

A randomized controlled trial of short-term clinical effects between total laparoscopy and laparoscopic-assisted radical gastrectomy for distal gastric cancer

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Abstract: To compare the safety and recent clinical efficacy of total laparoscopic distal gastrectomy (TLDG) with laparoscopic assisted distal gastrectomy (LADG), and to explore the advantages of TLDG, prospective clinical study methods were used to design gastric cancer patients treated with gastrointestinal surgery in the Affiliated Hospital of Qingdao University from March 2018 to October 2018, total of 60 patients were included in the study, including 30 in the TLDG group and 30 in the LADG group. The cases were divided into TLDG group and LADG group by random number table. The intraoperative and postoperative conditions of the two groups were compared and analyzed to measure the therapeutic effect. The operation time and number of lymph nodes dissected in the TLDG group were higher than those in the LADG group ($P>0.05$). There was no statistical difference in the distance of the upper cutting edge ($P>0.05$). The incision length was significantly smaller than that of the LADG group ($P<0.05$). The first anal exhaust time was earlier than LADG group ($P<0.05$). The postoperative hospitalization time was shorter than that of the LADG group ($P<0.05$). The hospitalization cost was slightly higher than that of the LADG group, but the difference was not statistically significant ($P>0.05$). The white blood cell count on the first day after the operation and the c-reactive protein on the first and third day after the operation were all smaller than the LADG group ($P<0.05$). VAS pain scores of postoperative patients: all the scores on the first, third and fifth days after the operation were smaller than those in the LADG group ($P<0.05$). The total amount of postoperative analgesic was lower than that of the LADG group ($P<0.05$). One case of incision infection and one case of postoperative intestinal obstruction occurred in the LADG group. Gastroparesis occurred in 1 case of TLDG group. Total laparoscopic radical gastrectomy for distal gastric cancer is safe and feasible, and has more advantages than laparoscopic-assisted radical gastrectomy for distal gastric cancer, which is worthy of clinical promotion and application.

Keywords: Total laparoscopy; Laparoscopic assistance; Radical resection of distal gastric cancer; Clinical efficacy and safety

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1. Introduction

Global cancer statistics annual report 2018, gastric cancer ranks fifth in global new cancer incidence, mortality rate as high as the third, radical resection is the only cure for stomach cancer. 1994, Japanese Kitano[1] reports the world's first laparoscopic early gastric cancer radical, created the laparoscopic assisted surgery of gastric cancer. From then on, laparoscopic gastric surgery has entered a rapid development period. Radical surgery with laparoscopic gastric cancer and digestive tract reconstruction ways mainly have totally laparoscopic gastric cancer radical laparoscopic assisted two gastric cancer radical. This paper used the ERAS under management mode totally laparoscopic distal gastric cancer radical prostatectomy (TLDG) and traditional laparoscopic assisted distal gastric cancer radical prostatectomy (LADG). 60 cases with comparing with recent clinical curative effect and safety of explores ERAS under the guidance of the application of laparoscopic surgery in the treatment of distal gastric cancer patients value, promote the

development of laparoscopic gastric cancer surgery and rapid rehabilitation surgery.

2. Materials and methods

2.1. Clinical data

60 patients with distal gastric cancer admitted to the Gastrointestinal Surgery Department of Qingdao University Affiliated Hospital from March 2018 to October 2018 were selected and divided into TLDG group and LADG group by random number table method (30 patients in TLDG group and 30 patients in LADG group). Inclusion criteria: it was diagnosed as distal gastric cancer in our hospital. Preoperative tumor invasion depth was confirmed as t2-t4a. No previous history of gastrointestinal surgery or neoadjuvant chemotherapy. Renal function is normal and no liver disease. The patients volunteered to participate in this study and signed the informed consent. Exclusion criteria: distant viscera metastasis or extensive intraperitoneal implantation metastasis were found before and during operation; Concurrent or

heterochronous tumors of other organs; Critically ill patients; Laparoscopic surgery to open or change to laparoscopic assisted; Palliative resection of tumor.

2.2. Surgical method

All patients were performed by the same group of physicians, and the surgical standards were in accordance with the Japanese gastric cancer guidelines, the 3rd edition of standard lymph node dissection in 2010. ERAS perioperative management mode was adopted for all patients. After lymphatic dissection in the TLDG group, gastrectomy and digestive tract reconstruction were performed in the abdominal cavity without auxiliary small incision. Digestive tract reconstruction was performed by BII+Braun anastomosis. After lymphadenectomy in LADG group, gastrectomy and reconstruction of digestive tract were performed through small abdominal incision, and the specific location of small abdominal incision was not

restricted. Digestive tract reconstruction was performed by BII+Braun anastomosis.

3. Results

3.1. Comparison of basic clinical features

All operations in the two groups were successfully completed, and there was no surgical procedure change in the middle of the study. There were no intraoperative complications in the two groups, and there were no adverse events of death in all patients during the study period. A total of 60 subjects were included in this study. Basic clinical characteristics, such as gender, age, weight, BMI and clinical stage, were not statistically significant between the two groups ($p > 0.05$). See Table 1.

