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REVIEW ARTICLE

Acute Care Surgeon: Use of the Endo GIA Stapler for Cystic Duct Ligation in Emergent Cholecystectomy

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ABSTRACT

Introduction: Endo GIA stapler use is a method to ligate cystic ducts during laparoscopic cholecystectomy in the elective and emergent setting. Its use has not been widely described in the acute care surgery (ACS) setting. Our study aims to determine factors predicting Endo GIA use by acute care surgeons and evaluate when applied its safety and efficacy in emergent cholecystectomy. Additionally, we investigate the use of Endo GIA stapler with respect to conversion to open surgery, reduction in postoperative morbidity, and impact on length of stay in an ACS setting.

Materials and methods: A retrospective chart review was conducted for laparoscopic cholecystectomy performed by ACS in a public university training hospital over 1 year. Variables associated with Endo GIA stapler use were identified through multivariate logistic regression and subsequently, assessed after optimizing the model to control for confounding effects.

Results: Of the 118 laparoscopic cholecystectomies performed, the Endo GIA Stapler was used for cystic duct ligation in 20 cases. Surgeons' dictated reason for stapler use included dilated cystic duct (45%), short cystic duct remnant (15%), inadequate room for clip ligation and division (10%), and nonspecific (45%). Patient demographic variables for Endo GIA stapled and clipped groups were not significantly different. Logistic regression revealed a significantly higher likelihood of Endo GIA stapler use in patients with comorbid biliary duct disease, preoperative endoscopic retrograde cholangiopancreatography (ERCP), and a trend towards significance in patients with previous emergency department (ED) visits. There was no significant difference in conversion to open surgery, postoperative morbidity, and postoperative length of stay.

Conclusion: Comorbid biliary duct disease, previous ED visits, and preoperative ERCP are predictive of patients requiring use of the Endo GIA stapler for cystic duct ligation during emergent cholecystectomy. The use of Endo GIA stapler by Acute Care Surgeons is safe and effective.

Keywords: Acute care surgery, Acute cholecystitis, Cystic duct ligation, Emergent cholecystectomy, Emergency general surgery, Laparoscopic stapler, Panamerican trauma society.

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RESÚMEN

Introducción: El uso de la engrapadora EndoGIA para ligar el conducto cístico es un método utilizado durante Colecistectomías laparoscópicas en situaciones electivas y emergentes. El uso de este método no ha sido descrito de una manera extensiva en el campo de Cirugía de Cuidados Agudos (ACS). Las metas de nuestro estudio son el poder determinar los diferentes factores que podrían predecir el uso de la engrapadora EndoGIA para el uso de Cirujanos de Cuidados Agudos y poder evaluar la eficacia y seguridad que provee durante una Colecistectomía emergente. Adicionalmente, investigamos el uso de la engrapadora EndoGIA considerando la conversión a cirugía abierta, reducir la morbosidad post-operativa, y el impacto de el tiempo de estadía en un establecimiento de cuidados agudos (ACS).

Materiales y métodos: Se hizo una revisión retrospectiva de documentos médicos de Colecistectomías laparoscópicas en una situación emergente (ACS) hechas en una Universidad/ Hospital publico de medicina durante un año. Los variables asociados con el uso de la engrapadora EndoGIA fueron identificados atreves de un estudio de Regresión logística multivariante y fue juzgado después de mejorar el modelo para controlar los efectos de confusión.

Resultados: De las 118 Colecistectomía laparoscópicas hechas, la engrapadora EndoGIA fue utilizada para ligaciones de conducto cístico en 20 casos. Los cirujanos tomaron la decisión de el uso de la engrapadora EndoGIA en las siguientes situaciones: Un Conducto Cístico Dilatado (45%), restos de conducto cístico cortos (15%), un espacio inadecuado para poder ligar con clips & el poder dividir (10%), y descripciones no especificas (45%). Los variables demográficos de los pacientes que fueron tratados con la engrapadora EndoGIA o con clips no fueron significantemente diferentes. El estudio de Regresión Logística demostró que hay una mayor probabilidad de el uso de la Engrapadora EndoGIA en pacientes que tienen una comorbilidad de enfermedad de conducto cístico, CPRE "Colangiopancreatografia Retrograda Endoscópica" Pre-Operativa, y una tendencia en pacientes con visitas previas a la sala de emergencia. No se encontró una diferencia significante en conversiones a cirugía abierta, morbosidad post-operativa, y el tiempo de estadía en un establecimiento de cuidados agudos (ACS).

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Conclusión: Comorbilidad de enfermedad de conducto cístico, visitas previas a la sala de emergencia, y CPRE "Colangiopancreatografia Retrograda Endoscópica" Pre-Operativa, son situaciones que predicen el uso de la engrapadora EndoGIA en pacientes para la ligación de conducto cístico durante una Colecistectomía emergente. El uso de la engrapadora EndoGIA por Cirujanos de Cuidados Agudos es un método seguro y efectivo.

