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Original Article

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Clinical Feasibility of Vascular Navigation System During Laparoscopic Gastrectomy for Gastric Cancer: A Retrospective Comparison With Propensity-Score Matching

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ABSTRACT

Purpose: The usability of a new surgical navigation system that provides patient-specific vascular information for robotic gastrectomy in gastric cancer remains unexplored for laparoscopic gastrectomy owing to differences in surgical environments. This study aimed to evaluate the applicability and safety of this navigation system in laparoscopic gastrectomy and to compare the post-operative outcomes between procedures with and without its use.
Materials and Methods: Between June 2022 and July 2023, 38 patients across 2 institutions underwent laparoscopic gastrectomy using a navigation system (navigation group). The technical feasibility, safety, and accuracy of detecting variations in vascular anatomy were measured. The perioperative outcomes were compared with 114 patients who underwent laparoscopic gastrectomy without a navigation system (non-navigation group) using 1:3 propensity score matching during the same study period.
Results: In all patients in the navigation group, no adverse events associated with the navigation system occurred during surgery in any patient in the navigation group. No accidental vessel injuries necessitate auxiliary procedures. All vessels encountered during the gastrectomy were successfully reconstructed and visualized. Patient demographics and operative data were comparable between the 2 groups. The navigation group exhibited a significantly lower overall complication rate (10.5%) than the non-navigation group (26.3%, P=0.043). Notably, pancreas-related complications were absent in the navigation group but occurred in eight cases in the non-navigation group (7.0%, P=0.093), although the difference was not statistically significant.
Conclusions: The patient-specific surgical navigation system demonstrated clinical feasibility and safety for laparoscopic gastrectomy for gastric cancer, potentially reducing complication rates compared with laparoscopic gastrectomy without its use.

Keywords: Gastric cancer; Gastrectomy; Anatomy; Surgical navigation

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Conflict of Interest
Dr. Han and Dr. Kwon had full access to all study data and ensured the integrity and accuracy of data analysis. The authors declare no potential conflicts of interest.

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INTRODUCTION

Gastric cancer is a prevalent and major cause of cancer-related mortality worldwide [1]. Radical gastrectomy with systemic lymph node dissection is the best treatment option for patients with gastric cancer [2-4]. Accurate systemic lymph node dissection requires complete removal of soft tissues along the vessels around the stomach. A precise knowledge of the vascular anatomy of the stomach is a prerequisite for safe systemic lymph node dissection during radical gastrectomy [5,6]. The vascular anatomy around the stomach is complex and varies widely. Moreover, it is impossible to predict the vascular structure in each patient. Thus, providing patient-specific vascular anatomy would facilitate safer and easier systemic lymph node dissection [7-10].

Technological advancements have enabled the visualization of patient-specific anatomy from diverse radiological images, such as computed tomography (CT) and magnetic resonance imaging [11-13]. Recently, a study that evaluated a new surgical navigation system that provides patient-specific 3-dimensional (3D) vascular information demonstrated its clinical feasibility and applicability in robotic gastrectomy for gastric cancer. This system enables patient-specific pre-operative planning and intraoperative vascular navigation by visualizing all vascular anatomies required for robotic gastrectomy without errors [7]. However, the unique surgical environment of laparoscopic procedures, which lacks a multiple-display system, imposes constraints on the surgeons' ability to manipulate the navigation system during the laparoscopic procedure. Thus, the technical feasibility of this navigation system for laparoscopic gastrectomy remains unexplored, highlighting a notable gap in our understanding of the potential benefits of laparoscopic approaches.

This study evaluated the applicability and safety of a navigation system that provides patient-specific vascular anatomy of the stomach for pre-operative planning and intraoperative guidance during laparoscopic gastrectomy with systemic lymph node dissection.

MATERIALS AND METHODS

Patients

The medical records of patients with gastric cancer who underwent laparoscopic gastrectomy at 2 institutions (Ajou University Medical Center and Gangnam Severance Hospital) were retrospectively reviewed. From June 2022 to July 2023, the 2 institutes employed a vascular navigation system (RUS-GA; Hutom, Seoul, Korea) when performing laparoscopic gastrectomy in patients with gastric cancer. The control group comprised patients who underwent laparoscopic gastrectomy for gastric cancer during the same period but without the navigation system. Owing to its retrospective nature, propensity score matching was performed to adjust for confounding variables for comparison between groups as much as possible. After propensity score matching, outcomes were compared between patients who underwent surgery (navigation group) and those who did not (non-navigation group). Patients with a history of gastric surgery that altered the major vascular structures around the stomach, those who underwent palliative or conversion surgery, or those who required simultaneous resection of other organs were excluded.

