

# Comparison of Bipolar Vessel Sealing Device Haemorrhoidectomy Vs Stapled Haemorrhoidopexy: A Prospective Study

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## ABSTRACT

**Aim:** To study and compare the results of haemorrhoidectomy using bipolar vessel sealing device and stapled haemorrhoidopexy.

**Study Design:** Prospective observational study.

**Material and Method:** The study was conducted at a tertiary care teaching hospital. The sample size was 60, patients with grade 3 and grade 4 hemorrhoids only included in study. Patients are randomly divided in two groups. The first group was operated by Bipolar Vessel Sealing Device (LIGASURE), whereas the second group patients were treated by stapled hemorrhoidopexy.

**Statistical Analysis:** The statistical analysis was done using statistical software package SPSS v22.0. Categorical variables were presented in number (n) and percentage (%) and continuous variables were presented as mean±SD. Continuous variables were compared using t-test/Mann-Whitney test and ordinal/nominal data was compared using Chi square/Fisher's test.

**Result:** It was observed that Bipolar Vessel Sealing Device takes less operative time, there was no residual skin tag and lower incidence of recurrence as compared to stapled hemorrhoidopexy; where patient had low postoperative pain and infection. There was no significant difference in postoperative urinary retention and procedure related early anal stenosis. Both the treatment modalities are effective; Bipolar Vessel Sealing Device hemorrhoidectomy has an edge over Stapled hemorrhoidopexy with respect to number of outcome variables.

**Conclusion:** Both treatment modalities were efficacious when compared to conventional haemorrhoidal surgeries. Bipolar VSDH haemorrhoidectomy was found to have edge over stapled haemorrhoidopexy.

**Key words:** Bipolar Vessel Sealing Device (VSDH), Stapled Hemorrhoidopexy (SH), Hemorrhoid, Hemorrhoidectomy.

## INTRODUCTION

Haemorrhoid is an age old disease. It affects the anorectal region. There is mention of haemorrhoids in Egyptian Papyrus (1700BC) 1. Hippocratic corpus (460BC) 1 discuss treatment of haemorrhoids in the form of rubber band ligation. There is also mention of haemorrhoids by Celsus (25BC), Galen<sup>2</sup> and Susruta Samhita (4th -5th century BC) 2. In 13th century European surgeon came out with surgical technique for haemorrhoids. Haemorrhoids or Piles is a very common condition prevalent in middle aged urban population in India. Most important causative factor is constipation; however it is also associated with raised anal canal resting pressure. There is caudal displacement of normal anal cushion's present at 3, 7 and 11 o'clock position due to straining at defecation, old age, obesity, pregnancy.

## **MATERIAL AND METHODS**

This prospective randomised observational study was conducted at ABVIMS & Dr. R.M.L. hospital, New Delhi. 60 patients were included in study. 30 patients were operated by using Bipolar Vessel Sealing Device (LIGASURE); in another 30 patients Stapled hemorrhoidopexy was done.

### ***Ethical approval***

Approval was taken for the study from institute ethical committee.

Randomization was done using randomization table method. The procedure was explained to the patients and consent was taken.

Surgery is done under regional anaesthesia in lithotomy position. Before surgery EUA, DRE and proctoscopy was done after anal dilatation.

### **Stapled Hemorrhoidopexy Technique**

Stapled hemorrhoidopexy is done using circular MIPH stapler. Anoscope is inserted following anal dilatation and fixed to the perianal skin margin. Purse string placed in mucosa approx 3-4 cm above dentate line using 2-0 polypropylene. Stapling device is inserted through Anoscope and anvil opened. Purse string suture pulled and tied and brought outside through opening provided in the device. Once after getting sure of the placement the stapling device is closed clockwise till the mark on the stapling device is visible. After waiting for 30 second, the stapler is fired and derotated bringing it out of Anoscope. A doughnut of excised mucosa is checked for completeness and through Anoscope examined for bleeding. If hemostasis is perfect the Anoscope is taken out.

### **Bipolar Vessel Sealing Device Hemorrhoidectomy**

Instrument consisting of a bipolar vessel sealing device (Ligasure). The steps of patient position and anesthesia are same as stapled hemorrhoidopexy. Skin incision at the base of hemorrhoids and submucosal dissection is done to define the pedicle and

bipolar VSDH were used to coagulate the pedicle. Scissors were used to excise the hemorrhoid mass by cutting across the coagulated tissue seal. Hemostasis achieved.

