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ORIGINAL ARTICLE

Randomized Clinical Trial Comparing Mean Postoperative Pain Score in Hemorrhoidectomy using a Bipolar Vessel Sealing System Ligasure with Conventional open Diathermy Hemorrhoidectomy

KIRAN NAZ[1], AMREEN A. RAZZAQUE[2], MISBAH MAHMOOD[3], WAQAS RIND[4], FARHAN SOZERA[5], AREEBAH SALIM[6]
[1]*Dow university of health sciences Consultant Liver Transplant and Hepatobiliary surgeon Karachi*
[2]*Resident Emergency Medicine The Indus Hospital Karachi*
[3]*Medical Officer Surgical Unit IV, Dr Ruth K M PFAU, Civil Hospital.Karachi*
[4]*Dow university of health sciences*
[5]*Consultant General surgeon Karachi*
[6]*Fellow Vascular Surgery Shaheed Muhterma Benazir Bhutto Trauma Centre.*
Correspondence to: Kiran Naz

ABSTRACT

Background: Hemorrhoids are one of the most frequent anorectal disorders and are responsible for considerable patient suffering and disability. Excisional hemorrhoidectomy is considered the gold standard[1] for grade 3 and 4 haemorrhoids. Milligan Morgan haemorrhoidectomy by LigaSure is being investigated by a number of studies in the literature for its comparison with conventional diathermy method in terms of post-operative pain scores. Many studies favor the use of LigaSure in haemorrhoidectomy while other studies have found conventional methods to be either comparable or even superior to Ligasure. The purpose of this study was to know which method is superior, so that the better method would be preferred over the other one to minimize the post-operative pain, the major cause of post-operative morbidity and also to reduce the post-operative analgesia requirement, an important factor influencing the cost-effectiveness of the proposed method.

Objective: To compare mean postoperative pain score in patients undergoing hemorrhoidectomy using Ligasure bipolar vessel sealing system with conventional open diathermy hemorrhoidectomy

Methods: Patients aged between 20 to 60 years with symptomatic, third or fourth degree haemorrhoids were included in the study. Randomization to Group A (LigaSure group) or Group B (Diathermy group) was done using sealed envelopes with allocations to either procedure determined just prior to surgery. Perioperative medical treatment was standardized. Operative time was recorded. Patients were inquired about the pain score by using Visual analogue score at 24 hours post-operatively. Numbers of doses of analgesia required in 24 hours were also recorded.

Results: Mean age of the patients was 42.05 ± 10.82 years. Study population consisted of 60 % males and 40% females. Mean operative time was significantly lower in Group A (17.10 ± 2.15 min) than Group B (24.63 ± 3.17 min) (P-value < 0.001). Mean VAS score at 24 hours post-operatively was also significantly lower in Group A (2.07± 2.13) versus Group B (4.67± 1.62) (P-value < 0.001). Mean number of doses of analgesia requirement in 24 hours post-operatively was also found to be significantly lower in Group A (0.97± 0.41) compared to Group B (2.17± 0.53) (P-value < 0.001).

Conclusion: LigaSure haemorrhoidectomy is significantly better than conventional method of open diathermy haemorrhoidectomy in terms of post-operative pain scores and post-operative analgesia requirement and it can be preferred over the conventional method due to its effect on reducing the morbidity and reducing the cost of analgesia requirement.

Keywords: Hemorrhoids, LigaSure, Hemorrhoidectomy, Milligan-Morgan

INTRODUCTION

Hemorrhoids are a very common ano-rectal condition defined as the symptomatic enlargement and distal displacement of the normal anal cushions. Millions of people around the world suffer from this condition and it represents a major medical and socioeconomic problem[1]. Surgical excision of hemorrhoids is generally done for grade III or IV hemorrhoids[2-4]. Open hemorrhoidectomy[5]is a classical technique, which is largely used worldwide[2].

