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Research Article

Use of Linear Endostaplers for the Cystic Duct Closure in Laparoscopic Cholecystectomy

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Summary

The laparoscopic approach has been the treatment of choice for cholecystectomy since 1987. However, in some cases (dilated cystic duct, >1cm, fibrous, edematous, or inflamed), the traditional technique of closing the cystic duct with metal endoclips may not be an appropriate approach, as complications such as biliary leakage or obstructive jaundice due to the formation of stones in the common bile duct from clip migration may occur, among others. In these circumstances, the use of linear endostaplers for the cystic duct has been proposed as a safe, quick, and feasible method with low morbidity associated with performing laparoscopic cholecystectomy.

The objective of this study is to assess the use of linear mechanical suture devices in the surgical treatment of complex laparoscopic cholecystectomies, which can be considered an effective technique in these cases of "difficult" cystic ducts.

To achieve this, we conducted a retrospective cohort study, analyzing all patients who underwent laparoscopic cholecystectomy by the General Surgery Department of the Hospital Universitario de Canarias between 01/01/2012 and 12/31/2015, comparing the usual sealing with endoclips and the use of endostaplers, and analyzing possible differences in complications.

We conclude that the use of mechanical suture devices in approaching gallbladder pathology when the cystic duct is dilated or its handling is very laborious is a safe and reliable way to treat this pathology. Its use does not result in a higher number of complications in closing the cystic duct compared to the standard endoclip technique.

Keywords: Cholecystectomy; Stapling Devices; Laparoscopic.

Introduction

Laparoscopic cholecystectomy (LC) has been the treatment of choice for gallbladder pathology since 1987. Currently the conversion rate varies between 1.03% and 11% depending on the series (1). This technique consists of placing metal clips or ligatures in the cystic duct to seal it. However, on some occasions, due to previous inflammatory processes, we may find an inflamed, edematous or fibrous cystic duct, or an excessively wide cystic duct during the surgical procedure. In these situations the ease and safety of cystic duct closure with endoclips can be compromised. Several methods have been proposed to ligate the cystic duct, including titanium endoclips, absorbable endoclips, endoloops, intracorporeal or extracorporeal ligatures with absorbable or nonabsorbable materials or ultrasonic coagulating scissors (2). Among these, the use of linear endoclips has also been suggested, and their use to safely divide structures, ligate vessels and create anastomoses is now fully established as a key tool in laparoscopic surgery, offering a fast, effective and often simple alternative.

Objectives

The primary objective of our study is to assess the usefulness and complications of linear mechanical suturing in complex cholecystectomies in which standard closure of the cystic duct with metallic endoclips cannot be performed.

Material and Methods

Between 01/01/2012 and 31/12/2015, 801 patients were treated with LC for gallbladder pathology in the department of General and Digestive Surgery of the University Hospital of the Canary Islands, Spain. A retrospective cohort study was performed with data from the medical records of these patients.

Definition of study group and control group

The inclusion criterion for the study group was the use of linear mechanical suture in surgery. From a total of 801 patients, 57 patients who underwent linear mechanical suture sealing of the cystic duct were identified, and these were considered as the study group.Patients undergoing laparoscopic cholecystectomy for symptomatic cholelithiasis during the same period, with cystic duct closure using endoclips, constituted the control group, consisting of 49 randomly selected patients

Patient review

In the analysis of clinical histories, the diagnostic procedures performed were assessed: liver function tests, ultrasound, endoscopic retrograde cholangiopancreatography (ERCP), computed tomography (CT), or magnetic resonance cholangiopancreatography (MRCP) performed to establish a preoperative diagnosis. In general, the actions taken included routine preoperative ERCP in patients with a history of cholangitis. In cases of jaundice, pancreatitis, patients with a dilated common bile duct on abdominal ultrasound, and patients with altered liver function tests, MRCP or endoscopic ultrasound was performed. Patients with lithiasis in the main bile duct had the stone removed endoscopically by ERCP, prior to laparoscopic surgery. In addition, endoscopic papillotomy with stone removal was performed to resolve fever, jaundice and/or removal of common bile duct stones.

