

# The effect of using nitroderm TTS in ERCP on precut, selective cannulation, and bleeding

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## ABSTRACT

**BACKGROUND:** The aim of the study was to investigate the use of prophylactic nitroglycerin patch in patients who applied to our clinic with occlusion icter and underwent endoscopic retrograde cholangiopancreatography (ERCP) for complications such as pancreatitis, bleeding, perforation that may occur during and after the procedure, duration of the procedure, length of hospitalization, precut and selective cannulation rates, and mortality.

**METHODS:** Patients were searched retrospectively using the hospital database. Patients under the age of 18, patients with poor general condition and patients treated under emergency conditions were excluded from the study. The effects of the drug on morbidity, mortality, duration of procedure, length of hospital stay, and cannulation techniques were investigated in patient groups with and without nitroglycerin patch.

**RESULTS:** It was observed that using nitroglycerin decreased the precut probability by 2.28 times ( $p<0.001$ ), and decreased perioperative bleeding by 3.4 times ( $p<0.001$ ). 75.1% selective cannulation was observed in the group not administered nitroglycerin, this rate was determined as 87.3% in the group administered nitroderm ( $p<0.001$ ). In the regression model, it was observed that the presence of nitroderm increased the probability of selective cannulation 2.21 times ( $p<0.001$ ). The effects of nitroglycerin use on mortality, patient's history of malignancy, presence of stones and mud, gender, age, post-operative pancreatitis, and perioperative bleeding variables were evaluated by regression analysis, and age increased mortality by 1.09 ( $p=0.023$ ).

**CONCLUSION:** It has been shown that the use of prophylactic nitroglycerin patch in ERCP procedure increases the prophylactic selective cannulation rate, shortens the precut rate, pre-operative bleeding, hospital stay, and procedure time.

**Keywords:** Bleeding; endoscopic retrograde cholangiopancreatography; pancreatitis.

## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive procedure used for the diagnosis and treatment of pancreaticobiliary diseases. It has become a safe and effective procedure with both technological innovation and improved procedural experience since its introduction.<sup>[1]</sup> Even though magnetic resonance imaging, magnetic resonance cholangiopancreatography, and endoscopic ultrasound (EUS) are imaging modalities that assist in the diagnosis, ERCP remains important in pancreaticobiliary diseases due to its therapeutic properties. It is a minimally invasive procedure, yet

it can cause serious complications.<sup>[2]</sup> The reported rate of complications and mortality associated with ERCP, although varying across studies, are 10–12% and 0.1–6%, respectively.<sup>[3–6]</sup> Post-ERCP pancreatitis (PEP) is the most common complication with a rate of 3–10%.<sup>[7]</sup> Among other complications are bleeding (0.3–2.0%), cholangitis (0.5–3%), and perforation (0.08–0.6%).<sup>[8–10]</sup> It is known that complications and the success of the procedure are directly related to the experience of the endoscopist.<sup>[11]</sup> Furthermore, many pharmacological agents such as gabexate, somatostatin, steroids, non-steroidal anti-inflammatory drugs (NSAIDs), allopurinol, and nitroglycerin have been used to reduce the incidence of pancreatitis

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and other procedure-related complications.<sup>[12]</sup> Nitroglycerin, a nitric oxide donor, has been long known to reduce the pressure of the sphincter of Oddi.

This retrospective study examined the effects of using nitroglycerin patch (Nitroderm TTS, Novartis®, India) in patients undergoing ERCP for obstructive jaundice on developing pancreatitis, intra- and postoperative bleeding, perforation, selective cannulation, precut, duration of the procedure, hospitalization, and mortality.

## MATERIALS AND METHODS

The approval for the study was granted by the Non-Interventional Clinical Research Ethics Committee of the Faculty of Medicine of Balikesir Onyedi Eylül University (Date: February 07, 2022, No: 2022-13). The study retrospectively analyzed 630 patients who underwent ERCP for obstructive jaundice in the General Surgery Department of Balikesir University Faculty of Medicine between 2016 and 2021.

