Impact of drain insertion after perforated peptic ulcer repair in a Japanese nationwide database analysis

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Authorsôcontributions

KO contributed to the study conception and design, data collection, analysis, interpretation of the results, drafting of the manuscript, and critical review for important intellectual content. KH contributed to the study design, analysis, interpretation of the results, and critical review for important intellectual content. SK contributed to the study design, data collection, analysis, interpretation of the results, and critical review for important intellectual content. TN contributed to the study design, analysis, interpretation of the results, and critical review for important intellectual content. HH contributed to the study design, interpretation of the results, and critical review for important intellectual content. YS contributed to the study design, interpretation of the results, and critical review for important intellectual content. YI contributed to the study design, data acquisition, interpretation of the results, and critical review for important intellectual content. All authors read and approved the final version of the manuscript.

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Abstract

Background Many perforated peptic ulcers (PPUs) require surgical repair due to diffuse peritonitis. However, few studies have examined the clinical effects of postoperative drainage after PPU repair. This study aimed to investigate the drain insertion rates in patients who underwent PPU repair in Japan, and to clarify the impact of drain insertion on the postoperative clinical course.

Methods A retrospective nationwide cohort study was performed using administrative claims data of patients who had undergone PPU repair between 2010 and 2016. These patients were divided into two groups based on whether or not they had received a postoperative abdominal drain. Using propensity score matching, we compared the incidences of postoperative interventions for abdominal complications between both groups.

Results A total of 4869 patients from 324 hospitals were analyzed. At the hospital level, drains were placed in all PPU repair patients in 229 (70.7%) hospitals. At the patient level, 4401 patients (90.4%) had drains inserted. The drain group was associated with a higher emergency admission rate, poorer preoperative shock status, longer anesthetic time, and a higher amount of intra-abdominal irrigation. In the propensity scoreï matched patients, the drain group had a significantly lower incidence of postoperative interventions than the no-drain group (1.9 vs. 5.6%; risk ratio = 0.35; 95% confidence interval = 0.16-0.73; *P* = 0.003).

Conclusion Postoperative drainage was performed in the majority of patients who underwent PPU repair in Japan. Drainage following PPU repair may facilitate patient recovery by reducing the need for postoperative interventions.

Introduction

Peptic ulcers, both gastric and duodenal, are a major cause of upper gastrointestinal tract perforation. Although the incidence of perforated peptic ulcers (PPUs) has dramatically decreased in recent years, the mortality rate after surgical repair remains relatively high [1-4]. If patients meet certain favorable conditions, physicians can adopt a conservative non-surgical therapeutic approach where the PPUs eventually seal off [5, 6]. However, surgical closure is employed in the majority of PPU cases. Perioperative management must be optimized to limit the risks of postoperative complications. In Japan, drain catheters are conventionally inserted after peritoneal cavity irrigation to discharge waste fluid from the inevitable peritonitis. A previous study reported substantial differences in the frequency of drain insertion among different countries and regions [7].

Only a few studies with limited sample sizes have previously examined the relationship between the use of surgical drains and postoperative complications in PPU patients, including only one study from Japan that was written in the Japanese language [8-11]. Although these studies have generally concluded that drain insertions are useless, none have sufficiently considered the differences in preoperative conditions between patients with and without drains. The proportion of patients with drain insertions throughout Japan and the effect of drain use on complications after PPU repair have yet to be elucidated.

This study aimed to investigate the drain insertion rates after PPU repair in Japan using a nationwide database, and to clarify the impact of drain insertion on the postoperative clinical course (including morbidity, mortality, and medical costs) while accounting for patient differences using propensity score matching.

Material and Methods

Data source

This study utilized a nationwide administrative claims database comprising Diagnosis Procedure Combination (DPC) data collected by the Quality Indicator/Improvement Project (QIP). The QIP has previously analyzed healthcare processes, patient outcomes, and disease management in Japan [12, 13]. In this project, administrative claims data are anonymously provided from more than 500 voluntarily participating acute care hospitals located throughout Japan. Data security is strictly enforced in compliance with International Organization for Standardization (ISO) 27001 standards.

