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Original Article

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

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Abstract: Objective: To compare the treatment outcomes of hand-assisted laparoscopic surgery (HALS) versus laparoscopic-assisted surgery (LAS) in radical gastrectomy for advanced distal gastric cancer. Methods: The prospective randomized control study was carried out to compare the short-term and long-term outcomes of the 124 patients who underwent radical treatment for advanced distal gastric cancer from May 2009 and April 2013. Patients were assigned to the HALS group or the LAS group, with 62 patients in each group. Results: Statistically significant difference was found between the HALS group and the LAS group in the Surgery type switching (P = 0.049), the surgical duration was (P<0.001), the number of lymph nodes resected (P = 0.007) respectively. No statistically significant difference was found between the HALS group and the LAS group in the length of surgical incision, intraoperative bleeding volume, distal and proximal incisal edges of tumors, postoperative time to anal exsufflation, perioperative complications, overall survival, disease-free survival and quality of life (QOL) scores at 1 year and 3 years (P>0.05). Conclusion: Compared with LAS, HALS has advantages, including a low rate of conversion to open surgery, short surgical duration, and more thorough dissection of lymph nodesin advanced distal gastric cancer, but its long-term outcomes were similar to LAS.

Keywords: Hand-assisted laparoscopic surgery (HALS), laparoscopic-assisted surgery (LAS), advanced gastric cancer, clinical comparison, prognosis of gastric cancer

Introduction

Laparoscopic surgery can be divided into three types, namely laparoscopic-assisted surgery, total laparoscopic surgery and hand-assisted laparoscopic surgery. D2 radical gastrectomy of gastric cancer under a laparoscope is a generally accepted as "minimally invasive" surgery. In recent years, there has been an increasing number of reports on radical gastrectomy for advanced gastric cancer with the use of laparoscopic-assisted surgery (LAS). According to Tong et al. [1-4], the outcome of LAS was superior to that of open surgery. With the evolution of LAS and the accumulation of surgical experience, the application of hand-assisted laparoscopic surgery (HALS) in radical gastrectomy for advanced gastric cancer has gradually widened. According to Cao et al. [5-9], radical gastrectomy for gastric cancer with LAS had a satisfactory short-term outcome and was able to achieve "minimal invasion". Both HALS and LAS have the advantage of "minimal invasion". However, which of them is more appropriate for "advanced distal gastric cancer"? We carried out to compare of 124 cases of advanced distal gastric cancer treated by radical gastrectomy with HALS or LAS from May 2009 to April 2013 and conducted a systematic comparative analysis of their short-term and long-term outcomes.

Materials and methods

General materials

The 124 patients were assigned to the HALS group and the LAS group, each comprising of 62 cases. The two groups were comparable without statistically significant differences in

Table 1. Comparison of general clinical data between the HALS group and the LAS group

	HALS group	LAS group	t/χ^2	*P*
Gender			0.144[a]	0.704
Male (cases)	42 (67.74%)	40 (64.52%)		
Female (cases)	20 (32.26%)	22 (35.48%)		
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
Stage IB	5 (8.16%)	5 (8.16%)		
Stage II	13 (20.97%)	14 (22.58%)		
Stage III	44 (70.97%)	43 (69.35%)		
Histological type (cases)			1.517[a]	0.824
Adenocarcinoma	42 (67.74%)	39 (62.90%)		
Papillary adenocarcinoma	4 (6.45%)	6 (9.68%)		
Mucinous adenocarcinoma	4 (6.45%)	7 (11.29%)		
Tubular adenocarcinoma	5 (8.06%)	4 (6.45%)		
Signet-ring cell carcinoma	7 (11.29%)	6 (9.68%)		
Degree of tumor differentiation (cases)			0.220[a]	0.896
Well differentiated	15 (24.19%)	17 (27.42%)		
Moderately differentiated	25 (40.32%)	25 (40.32%)		
Poorly differentiated	22 (35.48%)	20 (32.26%)		
Postoperative chemotherapy (cases)			0.806[a]	0.369
Folfox regimen	44 (70.97%)	40 (64.52%)		
Oral s-1	11 (17.74%)	15 (24.19%)		
History of abdominal surgery (cases)	6 (9.68%)	8 (12.90%)	0.322[a]	0.570
Complicated underlying diseases (cases)	16 (25.81%)	16 (25.81%)	0[a]	1

Note: a. Chi-square values of chi-square test statistics; b. t-values of paired t-test statistics.

gender, age, tumor size, TNM stage and underlying diseases (P>0.05) (see **Table 1**).

