



A Comparative Study of Hemorrhoidectomy using Ligasure v/s Conventional Open Method

Rahul Kaushik¹, Late SK Sethi², Prem Arora³

¹Resident, ²Ex H.O.D. General & Laparoscopic Surgery, ³Consultant General & Laparoscopic Surgery, Mata Chanan Devi Hospital, New Delhi

Received: 30-10-2018 / Revised Accepted: 12-12-2018 / Published: 01-01-2019

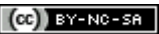
Abstract

Hemorrhoids are the cushions of sub mucosal tissue with venules, arterioles and smooth muscle fibers that are located in anal canal. Anal bleeding and mass per-rectum are common presenting symptoms. Hemorrhoidectomy is a frequently performed surgical procedure and associated with post-procedural pain. In the present study attempt has been made to compare the Conventional Open Hemorrhoidectomy with the new modality of Ligasure Hemorrhoidectomy in the treatment of Grade III and IV Hemorrhoids, thereby, trying to highlight the advantages and disadvantages if this new method. A randomized prospective study of 60 patients was conducted, study included patient of all age groups and both sexes. Study showed significant difference ($P < 0.001$) in Ligasure group with respect to intra-operative blood loss, time taken for surgery, duration of hospital stay. Ligasure group patient experienced significantly ($P < 0.001$) less pain than the Conventional group even at two weeks also return to work was earlier in Ligasure group. In the follow up, there was no major complication due to the use of Ligasure for hemorrhoidectomy with excellent patient acceptance and satisfaction. Technically the Ligasure method is much simpler and can be safely and effectively carried out by surgeons.

Keywords: Hemorrhoidectomy, Haemorrhoidectomy, Ligasure, Haemorrhoids, Hemorrhoid, Piles, Vessel Sealer, Open Hemorrhoidectomy, Ligasure Hemorrhoidectomy

Address for Correspondence: Dr. Md. Rafiqul Islam, PhD Researcher, Bangladesh University of Professionals (BUP), Bangladesh; E-mail: rafiqulph1979@gmail.com

How to Cite this Article: Rahul Kaushik, Late Dr SK Sethi and Dr Prem Arora. A Comparative Study of Hemorrhoidectomy using Ligasure v/s Conventional Open Method. Int J Res Health Sci 2019; 7(1): 1-8.

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INTRODUCTION

Hemorrhoids/Haemorrhoids are one of the most common ailments to afflict mankind, hemorrhoids have plagued humans since they attained the erect posture [1].

The word "Hemorrhoid" is derived from the Greek word "Hemorrhoides" meaning flow of blood (haem=blood, rhoos=flowing). The word "piles" comes from the Latin word "pila" meaning a pill or ball [2]. To be accurate, the disease is known as Piles when the patient complains of a swelling, and the term Hemorrhoids is used when patient complains of bleeding.

The incidence of piles increases with age and it seems likely that at least 50% of people over the age of 50 years have some degree of hemorrhoid formation. Men seem to be affected roughly twice as frequently as women [3].

Hemorrhoidectomy is superior to any proposed conservative procedure, including rubber band ligation, sclerotherapy, photocoagulation, and cryotherapy for treating symptomatic grades III and IV hemorrhoids [4].

The availability of new techniques and devices has stimulated researchers to look for the best treatment for curing hemorrhoids. The ideal technique should combine high safety and efficacy of the treatment with low postoperative pain and discomfort along with an effective cost for the same.

The Ligasure system (High frequency feedback-controlled electro thermal vessel sealing system) is a recently introduced device. It applies a precise amount of energy to vessel walls while they are being held in tight apposition under pressure, including through a cool-down phase, to produce a unique translucent seal of partially denatured protein. Thermal changes are essentially confined to within-the-jaw tissue. The entire process takes 2 to 5 sec, depending on vessel size and included tissue. Seal integrity in 3 to 7mm vessels approximates the burst strength of ligatures and clips, resists dislodgement, and is independent of proximal thrombus [5].

