



LigaSure or Diathermy Excision of III-IV Degree Pile? A Single-institution Experience: A Randomized Control Trials

Ali Abood Alnajim¹, Samer Al-Hakkak^{1*}, Ashraf Sami Ashraf Sami Muhammad¹, Alaa Abood Al-Wadess¹, Mahmood Albo Ahmed²

¹Department of Surgery, Faculty of Medicine, Jabir Ibn Hayyan Medical University, Najaf, Iraq; ²Department of Surgery, West Suffolk Hospital, Bury St Edmunds, England

Abstract

Edited by: Ksenija Bogoeva-Kostovska
Citation: Alnajim AA, Al-Hakkak S, Muhammad ASAS, Al-Wadess AA, Ahmed MA. LigaSure or Diathermy Excision of III-IV Degree Pile? A Single-institution Experience: Randomized Control Trials. Open Access Maced J Med Sci. 2022 Apr 14; 10(B):1158-1163. https://doi.org/10.3889/oamjms.2022.8878
Keywords: LigaSure; Hemorrhoidectomy; Pile; Diathermy; Third-fourth degree hemorrhoid
***Correspondence:** Samer Al-Hakkak, Department of Surgery, Faculty of Medicine, Jabir Ibn Hayyan Medical University, Najaf, Iraq. E-mail: sammerhakak1917@yahoo.com
Received: 25-Feb-2022
Revised: 02-Apr-2022
Accepted: 04-Apr-2022
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Funding: This research did not receive any financial support
Competing Interests: The authors have declared that no competing interests exist
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INTRODUCTION: Pile excision is frequently associated with post-operative pain and prolonged hospital stay. A modern technique performed with LigaSure (LS) seems to be especially efficient when large pile tissue removal is needed.

AIM: The research compares LS pile excision with diathermy for the treatment of III-IV degree pile.

PATIENTS AND METHODS: Two hundred and eight patients with pile III or IV degrees randomized into two groups: Group one LS and group two diathermy. The study evaluates the mean post-operative time, post-operative pain, discharge date, and time return to usual works early and late complication. All patients followed up for a range (12–24) months.

RESULTS: One hundred and eight patients managed by diathermy, 100 managed by LS. The operating time is considerably shortened in LS; post-operative pain disappears earlier in LS than diathermy. In addition, the timely return to work reduces in LS, while no distinction between hospitalization and post-operative complications.

CONCLUSIONS: LS is an efficient procedure in degree III or VI pile excision. Therefore, the procedure enhances to use LS as the treatment of choice for Classes III–IV pile, even it is more expensive than diathermy operation.

Introduction

Surgery remains the mainstay in patients with symptomatic pile grades III and IV. The usual operation by Milligan–Morgan and Ferguson is still most used and effective for symptomatic grades IV and some of grade III [1], [2], [3]. The two procedures get mimicked, like loss of blood and post-operative pain, which cause longer stay in hospital. Rapid wound healing permits the early return to usual works and day activity [4]. Many articles seek the best treatments of piles published in recent years and modern device the procedures trials to overcome the hemorrhoidectomy complication, such as stapling, laser, and Doppler-guided vessels ligation with different principles aimed at excisional surgery [5]. The LigaSure (LS) system vessels sealed were introduced newly in [6] as a tool for treatments of piles. It is a bipolar electro-thermal device; it offers both radiofrequency and pressure. Vessels blood are sealed up to 7 mm in diameter and create energy according to the impedance of tissue and confined 2 mm thermal injury over operation site. The limited thermal injury spread decreases the anal spasm and permits bloodless surgery to decrease post-operative

pain and promote rapid healing. Hence, the procedure is recommended as the preferred procedure due to the significant less tissue injury [7]. The objective of certain randomized trials is to estimate the advantage of the LS approach over the conventional diathermy (CD) techniques [8], [9], [10]. In spite of the favorite toward the LS, the conclusion gets some uncertainly regarding the cost of using disposable device. While there is a general positive trend with respect to LS, the results are not unequivocal and definitive; this creates a degree of uncertainty considering also the rising cost of using the disposable device so essential to compare our study with other centers to emphasize the real benefit present [11], [12]. The debate is the “gold standard” for III degrees. There are major arrangements, whereby Milligan–Morgan and Ferguson are the most efficient in the degree IV pile [2]. Ortiz mentions that stapled procedure is ineffective for curing itching in an IV degree pile [13]. Hence, the CD pile excision continues as an effective therapy for the symptomatic, irreducible, and prolapsed pile. The designed study is to estimate the LS procedures as effective as CD in all grades IV and III with less pain, less blood loss, and when we need large tissue excision needed.

