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Original Article

Hand-assisted laparoscopic versus open surgery radical gastrectomy for advanced distal gastric cancer: a prospective randomized study

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Abstract: Background: This study aims to comparative treatment outcomes of hand-assisted laparoscopic surgery (HALS) versus open surgery (OS) in radical gastrectomy of advanced distal gastric cancer. Methods: This was a prospective randomized controlled study of 124 patients who underwent radical treatment for advanced distal gastric cancer from May 2008 and April 2012. Among them, the patients were divided into a HALS group (n = 62) and an OS group (n = 62), and to compare the short-term and long-term outcomes between two groups. Results: All subjects in the two groups completed the surgery. Compared to the OS group, the HALS group exhibited a smaller incision size (P<0.001), lower intraoperative bleeding level (P = 0.009), and shorter postoperative anal exhaust time (P = 0.025), although the two groups showed no differences in the surgical duration, incidence of perioperative complications, or mortality rate and the surgical outcome. An examination of the long-term outcomes revealed that the two groups exhibited no differences in one-year survival, three-year survival, disease-free survival, or quality of life scores. Conclusion: HALS is a safe and feasible treatment for advanced distal gastric cancer and features advantages such as a small surgical incision, low intraoperative bleeding, and quick postoperative recovery of gastrointestinal function. Importantly, its long-term efficacy is similar to that of OS.

Keywords: Hand-assisted laparoscopic surgery (HALS), open surgery (OS), advanced gastric cancer, short-term efficacy, long-term efficacy, prognosis for gastric cancer

Introduction

Hand-assisted laparoscopic surgery (HALS) was initially used to treat colorectal cancer, and it achieved good outcomes [1, 2]. As laparoscopic instruments developed and surgical experience accumulated, HALS was gradually applied to radical gastrectomies for advanced gastric cancer, reportedly [3-7] achieves satisfactory outcomes and is minimally invasive when performing a radical gastrectomy. However, the long-term efficacy of using HALS to perform a radical gastrectomy has not been reported. To evaluate the overall efficacy of using HALS to treat advanced gastric cancer, we summarized the results of the treatment of 124 advanced distal gastric cancer patients who underwent HALS or OS between May 2008 and April 2012. We then systematically compared the two methods using the short-term and long-term efficacies, which revealed that both generated overall satisfactory results.

Materials and methods

Ethics statement: Hand-assisted Laparoscopic Versus Open Surgery Radical Gastrectomy for Advanced Distal Gastric Cancer: A Prospective Randomized Study of the data of this study was approved by the ethics committee of the people's liberation army general hospital of Cheng Du command, and also, this study has been gotten the consent and signature confirmation by the patients or their families.

General information

A total of 124 patients were divided into a HALS group and an OS group, each containing 62

Table 1. General information for the HALS and OS groups

	HALS group	OS group	T value/χ^2 value	*P* value
Gender			0.037[a]	0.847
Male (cases)	42	43		
Female (cases)	20	19		
Age (years)	64.02±15.25	63.98±15.37	0.012[b]	0.991
BMI (kg/m^2)	21.53±4.26	21.52±4.21	0.008[b]	0.993
TNM staging (cases)			0.049[a]	0.976
IB	5	5		
II	13	14		
III	44	43		
Histological type (cases)			1.032[a]	0.905
Adenocarcinoma	42	43		
Papillary adenocarcinoma	4	5		
Mucinous adenocarcinoma	4	4		
Tubular adenocarcinoma	5	6		
Signet ring cell carcinoma	7	4		
Tumor differentiation (cases)			0.643[a]	0.725
High	15	18		
Intermediate	25	21		
Low	22	23		
Postoperative chemotherapy (cases)			0.388[a]	0.824
Folfox	44	45		
Oral administration of s-1	11	12		
History of abdominal surgery (cases)	6	7	0.086[a]	0.769
Combined underlying diseases (cases)	16	19	0.358[a]	0.549

Note: a, the statistical values of a chi-square test; b, the t value of a group t test.

subjects. The two groups showed no significant differences in gender, age, tumor size, TNM staging, and underlying diseases ($P>0.05$) and were thus comparable (**Table 1**).

