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HEMORRHOIDECTOMY IN PATIENTS WITH GRADE III AND IV DISEASE: HARMONIC SCALPEL COMPARED WITH CONVENTIONAL TECHNIQUE.

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ABSTRACT… Objectives: To compare conventional hemorrhoidectomy with harmonic scalped hemorhoidectomy in terms of pain outcome as a patient perceives, time taken for operation and length of stay in hospital. **Study Design:** Randomized controlled trial. **Setting:** Services hospital Lahore. **Period:** From August 2015 to February, 2016. **Material & Methods:** Patients were divided into two equal groups: Group A: conventional hemorrhoidectomy and Group B: Harmonic Scalpel. The study was performed by a single surgical operating team. Patient's selection criteria were male and female between 20 to 80 ages with III and IV degree hemorrhoids. The outcomes were operative time, post-operative pain and duration of stay in the hospital. **Results:** One hundred patients with mean age 40.86+10.26 were included and randomly assigned. This came out significant difference in operative time 28.4+11.004, postoperative pain 3.73+1.96, and length of hospital stay 2.43+1.795. There were equal distribution in age and gender in both groups. **Conclusions:** It is concluded that harmonic scalpel technique in hemorrhoidectomy is better than conventional closed hemorrhoidectomy in 3rd and 4th degree hemorrhoids.

Key words: Conventional Hemorrhoidectomy, Harmonic Scalpel Hemorrhoidectomy, VAS Pain Score.

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INTRODUCTION

Hemorrhoidal disease is a not an uncommon pathology affecting all age group and gender. There are multiple factors that causes hemorrhoids but most contributory factors are difficulty in defecation, straining or constipation. Over the last decades, great emphasis has been made in modification in surgical procedures to treat III- and IV-degree hemorrhoids.[1]

Conventional hemorrhoidectomy open or closed, is the most widely used effective surgical management for symptomatic grade III and IV hemorrhoids.[2] However, it is associated with significant post-operative complications such as post-operative pain, bleeding, mucous discharge and anal stenosis which can require a protracted period of restoration.[3]

Different surgical modalities been introduced and recent advances in gadgets such as bipolar electro thermal devices, ultrasonic shears, circular staples have been introduced with intentions to reduce complication postoperatively as well as improve the surgical outcome.[4] These techniques have been proposed to tackle the shortcomings often associated with conventional procedures.

However none has proved superior to others and primary concern remains reduction of post-operative pain and operative time.[5] Compared with electro cautery, harmonic scalpel (HS) causes minimal tissue injury during tissue dissection with low energy transfer to adjacent structures and uses both cutting and coagulation safe as well as superior alternative to ligation of hemorrhoidal tissue at the exact point of application by using lower temperatures. Theoretically HS technique of excisional hemorrhoidectomy seems to be rather less painful postoperatively than its counterpart available treatment options.[6]

I.Ece did a comparative study of harmonic scalpel and conventional closed hemorrhoidectomy. According to study, duration of operation was significantly shorter with harmonic scalpel compared with conventional hemorrhoidectomy [14.5+3 min and 32+3.2 min], mean post-operative pain which was significantly less in harmonic scalpel (3.1+1.1) than in conventional hemorrhoidectomy (6.3+1.4) in 24 hours.[7]

Another study compared mean hospital stay in days (1.6+0.4 vs.1.4+0.3) and return to normal activities did not differ significantly between conventional and harmonic scalpel.[8]

Despite having the harmonic scalpel available for all types of vessel sealing, conventional hemorrhoidectomy is still being preferred world-wide[5] as they rely on traditional sutures and skills. This study will help us to find out the benefits and disadvantages of using harmonic scalpel over conventional hemorrhoidectomy as there is no local references available on harmonic scalpel in our population and most of the surgeons still prefers conventional technique over harmonic scalpel. So, if we find better results of outcome so that we can use harmonic scalpel rather than conventional hemorrhoidectomy.

MATERIAL & METHODS

After the approval of the Ethical committee IRB/503/SIMS and Research training and methodology cell of CPSP and registered in clinical trial NCT03938714, we conducted a prospective randomized controlled trial. The study was performed at services hospital Lahore, from August 2015 to February, 2016.

The sample size was estimated as 100 (50 each) using 95% confidence interval 80% power of study with hospital stay in days i.e. (1.6+0.4 versus 1.4+0.3)[(7)], in conventional versus harmonic scalpel hemorrhoidectomy group in patients with III and IV degree hemorrhoids. Patients between age 20-60 years, both genders with III- and IV-degree hemorrhoids assessed on proctoscopy has been included in this study.

