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LIGASURE VESSEL SEALING SYSTEM VERSUS CONVENTIONAL TOOLS IN MILLIGAN AND MORGAN HAEMORRHOIDECTOMY: A RANDOMIZED CONTROL TRIAL.

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ABSTRACT… Objectives: To evaluate the efficacy and safety of the LigaSure vessel sealing system in Milligan – Morgan Haemorrhoidectomy and compare to conventional tools. **Study Design:** Randomized control trial. **Setting:** Department of surgery Bolan University of Medical and Health Sciences at Sandeman Hospital Quetta. **Period:** January 2017 to June 2018. **Material & Methods:** Randomized controlled study designed for comparison was carried out. Total 86 patients of both gender had grade III and IV hemorrhoids were enrolled and randomly divided in two groups. LigaSure group and Conventional group. After obtained institutional permission and informed consent all patients were prepared for surgery as per unit protocol. Patients of both groups were evaluated for operative time, per operative bleeding, post-operative pain, hospital stay, wound healing time, and time return to work. Data collected and analyzed on SPSS version 20. **Results:** Total 86 patients enrolled for study 58 (66.4%) males and 28 (32.6%) females, age range 22-76 years. Patients randomly divided in LigaSure and conventional groups (43 in each group). Operative time and per operative bleeding was significantly less in LigaSure group as compared to conventional (P-Value, 0.001). Post-operative complications like pain and urine retention ware significantly less in LigaSure group (P-Value <0.001). Hospital stay, Healing time and return to routine life were significantly early in LigaSure group (p-Value <0.001). **Conclusion:** LigaSure sealing and cutting system is safe and effective tool in Milligan & Morgan Haemorrhoidectomy.

Key words: Haemorrhoidectomy, Haemorrhoids, LigaSure, Milligan & Morgan.

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INTRODUCTION

Haemorrhoids are normal vascular cushions of anal canal if symptomatic (Bleeding, itching or prolapsed) called haemorrhoidal disease or symptomatic heamorrhoids.[1] Surgical treatment is haemorrhiodectomy and based on excision and ligation of pedicle of these cushions was first introduced in 1939 by Milligan and Morgan[2] since then it is most popular and considered gold standard for the treatment of symptomatic grade III and IV haemorrhoids.[3] Because of its painful nature surgeons trying to modify or search an alternate technique to reduce the pain. Two decades latter Furguson introduced his own closed technique on the bases of same principles of Milligan & Morgan and claimed it is less painful. In both conventional techniques haemorrhoidal cushion is excised by using sharps or diathermy and pedicle is legated and defect is either left open as in Milligan & Morgan or closed as in Furguson. Surgeons throughout the world are continually trying to find alternate procedures to decrease pain and other complications but none of the newly adopted technique including Haemorrhoidopexy, Haemorrhoidal Artery ligation (HLA) with or without recto-anal repair (HLA-RAR) had shown to be significantly helpful.[2]

LigaSure a new bipolar device which has property to effectively seal and cut the vessels and tissues with minimal spread of tissue injury (0.2mm) and effective in sealing of vessels up to diameter of 7 mm[3] hence fewer trauma and less anal spasm leads to less pain as compare to conventional methods. LigaSure haemorrhoidectomy is not a new or alternate procedure but it is a new and

advanced tool used in Milligan and Morgan haemorrhoidectomy. In world literature several studies proved efficacy and safety of LigaSure with encouraging results[4,5,6,7] but in our region (Pakistan) very little work has done and only one study conducted with convincing results.[8] Using LigaSure the principles of surgery are essentially the same (excision of haemorrhoidal cushions and suture less sealing of its pedicle) but with minimal tissue damage. In present study we evaluated the use of LigaSure in Milligan and Morgan haemorrhoidectomy in terms of operative time, per operative bleeding, post operative pain, hospital stay and return to routine life and compared it with use of conventional too ls.

METHODOLOGY

This study was conducted in the Department of Surgery Bolan University of Medical & Health sciences at Sandman Provincial Hospital Quetta, from 1st January 2017 to 30th June 2018. After institutional permission obtained from head of institution and informed consent patients were enrolled for study.

Per calculated sample size total 86 patients of both gender (58 males and 28 females) were included in the study. Inclusion criteria were patients having symptomatic grade III and IV haemorrhoids admitted through OPD and gave informed consent. Exclusion criteria were, patients with symptomatic haemorrhoids secondary to Liver disease, needed additional procedure i.e. associated with anal fistula or fissure and those having other co-morbid conditions. Pre-operative work up and patients preparation for surgery done as per unit protocol. Patients were randomly divided in two groups, 43(50%) in LigaSure group and 43(50%) in conventional group. Conventional group were selected for excision of haemorrhoidal cushions by conventional tools i.e. diathermy or scissors and transfixation and ligation of its pedicle with absorbable sutures. In LigaSure group, we used LigaSure sealing and cutting system for excision of cushions and suture less sealing of its pedicle. All patients were operated by surgeons having equal qualification and experience or by senior residents under their direct supervision. Patients were observed per operative for time duration and bleeding and post operatively for pain, needs of analgesia, urinary retention, reactionary bleeding and hospital stay. After discharge from ward all patients prescribed oral analgesia (Paracetamol) and laxatives and called for follow up at one week, three weeks and after 6 months. Patients were assessed for pain, wound healing (defined by appearance of granulation tissue), return to work and anal stenosis. Observed data saved in pre designed Performa sheet and at the end of study all data entered in SPSS software and analyzed. For comparison of both groups Chi -Square test applied and result obtained.

