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Combined use of endosonography and endoscopic retrograde cholangiopancreatography in the same session

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Background/aims: *The diagnostic value of endoscopic ultrasound in common bile duct stones is high. In this investigation, we evaluated the feasibility of endoscopic ultrasound preceding endoscopic retrograde cholangiography in the same session and the potential benefits in increasing the therapeutic endoscopic retrograde cholangiography ratio in the treatment of choledocholithiasis.* ***Methods:*** *One hundred and sixty-five consecutive patients who presented with elevated ALP and bilirubin levels and were referred for endoscopic retrograde cholangiography of biliary stones diagnosed with magnetic resonance cholangiopancreatography were evaluated. During the evaluation period (mean: 2 weeks), 50 patients with reductions in ALP and bilirubin by at least half relative to baseline values were enrolled into the study. Endoscopic ultrasound was performed prior to endoscopic retrograde cholangiography. Time spent to perform endoscopic ultrasound was noted. For the presence of common bile duct stone, we used retrograde cholangiography findings as the standard of reference.* ***Results:*** *Median endoscopic ultrasound time was 10.66 minutes (SD±1.52). Bile duct stones were revealed with retrograde cholangiography in 34 patients (68%). Sensitivity, specificity (with 95% confidence intervals [CIs]), positive predictive value and negative predictive value of endoscopic ultrasound were calculated. In identifying common bile duct stones on endoscopic ultrasound, sensitivity, specificity, positive predictive value, and negative predictive value were statistically determined as 91.2% (95% CI), 88.3% (95% CI), 91%, and 81.3%, respectively.* ***Conclusions:*** *Our results indicate that in the presence of local experience and availability of endoscopic ultrasound, it is feasible to perform endoscopic ultrasound prior to endoscopic retrograde cholangiography. The sensitivity, specificity, positive predictive value, and negative predictive value for detecting choledocholithiasis in suspected cases are high. Endoscopic ultrasound preceding endoscopic retrograde cholangiography in the same session has the potential to decrease diagnostic endoscopic retrograde cholangiography and increase therapeutic endoscopic retrograde cholangiography. Need to perform magnetic resonance cholangiopancreatography in the presence of easily accessible endoscopic ultrasound should be questioned.*

Key words: Endosonography, ERCP, common bile duct, gallstones

Endosonografi ve endoskopik retrograd kolanjiopankreatografinin aynı bölümde birlikte kullanımı

Amaç: *Ana safra kanalı taşlarında endoskopik ultrasonun tanısal değeri yüksektir. Bu araştırmada, koledokolitiyazisin tedavisinde aynı seansta endoskopik retrograd kolanjiopankreatografi öncesi endoskopik ultrasonun kullanılabilirliğini ve terapötik endoskopik retrograd kolanjiopankreatografi oranını arttırmadaki potansiyel faydasının değerlendirdik.* ***Yöntem:*** *Magnetik rezonans kolanjiopankretaografide safra taşı tanısı alan, ALP ve bilirübin düzeyinde artış ile endoskopik retrograd kolanjiopankreatografi önerilen 165 olgu değerlendirildi. Ortalama 2 haftalık değerlendirme süresi boyunca, ALP'da azalma ve bilirübinde normal değerlere göre en az yarı değer kadar azalma olanlar çalışmaya dahil edildi. Endoskopik retrograd kolanjiopankreatografi öncesi endoskopik ultrason yapıldı. Endoskopik ultrason işlem süresi kaydedildi. Ana safra kanalı taşı varlığı için, referans standardı olarak retrograd kolanjiografi bulguları kullanıldı.* ***Bulgular:*** *Ortanca endoskopik ultrason zamanı 10.66 dakika (SD±1.52). Otuzdört hastada (%68) safra kanalı taşları, retrograd kolanjiografi ile tespit edildi. Endoskopik ultrasonun sensitivite, spesifisite (% 95 güven aralığı ile [CIs]), pozitif prediktif değer ve negatif prediktif değer hesaplandı. Endoskopik ultrasonda ana safra kanalı taşları tanısında, sensitivite, spesifite, pozitif prediktif değer ve negatif prediktif değer istatistiksel olarak sırasıyla %91,2 (%95 CI), %88,3 (%95 CI), %91 ve %81,3 olarak tanımlandı.* ***Sonuç:*** *Çalışmamız, endoskopik ultrason varlığı ve deneyimi durumunda, endoskopik retrograd kolanjiopankreatografi öncesi endoskopik ultrason kullanımının uygulanabilir olduğunu göstermektedir. Şüpheli olgularda, koledokolitiyazisi tanımlamada sensitivite, spesifite, pozitif prediktif değer ve negatif prediktif değer yüksektir. Aynı seansta endoskopik retrograd kolanjiopankreatografi öncesi endoskopik ultrason uygulaması, tanısal endoskopik retrograd kolanjiopankreatografiyi azaltma ve terapötik endoskopik retrograd kolanjiopankreatografiyi arttırma potansiyeline sahiptir. Magnetik rezonans kolanjiopankretaografi yapma ihtiyacı, kolay ulaşılabilir endoskopik ultrason varlığında, sorgulanmalıdır.*

