



Research Paper



Trocar puncture with modified sump drainage for duodenal stump fistula after radical gastrectomy for gastric cancer: A retrospective controlled study

Xiao-Tong Wang^{a,1}, Han-Qing Ya^{a,1}, Long Wang^{a,1}, Huan-Huan Chen^{b,1}, Yan-Fei Zhang^a, Xiao-Hong Luo^a, Lei Li^{a,*}, Fan-Biao Kong^{b,*}, Xiao-Gang Zhong^{a,*}, Wei Mai^{a,*}

^a Departments of Gastrointestinal, Hernia and Enterofistula Surgery, People's Hospital of Guangxi Zhuang Autonomous Region & Institute of Minimally Invasive Technology and Applications, Guangxi Academy of Medical Sciences, Nanning 530021, Guangxi Zhuang Autonomous Region, People's Republic of China

^b Departments of Colorectum and Anus Surgery, People's Hospital of Guangxi Zhuang Autonomous Region & Institute of Minimally Invasive Technology and Applications, Guangxi Academy of Medical Sciences, Nanning 530021, Guangxi Zhuang Autonomous Region, People's Republic of China

ARTICLE INFO

Keywords:

Duodenal stump fistula
Modified sump drainage
Radical gastrectomy
Gastric cancer
Trocar puncture

ABSTRACT

Duodenal stump fistula (DSF) is a serious complication of radical gastrectomy for gastric cancer. Herein, we illustrated an innovative choice for treating duodenal stump fistulas by placing a modified sump drainage through trocar puncture into the DSF-related abscess (DSF-abscess) cavity. We retrospectively analyzed 974 consecutive patients who underwent gastrectomy for gastric cancer between 2011 and 2021. Of these patients, 34 who developed postoperative duodenal stump fistulas postoperatively were enrolled into our study, and their clinical data were retrospectively assessed. From January 2011 to December 2017, 15 patients received conventional treatments (percutaneous catheter drainage, PCD group) known as the traditional percutaneous method, and 19 patients from January 2018 to December 2021 received new treatments (Troca's SD group) consisting of conventional therapies and placement of a modified sump drainage through trocar puncture into DSF-abscess cavity. The demographics, clinical characteristics and treatment outcomes were compared between two groups. Compared with the PCD group, the rates of postoperative complications, duodenostomy creation, subsequent surgery, fistula healing rates of the DSF, and length of postoperative hospital stay were significantly decreased in the Troca SD group. However, there was no significant difference in the abscess recurrence rate and mortality rates. Trocar puncture with a modified sump drainage is an safe, effective, and technically feasible treatment for duodenal stump fistula after radical gastrectomy for gastric cancer. This novel technique should be further investigated using large-scale RCT research.

Introduction

Gastric cancer (GC) is one of the most common digestive system malignancies. In 2021, a study of global cancer statistics showed that the number of new GC cases will rank sixth and third, respectively, among all cancer types [1].

Total or subtotal radical gastrectomies remain the optimal treatment for GC [1]. A duodenal stump fistula (DSF) is a serious complication of total or subtotal gastrectomy for GC [2]. Although its incidence is low, it can lead to a high mortality, long hospital stays, and high hospitalization expenses, consequently, more attention has been paid by surgeons.

However, the most reasonable and effective therapeutic approach for DSF remains controversial. Many studies have shown that intra-abdominal abscesses, especially hepatorenal crypt abscesses and right paracolic sulcus abscesses, are common clinical manifestations of DSF [3–5]. Therefore, effective drainage of abscesses is the key to treating DSF. Over the last several decades, DSF-related abscesses (DSF-abscesses) have been cured by surgical procedures, such as external drainage or enterostomy [6]. With the rapid development of imaging techniques such as computed tomography technology and B ultrasound imaging, percutaneous catheter drainage (PCD) has progressively replaced laparotomy as the first choice [7]. This conservative treatment

* Corresponding authors.

E-mail addresses: deanli1982@sina.com (L. Li), kfb.32@163.com (F.-B. Kong), zhong.xiaogang@163.com (X.-G. Zhong), 13977154858@139.com (W. Mai).

¹ Equal contributors.

<https://doi.org/10.1016/j.sopen.2023.09.015>

Received 14 June 2023; Received in revised form 10 August 2023; Accepted 17 September 2023

Available online 22 September 2023

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can provide more time for patients to optimize their nutritional condition and reduce inflammation, eventually contributing to a 1-stage operation in the future and decreasing the risk of surgery [8].

