LigaSure hemorrhoidectomy compared with stapled hemorrhoidopexy for management of grade III and IV hemorrhoids: A prospective randomized study.

Islam M. Ibrahim MD, Abd Elrahman Metwalli MD, Ashraf Goda MD

General Surgery department, Faculty of Medicine, Zagazig University, Zagazig, Egypt
ieslam4@yahoo.com

ABSTRACT: Background: Conventional hemorrhoidectomy often associated with post-operative complications, like pain, bleeding, anal stenosis, and incontinence, which can cause delayed convalescence. The Ligasure Vessel Sealing System (LVSS) enables us to do a bloodless hemorrhoidectomy with decreased pain postoperatively and rapid healing. Pain suspected to be low in stapled hemorrhoidopexy as the staple line is positioned above the dentate line and there is no external wound. **Objective:** To compare the efficacy and outcome of two surgical methods LigaSure versus stapler in the treatment of hemorrhoids. **Patients & Methods**: A prospective randomized study was done in the General Surgery department, Zagazig University hospital during the period from May 2016 till October 2017. Patients underwent surgical excision of hemorrhoids grade III or grade IV. They were divided into two groups: group (A) managed by Ligasure hemorrhoidectomy and group (B) managed by Stapled hemorrhoidopexy. Postoperative complications and Pain levels scoring were analyzed. **Results:** Group (A) had less operative time and recurrent prolapse while postoperative pain in Group (B) was statistically significantly lower with less analgesic requirement. As regarding other postoperative complications. The difference was not statistically significant between both groups. **Conclusion:** This study demonstratedthat Ligasure hemorrhoidectomy and stapled hemorrhoidopexy have good results, with a short operative time and few side effects in the treatment of hemorrhoids grade III and IV. Stapled hemorrhoidopexy offers much less pain but more recurrent prolapsed. Also we recommend a larger controlled study to prove recurrence of postoperative hemorrhoidalprolapse after treatment of hemorrhoids grade III and IV by LigaSure or stapler.
[Islam M. Ibrahim, Abd Elrahman Metwalli, Ashraf Goda. **LigaSure hemorrhoidectomy compared with stapled hemorrhoidopexy for management of grade III and IV hemorrhoids: A prospective randomized study.** *Life Sci J* 2018;15(4):92-99]. ISSN: 1097-8135 (Print) / ISSN: 2372-613X (Online). http://www.lifesciencesite.com. 11. doi:10.7537/marslsj150418.11.

Keywords: Hemorrhoids, Ligasure hemorrhoidectomy, Stapled hemorrhoidopexy.

1. Introduction

Hemorrhoids are engorged venous plexuses of the anal canal and can cause prolapse, bleeding, pain, thrombosis and prurities (**Burch et al., 2008).**

Hemorrhoids are classified to four degrees, first-degree if there is bleeding but do not prolapsed; second-degree hemorrhoids prolapsed with bowel movements, and then reduce spontaneously; third-degree hemorrhoids prolapsed on straining and need manual reduction; fourth-degree hemorrhoids prolapsed and cannot be reduced manually (**Ammaturo et al.,2012)**.

The standard operation for grades III and IV hemorrhoids is Hemorrhoidectomy results are better than other conservative procedure like rubber band ligation, photocoagulation, cryotherapy and sclerotherapy (**Agbo, 2011).**

Conventional hemorrhoidectomy involves submucosal excision of hemorrhoidal plexuses and the residual wound healed by secondary intention (Miligan Morgan) or closed primarily (Ferguson) (**Rakhonde et al., 2016)**.