Anahtar kelimeler: Endosonografi, endoskopik retrograd kolanjiopankreatografi, ana safra kanalı, safra taşları

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INTRODUCTION

Small stones in the gallbladder fall into the common bile duct (CBD) on their way to the duodenum, and they remain generally asymptomatic in the CBD. In addition, calcium carbonate and bile salts contained in bile cause stone formation in the CBD by combining with fatty acid complexes. Sixty to 80% of patients with CBD stones are asymptomatic. Severe pain, acute biliary pancreatitis and/or acute cholangitis may develop in some patients. For the purpose of identifying stones in the CBD, non-invasive methods such as ultrasound (US), magnetic resonance cholangiopancreatography (MRCP), and minimally invasive methods such as endoscopic ultrasonography (EUS) are used (1). Sensitivity and specificity levels of MRCP and EUS in identifying CBD stones are high and comparable. Although EUS is a more invasive method relative to MRCP, it can be administered before endoscopic retrograde cholangiography (ERC) in the same endoscopy session, and reduce the risk of second anesthesia and labor loss.

In this study, we aimed to examine the effectiveness and practicality of radial EUS performed together with ERC in the same session, and determine whether combined use of both procedures is helpful.

MATERIALS AND METHODS

This was a prospective cross-sectional single group study conducted in the gastroenterology clinic of İzmir Atatürk Training and Research Hospital between August 2009 - January 2010. The annual EUS and ERCP numbers were approximately 1800 and 1400, respectively. Biochemical values (total bilirubin, direct bilirubin, alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), amylase), white blood cell count (WBC) and upper abdominal US were evaluated in patients with total bilirubin levels >3.0 mg/dl, with direct bilirubin predominance and with ALP higher than 3-fold of normal value at presentation, followed by a MRCP evaluation of the CBD. ERC was arranged for those patients who were found to have filling defect in MRCP consistent with CBD stone. One day before the ERC procedure, biochemical tests (total bilirubin, direct bilirubin, ALP, GGT, amylase) and WBC were repeated in all patients. CBD examination was done by means of radial EUS (Hitachi EUB 6000 plus Pentax EG 3630 UR 270 5-10 MHz, Tokyo, Japan) in the same session before the ERC procedure in patients who were found to have a reduction in direct bilirubin and ALP levels by at least half relative to baseline values in biochemical examination performed before ERC, and who were considered to have CBD stone. All patients underwent ERC according to their MRCP data, regardless of whether they were positive or negative for CBD stone on EUS. Median waiting time between MRCP and ERC was 14 days (range: 10-21 days). Of the patients who were scheduled for inclusion in the study due to obstructive jaundice, those who were found to have symptoms of benign or malignant stenosis, external compression on CBD, acute biliary pancreatitis, or acute cholangitis on MRCP, those who were pregnant, those with bleeding diathesis or chronic liver disease, and those with surgical intervention (Billroth II operations, total gastrectomies, etc.) that interfered with the evaluation of CBD by means of EUS-ERC were excluded from the study.

Radial EUS was performed under sedation with 2 mg of midazolam by a physician experienced in evaluating the pancreatobiliary system after consents were obtained from patients. CBD was examined by locating in the second portion of duodenum, bulbus and gastric antrum. Existence of hyperechoic areas with acoustic shadowing and sludge were considered as stone and particle. CBD diameter, existence of stone, number of stones, and stone diameter were assessed. In the same endoscopy session, after informed consent was obtained for the procedure, ERC was performed in all patients by two physicians with ERC experience of 1400/year/10 years under anesthesia with 10 mg/kg of propofol in addition to 2 mg of midazolam. Cholangiogram was obtained with contrast agent following cannulation of the CBD. For the presence of CBD stone, we used retrograde cholangiography findings as the standard of reference. In the diagnosis of CBD stone, balloon sweeping of the CBD during ERC was accepted as diagnostic. Sphincterectomy followed by balloon- and basket-aided therapeutic procedure was performed in all patients who were found to have stone on the cholangiogram. After this procedure, patients were monitored for 3 hours. EUS was performed before ERC in the same room by a different physician from those who performed the ERC.