Hospitals that are reimbursed under Japanôs DPC Per-Diem Payment System (DPC/PDPS) are obligated to produce uniformly formatted DPC data in order to receive payments [13, 14]. Briefly, the DPC/PDPS is a case-mix classification system for reimbursements to acute care hospitals as part of Japanôs public medical insurance system. In this system, diagnoses for each patient are coded by physicians based on International Classification of Diseases, 10th revision (ICD-10) codes.

Patients

We retrospectively identified patients who had undergone PPU repair and had been discharged between July 2010 and March 2016 from the hospitals in the QIP database.

PPUs were identified as perforated gastric/duodenal ulcers (ICD-10 codes: K25.1ï 2, K25.5ï 6, K26.1ï 2, K26.5ï 6, K27.1ï 2, or K27.5ï 6) or diffuse peritonitis (ICD-10 codes: K65.0 or K65.8ï 9) caused by gastric/duodenal ulcers under the recorded disease designations of ñprimary diseaseò or ñdisease resulting in admission.ò The following repair surgeries were identified using unique Japanese surgery codes from DPC data: gastric/duodenal suturing operations (including omental patch or omental covering techniques) (codes: K647, K647ï 2) and diffuse peritonitis operations (codes: K639, K639ï 3).

Patients who fulfilled the following criteria were excluded from analysis: (1) confirmed diagnosis of perforated gastric/duodenal neoplasm, (2) iatrogenic gastric/duodenal perforation, (3) traumatic gastric/duodenal perforation, (4) perforation caused by foreign bodies, (5) pathogeneses other than peptic perforations, and (6) patients who underwent PPU repair only after 8 days or more from the admission date.

Definition of drain insertion

Drain insertion was defined through the reported use of indwelling catheters on the day of surgery based on reimbursement claims. Patients were then divided into a drain group and a no-drain group.

Outcome measures

First, the drain insertion rates and clinical course following PPU repair in Japan were investigated. Next, the impact of drain insertion on the postoperative clinical course was evaluated using propensity score matching. The primary outcome measure of comparison between the drain and no-drain groups was the incidence of postoperative interventions for abdominal complications from the day after the index surgery was conducted. These complications were identified using the DPC codes listed in Table 1. The secondary outcome measures were postoperative 30-day in-hospital mortality, postoperative fasting duration, length of postoperative hospital stay, and hospitalization expenses per diem (including surgery and nursing care).

Risk adjustment variables

The following variables were adjusted in the propensity score analysis: hospital case volume, the number of surgeons at each hospital, patient age, sex, steroid use, Charlson comorbidity index [15], ambulance use, emergency admission, preoperative shock, central venous catheter use, surgical methods, anesthesia time, and the amount of intra-abdominal irrigation.

Hospital case volume was defined as the average number of patients who underwent PPU repair per year, and hospitals were categorized into low case volume (≤5 cases/year), intermediate case volume (6-9 cases/year), and high case volume (≥10 cases/year) groups. Based on the protocol described in Quan et al. [16], the ICD-10 code for each comorbidity was converted into a score and summed up at the patient level to calculate the Charlson comorbidity index. Preoperative shock was defined as the need for vasopressor agents on the day of or before surgery.

Statistical analysis

Continuous variables were summarized as mean values with standard deviation or median values with interquartile range, and compared using the *t*-test or Mann-Whitney *U* test, respectively. Categorical variables were shown as numbers or prevalence, and compared using the χ^2 test or Fisherðs exact test, as appropriate.

The propensity score matching analysis was conducted to compensate for the differences in baseline patient characteristics between the two groups, thereby minimizing the effects of potential confounders and selection bias. A propensity score was calculated through logistic regression for each patient using the risk adjustment variables stated above. Subsequently, the patients in the drain and no-drain groups were matched according to their propensity scores. The incidences of postoperative complications were compared between the two groups using McNemarðs test and Wilcoxon signed-rank test in the propensity scoreï matched patients. We estimated the risk ratio, risk difference, and 95% confidence intervals (CI) for postoperative interventions, and calculated the number needed to treat as the reciprocal of the risk difference.

P values below 0.05 were considered significant in all statistical analyses. Statistical analyses were performed using JMP Statistics software version 11.0 (SAS Institute Inc. Cary, NC, USA).

