

8-18-2009

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Recommended Citation

Wenner, Donald; Jason Degani; Paul Whitwam; David Turner; James Rosser; Huining Kang; and Sally Fortner. "LCBDE Less Risky to Pancreas than ERCP." (2009). <https://digitalrepository.unm.edu/ume-research-papers/55>

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LCBDE Less Risky to Pancreas than ERCP

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Running Head: "LCBDE Less Risky to Pancreas than ERCP"

Keywords: Cholecystectomy, ERCP, Gall, Pancreatic, Technical:Surgical, CBD

Disclosures

Donald Wenner, MD FACS is a general surgeon in Roswell, NM and is the inventor of the Multiple Instrument Guide, a device marketed for use in laparoscopic common bile duct exploration. He currently owns the patent on this device and is a co-owner of LapSurgical Systems, LLC which manufactures and sells the Multiple Instrument Guide.

Jason Degani is a medical student at the University of New Mexico School of Medicine and has worked alongside Dr. Wenner in his surgery practice and assisted with previous research publications. He also designed the LapSurgical Systems, LLC website.

There are no other disclosures to report.

Abstract

Background: This study was undertaken to evaluate the safety and efficacy of LCBDE compared to ERCP. Special focus was placed on the post-operative incidence of pancreatitis after LCBDE in order to demonstrate that the procedure is less likely than ERCP to cause pancreatitis and its associated morbidity and mortality.

Methods: A comprehensive chart review was conducted on 140 consecutive patients undergoing LCBDE from January 2001-December 2006. The surgeons in this study are all proficient at LCBDE using both trans-cystic and choledochotomy techniques. Complication rates were analyzed for statistical significance. Clinical evidence and laboratory results including pre and post-operative amylase levels were analyzed to determine the incidence of pancreatitis caused by LCBDE.

Results: No cases of clinical pancreatitis were identified in any of these patients after the LCBDE procedure. The post-LCBDE amylase was significantly lower than the pre-LCBDE amylase. 1 case of post-LCBDE pancreatitis was identified using diagnostic guidelines of serum amylase above 3 times normal (375 U/L), for a total incidence of 0.71% (95% confidence interval 0.018%-3.92%). This incidence is significantly less than the 7-15% incidence reported for ERCP ($p=0.00045$). Successful stone clearance was accomplished in 96% ($n=134$) of cases. 19 patients presented with gall stone pancreatitis prior to undergoing LCBDE. In none of these patients was the post-LCBDE amylase level greater than the preoperative level. The most common complications due to LCBDE included a 2.9% ($n=4$) incidence of bile leakage, a 2.9% ($n=4$) incidence of T-tube dislodgement, and a 1.4% ($n=2$) incidence of cellulitis at the drain site.

Conclusions: LCBDE is found to be superior to ERCP in terms of the rate of serious complications, particularly that of post-operative pancreatitis. Because of the morbidity and mortality associated with pancreatitis, we conclude that LCBDE should be further investigated as a viable and potentially safer approach to the remediation of choledocholithiasis.

Introduction

Over 600,000 cholecystectomies are performed annually, making it the most common elective abdominal surgical procedure in the United States [1]. Of these, 10-15% are complicated by choledocholithiasis, defined as the presence of stones within the common bile duct (CBD) [2]. Endoscopic Retrograde Cholangio-Pancreatography (ERCP) with sphincterotomy has become the standard treatment for choledocholithiasis and is often an effective means of clearing stones from the CBD. In this procedure, a GI specialist passes a side viewing endoscope through the patient's mouth, esophagus, and stomach and into the duodenum. The Ampulla of Vater is visualized and x-ray contrast material is injected into the CBD and/or pancreatic duct for visualization of stones. Stone extraction generally necessitates Endoscopic Retrograde Sphincterotomy (ERS), which consists of cutting the sphincter of Oddi to allow stone passage.

Successful removal of stones by ERCP with ERS is accomplished in about 96% of cases [3]. However, the success rate falls to 80-90% in difficult cases such as when stones are large and/or impacted, with 20-30% of these patients requiring more than one session [4]. Recurrent bilirubinate duct stones occur in 6-12% of patients [5-6], and may be caused by bacterial colonization of the ducts due to ablation of the sphincter mechanism [5]. Concerns have also been raised about the elevated risk of cholangiocarcinoma following sphincterotomy, also due to bacterial reflux up the biliary tree causing chronic cholangitis [7]. Also, the need for x-ray visualization throughout most of the procedure results in significant radiation exposure for both the patient and the physician. Most troubling about ERCP, however, is its tendency towards serious complications. The most common of these is acute pancreatitis, defined as elevation of serum amylase levels at least 3 times that of normal along with clinical signs of pancreatitis including severe abdominal pain, nausea, emesis, fever, and tachycardia [8]. This complication occurs after 7-15% of all ERCP procedures with severe life-threatening pancreatitis occurring in about 1% of all cases [9-10]. Because of these serious complications, 2-3% of all patients undergoing ERCP can expect a prolonged hospital stay [11]. 0.4% of all patients undergoing ERCP die from the procedure [12].