Palabras Clave: Cirugía de Cuidados Agudos, colecistitis aguda, ligacion del conducto cístico, Colecistectomia emergentes, Cirugía de emergencia, colecistectomía laparoscópicas, engrapadora para laparoscopia, sociedad Panamericana de Trauma.

INTRODUCTION

Gallbladder disease is the mainstay of pathology treated by the acute care surgeon and represents a substantial burden of surgical disease.[1] The spectrum of disease warranting cholecystectomy ranges from elective to emergent including a broad range of chronicity and acuity. Significant anatomical differences exist depending on the degree of gallbladder inflammation, chronicity of disease, and scarring of the cystic duct. Surgeon preference for alternatives to the traditional 10 mm clip applier varies in the face of complex gallbladder disease where a single 10 mm clip will not adequately traverse the cystic duct. Determining the safety and efficacy of alternatives for cystic duct ligation will facilitate improved decision-making during emergent cholecystectomy performed by the acute care surgeon in this era.

Laparoscopic cholecystectomy has been the standard of care since its introduction in 1987.[2] The acute care surgery (ACS) model for treatment of gallbladder disease has decreased incidence of conversion to open surgery, decreased hospital length of stay, improved outcomes,[3] and decreased complication rates.[4-6] The study of current practice patterns among acute care surgeons that routinely encounter complicated acute gallbladder disease may help to identify patients who will go on to require alternatives to cystic duct ligation, and lead to improved safety in the operating room in regard to alternatives of duct ligation. Factors predicting alternatives to stapler use will afford surgeons and patients improved preoperative and intraoperative planning. Safety and efficacy of alternatives to clipping methods have largely been studied in the elective population, but have not been studied in the ACS population where a significant proportion of complicated, acute, acute on chronic, or advanced classification of gallbladder disease (based on Tokyo guidelines) are encountered.

Obtaining a critical view during laparoscopic cholecystectomy is essential prior to the security of the cystic duct and artery before resection of the gallbladder from the gallbladder fossa. Traditionally, division of the cystic duct and artery has been accomplished with a laparoscopic clip applier device using 5 or 10 mm clips.[7] Alternative techniques have been described for a larger cystic duct,[4] and include endoloops,[8] laparoscopic intracorporeal suturing of the cystic duct stump,[9] use of the Harmonic scalpel for division via energy,[10] endoclips,[11] absorbable clips,[12] sequential overlap pattern clipping of the cystic duct,[13] and stapled ligation.[14-16] Although the use of 10 mm clips has been well validated in the elective setting, safe and secure ligation and division of the cystic duct is intraoperatively dubious when the cystic duct is dilated or inflamed to sizes larger than 10 mm. In many emergent cases, as well as in the case of chronic and recurrent cholecystitis, application of metal clip is not feasible, and postoperative complications arise in the form of bile leak,[17,18] clip migration,[19] or leads to reprocedure and additional interventional and endoscopic-related treatment costs. In cases where inadequate laparoscopic cystic duct ligation occurs, open cholecystectomy or alternative techniques for duct ligation may be warranted to minimize occurrence and postoperative complication of cystic duct leak. Open cholecystectomy has a significantly higher incidence of postoperative morbidity,[20] and methods of cystic duct ligation have inherent risks. In fact, cystic duct stapling has been associated with cystic bile duct injury,[21] intracorporeal suturing of the cystic duct requires advanced laparoscopic skills,[9] sequential overlapping of clips in inflamed ducts may not offer 100% security,[13] and the Harmonic scalpel exposes adjacent structures to an energy source.[10,22,23]

Acute care surgeons are increasingly performing cholecystectomies for acute cholecystitis in the emergency setting.[24] This has been generated by cost savings and decreased length of hospital stay associated with quicker access to the operating room provided by in-house surgeons.[25] It is our institutional practice that acute care surgeons are responsible for treating the majority of acute cholecystitis cases presenting to the emergency department (ED). Since a pattern of Endo GIA stapler use for cystic duct ligation has been developed in our ACS practice, the safety, efficacy, preoperative factors, and intraoperative surgeon decision-making predictive of its use were examined.