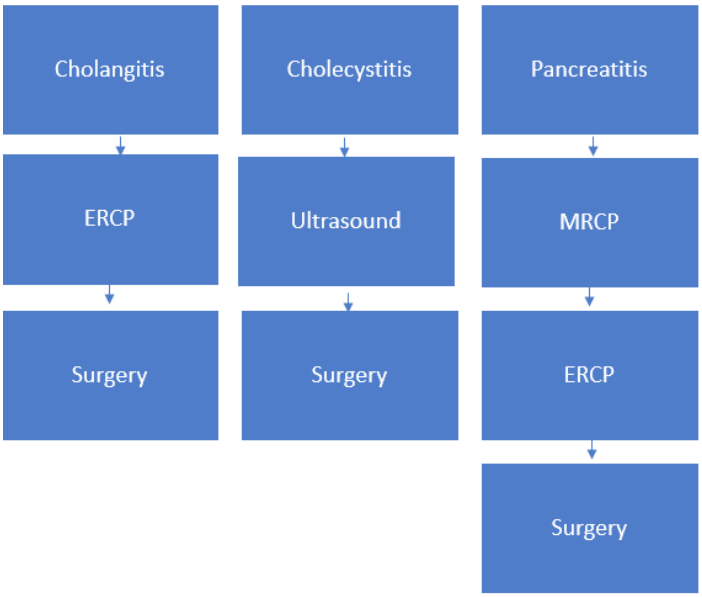

Figure 1: Action flow diagram according to diagnosis.

Surgical procedure in the use of mechanical staplers

Surgery was performed under general anesthesia using the standard four-trocar technique. The cystic artery was usually controlled first by placement of metal clips and subsequent sectioning. The dilated bile duct was dissected until the anatomy was clear and adequate space existed for Endostapler (US Surgical Corp., Norwalk, CT Endo-GIA) or Echelon (Johnson & Johnson Services, Inc. Ethicon USA, LLC, Echelon Endopath) placement. It was applied through a 12-mm port at the level of the left hypochondrium (epigastrium). During the procedure of adapting the mechanical load to the cystic duct the posterior branch of the mechanical suture is observed behind the cystic duct and the closure mechanism should be free of intervening tissue to facilitate and ensure closure of the Endo-GIA. After assessment by the surgeon during the surgical procedure, in some patients, the fundus was initially dissected and subtotal cholecystectomy was performed because of unclear anatomy in Calot's triangle. The gallbladder was dissected from the liver using electrocautery and removed through the umbilical trocar within an endocatch. Finally, the cystic duct stump was reexamined before removal of the instruments and laparoscope.

Follow-up

Follow-up was conducted through outpatient visits in General Surgery, based on clinical evolution, liver function assessment through blood tests, or imaging techniques.

Analyzed Variables

The variables analyzed in this study were: age, sex, reason for surgery, conversion to open surgery, gallbladder release technique with regard to the surgical site, linear mechanical suture, duration of surgery, admission time, early postoperative complications, treatment of early postoperative complications, late postoperative complications, treatment of late postoperative complications, complication due to surgery, follow-up time, patient mortality and the cause of mortality.

Statistical Study

The statistical package SPSS Statistics version 24 (IBM, Armonk, New York, United States) for Windows was used. Results were considered significant for data with a p value < 0.05, with a 95% confidence interval (CI).

For the qualitative variables of the project, frequency distributions and proportions expressed as percentages were analyzed, as well as risk distribution in dichotomous variables. To determine the existence of statistical significance regarding the non-association between variables, chi-square analysis (χ^2), Fisher's exact test, or Somers' d coefficient were used (when conditions for the first were not met).

For quantitative variables, the mean, median, mode, standard deviation, maximum, minimum, and range were calculated. These were analyzed using the Student's t-test when the sample followed a normal distribution; otherwise, the Mann-Whitney U test was applied. To determine if the distribution followed the normal pattern, the Kolmogorov-Smirnov test was performed.

Biases

Selection bias when selecting controls by randomization method and loss bias.

Results

A total of 801 patients operated on between 01/01/2012 and 12/31/2015 were reviewed. Of these, stapler devices were used in 57 patients. The control group consisted of 49 patients who underwent the conventional surgical endoclip procedure selected through simple random sampling.

The mean age of patients operated on with stapler devices was 65.53 ± 17.50 years. In the control group, it was 63.92 ± 17.828 years; p 0.641 (Table 1).

	Control Group	**Study Group**	**p**
Age (years old)	65,53	63,92	0,641
Sex (N)	29 (59,2%) W 20 (40,8%) M	32 (56,14%) 25 (43,86%)	0,752
Reason for surgery N (%))	19 (38,78%)	23 (40,35%)	
- Cholecystitis	1 (2,04%)	7 (12,28%)	
- Choledocolitiasis	1 (2,04%)	1 (1.75%)	
- Colangitis	8 (16,32%)	7 (12,28%)	
- Pancreatitis	19 (38,78%)	16 (28,07%)	0,344
- Symptomatic cholelithiasis			
- Mirizzi's syndrom	1 (2,04%)	3 (5,26%)	

Table 1: Epidemiological variables; N= number of cases; M= men; W= women.

