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Efficacy of Absorbable Clips Compared with Metal Clips for Cystic Duct Ligation in Laparoscopic Cholecystectomy

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Abstract

Purpose. This study was conducted to examine the usefulness and safety of absorbable clips in laparoscopic cholecystectomy (LC).

Methods. We retrospectively compared the clinical data of 328 patients who underwent LC using absorbable clips for cystic duct ligation and 444 patients who underwent LC using metal clips for cystic duct ligation.

Results. The mean operative time in the absorbable clip group was significantly shorter than that in the metal clip group. The mean intraoperative blood loss and hospital stay were not significantly different between the two groups. The rate of conversion to open laparotomy in the absorbable clip group was significantly higher than that in the metal clip group, at 6.7% *vs* 2.3%, respectively. The most common reason for conversion was difficult adhesions and inflammation around the gallbladder. The morbidity of the metal clip group was significantly higher than that of the absorbable clip group, at 8.4% *vs* 4.0%, respectively. The incidence of major postoperative complications requiring laparotomy did not differ between the two groups. There were no deaths in the absorbable clip group, but 1 of the 444 patients (0.23%) in the metal clip group died from disseminated intravascular coagulation on postoperative day 3.

Conclusion. The results of this study suggest that absorbable clips are as safe and effective as standard metal clips for vessel and duct ligation in LC.

Key words Absorbable clip · Metal clip · Complication · Laparoscopic cholecystectomy

Introduction

Laparoscopic cholecystectomy (LC)[1] has become the treatment of choice for most patients with benign gallbladder diseases such as symptomatic cholelithiasis and gallbladder polyps because of its advantages over open cholecystectomy, which include less postoperative pain, shorter hospitalization, earlier resumption of activity, and better cosmetic results. Although LC is essentially a safe procedure with low morbidity and mortality rates, many complications such as bile duct injuries, bowel injuries, postoperative bile leak, and hemorrhage have been reported.[2–6] The application of two proximal metal clips is the most popular method of securing the cystic duct during LC. However, recent reports have described endo-clip migration into the common bile duct, causing stone formation as a rare late complication of LC.[7–19] Our review of the literature revealed that almost all cases of migrating clips involved metal clips. In this respect, a polymeric absorbable clip is advantageous because it degrades by hydrolysis within 6 months. In September 1997, we began to perform LC using absorbable clips to ligate the cystic duct and cystic artery; however, the feasibility of using absorbable clips during LC and the associated clinical outcome of patients remain unclear. Therefore, we conducted a review of patients who underwent LC using absorbable clips, in an effort to compare the intraoperative course, postoperative recovery, and morbidity and mortality associated with LC using absorbable clips with those associated with conventional LC using metal clips. We also reviewed the past reports of cases of clip migration within the common bile duct after LC. Our research was aimed at determining whether LC using absorbable clips is safer and less invasive than LC using metal clips.

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Patients and Methods

Patients

Between September 1997 and December 2001, LC using absorbable clips (LC-AC) was performed in 328 patients with cholelithiasis, gallbladder polyps, adenomyomatosis, or cholecystitis at the Department of Surgery, NTT West Osaka Hospital. Another 444 patients who underwent the LC using metal clips (LC-MC) at our department between January 1992 and September 1997 were also evaluated as a control group. This study was carried out retrospectively, and we compared two populations operated on during different time periods.

Absorbable Clips

The Laparo-Clip[20–24] (Davis and Geck, Danbury, CT, USA), which is made from a bioabsorbable polymer, was used in this study. The clip is radiolucent and made of two components: an inner component manufactured from polyglyconate polymer and an outer component made of polyglycoic acid polymer. The inner track piece closes around the vessel or duct, and a rigid outer body then slides over the track piece to occlude the vessel or duct. The clip degrades by hydrolysis within 6 months and has a ligating length of 12 or 8 mm. It is applied with a reusable applicator introduced through a 10-mm port. During LC, the cystic duct was clipped with either one or two 12-mm absorbable clips on the patient's side and one clip on the gallbladder side. The cystic artery was clipped with one 8-mm absorbable clip on the patient's side and one clip on the gallbladder side (Fig. 1).

