Original Article

Yonsei Med J 2022 Dec;63(12):1106-1112
https://doi.org/10.3349/ymj.2022.0367

Yonsei Medical Journal
YMJ
pISSN: 0513-5796 · eISSN: 1976-2437

In Vivo Feasibility Test of a New Flexible Ureteroscopic Robotic System, easyUretero, for Renal Stone Retrieval in a Porcine Model

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Purpose: Using a new robotic endoscopic platform system developed for retrograde intrarenal surgery (RIRS) called easyUretero (ROEN Surgical Inc.), we evaluated the feasibility and safety of renal stone retrieval in a porcine model.
Materials and Methods: Six female pigs were used for our in vivo study. First, 0.3-cm-sized phantom stones were inserted into the kidneys of each pig via the ureteral access sheath. Next, renal stone retrieval was attempted using manual RIRS in three pigs and robotic RIRS in three pigs. Three surgeons performed extraction of 10 stones in each session.
Results: The mean stone retrieval time by manual RIRS was significantly shorter than that by robotic RIRS (399.9±185.4 sec vs. 1127.6±374.5 sec, p=0.001). In contrast, the questionnaire regarding usability showed high satisfaction in the surgeons' fatigue category for surgeons using robotic RIRS. The radiation exposure dose was also lower in robotic RIRS than in manual RIRS (0.14 μSv vs. 45.5 μSv). Postoperative ureteral injury assessment revealed Grade 0 in manual RIRS cases and Grades 0, 1, and 2 in robotic RIRS cases.
Conclusion: The easyUretero system is a new robotic RIRS system that was developed in Korea. The results of the present study suggest that using easyUretero for stone retrieval during RIRS is safe and ergonomic.

Key Words: Robot-assisted surgery, remote operation, ureteroscopy, urolithiasis

INTRODUCTION

Recently, there has been a global increase in the incidence and prevalence of urolithiasis.[1,2] Several factors, including diet, lifestyle, and global warming of the Earth, can play important roles related to the rising incidence of urolithiasis.[3] Moreover, the re-

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Received: August 18, 2022 **Revised:** September 26, 2022 **Accepted:** October 4, 2022 **Published online:** November 9, 2022

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•Hae Do Jung, Young Joon Moon, Hyunho Han, and Joo Yong Lee have received research grants from ROEN Surgical Inc. for this work. Joo Yong Lee and Sung Yong Cho hold a position on the advisory board of ROEN Surgical Inc. Joonhwan Kim and Dong-Soo Kwon have stock ownership of ROEN Surgical Inc. Jungmin Han declares no potential conflict of interest.
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currence rate of urolithiasis has been reported to be 52% within 10 years after a first stone episode.[4]

Shock wave lithotripsy (SWL) is a minimally invasive treatment for urolithiasis, but its success rate is low in cases of large urinary stones, which may require several additional SWL treatments.[5] Ureteroscopic lithotripsy (URS) was initially applied to lower ureteral stones, but the development of video endoscopy, disposable flexible renoureteroscopy, and laser equipment for lithotripsy has led to high success rates using URS for upper ureteral stone removal.[6,7] However, there are still limits to endoscopic treatment for large urinary stones.[8] As the surgery becomes more invasive, the side effects in patients after surgery increase, and the fatigue level of surgeons worsens due to long operation times.[9]

Retrograde intrarenal surgery (RIRS) using flexible ureteroscopy is widely used and recommended in major guidelines as the primary treatment for urinary stones less than 2 cm in size;[10] however, endoscopic manipulation may be technically difficult depending on the location of the urinary stones.[11] Furthermore, surgeons experience fatigue as surgeries are usually performed in a standing position while holding the ureteroscope. This position can cause musculoskeletal diseases in surgeons and may also affect surgical outcomes, especially in cases of larger stones that require a long operation time.[9,12-14] In addition, surgeons are repeatedly exposed to radiation.

