

## ORIGINAL ARTICLE

# Early outcomes of robotic extended cholecystectomy for the treatment of gallbladder cancer

Yoonhyeong Byun  | Yoo Jin Choi  | Jae Seung Kang  | Youngmin Han  |  
Hongbeom Kim  | Wooil Kwon  | Jin-Young Jang 

Department of Surgery and Cancer  
Research Institute, Seoul National  
University Hospital, Seoul, Korea

## Correspondence

Jin-Young Jang, Department of Surgery,  
Seoul National University College of  
Medicine, 101 Daehak-ro, Jongno-gu, Seoul  
03080, Korea.  
Email: jangjy4@snu.ac.kr

## Abstract

**Background:** Simple laparoscopic cholecystectomy is sufficient for patients with early gallbladder cancer (GBC). However, because advanced GBCs of T2 or more advanced stages require more complex procedures such as liver resection and lymph node dissection, minimally invasive surgery (MIS) has not been popularized. To evaluate the applicability of MIS for GBC, we report the early outcomes of robotic extended cholecystectomies (RECs).

**Methods:** Thirteen patients who radiologically suspected to have T2 or more advanced stages of GBC underwent REC from February 2018 to April 2019. Thirty-nine patients who underwent open extended cholecystectomy were selected by 1:3 propensity score matching, and the differences of clinicopathologic features according to surgical methods were analyzed.

**Results:** Compared with open method, operation time, estimated blood loss, postoperative complication rate, and number of retrieved lymph nodes were not significantly different. In REC group, duration of hospital stay was shorter (6.6 vs 8.3 days,  $P = .002$ ) and postoperative pain was significantly lower in the REC group ( $P = .024$ ).

**Conclusion:** The early outcomes of REC were favorable with regard to early recovery and less pain, with similar number of retrieved lymph nodes. REC is a promising option for treatment of GBC, but further long-term survival studies are needed.

## KEYWORDS

gallbladder cancer, minimally invasive surgical procedures, robotic extended cholecystectomy, robotic surgical procedures

## 1 | INTRODUCTION

Laparoscopic cholecystectomy (LC) is the standard treatment for benign gallbladder disease, and there have been several reports about the feasibility of minimally invasive surgery (MIS) for early gallbladder cancer (GBC).<sup>1</sup>

However, the application of MIS for advanced GBC of T2 stage or more is still concerning due to the characteristics

of its surgical procedure. First, the dissection of the regional lymph nodes around the hepatoduodenal ligament is performed in a very narrow space, and therefore extreme care is required to avoid damaging the surrounding critical structures. To achieve oncologically sufficient lymphadenectomy, the soft tissues around the hepatoduodenal ligament should be clearly dissected. However, because the resection plane is not unidirectional, it is difficult to

perform with a straight laparoscopic instrument. Second, in order to dissect the liver parenchyma around the gallbladder more safely, a distinct view is needed to distinguish small vessels or bile ducts during the dissection. Therefore, the robotic system has advantages such as filtration of hand tremor, wrist articulation, and 3-dimensional (3D) stereoscopic images. These advantages may help to overcome difficulties in applying MIS to extended cholecystectomy (EC).

However, there have been few reports of EC using a robotic system, and a lack of evidence supporting the feasibility and outcomes of the robotic extended cholecystectomy (REC) comparing the conventional open method. Therefore, here we analyzed the surgical outcome and verified the feasibility and oncologic safety of REC.

## 2 | METHODS

### 2.1 | Patients

This study was approved by the Institutional Review Board (IRB) of Seoul National University Hospital (approval number: H-1904-119-1028). The medical records of 13 patients who underwent REC from February 2018 to April 2019 were reviewed. All patients had a pancreatobiliary protocol 3D computed tomography (CT) and high-resolution ultrasonography (HRUS) or endoscopic ultrasonography (EUS) preoperatively. REC was recommended for patients diagnosed with tentative T2 or later stages by preoperative images, without involvement of hilar or extrahepatic biliary structures. Included patients were also expected to achieve complete resection without combined resection of adjacent organs other than the liver before the operation (distant metastatic cases were excluded). All included patients were well enough to tolerate the operation under general anesthesia and had no history of previous abdominal surgeries. Because of the cost associated with REC, REC was performed only on patients who voluntarily accepted the robotic surgery after being fully informed about the differences between the conventional open and robotic approaches. [Correction added on 26 May 2020 after first online publication: The IRB approval number “H-1904-119-102” has been changed to “H-1904-119-1028”]