In this study we compare the efficacy and outcome of Ligasure hemorrhoidectomy with the conventional Milligan-Morgan hemorrhoidectomy in terms of, operating time, per-operative blood loss, duration of stay in the hospital, post-operative pain, post-operative analgesic requirement, return to work or normal activity and complications.

MATERIALS AND METHODS

The study was conducted in the department of Surgery, Mata Chanan Devi Hospital, New Delhi, in all 60 patients were included in the study-30 underwent Ligasure hemorrhoidectomy and 30

underwent Open hemorrhoidectomy. A random sequence of alphabets A (Ligasure Hemorrhoidectomy) and B (Conventional Open Hemorrhoidectomy) were obtained using computer generated random numbers and incoming patients were assigned to the respective groups on the basis of this random sequence.

Inclusion Criteria

All patients of:-

1. Grade III hemorrhoids
2. Grade IV hemorrhoids

Were included in the study

Exclusion Criteria

1. Patient of Grade-I and II hemorrhoid
2. Acute episodes of thrombosed hemorrhoids.
3. Inflammatory bowel diseases.
4. Tuberculosis.
5. Patients with secondary hemorrhoids due to an intra abdominal pathology.
6. Co-existing anal diseases.
7. Rectal varices.

During The surgery the following parameters were recorded.

1. Operative time. (from the time of painting to the placement of anal pack after completion of the procedure)
2. Approximate blood loss during surgery. (Per-operative bleeding noted by counting the number of gauze pieces (4*4). Each blood soaked gauze accounted for 5 ml of blood loss)

Operative Procedure

The procedure will be carried out with the patient in lithotomy position and a slight reverse Trendelenburg tilt. The initial steps in both procedures were same and included:

- Manual Anal sphincter stretching up to 4 fingers.
- Delivery of hemorrhoidal masses with artery forceps, one being applied at the base of hemorrhoid, the other at the apex.

Ligasure hemorrhoidectomy: Allis clamp was applied to each hemorrhoid at the mucocutaneous junction and artery clamp was applied at the haemorrhoidal pedicle. (Counter traction may be applied on the skin, slightly lateral to the intersphincteric groove, by a third Allis clamp). Starting with the 7 o'clock hemorrhoid. The clamp like electrode (Ligasure handset) was positioned beneath the external component (external hemorrhoid or skin tag = site of V-shaped incision) and was activated. The feedback mechanism of the

device automatically stops the energy delivery when tissue sealing is complete (identified by an end tone). The resulting “seal zone” is transected using scissors. A second application of the electrode continues the sealed tissue line, now comprising the internal hemorrhoid and the inferior hemorrhoidal vascular pedicle and transected using scissors. A third application may be needed. Each hemorrhoid (3 o'clock then 11 o'clock hemorrhoids) was dealt with in the same manner; adequate mucosal bridges were preserved, Gauze dressings were then applied to the hemorrhoidal area.

Open conventional hemorrhoidectomy (Milligan-Morgan technique): A proctoscope was inserted to identify the site of the three principal hemorrhoids. Allis clamp was applied to each pile at the mucocutaneous junction and artery clamp was applied at the hemorrhoidal pedicle. Starting with the 7 o'clock hemorrhoid, followed by the 3 o'clock hemorrhoid, and finish with the 11 o'clock hemorrhoid, so that the operation field not obscured by bleeding. The Allis clamp holding the hemorrhoid and its adjacent skin was grasped in the left hand. A V-shaped incision was made in the surrounding perianal skin with scissors. The cut was deepened toward the anal canal to reveal the lower fibers of the internal anal sphincter at the level of the dentate line. The sphincter was gently swept away with scissors from the hemorrhoid. The scissors were then used to excise the hemorrhoidal tissue within the anal canal, which leaves the apex

The patients were discharged when there was no requirement for injectable analgesia in the last 12hours. Duration of hospital stay was recorded. On each follow up visit the patient was subjected to visual analogue pain score. On the second and subsequent visit, a gentle digital rectal examination and proctoscopic evaluation was done. Level of the patient satisfaction was assessed. A note on the number of days to return back to work was made. After the initial visits the patients were advised to follow up at 3rd and 6th month to look for—