Regarding sex, in the control group, 29 (59.2%) patients were women and 20 (40.8%) were men. In the group where mechanical suturing was used, 32 (56.14%) were women and 25 (43.86%) were men; p 0.752.

The reasons for surgery in the control group were: 19 cases (38.78%) of cholecystitis, 1 case (2.04%) of choledocholithiasis, 1 case (2.04%) of cholangitis, 8 cases (16.32%) of pancreatitis, 19 cases (38.78%) of symptomatic cholelithiasis, and 1 case (2.04%) of Mirizzi syndrome. In the study group: 23 cases (40.35%) of cholecystitis, 7 cases (12.28%) of choledocholithiasis, 1 case (1.75%) of cholangitis, 7 cases (12.28%) of pancreatitis, 16 cases (28.07%) of symptomatic cholelithiasis, and 3 cases (5.26%) of Mirizzi syndrome; p 0.344.

Regarding conversion to open surgery, in the control group, 47 cases (95.92%) did not require conversion, 1 case (2.04%) converted to open surgery, and 1 case (2.04%) underwent open surgery from the beginning. In the study group, 48 cases (84.21%) did not require conversion, 7 cases (12.28%) converted to open surgery, and 2 cases (3.51%) underwent open surgery from the beginning; p 0.119 (Table 2).

	Control Group	**Study Group**	**p**
Time(min)	89,86 ± 36,645	119,33 ± 52,333	0,001
Decollage (N (%))	46 (93,88%)[1] 3 (6,12%)[2]	31 (54,69%)[1] 26 (45,61%)[2]	0,073
Conversion to open surgery (N (%))	1(2,04%)	7 (12,28%)	0,119
Admission time (days)	5,84	8,77	0,138

Table 2: Surgical variables; N= number of cases; 1: from neck to fundus 2: from fundus to neck.

In terms of decollage in the control group, it was performed in 46 cases (93.88%) from neck to fundus and 3 cases (6.12%) from fundus to neck. In the study group, in 31 cases (54.39%) it was performed from neck to fundus and in 26 cases (45.61%) from fundus to neck; p 0.073, The size of the staple used was 2.5 mm in 16 cases (28.07%), 3.5 mm in 32 cases (56.14%), and 4.5 mm in 1 case (1.75%); for the remaining 8 cases (14.04%), the surgical protocol did not adequately specify the type of mechanical suture used. The relationship between preoperative diagnosis and endostapler use was analyzed, and no significant difference was found, p 0.344.The duration of surgery in the control group was 89.86 ± 36.645 minutes, while in the study group it was 119.33 ± 52.333 minutes; p 0.001.

Regarding early postoperative complications, in the control group, only 1 case (2.0%) presented early complications, related to hepatic abscess development. In the study group, 9 cases (15.8%) presented early complications, of which 4 cases (44.44%) were due to cystic duct leakage, 1 case (11.11%) to choledocholithiasis, 2 cases (22.22%) to bleeding, and 2 cases (22.22%) to postoperative ileus; p 0.092 (Table 3). A comparison of endostapler mm with the existence of early complications revealed no significant differences (p 0.967).

	Control Group	**Study Group**	**p**
Early postoperative complications (N (%))			
Cystic duct leakage		4 (44,44%)	0,092
Hepatic abscess	1 (2,0%)		
Choledocolithiasis		1 (11,11%)	
Bleeding		2 (22,22%)	
Postoperative ileus		2 (22,22%)	
Late postoperative complications (N (%))			
Bile duct stenosis	1 (2,04%)		

Choledocolitihasis	1 (2,04%)	2 (3,51%)	
Acute pancreatitis		1 (1,75%)	0,527

Table 3: Postoperative complications; N= number of cases.

Late postoperative complications: In the control group, 2 patients (4.1%) had long-term complications, one due to choledocholithiasis (2.04%) and another to bile duct stenosis (2.04%). In the study group, 3 cases (5.55%) had late complications: 2 (3.51%) due to choledocholithiasis and 1 (1.75%) due to acute pancreatitis; p 0.527. Regarding postoperative complications, both early and late, we found that in the control group, out of 3 total complications, 2 (66.66%) were due to the use of endoclips. In the study group, out of 12 total complications, 4 (33.33%) were due to mechanical suturing; p 0.292. For hospital stay, the control group had a mean of 5.84 ± 4.476 days, with a median of 3.00 days. The study group had a mean of 8.77 ± 11.88 days, with a median of 4.00 days; p 0.138.