For a comparison with the conventional open EC, we reviewed the medical records of all patients who underwent open EC from April 2012 to December 2018. Among these, all patients who had undergone combined resection of extrahepatic bile ducts or had any history of previous abdominal operations were excluded. We used propensity scores to match 150 patients 1:3 according to sex, age, body mass index (BMI), and T stage (based on T2).

### 2.2 | Surgical procedures

The patient was placed in the lithotomy and reverse Trendelenburg positions and tilted the right side upwards. The operation time was recorded by measuring the time from the first skin incision to the final skin closure. Four 8-mm trocars were used for the robotic arms, and one 12-mm, and one 5-mm trocar were used for the assistant surgeon. A total of six trocars were placed along the two concentric circles centered on the gallbladder (Figure 1). After the four 8-mm trocars were docked to the robotic arm, they were used to route robotic instruments or the video scope, and the 5- and 12-mm trocars were used for the assistant. The assistant was placed between the patient's legs, and the laparoscopic instruments were placed through the two trocars to assist. The position of the trocar was adjusted by considering anatomical factors such as the size of the abdominal area and obesity (Figure 2).

The Kocher's maneuver was performed until the posterior side of the pancreatic head was visualized (Figure 3A). At this time, the surrounding soft tissue was peeled off and lymph nodes 13 were dissected (Figure 3B). Then, while the soft tissues around the superior side of the duodenum were dissected, the structures composed of the portal triad were skeletonized. Vessel loops were hung on each identified major vessel and pulled to the left and right to resect all of the lymph nodes in the posterior part (Figure 3C). Through these procedures, lymph nodes 8, 9, and 12 were obtained (Figure 3D). The cystic duct and

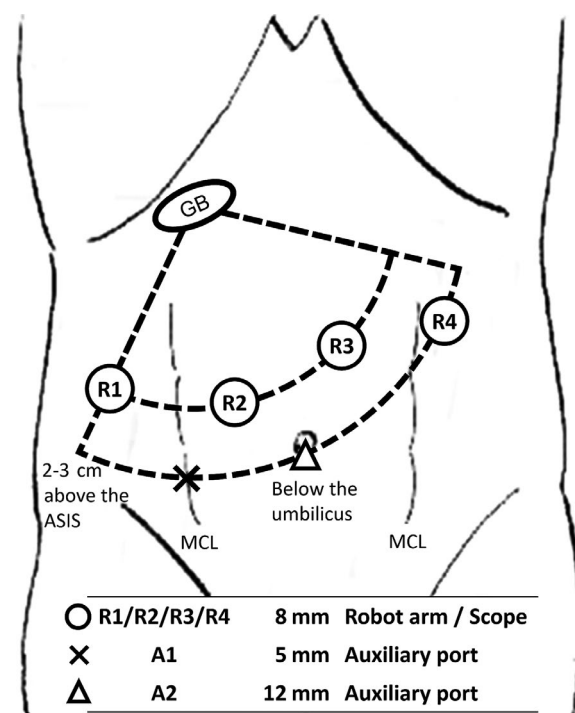
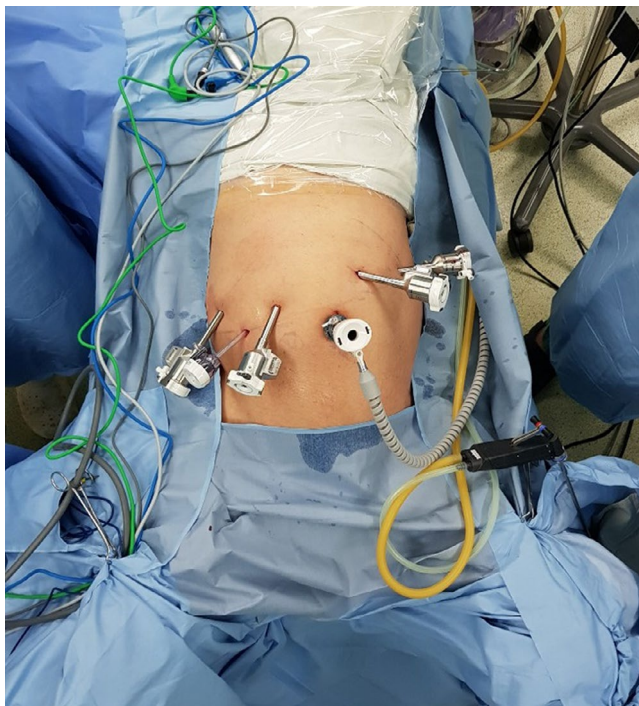