RESULT

The age range from 22-76 years, mean 46.65 $\pm$ 12.81 years. There were 58 males (64.4%) and 28 females (32.6%). Male to female ratio was 2.07:1. Patients were randomly divided in two groups LigaSure group and conventional group. Each group comprises 43(50%) patients. Majority of patients (87.2%) were between 31 to 70 years of age. Majority 53 (61.6%) patients had grade IV haemorrhoids. There was no significant difference in age, gender and haemorrhoidal grades in both groups. Table-I.

The operative time was significantly lower in LigaSure group. Majority of patients 35/43 (81.39%) in LigaSure Group took less than 10 minutes mean1.18 $\pm$ .39 range < 10 -15 minutes, while in conventional group majority patients took 15-25 minutes or more mean 2.02 $\pm$ 0.7 range 10- >25 minutes (P-Value <0.001). Per operative bleeding in LigaSure Group was less mean 11.27 $\pm$ 2.91 range 8-20 ml as compare to conventional group where mean was 30 $\pm$ 13.6 range 10-60 ml (P-Value 0.001). Moreover need of anal pack in conventional group was compulsory while in LigaSure group few patients required anal packing. Regarding postoperative complication 20(46.51%) patients developed urinary retention in conventional group while 8 (18.60%) patients got urinary retention in LigaSure group. No post operative bleeding observed in either group.

Majority of Patients in LigaSure had experienced

mild to moderate pain on Visual Analog Score (VAS) in immediate post operative period and on day one. On day 1 mean VAS was 1.48 ± 0.58 while on day 2 mean VAS was 1.16 ± 0.37. Almost all patients were pain free on day seven mean VAS score was 0.16 ± 0.43. In conventional group majority patients had moderate to severe pain score on day 1 mean 2.37 ± 0.48 and on day 2 mean score was 2.02 ± 0.63. On day seven mean VAS was 1.00 ±0.57 (p-value <0.001). Hospital stay was less in LigaSure group majority patients 33/43 (76.74%) discharge on day one (mean1.34 ±0.71 days) while in conventional group 25(58.13%) patients was able to discharge on 3rd day and 6 patients stayed 4-7 days (mean 1.9 ± 0.70 days) in hospital (P-value < 0.001). Healing time was significantly earlier in LigaSure group as compare to conventional group. In LigaSure group majority of patients 36 out of 43 (83.7%) resumed their work in one week after discharge (mean 1.2 ± 0.51 weeks) while in conventional group only 7 patients resumed routine work in one week majority patients of conventional group resumed work after 3-5 weeks (mean 2.13 ± 0.67 weeks) (P-value <0.001). Table-II. One case of stenosis was reported in conventional group while none in LigaSure group. No recurrence was reported in either group during follow up period.

Patient Variable	LigaSure Group				Conventional Group				P-Value
Age group # of Patients	22-30	31-50	51-70	71+	22-30	31-50	51-70	70+	0.134
	6	21	13	3	1	28	13	1	
Gender # of Patients	Male		Female		Male		Female		0.818
	30		13		28		15		
Haemorrhoids grade # of Patients	Grade III		Grade IV		Grade III		Grade IV		0.092
	13		30		20		23		

Table-I. Patients variables in both groups.

Variables	LigaSure group	Conventional group	P-Value
Operative time	Range 10-15 minutes	Range 10->25 minutes	0.000
Per operative Bleeding	Mean 11.27 +2.97	Mean 30 +13.36	0.000
Pain score on Day One	Mean1.41 + .58	Mean 2.37 +.48	0.000
Pain Score on Day Two	Mean 1.16 + .37	Mean 2.02 + .63	0.000
Pain Score on Day Seven	Mean 0.16 + .43	Mean 1.00 + .75	0.000
Hospital Stay (days)	Mean 1.34 + .71	Mean 1.93 + .70	0.000
Return to work (weeks)	Mean 1.20 + .51	Mean 2.13 + .67	0.000

Table-II. Comparisons of variables outcomes in both groups.

