

# Gadopentetate dimeglumine-enhanced MR cholangiopancreatography in infants with cholestasis

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## Abstract

**Background** Biliary atresia (BA) is a progressive, obliterative cholangiopathy that occurs in neonates with hepatic portoenterostomy the treatment of choice, but early surgery is important for optimum outcomes. MRI, including MR cholangiopancreatography (MRCP) may be a diagnostically useful alternative to US, but the heavily T2-weighted sequences used include not only bile duct signals, but also other heterogeneously high signal intensities from surrounding structures.

**Objective** To evaluate the effects of gadolinium when used to decrease background signal intensity on T2-weighted MR

cholangiopancreatography (MRCP) in infants and to evaluate the qualitative improvement of the depiction of the common bile duct (CBD) for evaluating neonatal cholestasis.

**Materials and methods** Our Institutional Review Board approved this prospective study. MRCP was performed with gadopentetate dimeglumine injection using a 1.5-T scanner. Pre- and postcontrast MRCP images were compared. Forty-nine infants (male:female=21:28; age 0–12 months, mean 2.3) were included. The final diagnoses were biliary atresia (BA) in 28 cases and non-BA in 21. Quantitative analysis was conducted using region-of-interest measurements of mean signal intensities of the liver, pancreatic head and gallbladder (if defined). Qualitative analysis was performed by four radiologists who subjectively scored image confidence in the presence of CBD on a 4-point scale (0 for definitely absent, 1 for probably absent, 2 for probably present, and 3 for definitely present).

**Results** The signal-to-noise ratios were significantly decreased in the liver and pancreatic head after contrast medium enhancement (mean 5.7→4.0 in liver and mean 44.9→12.7 in the pancreatic head;  $P<0.0001$ ), and this finding was constant in both the BA and the non-BA group. The mean confidence score in the presence of CBD decreased in the BA group (0.9→0.5;  $P<0.0001$ ), but did not change significantly in the non-BA group (2.0→2.1;  $P=0.459$ ) after contrast medium enhancement. Both intra- and interobserver agreement was higher after contrast medium enhancement ( $P=0.046$ ).

**Conclusion** Gadopentetate dimeglumine-enhanced MRCP increased the diagnostic confidence of absence of the CBD in cholestatic infants with increased intra- and interobserver agreement.

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## Introduction

Biliary atresia (BA) is a progressive, obliterative cholangiopathy that occurs in neonates. This disorder is rare and occurs most commonly in East Asian countries, with a reported frequency in Taiwan of about 1 in 5,000 [1]. A recent study suggested that detrimental cholestatic liver injury only begins at the time of birth despite prenatal occlusive biliary pathology [2]. Hepatic portoenterostomy is the treatment of choice, but early surgery is important for optimum outcomes [3]. Therefore, it is important to diagnose BA as early and accurately as possible. Many studies have been published on diagnostic imaging modalities as evaluation tools for cholestasis in infants; a large portion of these studies have employed US and MRI.

Numerous sonographic features have been reported for BA, including a triangular cord sign, abnormal gallbladder (GB: wall, shape, length and contractility), absent common bile duct (CBD) and enlarged hepatic arteries [4–7]. In recent studies, US demonstrated a 98% positive predictive value, a 100% negative predictive value and a 98% accuracy rate for the diagnosis of BA [4, 7]. However, US may be limited by the patient's condition, such as distended bowel loops with gas. US is dependent on the operator's experience and is sometimes inconclusive. US examination is also limited when evaluating anomalous pancreaticobiliary duct union if the biliary and pancreatic ducts are not dilated.

MRI, including MR cholangiopancreatography (MRCP), may be a diagnostically useful alternative [8, 9]. MRCP is not operator-dependent and it can evaluate detailed structural anomalies including anomalous pancreaticobiliary duct union [7]. Therefore, MRCP is promising for evaluating neonatal cholestasis in inconclusive cases. However, MRCP images, which rely on a heavily T2-weighted (T2-W) sequence, include not only bile duct signals, but also other heterogeneously high signal intensities from surrounding structures. In clinical practice, it is difficult to discriminate the CBD on MRCP in neonates and infants due to its small diameter (<1 mm in normal neonates), surrounding tissue noise and rapid respiration. One strategy for image improvement involves decreasing the surrounding tissue signal on the T2-W image. This can be achieved with administration of gadolinium, which reduces tissue signal on T2-W images [10–13], and therefore potentially enhances the depiction of the CBD. Some studies have investigated the efficacy of gadolinium chelate administration in depicting biliary structures compared to conventional T2-W MRCP [10, 14]. However, this has not been evaluated in children. Therefore, the purpose of this study was to quantitatively determine the T2 shortening effect of gadolinium in decreasing background signal intensity on T2-W MRCP in infants and to evaluate the qualitative improvement of depiction of the CBD for evaluating neonatal cholestasis.

