

ORIGINAL ARTICLE

**COMPARATIVE STUDY OF DIFFERENT TREATMENT MODALITIES
OUTCOMES FOR HEMORRHOIDAL DISEASE****Davinder Kumar¹, Reena Kothari¹, Dilip Thakur¹, Uday Somasekhar¹, Ritu Bhukal², Dhanajay Sharma¹, Narottam Singh Argal³**¹Department of Surgery, Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh, India²Department of Pathology, Pandit Bhagwat Dayal Sharma, Post Graduate Institute of Medical Science, Rohtak, Haryana³Department of Surgery Pandit Bhagwat Dayal Sharma, Post Graduate Institute of Medical Science, Rohtak, Haryana

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Abstract

The aim of this study is to compare the outcomes of different surgical modalities for mainly grade III and IV hemorrhoids in terms of operative time, postoperative pain, complications and duration of hospital stay. A prospective comparative study of outcomes of different modalities of treatment of hemorrhoids was done from October 2016 to 31st August 2018 at department of general surgery N.S.C.B. Medical College and Hospital, Jabalpur. We operated 94 patients and divided them into four groups. A (open hemorrhoidectomy MM), B (stapler hemorrhoidectomy MIPH), C (Laser hemorrhoidectomy), D (Harmonic Scalpel hemorrhoidectomy). A follow up of patient was done for 3 months in each group. The majority of patients fall in the age group of 30 to 60 years with mean age of 42.39 years. Around 74.50% were males and 25.50% were females. The average operating time was for group A: 51.8 ±9.34, B: 41.37 ±6.09, C: 17.6±4.11, D:22.25±3.98. VAS pain scores postoperative day 1, week 1, week 4, week 12 were for Group A:5.64±1.25, 4.16±1.11,2.68 ±0.99, 1.16±0.8; Group B: 3.5±1.32, 2±0.83, 1.12±0.34, 0.12±0.34; Group C: 2.7±1.16, 0.92±1.0, 0,0; Group D: 3.9±0.97, 2.15±0.87, 0.51±0.5,0. The average hospital stay in each group was A: 6±2, B: 2±1, C: 1±0, D: 1.1±0 days. Patient's acceptance was good with Harmonic Scalpel hemorrhoidectomy and Laser hemorrhoidectomy technique due to least complication rates and early return to work as compared to open and stapler hemorrhoidectomy.

Keywords: *stapler hemorrhoidectomy, laser hemorrhoidectomy, harmonic scalpel hemorrhoidectomy, open hemorrhoidectomy*

Introduction

Hemorrhoidal disease is ranked first amongst diseases of the rectum and large intestine, and the estimated worldwide prevalence ranges from 2.9% to 27.9%, of which more than 4% are symptomatic [1,2]. Approximately one-third of these patients seek physicians for treatment. Age distribution shows a gaussian distribution with a peak incidence between 45 and 65 years with

subsequent decline after 65 years [3,4]. Men are more frequently affected than women [5-7].

The treatment options for symptomatic hemorrhoids need to be tailored according to grade of hemorrhoids, patient preference and expertise of the procedure that vary over time. Treatment for symptomatic grade III and IV are mainly surgical i.e. open (Milligan Morgan Technique – MM), stapler hemorrhoidectomy (MIPH), Harmonic Scalpel hemorrhoidectomy

(HSH), Laser Hemorrhoidectomy (LH), closed hemorrhoidectomy, rubber band ligation, digital hemorrhoidal artery ligation, injection sclerotherapy, infrared coagulation, diathermy coagulation etc. [8].

In spite of so many treatment techniques available there is still no ideal and gold standard technique available for treatment of hemorrhoids. In our study we compared the following techniques of hemorrhoidectomy: open (MM), Harmonic Scalpel (HSH), stapler hemorrhoidectomy (MIPH), Laser hemorrhoidectomy (LH) on basis of pain (VAS score) and outcomes of these techniques, patient compliance, hospital stay, return to work.

