



Complications of Endoscopic Retrograde Cholangiopancreatography in Pediatric Patients; A Systematic Literature Review and Meta-Analysis

Danielle Usatin, MD¹, Melissa Fernandes, MD¹, Isabel E. Allen, PhD², Emily R. Perito, MD^{1,2}, James Ostroff, MD³, and Melvin B. Heyman, MD¹

Objectives To systematically review risks and summarize reported complication rates associated with the performance of endoscopic retrograde cholangiopancreatography (ERCP) in children during the past 2 decades.

Study design A systematic literature search of MEDLINE, Embase, and Web of Science from January 1995 to January 2016 was conducted for observational studies published in English. Studies reporting ERCP complications in patients <21 years without history of liver transplant or cholecystectomy were included. A summary estimate of the proportion of children who experienced complications following ERCP was derived via a random effects meta-analysis.

Results Thirty-two studies involving 2612 children and 3566 procedures were included. Subjects' ages ranged from 3 days to 21 years. Procedures were performed for biliary (54%), pancreatic (38%), and other (8%) indications; 56% of ERCPs were interventional. The pooled complication rate was 6% (95% CI 4%- 8%). Procedural complications included post-ERCP pancreatitis (166, 4.7%), bleeding (22, 0.6%), and infections (27, 0.8%). The pooled estimate of post-ERCP pancreatitis was 3% (95% CI 0.02-0.05), and other complications were 1% (95% CI 0.02-0.05). In the subgroup with neonatal cholestasis, the pooled complication rate was 3% (95% CI 0.01-0.07). Adult and pediatric gastroenterologists and surgeons performed the ERCPs. Available data limited the ability to report differences between pediatric-trained and other endoscopists.

Conclusions Complications associated with pediatric ERCP range widely in severity and are reported inconsistently. Our review suggests 6% of pediatric ERCPs have complications. Further studies that use systematic and standardized methodologies are needed to determine the frequency and risk factors for ERCP-related complications. (*J Pediatr* 2016;179:160-5).

Endoscopic retrograde cholangiopancreatography (ERCP) is a specialized procedure that combines gastrointestinal endoscopy and fluoroscopy for diagnostic and therapeutic management of disorders of the pancreas and biliary tract. The procedure has been applied widely in adults for more than 40 years. The first reported procedure in a child was in 1976 by Waye, using an adult-sized duodenoscope.¹ Smaller-diameter duodenoscopes developed in the 1980s and 1990s led to expanding the application of ERCP to children. ERCP allows less invasive access to the biliary tree and pancreatic duct than surgery or transhepatic procedures.

Although the utility and feasibility of ERCP in pediatrics has been demonstrated in case reports and series, concerns about safety remain. In 2000, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition subcommittee on Endoscopy Procedures published a narrative review of data on indications, technical considerations, risks, and complications of ERCP in children.² Since that time, the number of ERCPs performed on children has increased.³ In addition, many additional studies on ERCP in pediatric patients have made this procedure appear routine. Complication rates, however, appear to vary between case series, potentially dependent on multiple factors, including patient selection, operator, and underlying disease factors.⁴⁻⁷ By conducting a systematic literature review, we examined complication rates for pediatric patients undergoing ERCP and compared complication rates by patient characteristics, endoscopist training, and center type.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (ie, PRISMA) I statement was used to identify and collate studies.⁸ We systematically searched MEDLINE/PubMed, Ovid Embase, and Web of Science for full text articles in which subjects <21 years of age underwent ERCP. Complications were reported as an outcome. We used the following search phrase ([technical AND

From the ¹Department of Pediatrics, University of California, San Francisco, CA; ²Department of Epidemiology and Biostatistics, University of California, San Francisco, CA; and ³Department of Medicine, University of California, San Francisco, CA

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ERCP	Endoscopic retrograde cholangiopancreatography
PEP	Postendoscopic retrograde cholangiopancreatography-associated pancreatitis

{success OR successes OR outcome OR outcomes} OR quality assurance OR patient safety OR complications OR treatment outcomes OR intraoperative complications OR postoperative complications] AND [{pediatric OR child OR children OR childhood OR adolescent OR teen OR infant OR toddler}] AND ["Cholangiopancreatography, Endoscopic Retrograde" OR Endoscopic Retrograde Cholangiopancreatography OR ERCP]) to identify articles.

