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Assessment of the optimal temporal window for intravenous CT cholangiography

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Abstract The optimal temporal window of intravenous (IV) computed tomography (CT) cholangiography was prospectively determined. Fifteen volunteers (eight women, seven men; mean age, 38 years) underwent dynamic CT cholangiography. Two unenhanced images were acquired at the porta hepatis. Starting 5 min after initiation of IV contrast infusion (20 ml iodipamide meglumine 52%), 15 pairs of images at 5-min intervals were obtained. Attenuation of the extrahepatic bile duct (EBD) and the liver parenchyma was measured. Two readers graded visualization of the higher-order biliary branches. The first biliary opacification in the EBD occurred between 15 and 25 min (mean, 22.3 min±3.2) after initiation of the contrast agent. Biliary attenuation plateaued between the 35- and the 75-min time points. Maximum hepatic parenchymal enhancement was 18.5 HU±2.7. Twelve subjects demonstrated poor or non-visualization of higher-order biliary branches; three showed good or excellent visualization. Body weight and both biliary attenuation and visualization of the higher-order biliary branches correlated significantly ($P<0.05$). For peak enhancement of the biliary tree, CT cholangiography should be performed no earlier than 35 min after initiation of IV infusion. For a fixed contrast dose, superior visualization of the biliary system is achieved in subjects with lower body weight.

Keywords Intravenous CT cholangiography · Biliary system · Optimal temporal enhancement window

Introduction

Endoscopic retrograde cholangiography (ERC) remains the gold standard for evaluation of the biliary tract. While this technique offers high spatial resolution and a potential for image-guided therapy, ERC is expensive, invasive, and its reported complication rate ranges up to 5.0% [1, 2]. In response to these drawbacks, safer and more cost-effective alternatives to ERC to evaluate the biliary tree have been developed and utilized.

Magnetic resonance cholangiography (MRC) is one popular noninvasive alternative that has been shown to be both sensitive and specific for various hepatobiliary pathologies [3–7]. Limitations of MRC include high cost and unsuitability for patients with claustrophobia or cardiac pacemakers, or for those with multiple, artifact-producing metallic clips at the level of the porta hepatis. An alternative to MRC for noninvasive imaging of the hepatobiliary system is computed tomography (CT) cholangiography. With this technique the biliary system is opacified with either an intravenous (IV) or an oral cholangiographic contrast agent [8–11]. In the past 5 years, IV cholangiographic contrast agents (e.g., iodipamide meglumine, meglumine iotroxate) have been shown to be preferable to oral agents for CT cholangiography owing to their superior ability to opacify the biliary tree [9, 12–16]. Though numerous studies investigated the bile iodine concentration in animals and the biliary opacification in patients on serial radiographs after the administration of IV cholangiographic contrast agent in the 1970s and

1980s [17–22], to the best of our knowledge, to date, there have been no reports in the scientific literature on the optimal temporal window of CT cholangiography with IV cholangiographic contrast agents. Knowledge on the biliary enhancement profile may help optimize the technique and, in the future, provide a basis for other applications of CT cholangiography, for example, the evaluation of biliary kinetics.

Thus, the purpose of our study was to determine the timing of maximal biliary enhancement of CT cholangiography with IV cholangiographic contrast agents.

Materials and methods

Subjects

This HIPAA-compliant, prospective study was approved by the Institutional Review Board, and written informed consent was obtained from each enrolled subject after volunteers received risk information on radiation exposure and on adverse reaction to IV cholangiographic contrast agents. Bracco (Bracco Diagnostics, Inc., Princeton, NJ) provided financial support for a research technologist and subject compensation. However, only the authors of this manuscript had access to the study's data and the information submitted for publication.

