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A Prospective Randomized Case Controlled Trial of Vessel Sealer Haemorrhoidectomy versus Conventional Milligan- Morgan Haemorrhoidectomy

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Abstract

Aims and Objective: The aim of the present study was to compare the short term results of the VSH group to the MMH group, in grade 3rd and 4th haemorrhoid patients.

Methods: sixty patients were included in this study, and were divided into two groups consisting 30 patients in each group, Vessel sealer Haemorrhoidectomy group (VSHG) and Milligan Morgan Haemorrhoidectomygroup (MMHG). Demographic data, operative details and postoperative parameters were evaluated.

Result: There was no statistically difference in two groups in regard to mean age, gender, grade and number

haemorrhoids. The of Mean operative time (min)(9.7±2.42 versus 15.43±3.08, p value 0.001) and mean intraoperative blood loss per pile mass (ml) (6.76±2.09 versus 15.86±3.39, p value 0.001) were less in VSHG. The mean postoperative pain score on Day 1 (7.9±0.71 versus 8.8± 0.40, p value 0.001), on Day 2 $(4.06\pm1.28 \text{ versus } 6.86\pm1.22, \text{ p value } 0.001)$, on Day 7(1.4±0.49 versus 2.56±0.77, p value 0.001), the mean postoperative hospital stay (Days) (3.2±0.92 versus 4.13 ± 1.0 , p value 0.001), mean time to return to normal activity (Days) (10.43±3.14 versus 14.63±2.94, p value 0.0001), mean time to achieve complete wound healing

(Days) (13.6 ± 3.58 versus 17.4 ± 4.43 , p value 0.0001), and postoperative urinary retention significant (p value 0.02) were less in VSHG, although postoperative hemorrhage difference was insignificant. The mean patients satisfaction score (3.83 ± 0.8 versus 3.36 ± 0.96 , p value 0.04) was higher in higher in VSHG.

Conclusion: Our study concluded that vessel sealer haemorrhoidectomy is safe with many short term benefits. **Keywords:** Vessel Sealer Haemorrhoidectomy, Milligan Morgan Haemorrhoidectomy.

Introduction : Haemorrhoids are a very common anorectal condition defined as the symptomatic enlargement and distal displacement of the normal anal cushions. It is a major medical and socioeconomic problem which affects millions of people around the world. [1]Haemorrhoidectomy is the standard operation for grades 3rd and 4th hemorrhoid; it is superior to any proposed conservative procedure. [2]Recent advances in instrumental technology including the bipolar electrothermal device, ultrasonic scalpel and circular stapler are gaining popularity as effective alternatives in haemorrhoidectomy. Of these instruments, the bipolar vessel sealing system has been recently introduced to upgrade the conventional operation of haemorrhoids. [3]The aim of the present study was to compare the short term results of the Vessel Sealer haemorrhoidectomy (VSH) to the Milligan Morgan haemorrhoidectomy (MMH), in grade 3rd and 4th haemorrhoid patients.

Material & Methods : This study was a prospective randomized case controlled trial conducted at our center over a period of 1 year, after the approval of the Ethics committee of the institute. Sixty patients were randomized in two groups. Group A, Vessel Sealer Haemorrhoidectomy group (VSHG) and Group B, Vessel Sealer Haemorrhoidectomy group (MMHG) by close envelope method. A pretested proforma was used to collect the relevant information including demographic data, clinical findings, lab investigation, operative details, postoperative course, follow up events, etc.

Inclusion Criteria: Male and female were above 18 years of age with 3rd or 4th degree of haemorrhoids and willing to be included in study.

Exclusion Criteria: Patients with age less than 18 years, with grade 1st and 2nd haemorrhoids, patients having hematological disorders or on anticoagulants, having previous history of anorectal surgery, patients with co-HIV morbidities such as diabetes. infection. immunosupression, and rectal growth and those who were not willing for inclusion in the study. Patients were counselled in detail about the two procedures and the merits and demerits of each operation and a written informed consent was taken. All the operations were carried out under spinal anesthesia in lithotomy position. The primary steps in both surgeries were same and consisted of examination under anesthesia and delivery of haemorrhoids by artery forceps.In Group (VSHG), the haemorrhoid was grasped and retracted. The jaw of vessel sealer probe was applied 1-2mm away from the skinmucosa junction and the haemorrhoids were coagulated, sealed and divide by scissor. Once the pedicle was reached, it was coagulated twice and divided distally. In Group B (MMHG), MMH was performed in standard manner. [4]The operative blood loss was measured by a weighing of blood soaked gauzes before and after the procedure and the floor nurse was recorded operative time. In the postoperative period, patients were assessed on severity of pain which was measured by visual analogue scale (VAS) with maximum imaginable pain as 10 and least as one. [5]In both groups, similar antibiotics, pain killers and dietary advice was prescribed in the post

