Updates in Surgery (2021) 73:1029–1035
https://doi.org/10.1007/s13304-020-00877-5

ORIGINAL ARTICLE

Cholecystectomy using the Revo-i robotic surgical system from Korea: the first clinical study

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Received: 11 March 2020 / Accepted: 30 August 2020 / Published online: 16 September 2020

Abstract

This study evaluated the safety and efficacy of the newly developed Revo-i (Meerecompany, Yongin, Republic of Korea) robotic surgical system during robot-assisted cholecystectomy. This prospective, phase I clinical study involved 15 patients with gallbladder-related disease. The primary outcome evaluated was the intraoperative safety of the Revo-i; the secondary outcomes measured were the 30-day postoperative complications and patient satisfaction with the Revo-i's performance. Between August 17 and December 23, 2016, we performed 15 robot-assisted cholecystectomies. The operations were successfully completed, without any conversions to open or laparoscopic approaches. The mean patient age (53.07 years), mean operative time (115.3 ± 17.31 min [± standard deviation]), docking time (10.6 ± 3.16 min), console time (49.7 ± 15.41 min), actual dissection time (33.1 ± 10.53 min), and estimated blood loss (3.33 ± 6.17 mL) were determined. There were no intra- or postoperative complications, including gallbladder perforations. The mean hospital stay was 2.0 ± 1.00 days. Most patients reported satisfaction with the Revo-i's performance. Performing robot-assisted cholecystectomies using the Revo-i is feasible and safe. This report describes the first clinical study of the Revo-i robotic surgical system in human patients.

Keywords da Vinci · Revo-i · Robot · Cholecystectomy

Introduction

Since the da Vinci™ surgical system (Intuitive Surgical, Mountain View, CA, USA) was created in the late 1990s [1, 2], robot-assisted operations have been widely accepted, proven to be safe for patients, and associated with favorable patient outcomes [3–7]. The three-dimensional operative view, seven degrees of motion freedom, motion scaling, and tremor filtration enable surgeons to perform more delicate operations. However, although the da Vinci™ surgical system has been the sole leader in this area, debate continues regarding whether robot-assisted operations are necessary due to their high cost [8–10].

In Korea, Meerecompany, Inc. has invested in new robotic surgical systems since 2006, producing a new robotic surgical system called the Revo-i. Within the last 2 years, the Revo-i robotic surgical system has been used in in vivo porcine models. Preclinical studies of various operations, such as partial nephrectomy, cholecystectomy, and fallopian tube anastomosis, were successfully performed [11–14]. Following the results of these preclinical studies, the clinical testing of the system's feasibility and safety was approved by the Korean Ministry of Food and Drug Safety.

The present study evaluated the safety and feasibility of the Revo-I during robot-assisted cholecystectomy (RAC) in humans.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s13304-020-00877-5) contains supplementary material, which is available to authorized users.

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Methods

The Korean Food and Drug Administration (FDA) approved (no. 14, 2016–04-26) clinical testing of the Revo-I robotic surgical system, based on porcine model results of cholecystectomies and nephrectomies using the system [13, 14]. The Yonsei University Health System, Severance Hospital Institutional Review Board approved the current human study protocol (no. 1–2016-0019), after FDA approval. The committee requested countermeasures suitable for risk level III (moderate risk). We fully informed and discussed all possible complications with the involved patients and their families. Only the patients who agreed to participate in this study were enrolled.

A surgeon with experience of performing more than 2000 laparoscopic cholecystectomies and 400 RACs, using the da Vinci™ surgical system, performed RACs using the Revo-i. Further, training (12 h) was provided to medical teams regarding use of the Revo-i robotic surgical system; only teams completing the training participated in this study.

The primary study outcome was an evaluation of the intraoperative safety of the Revo-i, i.e., successful completion of planned Revo-i operations without conversion to open or laparoscopic approaches because of robotic system malfunctions. The secondary outcomes included 30-day postoperative complication assessment. Postoperative complications due to the Revo-i procedure were defined as grade 3 or greater complications, according to the Clavien–Dindo classification [15]. More than two cases of surgical procedure failure were defined as study failure. A minimum of 15 patients were planned for study enrolment to provide adequate statistical power.