This study was approved by the Institutional Review Boards (IRBs) of Gangnam Severance Hospital, Yonsei University Health System, and Ajou University School of Medicine (IRB

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number: 3-2024-0067, AJOUIRB-DB-2024-197). The requirement for informed consent from patients included in the study was waived by the IRB of the 2 institutes because of the study's retrospective nature.

Process of surgical navigation

The surgical navigation process for laparoscopic gastrectomy is similar to that for robotic gastrectomy, as described by Park et al. in a previous publication [7]. All patients in the navigation group underwent multidetector-row CT scanning according to a specific protocol for abdominopelvic CT angiography in a 15-degree reverse Trendelenburg position, as described previously. Thereafter, the Digital Imaging and Communications in Medicine (DICOM) file containing the other patients' CT scan images and clinical features was transferred to a server. Artificial intelligence technology performed 3D reconstruction of intra-abdominal organs and vessels and generated a patient-specific pneumoperitoneum model. This system provides anatomical navigation before and during surgery, allowing surgeons to reference recorded pre-operative planning and simulations during laparoscopic gastrectomy port placement. **Fig. 1** shows an example of virtual port placement based on patient-specific anatomy simulation. The navigation system provides five areas of predefined points of interest for easier control: the splenic lower pole, infra-pyloric artery, supraduodenal, celiac trunk, and upper border areas of the pancreas.

Laparoscopic gastrectomy for gastric cancer procedures with the navigation system

Surgeons with adequate experience in gastric cancer oncology performed all the surgeries. Four surgeons at Ajou University Medical Center with over 2-, 8-, 12-, and 25-year experience in gastric cancer surgery and a surgeon at Gangnam Severance Hospital with experience in gastric cancer surgery over 8-years performed all surgeries during the study period. During the laparoscopic gastrectomy procedure, the RUS GA client computer was connected to a separate monitoring system via an HDMI port to display the navigation images. A separate monitor system was placed side-by-side to the laparoscopic view monitor (**Fig. 2**). During surgery, the surgeon or assistant uses a Bluetooth mouse to control the navigation software to display the correlating vascular anatomy and intra-abdominal organs and to align them with the real-time laparoscopic operative view.

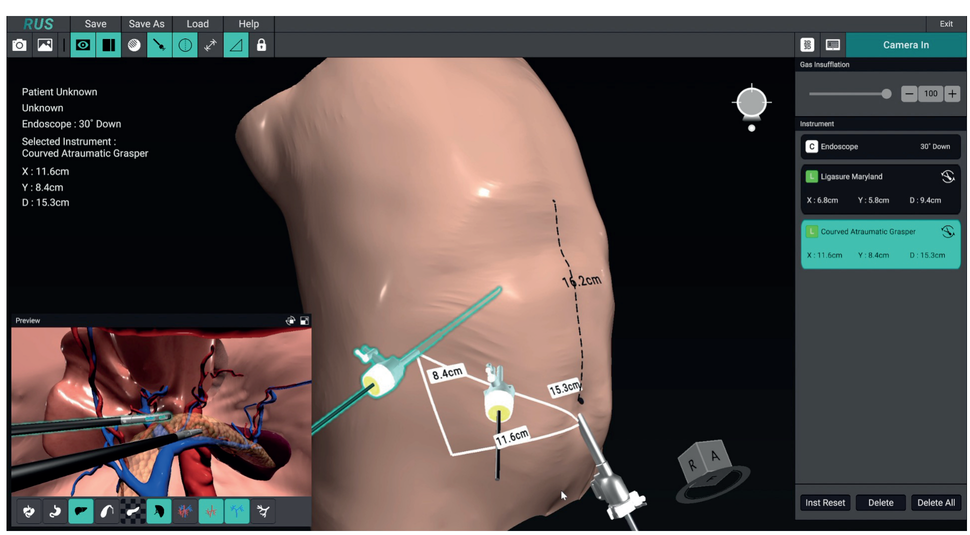

Fig. 1. Patient-specific anatomy simulation.

