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Detection and localization of post-operative and post-traumatic bile leak: hybrid SPECT-CT with 99mTc-Mebrofenin

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Abstract

Purpose: To evaluate the role of single photon emission tomography-computed tomography (SPECT-CT) with 99mTc-*N*-(3-bromo-2,4,6-trimethylacetanilide) iminodiacetic acid (Mebrofenin) for detection and localisation of post-operative and post-traumatic bile leak and compare the same with planar hepatobiliary scintigraphy (HBS).
Methods: Data of 32 consecutive patients (Age—35.7 ± !15.3 years; Female—53.2%) who underwent 99mTc-Mebrofenin planar HBS and SPECT-CT for suspected bile leak was prospectively collected and retrospectively analyzed. Twenty-six patients were post-operative and six had history of abdominal trauma. Planar HBS and SPECT-CT images were evaluated by two experienced nuclear medicine physicians. Sensitivity, specificity and predictive values, were calculated for planar HBS and SPECT-CT. Final diagnosis was established based on a combination of re-operative findings, follow up imaging and clinical follow up (1–4 week).For evaluation of observer confidence a third observer used a scoring scale of 1–5, with 1 being definite bile leak and 5 being no leak. Receiver operating characteristic (ROC) curves were drawn and the areas under the curves were compared.
Results: The sensitivity, specificity and accuracy of SPECT-CT were 88.8%, 100% and 96.8% while that of planar HBS were 77.7%, 60.8% and 65.6%, respectively. Planar HBS showed very low diagnostic accuracy compared to SPECT-CT (65.6% vs. 96.8%; $P = 0.021$). It was false positive in nine patients. SPECT-CT also correctly localised the site of bile leak in eight of nine patients. On ROC analysis the observer confidence for SPECT-CT was significantly better than that for planar scintigraphy ($P = 0.045$).
Conclusion: 99mTc-Mebrofenin hybrid SPECT-CT is highly sensitive and specific for detection and localisation of post-operative and post-traumatic bile leak. It is more accurate than planar HBS and should be routinely done in such patients.

Key words: Bile leak—99mTc-Mebrofenin—Hepatobiliary scintigraphy—SPECT-CT

Hepatobiliary surgery and trauma to hepatobiliary tract are the two major causes of bile leak. Bile leak is not an infrequent complication after hepatobiliary surgery and is a significant source of post-operative morbidity and mortality [1]. In fact bile leak should be considered in any patient after cholecystectomy who has unexplained abdominal pain after operation [2]. A post-operative bile leak is reported to be more prevalent in patients undergoing laparoscopic procedures compared with those who have open surgery [3]. The principal causes of bile leakage are intraoperative biliary injury, insufficiency of the bilioenteric anastomosis, and bile oozing from the transected liver surface [4]. Blunt abdominal trauma with bile duct injuries is also commonly reported. Patients with bile duct injuries usually present with right upper quadrant pain, jaundice, low-grade fever or increasing abdominal girth in the immediate post-operative period. The more common sites of bile leak are the gallbladder bed, subhepatic space, in a bilioma, right paracolic gutter or diffusely in the peritoneum [5]. Bile leakage is associated with an

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increase of sepsis and liver failure, greater hospital stay, and a greater post-operative mortality rate [6]. Therefore, prompt diagnosis and early management is warranted.

The precise site of bile leak is often difficult to detect with non-invasive techniques. To assess biliary leakage, several imaging methods are available such as ultrasound (USG), computed tomography (CT), endoscopic retrograde cholangiopancreatography (ERCP), percutaneous transhepatic cholangiography (PTC) and hepatobiliary scintigraphy (HBS). A perihepatic or intra-abdominal fluid collection combined with a history of post-operative abdominal pain is more likely to be a bile leak. Post-operative collections are typically hypoechoic on USG or hypoattenuating on CT. The main value of these is diagnostic and therapeutic-guided aspiration of a collection. Their main limitation is their limited ability to differentiate between a bile leak and other fluid collections like hematoma or seroma [2].

99mTc-*N*-(3-bromo-2,4,6-trimethylacetanilide) iminodiacetic acid (Mebrofenin) is a hepatobiliary imaging radiopharmaceutical with structural similarity to bilirubin. In the liver, in the space of Disse, 99mTc-Mebrofenin dissociates from the proteins and enters the hepatocyte by a mechanism similar to that of serum bilirubin. 99mTc-Mebrofenin traverses through the hepatocyte unmetabolized and enters the bile canaliculi. Normally, the tracer enters the gut usually within 10–20 min after intravenous administration. Among the non invasive procedures available, 99mTc-Mebrofenin HBS is considered a sensitive method of detecting bile leaks [7, 8]. However, the specificity of planar HBS is limited because of stasis of radiotracer at anastomotic site and overlap with tracer in liver or gut. Moreover, because of limited anatomical detail provided by planar HBS accurate localisation of site of bile leak is difficult. This is especially important because of shift in management strategy from more aggressive to minimally invasive [9].