Ethical standard

The collection and analysis of DPC data were approved by the ethics committee of each QIP participant hospital. Furthermore, approval for this specific study was granted (Approval number: R-0714) by the Ethics Committee of Kyoto University Graduate School of Medicine. The study complied with the Declaration of Helsinki and the Ethical Guidelines for Medical and Health Research Involving Human Subjects stipulated by the Japanese national government for the protection of patient anonymity.

Results

Patient characteristics

A total of 4869 patients who underwent PPU repair surgery at 324 hospitals were identified from the QIP database (Fig. 1). Drains were placed after PPU repair in 4401 patients (90.4%). At the individual hospital level, drains were inserted in all patients who underwent PPU repair in 229 hospitals (70.7%), as illustrated in Fig. 2. In contrast, there were five hospitals (1.5%) where none of the patients received a drain. The drain group was associated with a higher emergency admission rate, poorer preoperative shock status, longer anesthetic time, and a higher amount of intra-abdominal irrigation (Table 2). In addition, the hospitals with higher hospital case volume and higher number of surgeons tended to avoid drain insertion.

Postoperative outcomes

The postoperative outcomes are summarized in Table 3. Overall, 165 patients (3.4%) required postoperative interventions for abdominal complications, and 119 patients (2.4%) died during hospitalization within 30 days after PPU repair.

Postoperative abdominal complications requiring interventions occurred in 139 patients (3.2%) in the drain group and 26 patients (5.6%) in the no-drain group. Even when classified into the two separate subcategories of complications, the incidences of percutaneous drainage and reoperation were also higher in the no-drain group. The drain group had a lower postoperative 30-day in-hospital mortality rate (2.3%) than the no-drain group (3.6%).

Propensity score analysis

In the propensity score analysis, each group had 467 matched patients (Table 2). The incidence of postoperative interventions was significantly lower in the drain group than in the no-drain group (1.9 vs. 5.6%; risk ratio=0.35, 95% CI=0.16-0.73, P = 0.003). There were no significant differences between the two groups in postoperative 30-day in-hospital mortality, postoperative fasting duration, length of postoperative hospital stay, and hospitalization expenses per diem (Table 4). The number needed to treat was calculated to be 27.5 (Table 5).

Discussion

This study, which included almost 5000 patients from more than 300 hospitals throughout Japan, is one of the largest nationwide cohort studies conducted on drain insertion after PPU repair. Our findings showed that the vast majority (90.4%) of patients who underwent PPU repair in Japan received drains, which were associated with a reduction in postoperative complications that required interventions.

The results of a previous poll indicated that drain insertions after surgical repair of PPU were less likely performed in North America (6%), Western Europe (10%), or Latin America (13%) than in the Asian countries (40%), including Japan [7]. However, the evidence for those findings was limited because the positive response rate among the targeted surgeons was low at only 10%. Here, our nationwide study revealed that drain insertions in Japan were more frequent than previously reported [7]. Prior to the implementation of the DPC system, the Japanese medical system had conventionally permitted reimbursements to hospitals based only on the actual utilization of healthcare services using a fee-for-service approach. We believed that the DPC system contributed to reducing the use of drains. However, this study revealed that drains were still widely used after PPU repair in Japan.

Although previous studies have not ascertained the beneficial role of drain use after PPU, those studies did not adjust for patient characteristics that potentially affect postoperative complications [8, 17, 18]. This study revealed that patients with relatively severe conditions such as preoperative shock, central venous catheter use, or an emergency admission tended to have drains inserted. In addition, the propensity score analysis revealed that drain use predicted a 65% risk reduction in postoperative abdominal complications that required interventions. To the best of our knowledge, this is the first study to adjust for the differences in preoperative conditions in order to evaluate the impact of drain use on postoperative complications in PPU repair patients.

A systematic review reported that the mortality rate for PPU patients was 23.5% (95% CI = 15.5-

31.0) [19]. Among these studies, those that analyzed hospital-based cohorts described relatively high mortality in their patients. Previous nationwide studies based on administrative data sources have indicated that the mortality associated with PPU was 5.5% in Spain [1] and 3.2% in South Korea [20]. Our findings showed similar mortality in PPU cases in Japan. However, geographical variations and mode of data collection should be carefully considered when comparing reported mortality rates [21, 22].