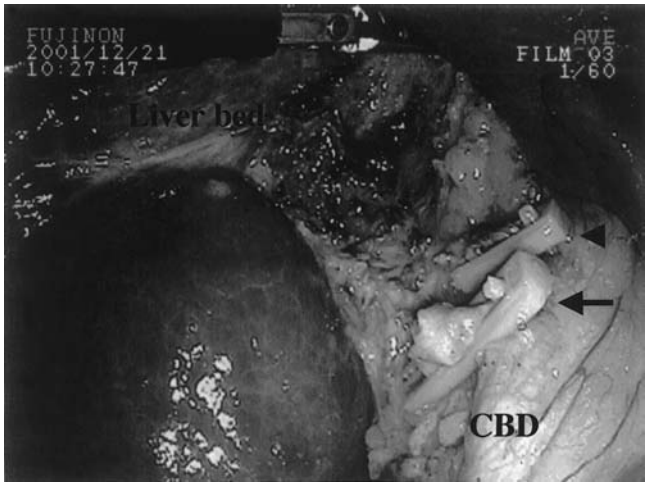

Fig. 1. Laparoscopic view of the liver bed after laparoscopic cholecystectomy showing the Laparoclip (*arrow*) used to ligate the cystic duct and the Laparoclip (*arrowhead*) used to ligate the cystic artery. *CBD*, common bile duct

Metal Clips

The Ligaclip (Ethicon, Somerville, NJ, USA), which is manufactured from titanium, was used in this study. After isolating the cystic duct in LC, the cystic duct was clipped with two metal clips on the patient's side and one clip on the gallbladder side. The cystic artery was also clipped with two metal clips on the patient's side and one clip on the gallbladder side during the same procedure.

The operative times, intraoperative blood loss, intraoperative complications, rates of conversion to open surgery and reoperation, hospital stay, and morbidity and mortality were evaluated in both groups. The intraoperative blood loss was determined by weighing the aspirated blood and blood-soaked gauze. The literature on clip migration within the common bile duct after LC was researched by MEDLINE/PubMed in the U.S. National Library of Medicine (Bethesda, MD, USA).

Statistics

The means and SDs of the collected data were calculated. Data values were statistically analyzed by Student's *t*-test and the chi-squared test, using the StatView software package (SAS Institute, Cary, NC, USA). All results were considered statistically significant if P values were less than 0.05.

Results

The clinical backgrounds of the patients in the two groups, including factors such as sex, mean age, mean weight, mean height, and distribution of diseases were similar (Table 1). Details of the operative course and postoperative recovery were evaluated in the two groups (Table 2). The mean operative time in the LC-AC group was significantly shorter than that in the LC-MC group at 84.6 *vs* 112.7 min, respectively. The mean intraoperative blood loss and hospital stay were not significantly different between the two groups. Conversion to open operation was necessary in 22 of the 328 patients (6.7%) who underwent LC-AC, and in 10 of the 444 patients (2.3%) who underwent LC-MC. The conversion rate in the LC-AC group was significantly higher than that in the LC-MC group ($P = 0.0022$). The reasons for the enforced conversion are shown in Table 3. The major reasons were severe inflammation and adhesion in the LC-AC group. One patient in the LC-MC group required conversion to open surgery, because a metal clip was not released from the disposable applicator. There were no deaths in the LC-AC group, although 1 of the 444 patients (0.23%) who underwent LC-MC died from disseminated intravascular coagula-