Robotic surgical system

The Revo-i robotic surgical system consists of a master surgeon control console (MSRC-5000), a slave four-arm robotic operation cart (MSRO-5000), and a high-definition vision cart (MSRV-5000) (Fig. 1) [16]. All instruments are designed to be reusable, and the number of uses per instrument is counted. The Revo-i has smaller instruments than the da Vinci-Xi™ surgical system. Details of the Revo-i robotic surgical system are shown in Table 1 and are described in previous reports [12, 13].

Surgical procedure

Robot-assisted cholecystectomy

Each patient was placed, supine, on the operating table (Supplemental Digital Content, Video 1). After inducing general anesthesia, the abdomen was draped in a usual, sterile manner, and a 1.5-cm supraumbilical vertical skin incision was made. The fascia and peritoneum were opened, and a camera trocar was inserted. Carbon dioxide gas was infused to create a pneumoperitoneum with a pressure of 12–14 mmHg. The table was tilted to a partial reverse Trendelenburg position (20°) and rotated on its right axis by about 30°. Three working ports for the robotic arms were created under laparoscopic vision, including two in the left and right upper quadrant areas and a third near the right anterior axillary line (used for exposure and retraction). The slave robot was

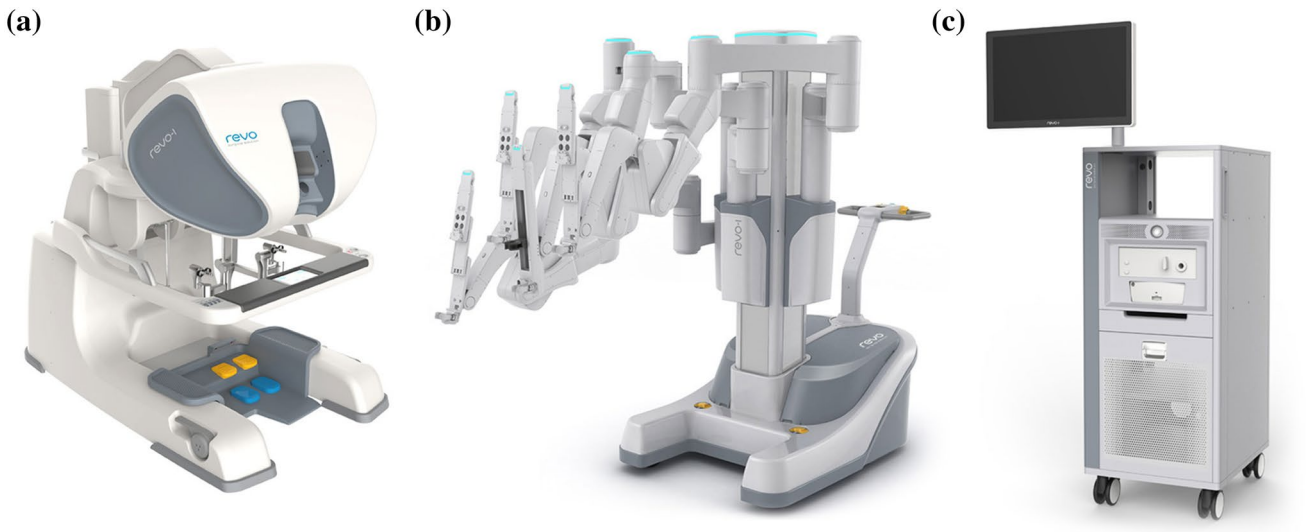

Fig. 1 Revo-i robotic surgical system. **a** Master surgeon control console (MSRC-5000). **b** Slave four-arm robotic operation cart (MSRO-5000). **c** High-definition vision cart (MSRV-5000)

Table 1 Comparison of the da Vinci Si and Revo-i robotic surgical systems

	da Vinci Xi	Revo-i
Mode of robotic movement	Master-slave	Master-slave
Components	Master console	Master console
	Slave robot	Slave robot
	Vision system	Vision system
Number of robotic arms	1 (camera) 3 (working)	1 (camera) 3 (working)
	1 (camera) 3 (working)	1 (camera) 3 (working)
Robotic control	Finger-grip type	Grip control
Wrist motion	Yes	Yes
Hand clutch	Yes	Yes
Pedal clutch	Yes	Yes
Camera control	Yes	Yes
Lateral arm-switching pedal	Yes	Yes
Clips	Micro-metal clip	Hem-o-lock clip
	Hem-o-lock clip	
Instrument diameter	8 mm	7.4 mm
3D scope diameter	8 mm	10 mm
Response delay (master-to-slave)	< 80 ms	< 80 ms
Console adjustment function (ergonomic)	Yes	Yes
Scale motion	Yes	Yes