Subjects were 15 healthy volunteers. Table 1 demonstrates the subjects' demographic and health characteristics. Subjects were a minimum age of 18 years and not pregnant. The exclusion criteria were a history of hepatic or biliary disease, or both, a history of hepatic surgery or cholecystectomy, recent alcohol abuse, known adverse reaction to IV contrast material, and an elevated serum bilirubin level (>2 mg/dl). Forty-eight hours before the CT examination, all subjects underwent a serum bilirubin test, and all fertile female subjects a beta-HCG test. All subjects fasted after midnight prior to the morning of the CT cholangiogram.

CT cholangiography protocol

Dynamic CT cholangiography images were obtained either on a single detector (n=7 examinations; HiSpeed CT/i; GE Healthcare, Inc., Milwaukee, WI) or a multi-detector row CT scanner (n=8 examinations; LightSpeed 16; GE Healthcare, Inc.). The assignment of the CT scanner was determined by availability. In an effort to reduce the radiation dose, we used a low-dose technique on both CT scanners (80 kV, 200 mAs). The effective dose of the entire dynamic CT cholangiography study, assessed by an anthropomorphic phantom study, measured 1.6 mSv. Over 30 min, all subjects received a 20-ml IV drip infusion of iodipamide meglumine 52% (Cholografin; Bracco Diagnostics, Inc.) diluted in 80 ml normal saline. No premedication was administered.

Table 1 Subject demographic and health characteristics

	Age (years)	Weight (kg)	Height (cm)	BMI (kg/m^2)	Bilirubin (mg/dl)
Mean	38	75.6	167.9	26.3	0.4
SD	2.8	15.3	19.3	6.3	0.1
Minimum	20	46.3	108.3	18.0	0.2
Maximum	52	105.8	190.5	39.6	0.6

Note: BMI: body mass index; SD: standard deviation

The scanning protocol consisted of three components. First, we acquired an anterior-posterior CT scout to choose a location at the level of the porta hepatis for the dynamic CT cholangiography examination. Second, we obtained two unenhanced, contiguous 10-mm-thick axial images at the porta hepatis. The unenhanced images were deemed adequate if they demonstrated the right hepatic lobe, gallbladder, and extrahepatic bile duct (EBD), consisting of either the common hepatic duct or common bile duct (Fig. 1a). Third, beginning 5 min after initiation of the IV contrast agent, we obtained, at the same location of the unenhanced image, a serial dynamic acquisition consisting of 15 pairs of 10-mm-thick, contiguous axial images, separated by 5-min intervals (Fig. 1b–f). The total scan interval from the initiation of the contrast agent to the last postcontrast scan was 75 min.

Quantitative image assessment and statistical analysis

Quantitative analysis was performed on a separate workstation (Advantage Windows 4.2; GE Healthcare, Inc.) by a 3rd-year radiology resident (S.T.S.). Each subject's 10-mm-thick unenhanced and enhanced datasets were reconstructed to 10-mm-thick images at 1-mm intervals (HiSpeed CT/i) or to 2.5-mm-thick images at 1-mm intervals (LightSpeed 16). Quantitative analysis comprised attenuation measurements in Hounsfield units (HU) of the liver parenchyma and the bile within the EBD. Measurements of liver parenchyma were obtained on the unenhanced and the 15 postcontrast pairs of images, providing a total of 16 different time points (0 min, and every 5 min up to 75 min). Special care was taken to avoid the inclusion of opacified intrahepatic biliary ducts. Owing to the inherent difficulty of delineating the EBD on the unenhanced images, biliary attenuation measurements were obtained only on postcontrast images demonstrating biliary enhancement. For each time point, three attenuation measurements were obtained from hepatic parenchyma by manually placing a circular region-of-interest (ROI) at three different locations. These three locations for the three different attenuation measurements were kept identical for each of the different time points. The size of the ROIs in the liver ranged from 800 to 1,300 mm^2 and in the EBD from 5