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Fig. 2. Intraoperative view of laparoscopic gastrectomy for gastric cancer using the navigation system.

Outcome measures

The primary outcome was the technical feasibility of using the navigation system for laparoscopic gastrectomy. The feasibility was evaluated by assessing the error rate of the model delivery and the percentage of successful use of the navigation system to perform the laparoscopic gastrectomy until its use for operation. The secondary outcomes were safety and perioperative compared with those of patients who underwent laparoscopic gastrectomy without the navigation system. Safety was assessed by monitoring for any adverse events related to CT scanning and intraoperative navigation system use. The reconstructed vascular model information regarding each blood vessel's origin, location, and variations were compared with the actual intraoperative findings during laparoscopic gastrectomy.

Statistical analyses

Propensity score matching was used to mitigate selection bias between the navigation and non-navigation groups by adjusting for the comparison of confounding variables between groups. Variables potentially affecting surgical outcomes were matched by adjusting for the following seven variables: patient demographics (age, sex, body mass index, and American Society of Anesthesiology score), surgical features (extent of resection and extent of lymph node dissection), and hospital factors. Using the above seven covariates, we used a logistic regression model to estimate the propensity scores. After that, we used the nearest neighbor matching method with a none-discard strategy at a 1:3 ratio, as implemented in the 'matchit' package in R. Although we did not explicitly set a caliper, we calculated standardized mean differences between the 2 groups after propensity score matching to evaluate the balance between the 2 groups.

Categorical variables were presented as numbers (percentages). The χ^2 or Fisher's exact tests were used for categorical variables, as appropriate. Continuous variables are presented

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as mean ± standard deviation or median with interquartile range (IQR), depending on whether the variable had a normal distribution. Student's t-test or Mann–Whitney U test was performed for continuous variables when comparing groups, as appropriate. Statistical significance was set at P<0.05. All statistical analyses were performed using R (version 4.2.0; R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Patients' characteristics

Between June 2022 and July 2023, 212 patients underwent laparoscopic gastrectomy at the Ajou University Medical Center and Gangnam Severance Hospital. Among them, 39 underwent laparoscopic gastrectomy using a vascular navigation system (21 at Ajou University Medical Center and 18 at Gangnam Severance Hospital), whereas 173 underwent laparoscopic gastrectomy without a vascular navigation system (78 at Ajou University Medical Center and 95 at Gangnam Severance Hospital). Six patients were excluded before propensity score matching: one from the navigation group because of simultaneous cholecystectomy and 5 from the non-navigation group, including 2 simultaneous cholecystectomies, 1 bilateral salpingo-oophorectomy, 1 small bowel segmental resection, and 1 palliative resection. After propensity matching, the navigation (n=38) and non-navigation groups (n=114) were well-balanced in terms of demographics, and the pathological outcomes between the navigation and non-navigation groups were comparable (**Table 1**). The process of study is illustrated in the diagram (**Fig. 3**).