## Materials and methods

This prospective study was approved by the Institutional Review Board at our hospital; informed consent was obtained from the parents of each child prior to commencement of the study. MRCP was performed in infants with cholestasis following abdominal US from January 2007 to March 2010. The indication for MRCP in infants with cholestasis was to rule out BA or to evaluate pancreaticobiliary duct anomaly. Fifty-four infants underwent MRCP both before and after contrast injection with gadopentetate dimeglumine (Gd-DTPA). We excluded five infants with choledochal cysts; the remaining 49 were divided into BA or non-BA groups according to the final diagnoses. There were 21 boys and 28 girls with a mean age of 2.3 months (range 0–12 months).

Final diagnosis was confirmed by surgical pathology in all BA patients without preoperative needle biopsy and based on clinical, laboratory and/or operative findings in non-BA patients. The final diagnosis was BA in 28 cases and non-BA in 21 cases. The non-BA cases included cytomegalovirus (CMV) hepatitis ( $n=14$ ), total parenteral nutrition (TPN)-induced cholestasis ( $n=3$ ), annular pancreas ( $n=2$ ), arthrogyrosis, renal dysfunction and cholestasis (ARC) syndrome ( $n=1$ ), and hepatic cyst ( $n=1$ ). CMV hepatitis and TPN-induced cholestasis were diagnosed from clinical and laboratory findings. ARC syndrome was confirmed from cardinal clinical features and agranular platelets on electron microscopic images [15]. Annular pancreas and hepatic cyst were confirmed intraoperatively. We retrospectively reviewed the MRCP images and compared them among groups.

### MR imaging

One hour before the MR imaging examination, infants were sedated with orally administered chloral hydrate (Pocral; Hanlym, Seoul, South Korea; 50 mg/kg). All MR images included in this study were obtained with a 1.5-T scanner (Signa Horizon, GE Medical System, Milwaukee, WI, USA, from 2007 to 2008; Achieva, Philips Medical System, Amsterdam, Netherlands, from 2009 to 2010). A head coil was used in the GE scanner and a SENSE cardiac coil was used in the Philips scanner. MRCP was performed with a non-breath-hold T2-W single-shot fast spin-echo (SSFSE) sequence with image acquisition parameters of TR/TE infinite/1,000–1,050 ms (effective) with matrix  $256 \times 256$ , field of view 20–24 cm, slab thickness 20–25 mm and receiver bandwidth 24.4 kHz in the GE scanner. In the Philips scanner, non-breath-hold T2-W single-shot turbo spin-echo (SSTSE) sequence was used with imaging parameters of TR/TE infinite/800 ms (effective) with matrix  $256 \times 256$ , field of view 20 cm, slab thickness 20 mm and receiver

bandwidth 29.8–31.4 kHz. Respiratory triggering was performed during MRCP. MRCP images were obtained both before and 5 min after the injection of contrast medium (0.1 mmol/kg Gd-DTPA [Magnevist, Schering, Berlin, Germany]).

#### Quantitative image analysis

The quantitative analysis was conducted using operator-defined region-of-interest (ROI) measurements of the mean signal intensity of the liver, pancreatic head (that was represented as the structure surrounding the CBD) and GB (if defined). The ROI size in each area was 30 mm<sup>2</sup> in the liver, 20 mm<sup>2</sup> in the pancreatic head and

20 mm<sup>2</sup> in the GB. The mean signal intensities (SI) were obtained by determining the sum of the value in three sites of each area divided by three. The background ROIs for the standard deviation (SD) of the mean signal intensities were drawn as the largest circle possible. Signal-to-noise ratios (SNRs) were calculated as the mean signal intensities of each area divided by the SD of the mean signal intensities of the background [16]. Contrast-to-noise ratio (CNR) was defined as the difference in SNR between two relevant regions. Therefore, CNRs of the GB to the liver and pancreatic head were calculated by dividing the difference between the mean signal intensities of the GB and liver or pancreatic head by the SD of the mean signal intensities of the background outside of the body.