DISCUSSION

Standard surgical treatment of symptomatic haemorrhoids based on principles of excision and ligation of anal cushions introduced by Milligan and Morgan in 1937.[9] Surgery generally recommended for grade III and IV haemorrhoids and Milligan and Morgan procedure is the most popular technique among surgeons all over the world but remains unpopular among general population because of its painful nature.[1] Furguson introduced a closed technique in 1959 and claimed that the procedure reduces the pain.[10] Both techniques having similar possible complications and outcomes in terms of pain, bleeding, and prolong hospital stay. Because of this researchers looking for optimal alternatives for treatment such as Haemorrhoidopexy, haemorrhoidal artery ligation with or without recto-anal repair (HLA-RAR).[2] In recent years new tools and devices are being used to overcome these complications such as harmonic scalpel and LigaSure sealing system.[11,12,13] Use of LigaSure in Milligan and Morgan haemorrhiodectomy seems to be safer and has less pain and other complications as compare with recent or conventional tools.[5,6,14,15] Despite clear advantages of newer tools such as LigaSure reported in literature[5,6,14,15] surgeons continue to

prefer traditional sharps and diathermy because newer tools are costly and not available in every institution especially in developing countries like Pakistan.[8] Moreover, studies have not yet standardized the significant effectiveness and long-term results.[1,6,8]

In present study we concluded that use of LigaSure in haemorrhoidectomy has statically significant clear advantages over conventional tools in terms of operative time, bleeding, post operative pain, hospital stay, and return to work. In our study we observed significant lower operative time in LigaSure group as compare to conventional group (<10 minutes VS 15 to >25 minutes P-value <0.001). In a study by Wagih M G [14] the mean operative time in LigaSure was significantly low (11.22 VS 28.42 minutes) as compare to diathermy (P-Value < 0.0001). In a study conducted by Ghimire P et al[16] mean operative time in LigaSure group was 7.6 min (±SD 2.5) and in conventional group it was 18.9 min (±SD 4.5). Similarly in other studies significantly less operative time was observed. In a study conducted by Islam M T et al[17] mean operative time was 7.7 VS 18.2 minutes, Talha A et al[18] observed less operative time in LigaSure and Harmonic Scalpel groups as compare to diathermy group{8 VS 18 minutes (P < 0.001)}. Nienhuijs and de hung[4] in a Meta analysis concluded from 12 studies on 1142 patients that use of LigaSure in heamorrhoids surgery was less painful and without adverse effect or any other complication. In our study we found that LigaSure is effective tool in Milligan and Morgan procedure in terms of pain. In present study the majority patients in LigaSure group score less on VAS on day 1, 2 and 7 (P- Value <0.001). In a study conducted by Khanna R et al[19] observed less VAS pain scores in patients of LigaSure group on day 0,1and7 compared with the Furguson's closed haemorrhoidectomy(P-value <0.001). Similarly Bakhtiar N et al[8], Ghimire P et al[16] and Islam MT et al[17] also observed less pain in LigaSure group.

Use of LigaSure in haemorrhoidectomy results less per operative bleeding as compared to open (M&M) or closed (furguson) haemorrhoidectomies.[20] In present study we observed less per operative bleeding in majority patients of LigaSure group (8-15 ml) while in conventional group majority patients bleed more than 25ml. Similarly in other studies significantly less per operative bleeding was observed[5,19] which is consistent with our study. In Studies conducted by Haksal CM et al[13] and Ghimire P et al[16] the hospital stay was significantly lower in LigaSure group. Similarly we observed that hospital stay in present study was significantly less in LigaSure group as compare to conventional group. In LigaSure group 33 out of 43(76.74%) patients were able to discharge on day 1 while in conventional group 25.58% (11/43) patients were discharged. In our series majority (83.72%) patients in LigaSure group returned their routine life in one week and (16.27%) returned work in 2-5 weeks while in conventional group (83.72%) patients resumed their work in 2-5 weeks.

Majority of studies conducted on short term benefits of LigaSure[5,6,8,12,13] while for long term benefits (recurrence and stenosis) patients needs prolong follow up on large scale studies that is possible in case of multi institutional cohort studies. Noori IF[6] followed his patients little longer time for late complications and found less stenosis in LigaSure group 6.25% as compared to 10.4% of conventional group and Haksal MC et al[13] found 2.7% stenosis in LigaSure group. Chen, CW and et al[15] found low recurrence in LigaSure group. In present study we followed our patients for 6 months there was no recurrence or stenosis in LigaSure group while only one stenosis in conventional group.

CONCLUSION

Use of LigaSure cutting and sealing system in Haemorrhoidectomy is safe and effective and has significantly low complications compared with conventional methods. LigaSure was also associated with faster wound healing.

RECOMMENDATIONS

1. Our study was conducted in a single institute and requires more extensive study involving multi institutional approach for better analysis.
2. A more extensive and long-term monitoring is required for long term complications.

Conflict of Interest

We have no conflict of interest.

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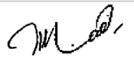
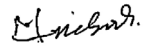
AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Manzoor Ahmed	Concept, data collection, manuscript writing, data analysis and references collection.	
2	Mukhtar Mehboob	Concept, data collection, manuscript writing and data analysis, Final review and approval.	
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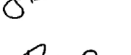
4	Saleem Javeed	Data collection, References search data collection.	
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