Unfortunately, it is often complicated with post-operative pain especially in the first week, bleeding, incontinence and anal stenosis that result in delayed convalescence (**Armstrong et al., 2001; Filingeri et al., 2004).**

Therefore, this has stimulated continuous efforts and attempts to develop other new techniques and modifications which allow a less post-operative pain and faster recovery (**Watson et al., 2016).**

The LigaSure Vessel Sealing System (LVSS) is an instrument conceived to upgrade the conventional treatment of hemorrhoids, it consists of a bipolar electro thermal device which permits an optimized combination of radiofrequency and pressure, seals blood vessels with diameter up to seven mm and generates an energy tailored to the tissue impedance and it's thermal injury is confined to two mm over the surgical site. This limited spread decreases anal pain, spasm and enables to do a bloodless hemorrhoidectomy with less postoperative pain and fast healing. So, this operation by the LVSS can be recommended as the ideal technique that reduces tissue trauma **(Selvaggi et al., 2014).**

Stapled hemorrhoidopexy is a technique that decreases the prolapse of hemorrhoidal tissue by using a circular stapling device to remove and excise a band

of the redundant and prolapsed anal mucosal membrane above the dentate line. This interrupts the hemorrhoidal blood supply with less rectal mucosa prolapse (**Singh et al., 2011).**

The aim of the current work is to compare the efficacy and outcome of two surgical methods LigaSure versus stapler in the treatment of grade III and IV hemorrhoids, in terms of 1. operation time; 2. post-operative pain; 3. Hospital stay; 4. Return to work and normal activity; 5. Complications; 6. Recurrence; 7. Patient satisfaction.

2. Patients and methods

A) Study design:

A prospective randomized controlled study was carried out on 60 patients all with hemorrhoids grades III or IV, who were simply randomized by closed envelop method in which a comparison was held between two groups of patients presented with hemorrhoids. The selected patients were randomly classified into two different groups of treatment: Group (A): 30 patients (12 female and 18 male) were managed by Ligasure hemorrhoidectomy and Group (B): 30 patients (10 female and 20 male) were managed by Stapled hemorrhoidopexy.

B) Study setting and time:

This study was done in the Department of General Surgery, Zagazig University Hospitals from May 2016 till October 2017.

C) Study population:

Inclusion criteria:

- Patients of both sexes aged ≥ 18years old.
- Symptomatic hemorrhoids grade III or IV.
- Co-morbidities: American society of anesthesiology (ASA) class I or II.

Exclusion criteria:

- Complicated (strangulated) hemorrhoid.
- Coexisting perianal disease, previous perianal surgery.
- Pregnancy or patients with bleeding tendency history.
- Cancer or other serious diseases, inability to cooperate with the requirement of the study, recent history of drug or alcohol abuse, current therapy of any anticonvulsant or immunosuppressive.

D) Study tools:

All patients were fulfilled the following:

1] Full History: Personal history name, age, sex, residence, admission date, telephone number, and other habits of medical interest. Past history: medical and surgical.

2] Full clinical assessment: Presenting symptoms as: prolapse, bleeding, pain, thrombosis, and purities. Signs as: hemorrhoids grades III or IV detected by digital rectal examination.

3] Investigations: Routine pre operative investigations as complete blood count (CBC), coagulation profile (PT, PTT & INR), liver and kidney function tests, random blood sugar, and ECG. Imaging studies abdominal ultrasound. Other studiesbyproctoscopy and rigidsigmoidoscopy.

E) Administrative and ethical design and approval: Informed consent was taken from the patients after receiving adequate information about the study (the characters of the study, benefits, and possible side effects). The study was approved by the local ethical committee.

F) Study method:

*Patient preparation: The patient was kept NPO before the operation for 6 hours. Prophylactic antibiotics (I.V 500 mg of metronidazole) were given with the anaesthesia induction. Patients were admitted to the hospital on the day of the operation and received before the operation a Fleet enema.

All selected patients were fit for surgery and anesthesia. Surgery was done under either general or spinal anesthesia technique according to the preference of the anesthetist.