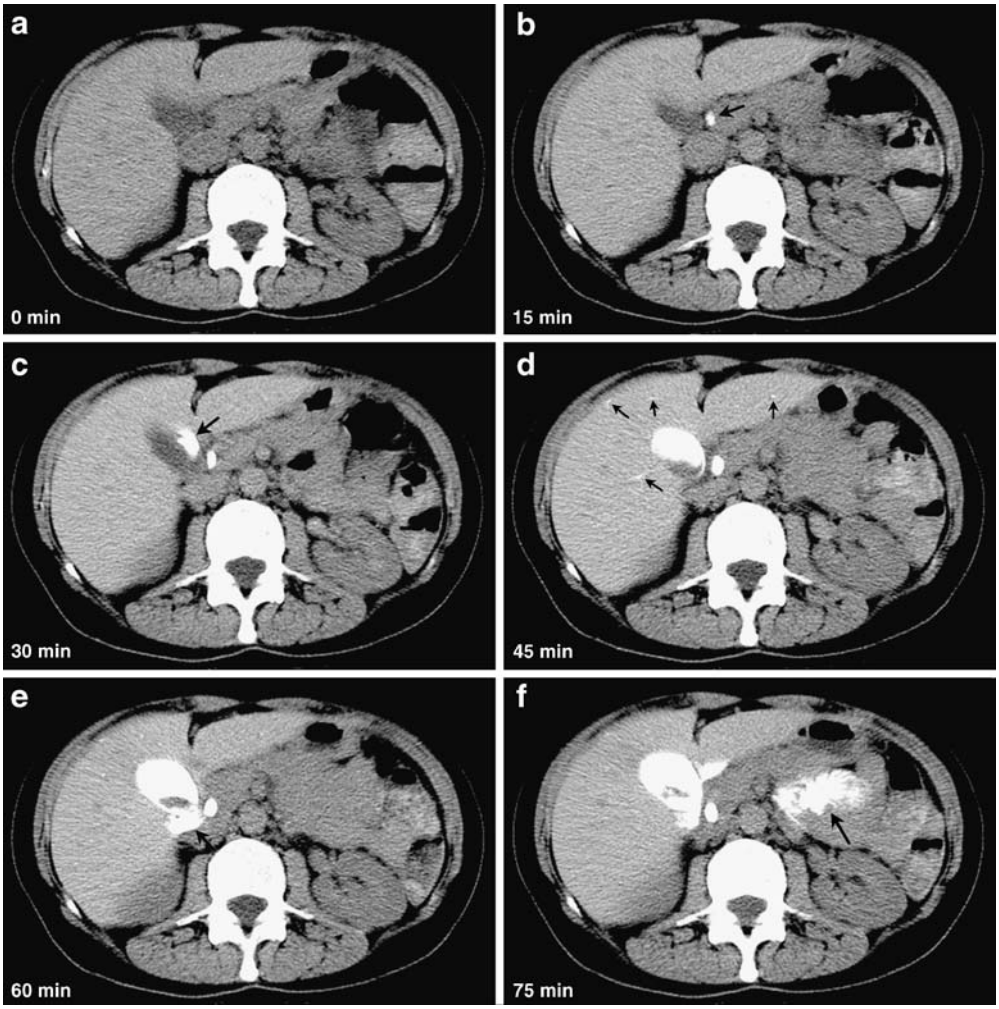

Fig. 1 Representative, sequential axial CT cholangiogram images of a 50-year-old female volunteer at the level of the porta hepatis. The images were acquired with a 16-slice, multidetector row CT scanner using 80 kV and 200 mAs. **a** Unenhanced image (0 min); **b** initial opacification of the EBD (arrow) 15 min after initiation of the contrast agent; **c** opacification of the gallbladder (arrow) and the EBD 30 min after initiation of the contrast agent; **d** opacification of the higher-order biliary branches (arrows), the gallbladder, and the EBD 45 min after initiation of the contrast agent; **e** opacification of the duodenum (arrow), the higher-order biliary branches, the gallbladder, and the EBD 60 min after initiation of the contrast agent; **f** opacification of the proximal jejunum (arrow), the duodenum, the higher-order biliary branches, the gallbladder, and the EBD 75 min after initiation of the contrast agent

to 15 mm^2. Contrast enhancement of the liver parenchyma was defined as the absolute difference in attenuation value between the average of the three mean pre- and postcontrast images.