However, PCD catheters are relatively small in diameter, easily occluded, and offer only passive suction drainage without active suction drainage or irrigation [9]. Consequently, the application of percutaneous catheter drainage in abscesses is limited because their abscesses usually contain a large amount of pus and necrotic tissue. Much research has proven that sump drainage can provide continuous irrigation, active suction function, and a lower rate of complications and recurrence of intra-abdominal abscess compared to the PCD catheter [10–12]. Liu et al. [13] pointed out that using trocar puncture to perform sump drainage in an intra-abdominal abscess is a safe, effective, and minimally invasive technology. On this basis, we modified the sump drainage and conceived that trocar puncture with this modified sump drainage was a better therapeutic strategy for DSF after radical gastrectomy for gastric cancer, which has been carried out for DSF in our institution since January 2018.

This study aimed to retrospectively analyze and compare the prognoses and clinical outcomes of modified sump drainage by trocar puncture and conventional PCD for duodenal stump fistulas after radical gastrectomy for gastric cancer.

Material and methods

Patients

We conducted a retrospective review of all patients who underwent gastrectomy for gastric cancer at Guangxi Zhuang Autonomous Region People's Hospital between January 2011 and December 2021. Patients who were diagnosed with duodenal stump fistulas were enrolled in this study. The diagnosis of duodenal stump fistula was confirmed using upper gastrointestinal contrast, contrast fistulography, or abdominal computed tomography (CT). Characteristics of the duodenal stump fistula were examined. Patients cured with antibiotics only, emergency surgery performed within 24 h after DSF, preoperative neoadjuvant therapy, or those with missing data were excluded. The following patient characteristics were reviewed: age, sex, pathology, accompanying diseases, surgical method, timing of diagnosis and treatment of the leak, hospital mortality, and duration of hospitalization. The patient characteristics are shown in Table 1. This study was approved by the Ethics Committee of the People's Hospital of Guangxi Zhuang Autonomous Region. Signed informed consent was obtained from the patients, who were assured that their participation was voluntary, that all data would be kept confidential, and that they had the right to withdraw from the study at any time without consequences.

Operation and postoperative care

For all patients with GC, radical gastrectomy, including total or subtotal radical gastrectomy, was performed by surgeons with extensive experiences in gastric cancer surgical techniques. The surgical technique, excision extension, and extent of lymph node dissection were performed according to the AJCC guidelines [14]. The duodenum was closed in all patients, an incision was made using a linear stapler, and Roux-en-Y digestive tract reconstruction was performed. A nasogastric tube and an abdominal drainage tube were inserted during the operation. All patients were cured with rapid gastrointestinal decompression, broad-spectrum antibiotics, parenteral nutrition (PN), and antacids. When the patient's condition stabilized, Ioversol upper gastrointestinal contrast was routinely carried out between the 5th and the 7th day after surgery. If pus appeared in the drainage tube, fever, dyspnea, empyema, or wound infection possibly related to the fistula was observed, Ioversol upper gastrointestinal contrast, contrast fistulography, and abdominal computerized tomography scan were performed at once to confirm DFS. The abdominal drainage tube was retained until oral feeding.

Table 1

Demographics and clinical characteristics of patients with duodena stump fistula after radical gastrectomy for gastric cancer.

	PCD group (n = 15)	Troca SD group (n = 19)	P value
Age (year, mean ± SD)	68.4 ± 3.9	69.2 ± 3.5	0.530
Gender			<0.001
Male	7	10	
Female	8	9	
Histological type			0.969
Well differentiated	2	2	
Moderately differentiated	5	7	
Poorly differentiated	8	10	
Tumor site			0.907
Fundus	6	7	
Corpus	2	4	
Antro	7	8	
Tumor stage			0.720
Stage I	1	1	
Stage II	2	1	
Stage III	10	15	
Stage IV	2	2	
Abscess size (max diameter (cm)) (mean ± SD)	7.3 ± 2.5	6.7 ± 3.1	0.543
Abscess location			0.846
Hepatorenal crypt	8	10	
Right paracolic sulci	3	3	
Pelvic	2	3	
Multiple abscesses	2	3	
Comorbidities			1.000
Hypertension	3	4	
Diabetes	4	5	
Operation method			0.206
Open	5	6	
Laparoscopic	10	13	
Timing of diagnosis (day, mean ± SD)	5.2 ± 1.6	4.9 ± 2.2	0.658
Laboratory values (mean ± SD)			
BMI (kg/m ²)	25.4 ± 2.7	26.1 ± 3.1	0.490
ESR (mm/h)	40.2 ± 10.3	48.7 ± 9.3	0.299
CRP level (mg/L)	74.3 ± 39.2	49.6 ± 20.4	0.652
WBC (10 ⁹ /L)	13.25 ± 3.4	10.3 ± 2.9	0.380
PLT (10 ⁹ /L)	255 ± 10.8	226 ± 9.7	0.307
ALB (g/L)	32.9 ± 5.2	31.6 ± 4.7	0.445