To find articles that may have been missed during the literature search, reference lists of candidate articles also were reviewed. The search was limited to English-language texts from January 1995 to January 2016. The final search was completed on February 10, 2016. The limitation to studies published since January 1995 was to avoid overlap with a previously published review.²

Study Selection Criteria

Two independent reviewers screened all articles for methodological validity and relevance before inclusion in the review. Any disagreements between the 2 reviewers were resolved through discussion with a third reviewer. Our selection criteria were specified in advance and included the following: (1) published in English in a peer-reviewed journal; (2) available in full text; (3) included youth <21 years of age, excluding children who had undergone previous liver transplant or other hepatobiliary surgical procedure (eg, for choledochal cyst, cholecystectomy, for cholelithiasis); (4) observational study designs; and (5) studies that examined the number and type of complications after an ERCP. If multiple articles were available from a single center, the most recently published article or the article containing the most comprehensive detail of study characteristics was selected for review.

Article Review and Data Extraction

Data were extracted from papers included in the review with a standardized data extraction tool created for this study in REDCap (Research Electronic Data Capture) electronic data capture tools hosted at University of California, San Francisco.⁹ REDCap is a secure, Web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources. The data were extracted by 2 reviewers (D.U., M.F.). Once completed, any disagreements were arbitrated by a third reviewer (M.H.).

The data extracted included details about the study population, study methods, and outcomes of significance to the review question and specific objectives. The study center type, endoscopist type, anesthetic type, patient characteristics, indications and findings of ERCP, and percent of procedures that were interventional were collected. If not specifically stated in the manuscript, we attempted to determine the training background of the endoscopist by searching the Internet to identify current position within hospital system in adult or pediatric

gastroenterology program. This systematic review is registered on Prospero (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016038065).

Data Synthesis

Studies were categorized on the basis of the author, year of publication, subjects' age, procedure indication, and interventional or diagnostic procedure type. The complication prevalence for each study was summarized and compiled. Statistical analysis was performed with Microsoft Excel (Microsoft, Redmond, Washington) and STATA Version 13 (StataCorp LP, College Station, Texas). Significant variations in study design and reporting among included publications precluded use of a standard definition for post-ERCP complications. We performed a random effects meta-analysis of the data using the Metaprop program (STATA 13) to provide a summary estimate of the proportion of children with complications following ERCP. We chose random effects to account for the variability among the studies, given that most were case reports and case series. Metaprop allowed for the inclusion of studies with complication proportions of 0 to 1.¹⁰

In addition to the overall complication rate, secondary analyses were performed to further understand factors impacting the summary estimate. A subgroup analysis was performed on cases from US centers. In addition, a sensitivity analysis of all studies was performed following the exclusion of 3 papers that were felt to be outliers. Outliers were identified on the basis of the findings from the inclusive summary estimate. Finally, a random effects meta-analysis of the complications that excluded postendoscopic retrograde cholangiopancreatography-associated pancreatitis (PEP) was performed.

Literature Search Results

The PRISMA flow diagram was used to document the literature search process (Figure 1; available at www.jpeds.com). We identified 1932 articles and imported them into Endnote software (Thomas Reuters, Philadelphia, Pennsylvania). Duplicates were removed and any remaining duplicates were manually removed, leaving 1642 articles. A thorough review of all article titles and abstracts yielded 44 articles that were reviewed in full. Subsequently, 12 articles were excluded for the following reasons: not reporting complication rates, presentation of patients counted in other included study, and/or including patients who had undergone liver transplant or cholecystectomy. Of the studies that included patients with a mixture of patients who did and did not meet our exclusion criteria (n = 3), it was not possible to distinguish the complication rates. As such, the entire study was excluded. Ultimately, 32 articles were identified.^{4,7,11-38}

Results

All 32 included studies were retrospective cohort studies or case series reporting on ERCP-related complications in pediatric patients. From these articles, data were obtained on 2612 children and adolescents, who underwent a total of 3566 ERCPS. Some children accounted for multiple procedures

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