In addition, our data clarified that the hospitalization expenses per diem were equally distributed between the two groups (Table 4). To date, there have been no reports that discuss the drainage-related expenses for patients with PPU, whereas cost-effectiveness of laparoscopic and open surgery of PPU has been compared [23]. While the drain itself is inexpensive and technologically simple, our findings suggest that its use may improve postoperative clinical course.

Table 3 shows that the no-drain group had a 5.6% intervention rate after PPU repair under Japanôs current medical standard. The effectiveness of drainage in patients with PPU was evaluated using the number needed to treat, which was estimated to be 27.5 (Table 5). Therefore, post-PPU repair drains should be inserted in more than 20 patients with abdominal pain or deterioration in quality of life in order for one patient to benefit. Accordingly, physicians must consider the balance between each patientôs benefit and risk from drain insertion.

This study has several limitations that should be considered. First, there were substantial variations in patient characteristics between the drain group and the no-drain group. As this was not a randomized controlled trial, we attempted to reduce potential selection bias through propensity score matching, including most of the risk factors previously reported [24-26]. Nevertheless, there may be several unobserved confounding factors not included in DPC data, such as patientsô vital signs, laboratory results, imaging data, and surgical delay. These clinical variables may reflect each patientôs condition more directly than the factors extracted from DPC data. However, information on ambulance use, vasopressor agent use, central venous catheter use, and intra-abdominal irrigation could substitute for clinical variables that reflect patient severity. Second, as the main surgical treatment for PPU is repair surgery [6, 18], we focused on PPU repair and did not include gastric resection or conservative therapy to evaluate the effectiveness of drainage. Finally, the study population was obtained from acute care hospitals that voluntarily participate in the QIP. Therefore, there may be a degree of selection bias that attenuates the generalizability of our findings.

Despite these limitations, the present study has advantages over previous studies that have generally suffered from insufficient sample size. We believe that these findings can contribute to the surgical management of PPU.

In conclusion, postoperative drainage was performed in the majority of patients who underwent PPU repair in Japan. Drainage following PPU repair may improve patient recovery by reducing the incidence of postoperative complications that require interventions. Further well controlled prospective study, most preferably a randomized controlled trial, is required to reveal the feasibility of drainage following PPU repair.

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Conflict of interest The authors declare no conflicts of interest.

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Fig. 1 Flow of patient selection from the Diagnosis Procedure Combination database

A total of 4869 patients who underwent perforated peptic ulcer (PPU) repair surgery were identified. Drains were placed in 4401 patients and were not placed in 468 patients. In the propensity score analysis, each group had 467 matched patients. * Patients who underwent PPU repair only after 8 days or more from the admission date.

Fig. 2 Hospital-level drain insertion rate

Each column indicates the drain insertion rate at one hospital. In 229 hospitals (70.7%), drains were inserted in all patients who underwent surgical repair of perforated peptic ulcer; in 5 hospitals (1.5%), no drains were inserted in any of the patients who underwent surgical repair of perforated peptic ulcer.

able 1 Outcome definitions

Outcomes		Definitions	DPC codes
Postoperative intervention	Percutaneous intervention	One-time abdominal puncture (not intended for prolonged drainage)	J010, J013, D408, D419-2
		Drain replacement	J021
		Percutaneous abscess drainage	K637-2
		Localized abscess drainage (local anethesia)	K637 without L008
	Reoperation	Gastric/duodenal suturing operation (including omental patch or omental covering techniques) after the index operation	K647, K647-2
		Diffuse peritonitis operation after the index operation	K639, K639-3
		Exploratory laparotomy	K636
		Localized abscess drainage (general anethesia)	K637 with L008

DPC, Diagnosis Procedure Combination.