The flow chart for patient enrollment and follow up (see **flow chart 1**).

Screening criteria

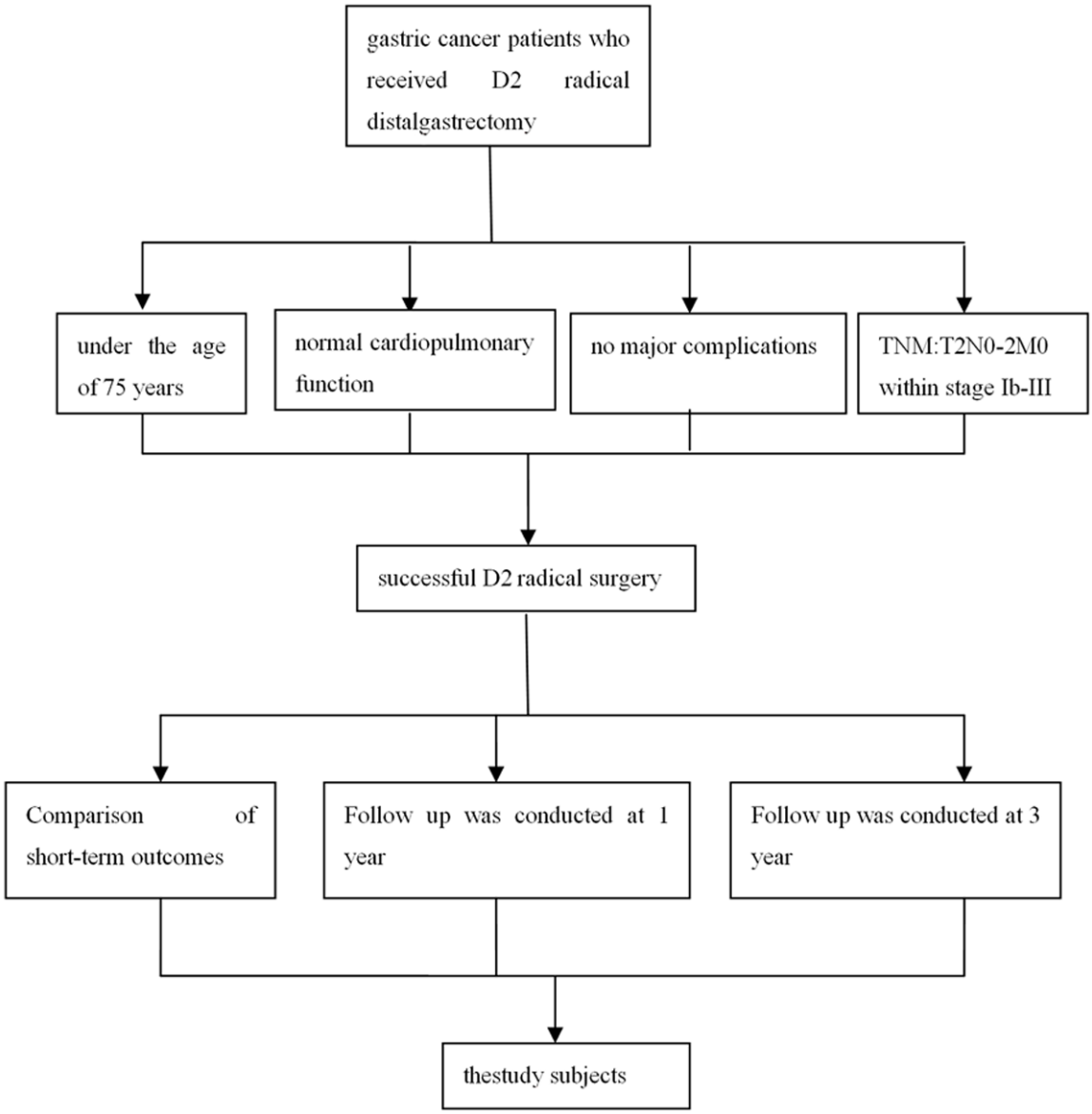
(1) Good general condition and the ability to tolerate laparoscopic surgery; (2) TNM stage: T2-4N0-3M0 and within stage Ib-III; (3) resectable tumor eligible for D2 radical gastrectomy for gastric cancer.

