ORIGINAL ARTICLE

Gut and Liver, Vol. 9, No. 4, July 2015, pp. 540-546

Intraductal Ultrasonography without Radiocontrast Cholangiogram in Patients with Extrahepatic Biliary Disease

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Background/Aims: Intraductal ultrasonography (IDUS) has been performed as an adjunct to endoscopic retrograde cholangiography (ERC) during radiocontrast cholangiography (RC). Radiation exposure during RC poses a health risk to both patients and examiners. We evaluated the feasibility of IDUS without RC in various extrahepatic biliary diseases. **Methods:** IDUS was performed with the insertion of an IDUS probe from the papilla of Vater to the confluent portion of the common hepatic duct without fluoroscopy. The technical success rate and procedure-related complications were evaluated retrospectively. **Results:** Wire-guided IDUS without RC was performed in 105 patients. The mean age was 66.5 years, and 50 (47.6%) were male. The IDUS diagnoses included choledocholithiasis (73, 69.5%), benign biliary stricture (11, 10.5%), choledocholithiasis with biliary pancreatitis (9, 8.6%), bile duct cancer (5, 4.8%), pancreatic cancer (1, 0.9%), and others (6, 5.7%). After IDUS, 66 (62.8%) underwent stone removal, 19 (18.1%) underwent biliary drainage, and 7 (6.6%) underwent brush cytology and biopsy. No significant complications such as perforation or severe pancreatitis occurred. **Conclusions:** IDUS without RC was a feasible and safe approach in patients with various extrahepatic biliary diseases. We anticipate a potentially important role of IDUS in various ERC procedures because it lacks the hazards of RC. **(Gut Liver 2015;9:540-546)**

Key Words: Intraductal ultrasonography; Radiocontrast cholangiography; Endoscopic retrograde cholangiography

INTRODUCTION

Standard endoscopic retrograde cholangiography (ERC) is performed under radiographic visualization of the biliary tree after the bile duct is filled with iodinated contrast agent. During radiocontrast cholangiogram, the radiation used poses a health threat to both examiners and patients. Radiocontrast cholangiogram is a hardship in special clinical situations such as the examination of pregnant women and critically ill patients in an intensive care unit.[1-4] The contrast medium used for the cholangiogram could also provoke a hypersensitivity reaction in sensitized patients.[5] Therefore, endoscopic retrograde ultrasonic cholangiogram without radiocontrast cholangiogram, minimizing the radiation exposure, would be desirable for both examiners and patients. However, it is still controversial which imaging method would be suitable for the replacement of fluoroscopy for ERC.

Intraductal ultrasonography (IDUS) allows real-time cross-sectional imaging of the biliary tract, and is one of the most useful diagnostic tools for various extrahepatic biliary diseases.[6-8] IDUS has been performed as an adjunct to ERC under radiocontrast cholangiogram. If it is practicable to perform IDUS without radiocontrast cholangiogram, it could be used as a fundamental imaging method, replacing the radiocontrast cholangiogram for ERC. The aim of this study was to evaluate the feasibility and safety of implementing IDUS without radiocontrast cholangiogram in patients with various extrahepatic biliary diseases.

MATERIALS AND METHODS

1. Patients

The clinical records of 105 patients who underwent IDUS without radiocontrast cholangiogram from November 2013 to December 2013 at Chonnam National University Hospital were

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Received on May 27, 2014. Revised on September 18, 2014. Accepted on October 6, 2014. Published online May 13, 2015
pISSN 1976-2283 eISSN 2005-1212 http://dx.doi.org/10.5009/gnl14200

analyzed. The inclusion criteria were choledocholithiasis, biliary pancreatitis, indeterminate biliary stricture, and periampullary tumor. This retrospective study was performed in accordance with the guidelines of the Institutional Review Board (IRB number: CNUH-2014-011).

