Endoscopic Treatment of Acute Biliary Diseases: Have We Optimized the Value of Inpatient Endoscopic Retrograde Cholangiopancreatography?

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Endoscopic retrograde cholangiopancreatography (ERCP) developed as a novel imaging modality for the pancreatobiliary tree in an era when cross-sectional imaging was extraordinarily limited. Now principally a therapeutic procedure, ERCP with biliary sphincterotomy, stone extraction, and stent placement has transformed the management of acute cholangitis, choledocholithiasis, and selected patients with acute gallstone pancreatitis. These indications have lower risk and complexity compared with other reasons for ERCP, yet at least 5%–10% of cases still result in technical failure or complications despite recent advances in the prevention of post-ERCP pancreatitis. Among high-risk patients, these include the use of prophylactic pancreatic duct stents, rectal indomethacin, and perhaps greater intravenous volume infusion.[1–4] Analyzing 166,438 admissions derived from the Nationwide Inpatient Sample (NIS), James et al[5] report significant reductions from 1998 to 2008 in same-stay mortality and ERCP failure rates among patients admitted for acute cholangitis, choledocholithiasis, or acute pancreatitis, henceforth referred to as acute biliary diseases. Have we optimized the delivery of inpatient ERCP services?

Decreasing Inpatient Mortality From Acute Biliary Diseases

Perhaps the most important message from this article is that inpatient mortality decreased from 1.1% in 1998 to 0.6% in 2008; there was a 22% relative reduction in unadjusted inpatient mortality when comparing the first 5 years (1998–2002, mortality rate = 0.9%) with the latter 6 years (2003–2008, rate = 0.7%). This is statistically and clinically significant, especially considering that patients with 3+ comorbidities increased over time. During the same period there was a 31% relative increase in inflation-adjusted and morbidity-adjusted charges from $33,810 to $44,295. Whereas negative patient factors could be anticipated (older age and comorbidities), the only technical factors associated with increased mortality were the need for open cholecystectomy (adjusted odds, 3.4; 95% confidence interval, 2.7–4.3) and unsuccessful ERCP (adjusted odds, 1.7; 95% confidence interval, 1.4–2.2). The former suggests more complex gallbladder disease at the time of presentation or lack of laparoscopic expertise locally. Insufficient training in laparoscopy is actually much less prevalent than inadequate exposure of surgical residents to open cholecystectomy and common bile duct exploration techniques.[6] Thus, the association of

open cholecystectomy and higher mortality is probably driven by a higher prevalence of complex gallbladder pathology in this subgroup. Why does unsuccessful ERCP connote a higher risk of inpatient mortality? Patients having unsuccessful ERCPs may have more severe periampullary inflammation that obliterates the papillary orifice (ie, more severe acute biliary pancreatitis), or the failed ERCP precipitated iatrogenic complications. In either case, ERCP success or perhaps avoidance would have improved outcomes on the basis of the analysis by James et al.[5]

Unsuccessful Inpatient Endoscopic Retrograde Cholangiopancreatographies: Have We Improved?

A notable strength of this study is the authors' use of the NIS, the largest all-payer database in the United States that includes discharge data from the full spectrum of acute care facilities. Importantly, this cohort includes facilities providing ERCP services with varying annual volume. Varadarajulu et al[7] undertook a similar analysis of ERCPs derived from the NIS between 1998 and 2001 and concluded that low-volume facilities, defined as fewer than 50 ERCPs/year, had longer hospitalizations (8.4 days) and higher failure rates (6.0%) compared with the highest-volume strata (6.7 days and 4.7%, respectively), after adjusting for comorbid conditions. In both studies the authors chose a stringent definition of ERCP failure, which was need to perform percutaneous transhepatic cholangiography or surgical exploration of the bile duct during the same hospitalization. Many failed ERCPs are managed with a second, repeat ERCP after a short interval or sent to a higher-volume facility for a second attempt.[8,9] Alternatively, patients may be managed conservatively without ever requiring a second intervention to drain their common bile duct.[10] Although the NIS broadly represents U.S. health care facilities (good external validity), readmission rates and follow-up testing such as repeating an outpatient ERCP after a short interval cannot be measured because each hospitalization is considered a unique event.