Postoperative pain is a major complication of conventional open diathermy hemorrhoidectomy, many new alternative techniques have been proposed to reduce this complication[6]. An example is the use of bipolar vessel sealing system like Ligasure which coagulates with high frequency current and has active feedback control over the power output resulting in minimal thermal spread and limited tissue charring[7].

Several studies have been conducted to compare the surgical outcomes of conventional open diathermy and Ligasure hemorrhoidectomy, which have shown the significant advantage of Ligasure hemorrhoidectomy over conventional one in terms of mean operative time and operative blood loss[1,9-16]but the results regarding postoperative pain are still debatable as some studies showed statistically significant low pain score in Ligasure hemorrhoidectomy[9, 10, 12, 17-19] while other studies showed either no difference in the results or statistically significant results in favor of conventional open diathermy hemorrhoidectomy[11, 15, 20, 21].

In one randomized control trial, M.F.Sakr[18] stated mean postoperative pain score at 24 hours to be 4.7 ± 0.7 (mean ± standard deviation) in Ligasure group while 7.6 ± 0.4 in conventional open diathermy group (result statistically significant p-value <0.0001). On the contrary, Peker k et al.[21] observed mean postoperative pain score at 24 hours in Ligasure group to be 5.13 ± 2.242 while 1.39 ± 0.499 in conventional open diathermy group (result statistically significant p-value <0.001). In view of the contradictory results of various studies, postoperative pain score was evaluated in this study, as to know either Ligasure or conventional hemorrhoidectomy is superior, so that the better method would be preferred over the other one to minimize the post-operative pain, the major cause of post-operative morbidity and also to reduce the post-operative analgesia requirement, an important factor influencing the cost-effectiveness of the proposed method. So, the purpose of this study was to compare these two methods of hemorrhoidectomy regarding postoperative pain score.

MATERIALS AND METHODS

It was conducted in Surgical Unit 4 of the Civil Hospital Karachi. Using the OpenEpi sample size calculator, the anticipated sample size for each group was 30 and the overall sample size was 60. Patients aged 20 to 60 years with symptomatic third or fourth degree haemorrhoids requiring hemorrhoidectomy were included. The study included symptomatic patients with grade 3 and 4 haemorrhoids who presented to the OPD with informed written consent. Milligan – Morgan open hemorrhoidectomy was accomplished by diathermy or Ligasure. The assignments to either technique were determined just prior to surgery using sealed envelopes. Group A used ligasure while Group B was open diathermy. Patients were blinded to the hemorrhoidectomy procedure but consented to both. All patients received a Kleen

enema before to surgery and a prophylactic antibiotic (Inj. Metronidazole 500 mg) during operation. Consultants handled every step. All surgeries were performed under lithotomy anaesthesia. Using diathermy in the cutting mode, a V-shaped incision was produced in the peri-anal skin distal to the hemorrhoidal cushion. The internal sphincter hemorrhoidal tissue was dissected using diathermy in coagulation mode. The pedicle was transfixed 0.5 cm above the dentate line, and the wound was left open. The medium-sized Ligasure device was used in Ligasure hemorrhoidectomy. The feedback sensors signified coagulation completion and hemorrhoidal tissue was removed along the coagulum.

During the first 24 hours after surgery, all patients received 75 mg diclofenac sodium intramuscularly as needed (up to 3 doses). After 24 hours, patients were asked about their pain score using the VAS. Allocation concealment was used until immediately before surgery when sealed envelopes were used to randomise. Patients were blinded to the method of hemorrhoidectomy to avoid information bias. Thrombosed, strangulated, and gangrenous haemorrhoids were omitted from the study.

Diabetics, chronic analgesic users, drinkers, and drug addicts were also excluded. In addition, spinal anaesthesia has a variable postoperative pain reduction impact. Complicated operations take longer and cause more postoperative pain. The study was supposed to analyse lengthy procedures separately, but none took longer than the study's proposed time. For the same reason, patients undergoing simultaneous fissure and fistula surgeries were excluded. The data was analysed using IBM SPSS Statistics v20. We calculated age, operation time, and post-operative pain score at 24. Gender frequency and % calculated. Both groups' postoperative pain scores were compared using Student's t-test, with 0.05 considered significant. Confounders were controlled by stratifying age, gender, and operative time to examine their effect on outcome variables, with a p value 0.05 considered significant.