Patients and Methods

Between January 2018 and January 2020, 208 patients undergo surgical treatments for III or VI degree pile with two different techniques (LS versus diathermy pile excision), as shown in Figure 1. The inclusion criteria permanently or permanently prolapsed pile, bleeding pile classified as grades III or VI in accordance with Nivatvongs [14], age ranged 18–65 years, Classes I–II ASA, both genders. All patients were evaluated preoperatively by complete proctoscopy examinations with history, anoscopy and

colonoscopy performed with 50 years and older patients excluding colonic cancer; the study project submits to get the approval by the University Ethics Committee. Post-explaining the procedure to the patients, and informed consent took from all patients. The patients included in the research were divided into two groups by randomized creation methods. This code is included in a numbered envelope for both procedures shown to the surgeon when the surgery started. All patients performed it by the same surgeon. The procedures did under spinal or epidural or general anesthesia accordingly. Pain was recorded starting from post-operative day 0 on day 28 on a self-administered VAS scale in cm (0–10). The

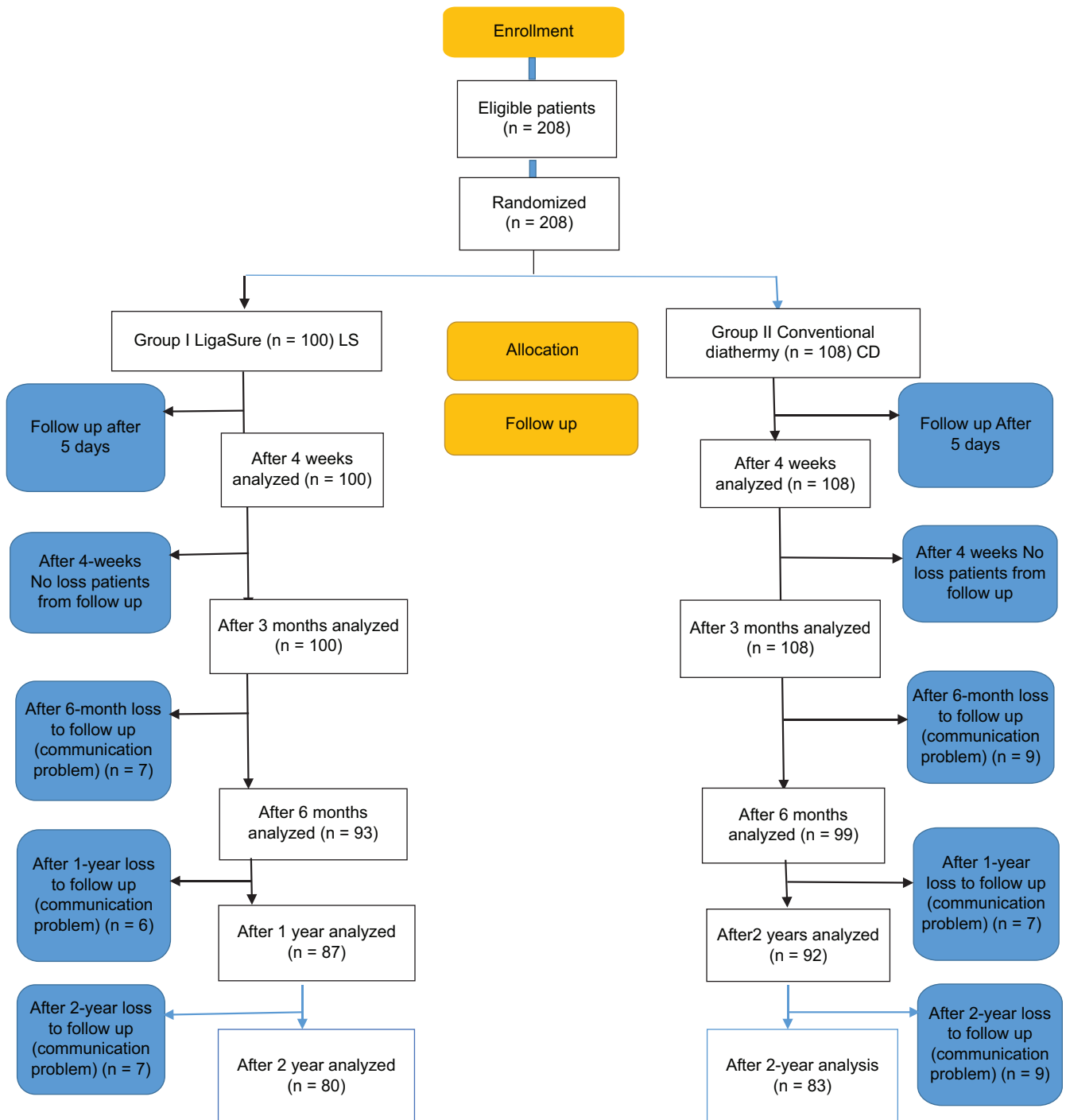


Figure 1: CONSORT flow diagram of study recruitment

overall pain score for the day was recorded either at rest or after approximately 12 h of defecation. Post-surgical complications are defined as “early” during the first 4-week post-operative and “Late” post the 1st month of surgery time. The patients assess 1 week, 2 weeks, 1 month, 6 months, and 12 months after surgery, the time of surgery, post-surgery pain, discharge time, time return to usual works, any early, and late complications were all recorded. All data were collected and observed as shown in (Figure 1).

Operative procedures