### Data Collection and Patient Selection

Patients who presented to our clinic with obstructive jaundice and underwent ERCP between the specified dates were reviewed retrospectively using the hospital database. All of the study patients included were individuals who underwent ERCP for the 1<sup>st</sup> time. The patient files were reviewed and those who underwent the procedure under emergency conditions without any time to discontinue anticoagulants or antiplatelets that might cause bleeding, patients in whom the discontinuation of anticoagulants or antiplatelets were contraindicated, hypotensive patients with poor overall condition (systolic blood pressure <90 mm/Hg), patients with a history of bleeding and pancreatitis, patients under 18 years of age, and those who were on nitrates were not included in the assessment. Based on the review of the patient files, those with a history of allergic reaction to nitrates, those who were on drugs that would react with nitrates, patients with a history of hypotensive attacks, patients for whom nitrate use was considered inappropriate after cardiology consultation, and patients who were reported having a problem in obtaining the nitroglycerin patch were included as the control group. Patients were randomized into nitroglycerin patch and non-nitroglycerin patch groups. The effects of nitroglycerin patch on potential complications such as pancreatitis, bleeding, and perforation during and after ERCP, duration of the procedure, length of hospital stay, precut and selective cannulation rates, and mortality were examined retrospectively.

### Pre-operative Assessment and ERCP Procedure

All of the patients scheduled for ERCP were preoperatively assessed for anesthesia to identify their risk status. Necessary medical treatments were planned to reduce mortality and morbidity in patients with comorbid and chronic diseases. Oral intake of the patients was stopped 6–8 h before

the procedure and intravenous fluid therapy was started. A 10 mg nitroderm (Nitroderm TTS) patch was placed on the left shoulder of patients who met the exclusion criteria. After scopolamine and prophylactic antibiotics were administered before the procedure, the patients were taken to the ERCP unit for the procedure. The ERCP unit covered with lead blocks were kept available with a radiolucent fluoroscopy table, bed-side anesthesia unit, patient monitor, oxygen system, emergency response equipment, C-arm fluoroscopy, video-endoscopy, and duodenoscopy unit and image transfer unit, advanced electrocautery unit, ERCP preparation table, and ERCP equipment (guidewire, sphincterotomy, basket catheter, balloon catheter, stent types, etc.). The patients were placed in the left lateral decubitus and semi-prone position for the ERCP procedure and administered topical local anesthetic spray before the procedure. All procedures were performed under deep sedation in the presence of an anesthesiologist and anesthetic technician. The procedure was started with a side-view video-duodenoscope. After evaluating the esophagus and stomach in general, the second part of the duodenum was accessed by passing through the pylorus. The ampulla of Vater was visualized, followed by the en face view of the papilla. Selective biliary cannulation was attempted by inserting a sphincterotome into the papillary orifice in the 11-o'clock direction. Our clinic usually performs guidewire-assisted cannulation and in cases where such cannulation is not possible, contrast-assisted cannulation and deep cannulation techniques are also used for selective cannulation. The guidewire-assisted biliary selective cannulation technique for the pancreas is also used in cases where biliary cannulation cannot be primarily performed but pancreatic cannulation can be performed. After the biliary tract is cannulated using the selective biliary cannulation technique, the bile ducts are filled with a contrast agent to visualize the biliary tract by C-arm fluoroscopy. After evaluating the biliary tract diseases, biliary sphincterotomy (EST) is performed by cutting the papilla between 11-o'clock and 1-o'clock through sphincterotomy and electrocautery. The upper border of the incision is the point where the intraductal papilla crosses the duodenal wall. Endoscopic Papillary balloon dilatation can also be used as an alternative to EST. However, EST was preferred for our cases. In cases where the bile duct cannot be cannulated selectively, the precut method can be used. Biliary and pancreatic sphincters are exposed by cutting the papillary mucosa and submucosa starting from the orifice with a needle-knife sphincterotome or from the upper part of the orifice using the fistulotomy technique, and EST is performed after the cannulation of the bile duct. However, this method is associated with a high risk for duodenal perforation, bleeding, and pancreatitis. Transpancreatic papillary septotomy (the Goff technique) can be performed in cases where the pancreas is cannulated but not the bile duct. The bile duct is tried to be cannulated by an incision through the septum between the pancreatic duct and the bile duct using a standard sphincterotomy with a guidewire. Due to the high risk of perforation after this procedure, transpancreatic stent placement is recommended. In cases where the bile duct can-

not be cannulated despite the techniques used, biliary cannulation can be performed by anterogradely passing the guidewire through the papilla through a percutaneous transhepatic cholangiography or EUS. After the cannulation of the bile ducts, the detected disease is treated accordingly.

