

Polymeric locking clips [Hem-o-lok] versus metallic clips in elective laparoscopic cholecystectomy: a retrospective study of 1496 patients

Zastosowanie zamykających klipsów polimerowych [Hem-o-lok] w porównaniu z klipsami metalowymi w planowej cholecystektomii laparoskopowej: retrospektywne badanie obejmujące 1496 pacjentów

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Article history: Received: 06.06.2020 Accepted: 14.04.2021 Published: 14.04.2021

ABSTRACT:

Introduction: Laparoscopic cholecystectomy is one of the most commonly performed operation. Various methods for securing the cystic artery and cystic duct are described in literature.

Aim: We aim to compare intra-operative and early post-operative outcomes of laparoscopic cholecystectomy using polymeric locking Hem-o-lok clips versus metallic ligaclips.

Material and methods: Retrospective study of prospectively maintained single institutional data including all consecutive patients who underwent elective laparoscopic cholecystectomy from 2013 to 2018. Patients in whom metallic ligaclips were used were grouped as Group I and those with Hem-o-Lok were grouped as Group II. The early post-operative outcomes of the two groups were compared.

Results: Total 1496 patients were included in the study; 836 patients in Group I and 660 in Group II. Study included 29.1% males and 70.9% females with mean age of 43.6 years. Hem-o-lok clip was better in securing wide cystic duct compared to metallic clips. Metallic clip failed to secure 8 out of 44 wide cystic duct compared to 0 out of 70 with Hem-o-lok clips ($p = 0.002$). The post-operative outcomes of both groups were comparable. There were no cystic duct leak, post-operative bleeding or major bile duct injuries in either group.

Conclusion: Use of Hem-o-lok clip is safe in laparoscopic cholecystectomy due to ease of application and security. Hem-o-lok is more useful in patients with thick and wide cystic duct which are difficult to secure with metallic clips with low risk of leak.

KEYWORDS:

Hem-o-lok clip, laparoscopic cholecystectomy, metallic clip, wide cystic duct

STRESZCZENIE:

Wstęp: Cholecystektomia laparoskopowa to jedna z najczęściej wykonywanych operacji. W literaturze opisywanych jest wiele metod zamykania tętnicy pęcherzykowej i przewodu pęcherzykowego.

Cel: Celem badania było porównanie wyników cholecystektomii laparoskopowej z zastosowaniem polimerowych klipsów zamykających Hem-o-lok z klipsami metalowymi Ligaclip w okresie śródoperacyjnym i wczesnym okresie pooperacyjnym.

Materiał i metody: W retrospektywnym badaniu wykorzystano prospektywnie prowadzoną bazę danych, obejmującą wszystkich pacjentów poddawanych planowej cholecystektomii laparoskopowej od stycznia 2013 do grudnia 2018 roku. Do grupy I włączono pacjentów, u których zastosowano klipsy metalowe Ligaclip, a do grupy II włączono pacjentów, u których zastosowano klipsy Hem-o-lok. Porównano wyniki we wczesnym okresie pooperacyjnym uzyskane w obydwu grupach pacjentów.

Wyniki: W badaniu uczestniczyło łącznie 1496 pacjentów: 836 pacjentów w grupie I oraz 660 pacjentów w grupie II. Badanie obejmowało 29,1% mężczyzn oraz 70,9% kobiet w wieku wynoszącym średnio 43,6 lat. Zastosowanie klipsów Hem-o-lok wiązało się z lepszymi wynikami zamykania szerokiego przewodu pęcherzykowego w porównaniu z klipsami metalowymi. Niepowodzenie zabezpieczenia szerokiego przewodu pęcherzykowego wystąpiło w 8 na 44 przypadków dla klipsów metalowych w porównaniu z 0 na 70 przypadków dla klipsów Hem-o-lok ($p = 0,002$). Wyniki pooperacyjne w obydwu grupach były porównywalne. W żadnej z grup nie obserwowano nieszczelności przewodu pęcherzykowego, krwawienia pooperacyjnego ani dużych uszkodzeń przewodu żółciowego.

Wnioski: Stosowanie klipsów Hem-o-lok w cholecystektomii laparoskopowej jest bezpieczne ze względu na łatwość i pewność ich aplikacji. Klipsy Hem-o-lok są bardziej przydatne u pacjentów z grubymi i szerokimi przewodami pęcherzykowymi przy niskim ryzyku nieszczelności, których zabezpieczenie jest trudne z zastosowaniem klipsów metalowych.