FIGURE 1 The locations of trocars used for the operation



**FIGURE 2** Patient position

artery located along the right side of the skeletonized common bile duct were identified and ligated. The tiny tissue obtained from the resection margin was examined by frozen section for invasion into the common bile duct (Figure 3E).

After the dissection of the regional lymph nodes, a wedge resection of liver parenchyma was performed. The Harmonic scalpel® (Ethicon Endo-Surgery) was mainly used to transect the liver parenchyma (Figure 3F). When any visible vascular or bile duct structures were encountered, they were clipped by the Endoclip applicator and ligated. Diffuse bleeding without any specific bleeding focus was controlled by bipolar coagulation with the Maryland forceps (Figure 3G). After confirming that there was no bile leakage or bleeding from the resection margin, the surgical drain was inserted and the operation was terminated. The specimen was placed in a plastic bag and taken out of the abdominal cavity through the infraumbilical incision.

### 2.3 | Postoperative care

The subjective pain score according to the visual analog scale (VAS) was collected daily at the same time, from the immediate postoperative day to postoperative day 5. An abdominal CT scan was performed at the postoperative day 4 to confirm that there was no problem in the surgical site. If there were no significant findings, the Jackson-Pratt drain tube was removed. At 2 weeks after the patient was discharged, the operation wound was assessed at the outpatient clinic. At