Materials and Method

This prospective comparative study of outcomes of different treatment modalities of hemorrhoids was done from October 2016 to 31st August 2018 in Netaji Subhash Chandra Bose Medical College Jabalpur Madhya Pradesh. Approval from the Institutional Ethical committee was taken. Informed consent was taken from all the patients. Inclusion criteria: all patients of age greater than 18 years irrespective of sex; symptoms of hemorrhoids disease i.e. pain during defecation, bleeding per rectum and had grade III or IV hemorrhoids. Exclusion criteria: deranged coagulation profile; pregnancy; uncontrolled diabetes; patient with ASA IV.

Patients were randomized in 4 groups by lottery system. Group A: Milligan Morgan's open hemorrhoidectomy (MM) (Figure 1), Group B: stapler hemorrhoidectomy (MIPH) (Figure 2), Group C: Laser hemorrhoidectomy (LH) (Figure 3), Group D: Harmonic Scalpel hemorrhoidectomy (HSH) (Figure 4).

All the patients were examined clinically, per rectal and by proctoscope to confirm the diagnosis and grading of the disease according to severity [8]. All the preoperative laboratory investigations were done for ASA grading [9].

Measured outcomes referred to early outcomes (0 to 4 weeks) such as bleeding, pain, prolapse, wound infection and late outcomes such as incontinence and recurrence. Different modalities of treatment were compared in terms

of patient compliance, hospital stay, operative time, return to work, patient satisfaction.

All the patients underwent surgeries under spinal anesthesia and in extended lithotomy position.

For MMH polyglactin 2-0 suture was used to ligate the vessels.

For MIPH Kangdi hemorrhoidal circular staplers were used with staple size of 4.2 mm.

For LH 980 nm diode laser through 1000 nm optic fibers in pulsed fashion at a power of 13W with duration of 1.2s each and a pause of 0.6s caused shrinkage of tissues to the depth of approximately 5 mm.

For HSH: hand probe wave Ethicon Endo-surgery GEN-1 which vibrates at 55000 MHz ultrasonically.



Figure 1 – Open hemorrhoidectomy. A – intraoperative aspect; B – postoperative aspect

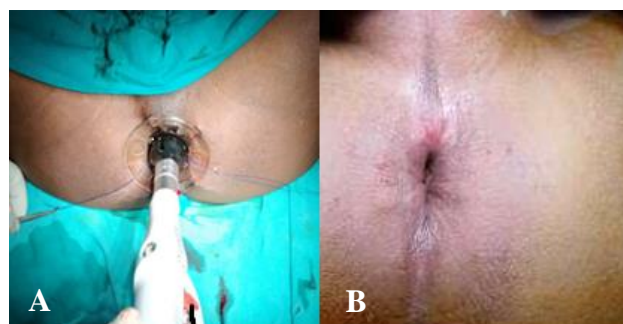


Figure 2 – Stapled hemorrhoidectomy. A – intraoperative aspect; B – postoperative aspect



Figure 3 – Laser hemorrhoidectomy. A – intraoperative aspect; B – postoperative aspect

Before the surgery, a single dose of intravenous antibiotic ceftriaxone 1 g was given and in postoperative period oral antibiotic was given along with laxatives syrup cremaffin and povidone iodine sitz bath and analgesic Tab Diclofenac 50 mg on basis of assessment of pain on VAS score (Table 1).

Pain intensity was measured using the VAS Score [10]:

Groups	Pain Score	0 week	1 week	4 Weeks	12 Weeks
Group A (n=25)	Mean ± SD	5.64±1.25	4.16±1.11	2.68±0.99	1.16±0.8
	Range	4-8	2-6	1-4	0-2
Group B (n=24)	Mean ± SD	3.5±1.32	2±0.83	1.12±0.34	0.12±0.34
	Range	2-6	1-4	1-2	0-1
Group C (n=25)	Mean ± SD	2.7±1.16	0.92±1.0	0	0
	Range	1-6	0-3	0	0
Group D (n=20)	Mean ± SD	3.9±0.97	2.15±0.87	0.51±0.5	0
	Range	2-6	1-4	0	0
F- Test		26.16	48.96	96.45	38.57
P – Value		<0.0001	<0.0001	<0.0001	<0.0001

Table 1 – Distribution of patients according to pain score assessed by visual analogue scale vas (1 – 10)

Patients were discharged as early as possible within 24 hour or once patients were comfortable

- Mild Pain: 1 To 3. Analgesic: Tab Diclofenac 50 mg once daily
- Moderate: 3 To 5.4. Analgesic: Tab Diclofenac 50 mg two times a day
- Severe Pain: 5.5 To 10 Analgesic: Tab Diclofenac 50 mg three times a day



Figure 4 –Harmonic Scalpel hemorrhoidectomy. A – intraoperative aspect; B – postoperative aspect

and able to carry out their daily routines without much difficulty.