### Follow-up

After the post-operative assessment in the recovery, some of the patients were discharged on the same day, while some were transferred to the ward for follow-up depending on their clinical condition. Patients with abdominal pain on physical examination were closely monitored for potential pancreatitis or perforation, and the follow-ups included complete blood count, liver function tests, and amylase testing.

### Statistical Analysis

Statistical analyses were performed using the SPSS version 22.0 (IBM Corp., USA). The normality of the data was analyzed by a statistical test (Kolmogorov–Smirnov) and visual graphs (histograms etc.). Two independent groups were compared by Independent Samples t-test or Mann–Whitney U test depending on the normality of distribution. Categorical data were assessed by the Chi-square or Fisher’s exact test. A logistic regression analysis was conducted to reveal the impact of independent variables on the prediction of precut, selective cannulation, mortality, and bleeding. The statistical significance level was set at  $p < 0.05$  for all analyses.

## RESULTS

The mean age  $\pm$  standard deviation was  $62.5 \pm 17.1$  in the Nitroderm patient group and  $64 \pm 14.5$  in the non-Nitroderm patient group. There was no statistically significant difference in mean age between the two groups ( $p = 0.265$ ). Female patients accounted for 56.2% of the Nitroderm group and 53.7% of the non-Nitroderm group, with no significant gender difference between the groups ( $p = 0.534$ ).

Concerning comorbidities in the Nitroderm and non-Nitroderm patient groups, no significant difference was identified in heart diseases ( $p = 0.524$ ), kidney diseases ( $p = 0.070$ ), lung diseases ( $p = 0.24$ ), and Oddi dysfunction ( $p = 0.143$ ), while there was a statistically significant difference in the history of malignancy ( $p = 0.042$ ), presence of stone-sludge in the common bile duct ( $p = 0.043$ ), and post-ERCP malignancy ( $p = 0.043$ ).

There was no statistically significant difference between the Nitroderm and non-Nitroderm patient groups in preoperative leukocytes ( $p = 0.641$ ), amylase ( $p = 0.337$ ), common bile duct diameter ( $p = 0.963$ ), total bilirubin ( $p = 0.144$ ), and direct bilirubin ( $p = 0.301$ ) (Table 1).

Examining the effects of Nitroderm TTS on ERCP complications, mortality, morbidity, and post-operative laboratory values revealed a statistically significant difference in precut, perioperative bleeding, duration of the procedure, and hospital stay between the Nitroderm and non-Nitroderm patient groups (Table 2).

To reveal the effect of Nitroderm on the precut procedure, the presence of stone-sludge in the common bile duct, the history of malignancy, age, and gender were included together in the regression analysis. The results showed that using Nitroderm reduced the precut probability by 2.28 times (adj Odds Ratio [OR]=2.28, 95% confidence interval [CI] 1.486–3.514, [ $p < 0.001$ ]), while age ( $p = 0.340$ ), gender ( $p = 0.992$ ), presence of stone-sludge in the common bile duct ( $p = 0.287$ ), and the history of malignancy ( $p = 0.874$ ) were not statistically significant.

Similarly, the effect of Nitroderm application on perioperative bleeding was examined, revealing that the Nitroderm application reduced perioperative bleeding by 3.4 times (OR=3.4, 95 CI%=1.99–5.83,  $p < 0.001$ ). On the other hand, age ( $p = 0.754$ ), gender ( $p = 0.366$ ), presence of stone-sludge ( $p = 0.390$ ), and history of malignancy ( $p = 0.988$ ), the parameters included in