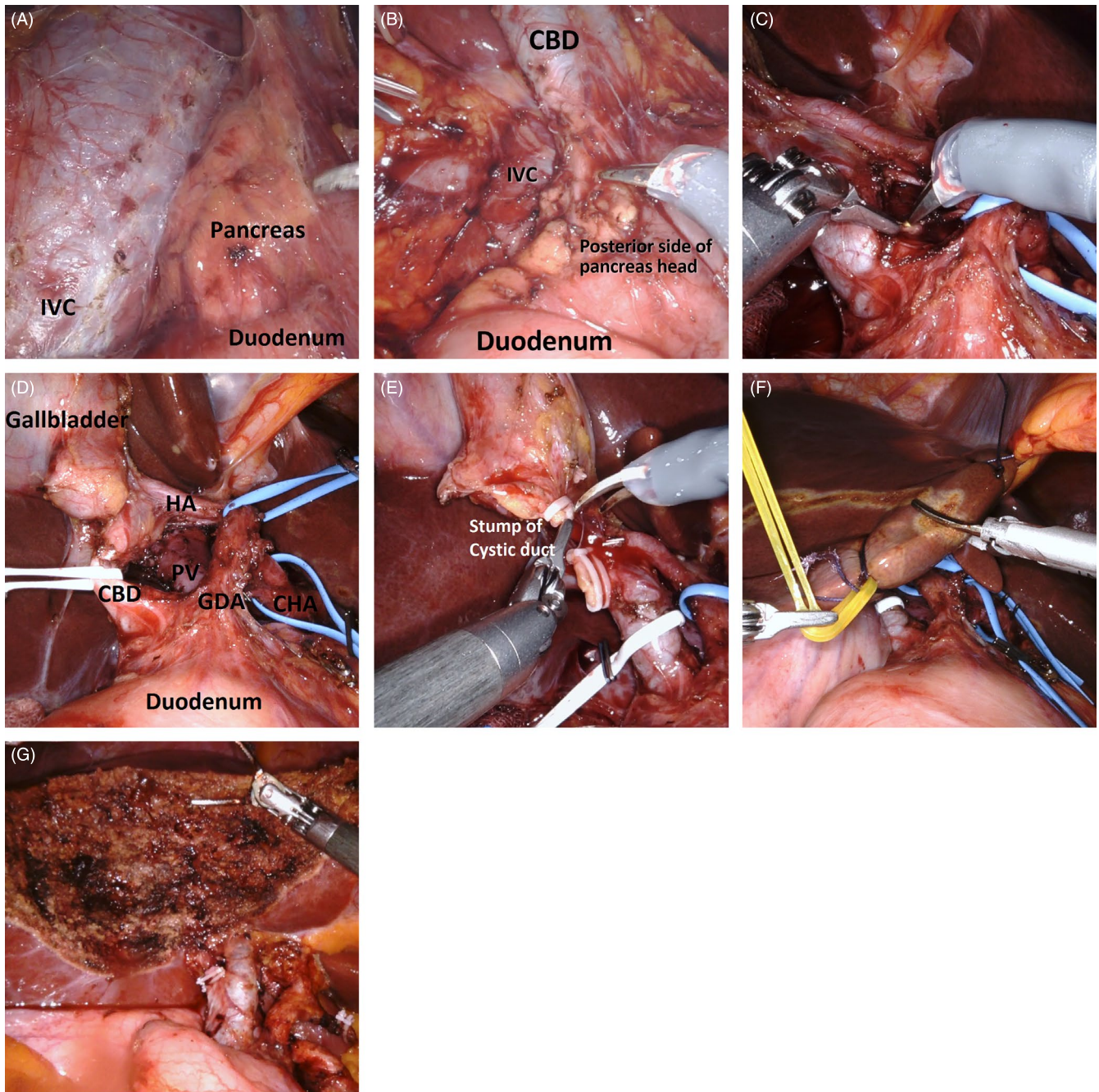
3 months after the operation, a CT scan was performed and tumor markers were assessed.

### 2.4 | Statistical methods

To compare the difference between conventional open and robotic EC, the two groups were matched by the 1:3 propensity score. The factors used in the match included sex, age, BMI, T stage. The independent *t* test was used for continuous variables with normal distribution, and the Kruskal-Wallis H test was used for continuous variables. Fisher's exact test was used for the ratio comparison between the two groups. The general linear model was used to compare the intensity of postoperative pain by the surgical method.

## 3 | RESULTS

Overall, 13 patients who were radiologically diagnosed with GBC before surgery underwent REC, eight of which (61.5%) were male, the mean age was  $63.5 \pm 10.5$  years, and the mean BMI was  $24.4 \pm 2.6$  kg/m<sup>2</sup>. All of the patients were diagnosed with clinical T2 or later stages of GBC based on the preoperative HRUS/EUS and CT. The mean operation time was  $187.7 \pm 34.6$  min, and the estimated blood loss was  $270.8 \pm 297.9$  mL. As all patients had no evidence of tumor involvement at the cystic duct margin, an additional biliary duct resection was not required. With regards to pathologic stages, five patients (38.5%) were confirmed with earlier than T2 stages, and the other eight patients (61.5%) had T2 or more advanced stages. The mean number of lymph nodes obtained after lymphadenectomy was  $7.2 \pm 3.1$ , and there was no case that the tumor cell involved the resection margin. The mean duration of hospital stay was  $6.6 \pm 1.7$  days. Overall, two patients (15.4%) showed the postoperative complications, one patient who had fluid collection in the gallbladder bed postoperatively was treated with percutaneous drainage and was hospitalized for 11 days. The other one complained of surgical wound problems and was treated via outpatient clinic after discharge. But, there were no cases of 90-day mortalities. According to the 1:3 propensity score matching, 39 cases with the same operation by the open method were compared, with 13 cases of REC. There were no significant differences in the operation time, estimated blood loss, number of retrieved lymph nodes, and percentage of complicated cases. However, with respect to the duration of hospital stay, the REC group was discharged earlier (6.6 vs 8.3 days,  $P = .002$ ) (Table 1). In order to compare the degree of postoperative pain by the operation method, the effect of time variation was corrected through a general linear model, and the degree of postoperative pain was significantly less in the REC group ( $P = .024$ ) (Figure 4). [Correction added on 26 June 2020