Inclusion criteria

We used the following including criteria: patients who displayed good general conditions and could withstand laparoscopic surgery; had a TNM staging of T2-4N0-3M0, corresponding to stage Ib-III; and had resectable tumors and could undergo D2 resection for gastric cancer.

Randomization

The patients in this study were randomized into two groups using the envelope method. The envelopes were drawn and opened by a nurse. The patients were randomized into two groups: the group HALS patients were treated with hand-assisted laparoscopic radical gastrectomy, whereas the group OS patients were treated with open surgery radical gastrectomy.

Preoperative examination

The 124 patients in this cohort were all confirmed to have gastric cancer based on a preoperative gastric endoscopic biopsy. The tumors were located in distal sites such as the gastric antrum and gastric angle. Endosonography was used to reveal the depth of tumor invasion. Chest computed tomography (CT) and abdominal CT examinations excluded metastasis of the liver, lung, and other distant sites. Echocardiography (ECG), biochemical tests, and coagulation tests revealed no apparent abnormalities. A complete blood count revealed that the HALS group contained eight patients with mild anemia, eight patients with moderate anemia, three patients with severe anemia, and eight patients with thrombocytopenia. The OS group contained nine patients with mild anemia, eight patients with moderate anemia, two

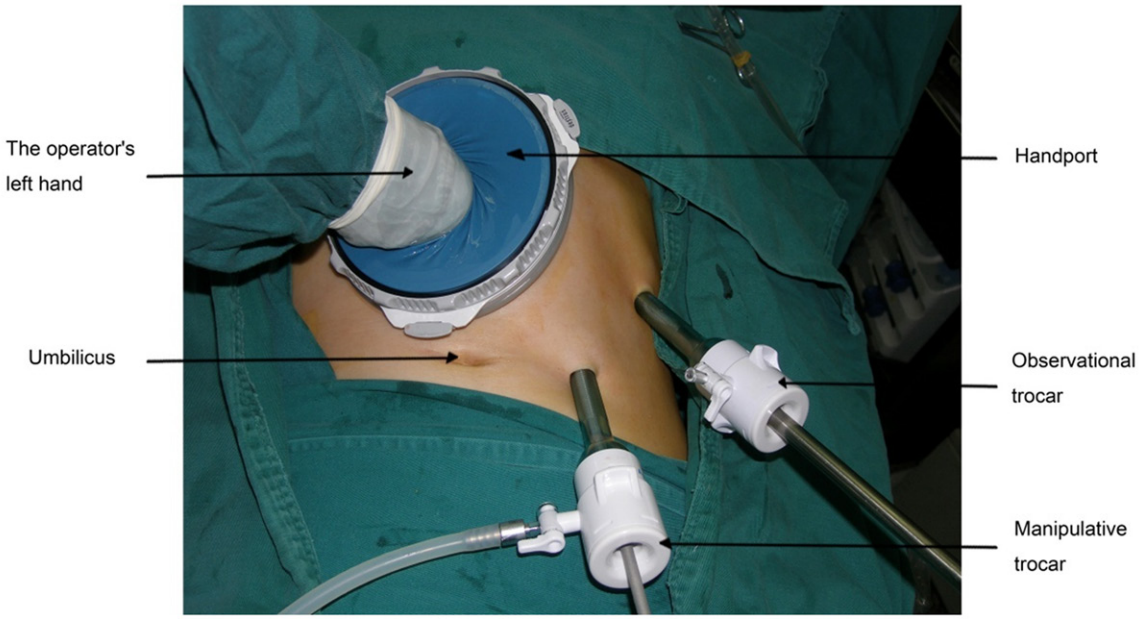

Figure 1. Positions of handport, observational trocar and manipulative trocar. The figure showed the specific positions of handport, observational trocar and manipulative trocar. The Handport was located at the upper middle of the abdomen that was 2 cm below the xiphoid, the observational trocar was located at the point of intersection between the left vertical axillary line and the left horizontal line 1 cm below the rib edge, the manipulative trocar was located 4 cm left of the flat umbilical point.

patients with severe anemia, and 10 patients with thrombocytopenia. Pulmonary function tests revealed that the HALS group contained five patients with mild ventilatory dysfunction and two patients with moderate ventilatory dysfunction. The OS group contained four patients with mild ventilatory dysfunction and two patients with moderate ventilatory dysfunction.