2. Methods

All procedures were performed using a standard side-viewing duodenoscope (JF-260F or TJF-160F; Olympus, Tokyo, Japan) in an endoscopy room without radiocontrast cholangiogram. After cannulation with a 0.035-inch-diameter guidewire (Jagwire; Boston Scientific, Natick, MA, USA), the "bile aspiration" technique or checking of the guidewire direction on fluoroscopy were used to indicate bile duct cannulation.[3] Some patients in who there was difficultly accessing the bile duct underwent infundibulotomy or a precutting method on the ampulla using a needle knife (Microknife XL; Boston Scientific). A 2.0-mm-diameter IDUS probe with a frequency of 20-MHz (UM-G20-29R; Olympus) was advanced over a guidewire into the bile duct. IDUS scanning was performed while inserting the IDUS probe from the papilla of Vater (POV) to the confluent portion of the common bile duct (CBD) over the guidewire. Stones, biliary stricture, and in-growing or out-growing masses were revealed by IDUS (Fig. 1).

3. Definitions

Technical success was defined as successful placement of the IDUS probe into the confluent portion of the common hepatic duct. The procedure time required for IDUS was defined as the duration from when the duodenoscope visualized the POV to when the IDUS probe was extracted from the papillary opening. Procedural-related complications were defined as any kind of newly developed complications after the IDUS procedure, such as bleeding, perforation, pancreatitis, and abdominal pain. Post-IDUS pancreatitis was defined as the presence of abdominal pain with post-IDUS elevation of amylase. Post-IDUS amylase elevation was defined as the elevation of serum amylase by more than 3 times the normal range and basal level.[9]

4. Statistical analysis

All statistical analyses were performed using SPSS software version 20.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were described using frequencies and percentages. Continuous variables were summarized using the mean and standard deviation. Comparisons between groups were performed using the Mann-Whitney U-test, the Wilcoxon U-test, and the chi-square

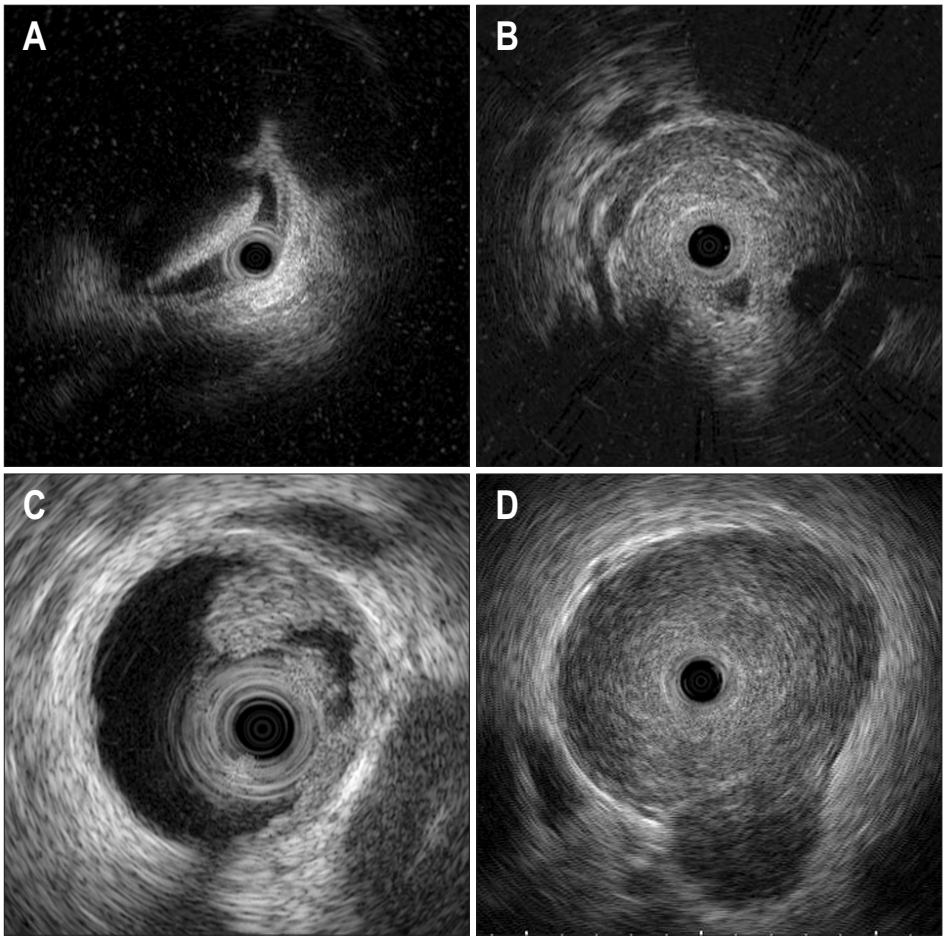

Fig. 1. Intraductal ultrasonographic findings. (A) Stone in the common bile duct. (B) Benign stricture. (C) Cholangiocarcinoma *in situ*. (D) Fungating cholangiocarcinoma.

test, as appropriate. p-values <0.05 were considered significant.