Robotic surgery is increasingly being used in various fields of urology, showing better treatment results compared to open and laparoscopic surgery; however, it is still insufficient in the field of urolithiasis.[15] Currently, robotic surgery in urolithiasis involves robot-assisted laparoscopic ureterolithotomy, pyelolithotomy, and anatrophic nephrolithotomy, but its role is limited compared to that of RIRS.[16]

Recently, robotic RIRS has emerged.[17,18] Desai, et al.[19] introduced robotic RIRS in porcine models for the first time in 2008 and showed promising results in clinical trials using the first robotic RIRS in 2011.[20] Since then, several studies on robotic RIRS have been conducted worldwide.[21,22] A new robotic RIRS system known as easyUretero (ROEN Surgical Inc., Daejeon, Korea) was developed in Korea. The easyUretero robotic system consists of master console and slave robots designed to combine existing flexible ureteroscopy with the use of the stone basket and laser fiber. The present study aimed to investigate the feasibility of using easyUretero, the flexible ureteroscopic robotic system, for renal stone retrieval in a porcine model.

MATERIALS AND METHODS

Robotic RIRS system of easyUretero

The easyUretero system is a master slave robot system designed specifically for RIRS (Fig. 1). The system consists of a slave robot and a master console. The slave robot can install a commercial flexible ureteroscope, and both a modified basket and a laser fiber can be attached to the slave robot and inserted into the channel of the ureteroscope. The master console provides a magnified ureteroscopic image and a handle controller that enables an operator in a sitting position to use one hand for teleoperation of the ureteroscope, stone basket, and laser fiber. Therefore, a single operator can perform telesurgery from an ergonomic and comfortable position behind a radiation shield barrier. Consequently, the whole body of the operator can be protected from radiation exposure without wearing any protective equipment. Fine motion of the ureteroscope can be obtained using intraoperative motion scaling. The robot features two advanced functions that can help improve efficiency and safety in stone retrieval; namely, an automation function which can re-access the renal calyces that were already accessed, and a safety alarm which detects the grasping of oversized stones that can collide with a ureter during extraction.

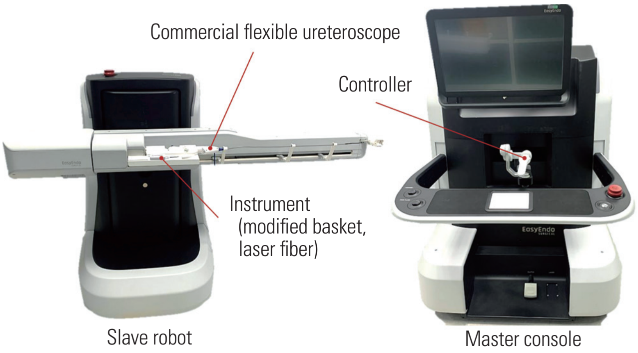

Fig. 1. System configuration of easyUretero.

Population and participants

Six female pigs (Yorkshire) aged 6 months and weighing 48.8±0.8 kg were used for an in vivo study in which both manual and robotic RIRS were used to retrieve renal stones. Three urology surgeons representing an RIRS beginner (<100 procedures), intermediate (100–400 procedures), and expert (>400 procedures) participated in the study.

Preparation for experiment

All procedures were performed using pigs under general anesthesia with endotracheal intubation. The anesthetized pigs were placed in the dorsal lithotomy position. Before stone retrieval, 0.3-cm phantom stones were inserted into various calyces inside the kidney via the ureteral access sheath.

Renal stone retrieval

After the manual insertion of the 11/13 Fr ureteral access sheath (Navigator HD, Boston Scientific, Marlborough, MA, USA), a LithoVue^{TM} (Boston Scientific) and a modified stone basket were installed to the easyUretero system. Renal stone retrieval was accomplished by manual RIRS in three pigs and robotic RIRS in three pigs. Three surgeons performed extraction of 10 stones in each session (Fig. 2). The stone retrieval time, defined as the time from when the ureteroscope was initially inserted into the kidney for the first stone retrieval to the extraction of the last tenth stone, was evaluated in each session. The kidney and ureter were inspected for injury after removal of the access sheath at the end of each session. All six pigs were exsanguinated via the cephalic vein before and after RIRS for renal function evaluation. The collected blood was used to measure hemoglobin and serum creatinine levels from pigs in both the manual and robotic RIRS groups.