Single photon emission tomography-computed tomography (SPECT-CT) is an imaging modality that provides anatomic and functional information [10, 11]. It is routinely employed in oncology [12], cardiology [13] and parathyroid imaging [14]. However, its role in hepatobiliary imaging hasn't been explored. Apart from few case reports [1, 11] there is no systemic study assessing the role of SPECT-CT for detection of bile leak. Therefore, the aim of this study was to evaluate the role of SPECT-CT with 99mTc-Mebrofenin for detection and localisation of post-operative and post-traumatic bile leak and compare the same with planar HBS.

Material and methods

This was retrospective analysis of prospectively collected data. Between February 2010 and April 2011 total 35 consecutive patients underwent planar HBS with 99mTc-Mebrofenin followed by SPECT-CT, for known or suspected bile leak. All of these patients were post-operative or had history of trauma. Conventional imaging [Ultrasonography (USG)/Computed tomography (CT)] was suspicious or positive for bile leak in all of these patients. Data of two patients was excluded because of significant misregistration between SPECT and CT. One patient was excluded because of lack of reference standard. Data of remaining 32 patients was used for final analysis.

99mTc-Mebrofenin preparation

99mTc-Mebrofenin was synthesised from commercially available kit (Kit for 99mTc-Mebrofenin injection, code: TCK-39, BRIT, Mumbai, India). The kit contains 25 mg of Mebrofenin and 0.2 mg of stannous chloride dihydrate in freeze-dried form. 2–3 ml of 99mTc sodium pertechnetate ($Na^{99m}TcO_4$), in 0.9% sodium chloride solution containing the required activity of 99mTc was added to the vial and equal volume of air withdrawn from the vial. After proper mixing, the vial was placed in boiling water bath for 5 min. Appropriate quality control tests were performed and the solution was ready for injection.

Radiotracer injection and planar scintigraphy

The patients were intravenously injected 80–200 MBq (2–5.5 mCi) of 99mTechnitium-Mebrofenin for HBS. Planar images were acquired either on a dual-head gamma camera (Symbia E, Seimens medical solutions, Illinois, USA) or hybrid SPECT-CT dual-head gamma camera (Symbia T6, Seimens medical solutions, Illinois, USA). Planar images were acquired using parallel-hole, low-energy, high-resolution collimators, with the patient in the supine position. Images were acquired on the 140-keV photopeak with a 20% symmetrical window and matrix size was 256×256. Anterior static images of the abdomen were acquired for 300 K counts at 5-min interval for 30 min, and then at 15 min interval for 1.5 h after injection. Delayed images were acquired at 4 and 24 h (if required). Right lateral and right and left anterior oblique images were also acquired when required. The abdominal drain when present was clamped throughout the 4-h study duration in all patients.

SPECT acquisition

SPECT was done only for the volume defined based on patient's clinical set-up. All studies were acquired using a hybrid SPECT-CT dual-head gamma camera (Symbia T6, Seimens medical solutions, Illinois, USA). Emission data were acquired by use of parallel-hole, low-energy, high-resolution collimators, with the patient in the supine position. The acquisition orbits were body contour orbits over 360° arcs, with the use of 60 stops each of 6°. For 60 stops, emission data were acquired for 30 s per

Table 1. Summary of patient characteristics and findings of planar HBS and SPECT-CT

