Original Article

Management of Stapfer Type II Perforations After Endoscopic Retrograde Cholangiopancreatography: A Retrospective Study

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ABSTRACT

Objective: Stapfer type II perforations are serious, rare complications associated with endoscopic retrograde cholangiopancreatography (ERCP). Controversies remain in the literature regarding the optimal management of these perforations. The aim of this study was to evaluate different management approaches for this complication.

Materials and Methods: In this retrospective study, data were collected from the medical records of adult patients treated for Stapfer type II perforations. Variables evaluated included demographics, ERCP indication, time to diagnosis and surgery, methods of management, length of hospital stay, and patient outcomes.

Results: Twenty-three patients were included in the study, with a mean (± standard deviation, SD) age of 54.8 (±11.1) years. The indications for ERCP were choledocholithiasis (n=17), suspected sphincter of Oddi dysfunction (n=5), and biliary fistula after cholecystectomy (n=1). Perforation was diagnosed on the day of the procedure in 12 patients (52.2%). Fifteen patients (65.2%) were managed surgically. Time to surgery was significantly correlated with the length of hospital stay. Three patients in the non-surgical group died, while there were no mortalities in the surgical group.

Conclusion: Patients with ERCP-related type II perforations can initially be treated non-surgically. However, clinicians must remain vigilant for failure of non-surgical management, and treatment approaches should be individualized based on the patient's clinical condition. Surgical intervention should be considered with appropriate patient selection and timing.

Keywords: Acute abdomen, endoscopic retrograde cholangiopancreatography, endoscopic sphincterotomy, intestinal perforation, postoperative complications.

INTRODUCTION

Endoscopic-retrograde cholangiopancreatography (ERCP) has emerged as a crucial diagnostic and therapeutic method for the management of biliary and pancreatic diseases. The most common indications include biliary stones, obstruction, fibrosis, malignancy, iatrogenic injuries,

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and dysfunction of the sphincter of Oddi. Since the 1980s, ERCP has increasingly been used for therapeutic interventions in hepatobiliary diseases. Due to potential complications that may arise during or after the procedure, some of which can be fatal, patients must undergo a comprehensive evaluation before ERCP. It is also essential to accurately determine the indications and ensure thorough patient follow-up.[1] Complications related to ERCP include pancreatitis, bleeding, infection, and perforation. Approximately 1–2% of these are considered serious complications, and a mortality rate of less than 1% has been reported. Perforation is one of the most important complications associated with ERCP. The incidence of perforation resulting from ERCP is approximately 1%, and the mortality rate associated with perforation ranges from 7.8% to 9.9%.[2,3]

The most commonly used classification system for ERCP-related perforations is the Stapfer classification, which categorizes perforations into four types based on the anatomical location and mechanism of the injury.[4] Type II perforations involve peri-Vaterian injuries. In a review by Vezakis et al.,[5] which included 142,847 patients, the incidence of ERCP-related perforations was reported as 0.39%, with an overall mortality rate of 7.8%. Additionally, type II injuries accounted for nearly half (46%) of all perforations.

There is ongoing debate in the literature regarding the preferred treatment approach (surgical or non-surgical) for type II perforations. In this study, we aimed to collect data from adult patients with post-ERCP Stapfer type II perforations to evaluate management approaches and outcomes.

MATERIALS AND METHODS

This was a retrospective study that included data from adult patients treated at two centers: Tekirdağ State Hospital and Tekirdağ Namık Kemal University Healthcare Application and Research Center. The research was conducted with permission number 42232655-605.01 obtained from the Tekirdağ Province Public Hospitals Union Secretariat and ethics committee approval number 2017/83/08/07 obtained from the Namık Kemal University Non-Interventional Clinical Research Ethics Committee. Hospital records from the past five years were retrospectively analyzed. The following data were collected from the medical records: patient demographics, ERCP indication, time to perforation diagnosis, time to corrective surgery (if performed) after ERCP, methods of management (conservative or surgical), types of surgery performed, length of hospital stay, and patient outcomes. The end of the ERCP procedure was defined as time zero, and the time to post-ERCP events was calculated in days accordingly. A total of 23 patients treated for Stapfer type II perforation after ERCP, with sufficient available data, were included in the study. Patients