$$\text{SNR} = \text{SI}_{\text{area}} / \text{SD}_{\text{background}}$$

$$\text{CNR}_{\text{liver}} = \text{SNR}_{\text{GB}} - \text{SNR}_{\text{liver}} = (\text{SI}_{\text{GB}} - \text{SI}_{\text{liver}}) / \text{SD}_{\text{background}}$$

$$\text{CNR}_{\text{pancreatic head}} = \text{SNR}_{\text{GB}} - \text{SNR}_{\text{pancreatic head}} = (\text{SI}_{\text{GB}} - \text{SI}_{\text{pancreatic head}}) / \text{SD}_{\text{background}}$$

#### Qualitative image analysis

Four radiologists, who were blinded to information about the patients, independently reviewed the pre- and postcontrast MRCP images of each patient and the imaging sequences in a random order. This review was conducted twice with an interval of at least 30 d.

These radiologists performed the qualitative analysis by subjectively scoring image confidence in the presence of the CBD on a 4-point scale, with a score of 0 assigned for the definite absence of the CBD; 1 for the probable absence of the CBD; 2 for the probable presence of the CBD; and 3 for the definite presence of the CBD. The intrahepatic bile ducts were not evaluated. We excluded cases with choledochal cyst because these may have introduced bias.

For the evaluation of diagnostic performance to distinguish BA and non-BA between pre- and postcontrast MRCP images, scores of 0 and 1 were considered as BA and scores of 2 and 3 were considered as non-BA.

#### Statistical analysis

The means of SNRs and CNRs in the BA and non-BA groups were compared using the Mann-Whitney *U* test. We used the Wilcoxon signed rank test to compare these data between images taken before and after contrast medium injection.

To assess intraobserver and interobserver agreement when assigning the confidence scores, Cohen's kappa was used. The strength of agreement beyond chance for various ranges of  $\kappa$  was used according to suggestions by Landis and Koch [17]. The agreement was compared between the

pre- and postcontrast enhanced scans with the Wilcoxon signed rank test. The mean confidence scores between the BA and non-BA groups were compared using the Mann-Whitney *U* test and the mean confidence scores between the images taken before and after contrast medium injection were compared with the Wilcoxon signed rank test.

Statistically significant differences were defined as those with *P*-values < 0.05, and analyses were performed with the statistical package for the social sciences (SPSS, version 18; SPSS, Chicago, IL, USA).

Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy were calculated from the qualitative score analysis result.

#### Results

Among the 49 infants, there were 10 boys and 18 girls in the BA group and 11 boys and 10 girls in the non-BA group (*P*=0.262). The mean age was 1.9 months in the BA group and 2.9 months in the non-BA group (*P*=0.274). The GB and CBD was defined in 16 cases of the non-BA group (16/21, 76.2%). The diagnoses of the remaining five cases with nonvisualized GBs and CBDs in the non-BA group were CMV hepatitis (*n*=2), TPN-induced cholestasis (*n*=1), ARC syndrome (*n*=1) and annular pancreas (*n*=1).

#### Quantitative image analysis

Comparisons of the SNRs of the liver, pancreatic head, and GB on pre- and postcontrast images are summarized in Table 1. On

**Table 1** Comparisons between SNRs of the liver, pancreatic head and GB on pre- and postcontrast MRCP images. *n.s.*, not significant; <sup>#</sup>SNR of GB, calculated only when GB was defined on MRCP images; \**P*-value, comparison between the pre- and postcontrast images with the Wilcoxon signed rank test; \*\**P*-value, comparison between the BA and non-BA group with the Mann-Whitney *U* test