No.	Age	Sex	Primary diagnosis	Surgery	Conventional imaging (CT/USG)	Planar HBS	SPECT-CT	Localisation on SPECT-CT	Final diagnosis
1	41	F	Biliary stricture	Hepatojejunostomy	Pneumobilia	Positive	Negative	–	No bile leak
2	54	F	Biliary stricture	Cholangiojejunostomy	Collection	Negative	Negative	–	No bile leak
3	22	M	Trauma	None	Segment 8 laceration with collection	Positive	Positive	Rt lobe, from laceration site	Bile leak
4	20	M	Trauma	None	Rt lobe laceration with perihepatic collection	Positive	Positive	Rt subdiaphragmatic	Bile leak
5	6	F	Choledocal cyst	Cholangiojejunostomy	Collection	Positive	Negative	–	No bile leak
6	62	M	HCC	Hepatectomy	Perihepatic collection	Positive	Negative	–	No bile leak
7	20	M	Gall stones	Laparoscopic cholecystectomy	Collection	Negative	Negative	–	No bile leak
8	35	F	Carcinoma gall bladder	Radical extended cholecystectomy	Collection	Positive	Positive	Rt sub hepatic	Bile leak
9	65	M	Periampullary carcinoma	Whipple's procedure	Collection	Negative	Negative	–	No bile leak
10	45	M	CBD stone	Hepaticojejunostomy	Collection	Negative	Negative	–	Bile leak
11	27	F	Choledocal cyst IV A	Cyst excision with hepatojejunostomy	Collection	Negative	Negative	–	No bile leak
12	45	M	Trauma	None	Collection	Positive	Negative	–	No bile leak
13	45	F	Post-cholecystectomy biliary fistula	Hepatojejunostomy	Collection	Negative	Negative	–	No bile leak
14	54	M	Chronic calcific pancreatitis	Whipple's procedure	Peri-anastomotic collection	Positive	Negative	–	No bile leak
15	48	M	Hydatid cyst with gall stones	Laparoscopic deroofing of the cyst with cholecystectomy	Collection	Negative	Positive	–	Bile leak
16	40	M	Gall stone	Laparoscopic cholecystectomy	Collection	Positive	Positive	Periportal; likely cystic duct stump	Bile leak
17	30	F	Choledocal cyst	Cyst excision	Collection	Positive	Negative	–	No bile leak
18	45	F	Biliary fistula	Roux-en-y hepatojejunostomy	Perianastomotic collection	Negative	Negative	–	No bile leak
19	3	F	Choledochal cyst	Cyst excision	Collection	Positive	Negative	–	No bile leak
20	45	F	Gall stone	Laparoscopic cholecystectomy with CBD injury	Perihepatic collection	Positive	Positive	Right perihepatic	Bile leak
21	35	F	Carcinoma gall bladder	Laparoscopic cholecystectomy with biliary peritonitis, drainage done	Abdominal collection	Positive	Positive	Loculated peritoneal collection	Bile leak
22	36	F	Post-open cholecystectomy biliary fistula	Hepatojejunostomy	Collection	Negative	Negative	–	No bile leak
23	45	M	Trauma	None	Perihepatic collection	Negative	Negative	–	No bile leak
24	35	M	ERCP injury	Exploratory laparotomy	Collection	Negative	Negative	–	No bile leak
25	35	F	Biliary stricture	Hepatojejunostomy	Collection	Negative	Negative	–	No bile leak
26	35	M	Gangrenous cholecystitis	Cholecystectomy	Collection	Positive	Negative	–	No bile leak
27	30	F	Gall stones	Laparoscopic cholecystectomy	Collection	Negative	Negative	–	No bile leak
28	40	M	Gall stones	Laparoscopic cholecystectomy	Collection	Positive	Negative	–	No bile leak
29	50	F	Carcinoma gall bladder	Open extended cholecystectomy	Perihepatic collection	Negative	Negative	–	No bile leak
30	22	M	Trauma	None	Liver laceration Grade 4 with perihepatic collection	Negative	Negative	–	No bile leak
31	28	F	Trauma	None	Liver laceration with perihepatic collection	Positive	Positive	Rt subcapsular	Bile leak
32	2	F	Choledochal cyst	Cyst excision	Collection	Negative	Negative	–	No bile leak

Table 2. Comparison of 99mTc-Mebrofenin SPECT-CT and planar scintigraphy for detection of bile leak (results with 95% confidence interval)

Parameter	SPECT-CT	Planar scintigraphy
Sensitivity	88.8% (51.7–98.1)	77.7% (40–96.5)
Specificity	100% (85–100)	60.8% (38.5–80.2)
PPV	100% (62.9–100)	43.7% (19.8–70)
NPV	95.8% (78.8–99.3)	87.5% (61.6–98)
Accuracy	96.8%	65.6%

PPV positive predictive value, *NPV* negative predictive value

Fig. 1. A 35-year-old female, case of carcinoma of the ▶ gallbladder. She underwent laparoscopic cholecystectomy. She continued to drain large amount of bile through the abdominal drain and developed abdominal pain 4th day post-op. 99mTc-Mebrofenin hepatobiliary scintigraphy was done to look for bile leak. Planar HBS images **A**, **B** show progressive accumulation of tracer in abdomen (*arrow*). Tracer accumulation in the pattern of stomach (*arrowhead*) was also noted suspicious for bile leak in the lesser sac. CT images **C**, **D** display collection in the lesser sac and peritoneal cavity. SPECT-CT images confirm the diagnosis of biliary collection in the lesser sac (**E**, *arrowhead*) and loculated collection in the peritoneal cavity (**F**, *arrow*). The findings were confirmed at surgery.

stop. The image acquisition matrix was 128 × 128, and the pixel size was 4.8 mm. Images were acquired on the 140-keV photopeak with a 20% symmetrical window.

CT acquisition

The SPECT was followed by CT examination with acquisition parameters of 130 Kv, 100 mAs, pitch-1, 512 × 512 matrix using standard filters. No oral or intravenous contrast was used. The CT images were reconstructed with reconstruction kernel B30s. The attenuation maps were created from the input CT image by converting the CT numbers to attenuation numbers, using look-up table, based on both CT effective energy spectrum (kV_{eff}) and the emission isotope energy.