RESULTS

Mean age of the patients was 42.05 ± 10.82 years. Study population consisted of 60 % males and 40% females. 70% of patients had grade 3 hemorrhoids while 30% had grade 4 hemorrhoids. All patients were randomized using sealed envelope method into Group A (Ligasure group) and Group B (Conventional diathermy group). Total of 60 patients were included in the study, 30 in each group. All procedures were completed within defined time limits i.e. Group A ≤ 20 min and Group B ≤ 30 min. Mean operative time was significantly lower in Group A (17.10 ± 2.15 min) than Group B (24.63 ± 3.17 min). (P value < 0.001). Mean VAS score at 24 hours post-operatively was also significantly lower in Group A (2.07± 2.13) versus Group B (4.67± 1.62). (P value < 0.001). Mean number of doses of analgesia requirement in 24 hours post-operatively was also found to be significantly lower in Group A (0.97± 0.41) compared to Group B (2.17± 0.53).(P value < 0.001). Stratification was done to see the effect of age and gender on the outcome. T-test was applied.

Table 1:

Factors	Values	Group A	Group B
Mean operative time	Mean ±SD (min)	17.10 ± 2.15	24.63 ± 3.17
	P-value	<0.001	
	95% CI	-8.93 to -6.13	
Mean VAS score at 24 hours	Mean ±SD (min)	2.07± 2.13	4.67±1.62
	P-value	<0.001	
	95% CI	-3.58 to -1.62	
Mean number of doses of analgesia requirement in 24 hours	Mean ±SD (min)	0.97± 0.41	2.17±0.53
	P-value	<0.001	
	95% CI	-1.44 to -0.95	

Table 2:

		Factors						
Gender	No of patients	Mean operative time		Mean VAS score at 24 hour		Mean number of doses of analgesia requirement		P-value
		Mean ±SD	95% CI	Mean ±SD	95% CI	Mean ±SD	95% CI	
Male (A)	21	17.33 ± 2.17	-09.40 to -5.79	2.29 ± 2.26	-3.62 to -1.00	1.05 ± 0.38	-1.42 to -0.88	<0.001
Male (B)	15	24.93 ± 3.17		4.60 ± 1.24		2.20 ± 0.41		
Female(A)	09	16.56 ± 2.12	-10.31 to -5.23	1.56 ± 1.81	-4.85 to -1.49	0.78 ± 0.44	-1.85 to -0.85	
Female (B)	15	24.33 ± 3.26		4.73 ± 1.98		2.13 ± 0.64		

Table 3

Factors	Group	Age/ Number of patients			
Mean VAS score		20-30 A=04, B=06	31-40 A=11, B= 10	41-50 A=07, B=09	51-60 A=07, B=05
		MEAN ±SD			
	A	1.75 ± 2.36	2.18 ± 2.18	2.57 ± 2.99	1.86 ± 1.06
	B	4.83 ± 2.63	4.80 ± 1.39	4.67 ± 1.58	4.20 ± 0.83
	p-value	0.09	0.004	0.092	0.799
Mean dose of analgesia required at 24 hours.		Age/ Number of patients			
		20-30 A=04, B=06	31-40 A=11, B= 10	41-50 A=07, B=09	51-60 A=07, B=05
		MEAN ±SD			
	A	1.25 ± 0.50	1.00 ± 0.44	0.86 ± 0.37	0.86 ± 0.37
	B	4.83 ± 0.40	2.30 ± 0.67	2.33 ± 0.50	2.00 ± 0.00
	p-value	0.07	<0.001	<0.001	<0.001