Table 1. Patient characteristics

Characteristic	LC-AC	LC-MC	*P* value
Sex			
Female	165	220	
Male	163	224	
Mean age (years)	53.6 ± 11.7	52.2 ± 12.3	0.1263
Mean height (cm)	161.1 ± 9.7	160.9 ± 8.9	0.7170
Mean weight (kg)	61.7 ± 11.4	61.6 ± 11.2	0.9130
Disease			
Cholelithiasis	266	376	
Gallbladder polyps	51	57	
Gallbladder adenomyomatosis	8	9	
Chronic cholecystitis without GS	3	2	

LC-AC, laparoscopic cholecystectomy with absorbable clips; LC-MC, laparoscopic cholecystectomy with metal clips; GS, gallstone

Table 2. Details of the operative course

	LC-AC	LC-MC	*P* value
Mean operative time (min)	84.6 ± 1.6	112.7 ± 2.3	0.0001
Mean intraoperative blood loss (g)	10.8 ± 0.4	11.8 ± 0.7	0.3104
Mean hospital stay (days)	7.9 ± 0.2	8.0 ± 0.1	0.6650

Table 3. Reasons for enforced conversion to open cholecystectomy

Complications	LC-AC	LC-MC
Severe inflammation	9	1
Severe adhesion	8	1
Common bile duct stone[a]	4	3
Gallbladder cancer[b]	1	2
Uncontrollable bleeding	0	1
Instrument failure	0	2
Total	22	10

[a] Common bile duct stone was detected by intraoperative cholangiography
[b] Gallbladder cancer was detected by intraoperative pathology

tion (DIC) on postoperative day (POD) 3. The morbidity rates were 4.0% (13/328) in LC-AC group and 8.6% (38/444) in LC-MC group, respectively, the morbidity in the LC-MC group being significantly higher than that in the LC-AC group ($P = 0.009$). The details of intra- and postoperative complications are shown in Table 4. The most frequent complications in the LC-AC group were gallbladder cancer and common bile duct stones, incidentally detected by intra- or postoperative pathology or intraoperative cholangiography. One of the LC-AC patients with a bile duct stricture, caused by misclipping of the common bile duct, was successfully treated by conservative therapy using percutaneous transhepatic balloon dilatation. The most frequent complication in the LC-MC group was postoperative bleeding from the liver bed or port sites. Two patients with a minor bile leak in the LC-MC group spontaneously improved on POD 3–4. The major postoperative complications requiring laparotomy are shown in Table 5. The complication rates in the LC-AC group and the LC-MC group were 1.5% (5/328) *vs* 1.6% (7/444), respectively. One

Table 4. Intra- and postoperative complications

Complications	LC-AC	LC-MC
Gallbladder cancer	4	2
Common bile duct stone	4	3
Bile duct injury	2	4
Port hernia	1	1
Jejunal perforation	0	1
Bleeding	0	11
Pancreatitis	1	1
Sepsis	1	0
Wound infection	0	6
Liver dysfunction	0	6
Ileus	0	1
Lung atelectasis	0	1
DIC	0	1
Total	13	38

DIC, disseminated intravascular coagulation

Table 5. Major postoperative complications requiring laparotomy

Complications	LC-AC	LC-MC
Gallbladder cancer[a]	3	0
Bile duct injury	1	2
Port hernia	1	1
Jejunal perforation	0	1
Bleeding	0	3
Total	5	7

[a] Gallbladder cancer was detected by postoperative pathology

Table 6. Summary of cases of clip migration within the common bile duct after laparoscopic cholecystectomy reported in the English literature

