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ORIGINAL ARTICLE

RANDOMIZED, CLINICAL TRIAL OF LIGASURE HAEMORHOIDECTOMY VERSUS CONVENTIONAL "FERGUSON" HAEMORHOIDECTOMY

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Aim: *To compare outcome of Ligasure and Ferguson" haemorhoidectomy.*
Methods: *Eighty patients with grade III & IV haemorhoids were prospectively randomized and underwent either Ligasureor "Ferguson" haemorhoidectomy. We documented preoperative data, perioperative, [operative time & blood loss], postoperative, [pain score, analgesia, morbidity, hospital stay, healing time, anorectal manometery and patient satisfaction over 6 months].*
Results: *Ligasure group achieved a significant reduction in operative time, blood loss (each, P = 0.001), pain score, analgesics at 1st, 3rd, 7th day, 2nd week (all, P<0.05), hospital stay and healing time (each, P < 0.05). Postoperative morbidity between both groups was insignificant. Manometeric changes {postoperative versus preoperative} were insignificant in Ligasure group (P>0.05), but in conventiona lgroup postoperative pressures were lower, resting (P, 0.0001), squeeze (P, 0.001). Also better 3rd month satisfaction was noticed in Ligasure group, p, 0.03.*
Conclusion: *Ligasure haemorhoidectomy is superior to conventional haemorhoidectomy. Ligasure patients gain short term benefits: Reduced postoperative pain, wound healing time and better satisfaction. Cost remains the most important point against LVSS.*

Keywords: *Haemorhoids, Ligasure, Ferguson haemorhoidctomy, cost benefit.*

INTRODUCTION

Haemorhoids is one of the most common diseases that lead to anal bleeding and pain,[1] Haemorhoidectomy remains the definitive procedure to treat symptomatic grade III and IV haemorhoids.[2]

Haemorhoidectomy has become a commonplace anorectal procedure, that's considered minor despite its postoperative course can be complicated by protracted anal pain.[3] New techniques provide a less painful course and faster recovery.[4]

The most popular haemorhoidectomy technique in the United States is the closed haemorhoidectomy described by Ferguson in (1959) that entails wound closure after excision of the haemorhoids.[5] Wound closure helps reduce postoperative pain and its sequel and assures faster wound healing.[6,7]

Recently, the "physics of quality" (BioGeometry) innovated spatial arrangement of energy (advanced feed back system that incorporates high current "4 folds as standard" with low voltage "1/5 – 1/20" and recognizes tissue changes 200 times/second to adjust current and voltage producing automated maintained power output) and physical pressure (brief cooling).[8]

The perfect balancing of energy and pressure function synergistically and properly to induce melting of collagen and elastin producing a seal area that has strength compatible to sutures. The feedback controlled sensor signals the completion of coagulation.[9]

Potential advantages of Ligasure vessel sealing system (LVSS) are the less pain and completely bloodless haemorhoidectomy.[10] Recent controlled studies have shown that LVSS had better results than the conventional techniques.[11]

The aim of this study was to compare LVSS and closed "Ferguson" haemorhoidectomy regarding "operative" time & intra-operative blood loss & accidental excision of internal sphincter muscle strips, "postoperative" pain & analgesics required & hospital stay & immediate postoperative (PO) complications (bleeding, urinary retention and constipation) & remote (PO) complications (anorectal incontinence, stricture), "Time" till complete wound healing & manometeric studies (maximum resting and squeeze) pressures and "patient satisfaction".

PATIENTS AND METHODS

The study design was a prospective, randomized and double blinded (surgeons 1,2,3 performed surgery while surgeon 4 followed up the cases) clinical trial. Local ethics committee approval was obtained. The study included 80 patients with grade III and IV haemorhoids [after Goligher, et. al].[12] Forty patients underwent standard conventional closed "Ferguson" technique [Control (Group-II)] and forty patients underwent Ligasure haemorhidectomy [Experimental (Group-I)] (Both involved wound closure for comparison) in Mansoura ColoRectal Surgery Unit between November 2005 and April 2007.

