ORIGINAL ARTICLE

Hem-o-lok clips versus intracorporeal knotting for the closure of the appendix stump in laparoscopic appendectomy: A prospective randomized study

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ABSTRACT

BACKGROUND: In this study, we aimed to evaluate the superiority of intracorporeal sutures and Hem-o-lok clips about efficiency, reliability and cost.

METHODS: We performed laparoscopic surgery for acute appendicitis in this study. Appendiceal stump was closed by Hem-o-lok clips (Group I) and intracorporeal knotting (Group II) in a randomized manner. Groups were compared for demographic data (age, sex, body mass index, American Society of Anesthesiologists score) operation time, total cost, 2.6.12.24.hours and 7th day pain score.

RESULTS: Demographic data, such as age, gender and BMI, were similar between groups (p>0.05). There was no significant difference between the groups concerning peroperative and postoperative complications (p>0.05). No postoperative nausea, vomiting, ileus and intraabdominal abscess were observed in patients. There was no significant difference between the groups about duration of operation, length of hospital stay and cost analysis (p>0.05). There was no significant difference in pain scores of groups. The effect of the operation type on pain scores was not statistically significant (p>0.05).

CONCLUSION: This study showed that both intracorporeal knotting and Hem-o-loc clips were effective, reliable and similar costeffective in laparoscopic appendectomy. The decision should be based on the surgeon's experience.

Keywords: Appendicitis; cost-effectiveness; laparoscopic surgery.

INTRODUCTION

Acute appendicitis is a health problem affecting a significant part of the population. Although antibiotic treatment can be applied in very few selected cases, the main treatment method is surgery.^[1] Open appendectomy is an easy and safe method in surgical treatment. The other surgical treatment method is laparoscopic appendectomy. Because of its advantages, such as less postoperative pain, faster recovery, shorter hospital stay and better visualization of lower abdominal quadrants, laparoscopic appendectomy is getting used more commonly nowadays.^[2] Recent guidelines recommend laparoscopic appendectomy as the first choice for the treatment of acute appendicitis.^[3,4] The critical step of this surgery is the closure of the appendix stump, which may lead to very serious postoperative complications when not closed properly.^[5] In laparoscopic surgery, the appendix stump can be closed by different methods, such as endostapler,^[6] endoloop, metal clip^[5] bi-polar endocoagulation,^[7] Hem-o-lok clips^[8,9] and intracorporeal knotting.^[10] Each method has advantages and disadvantages.^[5,11] Current studies are inadequate about cost, postoperative pain scale and recovery time.^[11] Therefore, the proper closure method of the appendix stump in laparoscopic appendectomy has not been decided yet. Recently, hem-o-lok clips have become quite popular in the closure of the appendix stump.^[9,12,13] On the other hand, intracorporeal knotting is the other closure method that is safe and relatively inexpensive.^[1,10,14–16]

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In our study, we aimed to evaluate the superiority of intracorporeal sutures and Hem-o-lok clips concerning efficiency, reliability and cost.

MATERIALS AND METHODS

Laparoscopic appendectomy was performed in patients with acute appendicitis.

The closure of the appendix stump was randomized before the operation. Appendiceal stump was closed with Hem-olok clips (Group I) and intracorporeal knotting by 2/0 silk (Katsan, Izmir, Turkey) (Group II). All expenses included in total cost from the admission to emergency room until the time of discharge. Groups were compared for demographic data (age, sex, body mass index (BMI) American Society of Anesthesiologists score (ASA), operation time, total cost, 2.6.12.24. hours and 7^{th} day pain score. The pain score was evaluated using the visual analog scale (VAS). Tramadol hydrochloride 100 mg (Menta Farma, Istanbul, Türkiye)^R used for postoperative analgesia. Patients with an appendiceal stump higher than 10 mm in diameter, under 18 years of age, and other pathology in addition to appendiceal pathology were excluded from this study. The primary endpoint of this study was the significant difference between the groups concerning morbidity and mortality in the early period. Our study was planned in accordance with the Helsinki Declaration and the informed consent of the patients was obtained. This study is registered retrospectively on the clinicaltrials. gov database and approved by the Ethics Committee of University of Health Sciences, Izmir Bozyaka Training and Research Hospital (decision date: 24.03.2015-no:3).

