

Chapter 1. Introduction

This systematic review of the literature primarily addresses the diagnostic and therapeutic efficacy of endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic intervention in comparison with available alternative diagnostic or therapeutic techniques in specifically defined clinical settings. This section will outline the clinical scope of this review, highlight the relevant epidemiology and public health impact of the relevant pancreaticobiliary diseases, describe briefly ERCP and the available alternative techniques, and provide an overview of the major topics and key questions guiding this systematic review.

Scope of Systematic Review

The National Institutes of Health Office of Medical Applications of Research (OMAR) is convening a State-of-the-Science conference in January 2002 to discuss the role of endoscopic retrograde pancreatography (ERCP) in diagnosing and treating 4 specific pancreaticobiliary conditions: common bile duct stones, pancreaticobiliary malignancy, pancreatitis, and abdominal pain of suspected pancreaticobiliary origin. In addition, the conference will discuss risk factors relating to complications of ERCP.

Epidemiology and Public Health Impact of Pancreaticobiliary Disease

Diseases of the pancreas and biliary tree are common in the United States population with various anatomic or acquired conditions resulting in a variety of obstructive, inflammatory, neoplastic, or functional conditions. An estimated 6 per 100,000 people are afflicted with common bile duct stones, representing only a small fraction of those with gallstones (WebMD/Lycos, 1999). Malignancy of the pancreas, gallbladder, or extrahepatic biliary tract represents approximately 57,400 newly diagnosed cases in the United States each year (Greenlee, Hill-Harmon, Murray, et al., 2001), and the associated prognosis is usually poor. Pancreatitis can occur in an acute, acute recurrent, or chronic pattern and may be associated with a variety of causes, with common etiologic factors including alcohol consumption and choledocholithiasis (Greenberger, Toskes, and Isselbacher, 1994).

In patients with persistent abdominal pain of suspected pancreaticobiliary origin, where no structural abnormality has been identified, functional disorders including sphincter of Oddi dysfunction may be present. Finally, complications of ERCP, such as pancreatitis, hemorrhage, infection, or intestinal rupture, occur in approximately 8% of patients undergoing ERCP depending on the case mix of diagnostic and therapeutic ERCP (Cotton, Lehman, Vennes, et al., 1991). Improving the understanding of risk factors for ERCP-related complications may improve patient selection or lead to improved methods of preventing complications in those at highest risk.

Endoscopic Retrograde Pancreatography (ERCP)

Patients with suspected pancreaticobiliary pathology require diagnostic assessment of the pancreaticobiliary tract to establish the correct diagnosis. Diagnostic assessment frequently

includes imaging to detect the presence of dilation or narrowing of the ducts and to determine the cause of such morphologic changes.

Endoscopic retrograde pancreatography was first introduced for diagnostic evaluation of the pancreatic and biliary tree in the late 1960s. Using an endoscope inserted orally into the duodenum, a catheter can be placed into the biliary and/or pancreatic ducts for direct injection of radiographic contrast to provide X-ray images of the pancreaticobiliary ducts. Direct cholangiopancreatography can also be accomplished via a percutaneous transhepatic insertion of a needle or catheter with injection of radiographic contrast.

Noninvasive or less-invasive alternatives for imaging the pancreaticobiliary tree have been developed using magnetic resonance imaging, so-called magnetic resonance cholangiopancreatography (MRCP), ultrasound through an orally placed endoscope, so-called endoscopic ultrasonography (EUS), computed X-ray tomography often using specific biliary contrast agents, so-called computed tomography cholangiography (CTC), and nuclear medicine imaging with radiotracers specific to the biliary system, so-called biliary scintigraphy.

The endoscope used for ERCP can also be used selectively place catheters into the pancreaticobiliary ducts to obtain samples of pancreaticobiliary fluid or to deploy specialized tissue sampling devices (e.g., brush, fine-needle aspiration, forceps) to obtain cellular material for cytologic or histologic assessment. Alternative techniques for obtaining tissue samples for diagnosis include surgical biopsy, percutaneous fine-needle aspiration using imaging guidance, or endoscopic ultrasound guided fine-needle aspiration (EUS-FNA).

Once an accurate diagnosis has been established, surgical and nonsurgical treatment alternatives are frequently available. The ERCP scope permits access to the biliary tree to deliver endoscopic therapeutic interventions. Such interventions frequently include sphincterotomy of the sphincter of Oddi, which involves using an electrocautery device to cut and enlarge the opening of the pancreaticobiliary tract into the duodenum. Additional devices such as balloon catheters and specially designed wire baskets may be used to facilitate removal of duct stones, and specialized catheter insertion systems permit endoscopic placement of a variety of stents into the biliary or pancreatic ducts.