Methods: All patients were placed in the lithotomy position**. Group (A (:**30 patients managed by LigaSure hemorrhoidectomy. The LVSS device remove each one of hemorrhoidal cushion by three applications. The first application included the perianal skin and the external component of thehemorrhoidal cushion, the second application included the hemorrhoidal part overlying the internal sphincter, and the third included the pedicle lie 0.5 cm above the dentate line. Completion of coagulation after each application was signaled by the characteristic two-tone sound from the machine and a pair of scissors was used to cut along the middle of the line of the coagulum until complete excision of the hemorrhoidal cushion was achieved **(Figure1: A, B, C, D, E, F).**

Group (B): 30 patients managed by Stapled hemorrhoidopexy. Insert dilator in anal canal and secure to perineum then take 2-0 Prolene purse-string suture approximately 1.5 cm above the dentate line then open circular stapler (AVENTAL hemorrhoidal circular stapler) and position head proximal to purse string and tie. Then traction on purse string, tighten device and hold for 30 s then fire stapler and keep closedfor 20s. Then remove stapler. Then Examine staple line and finally secure hemostasis. External hemorrhoids were usually left alone, as they normally shrink after interruption of their blood supply by the stapling procedure **(Figure 2: A, B, C, D, E, F, G).**

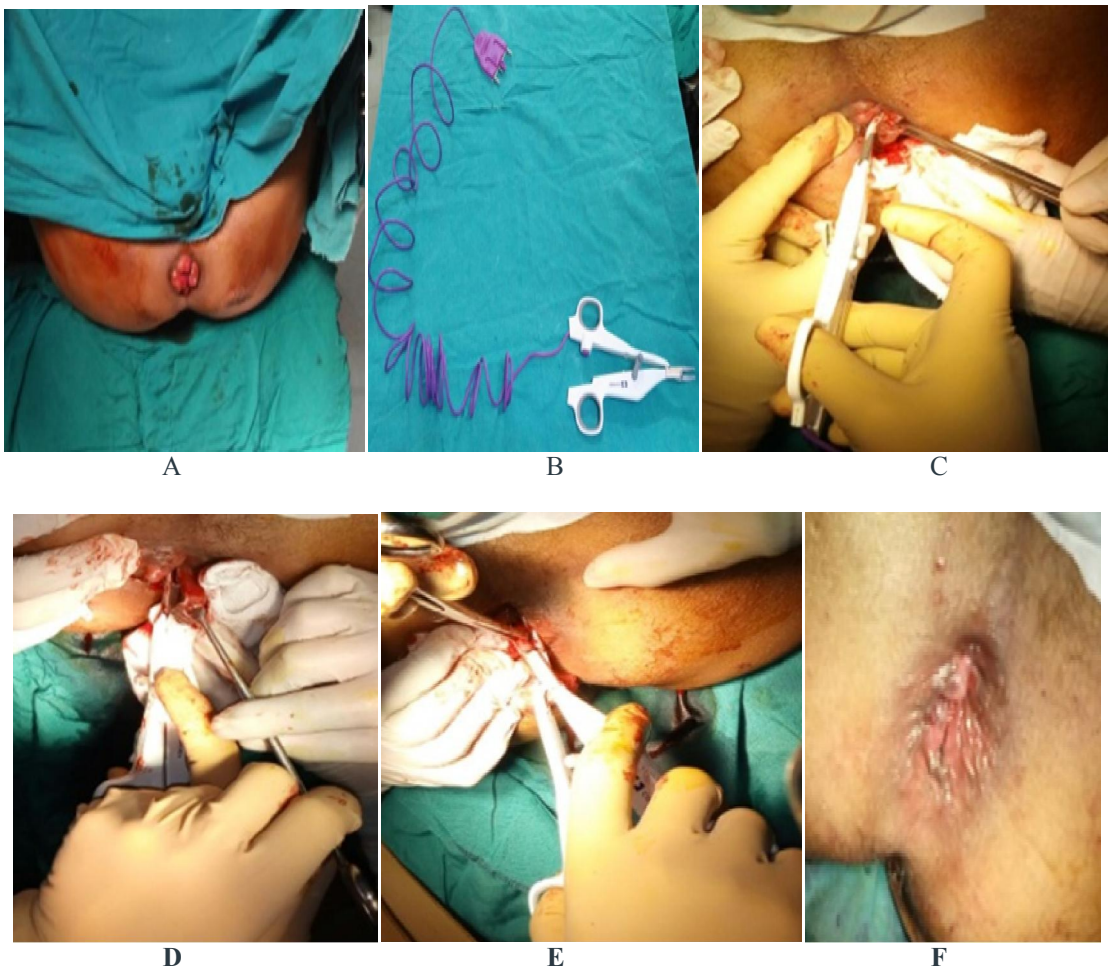
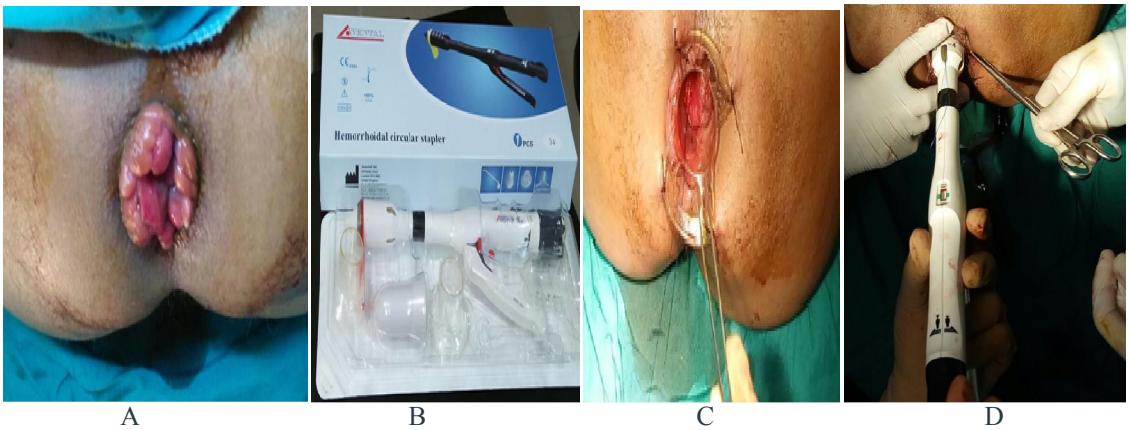