able 2 Demographic, clinical, and surgical characteristics of patients

	Eligible patients			Propensity score-matched patients		
	No-Drain $n = 468$	Drain $n = 4401$	P value [b]	No-Drain $n = 467$	Drain $n = 467$	P value [b]
	n (%)	n (%)		n (%)	n (%)	
Hospital case volume (/year)						
Low (≤5)	111 (24)	2214 (50)	<0.001	111 (24)	112 (24)	0.996
Intermediate (6-9)	152 (32)	1262 (29)		151 (32)	150 (32)	
High (≥10)	205 (44)	925 (21)		205 (44)	205 (44)	
The number of surgeons (/hospital/year)						
Low (<10)	214 (46)	2597 (59)	<0.001	213 (46)	213 (46)	1.000
High (≥10)	254 (54)	1804 (41)		254 (54)	254 (54)	
Age						
<75	371 (79)	3336 (76)	0.094	371 (79)	370 (79)	0.936
≥75	97 (21)	1065 (24)		96 (21)	97 (21)	
Sex ratio (M : F)	353 : 115	3188 : 1213	0.167	353 : 114	353 : 114	1.000
Steroid use	26 (6)	299 (7)	0.308	26 (6)	26 (6)	1.000
Charlson Comorbidity Index						
0	293 (63)	2678 (61)	0.333	292 (63)	286 (61)	0.922
1 to 2	148 (32)	1516 (34)		148 (32)	153 (33)	
≥3	27 (6)	207 (5)		27 (6)	28 (6)	
Ambulance use	290 (62)	2790 (63)	0.572	290 (62)	288 (62)	0.893
Emergency admission	276 (59)	2942 (67)	<0.001	276 (59)	272 (59)	0.790
Preoperative shock status	45 (10)	798 (18)	<0.001	45 (10)	43 (9)	0.823
Central venous catheter use	38 (8)	663 (15)	<0.001	37 (8)	40 (9)	0.721
Surgical methods						
Open	179 (38)	1699 (39)	0.880	178 (38)	192 (41)	0.349
Laparoscopic	289 (62)	2702 (61)		289 (62)	275 (59)	
Anesthesia time (min)[a]	130 (37)	144 (50)	<0.001	130 (37)	130 (38)	0.972 [c]
The amount of intraabdominal irrigation (/L)						
Low (<10)	350 (75)	3043 (69)	0.012	349 (75)	359 (77)	0.445
High (≥10)	118 (25)	1358 (31)		118 (25)	108 (23)	

[a] Valuesshown in mean(Standard Deviation) [b] $\chi 2$ test, excwpt [c] t-test.

able Postoperative outcomes of the overall sample

	Total *n* = 4869	No-Drain *n* = 468	Drain *n* = 4401
Postoperative interventions, *n* (%)	165 (3.4)	26 (5.6)	139 (3.2)
Percutaneous intervention	140 (2.9)	21 (4.5)	119 (2.7)
Reoperation	40 (0.8)	8 (1.7)	32 (0.7)
30-day in-hospital mortality, *n* (%)	119 (2.4)	17 (3.6)	102 (2.3)
Fasting Duration, median (IQR)	6 (4-7)	5 (3-7)	6 (4-7)
Length of postoperative hospital stay, median (IQR)	14 (10-21)	12 (9-17)	14 (11-21)
Hospitalization expences per diem (US$)[a], median(IQR)	657 (539-808)	705 (560-911)	654 (537-802)

IQR, interquartile range. [a] US$1 = ￥110.

able Postoperative outcomes of the propensity score-matched patients

	No-Drain n = 467	Drain n = 467	P value [b]
Postoperative interventions, n (%)	26 (5.6)	9 (1.9)	0.003
Percutaneous intervention	21 (4.5)	8 (1.7)	0.016
Reoperation	8 (1.7)	1 (0.2)	0.020
30-day in-hospital mortality, n (%)	17 (3.6)	8 (1.7)	0.072
Fasting Duration, median (IQR)	5 (3-7)	5 (4-7)	0.219 [c]
Length of postoperative hospital stay, median (IQR)	12 (9-17)	12 (10-17)	0.106 [c]
Hospitalization expences per diem (US$)[a], median (IQR)	704 (563-913)	683 (566-867)	0.403 [c]

IQR, interquartile range. [a] US$1 = ￥110 [b] McNemar's test, except [c] Wilcoxon signed-rank test.

able The risk ratio, risk difference, and the number needed to treat for postoperative interventions in the drain group and the no-drain group

	Postoperative interventions *n* (%)	RR [a]	RD [a]	NNT [a]
Propensity score-matched patients				
No-Drain (*n* = 467)	26 (5.6)	0.35 (0.16-0.73)	0.036 (0.011-0.060)	27.5 (16.4-87.4)
Drain (*n* = 467)	9 (1.9)			

RR, risk ratio RD, risk difference NNT, number needed to treat. [a] Values in parentheses are 95% confidence intervals.