The workload of the surgeons during RIRS was evaluated using a modified version of the ergonomic problems survey during video endoscopic surgery.[23] Using a radiation detector (QSF 104, Analog Research System), the maximum radiation level around the operator during the experiment was measured immediately after fluoroscopic imaging. In manual RIRS, the radiation measurement was made at the operator's location within 1 m from the X-ray source of the C-arm. In robotic RIRS, the radiation measurement was made at the location of the master console (the back of the radiation shielding wall) at least 2 m away from the X-ray source of the C-arm.

Statistics and ethics statement

Data are expressed as mean±standard deviation. Statistical comparisons of the data were made using either the Wilcoxon rank sum test or the paired t-test. Statistical analyses were performed using R software (version 4.1.1, R Foundation for Statistical Computing, Vienna, Austria; http://www.r-project.org). The Institutional Animal Care and Use Committee (IACUC, Yonsei University Health System, Seoul, Korea) approved the study protocol (Approval No. 2020-0309). All methods were conducted in accordance with relevant guidelines and regulations. This study has been reported in accordance with the ARRIVE guidelines (Animal Research: Reporting of In Vivo Experiments).[24]

Fig. 2. Stone retrieval using easyUretero. (A) Stone grasping using a stone basket. (B) Automatic stone extraction.

RESULTS

Docking time

The docking time included the slave robot approach to an operation bed, attachment of a ureteral access sheath, and LithoVue to the slave robot. In our study, the average docking time was 2.6±0.3 minutes.

Stone retrieval time

The experimental results demonstrated that the stones located in the various calyces could be successfully accessed and retrieved without damage to the kidney or ureteroscope. The mean stone retrieval time of total cases was significantly shorter for manual RIRS than for robotic RIRS using easyUretero (399.9±185.4 sec vs. 1127.6±374.5 sec, respectively; *p*=0.001). The mean stone retrieval times in manual and robotic RIRS for each of the three surgeons were as follows: 209.7±74.2 sec and 772.0±120.8 sec for the RIRS expert (*p*=0.002); 380.3±48.4 sec and 1226.7±329.4 sec for the RIRS intermediate (*p*=0.044); and 609.7±94.0 sec and 1384.0±367.1 sec for the RIRS beginner (*p*=0.024) (Table 1).

Surgeons' fatigue

The postoperative questionnaire revealed that surgeons felt less pain or discomfort due to device handling during robotic RIRS than during manual procedure. The mean and standard deviation of the sum score of items related to ergonomics (pain or discomfort due to handling the apparatus, discomfort due to static body posture, discomfort due to continuous foot flexion during foot pedal manipulation, back pain during operation, and neck pain due to extension of head by looking at the monitor) for each participant was lower in robotic RIRS than in manual RIRS, although it was not statistically significant (6.0±5.6 vs. 17.3±4.3, *p*=0.053). In contrast, there were no differences in perception or communication problems (Fig. 3).

Postoperative ureteral injury

Postoperative ureteral injury was grade 0 in manual RIRS and grades 0, 1, and 2 in robotic RIRS. All ureteral injuries were confirmed to have occurred in the middle of the ureter protected by the ureteral access sheath. Thus, ureteral injuries were considered to be related to ureteral access sheath insertion in all cases.