SŁOWA KLUCZOWE: cholecystektomia laparoskopowa, klips Hem-o-lok, klips metalowy, szeroki przewód pęcherzykowy

ABBREVIATIONS

CT – computed tomography
ERC – endoscopic retrograde cholangiography
LC – Laparoscopic cholecystectomy
MRI – magnetic resonance imaging
SPSS – Statistical Package for Social Sciences

INTRODUCTION

Laparoscopic cholecystectomy (LC) is the most common laparoscopic operation performed worldwide. Safe occlusion of the cystic artery and cystic duct are important steps of the procedure to prevent complications like bleeding and cystic duct leak which can be life-threatening. The incidence of cystic duct leak varies from 0.5 to 3%, following laparoscopic cholecystectomy which is higher in complicated gall stone disease [1]. Clipping the artery and cystic duct using metallic clips is the most preferred technique practiced by the majority of laparoscopic surgeons [1]. Various other techniques, like clipping with non-absorbable and absorbable locking clips, suturing, stapling, application of pretied loops, use of energy sources like Ligasure and harmonic scalpel are described in literature for the closure of cystic ducts [2–8]. Non-absorbable polymeric clips (Hem-o-lock, Weck Surgical Instruments, Teleflex Medical, Durham, NC, USA) have gained increasing importance to secure the cystic duct and artery [9]. A recent study of 1017 laparoscopic cholecystectomies observed a zero leak rate from cystic duct with the use of locking clips [10]. Even though there are studies comparing absorbable locking clips with other methods in LC, there are no randomised trials comparing Hem-o-lok and metal clips published in the literature. The aim of this study was to compare safety and short-term outcomes of polymeric locking clips [Hem-o-lock] and of conventional metallic ligaclips in laparoscopic cholecystectomy.

MATERIALS AND METHODS

This retrospective study was conducted in the Department of Surgical Gastroenterology in a tertiary care teaching hospital in Northern India. Institutional Ethics Committee approval was obtained for the study for an observational study design with IEC No 10/2018. Prospectively maintained data of all the patients who underwent elective laparoscopic cholecystectomy from January 2013 to December 2018 were included in the study. Patients who were converted to open procedure for reasons other than clip failure were excluded from the study. During the initial part of the study period metallic clips were used for securing the cystic artery and cystic duct. In the later part, polymeric locking clips [Hem-o-lok] were used, which is the current practice in the department (Fig. 1.). Patient demographics, operative findings, events related to clipping the cystic artery and cystic duct and post-operative complications were analysed.

Primary outcomes studied were the successful clipping of the cystic artery and the cystic duct including wide cystic ducts, events related to clipping and post-operative bleeding and bile leak. Patients in whom metallic clips were used were then categorised as group I [LC] and polymeric clips as group II [HL]. Outcomes of group I patients were compared with those of group II.

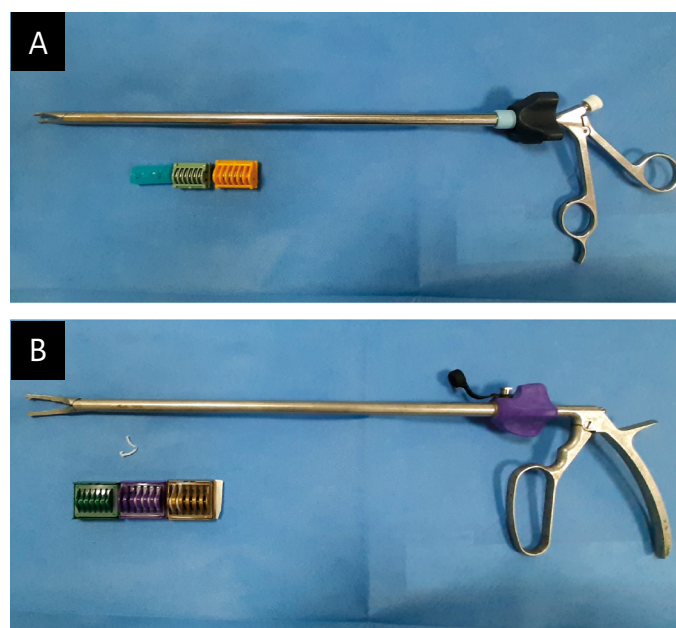


Fig. 1. Two types of clips used. (A) metallic clips [Ligaclip] with applicator; (B) Polymeric locking clips [Hem-o-lok] with applicator.