Patients randomization was done at anesthesia time using sealed envelops (independent nurse) and kept unaware of the procedure until consignment of the research data in the outpatient clinic "8th week postoperative (PO)". (Both groups were completely pain free).

Patients were assessed preoperatively by documentation of clinical symptoms, full discussion of satisfaction score, {after},[9] continence score grading,[13] visual pain analogue score described by[14] and proctoscopic examination.

Patients with co-existing peri-anal diseases, previous peri-anal surgery, pregnant females, those having inflammatory bowel diseases or thrombosed piles or on anti-coagulants were excluded.

Routine laboratory investigations and anorectal manometery "water perfused manometery system" {done by eight channel hydraulic capillary infusion system (Arndorfer, Inc, Greendale, USA)} to document pressures (maximum resting & maximum squeeze) were done and the patients were prepared with overnight evacuation enema.

The patients were anaesthetized with spinal anesthesia, placed in the lithotomy position and operated by the same team of surgeons.

Group I underwent Ligasure haemorhidectomy (ValleyLab, Boulder, CO, USA); the haemohoidal tissues were lifted by 1.200.000 adrenaline then the Ligasure handset was applied and the haemorhoidal tissues above the "welding area" were excised by scissors.

Group II patients underwent the closed conventional "Ferguson" technique[15] using monopolar electrocautary dissection and excision followed by pedicle transfixation and wound closure using Vicryl 00 (M-Nature international-sutures Manufacturing Company, Egypt).

Haemostasis was secured, wound cleansing was assured and a moist anal pack was applied, the operation time and operative blood loss [each gauze equal 5.ml, abdominal towel equal 50.ml] were recorded by an independent observer, then the haemorhoidal tissues were sent for pathologic assessment to detect internal sphincter muscle strips.

Pain score was evaluated PO using a Visual Analogue Scale (VAS),[14] at the time of waking {the 1st day, 7th day, 2nd week and 6th week "weekly mean score calculation"}.

Allowed inpatient parenteral analgesics were diclofenac sodium 75mg amp IM & pethidine 1 mg/kg IM, PO, but home analgesia was diclofenac sodium 75mg tablets every 12 hours when required ["all were recorded"].

The patients were discharged when gastrointestinal function [normal intestinal sounds & bowel motion] regained provided no spinal headache or other complications had occurred.

The patients were followed up in-patient then at 2nd, 4th, 6th weeks, 2nd month, 3rd month and the 6th month to detect immediate PO complications "bleeding, urinary retention, constipation "too hard stool & too difficult to expel"" and late PO complications "wound healing, discharge, anorectal incontinence, anal stricture" restrictive scar tissue"

Also, anorectal manometry was performed at the 2nd month and patient satisfaction measurement at the 3rd and 6th months using the same visual analogue scale for pain; 0 maximal dissatisfied and10 maximal satisfaction.[9]

The primary outcome measure was PO pain (considered clinically relevant if reduced by 50 percent,[21] while secondary outcomes were hospital stay, complete wound healing time, morbidity (immediate &delayed)and short term (6 months) patient satisfaction

Statistical analysis: The reported data were processed using SPSS (Statistical Package for Social Science) version 10 under Microsoft Windows XP. Continuous data were expressed in the form of Mean ± SD, Student t test was used to compared numerical data, while categorical data were compared using Chi-Square test. P value < 0.05 was considered significant.

RESULTS

Forty patients {that sample size selected to avoid any influence on the inflation of type I error (for 50% pain reduction to be detected with a 80% power at 0.05 significant level, 23 patients are required per group), also type II error is of no statistical value as all patients experienced positive event "pain"} were randomized in each group with insignificant statistical difference between both groups regarding the studied preoperative demographic and clinical data Table 1.