Regarding follow-up time, the control group had a mean of 25.78 ± 20.88 months. The study group had a mean of 17.46 ± 14.932 months; p 0.19. In the control group, the mortality rate was 8.16%, while in the study group it was 8.77%. In all cases, no death was related to surgery.

Discussion

Endostaplers are useful in a wide range of surgical procedures, providing a quick, effective, and straightforward technique for safely dividing structures, ligating vessels, and creating anastomoses. Technical failures of endostaplers, though uncommon, have been reported, resulting in bleeding, anastomotic leaks, or tissue laceration secondary to traction during the withdrawal of the endostapler.

A study conducted by showed that laparoscopic stapler use was associated with infrequent but severe complications, such as bile leaks from the staple line and bile duct injury [1]. Bile leaks caused by staplers occur in 0.5%-3% of patients, with over three-quarters of these originating from the cystic duct. These leaks may result from slippage of the occlusion mechanism during stapling or necrosis of the stump. Staplers are typically used for dividing blood vessels, where the integrity of the staple line is reinforced within minutes by local hemostasis and clot formation. This reinforcement does not occur with bile, increasing the likelihood of leaks if a stone is retained within the bile ducts. The most feared complication in LC is the clipping and division of the common bile duct, usually caused by misinterpreting biliary anatomy. The intraoperative discovery of a dilated cystic duct should prompt an immediate reevaluation of the anatomy, including a systematic search for additional pathology, before assuming the cystic duct can be divided. Cholangiography, ERCP, or MRCP can confirm the biliary anatomy and identify any unexpected ductal abnormalities before surgery.

Other disadvantages of staplers in this context include the need for larger ports (minimum 12 mm in diameter), accidental injuries during stapler insertion and removal, and the potential risk of trapping and dividing nearby structures, such as anomalous branches of the right hepatic artery found on the medial edge of Calot's triangle.

Conversely, the advantages of staplers include their relatively easy and quick use, which can contribute to reduced operative time. The safe use of Endostaplerfor laparoscopic cystic duct ligation requires a sufficient length of the duct to avoid injury to the common bile duct walls and adequate space to visualize the end of the stapler closure mechanism before deployment. These authors conclude that staplers should not be used to divide the cystic duct during LC without extra caution and careful evaluation of the biliary anatomy, especially in the presence of a wide cystic duct.

However, other authors affirm that the endostapleris safe and easy to use [2]. emphasize that correct use requires clear cystic duct anatomy and sufficient space before deploying the device. A stone in the cystic duct can migrate to the common bile duct; therefore, retraction is crucial. Before applying the Endo-GIA, the cystic duct must be compressed toward the gallbladder to prevent stone rupture within the duct.

Additionally, in their study, the mean hospital stay was 3.4 days. While the length of stay was longer than standard LC, this was due to some patients being hospitalized for over a week early in the study due to concerns about complications. These authors conclude that the use of endostaplers is a safe and easy treatment method for patients with dilated and difficult cystic ducts. The cystic artery should be isolated and ligated if possible before deploying the Endo-GIA. Hospital stay is similar to that of the standard group without staplers [3] also noted that the endostapler is easy to use and effective. However, certain safety points must be considered. First, the dilated cystic duct should be dissected until the anatomy is clear to prevent misinterpreting it as the common bile duct and to ensure sufficient space for applying the Endo-GIA. Second, an adequate length of the cystic duct stump is required to avoid injury to the common bile duct wall. One of the endostapler blades, with the locking mechanism at its end, should be clearly visible behind the duct, and the locking mechanism must be free of intervening

tissue to ensure proper closure. This protects against partial injury to the common bile duct and ensures the safe closure of the cystic duct.

For these authors, the use of endostaplers is effective and practical in selected patients, and therefore should be the treatment of choice for dilated and difficult cystic ducts due to its ease of application. Also concluded that closure of the gallbladder remnant with an endoscopic stapler is also a quick, safe, and effective method compared to manual suturing and did not result in bile leaks in their series.The existing literature on this topic is contradictory. However, most agree that mechanical devices are safe and reliable for cystic duct closure, with low morbidity and hospital stay similar to metallic endoclips.

