EARLY REMOVAL OF THE PROPHYLACTIC DRAIN AFTER DISTAL GASTRECTOMY: RESULTS OF A RANDOMIZED CONTROLLED STUDY

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Abstract : *Background* The optimal timing of the drain removal after gastrectomy has been unclear. The aim of this prospective randomized controlled study was to assess the optimal timing of removal of prophylactic drains after distal gastrectomy (DG) or pylorus-preserving gastrectomy (PPG).
Methods : All patients undergoing DG or PPG for gastric cancer were eligible for this study. The exclusion criteria were combined organ resection, the use of postoperative anticoagulant therapy, intraoperative injury of other organs and anastomotic problems. Just after the operation, the eligible patients were randomly assigned to either the early removal group (n = 50), where the drain was removed in the morning of the postoperative day (POD) 1, or the control group (n = 50), where the drain was removed on POD 3 or later. We compared the surgical outcomes between the groups.
Results : The rate of overall postoperative complications was 18% in the early removal group and 18% in the control group, with no significant difference between the groups. The severity of complications was also similar between the groups. There were no significant differences between the groups with regard to the postoperative recovery, pain or the length of the postoperative hospital stay.
Conclusions : The present study demonstrated the safety and feasibility of the early removal of prophylactic drains in selected patients undergoing DG or PPG for gastric cancer.

Key words : Prophylactic drain, Drain removal, Gastrectomy, Postoperative complication

Introduction

In gastroenterological surgery, drains are routinely placed in order to remove blood, lymph and other exudates that may have accumulated after surgery, and these placed drains might also allow for early recognition of postoperative complications [1, 2]. Furthermore, some postoperative complications may be treated successfully using surgically placed drains. On the other hand, recent advances in surgical techniques and devices, and improvements in perioperative management, have reduced the incidence of postoperative complications after gastrectomy, and the use of drains in itself can cause complications such as organ damage, infection, adhesions and pain [1-4]. In these contexts, there has been much debate concerning

appropriate drain management.

Some randomized clinical trials have failed to show any benefit from prophylactic drain placement, and suggested that routine drain insertion is unnecessary after gastrectomy with lymphadenectomy [5-7]. In addition, recent reviews and meta-analyses also failed to demonstrate evidence to support the use of prophylactic drains in gastrectomy [8, 9]. However, in Japan, the prophylactic placement of drains during gastrectomy is still a common practice. In addition, once a drain has been placed, there is controversy among surgeons as to when to remove it, and the optimal timing of drain removal has been unclear. The present study was performed to determine the optimal timing of removal of prophylactic drains after distal gastrectomy (DG) or pylorus-preserving gastrectomy (PPG) for gastric cancer, and the present study also compared the surgical outcomes between patients in whom drains were removed during the early postoperative period and patients treated with the conventional drain management.

Patients and methods

Before this study, prophylactic drains were generally removed on postoperative day (POD) 3 or later in patients who underwent DG or PPG, based on a physical examination and the aspects of the drainage fluid. In the present study, we compared the surgical outcomes between the group of patients where the drain was removed in the morning of POD 1 (early removal group) and the group where the drain was removed on POD 3 or later (control group). This prospective randomized clinical trial was conducted in the Department of Surgery, Nara Medical University, and was approved by the Local Ethics Committee on Clinical Investigation of Nara Medical University Hospital (No. 641). All patients undergoing DG or PPG with lymph node dissection for gastric cancer were eligible for this study. Written informed consent was obtained from all patients before the operation. The exclusion criteria were (1) combined organ resection (e.g., gall bladder and colon); (2) the use of postoperative anticoagulant therapy and (3) intraoperative injury of other organs and/or intraoperative anastomotic problems. Just after the operation, eligible patients were randomly assigned to either the early removal group or the control group using sealed envelopes made in blocks of 20.

Perioperative management

The surgical procedure and extent of lymph node dissection generally followed the Japanese Gastric Cancer Treatment Guidelines 2010 (version 3) [10]. Perioperative management was performed as reported previously [11]. Briefly, all patients received a prophylactic antibiotic (Cefamezin alpha) before skin incision, and an additional dose was administered when the operation exceeded 3 hours. All antimicrobial prophylaxes were discontinued within 24 hours after the operation. After completion of the intestinal reconstruction, at least one drain was routinely placed at the superior margin of the pancreas. A 6.5-mm silicon multi-channel drain with a closed-suction reservoir (Covidien, Mansfield, MA, USA) was used during the period from January 2012 to November 2012. From December 2012, a 20-F thoracic catheter (Covidien) connected to a closed non-suction system was principally used. Epidural patient-controlled

analgesia (PCA) was principally used in patients undergoing open gastrectomy for postoperative pain, while intravenous patient-controlled analgesia (IVPCA) was used in patients undergoing laparoscopic gastrectomy. In all patients, the amylase concentrations of the drainage fluid (D-AMY) were measured in the morning of POD 1.