**Table 1.** Clinical and demographic data

	Nitroderm TTS (+) (n=276)	Nitroderm TTS (-) (n=354)	p
Age (years) (Mean $\pm$ SD)	62.5 $\pm$ 17.1	64.1 $\pm$ 17.5	0.265
Gender (Female %)	56.2%	53.7%	0.534
Amylase (IU/L), Median (min-max)	53 (12–3600)	50 (8–3019)	0.337
Leukocytes (uL), Median (min-max)	7800 (600–3200)	8000 (700–37000)	0.641
The common bile duct diameter (mm), (Mean $\pm$ SD)	14.2 $\pm$ 4.5	14.2 $\pm$ 4.5	0.963
Preop. T. Bilirubin, Median (min-max)	2.2 (0.1–27.8)	2.8 (0.1–32.6)	0.144
Preop. D. Bilirubin, Median (min-max)	2.0 (0.1–23.0)	2.4 (0.1–33.0)	0.301
Oddi dysfunction	38.5% (n=55)	61.5% (n=88)	0.143
History of malignancy	21.1% (n=4)	78.9% (n=15)	0.042
Stone-sludge in the common bile duct	82.6% (n=228)	76.0% (n=269)	0.043

SD: Standard deviation.

**Table 2.** Effects of using nitroderm TTS on ERCP complications, mortality, morbidity, and postoperative laboratory values

	Nitroderm TTS (+) (n=276)	Nitroderm TTS (-) (n=354)	p
Precut	28% (n=35)	72% (n=90)	<0.001
Perioperative bleeding	21.3% (n=19)	78.7% (n=70)	<0.001
Periop. perforation	0% (n=0)	100% (n=3)	=0.260
Postop. bleeding	100% (n=1)	0% (n=0)	=0.438
Postop. pancreatitis	46.3% (n=31)	53.7% (n=36)	=0.668
Mortality	12.5% (n=1)	87.5% (n=7)	=0.072
Duration of procedure, Median (min-max)	20 (10–60)	30 (10–60)	<0.001
Postop. Amylase, Median (min-max)	60.5 (11–3472)	61.0 (4–11900)	0.581
Postop. T. Bilirubin, Median (min-max)	1.3 (0.1–22.0)	1.4 (0.1–22.6)	0.369
Postop. D. Bilirubin, Median (min-max)	0.9 (0.1–20.0)	0.9 (0.1–19.7)	0.469
Length of hospital stay (days), Median (min-max)	1.0 (0–10.0)	1.0 (0–30.0)	0.001

ERCP: Endoscopic retrograde cholangiopancreatography; SD: Standard deviation.

the regression equation, did not have a statistically significant effect on the presence of perioperative bleeding.

The rate of selective cannulation was 75.1% in the non-Nitroderm patient group, compared with 87.3% in the Nitroderm group ( $p<0.001$ ). According to the regression model, the presence of Nitroderm increased the probability of selective cannulation by 2.21 times (adjOR=2.21, 95 CI%=1.44–3.41,  $p<0.001$ ), while age ( $p=0.0285$ ), gender ( $p=0.862$ ), stone-sludge ( $p=0.795$ ), and history of malignancy ( $p=0.823$ ) had no statistically significant effect on selective cannulation.

The effects of using Nitroderm, history of malignancy, presence of stone-sludge, gender, age, post-operative pancreatitis, and perioperative bleeding on mortality were assessed by regression analysis, and the results showed that age increased mortality by 1.09 (OR=1.09, 95 CI%=1.01–1.17,  $p=0.023$ ). There was no statistically significant effect of using Nitroderm ( $p=0.153$ ), history of malignancy ( $p=0.536$ ), presence of stone-sludge ( $p=0.171$ ), gender ( $p=0.764$ ), post-operative pancreatitis ( $p=0.348$ ), and perioperative bleeding ( $p=0.996$ ) on mortality.

## DISCUSSION

The ERCP procedure has been widely used for about half a century, yet varying rates of mortality and morbidity have been reported. It is known to be associated with complications such as PEP, perforation, and bleeding, while the most common complication is PEP.<sup>[7]</sup> Patients are diagnosed with epigastric pain radiating to the back, nausea, and elevated pancreatic enzymes within a few hours after the procedure. Many pharmacological agents have been tried to prevent the development of PEP. There are conflicting reports on nitroglycerin in the literature. The study by Liu et al.<sup>[13]</sup> on 5031 patients showed that NSAIDs achieved a significant reduction

in the risk of PEP. The meta-analysis by Shao et al.<sup>[14]</sup> chose nitroglycerin as the pharmacological agent, examined four randomized controlled trials and, established a significant relationship between the use of nitroglycerin and the reduction of PEP incidence. The following regression analysis, however, could not demonstrate its superiority to placebo. The study by Katsinelos et al.<sup>[15]</sup> on sublingual nitroglycerin and intravenous glucagon showed a significantly lower rate of PEP. Our study, on the other hand, could not demonstrate the efficacy of nitroglycerin patches in reducing the risk of PEP.