For data management and statistical analysis SPSS 2.0 software was used. All quantitative data was expressed as mean with standard deviation and compared with chi-square test, Fischer test, and p value of less than 0.05 was considered significant.

Results

In our study we screened 140 patients out of which 10 patients refused to give consent for the procedures and 10 patients were excluded by the exclusion criteria for surgery (deranged coagulation profile = 2, pregnancy = 1 uncontrolled diabetes = 4, patient ASA IV = 3). We assigned 120 patients randomly into 4 groups of 30 patients in each group. Group A patients underwent conventional Milligan Morgan hemorrhoidectomy, Group B patients underwent stapler hemorrhoidectomy, Group C Laser hemorrhoidectomy and Group D Harmonic Scalpel hemorrhoidectomy.

After discharge patients were followed-up for 12 weeks on OPD basis and telephonic conversation. At 1 weeks of follow up in group A out of 30 patients 5 patients lost to follow up.

In group B, 6 patients lost to follow up, in group C, 5 patients lost to follow up and in group D, 10 patients lost to follow up.

At the end of the follow-up of the patient, a total number of 94 patients were included in primary analysis. Groups A+B+C+D = 25+24+25+20=94 (Figure 5).

The majority of patients fall in the age group of 30 to 60 years with mean age of 42.39 years (range 18-78 year) and the male: female ratio was 70:24 (74.6%: 24.4%) (p<0.0001).

Analysis of pain score showed that pain was continuously declined after the procedures in all the four study groups. In group A (MM), a comparatively higher pain score was observed up to 4 weeks (VAS 2.68±0.99), followed by group B (MIPH) which was statistically significant (p value 0.0001) VAS score (1.12±0.34). In group C (LH) and group D (HSH), pain was significantly low (p<0.0001). At 12 weeks, the pain score in group A (MM) was higher than group B, group C and group D and the difference was statistically significant (p<0.0001).

After the day of surgery, patients were followed at 1 week and 4 weeks for bleeding, pain, prolapse, wound infection and at 12 weeks for incontinence and recurrence (Table 2).

Postoperative symptoms		Group A n=25	Group B n=24	Group C n=25	Group D n=20	Chi Square Test	p value
Bleeding	0 Week	15(60%)	7(29.1%)	3(12%)	2(10%)	18.79	<0.001
	1 Week	7(28%)	6(25%)	0(0%)	0(0%)	13.95	0.003
	4 Weeks	2(8%)	4(16.6%)	0(0%)	0(0%)	7.42	0.06
	12 W.	1(4%)	0(0%)	0(0%)	0(0%)	2.79	0.425
Prolapse	0W	2(8%)	5(20.8%)	0(0%)	0(0%)	7.33	0.062
	1W	4(16%)	0(0%)	0(0%)	0(0%)	11.53	0.009
	4W	0(0%)	0(0%)	0(0%)	0(0%)	-	-
	12W	0(0%)	0(0%)	0(0%)	0(0%)	-	-
Wound infection	0W	10(40%)	5(20.8%)	3(12%)	4(20%)	5.87	0.118
	1W	8(32%)	3(12.5%)	2(8%)	2(10%)	10.88	0.012
	4W	8(32%)	3(12.5%)	0(0%)	0(0%)	15.95	0.001
	12W	0(0%)	0(0%)	0(0%)	0(0%)	-	-
Recurrence	0W	0(0%)	0(0%)	0(0%)	0(0%)	-	-
	1W	0(0%)	0(0%)	0(0%)	0(0%)	-	-
	4W	0(0%)	0(0%)	0(0%)	0(0%)	-	-
	12W	1(4%)	4(16.6%)	0(0%)	0(0%)	-	-
Days in hospital	Mean ± SD	6±2	2±1	1±0	1.1±0	f test: 121.08	<0.0001
	Mean ± SD	51.8±9.3	41.37±6	17.6±4.1	22.25±3.98	f test: 153.61	<0.0001