Conventional management (PCD group)

All patients from January 2011 to December 2017 underwent conventional management (PCD group) as follows. First, when a duodenal stump fistula was diagnosed, the drainage tube placed during the operation was removed because it was usually not in the abscess cavity, and all patients were placed in a naso-jejunal three-lumen feeding tube by using the endoscope technique. This device not only guarantees gastrointestinal decompression, but also provides enteral nutrition (EN). Secondly, the localization of the maximum transverse diameter of the DSF related abscess (DSF-abscess) was determined using B-ultrasound or abdominal computed tomography (CT). Body surface localization was also determined. Finally, after successfully local anesthesia, the collection was punctured with an 18-gauge sheath needle using B ultrasound or computed tomography guidance. A guidewire was inserted an 8-F - 16-F pigtail catheter was advanced and sutured to the skin. The catheter size depends on the maximum transverse diameter of the abscesses. When the illness stabilized, Ioversol upper gastrointestinal contrast and contrast fistulography were performed every other week. None of the patients could begin oral feeding until the fistula healed radiologically.

New management (Troca SD group)

All patients underwent the new treatments (Troca SD group) from January 2018 to December 2021. Zheng et al. [9] suggested that trocar puncture with a sump drain was a technological innovation and revolution for in intra-abdominal abscesses because it can provide

continuous suction and irrigation. However, the flushing tube, which is a part of the sump drain, is often obstructed when it is used for obese patients. Therefore, we altered the position of the flushing tube and inserted it into the outer cannula for improved irrigation. We named this innovative device the “modified sump drainage” (Fig. 1). The operating modified sump drainage procedure was as follows: first, after estimating the localization of the maximum transverse diameter of the DSF abscesses by B-ultrasound or abdominal CT scan, the drainage tube placed during the operation was removed, and body surface localization was confirmed. Second, we incised the skin (10–15 mm) after successful local anesthesia and bluntly isolated the subcutaneous tissue. Third, a 20-gauge needle was inserted into the abscess under the guidance of a B-ultrasound or abdominal CT scan, and the drainage characteristics were evaluated to confirm that the needle had reached the abscess cavity. After confirmation of an abscess with B-ultrasound or CT-guided needle aspiration, the needle was removed, and a 12-mm laparoscopic trocar was then inserted into the DSF-abscesses cavity under the guidance of B-ultrasound or abdominal CT. Finally, the modified sump drainage, which included a flushing tube and negative-pressure drainage, was inserted through the trocar, and then the trocar was removed, leaving the modified sump drainage in situ (Fig. 2).

Statistical analysis

All statistical tests were performed using SPSS 21.0. Continuous variables were shown as means±SD, and categorical variables were shown as percentages. Inter-group continuous variables were compared using two independent samples *t*-tests. Categorical data were compared using the χ^2 test or Fisher's exact test. All tests were two-sided; $p < 0.05$ was regarded as significant statistically. Given the time-dependent property of the probabilities of subsequent surgery and ultimate stoma creation, the cumulative incidence was calculated (one minus the survival function estimate) using the Kaplan-Meier method and compared using the log-rank test.

Results

Demographics and clinical characteristics

This study included 974 patients who underwent gastrectomies for gastric cancer were included between January 2011 and December 2022. Duodenal stump fistula was diagnosed using upper gastrointestinal contrast and contrast fistulography or abdominal computed tomography (CT) in 34 patients (3.5 %). Among them, 15 patients were divided into conventional treatments (PCD group), known as the traditional “percutaneous catheter drainage method”. Nineteen patients received a new treatment (Troca's SD group) as described as above.