In the control group, the drain was removed as described above. In the early removal group, the drain was removed in the morning of POD 1 before knowing the D-AMY level; however, the drain was left in place when abnormal discharge was present, and was only removed when the surgeon judged the drainage to be insignificant. In both groups, the postoperative management was based on the standard practices of our institution; the patients who underwent DG or PPG were permitted to drink water on POD 3 and to eat a soft diet on POD 4 until April 2012. From April 2012, the patients were permitted to drink water on POD 1 and to eat a soft diet on POD 3.

Outcome assessment

The baseline patient characteristics evaluated in each group included the age, sex, body mass index (BMI), the American Society of Anesthesiologists (ASA) score, the presence of comorbidities, the use of preoperative chemotherapy and the clinical tumor stage according to the seventh edition of the American Joint Committee on Cancer TNM classification system [12]. The following surgical data were also included: the approach (open or laparoscopic), the extent of lymph node dissection, the method used for reconstruction, the duration of surgery, the amount of blood loss and the need for a transfusion.

We recorded and evaluated the incidence of postoperative complications for at least 30 days after surgery. The rate of overall postoperative complications was defined as the primary endpoint of the study. The severity of complications was defined according to the Clavien–Dindo classification [13]. An intra-abdominal abscess was defined as described previously [11]. Delayed gastric emptying (DGE) was diagnosed as reported previously [14]. Briefly, DGE was diagnosed when the following were noted: (1) the presence of symptoms such as nausea, vomiting or abdominal fullness, and (2) starting a solid diet after POD 7 or the need for re-fasting. In addition, several surgical outcomes were measured, including the time to first flatus and first walking, the use of analgesics other than PCA, delayed initiation of water and soft diet intake and postoperative changes in the serum total protein level, serum albumin level, white blood cell count and serum C-reactive protein level.

Statistical analysis

The analyses were performed on an intent-to-treat basis. Continuous variables were expressed as the medians and ranges, and the medians were compared using the Mann-Whitney U test. Categorical variables were presented as numbers and percentages, and the groups were compared using the chi-square test or Fisher's exact test. A value of $P < 0.05$ was considered to be significant. The statistical analyses were performed using the SPSS® software program, version 19.0 (SPSS, Chicago, IL).

Results

The trial profile is shown in Fig. 1. A total of 132 patients with histologically confirmed gastric cancer underwent DG or PPG between February 2011 and September 2013. Of these 132 patients, 32 patients met the exclusion criteria due to combined organ resection (n = 18), the use of postoperative anticoagulant therapy (n = 10), intraoperative organ injury (n = 3) or intraoperative anastomotic problems (n = 1). Therefore, 100 eligible patients were randomized to either the early removal group (n = 50) or the control group (n = 50), and all were available for the analysis. In all 100 patients, one drain was placed at the superior margin of the pancreas. Among the 50 patients in the early removal group, the drain was removed on POD 1 in 49 patients. In one patient, the drain was left in place because blood discharge from the drain was evident, and the drain was removed on POD 2 because of a lack of evidence of continuous bleeding. Among the 50 patients in the control group, the drain was removed on POD 3 in 45 patients, on POD 4 in two patients and on POD 5 in one patient. The drain was removed on POD 1 in one patient and on POD 2 in one patient because of drain-related pain.

The baseline characteristics of both groups are shown in Table 1. The median age was

