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PILE SUTURE TECHNIQUE FOR TREATMENT OF HAEMORRHOIDS VERSUS LIGATION EXCISION HAEMORROIDECTOMY: A RANDOMIZED TRIAL EVALUATING CLINICAL EFFECTS AND ANAL SPHINCTER MANOMETRY.

By

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Background and aim: *To compare clinical and anal manommteric effects of ligation excision surgery for haemorrhoidal disease to that of pile suturing.*

Patients and methods: *The study included 45 patients with haemorrhoids. They were randomised to either undergo the pile suture technique (Ps) or ligation and excision haemorrhoidectomy (Le). Clinical and manommetric assessment of all patients was performed preoperatively and at 6 weeks and 3 months postoperatively. A control group of 20 volunteers free of anal disease was included to establish the normal anal manometric values.*

Results: *Patients in the Ps group had significantly less postoperative pain. Two (8.7%) patients required narcotic analgesics in the Ps group in comparison to 12 (54.55%) in the Le group (Fisher's exact test: $p < 0.01$). The time to the first bowel motion and hospital stay was significantly shorter in the Ps group (Unpaired t test: $p < 0.01$). Two patients in the Le group suffered from incontinence to liquid stools at 6weeks The resting anal pressure significantly decreased after surgery in both groups (Paired t test: $p < 0.01$). The squeeze anal pressure and vector symmetry index decreased significantly only in Le group (Paired t test: $p < 0.05$).*

Conclusion: *Ligation excison operation is traumatic and it is recommended to use more conservative operations such as the pile suture in the management of patients with haemorrhoidal disease and strongly recommend its inclusion in the training programmes of Egyptian surgeons.*

INTRODUCTION

Haemorrhoids are certainly one of the commonest ailments of mankind. Clinical experience suggests that many people of both sexes suffer from haemorrhoids and that even more perhaps have haemorrhoids in a symptomless form.[1] The treatment of haemorrhoids is as old as the age of man and many different treatments have been described, none of which is entirely satisfactory.[2]

Ligation excision haemorrhoidectomy, as described by Milligan in 1973[3] is considered the gold standard for treatment of haemorrhoids. However, haemorrhoidectomy, although producing excellent results may be complicated by pain, urinary retention, anal stenosis, haemorrhage, incontinence, skin tags, fissures and anal abscesses.[4] The surgical technique for haemorrhoidectomy has been modified in an attempt to lessen postoperative complications and allow earlier patient discharge.[5]

Ligation excision is considered a painful operation to the extent that patients conceal rectal bleeding because of their dread of experiencing pain in the postoperative period.[6] The widely used operation of ligation excision involves excision of the sensitive anal mucosa which leads to large areas of denuded anal wall causing spasm and

painful bowel action.[7] Because of this effect and of difficulty in re-establishing a normal bowel habit, the ligation excision operation has largely remained an inpatient procedure despite the popularity of day surgery with other procedures.[8]

This has led to the development of numerous non-surgical haemorrhoid therapy such as band ligation, injection sclerotherapy, cryotherapy and staplers, however, none has proven to be consistently more efficient than surgical management.[9,10]

In 1978 Farag[2] introduced his new pile suture technique for the treatment of haemorrhoids which he reports to give better clinical impact than the conventional ligation and excision technique. However, the functional outcome of this technique in comparison to the standard ligation excision has not yet been established. This study aims at answering this issue by comparing the efficacy and anal sphincter manometric effects of the pile suture technique with that of the conventional ligation excision haemorrhoidectomy.

PATIENTS AND METHODS

Patient population

Patients referred to the Department of Surgery, Medical Research Institute, University of Alexandria for surgical treatment of minor anal conditions formed the study population.

Inclusion criteria

All patients presenting with haemorrhoids.

Exclusion criteria

Patients with associated anorectal pathology such as fissures, anal polyps and haemorrhoids secondary to anorectal tumors.