operative period. The patients were encouraged to take high fiber diet, Lactulose syrup was prescribed 3 tsf twice daily. Warm Sitz baths were advised thrice in a day for 15-20 minutes each. In the follow up period, post operative complications such as hemorrhage, urinary retention, etc were noted. Patient's satisfaction was recorded by patient satisfaction (PS) scale with score as 1 (extremely dissatisfied), 2 (dissatisfied), 3 (neither dissatisfied nor satisfied), 4 (satisfied) and 5 (extremely satisfied). The patients were kept on weekly follow up till complete wound healing occurred and patients returned to normal activity.

Statistical analysis: The data was entered in a computerized database. Statistical analysis was performed with SPSS software (ANOVA 3.0). Result was expressed as Mean \pm SD or frequency (%). Unpaired independent T –test, independent chi square test and other statistical test were applied to various parameters in the two groups. P value <0.5 was taken as statistically significant.

Result: The two groups were equally matched in terms of age, gender, grade and number of pile mass.

(Table no.1)Table no. 1 Demographic and Preoperative Data between the Two Groups

Parameter	VSHG	MMHG	P value
Mean age± SD(years)	42.26±16.0	44.56±14.18	0.94
Gender -			
Male	26 (86.66%)	21 (70.0%)	
Female	4 (13.33%)	9 (30.0%)	0.11
Grade of haemorrhoids-			
3 rd grade	27 (90%)	24 (80%)	0.28
4 th grade	3 (10%)	6 (20%)	
Pile mass-			
1 pile mass	5 (16.66%)	4 (13.33%)	
2 pile mass	11 (36.66%)	11(36.66%)	0.92
3 pile mass	14	15 (50%)	
	(46.66%)		

The operative and postoperative results are summarized in the Table 2 given below.

Table no.	2-	Operative	and	Postor	perative	Results
	_	- r		r		

Parameters	VSHG	MMHG	P value
	(7()()	15.05.0.00	0.001
Mean blood loss/ pile	6.76±2.09	15.86±3.39	0.001
mass (ml)±SD			
Mean operative time/	9.7±2.42	15.43±3.08	0.001
pile mass (min)±SD			
Mean post operative pain			
(VAS Score)±SD			
Day 1	7.9±0.71	8.8±0.40	0.001
Day 2	4.06±1.28	6.86±1.22	0.001
Day 7	1.4±0.49	2.56±0.77	0.001
Postoperative urinary			
retention			
Yes	2 (6.66%)	9(30%)	
No	28	21 (70%)	0.02
	(93.33%)		
Postoperative			
hemorrhage			
Yes	1(3.33%)	2 (6.66%)	
No	29	28 (93.33%)	0.55
	(96.66%)		
Mean Postoperative	3.2±0.92	4.13±1.0	0.001
hospital stay (days)±SD			
Mean time to return to	10.43±3.14	14.63±2.94	0.0001
normal activity			
(days)±SD			
Mean time to complete	13.6±3.58	17.4±4.43	0.0001
wound healing			
(days)±SD			

Table no. 3 Patients Satisfaction Score

Patient's satisfaction	VSHG	MMHG	P value
Score			
Mean ±SD	3.83±0.8	3.36±0.96	0.049
1 (extremely	0 (00%)	0 (00%)	
dissatisfied)			
2 (dissatisfied)	2 (6.66%)	5 (16.66%)	
3 (neither dissatisfied	6 (20%)	14 (46.66%)	0.038
nor satisfied)			
4 (satisfied)	16 (53.33%)	7 (23.33%)	
5 (extremely satisfied)	6 (20%)	4 (13.33%)	

Discussion

There was no statistically difference in the two groups in regard to the mean age, gender, grade of haemorrhoids and number of pile mass, therefore the difference in the results cannot be attributed to the difference in these preoperative factors. The mean age of our study (Table no.1) was similar to study by Kemal Peker et al. [6] In a metanalysis study done on 11 studies, the percentage of males varied from 33% to 60% in Ligasure group and from 38% to 63% in conventional group. In our study, the female's percentages were lower, (Table no.1). This may be related to either decreased incidence of haemorrhoids in the female population or it may be due to females being shy and not willing to come for the treatment to hospital.