Table 1. Mean Stone Retrieval Time

Surgeon	Manual RIRS (sec)	Robotic RIRS (sec)	*p* value*
RIRS expert	209.7±74.2	772.0±120.8	0.002
RIRS intermediate	380.3±48.4	1226.7±329.4	0.044
RIRS beginner	609.7±94.0	1384.0±367.1	0.024
Total	399.9±185.4	1127.6±374.5	0.001

RIRS, retrograde intrarenal surgery.
*Wilcoxon rank sum test with continuity correction.

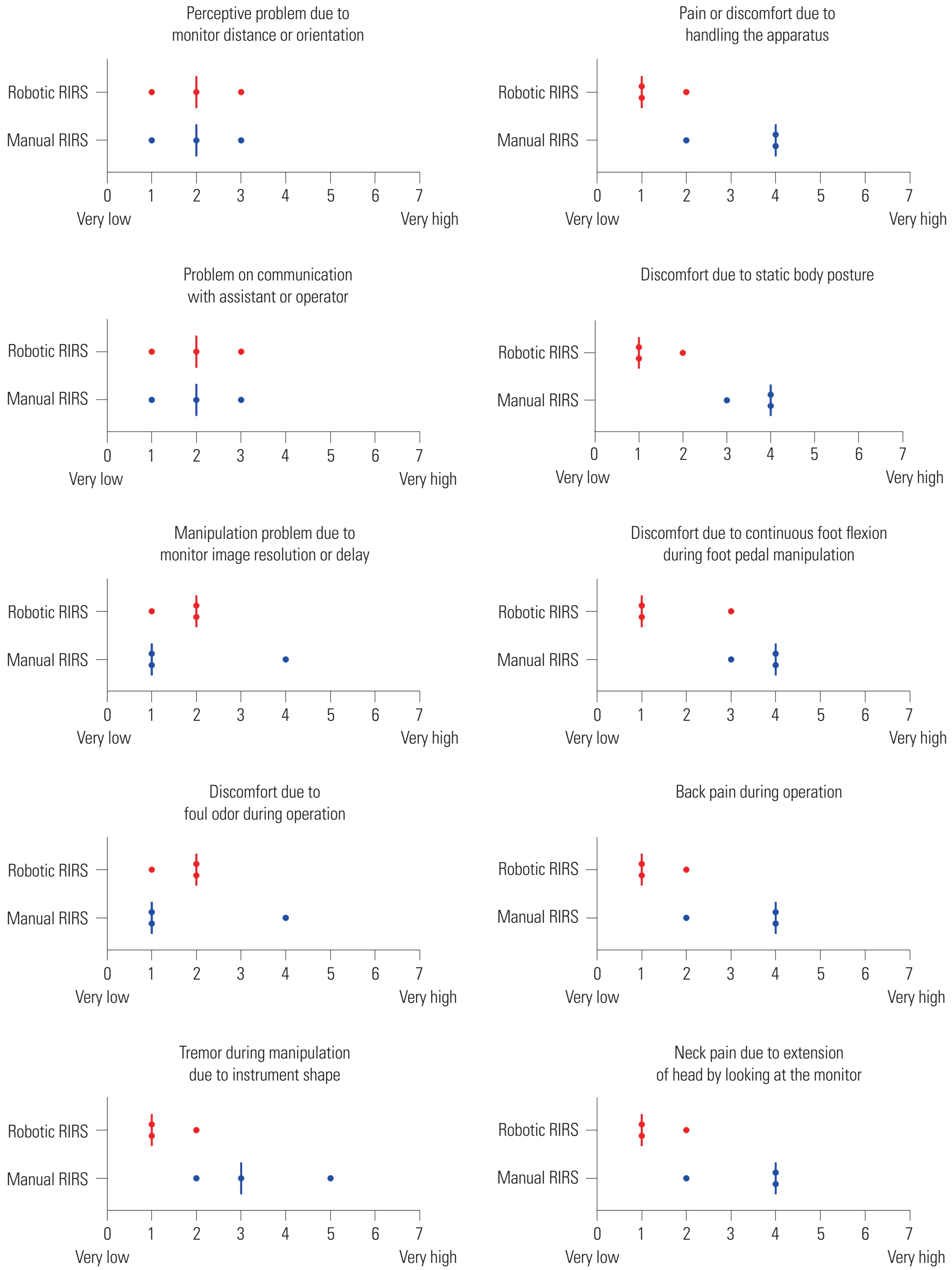

Fig. 3. Pain or discomfort during RIRS. Each dot represents an answer from the operators. Bar, median; RIRS, retrograde intrarenal surgery.

