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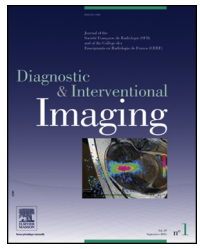

ORIGINAL ARTICLE / *Technical*

Biliary complications of arterial chemoembolization of hepatocellular carcinoma

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KEYWORDS
Hepatocellular carcinoma (HCC);
Transarterial chemoembolization (TACE);
Biliary complications;
Biloma

Abstract
Rationale and background: Transarterial chemoembolization (TACE) is the most frequently used palliative therapy for unresectable hepatocellular carcinoma (HCC). It is a safe and effective procedure with few major and minor complications. Rarely, biliary complications are also encountered following TACE. The goal of our study was to investigate the incidence and the presentation of biliary complications following TACE in patients with HCC.
Material and methods: In this retrospective study, data of patients with HCC who underwent TACE between June 2002 to December 2014 were obtained from the records. Their detailed information about the procedure of TACE, diagnosis of biliary complications and subsequent management details were reviewed.
Result: One hundred and sixty-eight patients with HCC underwent 305 procedures of TACE. Of these, biliary complications of various severities developed in 6 (3.6%) patients leading to an incidence of 1.9% (6/305). Minimal intrahepatic biliary dilatation (IHBD) occurred in three, biliary stricture in one and intrahepatic biloma in two patients. Supportive management was undertaken for IHBD patients while percutaneous aspiration and naso-biliary drainage was performed for the infected bilomas.
Conclusion: Biliary complications following TACE are infrequent. Diagnosis should be suspected clinically and confirmed with imaging. Treatment depends on the severity. Enforcing specific measures can minimize its frequency.

Abbreviations: TACE, transarterial chemoembolization; HCC, hepatocellular carcinoma; AFP, alpha-fetoprotein; MDCT, multi-detector computed tomography; MRI, magnetic resonance imaging; EASL, European Association for the Study of Liver; BCLC, Barcelona clinic of liver cancer; IHBD, intrahepatic biliary dilatation; mRECIST, modified response evaluation criteria in solid tumors.

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Introduction

Transarterial chemoembolization (TACE) is a well-established therapy for unresectable hepatocellular carcinoma (HCC) worldwide [1]. It is a minimally invasive, effective and safe technique with minor and few major complications. Post-embolization syndrome is the most frequently occurring complication, which is self-limiting and managed conservatively. Rarely, biliary complications of various severities may occur following TACE, which may be fatal if unrecognized [2—4]. It is thus important for the interventional radiologist to be aware of these life threatening adverse events following a procedure that is widely used. Once biliary damage is diagnosed, the repeat procedure of TACE is preferably avoided. The goal of our study was to investigate the incidence and the presentation of biliary complications following TACE in patients with HCC.

Materials and methods

This retrospective work is a part of the ongoing study on TACE at our centre, which has been approved by the Institute ethics committee. Between June 2002 to December 2014, patients of unresectable HCC, who underwent TACE, were studied. Their data pertaining to the clinical, demographic profile, biochemical parameters, imaging findings and treatment details with follow-up were retrieved from the case records. The laboratory tests included complete hemogram, liver function tests, serum alpha-fetoprotein (AFP) and viral markers for hepatitis B and C. Findings of ultrasonography, multi-detector computed tomography (MDCT) and magnetic resonance imaging (MRI) were analyzed. The diagnosis of HCC was based on the European Association for the Study of Liver (EASL) criteria [5]. Staging with treatment allocation of TACE was done on the basis of Barcelona Clinic of Liver cancer (BCLC) staging [6].

TACE was performed on HCC patients with BCLC-B/C stage, having underlying Child's A or B cirrhosis, normal main portal vein, tumor burden involvement less than 50% of the liver and patients willing for therapy and follow-up. Few patients of BCLC-A stage unsuitable for curative therapy were also included. Patients of HCC having extrahepatic disease; coagulopathy, intrahepatic biliary dilatation (IHBR) and associated co-morbid illness like coronary artery disease, congestive heart failure, chronic renal failure, etc. were excluded.