RESULTS

1. Patient characteristics

A total of 105 patients underwent wire-guided IDUS without radiocontrast cholangiogram (Table 1). The mean age of the patients was 66.5 years, and 50 of the patients (47.6%) were men. Two of the patients had a history of anaphylaxis to the iodine-based contrast agent. Forty-one patients (39.0%) were clinically diagnosed with recurrent choledocholithiasis and had a history of previous endoscopic sphincterotomy (EST). Periampullary diverticulum (PAD) was noted in 31 patients (29.5%), with the following subgroups: Type I, ampullary orifice in the diverticulum (8, 7.6%); Type II, ampullary orifice in the margin of the diverticulum (9, 8.6%); and Type III, ampullary orifice beyond the diverticulum (14, 13.3%).

2. IDUS findings and outcomes

Wire-guided IDUS without radiocontrast cholangiogram was successfully performed in all patients (Table 2). Because of the difficulty with biliary cannulation, the precut technique was carried out in 13 (12.4%) patients (nine patients, infundibulotomy; four patients, precut sphincterotomy). The mean diameter of CBD was 13.1±4.5 mm, and the mean size of stones detected on IDUS was 6.4±3.5 mm. Pneumobilia was detected in 24 cases (22.9%). The mean procedure time required for IDUS was 8.2±4.0 minutes. Fluoroscopy was used in 10 cases (9.5%) for selective biliary cannulation, nine cases (8.5%) for stone capture with a basket, four cases (3.8%) for endoscopic retrograde biliary drainage (ERBD) insertion, and eight cases (7.6%) for the clearance of remnant stones. The total mean fluoroscopy time was 86 seconds (range, 8 to 273 seconds). The diagnoses made through IDUS were choledocholithiasis (73, 69.5%), biliary stricture (11, 10.5%), choledocholithiasis for biliary pancreatitis (9, 8.6%), bile duct cancer (5, 4.8%), pancreatic cancer (1, 0.9%), and others (6, 5.7%; two bile duct dilatations due to extrinsic compression, four ampullary masses or enlargement for ampullary adenoma or carcinoma). Magnetic resonance cholangiopancreatography was performed in nine patients (9/105, 8.6%) before ERC for evaluation of suspicious malignancy. Computed tomography coronal reconstruction was very useful for longitudinal imaging of the biliary tree like in magnetic resonance cholangiopancreatography or ERC, and was performed before ERC in 89 patients (84.8%). After IDUS, 66 of the patients (66/105, 62.8%) underwent stone removal, 19 (19/105, 18.1%) underwent biliary drainage, and 7 (7/105, 6.6%) underwent brush cytology and

Table 1. Characteristics of Patients Undergoing Wire-Guided Intraductal Ultrasonography without Radiocontrast Cholangiogram

Characteristic	Value
No. of patients	105
Age, yr	66.5 (27–90)
Gender, male:female	50:55
Anaphylaxis history to contrast agent	2
Periampullary diverticulum	31 (29.5)
Type I	8 (7.6)
Type II	9 (8.6)
Type III	14 (13.3)
Papilla state before cannulation	
Intact papilla	64 (61.0)
Previous sphincterotomy	41 (39.0)

Data are presented as number (%) or mean (range).

Table 2. Outcomes Following Wire-Guided Intraductal Ultrasonography without Radiocontrast Cholangiogram

Outcome	Value
Diagnoses of IDUS	
Choledocholithiasis	73 (69.5)
Biliary stricture	11 (10.5)
Choledocholithiasis for biliary pancreatitis	9 (8.6)
Cholangiocarcinoma	5 (4.8)
Pancreatic cancer	1 (0.9)
Others*	6 (5.7)
Diameter of CBD, mm	13.1±4.5
Size of bile duct stone, mm	6.4±3.5
Pneumobilia on IDUS	24 (22.9)
Procedure time, min	8.2±4.0
Fluoroscopic time, sec	86.1±82.3
Technical success	105 (100.0)
Sphincterotomy for cannulation	
None	92 (87.6)
Infundibulotomy	9 (8.6)
Precut	4 (3.8)
Subsquent procedure	
Stone removal	66 (62.8)
Biliary drainage	18 (17.1)
Brush cytology and biopsy	7 (6.6)
None	14 (13.3)
ERC during following procedure	17 (16.2)
Procedure-related complication	
Bleeding	0
Perforation	0
Acute pancreatitis	1 (1.0)
Abdominal pain	0