Key Questions for this Systematic Review

In preparation for the NIH State-of-the-Science conference on ERCP, an evidence-based assessment of the ERCP literature was commissioned through a partnership agreement with the Agency for Healthcare Research and Quality Evidence-based Practice Center program. This report outlines 5 major topics selected for discussion at the NIH OMAR ERCP State-of-the-Science conference. For each major topic, several key questions have been designed to specifically address the most pertinent diagnostic and therapeutic issues.

Topic 1: In patients with known or suspected common bile duct stones,

- a. What is the diagnostic performance of ERCP in detecting common bile duct stones in comparison to alternatives (e.g., EUS, MRCP, or CTC)? (*Section 1: Diagnostic Performance of ERCP in Detecting Common Bile Duct Stones – Comparison to Alternatives*)
- b. What are the outcomes of treatment using ERCP strategies compared to using surgical or medical management? (*Section 2: Outcomes of Treatment Using ERCP for Common Bile Duct Stones – Comparison of Strategies Using ERCP, Surgery, or Medical Management*)
- c. What is the diagnostic value of individual risk factors or predictive models for assessing the likelihood of having a common bile duct stone? (*Section 3: Diagnostic Value of Individual Risk Factors or Predictive Models for Assessing the Likelihood of Having a Common Bile Duct Stone*)

Topic 2: In patients with known or suspected pancreaticobiliary malignancy,

- a. What is the diagnostic performance of ERCP tissue sampling techniques, in establishing a tissue biopsy diagnosis of pancreaticobiliary malignancy in comparison to each other or alternative nonsurgical tissue sampling techniques (e.g., endoscopic ultrasound-guided fine-needle aspiration (FNA) or percutaneous FNA)? (*Section 1: Diagnostic Performance of Nonsurgical Tissue Sampling Techniques in Pancreaticobiliary Malignancy – Comparison of Strategies Using ERCP, EUS, or Percutaneous Approach*)
 - b. What is the diagnostic performance of ERCP, in diagnosing the presence of malignant pancreaticobiliary obstruction in comparison to other imaging alternatives (e.g., EUS or MRCP)? (*Section 2: Diagnostic Performance of ERCP in Pancreaticobiliary Malignant Obstruction – Comparison To Alternatives*)
 - c. What are the outcomes of treatment using ERCP strategies to treat malignant pancreaticobiliary obstruction compared to using surgical or interventional radiology treatment? (*Section 3: Outcomes of Treatment Using ERCP for Palliation of Pancreaticobiliary Malignancy – Comparison of Strategies Using ERCP, Surgery, or Interventional Radiology; A. Comparison of ERCP stent versus Surgical Bypass; B. Comparison of Metal vs. Plastic stents During ERCP; C. Additional Comparisons of ERCP Strategies*)
- (*Section 4: Outcomes of Treatment Using Preoperative ERCP Drainage for Relief of Malignant Obstructive Jaundice*)

Topic 3: In patients with pancreatitis,

- a. What is the diagnostic performance of ERCP in detecting underlying causes or complications of pancreatitis that are amenable to treatment in comparison to alternatives (e.g., EUS or MRCP)? (*Section 1: Diagnostic Performance of ERCP in Detecting Underlying Causes or Complications of Pancreatitis Amenable to Treatment – Comparison to Alternatives*)

b. What are the outcomes of treatment using ERCP strategies compared to using surgical or medical therapy? (*Section 2: Outcomes of Treatment Using ERCP for Pancreatitis – Comparison of Strategies Using ERCP, Surgery, or Medical Management*)

Topic 4: In patients with abdominal pain of possible pancreaticobiliary origin ,

a. What is the diagnostic performance of ERCP with sphincter of Oddi manometry in identifying a pancreaticobiliary origin of pain in comparison to alternatives (e.g., biliary scintigraphy, EUS, or MRCP)? (*Section 1: Diagnostic Performance of ERCP Manometry in Evaluation of Abdominal Pain of Possible Pancreaticobiliary Origin – Comparison To Alternatives*)

b. What are the outcomes of treatment using ERCP strategies compared to using surgical or medical therapy? (*Section 2: Outcomes of Treatment Using ERCP for Abdominal Pain of Possible Pancreaticobiliary Origin*)

Topic 5: What patient, procedure, or provider factors are determinants of adverse events of ERCP?

(*Section 1: Multivariable Analyses*)

(*Section 2: Randomized, Controlled Comparison Trials*)