DISCUSSION

Hemorrhoids are one of the most frequent anorectal disorders and are responsible for considerable patient suffering and disability. Excisional hemorrhoidectomy is considered the gold standard against which the newer surgical techniques are compared, yet all operative procedures aim to alleviate the hemorrhoidal symptoms[22]. It is common observation that innovative modalities can give a faster and safer technique for any surgical procedure. Pain is the major complication after open Milligan Morgan haemorrhoidectomy using diathermy method, considering this fact, haemorrhoidectomy by LigaSure is a newly designed technique

which helps in decreasing the complications of this surgical procedure and it is compared to many other traditional haemorrhoidectomy procedures in many published randomized trials[8-15]. Post-operative pain and analgesia requirement after haemorrhoidectomy using different techniques have been assessed in various studies. Many randomized clinical trials supports LigaSure as the preferred technique because of its lower operative time, lower intra-operative blood loss, less post-operative pain, lower doses of analgesia requirement and lower complication rate[4,10,12].

Like Bessa[10] evaluated the use of the LigaSure compared with diathermy in haemorrhoidectomy and found that the daily median pain score for the first 7 postoperative days was significantly lower in the LigaSure group than in the diathermy group. But there are many trials available in the literature that failed to find any advantage of Ligasure use in Milligan Morgan haemorrhoidectomy in terms of post-operative pain scores[7, 20-21] and did not recommend the use of Ligasure due to its cost and no added advantage over conventional open diathermy haemorrhoidectomy. In this study, compared to conventional diathermy method, Ligasure group was found to have lower mean post-operative pain scores (2.07 ± 2.13 and 4.67 ± 1.62, p-value <0.001) as well as mean post-operative analgesia requirement (0.97 ± 0.41 and 2.17 ± 0.53, p-value <0.001) at 24 hours.

Ligasure haemorrhoidectomy was found to be faster than conventional method in our study (17.10 ± 2.15 and 24.63 ± 3.17 min respectively, p-value <0.001). So, this study supports the use of Ligasure in open Milligan Morgan haemorrhoidectomy as the preferred technique because of its significantly lower post-operative pain score and post-operative analgesia requirement. Use of Ligasure for the treatment of 3rd and 4th degree haemorrhoids will reduce the morbidity significantly in terms of post-operative pain and it will also reduce the number of doses of analgesics required post-operatively and this makes LigaSure haemorrhoidectomy to be more acceptable and cost-effective procedure compared to conventional diathermy method.

CONCLUSION

LigaSure haemorrhoidectomy is significantly better than conventional method of open diathermy haemorrhoidectomy in terms of post-operative pain scores and post-operative analgesia requirement and it can be preferred over the conventional method due to its effect on reducing the morbidity and reducing the cost of analgesia requirement.