- Anal stenosis
- Recurrent haemorrhoids
- Anal skin tags or fibrosis
- Incontinence
- Level of Satisfaction

The patient who were unable to come for follow up (due to any reason) were inquired telephonically.

of the hemorrhoid with its arterial supply and venous drainage intact for ligature. The pedicle of each hemorrhoid was then enclosed in an artery clamp, and the pedicle was transfixed using absorbable (vicryl 2-0) sutures. Hemostasis was then secured from the bed of the hemorrhoid by use of cautery (for the bleeding points). The ligature was left long so that if any further bleeding occurs, the pedicle can be easily identified and delivered into the operative field. Each hemorrhoid was dealt with in the same manner; well-established mucocutaneous bridges between each V-shaped segment must remain. At the end of the operation, an anoscope was inserted to be certain that there is complete hemostasis. Gauze dressings were then applied to the hemorrhoidal area.

In the post operative period the parameters recorded were-

1. Analgesia required (injectable/oral)
2. Soakage of the pad with blood
3. Any episode bleeding per rectum
4. Episode of urinary retention
5. Visual analogue score.
6. Patient satisfaction

Visual analogue score:-The concept of Visual analogue score was explained to each patient in the pre-operative period with the maximum imaginable pain as 10 and least as 1. The patient was assessed for pain by VAS at 24hrs, 3 day, 7 days and 14 days post-op.

Statistical Tests

For comparing the quantitative variables between the 2 groups, we use unpaired t-test/Mann-Whitney test. For comparing qualitative variables between the 2 groups, we use chi-square/Fisher's Exact test. A p-value <0.05 will be considered as statistical significant.

The data is entered in MS Excel spread sheet and analysis is performed using Statistical package for Social Sciences (SPSS) version 15.0 software.

RESULTS

A total of 60 patients were included in the study.

Group A: Those who underwent Ligasure Hemorrhoidectomy (n₁-30)

Group B: Those who underwent Open Conventional Hemorrhoidectomy (n₂-30)

Preoperative data:

Age Distribution: The youngest patient was 21 yrs. and the oldest was 77 yrs. old in the study (p value = 0.169 i.e. > 0.05). Hence, the age difference in group A and group B is not statistically significant.