In the pre-operative protocol, both groups of patients were put on clear oral fluid 1 day before surgery and saline enema the night before surgery, with 1 g ceftriaxone slow intravenous before anesthesia inductions and continued on metronidazole 500 mg orally twice daily for 1 week after surgery. The surgery did in a lithotomy position. The patient receives analgesic administrations with 1-g paracetamol vial after the end the effect of anesthesia and continuous infusion of tramadol for about 12 h patient-controlled analgesia, and hospital discharged analgesia achieved by 10 mg Ketorolac and oral Nefopam tablets twice daily or on-demand but not more than 3 times daily. Both groups carried up using Fansler retractors and applying LS forceps up to vascular pedicles, the vascular pedicle sealed without the use of suture transfixion, the wound leaves it open, the techniques were repeated for 3, 7, and 11 O'clock according to pile locations, keep the bridge between each pile, and avoid further anal stenosis. Sofra-tulle framycetin impregnated with 2% lidocaine gel as homeostasis sponge stay in the anus post precisely visualization of anal verge for any blood oasis. In a group of diathermy procedures performed by artery, forceps left the pedicle and Allis forceps in the mucocutaneous junction of anal verge at the base of pile excised according to the procedure described by Phillips and Loder [15]. The hemorrhoid excision by diathermy cautery until reach the pile pedicle and vascular pedicle was which sutured by transfixion Vicryl 0. The wound was left open. Anal sponge by Sofra-tulle framycetin impregnated with 2% lidocaine gel as in (Figures 2 and 3).

Statistical analysis

Data reported as median values and values below 0.05 were considered significant statistically. Mann–Whitney U-test for assessing

pain postoperatively in both groups. Post-operative complication tested by Fisher exact test. Reducing post-operative anal pain in 20% at least an alpha error of 5% and beta error of 10% considered statistically significant.