Table 2 – Distribution of patients’ post-operative symptoms

Studies and Author Name	Parameters Compared					
	Pain VAS Score		Operating Time	Hospital Stay	Return to work	Complications
	Mean ± SD	Mean ± SD	Mean	Mean	%	
Angus J M Watson et al. [12]	MM	2.8 (2-7)	40 Min	0 to 4 days	Late	Ble 1% Recur 14%
	SH	2.5 (2-5)	40	0 to 4 days	Early	Ble 2% Recur 32%
Muhammad User Fayaz et al. [11]	HSH	4.32	18.13	0 to 2 days	Early	-
	MM	6.97	22.90	0 to 4 days	Late	-
E. Ramadan et al. [13]	HSH	4.3	13.2	21 hours	Early	Ble 0.6% Abscess 0.8% Incont 0.2%
	MM	7.4	29.6	40.6 hours	Late	Ble 10.2 mL
ILhan Ece et al. [4]	HSH	3.1±1.1	14.5±3	0 to 2 days	Early	Ble 10.2±2.5 mL
	FERGUSON	6.3±1.4	32±3.2	0 to 4 days	Late	Ble 22±4.5 mL
Y. Bilgin et al. [7]	HSH	70.8%Pt	17	2.4 days	6.1 days	Ble 10.4 % Recur 2.1%
	SH	72.6%Pt	22	2.6 days	6.2 days	Ble 15.6% Recur 13.7%
Halit Maloku et al. [12]	LHP	15/20	15.94	-	Early	-
	MM	18/20	26.76	-	Late	-
Our Study	SH	3.5 ±1.32	41.37±6.09	2±1 days	Early compare to MM	Ble 29.6% Wi 20.83% Prol 20.83% Recur 16.6%
	HSH	3.9±0.97	22.25±3.98	1.1±0 days	Early compare to MM	Ble 12% Wi 20% Prol 0% Recur 0%
	MM	5.64±1.25	51.8±9.34	6±2 days	Late	Ble 60% Wi 40% Prol 8% Recur 4%
	LHP	2.7±1.16	17.6±4.11	1±0 days	Early compare to MM	Ble 10% Wi 12% Prol 0% Recur 0%

Table 3 – Comparing various studies with our study (Ble – Bleeding, Wi – wound infection, Prol – prolapse, Recur – recurrence, Incont – Incontinence)

Patient's response was assessed in terms of postoperative pain, cosmetic appearance, total hospital stays, any complications in the postoperative period and early return to work.

We found that patient compliance was good with LHP and HSH due to least postoperative pain, shorter hospital stays, faster return to work and

higher patient satisfaction as compared to MIPH and least in MM (Table 3).