Processing of SPECT images and coregistration

All studies were uniformly processed with commercially available E.soft (Seimens medical solutions, Knoxville, TN, USA) software on a Syngo nuclear medicine workstation (Seimens medical solutions, Illinois, USA). SPECT emission image data was processed by use of ordered-subsets expectation maximization reconstruction (OSEM-2D) software with two iterations and eight subsets. A gaussian filter with full width at half maximum (FWHM) of 7.0 was applied. Attenuation correction was applied to these images using the CT-based attenuation maps. Scatter correction was also applied. The corrected SPECT images were again reconstructed with Flash-3D software with eight subsets and eight iterations. Subsequently, tomographic slices were generated and displayed transaxial, coronal and sagittal slices. SPECT emission images were coregistered and fused with the transmission CT images using object versus target matrix method. Fused emission and transmission images were visually inspected for correctness of coregistration. Studies with significant misregistration were excluded from further analysis.

Image analysis

Planar and SPECT-CT images were evaluated by two experienced nuclear medicine physicians in consensus. They were blinded to all clinical information and findings of conventional imaging. Planar and SPECT-CT images were evaluated in separate sessions 1 week apart to minimise recall bias. The images were displayed in a random order. Any abnormal radiotracer activity in the abdomen, outside the biliary or gastrointestinal tracts, which increased with time, was taken as a bile leak. If any leak was found, attempt was made to localize the site of leak. In case of any discrepancy regarding findings of planar and SPECT-CT images a consensus was reached after intelligent discussion. Planar scintigraphy and SPECT-CT were compared in terms of the accuracy on per patient basis.

ROC curve analysis

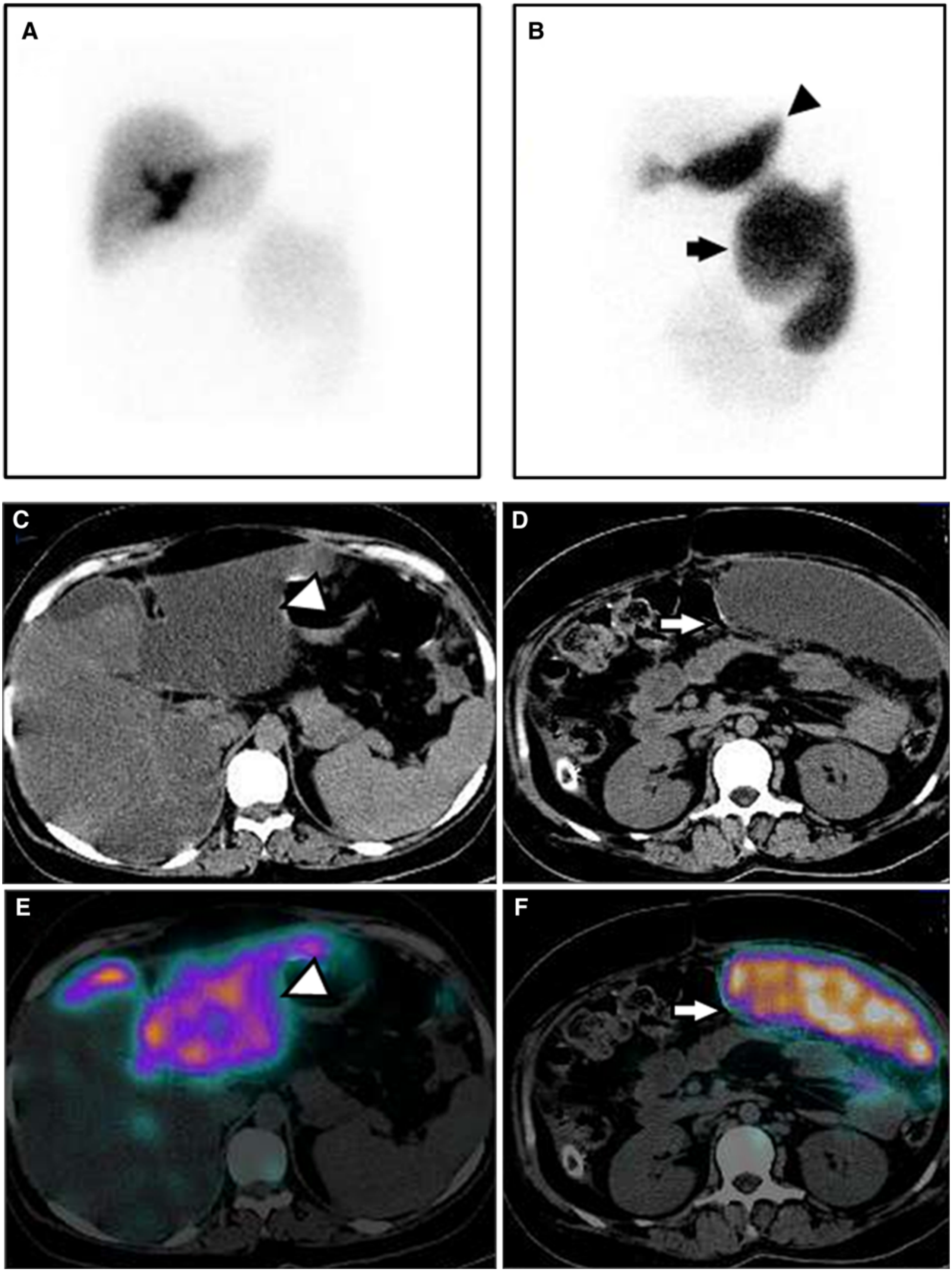
For the purpose of constructing receiver operating characteristic (ROC)curves, a third nuclear medicine physician used a scoring scale of 1–5, in which 1 is definite bile leak, 2 is probable bile leak, 3 is equivocal, 4 is probably no bile leak and 5 is definitely no bile leak. As previously described, ROC curves were created by shifting the diagnostic criterion level for positives and negatives over the entire range of scores from 1 to 5 [15]. Sensitivity and 1 minus specificity for each diagnostic criterion level were plotted against each other.