Results

Two hundred and eight patients with a pile of degrees III–IV randomly distributed into two groups. One hundred and eight patients get operation by CD Milligan–Morgan and 100 undergo by LS excision; all patients are monitored for a minimum of 12 months (range 12–24 months). The two groups are similar in terms of age (mean age: 42 for CD, 44 for LS patients; overall range 18–65), sex (male/female not difference statistically), and then return to working activity and symptoms as in (Table 1). There were no patients suffering from post-surgical incontinence. Twenty-eight patients lost from follow-up group CD and 17 in LS group after 2 year follow-up. The mean surgical time in the LS group was 26.5, compared to the CD of 31.6, which had statistically significant difference ($p < 0.0001$) (Figure 4). The hospital continues to be the same for both groups since. Patients departed 8 ± 2 h post the operations of both groups and acute urinary retention in (4 LS) and ($p = 4$ NS). There is no difference in the general complications between the two groups, 24 patients (22%) after CD versus 15 (15%) in LS group ($p = 0.768$ NS). Early post-operative complications are among them, 12 patients in the CD group undergo minor bleeding, compared to four in LS ($p = 0.611$ NS); none of the patient needs re-intervention. One case anal fissure was observed in the CD group after 1 month of monitoring. One anal fissure was observed in the CD group after 1 month follow-up ($p = 1$). As a late complication, two anal stenosis in the LS group and three in the CD group ($p = 3$ NS) ($p = 2$) which treated by frequent anal dilator and local ointment nifedipen with good results. The complete healing observes in 12 (11.1%) patients with CD compared to eight patients (8%) of the LS group. However, the difference is insignificant statistically ($p = 0.66240$ NS) (Table 2). Pain controlled postoperatively by continuous infusion in LS and CD groups, so there was no significant difference during the first 12 h between the two groups ($p = 0.0799$ NS) and during the first post-operative day



Figure 2: LigaSure procedure. (a) Fourth degree pile (Prolapsed, irreducible), (b) starting LigaSure device surgery, (c) large pile excised, and (d) end result bloodless surgery



Figure 3: Conventional diathermy procedure. (a) Fourth degree pile (Prolapsed, irreducible), (b) wick inside orifice to become more prominent in surgery, (c) starting with diathermy, (d) continues diathermy pile excision, and (e) transfixing pile edicle by vicryl 0 suture

Table 1: Two group patient characteristics

Patient demographic data and early post-operative complications	Diathermy (108) patients	LigaSure (100) patients	p-value
Age (years)(range)	42 (18–65)	44 (18–65)	NS
Male/female ratio	1.5	1.4	NS
Wexner Continence score (range)	0 (0–2)	0 (0–2)	NS
Bleeding (patients)%	12 (11)	4 (4)	1
Pain (patients) %	21 (19.4)	18 (18)	0.7523
Itching (patients) %	17 (15.7)	23 (23)	0.1933

(3.7 VAS score against 4.0 VAS score $p = 0.0408$ NS). In second, third observed (3.14 versus 4.46 VAS score $p < 0.0002$) and 4th day (2.43 versus 4.42 VAS score, $p < 0.0001$). The requirement for painkillers is lower in the LS group. After nine days, the pain is reduced similarly between the two groups.

Table 2: After surgery complication of the two groups

Post-operative complications	Diathermy (Patients)(%)	LigaSure (Patients) (%)	p-value
Acute urinary retention	3	2	0.6110
Anal fissure	1	0	1
Incomplete healing	4	4	1
Anal stenosis	0	1	0.4808
Sphincters damage	0	0	1
Over all complications	8 (7.4%)	7 (7%)	0.768

The LS is near to baseline (no pain at all) on the 14th day (0.2 versus 1.3 VAS score < 0.0042), which is earlier than the CD group, which needs 28 days to reach the baseline. After 28 days of operations, the two values were insignificant (0.3 $p = 0.37722$ VAS score at the 28th day NS) (Figure 3). Twenty-eight days after the surgery, the two values were insignificant (0 versus 0.3 $p = 0.37722$ VAS score at the 21th day NS) (Figure 4). The patients which operated by LS returned to routine work activities 12.3 days compared to CD 16.5, so there is a significant difference with respect to the LS systems ($p < 0.0001$) (Figures 5 and 6).