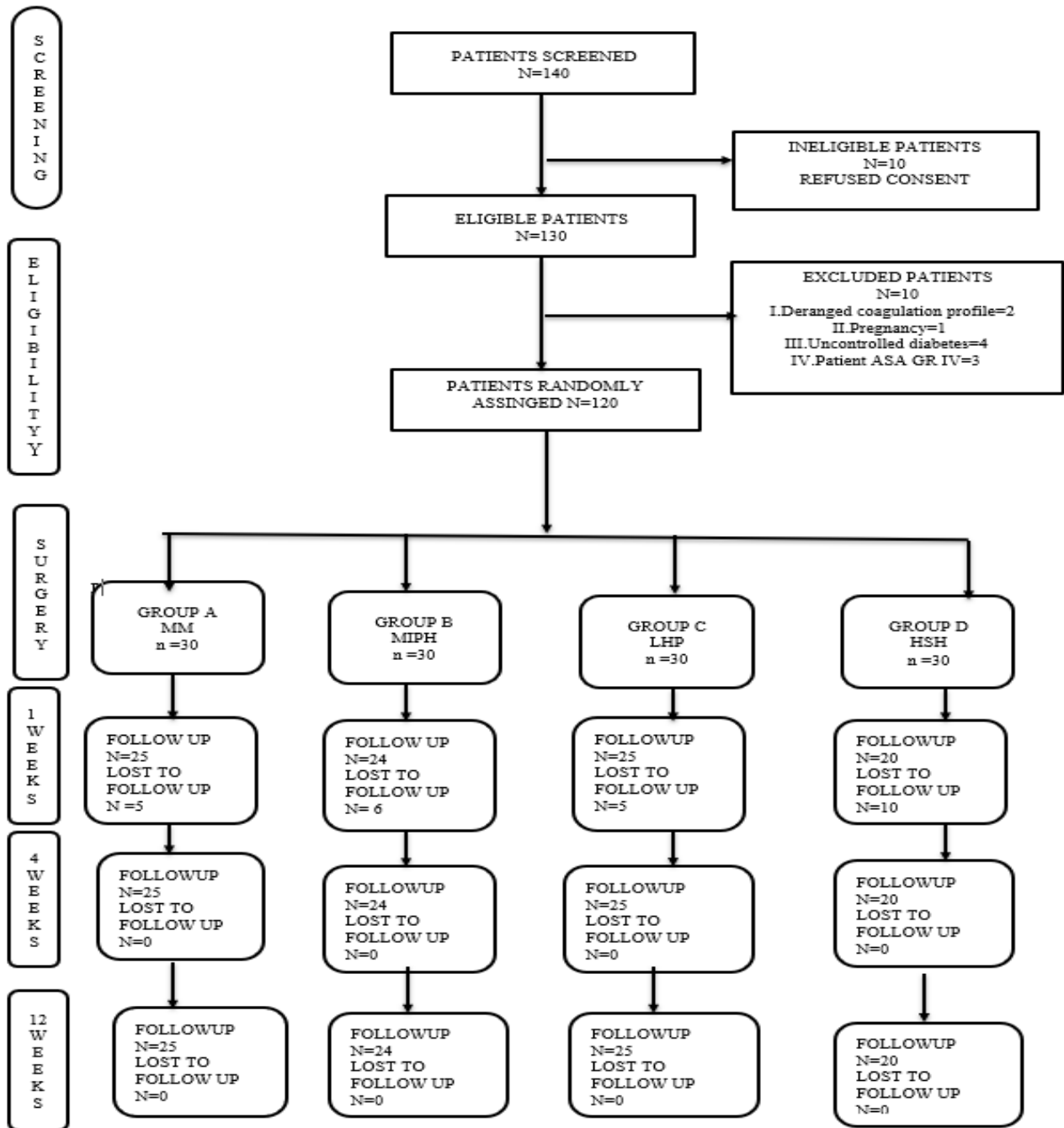


Figure 5 – Prismatic flow chart

Discussions

Surgical hemorrhoidectomy is considered as the gold standard for treatment of grade III and Grade IV hemorrhoids worldwide. In the Angus JM Watson et al [12] study, majority patients presented with grade III hemorrhoids. On proper detailed history and clinical examination with per rectal and proctoscopy findings, we found that the majority of patients also belong to Grade III:

59.5% hemorrhoids followed by Grade IV: 22.34% and then Grade II: 18.08%. Previously, no study was performed comparing 4 surgical techniques of hemorrhoid treatment. MM, MIPH, HSH and LHP. Though studies are available comparing MIPH vs MM, HSH vs MM, LHP vs MM and MIPH vs HSH (Table 3).