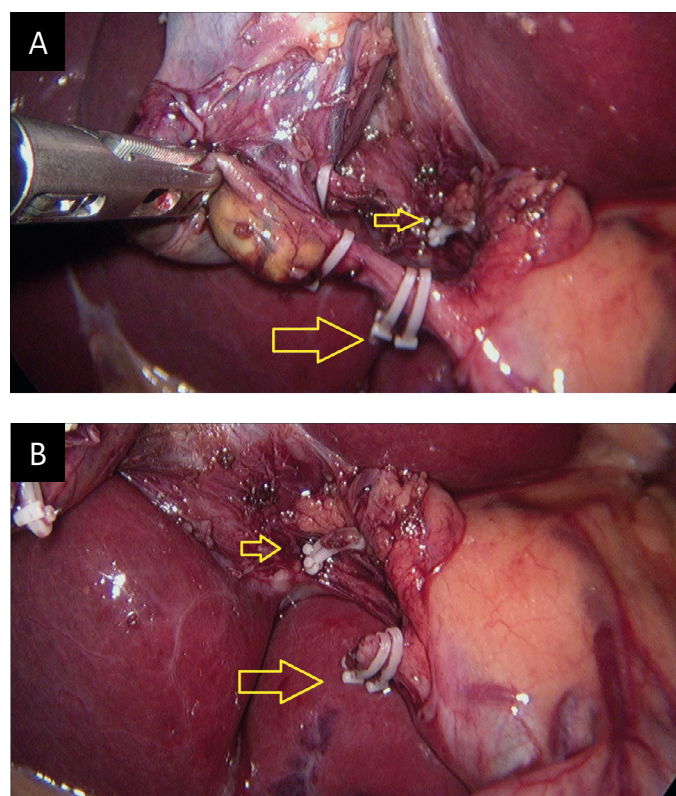


Fig. 2. (A, B) Hem-o-lok applied on the cystic artery [small arrow] and cystic duct [large arrow].

SURGICAL PROCEDURE

The surgeries were performed by 3 consultants and six residents under supervision. Each resident had performed ≥ 20 laparoscopic cholecystectomies before. Standard 4-port cholecystectomy was performed in all patients. Operative technique and steps in both groups of patients were the same, except for the type of clips used for clipping the cystic artery and the duct. After the Calot's triangle dissection, a critical view of safety was attained. Cystic artery was secured with a single clip on the patient's side

Tab. I. Indication for surgery in two groups.

DIAGNOSIS	GROUP I [HL] N = 836	GROUP II [HL] N = 660	TOTAL N = 1496
Symptomatic GSD	769 [82.0]	557 [84.4]	1326 [88.6]
Biliary Pancreatitis	25 [3]	27 [4.1]	52 [3.5]
CBD stones	22 [2.6]	40 [6.1]	62 [4.2]
Mucocele	13 [1.6]	24 [3.6]	37 [2.5]
Empyema	7 [0.8]	9 [1.4]	16 [1.1]
Polyp	0	1 [0.2]	1 [0.1]
Porcelain GB	0	2 [0.3]	2 [0.1]
Total	836	660	1496

GSD—gall stone disease, CBD—common bile duct, GB—gall bladder

with/without a clip on the gall bladder side and divided with energy source/scissors in both groups. Two clips were applied on the cystic duct stump and one clip on the gall bladder side. The cystic duct was divided with scissors in both groups (Fig. 2.).

Clip failure for cystic artery was defined as intraoperative or postoperative bleeding, requiring additional clips, conversion to open surgery or re-exploration or radiological intervention for postoperative bleeding. Clip failure for cystic duct was defined as being unable to secure the cystic duct with the clip, need for suture ligation and postoperative leakage of bile from the cystic duct stump. Cystic duct of 4 mm in size or more was defined as wide cystic duct for the study purpose. Cystic duct diameter was measured before clipping by a 5-mm instrument with custom-made markings. The same was confirmed by measuring with a ruler on the gall bladder specimen and documented in the operative findings.

STATISTICAL ANALYSIS

The data were entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 16.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were presented in numbers and percentages (%) and continuous variables were presented as mean \pm SD. Quantitative variables were compared using Unpaired t-test between two groups. Qualitative variables were compared using Chi-square test/Fisher's exact test as appropriate. A P-value of < 0.05 was considered statistically significant.