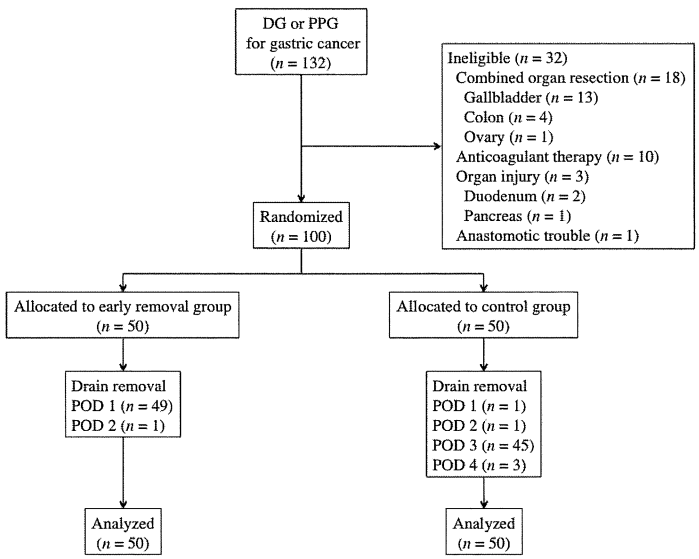

Fig. 1. The patient flow chart. *DG* distal gastrectomy, *PPG* pylorus-preserving gastrectomy, *POD* postoperative day

significantly higher in the early removal group than in the control group, while both groups were comparable with respect to the sex, BMI, ASA score, presence of comorbidities, use of preoperative chemotherapy and clinical tumor stage.

The perioperative data are shown in Table 2. There were no significant differences between the groups in terms of the surgical approach, extent of lymph node dissection, method used for reconstruction, duration of the operation, blood loss, transfusion and the D-AMY level on POD

Table 1. The baseline characteristics of the patients

	Early removal group ($n = 50$)	Control group ($n = 50$)	*P* value
Age (years)[a]	70.5 (52–87)	65 (36–83)	0.043
Sex, *n* (%)			0.133
Male	30 (60)	38 (76)	
Female	20 (40)	12 (24)	
BMI[a]	22.7 (16.6–27.4)	22.4 (15.3–35.9)	0.707
ASA score, *n* (%)			0.476
1	8 (16)	11 (22)	
2	39 (78)	38 (76)	
3	3 (6)	1 (2)	
Comorbidity, *n* (%)			
Present	30 (60)	30 (60)	>0.999
Hypertension	19 (38)	17 (34)	
Cardiovascular	7 (14)	7 (14)	
Diabetes mellitus	10 (20)	8 (16)	
Chronic renal disease	0 (0)	1 (2)	
Pulmonary disease	2 (4)	3 (6)	
Steroid use	1 (2)	1 (2)	
Preoperative CTx, *n* (%)	0 (0)	3 (6)	0.121
Clinical tumor stage, *n* (%)			0.161
0, IA, IB	37 (74)	35 (70)	
IIA, IIB	6 (12)	12 (24)	
IIIA, IIIB, IIIC	7 (14)	3 (6)	

BMI body mass index, *ASA* American Society of Anesthesiologists, *CTx* chemotherapy

[a]The values are expressed as the medians with ranges

Table 2. The perioperative data

	Early removal group ($n = 50$)	Control group ($n = 50$)	*P* value
Approach, *n* (%)			>0.999
Open	21 (42)	21 (42)	
Laparoscopic	29 (58)	29 (58)	
LN dissection, *n* (%)			0.527
D1 or D1+	35 (70)	31 (62)	
D2 or more	15 (30)	19 (38)	
Reconstruction, *n* (%)			0.249
Billroth-I	28 (56)	20 (40)	
Roux-en-Y	20 (40)	26 (52)	
Pylorus-preserving	2 (4)	4 (8)	
Duration of the operation (min)[a]	287.5 (167–436)	308 (167–488)	0.379
Blood loss (mL)[a]	100 (20–653)	109.5 (17–740)	0.426
Transfusion, *n* (%)	0 (0)	0 (0)	>0.999
Drain amylase level on POD 1 (U/L)[a]	545.5 (58–9,200)	489.5 (55–5,786)	0.588

LN lymph node, *POD* postoperative day

[a]The values are expressed as the medians with ranges

Postoperative complications

The incidence of postoperative complications is shown in Table 3. The rate of overall postoperative complications was 18% in the early removal group and 18% in the control group, with no significant difference between the groups (P >0.999). The incidence of severe complications (grade IIIa or greater) was also similar between the groups. One patient in the early removal group died of aspiration pneumonia 142 days after gastrectomy. One patient in the control group developed a superficial surgical site infection requiring incisional drainage under local anesthesia. Two patients, one in each group, had an intra-abdominal abscess that resulted from a pancreatic fistula, and these patients were successfully treated with antibiotics. No patients required secondary procedures, such as reoperation or radiological or endoscopic intervention.