MATERIALS AND METHODS

The Division of ACS at Rutgers Robert Wood Johnson University Hospital between July 1, 2013 and July 1, 2014 performed a retrospective chart review for patients who underwent laparoscopic cholecystectomy for acute cholecystitis. Elective cholecystectomy patients, pediatric patients, and patients who had a cholecystectomy as part of a larger procedure were excluded from the study. All patients with clipped cystic ducts underwent ligation with three 10 mm clips along the cystic duct. For all patients with stapled ligation of the cystic duct, an Ethicon Endo

GIA 45 mm stapler with a blue load was used to ligate the cystic duct. Potential variables predictive of Endo GIA stapler were identified through multivariate logistic regression and subsequently assessed after optimizing the model to control for confounding effects. The final logistic regression included age, race, sex, comorbid biliary duct disease (defined as choledocholithiasis or elevated liver function tests), preoperative endoscopic retrograde cholangiopancreatography (ERCP) and previous ED admissions. Safety and efficacy were assessed using independent samples t-test or chi-square to compare conversion to open surgery, postoperative morbidity (defined as wound infection, bacteremia, common bile duct injury, postoperative right upper quadrant fluid collection, postoperative pneumonia), mortality (death within 30 days of operation), and postoperative length of stay. All results were regarded as significant at $p < 0.05$.

RESULTS

A total of 118 patients underwent laparoscopic cholecystectomy for acute cholecystitis during the study period of 1 year. The 10 mm clips were used on the remaining 98 patients (clipped). The cystic duct was ligated using the Endo GIA stapler in 20 patients (stapled). There were no cases of endoloop, Harmonic scalpel, or extracorporeal suturing. Within the stapled group, the most common indication dictated for its use was dilated cystic duct (45%), followed by short cystic duct remnant (15%), inadequate room for clip ligation and division (10%), or no specific reason (45%). In two cases, more than one reason was dictated for stapler use resulting in percentages that do not add up to 100% (Table 1). Demographic variables compared between stapled and clipped were not significantly different (Table 2). Logistic regression revealed a significantly higher likelihood of the Endo GIA stapler used in patients with comorbid biliary ductal disease (20 *vs* 4%; chi-sq = 5.87, p = 0.01), and a trend toward significance in patients with previous ED visits (31 *vs* 52%, chi-sq = 3.96, p = 0.06). Additionally, an individual Fisher exact test showed that preoperative ERCP was also significantly higher in the stapled group (20 *vs* 10%, p = 0.03), but this was not significant within the logistic regression model. Tokyo grading was not statistically different between the two groups in a logistic regression model. Of the 118 patients, 86 were Tokyo grade I (76.9%), 29 were grade II (24.6%), and 3 were grade III (2.5%). Tokyo grading among stapled patients was grade I in 14/20 (70%) patients, grade II in 6/20 (30%) patients, and grade III in 0/20 (0%) patients. For unstapled patients, Tokyo grading was not statistically significant: Grade I in 72 (73.4%), grade II in 23 (23.4%) patients, and grade III in 3 (3%) of unstapled patients. Duration of complaint in hours prior to admission was predominantly less than 12 hours: [0–12 (67, 57.3%), 12–24 (14, 12.0%), 24–36 (5, 4.3%), 36–48 (5, 4.3%), 48+ (26, 22.2%)]. On average, patients underwent surgery 1.84 days after admission with a minimum of zero and maximum of 8 days. In terms of safety and efficacy, there was no significant difference between the two groups: Conversion to open (stapled 3/20, 15% *vs* clipped = 6/118, 5%, p = 0.178), postoperative morbidity (0/20, 0% for stapled, 4/118, 4% for nonstapled, p = 0.357), mortality (0% for both groups), and postoperative length of stay (mean (standard error): Stapled = 1.95 (0.1) *vs* clipped = 1.28 (0.4), $p > 0.05$).

Table 1: Operative reasons for Endo GIA stapler use

Patient number	*Reason dictated for Endo GIA stapler use*
1	Dilated cystic duct and short cystic duct
2	Cystic duct great than 1cm in diameter
3	No need dictated
4	Cystic duct size
5	No need dictated
6	Severely dilated after decompression of Gallbladder
7	Cystic duct size. Infected gangrenous
8	Not enough room
9	No need dictated
10	Short cystic duct
11	Not safe to clip what was left of cystic duct
12	Dilated and shortened cystic duct
13	No need dictated
14	Not enough room
15	Quite dilated and stones present in duct
16	No reason dictated
17	No reason dictated
18	Cystic duct was enlarged
19	Quite foreshortened cystic duct
20	Dilated cystic duct

Table 2: Demographics of stapled *vs* clipped patients

		Stapled (n = 20)	*Clipped (n = 98)*	*Significance (p)*
Age	Mean (range)	42.35 (21-83)	38.83 (21-82)	NS
Race	% White	40%	39%	NS
	% Black	40%	33%	
	% Hispanic/Latino	20%	16%	
	% Asian	0%	8%	
Sex	% Female	70%	78%	NS

NS: Nonsignificant

DISCUSSION

As acute care surgeons continue to treat complex cholecystitis, they will encounter disease severity in which alternative methods for reliably ligating the cystic duct are needed. Several large retrospective studies have analyzed the safety and efficacy of the Endo GIA stapler use during laparoscopic cholecystectomy in the hands of general and laparoscopic surgeons.[14-16,26] Alternatively, case studies have highlighted the dangers of the Endo GIA stapler, yet its use continues among surgeons. We sought to investigate two key aspects of Endo GIA stapler use specifically among acute care surgeons in cases of acute cholecystitis: (1) Independent preoperative predictors for stapler use among acute care surgeons and (2) safety and efficacy in the hands of acute care surgeons.

