

Polymeric Locking Clips (Hem-o-loc) Versus Metallic Clips For Control Of Dilated Cystic Duct During Laparoscopic Cholecystectomy

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Introduction

Gallbladder (GB) stones is a popular condition which is affecting the human beings. Laparoscopic cholecystectomy (LC) is considered the gold standard in the treatment of symptomatic gallbladder stones. The primary cause of vascular and bile duct damage during laparoscopic cholecystectomy is misidentification of the anatomical components. The following three features characterize critical View of Safety (CVS) presented by Strasberg, This view: (1) the hepatocystic triangle's fibrous and fatty tissue has been cleared away; (2) there are only two tubular structures visible entering the gallbladder's base; and (3) the lower third of the gallbladder has separated from the liver to reveal the cystic plate. After achievement of (CVS),The cystic duct and cystic artery are clipped and divided with great care. Sometimes, surgeons face some difficult situations during the performance of an LC. This includes anatomic anomalies, such as a short cystic duct, and pathological problems, such as frozen Calot’s triangle, or a dilated cystic duct, which is defined as 4mm or more in its diameter. During LC, it is essential to adequately close the cystic duct to avoid leakage of bile from the cystic stump into the abdominal cavity.Traditionally, metallic clips have been the preferred choice for cystic duct closure even if dilated during (LC). While effective in many cases, these clips have limitations that contribute to the challenges in cystic duct management. Concerns such as possibility of bile leak from cystic duct stump is higher, and potential interference with postoperative imaging modalities have prompted a quest for alternative technologies, leading to the emergence of polymeric locking clips like Hem-O-Loc.

Aim of the work

This prospective study aims to evaluate safety, feasibility, and short-term outcomes of non-absorbable polymeric locking clips versus conventional metallic clips for control of the dilated cystic duct in elective Laparoscopic Cholecystectomies operated in Alexandria Main University Hospital and the Medical Research Institute Hospital.

Patients and Methods

After approval of local ethics committee, informed written consents were taken from all patients included in this study. This randomized clinical trial included 80 patients with symptomatic gallstone disease admitted to the Hepatobiliary-Pancreatic (HBP) Surgical Unit at Alexandria University Main Hospital and the Surgical Unit at Medical Research Institute Hospital.Using a web-based simple randomization generator, the patients were equally, simply, and randomly assigned in a ratio of 1:1 to either receive Hem-o-Lok clips or metallic clips. Prospective assessment: thorough history taking, physical examination, routine labs with focusing on serum bilirubin, alkaline phosphatase and liver enzymes and ultrasound abdomen with biliary assessment.