In terms of operative duration, in our experience, surgeries using mechanical suturing devices took an average of 29.47 minutes longer than LC with endoclips. This may be partly due to the more labor-intensive assembly and use of mechanical sutures compared to endoclips and the complexity of patients requiring these devices, as biliary tract anatomy is often challenging to identify due to inflammation, fibrosis, or edema. These factors, combined with the fact that most patients using mechanical sutures presented with complicated biliary pathology, may explain the differences between the two techniques.

Regarding postoperative complications, both early and late, we found no significant differences compared to patients treated with endoclips ($p>0.092$ for early complications and $p>0.527$ for late complications). This demonstrates that mechanical suturing is a safe and reliable technique for the laparoscopic treatment of gallbladder pathology. To enhance the analysis, we introduced a new variable: surgery-related complications. Among the 12 patients in the study group who experienced postoperative complications (both early and late), only 4 had complications specifically related to the use of mechanical staplers. A comparison in this regard confirmed no significant difference in complication rates between mechanical sutures and endoclips (χ^2 $p>0.292$).

Therefore, we can conclude that the use of mechanical suturing devices in gallbladder pathology is a safe and reliable method for its management. Furthermore, we compared the type of mechanical load used and the presence of complications (χ^2 $p>0.967$), determining that there are no differences in complication rates based on the type of mechanical load chosen for cystic duct closure.

One fact worth mentioning is hospital stay. The control group had an average stay of 5.84 ± 4.476 days (median: 3.00 days), while the study group had an average stay of 8.77 ± 11.88 days (median: 4.00 days). However, when focusing on the medians of both groups, hospital stays were consistent with other studies. For example, [3-7] reported an average stay of 3.4 days. In our study, hospital stays were extended for some patients due to the inability to perform surgery on the same day of admission or within the following two days because of the heavy workload at the Hospital Universitario de Canarias. Prolonged stays were also attributed to severe complications unrelated to gallbladder pathology, such as intensive care unit admissions due to respiratory or abdominal sepsis. Additionally, some patients presented with complicated biliary pathology, such as gangrenous gallbladders, leading to longer postoperative recovery times. These complications were related to the patient's pre-existing condition rather than the surgical procedure itself.

These findings explain the longer hospital stay compared to other series. Nevertheless, we can affirm that when analyzing this series, hospital stay durations for patients treated with mechanical sutures were not longer than those for patients treated with endoclips. One limitation of the study was the loss of data regarding staple size, as some surgical protocols did not specify the type of load used. This limitation is inherent to retrospective cohort studies, where such bias is common.

A comparative table was created summarizing studies conducted to date on the use of mechanical sutures for cystic duct closure in living patients. We observed that the results reported by [3,4], were similar to ours, except that our study included a larger number of cases (57) compared to theirs (Table 5).

	Yeh et al [3]	Odabasy et al [4]	Morales et al [5]
N (number of cases)	24	19	57
Age (years)	52,1	62	65,53
Sex	11 M 13 W	12 M 7 W	35 W 25 M
Reason for surgery	Symptomatic cholelithiasis 11 (45,83%) Mirizzi's syndrome 2 (8,33%) Acute cholecystitis 5 (20,83%) Acute cholecystitis 1 (4,16%) Pancreatitis 2 (8,33%) Gallblader polyp 1 (4,16%)	Symptomatic cholelithiasis 10 (52,63%) Acute Cholecystitis 7 (36,84%) Cholangitis 1 (5,26%) Pancreatitis1 (5,26%)	Cholecistitis 23 (40,35) Choledocolithiasis 7 (12,28%) Cholangitis 1 (1,75%) Pancreatitis 7 (12,28%) Symptomatic cholelithiasis 16 (28,07%) Mirizzi's syndrome 3 (5,26%)
mmGIA	3,5	4,8	3,5
Operative time (min)		91,3	119,33
Postoperative complications	2/24 (8,33%)	4/19 (21,05%)	12/57 (21,05%)
Follow-up (months)	1,0-40,2 (18,5)	1,0-50,4	17,46
Admission time (days)	4	3,4 (post surgery)	4

Table 4: Comparison with other authors, M= man; W= women.

Conclusion

The use of mechanical suturing devices in the management of gallbladder pathology, especially when the cystic duct is dilated or its handling is challenging, is a safe and reliable method for treating this pathology. Their use does not result in a higher number of complications for cystic duct closure compared to the standard technique of endoclips, nor does it increase postoperative hospital stay.

Acknowledgements

The use of mechanical endostaplers is safe in the cystic duct closure.

Ethical considerations

The patient's medical record review had been approved by ethical committee.

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