Original Article / Özgün Araştırma

Is Outpatient ERCP Safe for Choledocholithiasis?

Koledok Taşı için Ayaktan ERCP Güvenli midir?

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Abstract

Objective: This study aimed to compare the complications of outpatient and inpatient endoscopic retrograde cholangiopancreatography (ERCP) procedures in patients with bile duct stones and to investigate whether it is a safe approach to perform outpatient ERCP or not.

Materials and Methods: This prospective study consisted of 203 patients who had undergone ERCP for the first time with a diagnosis of choledocholithiasis between January 2013-July 2013.

Results: Of the patients included in the study, 102 had undergone outpatient and 101 had undergone inpatient ERCP. Complications following ERCP occurred in 9.8% of the outpatient group (pancreatitis in 5.9%, hemorrhage in 1.9%, cholangitis in 1%, perforation in 1%), while they occurred in the 11.9% of the inpatient group (pancreatitis in 6.9%, bleeding in 1%, cholangitis in 2%, perforation in 2%) (p=0.230, p=0.386, p=0.386, p=0.333, respectively; total complication comparison p=0.618). An amylase level below 150 U/L at the 4th hour after ERCP had a negative predictive value of 99.4% for pancreatitis to be negative. When the 4th hour amylase value of 300 U/L was taken as a limit, it had a positive predictive value of 52.1% in terms of pancreatitis positive. Additionally, the outpatient procedure was more cost-effective when the two groups were compared in terms of the cost [873.6±272.2 Turkish lira (TL) vs 1389.7±612.6 TL, p=0.001].

Conclusion: Our study demonstrated that outpatient ERCP was safe and cost-effective in selected cases with bile duct stones. The 4th hour amylase level below 150 U/L after ERCP showed that patients can be safely sent home and that the amylase value above 3-fold at the 4th hour can be considered the limit value for admission to the hospital for pancreatitis.

Keywords
Amylase, outpatient ERCP, choledocholithiasis

Anahtar Kelimeler
Amilaz, ayaktan ERCP, safra yolu taşı

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Öz

Amaç: Bu çalışmada safra yolu taşı olan hastalara ayaktan ve yatırılarak uygulanan endoskopik retrograd kolanjiyopankreatografi (ERCP) prosedürünün komplikasyonları karşılaştırılarak, ayaktan ERCP işleminin emniyetli bir yaklaşım olup olmadığı araştırılmıştır.

Gereç ve Yöntemler: Çalışmaya, 2013 Ocak-Temmuz ayları arasında safra yolu taşı tanısı almış olup ilk defa ERCP uygulanan 203 vaka prospektif olarak alınmıştır.

Bulgular: ERCP yapılan vakaların 102'si ayaktan, 101'i yatırılarak uygulanan hastalardı. Ayaktan grupta ERCP sonrası komplikasyon toplam %9,8 (pankreatit %5,9, kanama %1,9, kolanjit %1, perforasyon %1), yatan grupta %11,9 (pankreatit %6,9, kanama %1, kolanjit %2, perforasyon %2) olarak saptandı (sırasıyla p=0,230, p=0,386, p=0,386, p=0,333 toplam komplikasyon kıyaslaması p=0,618). ERCP

sonrası 4. saat amilaz ölçümünün 150 U/L'den düşük olması pankreatit olmama açısından %99,4 oranında negatif prediktif değere sahipti. 4. saat amilaz değerinin sınırı 300 kabul edildiğinde pankreatit olma açısından %52,1 oranında pozitif prediktif değere sahipti. Aynı zamanda iki grup maliyet açısından da kıyaslandığında ayaktan grup daha avantajlıydı [873,6±272,2 Türk lirası (TL) vs 1389,7±612,6 TL, p=0,001].

Sonuç: Bu çalışma safra yolu taşı olan seçilmiş hastalarda ayaktan ERCP işleminin emniyetli ve maliyet açısından daha etkin olduğunu, ERCP sonrası 4. saat amilaz ölçümünün 150 U/L'den düşük olması hastaları emniyetli bir şekilde taburcu edebileceğimizi aynı zamanda 4.saat amilaz ölçümünün 3 katın üzerinde olmasının pankreatit açısından hastaneye yatış için limit değer olabileceğini göstermiştir.