Number of patients

The study included 45 patients.

Randomization

The patients were randomly allocated to 2 groups through a computer generated random table. The first group included 23 patients who underwent the pile suture technique (Ps). The second group included 22 matched patients who underwent ligation and excision haemorrhoidectomy (Le).

Control group

A control group of 20 volunteers free of anal disease and not subjected to previous anal surgery, underwent anal manometric studies to establish the normal anal manometric values.

Informed consent

The trial was explained to each patient and his/her informed consent obtained prior to randomization

Clinical data

A detailed clinical history was obtained from each patient with special emphasis on anorectal complaints such as pain, bleeding per rectum, incontinence (minor and major), anal swelling, discomfort, pruritis and discharge. Anorectal examination for grading the haemorrhoids and exclusion of sentinel pile, fissure and fistula in ano. Per rectal examination to exclude other anorectal pathologies e.g. benign or malignant masses or polyps.

Proctoscopy

To inspect the anal canal and lower rectum for the presence of internal piles and to exclude presence of ulcers, fissures, etc.

Anal manometry

Manometric evaluation of the anal sphincters were performed pre-operative, 6 weeks and 3 months post-operative. After an overnight fast anorectal motility analysis was performed in the left lateral position with the hips flexed to 90° on the day before surgery using a water-perfused manometric system (Sandhill, Denver, Colorado, USA). Pressures were measured in cm H_2O using the station pull-through technique at 0.5 cm intervals from the anal verge. No bowel preparation and no anal examination was performed before manometry. Anal sphincter pressures, anal sphincter length, and anal sphincter symmetry index (VSI) were measured at rest using an eight-channel water perfusion catheter (Zinectics Medical Inc, Salt Lake City, Utah, USA). The measurements were then repeated at squeeze with the patient instructed to maximally contract the anal sphincter without straining or using the gluteal or the abdominal muscles. At each interval three squeeze pressures were measured .Anorectal inhibitory reflex and rectal sensation for distension, pain and defecation were measured using a balloon-tipped eight-channel catheter (Zinectics Medical Inc, Salt Lake City, Utah, USA). The balloon was inserted in the rectum without the aid of a proctoscope or sigmoidoscope. The rectal balloon was rapidly inflated manually with air, using a 100-mL syringe, first with 10 mL for 5-10 seconds and then deflated for the same time, and the procedure repeated with air increments of 10 mL up to 60 mL. The volumes that elicited sense of rectal distension, pain or desire to defecate were recorded.

Operative technique

Pile Suture[2]

With the patient in the lithotomy position the skin tags corresponding to the 3 major piles were held by tissue forceps. A curved haemostat was applied to the right posterior haemorrhoid above the level of the pectinate line. Number 0 polyglactin 910 (Vicryl, Ethicon) suture was passed through the mucous membrane at the proximal end of the internal haemorrhoid in order to occlude the superior haemorrhoidal vessels as they enter the internal haemorrhoid, the second suture was introduced into the distal end of the internal haemorrhoid above the level of the pectinate line, thus interrupting the connection between the internal and external haemorrhoidal plexuses. A third suture was placed between the previous two as shown in (Fig. 1). The right anterior and left lateral haemorrhoids were then ligated in the same manner.

Ligation Excision

Haemorrhoidectomy by the conventional ligation and excision technique[3]

Post-operative observation

Postoperative pain was assessed with the help of a visual analogue scale (VAS). Urine retention, time to first bowel motion, bleeding, length of hospital stay were recorded for each patient.

Follow-up

At six weeks patients were interviewed for anal incontinence to flatus, liquid stools or solid stool and an anal manomteric follow-up study was performed. At three months patients were interviewed for recurrence of symptoms and examined for presence of skin tags and anal stenosis. An anal manometric follow-up study was also performed.