In the study Muhammad User Fayaz et al [11] comparing HSH vs MM, (VAS score 6.97) in MM. In our study postoperative pain score was maximum at 0 week (VAS score 5.64±1.25) in MM group, which later decreased in the following weeks and at 12 weeks (VAS

1.16±0.8) which led to patient's morbidity and delayed return to work in this group. In MIPH pain score at 0 week was 3.5±1.32, which was less as compared to MM. In LHP Pain score at 0 week was 2.7±1.16 and patients became painless, at 4 weeks of follow up [2]. In HSH the pain score at 0 week was 3.9±0.97 and patients became painless at 4 weeks of follow up [13]. In MM a comparatively higher pain score was observed up to 4 (VAS 0.51±0.5) weeks followed by MIPH which was statistically highly significant (p value <0.0001). In LHP and HSH pain was significantly low (p value <0.0001). At 12 weeks the pain score in MM was highest followed by MIPH which was statistically significant (p value <0.0001). In LHP and HSH at 12 weeks there were no patients with pain but the difference was not statistically significant. (p value =0). So, it has been observed through our study that the least pain score seen in LHP and HSH groups so the analgesic requirement was also least in LHP and HSH as compared to MIPH and maximum consumption on analgesic in MM.

Another important complication seen in patients in the immediate postoperative period (at 0 weeks) was per rectal bleeding, more in MM 60% which was statistically significant (p value <0.0001), followed by MIPH 29% and the LHP 12% and HSH 10%. At 1 week per rectal bleeding was 28% in MM, 25% in MIPH and no bleeding in any patients in LHP and HSH [4].

Wound infection rate in our study was higher in MM at 0 week and 1 week because the wound was left open to heal by secondary intention which significantly decreased in later weeks of follow up (p value <0.0001) similar to Ramdan et al [13] (wound infection 0.8%). Although the wound infection rate was minimal in MIPH but dreaded complications like rectal perforation in the extra-peritoneal part followed by bacterial leakage causing pelvic sepsis and requiring a diverting stoma or low anterior resection, also the pelvic sepsis, rectal hematoma leading to intestinal obstruction requiring laparotomy [14]. Despite surgical treatment and resuscitation, four patients (10%) out of 40 patients died from the complication. 29 articles reporting complications in 40 patients were identified. Thirty-five patients underwent laparotomy with fecal diversion and a further patient was treated by low anterior resection. A specific complication was rectal perforation with peritonitis. Factors that led to

life-threatening sepsis were identified in 30 patients. Despite surgical treatment and resuscitation, there were four deaths because of these complications.'

Stapler hemorrhoidectomy is least preferred nowadays. In our study LHP and HSH wound infection were least (p value <0.0001). Complications such as urinary retention, abscess [5,13], fistula, fissure, and pseudo-obstruction [14] have been reported in association with the HSH technique, but no such complications were reported in our study.

Around 16.6% to 32% patients developed recurrence in MIPH compared to 4%-14% patients in MM group [2] and no one developed fecal incontinence in any groups.

In the MM mean ± SD in postoperative stay in hospital was 6±2 days, in MIPH was 2±1 day, in LHP was 1±0 days and in HSH was 1.1±0 days [12]. MM patients had longer hospital stay than in any other group which were statically significant (p value <0.0001).

In our study mean time in surgery was least in LHP 17.6±4.11 minutes which was statistically significant (p value <0.0001), HSH was 22.25±3.98 minutes, MIPH was 41.37±6.09 minutes and longest was in MM 51.8±9.34 minutes [2,12].

So, in nutshell, LH and HSH are comparable or LH is slightly better in terms of postoperative pain bleeding, recurrence, technical ease, patient's compliance. Although for pain MIPH is better than HSH as it works above the dentate line but technically most demanding in all the modalities and most severe complications are reported. Cost wise MM is a cheap and most trusted technique.

Conclusion

Patient acceptance was good with Harmonic Scalpel hemorrhoidectomy and Laser hemorrhoidectomy technique due to least complication rates and early return to work as compared to open hemorrhoidectomy and stapler hemorrhoidectomy. Though open hemorrhoidectomy technique was more economical than stapler hemorrhoidectomy, Harmonic Scalpel hemorrhoidectomy and Laser hemorrhoidectomy technique.

Still Milligan Morgan open hemorrhoidectomy is considered as the gold standard for hemorrhoids requiring surgical treatments and all other newer surgical techniques have their own advantages and disadvantages. The choice and feasibility can be decided according to the severity of disease, available infrastructure and surgical skills.