In order to summarize the hepatobiliary enhancement profile, descriptive data were calculated for the first time point of biliary opacification (time-Bile), mean biliary attenuation during the time interval of 30 to 65 min ($Bile_{mean}$), maximum biliary attenuation ($Bile_{max}$), the time to maximum biliary attenuation (time-$Bile_{max}$), maximum liver enhancement ($Liver_{max}$), and the time to maximum liver enhancement (time-$Liver_{max}$). Furthermore, time-attenuation curves (expressed as HU vs. time) for the bile and for the hepatic parenchyma were calculated. To investigate the influence of age, weight, height, body mass index (BMI), and serum bilirubin level on the hepatobiliary enhancement, we calculated the correlation between age, weight, height, BMI, and serum bilirubin level; and time-Bile, $Bile_{mean}$, $Bile_{max}$, time-$Bile_{max}$, $Liver_{max}$, and time-$Liver_{max}$ with the Kendall τ correlation coefficient. A P value of less than 0.05 was considered to indicate a statistically significant difference. All statistical analyses were performed with SAS software (Version 9.1.3; SAS, Cary, NC).

Qualitative image assessment and statistical analysis

At the separate workstation, all CT cholangiograms, the reconstructed 2.5-mm- and 10-mm-thick images, were reviewed for visualization of higher-order biliary branches by the radiology resident (S.T.S.) and a board-certified, fellowship-trained abdominal radiologist (R.C.N.) with more than 20 years' experience. Due to the inherent difficulty of defining the exact order of the biliary branches beyond the first-order on a CT scan with a total longitudinal coverage of 20 mm, we defined the biliary branches with a diameter between 1 and 2 mm as higher-order biliary branches. The conspicuity of higher-order biliary branches was graded by consensus on a continuous four-point scale: 1=not visualized, 2=poor opacification, 3=good opacification, and 4=excellent opacification. For the qualitative

Table 2 Quantitative image assessment, descriptive data

	Time-Bile (min)	$Bile_{mean}$ (HU)	$Bile_{max}$ (HU)	Time-$Bile_{max}$ (min)	$Liver_{max}$(HU)	Time-$Liver_{max}$ (min)
Mean	22.3	334.2	387.0	47.3	18.5	38.7
SD	3.2	118.9	115.7	12.8	2.7	6.7
Median	25.0	286.3	338.7	45.0	18.3	35.0
Minimum	15.0	192.0	212.3	35.0	14.0	35.0
Maximum	25.0	542.0	581.3	75.0	23.0	60.0

Note: Time-Bile: the first time point of biliary opacification; $Bile_{mean}$: mean biliary attenuation during the time interval 30 to 65 min; $Bile_{max}$: maximum biliary attenuation; Time-$Bile_{max}$: the time to maximum biliary attenuation, $Liver_{max}$: maximum hepatic enhancement; Time-$liver_{max}$: the time to maximum liver enhancement; SD: standard deviation

image assessment, a dedicated liver window (width, 200 HU; level, 35 HU) was used.

Descriptive analysis was calculated for the scores of the visualization of the higher-order biliary tree. The correlation between age, weight, height, BMI, serum bilirubin level, and the visualization of the higher-order biliary tree was measured with the Kendall τ correlation coefficient. A *P* value of less than 0.05 was considered to indicate a statistically significant difference.

Twenty-four hours after the CT cholangiogram, all subjects were contacted by phone by a dedicated research nurse to monitor for possible adverse reactions to the contrast agent.

