how the approach affected the workload of the surgeon, the NASA task load index was introduced as an outcome measurement. This is a validated and highly reproducible tool that is frequently employed to measure workload in various aspects of medical care. The R-LESS approach was shown to significantly improve the ergonomics and reduce the difficulty of both procedures. This may potentially reduce the chances of intraoperative adverse events.

On the other hand, while the NASA task load index and difficulty scores of the 2 procedures were all reduced by the R-LESS approach, this did not result in a universal reduction in procedural times. This may be due to the fact that significant instrument clashing still occurs with the R-LESS approach, thus limiting the free movements of the robotic arms. In addition, this also reflects that for surgeons who are experienced with the H-LESS approach, the R-LESS approach may not reduce the operative time. Furthermore, whether results in this porcine study could be translated to humans is uncertain.

In the future, the development of new R-LESS systems incorporating the EndoWrist function is likely to impact future surgical procedures in several ways [28]. Firstly, conventional laparoscopic procedures could be performed with R-LESS approach without significantly increasing the difficulty and operative time of the procedures. Furthermore, new systems are becoming smaller and more mobile, making the use of robotic instruments during surgery more intuitive. Novel procedures previously deemed too difficult to be done laparoscopically may become possible with the new systems. This is particularly applicable for procedures performed in tight anatomical spaces (transoral, transhiatal, or transanal R-LESS procedures). Hence, the current study would provide a good scientific basis supporting the use of the R-LESS approach.

In conclusion, the R-LESS approach significantly reduced the workload and difficulties of the LESS procedure for cholecystectomies and gastrojejunostomies. A dedicated single-site platform that could reduce instrument clashing while retaining the EndoWrist function is eagerly awaited.

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Author contributions Anthony Yuen Bun Teoh: Concept and design, writing of the manuscript, data analysis and interpretation. Shannon Melissa Chan: Data analysis and interpretation. Hon Chi Yip: Critical revision of the article. Vivien Wai Yin Wong: Critical revision of the article. Philip Wai Yan Chiu: Critical revision of the article. Enders Kwok Wai Ng: Critical revision and final approval of the article.

Compliance with ethical standards

Disclosures Anthony Yuen Bun Teoh, Shannon Melissa Chan, Hon Chi Yip, Vivien Wai Yin Wong, Philip Wai Yan Chiu, and Enders Kwok Wai Ng have no conflicts of interest or financial ties to disclose.

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