Introduction

The endoscopic retrograde cholangiopancreatography (ERCP) procedure is a relatively complex endoscopic procedure that requires special equipment and a long learning period. Although it can be seen as a safe procedure in experienced hands, it may cause more serious complications with higher rates than other standard endoscopic techniques. The rate of all complications of ERCP have been reported in the literature to be between 9.8-11.6%, with a mortality rate of 0.4% (1-5). For this reason, the ERCP procedure is generally performed as an inpatient procedure. Since some of the ERCP-related complications are noticed and intervened during the procedure and most of them are recognized during the first 2-6 hours post-procedure, outpatient ERCP has been increasingly studied in selected cases over the last 20 years and has become a reasonable option by experienced centers to reduce bed occupation and decrease costs (5-7). Bleeding and perforation during ERCP are often complications that can be recognized during the procedure. Early diagnosis of pancreatitis, which is the most common complication after ERCP, is very important. Hyperamylasemia after ERCP is known to peak between 90 minutes and 4 hours. Therefore, the amylase value at the 4-h has an important role in predicting pancreatitis (8). The aim of this study was to determine the reliability of outpatient ERCP procedure in patients with choledocholithiasis and to ensure that patients with 4-h amylase values lower than 150 units/L can be discharged safely in terms of the risk of pancreatitis, which is one of the complications of the procedure.

Materials and Methods

The ethics committee approval for the study was obtained from the Yüksek İhtisas Training and Research Hospital Non-Interventional Clinical Research Ethics Committee (decision no: 312, date: 05.12.2013).

This prospective study consists of 203 patients diagnosed with choledocholithiasis who received ERCP for the first time between January 2013 and July 2013 in a tertiary hospital where more than 2000 ERCP procedures are performed each year.

Prior to the ERCP procedure, age, sex, drug use, allergy to the contrast agent, comorbid diseases, American Society of Anesthesiologist (ASA) assesment scores and the cholecystectomy status of all patients were evaluated. Written informed consent was obtained from all patients, which described the ERCP procedure and provided information about possible complications. Complete blood count (CBC), coagulation parameters and biochemical profiles (renal functions, liver tests, amylase) were measured before the procedure in all patients. All patients had undergone at least one imaging technique (ultrasonography, computed tomography, magnetic resonance cholangiopancreatography, endosonography) before the procedure.

Before the each ERCP procedure, rectal non-steroidal anti-inflammatory drugs (NSAIDs) were routinely administered to patients.

The exclusion criteria of the patients were determined as follows; previous sphinceterotomy, patients <18 years of age, patients with cholangitis, patients with biliary pancreatitis, patients who received anticoagulation other than aspirin (clopidogrel, warfarin etc.), those with coagulation disorders (international normalized ratio >1.5, platelet <50,000/mm3), ASA score of 4 and above for inpatients, ASA score of 3 or above for outpatients, and patients with altered gastointestinal system anatomy (Billroth-2 gastrectomy, Roux-en-Y hepaticojejunostomy, etc.). Patients with these criteria were not included in the study. The selection of the patients is summarized in Figure 1.

All patients were treated at least 8 hours after fasting. The outpatients were followed up post-opeatively for at least 4 hours in the 2-bed follow-up

unit, which was allocated to the gastroenterology department in the emergency unit of our hospital. All patients were fasted for the first 4 hours after ERCP procedure. Amylase and CBC values were measured at the 4-h after the procedure. The patients were evaluated by the gastroenterology fellow at the end of the 4-h. For outpatients, amylase levels of <150 units/L, normal hemoglobin and leukocyte levels and absence of epigastric tenderness and abdominal pain on the abdominal examination were accepted as the criteria for discharge. The patients were advised to follow an only-liquid diet during the first 24 hours of discharge. If the 4-h amylase value was >150 units/L in the outpatients, regardless of the presence of symptoms, the oral intake of the patient was not initiated and 24-h follow-up and control of the 24-h amylase values were planned. The 24-h amylase value of lower than 300 units/L and/or absence of any symptoms was accepted as a criterion for discharge. The outpatients who developed complications in the first 4 hours were admitted to the inpatient ward or the intensive care unit without delay. The inpatients were also evaluated by the gastroenterology fellow at the end of the 4-h. The oral intake of the patient was initiated with a liquid diet regime when the 4-h amylase value was <150 units/L and abdominal examination was normal, and the regime was turned to a normal diet when there was no additional problem at the end of 24 hours. In case when the 4th hour amylase value was >150 units/L, the amylase value was measured at the 24-h before the oral intake of the patient was initiated. The oral intake of the patient was initiated when the 24-h amylase value was below 300 units/L and/or in the absence of symptoms. Figure 2 summarizes how to manage patients according to their 4-h amylase value and complaints.