Results

Quantitative assessment

All 15 subjects demonstrated opacification of the EBD. Biliary opacification was first seen between 15 and 25 min [mean, 22.3 min±3.2 (standard deviation)] after initiation of the IV cholangiography contrast agent (Table 2). The mean biliary attenuation measured 334.2 HU±118.9 (range, 192.0 to 542.0 HU). The mean maximum biliary attenuation was 387.0 HU±115.7 (range, 212.3–581.3 HU). Maximum biliary attenuation occurred between 35 and 75 min (mean, 47.3 min±12.8). The time-attenuation curve for the bile demonstrated a plateau between the 35- and 75-min time points (Fig. 2). The mean maximal enhancement of the liver parenchyma measured 18.5 HU±2.7 (range, 14.0–23.0 HU) and occurred between 35 and 60 min (mean, 38.7 min±6.7) after the start of contrast media infusion (Fig. 3).

Subjects' body weight correlated significantly with the time-Bile, the $Bile_{mean}$, and $Bile_{max}$ (τ=0.69, τ=−0.56, and τ=−0.54, respectively; P<0.005). Furthermore, the BMI correlated significantly with the time-Bile (τ=0.50, P<0.05) (Table 3).

Qualitative assessment

In six subjects (mean weight, 89.1 kg), the higher-order biliary branches were not visualized (Table 4). Poor opacification was seen in another six subjects with a mean weight of 70.0 kg. Opacification of the higher-order biliary tree was graded as good in only two subjects (mean

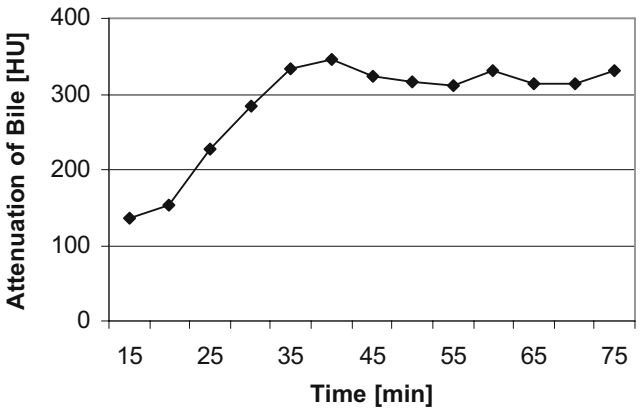

Fig. 2 Time-attenuation curve of the bile demonstrating a plateau between the 35- and 75-min time points. The biliary attenuation value represents the mean value of 15 subjects

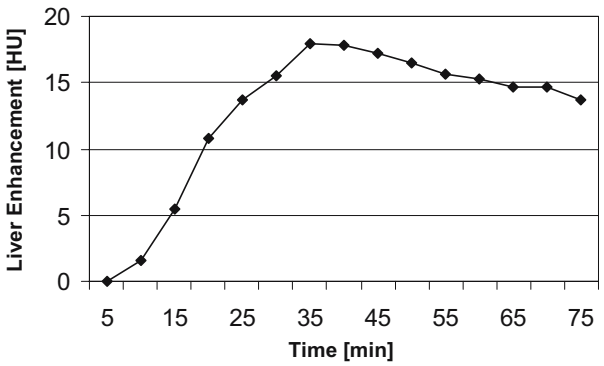

Fig. 3 Time-enhancement curve of the liver parenchyma demonstrating first hepatic enhancement 10 min after initiation of the contrast agent. The hepatic enhancement value represents the mean value of 15 subjects

Table 3 Statistical correlation of quantitative and qualitative image assessment values with other parameters

	Time-Bile (min)	$Bile_{mean}$ (HU)	$Bile_{max}$ (HU)	Time-$Bile_{max}$ (min)	$Liver_{max}$(HU)	Time-$Liver_{max}$ (min)	Higher-order biliary tree
Age	−0.33†	0.28†	0.14†	0.13†	0.22†	0.21†	0.37†
Weight	0.69**	−0.56**	−0.54**	−0.17†	0.05†	−0.16†	−0.64**
Height	0.21†	−0.32†	−0.36†	0.11†	−0.04†	0.05†	−0.06†
BMI	0.50*	−0.23†	−0.29†	0.04†	0.02†	−0.15†	−0.43*
Bilirubin	0.18†	0.02†	0.02†	0.18†	−0.20†	−0.19†	0.01†