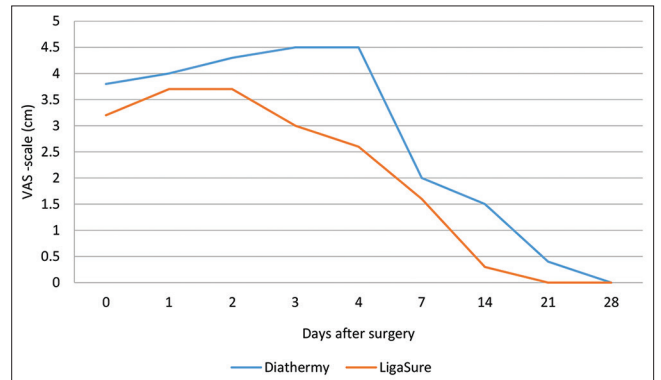


Figure 5: Post-operative pain in the two groups. Significant difference 3–5 days after surgery

Discussion

The CD pile excision is yet recommended as an operation of choice for a patient with symptomatic, irreducible, and prolapsed hemorrhoids. The LS procedure on new tools is recently utilized to avoid main complaints compared to many diathermies other closed hemorrhoidectomy methods in many randomized studies [8], [9], [10], [11]. It is not easy to establish univocal proof of the benefit of post-operative pain and analgesic requirements in a single-institutional experience. Therefore, the study needs to enroll more patients and precise, more subjective evaluation of patient symptoms. Mastakov *et al.* [14] introduced a many meta-analysis of 11 trials, and 1046 patients established the effectiveness of usage of LS, utmost all of the results evidence are superior in the LS group except no difference in the overall occurrence of sequels. The Italian LS study group by Altomare *et al.* [15] in multicentric prospective

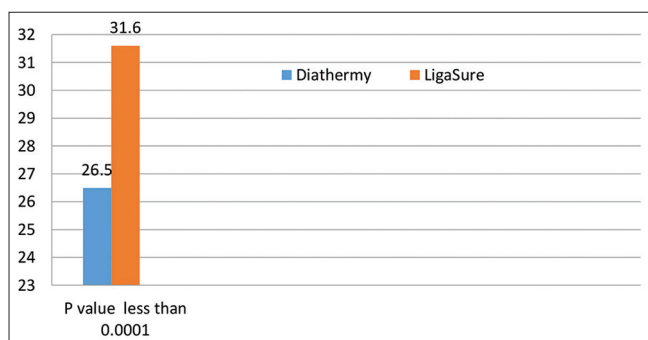


Figure 4: The mean operative time of the two groups. LigaSure significantly faster

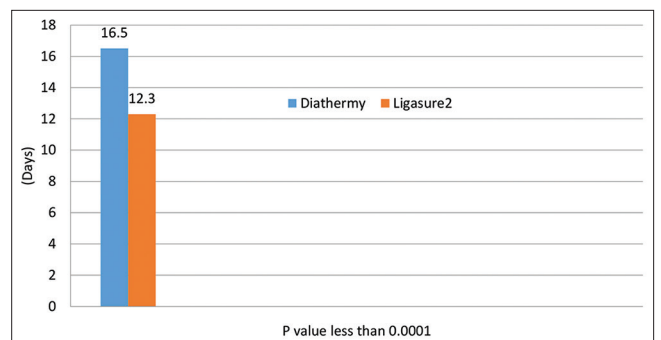


Figure 6: Median recovery time after operations. The patient faster return to work after LigaSure