In post-op period, patient is shifted to ward. Oral sips and soft diet allowed after 4 hours. Patient discharged with advice of Sitz bath and laxative and later followed up.

The patients were called for follow up on 7th post op day and at the end of 1st, 2nd and 3rd month of surgery. We studied operative time, early postoperative pain, postoperative urinary retention, procedure related wound problems, postoperative flatus and faecal incontinence, postoperative anal stenosis, duration of hospital stay, incidence of residual skin tag and prolapsed and incidence of recurrence.

After obtaining all the above mentioned outcomes, the data were analyzed using appropriate statistical methods.

### ***Statistical analysis***

The data was entered in MS EXCEL spread sheet and statistical analysis was done using statistical software package SPSS v22.0. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean±SD. Normality of data was tested and if the normality was rejected then non parametric test was used. Continuous variables were compared using t-test/Mann-Whitney test and ordinal/nominal data was compared using Chi square/Fisher's test. P-value

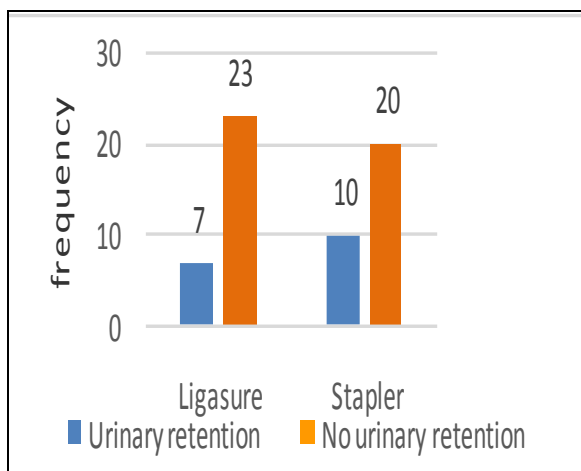
## **OBSERVATIONS AND RESULTS**

In both the groups there were no significant difference in age and sex.

Mann Whitney U analysis suggests that VAS scoring scale was significantly higher in Bipolar vessel sealing device haemorrhoidectomy (VSDH) group than stapled hemorrhoidopexy (SH) group of subjects on Day 0, 1 or 7 suggestive of early postoperative pain was significantly higher in bipolar VSDH group.

Chi square analysis suggests that there was no difference in incidences of

postoperative urinary retention between the two groups. The chi square value was 0.739 and it was statistically not significant.



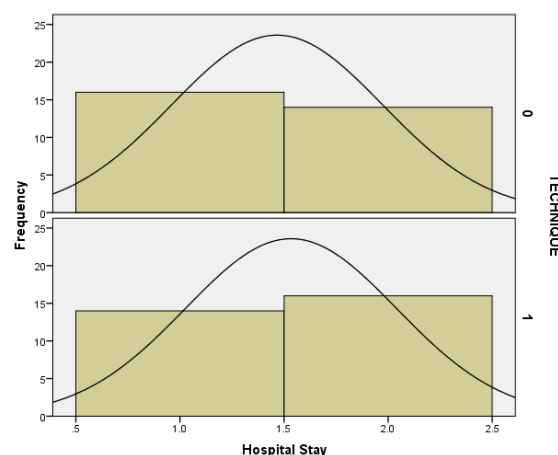
Graph 1: bar diagram showing comparison of post-operative urinary retention between the two groups.

Chi-square analysis suggests that there was a significantly higher chance of wound problems in bipolar vessel sealing device haemorrhoidectomy (VSDH) group

of subjects. The chi square value was 4.286 and the p-value was <0.05.

Both the group had one case of post-operative anal stenosis. So no difference in the incidence was present between the two groups.

There was no significant difference of hospital stay between the two groups.



