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HEPATOBILIARY

Diagnostic performance of magnetic resonance cholangiopancreatography (MRCP) versus endoscopic retrograde cholangiopancreatography (ERCP) in the pediatric population: a clinical effectiveness study

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Abstract

Purpose To determine the diagnostic performance of magnetic resonance cholangiopancreatography (MRCP) for detecting biliary and pancreatic abnormalities in a pediatric population, using endoscopic retrograde cholangiopancreatography (ERCP) as the reference standard.

Materials and methods Institutional review board approval with a waiver of informed consent was obtained for this retrospective investigation. Records from the Cincinnati Children's Hospital Medical Center, Division of Gastroenterology and Department of Radiology were used to identify patients aged ≤ 18 years who had undergone both ERCP and MRCP within a 4-week interval between January 2013 and May 2017. Biliary and pancreatic duct findings were documented for each modality to determine the diagnostic performance of MRCP (with 95% confidence intervals), using ERCP as the reference standard.

Results 54 patients met inclusion criteria. Mean patient age at time of ERCP was 10.4 ± 4.9 years, and 25 (46%) were male. Mean interval between ERCP and MRCP was 11.2 ± 9.7 days. For detection of any abnormality ($n=99$ ERCP findings), MRCP had a sensitivity of 76.8% (67.5–84.0%) and a positive predictive value (PPV) of 81.7% (72.7–88.3%). MRCP was 75.7% (59.9–86.6%) sensitive, with a PPV of 84.9% (69.1–93.4%) for biliary findings ($n=37$) and 73.5% (59.7–83.8%) sensitive, with a PPV of 78.3% (64.4–87.7%) for pancreatic findings ($n=49$). For pancreatobiliary abnormalities ($n=13$), MRCP had a sensitivity of 92.3% (66.7–99.6%) and a PPV of 85.7% (60.1–97.5%).

Conclusion In clinical practice, MRCP is moderately sensitive for biliary and pancreatic abnormalities, with false-negative and false-positive examinations being relatively common.

Keywords Clinical effectiveness · Diagnostic performance · Endoscopic retrograde cholangiopancreatography (ERCP) · Magnetic resonance cholangiopancreatography (MRCP) · Pediatric

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) was first described nearly five decades ago and generally has been considered the diagnostic reference standard for the evaluation of a wide range of abnormalities involving the pancreatobiliary tree, including choledocholithiasis, stricturing diseases, and duct leaks/disruptions [1, 2]. Although ERCP can be safely performed in pediatric patients [3, 4], it is an invasive procedure that requires sedation (or general anesthesia) and analgesia, ionizing radiation, and may result in post-procedural pancreatitis [5–11]. Also, the availability of ERCP in pediatric patients mostly remains limited to a select number of pediatric and adult tertiary care hospitals.

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Because of these drawbacks, noninvasive imaging tests are more commonly the first-line diagnostic methods for evaluating the pancreatobiliary system, including ultrasound and magnetic resonance imaging (MRI) [2, 10, 12]. A primary objective of noninvasive imaging is to identify clinically significant abnormalities, and in those with such findings, differentiate the patients that would likely benefit from ERCP for further diagnosis and treatment from those who would not.

Magnetic resonance cholangiopancreatography (MRCP) refers to MR imaging optimized for evaluation of the pancreatobiliary system. This generally includes a variety of heavily T2-weighted imaging sequences that increase the conspicuity of fluid, including thin-section single-shot fast spin-echo (SSFSE), thick-section SSFSE, and very thin-section 3D fast spin-echo imaging which allows both 2D reformats and 3D reconstructions [13, 14]. When compared to ERCP, MRCP is a lower cost diagnostic examination that does not require exogenous contrast material, can often be performed without sedation (or general anesthesia) and analgesia (especially in older and cooperative children), and has no risk of post-procedural pancreatitis [2, 5–8, 15]. Unlike ERCP, MRCP also allows direct visualization of hepatic and pancreatic parenchyma and surrounding structures.

Several, mostly adult, studies have compared the diagnostic performance of MRCP to ERCP [5, 12, 15–25]. Some studies have demonstrated the diagnostic value of MRCP in patients that fail ERCP [21, 26, 27], while other studies have compared MRCP to ERCP for specific diagnoses [5, 22–25, 28, 29]. There is a paucity of literature comparing MRCP to ERCP in children and adolescents.