Power analysis was carried out to determine the minimum sample size. (1b)=0.80 power with a probability value of a=0.05. This analysis suggested that the sample size should be a minimum of 16 patients in each group. After We explained the details of the surgical procedure to the participants and obtained their written informed consent. The patients were randomized by a coin toss. IBM SPSS Statics Version 24 was used for the statistical analysis of the data. In the comparison of categorical data between groups, Fisher's Whits Exact test was used. Mann-Whitney U test in the comparison of continuous data between groups was used. Repeated Measures ANOVA statistical analysis was used in comparing pain scores. P<0.05 was considered statistically significant.

Surgical Method

All operations were performed by two surgeons. Prophylactic antibiotic (100 ml (500 mg) Metronidazole IV Infusion) was performed 30 min before the operation. The first 10 mm trocar was inserted above the umbilicus using Hasson technique and pneumoperitoneum was formed. 5 mm trocar was inserted at the suprapubic region, and 10 mm trocar was in-

serted at the left lower quadrant under direct vision. $15-20^{\circ}$ Trendelenburg and $10-15^{\circ}$ left side position was given to the operation table. Appendix meso was dissected and coagulated. For hem-o-lok group 2 clips applied in the stump side and one clip for the appendix side. Then, cut with endoscissors between them. The appendix was taken out of the abdomen inside an endobag. For intracorporeal knotting group, 2/0 multiflaman silk was used. Two for the stump side and one for the appendix side were used. Again using an endobag, the specimen was taken out. In both groups, 10 mm trocar entrance fascia closed with 0 polyglactin and skin closed with 3/0 polypropylene.

RESULTS

In our study, 41 patients met the inclusion criteria. 20 patients for group I and 21 for group 2. Randomization protocol is given in Figure 1. Demographic data, such as age, gender and BMI, were similar between groups (p>0.05) (Table I). Perop complications were in one patient. Hemoo-lok clip bit the cekum. No events seen in the follow-up period and discharged at day 6. In Group II, no complication seen peroperatively. For postoperative complications, group I was uneventfully. In group 2, postoperative complications were seen in three cases, including fever, right shoulder pain and wound infection. There was no significant difference between the groups concerning peroperative and postoperative complications (p>0.05). No postoperative nausea, vomiting, ileus and intraabdominal abscess were observed in patients. There was no significant difference between the groups about duration of operation, length of hospital stay and cost analysis (p>0.05) (Table 2). There was no significant difference in 2-6-12-24-36th hour and 7th day pain scores of groups (p>0.05) (Table 3). Repeated Measures ANOVA analysis results were evaluated for the relationship between the operation type and the pain scores in 2-6-12-24-36th hour and 7^{th} day. The decrease in pain by time was found



Figure 1. Analysis of patients.

	Hem-o-lok Clips			Suture			р
	n	%	Mean±SD	n	%	Mean±SD	
Gender							0.454
Male	15	75		18	85.7		
Female	5	25		3	14.3		
Age			38.40±16.36			33.10±11.63	0.361
Body Mass Index			25.90±3.82			25.73±6.25	0.521
American Society of Anesthesiologists			1.75±0.44			1.86±0.48	0.485
Histopathology							0.769
Acute appendicitis	15	75		18	85.7		
Lymphoid tissue hyperplasia	4	15		2	9.5		
Perforated	2	10		1	4.8		

Table I. Demographic and histopathological re-

Table 2. Operation time, length of the hospital stay and hospital cost according to groups

	Hem–o–Clips			p*	
	Mean±SD	Median (MinMax.)	Mean±SD	Median (MinMax.)	
Operation time (minute)	69.00±15.78	65 (45–100)	80.71±23.15	75 (45–120)	0.101
Length of hospital stay (day)	2.00±1.21	2 (1–5)	2.14±1.42	2 (1–6)	0.707
Hospital cost (\$)	221±60	205 (152–375)	199±70.8	170 (127–385)	0.100

*Mann–Whitney U analysis. SD: Standard deviation; Min.: Minimum; Max.: Maximum.