Statistical analysis

Fisher's exact test was used for comparison of nominal data. ANOVA test was used for comparing more than two variable sets with follow up analysis using LSD test. The paired *t*-test was used for comparison of two continuous matched data sets and the unpaired *t*-test used for two continuous unmatched data sets. All comparisons were two tailed and a 5% level of significance was chosen.

Ethical considerations

The study protocol was approved by the local ethical committee.

RESULTS

The clinical features of the patients in the Ps group and Le group are shown in Table I. The two groups were well matched regarding their presentation and degree of disease. The manommetric features of both groups and their control are listed in Table II. There was no significant difference in the manommetric findings between patients in the Ps group and the Le group. However, patients with haemorrhoids (group Ps and Le) had significantly higher resting and squeeze pressures than patients in the control group (ANOVA: $p < 0.01$ and $p < 0.05$, respectively).

The immediate postoperative observations were in favour of the pile suture technique. Patients in the Ps group had significantly less postoperative pain as shown by their lower VAS in TableIII. Two (8.7%) patients in the Ps group required narcotic analgesics in comparison to 12 (54.55%) in the Le group (Fisher's exact test: $p < 0.01$). The time to the first bowel motion was significantly shorter in the Ps group as shown in Table III. One (4.35%) patient in the Ps suffered from urine retention in comparison to five (22.73%) patients in the Le group, however this difference was not statistically significant (Fisher's exact test: $p > 0.05$). The hospital stay was significantly shorter in the Ps group as shown in Table III.

Clinical follow showed that two patients in the Le group suffered from incontinence to liquid stools at 6weeks, which disappeared at 3 months. One patient in the Le group suffered from recurrent bleeding at 3 months while none of the patients in the Ps group suffered from any adverse events at 6 weeks or 3 months (Fisher's exact test: $p > 0.05$)

The resting anal pressure significantly decreased after surgery in both groups as measured 6 weeks postoperatively (Paired t test: $p < 0.01$) and continued to decrease as measured at 3 months postoperatively as shown in Fig. 2. The degree of loss of anal sphincter pressure was greater in the Le group than the Ps group as shown in Fig 2 where the mean resting anal pressure of the Le group intersected the mean pressure of the Ps group in the early postoperative period (6 weeks) and stayed at a low value in the late postoperative period (3 months).

The squeeze anal pressure in the Le group significantly decreased (Paired t test: $p < 0.05$) postoperatively as measured at 6 weeks and 3 months as shown in Fig. 3. On the other hand, a slight insignificant decrease (Paired t test: $p > 0.05$) was observed in the Ps group as shown in Fig. 3.

The vector symmetry index in the Le group significantly decreased (Paired t test: $p < 0.05$) postoperatively as measured at 6 weeks and 3 months as shown in Fig 4. The vector symmetry index in the Ps group increased slightly at 6 weeks and 3 months, which was insignificant (Paired t test: $p > 0.05$) as shown Fig. 4.

When comparing the manommetric measurements of the two groups at 6 weeks and 3 months it was found that the squeeze anal pressure of the patients in the Le group became significantly lower than the squeeze pressure of the patients in the Ps group (Unpaired t test: $p < 0.05$) as shown in Table IV. A difference that was not present preoperatively.

Table I: ***Patient characteristics***

Item	*Pile Suture Group (n = 23)*	*Ligation Excision Group (n = 22)*
Mean (±SD) age in years	32.74 ±14.82	36.68 ±10.82
Male : female	17:6	17:5
Clinical presentation		
Bleeding	20	15
Prolapse	23	21
Pruritis and discharge	3	3
Clinical grading		
Grade 1	0	0
Grade 2	12	7
Grade 3	10	13
Grade 4	1	2