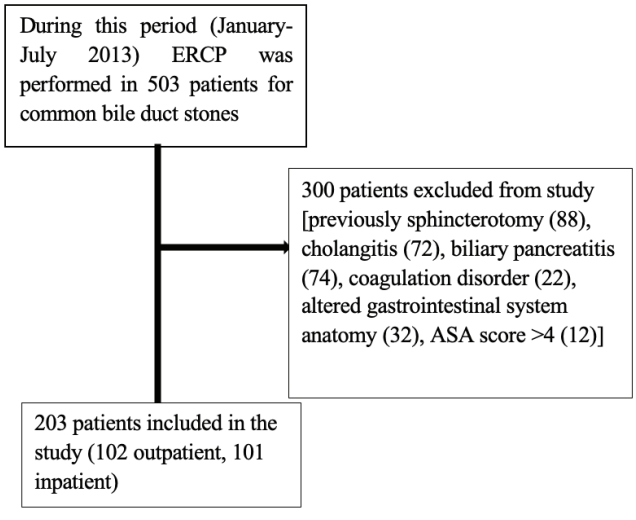

Figure 1. Patient selection
ERCP: Endoscopic retrograde cholangiopancreatography, ASA: American Society of Anesthesiologist

Support was received from the financial unit of our hospital in terms of cost calculation for outpatient and inpatient groups.

ERCP-specific complications (pancreatitis, cholangitis, bleeding, perforation) were defined and graded according to some special classifications (1,9,10).

Statistical Analysis

Statistical analysis of the data was performed using the Statistical Package for Social Sciences (SPSS) version 18 (SPSS Inc., Chicago, IL, United States). The difference between the groups in terms of categorical variables in outpatients and inpatients was evaluated using the chi-square or the Fisher's tests (where the values observed in the cells did not meet the chi-square test assumptions), and the t-test was used for the numerical data showing normal distribution and the Mann-Whitney U test was used for the data that were not normally distributed. A p value lower than 0.05 was considered statistically significant.

Results

Of the patients, 102 had undergone outpatient and 101 had undergone inpatient ERCP. 65 (63.7%) of the patients who had undergone outpatient ERCP were female and 37 (36.3%) were male. 56 patients (55.6%) of the patients who had undergone inpatient ERCP were female and 45 (44.6%) were male (p=0.220). The mean age of the outpatient group was 53.9±18.1

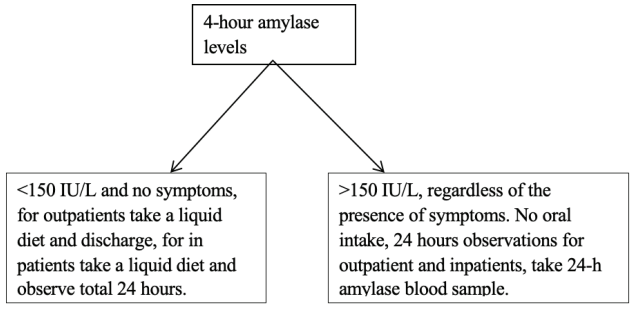

Figure 2. Patient management according to the 4-hour amylase level

years and that of the inpatient group was 65.6±16.6 years (p=0.001).

When the groups were compared according to the ASA score, 69 (67.6%) patients with an ASA score of 1 and 33 (32.4%) patients with an ASA score of 2 were identified in the outpatient group. In the inpatient group, 37 patients (36.6%) with ASA score of 1, 54 patients (53.4%) with a score of 2, and 10 patients with a score of 3 (10%) were identified. The ASA scores were found to be different between the groups (p=0.001).