The purpose of our study was to assess the diagnostic performance of MRCP for detecting pancreatobiliary abnormalities in a pediatric population, using ERCP as the reference standard. This investigation used a clinical effectiveness approach defined as the diagnostic performance of a test in "real life" clinical circumstances (as opposed to clinical efficacy which is the diagnostic performance under more ideal circumstances, such as a clinical trial or retrospective study with expert readers) [30].

Methods and materials

Institutional review board approval was obtained for this retrospective, HIPAA-complaint investigation. The requirement for informed consent was waived.

Using Cincinnati Children's Hospital Medical Center Department of Radiology and Division of Gastroenterology, Hepatology & Nutrition records, we identified pediatric patients (≤18 years-old) who underwent both ERCP and MRCP within four weeks of each other between January 1, 2013 and May 15, 2017. If a patient had more than one instance where contemporaneous ERCP and MRCP were performed, only the initial pair of examinations was included in our study. Encounters were excluded if the ERCP was nondiagnostic or incomplete (e.g., due to failure to cannulate and/or inject the targeted biliary or pancreatic duct), as ERCP was the reference standard against which we would compare MRCP.

During the study period, ERCP was performed by a single board-certified Pediatric Gastroenterologist with formal ERCP fellowship training and seven years of clinical procedural experience (T.K.L.). MRCP examinations were performed according to predefined clinical protocols that included a coronal 3D fast spin-echo MRCP sequence as well as a variety of single-shot fast spin-echo sequences (axial and coronal thin slice (4–6 mm) and/or thick slab (4–5 cm)) that changed over the study period. MRCP studies were performed using 1.5 Tesla (Philips Healthcare, Best, the Netherlands; GE Healthcare, Waukesha, WI) and 3 Tesla (Philips Healthcare, Best, the Netherlands; GE Healthcare, Waukesha, WI) MR imaging systems. Imaging studies were clinically interpreted by a group (~ 15) of subspecialty-trained pediatric radiologists.

ERCP-procedure reports (which included both procedural findings and impressions) and MRCP reports were initially separately retrospectively reviewed by two investigators, a radiology resident (R.M.P.) and a subspecialty-trained pediatric radiologist with nine years' post-fellowship experience interpreting MRCP examinations (J.R.D.), to identify pertinent biliary and pancreatic findings. Any discrepancies in documented report findings between the two reviewers were resolved by a second subspecialty-trained pediatric radiologist with five years' post-fellowship experience interpreting MRCP examinations (A.T.T.). Pancreatobiliary findings documented included, but were not limited to duct dilatation (biliary and/or pancreatic), calculus, duct (biliary and/or pancreatic) stricture, multiple intrahepatic biliary strictures indicative of sclerosing cholangitis, congenital anomalies (e.g., pancreas divisum, annular pancreas, and choledochal cyst), anomalous pancreatobiliary junction (APBJ)/long common channel, and chronic pancreatitis. The presence of a calculus at ERCP required visualization of a filling defect with the pancreatic duct or biliary tree as well as stone retrieval (e.g., using a balloon sweep). Additional data extracted from ERCP and MRCP reports included: indication for imaging/procedure, date of imaging/procedure, duct(s) injected at ERCP (biliary, pancreatic, or both), and secretin use at MRCP. Electronic medical records (EPIC Systems Corporation; Verona, WI) were reviewed by a single investigator (R.M.P.) to document patient demographic data, including age and sex.

Statistical analysis

Continuous data were summarized as means and standard deviations, while categorical data were summarized as counts and percentages. Using ERCP as the reference standard (and considering only findings related to the duct system(s) injected), the diagnostic performance of MRCP was calculated, including sensitivity and positive predictive value (PPV). Diagnostic performance measures were calculated with 95% confidence intervals (CI) for all patients and all findings, by indication (e.g., biliary, pancreatic, or pancreatobiliary), and by duct injected at ERCP (biliary, pancreatic, or both). Specificity and negative predictive value (NPV) were not calculated as MRCP is generally used as a screening diagnostic test, and patients with negative examinations commonly do not go on to ERCP. Analyses were performed using GraphPad Prism7 (GraphPad Software; La Jolla, CA).