Table II: ***Baseline manommteric features***

Item	*Pile Suture Group (n = 23)*	*Ligation Excision Group (n = 22)*	*Control Group (n = 20)*	*F value*
Sphincter pressure (cm H_2O)				
At rest	143.61 ±35.02	150.45 ±33.25	101.14 ±19.9	16.57**
During squeeze	252.52 ±80.07	244.52 ±92.27	190.71 ±36.0	4.37*
Vector symmetry index				
At rest	0.66 ±0.21	0.71 ±0.14	0.61 ±0.16	1.87
During squeeze	0.64 ±0.2	0.70 ±0.20	0.63 ±0.11	0.89

Data presented as mean ±SD
*$p < 0.05$, ** $p < 0.01$

Table III: ***Immediate postoperative observations***

Item	*Pile Suture Group (n = 23)*	*Ligation Excision Group (n = 22)*	*t value*
Pain score (VAS)	5.3 ±1.69	8.0 ±0.87	6.67*
Time to first motion (days)	1.43 ±0.79	2.36 ±0.66	4.28*
Hospital stay (days)	2.31 ±0.55	2.64 ±0.66	2.81*

Data presented as mean ±SD
* $p < 0.01$

Table IV: *Postoperative manommetric values*

Item	*Pile Suture Group (n = 23)*	*Ligation Excision Group (n = 22)*	*t value*
Sphincter pressure (cm H_2O)			
At rest			
6 weeks	119.13 ±28.05	150.45 ±33.25	0.08
3 months	103.17 ±25.11	95.56 ±18.51	0.46
During squeeze			
6 weeks	251.2 ±93.76	189.77 ±77.41	3.29*
3 months	235.25 ±78.93	170.94 ±85.85	3.29*
Vector symmetry index			
At rest			
6 weeks	0.64 ±0.15	0.58 ±0.18	1.00
3 months	0.68 ±0.12	0.58 ±0.08	0.25
During squeeze			
6 weeks	0.63 ±0.10	0.68 ±0.12	0.39
3 months	0.67 ±0.15	0.68 ±0.06	0.93