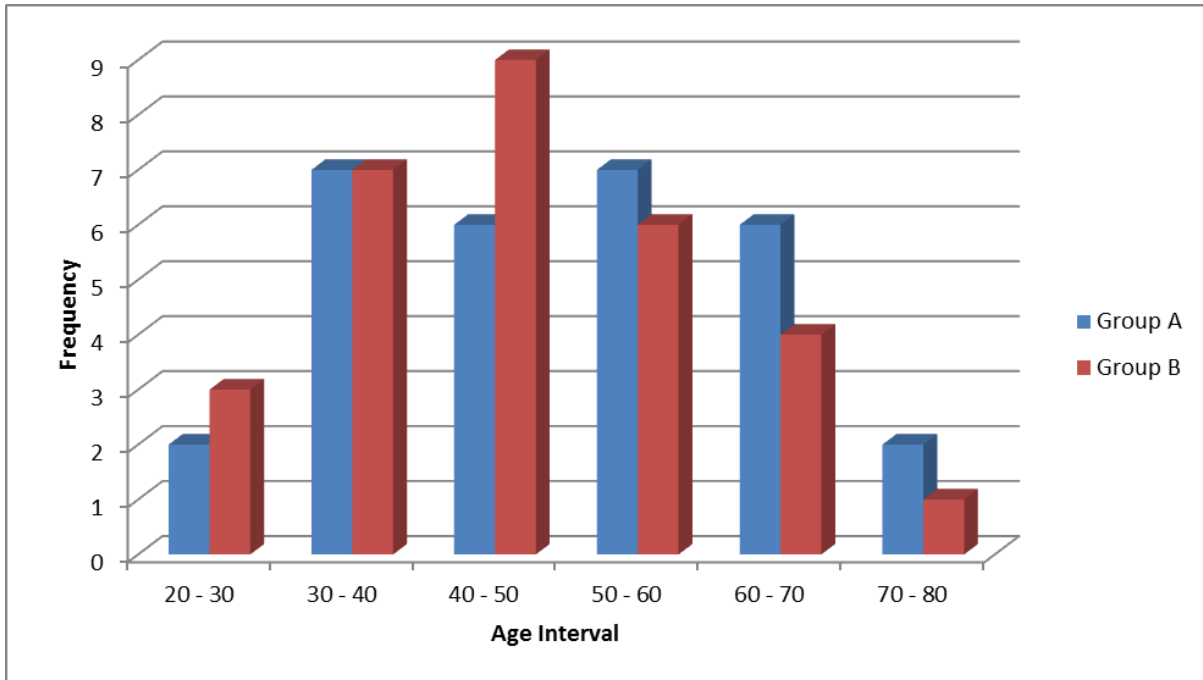


Fig. 1

Gender Distribution: The majority of the patients included in the study were males 44 (21 in group A and 23 in group B). Grades of Hemorrhoids: In the present study 39 of 60 patients (65%) had grade-III hemorrhoids

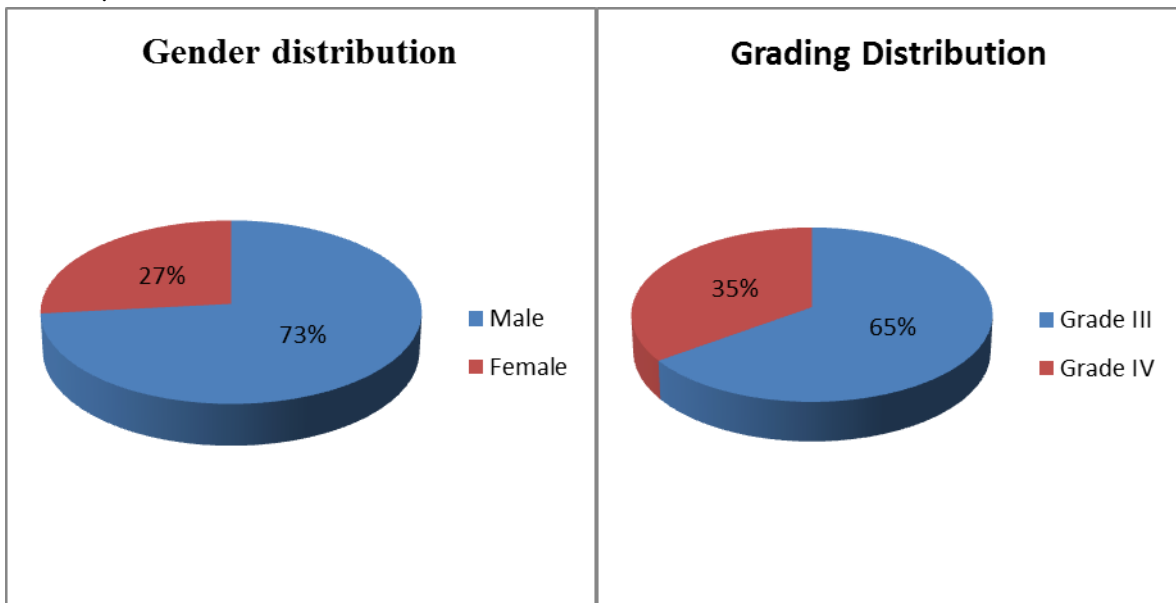


Fig. 2

Fig. 3

Most Common Complaints: The main complaints presented by our patients were bleeding and prolapse (43.33%), bleeding alone (33.33%), prolapse alone (23.33%).