Results

A total of 508 MRCP exams were performed during the study period. 56 patients underwent MRCP with a comparative ERCP within four weeks. Two ERCP studies were aborted due to inability to cannulate the duct of interest, and these patients were excluded from our analysis. Of the 54 included patients, MRCP preceded ERCP for 38 patients and followed ERCP for 15 patients. MRCP and ERCP were performed on the same day for 1 patient. Mean time interval between ERCP and MRCP was 11.2 ± 9.7 days. Twenty-five of 54 (46%) patients were male. Mean patient age at the time of ERCP was 10.4 ± 4.9 years. Secretin (ChiRhoStim®; ChiRhoClin, Burtonsville, MD) was administered in 8 of 54 studies (15%) at the request of the ordering practitioner.

Common indications for ERCP included pancreatitis (including acute pancreatitis, acute recurrent pancreatitis, chronic pancreatitis, and evaluate for pancreas divisum) and pancreatitis-related complication (including main pancreatic duct stricture) ($n = 26$), biliary obstruction (including primary sclerosing cholangitis, choledocholithiasis, and common bile duct dilatation) ($n = 22$), suspected congenital pancreatobiliary anomaly (other than pancreas divisum) ($n = 3$), pancreatic trauma ($n = 2$), and biliary tumor ($n = 1$).

Diagnostic performance of MRCP versus ERCP

The diagnostic performance of MRCP versus ERCP for detecting pancreatobiliary abnormalities is presented in Table 1, with 95% confidence intervals. For detection of all pancreatobiliary findings, regardless of indication or injected ductal system ($n = 99$ findings based on ERCP), MRCP had

Table 1 Diagnostic performance of MRCP for detecting biliary and pancreatic findings, using ERCP as the reference standard

Analysis	Sensitivity (%) (95% CI) [N/D]	Positive predictive value (%) (95% CI) [N/D]
Overall patient population ($n = 99$ ERCP findings)	76.8 (67.5–84.0) [76/99]	81.7 (72.7–88.3) [76/93]
Biliary indication for MRCP ($n = 37$)	75.7 (60.0–86.6) [28/37]	84.9 (69.1–93.4) [28/33]
Pancreatic indication for MRCP ($n = 49$)	73.5 (59.7–83.8) [36/49]	78.3 (64.4–87.7) [36/46]
Both biliary and pancreatic indication(s) for MRCP ($n = 13$)	92.3 (66.7–99.6) [12/13]	85.7 (60.1–97.5) [12/14]
Biliary duct injection only ($n = 29$)	79.3% (61.6–90.1%) [23/29]	85.2% (67.5–94.1%) [23/27]
Pancreatic duct injection only ($n = 5$)	100% (56.6–100%) [5/5]	62.5% (30.6–86.3%) [5/8]
Biliary & pancreatic duct injection ($n = 65$)	73.9% (62.1–83.0%) [48/65]	82.8% (71.1–90.4%) [48/58]

$n = 99$ findings in 54 patients

CI confidence interval, *N/D* numerator/denominator

Table 2 True-positive (TP) MRCP findings from overall patient population, using ERCP as the reference standard

MRCP findings	MRCP TP (*n*)
Biliary dilatation	23
Biliary duct stone	8
Chronic pancreatitis	8
Main pancreatic duct stricture	6
Choledochal cyst	4
Pancreatic duct stone	4
Anomalous pancreatobiliary junction	3
Sclerosing cholangitis	3
Extra-hepatic biliary stricture	3
Cyst/fluid collection	2
Other ($n=1$)	12

$n=76$ findings

Table 3 False-positive (FP) MRCP findings from overall patient population, using ERCP as the reference standard

MRCP findings	MRCP FP (*n*)
Biliary duct stone	3
Chronic pancreatitis	3
Sclerosing cholangitis	3
Acute pancreatitis	2
Other ($n=1$)	6

$n=17$ findings

Table 4 False-negative (FN) MRCP findings from overall patient population, using ERCP as the reference standard

ERCP findings	MRCP FN (*n*)
Extra-hepatic biliary stricture	8
Pancreatic duct stone	4
Anomalous pancreatobiliary junction	2
Intrahepatic biliary stricture (s)	2
Other ($n=1$)	7

$n=23$ findings

a sensitivity of 76.8% (95% CI 67.5–84.0%) and a PPV of 81.7% (95% CI 72.7–88.3%).