RESULTS

A total of 1531 patients underwent elective LC during the study period; thirty-five patients were converted to an open procedure before the dissection and application of a clip, and were excluded from the study. Among the remaining 1496 patients included, there were 436 males and 1060 females. Their mean age was 43.6 years (range 14 to 90 years). There were 836 patients in group I (229 males, 607 females) and 660 patients in group II (207 males and 253 females). The majority of the patients had symptomatic uncomplicated gall stones. The indications for surgery in both groups are presented in Tab. I. Forty-one patients had undergone additional procedures with LC (Tab. II.).

Tab. II. Additional procedures.

ADDITIONAL PROCEDURE	GROUP I	GROUP II	TOTAL
CBD Exploration	1		1
Repair of cholecystoduodenal fistula	2	5	6
Suturing of bile leak from GB fossa	1		1
Umbilical hernia repair	2	3	5
Liver biopsy	1		1
Clipping of accessory duct	1		1
Cystogastrostomy	1	2	3
Thoracotomy for excision of esophageal cyst		1	1
IPOM		6	6
IO USG		1	1
Converted to open procedure for bleeding		1	1
Splenectomy		1	1
Sleeve gastrectomy		5	5
Appendectomy		3	3
Inguinal hernia repair TAAP		1	1
Rectopexy		1	1
Pacemaker implantation		1	1
Clipping of vein [MHV] in GB fossa		1	1
Total	9	32	41

CBD—common bile duct, IPOM—intraperitoneal onlay mesh repair, IOUS—intraoperative ultrasound, TAAP—Trans abdominal preperitoneal repair, MHV—middle hepatic vein, GB—gall bladder

About one-fourth of patients in both groups had one or more comorbid illnesses. The most common comorbidities observed were hypertension (12.3%), diabetes mellitus (8.2%) followed by hypothyroidism (7.1%). Sixty-four patients had preoperative endoscopic retrograde cholangiography (ERC) and stenting; fifty-two patients had a prior history of biliary pancreatitis.

Cystic artery clipping was uneventful in patients of both groups. None of the patients in either group required conversion for cystic artery bleeding or events related to clipping of the artery. Outcomes of patients in both groups are given in Tab. III.

Wide cystic duct was observed in 44 patients in the LC group and 70 patients in the HL group ($P = 0.026$). Clip failure (inability to clip the cystic duct securely, requiring suture ligation) was observed in 8/44 patients with wide cystic duct in group I and 0/70 in group II ($P = 0.002$). None of the patients in either group required conversion to open procedure due to clip failure.

One patient in group II who had a pacemaker in-situ, had bleeding from the gallbladder fossa; which was not controlled by routine measures. He required conversion to an open procedure, for haemostasis. Another patient, also in group II, who had bleeding from exposed tributaries of the middle hepatic vein in the gallbladder fossa, was managed with metallic clip ligation. There were no major bile duct injuries in both groups. One patient had a bile leak from the gallbladder fossa intraoperatively which was managed by suturing and clip ligation of a minor duct. There was one postoperative bile leak in the metallic clip group who had

Tab. III. Outcomes of patients in two groups.

OUTCOME	GROUP I [LC] N = 836	GROUP II [HL] N = 660	P-VALUE
Hospital stay	3.06 [SD 1.6]	2.37 [SD 1.21]	<0.001
Post-op stay	1.45 [SD 1.23]	1.19 [SD 0.82]	<0.001
Comorbidities	26.7%	22.1%	0.66
HYP	7.86%	6.26%	0.242
HT	14.2%	9.8%	0.010
DM	9%	7.3%	0.235
Others	5.3%	7.9%	0.219
Additional procedure	1.1%	4.8%	0.027
Wide CD	5.3%	10.6%	0.029
Clip failure in wide CD	8/44	0/70	0.002
Bile/stone spillage	6.8%	9.7%	0.055
Bile leak	1	0	1.00
Post-op complications	5.4%	7.3%	0.241
Drains	10.8%	15.2%	0.011

HYP – Hypothyroidism, HT – Hypertension, DM – Diabetes mellitus

also undergone laparoscopic CBD exploration, which was managed conservatively and subsided in 5 days. No other patients in either group had any postoperative bile leak.