TACE was undertaken through the transfemoral route. Initially, a superior mesenteric artery and celiac axis arteriogram were obtained using 5F RC1 (reverse curve, Cook, Bloomington, IN, USA) or C1 (Celiac, Cook, Bloomington, IN, USA) diagnostic catheter and 0.035-inch j-tip terumo guidewire (Terumo; Terumo Corporation, Tokyo, Japan). Whereas, for reaching the distal tumor bed, we used either 4F slip catheter (VERT slip-cathBeacon Tip Catheter; Cook, Bloomington, IN, USA) after exchanging with 5F catheter (Cook, Bloomington, IN, USA) or 2.7F micro-catheter (Progreat 2.7 F micro-catheter, Terumo; Terumo Corporation, Tokyo, Japan) as co-axial system through 5F catheter. These diagnostic 4F or 5 F catheters were partially occlusive. We used two chemotherapeutic drugs (doxorubicin 50 milligram [mg] and cisplatin 100 mg) till 2008, and later changed over to a single drug (epirubicin 60 mg). The chemotherapeutic drug emulsion was prepared with 10 ml of iodinated/nonionic contrast media and 20 ml of iodized oil (Lipiodol, Guerbet, Roissy-Charles de Gaulle, France) and this emulsion was delivered by placing the catheter tip as close as possible to the tumor. In masses less than 5 centimeters in diameter, we used the chemotherapeutic emulsion prepared with a smaller amount of Lipiodol® (10 ml). Following the injection of the drug emulsion, the same feeding artery was embolized using gel foam slurry made from shaved gelfoam mixed with contrast material. No aggressive embolization was done. The gelfoam slurry was injected till there was sluggish blood flow seen as to and fro movement of contrast column in the feeding artery on real time fluoroscopy. Intra-arterial lidocaine (10 mg) (xylocard 2%, AstraZeneca, Bangalore, India) was given between 10-ml aliquots of chemoembolization material to minimize the pain occurring post-embolization. Gradually, over a period of time, the micro-catheter co-axial system became available at our centre and then this was used to access narrow tortuous feeders.

Follow-up post-procedure was carried out at 1, 3, 6 and 12 months. Clinical, laboratory and imaging evaluation was performed at each visit. Patients reported earlier if any untoward symptom appeared and they were then subjected to an abdominal ultrasonography/MDCT or MRI depending upon the indication. The findings of the treated mass and complications if any were recorded. MRI was undertaken in inconclusive situations or to delineate the site of narrowing if any focal intrahepatic biliary dilatation was observed on ultrasonography/MDCT.

Diagnosis of intrahepatic bilomas was made on ultrasonography when a well-defined cystic mass was detected in the liver that was anechoic (when sterile), or had echogenic contents (if infected or had hemorrhage within). On MDCT, biloma was seen as a well-defined hypodense lesion (attenuation less than 20 Hounsfield Unit) communicating with the IHBR [7] (Fig. 1A—D). On MRI, biliary channels were seen as hyperintense branching structures while a biloma was seen as a hyperintense collection with or without communication with the bile ducts (Fig. 2A and B). We used heavily T2-weighted MR sequence, Half-Fourier Acquisition Single-Shot Turbo Spin-Echo (HASTE) and T2-weighted fat-saturated sequence for evaluating the biliary radicals. Narrowing of the bile duct was suggestive of stricture. Tumor response was classified according to the modified Response Evaluation Criteria in Solid Tumors (mRECIST) criteria [8].

In patients who developed biliary complications, the predisposing factors were studied and analyzed. Statistical analyses was done using Stata 12.1, Stata Corp, 4905 Lakeway Drive, College Station, Texas 77845 USA.

Results

Table 1 illustrates the demographic and biochemical profile of the 168 HCC patients enrolled. These were 146 men and 22 women, with a mean age of 52 ± 12.6 (SD) years, [range: 16—75 years], Child-Pugh status A 122/167 (72.6%), Child's B 46/167 (27.4%) and had HCC of BCLC stage A, B and C. The masses were single in 73/168 (43.4%) and multiple in 95/168 (56.6%) patients. The mean