Age, sex, histological type, tumor site, tumor stage, abscess size, abscess location, comorbidities, surgical method, and timing of diagnosis were similar between the two groups ($P > 0.05$) (Table 1). No

significant differences were found between the Troca SD group and PCD group in laboratory values, such as body mass index (BMI), ESR, CRP level, WBC, PLT and ALB, before the management of DSF-abscesses ($P > 0.05$). Details are presented in Table 1.

Postoperative and follow-up outcomes

The follow-up periods were similar ($P = 0.592$) in the SD and PCD groups. Only 3 patients (15.8 %) had postoperative complications (1 wound infection and 2 pulmonary infections) in the Troca SD group and 9 patients (60.0 %; 2 bleeding, 1 wound infection, and 4 cholestasis) in the PCD group. Significant statistical differences existed between Troca's SD and PCD groups ($P = 0.012$) (Table 2).

As shown in Table 2, in the Troca SD group, only one patient (5.26 %) underwent duodenostomy creation, whereas six patients (40.0 %) in the PCD group did. The risk of ultimate duodenostomy creation was significantly lower in the duodenostomy creation than in the PCD group ($p = 0.028$). Two patients (10.5 %) in the Troca's SD group and 11 cases (73.3 %) in the PCD group underwent subsequent surgery. Patients in the Troca SD group had a significantly decreased incidence of subsequent operation ($P < 0.001$). As shown in the Kaplan-Meier analysis (Fig. 3), the cumulative incidence of subsequent operation and ultimate duodenostomy creation of patients accepting new management was also significantly lower in the Troca SD group than in the PCD group during the follow-up period ($p < 0.05$).

As shown in Table 2, 15 patients (78.9 %) in the Troca's SD group and 4 patients (26.7 %) in the PCD group were successfully cured, and the fistula healing rates of DSF were significantly higher in the Troca's SD group than in the PCD group ($p = 0.005$). The mean length of postoperative hospital stay was 20.4 ± 7.3 and 52.3 ± 6.7 days in the Troca SD and PCD groups, respectively. A significant reduction in postoperative hospital stay was observed in Troca's SD group ($P < 0.001$).

Table 2 presents two cases (10.5 %) with abscess recurrence in the Troca's SD group and two cases (13.3 %) in the PCD group. In the Troca's SD group, two patients (13.3 %) died due to duodenal stump fistula, while three patients (20 %) died in the PCD group. Importantly, there was no significant difference in the rate of abscess recurrence ($P = 1.000$) or mortality ($p = 0.634$) between the Troca's SD group and the PCD group.

Discussion

Duodenal stump fistula is the most serious complication of radical gastrectomy for gastric cancer because it would lead to a high rate of postoperative morbidity and mortality [15]. In our study, the incidence of duodenal stump fistulae was 3.2 %, which is almost consistent with other literature reviews [16–18]. This can be interpreted by using a linear stapler to close and incise the duodenum, followed by manual intermittent seromuscular suturing of the duodenal stump for reinforcement. However, the optimal therapeutic strategy for duodenal

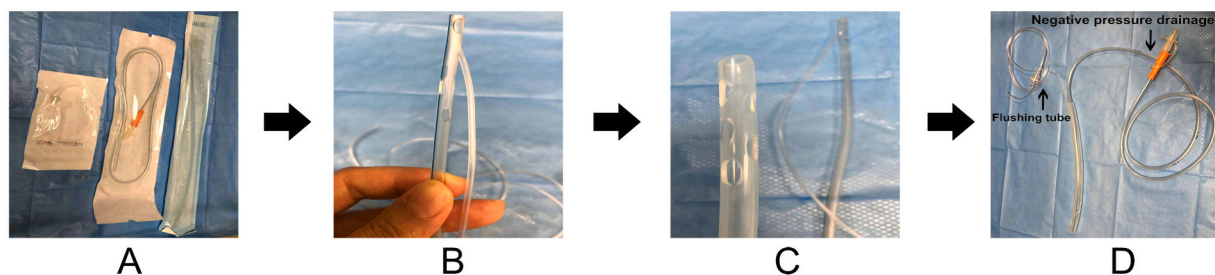


Fig. 1. Procedure of making modified sump drainage. (A) The composition of the modified sump drainage includes a 34F-Chest drainage tube, a 16F-nasogastric tube, and an infusion extension tube. (B) Manufacture of inner cannula: Four to five holes were cut at the front of 16F-nasogastric tube, and the infusion extension tube was inserted into it. (C) Four to five holes were cut at the front of 34F-Chest drainage tube, and the inner cannula was inserted into it. (D) The modified sump drainage setup consists of a flushing tube for irrigation and negative pressure drainage for vacuum aspiration.