Mean postoperative stay was 1.49 days in group I and 1.19 days in group II ($P < 0.001$). Superficial surgical site infection in the port site occurred in 45 patients in group I and 46 patients in group II $P = 0.241$. One patient in group I had postoperative sepsis which required intravenous antibiotics and longer hospital stay, however there was no bile leak or collection identified on imaging.

DISCUSSION

LC is the gold standard treatment for symptomatic gall stone disease. Safe occlusion of the cystic artery and duct is the key step in LC to prevent complications like bleeding and bile leak, which can be life-threatening. Various methods, like clipping with metallic or polymeric clips, suture ligation and use of energy devices are described in literature for securing the cystic artery. Various methods like clipping with metallic or polymeric absorbable and non-absorbable locking clips, suturing, tying, use of pretied loops, sealing with various energy devices like Harmonic scalpel and Ligasure are described for cystic ducts in literature with comparable results [1–8]. Clipping with metallic clips is the most common method used to secure the cystic artery and cystic duct worldwide. According to a recent systematic review and meta-analysis, 81.5% of surgeons use metallic clips to secure the cystic artery and cystic duct [1]. Even though metallic clips are used most frequently, they are considered to be less secure than locking clips. Metallic clips are not very tightly secured and can be removed or dislodged easily leading to cystic duct leakage. Similarly, too thick or wide cystic ducts are difficult to secure due to insufficient closure of the metal clip arms. This can lead to slippage of the clips off the end of the duct, or necrosis of the duct at the site of clipping caused by an electro-surgical burn, leading to leak [10, 11]. Chong et al. in their review of 69

cases, found that post-cholecystectomy clip migration was seen nearly exclusively with the use of metallic clips (67/69). The remaining two cases were following absorbable locking clips [12].

Hem-o-lock polymeric locking clips are non-absorbable, inert, non-conductive, and compatible with computed tomography (CT) scan and magnetic resonance imaging (MRI). The lock engagement and presence of teeth provide good security, and the flexible mechanism virtually prevents the clip from falling out of an applicator (Fig. 3.). These features make the hem-o-lok clip a favourite tool for securing blood vessels in the majority of advanced laparoscopic procedures [13]. These clips are more secure than titanium metal clips on larger arteries and veins and can withstand more pressure [14]. There are 4 sizes of Hem-o-lok clips and applicators (M, ML, L, and XL) available for use in minimal invasive surgery [13]. The smallest size is M, for vessel 2 to 7 mm, and the largest is XL, for 7 mm to 16 mm. Even though they provide secure closure of vessels, there are reports of adverse events in the literature, like clip failure leading to bleeding and erosion into the viscera following different kind of laparoscopic surgeries [15–17]. The manufacturer and FDA do not recommend the use of Hem-o-lok for clipping the renal artery during laparoscopic donor nephrectomy following mortalities due to bleeding. The same is also notified by the American Society of Transplant Surgeons [18].

Hem-o-lock clips have also been used by many surgeons for securing the appendicular stump in laparoscopic appendectomy with good results [19, 20]. There are randomised controlled trials and non-randomised studies comparing the efficacy of Hem-o-lok with other methods of stump closure in appendicitis [19–25]. These studies favour the use of Hem-o-lok. There are also studies comparing Hem-o-lok with absorbable clips in laparoscopic appendectomy. There were no statistically significant differences in adverse events, complications or outcomes between two groups [26].

Hem-o-lock is not the preferred method used in laparoscopic cholecystectomy probably due to its higher cost as compared to metallic clips which are commonly used on the cystic artery and duct with good results. Many surgeons prefer to use Hem-o-lok to close the cystic duct in LC [9] due to the ease of its use, security, shorter operating time and cost-effectiveness. There are no randomised trials comparing the use of Hem-o-lok clips with metallic clips in laparoscopic cholecystectomy. The only retrospective study published by Matsui et al., comparing locking clips with other methods, showed no cystic duct leak in 1017 patients with locking clips [10]. In their study they compared 110 non-absorbable and 907 absorbable locking clips with other methods of closure in 31 patients and no closure in 5 patients. There was only one cystic duct leak in one of the non-closure patients in their study. Aminian et al. reviewed 856 laparoscopic procedures including 770 laparoscopic cholecystectomies and did not observe any clip failure or adverse events with the use of Hem-o-lok clips [13]. They observed that the Hem-o-lok clips are safe and secure if applied properly. They also emphasised the need of education regarding a proper application technique. Even though there are many advantages, various complications following the use of Hem-o-lok in laparoscopic cholecystectomy have also been reported on in the literature [14–17]. In our centre we used metallic clips during the earlier part of the study. We moved on to Hem-o-loks

since we felt that they are more secure and a significant number of our patients had a wide cystic duct which was difficult to secure and required suturing. With the use of Hem-o-lok we found that almost all the cystic ducts could be secured safely and required no suturing. Accidental occlusion and slippage of the clips from the applicator is less frequent as compared to metallic clips and there is no partial clipping. In our study we did not observe any adverse events or clip failure with the use of Hem-o-lok which is consistent with the previous studies [1, 10, 13].