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, where as the group LAS patients were treated with laparoscopic-assisted surgery radical gastrectomy.

Information on preoperative examination

All 124 patients had a diagnosis of gastric cancer confirmed by preoperative gastroscopic histopathological examination. The tumors were located in the distal stomach, including the antrum and gastric angle. Endoscopic ultrasonography was performed to measure the depth of the tumors. Chest and abdominal CTs were performed to exclude distant metastasis to the liver and lungs. No abnormalities were found in UCG, ECG, blood biochemistry or blood coagulation examination. Routine blood tests revealed 8 cases of mild anemia, 8 cases of moderate anemia, 3 cases of severe anemia, and 8 cases of thrombocytopenia in the HALS group; 9 cases of mild anemia, 8 cases of moderate anemia, 2 cases of severe anemia, and 10 cases of thrombocytopenia were found in the LAS group. Pulmonary function testing



Flow chart 1. The flow chart for patient enrollment and follow up.

identified 5 cases of mild ventilation dysfunction and 2 cases of moderate ventilation dysfunction in the HALS group and 4 cases of mild ventilation dysfunction and 2 cases of moderate ventilation dysfunction in the LAS group.

Treatment methods

Surgical methods: "D2 radical gastrectomy of gastric cancer" was performed on all patients under general anesthesia.

Key points of D2 radical gastrectomy of gastric cancer with HALS: (1) placing of the handport: the surgeon stands on the patient's right side, makes an incision approximately 7 cm in length at the center of the upper abdomen approximately 2 cm below the xiphoid process into the abdominal cavity layer by layer, and places the handport into the incision; (2) the abdominal cavity is probed through the handport; (3) the transverse colon is pulled out of the body through the handport, completing only the separation of part of the greater omentum and the transverse colon under direct visualization, and peeling off the anterior lobe of the transverse mesocolon to expose tissues and organs, such as the pancreas and the posterior wall of the stomach; (4) the observation hole is located using the intersection point of the line 1 cm

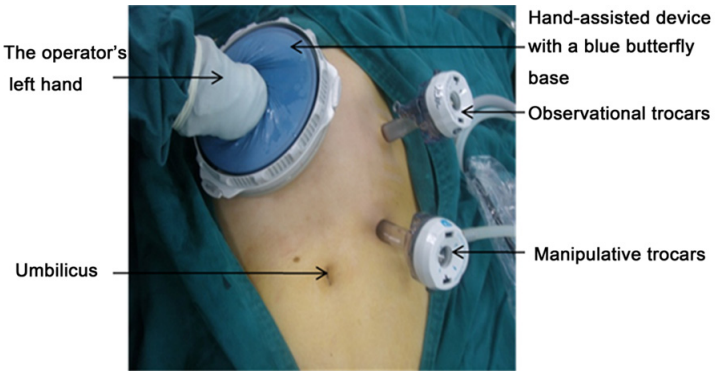


Figure 1. Positions of handport, observational trocar and manipulative trocar.

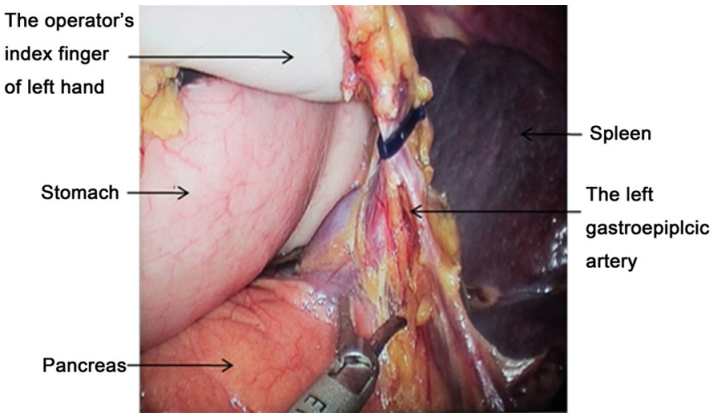


Figure 2. Lymph node dissection in groups 4.