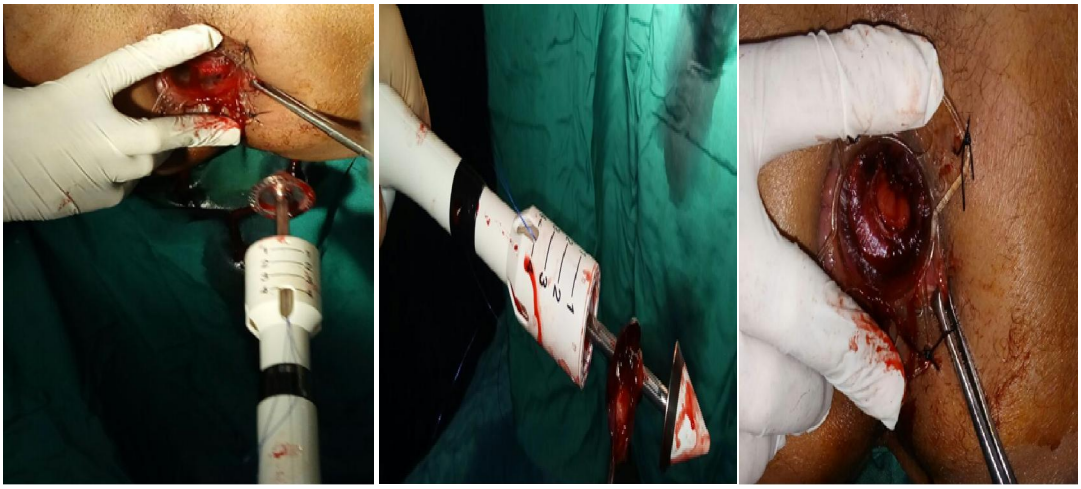
Figure 1: Steps of LigaSurehemorrhoidectomy (A, B, C, D, E, F)



Postoperative follow up:

Both groups patients were instructed postoperatively to receive laxatives for two weeks, daily sitz path and antibiotics continued for six days. Postoperative variables as bleeding, pain, and retention of urine were noted. Pain was evaluated postoperatively by a visual analogue scale (VAS) that was explained to the patients. a score of 0 (no pain) to 10 (worst pain possible). Patients were asked about their pain on preoperative period and on days one, three, four, seven and 14 postoperatively. Follow up of patients was done in the outpatient clinic and by the telephone after overnight keeping in the hospital.