Case/age (years):sex	Clip	Time after surgery	First author[Ref.]
Cholelithiasis/59:F	Absorbable	11 weeks	Onghena (1992)[7]
Cholelithiasis/42:F	Metal	3 weeks	Matsuura (1992)[8]
Cholelithiasis/34:F	Metal	10 months	Raoul (1992)[9]
Not shown/65:F	Metal	6 months	Raoul (1992)[9]
Cholelithiasis/51:F	Metal	5 months	Raoul (1992)[9]
Cholelithiasis/47:F	Metal	8 months	Raoul (1992)[9]
Cholelithiasis/45:M	Metal	11 days	Arnaud (1993)[10]
Gallbladder polyp/57:M	Metal	3 years	Fujita (1994)[11]
Cholelithiasis/42:F	Metal	3 weeks	Sato (1994)[12]
Cholelithiasis/63:F	Metal	15 days	Cetta (1997)[13]
Cholelithiasis/52:M	Metal	2 years	Alberts (1999)[14]
Cholelithiasis/71:F	Metal	1 year	Matsumoto (2000)[15]

Table 7. Summary of cases of clip migration within the common bile duct after laparoscopic cholecystectomy reported in the Japanese literature

Case/age (years):sex	Clip	Time after surgery	First author[Ref.]
Cholelithiasis/79:M	Metal	7 months	Takahashi (1996)[16]
Cholelithiasis/72:F	Metal	1 year	Ito (1999)[17]
Cholelithiasis/53:F	Metal	11 months	Obama (2000)[18]
Cholelithiasis/60:M	Metal	3 years	Uehara (2001)[19]

patient in the LC-AC group underwent open laparotomy on POD 5 due to bile peritonitis, caused by a clip falling off the cystic duct stump. There was no case of clip migration into the common bile duct in either group.

Our review of the literature revealed 16 cases of clip migration within the common bile duct after LC, reported in nine English papers (Table 6) and four Japanese papers (Table 7) with an English abstract.[7–19] In 15 cases (93.8%), the migrating clips were metal. The only case (6.2%) of absorbable clip (Absolok Plus, Ethicon, Johnson & Johnson, Norderstadt, Germany) migration after LC was reported by Onghena et al.[7] The clips migrated from their initial sites of the various intervals, ranging from 11 days to 3 years, but most frequently (13/16) within 1 year of the operation. In 10 (66.7%) of the 15 cases of metal clip migration, the clips migrated from 6 months onward after surgery.

Discussion

In 1992, Raoul et al.[9] reported the first case of the migration of surgical clips into the biliary tract, which acted as a nidus for stone formation after LC, and suggested that clip migration might be a new complication of this procedure. Since then, a total of 16 cases of clip migration within the common bile duct after LC have been documented according to our review of the literature. In 15 cases (93.8%), the migrating clip was reported to be metal, although this could simply reflect the ratio of metal *vs* absorbable clips used in LC throughout the world. Although this complication after LC occurs rarely, some metal clips have caused bile duct stricture which required an open laparotomy.[15,18,19] In 10 (66.7%) of the 15 cases of metal clip migration, the clips had migrated from 6 months onward after surgery. Thus, absorbable clips might help to avoid this complication, because the clip degrades by hydrolysis within 6 months. Moreover, some authors believe that cystic duct ligation with absorbable thread should be the gold standard in LC, although the operative techniques involved require much concentration and coordination by the surgeon.[25–27] Therefore, we began to perform LC using absorbable clips for ligation of the cystic duct and artery in 1997. Nevertheless, the usefulness and safety of absorbable clips in LC remain unclear. To help answer this question, we compared the clinical data of patients who underwent LC using either absorbable clips or metal clips for cystic duct and cystic artery ligation.

The mean operative time in the LC-AC group was significantly shorter than that in the LC-MC group, which might be related to the learning curve in LC, considering that the mean operative time in 2001 was 79.6 min, whereas in 1992 it was 181.2 min. The mean