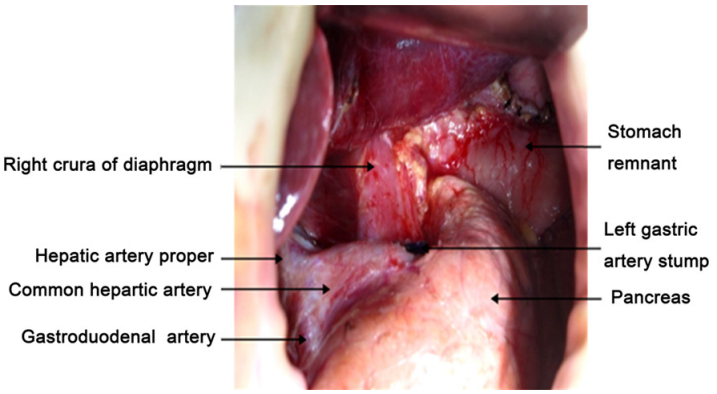


Figure 3. Lymph node dissection in groups 7, 8, 9 and 12a.

below the left costal margin and the leftmidaxillary line as the observation hole. The trocar is inserted, establishing an artificial pneumoperitoneum, and maintaining the intraoperative pneumoperitoneum pressure at approximately 11-12 mmHg (1 mmHg = 0.133 KPa); (5) the operation hole is located using the point 4 cm to the left of the umbilicus. The other surgical procedures were previously described by Cao Yongkuan [10] and Gong Jiaqing [11, 12] et al. (see **Figures 1-3**).

The surgical procedures of the D2 radical gastrectomy for gastric cancer with LAS have been previously described in the report by Luo Guode [13] et al.

Postoperative treatment: Fifty-five patients in the HALS group received postoperative chemotherapy with Folfox (44 patients) and S-1 (11 patients) regimens; fifty-five patients in the LAS group received postoperative chemotherapy with Folfox (40 patients) and S-1 (15 patients) regimens.

Observations

Comparison of short-term outcomes

Surgical outcomes: Comparison of the length of the surgical incision, the intraoperative bleeding volume, the postoperative time to anal exsufflation, the operation duration, the postoperative complications and the perioperative mortality between the HALS group and the LAS group were noted.

Tumor eradication outcomes: Comparison of the numbers of lymph nodes resected, the distance between the distal and the proximal incisal edges of tumors, and the residual tumors at the incisal edges were made between the HALS group and the LAS group.

Follow-ups

Follow-ups were conducted for both groups at 1 year and 3 years; the results are detailed below.

Follow-up results at 1 year in the HALS group included 2 cases lost to follow-up, 4 cases of death and 51 cases of disease-free survival. In the LAS group, we observed 4 cases lost to

Table 2. Perioperative conditions of patients in the HALS group and the LAS group

	Operation duration (min)	Length of surgical incision (cm)	Intraoperative bleeding volume (ml)	Postoperative time to anal exsufflation (h)	Postoperative complications (cases)	Surgery type switching (cases)
HALS group	180.03 ± 21.52	7.06 ± 0.50	107.90 ± 63.59	77.85 ± 17.60	5 (8.06%)	0 (0.00%)
LAS group	196.94 ± 22.90	6.74 ± 1.03	123.55 ± 91.49	78.03 ± 17.80	6 (9.68%)	4 (6.45%)
$t/Z/\chi^2$	4.235[a]	4.574[b]	0.554[a]	0.056[a]	0.003[c]	3.879
P	<0.001	0.058	0.581	0.959	0.955	0.049

Note: a. t-values of paired t-test statistics; b. Z-value of Mann-Whitney U test statistics; c. Chi-square values of chi-square test statistics.

follow-up, 4 cases of death and 47 cases of disease-free survival. Postoperative quality of life was evaluated using a scale introduced by Chew-wunWu [14]. The scale had 14 entries, each having a three-level rating system, namely "good", "fair" and "poor", with corresponding scores of 2, 1 and 0. The full score is 28. Higher scores mean better quality of life.

Follow-up results at 3 years in the HALS group included 5 cases lost to follow-up, 15 cases of death and 33 cases of disease-free survival. In the LAS group, we observed 9 cases lost to follow-up, 15 cases of death and 26 cases of disease-free survival. Quality of life was evaluated using the same method as in the 1-year follow-up.

Comparison of long-term outcomes

Comparisons of overall survival, disease-free survival and postoperative quality of life were made between the HALS group and the LAS group at 1 year and 3 years.

Statistical methods

The statistical methods of this study were reviewed by Yun-Ming Li from the Information Department, Chengdu Military General Hospital of People's Liberation Army.