Reference standard

Final diagnosis was established based on a combination of re-operative findings, follow up imaging (USG/CT/ Planar HBS/SPECT-CT) and clinical follow up (1–4 week).

Statistical analysis

Continuous data were expressed as mean ± SD and categorical data was expressed as number and percentage. Sensitivity, specificity and predictive values, were separately calculated for planar HBS and SPECT-CT. McNemar test was used to compare the accuracy of planar HBS and SPECT-CT. For quantitative interpre-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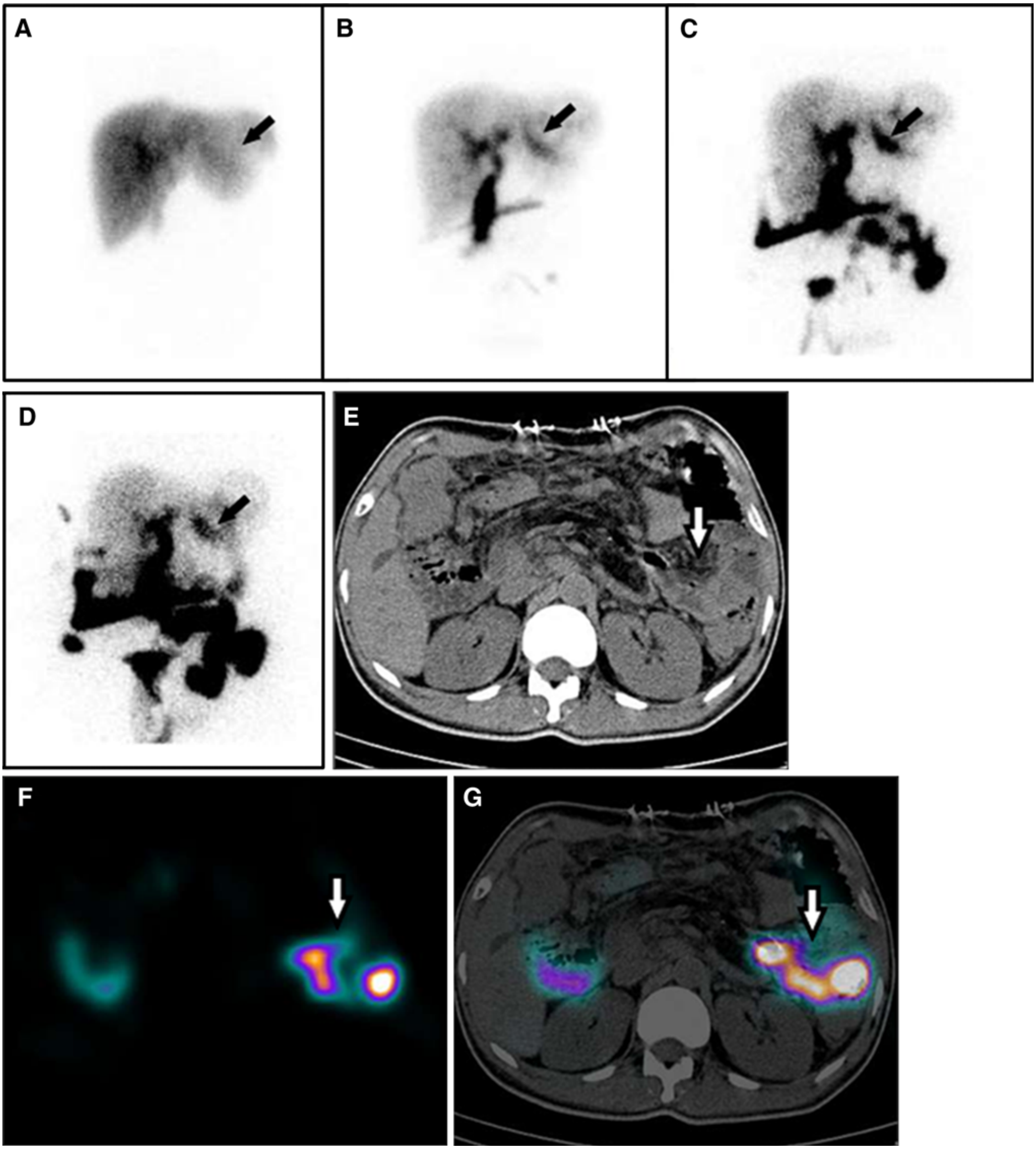