In our study the percentage of 3rd grade of haemorrhoids (Table no.1) was higher and 4th grade haemorrhoids was lower as compared to study by Manoj kumar et al [7] and Nighat Bakhtiar et al. [8]

A lesser intraoperative blood loss was seen in the VSHG as compared to the MMHG which is similar to other studies (Table no.4). This may be due to the virtually bloodless closed system of coagulation and cutting in the VSH, although the amount of blood loss reported shows a wide range in the VSHG, from 1.2 ± 1.6 ml [9] to 51.92 ± 15.68 ml [8] as reported in the literatures. (Table no. 4)

Table no. 4 shows the Intraoperative Blood Loss (ml) as compared to literature.

Studies	VSHG (ml)±SD	MMHG (ml)±SD	P value
Our study	6.76±2.09	15.86±3.39	0.001
Manoj kumar et al [7]	8.79±4.81	57.67±15.9	S
Rahul Kaushik et al [5]	23.33±6.74	44.67±9.28	0.001
Dr. Vinayaka et al [4]	17.50±6.66	27.17±2.52	0.001

Nighat	51.92±15.68	70.34±25.59	S
bakhtiar et al			
[8]			
Wagih M.	6.53±2.9	28.79±7.32	0.0001
Ghnnam et al			
[10]			
Olfat Issa EL	1.2±1.6	22.2±6.58	0.0001
et al [9]			

The mean operative time as seen in our study is significantly (p value 0.0001) lower in the VSHG as compared to the MMHG. This is similar to other studies as reported in literatures. [4,5,8,9] (Table no.5)

Table no. 5 the Operative Time (min) as Compared to Literature

Studies	VSHG (min)±SD	MMHG (min)±SD	P value
Our study	9.72±2.42	15.43±3.08	0.001
Olfat Issa EL et	6.6±2.1	21.7±4.3	0.001
al [9]			
Rahul Kaushik et	26.17±5.25	47.33±5.87	0.001
al [5]			
Dr. Vinayaka et	25.17±9.50	41.33±4.97	< 0.001
al [4]			
Nighat bakhtiar	36.6±9.8	52.5±11.9	-
et al [8]			

The higher operative time in the conventional (MMHG) may be due to the need for dissection and to achieve hemostasis. (Table no.5)

Our mean postoperative pain score (Table no.2) on Day 1 was less in the VSH as compared to the MMH which was similar to other studies, [7] (Table no. 6) although one study showed no significant difference in the pain score on Day one. [4]

On Day 2 and day 7, our mean post operative pain score was less in the vessel sealer group as compared to Milligan Morgan group which was similar to other studies.[4,5,7] (Table no.6)

The mean postoperative pain score was less in VSH group as compared MMH group, this may be due to the presence of open wound in MMH.

Studies	Day 1		P Value	Day 2		P value	Day 7		P value
	VSHG	MMHG		VSHG	MMHG		VSHG	MMHG	
Our study	7.9±0.71	8.8±0.40	0.001	4.06±1.28	6.86±1.22	0.001	1.4±0.49	2.56±0.7	0.001
			(S)			(S)			(S)
Dr. Vinayaka	46.00±8.14	47.33±5.83	0.469	26.00±9.68	32.33±4.30	0.002(S)	-	-	
et al [4]			(NS)*						
Rahul Kaushik	6.33±0.76	6.87±0.73	0.004	-	-		2.23±0.63	2.97±0.89	0.001
et al [5]			(S)						(S)
Manoj Kumar et al	2.80±0.76	5.73±1.28	S	2.57±0.73	5.20±1.52	S	1.63±0.81	2.97±1.33	S
[7]									

Table no. 6 Postoperative Pain Score as compare to literature

S= statistically significant (P value<0.05)

NS= Not statistically significant

The VSHG shows statistically significant less number of patients with postoperative urinary retention as compared to MMHG, (Table no.2) this may be due to less postoperative pain in the VSHG. The result of our study is similar to other studies. [4,5,7,10] In the VSHG lesser patients had postoperative hemorrhage, although the difference was not statistically significant, (Table no.2) this may be due to our taking adequate care to achieve good hemostasis in open technique also. The result of our study is similar to other studies, [7,10] although one study by Rahul Kaushik et al⁵ showed different results with increased bleeding in the vessel sealer group.