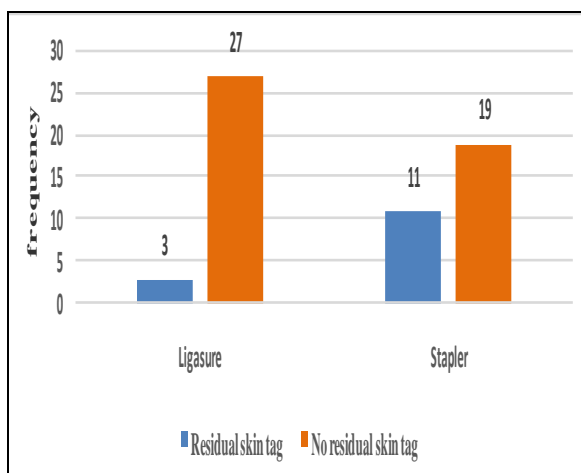
Graph 2: Histogram showing Comparison of hospital stay duration between two groups.

Table 1: comparison of operation duration between the two groups

Operation time (MINUTES)	TECHNIQUE	N	Mean	Std. Deviation	Std. Error Mean	p-value
	Bipolar VSDH	30	24.70	2.070	0.378	<0.001***
Stapled Hemorrhoidopexy (SH)	30	30.87	2.285	0.417		

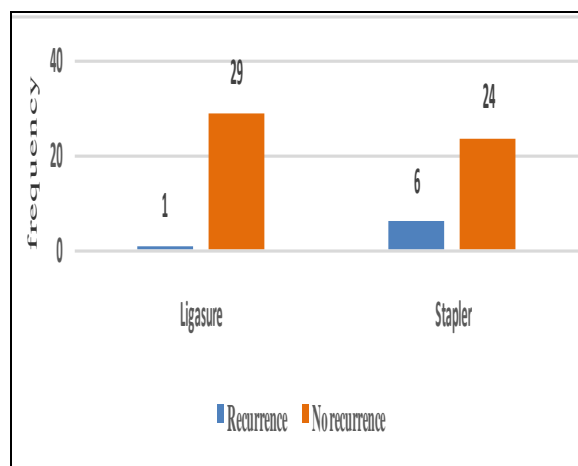
t-test analysis shows that there was significantly greater operation duration in stapled hemorrhoidopexy (SH) group of subjects than bipolar VSDH. (P-value<0.05)

residual skin tag in stapled hemorrhoidopexy (SH) technique than bipolar VSDH. The chi square value is 5.963 and the p-value <0.05.



Graph 3: Bar diagram showing comparison of incidence of residual skin tag between the two groups.

Chi square analysis suggests that there is significantly higher chances of



Graph 4: Bar diagram showing comparison of incidence of recurrence between two groups.

Incidence of recurrence was significantly higher in SH group of subjects

than bipolar VSDH. The chi square value was 4.043.

## DISCUSSION

Bleeding per rectum is the commonest symptom for which patients visit outpatient. However patient may also complain with mucus discharge, prolapse or perianal pain. Classically bleeding is fresh and painless and usually noticed by patient at the end of defecation.

Goligher classified haemorrhoid in grades, where Grade I and Grade II are early stage and managed by medical or conservative treatment. Grade III where hemorrhoidal prolapsed is noted and required manual reposition. Grade IV haemorrhoid are chronically prolapsed and cannot be reduced back and maybe associated with complications like profuse bleeding, ulceration or strangulation.

Diagnosis is clinical and protoscopy is done in outpatient department if patient has chronic symptoms. It's always advisable to do a sigmoidoscopy or colonoscopy to rule out any concurrent pathology.

Early stage haemorrhoids are treated by conservative measures like stool softeners, Sitz bath, injection sclerotherapy, rubber band ligation depending on grade and presentation.

Surgical treatment is indicated for grade 3 and grade 4 hemorrhoids; inter-external haemorrhoids, failed conservative treatment for grade 2 hemorrhoids.

There are various operative techniques for hemorrhoidectomy. The oldest and still today year--, most practiced is Milligan-Morgan operation. It can be performed by open or closed method and ligation and excision of haemorrhoid mass is done. The other operative modalities are trans-anal hemorrhoidal dearterialisation (THD) or Hemorrhoid artery ligation operation (HALO).

Stapled hemorrhoidopexy; propagated by Longo in 1998<sup>3</sup>. The principle of this technique is preservation of anal cushion, and circumferential excision of small segment of mucosa and submucosa

above dentate line using a specially designed stapling gun. This procedure is quick, postoperative pain is less and patient can be discharged early. Other modifications of Milligan-Morgan operation using bipolar vessel sealing device or harmonic scalpel are also commonly performed. It is seen that BVSD reduced operative time, complication and duration of stay in hospital and less incidence of reduced post-op pain and retention of urine.