Data are presented as number (%) or mean±SD.
IDUS, intraductal ultrasonography; CBD, common bile duct; ERC, endoscopic retrograde cholangiography.
*Others: dilatation due to extrinsic compression, ampullary mass or enlargement for ampullary adenoma or carcinoma.

biopsy. The procedural-related complications observed included mild post-IDUS pancreatitis in one patient (1.0%), following ERBD. No significant complications such as bleeding, perforation, or severe pancreatitis occurred.

3. Comparisons of clinical characteristics and outcomes of IDUS along with papillary conditions before cannulation

The clinical characteristics of the group with previous EST and the group with intact papilla are summarized in Table 3. No significant differences were seen between the two groups in terms of age, gender, IDUS diagnoses, presence of PAD, and therapeutic ERC procedures used. The technical success rate of IDUS was 100% in both groups. The previous EST group did not require the precut technique or EST extension for selective biliary cannulation, as opposed to the intact papilla group (0% vs 20.3%, p<0.001). However, pneumobilia was significantly higher in the previous EST group (20/41, 48.8%) than in the intact papilla group (4/64, 6.3%). In addition, pneumobilia occurred often in patients with recurrent cholelithiasis (17/35, 48.6%). However, diagnostic disturbance of pneumobilia was very rare (1/24, 4.1%). The procedure time required for IDUS was significantly shorter in the previous EST group than in the intact papilla group (7.0±3.6 minutes vs 8.9±4.0 minutes, p=0.018). No significant differences in IDUS-associated complications were observed between the groups.

Table 3. Comparisons with Papillary Condition before Cannulation

	Previous EST (n=41)	Intact papilla (n=64)	p-value
Age, mean (range), yr	68.9 (27–87)	65.0 (27–90)	0.153
Gender, male:female	18:23	32:32	0.529
Diagnoses of IDUS			0.121
Choledocholithiasis	32 (78.1)	41 (64.1)	
Biliary stricture	4 (9.8)	7 (10.9)	
Choledocholithiasis for biliary pancreatitis	3 (7.3)	6 (9.4)	
Cholangiocarcinoma	1 (2.4)	4 (6.3)	
Pancreatic cancer	0	1 (1.6)	
Others	1 (2.4)	5 (8.0)	
MRCP before ERCP	1 (2.4)	8 (12.5)	0.158
Periampullary diverticulum	14 (34.1)	17 (26.6)	0.080
Type I	5 (12.2)	3 (4.7)	
Type II	6 (14.6)	3 (4.7)	
Type III	3 (7.3)	11 (17.2)	
Pneumobilia on IDUS	20 (48.8)	4 (6.3)	<0.001
Technical success	41 (100)	64 (100)	1.000
Precut technique	0	13 (20.3)	<0.001
Following ERC procedure			0.108
Stone removal	32 (78.0)	35 (54.7)	
Biliary drainage	4 (9.8)	12 (18.7)	
Brush cytology and biopsy	2 (4.9)	6 (9.4)	
None	3 (7.3)	11 (17.2)	
Procedure time, min	7.0±3.6	8.9±4.0	0.018
Fluoroscopy time, sec	110.2±79.8	76.9±84.5	0.459
Complications			1.000
Mild pancreatitis	0	1 (1.6)	
Bleeding	0	0	
Perforation	0	0	
Death	0	0	

Data are presented as number (%) or mean±SD.
EST, endoscopic sphincterotomy; IDUS, intraductal ultrasonography; MRCP, magnetic resonance cholangiopancreatography; ERCP, endoscopic retrograde cholangiopancreatography; ERC, endoscopic retrograde cholangiography.