The mean operative time ± SD in the Ligasure group was shorter compared with the closed conventional group [9.0 ± 2.44 (5 – 10) minutes vs 24.1 ± 3.67 (20 – 30) minutes P = 0.001)] (Fig. 1). Also the mean ± SD intra-operative blood loss in group(I) was significantly lower [1.2 ± 1.6 (0 – 5) ml vs 22.2 ± 6.5 (15 – 35) ml in group(II) (P 0.001)] (Fig. 2). The postoperative muscle biopsy was recorded in 4 (10%) cases in the experimental group and in 20 (50%) cases in the control group (P = 0.06).

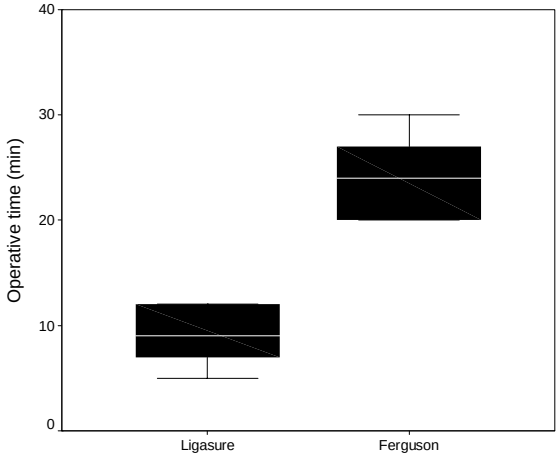

Fig 1. Operative time the Ligasure and conventional groups.

Patients in the Ligasure group reported less pain score values at postoperative "PO" day 1, day 7 and the 2nd week, every (P < 0.05) but the difference was insignificant at the 6th PO week Table 2. For the first 24 Hours PO pain relief, the parenteral analgesics required in the LVSS group were (diclofenac sodium 2 doses in 16 patients, single dose in 24 patients) but in the other group were (diclofenac sodium 2 doses in 30 patients single dose in 10 patients and 20 patients required pethidine) (P=0.006), also the at the 3rd PO day {6(15%) patients in the LVSS group & 22 (55%) in the other group} required analgesia, P=0.008} and at the 7th PO day {2(5%) patients in the LVSS group & 4 (10%) in the other group required analgesia, P=0.05}, but at the 2nd week end there was no significant difference (P=0.15).

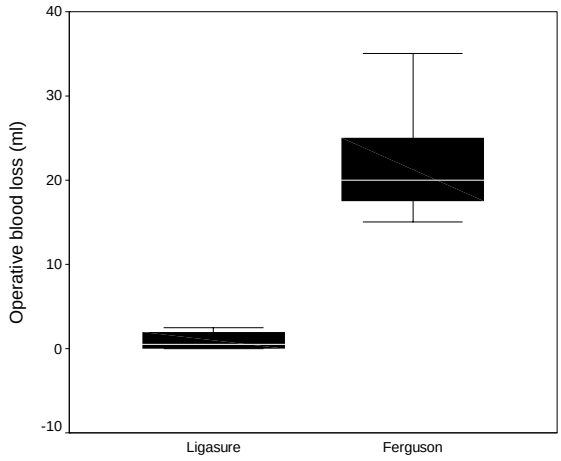

Fig 2. Operative blood loss in the Ligasure and conventional groups.

There were 6 immediate PO complications in the LVSS group that occurred 14 times in the conventional Ferguson group (P > 0.05) Table 3A.

The Ligasure group achieved significantly shorter hospital stay, {Mean ± SD (2.2 ± 0.1 day)} compared to the 2nd group, {Mean ± SD (3.5 ± 1 day) (P = 0.001)}.

The remote PO complications were common in the conventional Ferguson group such as anal discharge (20 cases in LVSS & 38 cases in the 2nd group), anal stricture (Two cases in the control group) and flatus incontinence (Four cases in the Ferguson group), for all P > 0.05. Table 3B. All complications were managed conservatively.