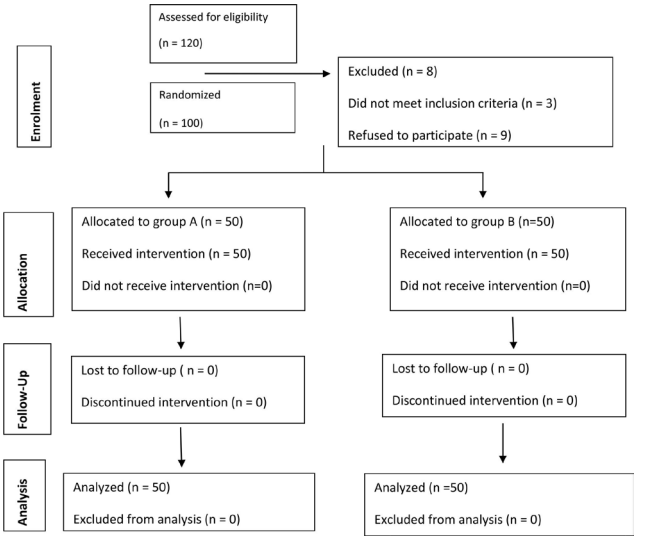

Figure-1. Study diagram.

Patients with prolapsed hemorrhoids limited to one quadrant, any other anorectal disease, previous anal surgeries, inability to give informed consent, ASA grade III/IV were excluded after a detail history and examination. A hundred patients fulfilling the inclusion criteria were recruited from outdoor and emergency department. A detailed history was taken including demographic data and all patients were clinically examined. Patients were divided into two equal groups randomly using random number table.

Group A: Conventional Hemorrhoidectomy.

Group B: Harmonic Scalpel Hemorrhoidectomy. Patient was requested to sign an informed consent. They were assured regarding confidentiality and expertise used for the procedure. All procedures had been performed by a single surgical team to control bias. Preoperatively operative time was noted. Post operatively pain had been assessed in 24 hours, hospital stay had been measured in days from postoperative day till day of discharge. All data was collected and recorded on the attached Performa and organized in tabulated and graphical presentation. All data was analyzed by using SPSS version 20.

Quantitative variables like age, operative time and postoperative pain on VAS pain score and

hospital stay had been measured by calculating mean, standard deviation, student T-test to compare both groups. Qualitative variables like gender were measured by calculating frequency and percentage. P-value < 0.05 was considered as significant. Data was stratified for age, gender and degree of hemorrhoids to address the effect of modifier-post-stratification. T-test had been used to compare with P < 0.05 as significant.

RESULT

One hundred patients were randomized to the trial. Adequacy of randomization was demonstrated by the similarity in patient characteristics in both groups (Table-I). No violations of protocol were recorded throughout the study. The mean number of hemorrhoids excised was similar between the groups (Table-II). Mean operating time was significantly shorter in group B [17.68+2.11min, 95% CI: 0.60] than in group A [(39.12+2.37 min, 95% CI: 0.67)], P < 0.00001. Analysis of the mean postoperative pain scores were significantly lower after using harmonic scalpel compared to using conventional technique in the 24 hours (1.92+0.600,95%CI:0.170 versus 5.54+0.862,95% CI:0.245), P <0.00001(Table-III). The duration of hospital stay was significantly shorter after harmonic scalpel (1.82+0.62, 95%CI: 0.18), reaching less than half the time required after conventional group (3.04+0.66, 95%CI: 0.19), P< 0.00001. The data of outcomes were analyzed and stratified with age, gender and degree of hemorrhoids as shown in Table-IV.

	N	Minimum	Maximum	Mean	Std. Deviation
Age	100	20	60	40.86	10.26
Operative time	100	14	45	28.4	11.004
VAS	100	1	8	3.73	1.963
Hospital stay	100	1	4	2.43	0.795

Table-I. Descriptive Statistics.

	Group A (CH)	Group B (HS)
No. of patients	50	50
Age	40.04±9.29	41.68+11.18
Gender ratio(M:F)	23:27	24:26

Table-II. Characteristics of patients randomized to Group A (conventional group) or Group B (harmonic scalpel) for hemorrhoidectomy.

Parameter	CH (n=50)	HS(n=50)	P
Operative time	39.12±2.37	17.68±2.11	.00
VAS	5.54±0.862	1.92±0.60	.00
Hospital stay	3.04+0.66	1.82±0.62	.00

Table-III. Outcomes of patients undergoing conventional group (group A) or harmonic scalpel (group B)

		Operative Time		VAS		Hospital Stay	
		CH	HS	CH	HS	CH	HS
AGE	**<38 years**	39+2.11	17.29+2.33	5.65+0.88	1.76+0.56	3.08+0.66	1.58+0.71
	>38 years	39.2+2.62	17.87+1.99	5.44+0.84	2+0.61	3.07+0.54	1.87+0.54
Gender	**Male**	38.78+1.83	17.41+1.99	5.30+0.87	1.83+0.63	3.30+0.55	1.83+0.63
	Female	39.40+2.74	17.92+2.22	5.74+0.81	2.07+0.56	2.88+0.57	1.73+0.60
Degree of Hemorrhoids	**3rd degree**	27.94+11.1	29.06+11.0	3.31+1.73	4+1.95	2.47+0.90	2.39+0.93
	4th degree	28.34+11.5	27.86+11.0	3.69+0.91	3.72+2.27	2.38+0.85	2.45+0.96

Table-IV. Age and Gender stratification of the VAS, Operative time and Hospital stay between two groups.