The diagnostic performance of MRCP when performed for either a biliary or pancreatic indication was similar to the overall diagnostic performance. MRCP was 75.7% (95% CI 59.9–86.6%) sensitive with a PPV of 84.9% (95%: 69.1–93.4%) for biliary findings ($n=37$), and it was 73.5% (95% CI 59.7–83.8%) sensitive with a PPV of 78.3% (95% CI 64.4–87.7%) for pancreatic findings ($n=49$). For detecting findings on MRCP that were performed for both biliary and pancreatic (pancreatobiliary) indications ($n=13$), MRCP had a sensitivity of 92.3% (95% CI 66.7–99.6%) and PPV of 85.7% (95% CI 60.1–97.5%).

Diagnostic performance of MRCP based on whether only the pancreatic duct, only the biliary duct, or whether both ducts were injected at ERCP is presented in Table 1.

MRCP false positives and false negatives versus ERCP

True-positive, false-positive, and false-negative MRCP findings using ERCP as the reference standard are presented in Tables 2, 3, and 4, as well as Figs. 1, 2, and 3, respectively. The most common true-positive MRCP finding in our patient population was bile duct dilatation ($n=23$). Common false-positive MRCP diagnoses included bile duct calculus, chronic pancreatitis, and sclerosing cholangitis (all $n=3$). Common false-negative MRCP diagnoses included extra-hepatic bile duct stricture ($n=8$) and pancreatic duct calculus ($n=4$).

Discussion

Since ERCP was first introduced in 1968, it has remained a key diagnostic test and therapeutic modality for numerous pancreatobiliary pathologies. The introduction of MRCP in the early 1990s and subsequent advancements in hardware and pulse sequences have gradually allowed ERCP to play more of a therapeutic than diagnostic role [5, 12, 18, 26, 27, 31–33]. Some distinct advantages of MRCP over ERCP for purely diagnostic indications include its noninvasive nature, absence of ionizing radiation exposure, ability to evaluate the biliary and pancreatic ducts upstream of an obstructing stricture, ability to evaluate hepatic and pancreatic parenchyma, and ability to assess biliary-enteric anastomoses as well as the biliary system in the immediate postoperative period [34]. Multiple studies have demonstrated the diagnostic value of MRCP in adult populations. Fewer studies have been performed in the pediatric population [28, 35–37]. Reported sensitivities and specificities in the literature for MRCP compared to ERCP in adults range from 50–100% and 83–100%, respectively.

Our study has demonstrated that MRCP is moderately sensitive compared to ERCP in pediatric patients in a "real-life" clinical practice. Sensitivities were similar whether comparing our entire study population, patients undergoing MRCP for a biliary indication, or patients undergoing MRCP for a pancreatic indication (73.5–76.8%). Positive predictive values also were similar despite the MRCP indication (78.3–84.9%). Unfortunately, our study cannot determine the specificity of MRCP, as MRCP is typically used as a