Demographics, baseline and pre-ERC values, detection of stone on EUS and ERC, and numbers and diameters of detected stones were recorded and statistically evaluated.

Statistical calculations were done using SPSS version 17.0 statistical software. Sensitivity, specificity, and positive and negative predictive values (PPV, NPV) were calculated in 95% confidence interval (CI). Data analyses were done using chi-square test, Fisher's exact chi-square test and Student's t-test. A value of $p<0.05$ was considered statistically significant.

RESULTS

One hundred and sixty-five patients with obstructive jaundice were evaluated by means of MRCP to be included in the study, and ERC was scheduled. The assessment performed in 54 of 165 patients before ERCP showed marked reductions in direct bilirubin and ALP values. Of these patients, 4 patients were excluded from the study: 3 due to history of gastric surgery that could pose an impediment to EUS and ERC, and 1 due to acute cholangitis. Fifty patients who were suspected to have CBD stone were included in the study. Four of 50 patients had a history of stone removal after ERC and endoscopic sphincterotomy (ES). Fifty EUS procedures were performed in 50 patients. Repeated EUS was not needed. Due to unsuccessful or inadequate procedure, a second ERC was performed in 3 patients at week 1 and in 1 patient at week 3. During the 24-hour follow-up period after ERCP, mild acute pancreatitis developed in 1 patient in whom no stone was seen on ERC, and this patient was hospitalized for 4 days of medical treatment. No complication related to EUS was observed.

The mean age of the 50 patients included in the study was 58±16 years, and 30 of them were female. There was no statistically significant difference between biochemical values of patients who were found to have stone on EUS and ERCP and the biochemical values of those who were not found to have stones on both ($p>0.05$). There was no statistically significant difference between CBD diameters of patients who were found to have stone on EUS and ERC and the CBD diameters of those who were not found to have stones on both ($p>0.05$).

All EUS procedures were successful. Median EUS time was 10 minutes. In EUS analysis, while stone was observed in CBD in 34 (68%) of 50 patients, no stone was observed in 16 (32%). Of the 34 patients with stone detected on EUS (Figure 1), 3 (9%) were not found to have stone on cholangiogram obtained by means of ERC. Of the 16 patients who were not found to have stone on EUS, 3 (19%) were found to have stone on cholangiogram obtained by means of ERC (Figure 2).

Of the 31 patients who were found to have stone on both EUS and ERC, stone diameter was >10 mm in 8, 5-10 mm in 16, and <5 mm in 7. In this group, 24 patients had more than 1 stone. In the 3 patients in whom stone was seen on EUS but not on ERC, diameters of stones were found to be <5 mm, and the number of stones was detected to be 1. Of the 3 patients in whom no stone was detected on EUS, but stones were detected on cholangiogram obtained by means of ERC, the diameters of stones were <5 mm in 2 and >5 mm in 1, and 1 stone was removed from each patient (Figure 3). Two patients in whom no stone was detected in EUS, but a stone with diameter <5 mm was moved out during ERC, had previous history of stone removal by ERCP and EUS. Data are shown in Table 1 and 2.

Table 1. Demographics and laboratory data of the groups

	**EUS stone(+) ERCP stone (+) n= 31	**EUS stone (-) ERCP stone (-) n= 13	EUS stone (+) ERCP stone (-) n= 3	EUS stone(-) ERCP stone (+) n= 3
Age (year)	61± 31	59± 32	57± 30	61±27
Gender (F/M)	17/13	8/5	2/1	3/0
ALT (IU/L)	98±39	86±37	109±36	89±38
Total bilirubin (mg/dl)	6,4±3,4	7,2±2,9	5,9±3,9	5,4±3,6
Amylase (IU/L)	52±35	47±27	39±21	37±20
ALP (IU/dl)	283±128	368±146	218±67	371±159
Number of stones ≥2/1 (seen on ERCP)	24/ 8	-	-	0/3
Stone diameter (mm) >5 mm / <5 mm (seen on ERCP)	24/7	-	-	1/2
CBD diameter on EUS *dilated/non dilated	20/11	8/5	2/1	2/1

**Dilated CBD =CBD diameter > 8 mm intact gallbladder, CBD diameter > 10 mm operated gallbladder **(+)= stone exists (-)= no stone*

ALT: Alanine transaminase. ALP: Alkaline phosphatase. ERCP: Endoscopic retrograde cholangiopancreatography. CBD: Common bile duct. EUS: Endoscopic ultrasound.

