Optimum cystic duct closure: a comparative study using metallic clips, ENSEAL, and ENDOLOOP in swine

Derek Mcvay, D.O., Daniel Nelson, D.O., Christopher R. Porta, M.D., Kelly Blair, M.D., Matthew Martin, M.D.*

Department of Surgery, Madigan Healthcare System, Madigan Army Medical Center, 9040-A Fitzsimmons Avenue, Tacoma, WA 98431, USA

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Abstract

BACKGROUND: Metal clips are commonly used to secure the cystic duct during cholecystectomy, although use of an ENDOLOOP (Ethicon Endo-Surgery, Blue Ash, OH) is often touted as a more secure closure when postoperative endoscopic retrograde cholangiopancreatography (ERCP) is anticipated. The objective of this study was to test the strength of 3 different cystic duct closure methods in a model simulating postoperative biliary insufflation.

METHODS: The extrahepatic biliary system, including common bile duct, gallbladder, and cystic duct, was harvested en bloc from 22 swine postmortem. A cholecystectomy was performed and the cystic duct was secured using 1 of 3 randomly assigned methods: metallic clips (Ethicon Endo-Surgery), an ENDOLOOP (Ethicon Endo-Surgery), or an ENSEAL tissue sealing device (Ethicon Endo-Surgery). The common bile duct was cannulated with a pressure-monitoring system and insufflated with air. The burst pressures, location of rupture, and size of the common bile duct and cystic duct were recorded and compared.

RESULTS: There were 7 pigs each in the ENDOLOOP and ENSEAL groups and 8 in the metallic clip group, with no statistical significance between cystic and common bile duct size. Mean burst pressure was 432 mm Hg for metallic clips, 371 mm Hg for the ENDOLOOP, and 238 mm Hg for the ENSEAL device ($P = .02$). Post hoc analysis revealed clips to be statistically superior when compared with the ENSEAL ($P = .01$). There was no statistical difference between the ENDOLOOP and metallic clips or between the ENDOLOOP and the ENSEAL.

CONCLUSIONS: All 3 closure methods successfully secured the cystic duct, with mean burst pressures exceeding 195 mm Hg. Metallic clips demonstrated the highest burst pressures and no cystic duct stump leaks. This study challenges the traditional dogma of additionally securing the cystic duct with an ENDOLOOP when postoperative biliary instrumentation is expected and also suggests that an adequately secure closure may be obtained with thermal sealing devices.

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ENSEAL devices were provided by Ethicon Endo-Surgery, Blue Ash, OH.

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* Corresponding author. Tel.: +1-253-968-2361; fax: +253/968-5900.

E-mail address: matthew.martin1@us.army.mil

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Laparoscopic cholecystectomy (LC) is the current gold standard for the surgical treatment of gallstone disease. The usual practice for an uncomplicated LC at most institutions is to secure both the cystic duct and cystic artery with metallic clips, although several studies have examined alternative methods and devices for cystic duct closure. Of particular concern is possible clip dislodgment in a situation in which early postoperative endoscopic retrograde cholangiopancreatography (ERCP) is indicated to treat known or suspected retained common bile duct stones or ductal injury. The need for intraluminal insufflation and the injection of intraductal contrast medium during ERCP are often-cited risk factors for dislodging the cystic duct clips, resulting in postoperative bile leak and associated morbidity or need for reoperation.

In the event that postoperative ERCP is likely, a common practice is to secure the cystic duct with an ENDOLOOP (Ethicon Endo-Surgery, Blue Ash, OH) instead of standard clips. This practice has also been promulgated in multiple surgery textbooks. However, there is a paucity of scientific literature and available data to support this as a standard of care. Most studies documenting specific postoperative complications of ERCP list pancreatitis and perforation as the most common complications and do not clearly address biliary leak. Regardless of the cause, bile injuries or leaks after LC occur in approximately 1% of cases and can result in significant morbidity and added costs.

Another alternative for securing the cystic duct is an energy device, such as the HARMONIC SCALPEL (Ethicon Endo-Surgery) or LigaSure (Covidien, Boulder, CO). These devices offer the attractive alternative of being multipurpose because they can potentially secure both the duct and the artery and perform the tissue dissection with a single instrument. The purpose of the current study was to evaluate and compare the strength and security of cystic duct closure using metallic clips, the ENDOLOOP, and the ENSEAL devices in a large animal model of cholecystectomy with simulation of postoperative biliary insufflation.