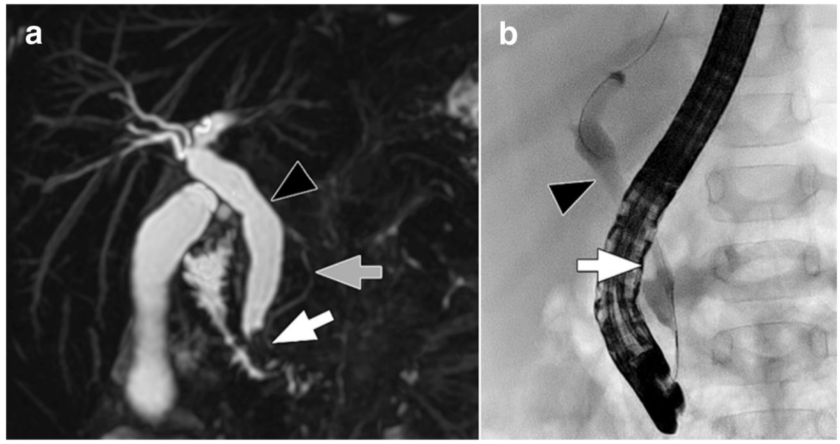

Fig. 1 True-positive MRCP in a 4-year-old boy with elevated liver function tests. **a** MRCP identified dilation of the common bile duct (black arrowhead) with a stone in the distal common bile duct (white arrow). The pancreatic duct is normal in caliber (grey arrow). **b** ERCP performed two days later confirmed the presence of both bile duct dilation (black arrowhead) and the stone (white arrow)

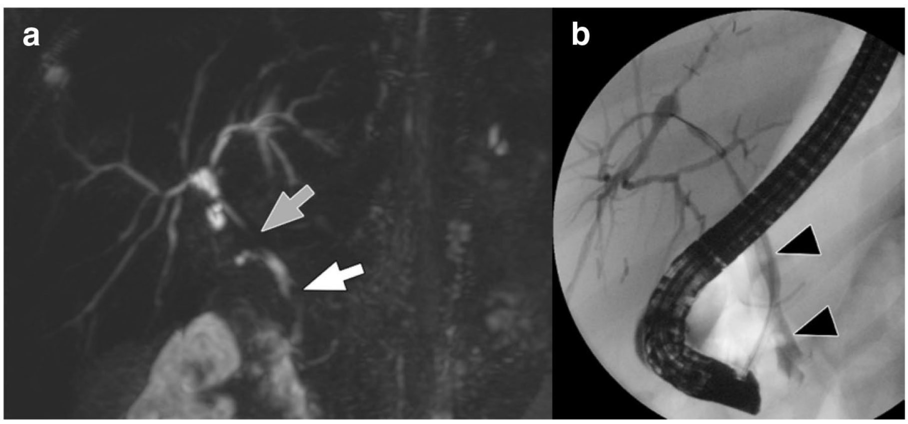

Fig. 2 False-positive MRCP in an 11-year-old girl with history of liver transplantation, now with elevated liver function tests. On MRCP **a**, the possibility of a common bile duct stricture (grey arrow) and common bile duct stone (white arrow) were raised. **b** ERCP performed nine days later showed no common duct stricture and no biliary duct stone. Ovoid filling defects on ERCP (black arrowheads) reflect gas bubbles introduced during the procedure

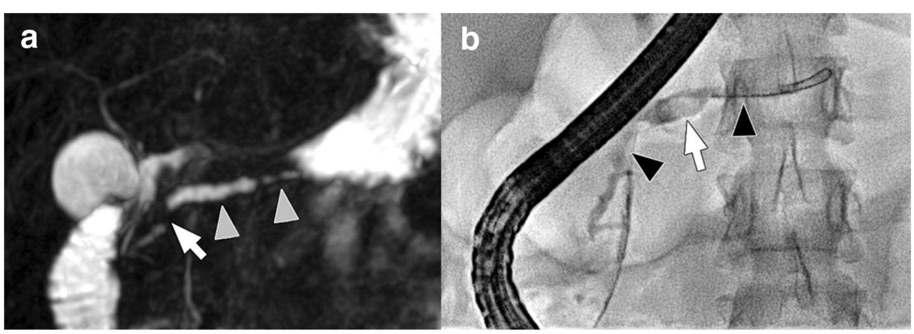

Fig. 3 False-negative MRCP in a 15-year old girl with chronic pancreatitis. Both MRCP (**a**) and ERCP (**b**, performed three weeks later) showed changes of chronic pancreatitis including pancreatic duct dilation and irregularity (arrowheads). A stone in the pancreatic duct identified by ERCP (white arrow) was not recognized on the MRCP. In retrospect, a filling defect is present in the pancreatic duct (white arrow) on MRCP that may reflect the stone

screening test and many children with a normal (or negative) MRCP examination never undergo subsequent ERCP evaluation.