The estimated incidence of post-ERCP bleeding varies between 0.3 % and 2% in the literature.<sup>[10]</sup> A single-center study of 2715 cases regarding ERCP-related complications identified post-operative bleeding in 122 patients (4.5%), with bleeding during the procedure in 85 patients (69.7%), in the early period in nine patients (7.4%), and the late period in 27 patients (22.1%).<sup>[16]</sup> Another study evaluated the risk factors for post-ERCP bleeding on 3620 patients and reported that endoscopic sphincterotomy (ES) was performed in a total of 1121 patients and bleeding occurred in 108 (9.6%). The study identified the length of ES length as an independent risk factor for bleeding during and after the procedure.<sup>[17]</sup> In our study, post-operative bleeding occurred in one patient (0.15%) with Nitroderm TTS and was controlled with symptomatic treatment. The use of Nitroderm TTS was also not demonstrated to have a statistically significant effect. Our study identified intraoperative bleeding in 89 patients (14.12%), with 19 (31.3%) patients in the Nitroderm TTS group and 70 (78.7%) in the non-Nitroderm TTS group. Our study further found Nitroderm TTS to reduce bleeding during the ERCP procedure by 3.4 times.

Perforation secondary to ERCP is rare but one of the most fatal complications.<sup>[9]</sup> Mimicking PEP, it may present with back pain, epigastric tenderness, subcutaneous emphysema, fever,

and tachycardia. In the case of peritonitis, untreated patients may develop sepsis.<sup>[2]</sup> Patil et al.<sup>[18]</sup> detected post-ERCP perforation in 380 (1.5%) of 25,300 patients over 12 years and reported non-operative treatment in 330 (86.8%) patients and operative treatment in 50 (13.2%) patients. In the present study, perforation occurred in three (0.47%) patients, with all in the non-Nitroderm group. Of these patients, one died in the intensive care unit while being followed up without surgery due to comorbidities, and the second one died on the 2<sup>nd</sup> day of the operation. The third patient was treated non-operatively after stent placement. The rate of perforation in our study is consistent with the literature. The effect of using Nitroderm on perforation could not be demonstrated ( $p=0.260$ ).

Biliary cannulation in ERCP is defined as the insertion of a guidewire catheter or another device into the biliary tract. Catheterization (selective cannulation) of the biliary duct without entering the pancreatic duct by any means is important for PEP. More than 5 min of cannulation, more than five repetitions, or undesirable manipulation of the pancreatic duct means delayed cannulation. Even when performed by experienced endoscopists, the rate of failure is 5–10%.<sup>[19,20]</sup> The study of Katsinelos et al.<sup>[15]</sup> including 455 patients reported high rates of selective cannulation in the sublingual nitroglycerin group. Similarly, our study established a selective cannulation rate of 87.3% in the Nitroderm TTS group and 75.1% in the non-Nitroderm TTS group. In addition, the regression model revealed that the use of Nitroderm TTS increased the selective cannulation rate by 2.21 times (adjOR=2.21, 95% CI=1.44–3.41,  $p<0.001$ ).

Precut sphincterotomy is an ERCP procedure performed when cannulation fails, which has been reported to reduce the incidence of PEP because it increases the possibility of cannulation.<sup>[21]</sup> It has been reported that NSAIDs, nitroglycerin derivatives, somatostatin, octreotide, and protease inhibitors increase the cannulation rate by relaxing the sphincter of Oddi and thereby reducing the risk of PEP.<sup>[22]</sup> Our study established that the use of Nitroderm TTS reduced the rate of precut by 2.28. (adjOR=2.28, 95% CI 1.486–3,514, [ $p<0.001$ ]). The duration of ERCP, although depending on the experience of the endoscopist, has been reported as 10–30 min in studies.<sup>[23,24]</sup> Our study found the median (min-max) duration of the procedure to be 20 (10–60) min in Nitroderm group patients and 30 (10–60) min in the non-Nitroderm group, with a statistically significant difference between the two groups.