Narcotic analgesic (NA) (Pethidine) administered up to the end of the third day postoperatively and thereafter using NSAIDs as Diclofenac Sodium (DS). We recorded analgesic doses and analyzed it as a marker for pain severity. All patients complete the study to the end. We compared the mean pain scores using Wilcoxon's rank-sum test. for day one, three, four, seven and 14 of follow up in both groups Also, we calculated the amount of narcotic analgesics and NSAIDs needed for each group and compared using two-sample t-test.



E F G

Figure 2: Steps of Stapledhemorrhoidopexy (A, B, C, D, E, F, G)

3. Results

Table (1): Age and sex distribution in both groups:

Demographics			Groups		P
			Group A Ligasure	Group B Stapler	
Age		Mean ±SD	37.8±9.9	39.5±8.2	> 0.05
Sex	Female	Count (%)	12(40.0%)	10(33.3%)	> 0.05
	Male	Count (%)	18(60.0%)	20(66.7%)	
Total		Count (%)	30 (100.0%)	30 (100.0%)	

This table shows that the mean age in Group A Ligasure hemorrhoidectomy was (37.8±9.9) year (range 18–55) and it was (39.5±8.2) year (range 20–60) in Group B Stapled hemorrhoidopexy and the difference was not statistically significant regarding both age or sex.

Table (2): Clinicalpictureinboth groups:

Clinicalpicture			Groups		P
			Group A Ligasure	Group B Stapler	
Symptoms	None	Count (%)	20 (66.7%)	22 (73.3%)	> 0.05
	pain	Count (%) VAS score	3 (10.0%) 2.5±0.4	2 (6.7%) 2.2±0.9	> 0.05
	purities	Count (%)	2 (6.7%)	1 (3.3%)	> 0.05
	bleeding	Count (%)	6 (20.0%)	5 (16.7%)	> 0.05
	prolapse	Count (%)	7 (23.3%)	5 (16.7%)	> 0.05

This table shows that the difference was not statistically significant regarding preoperative symptoms (pain, purities, bleeding, prolapse) in both study groups.

Table (3): Hemorrhoidgradesinboth groups:

Clinicalpicture			Groups		P
			Group A Ligasure	Group B Stapler	
Hemorrhoid Grades	III	Count (%)	23(40.0%)	25(33.3%)	> 0.05
	IV	Count (%)	7(60.0%)	5(66.7%)	

This table shows that the difference was not statistically significant regarding hemorrhoid grades in both study groups.

Table (4): Operative time and intraoperative blood loss distribution inboth groups:

Intraoperative	Group A Ligasure	Group B Stapler	P
Operative time (min) **Range (min)**	20.66±4.6 10-30 min	25.4±8.8 15-40 min	< 0.05*
Blood loss (ml) **Range (ml)**	8.55±3.2 6-18 ml	10.15±2.5 7-20 ml	> 0.05

This table shows that the operating time was statistically significantly shorter in Group (A) than Group (B) and the difference was not statistically significant regarding blood loss in both study groups.