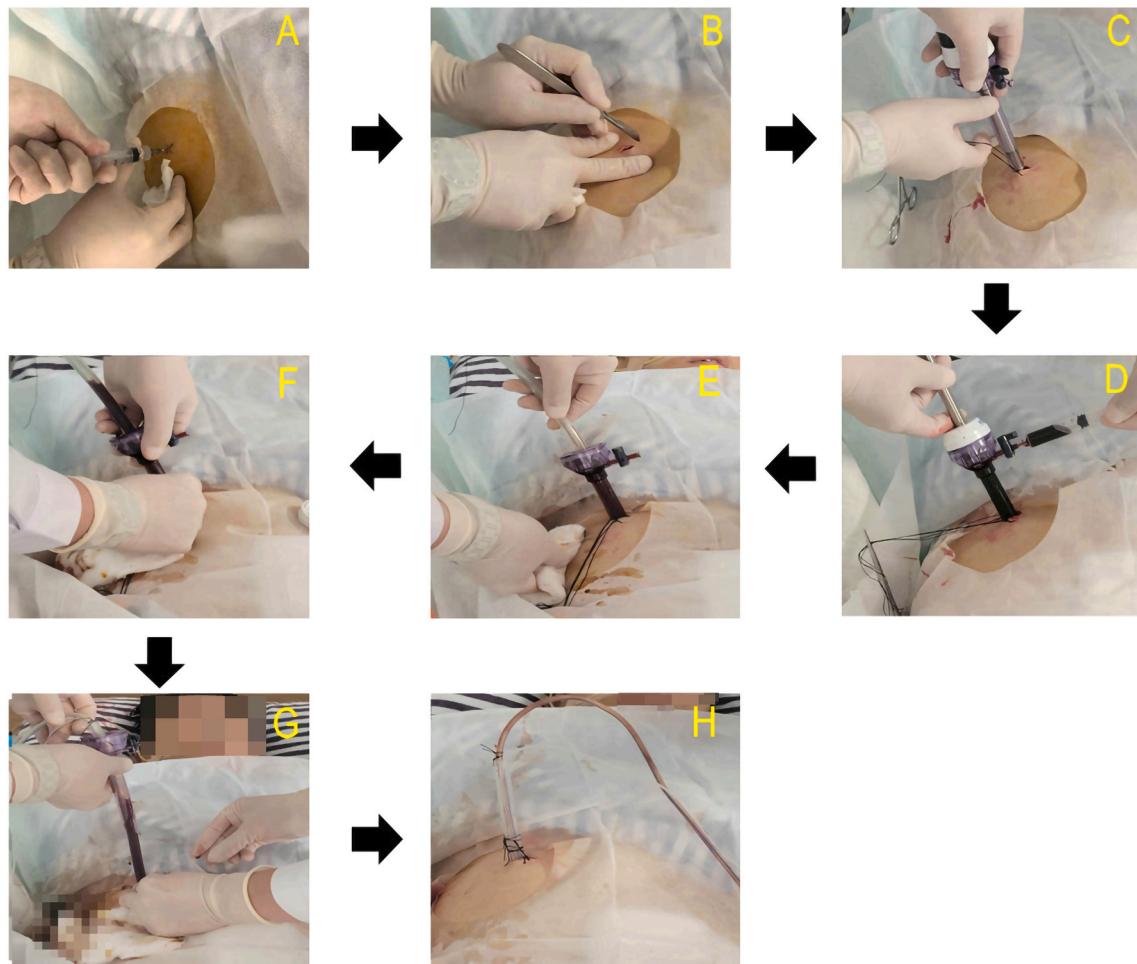


Fig. 2. Procedure of trocar puncture with modified sump drainage in the management of DSF-abscesses in duodena stump fistula after radical gastrectomy for gastric cancer. (A) Local anesthesia using a syringe with lidocaine. (B) Skin incision (usually 10–15 mm) for trocar placement. (C) A 12-mm laparoscopic trocar is placed into the abscess cavity. (D) Purulence is aspirated from the abscess cavity. (E) Modified sump drainage is inserted through the trocar cannula. (F) The trocar is removed, leaving the modified sump drainage in situ. (G) Fixation of the modified sump drainage.