**FIGURE 3** Surgical procedures. A, Kocherization. B, The picture after No. 13 lymph node dissection. C, Lymph node dissection using articulated robotic scissors. D, Lymph node dissection. E, Ligation of cystic duct. F, End of procedures

after first online publication. Table 1 was missed when the article was first published online due to publisher's error. The table is now included in the updated article.]

## 4 | DISCUSSION

Since the introduction of laparoscopic methods in the 1980s for the resection of the gallbladder, the conventional open approach has been replaced. Even if there are factors that make the laparoscopic approach difficult, the cases of upfront

laparotomy for benign gallbladder disease are very rare.<sup>2-4</sup> Furthermore, there have been reports of successful results of a single-port LC or robotic cholecystectomy, which has been further advanced for MIS. This trend towards MIS has been reported not only in simple cholecystectomy but also in pancreaticoduodenectomy or major hepatectomy, which is regarded as a relatively difficult procedure.<sup>5,6</sup>

Nevertheless, the laparoscopic approach for GBC has not been universally introduced in the 40 years since the introduction of laparoscopic surgery for benign gallbladder disease.<sup>7,8</sup> According to the guidelines published by the Japanese Society

**TABLE 1** Comparison REC and open EC cases by 1:3 propensity score matching

Variables	REC (n = 13)	Open EC (n = 39)	P-value
Sex (male, %)	8 (61.5%)	22 (56.4%)	.503
Age (y, mean ± SD)	63.5 ± 10.5	65.0 ± 10.5	.660
BMI (kg/m <sup>2</sup> , mean ± SD)	24.4 ± 2.6	24.0 ± 2.7	.681
Location			.837
Fundus	7 (53.8%)	16 (42.1%)	
Body	4 (30.8%)	17 (44.7%)	
Neck	1 (7.7%)	2 (5.3%)	
Multiple	1 (7.7%)	3 (7.9%)	
Operation time (min, mean ± SD)	187.7 ± 34.6	187.4 ± 50.3	.984
EBL (mL, mean ± SD)	209.2 ± 118.6	311.9 ± 204.4	.079
T stage <sup>a</sup>			
Early than T2	5 (38.5%)	12 (30.8%)	.425
T2 or later	8 (61.5%)	27 (69.2%)	
Number of retrieved lymph nodes (mean ± SD)	7.2 ± 3.1	7.8 ± 4.9	.650
Number of metastatic lymph nodes (mean ± SD)	0.7 ± 1.3	0.6 ± 1.6	.931
Hepatic invasion (%)	2 (15.4%)	5 (12.8%)	.568
Postoperative complication (%) <sup>b</sup>	2 (15.4%)	7 (17.9%)	.601
Hospital stay (d, mean ± SD)	6.6 ± 1.7	8.3 ± 1.9	.002
90 d mortality (%)	0	0	
Follow-up duration (d, mean ± SD)	4.3 ± 4.6	27.0 ± 20.1	<.001

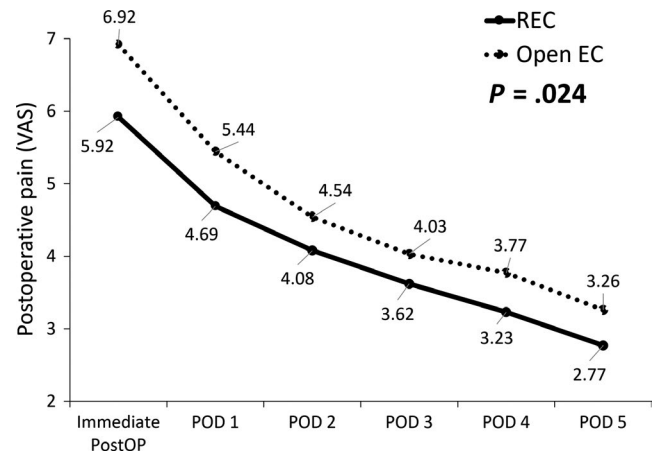
Abbreviations: BMI, Body mass index; EBL, Estimated blood loss; EC, Extended cholecystectomy; REC, Robot extended cholecystectomy; SD, Standard deviation.