intraoperative blood loss and mean length of hospital stay were not significantly different between the two groups. The morbidity of the LC-MC group was significantly higher than that of the LC-AC group, at 8.4% *vs* 4.0%, respectively. The high incidence of intra- and postoperative complications in the LC-MC group in the early reported series might be related to the learning curve of LC. Generally, evaluating morbidity after LC differed in individual series, and ranged from 0.5% to 12.4%.[2–6] The rate of conversion to open laparotomy in the LC-AC group was significantly higher than that in the LC-MC group, at 6.7% *vs* 2.3%, respectively. The most common reason for conversion was difficult adhesions and inflammation around the gallbladder. The high incidence of the conversion in the LC-AC group might be related to the extended indication for LC to treat cholelithiasis in the acute phase of cholecystitis. In our hospital, LC was contraindicated for cholelithiasis with acute cholecystitis from 1992 to 1995; however, since 1996, we have been performing LC for cholelithiasis with acute cholecystitis as well as asymptomatic cholelithiasis. When the conversion rate to open laparotomy was compared between these two groups operated on from 1996 onwards, no significant difference was found (LC-AC group: 6.7%; LC-MC group: 4.7%). The overall conversion rate varies from 1.8% to 8.3% according to different reports.[5] The rate of the major postoperative complications requiring laparotomy did not differ between the two groups in this study, although there was an important accident related to an absorbable clip falling off the cystic duct stump. The cystic duct in this patient was clipped with one clip on the patient's side and one clip on the gallbladder side. We could not perform double clipping on the patient's side, because the cystic duct was too short. The single clip on the patient's side might have been incompletely ligated causing it to fall off the cystic duct stump. This could indicate that it would be safer to use two absorbable clips on the patient's side and one metal clip on the gallbladder side for short cystic duct ligations, because the absorbable clip is thicker than the metal clip. Nevertheless, the results of this study suggest that the absorbable clip is as safe and effective as standard metal clips for vessel and duct ligation in LC.

In 1993, Mansvelt et al.[28] reported a case of cholangitis caused by the migration of a metal clip used for surgical cholecystectomy, and suggested that since LC had become very popular with the routine application of metal clips, other accidents would certainly appear in the future. This risk might be obviated by the use of absorbable clips already available for laparoscopic surgery. However, an objective study relating to a sensible comparison between metal and absorbable clips would seem to require thousands of cases in each group because migration is such a rare event. Further investigations on a greater number of cases will be necessary.