Table 2
Clinical outcomes of management of duodena stump fistula after radical gastrectomy for gastric cancer.

	PCD group (n = 15)	Troca SD group (n = 19)	P value
Follow-up period (month) (mean ± SD)	24.7 ± 6.8	23.4 ± 7.2	0.592
Postoperative complication	9	3	0.012
Bleeding	2	0	
Wound infection	1	1	
Pulmonary infection	2	2	
Cholestasis	4	0	
Duodenostomy creation	6	1	0.028
Subsequent surgery	11	2	<0.001
Fistula healing rates	4	15	0.005
Length of postoperative hospital stay (days) (mean ± SD)	52.3 ± 6.7	20.4 ± 7.3	<0.001
Postoperative recurrence of abscess	2	2	1.000
Death	3	2	0.634

stump fistulae remains controversial. Bile and pancreatic juices are highly corrosive and can hinder the healing of duodenal stump fistula difficult to heal [19]. A variety of fatal bacteria from a patient's stomach and small intestine can lead to serious infections, and resulting in peritonitis, intra-abdominal abscesses, or multiple organ dysfunction syndrome [20]. Numerous studies have pointed out that rapid

gastrointestinal decompression with a nasogastric tube, PN or EN and broad-spectrum antibiotics are the basic treatments for duodenal stump fistulas [21]. Thus, early and adequate drainage of intra-abdominal abscesses is essential [22]. This often requires appropriate abdominal drainage tube placement in a suitable position.

Over the past several years, PCD has been the first treatment choice for intra-abdominal abscesses, especially DSF abscesses [23]. According to the Surgical Infection Society and the Infectious Disease Society of America guidelines, PCD is recommended and preferable for the surgical drainage of intra-abdominal abscesses, because PCD has significantly fewer physiological alterations and decreases the need for surgery [24]. However, PCD can only be performed on well-localized and low-density abscesses [25]. As we known, abscesses are sticky, have multiple internal septations, and are rich in necrotic tissues. Therefore, the modification of PCD devices for better drainage of DSF abscesses has become a research hot spot in the field of surgery.

In this research, we widely used an innovative drainage device called “modified sump drains” for duodenal stump fistula treatment since 2018, different from the sump drain proposed in other studies [9,13,23]. We mainly changed the position of the flushing tube in the innovative drainage device and placed it inside an outer cannula for better irrigation and suction. Moreover, because of its larger diameter, intervals at the ends between the inner and outer tubes, and 4–5 holes in the outer tube, the modified sump drain was difficult to block when placed into the DSF abscesses. Furthermore, trocar puncture is one of the safest ways