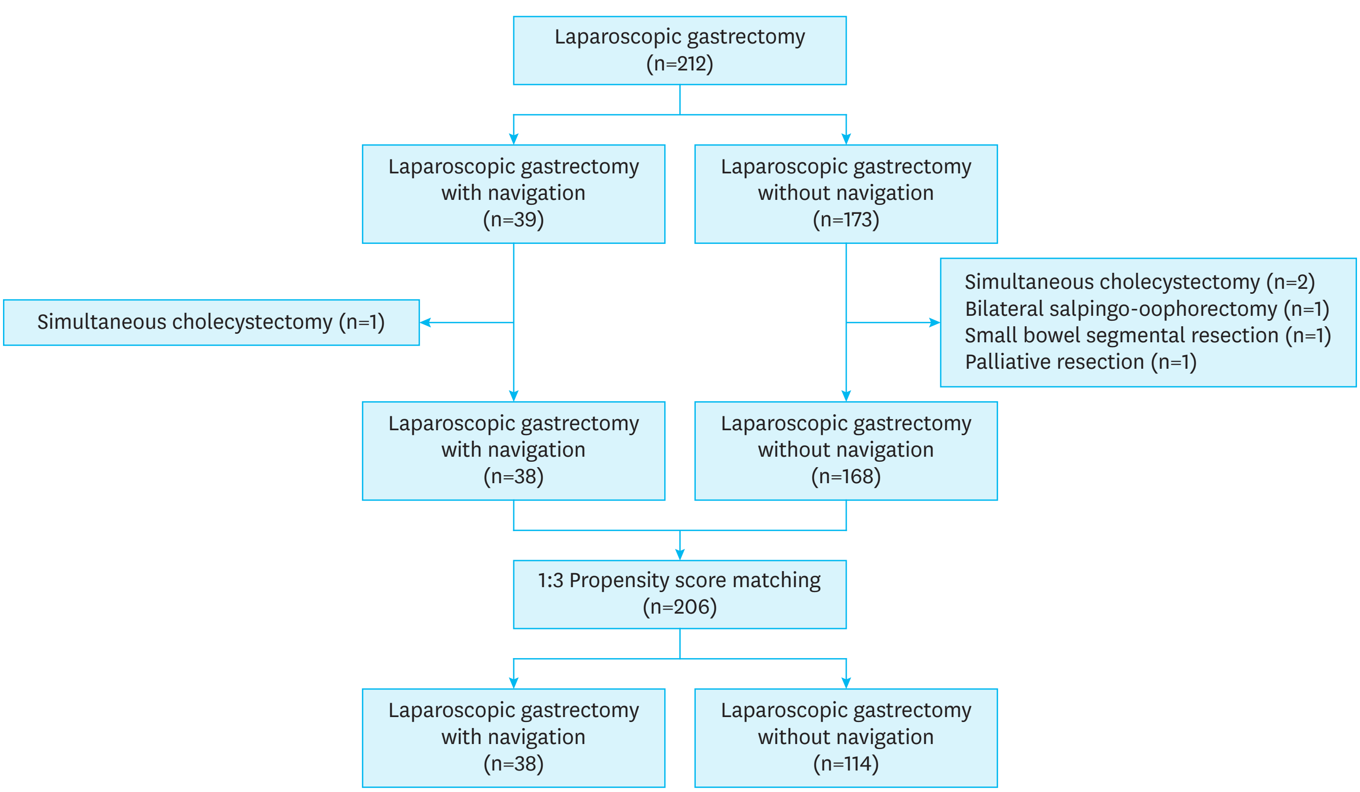

Fig. 3. The study flow diagram.

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Table 1. Comparison of patient characteristics between the 2 groups (navigation vs. non-navigation) after propensity score matching

Characteristics	Navigation (n=38)	Non-navigation (n=114)	P-value (SMD, %)
Institution*			0.639
Institution A	21 (55.3)	58 (50.9)	(8.8)
Institution B	17 (44.7)	56 (49.1)	(−8.8)
Sex			0.847
Male	24 (63.2)	70 (61.4)	(3.6)
Female	14 (36.8)	44 (38.6)	(−3.6)
Age (yr)	59.7±11.1	61.0±11.8	0.526 (−12.5)
Body mass index (kg/m²)	24.3±3.5	24.3±3.7	0.944 (−1.4)
ASA score			0.533
1	9 (23.7)	18 (15.8)	(18.6)
2	24 (63.2)	81 (71.1)	(−16.4)
3	5 (13.2)	15 (13.2)	(0.0)
Previous abdominal surgery			0.913
Yes	9 (23.7)	28 (24.6)	(2.0)
No	29 (76.3)	86 (75.4)	(−2.0)
Clinical T stage			0.95
T1	25 (65.8)	78 (68.4)	(−5.6)
T2	5 (13.2)	13 (11.4)	(5.2)
T3	4 (10.5)	13 (11.4)	(−2.9)
T4	4 (10.5)	10 (8.8)	(5.7)
Clinical N stage			0.327
N0	32 (84.2)	99 (86.8)	(−7.2)
N1	2 (5.3)	10 (8.8)	(−15.7)
N2–3	4 (10.5)	5 (4.4)	(20.0)
Extent of gastric resection			0.697
Distal subtotal	35 (92.1)	108 (94.7)	(−9.8)
Total	2 (5.3)	4 (3.5)	(7.9)
Proximal	1 (2.6)	2 (1.8)	(5.5)
Extent of lymphadenectomy			0.917
D1+	27 (71.0)	82 (71.9)	(−1.9)
D2	11 (28.9)	32 (28.1)	(1.9)
Anastomosis			0.960
Billroth I	10 (26.3)	30 (26.3)	(0.0)
Billroth II	16 (42.1)	49 (43.0)	(−1.7)
Roux-en-Y gastrojejunostomy	9 (23.7)	29 (25.4)	(−4.1)
Roux-en-Y esophagojejunostomy	2 (5.3)	4 (3.5)	(7.8)
Double tract	1 (2.6)	2 (1.8)	(5.5)
Tumor size (mm)	26.0 (12.8–46.8)	23.5 (16.0–40.0)	0.975 (8.8)
Pathologic T stage			0.585
T1	30 (78.9)	93 (81.6)	(−6.5)
T2	2 (5.3)	8 (7.0)	(−7.9)
T3	4 (10.5)	5 (4.4)	(20.0)
T4a	2 (5.3)	8 (7.0)	(−7.9)
Pathologic N stage			0.723
N0	30 (78.9)	94 (82.5)	(−8.6)
N1	4 (10.5)	12 (10.5)	(0.0)
N2–3	4 (10.5)	8 (7.0)	(11.4)
AJCC 8th stage			0.468
I	30 (78.9)	98 (86.0)	(−17.2)
II	3 (7.9)	7 (6.1)	(6.5)
III	5 (13.2)	9 (7.9)	(15.6)