Statistical analysis was performed using SPSS 16.0 software (SPSS Inc., Chicago, IL, United States). Quantitative variables were described using mean ± standard deviation. Categorical variables were described using frequency and percentage. In the between-group comparison of quantitative variables, Student's *t*-test was used to identify differences of variable between the HALS group and LAS group and the Mann-Whitney U test was used when the variance was heterogeneous. The chi-square test was used for between-group comparison of categorical variables. P<0.05 indicates a statistically significant difference.

Results

The surgery was uneventfully completed in all patients in the HALS group. In the LAS group, the surgery was completed in 4 cases after conversion to HALS. This between-group difference was statistically significant (χ^2 = 3.879, P = 0.049). The surgical duration was 180.03 ± 21.52 minutes and 196.94 ± 22.90 minutes in the HALS group and the LAS group, respectively, with statistical significance between the groups (t = 4.235, P<0.001). The length of the surgical incision was 7.06 ± 0.50 cm and 6.74 ± 1.03 cm in the HALS group and the LAS group, respectively, without statistical significance between the groups (t = 4.574, P = 0.058). The intraoperative bleeding volume was 107.90 ± 63.59 ml and 123.55 ± 91.49 ml in the HALS group and the LAS group, respectively, without statistical significance between the groups (t = 0.554, P = 0.581). The postoperative time to anal exsufflation was 77.85 ± 17.60 h and 78.03 ± 17.80 h in the HALS group and the LAS group, respectively, without statistical significance between the groups (t = 0.056, P = 0.959).

The assessment of postoperative complications and perioperative mortality in the HALS group identified no additional intraoperative injury or conversion to open surgery, while 5 cases of postoperative complications occurred (including 2 cases of mild bleeding at the stoma, 1 case of left sided pleural effusion, 1 case of subcutaneous emphysema at the thorax and abdomen, and 1 case of fat liquefaction in the incision). In the LAS group, 6 cases of postoperative complications occurred (in-

Table 3. Comparison of eradication outcomes of gastric cancer between the HALS group and the LAS group

Group name	Number of lymph nodes resected	Distance to the proximal incisal edge of the tumor (cm)	Distance to the distal incisal edge of the tumor (cm)	Residual tumors at the incisal edges (cases)		
				R0	R1	R2
HALS group	28.37 ± 11.12	5.39 ± 0.78	2.46 ± 0.86	60	2	0
LAS group	22.44 ± 5.64	5.33 ± 0.72	2.43 ± 0.87	57	4	1
t/χ^2	2.680[a]	0.421[a]	0.197[a]		1.744[b]	
P	0.007	0.675	0.844		0.418	

Note: a. t-values of paired t-test statistics; b. Chi-square values of chi-square test statistics.

Table 4. Comparison of survival conditions at 1 year between the HALS group and the LAS group

	Overall survival at 1 year	Disease-free survival at 1 year	Quality of life score at 1 year (points)
HALS group	56/60 (93.33%)	51/60 (85.00%)	20.53 ± 3.07
LAS group	54/58 (93.10%)	47/58 (81.03%)	20.01 ± 2.85
t/χ^2	0.002[a]	0.031[a]	0.953[b]
P	0.960	0.861	0.343

Note: a. Chi-square values of chi-square test statistics; b. t-values of paired t-test statistics.

Table 5. Comparison of survival conditions at 3 years between the HALS group and the LAS group

	Overall survival at 3 years	Disease-free survival at 3 years	Quality of life score at 3 years (points)
HALS group	42/57 (73.68%)	33/57 (57.89%)	21.88 ± 2.35
LAS group	38/53 (71.70%)	26/53 (49.06%)	20.46 ± 3.02
t/χ^2	0.009[a]	0.261[a]	2.760[b]
P	0.926	0.609	0.057

Note: a. Chi-square values of chi-square test statistics; b. t-values of paired t-test statistics.

cluding 4 cases of mild bleeding at the stoma, 1 case of left sided pleural effusion, and 1 case of gastrointestinal dysfunction); All cases were cured after treatment. No statistically significant difference was found between the groups (χ^2 = 0.003, P = 0.955). During the perioperative period, 1 death caused by pulmonary infection occurred in the HALS group, while 1 death as a result of cerebral vessel rupture occurred in the LAS group. The between-group difference was without statistical significance (χ^2 = 0.000, P = 1.000) (see **Table 2**).