KEY MESSAGES

- Perforation, one of the serious complications that can occur during the ERCP procedure, should always be kept in mind. Recognizing or suspecting perforation during ERCP is crucial for early diagnosis.
- After the diagnosis of perforation, surgical treatment should be considered in the presence of contrast leakage on contrast-enhanced tomography or signs of an acute abdomen.
- In cases of non-operative management failure, the decision for surgical intervention should not be delayed.

with ERCP-related perforations other than Stapfer type II, and those with missing data, were excluded. This study was designed in accordance with the ethical principles of the Declaration of Helsinki.

Statistical Analysis

Descriptive statistics were used to summarize the information collected for each patient; numerical variables were presented as mean (standard deviation), and categorical variables were reported as number and percentage. The Shapiro-Wilk test was used to assess the normality of data distribution. As the Shapiro-Wilk test indicated a normal distribution, parametric values between groups were compared using an independent samples t-test. Spearman's rank correlation was used to analyze the association between the length of hospital stay and time to surgery. To evaluate the association between the day to diagnosis and mortality, a binary logistic regression analysis was performed. Statistical analyses were conducted using PASW 18.0 for Windows (IBM SPSS Corp.; Armonk, NY, USA). A p-value of 0.05 was considered statistically significant.

RESULTS

The study included data from 23 patients (14 women and nine men), with a mean age of 54.8 (±11.1) years. The indications for ERCP were choledocholithiasis (n=17), suspected sphincter of Oddi dysfunction (SOD, n=5), and biliary fistula after cholecystectomy (n=1) (Table 1).

The mean time to diagnosis of perforation after ERCP was 1.0 (±1.3) days. In 12 patients (52.2%), the diagnosis was made within 24 hours following ERCP. In the remaining 11 patients, the mean time to diagnosis was 2.1 (±1.1) days, with a range of one to four days. All patients received prophylactic antibiotic treatment: imipenem in 16 patients (69.6%), ceftriaxone-metronidazole in six patients (26.1%), and cefoperazone-sulbactam in one patient.

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Table 1. Demographic characteristics and ERCP indications of the patients

Characteristics	
Age (years), mean (SD)	54.8 (11.1)
Female, n (%)	14 (60.9)
Indication for ERCP, n (%)	
Choledocholithiasis	17 (73.9)
Suspected sphincter of Oddi dysfunction	5 (21.7)
Biliary fistula	1 (4.3)

ERCP: Endoscopic retrograde cholangiopancreatography; SD: Standard deviation.

In the logistic regression analysis, an increase in the time to diagnosis was significantly associated with a higher risk of mortality (B=1.38, SE=0.655, Wald=4.43, p=0.035). Each one-day delay in diagnosis increased the odds of mortality by approximately fourfold (odds ratio (OR)=3.98; 95% confidence interval (CI): 1.10–14.37). Mortality increased with delayed diagnosis of perforation after ERCP.

A total of 15 patients (65.2%) underwent surgery for the management of ERCP-related perforation. Three patients underwent surgery one day after ERCP based on findings of contrast leakage on computed tomography. Of the 20 patients who were initially managed non-surgically with antibiotics, fasting, and nasogastric suction, 12 required surgical treatment 2–7 days after the procedure due to clinical deterioration. Among the remaining non-surgically treated patients, two underwent percutaneous drainage and one received a plastic biliary stent. Details of the surgical procedures are provided in Table 2. The demographic and clinical characteristics of the patients are shown in Table 3.

Three patients in the conservative management group died, whereas there were no deaths in the surgical group. A significant association was found between the conservative and surgical groups (p=0.032).

The mean length of hospital stay was 12.9 (±9.5) days for non-surgically managed patients and 18.0 (±11.3) days for surgically treated patients, with no statistically significant difference between the groups (p=0.101). However, a significant correlation was observed between the time to surgery and the length of hospital stay (p=0.017), indicating that delayed surgical intervention was associated with prolonged hospitalization.