Methods

Twenty-two Yorkshire swine were included in this study. These animals were part of a larger trauma resuscitation protocol and were used for this study at the time of euthanasia. ENSEAL devices were provided by Ethicon Endo-Surgery; however, they did not have a part in funding, research design, or manuscript drafting. Animals underwent midline laparotomy, and the gallbladder and entire extrahepatic biliary system were harvested en bloc. Exclusion criteria included any aberrant anatomy of the cystic duct or common bile duct, injury to the biliary tree during harvest, or any other abnormality compromising the involved tissue. Blunt and sharp dissection of the cystic duct was then performed to isolate an adequate segment for division, similar to a standard cholecystectomy. The cystic duct and common bile duct length and diameter were then measured and recorded before division. Using a random assignment system, the proximal cystic duct was then secured or ligated and divided using 1 of 3 methods: double stainless steel clips (10-mm multifire clip applier, Ethicon Endo-Surgery), the ENDOLOOP (Ethicon Endo-Surgery), or the ENSEAL device (Ethicon Endo-Surgery). After removal of the gallbladder by division of the cystic duct 1 cm distal to the area of ligation or closure, the open distal end of the common bile duct was cannulated with a rubber catheter and secured in place using silk ties. This catheter was connected to an electronic pressure monitoring device, and the biliary system including the cystic duct was insufflated with air after submerging the biliary system in saline. Insufflation was performed at a standard rate, and the intraluminal biliary pressures were continuously monitored and recorded. The system was insufflated until either failure of the cystic duct closure or rupture of the biliary system at a separate location occurred. The final pressure was recorded just before the sudden decrease in pressure on the monitor.

A total of 8 animals were randomized to the metal clip group, 7 to the ENDOLOOP group, and 7 to the ENSEAL group. Univariate statistical analysis using chi-square and analysis of variance (ANOVA) was used to compare the 3 study groups for basic demographics, biliary duct size, difference in peak rupture pressures, and location of rupture. Post hoc analysis of ANOVA results with the Tukey HSD (honestly significant difference) test was performed to determine specific differences in mean bursting pressures between study groups, and significance was set at $P < .05$. All data analysis was done using PASW Statistics, version 18 (SPSS, Inc, Chicago, IL). This study was reviewed and approved by the Institutional Animal Care and Use Committee at our institution.

Results

We found no statistically significant difference between the cystic duct and common bile duct sizes between the 3 study groups. The mean burst pressures were $432\; mm\; Hg$ (range, 338 to 524), $371\; mm\; Hg$ (range, 262 to 479), and $238\; mm\; Hg$ (range, 118 to 357) for metallic clips, the ENDOLOOP, and the ENSEAL, respectively ($P = .017$) (Fig. 1). Post hoc analysis revealed the statistical difference to be between metallic clips and the ENSEAL device, with metallic clips being statistically superior to the ENSEAL (Table 1). There was no statistical difference between metallic clips and the ENDOLOOP or between the ENDOLOOP and the ENSEAL.

Device failure rates were also noted and recorded if there was a leak at the cystic duct stump closure. Metallic clips did not have any device failures, the ENDOLOOP had 1 failure (14%), and the ENSEAL had 3 device failures (42%; $P = .09$). The locations of rupture were also recorded. The cystic duct side wall was the most common location of rupture (35%) and the common bile duct was the second most common location (30%). The cystic duct
stump leaked in 20% of the specimens (Fig. 2). There was no statistically significant difference in the location of the rupture between the 3 study groups, although the ENSEAL device demonstrated a significantly higher rate of failure at the cystic duct when compared with the other 2 groups combined (42% vs 7%; \( P < .04 \)).

**Comments**

The management of a patient with choledocholithiasis that is recognized preoperatively or intraoperatively is controversial. Current options include preoperative ERCP and sphincterotomy, laparoscopic or open common bile duct exploration, or cholecystectomy with postoperative ERCP. The option of simple cholecystectomy with postoperative ERCP is a common and reasonable choice, particularly if the surgeon is not experienced with laparoscopic common bile duct exploration or the equipment is not available. Although securing the cystic duct with metallic clips is the most common practice for routine cholecystectomy, if postoperative ERCP is anticipated, there is a widely accepted dogma of securing the cystic duct stump with an ENDOLOOP suture. This may be done in addition to the metal clips or as a replacement for the metal clips and is commonly touted as a more “secure” closure of the cystic duct that will be more resistant to dislodgment if the biliary system is insufflated or instrumented. Although well intentioned, there are no data to support or refute this practice, and this was the impetus for the current study.