SNRs		Precontrast image	Postcontrast image	* <i>P</i> -value
Liver	All ( <i>n</i> =49)	5.7±4.0	4.0±2.2	<0.001
	BA ( <i>n</i> =28)	6.2±4.0	4.4±2.6	<0.001
	Non-BA ( <i>n</i> =21)	4.9±4.0	3.4±1.6	0.035
	** <i>P</i> -value	<i>n.s.</i>	<i>n.s.</i>	
Pancreatic head	All ( <i>n</i> =49)	44.9±38.0	12.7±15.5	<0.001
	BA ( <i>n</i> =28)	52.8±43.8	16.0±19.5	<0.001
	Non-BA ( <i>n</i> =21)	34.4±26.0	8.3±5.2	<0.001
	** <i>P</i> -value	<i>n.s.</i>	<i>n.s.</i>	
<sup>#</sup> GB	All ( <i>n</i> =16)	130.7±72.4	106.8±73.3	0.017

precontrast images, SNRs of the liver and pancreatic head were not significantly different between the BA and non-BA groups. However, these values significantly decreased after contrast medium enhancement in all cases regardless of the final diagnosis (Fig. 1). GB signal intensities were measured in 16 cases of the non-BA group and SNRs of the GB also decreased after enhancement (mean, from 130.7 on precontrast images to 106.8 on postcontrast images; *P*=0.017). Comparisons of CNRs of the GB to the liver and pancreatic head on pre- and postcontrast images are summarized in Table 2. CNRs of the GB and liver decreased after contrast enhancement (*P*=0.020), while CNRs of the GB and pancreatic head did not change.

Qualitative image analysis

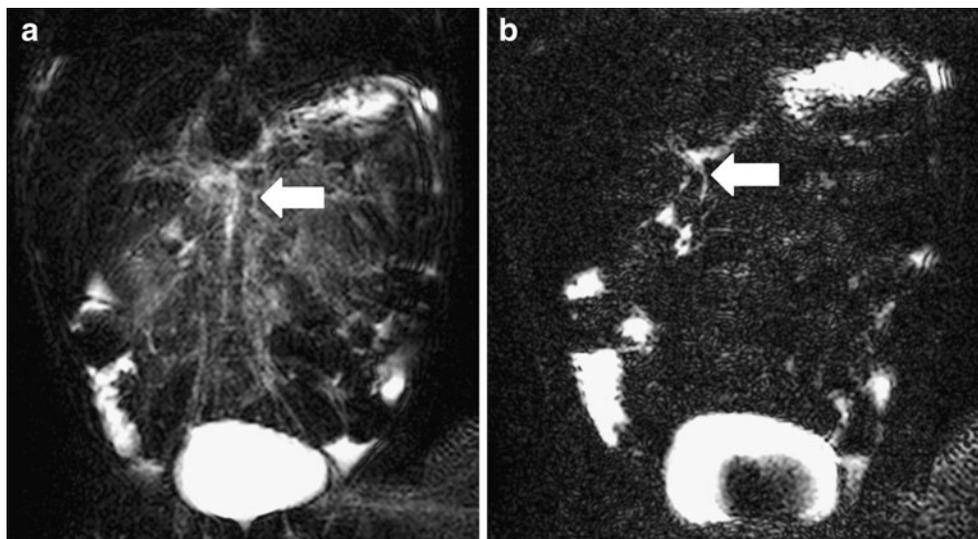
Intraobserver agreement was moderate to substantial in both precontrast (0.391–0.835) and postcontrast (0.457–0.967) images. Interobserver agreement was substantial in

both precontrast (0.591–0.781) and postcontrast (0.673–0.841) images and this agreement significantly increased after contrast medium enhancement (*P*=0.046).

The mean confidence scores significantly decreased after contrast medium enhancement in BA patients (mean 0.9→0.5; *P*<0.0001) (Table 3). However, these scores did not change after contrast medium enhancement in the non-BA patients (mean 2.0→2.1; *P*=0.459).

Qualitative scoring results and final diagnoses are presented in Table 4. Sensitivity, specificity, PPV, NPV and accuracy were 82.1% (184/224), 70.2% (118/168), 78.6% (184/234), 74.7% (118/158) and 77.0% (302/392), respectively, on precontrast MRCP, and 87.9% (197/224), 70.8% (119/168), 80.0% (197/246), 81.5% (119/146) and 80.6% (316/392), respectively on postcontrast MRCP.