We noted the reasons for Endo GIA stapler use in order to evaluate patterns that may be useful for predicting stapler use from the operating surgeon's decision-making. Reason for Endo GIA stapler use varied. The most common reason dictated for the intraoperative decision to use the Endo GIA stapler was dilated cystic duct. In some cases, surgeons dictated specific duct sizes, while others referred to only the presence of an "enlarged" or "dilated" cystic duct. This reasoning represents a decision to favor the use of the Endo GIA stapler over other described alternatives for ligating and securing the cystic duct. Acute care surgeons did not report alternative methods of ligation during the year analyzed, although an endoloop was used in one case to reinforce a staple line.

We identified independent variables of those patients who went on to receive Endo GIA stapler use during laparoscopic cholecystectomy in emergent cholecystectomy. Predicting and classifying complex gallbladder disease has been primarily conducted using the Tokyo guidelines,[27-29] which includes large populations of elective cholecystectomy. Improving and expanding means to predict difficult gallbladder cases in the setting of emergent, acute, and advanced cholecystitis will provide surgeons with improved operative decision-making when enlarged and chronic cystic ducts are suspected and/or encountered. Among our patient population, comorbid biliary duct disease, previous ED visits, and the need for preoperative ERCP were potentially predictive of patients who will require Endo GIA stapler use for cystic duct ligation. All three of these may represent disease severity that includes cystic duct dilation from unknown variables, chronicity, choledocholithiasis, or from recent endoscopic manipulation of the biliary system. Ethnicity, age, or gender did not lead to surgeon's choice to use a stapler for cystic duct ligation. Investigation with larger study groups may reveal independent patient predictors of alternative methods for cystic duct ligation.

Outcomes of those undergoing clip ligation were compared with those who had stapler ligation. Use of 10 mm clips has been the standard of care since the introduction of laparoscopic technique for cholecystectomy, and offers an ideal balance between ease of use, cost, and safety. The use of Endo GIA stapler appears as safe and effective as traditional 10 mm clips, evidenced by the lack of significant differences in conversion to open surgery, postoperative morbidity, and postoperative length of stay. Patients with Endo GIA stapler cystic duct ligation were those with higher difficulty due to chronic inflammation and dilated cystic ducts, representing a group of patients that may have a potential higher risk for postoperative complications than those with uncomplicated disease. Admittedly, cost of the Endo GIA stapler is higher than traditional clips, suture ligation, or overlapping clips. However, the ease of use with the Endo GIA stapler once a critical view is obtained makes its use appropriate.

Limitations of our study include the small population of patients undergoing Endo GIA stapling in our single institution study, and the lack of variability of alternative techniques for comparison. Analysis of a larger pool of dictations and stated reason for Endo GIA standardization will allow for a greater understanding of operative decision-making among acute care surgeons performing laparoscopic cholecystectomy in the emergent setting. Ideally, surgeons' decision-making should be evaluated within skill set and experiential context regarding other surgical alternatives for cystic duct closure in a predominantly laparoscopic era. We did not see a statistically significant difference in operating room time between the two groups, which may suggest no time benefit to stapler use. We did not analyze for cost, but we found no significant difference in operating room time between the two groups. The benefit of decreasing length of operating room time by employing the Endo GIA stapler warrants further study in the context of total costs and among a larger patient population.

Future studies are needed to identify additional independent predictors of patients requiring alternatives to cystic duct ligation and decreasing the incidence of cholecystitis chronicity. This could improve time to surgery and look to improve outcomes for patients who are prone to develop dilated cystic ducts from gallbladder disease and/or progress to dilation as a result of lack of access to timely surgical intervention or discharge from the hospital with primary presentation. Additionally, more studies are needed to compare the effectiveness of other methods of duct ligation with the Endo GIA stapler in terms of cost and efficacy.

Comorbid biliary ductal disease, previous visits to the ED for cholecystitis, and preoperative ERCP are potentially predictive of patients for whom an acute care surgeon will decide to use the Endo GIA stapler for cystic duct ligation and dilated cystic duct disease. As

the prevalence of patients with biliary disease continues to grow due to comorbid conditions and lack of access to emergency surgical care, methods of alternative duct ligation are applicable. The use of Endo GIA stapler by acute care surgeons is safe and effective as evidenced by the lack of significant differences in conversion to open surgery, postoperative morbidity, complications, and postoperative length of stay. Predicting patient disease and other factors for its use will allow for improved decision-making by acute care surgeons addressing the large burden of complicated emergent surgical disease.

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