Fig. 2. A 54-year-old male, with severe calcific pancreatitis who underwent Whipple's procedure. Ultrasound showed some peri-anastomotic collection (*not shown*). 99mTc-Mebrofenin hepatobiliary scintigraphy was done to rule out bile leak. Planar HBS images (**A**–**D**) show focal area of increasing tracer accumulation in the region of the left lobe of liver (*arrow*), suspicious for bile leak. CT (**E**), SPECT (**F**) and SPECT-CT (**G**) images localize the focal uptake in the gut (*arrow*). The patient improved without any treatment and follow up imaging after 2 days was normal. Planar HBS was false positive in this case.

tation of the ROC curves, the area under the curve (AUC) was calculated and compared. A larger area indicates improved observer confidence. All statistical analysis was done using SPSS 11.5 (SPSS Inc, Illinois, USA) and STATA (STATA Corporation, College Station, Texas, USA).

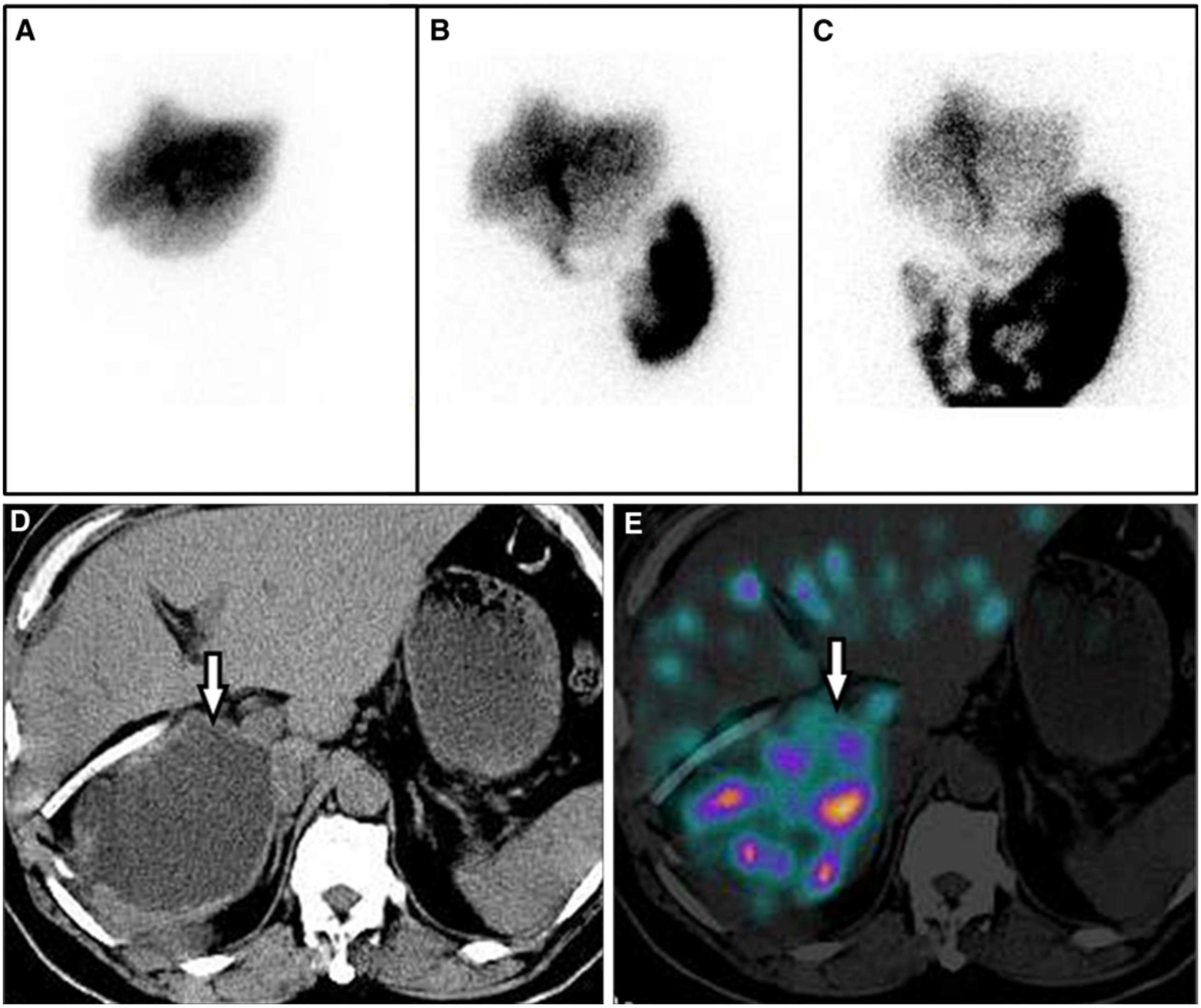

Fig. 3. A 48-year-old male, with hydatid cyst of the liver along with cholelithiasis, underwent laparoscopic cholecystectomy with deroofing of the hydatid cyst. The patient developed abdominal pain 2 days after surgery. 99mTc-Mebrofenin hepatobiliary scintigraphy was done to see if the patient had developed any cystobiliary communication. Planar HBS (**A**–**C**) images are essentially normal with patent biliary-enteric pathway and no scan evidence of cystobiliary communication. CT image (**D**) demonstrates fluid in the cyst cavity (*arrow*), but is unable to characterize its nature. SPECT-CT images (**E**) display accumulation of radiotracer in the cyst (*arrow*), confirming the presence of cystobiliary communication. The diagnosis was confirmed at surgery. Planar HBS was false negative in this case.

Results

Patient characteristics

Total 32 patients were finally evaluated. Patient demographic, finding of planar HBS, SPECT-CT and final diagnosis are detailed in Table 1. The mean patient age was 35.7 ± 15.3 years (Range: 2–65). Seventeen (53.2%) patients were female. Three (9.4%) patients had deranged liver function. The etiology of suspected leak was surgery in 26 (81.2%) and trauma in 6 (18.8%) patients. Based on the reference standard 9 (28.1%) patients had bile leak and no bile leak was observed in 23 patients (71.9%). The final diagnosis was established by re-operation in seven patients, follow up imaging in 22 patients (USG/CT-17; planar HBS/SPECT-CT-5) and clinical follow up in three patients.