Hematological changes

In manual RIRS, there was no statistical difference between preoperative and postoperative hemoglobin and serum creatinine (Table 2). In robotic RIRS, there was no statistical difference between preoperative and postoperative hemoglobin, but postoperative levels of serum creatinine increased compared to preoperative levels (p=0.022) (Table 3). The increased ratio of serum creatinine in robotic RIRS was statistically significantly higher than that of manual RIRS (p=0.025) (Table 4). However, the increase was not significant enough to indicate

Table 2. Manual RIRS: Postoperative Changes in Hemoglobin and Serum Creatinine

	Preoperative	Postoperative	*p* value*
Hemoglobin (g/dL)	9.27±1.20	9.00±0.26	0.691
Creatinine (mg/dL)	0.99±0.21	1.07±0.26	0.320

RIRS, retrograde intrarenal surgery.
*Paired t-test after Shapiro-Wilk normality test.

Table 3. Robotic RIRS: Postoperative Changes in Hemoglobin and Serum Creatinine

	Preoperative	Postoperative	*p* value*
Hemoglobin (g/dL)	9.50±0.62	9.93±1.01	0.238
Creatinine (mg/dL)	1.03±0.15	1.34±0.22	0.022

RIRS, retrograde intrarenal surgery.
*Paired t-test after Shapiro-Wilk normality test.

Table 4. Postoperative Serum Creatinine Changes for Each Pig in Manual and Robotic RIRS

Object number	Preoperative, a (mg/dL)	Postoperative, b (mg/dL)	Difference, (b-a) (mg/dL)	Increase ratio* (b-a)/a
Manual RIRS				
#1	1.09	1.07	-0.02	-0.02
#2	0.75	0.82	0.07	0.10
#6	1.14	1.33	0.19	0.17
Robotic RIRS				
#3	1.04	1.40	0.36	0.35
#4	1.17	1.53	0.36	0.31
#5	0.88	1.1	0.22	0.25

RIRS, retrograde intrarenal surgery.
**p*=0.025.

Table 5. Radiation Exposure Dose: Manual RIRS vs. Robotic RIRS

	Manual RIRS (Unprotected)	Robotic RIRS
Maximum radiation exposure dose (μSv)	45.5	0.14

RIRS, retrograde intrarenal surgery.

acute renal damage, and was confirmed as an increase within the reference range.

Radiation exposure dose

The radiation exposure doses in manual RIRS and robotic RIRS are shown in Table 5. In manual RIRS, the radiation exposure dose of surgeons' unprotected areas without a lead gown was 45.5 μSv. In robotic RIRS, the radiation exposure dose of surgeons' whole body was 0.14 μSv.

DISCUSSION

No complication occurred in the first 18 patients who underwent robotic RIRS for 5–15 mm renal stones by Desai, et al.[20] The complete stone clearance rate was 89% at 3 months, and one patient underwent a second surgery (percutaneous nephrolithotomy) on the remnant stones.