In the BA group, one case (1/28, 3.6%) had a high (>2) mean confidence score on the postcontrast MRCP image. In this case, fluid between bowel loops mimicked the CBD. In



**Fig. 1** MRCP images in a 3-month-old male neonate with CMV hepatitis. **a** Precontrast MRCP shows heterogeneous soft-tissue signal intensities in the pancreatic head portion (*arrow*). The SNR of the pancreatic head was 111.1 and the mean confidence score in the presence of CBD was 1.9. **b** Postcontrast MRCP shows background

soft-tissue signal intensities markedly decreased and the CBD (*arrow*) is well-defined. In this image, the SNR of the pancreatic head decreased to 11.8 and the mean confidence score in the presence of the CBD increased to 2.8. The CNR of the CBD to the pancreatic head also increased from 10.7 to 49.7 after contrast medium enhancement

**Table 2** Comparisons between CNRs of the GB to the liver and pancreatic head on pre- and postcontrast MRCP images. \**P*-value, from the Wilcoxon signed rank test

CNR	Precontrast image	Postcontrast image	* <i>P</i> -value
GB to liver ( <i>n</i> =16)	126.8±72.2	103.7±72.7	0.020
GB to pancreatic head ( <i>n</i> =16)	99.2±76.3	98.8±72.8	n.s.

the non-BA group, two cases (2/21, 9.5%) showed a low (<1) mean confidence score on both pre- and postcontrast MRCP images. However, the CBD could be identified on operative cholangiography in both cases. The final diagnosis was TPN-induced cholestasis in one case and CMV hepatitis in the other.

## Discussion

MRI is noninvasive and helpful for hepatobiliary system evaluation, even in children [18]. MRCP is primarily represented by heavily T2-W sequences [8, 19, 20]. On these images, stationary protons with a long T2 relaxation time (including water and bile) yield high signal intensities. However, tissues with a short T2 relaxation time, such as the liver and pancreas, as well as circulating blood, have low signal intensities. This difference allows for optimal contrast between the hyperintense bile and the hypointense background [21]. Based on these characteristics, MRCP can be used to exclude BA as the cause of cholestasis in infants when the extrahepatic bile duct can be observed [9, 22, 23].

However, MRCP also has limitations for evaluating the infant biliary system. Discriminating the CBD on MRCP is not easy in these patients because of the small size of the CBD and also due to surrounding tissue noise. Therefore, additional methods are needed to visualize the CBD on MRCP in infants.

Gadolinium chelate is known to have T2- and T2\*-shortening effects as well as a T1-shortening effect. Several studies have reported this effect on MRCP in adult patients

**Table 3** Mean confidence scores in the presence of the CBD on pre- and postcontrast MRCP images. \**P*-value, comparison between the pre- and postcontrast images with the Wilcoxon signed rank test; \*\**P*-value, comparison between the biliary atresia and the non-biliary atresia group with the Mann-Whitney *U* test. Four separate radiologists twice reviewed 392 scores from 49 cases

	Precontrast image	Postcontrast image	* <i>P</i> -value
All ( <i>n</i> =392)	1.4±1.0	1.2±1.2	0.001
BA ( <i>n</i> =224)	0.9±0.7	0.5±0.8	<0.001
Non-BA ( <i>n</i> =168)	2.0±1.0	2.1±1.2	n.s.
** <i>P</i> -value	<0.001	<0.001	

**Table 4** Qualitative analysis results and final diagnoses on pre- and postcontrast MRCP images

	Final diagnosis	Confidence scores in the presence of CBD	
		2 or 3	0 or 1
Precontrast MRCP	Non-BA	118	50
	BA	40	184
Postcontrast MRCP	Non-BA	119	49
	BA	27	197

with increased image quality after contrast medium enhancement [10, 14]. Takahashi et al. [14] found that both the signal intensity ratio of the CBD to the main pancreatic duct and the image quality significantly improved after contrast medium injection on MRCP. Kanematsu et al. [10] also showed that administration of gadolinium chelate improved the depiction of pancreaticobiliary ducts in some patients. However, no study has examined this effect or clinical usage in children. In our study, this T2-shortening effect of gadolinium was observed both quantitatively and qualitatively in infants.