No significant difference was found between the outpatient and the inpatient groups in terms of imaging techniques performed for suspicion of bile duct stone (p=0.07). The therapeutic procedures performed during the ERCP procedure were found to have a similar distribution in both groups (p=0.091). The baseline demographic data of the patients have been presented in Table 1.

When the baseline laboratory values were compared between the two groups, it was found that parameters other than creatinine and platelet levels were not different between the two groups (Table 2).

In the outpatient group, 8 (7.8%) patients had 10 ERCP-related complications (1 patient had pancreatitis+cholangitis, the other 1 had pancreatitis + bleeding), and the patients were followed up with hospitalization. In the inpatient group, 11 (10.8%) patients had 12 complications (pancreatitis + cholangitis were observed together in 1 patient). No statistically significant difference was observed between the two groups in terms of complications (p=0.618) (Table 3).

When the outpatient and the inpatient groups were compared in terms of cost, the outpatient group was found to have lower cost and this was found to be statistically significant [873.6±272.2 Turkish lira (TL) vs 1389.7±612.6 TL p=0.001].

No statistically significant difference was observed between the outpatients and the inpatients with similar ASA scores in terms of complications (Table 4).

Eighty five patients were determined with 4-h amylase values below 150 U/L in the outpatient group (n=102). Only 1 of these patients was admitted to the hospital again after 24-h and was diagnosed with pancreatitis+cholangitis. Again in this group, there were 7 patients with 4-h amylase values between 150-300 U/L and none of them developed pancreatitis.

Table 1. Patients demographics

	Outpatient group (n=102) n (%)	Inpatient group (n=101) n (%)	p-value
Age	53.9±18.8	65.6±16.6	0.001
Female/male	65 (63.7)/37 (36.3)	56 (55.4)/45 (44.6)	0.22
Comorbidity	39 (37.5)	65 (62.5)	0.001
Cholecystectomy (+)	23 (22.5)	15 (14.8)	0.4
Aspirin (+)	18 (17.6)	28 (27.7)	0.161
NSAID (+)	19 (18.6)	20 (19.8)	0.831
Cannulation type	82 (79.4)/20 (19.6)	85 (84.2)/16 (15.8)	0.482
Normal/ preincision			
Bile duct size (mm)	10±2.3	11.2±3.7	0.337
ASA score			
1	69 (67.6)	37 (36.6)	0.001
2	33 (32.4)	54 (53.4)	
3	0	10 (%10)	
Therapeutic procedure			
Sphincterotomy	102 (100)	101 (100)	0.091
Stent	10 (9.8)	10 (9.9)	
Mechanical lithotripsy	3 (3)	5 (5)	
Dilatation (TPBD)	5 (4.9)	14 (13.8)	
Pancreatic stent	5 (4.9)	0	
Diagnostic tool			
USG	71 (69.6)	82 (81.2)	0.07
EUS	15 (14.7)	14 (13.9)	
MRCP	14 (13.7)	5 (5)	
CT	2 (2)	0 (0)	
Cost, TL	873.6±272.2	1389.7±612.6	0.001

NSAID: Non-steroidal anti-inflammatory drugs, ASA: American Society of Anesthesiologist, USG: Ultrasonography, MRCP: Magnetic resonance cholangiopancreatography, CT: Computed tomography, TL: Turkish lira

Pancreatitis developed in 5 out of 10 patients with 4-h amylase values above 300 U/L.