Our study showed that bipolar vessel sealing device haemorrhoidectomy (VSDH) has some advantages over SH in terms of shorter operating time to complete the procedure.

In our study early post-operative pain was significantly higher in bipolar VSDH group than in SH groups. Pain was analyzed on Visual Analogue Scale on post-operative day 0, 1 and 7. Mann Whitney U analysis suggests that VAS scoring scale was significantly higher in bipolar (VSDH) group than stapled haemorrhoidopexy (SH) group of subjects on Day 0, 1 or 7.

Study conducted by Ko-Chao Lee. et al<sup>5</sup>, shows that primary VAS endpoint in two of the studies assessed pain 24 h after surgery, while pain scores for the other two studies reported pain over the first five postoperative days. VAS pain scores among the four studies ranged from values of 3- 6 and were the highest in the first 24 hr. None of the studies reported a significant difference between the VAS pain scores for the two techniques.

In our study incidence of post-operative urinary retention was slightly more in SH group than bipolar vessel sealing device haemorrhoidectomy (VSDH) group. In SH group, 10 out of 30 patients showed post-operative urinary retention whereas in bipolar vessel sealing device haemorrhoidectomy (VSDH) group only 7 out of 30 patients showed post-operative urinary retention, however Chi square analysis suggested that there was no significant difference in incidences of postoperative urinary retention between the

two groups. The chi square value was 0.739 and it was statistically not significant.

Studies conducted by Jun Yang et al showed that four trials reported urinary retention<sup>6,8,9,10</sup> after the procedure and there was no significant difference between the bipolar vessel sealing device haemorrhoidectomy (VSDH) and SH groups [11/156 (7.1%) Vs13/155 (8.4%); P = 0.74; OR = 0.87, 95%CI: 0.37-2.01).

Ko-Chao Lee. et al<sup>5</sup> concluded that the incidence of urinary retention varied from 2.2% to 16% in the four studies, but none reported a difference between SH and bipolar VSDH.

Our study showed that there was procedure related wound problems more in bipolar vessel sealing device haemorrhoidectomy (VSDH) groups than in SH groups. 4 out of 30 patients showed procedure related wound problems in bipolar vessel sealing device haemorrhoidectomy (VSDH) group whereas the incidence of procedure related wound problems in SH group was nil. Chi-square analysis suggested that there were significantly higher chances of wound problems in bipolar (VSDH) group of subjects. The chi square value was 4.286 and the p-value was <0.05.

In a study by Jun Yang et al it was found that four trials reported procedure-related wound problems, including irritation, itching and moisture<sup>6,7,8,9</sup>. There was no significant difference between the bipolar vessel sealing device haemorrhoidectomy (VSDH) and SH groups [46/146 (31.5%) Vs12/153 (7.8%); P = 0.3; OR = 3.49, 95%CI: 0.33-37.32).

We found that there was no significant difference in incidence of flatus and faecal incontinence in both the groups. In both the groups the number of patients with gas and faecal incontinence were nil.

Jun Yang et al showed that four trials reported the incidence of postoperative gas or faecal incontinence<sup>6,8,9,10</sup>. There was no significant difference between the bipolar vessel sealing device haemorrhoidectomy (VSDH) and SH groups

[5/156 (3.2%) stapled haemorrhoidopexy (SH) Vs 7/155 (4.5%); P = 0.55; OR = 0.70, 95%CI: 0.22- 2.24].

Study conducted by Ko-Chao Lee. et al<sup>5</sup>, shows that there was no significant difference in incidence of gas and faecal incontinence in between two groups. We found that there was no significant difference in incidence of post-operative anal stenosis in bipolar vessel sealing device haemorrhoidectomy (VSDH) and SH groups. In both the groups the numbers of patients with post-operative anal stenosis were one each.

Jun Yang et al showed that three trials reported postoperative anal stenosis<sup>8,9,10</sup>. There was no significant difference between the bipolar vessel sealing device haemorrhoidectomy (VSDH) and SH groups [3/111 (2.7%) Vs4/105 (3.8%); P = 0.65; OR = 0.71, 95%CI: 0.16-3.17].