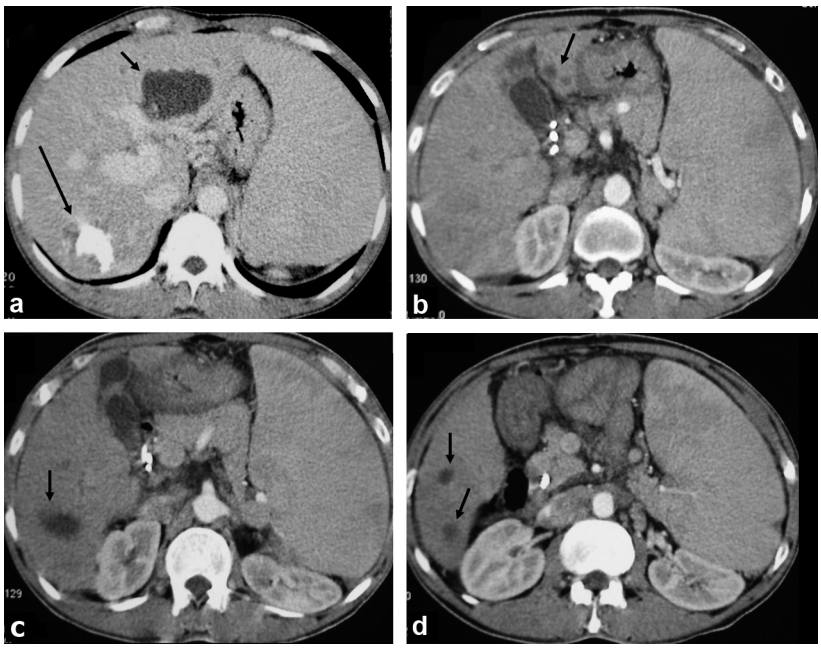

Figure 1. A 48-year-old man with HCC treated with TACE (patient 1). CT image in the axial plane obtained after intravenous administration of iodinated contrast material shows mass lesion in segment 6 of the liver (a), which is partially covered by Lipiodol® (long arrow). In addition, there are multiple hypodense lesions of varying sizes seen in segment 2, 3 and segment 6 (a—d) suggestive of bilomas (small arrows).

tumor size was 6.1 ± 4.5 cm (range: 2—24 cm). Serum alpha-fetoprotein level (AFP) was less than 20 ng/ml in 59/167 (35.3%) patients. These 168 patients underwent a total of 305 procedures of TACE. Biliary complications of variable severity developed in 6/168 (3.6%) patients leading to a complication rate of 1.9% (6/305 procedures). Mild IHBD developed (Fig. 3) in 4 (one had right hepatic duct stricture, 3 bilateral biliary dilatation), while the remaining 2 patients had severe form of complications manifesting as intrahepatic bilomas (Figs. 1, 2 and 4). Their clinical, demographic profile, procedural details, complications and management are illustrated in details in Table 2.

Intrahepatic bilomas were diagnosed in one patient at 8 months following TACE. He developed features of cholangitis like, fever and abdominal pain. A percutaneous drainage was done using 8 F pigtail catheter (Cook, Bloomington, IN, USA) along with a course of broad spectrum antibiotics. Thereafter, stenting of common bile duct was performed by placing 7—10 F plastic biliary stent (Cook, Bloomington, IN, USA) across the biliary channel to drain the biloma. Subsequent to the percutaneous drainage, a bilo-cutaneous fistula developed for which naso-biliary drainage was resorted to. Despite all measures, sepsis developed and the patient died.

In the second patient, biloma developed 5 months post-procedure. A percutaneous pigtail insertion under antibiotic coverage was given. He too developed a bilo-cutaneous fistula; however, his bile culture remained sterile throughout. Patient survived for 6 months, during this period his hepatic tumor progressed leading to poor liver function, hepatic failure and subsequent death.

Of the 4 patients with mild IHBR dilatation (at 6/7 months post TACE), one had focal IHBD due to right hepatic duct stricture and the remaining 3 had bilateral biliary dilatation.

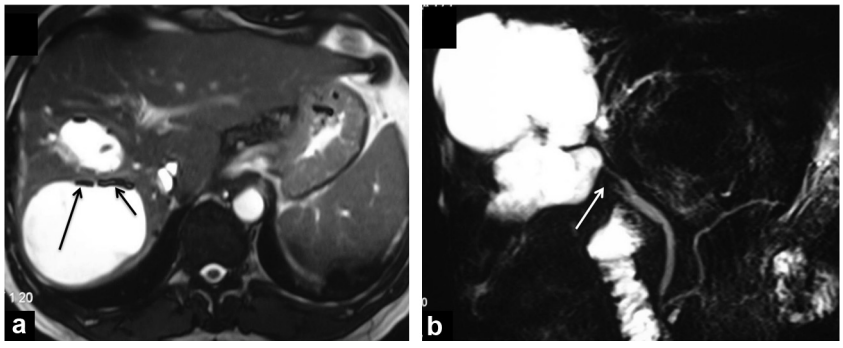

Figure 2. A 54-year-old man with HCC treated with TACE (patient 2). Axial T2-weighted MR image (a) and MRCP image in coronal (4000/970 ms) plane (b) show multiloculated large hyperintense lesion with nondependent dark foci inside suggestive of air foci (black arrow) seen in segment 7 with possible communication with right-sided biliary duct (white arrow).