A small retrospective study by Tipnis et al. in 32 children documented a higher sensitivity for MRCP than our study, with only one false-positive finding and no false-negative findings [37]. However, in their study, only 15 individuals (less than half the study population) had correlative ERCP or other reference study. Another study by Delaney et al. included 16 children that underwent both MRCP and ERCP, demonstrating MRCP–ERCP concordance in 13 of 16 (81%) individuals [36].

There were a variety of MRCP true-positive diagnoses when correlated with ERCP in our study. Biliary dilatation, by far, was the most common MRCP finding that was confirmed by ERCP. MRCP also commonly established other findings/diagnoses, including choledocholithiasis, chronic pancreatitis and main pancreatic duct stricture, choledochal cyst, pancreatic duct stone, and APBJ/long common channel.

Our study also has shown that MRCP may be falsely positive or negative compared to ERCP. The three most common MRCP diagnoses that were unconfirmed at ERCP were choledocholithiasis, intrahepatic bile duct abnormalities suggestive of sclerosing cholangitis, and chronic pancreatitis. It is conceivable that in some situations the bile duct filling defects seen at MRCP were real stones that spontaneously passed by the time of ERCP. The false-positive diagnoses of sclerosing cholangitis and chronic pancreatitis suggest that apparent pancreatobiliary narrowing and/or dilatation at MRCP may not actually be a significant or real finding in certain children, when using ERCP as the reference standard. In the setting of chronic pancreatitis, it is worth noting that MRCP may be the superior test as it also allows assessment of pancreatic parenchymal changes (e.g., atrophy, signal alterations) that may go undetected by ERCP.

The two most common observations made by ERCP that went undetected by MRCP were extra-hepatic biliary stricture and pancreatic duct stones. It is likely that ERCP is more sensitive for biliary strictures due to imaging of the common bile duct under pressure related to contrast material injection. Pancreatic stones also were relatively frequently missed. This could be due to small stone size, relative tortuosity of the pancreatic duct compared to the biliary tree making these stones difficult to detect, or simply radiologist inattention to the pancreatic duct lumen. Importantly, two instances of APBJ were not detected by MRCP. Missing this diagnosis can be clinically significant, particularly in children with mild extra-hepatic biliary dilatation that may represent a subtle type I choledochal cyst. It is conceivable that intravenous secretin administration could improve visualization of the pancreatobiliary junction region when there is concern for an anatomic abnormality in this region, thus eliminating such false-negative cases. Radiologist education regarding this entity and its clinical importance could also potentially decrease the rate of false-negative diagnosis.

Our study has limitations. First, it was retrospective in design and subject to recall bias based on the availability and completeness of ERCP and MRCP records. That said, there were no missing imaging reports or pertinent clinical data. Second, the clinical MRCP interpretations which were used to assess the clinical effectiveness of MRCP were provided by a relatively large group of dedicated pediatric radiologists that rotated through our body imaging division during the study period. However, this is a necessary limitation of a "clinical effectiveness" investigation. It is also likely that because of this limitation, the sensitivity and positive predictive value observed in our study underestimate those that would be observed in a clinical efficacy study (i.e., ideal conditions, such as a clinical trial with expert readers).

Third, the order of performance of MRCP versus ERCP and time between examinations varied between patients, indicative of real life. Fourth, our data did not allow us to adequately compare the diagnostic performance of MRCP at different field strengths (1.5 T vs 3T) in our pediatric patient population. We believe this should be the subject of future investigations. Fifth, our study design assumes that ERCP is the reference standard and superior test, although this is likely not true in certain instances (e.g., chronic pancreatitis, as mentioned above). Finally, there is no way to account for possible bias in examination interpretation related to availability of the report for the other examination at the time of interpretation.

In summary, MRCP is moderately sensitive in real-life clinical practice for detecting biliary and pancreatic abnormalities in the pediatric population. Our results show that MRCP can confirm the presence of numerous pancreatobiliary pathologies. However, our study also shows that MRCP false-positive and false-negative instances are common in clinical practice, and that there is room to improve the diagnostic performance characteristics of this examination in the pediatric population. Potential ways to improve the interpretation and diagnostic performance of pediatric MRCP include additional radiologist education, evaluating MRCP–ERCP concordance at the department level as a quality metric which would allow radiologists to identify errors and learn from them, and the potential use of secretin for all studies with a pancreatic indication.

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