 Table 3.
 2-6-12-24-36th hour and 7th day pain scores according to groups

	Hem-o-Clips			P*	
	Ave.±SD	Median (Min.–Max.)	Ave.±SD	Median (Min.–Max.)	
2. hour	4.35±2.41	4 (0–8)	3.86±3.04	2 (0–10)	0.355
6. hour	3.4±2.62	4 (0–8)	2.76±2.86	2 (0–8)	0.396
12. hour	2.8±2.69	3 (0-8)	1.9±2.12	I (0–6)	0.311
24. hour	1.4±1.9	0.5 (0–7)	0.95±1.36	I (0–5)	0.615
36. hour	0.65±1.81	0 (0–8)	0.33±0.8	0 (0–3)	0.665
7. hour	0.2±0.52	0 (0–2)	0±0	0 (0–0)	0.069

*Mann–Whitney U analysis. Ave: Average; SD: Standard deviation; Min.: Minimum; Max.: Maximum.

statistically significant (p<0.0001). The effects of the operation type on pain scores were not statistically significant (p>0.05) (Fig. 2).

DISCUSSION

The method for laparoscopic closure of the appendix stump should be simple, reliable, inexpensive and feasible. Intracorporeal knotting requires more experience but do not require a certain cost as hem-o-lok clips.^[16] One of the most feared complications after laparoscopic appendectomy is an intraabdominal abscess. It is argued that the closed stump may open again and lead to the development of abdominal abscess. ^[12] Soll et al.^[12] compared Hem-o-lok clips with endoloop in their series of 813 cases. They found 1% intraabdominal abscess in hem-o-lok gorup and 4% in the endoloop group. There was no intraabdominal abscess in the intracorporeal



Figure 2. The relationship between the operation type and 2–6–12–24–36. hour and 7. day pain scores.

knotting group in a series of 61 patients comparing the intracorporeal knotting with titanium clips.^[10] In our study, there was no intraabdominal abscess in both suture and Hem-o-lok clip groups. Concerning complications, there was no significant difference between intracorporeal knotting Hem-o-loc clipsin our study. Our complication rates were similar to the literature.^[10,13]

In a cohrane analysis for the proper closure method of the appendix stump, it was stated that there is a need for studies with high evidence value between the closure methods. ^[17] In a meta-analysis of the closure of the appendix stump, intracorporeal knotting was found to be more advantageous in the development of intra-abdominal and wound infection compared to other methods. In this study, it was emphasized that studies about suture ligation should be conducted. ^[1] In the comparative studies of intracorporeal suture with titanium clips, Ates et al.^[10] found that only the duration of surgery was higher in the intracorporeal knotting. There was no prospective randomized study comparing hemoclips with intracorporeal knotting in the literature. To our knowledge, our study is the first study in this respect. In a retrospective series similar to our study conducted by Subasi et al.,[16] there was no difference observed between the two groups about hospital stay, complication and duration of surgery.

In different studies, the cost of hemoloc clips was 21 euro^[13] and 29 dollars,^[9] while the suture cost was about 2 dollars. ^[18] In our study, the suture cost was about 2 dollars, while the hemoloc clip was about 29 dollars. The total cost for the laparoscopic appendectomy was \$199 in the intracorporeal group, and \$ 221 in the hemoclips group. Although the cost difference between the two groups is not statistically significant, the closure of the appendiceal stump with intracorporeal knotting may be the primary choice in economically low-income countries.