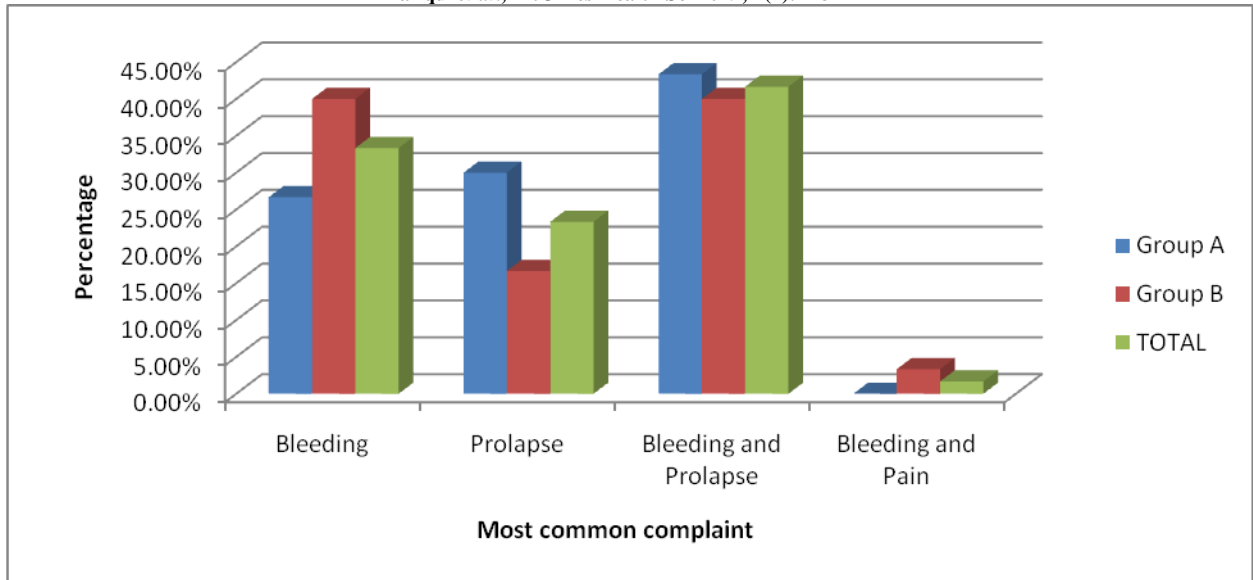


Fig. 4

Associated Condition: More than 50% of patients had constipation as an associated condition at some point of time.

Operative data:

Duration of Surgery (minutes): In comparison with group B, group A had a shorter operating time with significant p value.

Operating Time (minutes)	Group A	Group B	p-value
Mean	26.17	47.33	0.001
± SD	5.25	5.87	

Table. 1

Intra operative bleeding (milliliter): Operative blood loss in group A is significantly lesser than group B.

Blood Loss (ml)	Group A	Group B	p-value
Mean	23.33	44.67	0.001
± SD	6.74	9.28	

Table. 2

Postoperative data:

Hospital stay: Duration of stay in the hospital was significantly less (p<0.001) in group A (3.13±0.35 days) than in group B (4.13±0.51days).

Stay (days)	Group A	Group B	p-value
Mean	3.13	4.13	0.001
± SD	0.35	0.51	

Table. 3

Pain measurement: according to Visual Analogue Scale (VAS): Post-operative pain assessed by Visual analogue score showed significantly less incidence of pain in group A than group B, with statistical significance on post-operative Day 1,3, 7 & 14.

Visual analogue scores		Day 1	Day 3	Day 7	Day 14
Group A	Mean	6.33	4.00	2.23	0.67
	± SD	0.76	0.64	0.63	0.66
	p-value (vs. Day1)	-	0.000	0.000	0.000
Group B	Mean	6.87	4.80	2.97	1.57
	± SD	0.73	0.92	0.89	0.57
	p-value (vs. Day1)	-	0.000	0.000	0.000
p-value (group A VS group B)		0.004	0.001	0.001	0.001