Table 1 Demographic and clinical profile of study population.

Variable	$n = 168$ (%)
Age (years)	
Mean ± SD, range	51.6 ± 12.6, 16—75 years
Male	146 (86.9)
Female	22 (13.1)
Child's status	$n = 167$
A	121 (72.4)
B	46 (27.6)
BCLC stage	
A	49 (29.2)
B	92 (54.7)
C (portal vein patent)	27 (16.1)
Etiology of cirrhosis	$n = 167$
HBV	103 (61.7)
HCV	28 (16.7)
HBV + HCV	6 (3.6)
Cryptogenic	8 (4.8)
Alcoholic	9 (5.4)
HVOTO	5 (3.0)
NASH	8 (4.8)
AFP (ng/dL)	$n = 167$
> 20 ng	109 (64.7)
Jaundice	10 (5.9)
Weight loss	52 (30.9)
Pain	76 (45.3)
Abdominal mass	14 (8.3)
Abdominal distension	34 (20.2)
Fever	17 (10.1)
Gastrointestinal bleeding	13 (7.7)
Anorexia	52 (30.9)
Oesophageal varices	121 (74.7)
Cirrhosis	139 (82.7)
Tumor size (Mean ± SD)	6.1 ± 4.5 cm
Range	1 to 24 cm
Number of masses	
Single	72 (43.0)
Multiple	96 (57.0)
Splenic enlargement	93 (55.4)
Abdominal collateral vessels	76 (45.2)
Ascites	43 (25.6)
Portal hypertension	99 (58.9)

SD: standard deviation; BCLC: Barcelona Clinic Liver Cancer; AFP: alpha-fetoprotein; ng/dL: nanogram/milliliter; cm: centimeters; HBV: hepatitis B virus; HCV: hepatitis C virus; HVOTO: hepatic venous outflow tract obstruction; NASH: non-alcoholic steato-hepatitis.

Decision to defer further repeat session of TACE was taken and instead, patient was kept under close monitoring by imaging and biochemical investigations. Only one patient developed features of cholangitis on blood tests but since he had no clinical symptoms, conservative approach was taken. On follow-up, there was no progression of the biliary dilatation whereas the tumor progressed leading to progressive hepatic failure and death. The mean survival period of these six patients was 12.2 ± 11.8 months (range: 4—36 months).

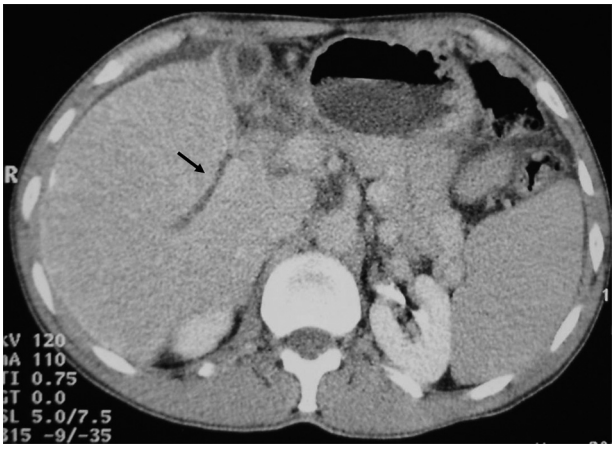

Figure 3. A 35-year-old man with HCC treated with TACE (patient 3). CT image in the axial plane obtained after intravenous administration of iodinated contrast material shows linear hypodensity suggestive of mild dilatation of the right hepatic duct (arrow).

Discussion

TACE is an established palliative therapy for unresectable HCC. It consists of intra-arterial injection of the emulsion of chemotherapeutic drugs and Lipiodol® into the tumor bed through the selective cannulation of the feeding artery of the hepatic tumor. This is followed by embolization of the feeding hepatic arterial supply by temporary embolizing agent (gelfoam slurry) to produce tumor hypoxia and resultant tumor necrosis. The chemotherapeutic drugs produce cytotoxic effects, while Lipiodol® acts as a carrier and helps in prolonged intratumoral retention of these chemotherapeutic drugs and enhance their anti-tumoral effects. TACE can be performed with other embolic agents as well and recently, drug eluting BEADS have been proposed [9].

