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Early repeat endoscopic retrograde cholangiopancreatography: Predictive factors and interventions required

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Background/aims: *Early repeat endoscopic retrograde cholangiopancreatography may be required due to various conditions in patients who underwent planned endoscopic retrograde cholangiopancreatography. We aimed to assess the factors leading to early repeat endoscopic retrograde cholangiopancreatography and to determine the patients who need closer follow-up.* ***Materials and Methods:*** *A total of 691 patients with a mean age of 60.3±16.4 years who had naive papilla on endoscopic retrograde cholangiopancreatography were involved in the study. The patients who required repeat endoscopic retrograde cholangiopancreatography were identified. Presentations, predictive factors, treatment modalities, and outcomes of the patients were investigated.* ***Results:*** *Early repeat endoscopic retrograde cholangiopancreatography was needed in 19 (2.7%) patients. The most common presentation was cholangitis in 10 (52.6%) and unresolved jaundice in 4 (21.1%). Multivariate analysis identified biliary stricture (p=0.024), stricture at the hilus (p=0.005) and unilateral drainage in the presence of hilar stricture (p=0.017) as the independent risk factors for early repeat endoscopic retrograde cholangiopancreatography. Stent migration or dysfunction was the most common underlying cause. Therapeutic interventions were nasobiliary drainage in 13, stent exchange in 4 and stone removal in 2. Additionally, percutaneous drainage in 4 patients, drainage of abscess in 2 patients and percutaneous drainage of gallbladder in 1 patient were performed. Three patients died due to their underlying illness.* ***Conclusions:*** *Unilateral stenting especially in hilar strictures is a predictive factor for early repeat endoscopic retrograde cholangiopancreatography with high mortality. These patients should be under close follow-up.*

Key words: Repeat endoscopic retrograde cholangiopancreatography, predictive factors, treatment

Endoskopik retrograt kolanjiografinin erken yeniden tekrarı: prediktif faktörler ve müdahaleler

Amaç: *Endoskopik retrograt kolanjiografi yapılan bazı hastalarda "definitive" tedavi yapıldığı düşünüldüğü halde, çeşitli sebeplerle "erken-yeniden" endoskopik retrograt kolanjiografi gerekebilmektedir. Bu çalışmanın amacı bu duruma yol açan faktörleri ve daha yakından izlenmesi gereken hastaları saptamaktır.* ***Yöntem ve Gereç:*** *Endoskopik retrograt kolanjiografi yapılan "naive" papillalı 691 olgu [yaşları 60.3+16.4 (4-94) yıl, 353 (%51.1) kadın, 338 (%48.9) erkek] çalışmaya alındı. Erken yeniden endoskopik retrograt kolanjiografi (ilk işlemden sonraki 15 gün içinde) gerektiren hastaların prezentasyonları, prediktif faktörleri, çözümü ve sonucu araştırıldı.* ***Bulgular:*** *Erken yeniden endoskopik retrograt kolanjiografi 19 (% 2.7) hastada gerekti. En sık prezentasyon kolanjit (10, %52.6) ve sarılığın gerilememesi (4, %21.1) idi. Çok değişkenli analizlerde erken yeniden endoskopik retrograt kolanjiografi için bağımsız risk faktörü olarak darlık varlığı [darlık varlığında risk 4,323 kat (%95 CI 1.215-15.382) fazla (p=0.024)], darlığın hiler seviyede olması [distal darlığı olanlara göre hiler darlığı olanlarda risk 5.492 kat (%95 CI 1.657-18.204) fazla (p=0,005)] ve hiler darlıkta unilateral drenaj yapılması [hiler darlığı olan ve unilateral drenaj uygulananlarda risk 4.013 kat (%95 CI 1.291 – 12.475) fazla (p=0.017)] saptandı. En sık sebebin stent migrasyonu veya disfonksiyonu olduğu saptandı. Onüç (%68.4) nazobiliyer drenaj, 4 (%21.1) stent değişimi, 2 (%10.5) taş çıkartılması ile soruna müdahale edildi. 4 (%21.1) hastada ilave perkütan drenaj, 2 hastada apse drenajı ve 1 hastada safra kesesi perkütan drenajı yapıldı. Bu hastaların 3 (%15.8) tanesi mevcut tablodan kurtulamayarak kaybedildi.* ***Sonuç:*** *Özellikle yüksek seviyeli darlıklarda, diğer tarafa kontrast verilmese bile tek taraflı stent takılması erken yeniden endoskopik retrograt kolanjiografi için prediktif bir faktör olup, mortalitesi yüksek bir durumdur. Bu hastaların dikkatle izlenmesi gerekir.*