ERCP was first performed in the 1970s and has revolutionized the treatment of choledocholithiasis and biliary leak after LC. ERCP is most commonly performed after LC for retained stones, pain after LC, and biliary leaks. Morbidity with ERCP in this situation is 15% and is similar to results with ERCP performed for other indications. Kent et al reported 1 of the only series to specifically address ERCP performed after LC for reasons other than biliary leak. Interestingly, this study did not list bile leak as a complication after ERCP. Likewise, other studies do not mention this as a common complication after ERCP or other biliary manipulation after cholecystectomy.

Our study contradicts currently accepted dogma and suggests that there is no added benefit in securing the cystic duct with an ENDOLOOP instead of metal clips if postoperative ERCP is expected. In fact, metal clips appear to offer a more secure closure of the duct than either the ENDOLOOP or the thermal energy devices. In addition, all 3 methods appeared to offer adequate security of the cystic duct because they all maintained their integrity at greater than 200 mm Hg insufflation pressures, which is likely much greater than the pressure levels that would be seen during a standard ERCP with insufflation and cholangiography.

The development of laparoscopic surgery has been greatly aided by major advancements in thermal energy devices that allow hemostatic tissue dissection and division. The ideal energy device for cholecystectomy would provide fine tissue dissection, hemostatic sealing of cystic vessels, and a strong sealed closure of a cystic duct across the spectrum of normal duct sizes. We believe this to be the first published study of using the ENSEAL energy device to secure the cystic duct in a cholecystectomy model. Although the ENSEAL was outperformed by endoclips, there was no statistical difference in burst pressures between the ENDOLOOP and the ENSEAL device, suggesting that the

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<td>Metallic clips vs ENSEAL</td>
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Tukey HSD (honestly significant difference) test showing statistical comparison between each group included in the analysis of variance (ANOVA).
ENSEAL may be a valid option for securing the cystic duct. However, it is important to note that there was a higher failure rate at the cystic duct stump with this thermal device at high insufflation pressures. Previous studies of other thermal devices have used different techniques to enhance the cystic duct closure, such as applying the device several times (double activation) on the cystic duct stump. Our study used only a single energy application to both seal and divide the cystic duct, and thus different results may be obtained with variations in the exact technique.

It is somewhat surprising that there have been no studies to date on the effects of bile duct insufflation and the cystic duct closure. In a review of the literature, we found minimal references regarding the intraductal pressure during ERCP after LC. Manometry studies in patients with biliary dyskinesia have shown pressures as high as 195 mm Hg with contraction of the sphincter of Oddi and a normal resting pressure of 15 mm Hg. Even if intrabiliary pressure during ERCP approximates this pattern with obviously higher pressure during insufflation and with contrast bolus, our study showed that all 3 devices would provide adequate duct closure. We found metallic endoclips to have a burst pressure more than twice the highest recorded in vivo pressures found in the literature. Both the ENDO-LOOP and the ENSEAL demonstrated lower burst pressures, but these were still more than 200 mm Hg, which is likely more than adequate to tolerate the standard insufflation and injection pressures seen during ERCP. Our results compare favorably with previously reported series examining various methods of closure and associated burst pressures. In addition, this is the first study that we are aware of to measure intraluminal and burst pressures from the common bile duct and proximal cystic duct stump and thus provides new information that may be useful in clinical scenarios or future research.

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References


Discussion

Timothy W Bax, M.D., Spokane, Washington

Although we may be a little behind the times, my group here in Spokane will be doing gallbladder surgery in our own surgery center starting in January, and the various types of cystic duct closure have come under scrutiny. First of all, which type of closure is the most secure and second, which type of closure is the most cost-effective? I am grateful for the authors’ contribution to this question. It seems to me the first question one must ask in determining the adequacy of cystic duct closure is, “What is the maximum pressure that closure device is expected to withstand?” It turns out that question is very difficult to answer. In the 1970s several studies were done looking at common bile duct and sphincter of Oddi function. What I learned reviewing these studies is that although the sphincter of Oddi pressure can approach 100 mm Hg, the average common bile duct pressure is...
around 10 mm Hg, and a pressure of about 30 mm Hg will stop the flow of bile into the bile duct system. I could not find a single reference in the literature that defines the pressure during injection of dye or insufflation of air during endoscopic retrograde cholangiopancreatography (ERCP). I did speak to my gastroenterology colleagues here in Spokane, and they all thought that the hand injection of dye would not generate all that much pressure but that insufflation of air after sphincterotomy may. This leads to my questions:

1. Have you been able to determine the pressure the common bile duct is exposed to during ERCP?
2. Having never operated on swine, is the swine biliary system comparable to the human biliary system? Is this model transferable?
3. Did you use a multifire disposable clip applier or a reusable applier? Is there a difference?
4. What are the costs of the 3 devices used and should that influence our decision about securing the cystic duct?