Treatment methods

Surgical method: All patients received "D2 gastric resection" under systemic general anesthesia.

The surgical highlights of the HALS-based D2 gastric resection were as follows. i) The surgeon stood on the right side of the patient and introduced a 7-cm incision in the upper middle of the abdomen that was 2 cm below the xiphoid, thereby gradually entering the abdomen to place a LapDisc. ii) The LapDisc was used to perform abdominal exploration. iii) The LapDisc was then used to pull the transverse colon out of the body. Then, the omentum and transverse colon were partially separated under direct visualization, and the anterior lobe of the transverse colon was isolated to expose the pancreas and the posterior wall of the stomach. iv)The observation port was located at the point of intersection between the left vertical axillary line and the left horizontal line 1 cm below the rib edge, through which a trocar was inserted to establish artificial pneumoperitoneum to control the intraoperative abdominal pressure at approximately 11-12 mmHg (1 mmHg = 0.133 kPa). v) The surgical port was located 4 cm left of the flat umbilical point. The remaining surgical procedures were performed as described previously by Cao et al. [8] and Gong et al. [9, 10] (**Figures 1**-**3**).

The surgical highlights of the OS-based D2 gastric resection were as follows. i) An incision (12-15 cm) was made in the upper middle portion of the abdomen to access the intraperitoneal cavity. ii) Abdominal exploration was performed under direct visualization. iii) The remaining procedures were the same as those described previously [11].

Postoperative treatment: Fifty-five subjects in the HALS group received postoperative chemotherapy using a Folfox (44 individuals) or S-1 (11 individuals) regimen; 57 subjects in the OS

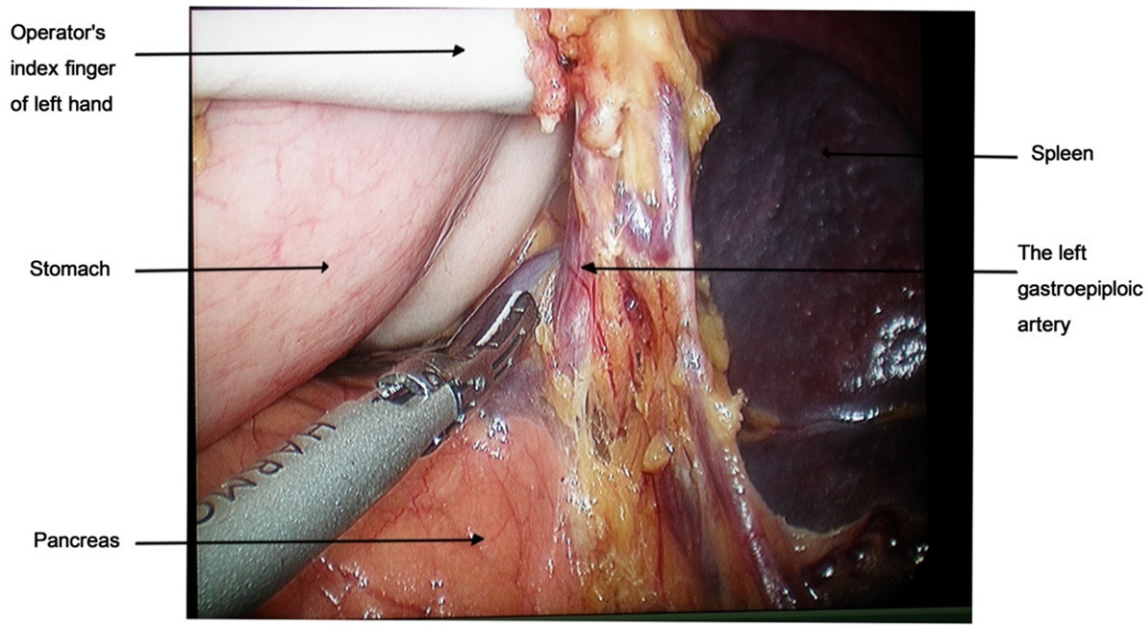

Figure 2. Lymph node dissection in groups 4. The figure clearly showed the left gastroepiploic artery and lymph node dissection in groups 4 of the gastric cancer.

group received postoperative chemotherapy using a Folfox (45 individuals) or S-1 (12 individuals) regimen.