Anahtar kelimeler: Tekrar ERCP, prediktif faktörler, tedavi

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INTRODUCTION

Since therapeutic procedures were initiated in the early 1970's, endoscopic retrograde cholangiopancreatography (ERCP) has been widely used in the well-defined indications for the diagnosis and treatment of biliopancreatic diseases. Except in particular circumstances, diagnostic ERCP has been abandoned as the new imaging modalities were developed, and the procedure has been focused on palliative or curative treatment (1).

Although ERCP has a better efficiency/complication ratio compared to alternative percutaneous and surgical treatments, and complications were somewhat diminished by some measures (e.g., lowering pancreatitis risk by placing a stent into the pancreatic duct), some inevitable risks remain. Pancreatitis, bleeding due to sphincterotomy and perforation are the specific complications that have special treatments including endoscopic methods. Biliary colic, non-regressing (even progressing) cholestasis, cholangitis, and cholecystitis are the other post-ERCP complications for which endoscopic treatments may be effective. Repeat ERCP (re-ERCP) may be required for better drainage of the biliary tree and gallbladder, although percutaneous and surgical methods can also be used as salvage therapy (2).

The aim of this study was to determine the factors that necessitate early re-ERCP and the patients who should be under close follow-up, even though they were considered to have been given definitive treatment with ERCP.

MATERIALS AND METHODS

The patients with naive papilla who underwent ERCP between October 2006 and June 2007 were enrolled in the study. During this period, 1325 ERCP procedures were performed in our unit. Since the biliary tract was possibly infected, the patients who had previous sphincterotomy (65 procedures), stent replacement (485 procedures) or who underwent planned complementary early ERCP because of incomplete initial procedure (77 procedures) and those who had re-ERCP to check bleeding when the initial procedure was complicated by hemorrhage (7 procedures) were not included in the study. Thus, the study group involved the remaining 691 patients (mean age: 60.3±16.4; range: 4-94; 353 (51.1%) female, 338 (48.9%) male) who underwent ERCP in our institution.

Early re-ERCP was defined as the case with an unsolved biliary problem requiring repeat procedure within 15 days after the first ERCP. The patients who had been considered to have been definitively treated via ERCP were evaluated by complete blood count (CBC), chemistries and imaging methods (transabdominal ultrasound in all; computed tomography (CT) and/or magnetic resonance cholangiopancreatography (MRCP) and/or endoscopic ultrasound as needed) when they returned for any reason within 15 days following the procedure. Therapeutic procedures as per present pathology (i.e., stent placement/replacement, nasobiliary drainage (NBD) or stone extraction) were performed in the second ERCP. 10 F plastic stents were preferred in most cases; in the case of failure, 7 F stents were used. In addition, percutaneous biliary drainage and abscess drainage were also accomplished when needed. Presentations of the patients who underwent early re-ERCP, causes of early re-ERCP, therapeutic procedures, patient prognosis, and predictive factors of early re-ERCP were investigated. Predictive factors such as age, gender, laboratory values (i.e., liver chemistries, amylase, international normalized ratio [INR], white blood cell [WBC] and platelet counts), position and structure of papilla (i.e., in the bulb, near diverticulum, Billroth II anastomosis) and the findings in the first ERCP (i.e., presence and type - benign vs malignant or polypoid vs nonpolypoid - of strictures) were determined. The level of stenosis as well as the cause (i.e. [1]before the level of biliary hilum: tumor of Oddi or of the head of the pancreas, distal cholangiocarcinoma, acute/chronic pancreatitis or traumatic stenosis and [2]at the level of hilum: Klatskin tumor, metastatic tumors, postoperative stenosis), insertion of NBD (NBD was inserted first and stent was placed days after or NBD and stent were inserted synchronously, or no NBD was placed according to the patient's condition and endoscopist's choice) and preference of stenting (unilateral or bilateral) were noted. All patients provided written informed consent for the procedures, and ethical approval for this study was obtained from the Gastroenterology Clinical Council.