Laparoscopic Common Bile Duct Exploration (LCBDE) is a surgical solution to choledocholithiasis. Using minimally invasive surgical techniques, the surgeon gains access to the CBD either by passing a flexible choledochoscope through the cystic duct (trans-cystic approach) or through a small incision in the CBD (choledochotomy approach). The CBD may be visualized by the surgeon in real time and stones may be identified and removed by a variety of methods. Such methods include the deployment of irrigation catheters to flush the

stones out, using balloon catheters inflated behind the stone and retracted, or using stone baskets to trap and remove the stones. Impacted stones may be fractured by the use of lasers or electrohydraulic lithotripters, and the fragments may then be removed by the previous techniques. The trans-cystic approach is preferred by many surgeons, as it is less invasive than choledochotomy; access through the cystic duct is already provided during cholecystectomy, so no further invasion into the CBD is necessary, no laparoscopic suturing is required, and there is no need for placement of a T-tube for CBD drainage. The limited size of the cystic duct is a disadvantage, however. Only one tool may be deployed through the working channel of the choledochoscope and into the CBD at a time, and the stones to be removed must be smaller than the diameter of the cystic duct. Thus, large or impacted stones are difficult to remedy using the trans-cystic technique. The choledochotomy approach is more invasive, requires laparoscopic suturing skills, and may necessitate the placement of a T-tube for CBD drainage if the surgeon is uncomfortable with the adequacy of primary closure or in difficult cases involving adhesions, cholangitis, or a severely dilated CBD. Advantages of choledochotomy include the ability to simultaneously deploy multiple tools into the CBD and virtually no limitation on stone diameter. In this way, multiple, large, and impacted stones may be dealt with more effectively and efficiently. Choice of surgical technique is left to the discretion of the surgeon and depends on the location and size of the CBD stones, as well as the expected difficulty of the case.

LCBDE has been demonstrated in controlled studies to be as effective as ERCP in the clearance of CBD stones [13-14]. There is no need for long exposure to ionizing radiation, and the ampullary sphincter is left intact. LCBDE also results in significantly shorter hospital stays compared to ERCP [13-14]. If the surgical team practices routine cholangiography during cholecystectomy as is suggested [15-16], CBD stones may be identified and the decision made to proceed with concurrent LCBDE. This allows both cholelithiasis and choledocholithiasis to be rectified in a single minimally invasive surgical procedure and eliminates the need for costly transfers to another physician or facility. This is especially useful when CBD stones are identified during routine cholecystectomy at a freestanding ambulatory care center, as LCBDE can be safely and effectively performed in an ambulatory setting [17]. Not only may both conditions be treated in a single procedure, but such patients generally remain able to return home the same day. Treating the condition when found may lead to significant cost savings for both the patient and the healthcare system at large.

Of course, the most important consideration when comparing two competing procedures should always be safety. With this in mind, our goal was to compare the incidence of complications after ERCP to those of LCBDE

in an effort to better understand their respective risk profiles. We were specifically interested in evaluating the post-LCBDE incidence of pancreatitis, the most common and potentially debilitating complication of ERCP.

Materials and Methods

A comprehensive chart review was conducted on 140 consecutive LCBDE procedures taking place from January 2001 to December 2006. All procedures were performed by Drs. Wenner, Whitwam, or Turner in Roswell, NM at one of three surgical venues: Eastern New Mexico Medical Center (Inpatient), Eastern New Mexico Medical Center (Outpatient), or the Center for Ambulatory Surgery and Endoscopy (Outpatient). The surgeons in this study are all proficient at LCBDE using both transcystic and choledochotomy techniques. Relevant information from the patient charts was entered into a database, including surgical technique used, data on pre and post-operative laboratory values, operative time, pathologic findings, and success/complication rates. Entered data was analyzed for statistical significance. Finally, clinical evidence and laboratory results including pre and post-operative amylase levels were analyzed to determine the incidence of pancreatitis caused by LCBDE.