situated near the operating table, and each robotic arm was docked to its respective port. After cholecystectomy preparations were completed, the surgeon began the cholecystectomy using the master console. The operative procedure was similar to a general laparoscopic cholecystectomy. Cadiere forceps were inserted through the third port, and the gallbladder was retracted for visualization of the Calot triangle. After performing dissection of the tissue surrounding of the cystic artery and duct, the cystic artery was ligated using a medium–large-sized clip and divided. The cystic duct was ligated using Vicryl 3–0 suture material and a medium–large-sized clip, and divided. The gallbladder was detached from the liver bed using monopolar hook cautery, and removed from the abdominal cavity in an endopouch. Postoperative data, including the docking time, console time, total operative time, blood loss, and intraoperative complications, were recorded.

Patient satisfaction survey

Patient satisfaction with the robot-assisted operation was determined using postoperatively administered questionnaires. The questionnaires assessed the degree of pain at discharge (using a numeric rating scale), inconvenience associated with the preoperative preparation and procedure, and willingness to undergo future operations involving the Revo-i (using a Likert scale) [17].

Results

Between August and December 2016, 15 patients (8 males) underwent RAC using the Revo-i robotic surgical system (patient demographics and outcomes are shown in Table 2). The mean patient age was 53.07 ± 12.05 years and the mean body mass index was 25.94 ± 2.56 kg/m^2. The preoperative diagnoses included gallbladder stones with chronic cholecystitis (9 patients, 60%), gallbladder polyps (4 patients, 26.67%), and gallbladder polyps and stones (2 patients, 13.33%). All operations were completed using the Revo-i robotic surgical system, without any laparoscopic or open conversions. The mean total operative time (115.3 ± 17.31 min), docking time (10.6 ± 3.16 min), and console time (49.7 ± 15.41 min) were determined. The mean actual dissection time (time from exposure of Calot's triangle to gallbladder detachment from the liver bed) was 33.1 ± 10.53 min. The mean estimated blood loss was 3.3 ± 6.17 mL. No intra- or postoperative complications, including gallbladder perforations, occurred. All patients were prescribed a general soft diet, after recovering from anesthesia, and were discharged 2.0 ± 1.00 days after surgery. No wound infections were noted at the initial postoperative visit at 2 weeks (Table 2).

Table 2 Patient demographic characteristics and perioperative data for cholecystectomies using the Revo-i robotic surgical system

Case no	Age (years)	Sex	BMI (kg/m^2)	Diagnosis	Operative time (min)	Docking time (min)	Console time (min)	Actual dissection time (minutes)	EBL (mL)	ASA score	Intraoperative complications	Postoperative complications	LOH (days)
1	50	Male	28.93	Polyp	130	11	69	40	0	2	–	–	1
2	64	Male	25.06	Cholecystitis	95	15	40	33	0	3	–	–	2
3	52	Female	27.55	Polyp and stone	90	8	55	29	0	2	–	–	4
4	45	Male	26.42	Polyp and stone	120	13	55	40	0	1	–	–	2
5	29	Male	22.04	Cholecystitis	120	7	55	45	0	2	–	–	2
6	63	Female	29.78	Polyp	160	10	77	30	0	2	–	–	4
7	78	Female	22.89	Polyp	120	12	55	35	0	2	–	–	2
8	43	Male	21.47	Cholecystitis	108	9	40	30	0	1	–	–	1
9	44	Male	25.59	Polyp	101	13	38	28	0	1	–	–	1
10	60	Female	26.99	Cholecystitis	105	9	44	40	10	1	–	–	2
11	54	Female	24.65	Cholecystitis	101	16	39	20	10	2	–	–	3
12	60	Female	28.81	Cholecystitis	132	8	27	18	0	1	–	–	2
13	43	Male	28.08	Cholecystitis	113	14	51	30	10	2	–	–	1
14	47	Male	26.73	Cholecystitis	118	5	27	20	0	1	–	–	2
15	64	Female	24.09	Cholecystitis	117	9	74	58	20	3	–	–	1

No., number; *BMI*, body mass index; actual dissection time, the time from exposure of the Calot triangle to gallbladder detachment from the liver bed; *EBL*, estimated blood loss; *ASA*, American Society of Anesthesiologists; intraoperative complications included gallbladder perforations; postoperative complications were those determined according to the Clavien–Dindo classification; *LOH*, postoperative length of hospital stay

Patient satisfaction with Revo-i.