Statistical Analysis

All analyses were performed with the Statistical Package for the Social Sciences (SPSS) for Windows, version 11.5. Continuous variables were analyzed as to whether they were in accordance with normal dispersion by Shapiro-Wilk test. Des-

criptive statistics for continuous variables were shown as means and standard deviations and for categorical variables as frequencies and percentages. The significance of differences between the groups regarding medians was evaluated by Mann-Whitney U test. The chi-square or Fisher's exact test was used for categorical comparisons. To investigate multiple impacts of the factors determined by univariate statistical analysis on early re-ERCP, multiple logistic regression analysis was performed. Odds ratios of each independent risk factor, 95% confidence intervals (CIs) and levels of significance were identified, and p values less than 5% were determined to be statistically significant.

RESULTS

Early re-ERCP was required in 19 (2.7%) patients. Time to re-ERCP was 9.3±4.47 (range: 3-15) days. All re-ERCPs were performed in our unit. The most frequent presentation was cholangitis (10 cases, 52.6%; 4 had biliary sepsis, 2 had liver abscess) and unresolved jaundice (4 patients, 21.1%). The other presentations were biliary colic in 2 (10.5%), unremitting pruritus in 2 (10.5%) and cholecystitis in 1 (5.3%).

By univariate analysis (Table 1), the predictive factors for early re-ERCP were elevated aspartate aminotransferase (AST), alkaline phosphatase (ALP), total and direct bilirubin, and platelets, presence of stenosis, stenosis at the hilar level, and unilateral stenting in patients with hilar stenosis. Early re-ERCP was required in only 4 out of 457 patients (0.8%) without stenosis, whereas it was needed in 15 of 222 patients (6.7%) with stenosis. Furthermore, early re-ERCP was performed in 4 out of 138 patients (2.9%) with distal stenosis, whereas it was required in 10 of 71 patients (14.1%) with hilar stenosis.

Multivariate analysis revealed that the independent risk factors for early re-ERCP were elevated direct bilirubin, presence of stenosis, hilar stenosis, and unilateral drainage in hilar stenosis (Table 2). The risk for performing early re-ERCP was 4.786-fold higher (95% CI 0.471-48.665) in patients with choledochal polypoid mass compared to those with distal stenosis, even though the difference was statistically insignificant (p=0.186). The risk for performing early re-ERCP in patients with hilar stenosis was 5.492-fold higher (95% CI 1.657-18.204) than in those with distal stenosis (p=0.005). Early re-ERCP was required in 5 of 126 patients (4%) with distal stenosis who had stent placement, while it was necessary in 3 of 37 cases (8.1%) with hilar stenosis who had bilateral drainage and in 6 of 33 (18.2%) with hilar stenosis and unilateral drainage. Thus, unilateral drainage in case of hilar stenosis increases the risk for early re-ERCP by 4.013-fold (95% CI 1.291–12.475).

When we classified the patients according to level of stenosis, inserting NBD did not reduce statistically the need for early re-ERCP at any stenosis level. However, there was a remarkable difference, albeit statistically insignificant, in hilar stenosis. In this group of patients, early re-ERCP was required in 9 out of 50 patients (18%) with no NBD placed, although it was necessary in only 1 of 21 patients (4.8%) who had NBD (Table 3).