Different studies using intracorporeal knotting reported mean operation time as 79 and 63 minutes.^[10,15] The operation time may be longer if the surgeons are not experienced in the suture technique.^[15] In the studies evaluating the cases using hemoclips, they found that the mean operation time was 61.5 and 59 minutes.^[12,13] Also, hemoclips can be administered without a learning curve or specific experience.^[8] In our study, the median operation time was 75 minutes in the suture group and 65 in the hemoclips group. Although there was no significant difference between them, we have attributed the excess time of the suture arm to because we do not use intracorporeal knotting in our daily laparoscopy experience. Many methods have been compared in the studies about the closure of appendix stump. Limited data for cost analysis, failure to determine the exclusion criteria, no observation for the quality of life, postoperative pain scale and recovery time were seen as the limitations of these studies. ^[1] Our study is important in this respect. There was no difference between the intracorporeal knotting and the Hemo-lok clips about postoperative pain scale and postoperative recovery (postoperative nausea, vomiting, gaita discharge, andoral intake time). The pain scale was similar in both groups. Nearly 36 hours later, the pain was almost completely lost.

The limitation of our study was the small number of patients in both groups. Also, as the follow-up period was one month, we have no comments about long term results.

Conclusion

Our study showed that either intracorporeal knotting or Hem-o-loc clips were effective, reliable and cost-effective in laparoscopic appendectomy. Because the suture is always accessible, intracorporeal knotting can be used safely by experienced surgeons in the closure of the appendix stump.

Ethics Committee Approval: This study is registered retrospectively on the clinicaltrials.gov database and approved by the Ethics Committee of University of Health Sciences, Izmir Bozyaka Training and Research Hospital (decision date: 24.03.2015-no:3).

Peer-review: Internally peer-reviewed.

Authorship Contributions: Concept: O.U., E.İ., E.D.; Design: O.U., E.D., E.İ.; Supervision: E.İ., M.Y., O.U.; Fundings: S.T., E.D., O.U.; Materials: O.U., S.T., E.D.; Data: E.İ., M.Y., O.U.; Analysis: O.U., S.T., M.Y.; Literature search: O.U., E.İ., E.D.; Writing: O.U., S.T., E.D.; Critical revision: E.İ., M.Y., S.T.

Conflict of Interest: None declared.

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ORİJİNAL ÇALIŞMA - ÖZET

Laparaskopik apendektomide apendiks güdüğünün kapatılmasında intrakorporial sütüre karşı Hem-o-lok clips: Randomize ileriye yönelik çalışma

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AMAÇ: İntrakorporial sütür ve Hem-o-lok klipsin birbirlerine etkinlik, güvenilirlik ve maliyet açısından üstünlüklerinin araştırılması amaçlandı. GEREÇ VE YÖNTEM: Acil servise başvuran ve akut apandist tanısı ile ameliyat kararı verilen olgulara laparoskopik apendektomi uygulandı. Apendiks güdüğü Hem-o-lok klips (Grup I) ve intrakorporial sütür 2/0 ipek (Grup II) ile kapatıldı. Gruplar demografik veriler (yaş cinsiyet, vücut kitle indeksi [VKİ], ASA), operasyon süresi, maliyet, operasyondan sonra 2.-6.-12.-24.-36. saat ve 7. gün ağrı yönünden karşılaştırıldı.

BULGULAR: Olguların yaş, çinsiyet ve VKİ gibi demografik verileri gruplar arası benzerdi (p>0.05). Peroperatif ve ameliyat sonrası görülen komplikasyonlar açısından gruplar arası karşılaştırmalarında anlamlı fark bulunmadı (p>0.05). Hiçbir olguda ameliyat sonrası bulantı kusma, ileus ve karıniçi apse görülmedi. Olguların ameliyat süreleri, hastanede kalış süreleri ve maliyeti açısından gruplar arasında anlamlı fark bulunmadı (p>0.05). Olguların gruplara göre ağrı skorları arasında anlamlı fark bulunmadı. Ameliyat tipi ağrı skorlarını etkilemedi (p>0.05).

TARTIŞMA: Bu çalışma laparoskopi apendektomi de, apendiks güdüğünün kapatılmasında hem intrakorporial sütür hemde Hem-o-lok klipsin etkin, güvenilir ve benzer maliyetli olduğunu gösterdi. Uygulanacak yöntemin seçiminde cerrahın deneyimi baz alınmalıdır. Anahtar sözcükler: Apandisit; laparaskopik cerrahi; maliyet etkinliği.

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