Table (5): Postoperative complicationsinboth groups:

Postoperative Complications		Group A Ligasure	Group B Stapler	P
Bleeding	Count (%)	1 (3.3%)	2 (6.7%)	> 0.05
urinary retention	Count (%)	3 (10.0%)	2 (6.7%)	> 0.05
Wound infection	Count (%)	1 (3.3%)	1 (3.3%)	> 0.05
Short term Incontinence	Count (%)	2 (6.7%)	1 (3.3%)	> 0.05
recurrent prolapse	Count (%)	1 (3.3%)	3 (10.0%)	< 0.05*

This table shows that the bleeding postoperatively was nearly comparable in both study groups. Only one patient in Group (A) and two patients in Group (B) had reactionary hemorrhage and were managed by anal packing under anesthesia. Post operative retention of urine was more in group (A) (only three out of 30 patients) while in Group (B) it occurred in two patients but not statistically significant (P-value > 0.05). Again, the difference was not statistically significant between both study groups regarding wound infection, short-term incontinence. Recurrent prolapse was found statistically significantly lower (P-value < 0.05) in Group (A) (one patient) than in the Group B (three patients) and appeared after 12 months.

Table (6) Postoperative paininboth groups:

Postoperative pain Pain score (VAS)	Group A Ligasure	Group B Stapler	P
1st day	5.7±0.6	4.1±0.4	< 0.05*
3rd day	5.1±0.3	3.5±0.2	< 0.05*
4th day	4.5±0.4	3±0.6	< 0.05*
7th day	3.8±0.5	2.2±0.3	< 0.05*
14th day	2.2±0.3	2.1±0.5	> 0.05

This table shows that postoperative pain was found to be statistically significant less in Group (B) in first week of postoperative follow up.

Table (7) Postoperative mean dose of narcotic analgesics inboth groups:

Mean dose of narcotic analgesics (dose/mg)	Group A Ligasure	Group B Stapler	P
1st day (dose/mg)	175	125	< 0.05*
2nd day (dose/mg)	150	100	
3rd day (dose/mg)	150	75	

This table shows that the mean dose of narcotic analgesia was used in the first postoperative three days was reduced in Group (B) when compared to Group (A).

Table (8): Postoperative mean dose of Diclofenac sodium analgesics inboth groups:

Mean dose of Diclofenac sodium	Group A Ligasure	Group B Stapler	P
4th day (dose/mg)	175	125	< 0.05*
7thday (dose/mg)	150	100	
14th day (dose/mg)	50	50	> 0.05

This table shows that there was statistically significant difference between both study groups in required doses of Diclofenac sodium with less doses needed in Group (B). This was found up to day seven

after which the difference was not statistically significant between both study groups.

Table (9): Postoperative Outcome inboth groups:

OUTCOME	Group A Ligasure	Group B Stapler	P
Hospital stay (hours) **Range (day)**	21±2.3 1-2	20±1.25 1-2	> 0.05
Wound healing (day)	16.25±5.2	14.25±4.2	> 0.05
Return to work or normal activity (day) (Mean±SD)	9.65±0.42	8.46±0.62	> 0.05

This table shows that the difference was not statistically significant regarding hospital stay, healing of the wound, and return to normal activity or work in both study groups.

4. Discussion

Hemorrhoidectomy still the most effective treatment for prolapsed hemorrhoids but postoperative pain is the main problemafter thisprocedure (**El Sebaeiet al., 2015)**. Therefore, other new modalities have been developed to overcome this; none is clearly superior to the other (**Pattana-Arun et al., 2006)**.

Using the LVSS procedure, the level of pain postoperatively expected to be minimal because the collateral thermal spread is minimal, tissue charring is limited, improved tissue apposition promoting rapid healing (**Tan et al., 2008)** and reduced anal spasm (**Ramcharan and Hunt, 2005):** while with stapled hemorrhoidopexy, there is no external wound and the staple line is positioned above the dentate line so pain levels postoperatively would also be expected to be low.

In our study we aimed to compare outcome after the stapled technique with LigaSurehemorrhoidectomy and to assess the efficacy of each technique as a definitive cure for grade III and IVhemorrhoids. We avoided many potential confounders by standardizing many variables in this performed study. Starting with choice of the patients, we excluded patients with chronic pain syndromes or neurological defects and those currently taking narcotic analgesics and patients with other ano-rectal pathology. This gave us the advantage of avoiding variation in the results of pain assessment.