Distal migration of stents was observed in 6 of 15 patients (31.6%) with stenosis on re-ERCP. The other stents, albeit in place, did not provide sufficient drainage. All 4 patients who had no stenosis and underwent early re-ERCP were diagnosed to have choledochal stone. Stone extraction was performed in 2 of them (1 with cholelithiasis, 1 with cholecystectomy), while no pathology was found in the other 2.

Therapeutic management during early re-ERCP was insertion of NBD in 13 (68.4%), stent exchange in 4 (21.1%) and stone extraction in 2 (10.5%). In addition, percutaneous drainage was performed in 4 (21.1%), abscess drainage in 2 and percutaneous gallbladder drainage in 1. Three of 19 patients (15.8%) succumbed to death from their present illness, and all had malignant biliary stenosis involving also the segmental branches.

DISCUSSION

The results of this study have shown that early re-ERCP might be needed in patients with biliary stenosis, especially if it is at the hilar level and if the stent is placed unilaterally. Since the outcome is poor, with a death rate of 15.8%, and aggressive interventions may be necessary, this group of patients should be under closer follow-up than those without stenosis.

When ERCPist cannot complete the curative or palliative procedure in one session, stent or NBD may be inserted and a planned re-ERCP is performed. However, there are two possibilities when the ERCPist unexpectedly faces the same patient in the early period after he/she thinks the mission

Table 1. Univariate analysis of variables associated with early repeat ERCP

Parameter	Re-ERCP No (n: 672)	Re-ERCP Yes (n: 19)	P value
Pre-ERCP data			
Age ± SE (y)	60.2±16.4	62.7±14.6	.562
Gender n (%)			.742
Male	328 (48.8)	10 (52.6)	
Female	344 (51.2)	9 (47.4)	
ALT (median ± SD, U/L)	130.7±110.3	154.1±88.0	.087
AST (median ± SD, U/L)	105.1±96.2	123.8±76.3	.033
GGT (median ± SD, U/L)	307.5±277.8	404.9±269.6	.073
ALP (median ± SD, U/L)	563.7±465.9	731.8±364.1	.025
Total bilirubin (median ± SD, mg/dl)	6.1±9.1	17.6±11.8	.001
Direct bilirubin (median ± SD, mg/dl)	3.8±6.1	11.3±6.9	.001
INR	0.9±0.1	1.0±0.1	.144
Platelet (median ± SD, billion/L)	341.2±87.7	379.4±64.9	.042
White blood cell (median ± SD, billion/L)	9324±1325	8354±3325	.477
Position and structure of papilla			
Bulb, n (%)	18 (2.7)	0 (0)	1.000
Fibrotic, n (%)	11 (1.6)	1 (5.3)	.287
Near diverticula, n (%)	95 (14.2)	2 (10.5)	1.000
Billroth II anastomosis, n (%)	9 (1.3)	1 (5.3)	.564
ERCP findings/interventions			
Stenosis, n (%)	207 (30.8)	15 (78.9)	.000
Type of stenosis			.443
Benign, n (%)	29 (14.4)	1 (6.7)	
Malignant, n (%)	167 (83.1)	14 (93.3)	
Unknown, n (%)	11 (5)	0 (0)	
Level of stenosis			.010
Distal, n (%)	134 (66.3)	4 (26.7)	
Hilar, n (%)	61 (30.2)	10 (66.7)	
Polypoid mass, n (%)	12 (5.4)	1 (12.5)	
NBD placement**			.76
No, n (%)	172 (85.6)	13 (86.7)	
Yes, n (%)	29 (14.4)	2 (13.3)	
Stenting***			.032
Distal, 1 stent, n (%)	121 (61.4)	5 (31.7)	
Hilar, unilateral drainage, n (%)	27 (13.7)	6 (42.9)	
Hilar, bilateral drainage, n (%)	34 (17.3)	3 (21.4)	

•Distal (e.g.: Oddi tumor, tumor of the pancreatic head, distal cholangiocarcinoma, acute/chronic pancreatitis or strictures due to injuries), hilar (e.g.: Klatskin tumor, metastatic tumors, strictures due to operations) ** Synchronous with stent or first NBD then stent placement (all patients) ***More frequent in unilateral drainage than the others. The number of cases in this group is lower than that of the patients with stenosis because no stent was placed in some patients with Oddi tumor.