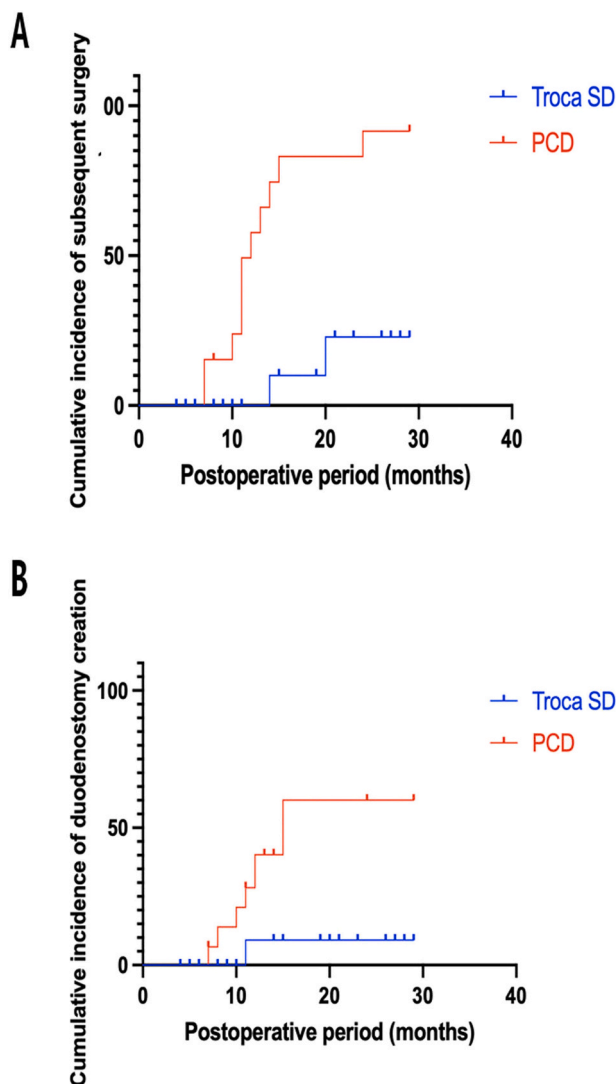


Fig. 3. Cumulative incidence of subsequent surgery and duodenostomy creation in the Trocar SD group and PCD group. (A) Patients in the Trocar group tended to have a lower incidence of subsequent surgery during the follow-up period. (B) The cumulative incidence of duodenostomy creation in patients receiving trocar puncture was significantly lower than in the PCD group during the follow-up period. Cumulative incidence is one minus the estimate of the survival function.

to place a sump drain into intra-abdominal abscesses [23]. Therefore, we combined trocar puncture with a modified sump drain to treat the duodenal stump fistula.

The results of this study show that the clinical outcomes and prognoses of patients with DSF were better in the Trocar's SD and PCD groups. Compared to traditional PCD, trocar puncture with a modified sump drain has several advantages. First, the rate of postoperative complications has decreased. Second, the rates of duodenostomy creation and subsequent surgeries should be reduced. Third, we increased the fistula healing rate of the DSF and shortened the duration of postoperative hospitalization. In addition, although the mortality and abscess recurrence were significantly similar between the SD and PCD groups, there was still a tendency toward a lower rate in the SD group. These results may be due to the small sample size in this study. Therefore, trocar puncture with a modified sump drainage can result in better clinical outcomes and prognoses.

This study has some limitations. Potential selection bias is one of the most common drawbacks of retrospective controlled studies [26]. All

patients included in this study were from the same medical team, and the same physician collected all data; therefore, the selection bias in operative skills and perioperative management, which affected the accuracy of conclusions, was maximally reduced. Moreover, because of the demographic and clinical parameters and DSF-abscesses parameters (such as age, sex, and abscess size,) were not statistically different between the Trocar SD and PCD groups, we believed that all included cases were relatively well matched in this research. Second, only 34 patients were analyzed, and the small sample size may have influenced the reliability of the statistical results. In addition, the duration of follow-up in this study was generally short; thus, a longer follow-up period is required in larger and multicenter studies.

Conclusion

In conclusion, our results demonstrated that trocar puncture with a modified sump drainage is a better option for duodenal stump fistulas after radical gastrectomy for GC. RCTs with larger sample sizes and long-term follow-up are necessary to verify this result.

Ethical approval

The protocol for this research project has been approved by an Ethics Committee of People's Hospital of Guangxi Zhuang Autonomous Region. Signed informed consent for the publication of their images was obtained from the patients, who were assured that their participation was voluntary.

CRediT authorship contribution statement

Dr. Xiao-Tong Wang and Fan-Biao Kong participated in the design and coordination of the study, carried out the critical appraisal of studies and wrote the manuscript. Prof Wei Mai, Han-Qing Ya and Lei Li developed the literature search, carried out the extraction of data, assisted in the critical appraisal of included studies and assisted in writing up. Prof Xiao-Gang Zhong, Long Wang, Huan-Huan Chen, Yan-Fei Zhang and Xiao-Hong Luo carried out the statistical analysis of studies. All authors read and approved the final manuscript.

Funding sources

This work was supported by The National Natural Science Foundation of China (NO. 81660416 and 82260468), the Guangxi Popularization and Application Program of Appropriate Medical Care and Public Health Technology (S2021043 and S2022002), Guangxi Natural Science Foundation (2022JJA141179 and 2022JJA140647), the Science and Technology Research Project of the Health Commission of Guangxi Zhuang Autonomous Region (Z20180739 and Z-A20230002), and the Youth Fund of Guangxi Zhuang Autonomous Region People's Hospital (QN2018-22).

Declaration of competing interest

The authors declare no conflict of interests for this article.

Data availability

Data will be made available on request.

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