randomized trials on 273 displayed signs of less post-operative pain, less operating time, and early return to usual work activities also showed no difference in post-operative bleeding and complication up to date 4-week post-surgery. A review of 11 randomized trials by Milito *et al.* [16] of 850 patients have significantly improvement of healing time, post-operative pain, a timely return to work, but no evidence of a difference in post-operative bleeding other complications between two groups. Another study done by Kraemer *et al.* [17] compared stapled pile excision with LS showed slightly favorable of LS group with IV-degree pile. The present research compares the CD with LS in III-IV degree pile, where the Milligan–Morgan regarded as preferred treatments. The LS is efficient, according to the majority of studies with shorter operating times (26.5 vs. 31.6 min). Furthermore, the LS tool is easy to learn, so from 18.4 to 31.6 min, which is mainly according to size and numbers of piles excised. The reduction of post-operative pain score, due to less tissue injury, rapid-wound remodeling, and the trends do not vary between the two groups in a 1st post-operative day, but appear more significant in the 3rd, 4th, and 5th days similar decrease for both groups up to 1 week after surgery. Finally, LS patients were pain free earlier than the CD group. The usage of analgesic infusion explained a similar early post-operative pain in both groups. However, the post-operative pain differs, while the patient takes a pain-killer on demand. The pain registered for every day differently. Altomare *et al.* [15] pain measure after evacuation or at rest (12 h after) shows a significant difference between the two groups. However, the consideration at rest pain, with mechanical stimulation of the anal-endoderm, produce the similar pain with any device used. Furthermore, the absence of sutures that transfixe the vascular pedicles could be another benefit to decrease pain. It helps prevent local ischemia and necrosis, which may lead to acute post-operative pain and may be secondary bleeding [18]. In our experience, the LS procedure is a safe and low complication rate, with the overall incidence of complication not differing between the two groups ($p = 0.7683$ NS), even 2-year post-operative follow-up. All patients operated as day-cases, Filingeri *et al.* [19] reported four cases of stenosis post out of 203 LS techniques (2%), thermal injury also contributes to anal stenosis. Wang *et al.* [20] recorded one case in 42 patients. In our experience of some of III and IV-degree (higher risk), two cases have been identified and the incidence appears to be consistent with the literature (4–5%) [14], [15], [16], [17]. Within our experience of IV-degree patients (higher risk), the anal stenosis was managed by frequent anal dilatation and local ointments of nifedipen with a very good anal result. Important note, when using LigaSure avoid circular scar tries and preserve anoendoderm bridges between pile. Another advantages of using LigaSure is rapid healing time, more comfortable conditions, rapid return to day to day activities (LS 12.3 days vs

CD 16.5 days, P less than 0.0001). The study done by Wang *et al.* [20] showed no difference in outcome between groups. Milito *et al.* [16] registered a quicker return to work after LS compared to other procedures ($p < 0.001$). Sayfan *et al.* [6] recorded the time return to normal activities (7.4 vs. 18.6). No recurrence rate, no incontinence detected with LS group within 2 years follow-up comparable to CD group. Despite 2 years of follow-up may be short times, large clinical trials confirmed the benefit of both procedures and techniques if the device is correctly applied. The economic concern about using disposable devices (about 300 \$) is balanced by shorter time and early return to work. We use COVIDIEN LS (Curved, Small jaw Open sealer/Divider), also our experience can sterilize the device in plasma sterilizer, and it found that it is effective up to 5 patients or may more, so mean cost-effective applies or add (60 \$) for better results which affordable by most of the patients. The device COVIDIEN works perfectly, even in many cases more than 5, the problem with the knife of the LS, which is become blind after a series of cases. Another advantage of the LS device is that it can easily excise piles and keep bridges between hemorrhoids; it can also demolish the internal pile without affecting the mucocutaneous junction, so the manipulation is easier, especially in piles that present in whether internal or external or both.

Conclusions

Our study confirmed the benefit of LS in III-IV degree pile surgery over diathermy, especially in large, irreducible, and prolapse piles, where large tissue needs excision. The additional cost-effective and added cost can reduce by reusing sterilized tools. In addition, LS advantages are less pain and early return to usual activities. More data sample and more time follow-up are needed to establish as standard technique for III-IV degree pile for such a tool.

Authorship

1. Samer Makki Mohamed Al-Hakkak: Corresponding author, data collection and analysis, drafting the article, revising it critically for important intellectual content, and final approval of the version to be submitted, study design, conception, and interpretation
2. Ali Abood Alnajim: Data acquisition, analysis, and interpretation
3. Ashraf Sami Muhammad: Data acquisition,

analysis, and interpretation.

4. Alaa Al Wadees: data collection
5. Mahmood Albo Ahmed: check the manuscript Grammarly and add in data collections

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