Note: Data are Kendall τ correlation coefficients; time-Bile: the first time point of biliary opacification; $Bile_{mean}$: mean biliary attenuation during the time interval 30 to 65 minutes; $Bile_{max}$: maximum biliary attenuation; time-$Bile_{max}$: the time to maximum biliary attenuation, $liver_{max}$: maximum liver enhancement; time-$liver_{max}$: the time to maximum liver enhancement; BMI: body mass index.
*$P<0.05$
**$P<0.005$
†$P>0.05$

weight, 56.2 kg), and as excellent in only one subject (67.3 kg). Statistically significant correlations were found between the opacification of the higher-order biliary tree and weight ($\tau=-0.64$, $P<0.005$), and between opacification and BMI ($\tau=-0.43$, $P<0.05$) (Table 3).

Twenty-four hours after the CT exam, no adverse reactions to the contrast agent were reported.

Discussion

In recent years, several studies on CT cholangiography with IV cholangiographic contrast agent have shown promising results in the evaluation of obstructive biliary disease and of the biliary tract in potential living liver donors [9, 12–15]. Besides pathomorphological information, CT cholangiography with the use of an IV contrast agent can also provide additional information on biliary kinetics [8]. In order to optimize CT cholangiography and to construct a base for the assessment of biliary kinetics, it is essential to gain normal reference data. Therefore, we evaluated the biliary enhancement profile of CT cholangiography after IV administration of iodipamide meglumine.

No consensus exists on the optimal timing for CT cholangiography after administration of an IV cholangiographic contrast agent. The radiological literature has reported scan delays ranging from 25 to 75 min [8, 12–14, 16, 23]. In the package insert, the manufacturer of iodipamide meglumine recommends scanning about 25 min after agent administration [24]. In the present study, the earliest biliary appearance of the agent occurred between 15 and 25 min following the initiation of contrast infusion. The attenuation profile reached a plateau at 35 min and persisted until the last time point at 75 min. Similar results were seen in two animal studies in which biliary iodine concentration was assessed: peak concentration was reached about 45 min after the start of the infusion, followed by a 30-min plateau [17, 18]. Since we expect a similar dynamic attenuation profile for the opacification of the intrahepatic biliary tree, we propose to perform CT cholangiography no earlier than 35 min after initiation of the contrast agent.

Table 4 Visualization of the higher-order biliary branches

Visualization score	Subjects (n)	Weight (kg)	Height (cm)	BMI (kg/m^2)
1	6	89.1±12.3	163.7±29.8	29.2±5.8
2	6	70.0±6.8	172.7±9.5	25.9±7.0
3	2	56.2±14.0	165.1±7.2	20.4±3.4
4	1	67.3	170.2	23.2

Note: Data are mean values±standard deviation; BMI: body mass index; visualization score of the grading of the higher-order biliary tree: 1=not visualized, 2=poor opacification, 3=good opacification, and 4=excellent opacification

Our results also show a substantial correlation between the subject's body weight and the magnitude of biliary opacification. Mean and maximal biliary attenuation were found to be significantly lower in heavy compared to light subjects. Furthermore, heavy subjects tended to have either no or poor visualization of the higher-order biliary branches. Previous studies have demonstrated good correlation between body weight and liver volume ($r^2=0.48$–0.61), and various formulas have been derived to estimate graft volume before liver transplantation [25–27]. The correlation between body weight and liver size may explain the correlation we found between the subject's body weight and the degree of biliary opacification. A larger liver containing more fluid in the biliary tree could potentially result in greater dilution of the contrast agent, which may further decrease biliary opacification [28].