DISCUSSION

With the widespread use of ERCP, there is increasing evidence regarding the characteristics and management of ERCP-related perforation, one of its most significant

Table 2. ERCP-related perforation characteristics

Characteristics	
Time to perforation diagnosis, n (%)	
Day 0	12 (52.2)
Day 1	4 (17.4)
Day 2	4 (17.4)
Day 3	1 (4.3)
Day 4	2 (8.7)
Length of hospital stay (days), mean (SD)	
Non-surgical management (n=8)	12.9 (9.5)
Surgical management (n=15)	18.0 (11.3)
Time to surgery, n (%)*	
Day 1	3 (20.0)
Day 2	6 (40.0)
Day 3	3 (20.0)
Day 4	1 (6.7)
Day 5	0
Day 6	0
Day 7	2 (13.3)
Type of surgery, n (%)*	
RD	3 (20.0)
RD + cholecystectomy	3 (20.0)
RD + CBD stone extraction + cholecystectomy + T-tube placement	3 (20.0)
RD + CBD stone extraction + T-tube placement	2 (13.3)
RD + cholecystectomy + T-tube placement	2 (13.3)
RD + T-tube placement	1 (6.7)
RD + CBD stone extraction + cholecystectomy + choledochoduodenostomy	1 (6.7)

ERCP: Endoscopic retrograde cholangiopancreatography; SD: Standard deviation; RD: Retroperitoneal drainage; CBD: Common bile duct; *: n=15.

complications. In this retrospective study, we evaluated the clinical characteristics and outcomes of patients with ERCP-related Stapfer type II perforations.

Since Stapfer type II perforation is a very rare complication,[5] the available information in the literature regarding risk factors is quite limited. Enns et al.[6] reported that patients with sphincter of Oddi dysfunction had an increased risk for ERCP-related perforations. Another study also evaluated 12 ERCP-related perforations, of which 41% were associated with SOD.[7] In our study, ERCP was performed for suspected SOD in 21.7% of patients, which may have contributed to the occurrence of perforation.

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Table 3. Clinical details of patients

Patient no.	Age	Sex	Time to diagnosis (days)	Initial treatment method	Conservative treatment failure	Time to surgery (days) (day)	Hospital stay (days)	Outcome
1	42	F	3	Conservative	No	-	14	Exitus
2	67	M	2	Conservative	No	-	10	Exitus
3	54	F	4	Conservative	No	-	17	Exitus
4	37	M	1	Conservative	No	-	10	Survived
5	35	M	0	Surgery	-	1	12	Survived
6	69	F	0	Conservative	Yes	2	14	Survived
7	54	M	0	Conservative	Yes	2	9	Survived
8	42	M	0	Conservative	Yes	7	44	Survived
9	55	F	0	Conservative	Yes	2	14	Survived
10	58	M	0	Conservative	Yes	4	22	Survived
11	60	F	0	Conservative	Yes	2	16	Survived
12	55	M	0	Conservative	Yes	2	18	Survived
13	46	F	2	Conservative	Yes	7	45	Survived
14	68	F	2	Conservative	No	-	7	Survived
15	74	F	2	Conservative	No	-	5	Survived
16	53	M	1	Conservative	No	-	6	Survived
17	63	F	1	Conservative	Yes	3	13	Survived
18	68	F	0	Surgery	-	1	12	Survived
19	52	F	1	Conservative	Yes	3	10	Survived
20	36	F	4	Conservative	No	-	34	Survived
21	61	F	0	Surgery	-	1	12	Survived
22	55	F	0	Conservative	Yes	3	18	Survived
23	57	M	0	Conservative	Yes	2	11	Survived

F: Female; M: Male.