References

- [1] JF Johanson, A Sonnenberg, "The prevalence of hemorrhoids and chronic constipation. An epidemiologic study", *Gastroenterol*, vol.2, pp.380-386, Feb 1990
- [2] H Maloku, Z Gashi, Lazovic, H Islami, Juniku-Shkololli, "Laser Hemorrhoidoplasty Procedure vs Open Surgical Hemorrhoidectomy: a Trial Comparing 2 Treatments for Hemorrhoids of Third and Fourth Degree", *Acta Inform Med.*, Vol. 22(6), pp.365-367, Dec 2014.
- [3] MC Schubert, S Sridhar, RR Schade RR, SD Wexner, "What every gastroenterologist needs to know about common anorectal disorders", *World J Gastroenterol*, vol.15(26), pp. 3201-3209, Jul 2009
- [4] E Ilhan, Y Huseyin, A Fahrettin, Y Serdar, S Mustafa, "Harmonic Scalpel Compared with Ferguson's Hemorrhoidectomy, retrospective evaluation", *Sch. J. App. Med. Sci.*, Vol. 2(6F), pp.3247-3249, 2014.
- [5] CC Chung, HY Cheung, ES Chan, SY Kwok, MK Li, "Stapled hemorrhoidopexy vs. harmonic scalpel hemorrhoidectomy: a randomized trial", *Dis Colon Rectum*, vol.48, pp. 1213-1219, Jun 2005.
- [6] S Kulkarni, M ShivaMalavaiah, RJ Sankaran, AJ Rajkumar, "Stapled Versus Open Haemorrhoidectomy, Prospective, comparative study", *Intern Journ of Anatomy, Radiol and Surgery*, Vol-5(3), pp 001-006, Jul 2016.
- [7] Y Bilgin, S Hot, IS Barlas, A Akan, Y Eryavuz, "Short- and long-term results of harmonic scalpel hemorrhoidectomy versus stapled hemorrhoidopexy in treatment of hemorrhoidal disease", *Asian J Surg.*, vol. 38(4), pp.214-219, Oct 2015.
- [8] HM MacRae, RS McLeod, "Comparison of Hemorrhoidal Treatment Modalities A meta-analysis", *Dis Colon Rectum*, vol.38(7), pp. 687-694, Jul 1995
- [9] DJ Doyle, EH Garmon. American Society of Anesthesiologists Classification (ASA Class) [Updated 2020 Feb 17]. In: *Stat Pearls* [Internet]. Treasure Island (FL): StatPearls Publishing; Jan 2020.
- [10] S L Collins, A.R. Moore, & H.J. McQuay, "The visual analogue pain intensity scale: what is moderate pain in millimeters?" *Pain*, vol.72(1), pp.95-97, Aug 1997.
- [11] MU Fayyaz, MS Shafique, JS Khan, R Ahmad, SH Ahmad, N Adnan, "Harmonic Scalpel Hemorrhoidectomy Vs Milligan-Morgan Hemorrhoidectomy, prospective study", *Journal of Rawalpindi Medical College*; vol.21(3), pp 233-236, Sep 2017.
- [12] A J M Watson, J Hudson, J Wood, M Kilonzo, SR Brown, A McDonald, J Norrie, H Bruhn, JA Cook, "Stapled hemorrhoidopexy with traditional excisional surgery for haemorrhoidal disease randomized controlled trial", *Lancet*, vol.388, pp.2375-2385, Nov 2017.
- [13] E Ramadan, T Vishne, Z Dreznik, "Harmonic scalpel hemorrhoidectomy: preliminary results of a new alternative method", *Tech Coloproctol*, Vol.6(2), pp.89-92, Sep 2002.
- [14] JL Faucheron, D Voirin, J Abba, "Rectal perforation with life-threatening peritonitis following stapled haemorrhoidopexy", *Br J Surg*, vol.99(6), pp.746-753, Jun 2012.
- [15] DN Armstrong, C Frankum, ME Schertzer, WL Ambroze, GR Orangio, "Harmonic scalpel hemorrhoidectomy: five hundred consecutive cases", *Dis Colon Rectum*, vol.45(3), pp.354-359, Mar 2002.