Table 2. Stone size

	0-5 mm	5-10 mm	>11 mm
EUS (n=34)	9	17	8
ERC (n=31)	7	16	8

n=number

No complication related to ERC was observed during ERCP and the 24-hour follow-up afterwards. Only one sedation procedure using anesthesia was performed for the two procedures in the same session. In one patient, hypoxia and bradycardia occurred during the procedure. ERC procedure was terminated in this patient and repeated within 1 week.

In identifying CBD stones on EUS, the sensitivity, specificity, PPV and NPV were statistically determined as 91.2% (95% CI), 88.3% (95% CI), 91%, and 81.3%, respectively.

DISCUSSION

Endoscopic retrograde cholangiography (ERC) is frequently used in detecting and treating CBD stones. Since ERC is an invasive method, there is risk for the development of serious complications during (bleeding, perforation) or after (acute pancreatitis, bleeding, infection) the procedure. Therefore, highly sensitive and specific imaging methods should be used, and the therapeutic ERC rate should be increased while minimizing the number of diagnostic ERCs in detecting CBD stones. In the imaging of CBD stones, US, MRCP and EUS have become prominent as non-invasive or minimally invasive methods (2). Since it can be implemented easily and is non-invasive, US is used as an initial diagnostic method. However, its sensitivity in detecting CBD stones is relatively low, i.e., 20-50% (3,4). Sensitivity and specificity levels of MRCP are very high (5). When clinical symptoms improve, blood biochemical parameters have normalized, and MRCP shows there are no stones in the CBD, it can be considered that the stone has spontaneously passed and thus ERCP is not necessary (6). However, as time intervals between the date of MRCP imaging and ERC increase, some of the stones pass into CBD; thus, the sensitivity and specificity of the method decrease depending on the time interval. Moreover, sensitivity and specificity of MRCP decrease for stones < 3 mm. In our study, we assessed all patients presenting with CBD stone by means of MRCP. We decided to implement ERC for patients in whom a stone was detected. However, taking into account the possibility of the passing of a stone, we repeated biochemical tests before the ERC. We performed EUS in patients who showed marked improvement in their biochemical values and who showed a possibility of having passed the stone.

Endoscopic ultrasonography (EUS) is highly accurate for the diagnosis of choledocholithiasis. The EUS learning curve is relatively short for CBD stones (7). EUS is highly sensitive and specific in identifying the stones <5 mm. In the study conducted by Fabbri et al. (8) to identify CBD stone by means of ERC-confirmed EUS, the sensitivity and specificity of EUS were determined as 100% and 98%, respectively. In the wide range study of 463 patients by Buscarini et al. (9), sensitivity and specificity were determined as 98% and 99%, res-

Figure 1. CBD stone in EUS.

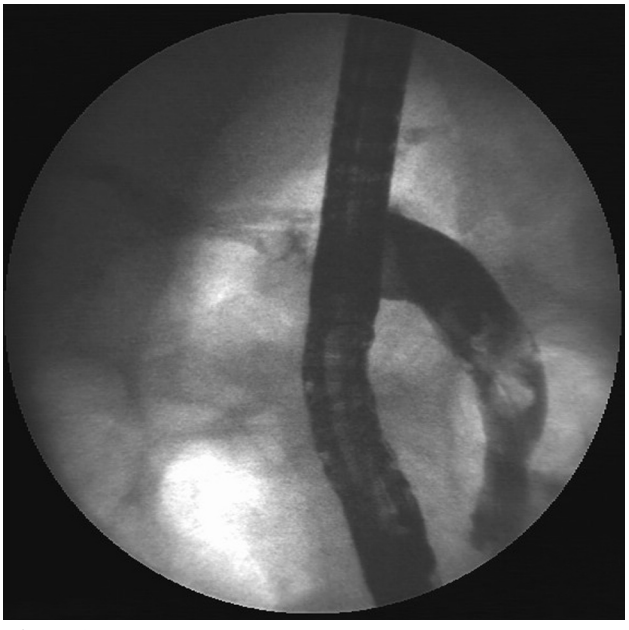

Figure 2. CBD stone in ERC.