Table 1. Comparison of basic clinical features

	TLDG	LADG	p
Gender (male/female)	14/16	21/9	0.115
Age (year)	59.2±9.9	60.7±7.7	0.486
Height (m)	1.65±0.1	1.64±0.1	0.854
Weight (kg)	67.8±9.9	65.9±9.2	0.444
BMI (kg/m ²)	24.8±3.0	24.3±2.7	0.500
TNM			0.454
I	13	10	
II	5	9	
III	12	11	

Table 2. Comparison of intraoperative data

	TLDG	LADG	t	p
Anastomosis time (min)	35±7	27±5	5.277	<0.001
Operation time (min)	227±43	219±35	0.717	0.476
Bleeding (ml)	36.5±7.1	35.3±7.5	0.654	0.515
Number of lymph node dissection	36.6±4.1	32.2±12.0	1.300	0.199
Upper cut margin distance (cm)	5.2±2.6	5.4±2.5	-0.382	0.704
Length of incision (cm)	4.3±0.7	7.7±1.0	-14.977	<0.001

3.2. Comparison of intraoperative data

The anastomosis time in the TLDG group was longer than that in the LADG group, and the difference was statistically significant ($p < 0.05$), which was

caused by the greater difficulty in laparoscopic gastrointestinal reconstruction. The operation time and number of lymph nodes dissected were slightly higher than those in the LADG group, but the difference was

not statistically significant ($p>0.05$). There was no significant difference in the distance between the two groups ($p>0.05$), and the length of the main incision in the TLDG group was significantly smaller than that in the LADG group ($p<0.05$). See Table 2.

3.3. Comparison of postoperative data

The postoperative hospitalization time was shorter than that of the LADG group, and the difference was statistically significant. The hospitalization cost was slightly higher than that of the LADG group, but the difference was not statistically significant, Table 3.

3.4. Comparison of inflammatory indicators

3.4.1. WBC

There was no statistical difference in leucocyte count between TLDG group and LADG group ($p>0.05$). The WBC count in the TLDG group was slightly lower than that in the LADG group on the first day after surgery, and the difference was statistically significant. There was no significant difference in leucocyte count between the TLDG group and the LADG group on the 3rd and 5th days after surgery ($p>0.05$), Table 4.

3.4.2. C-Reactive Protein (CRP)

There was a significant difference between the first and third c-reactive proteins in the TLDG group and the LADG group ($p<0.05$). The difference was insignificant on the 5th day after surgery, Table 5.

Table 3. Comparison of postoperative data

	TLDG	LADG	t	p
First anal exhaust time (h)	71.3±10.2	76.9±9.8	-2.181	0.033
Postoperative hospitalization time (d)	5.7±0.7	6.3±0.9	-2.592	0.012
Hospitalization expenses (ten thousand yuan)	7.10±0.58	6.89±0.65	1.299	0.199

Table 4. Comparison of WBC

WBC ($\times 10^9/L$)	TLDG	LADG	t	p
PRE	5.99±0.83	6.09±0.76	-0.494	0.623
POD1	9.41±2.35	11.62±2.91	-3.228	0.002
POD3	7.54±1.57	8.25±1.69	-1.685	0.097
POD5	6.32±0.95	6.66±0.65	-1.524	0.133

Table 5. Comparison of CRP

CRP (mg/L)	TLDG	LADG	t	p
PRE	7.9±2.9	7.1±1.9	1.151	0.254
POD1	24.2±8.7	39.1±22.4	-3.403	0.001
POD3	13.1±3.4	21.9±13.1	-3.571	0.001
POD5	6.8±1.3	6.9±1.6	-0.155	0.877

3.5. Comparison of Pain index

The VAS pain scores of the TLDG group were lower than those of the LADG group on the first, third and fifth days after the operation, and the differences were statistically significant, Table 6.

3.6. Comparison of postoperative complications

There was no statistical significance in the incidence of postoperative complications between the TLDG group and the LADG group ($p>0.05$). Among them, 1 case of incision infection and 1 case of postoperative

intestinal obstruction occurred in the LADG group. In the TLDG group, gastroparesis occurred in 1 patient, without anastomotic leakage, anastomotic stenosis,

bleeding, incision infection and other related complications, Table 7.

Table 6. Comparison of pain index

	TLDG	LADG	t	p
POD1	3.1±0.9	4.7±0.6	-7.519	0.001
POD3	1.7±0.6	2.9±0.7	-6.650	0.001
POD5	0.9±0.3	1.7±0.5	-6.444	0.001

Table 7. Comparison of postoperative complications

	TLDG(30)	LADG(30)	p
Incision infection	0 (0.0)	1 (3.3)	1
Postoperative ileus	0 (0.0)	1 (3.3)	1
Gastroplegia	1 (3.3)	0 (0.0)	1
other	0 (0.0)	0 (0.0)	-
total	1 (3.3)	2 (6.7)	1

4. Discussion

Total laparoscopic distal gastrectomy compared with laparoscopic assisted distal gastrectomy, the digestive tract reconstruction with the relatively large space, matches finer pull small, reduce the adjacent tissue damage[2-4], and requires no additional incision anastomosis in vitro, thus reducing the use of postoperative pain, pain killer agent quantity and incision infection, better cosmetic effect[5-8]. However, compared with LADG, intra-luminal TLDG anastomosis in the early stage requires more experience in laparoscopic surgery[9]. It is difficult to operate the linear stapler under laparoscope, which may lead to increased incidence of related complications[10, 11].