Patients were postoperatively surveyed about their satisfaction with the Revo-i robot-assisted surgery. Most patients did not complain of inconvenience due to the preoperative preparation or the procedure. All patients, except one, were willing to undergo another operation involving Revo-i, if necessary; the one patient did not agree to a future operation if additional costs were incurred for the robot-assisted surgery (Fig. 2).

Discussion

This is the first clinical trial to evaluate the safety and feasibility of the Revo-i robotic surgical system in humans undergoing minimally invasive operations. Cholecystectomies were carefully chosen as the first procedures to test the Revo-i because, historically, they were the first surgeries in which laparoscopic techniques were popularized [18]. Thus, cholecystectomies have standardized laparoscopic procedures, making them appropriate procedures for evaluating the basic performance of a new robotic surgical system [19]. Additionally, the close proximity of important anatomic structures, such as the cystic duct, hepatic artery, and common bile duct, makes this procedure one of the best for testing the safety and feasibility of new robotic surgical systems.

All of the Revo-i cholecystectomies performed in this study were successful, and did not involve any major intraoperative complications, organ injuries, or conversions to open or laparoscopic approaches. Docking time and console time were so long than general robotic cholecystectomy. We spent a lot of time checking whether we could safely perform the surgery rather than reducing the time because this study is the first attempt to apply the robot system to humans. Early period report about robotic cholecystectomy using da Vinci™ system also spent long docking time and console time [20, 21]. Moreover, there were no postoperative complications defined as Clavien–Dindo grade ≥ 3. According to the postoperative patient satisfaction survey, the patients were generally satisfied with the operations using the new system, and patient satisfaction is an important component of minimally invasive surgeries. Further, patient satisfaction is closely associated with short hospitalization periods, extent of postoperative pain, and resultant wound sizes. These results reflect the effectiveness of RACs, using Revo-i, despite the study not involving a comparison with currently available robotic systems.

Hospital stay after cholecystectomy in Korea was longer than other country. That was related with Korean culture and almost complete national health insurance system. Many studies from Korea also reported one or two hospital stays after cholecystectomy [22, 23].

After the introduction of the da Vinci™ system, robot-assisted operations have become a major treatment option in the fields of gastrointestinal, gynecologic, and urologic operations [24–27]. The da Vinci™ system has had a great impact on the initiation of robotic abdominal operations and has led to the development of this surgical field. This system has been used to conduct more than 3,000,000 procedures in 64 countries, and there are more than 10,000 peer-reviewed publications about the use of the da Vinci™