The number of lymph nodes resected was 28.37 ± 11.12 in the HALS group and 22.44 ± 5.64 in the LAS group, with statistical significance between the groups (t = 2.680, P = 0.007). The distal incisal edge was 2.46 ± 0.86 cm in the HALS group and 2.43 ± 0.87 cm in the LAS group, without statistical significance between the groups (t = 0.197, P = 0.844). The proximal incisal edge was 5.39 ± 0.78 cm in the HALS group and 5.33 ± 0.72 cm in the LAS group, without statistical significance between the groups (t = 0.421, P = 0.675). Residual tumors at the incisal edges were observed in 60 cases with R0, 2 cases with R1 and 0 cases with R2 in the HALS group; in the LAS group 57 cases with R0, 4 cases with R1 and 1 case with R2 had residual tumor, but without statistical significance between the groups (χ^2 = 1.744, P = 0.418) (see **Table 3**).

The overall survival at 1 year was 56/60 (93.33%) in the HALS group and 54/58 (93.10%) in the LAS group, without statistical significance between the groups (χ^2 = 0.002, P = 0.960); the disease-free survival at 1 year was 51/60 (85.00%) in the HALS group and 47/58 (81.03%) in the LAS group, without statistical significance between the groups (χ^2 = 0.031, P = 0.861). The quality of life score at 1 year was 20.53 ± 3.07 in the HALS group and 20.01 ± 2.85 in the LAS group, which was not a significant difference between the groups (t = 0.953, P = 0.343) (see **Table 4**).

The overall survival at 3 years was 42/57 (73.68%) in the HALS group and 38/53 (71.70%) in the LAS group, without statistical significance between the groups (χ^2 = 0.009, P = 0.926); the disease-free survival at 3 years was 33/57 (57.89%) in the HALS group and 26/53 (49.06%) in the LAS group, without sta-

tistical significance between the groups (χ^2 = 0.261, P = 0.609). The quality of life score at 3 years was 21.88 ± 2.35 in the HALS group and 20.40 ± 3.03 in the LAS group, which was not a significant difference between the groups (t = 2.760, P = 0.057) (see **Table 5**).

Discussion

Currently, the use of laparoscopic surgery in the treatment of early-stage gastric cancer has been generally accepted by practitioners. Compared with traditional open surgery, laparoscopic surgery has the advantages of a small surgical incision size, a low intraoperative bleeding volume, a rapid postoperative recovery of gastrointestinal function, and a short postoperative hospital stay [15]. More importantly, for early-stage gastric cancer, which has few lymph node metastases, the tumor eradication outcomes are comparable between laparoscopic surgery and traditional open surgery. Therefore, laparoscopic surgery is now widely applied. In Japan, laparoscopic surgery was defined as the standard of care for stage IA gastric cancer in the Japanese Gastric Cancer Treatment Guidelines 2010 [16]. There has been some dispute in the medical field as to whether laparoscopic surgery can be used for advanced gastric cancer. The focus of such dispute lies in the eradication of tumors [17, 18]. Due to the high rate of lymph node metastases in advanced gastric cancer (up to 60% according to some reports), the large number of tissues and organs adjacent to the stomach, and the need for safe and effective digestive tract reconstruction, a wide range of surgeries involving many anatomical layers with high degree of difficulty have been used for radical gastrectomy of advanced gastric cancer [19]. In recent years, with the continuous evolution of laparoscopic instruments and the gradual maturation of the surgical techniques, Chen K et al. [20-24] achieved a favorable outcome in radical gastrectomy for advanced gastric cancer by using laparoscopic-assisted surgery.

There are 3 approaches to laparoscopic surgery for gastric cancer, namely radical gastrectomy with hand-assisted laparoscopic surgery, radical gastrectomy with laparoscopic-assisted surgery and radical gastrectomy with total laparoscopy. Radical gastrectomy with laparoscopic-assisted surgery and radical gastrectomy with total laparoscopy are currently widely accepted and applied, while radical gastrectomy with hand-assisted laparoscopic surgery is less commonly used. Hand-assisted laparoscopic surgery is performed by a surgeon using the laparoscope with one hand entering the abdominal cavity through a handport to accomplish the anatomical procedures of the surgery [25, 26]. Because of the tactile feedback and resistance to the retracted tissues provided by the intracavitary hand, the complexity of the surgery is significantly reduced [27-32].