Table. 4

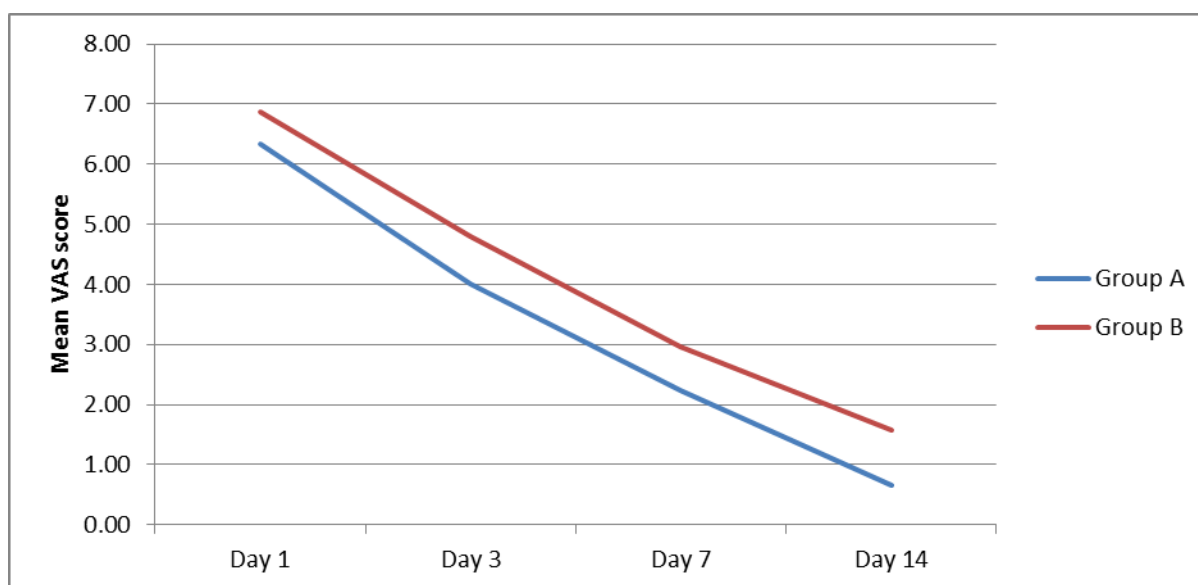


Fig. 5

Analgesia requirement: There is a clear difference in regard to oral and parenteral analgesic requirement with statistically significance.

	Group A		Group B		p-value
	Mean	± SD	Mean	± SD	
Oral analgesic consumed (in first week)	11.27	1.08	12.77	0.50	0.001
Parenteral analgesic consumed (in first week)	4.37	0.49	4.80	0.76	0.006

Table. 5

Return to work: The time range required by the patients to return to their normal activities was significantly lesser in group A than in group B, with a statistically significant P-value.

RTW(days)	Group A	Group B	p-value
Mean	9.80	12.93	0.001
± SD	1.42	2.72	

Table. 6

Complications: Early postoperative complications: Minor spotting of blood occurred in three patients (10.00%) of group A and in two patients (6.67%) of group B. Urine retention occurred in four patients (13.33%) of group A and in five patients (16.67%) of group B. Long Term Sequelae in follow up: Skin tags were found in one patient of group B (3.33%). Anal stenosis occurred in one patient of group A (3.33%) and one patient of group B (3.33%).

DISCUSSION

Present study is a randomized prospective control study comparing hemorrhoidectomy using Ligasure v/s Conventional Open method designed to evaluate the advantages and disadvantages of ligasure hemorrhoidectomy. A random sequence of alphabets A (Ligasure Hemorrhoidectomy) and B (Conventional Open Hemorrhoidectomy) were obtained using computer generated random numbers and incoming patients were assigned to the respective groups on the basis of this random sequence. A total of 60 patients were part of the study.

The two groups of patients were matched with respect to age. Mean age in group A was 48.37 ± 13.57 years and in group B was 45.03 ± 13.19 years (Fig. 1). There was no statistical difference in the mean age group between the two groups comparable to other studies^[6-10]. Males were commonly affected 73.3% (Fig. 2) as in other studies to^[6, 10, 11, 12].

In the present study 39 of 60 patients (65%) had grade-III hemorrhoids (Fig. 3). Third degree hemorrhoids are the commonest hemorrhoids requiring surgical treatment as reported in various studies^[7-9]. However the condition of fourth degree hemorrhoids was more common in some studies^[12-14]. The main complaints (Fig. 4) faced by our patients were bleeding and prolapse (43.3%), bleeding alone (33.3%), prolapse alone (23.3%), bleeding and pain (1.6%). There was no significance between the two groups as regard to the complaint of patients and this was reported in other studies^[4, 10, 11] also. More than 50% of patients had constipation as an associated condition at some point of time.