Subsequently, Saglam, et al.[22] published a robotic RIRS study of 81 patients using Roboflex Avicenna developed by ELMED (Ankara, Turkey). The average volume of stones was 1296±544 mm^3 (range: 432–3100 mm^3). A secondary RIRS was necessary in two patients, due to dysfunction of the flexible ureteroscope in one and large remnant stones in the other. In the remaining 79 patients, the stones were completely fragmented during robotic RIRS. At 3 months, 65 patients (80%) had completely removed stones, and 16 patients (20%) showed clinically insignificant residual stones (<3 mm). No specific complication was found. The average console time (53 min, range: 23–115 min) and average operative time (74 min, range: 40–182 min) were reasonable time frames compared to manual RIRS. Geavlete, et al.[25] randomly divided 132 patients and conducted a prospective comparative study on robotic and manual RIRS using the Roboflex Avicenna system (prototype 2). The average stone size of the manual RIRS group was 2.1 cm (range: 1.1–3.6 cm) and that of the robotic RIRS group was 2.4 cm (range 1.0–3.7 cm). The complications were similar in the two groups, and the stone-free rate at 3 months was 89.4% in manual RIRS and 92.4% in robotic RIRS.

Most recently, Klein, et al.[21] published the results of robotic RIRS conducted on 240 patients. The total operative time was 91 min, stone treatment time was 55 min, robot preparation time was 5 min, robot docking time was 6 min, total console time was 75 min, postoperative hospital stay was 1.5 days, stone-free rate (<2 mm) was 90%, re-treatment rate was 8.75%, and the complication rate was 5.4%. In their study, Klein, et al.[21] concluded that robotic RIRS could overcome the ergonomic constraints of surgeons and differences in surgical experience arising from manual RIRS. Moreover, they also stated that radiation exposure could be reduced.

In the present study, the average docking time was reasonable, and all stone retrieval trials were successfully completed with easyUretero. Unlike the prior robotic RIRS system (Roboflex Avicenna), easyUretero integrates the operation of the stone basket into the system. This integrated functionality was applicable and beneficial in practical RIRS procedures. However, compared to manual RIRS, the stone retrieval time was longer in robotic RIRS. This difference may be due to the participants failing to reach sufficient proficiency with the new control interface of the ureteroscope and stone basket during the experiment. All participants had approximately 10 h of training before the experiment. As manual RIRS requires approximately 56 procedures to reach a plateau in the learning curve,[26] robotic RIRS may also require a certain amount of experience. Due to the easy and ergonomic control interface of easyUretero, we expect that robotic RIRS would require less experience than manual RIRS. Following this study, in the experiment of lasering and stone retrieval performed after being more accustomed to robotic RIRS, there was no difference in lasering time and stone retrieval time between manual and robotic RIRS for the RIRS intermediate and beginner (127.8±93.2 vs. 241.8 sec/stone, *p*=0.14; 85±30.5 vs. 96.1±32.7 sec/stone, *p*=0.63).[27]

Robotic RIRS using easyUretero showed convenience in operation and less fatigue in the present study. In manual RIRS, the surgeon operates in a standing position wearing a protective lead gown to prevent radiation exposure. This may increase the risk of discontinuation of surgery as the surgeon's muscle fatigue increases as the operative time becomes longer.[9,12-14] Moreover, this fatigue may cause health problems for the surgeon.[21] However, in robotic RIRS, the surgeon operates in a sitting position at the console site with the ergonomic control interface. In addition, the increased distance between the surgeon and the radiation source as well as the use of a radiation shield barrier allow the surgeon to operate without wearing the lead gown, which reduces the surgeon's physical fatigue, improves endurance,[22] and minimizes radiation exposure. Radiation exposure is as important as the treatment of stones, and relates to the working conditions of surgeons and hospital workers.[28] In our study, the radiation exposure dose per each fluoroscopy shooting in robotic RIRS was lower than that in manual RIRS (0.14 μSv vs. 45.5 μSv). In addition, in manual RIRS, the surgeon holds the ureteroscope throughout the operation, and the wrist is frequently bent excessively for the rotation of the ureteroscope, which can cause high amount of fatigue in the operator's shoulder, arm, and wrist. However, in robotic RIRS, the operator can operate the controller with the arm placed on the armrest. Moreover, for the rotation of the ureteroscope, the wrist's scaled pronation/supination movement is used, not the extension/flexion movement.