REFERENCES

1. Lohsiriwat V. Hemorrhoids: from basic pathophysiology to clinical management. World J Gastroenterol. 2012 May 7;18(17):2009-2017.
2. Rivadeneira DE, Steele SR, Ternent C, Chalasani S, Buie WD, Rafferty JL. Practice parameters for the management of hemorrhoids (revised 2010). Dis Colon Rectum. 2011 Sep;54(9):1059-1064.
3. Shaikh B, Khan A, Moosa F, Sultan N. Stapled hemorrhoidectomy in third degree hemorrhoids: a prospective study. J Dow Uni Health Sci. 2011 May-Aug;5(2):66-69.
4. Khanna R, Khanna S, Bhadani S, Singh S, Khanna AK. Comparison of Ligasure hemorrhoidectomy with conventional Ferguson's hemorrhoidectomy. Indian J Surg. 2010 July-Aug;72(4):294-297.
5. Hadi A, Khan SA, Aman Z, Zafar H, Shah FO, Rehman A, et al. Post-operative outcomes of open versus closed haemorrhoidectomy. J Postgrad Med Inst. 2011;25(3):252-256.
6. Santos GdA, Coutinho CP, Meyer MMMMD, Sampaio DV, Cruz GMGd. Surgical complications in 2,840 cases of hemorrhoidectomy by Milligan-Morgan, Ferguson and combined techniques. J Coloproctol. 2012 July-Sep;32(3):271-290.
7. Tsunoda A, Sada H, Sugimoto T, Kano N, Kawana M, Sasaki T, et al. Randomized controlled trial of bipolar diathermy vs ultrasonic scalpel for closed hemorrhoidectomy. World J Gastrointest Surg. 2011 Oct;3(10):147-152.
8. Nienhuijs SW, de Hingh IHJT. Pain after conventional versus Ligasure haemorrhoidectomy. A meta-analysis.Int J Surg. 2010;8(4):269-273.
9. Gentile M, De Rosa M, Carbone G, Pilone V, Mosella F, Forestieri P. Ligasure haemorrhoidectomy versus conventional diathermy for iv-degree haemorrhoids: is it the treatment of choice? A randomized, clinical trial.ISRN Gastroenterol. 2010;2011.
10. Bessa SS. Ligasure™ vs. Conventional Diathermy in Excisional Hemorrhoidectomy: A Prospective, Randomized Study. Dis Colon Rectum. 2008;51(6):940-944.
11. Tan K-Y, Zin T, Sim H-L, Poon P-L, Cheng A, Mak K. Randomized clinical trial comparing LigaSure haemorrhoidectomy with open diathermy haemorrhoidectomy.Tech Coloproctol. 2008 Jun;12(2):93-97.
12. Islam T, Sarkar BK, Rakib A. Ligasure versus open haemorrhoidectomy–An experience in CMH Dhaka. Bangladesh Armed Forces Med J. 2011;44(1):25.
13. Muzi M, Milito G, Nigro C, Cadeddu F, Andreoli F, Amabile D, et al. Randomized clinical trial of Ligasure™ and conventional diathermy haemorrhoidectomy. Br J Surg. 2007 Aug;94(8):937-942.
14. Teksöz S, Aytaç E, Yavuz N, Tortum OB, Özcan M, Ergüney S, et al. Comparison of a vessel sealing system with a conventional technique in hemorrhoidectomy. Balkan Med J. 2011 Apr;28:189-192.
15. Jayne DG, Botterill I, Ambrose NS, Brennan TG, Guillou PJ, O'Riordain DS. Randomized clinical trial of Ligasure™ versus conventional diathermy for day-case haemorrhoidectomy. Br J Surg. 2002;89(4):428-432.
16. Agbo SP. Surgical management of hemorrhoids. J Surg Tech Case Rep. 2011 Jul-Dec;3(2):68-75.
17. Mastakov MY, Buettner PG, Ho Y-H. Updated meta-analysis of randomized controlled trials comparing conventional excisional haemorrhoidectomy with LigaSure for haemorrhoids.Tech Coloproctol. 2008 Sep;12(3):229-239.
18. Sakr MF. LigaSure versus Milligan–Morgan hemorrhoidectomy: a prospective randomized clinical trial. Tech Coloproctol. 2010 Mar;14(1):13-17.
19. Altomare DF, Milito G, Andreoli R, Arcanà F, Tricomi N, Salafia C, et al. Ligasure Precise vs. conventional diathermy for Milligan-Morgan hemorrhoidectomy: a prospective, randomized, multicenter trial. Dis Colon Rectum. 2008 Jan;51(5):514-519.
20. Palazzo FF, Francis DL, Clifton MA. Randomized clinical trial of Ligasure™ versus open haemorrhoidectomy. Br J Surg. 2002 Feb;89(2):154-157.
21. Peker K, İnal A, Güllü H, Gül D, Şahin M, Ozcan AD, et al. Comparison of Vessel Sealing Systems with Conventional. Iran Red Crescent Med J. 2013 Jun;15(6):488-496.
22. Luchtefeld M, Hoedema RE. Hemorrhoids. In: Steele RS, Hull LT, Read ET, Saclarides JT, Senagore JA, Whitlow BC, editors. The ASCRS Textbook of Colon and Rectal Surgery. Cham: Springer International Publishing; 2016. p. 183-203.