This difference in the presentations among patients through different studies may be attributed to the degree of awareness of those patients to themselves and to the nature of their activities.

In comparison with group B (Table 1), group A had a shorter operating time (26.17 ± 5.25 min versus 47.33 ± 5.87 , P value < 0.001) like other studies^{[6-}

^{11, 14, 15]}, operative blood loss in group A was also significantly less (Table 2) than group B (23.33 ± 6.74 ml versus 44.67 ± 9.28 ml, P value < 0.001) as also in other studies^[6-8]. Above point highlights the effective hemostatic control of Ligasure system.

The calculation of the hospital stay was made from the day of surgery and not from the day of admission thus excluding the duration in the hospital for getting Pre-anesthetic fitness or managing other co-morbid condition e.g. anemia, hypertension or diabetes. The postoperative duration of stay in the hospital was also significantly less with group A (Table 3) as compared to group B (3.13 ± 0.35 v/s 4.13 ± 0.51 days, P value < 0.001), comparable to other studies^[6-8, 15]. Jayne DG et al. and Khanna et al. recommend that Ligasure hemorrhoidectomy has the potential of making hemorrhoidectomy in to a day-care procedure.

The VAS pain scores to assess Post-operative Pain were lesser in group A (Table 4) than group B with statistically significance (6.33 ± 0.76 v/s 6.87 ± 0.73 , P value < 0.01) in the first day, (4.00 ± 0.64 v/s 4.80 ± 0.92 , P value < 0.001) in the third day, (2.23 ± 0.63 v/s 2.97 ± 0.89 , P value < 0.001) in the seventh day and (0.67 ± 0.66 v/s 1.57 ± 0.57 , P value < 0.001) in 14th day, comparable results were also seen in other studies^[6-11, 13, 14, 15].

As regard to the patient requirement of oral analgesic in first week, which was significantly less in group A as compare to group B (11.27 ± 1.08 v/s 12.77 ± 0.50 tab., P value < 0.001), comparable with other studies^[14, 15]. Also significant difference was found between both groups and other studies^[8, 11] as regard to requirement of IM analgesia in first week, which was less in group A (Table 5) than group B (4.37 ± 0.49 v/s 4.80 ± 0.76 inj., P value < 0.01).

There was a clear difference in regard to the time needed by the patient to return to work or normal activities, statistically significant less in group A (Table 6) as compare to group B (9.80 ± 1.42 versus 12.93 ± 2.72 days, P value < 0.001). Comparable results were met in other studies^[9, 10, 14].

As regard to early postoperative complications minor spotting of blood has occurred in three patients (10%) of group A and in two patients (6.67%) of group B. Urine retention has occurred in four patients (13.33%) of group A and in five patients (16.66%) of group B^[3, 4, 10, 11]. In late postoperative complications skin tags were met in only one patient of group B (3.33%) due to development of an anal fissure. Anal stenosis has

occurred in only one patient of group A (3.33%) and also in one patient of group B (3.33%) which responded successfully to repeated anal dilatation,

major complications were not met with in any patients in our study.

CONCLUSION

We conclude that hemorrhoids are more common in males, patients of hemorrhoids usually avoid surgery due to the fear of severe pain after Hemorrhoidectomy. Among the associated ailments, anemia was the commonest, mainly secondary to bleeding.

Ligasure Hemorrhoidectomy is a sutureless hemorrhoidectomy technique dependent on a

modified electrosurgical unit to achieve tissue and vessel sealing. It is safe and effective, has lesser blood loss, shorter operative time, shorter hospital stay, lesser postoperative pain, lesser requirement for analgesia, early return to daily activities and absence of major complications. Technically, it is a much simpler procedure because suturing is not required and haemostasis is easy to achieve. Ligasure Hemorrhoidectomy is another surgical method available for treatment of hemorrhoids.

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