99mTc-Mebrofenin SPECT-CT

The sensitivity, specificity, PPV, NPV and accuracy of SPECT-CT for detecting bile leak is detailed in Table 2. SPECT-CT showed only one false negative result and no false positive result. SPECT-CT correctly localised the site of leak in eight patients (Fig. 1). In one patient it was unable to localise the site of leak. In this patient minimal leak was detected from the anastomosis site at surgical exploration.

Comparison of SPECT-CT with planar HBS

The sensitivity, specificity, PPV, NPV and accuracy of planar HBS for detecting bile leak is detailed in Table 2. Compared to no false positive finding on SPECT-CT, planar scintigraphy showed nine false positive results (Fig. 2). In all of them cause of false positivity on planar HBS was radiotracer activity in the gut. Planar HBS was false negative in two patients. One patient, who was false negative on SPECT-CT, was also false negative on planar HBS. In the other patient, there was collection in the marsupialized hydatid cyst due to cysto-biliary communication, which was missed on planar HBS (Fig. 3). SPECT-CT was true positive in this case. McNemar analysis showed that SPECT-CT was significantly better than planar scintigraphy ($P = 0.021$). On ROC analysis (Table 3; Fig. 4) the observer confidence for SPECT-CT was significantly better than that for planar scintigraphy for detection of bile leak ($P = 0.045$). There was only one equivocal finding on SPECT-CT as compared to 6 equivocal findings on planar HBS.

Discussion

Hybrid SPECT-CT is gaining widespread popularity because of its ability to provide both structural and functional information. This dual modality imaging technique lends itself to a wide variety of useful diagnostic applications whose clinical impact is in most instances already well-established, while the evidence is growing for newer applications [16]. To our knowledge the present study is the first one to systemically evaluate the role of 99mTc-Mebrofenin SPECT-CT for detection and localisation of post-operative and post-traumatic bile leak.