Table 3. The postoperative complications

	Early removal group (n = 50)	Control group (n = 50)	P value
Total, n (%)	9 (18)	9 (18)	>0.999
Intra-abdominal abscess, n (%)	1 (2)	1 (2)	
DGE, n (%)	6 (12)	2 (4)	
Superficial incisional SSI, n (%)	0 (0)	1 (2)	
Remote infection, n (%)	2 (4)	2 (4)	
Pneumonia	1	1	
Cholecystitis	1	0	
Epididymitis	0	1	
Bleeding, n (%)	1 (2)	2 (4)	
Intracorporeal	1	1	
Drain site	0	1	
Medical, n (%)	1 (2)	2 (4)	
Clavien-Dindo classification, n (%)			
I	1 (2)	3 (6)	
II	7 (14)	5 (10)	
IIIa	0 (0)	1 (2)	
V	1 (2)	0 (0)	

DGE delayed gastric emptying, *SSI* surgical site infection

Postoperative clinical course

The postoperative clinical course of each group is shown in Table 4. There were no significant differences between the groups in terms of the day until first flatus and first walking, the analgesic use, the delayed initiation of water intake and a soft diet, the postoperative serum total protein level, serum albumin level, white blood cell count or the serum C-reactive protein level. The median length of postoperative hospital stay was 11 days in the early removal group and 11 days in the control group, with no significant difference between the groups (P = 0.612).

Table 4. The surgical outcomes

	Early removal group ($n = 50$)	Control group ($n = 50$)	P value
First flatus, POD[a]	3 (1–6)	3 (1–6)	0.925
First walking, POD[a]	1 (1–4)	1 (1–2)	0.402
Analgesic use[a]	0 (0–8)	0 (0–11)	0.916
Delayed initiation of water intake, n (%)	2 (4)	4 (8)	0.339
Delayed initiation of soft diet, n (%)	0 (0)	4 (8)	0.059
Serum total protein level (g/dL)[a]			
POD 1	5.4 (4–6.9)	5.3 (3.8–6.3)	0.592
POD 3	6.1 (4.8–7.3)	5.8 (4.6–7.3)	0.116
POD 7	6.45 (4.8–7.7)	6.4 (4.8–7.6)	0.966
Serum albumin level (g/dL)[a]			
POD 1	3.15 (2.2–4.7)	3.3 (2–3.9)	0.673
POD 3	3.4 (1.9–4.2)	3.25 (2.4–4)	0.427
POD 7	3.65 (2.6–4.7)	3.75 (2.4–4.5)	0.493
White blood cell count (/μL)[a]			
POD 1	9,850 (3,700–16,200)	9,000 (4,800–15,900)	0.799
POD 3	8,000 (3,400–12,100)	6,700 (3,400–15,200)	0.085
POD 7	6,200 (2,700–12,900)	6,250 (3,400–11,000)	0.238
C-reactive protein (mg/dL)[a]			
POD 1	5.85 (1.6–12.7)	5.75 (1.6–12.9)	0.707
POD 3	7.95 (1.3–21.7)	8.2 (0.8–26.3)	0.817
POD 7	2.15 (0.1–10.5)	2.55 (0.2–10.7)	0.403
Postoperative hospital stay (days)[a]	11 (7–171)	11 (8–27)	0.612

POD, postoperative day

[a]The values are expressed as the medians with ranges

Discussion

In this prospective randomized controlled study, we compared the surgical outcomes of patients treated with the early removal of the prophylactic drain with those who were treated with conventional drain management following DG or PPG for gastric cancer. We found no significant differences between the two treatment arms with regard to the rate of overall postoperative complications. Furthermore, none of the patients in either group required secondary interventions. These results indicate that early removal of the prophylactic drain may be safe and feasible in selected patients after DG or PPG for gastric cancer.

One of the rationales behind the placement of drains is that the drain can provide an early warning sign of postoperative complications such as intra-abdominal bleeding, pancreatic fistula formation and anastomotic leakage. Early postoperative bleeding usually occurs during the first 24 hours postoperatively. Although intra-abdominal bleeding has been reported to be rare [15-17], massive bleeding can lead to a serious or fatal condition. Recently, some studies demonstrated that the use of a prophylactic drain did not provide any additional benefit for patients undergoing gastrectomy, and advocated that such postoperative complications can be diagnosed by clinical and radiological findings [7, 18]. However, it seems premature to conclude that omitting drains after gastrectomy is safe, because those studies did not include a large

number of patients. In addition, the responses to such serious complications may be delayed in patients without drains. In the present study, postoperative intra-abdominal bleeding occurred in two patients (2%), one on the night of the operation and one in the morning of POD 2, and these patients were closely monitored. As a consequence, both patients required neither transfusion nor therapeutic interventions because they were hemodynamically stable. We believe that prophylactic drains might be meaningful for the early detection and immediate treatment of early postoperative bleeding to avoid mortality.