Previous studies have shown that early diagnosis of this complication is associated with a better prognosis.[8–10] In a review by Vezakis et al.,[5] which included 437 ERCP-related perforation cases from 15 studies, the diagnosis was made during ERCP in 73% of cases. In contrast, another study involving 55 patients reported a diagnosis rate of 10.91% (six patients) during the procedure.[8] Koç et al.[11] evaluated data from 28 ERCP-related perforations and showed that although perforation was suspected during the procedure in 23 patients, only 10 perforations (35.7%) were actually identified during ERCP. In the same study, the time to diagnosis after ERCP ranged from 1 to 72 hours, with a mean time of 5.5 hours. In our study, 12 patients were diagnosed within the first 24 hours. In the remaining 11 patients, diagnosis was made between one and four days. Mortality was found to be significantly higher in patients with delayed diagnosis (p=0.035). These results suggest that early diagnosis improves prognosis, in accordance with findings in the literature. The diagnosis of Stapfer type II perforations may be delayed in some patients. This delay may be attributed to the subtle clinical findings associated with retroperitoneal perforations, which can make differential diagnosis more difficult. Therefore, close observation and follow-up of clinical, laboratory, and imaging findings, as well as maintaining a high index of suspicion for perforation, are essential for timely diagnosis of this complication.

Unlike the other three types of perforations, the management of Stapfer type II perforations, whether surgical or conservative, remains a dilemma. For type II injuries, Stapfer et al.[4] suggested a non-operative management (NOM) strategy, recommending surgical intervention only if large free or retroperitoneal fluid

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collections are present. In a study by Weiser et al.,[12] eight of 19 patients with type II perforation underwent surgical intervention, while the remaining 11 patients were managed conservatively. In the conservative group, only one patient eventually required delayed surgery. Sekerci et al.[13] reported surgical treatment in 12 patients with Stapfer type II perforation, with mortality occurring in only one patient who underwent late surgical intervention and had significant comorbidities. In a review by Cirocchi et al.[14] which included 177 Stapfer type II perforations among a total of 305 ERCP-related duodenal perforations, the initial NOM rate was high (84.2%, 149 patients), although the failure rate of NOM was 28.9% (43 out of 149 patients). In the same study, data were available for 24 patients who underwent primary surgical treatment, of whom 70.8% (17 patients) had early operative intervention (within 24 hours of ERCP), while the remaining seven patients underwent surgery at a later time. Additionally, 40 patients were recorded to have undergone surgical treatment following the failure of non-operative management, with a mortality rate of 22.5% (nine out of 40 patients). In a recent systematic review and meta-analysis including 131 patients with Stapfer type II perforations from 10 studies, a statistically significant difference in success rates was observed between initial surgery and non-operative management, favoring initial surgery for type II perforations (p=0.02).[15] In our study, the rate of initial NOM (87%) was consistent with the findings of those reviews. However, the failure rate of NOM was found to be higher (60%, 12 out of 20 patients). Despite this, the absence of mortality in the surgical group was a promising result. While three patients died in the NOM group (three out of eight, 37.5%), no deaths were observed among surgically treated patients. This difference in mortality was statistically significant (p=0.032). We believe this outcome could be attributed to the close follow-up of patients, along with a careful approach to patient selection and the timing of surgical intervention.

In our experience, the mean length of hospital stay was longer for surgically treated patients compared to those managed with NOM, but the difference was not statistically significant (p=0.101). Previous studies have reported similar findings, although the length of hospital stay varies across the literature.[16,17] Additionally, we found a significant correlation between time to surgery and length of hospital stay (p=0.017), indicating that delayed surgical treatment prolongs hospitalization.

Our study had certain limitations. First, the total number of ERCP procedures performed could not be reported, as the study centers also managed patients with ERCP-related complications who had undergone the procedure at other institutions. Second, there was a lack of clinical data regarding previously reported prognostic factors, such as patient comorbidities, history of prior surgery, and anatomical details.

CONCLUSION

The characteristics and management of ERCP-related Stapfer type II perforations can vary widely. Patients may initially be treated non-surgically; however, must remain vigilant for failure of non-operative management. Treatment approaches should be individualized based on the patient's clinical condition. Considering the associated mortality rates, surgical treatment should be considered with appropriate patient selection and timely intervention.

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