Figure 3. CBD stone extraction.

pectively, and EUS was seen to markedly reduce the cost. In another study, in which 38 patients with no stone seen in CBD on US were examined through EUS and were verified to have CBD stone by ERC, sensitivity of EUS was determined as 96% (10). In our study, we determined the sensitivity, specificity and accuracy of EUS as 91.2%, 88.3% and 88%, respectively. In our study, sensitivity and specificity were determined to be lower than in the studies discussed above. Of the patients in whom we did not find stone on EUS, 2 were the patients who had previous stone extraction from the CBD by means of ES. One stone <5 mm was removed from each of these patients in ERC performed in the same session with EUS. Free air within the organs is known to cause artifact and reduce visibility in US examinations. We think that because the air in the CBD due to the previous ES created artifact during the CBD examination, and because stones that could not be identified by means of EUS were <5 mm, the sensitivity of EUS in our cases was reduced.

Sensitivity and specificity of ERC are considerably high. In the study conducted by Stabuc et al. (11), the sensitivity and specificity of ERC were determined as 96% and 92%, respectively. Although the sensitivity and specificity are considerably high, complication risk related to this procedure is also high. Endoscopic retrograde cholangiopancreatography (ERCP) is a potential cause of acute pancreatitis. Asymptomatic hyperamylasemia occurs in 35-70% of patients after the procedure (12). In one patient in whom no stone was detected in EUS and ERC, mild pancreatitis developed, which was treated with medical therapy. It is known that in patients with 1 stone <4 mm in dilated CBD, sensitivity and specificity in cholangiogram obtained with ERC and in post-ES screening performed with balloon are lower compared to the patients with non-dilated CBD (13). In our study, in 3 patients with stone monitored on EUS but not detected on ERCP, the diameters of stones were <5 mm, and of these patients, 2 had CBD diameter >10 mm. We think that stones identified in EUS may not be observed in ERC, thus reducing the sensitivity and specificity of EUS.

One of most important differences of EUS from other diagnostic methods (US, MRCP) is that it can be performed before ERC in the same endoscopy session. EUS and ERCP performed in the same session reduce patients' labor loss, risk of second anesthesia, pre-procedure psychic stress that may occur in patients, and risk of complication that may develop due to diagnostic ERC. Moreover, performing two procedures in the same session ensures marked cost reduction. Performing EUS in combination with ERC is thought to prolong the duration of the procedure. However, there is no marked prolongation in the duration of the procedure if the endoscopist in charge of performing the ERC starts the procedure with the intent of performing therapeutic ERC, having ruled out the other pathologies that cause CBD obstruction and having the necessary equipment available (precut sphincterotomy, etc.) (14). Rocca et al. (15) concluded that EUS and ERC with biliary treatment using an oblique-viewing echoendoscope appeared to be feasible and safe. This technique provided an accurate diagnosis and at the same time, an appropriate treatment of CBD stones. The mean time for diagnosis and treatment was 27 minutes. Artifon et al. (16) reported that outcomes following EUS-guided CBD stone retrieval were equivalent to those following ERCP. In our study, we firstly performed radial EUS followed by ERC in the same session and in the same room. We administered anesthesia just once, and completed the two procedures under the same induction conditions. We did not observe any complications related to radial EUS and ERC. In accordance with our study protocol, we presumed MRCP as the main guideline before ERC, and performed ERC in all patients regardless of EUS showing existence of stone. We performed diagnostic ERC in

38% of 50 patients and therapeutic ERC in 68%. If we had performed ERC using EUS as guidance, only 34 instead of 50 patients would have had ERCP, with diagnostic ERC in 3 (8%) and therapeutic ERC in 31 (92%). Alhayaf et al. (17) concluded that EUS performed before ERCP resulted in a 14% reduction in diagnostic procedures for choledocholithiasis and was cost-effective. Pre-procedure EUS evaluation is recommended in studies on patients with suspected CBD stone (18,19).

Our results indicate that in the presence of local experience and availability of EUS, it is feasible to perform EUS prior to ERC. The sensitivity, specificity, PPV and NPV for detecting choledocholithiasis in suspected cases are high. EUS preceding ERC in the same session has potential to decrease diagnostic ERC and increase therapeutic ERC. Need to perform MRCP in the presence of easily accessible EUS should be questioned.

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