This article, there are 30 cases of patients with laparoscopic surgery, all 30 patients of laparoscopic assisted surgery, on the operation security and the recent curative effect, all operations are completed smoothly. In this study, two groups of patients with postoperative VAS pain score difference is higher. TLAD group VAS score (1, 3, 5 days postoperatively) are much smaller than LADG group, and the related research results similar[12]. Main consideration TLDG no abdominal incision, less postoperative pain source, relatively fast recovery of gastrointestinal function and exhaust the earlier, make abdominal pain can also ease, early postoperative pain in patients with greatly reduced.

The incision length in TLDG group was significantly superior to that in LADG group, and the

difference was statistically significant (P<0.05). Other studies have shown that TLDG could reduce postoperative pain due to wound shrinkage, and it has advantages in postoperative recovery compared with LADG[13-15]. However, some studies have reported that there is no significant difference between TLDG and LADG in short-term efficacy. A prospective randomized study showed no significant difference in postoperative pain between the two groups [16], which was significantly different from the results of this study.

TLDG group's operating time slightly longer than LADG group of patients, but it has no statistically significant difference (P>0.05). TLDG through a small incision after the residual stomach, intraoperative anastomose operation range is relatively narrow, linear stapling operation requires more precise technology[17], difficulty is big, after anastomosis in laparoscopic suture embedding anastomotic need higher technical level, lead to a slightly longer surgical time.

In terms of tumor treatment, full resection of the original lesion, adequate surgical margin and thorough lymph node dissection are the key to gastric cancer surgery [18,19]. In TLDG, the gastric tissue cannot be directly touched, and only the proximal gastric resection boundary can be determined in the abdominal cavity[20]. May cause the upper cutting edge to be too long. However, in this study, there was no significant difference between TLDG group and

LADG group. All the postoperative pathologic findings were negative. TLDG group of cleaning the number of lymph nodes is slightly more than LADG group, but the difference is not statistically significant. Considering the small sample size, the number 2 the lymph node in more than 30 pieces, embodies the TLDG can achieve the same as the LADG effect. Study have shown that the average laparoscopic gastric cancer radical lymph node cleaning the number 31.8, no obvious difference was found between patients with open operation, and postoperative follow-up of 14 months, no recurrence[21, 22]. These results fully demonstrate the safety and feasibility of TLDG in tumor therapy.

In the postoperative complications, 1 case of incision infection and 1 case of postoperative intestinal obstruction occurred in the LADG group. In the TLDG group, gastroparesis occurred in 1 case, and no anastomotic leakage, anastomotic stenosis, bleeding, incision infection and other related complications were found. In this study, TLDG did not increase the incidence of postoperative complications, and there was no significant difference with the incidence ratio of LADG, which was consistent with the relevant reports[23]. Therefore, both surgical methods are feasible in terms of surgical safety. Retrospective case-control studies showed that there was no significant difference between the two anastomotic methods in terms of gastrointestinal function recovery and hospital stay[24]. However, this study found that according to the first postoperative exhaust, the intestinal function of TLDG recovered faster than that of LADG. The first anal exhaust time of TLDG group was earlier than that of LADG group.

The postoperative leucocyte count and c-reactive protein of the TLDG group were lower than those of the LADG group, and the differences were statistically significant. Other studies showed that the inflammatory indicators of TLDG were slightly or significantly reduced[23, 24], which was similar to this study. This result may be related to the fact that the reconstruction of digestive tract was carried out in the body. The anastomosis in the body has a better surgical vision and more accurate operation can reduce the damage to surrounding tissues. It can be seen that the gastrointestinal function of TLDG recovers faster after surgery, which is more advantageous than LADG in reducing surgical stress and reducing inflammatory response to promote postoperative recovery of patients.

5. Conclusion

Above all, laparoscopic assisted with laparoscope can complete standard distal gastric cancer radical, and compared with LADG. TLDG further reduce the surgical trauma, postoperative pain of patients, shorten the postoperative hospitalization time. Insure the effect of treatment in did not increase the risk of

postoperative complications occurred at the same time, also did not add extra economic burden to patients, can reflect the thought of people-oriented, more conducive to comprehensive recovery of patients with body and mind. However, TLDG requires a higher level of laparoscopic operation for the surgeons, with a steep learning curve. Although the initial application requires time and energy, as long as the technology is well mastered, the rapid and safe laparoscopic anastomosis can eventually be achieved. With the continuous innovation of laparoscopic instruments, improvement of laparoscopic techniques by surgeons and accumulation of experience, total laparoscopic radical gastrectomy for distal gastric cancer will be more and better applied, bringing greater benefits to patients.

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