Continuous variables were presented as mean ± standard deviation or median (interquartile range), depending on whether they followed a normal distribution. Categorical variables are presented as numbers (percentages).
SMD = standardized mean difference; ASA = American Society of Anesthesiology; AJCC = American Joint Committee on Cancer.
*Institutions A and B refer to Ajou University Medical Center and Gangnam Severance Hospital, respectively.

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Safety and feasibility

None of the 38 patients in the navigation group had comorbidities that rendered the pre-operative CT with angiography unsafe. All CT examinations were performed without adverse events. The DICOM file containing the CT scan images and patients' clinical information was successfully transferred to a server for all 38 patients (100.0%). Reconstruction of intra-abdominal organs and vessels around the stomach using artificial intelligence-based technology, texturing of the reconstructed intra-abdominal organs and vessels, and generation of a patient-specific pneumoperitoneum model were completed without any system errors in all 38 patients (100.0%). All reconstructed pneumoperitoneum models were successfully delivered to a client computer with a navigation system. All the pre-operative simulation processes for virtual trocar placement, instrumentation, and intraoperative vascular navigation were completed without transfer or connection problems. No adverse events were associated with using the navigation system during surgery. Additionally, no accidental vessel injuries caused by the combined operation on other organs occurred.

Operative outcomes

The operative details of the 2 groups were comparable (**Table 1**). Regarding the efficacy of the lymph node dissection, the number of retrieved lymph nodes was similar between the navigation group (41.5; IQR, 33.25–53.75) and in the non-navigation group (43.0; IQR, 33.0–51.75; P=0.732). Anesthesia, operative time, and estimated blood loss were similar between the 2 groups (P=0.216, P=0.250, and P=0.476, respectively). The length of hospital stays between the 2 groups did not differ (P=0.733) (**Table 2**).

The complication rates were significantly lower in the navigation group (10.5%) than in the non-navigation group (26.3%, P=0.043). Complications more significant than Clavien–Dindo grade 2 were also significantly lower in the navigation group (7.9%) than in the non-navigation group (24.6%, P=0.027). However, the post-operative C-reactive protein levels were similar between the navigation and non-navigation groups pre-operatively and on post-

Table 2. Comparison of surgical outcome and laboratory results between the 2 groups (navigation vs. non-navigation)

Surgical outcome and laboratory results	Navigation (n=38)	Non-navigation (n=114)	P-value
Anesthesia time (min)	207.5 (180.0–232.5)	195.0 (181.3–223.8)	0.216
Total operation time (min)	166.2±37.4	158.4±34.7	0.245
Estimated blood loss (mL)	50.0 (30.0–100.0)	50.0 (30.0–100.0)	0.476
Retrieved lymph node number	41.5 (33.25–53.75)	43.0 (33.0–51.75)	0.732
Length of hospital stay (days)	6.0 (5.0–7.0)	6.0 (5.0–6.0)	0.733
Serum C-reactive protein (mg/L)			
Pre-operative	0.534±1.05	0.576±1.06	0.831
POD #1	26.7±20.8	26.4±19.6	0.959
POD #2	26.1±36.7	34.6±52.1	0.464
POD #3	104.8±74.7	106.7±67.8	0.922
POD #5	56.8±50.8	73.8±50.5	0.229
Serum amylase (u/L)			
POD #1	153.5±303.8	115.3±151.0	0.304
POD #3	102.4±79.5	80.8±87.9	0.353
POD #5	90.7±53.5	87.2±73.8	0.801
Serum lipase (u/L)			
POD #1	60.9±47.6	68.5±111.1	0.683
POD #3	75.9±61.3	58.0±49.9	0.215
POD #5	123.4±58.9	141.5±124.6	0.555