ALT: Alanine aminotransferase. AST: Aspartate aminotransferase. GGT: Gamma glutamyl transpeptidase. ALP: Alkaline phosphatase. INR: International normalized ratio. NBD: Nasobiliary drain.

was accomplished. First, an ERCP-related complication has developed independent of the underlying disease; missed perforations during ERCP, late hemorrhages and pancreatitis are diagnosed within a few days after the procedure. Second, a favorable result could not be obtained by ERCP due to a missed stone in the biliary duct or another stone dropping down from the gallbladder. On the other hand, stent malfunction or migration is the main cause of obstructive disease. These patients present with unremitting signs of obstruction such as jaundice, pruritus and/or an infectious process like cholangitis or sepsis. The reduction in bilirubin levels with subsiding pruritus is expected usually in one to two weeks. Ascending infection, however, occurs typically in 24 to 72 hours (3).

Therefore, the two-week period that we determined may be considered a reasonable interval for early re-ERCP.

The most common cause of early re-ERCP in our cohort was inefficient drainage of biliary ducts. The majority of these patients had ascending cholangitis, while some presented with jaundice and worsening pruritus. Essentially, somewhat incomplete drainage is also the main issue in patients with retained stone.

Infectious complications like ascending cholangitis, liver abscess and acute cholecystitis are the most dreadful complications of ERCP, and are a common cause of ERCP-related deaths. Ascending cholangitis most commonly results from incomplete drainage of an infected and obstructed biliary system. Incidence of clinically significant cholangitis has ranged from 0.4% to more than 10% in various reports, depending upon the study population (4-6). The highest rates have been observed in patients with malignant hilar strictures, which are difficult or sometimes impossible to drain adequately (2,7,8). In fact, a substantial number of our patients who required early re-ERCP had hilar strictures (Tables 1, 2).

The method used for endoscopic palliation of biliary strictures varies according to the localization of stenosis. Inserting a single stent provides enough palliation in case of benign distal strictures, tumor of the pancreatic head, distal cholangiocarcinoma, and Bismuth type 1 cholangiocarcinoma. Palliation in such patients is relatively simple with fewer complications. Thus, early re-ERCP was required in only 5 of 126 patients (4%) with distal stenosis in our cohort. When plastic and metallic stents were compared in endoscopic palliation of distal malignancies, Kaassis et al. (9) reported stent occlusion in 3 of 59 patients with plastic stents, while none of those with metallic stents had stent occlusion. Likewise, none of 44 patients who underwent metallic stent placement in our cohort of 126 patients needed early re-ERCP.

On the other hand, palliation in hilar carcinomas is more difficult and controversial. First, there is a debate over which method to choose. In contrast to endoscopic treatment in distal stenosis, some also prefer percutaneous drainage in proximal stenosis. However, it is known that endoscopic, percutaneous and surgical methods provide essentially the same palliation (10), with nonsurgical methods having less morbidity and mortality (11). Se-

Table 2. Multivariate analysis of conditions affecting early repeat ERCP

	P value	Odds ratio	95% CI
Elevated bilirubin	.017	1.046	1.008 - 1.086
Presence of stenosis	.024	4.323	1.215 - 15.382
Hilar stenosis	.005	5.492	1.657 - 18.204
Unilateral drainage in hilar stenosis	.017	4.013	1.291 - 12.475

CI: Confidence interval.