Our study concluded that there was no significant difference in duration of hospital stay in both the groups.

Jun Yang et al showed that four trials reported the length of hospital stay after haemorrhoidectomy<sup>6,7,8,9</sup>. However, two of them only reported the average time. Combined data from the other two trials showed that there was no difference between bipolar vessel sealing device haemorrhoidectomy (VSDH) and SH (P = 0.44; OR = 0.82, 95%CI: -1.27-2.91).

In a study by Sakr MF et al<sup>9</sup> there was no significant difference in duration of hospital stay in two groups.

Study conducted by Ko-Chao Lee. et al<sup>5</sup>, shows that no differences were found in the length of hospital stay in both the groups.

Our study shows that there was significantly more operating time was consumed in SH than in bipolar VSDH. T-test analysis shows that there was significantly greater operation duration in stapled haemorrhoidopexy (SH) group of subjects than bipolar (VSDH). (P-value <0.05)

Jun Yang et al showed that four trials reported the operating time during

haemorrhoidectomy<sup>4,6,7,8,9</sup>. However, two of them only reported the average operating time. The combined data showed that the operating time of SH was significantly longer than that of bipolar vessel sealing device haemorrhoidectomy (VSDH) ( $P < 0.00001$ ; OR = -6.39, 95% CI: -7.68 - -5.10)

Basdanis G. et al<sup>6</sup> showed that operation time for open haemorrhoidectomy using bipolar vessel sealing device haemorrhoidectomy (VSDH) was shorter [median 13 (range 9.2-16.1) min vs. 15 (range 8-17) minutes,  $p < 0.05$ ].

Sakr MF et al<sup>9</sup> showed that no significant differences between bipolar vessel sealing device haemorrhoidectomy (VSDH) haemorrhoidectomy and stapled haemorrhoidopexy were observed in mean operating time.

We came to a conclusion that the incidence of residual skin tag is significantly more in SH than in bipolar vessel sealing device haemorrhoidectomy (VSDH) group. In bipolar vessel sealing device haemorrhoidectomy (VSDH) group 3 out of 30 patients have post-operative residual skin tag as compared to 9 out of 30 patients have postoperative residual skin tag in SH group. Chi square analysis suggests that there are significantly higher chances of residual skin tag in stapled haemorrhoidopexy (SH) technique than bipolar (VSDH). The chi square value is 5.963 and the p-value  $< 0.05$ .

Studies conducted by Jun Yang et al showed that three trials reported residual skin tags and prolapse<sup>8,9,10</sup>. The data showed that the incidence of residual skin tags and prolapse was significantly lower in the bipolar vessel sealing device haemorrhoidectomy (VSDH) group than in the SH group [2/111 (1.8%) Vs 16/105 (15.2%);  $P = 0.0004$ ; OR = 0.17, 95% CI: 0.06-0.45].

In our study the incidence of recurrence was significantly higher in SH group than in bipolar vessel sealing device haemorrhoidectomy (VSDH) group. In SH group 5 out of 30 patients had post-operative recurrence of haemorrhoid as compared to 1 out of 30 patients in bipolar

vessel sealing device haemorrhoidectomy (VSDH) group. Incidence of recurrence was significantly higher in SH group of subjects than bipolar VSDH. The chi square value was 4.043.

## CONCLUSION AND RECOMMENDATION

Symptomatic hemorrhoidal disease is a prevalent condition in our society, and patients often seek surgical opinion for relief. As a surgical approach, stapled hemorrhoidopexy and bipolar VSDH haemorrhoidectomy yield results that are comparable, with a decreased operative time and almost minimal side effects for management of grade III and IV hemorrhoids. The two procedures offer decreased levels of postoperative pain with respect to other surgical procedures. In comparison stapled hemorrhoidopexy had much less pain and wound infection than bipolar VSDH haemorrhoidectomy. However bipolar VSDH haemorrhoidectomy had advantage of having less recurrence, less chances of residual skin tag and consuming less time. Duration of hospital stay was almost same in both procedures. There was no significant difference in post operative urinary retention and post procedural anal stenosis. Therefore the both treatment modalities were efficacious when compared to conventional hemorrhoidal surgeries. Bipolar VSDH haemorrhoidectomy was found to have edge over stapled haemorrhoidopexy in our study.

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