In our study, 114 patients had a wide cystic duct with 70 patients in the Hem-o-lok group and 44 patients in the metal clip group. A higher number of wide CDs could be due to more patients who had CBD stones/post-ERCP in group II. All the wide cystic ducts, including a cystic duct of almost 15 mm, could be safely occluded with the Hem-o-lok clips (Fig 4.). We did not observe any cystic duct leak, neither with the use of metallic clips nor with Hem-o-loks. In the recent systematic review and meta-analysis of various closure techniques of cystic ducts by van Dijk AH et al. showed that the pooled cystic duct leak rate is about 1% for metal clips and harmonic energy and 0% for locking clips and ligatures [1]. In our study we observed the following advantages with the use of Hem-o-lok clips. They provide more secure closure due to their locking mechanism and serrations. They are inert and do not interfere with CT/MRI imaging. Almost all the cystic ducts including those very wide ones, more than 1 cm wide, can be securely closed with the Hem-o-lok clips. Clip wastage due to accidental fall from the applicator during introduction is lower as compared to metallic clip. All the cystic arteries can be safely closed with a single clip. Instead, the most important features of Hem-o-lok is that no additional skills are required for its application, unlike in suturing, which is an advanced skill for the resident surgeons. The difference in the cost for clips in both groups was not significant in our study. The post-operative outcomes and complications in both groups were comparable in our study. Even though the difference in the mean hospital stay and post-operative stay is statistically significant, authors feel that it is not clinically significant. Increase in hospitalization time in group I is probably due to delayed discharge policy in all the patients in the earlier part of the study.

Our study is limited by the retrospective nature and lack of long-term follow-up to show the adverse effects described in the literature, like erosion of clips and related complications. Further prospective studies with a long-term follow-up are required to make comments on these complications.

CONCLUSION

The use of Hem-o-lok clips in laparoscopic cholecystectomy is safe with comparable results with added benefits. Due to the availability of a bigger size and a locking mechanism, it can securely close most of the wide cystic ducts without the need for suturing, but with saving the operating time and being cost-effective.

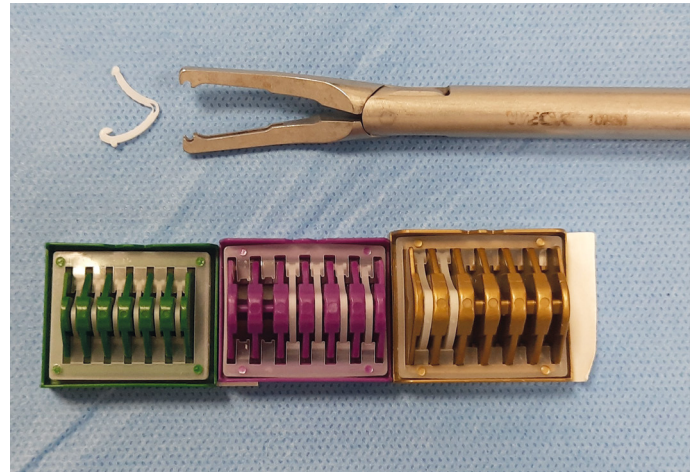


Fig. 3. Locking mechanism of Hem-o-lok clip with special applicator preventing accidental slippage of the clip.



Fig. 4. Wide cystic duct secured with XL Hem-o-lok.

ACKNOWLEDGEMENT

Pankaj Patel and Saurabh Verma, Computer operators in the department for the general and technical Support in retrieving the data.

Manoj Pandey, statistician for performing statistical analysis and support.

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Word count: 4032

Page count: 7

Tables: 3

Figures: 4

References: 26

DOI: 10.5604/01.3001.0014.8378

Table of content: <https://ppch.pl/issue/13669>

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Competing interests: The authors declare that they have no competing interests.



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