DISCUSSION

In previous studies, IDUS was performed with radiocontrast cholangiogram as an adjunct to ERC.[7,10,11] In the present study, it was performed without radiocontrast cholangiogram in a relatively large number of patients with various extrahepatic biliary diseases. After IDUS, 91 of the patients (86.6%) underwent CBD stone removal, biliary drainage procedure, or brush cytology with biopsy. No significant complications such as bleeding, perforation, or severe pancreatitis were observed.

Radiation exposure during radiocontrast cholangiogram is harmful to both patients and examiners. Previous reports have demonstrated a linear relationship between the radiation dose and fluoroscopy time.[11] In particular, radiation exposure during radiocontrast cholangiogram carries a potential risk to fetuses. The necessity for a nonradiation ERC technique during pregnancy has been presented in a number of studies.[1-3] Many examiners are also exposed to the radiation from fluoroscopy. Although the use of lead protectors minimizes the risk of radiation exposure and the dose of a single ERC procedure is insufficient to cause harm, the accumulated dose of radiation should not be ignored in large-volume interventional endoscopists.[12,13] In addition, the radiocontrast media can be harmful to patients with adverse reactions to iodine-containing contrast media. Iodine contrast media are detectable in the bloodstream after ERC, and systemic adverse reactions have been described.[5] Radiocontrast cholangiogram is also not able to be performed on critically ill intensive care unit patients in need of ERC, because moving the patients to a critical-care setting with facilities for fluoroscopy presents a formidable obstacle.[14] Therefore, performing ERC without radiocontrast cholangiogram is desirable for both examiners and patients.

It is controversial as to which imaging method could be used as a suitable replacement for the radiocontrast cholangiogram in ERC. It would be possible to use different imaging methods. First, contrast-enhanced ultrasonography (US) could replace the fluoroscopy for ERC. A case of contrast-enhanced US-guided ERC was reported for the treatment of CBD stones during pregnancy.[15] However, the procedure requires further evaluation because experience with it has been limited. Second, endoscopic ultrasonography (EUS) could replace the radiocontrast cholangiogram for ERC. Artifon *et al*.[16] reported EUS-guided sphincterotomy followed by stone extraction under US guidance to be feasible as a single-step intervention. Additional studies are required to validate their preliminary results. It is conceivable that a dual endoscope allowing both EUS imaging and therapeutic intervention will be developed to make the diagnosis and treatment of CBD stones with the same endoscope in the same setting feasible.[16] Third, direct retrograde cholangioscopy (DRC) could also be used to replace the radiocontrast cholangiogram for ERC. DRC has been increasingly applied, thereby allowing high resolution video imaging and optical enhancement techniques.[17] It was a useful complementary investigation to ERC in a selected group of patients with biliary disease.[18] Future design developments of DRC will enable direct and easy access into the bile duct without any accessories in the near future.[19] Fourth, IDUS could be applied to replace the radiocontrast cholangiogram for ERC. A recent study revealed IDUS to be a more accurate diagnostic modality for extrahepatic biliary diseases than any other examination.[7] It has many benefits for ERC. First, it can be performed quickly and conveniently in most patients.[6,20] Second, no special accessories or agents without a guidewire are needed for IDUS. However, contrast-enhanced US requires a contrast agent, DRC requires an anchoring balloon catheter for scope replacement, and EUS needs a linear array echoendoscope. Third, therapeutic ERC can be performed as a single-step intervention under IDUS guidance.

In the present study, IDUS was performed easily without radiocontrast cholangiogram patients who had previously undergone EST. Neither the precut technique nor EST extension was needed in the previous EST group, causing the time required for IDUS to be significantly shorter than in the intact papilla group. In accordance with the IDUS findings, therapeutic ERC was performed as a single-step intervention. In addition, no significant IDUS-associated complications were observed in the previous EST group. These results suggest that IDUS could be considered as a first step diagnostic imaging modality for the evaluation of extrahepatic biliary disease in patients who have previously undergone EST.