The T2-shortening effect of gadolinium was demonstrated in the quantitative analysis of SNRs and CNRs. Gd-DTPA-enhanced MRCP showed decreased SNRs of the liver and pancreatic head compared to precontrast MRCP regardless of the final diagnosis (BA or not). However, SNRs of the GB also decreased in this study (mean 130.7→106.8; *P*=0.017). Gd-DTPA is an extracellular paramagnetic contrast agent and is predominantly excreted through the kidneys [24]. Because of the rapid renal elimination and the lack of biliary excretion, a contrast effect in the biliary system cannot be achieved with this substance. Therefore, the decrease of SNRs of the GB could not be a T2-shortening effect of gadolinium, but it may instead be due to the partial volume effect. Motion artefacts also may have influenced the results.

CNRs of the GB to the liver and pancreatic head did not change, although SNRs of the liver and pancreatic head decreased. This finding may be due to the unexpectedly decreased SNRs of the GB. Our study cannot elucidate this any further however; this effect may be due to the relatively thick slabs used.

The T2-shortening effect of gadolinium was also proven qualitatively in our study. Contrast enhancement influenced the subjective scoring of confidence in the presence of CBD, especially in the BA group. Moreover, intra- and interobserver agreement also increased after contrast enhancement. In the BA group, mean confidence scores decreased on enhanced scans compared to unenhanced images. On precontrast MRCP, the mean confidence score in the presence of CBD was 0.9 in this group. Therefore, most of the reviewers thought that the CBD would probably

be absent. The mean confidence score decreased to 0.5 after enhancement; more reviewers thought that the CBD would definitely be absent. Therefore, the confidence in the absence of the CBD increased after enhancement in BA patients. The mean confidence scores did not change after enhancement in the non-BA group (2.0 on precontrast image and 2.1 on postcontrast image). Contrast enhancement is not needed when the presence or absence of the CBD has already been determined on precontrast MRCP images. However, when we cannot be sure of the presence of the CBD on precontrast MRCP, contrast enhancement may, based on our results, improve the likelihood of depiction of the CBD. Following contrast enhancement, the sensitivity, specificity, PPV, NPV, and accuracy were all slightly increased (from 82.1%, 70.2%, 78.6%, 74.7% and 77.0% to 87.9%, 70.8%, 80.0%, 81.5% and 80.6%, respectively).

There are several limitations to this study. First, both our quantitative and qualitative analyses had methodological limitations. During quantitative analysis, we drew an ROI in the pancreatic head, which was represented as the structure surrounding the CBD. However, on MRCP images it was not easy to discriminate the head of the pancreas, especially if motion artefacts were present. Although we used respiratory triggering, motion artefacts remained on the MRCP images, probably because of rapid breathing. We could not completely avoid this artefact when placing ROIs, especially in the pancreatic head. Moreover, bowel peristalsis may have influenced signal intensity in the pancreatic head area. We did not attempt to attenuate bowel peristalsis.

Confidence scoring for the presence of the CBD is extremely subjective. Generally, we consider several factors, including the presence and shape of the CBD and GB, liver parenchymal signal intensity on T2-W images and other combined lesions, when making the diagnosis of BA. Among these factors, we feel that determining the presence of the CBD is the most difficult. Therefore, we wanted to consider only the CBD in this study and to suggest an objective effect of gadolinium on MRCP images for the visualization of the CBD.

The second limitation of our study is that a selection bias may have been present in terms of the universal contrast medium enhancement in the non-BA group. In clinical practice, we do not use contrast medium when we can be sure that the CBD is definitely present and when contrast enhancement is not needed to evaluate other problems. Gadolinium agents have limitations in their use in children, especially in infants. In our study, we used gadopentetate dimeglumine (Magnevist) for contrast-enhanced MRCP. However, the safety and efficacy of this agent in children younger than 2 years has not been established. This contrast agent is eliminated primarily by the kidneys; it is not recommended in neonates and infants up to 12 months of

age because of their immature renal function. Therefore, gadopentetate dimeglumine should only be used in these patients after careful consideration at a dosage not exceeding 0.2 ml/kg (0.1 mmol/kg) body weight. In our study, we followed this dose limitation and observed any adverse reactions (such as nephrogenic systemic fibrosis) during the study period. We found no remarkable adverse reaction from gadolinium in this study. However, caution and careful usage of the gadolinium agent is mandatory.

## Conclusion

There is a T2-shortening effect of Gd-DTPA on MRCP in infants both with and without BA. Gd-DTPA-enhanced MRCP may allow a more definitive determination of the presence or absence of the CBD in infants with cholestasis, especially when conventional MRCP is indeterminate.

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