Evaluation parameters

Comparison of the short-term efficacy: The surgical outcome and radical effect of tumor resection in the two groups were compared.

(1) Surgical outcome. The incision length, intraoperative bleeding, postoperative anal exhaust time, surgical duration, postoperative complications, and number of perioperative deaths in the two groups were compared.

(2) Radical effect of tumor resection. The number of lymph node dissections, distance of the distal and proximal resection margins of the tumor, and tumor residue at the resection margin were compared between the two groups.

Follow-up visits: The two groups of patients underwent follow-up evaluations at one year and three years, which generated the following results.

(1) One-year follow-up visits: In the HALS group, two patients were lost to follow-up, four patients died, and 51 patients exhibited disease-free survival. In the OS group, three patients were lost to follow-up, three patients died, and 52 patients exhibited disease-free survival. We then evaluated the postoperative quality of life of the patients using the assessment scale developed by Chew-Wun Wu [12]. The assessment scale comprises 14 items, with each classified as good (corresponding to 2 points), intermediate (1 point), or poor (0 point) based on the patient's condition. As a result, a perfect score of the assessment was 28 points. Higher scores indicate better patient quality of life.

(2) Three-year follow-up visits: In the HALS group, five patients were lost to follow-up, 15 patients died, and 33 patients exhibited disease-free survival. In the OS group, six patients were lost to follow-up, 14 patients died, and 32 patients exhibited disease-free survival. The quality of life of the patients was then assessed using the scheme described above.

Comparison of long-term outcomes: The one-year and three-year total survival rates, disease-free survival rates, and postoperative quality of life of the two groups were compared.

Statistical methods

SPSS16.0 software was used to perform the statistical analyses. Measurement variables

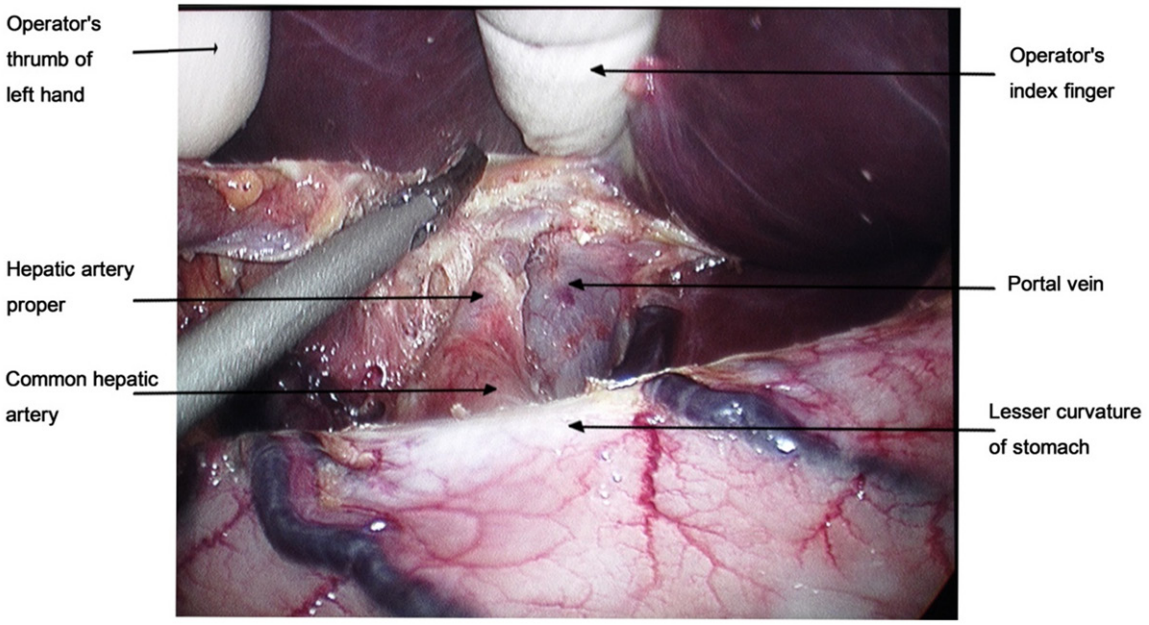

Figure 3. Lyph node dissection in groups 1, 3, 5, 7, 8, 9 and 12a. The figure clearly showed portal vein, hepatic artery proper, common hepatic artery, lesser curvature of stomach and lymph node dissection in groups 1, 3, 5, 7, 8, 9 and 12a of the gastric cancer.