Takahashi et al. did not detect a statistically significant correlation between body weight and the degree of biliary enhancement on CT cholangiograms in 100 patients [29]. A possible explanation for the discrepancy between this finding and ours is that Takahashi's study included patients with elevated serum bilirubin levels, up to 4 mg/dl. An elevated serum bilirubin level is a well-documented predictor of poor biliary opacification [23, 29, 30]. Thus,

inferior biliary opacification due to an elevated serum bilirubin level might have impacted the correlation between body weight and the degree of biliary enhancement in the study by Takahashi et al. [29].

Faint or non-opacification of the intrahepatic biliary tree can be a limiting factor of CT cholangiography [29, 30]. Our study showed this limitation, with non-opacification of the higher-order biliary branches in 12 out of 15 subjects (mean weight >70 kg). Only three subjects demonstrated good or excellent opacification (mean weight <67 kg). Since we studied peripheral ducts, it is not possible to comment on the adequacy of first- and second-order branch opacification. It should be noted, however, that in a study by Gibson et al. 55 out of 65 patients (61 patients with normal bilirubin levels) undergoing CT cholangiography with meglumine iotroxate demonstrated good opacification of at least third-order intrahepatic branches [14]. Although the present study used iodipamide meglumine rather than meglumine iotroxate, by assessing very peripheral ducts, the study may have underestimated the ability of CT cholangiography to produce good opacification of intrahepatic ducts.

The dosing instructions for iodipamide meglumine recommend an adult dose of 20 ml irrespective of the patient's body weight [24]. To date, an accurate dosage regime has not been established for the application of IV cholangiographic contrast agents. Instead of relying on a fixed dose, tailoring the dose to the patient's body weight might improve visualization of the intrahepatic biliary tree. In 1975, Scholz et al. demonstrated that a double-dose infusion of methylglucamine iodipamide results in a significant improvement in biliary opacification on a conventional cholangiogram compared to a single-dose infusion [21]. At the same time, the double-dose infusion correspondingly doubled the adverse reaction rate [21]. It is possible that a double dose regime may improve biliary opacification in heavier patients. This needs to be tested by an appropriate study to evaluate efficacy and safety.

The administration of IV cholangiographic contrast agents does yield potential risks for adverse reactions. The rate of these adverse reactions is determined by the dose of the contrast agent, its dilution, and the infusion rate [9, 30, 31]. For example, slow infusion of the contrast agent over at least 20 min results in a lower rate of allergic reactions [23, 30, 31]. Several studies using iodipamide meglumine and meglumine iotroxate have demonstrated minor contrast reactions (up to 3.0%) similar to those encountered during IV contrast-enhanced CT examinations [9, 23, 32, 33]. Severe systemic reactions are associated in less than 0.2% of patients [9, 23, 32, 33].

There were limitations to our study. First, our scanning protocol, comprised of two contiguous, 10-mm-thick axial images at the level of the porta hepatis, provided a limited view of the liver and its biliary tree. As a result, we were not able to qualitatively assess in each patient the primary and secondary confluence. However, a dynamic acquisition of the entire liver, consisting of 15 single CT scans, would have resulted in high radiation exposure to our group of otherwise healthy volunteers. Second, we investigated only one IV cholangiographic contrast agent with one infusion protocol. Other contrast agents might have demonstrated slightly different hepatobiliary enhancement profiles. Furthermore, the use of faster infusion rates might have led to an earlier appearance of the contrast agent and to greater maximum and mean biliary attenuation values. Third, our study did not include patients with hepatobiliary diseases or healthy subjects after cholecystectomy, which might have varied biliary attenuation profiles, depending upon several factors, including biliary dilatation and elevated serum bilirubin level. Therefore, the biliary attenuation profiles of patients with hepatobiliary diseases and of cholecystectomized subjects should be investigated in future studies.

In conclusion, our results indicate that CT cholangiography should be performed no earlier than 35 min after the initiation of IV contrast when using a regime of 20 ml iodipamide meglumine 52% administered over 30 min. There is at least a 40-min temporal window during which scanning may be performed. Tailoring contrast dose to body weight may be a means of improving biliary opacification although the efficacy and safety of this procedure requires further investigation.

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