Complete wound healing was achieved significantly faster in the experimental Ligasure group (mean ± SD: 4.40±0.68, range: 4 – 6 weeks) compared to the control group (mean ± SD 6.40 ± 0.99, range 5 – 8 weeks) (P = 0.001).

The difference in preoperative pressures (maximum resting and squeeze) between both groups was insignificant [but higher when compared to normal values] Table 4A. these pressures regained normal postoperative values in the Ligasure group but a marked drop was noticed in the conventional group, that made a significant difference in resting and squeeze pressures in-between both groups (P= 0.01, 0.02 respectively) Table 4B. In the conventional group the postoperative pressures were markedly lower than their preoperative values; resting (P=0.0001), and squeeze (P=0.001) Table 4C. While the difference in postoperative pressures in the Ligasure group (resting & squeeze) versus their preoperative values were insignificant (P > 0.05). Table 4D.

Finally, the 3rd month patient's mean satisfaction score in the LVSS group was significantly higher (8.7 ± 1.67, range: 7 – 10) vs (7.1 ± 1.3, range: 4 – 10) in the closed Ferguson group (P=0.03)} but the 6th month score showed insignificant difference {(9.2 ± 1.26) for Ligasure group vs (8.91 ± 1.14) for conventional group (P > 0.05).

Table 1. Demographic and clinical data of the studied groups.

Variables		Ligasure (n = 40)	Conventional (n = 40)	P value
Age		35.850 ± 6.627	35.10 ± 5.702	0.70*
Sex	Male	24 (60%)	28 (70%)	0.51#
	Female	16(40%)	12 (30%)	
Duration		13.250 ± 3.823	12.350 ± 2.814	0.40*
Grade	III	32 (80%)	34 (85%)	0.68#
	IV	8 (20%)	6 (15%)	
Bleeding		40 (100%)	40 (100%)	–
Discharge		12 (30%)	14 (35%)	.074#
Prolapse		28 (70%)	28 (70%)	1.0#
Constipation		28 (70%)	26 (65%)	.074#
Pain		10 (25%)	10 (25%)	1.0#

Test: Student's test (*) and $\chi 2$ (#) p<o.o5 is significant

Table 2. Pain score in the Ligasure and conventional groups.

Variables	Ligasure (n = 40)	Conventional (n = 40)	P value
1st day Range	5.40 ± 1.729 2 – 9	7.0 ± 1.716 4 – 10	0.006*
7th day Range	1.70 ± 0.864 0 – 3	2.50 ± 1.051 1 – 4	0.012*
2nd week Range	0.30 ± 0.470 0 – 1	1.0 ± 0.648 0 – 2	0.001*
6th week Range	0.00 ± 0.00 0	0.10 ± 0.307 0 – 1	0.16*

Student's test (*) p<0.05 is significant, data expressed as Mean ± SD.

Table 3. Postoperative morbidity in Ligasure and conventional groups.

	Variables	Ligasure (n = 40)	Conventional (n = 40)	P value
(A) Immediate PO	Bleeding	2 (5%)	2 (5%)	1.0#
	Urinary retention	2 (5%)	8 (20%)	0.15#
	Constipation	2 (5%)	4 (10%)	.055#
(B) Remote PO	Discharge	20 (50%)	38 (95%)	0.001*
	Stricture	–	2 (5%)	0.31#
	Incontinence	–	4 (10%)	0.15#
	Recurrence	–	–	–

Test: Student's test (*) and $\chi 2$ (#) $p<0.05$ is significant

Table 4. Pressure results in Ligasure and conventional groups.