Therapeutic ERC with IDUS was performed successfully without radiocontrast cholangiogram in most patients, except for 18 (18/105, 17.1%). These cases included therapeutic procedures involving difficult stone capture (nine patients), confirmation of ERBD location (four patients), difficult biliary recannulation after EST (one patient), and confirmation of stone clearance (four patients). Obviously, stone capture is easy with the assistance of radiocontrast cholangiogram. However, blind capture was possible in this study after checking the positions and sizes of stones with IDUS. If the blind capture method was unsuccessful 2 or 3 times, the location of the stone was then confirmed by fluoroscopy and captured with a fluoroscopy-aided basket without the use of radiocontrast cholangiogram. Radiocontrast cholangiogram was needed only in nine of the patients (9/66, 13.6%) while removing CBD stones. The successful completion of the therapeutic procedure was confirmed with IDUS or radiocontrast cholangiogram. Stone clearance was confirmed by IDUS with basket sweeping 2 times (57 patients) or by radiocontrast cholangiogram (24 patients), and ERBD location was confirmed by bile aspiration and IDUS for guidewire positioning (eight patients) or radiocontrast cholangiogram (two patients) through all sessions (Fig. 2).

Pneumobilia was an important obstacle in the IDUS-assisted ERC procedure without radiocontrast cholangiogram. Pneumobilia was noted in 20 patients (20/41, 48.8%) who previously

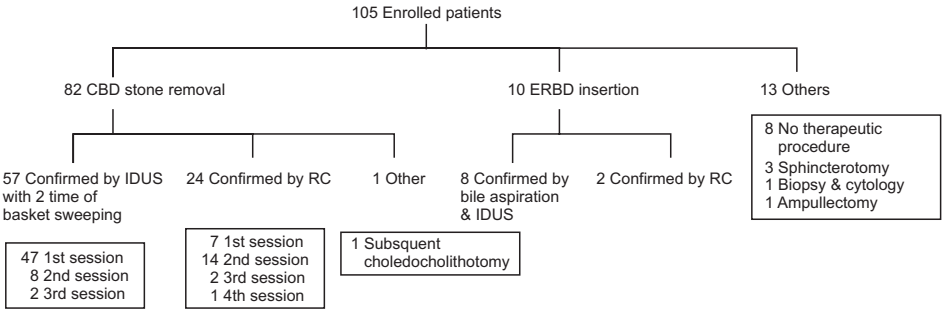

Fig. 2. Flow of therapeutic procedures through all endoscopic retrograde cholangiopancreatography sessions.
CBD, common bile duct; ERBD, endoscopic retrograde biliary drainage; IDUS, intraductal ultrasonography; RC, radiocontrast cholangiogram.

underwent EST. However, it was not difficult to differentiate between stones and air bubbles with saline flushing. First, in spite of obvious pneumobilia, small amounts of air did not disturb detection of the CBD stones. Air bubbles tended to be located on the upper biliary tree in the longitudinal section. While the position of the air bubbles was in the upper part, and stone position was lower part mostly on cross-sectional IDUS image. Second, echo finding of air reveals reverberation of fan-shaped and step ladder pattern, but that of stone shows hyper-acoustic crescent-like edge in probe side and posterior acoustic shadow in opposite side. Ang *et al*.[21] revealed that water infusion method following IDUS after stone removal was more effective than radiocontrast cholangiogram and that stone and air bubble on cross section image of IDUS could be easily discriminated .

Recent studies have reported that mild pancreatitis occurs in 2% to 5% of patients as an IDUS-related complication.[7] Those authors performed IDUS with a radiocontrast cholangiogram during or after ERC.[22,23] In the present study, IDUS was performed without the radiocontrast cholangiogram. The only IDUS-associated complication was mild pancreatitis in one patient after ERBD (1.0%). Filling the CBD with iodine-contrast media for conventional IDUS might increase the risk of pancreatitis. However, IDUS without the radiocontrast cholangiogram reduces the risk of pancreatitis by minimizing contrast injection into the pancreatic duct and by limiting papillary trauma.[24] In addition, no significant complications related to inserting the IDUS probe were observed in the present study. These findings suggest that IDUS without the radiocontrast cholangiogram might be a safe procedure.

The present study had some limitations. First, the study was a nonrandomized retrospective single center study without a comparison group. Second, IDUS without fluoroscopy was performed by a single endoscopist (C.H.P.).

In conclusion, IDUS without the radiocontrast cholangiogram was feasible and safe in patients with various extrahepatic biliary diseases. We anticipate a potentially important role of IDUS in the field of various endoscopic retrograde cholangiopancreatography procedures without hazards of radiocontrast cholangiogram.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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