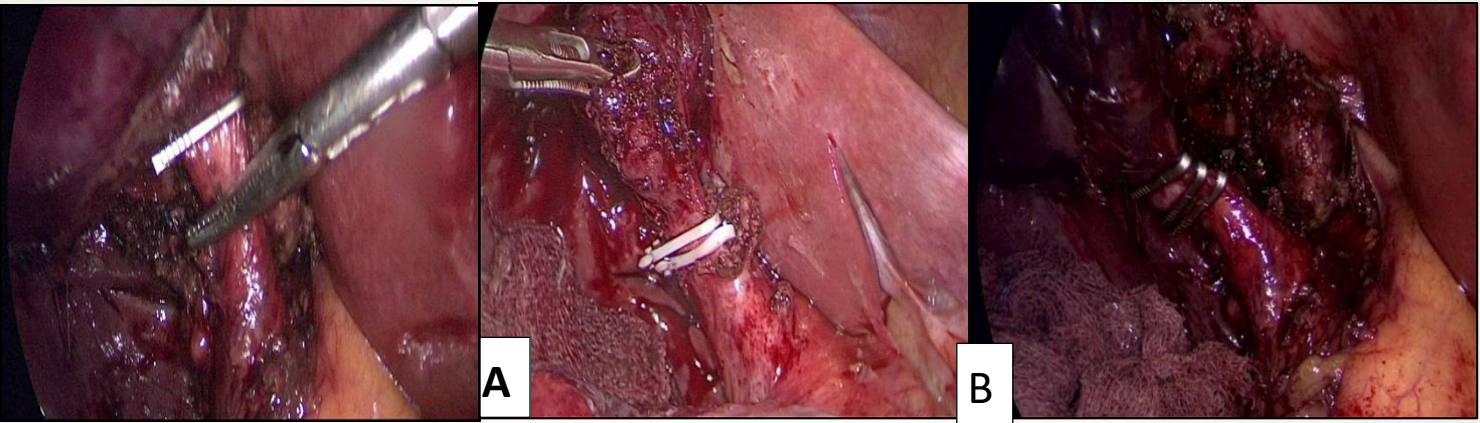


Fig (1) : Measurement of cystic duct diameter using Maryland blade

Fig (2) Successful control of dilated cystic duct using Hem-o-Lok (A), and metallic clip (B)

Results

In 80 patients with symptomatic gallstone, Regarding intra-operative data between both study groups, both groups showed no statistically significant differences in all intraoperative data. Intraoperative Successful control of the dilated cystic duct was achieved in all participants (100%) in both the Hem-o-Lok and Metallic Clip groups

Table (1): Intra-operative Data Between Both Study Groups.

Intra-operative Data	Hem-o-Lok Group (n= 40)	Metallic Clip Group (n= 40)	Statistical Analysis	P
1. Successful control of dilated cystic duct			x ²	P
- Yes	40 (100%)	40 (100%)	0.737	0.091
- No	0 (0.0%)	0 (0.0%)		
2. Operative Time (minutes)			T	P
- Mean ± SD	30 ± 15	40 ± 12	1.63	0.721
3. The need for conversion to open surgery				
- Number (%)	0 (0.0%)	0 (0.0%)	----	----
4. Amount of blood loss (ml)			T	P
- Mean ± SD	90 ± 30	87 ± 25	1.67	0.145
5. Cystic duct leak				
- Number (%)	0 (00.0%)	0 (0.0%)	----	----
6. Visceral injury				
- Number (%)	0 (0.0%)	0 (0.0%)	----	----

Regarding postoperative course and complications, there were no statistically significant differences between the two study groups regarding postoperative course and complications. cystic duct control was successful in 100% of the Hem-o-Lok group but in 97.5% of the Metallic Clip group, with one case of bile leakage due to clip failure.

Table (2):Postoperative Course and Complications Between Both Study Groups.

Postoperative Course and Complications	Hem-o-Lok Group (n= 40)	Metallic Clip Group (n= 40)	Statistical Analysis	P
1. Successful Control Outcome			x ²	P
- Yes	40 (100%)	39 (97.5%)	0.09	0.765
- No	0 (0.0%)	1 (2.5%)		
2. Complications Related to Anaesthesia			x ²	P
- Yes	0 (0.0%)	0 (0.0%)	---	---
- No	40 (100%)	40 (100%)		
3. Complications Specific to Laparoscopic Cholecystectomy			x ²	P
A. Bile Leak	0 (0.0%)	1 (2.5%)	0.05	0.481
B. Bleeding	0 (0.0%)	0 (0.0%)	---	---
C. Cystic duct leak	0 (0.0%)	1 (2.5%)	0.36	0.548
4. Need for Readmission within the First Postoperative Month			x ²	P
- Yes	0 (0.0%)	1 (2.5%)	0.10	0.09
- No	40 (100%)	39 (97.5%)		
5. Trocher Site Infection:			x ²	P
- Yes	2 (5.0%)	1 (2.5%)	0.25	0.617
- No	38 (95.0%)	39 (97.5%)		

Regarding secondary endpoints between both study groups, there was a significant difference between the groups regarding clip costs metallic clip cartilage 5\$ and Hem-O-Loc cartilage 20\$; otherwise there was no statistically significance between two groups in other parameters.

Conclusion

Both clip types demonstrated comparable safety and efficacy in controlling the dilated cystic duct during laparoscopic cholecystectomy, with similar rates of technique success and clip failure. Additionally, postoperative recovery and complication rates were similar between the two groups during the follow-up period. However, a statistically significant difference in Clip cost was found between the two clips.