	Variables		Ligasure (n = 40)	conventional (n = 40)	P value
(A)	Preoperative	Resting	74.78 ± 6.27	75.2 ± 5.46	0.79
		Squeeze	154.2 ± 13.3	158 ± 11.5	0.37
(B)	Postoperative	Resting	70.2 ± 6.35	64.8 ± 5.75	0.018
		Squeeze	150.7 ± 13.5	143.2 ± 10.8	0.02
	Variable		Preoperative	Postoperative	P value
(C)	Ferguson group	Resting	75.2 ± 5.64	64.8 5.75	0.0001
		Squeeze	158 ± 11.5	143.2 ± 10.8	0.001
(D)	Ligasure group	Resting	74.78 ± 6.27	70.2 ± 6.35	0.13
		Squeeze	154.2 ± 13.3	150.7 ± 13.5	0.35

Student t test is used. $P<0.05$ is significant, data expressed as Mean ± SD.

DISCUSSION

In recent years, several new technologies have been employed to reduce postoperative haemorhoidectomy consequences.[16] Of these, the Ligasure diathermy that incorporates in perfect balance the physics of quality to function properly ("complete coagulation"– "minimal thermal spread" – "limited tissue charring").[17]

In this study, that precise technology resulted in a shorter operative time as declared by (1 & 11). This might be related to the better haemostatic control, absence of pedicle ligation and mucosa closure. Also, it resulted in minimal intra-operative blood loss as[10] found. Moreover, the improved haemostasis offered better visibility and accurate dissection of the haemorhoidal tissue preserving the internal sphincter muscle, but[18] found muscle strips in 7% of LVSS group & 22% in the conventional "Ferguson" group. We suppose that muscle strips were parts of the conjoined longitudinal muscle. It is suggested to be studied endosonographically and manometerically in the preoperative and postoperative settings as here haemohoidal tissue were lifted by 1.200.000 adrenaline.

In general, thermal injury at the surgical site (degree) may be translated into postoperative pain (severity), and the LVSS creates 1.5 mm injury depth but the monopolar variant creates 240 µm width x 15 mm deep[19] So, the studied pain parameters; visual analogue score "subjective" and analgesics required "objective" were better in the LVSS group as noted by.[10,11,20]

Noteworthy, the immediate postoperative (PO) pain is the most critical point that may exacerbate PO urinary retention and constipation, that were common in the conventional "Ferguson" group as found by.[17,9] The intrinsic properties of LVSS such as less PO pain, less analgesic requirements and very infrequent immediate PO complications, facilitated early patient discharge as found here and similar to.[10,17,21] These advantages encompass the validity of LVSS haemorhoidectomy as day case outpatient haemorhoidectomy procedure.

Significantly, no troublesome late complications in this study (only 6 months follow up) as[1,22,23] reported, so long term efficacy and safety of LVSS is required as inadvertent internal sphincter muscle injury may not become apparent for many years. Moreover, the difference in the internal sphincter anatomy may not be translated into a clinical difference in the continence rates.

In this study, complete wound healing was slower in the conventional group as[3] noted, and faster in the Ligasure patients as reported by.[17,24] This may be related to limited tissue injury which reduces wound sepsis and facilitates wound healing.

Seeming logic that the pressures (maximum resting & squeeze) returned to normal (PO) in the LVSS group ($P > 0.05$) but in the conventional group tended to be significantly lower (PO) than their preoperative pressures as found by.[18] The trend for low pressures could be postulated to more radical (imprecise) tissue excision, inadvertent internal muscle excision, prolonged anal canal retraction or prolonged PO inflammatory healing process.

Along with most reports,[24,25,17] this study defined better 3rd month patient satisfaction in the LVSS group, that's attributed to more advantages "less pain – wound healing" and safety "less PO complications.

In conclusion: The LVSS is a less painful, fast, bloodless, safe, user friendly, low morbidity preferred surgical alternative for the conventional haemorhidectomy in symptomatic grade III & IV haemorhoids, specially cases with compromised sphincters, moreover the LVSS could confer haemorhoidectomy into day case out-paint procedure .Cost seems to be the most important point against LVSS, but we think that is balanced by its valuable advantages. Also long term follow up is warranted to evaluate secondary outcomes.

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