Also, we selected patients with symptomatic internal hemorrhoids Grade III with prominent external ones or Grade IV disease. Regarding the surgical technique we used the open method not the closed technique to avoid the debate around the postoperative pain perception. The present study revealed that the difference was not statistically significant between treatment groups who were observed regarding age, gender, preoperative symptoms (pain, purities, bleeding, prolapse), or severity grade of hemorrhoids, that were similar to other studies (**Yang et al.,2013; Abousteitet al., 2015; Sakr and Moussa, 2010).**

The operative time in this work was statistically significant-ly longer in stapled hemorrhoidopexy in agreement with other clinical studies (**Yang et al.,2013; Chen et al.,2007)** While in other researches the differences as regards the operative time in both groups were statistically non significant **(Sakr and Moussa, 2010; Kraemer et al.,2005).**

As regards the early post-operative complications in our study, post hemorrhoidectomybleeding occurred in one case from group (A) and in two cases from group (B), this bleeding was little in the first two postoperative days and didn't require any surgical intervention, the difference was statistically insignificant between both study groups, which was similar to other studies (**Sakr and Moussa, 2010; K-C Lee et al., 2013).**

Postoperative urinary retention was more in Group (A) (only three out of 30 patients) while in Group (B) it occurred in two patients with no significance. These results were similar to other studies **(Abousteitet al., 2015; Sakr and Moussa, 2010; Arslani et al., 2012).**

Short term incontinence to flatus occurred in two cases from group (A) and one case from group (B) with no significant difference that was like other studies (**Yang et al.,2013; Sakr and Moussa, 2010; Arslani et al., 2012).**

The study at hand demonstrated that recurrent prolapse was significantly more in stapled hemorrhoidopexy that was like other studies (**Sakr and Moussa, 2010).**

This might have been because stapled hemorrhoidectomy doesn't excise the hemorrhoids but rather a circumferential column of mucosa and submucosa two-three cm above dentate line and then staple the defect. also, it doesn't deal with external hemorrhoids or associated problems of anal canal (**Mattana et al.,2007; Panarese et al.,2012)** While LigaSurehemorrhoidectomy is preferred to treat anatomical deformities such as skin tags and prolapsed (**Chung and Wu, 2003; Wang et al.,2006)**.

Regarding postoperative pain in our study, visual analogue scores at 24, 48, and 72 hours post-surgery were statistically significantly more favorable in stapled group, when compared to LigaSure group. this was similar to other works (**Yang et al.,2013; Abousteitet al.,2015**; **Chen et al.,2007)** in which the

mean pain scores were less with stapled technique. The pain in stapled group was less than LigaSure group as it didn't involve the mucosa below the dentate line.

We showed that long term postoperative use of such narcotic analgesics (NA) may lead to habituation or even drug addiction. So; from the third day postoperatively we replaced the NA by using Diclofenac sodium (DS). In addition to, the finding mentioned before regarding to postoperative pain there was statistically significantly fewer doses of both NA and DS in the Group (B) in comparison to Group (A), which was the same similar to other study (**Yang et al.,2013**). In our work we found that it was quite suitable to use narcotic analgesic (Pethidine) for the first three postoperative days only, then to continue after that by DS for adequate pain control. Other studies revealed that the difference was not statistically significant in both groups regarding postoperative pain and parenteral analgesic injections (**Sakr and Moussa, 2010; Kraemer et al.,2005).**

This study showed that the difference was not statistically significant as regard to hospital stay, healing of the wound, and return to normal activity or work in both study groups that were close to other study (**Yang et al.,2013; Sakr and Moussa, 2010).**

Conclusion

This study demonstrates that Liga Surehemorrhoidectomy and stapled hemorrhoidopexyhad good results, with a short operative time and minimal side effects in the treatment of hemorrhoids grade III and IV. Stapled hemorrhoidopexy offers much less pain but more recurrent prolapse. we recommend to do other studies on more patients in who we can do combination between Stapled hemorrhoidopexy and LigaSurehemorrhoidectomy as a one technique.

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4/24/2018