In the inpatient group (n=101), 87 patients with 4-h amylase values below 150 U/L were determined and none of the patients developed pancreatitis. Pancreatitis did not develop in any of the 6 patients with 4-h amylase values between 150-300 U/L in the same group. The remaining 8 patients had 4-h

Table 2. Laboratory parameters

	Outpatient group (n=102) n (%)	Inpatient group (n=101) n (%)	p-value
Hgb (g/dL)	13.7±1.6	13.3±1.6	0.267
WBC (x10^3/uL)	7.945±3.3	7.000±3.6	0.08
Plt (x10^3/uL)	287.069±84.3	247.604±69.9	0.001
INR	1.07±0.7	1.2±0.8	0.054
ALT (U/L)	180±93	154±83	0.082
AST, median (U/L)	83.5 (12-644)	48 (10-770)	0.106
GGT (U/L)	313±275	336±313	0.907
Total bilirubin, median (mg/dL)	1.47 (0.2-14.3)	1.3 (0.3-29.5)	0.685
ALP (U/L)	243±141	258±209	0.522
Creatinin (mg/dL)	0.8±0.2	0.9±0.4	0.044
Amylase-base line (U/L)	79.3±46.2	79.8±44.5	0.765
Amylase-4-h, median (U/L)	83.5 (21-1836)	82 (24-2819)	0.858

Hgb: Hemoglobin, WBC: White blood cell, Plt: Platelet, INR: International normalized ratio, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, GGT: Glutamyl transferase, ALP: Alkaline phosphatase, *The median value is used because AST, total bilirubin, amylase 4-h did not have normal distribution

Table 3. Distribution of complications

Complication	Outpatient group (n=102) n (%)	Inpatient group (n=101) n (%)	p-value
Bleeding	2	1	0.386
Mild	1	0	-
Moderate	1	1	-
Severe	0	0	-
Pancreatitis	6	7	0.230
Mild	5	6	-
Moderate	1	1	-
Severe	0	0	-
Cholangitis	1	2	0.386
Mild	1	1	-
Moderate	0	1	-
Severe	0	0	-
Perforation	1	2	0.333
Mild	1	2	-
Moderate	0	0	-
Severe	0	0	-
Total post-ERCP complications	10 (9.8)	12 (11.9)	0.618

ERCP: Endoscopic retrograde cholangiopancreatography, * n shows the number of complications

amylase levels of over 300 U/L and 7 developed pancreatitis.

In the light of these data, the 4-h amylase value lower than 150 U/L stood out with a 99.4% negative predictive value for the absence of pancreatitis. An amylase level of up to 300 U/L in this analysis was also found to be safe. An amylase value of 300 U/L or higher was found to be an increased positive predictive value for pancreatitis (Table 5).

Discussion

In studies conducted on outpatient ERCP, it is recommended that outpatient ERCP be performed in selected cases by experienced centers, since most of the complications occur during the procedure or during the follow-up periods ranging from 2-6 hours.

In our study, the overall complication rate after ERCP was determined as 9.8% in the outpatient group and as 11.9% in the inpatient group. There was no difference between the two groups in terms of complications. When the literature was examined, it is seen that there was a similarity in terms of total and individual complications. In our study, ERCP-related mortality was not observed. In studies conducted by Cotton et al. (1) in 1991, Freeman et al. (2) in 1996, Johanson et al. (3) in 2002, and Mallery et al. (4) in 2003, complications after ERCP were reported to be between 9.8-11.6% and the mortality as 0.4%. In a study by Rábago et al. (5) in 2010, the total complication rate after ERCP was determined as 12.1%.

In our study, 10 (9.8%) complications were detected in 8 patients in the outpatient group. Eight of these complications (7.8%) were recognized during the first 4 hours of follow-up and these patients were hospitalized. Twelve (11.9%) complications were determined in 11 patients in the inpatient group. Ten (9.9%) of these complications were recognized during the first 4 hours of follow-up. Most of the complications of the patients occurred during the procedure or during the first 4 hours of the follow-up period.

In Hui et al.'s (6) study in 2004, the rate of complications in outpatient ERCP patients was similar to the rate of complications in patients who were hospitalized for at least one day after ERCP. Most complications occurred in the first 6 hours.