The length of hospital stay varies by the experience of the center, just like the duration of the procedure. A large-scale study of 199, 625 ERCP cases performed in 2629 hospitals reported reduced hospital stay in high-volume centers. Similarly, the study found a mean hospital stay of  $7.7\pm 7.2$  days in systemic lupus erythematosus patients after ERCP.<sup>[25,26]</sup> In our study, the mean hospital stay was 1 day in both groups, and the longest hospital stay was identified in the non-Nitroderm group (Table 2).

Considering the mortality rates, there was no statistically significant difference between the two groups; however, one patient died in the Nitroderm group, while eight patients died in the non-Nitroderm group. The reported mortality rate in the literature varies between 0.4% and 1.4% and our study found a mortality rate of 1.26%.<sup>[4,5]</sup> The mortality rate of our study is consistent with the literature.

## Conclusion

Our study examined the effects of Nitroderm TTS, a pharmacological agent, on selective cannulation, precut, pancreatitis, bleeding, perforation, length of hospital stay, duration of the procedure, and mortality related to ERCP. Nitroderm TTS was shown to increase the rate of selective cannulation and reduce the rate of precut, perioperative bleeding, hospital stay, and duration of the procedure. Our study is limited by its retrospective design, but it is of importance as it comprehensively addresses the effects of Nitroderm, a pharmacological agent that has only been studied concerning PEP, on ERCP. We believe that prospective randomized and controlled trials are needed to better demonstrate the effects of Nitroderm on ERCP.

**Ethics Committee Approval:** This study was approved by the Balikesir University Clinical Research Ethics Committee (Date: 07.02.2022, Decision No: 2022-13).

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## ORIJİNAL ÇALIŞMA - ÖZ

### ERCP işleminde nitroderm TTS kullanımının precut, selektif kanülasyon ve kanama üzerine etkisi

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**AMAÇ:** Çalışmanın amacı tıkanma ikteri ile kliniğimize başvuran ve endoskopik retrograd kolanjiyopankreatografi (ERCP) yapılan hastalarda profilaktik nitrogliserin yama kullanımının işlem sırasında ve sonrasında meydana gelebilecek pankreatit, kanama, perforasyon gibi komplikasyonlar, işlem süresi, hastanede yatış süresi, precut ve selektif kanülasyon oranları ile mortalite üzerine etkisini araştırmaktır.

**GEREÇ VE YÖNTEM:** Hastalar hastane veri tabanı kullanılarak geriye dönük olarak taranmıştır. Acil şartlarda yapılan ve çalışmanın sonucunu etkileyecek ilaç kullanımı olan hastalar, 18 yaşından küçük hastalar, genel durumu bozuk olan hastalar çalışma dışı bırakılmıştır. Nitrogliserin yama kullanılan ve kullanılmayan hasta gruplarında ilacın morbidite, mortalite, işlem süresi, hastanede kalış süresi ve kanülasyon teknikleri üzerine etkisi araştırılmıştır. **BULGULAR:** Nitrogliserin kullanmanın precut olasılığını 2.28 kat azaltırken [adjOR=2.28, CI95% 1.486-3.514, (p<0.001)], peroperatif kanamayı 3.4 kat azalttığı (OR=3.4, 95CI%=1.99-5.83, p<0.001) gözlenmiştir. Nitrogliserin uygulanmayan grupta %75.1 selektif kanülasyon olmuşken nitroderm uygulanan grupta bu oran %87.3 olarak belirlenmiştir (p<0.001). Regresyon modelinde nitroderm varlığının selektif kanülasyon olasılığını 2.21 kat artırdığı (adjOR=2.21, 95CI%=1.44-3.41, p<0.001) gözlenmiştir. Mortalite üzerine nitrogliserin kullanımı, özgeçmişinde malignite öyküsü, taş ve çamur varlığı (OR=1.09, 95CI%=1.01-1.17, p=0.023) gözlenmiştir.

**TARTIŞMA:** ERCP işleminde profilaktik selektif kanülasyon oranını artırdığı, precut oranını, peroperatif kanamayı, hastanede kalış süresini ve işlem süresini kısalttığı gösterilmiştir.

**Anahtar sözcükler:** Endoskopik retrograde kolanjiyopankreatografi; kanama; pankreatit.

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