The authors excluded 75% of admissions for acute biliary diseases without same-stay ERCP. This is a reminder that early ERCP is only proven to improve outcomes from acute gallstone pancreatitis in the setting of concomitant acute cholangitis or severe pancreatitis with biliary obstruction; many patients with choledocholithiasis often present with symptoms related to a passed common bile duct stone. Clinicians should use endoscopic ultrasound and magnetic resonance cholangiopancreatography to minimize the use of diagnostic ERCP. By excluding admissions without same-stay ERCP, we cannot extrapolate the impact of same-stay ERCP on hospital length of stay or inpatient mortality. It would have been interesting to report trends in the use of same-stay ERCP for acute biliary diseases. Many of the trials and meta-analyses defining the selected subgroups likely to benefit from early ERCP were published between 1998 and 2008[11]; perhaps inpatient ERCP is used less for these indications. The authors' comparison of outcomes and costs related to the use of early ERCP mixes 2 patient populations, one very likely to improve from early ERCP (acute cholangitis)[12,13] and another where only the minority benefit (acute pancreatitis).[14]

Optimizing the Value of Inpatient Endoscopic Retrograde Cholangiopancreatography Services

Unsuccessful ERCP, but not ERCP facility volume, was associated with higher inpatient mortality. However, it is not clear from the analysis whether facility ERCP volume was independently associated with unsuccessful ERCP. Should we conclude that a minimum volume standard for ERCP is unnecessary, contrary to other procedures where an inverse relationship between provider or facility volume and outcomes is established?[15–20] In a related retrospective cohort study of >16,000 ERCPs for all indications derived from a regional health information exchange, unsuccessful ERCPs were significantly more likely when the index procedure was performed by an endoscopist performing the equivalent of <117 ERCPs/ year.[8] Of greater concern is that nearly 90% of ERCP providers in this study —and across the United States—fall at or below this annual volume threshold. Nevertheless, it is encouraging to note that failed ERCPs by using the authors' stringent definition decreased from 5% to 4%, and fewer ERCPs were performed in lower-volume (<100 ERCPs/year) facilities during the latter 6-year period (2003–2008, 30% vs 35% from 1998– 2002). This suggests a favorable trend for the concentration of ERCP services in higher-volume units. It is still befuddling that one-third of ERCP facilities in the United States perform fewer than 2 ERCPs/week. The interaction of provider and facility ERCP volume requires further investigation.

A second and perhaps equally important benchmark of ERCP quality is the provision of services during the procedure. With improvements in less invasive imaging modalities, ERCP should be a therapeutic procedure in the vast majority of patients with acute biliary diseases. The rates of purely diagnostic ERCP decreased from 29% in 1998 to 10% in 2008. On the other hand, why did only 32% of patients undergoing a same-stay ERCP for acute cholangitis, choledocholithiasis, and acute biliary pancreatitis have removal of gallstones? This suggests an unacceptably high rate of individuals underwent ERCP after spontaneous passage of a stone, which represents the majority of cases of acute biliary pancreatitis and symptomatic choledocholithiasis. One can only assume that many of the ERCPs analyzed in this cohort could have been avoided altogether.

James et al[5] present an important update on the epidemiology of acute biliary diseases and related inpatient ERCP in the United States; their observations provide several reminders that the value (ie, outcome for each dollar spent[21]) of ERCP services needs improvement. Unsuccessful ERCPs represent an independent risk factor for inpatient mortality and prolonged hospitalizations. Only one-third of inpatient ERCPs for acute cholangitis, choledocholithiasis, and presumed biliary pancreatitis resulted in extraction of a common bile duct stone, the *sine qua non* for >90% of inpatient ERCPs performed for these indications. By using a highly stringent definition in this study, ERCP failure rates have not decreased sufficiently; in fact, there appears to be a steady increase in failed ERCPs referred to higher-volume units, an outcome that would not be easily recognizable in the NIS.[9] Although the "ERCP denominator," approximately 500,000 cases performed annually, is not as great as colonoscopy, more than 10 million cases annually, I would argue that a failed ERCP is more likely to result in short-term and long-term sequelae than a suboptimal

colonoscopy. In an effort to provide the best care at a lower cost, facility and endoscopist outcomes from ERCP should be transparent to insurers and patients as the U.S. health care system transitions from a fee-for-service to a pay-for-performance system. In the United States, ERCP services should be concentrated in population-dense regions while developing creative systems to expand access to ERCP in rural regions.[22]

Summary

James et al[5] provide convincing evidence that hospital outcomes from acute biliary diseases have improved. However, unsuccessful ERCPs performed for these indications have significant consequences, including higher inpatient mortality. Appropriate utilization of inpatient ERCP saves lives, whereas its overuse and poor execution have grave results.

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