Table 4. Distribution of the number of patients who developed complications according to ASA 1 and ASA 2 scores in both groups

	Outpatient group n=102 (%)	Inpatient group n=91 (%)	p-value
Number of ASA 1 patients/number of patients with complications	69 (67.6)/4 (5.8)	37 (40.6)/5 (13.5)	0.189
Number of ASA 2 patients/number of patients with complications	33 (32.4)/4 (12.1)	54 (59.4)/6 (11.1)	0.910

ASA: American Society of Anesthesiologist

Table 5. Four h amylase level cut-off values and test performance

Amylase levels	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
100 (normal)	100	64	18	100
150 (1.5x normal)	92.3	87.3	33.3	99.4
300 (3x normal)	92.3	94.2	52.1	99.4

The study of Katsinelos et al., (7) which was performed in 2011, shows similarity to our study. In this study, the outpatient group was found to be cost effective. Similarly, in our study, when the two groups were compared in terms of cost, it was seen that the outpatient group was found to be less costly.

When the outpatient and the inpatient groups were compared in terms of age and ASA scores, a difference was found between the two groups (age and ASA scores were higher in the inpatient group). This is due to the fact that patients with ASA score of 3 had not undergone an outpatient ERCP procedure. When the patients with ASA score of 3 were excluded from the inpatient group and the two groups were compared according to the similar ASA score, no difference was found between the two groups in terms of complications.

The most common complication after ERCP is pancreatitis. Bleeding and perforation are often recognized during the procedure. For this reason, amylase levels and the presence of abdominal pain in the outpatient group are the most frequently used parameters to be safely discharged and patients are discharged accordingly. In studies conducted for this purpose, the amylase levels obtained at the 2nd or 4th hours without waiting for 24 hour, can be a marker for pancreatitis.

In the study conducted by Thomas et al. (8), the 4-h amylase levels of lower than 150 U/L excluded pancreatitis with a 100% negative predictive value. A serum amylase level of above 3-fold was accepted as the limit value for hospital admission with a positive predictive value of 36.8%. If the amylase level were between 1.5-3.0 times, evaluation of additional risk factors for clinical findings and pancreatitis have been proposed.

In our study, the 4-h serum amylase level of below 150 U/L was found to have a rate of 99.4% negative predictive value for the absence of pancreatitis after ERCP. This showed that we can safely discharge patients with a 4-h amylase value below 150 U/L after ERCP. When the 4-h serum amylase level of 3 times above the normal value was taken as the cut-off value, it was found to have a positive predictive value of 52.1% in terms of pancreatitis. This value was considered to be a cut-off level for admission to hospital for pancreatitis.

In a study by Gottlieb et al. (11), the 2nd hour amylase level of lower than 276 U/L is reported to exclude pancreatitis with a high negative predictive value (97%).

In the European Society of Gastrointestinal Endoscopy guidelines, it was stated that the 4th hour serum amylase level of 1.5 times below normal values after ERCP eliminates pancreatitis after ERCP. It has also been stated that the same situation can be accepted as a criterion for the safe discharge of patients (12-14).

Up to the present, outpatient ERCP studies have conducted with heterogenous group patients (5-8,11,15). For the first time, our study has shown that

it is safe to perform ERCP on an outpatient basis in selected patients (choledocholithiasis).

There were some limitations in our study. These limitations were: working with a low-risk group for pancreatitis after ERCP (choledocholithiasis), the fact that all procedures were performed by experienced endoscopists (not reflecting the general population), use of preventive measure (rectal NSAIDs), use of amylase instead of lipase and incomplete randomization in patient selection.

Conclusion

Our study showed that performing outpatient ERCP was safe and cost-effective in selected cases with choledocholithiasis; patients with 4-h amylase levels of lower than 150 U/L can be safely sent to their homes, patients with 4-h amylase levels above 3-fold can be admitted to the hospital for pancreatitis and this value can be used as a cut-off value.

Ethics

Ethics Committee Approval: The ethics committee approval for the study was obtained from the Yüksek İhtisas Research and Training Hospital Non-Interventional Clinical Research Ethics Committee (decision no: 312, date: 05.12.2013).

Informed Consent: Written informed consent was obtained from all patients.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: İ.T., B.Ö., H.Y., E.P., Concept: İ.T., B.Ö., Design: İ.T., B.Ö., H.Y., E.P., Data Collection or Processing: İ.T., H.Y., Analysis or Interpretation: İ.T., B.Ö., H.Y., E.P., Literature Search: İ.T., Writing: İ.T.

Conflict of Interest: No conflict of interest was declared by the authors.

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