Our results suggested that robotic RIRS can be used to remove large stones without invasive percutaneous nephrolithotomy. Robotic RIRS might also lead to improved surgical outcomes, including stone-free rate and complication rate, as it can facilitate longer procedure times due to low radiation exposure and less fatigue for surgeons. Our future research will focus on validating the efficacy of robotic assistance in difficult and demanding cases, such as large stones, which require a longer procedure time. In addition, the effectiveness of automatic re-access to the renal calyx in repetitive stone removal will be evaluated.

Grades 1 and 2 ureteral injury in robotic RIRS occurred when the ureteral access sheath was inserted, and not as a complication of robotic RIRS itself. Hematologic changes before and after surgery, confirmed through blood collection from the pigs, were not different from previous studies on hematologic changes after manual RIRS.[29,30] These results suggest that robotic RIRS is safe.

Our study had some limitations. First, there was some bias from not performing manual RIRS and robotic RIRS in the same pig. We chose to perform manual RIRS and robotic RIRS in different pigs rather than in the same pig to compare safety indices such as ureter injury and hematological changes. Although the number of pigs was not large enough to ignore the differences in the characteristics of each pig (e.g., the differences in ureter and kidney anatomy), we observed that the differences between each pig did not critically affect the experimental results. Nonetheless, it is clear that the hematological changes cannot be solely attributed to the differences between manual RIRS and robotic RIRS.

Another limitation is that manual RIRS and robotic RIRS were performed on one pig by three surgeons consecutively. This resulted in some disadvantages, such as poor visualization due to hematuria, for later procedures. However, we tried to minimize this effect by having the three surgeons perform the surgery in a different order for each pig. Third, in robotic RIRS, there is a need to minimize the delay in the manipulation of the endoscope and improve the precision of the opening/closing amount of the stone basket. Nevertheless, this important, initial pilot study evaluated the feasibility of robotic RIRS. Robotic RIRS using easyUretero showed convenience (low level of fatigue for surgeons) and safety (acceptable complication rate) in stone retrieval.

In conclusion, the easyUretero system is a new robotic RIRS system that was developed in Korea. Although using a different porcine model as a comparator, robotic RIRS using easyUretero was feasible in stone retrieval and showed comparable safety to manual RIRS. In addition, easyUretero showed high level of satisfaction regarding surgeons' fatigue and radiation exposure. However, more evidence is still required to ascertain that robotic RIRS is predicted to be more effective than manual RIRS with sufficient training. The easyUretero used in this study was the first-generation model, and the updated model is expected to show better effectiveness and safety.

ACKNOWLEDGEMENTS

This work was supported by ROEN Surgical Inc. The authors deeply appreciate Se Hoon Kim, D.V.M. and Gyuri Park D.V.M. from the Department of Laboratory Animal Resources, Yonsei Biomedical Research Institute, for their support with animal care and perioperative hematological examination, and Hyun Se Seo and Sukju Kang from ROEN Surgical Inc. for their technical support during the study.

AUTHOR CONTRIBUTIONS

Conceptualization: Joo Yong Lee and Dong-Soo Kwon. Data curation: Hae Do Jung, Hyunho Han, and Joo Yong Lee. Formal analysis: Joonhwan Kim and Hae Do Jung. Investigation: Joonhwan Kim, Hae Do Jung, Young Joon Moon, and Hyunho Han. Methodology: Hae Do Jung and Joo Yong Lee. Project administration: Byungsik Cheon, Sung Yong Cho, Joo Yong Lee, and Dong-Soo Kwon. Resources: Joonhwan Kim, Byungsik Cheon, and Jungmin Han. Software: Hae Do Jung and Young Joon Moon. Supervision: Sung Yong Cho, Joo Yong Lee, and Dong-Soo Kwon. Validation: Sung Yong Cho and Joo Yong Lee. Visualization: Joonhwan Kim, Young Joon Moon, and Jungmin Han. Writing—original draft: Joonhwan Kim and Hae Do Jung. Writing—review

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