Table 3. The association between NBD placement and frequency of early repeat ERCP according to the type of stenosis

Parameter	Stenosis (Re-ERCP-No) (n: 207)	Stenosis (Re-ERCP-Yes) (n: 15)	p
NBD placement			
Distal, n (%)			.569
Not placed, n: 133	129 (62.3)	4 (26.6)	
Placed, n: 5	5 (2.4)	0 (0)	
Hilar, n (%)			.262
Not placed, n: 50	41 (19.8)	9 (60)	
Placed, n: 21	20 (9.6)	1 (6.7)	
Polypoid mass, n (%)			.943
Not placed, n: 5	5 (2.42)	0 (0)	
Placed, n: 8	7 (3.38)	1 (6.7)	

NBD: Nasobiliary drain

cond, unilateral versus bilateral stenting is strongly controversial in this group of patients. As previously shown, drainage of 25%-30% of the biliary tree is enough for palliation of jaundice (12). Thus, insertion of a single stent is adequate theoretically unless other segments are stained with contrast agent. However, patient survival has reduced in unilateral drainage possibly due to cholangitis (13,14). In our study, the decision to choose unilateral vs bilateral drainage of hilar strictures was determined according to imaging studies like MRCP, CT or ultrasound before the ERCP. We found that the need for early re-ERCP was higher in patients with proximal stenosis who had unilateral drainage compared to those who had bilateral drainage (18.2% vs 8.1%). The persistence of this difference even in patients who were not considered to be contaminated with contrast agent suggests the possibility of radiologically non-imageable leakage of contrast agent into the undrainable segments. Unilateral stenting into the appropriate branch without giving excessive contrast agent may be achieved by MRCP-guided ERC, which was described previously (15). In this study, re-intervention was required in 29% (10/25) of the patients with type II-IV malignant hilar stenosis. Re-intervention was metallic stent placement by ERCP in 7 and by percutaneous method in 3 patients.

Early re-ERCP was required in 18% of patients with hilar tumors who did not have NBD placement and in 4.8% of those who had NBD (Table 3). Although the difference was statistically insignificant, it should be interpreted with caution since the study is retrospective. In fact, the patients who had NBD are more difficult to drain, and therefore, the endoscopist placed NBD in this group of patients considering he could not drain efficiently by stenting. If NBD had not been placed in these patients, they would probably have needed early re-ERCP more often. Therefore, our study suggests that placement of NBD in hilar strictures may be recommended as an adjunctive method to prevent complications that could result from stenting alone. Further study is needed to support this conclusion.

It has been reported that polypoid cholangiocarcinomas are more operable than scirrhous ones (16). However, there is no data in the literature about endoscopic palliation. In our study, we found that palliation is more difficult in patients with biliary polypoid mass than in those with distal stenosis, albeit statistically insignificant. Early re-ERCP was needed in 1 out of 13 patients with polypoid mass. These were mobile, large masses, the level of origin of which could not be determined precisely by cholangiography. Some of these patients underwent surgery after placement of NBD since a stent could not be inserted due to the flexing effect of the mass.

Re-ERCP was performed because of acute cholecystitis in only one of our patient cohort. The incidence of post-ERCP acute cholecystitis ranged from 0.1-8.6% in various reports. The pathogenesis may be related to the introduction of contrast medium into a poorly emptying gallbladder and obstruction of the cystic duct by an endoprosthesis, malignancy, or gallstone (17,18). Occlusion of the cystic duct by a plastic stent was considered as the cause of cholecystitis in our single case. Removal of the stent and placement of NBD were followed by percutaneous drainage of the gallbladder since the patient was unfit for surgery.

In conclusion, unilateral stenting, particularly in proximal stenosis, is a predictive factor for early re-ERCP, even if the contralateral side is not exposed to contrast agent. Cholangitis and unresolved jaundice are red flags for an early re-ERCP. Therefore, these patients should be followed with caution. More efficient biliary drainage with NBD with or without stenting might yield better results in patients with hilar stenosis.

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