This research protocol was reviewed and approved by both the Human Research Review Committee (HRRC) and the Conflicts of Interest Committee (COIC) at the University of New Mexico. The COIC approved the research protocol with the addition of a 10% third-party chart audit to ensure accuracy of the patient information entered into the database and to minimize any possible conflicts of interest due to Dr. Wenner's participation in a company that does business related to LCBDE. This chart audit was conducted to satisfaction by Dr. Fortner, and permission was granted to proceed.

Results

Mean operative time was 121 min. (median 115, range 51-270). Multiple stones were encountered in 47% (n=66) of cases, stones larger than 8cm were encountered in 31% (n=43) of cases, and stones were impacted in 37% (n=52) of cases. 2 cases (1.4%) were converted to open common bile duct exploration secondary to adhesions (1) and aberrant anatomy (2). Successful single-stage remediation of stones was accomplished in 96.4% (n=135) of cases.

Post-op amylase was greater than pre-op amylase in 11.4% (n=16) of cases. In all but one of these cases the post-op amylase values were below 249 U/L, far below the 375 U/L required for diagnosis of pancreatitis. The remaining case showed a pre-op amylase of 93 U/L and post-op amylase of 467 U/L. Interestingly, this patient did not demonstrate any clinical signs of pancreatitis and made an uneventful recovery. 19 cases demonstrated pancreatitis at the time of undergoing LCBDE (mean pre-op amylase 1633 U/L, median 1277, range 404-3860). Of these, 95% (n=18) demonstrated resolution of their pancreatitis after LCBDE (mean post-op amylase 114 U/L, median 105, range 22-293). The remaining case experienced a reduction in amylase from 2493 to 537 U/L. Mean pre and post-op amylase levels overall were 327 U/L (median 75, range 21-3866) and 88 U/L (median 57, range 19-537), respectively.

Given our single case of elevated amylase attributable to the procedure, we estimate a 0.71% incidence of pancreatitis after LCBDE (95% confidence interval 0.018%-3.92%). This value is significantly less than the 7-15% incidence of pancreatitis reported for ERCP (p=0.00045). As pancreatitis is associated with significant morbidity and mortality, we believe this to be an important distinction between ERCP and LCBDE that should be considered when evaluating the two procedures.

Our overall complication rate was 11.4% (n=16). 2.9% (n=4) of cases developed post-operative bile drainage. Of these cases, 2 resolved without intervention, 1 occurred after T-tube removal and required percutaneous drain placement, and 1 occurred in a patient in which the choledochotomy had been closed primarily and necessitated laparoscopic T-tube placement. 2.9% (n=4) of cases experienced dislodgement of their T-tube. No complication resulted in 3 of these cases, as the T-tube was simply removed with no other intervention required. 1 case involved patient non-compliance and patient self-removal of the T-tube resulting in cholangitis. 1.4% (n=2) of cases developed cellulitis around the drain site which responded to oral antibiotics. 0.71% (n=1) of cases experienced bleeding during the procedure. This patient had recently been treated with Clopidogrel. 0.71% (n=1) of cases experienced post-operative urinary retention requiring placement of a Foley catheter. 0.71% (n=1) of cases experienced post-operative dehydration requiring IV fluid replacement. This was likely due to insufficient fluid intake and water losses through bile drainage. 0.71% (n=1) of cases required readmission to the hospital for a lower lobe pneumonia. 0.71% (n=1) of cases experienced a mild post-operative MI, likely due to preexisting coronary arterial blockage and increased cardiovascular stress due to the operation. Finally, we include in this total the 0.71% (n=1) incidence of pancreatitis as discussed above. There was no mortality (n=0) in this study.

Discussion

LCBDE is clearly superior to ERCP in terms of the risk of pancreatitis, having demonstrated a significantly smaller incidence of this complication. This is likely accounted for by the fact that LCBDE inflicts significantly less trauma to the pancreatico-duodenal sphincter by nature of its more caudal approach to the CBD. Our rate of 96.4% success in single-stage remediation of CBD stones is in agreement with most published studies evaluating the success of LCBDE and is equal to the success rates published for ERCP. Excluding those above complications which can be considered “minor inconveniences” (bile drainage that resolved without intervention or uncomplicated T-tube dislodgement) or unrelated to the procedure (pneumonia), our overall complication rate falls to 7.1%. In terms of these rarer complications, our study lacks sufficient power to demonstrate a statistically significant benefit over ERCP. Also, this study is incapable of making any statement on whether the complication profile of LCBDE or the capability to concurrently treat both cholelithiasis and choledocholithiasis in a single procedure leads to any remarkable differences in morbidity, mortality, or overall cost of treatment. It is our hope, however, that other physicians and clinical researchers will take these findings as an opportunity to further investigate LCBDE as a useful and potentially safer alternative to ERCP.

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