DISCUSSION

Hemorrhoids are sub mucosal cushion that develop in perianal region with a highly vascular pedicle. These hemorrhoids are arranged in a three-column fashion along the lining of anal canal. The treatment strategies vary from conservative therapy such as dietary and life-style modification to invasive interventions and radical surgery depending on degree and severity of symptoms.

The symptomatic hemorrhoids of grade 3 and 4 are treated with hemorrhoidectomy, which remains an accepted modality of management. The common procedures like Milligan Morgan[9] and Fergusons[10] are the traditional methods which have been in practice for more than two-third of decade. The major draw backs of hemorrhoid surgery are the post-operative pain and protracted healing period and there has been a quest to develop better alternative to reduce pain in post- operative duration. In recent years, there have been introduction to several new techniques to ease the post-operative pain with relative merits and demerits.

The vessel sealing device is one of the tools recently brought into view to control the major complication of the surgery and have been differentiated to conventional methods.[11-14,16,17]

A Harmonic scalpel system is a bipolar device which is derived by electro thermal energy to delivers optimal current between the diathermy forceps, this ensures the device to coagulate the desired tissue locally along with minimal thermal spread, compared with other electro cautery instruments.[18] The ultrasonically activated scalpel works at a temperature of less than 100°C using high-frequency ultrasonic energy which divides the tissue and causes tissue desiccation, charring and a zone of thermal injury compared with other electro cautery instruments.[21] Either system may contribute to lower postoperative pain.

Harmonic scalpel is an effective and simple as well a safe procedure. It is far superior to conventional in terms of reduced operative time, post-operative pain.[6] The reduced operative time was related to better control of hemostasis and lack of need to ligate the vascular pedicles.

Sympathetic and parasympathetic nerves supply the rectal wall and causes pain while stretching or excising the rectal mucosa as it is sensitive and have increase threshold of pain. The level of pain in postoperative period is reduced in harmonic scalpel group as compared to other techniques, as there is no need for anal dilatation. In addition, reduction of the anal spasm and minimal tissue handling improves tissue approximation which enhances the healing process of the wound rapidly.[21]

Dinesh et all reported that a significant difference in harmonic scalpel and conventional Ferguson's technique in terms of post-operative pain, operative time and hospital stay. Our study shows mean post-operative pain of VAS 1.92+0.60 in harmonic scalpel technique which is significantly lower as reduced anal spasm and smaller size of surgical wound associated with harmonic scalpel technique compared to conventional hemorrhoidectomy.

Our study shows mean operative time 17.68+2.11 with hospital stay 1.82+0.62 in harmonic scalpel show significant difference and better outcome when compared to conventional hemorrhoidectomy as shown in previous studies

Gender distribution shows 53% of total were females and 47% were male making it 53 females and 47 males, who were subjected to study.CH was offered to 23 males and 24 were subjected to HS where out of 53 females 27 was offered to CH and 26 in LH group. Ilhan ece et all in his study showed male to female ratio of 7:5 in CH group and 9:5 in HS group which shows that in our study female gender are becoming more aware regarding the disease process.

Our studies show mean VAS was 5.54+0.86 in CH and 1.92+0.60 in HS group whereas mean operative time in 39.12+2.37 in CH and 17.68+2.11 in HS group, length of hospital stay was observed 3.04+0.66 in CH and 1.82+0.62 in HS. Our studies show that in HS group length of hospital stay and return to normal activities

were significantly faster than after CH owing to reduced postoperative pain with addition of reduced operative time. Contrarily, E.G Dumlu et all in his studies reported no significant difference in both groups in terms of post-operative pain and length of hospital stay but significant difference in operative time.[7]

CONCLUSION

Based on the data, it is concluded that harmonic scalpel technique of hemorrhoidectomy is significantly better than conventional hemorrhoidectomy and a better alternative in treating in III and IV-degree hemorrhoids in terms of reduced postoperative pain, operative time and hospital stay.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Safia Zahir Ahmed	Contributed to concept of questionaire, data analysis, interpretation and drafting of manuscript.	
2	Noor ul Mobeen	Contributed to the main research, design and data collection.	
3	Bilal Ahmed	Arrangment of gadgets used and questionaire design.	