Other complications like incontinence, anal stenosis, etc. were not seen in any patients in both groups.

Table no.7 Postoperative Complications as Compared to Literature

Studies	Urinary retention (no. of 2 patients)		Hemorrhage (no. of patients)	
	VSHG	MMHG	VSHG	MMHG
Our study	2	9	1	2
Dr. Vinayaka et al [4]	5	18	-	-
Rahul Kaushik et al [5]	4	5	3	2
Manoj Kumar et al [7]	2	4	2	5
Wagih Mommtaz Ghnnam et al [10]	0	1	0	2

Table no.8 Postoperative Hospital Stay (in days) as Compared to Literature

Studies	VSHG (Days)±SD	MMHG (Days)±SD	P value
Our study	3.2±0.92	4.13±1.0	0.001
Manoj kumar et al [7]	2.13±0.78	2.30±0.75	S
Rahul Kaushik et al [5]	3.13±0.35	4.13±0.51	0.001
Dr. Vinayaka et al [4]	6.20±1.37	10.40±1.52	<0.001

S- significant

The mean postoperative hospital stay on reported in literatures is lower in the VSHG as compared to the MMHG, which is similar to our findings,(Table no.8) This may be attributed to the low pain score, lesser postoperative complications and better wound healing rate as seen in the VSHG.

Table no. 9 – Time to Return to Normal Activity (days) as Compared to Literature

Studies	VSHG (days)	MMHG (days) ±SD	P value
	±SD		
Our study	10.43±3.14	14.63±2.94	0.0001
Wagih M.	6.93±1.7	15.46±3.2	0.001
Ghnnam et al			
[10]			
Manoj Kumar et	14.27±1.96	17.80±3.01	0.0001
al [7]			
Rahul Kaushik	9.80±1.42	12.93±2.72	0.001
et al [5]			
Dr. Vinayaka et	11.90±2.04	10.20±1.42	-
al [4]			

The time return to normal activity is earlier in the VSHG as compared to the MMHG which is seen in other studies. [5,7,10] (Table no. 9) The reason for this may be as given below is shorter time taken to achieve wound healing in the VSH, although one study⁴ showed different result. Table no.10 Time to Complete Wound Healing (in days) as Compared to Literature

Studies	VSHG±SD	MMHG±SD	P value
Our study	13.6±3.58(days)	17.4±4.43(days)	0.0001
Wagih	15.24±3.3(days)	31.16±6.7(days)	0.001
M.Ghnnam et			
al [10]			
Olfat Issa EL et	4.4±0.68(weeks)	6.4±0.99(weeks)	0.0001
al [9]			

The time taken to achieve complete wound healing is significant less in the VSHG as compared to MMHG, which is also seen in other studies. [9,10] (Table no.10) The mean patient satisfaction score was 3.83 ± 0.80 in VSHG and 3.36 ± 0.96 in MMHG. The difference was statistically significant (P value-0.038). (Table no. 3)

Most of patients in VSHG the patient satisfaction score 24 (73.33%) was 4 (satisfied) and 5 (extremely satisfied) in our study.

In VSHG showed significantly more patients satisfaction as compared to MMHG. (Table no. 3)

As compared with another study by Olfat Issa EL Sebaei et al⁹, shows that the mean patient's satisfaction score (ranging from 0 to 10) was 8.7 ± 1.67 in Ligasure group as compared with mean was 7.12 ± 1.31 in conventional group after 3 months of postoperative period. The mean of patient's satisfaction score was higher in the Ligasure group compared to conventional group which is similar to result of our study.

The reason for the better patient's satisfaction score in the VSHG may be, due to early wound healing, decreased postoperative complications, early hospital discharge and early return to normal activity.

Conclusion: The findings of our study confirm that the vessel sealing haemorrhoidectomy is associated with lower intraoperative blood loss, lesser operative time, lower post operative pain, lesser postoperative complications, shorter duration of post operative hospital stay, early return to normal activity, less time to achieve wound healing and better patient's satisfaction. We conclude that the VSH is safe with many short term benefits.

Limitations of study: The limitations of our study are the small sample size, Vessel sealing compared with only the Milligan Morgan procedure, short and limited follow up period and no observation of long term complications.

Recommendation: We recommend that the vessel sealer hemorrhoidectomy be offered to all patients with grade 3rd and 4th hemorrhoids who not having any contraindications to this method.

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