We found that 99mTc-Mebrofenin SPECT-CT have very high sensitivity (88.8%: CI-51.7 to 98.1) for detection of bile leak. There was only one false negative result, in a patient who had undergone laparoscopic choledocho-jejunostomy for benign biliary stricture. In this patient SPECT-CT failed to show any bile leak. The patient underwent surgical re-exploration the next day because of exacerbation of symptoms. Minimal anastomotic site leak was seen at surgery. This might have been missed on SPECT-CT because of the presence on minimal leak. Moreover, the liver function in this patient was also

Table 3. Results of receiver operating characteristic (ROC) analysis

Modality	AUC	SE	95% CI
Planar scintigraphy	0.846	0.0702	0.675–0.948
SPECT-CT	0.987	0.0179	0.867–0.988

AUC area under the curve, *SE* standard error, *CI* confidence interval

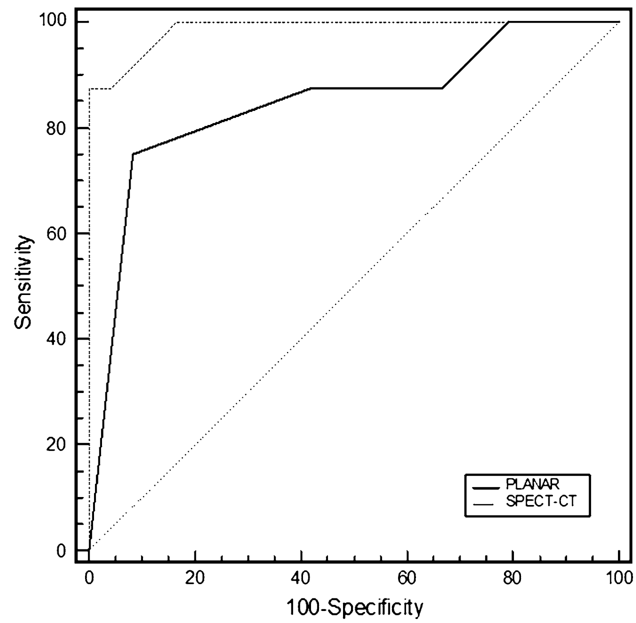

Fig. 4. Receiver operating characteristics (ROC) curves for planar HBS and SPECT-CT, demonstrating the diagnostic confidence of the observer. The area under the curve (AUC) was significantly larger for SPECT-CT compared to planar HBS ($P = 0.045$).

deranged. Perhaps more importantly we found that the specificity and PPV of 99mTc-Mebrofenin SPECT-CT were 100%. Thus a patient with positive SPECT-CT should be considered to have bile leak and will require further management. In our study population all 32 patients were known or suspected to have bile leak on CT or USG. However, only nine patients had actual leak. Thus 99mTc-Mebrofenin SPECT-CT overcomes the lack of specificity of CT alone or USG, where it is difficult to characterise a post-operative or post-traumatic collection as bile leak [2]. Apart from detecting bile leak, SPECT-CT was also able to localise the site of leak in all eight patients. This is vital given the current change in approach regarding management of bile leak from more invasive to minimally invasive [9, 17]. In addition, SPECT-CT demonstrates the functional capacity of liver as well as patency of biliary-enteric anastomosis, if any, in the same setting.

Planar HBS showed lower sensitivity than that of SPECT-CT (77.7% vs. 88.8%). One patient, who was false negative on SPECT-CT, was also negative on planar HBS. Its specificity, however, was very low as compared to SPECT-CT (60.8% vs. 100%). There were nine false cases on planar HBS. In all of these patients SPECT-CT was able to correctly identify the site of false positivity. SPECT-CT was significantly better than planar HBS ($P = 0.021$). Apart from its low specificity, another major disadvantage of planar HBS is its low anatomical resolution. Although it gives a crude idea regarding the site of bile leak, accurate localisation is lacking. SPECT-CT appears to be very advantageous in this regard. We also performed a ROC analysis to compare the observers confidence for planar HBS and SPECT-CT. SPECT-CT was significantly better than planar HBS ($P = 0.045$) and showed a larger AUC (0.987 vs. 0.846). The number of equivocal findings was much less on SPECT-CT compared to planar HBS (1 vs. 6).

This study had few limitations. First, this was retrospective analysis of prospectively collected data of a small sample size. A large prospective study might better address this issue. Second, we didn't perform dosimetric analysis of the additional radiation exposure due to CT. An abdominal CT generally gives a radiation exposure of 5–10 mSv. This will be in addition to the radiation exposure due to HBS (0.024 mSv/MBq; approximately 3–5 mSV) [18]. Finally, no oral or intravenous contrast agent was used in this study. Hence, the positive (due to detection of minimal leak) or negative (due to attenuation over correction) impact of use of contrast in such scenario cannot be commented upon. However, given high sensitivity and specificity of non contrast SPECT-CT alone, it is unlikely that contrast enhancement will add much.

Conclusion

Hybrid SPECT-CT with 99mTc-Mebrofenin is highly sensitive and specific modality for detection and localisation of post-operative and post-traumatic bile leak. It is more accurate than planar HBS in this setting and should be routinely employed in such patients.

Conflict of interest. The authors declare that there is no conflict of interest. No funding received from any organization for this study.

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