are expressed as the means ± standard deviation, and count variables are expressed as frequencies and percentages. When the measurement variables for the two groups were compared, a group *t* test was conducted if the data exhibited homogeneity of variance; otherwise, a Mann-Whitney U test was used. A chi-square test was used to compare count variables between the two groups. A value of $P<0.05$ was considered statistically significant.

Results

Comparison of surgical outcomes

The surgical incision in the HALS group was 7.83±0.80 cm, whereas that of the OS group was 13.35±1.73 cm, which was a statistically significant difference ($Z = 9.596$, $P<0.001$). The intraoperative blood loss in the HALS group was 107.90±63.59 ml, whereas that of the OS group was 142.10±78.56 ml, which was a statistically significant difference ($t = -2.664$, $P = 0.009$). The postoperative anal exhaust time of the HALS group was 77.85±17.60 hours, whereas that of the OS group was 84.84±16.74 hours, which was a statistically significant difference ($t = -2.264$, $P = 0.025$). The surgical duration in the HALS group was 180.03±21.52 min, whereas that in the OS group was 178±22.87 min, which was not a statistically significant difference ($t = 0.433$, $P = 0.666$).

With regard to postoperative complications and perioperative deaths, in the HALS group, no case of intraoperative collateral injury or avert abdomen occurred, but five subjects exhibited postoperative complications (i.e., two cases of anastomotic bleeding, one case of left pleural effusion, one case of gastroparesis syndrome, and one case of abdominal subcutaneous emphysema); in the OS group no case of intraoperative collateral injury or avert abdomen occurred, although six subjects displayed postoperative complications (i.e., two cases of minor anastomotic bleeding, one case of bilateral pleural effusion, one case of left pleural effusion, one case of incision fat liquefaction, and one case of incision infection). All cases of complications in the two groups were resolved. A comparison of the two groups revealed no significant difference regarding complication rates ($\chi^2 = 0.003$, $P = 0.955$). During the perioperative period, one patient died in each of the two groups; both cases were the result of a lung infection. No significant difference was found between the groups ($\chi^2 = 0.000$, $P = 1.000$, **Table 2**).

Table 2. Perioperative clinical data of the HALS and OS groups

	Operative duration (min)	Length of incision (cm)	Intraoperative blood loss (ml)	Postoperative time to passage of gas by anus (h)	Postoperative complications (case)	Postoperative death (case)
HALS (n = 62)	180.03±21.52	7.83±0.80	107.90±63.59	77.85±17.60	5	1
OS (n = 62)	178.31±22.87	13.35±1.73	142.10±78.56	84.84±16.74	6	1
t value/Z value/χ^2 value	0.433[a]	9.596[b]	2.664[a]	2.264[a]	0.003[c]	0.000[c]
P value	0.666	*P*<0.001	0.009	0.025	0.955	1.000

Note: a. the statistical values of a chi-square test; b. the Z value of Mann-Whitney U test; c. the t value of a group t test.

Table 3. Comparison of the achievement of a radical effect in gastric cancer resection of the HALS and OS groups

	Lymph nodes scavenged (n)	Proximal resection margin (cm)	Distal resection margin (cm)	Residual tumor at the resection margin (case)		
				R0	R1	R2
HALS (n = 62)	28.37±11.12	5.39±0.78	2.46±0.86	60	2	0
OS (n = 62)	28.84±11.27	5.49±0.97	2.51±0.89	59	2	1
t value/χ^2 value	0.233[a]	0.614[a]	0.327[a]		1.008[b]	
P value	0.816	0.541	0.744		0.604	

Note: a. the statistical values of a chi-square test; b, the t value of a group t test.