From the viewpoint of the severity of postoperative complications, the present study demonstrated the safety of early removal of the prophylactic drain in patients who underwent DG or PPG. Another role for drains is to treat postoperative complications, such as a pancreatic fistula and anastomotic leakage, if they occur. In Japan, the placement and management of drainage tubes is generally considered to have an important role in the postoperative care of gastrectomy patients, because adequate management through well-placed drains may reduce or obviate the need for reoperations [19, 20]. On the other hand, the incidence of intra-abdominal infectious complications has been reported to be less common in distal gastrectomy than in total gastrectomy [21, 22]. Furthermore, in the event of such complications, patients without a drain in place can still be treated by interventional radiology [23, 24]. In the present study, one patient in each group had an intra-abdominal abscess associated with a pancreatic fistula. Both complications were diagnosed after the drain removal, and these patients were successfully treated without the need for radiological intervention. These data suggest that early drain removal may be safe in the patients who undergo DG or PPG, except in cases with evidence of intraoperative adjacent organ injury or anastomotic problems. In such cases, the drain is therapeutic but not prophylactic.

The surgically placed drain itself can cause intra-abdominal infectious complications by providing a route for ascending infections. Kawai et al. reported that early removal of surgically inserted drains reduced the incidence of ascending infections, and reduced subsequent intra-abdominal infections, including intra-abdominal abscess formation and infected intra-abdominal accumulation, and further showed that a longer period of drain insertion was an independent risk factor for such complications in patients undergoing pancreatic head resection [25]. We recently investigated the impact of bacterial culture positivity of the drainage fluid on the subsequent development of an intra-abdominal abscess in gastrectomy patients, and demonstrated that the patients with positive bacterial cultures on POD 1 had a significantly higher percentage of intra-abdominal abscesses than those with negative cultures, especially among the patients with a higher D-AMY level [11]. Furthermore, bacterial culture positivity of the drainage fluid on POD 1 was the only independent risk factor for intra-abdominal abscess formation in patients without anastomotic leakage after gastrectomy. The presence of bacteria, in addition to a high D-AMY level, seems to be crucial for intra-abdominal abscess formation after gastrectomy. In addition, it is widely recognized that the incidence of drain-fluid infection is increased when drain placement is prolonged [1, 3, 26]. Therefore, long-term drain placement itself may contribute to the incidence of intra-abdominal infectious complications after gastrectomy, and prophylactic drains should be removed as early as possible to prevent such complications in patients undergoing gastrectomy. In the present study, we found no

significant difference in the incidence of intra-abdominal infectious complications between the groups, probably due to the relatively small number of patients included and the relatively short duration of the drain insertion in the control group.

The placement and prolonged use of drains themselves can also contribute to increased postoperative pain, preventing deep inspiration and preventing ambulation [4, 27]. Previous studies reported that gastrectomy patients with a drain used analgesics more frequently and resumed eating and passed flatus significantly later compared with those without the drain [5, 18]. The postoperative hospital stay was also significantly longer in the patients with the drain than in those without the drain [6]. In addition, a previous study reported that 7.1% of patients developed drain-related complications after subtotal gastrectomy [7]. In the present study, there were no significant differences between the groups in terms of the incidence of postoperative pneumonia, time to first flatus and first walking, analgesic use or the length of the postoperative hospital stay, while we found some drain-related complications. Two patients in the control group had severe drain-related pain. Their drains were removed on POD 1 and POD 2, and the pain disappeared completely. In one patient, drain site bleeding occurred in the morning of POD 1. He developed anemia on POD 2, but did not require a transfusion because his vital signs were stable. Taken together, these findings indicate that the early removal of the prophylactic drain may contribute to accelerating the postoperative physiological recovery, and seems to be essential for enhanced recovery after surgery protocols.

In conclusion, the present study demonstrated the safety and feasibility of the early removal of the prophylactic drain in selected patients after DG or PPG for gastric cancer. However, the present study is associated with some limitations because the number of patients included was small. Further studies are needed to validate our results.

Conflicts of interest

None of the authors has any financial conflict to disclose in association with this study.

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