<sup>a</sup>AJCC 8th.

<sup>b</sup>Clavien-Dindo classification grade IIIA or over.

of Hepato-Biliary-Pancreatic Surgery in 2015, laparoscopic surgery should not be performed if GBC is suspected, but it is recommended that laparotomy be performed instead.<sup>9</sup> Based on the National Comprehensive Cancer Network (NCCN) in 2019, EC is also recommended for T1b GBC. However, favorable reports have been published recently on simple LC for T1b and T1a GBC.<sup>10-13</sup>

Recently, Kim et al<sup>1</sup> reported the results of an international multicenter study of 237 patients (189 Asians, 48 Americans) with T1b GBC. According to this study, the 5-year disease-specific survival rate did not differ statistically according to the surgical method (EC, 95.5%; simple

**FIGURE 4** Comparison of the trends of postoperative pain between robotic extended cholecystectomy (REC) and open extended cholecystectomy (EC) by general linear model (GLM)

cholecystectomy, 93.7%;  $P = .496$ ). There was no statistically significant difference in the 5-year disease-specific survival rates according to laparotomy and laparoscopy in patients undergoing simple cholecystectomy (open, 94.9%; laparoscopic, 92.8%;  $P = .267$ ). They concluded that EC was unnecessary in T1b GBC, based on accurate pathological diagnosis.

However, in cases of advanced GBC that require EC, there are several concerns for laparoscopic resection. Although there have been several reports of successful results for laparoscopic EC recently, these have been limited to some highly specialized centers.<sup>14-17</sup>

In terms of regional lymph node dissection, which is essential for EC, MIS may result in an oncologically insufficient dissection compared to the conventional open method.<sup>18</sup> Because advanced GBC has a higher possibility of nodal involvement, obtaining a sufficient number of lymph nodes is associated with prognosis.<sup>19-21</sup> Generally, the resection and histologic evaluation of at least six lymph nodes improves risk-stratification of GBC.<sup>19,20,22,23</sup> Although there is no absolute criterion for the minimum number of lymph nodes needed for lymphadenectomy in GBC, according to the results reported so far, at least six lymph nodes are appropriate for accurate staging and stratification of prognosis. In a review of 51 patients with incidental GBC who underwent the laparoscopic lymphadenectomy, De Aretxabala et al<sup>24</sup> reported that the average number of harvested lymph nodes was 7.9 (range 3-16), which was not statistically different from the converted group (mean 8.7; range 4-12) ( $P > .05$ ).

In our study, the number of lymph nodes retrieved through REC was  $7.2 \pm 3.1$ , and there was no statistically significant difference in comparison with the open method ( $7.8 \pm 4.9$ ,  $P = .650$ ). Although there has been no established standard for lymph node dissection in cases of GBC, the number of retrieved lymph nodes in this study through MIS using a robot satisfies at least six lymph nodes criteria. Furthermore, there was no statistically significant difference compared with the open method.

Currently, there is no widely accepted consensus for the extent of lymphadenectomy for GBC. According to some related studies, we can conclude that the range of lymphadenectomy should include the posterosuperior pancreatic head lymph nodes along the hepatoduodenal ligament and the hepatic artery.<sup>25-27</sup> For sufficient lymphadenectomy in these narrow areas, critical structures such as the hepatic artery, portal vein, and common bile duct must be fully skeletonized. It is neither safe nor easy to perform with conventional straight laparoscopic instruments.

In addition, laparoscopic liver resection may be an obstacle of MIS for EC. However, in the field of liver resection, since the introduction of MIS, it has been reported that laparoscopic liver resection is feasible for oncologic and safe resection.<sup>5,28,29</sup>

However, these results were all reported by experienced operators in the limited number of specialized centers, so it is still challenging to dissect the liver parenchyma through MIS. This is because when the liver is resected through MIS, it is difficult to obtain a clear image that can distinguish the liver parenchyma from the microvessels and bile ducts, and to cope with these cases when a significant amount of bleeding occurs as a result of these structures being damaged.