TACE is a safe and an effective procedure with very minimal incidence of complications (4.4%) and risk of

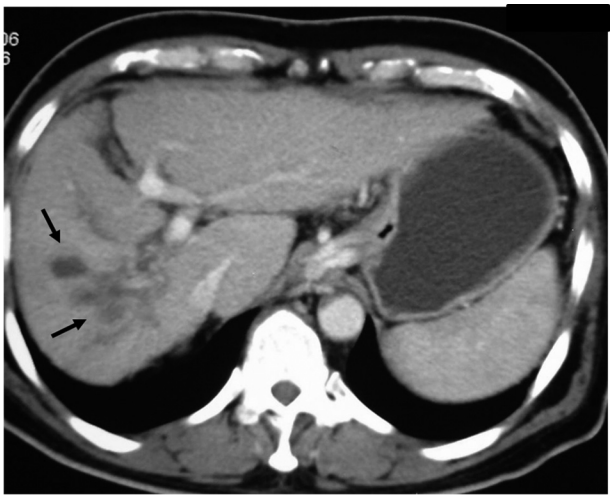

Figure 4. A 45-year-old man with HCC treated with TACE (patient 4). CT images in the axial plane obtained after intravenous administration of iodinated contrast material shows hypodense periductal collections in the right lobe (arrows) suggestive of intrahepatic bilomas.

Table 2 Demographic profile and details of TACE in patients with biliary complications ($n = 6$).

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Age (years)	48	54	35	45	33	63
Gender	M	M	M	M	M	M
Child's status	A	A	B	A	A	A
BCLC stage	A	A	B	B	A	B
AFP (ng/ml)	25.1	6.06	17737	963	65.73	163
Number of focal lesions	Single	Multiple	Single	Multiple	Multiple	Multiple
Size (cm) of largest focal lesion	3.5	2.9	10	2.6	4.5	5.6
Interval between TACE procedures (months)	6	NA	11.5	NA	NA	2.4
Bilary complications						
Time of onset (months)	5.6	3.6	1.8	10.2	6.7	9
Severity	Intrahepatic biloma	Mild IHBRD biloma	Mild IHBRD	Mild IHBRD	Mild IHBRD	Mild IHBRD
Treatment given	Percutaneous pigtail f/b naso-biliary drainage f/b CBD stenting	Percutaneous pigtail f/b CBD stenting f/b naso-biliary drainage	Follow-up with imaging. Further TACE deferred	Broad spectrum antibiotics	Follow-up with imaging. Further TACE deferred	Follow-up with imaging. Further TACE deferred
Treatment response (clinical)	Initially responded- bile c/s- sterile, Re-infection: low grade fever and *E. coli* in bile c/s	Sepsis	No cholangitis	Biochemical cholangitis	No cholangitis	No cholangitis
Final outcome						
Imaging	Bilo-cutaneous fistula, Residual and fresh abscess	Bilo-cutaneous fistula	Mild IHBRD persisted	No progression	No progression	Mild IHBRD 10-12-2007; RHD stricture
Tumor status	CR Recurrence	CR	PR, lung metastasis	CR	CR, FL	PR, FL
Survival (months)	6.6 (died)	8.5 (died)	4 (died)	41.2 (alive)	8 (died)	9.4 (died)
Cause of death	Progressive HCC, HF and sepsis	Uncontrolled sepsis	HF	Then, lost to FU	HF	HF

TACE: transarterial chemoembolization; AFP: alpha-fetoprotein; cm: centimeters; SD: standard deviation; NA: not applicable; IHBRD: intrahepatic bile duct; FU: follow-up; f/b: followed by; c/s: culture sensitivity; CBD: common bile duct; RHD: right hepatic duct; b/w: between; HCC: hepatocellular carcinoma; HF: hepatic failure; CR: complete response; PR: partial response; FL: fresh lesion.

mortality (0.5—2.6%) [3,10]. Minor complications are common and post-embolization syndrome is seen in about 80 to 90% of the cases. This syndrome is self-limiting and consists of abdominal pain, nausea, vomiting, leucocytosis and raised liver enzymes. Rarely, major complications have been reported which include acute hepatic failure, liver infarction or abscess, intrahepatic biloma, intrahepatic aneurysms, cholecystitis, splenic infarction, gastrointestinal mucosal lesions, pulmonary embolism or infarction, tumor rupture, variceal bleeding, and iatrogenic dissection or perforation of the celiac artery [2,3,11].