Table 4. Comparison of the one-year survival status of the patients of the HALS and OS groups

	The one-year total survival rate	The one-year disease-free survival rate	The one-year quality of life score (point)
HALS (n = 60)	56/60 (93.33%)	51/60 (85.00%)	20.53±3.07
OS (n = 59)	56/59 (94.91%)	52/59 (88.14%)	20.40±3.09
t value/χ^2 value	0.134[a]	0.251[a]	0.213[b]
P value	0.714	0.616	0.832

Note: a. the statistical values of a chi-square test; b, the t value of a group t test.

Comparison of the achievement of a radical effect in gastric cancer resection

The number of lymph node dissections was 28.37±11.12 in the HALS group and 28.84±11.27 in the OS group, and no significant difference was observed between the two groups (t = 0.233, *P* = 0.816). The distal resection margin was 2.46±0.86 cm in the HALS group and 2.51±0.89 cm in the OS group, and no significant difference was observed between the two groups (t = 0.327, *P* = 0.744). The proximal resection margin was 5.39±0.78 cm in the HALS group and 5.49±0.97 cm in the OS group, and no significant difference was observed between the two groups (t = 0.614, *P* = 0.541). With regard to residual tumor at the resection margin, the HALS group included 60 cases of R0, two cases of R1, and no cases of R2 resections. The OS group included 59 cases of R0, two cases of R1, and one case of R2 resections. No significant difference was observed between the two groups with regard to tumor resection (χ^2 = 1.008, *P* = 0.604, **Table 3**).

Comparison of long-term efficacy

The one-year survival rate was 56/60 (93.33%) in the HALS group and 56/59 (94.91%) in the OS group, and no significant difference was observed between the two groups (χ^2 = 0.134, *P* = 0.714). The one-year disease-free survival rate was 51/60 (85.00%) in the HALS group and 52/59 (88.14%) in the OS group, and no significant difference was observed between the two groups (χ^2 = 0.251, *P* = 0.616). The one-year quality of life score was 20.53±3.07 in the HALS group and 20.40±3.09 in the OS group, and no significant difference was observed between the two groups (t = 0.213, *P* = 0.832, **Table 4**).

The three-year total survival rate was 42/57 (73.68%) in the HALS group and 42/56 (75.00%) in the OS group, and no significant difference was observed between the two groups (χ^2 = 0.100, *P* = 0.751). The three-year disease-

Table 5. Comparison of the three-year survival status of the patients of the HALS and OS groups

	The three-year total survival rate	The three-year disease-free survival rate	The three-year quality of life score (point)
HALS (n = 57)	42/57 (73.68%)	33/57 (57.89%)	21.88±2.35
OS (n = 56)	42/56 (75.00%)	32/56 (57.14%)	21.60±2.78
t value/χ^2 value	0.100[a]	0.005[a]	0.494[b]
P value	0.751	0.946	0.622

Note: a. the statistical values of a chi-square test; b, the t value of a group t test.

free survival rate was 33/57 (57.89%) in the HALS group and 32/56 (57.14%) in the OS group, and no significant difference was observed between the two groups (χ^2 = 0.005, *P* = 0.946). The three-year quality of life score was 21.88±2.35 in the HALS group and 21.60±2.78 in the OS group, and no significant difference was observed between the two groups (t = 0.494, *P* = 0.622, **Table 5**).

Discussion

Gastric cancer is a common malignant gastrointestinal cancer in China; approximately 90% of gastric cancer patients have advanced gastric cancer at the time of diagnosis [13]. In recent years, although tremendous progress has been achieved in the diagnosis and treatment of gastric cancer in China, the post-treatment, five-year survival rate of gastric cancer patients has remained at only 30% [14].