Therefore, the application of MIS for advanced GBC performed by an experienced surgeon at the specialized center is a viable surgical option.<sup>14-17</sup> However, by only accumulating experience, it is impossible to overcome all the technical obstacles mentioned above. In this regard, it can be considered that some features of a robotic system can be applied to help overcome the obstacles.

First, because the robot arm has a wrist articulation, it can safely perform the regional lymphadenectomy compared to the straight laparoscopic instruments even in a confined space. In order to completely and safely dissect the surrounding soft tissues of the hepatoduodenal ligament, the robot's wrist arms can play a major role in this approach (Figure 3C). Since the robot system provides 3D stereoscopic images, it is helpful when performing relatively sophisticated work. These features are particularly advantageous in procedures in confined spaces, such as the lymph node dissection around the hepatoduodenal ligament,<sup>6</sup> and the hand tremor filtration helps the operator to perform the more exquisite works more safely.<sup>30</sup> There are no statistically significant differences in the operation time, estimated blood loss, and rate of complication compared to the conventional open method. The total number of retrieved lymph nodes demonstrated that oncologically sufficient lymphadenectomy can be performed as safely as with the open method.

Second, conventional open EC requires the inverted L-incision or the subcostal incision transecting the rectus abdominis muscle, which may lead to relatively severe pain and longer time to recovery. In our study, the postoperative pain was less in the REC group than those in open EC group, which showed a statistically significant difference in the

analysis using the general linear model (Figure 4). The REC group also showed shorter recovery period after surgery (6.6 vs 8.3 days,  $P = .002$ ).

Lastly, according to a published report of robot-assisted pancreaticoduodenectomy in our institution, 10-20 cases of robotic surgery showed a shorter learning curve and better manipulation than that observed in laparoscopic surgery.<sup>31</sup> The learning curve of robotic surgery is reportedly shorter than that of laparoscopy.<sup>32</sup> Additionally, the robot has a well-designed simulator system, which is helpful for new users who are seeking additional experience with the robot surgical system.<sup>33</sup>

However, similar to the laparoscopic instruments, there are limitations to the use of several instruments in robotic surgery. In particular, instruments such as the cavitron ultrasonic surgical aspirator, widely used in open hepatic resection, are not yet available for robotic surgery. However, it can be replaced with various ultrasonic electric shears or bipolar coagulators developed for robots.

This study has several limitations. First, this was a retrospective study with potential bias due to certain factors. In particular, the study cohort was small, therefore, the effects may not be clearly revealed. However, as the incidence of GBC is very rare and patients with stages treatable by minimally invasive EC are rare, the results of this study may be valuable as a basis for further studies. Second, because laparoscopic EC has not been performed at our center, a comparative study with laparoscopic EC was not possible. Third, since this study focused on early outcomes of REC, we did not perform the procedure on patients who required combined resection of the extrahepatic bile duct. However, as related experience accumulates, these indications may be extended in the future.

Because of the nature of the procedure, EC is not easily applied for MIS. However, this study shows that the application of the robotic system in GBC is a safe and feasible option, and can obtain oncologically sufficient lymph nodes. In addition, it can contribute to shorter recovery period and less postoperative pain. By improving the faults of the current robotic system and by further analysis of long-term survival data, REC is expected to be a promising treatment option for GBC.

## CONFLICT OF INTEREST

None declared.

## ORCID

Yoonhyeong Byun  <https://orcid.org/0000-0002-4258-891X>

Yoo Jin Choi  <https://orcid.org/0000-0002-1142-1842>

Jae Seung Kang  <https://orcid.org/0000-0001-6587-9579>

Youngmin Han  <https://orcid.org/0000-0003-0456-7824>

Hongbeom Kim  <https://orcid.org/0000-0002-1595-0135>

Wooil Kwon  <https://orcid.org/0000-0002-4827-7805>

Jin-Young Jang  <https://orcid.org/0000-0003-3312-0503>

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