Biliary complications are uncommon (0.87%), difficult to treat and may prove fatal despite aggressive management [2—4]. Biliary ducts have a characteristic vascular supply. The normal hepatic parenchyma receives dual blood supply (75—80% from portal vein and 20—25% from hepatic artery) whereas the biliary ducts have exclusive blood supply from the hepatic artery branches, which form the peribiliary capillary plexus. During TACE, the hepatic artery branch supplying the hepatic tumor is embolized [12—14]. Occasionally, as a consequence of hepatic artery embolization, inadvertent occlusion of the biliary vascular supply may occur causing bile duct necrosis, biliary stasis and formation of intrahepatic biloma and biliary stricture [15,16]. This predisposes to cholangitis and its sequelae.

No definitive treatment guidelines have been advocated for management of these biliary complications. Sakamoto et al. [4] kept patients with sterile biloma on follow and managed conservatively. Percutaneous drainage or surgery was performed along with broad spectrum antibiotics if the patient had signs of sepsis [4]. Left untreated, these may lead to grave consequences of liver abscess formation and uncontrolled sepsis. We too followed the same approach.

We did not repeat TACE in any of our patients when IHBD was detected. These complications were managed by either supportive therapy or by interventional treatment for control of sepsis depending upon the severity. During follow-up, in 4 patients of mild IHBD, there was no progression of the biliary dilatation but the tumor progressed in 3 patients leading to progressive hepatic failure and death. In the two bilomas patients, the cause of death was sepsis and hepatic failure (Table 2).

Several predisposing factors have been postulated for biliary duct injury following TACE. This includes tumor size smaller than 5 cm, bile duct dilatation prior to TACE, proximal intra-arterial injection site for drug delivery to the tumor, interval between repeat TACE procedure less than 3 months and injection of Lipiodol® suspension along with the anticancer drugs [4,17,18]. The particle size of embolization material used has also been attributed to the cause of bile duct necrosis [13,19].

We looked into the possible factors responsible for these complications in our 6 patients (Table 2). None of our patients had biliary dilatation prior to the treatment of TACE. We found that the mean tumor size of the index mass in our patients was 4.8 ± 2.7 cm (range: 2.6—10 cm) and strikingly, 4 of them had tumors less than 5 cm in diameter. The mean interval between repeat sessions of TACE was 5.9 ± 2.8 months and in only one patient a repeat session was undertaken at 2.4 months. Superselective cannulation of the HA could not be done in 2 patients as the catheter could not be negotiated further due to narrow caliber and tortuosity, failing which the delivery of the chemotherapeutic drug mixture was done from a proximal site. We performed TACE in all these 6 patients by using 4 or 5 F catheter. These diagnostic 4 or 5 F catheters were partially occlusive. During early part of our study we did not have access to micro-catheter system because of non-availability. As regards the embolization material, gel foam slurry was routinely used for all our patients undergoing TACE. The number of patients developing biliary complications were very small (just 6), hence the statistical significance of the risk factors could not be ascertained.

A variable incidence rate of biliary complications (0.87% to 3.3%) has been reported in various studies [3] and the incidence rate in our study was 1.9% (6/305 procedures). All our cases of biliary damage occurred during the earlier phase (2006—2008) of the study. With further refinements of the procedure over period of time, better expertise, availability of micro-catheters for superselective cannulation, implementation of a stringent inclusion criteria, mandatory interval of more than 3 months for repeat TACE, no such complications were encountered in the subsequent procedures thereafter.

In conclusion, biliary complications following TACE are rare but grave. It is important for the interventional Radiologist to be aware of this entity and enforce specific preventive measures as far as possible. Diagnosis should be suspected clinically and confirmed on imaging. Treatment depends on the severity. Factors like tumor size, status of biliary channels and interval between repeat procedures should be kept into consideration. Once biliary damage is detected following TACE, a repeat procedure should be avoided to prevent further bile duct necrosis. Early detection of intrahepatic biloma is mandatory to prevent further fatal consequences. Conservative management with imaging follow-up has been shown to be enough in cases of sterile bilomas whereas prompt intervention is mandatory in infected bilomas. Surgery may be considered in non-responders.

Part of the work was presented as an e-poster in the UKRC conference, held on 9—11 June 2014.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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