For patients with advanced gastric cancer, radical surgery is the only hope of a clinical cure [15-18]. Currently, widely employed surgical options include OS and LP-assisted techniques. In 2010, the Japanese Gastric Cancer Association issued the *Japanese gastric cancer treatment guidelines*, which limited laparoscopic surgery to early gastric cancer [19]. One controversy concerns whether laparoscopic surgery can be applied to advanced gastric cancer. The key argument is the radical outcome of tumor resection [20, 21]. The standard operation for the treatment of advanced gastric cancer is D2 gastric resection (lymphadenectomy) [22], which is followed by both the traditional open surgery and laparoscop surgery. Nevertheless, a D2 lymphadenectomy for gastric cancer is associated with extraordinary anatomical complexity due to the need to navigate through the delicate networks of blood vessels and gastric regional lymph nodes and is compounded by the manifold of lymph node metastasis pathways. Hence, exceptionally high technique requirements are needed to perform a gastric cancer D2 lymphadenectomy, particularly for a D2 laparoscopic gastrectomy [23].

In other words, the key point in determining whether a D2 laparoscopic gastrectomy is suitable for the treatment of advanced gastric cancer is whether radical resection can be accomplished. Therefore, in surgery, it is crucial to fully remove primary gastric foci and the infiltrated surrounding tissues and organs, thereby ensuring an adequate margin. This is the foundation of successful radical gastrectomy for complete cancer removal. Moreover, it is also important to complete a gastric D2 lymphadenectomy, which is also a great challenge for D2 laparoscopic gastrectomy [24].

HALS is a laparoscopy-based surgical option in which the surgeon employs an auxiliary apparatus (telescopic rod lens system) to enter the abdomen and assist in surgical manipulations such as dissection [25, 26]. Because the telescopic rod can provide physical feedback and pull and drag tissues, it greatly decreases surgical complexity [27-32]. When performing a radical distal gastrectomy for the treatment of advanced gastric cancer, we argue that the lymph node stations 8, 9, and 11 are likely to be covered by other tissues and organs (e.g., the pancreas) and are therefore difficult to expose. In HALS, the rod system can be used to push the pancreas to facilitate full exposure of lymph node stations 8, 9, and 11 [33-35]. In addition, the laparoscope provides an excellent magnification effect, which helps to completely eradicate lymph nodes [33-35]. Moreover, upon fully separating the stomach, we used laparoscopic instruments to sever the stomach portion e lym from the distal end of the tumor, which, when accomplished under pneumoperitoneum conditions, ensured the distance of the proximal tumor margin. Upon severing the

stomach, the distal end could be lifted to expose its posterior wall, whereby lymph node stations 8, 9, and 11 could be conveniently dissected.

We propose that a radical outcome of gastric cancer resection is a key in the surgical process. In this study, we employed several parameters to assess the therapeutic efficacy, which included the number of lymph node dissections, distal resection margin, and tumor residue at the margin. The number of lymph node dissections was 28.37±11.12 in the HALS group and 28.84±11.27 in the OS group, which was not significantly different (P = 0.816). The distal resection margin was 2.46±0.86 cm in the HALS group and 2.51±0.89 cm in the OS group, which was not significantly different (P = 0.744). The proximal resection margin was 5.39±0.78 cm in the HALS group and 5.49±0.97 cm in the OS group, which was not significantly different (P = 0.541). Moreover, the two groups displayed no significant difference in the residual tumor at the margin (P = 0.604). These results revealed that the two groups exhibited similar results and thus strongly indicated that, for the treatment of advanced distal gastric cancer, HALS could generate a radical gastric outcome similar to that of OS. Furthermore, the one-year survival, three-year survival, and disease-free survival rates further confirmed the radical therapeutic outcome of HALS for the treatment of advanced distal gastric cancer. Importantly, the HALS group had a smaller incision (7.83±0.80 cm vs. 13.35±1.73 cm, P<0.001), lower blood loss (107.90±63.59 ml vs. 142.10±78.56 ml, P = 0.009), and a shorter postoperative anal exhaust time (77.85±17.60 h vs. 84.84±16.74, P = 0.025) than patients in the OS group, illustrating the treatment advantages of HALS for the treatment of advanced distal gastric cancer. Lastly, five patients had postoperative complications in the HALS group and six patients experienced complications in the OS group, resulting in no significant difference (P = 0.955). One case of perioperative deaths occurred in each group (P = 1.000). These findings demonstrated that HALS is a safe approach for the treatment of advanced distal gastric cancer.

Disclosure of conflict of interest

None.

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