The goal of the surgery is the eradication ofgastric cancer [33]. In this study, we took the number of lymph nodes resected, the distance between the distal and the proximal incisal edges of tumors, and the residual tumors at the incisal edges as the indicators of tumor eradication. The numbers of lymph nodes resected were 28.37 ± 11.12 and 28.84 ± 11.27 in the HALS group and the LAS group, respectively, with statistical significance between the groups (P = 0.816). In D2 radical gastrectomy for gastric cancer, the second step or lymph node dissection is the most important and most difficult procedure in the entire surgery. For D2 radical gastrectomy of distal gastric cancer, lymph nodes in groups 7, 8, 9, 10 and 11 should be resected. However, such lymph nodes have deep locations and are easily covered by the pancreas and other tissues and organs. Therefore, they are hard to expose, especially in obese patients, which may make the lymph node dissection during the laparoscopic-assisted surgery incomplete. In hand-assisted laparoscopic surgery, the surgeon's intracavitary hand provides the advantage of tactile feedback and can push and pull the pancreas and tissues according to the surgeon's judgment to fully expose the lymph nodes in groups 7, 8, 9, 10 and 11. In addition, the laparoscope has a good amplification effect, which makes the thorough eradication of lymph nodes possible. Moreover, in the event of bleeding from a large vessel during the lymph node dissection, the intracavitary hand can immediately close the bleeding point, which keeps the wound surface clean and clear, and provides a good environment for treatment of the vessel, which is unattainable with laparoscopic-assisted surgery [34-36]. On the other hand, after the stomach is fully separated, we can complete the detachment of the portion of the stomach ≥5 cm from the proximal end of the tumor under pneumoperitoneum by using the laparo-

scopic instruments, to ensure a distance from the proximal incisal edge of the tumor. After detachment of the stomach, the distal stomach can be lifted up, and the posterior gastric wall can be fully exposed, which makes it easier to resect the lymph nodes in groups 5, 6, 8 and 12.

An auxiliary incision must be made in the abdomen in both hand-assisted laparoscopic surgery and in laparoscopic-assisted surgery. The collection of specimens and the reconstruction of the digestive tract are both completed via this auxiliary incision. In addition these two functions, the auxiliary incision in hand-assisted laparoscopic surgery also serves as the pathway for the intracavitary hand to enter the abdominal cavity to complete the surgical procedures. In hand-assisted laparoscopic surgery, the length of this incision varies greatly depending on the size of the surgeon's hands. If the surgeon has small hands, the length of such incision may be similar to that in the laparoscopic-assisted surgery group. This study showed that the length of surgical incision was 7.06 ± 0.50 cm in the HALS group and 6.74 ± 1.03 cm in the LAS group, with statistical significance between the groups (P = 0.058).

A low rate of conversion to open surgery is a prominent advantage in the hand-assisted laparoscopic surgery group achieved by an ideal combination of the intracavitary hand and the laparoscopic instruments. None of the 62 cases in the hand-assisted laparoscopic surgery group required conversion to open surgery, while due to intraoperative hemorrhage, abdominal adhesion, additional injury and other reasons. 4 cases in the laparoscopic-assisted surgery group required this conversion to hand-assisted laparoscopic surgery and also achieved "minimal invasion", which is difficult to accomplish with other types of laparoscopic surgery. A short surgical duration is also an advantage of hand-assisted laparoscopic surgery. In this study population, the operation duration was 180.03 ± 21.52 min in the HALS group and 196.94 ± 22.90 min in the LAS group, with significant difference between the groups (P<0.001), which was due to the direct participation of the intracavitary hand.

In summary, in the treatment of advanced distal gastric cancer, hand-assisted laparoscopic surgery has superior short-term outcomes compared with laparoscopic-assisted surgery and comparable long-term outcomes, which justifies its wide clinical application.

In conclusion, this study was a comparative analysis of the treatment outcomes of HALS versus LAS in radical gastrectomy for advanced distal gastric cancer. The results suggested that HALS was associated with a low rate of conversion to open surgery, short operation duration, more thorough dissection of lymph nodes and other advantages in the treatment of advanced distal gastric cancer, while its long-term outcome was comparable with that of the LAS group.

Disclosure of conflict of interest

None.

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