Continuous variables were presented as mean ± standard deviation or median (interquartile range), depending on whether they followed a normal distribution. The Student's t-test or Mann–Whitney U test was performed depending on the normality of distribution when comparing groups, as appropriate.
POD = postoperative day.

Table 3. Comparison of post-operative complications between the 2 groups (navigation vs. non-navigation)

Post-operative complications	Navigation (n=38)	Non-navigation (n=114)	P-value
Post-operative complication			0.043
No	34 (89.5)	85 (73.7)	
Yes	4 (10.5)	29 (26.3)	
Clavien-Dindo grade			0.183
I	1 (2.6)	1 (0.9)	
II	3 (7.9)	23 (20.2)	
III	0 (0.0)	5 (4.4)	
Post-operative complication, Clavien-Dindo grade ≥2			0.027
No	35 (92.1)	86 (75.4)	
Yes	3 (7.9)	28 (24.6)	
Post-operative pancreas-related complication			0.093
No	38 (100.0)	106 (93.0)	
Yes	0 (0.0)	8 (7.0)	
Complication type			0.772
No	34 (89.5)	85 (73.7)	
Surgical	4 (100.0)	14 (48.3)	
Pancreatitis or pancreatic abscess		8	
Chylous ascites	1	0	
Intraluminal bleeding	1	1	
Intraabdominal bleeding		1	
Anemia		2	
Intestinal obstruction		1	
Roux stasis	1		
Afferent loop perforation		1	
Unknown origin inflammation	1		
Medical	0 (0.0)	15 (51.7)	
Pulmonary		5	
Urinary		4	
Cardiac		2	
Others		4	

Continuous variables were presented as mean (standard deviation) or median (interquartile range), depending on whether they followed a normal distribution. The Student's t-test or Mann–Whitney U test was performed depending on the normality of distribution when comparing groups, as appropriate.
Categorical variables were presented as numbers (percentages). The χ^2 or Fisher's exact test was used depending on the expected frequency counts when comparing groups, as appropriate.

operative days 1, 2, 3, and 5 (P>0.05). Notably, no pancreas-related complications occurred in the navigation group, while eight (7.0%) pancreatitis- or pancreas-related complications occurred in the non-navigation group (P=0.093), although the difference was insignificant. The post-operative pancreatic enzyme levels were similar between the 2 groups (**Table 3**).

DISCUSSION

This study demonstrated the clinical feasibility of using a patient-specific gastrectomy navigation system for laparoscopic gastrectomy in gastric cancer without any adverse events. This surgical navigation system successfully delivered virtual models containing important information on the vascular variations and paths of all vessels encountered during lymph node dissection. This surgical navigation system enables surgeons to implement patient-specific pre-operative planning and intraoperative vascular navigation for laparoscopic gastrectomy in patients with gastric cancer. Additionally, patients who underwent gastrectomy with the navigation system had fewer post-operative complications than those without the navigation system.

Several studies have demonstrated successful visualization of perigastric vessels essential for gastrectomy using reconstructed images of 3D CT angiography images [8-10]. However, these studies only provided anatomical information about blood vessels around the stomach and demonstrated its availability for laparoscopic gastrectomy without showing clinical applicability or clinical outcomes. Although some software systems enable the reconstruction of vascular structures from CT images, this requires a time-consuming, laborious, and difficult manual reconstruction process [14,15]. Furthermore, patients are positioned supine during CT scanning and placed in a reverse Trendelenburg position during surgery. Consequently, a disparity arises between the reconstructed CT image and the actual intraoperative image owing to the gravitational effects on organs and blood vessel deformation caused by differences in patient posture.