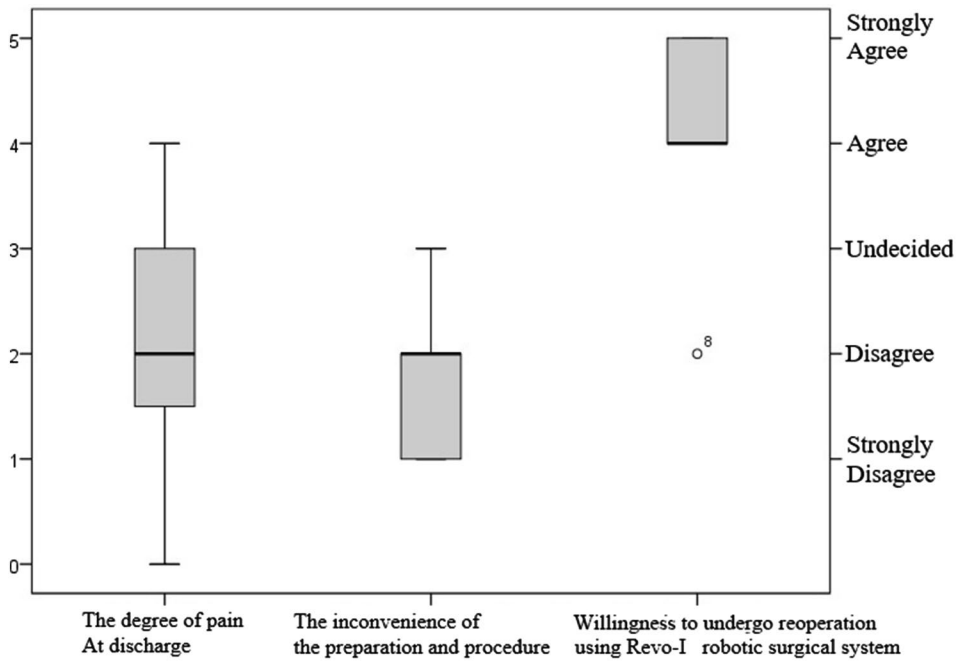

Fig. 2 Patient satisfaction with the Revo-i robotic surgical system

system in various surgical fields [28]. As a result, robot-assisted operations, in the abdominal field, are considered to involve use of the da Vinci™ system. This monopoly of the da Vinci™ system has influenced the high operative expenses associated with the procedure, and da Vinci™ system has expensive annual service costs. Thus, this situation has hindered the development and evolution of robotic surgical technologies.

The Meerecompany has been developing its robotic surgical system since 2006, with a prototype being introduced in 2007. Accordingly, the Korea Ministry of Knowledge Economy selected Meerecompany to further develop its surgical robot system. This resulted in many prototypes being developed that had improved function and performance. During this period, several preliminary animal studies were also performed, and the incremental system models became more stable and showed good function. A preclinical study was successfully performed, and KFDA approval for the clinical use of the system followed in 2016 [13, 14].

Recently, a new robotic surgical system, Telelap Alf-x (now, Senhance™, TransEnterix, Morrisville, NC, USA), was developed and its first clinical study was published [29]. This system has haptic feedback and an eye tracking endoscope, but is limited by non-articulated instrumentation. In contrast, the Revo-i system has three arms with seven degrees of freedom. The three articulating arms allow the surgeon to perform delicate procedures and meticulous dissections. An articulating arm that functions similarly to a human hand is an important element that distinguishes robot-assisted operations from conventional laparoscopic operations.

Based on the current results, the KFDA approved the clinical use of Revo-i in minimally invasive operations in early August 2017. Hence, the Revo-i is expected to be used in minimally invasive operations beginning in early 2018, making this system an alternative to the da Vinci™ system. This advancement is expected to somewhat resolve the cost–benefit issue associated with current robot-assisted operations. The clinical efficacy and safety of the Revo-i require further validation in various surgical procedures in the near future.

Conclusion

In our studies, RAC was successfully performed in 15 patients. There were no complications and no open or laparoscopic conversion. Most patients were satisfied with the surgical results. Revo-i show good performance during RAC. Performing RACs using the Revo-i is feasible and safe. This report describes the first clinical study of the Revo-i robotic surgical system in human patients.

Availability of data and material

All data was included in the paper.

Acknowledgements This work was supported by a National Research Foundation of Korea grant funded by the Korea Government (NRF-2015R1A2A2A04003460). The funding agency had no role in the data collection, study design, or writing of the manuscript. Dr. W.J. Lee serves as a consultant for Meerecompany (Yongin, Republic of Korea). The other authors have no conflicts of interest or financial ties to disclose.

Author contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by JHL, SHC and CMK. WJL provided advice about robotic systems and the setting up of a clinical trial. The first draft of the manuscript was written by JHL and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding This work was supported by a National Research Foundation of Korea Grant, funded by the Korea Government (NRF-2015R1A2A2A04003460). The funding body did not have a role in the data collection, study design, or writing of the manuscript.

Compliance with ethical standards

Conflicts of interest This work was supported by a National Research Foundation of Korea Grant funded by the Korea Government (NRF-2015R1A2A2A04003460). The funding agency had no role in the data collection, study design, or writing of the manuscript. Dr. W. J. Lee serves as a consultant for Meerecompany (Yongin, Republic of Korea). He was not involved in the surgeries, data collection, or analyses. He provided advice about robotic systems and the setting up of a clinical trial. None of the other authors have conflicts of interest or financial ties to disclose.

Ethics approval Severance Hospital Institutional Review Board approved the current human study protocol (No. 1–2016-0019).

Informed consent Informed consent was obtained from all individual participants included in the study.

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