References

1. Muhe E. Long-term follow-up after laparoscopic cholecystectomy. Endoscopy 1992;24:754–8.
2. The Southern Surgeons Club. A prospective analysis of 1518 laparoscopic cholecystectomy. N Engl J Med 1991;324:1073–8.
3. Peters JH, Gibbons GD, Innes JT, Nichols KE, Front ME, Roby SR, et al. Complications of laparoscopic cholecystectomy. Surgery 1991;110:769–78.
4. Soper NJ, Stockmann PT, Dunnegan DL. Laparoscopic cholecystectomy — the new "Gold standard?" Arch Surg 1992;127:917–23.
5. Yamakawa T. Complications of laparoscopic cholecystectomy — how to prevent bile duct injury. A review of the literature. Dig Endosc 1994;6:129–35.
6. MacFadyen BV Jr, Vecchio R, Ricardo AE, Mathis CR. Bile duct injury after laparoscopic cholecystectomy. The United States experience. Surg Endosc 1998;12:315–21.
7. Onghena T, Vereecken L, Van den Dwey K, Van Loon C. Common bile duct foreign body: an unusual case. Surg Laparosc Endosc 1992;2:8–10.
8. Matsuura T, Kanisawa Y, Sato T, Hirata K. Migration of "endoclips" into common bile duct after laparoscopic cholecystectomy (letter). Lancet 1992;340:306.
9. Raoul JL, Bretagne JF, Siproudhis L, Heresbach D, Campion JP, Gosselin M. Cystic duct clip migration into the common bile duct: a complication of laparoscopic cholecystectomy treated by endoscopic biliary sphincterotomy. Gastrointest Endosc 1992; 38:608–11.
10. Arnaud JP, Bergamaschi R. Migration and slipping of metal clips after celioscopic cholecystectomy. Surg Laparosc Endosc 1993;3: 487–8.
11. Fujita N, Noda Y, Kobayashi G, Kimura K, Watanabe H, Mochizuki F. Foreign bodies in the bile duct after laparoscopic cholecystectomy. Dig Endosc 1994;6:287–9.
12. Sato T, Denno R, Yuyama Y, Matsuura T, Kanisawa Y, Hirata K. Unusual complications caused by endo-clip migration following a laparoscopic cholecystectomy: report of a case. Surg Today 1994;24:360–2.
13. Cetta F, Lombardo F, Baldi C, Cariati A. Clip migration within the common bile duct after laparoscopic cholectystectomy: report of a case of transient acute pancreatitis in the absence of associated stones. Endoscopy 1997;29:S59–S60.
14. Alberts MS, Fenoglio M, Ratzer E. Recurrent common bile duct stones containing metallic clips following laparoscopic common bile duct exploration. J Laparoendosc Adv Surg Techn 1999;9: 441–4.
15. Matsumoto H, Ikeda E, Mitsunaga S, Naitoh M, Furutani S, Nawa S. Choledochal stenosis and lithiasis caused by penetration and migration of surgical metal clips. J Hepatobil Pancreat Surg 2000;7:603–5.
16. Takahashi H, Yokoi K, Wada M, Yamato T, Miyamoto N, Higashide S, et al. A case of postoperative bile duct stone by aberrant surgical clip after laparoscopic cholecystectomy (in Japanese with English abstract). Jpn J Gastroenterol Surg 1996; 29:85–8.
17. Ito A, Hashimoto T, Nagaoka M, Nakaba H, Sunada S, Akamatsu H, et al. Choledocholithiasis due to aberrant end-clips after laparoscopic cholecystectomy (in Japanese with English abstract). J Jpn Surg Assoc 1999;60:1892–6.
18. Obama K, Nakamura Y, Hashida H, Takabayashi A. Gallstone caused by migration of cystic duct metal clips into the common bile duct (in Japanese with English abstract). Jpn J Gastroenterol Surg 2000;33:347–51.

19. Uehara H, Abe T, Hosokawa M, Kondo S, Kato H. Choledocholithiasis due to a migrated metal clip after laparoscopic cholecystectomy — report of a case (in Japanese with English abstract). J Jpn Surg Assoc 2001;62:487–90.
20. Klein RD, Jessup G, Ahari F, Connolly RJ, Schwaitzberg SD. Comparison of titanium and absorbable polymeric surgical clips for use in laparoscopic cholecystectomy. Surg Endosc 1994;8:753–8.
21. Hawasli A. The use of absorbable clips in laparoscopic cholecystectomy. J Laparosc Surg 1994;4:333–8.
22. Leung KL, Kwong KH, Lau WY, Chung SCS, Li AKC. Absorbable clips for cystic duct ligation in laparoscopic cholecystectomy. Surg Endosc 1996;10:49–51.
23. Darzi A, Soin B, Coleman J, Lirici NM, Angelini L. Initial experience with an absorbable laparoscopic ligation clip. Br J Surg 1997;84:974–6.
24. Tan TM, Okada M. The efficiency of absorbable clips in minimally invasive surgery. Surg Today 1999;29:828–31.
25. Nathanson LK, Easter DW, Cuschieri A. Ligation of the structures of the cystic pedicle during laparoscopic cholecystectomy. Am J Surg 1991;161:350–4.
26. Lim BS. Intracorporeal ligation of the cystic duct during laparoscopic cholecystectomy. Surg Laparosc Endosc 1996;6:388–91.
27. Saha SK. Ligating the cystic duct in laparoscopic cholecystectomy. Am J Surg 2000;176:494–6.
28. Mansvelt B, Harb J, Farkas B, Mourou M, Huguet C. "Clipstone" filiation within the biliary tract. HPB Surg 1993;6:185–8.