By using the navigation system, surgeons can avoid additional manual reconstruction when using virtual vascular models for laparoscopic gastrectomy because 3D reconstruction models are provided for the navigation system without extra work. Moreover, this navigation system delivers the patient-specific perigastric vascular anatomy in a virtual simulation environment and a patient-specific pneumoperitoneum model. The patient-specific pneumoperitoneum model enables pre-operative planning, such as trocar placement, and provides a virtual view of the actual operative view by employing a virtual 30° downview camera through a virtual trocar camera. To minimize the effects of gravity-induced organ and vessel deformation, the system requires a CT scan in the 15° reverse Trendelenburg position, consistent with the position during laparoscopic gastrectomy. Consequently, the navigation system's virtual vascular images closely mimic the blood vessels observed during surgery, with nearly identical locations. Moreover, no commercially available vascular navigation system has been explicitly used for laparoscopic gastrectomy except the one used in this study.

The navigation system also provides clinical benefits. Systematic lymphadenectomy is essential for gastric cancer gastrectomies. For safer lymphadenectomy, identifying the vessels around the stomach is critical because the lymphadenectomy procedure involves skeletonizing and dividing vessels covered by fat tissue. The navigation system provided the vascular anatomy required for gastrectomy, facilitating safer lymphadenectomy, although the number of retrieved lymph nodes was similar between the 2 groups. Lymphadenectomy around the infrapyloric and suprapancreatic areas is critical during laparoscopic gastrectomy. Specifically, infra-pyloric and supra-pancreatic area lymphadenectomies require the removal of soft tissue around the pancreas, which may cause post-operative complications such as pancreatitis, pancreatic fistula, and peripancreatic abscess [16-18]. Complicated vascular anatomy around the pancreas poses technical difficulties and may cause direct injury to the pancreas. By adopting a navigation system, surgeons can dissect the soft tissues around small or deep-seated vessels more accurately and carefully around the pancreas, based on the exact vascular anatomy rather than guesswork or knowledge from previous experience.

Providing accurate patient-specific vascular anatomical information would reduce the experience gap from anatomical knowledge barriers between experienced and novice surgeons. Therefore, this navigation system helps inexperienced surgeons safely and efficiently perform laparoscopic gastrectomy by providing patient-specific anatomy. Accurate anatomical information about the pancreas may prevent potential injury during lymphadenectomy [19-21]. These benefits likely influenced the lower complication rate observed in the navigation group. No pancreas-related complications were observed with the navigation system. In contrast, pancreas-related complications occurred in 7.0% of patients

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who underwent laparoscopic gastrectomy without this complication in this study. However, no significant differences were observed between the groups.

First, this was a retrospective study with a small sample size. The small number of patients included in the navigation group limited the verification of the clinical benefits of this navigation system compared to that of the non-navigation group. However, 1:3 propensity score matching was performed to reduce selection bias by adjusting as much as possible for confounding variables between groups. Therefore, a randomized controlled study with a larger patient cohort is required to validate its clinical efficacy for routine application.

The use of a navigation system during laparoscopic gastrectomy presents a technical challenge. Unlike robotic surgery, which uses embedded multi-image display software to view navigation and operative images simultaneously, laparoscopic surgery requires an additional monitor to visualize the navigation system owing to its lack of multi-image display functionality. Moreover, simultaneously viewing images on 2 separate side-by-side monitors poses a challenge. Therefore, better image display tools that accommodate operative and navigational system images are required. Another aspect is the complexity of manipulating the navigation software during surgery, which entails manual manipulation during procedures, necessitating an additional individual to control the software in the operating room. Alternatively, the operator or assistant can use an aseptically covered Bluetooth mouse during surgery, further complicating the performance of the operational team. Therefore, implementing a voice control system or automatic synchronization of the navigation image to align it with the actual operative view would prevent interruptions during surgery for navigation system control.

In conclusion, this study confirmed the feasibility and safety of a patient-specific surgical navigation system for laparoscopic gastrectomy in patients with gastric cancer without any observed adverse effects. Because this navigation system has already demonstrated technical applicability in robotic gastrectomy for gastric cancer, it can be effectively used for minimally invasive gastrectomy. Moreover, the navigation system may reduce post-operative complications compared to laparoscopic gastrectomy without integration. Specifically, it may enhance safe lymph node dissection during laparoscopic gastrectomy, particularly in the peripancreatic area, thereby potentially reducing surgery-related pancreatic complications. The navigation system facilitates patient-specific pre-operative planning and intraoperative navigation by comprehensively visualizing all relevant vascular anatomies for laparoscopic gastrectomy.

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