Data presented as mean ±SD
* $p < 0.05$

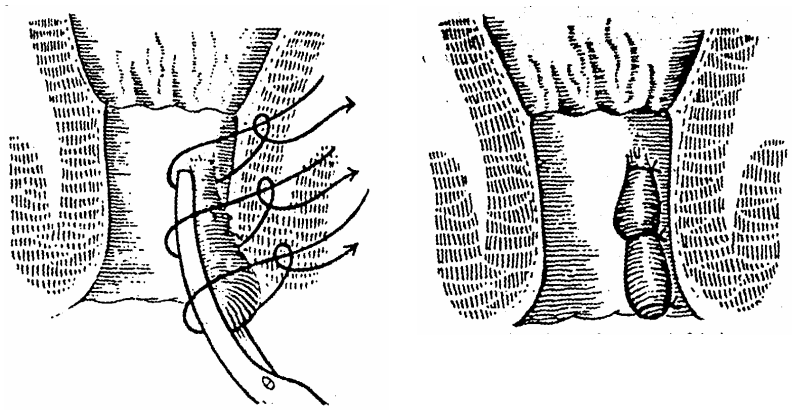

Figure 1*: Pile suture operation*

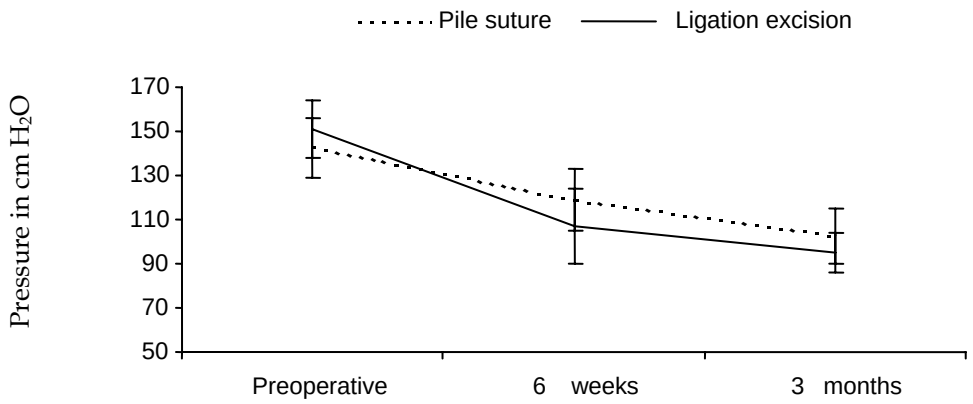

Figure 2: *Resting Pressure changes*

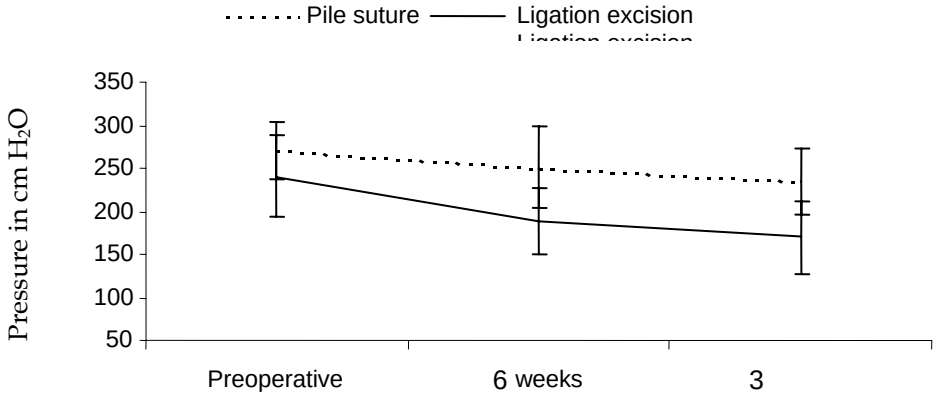

Figure 3: ***Squeeze Pressure changes***

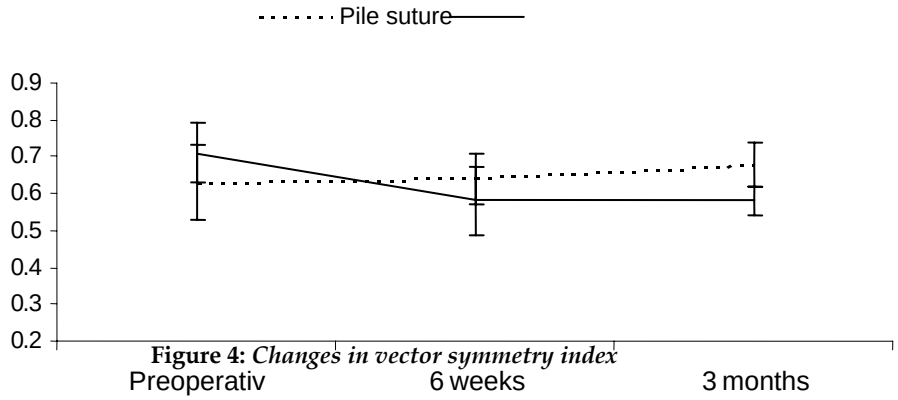

Figure 4: ***Changes in vector symmetry index***

DISCUSSION

The pressure in the anal canal of patients with haemorrhoidal disease is higher than that of the normal population. This increase affects both resting and squeeze anal pressures as confirmed by our study and as previously found by others.[11,12] The increase in the resting anal pressure seems to be due to the presence of the haemorrhaidal mass in the anal canal rather than an increase in the tone of the internal sphincter. All our patients were operated upon without anal dilatation, thus damage to the internal sphincter was minimum. Postoperative manommetric findings revealed a significant drop in resting anal pressures in both groups. This indicates that the bulk of the increase in the resting anal pressure is due to the haemorrhoids rather than to over activity of the internal sphincter. This is supported by previous studies where the addition of internal sphincterotomy[13] or anal dilatation[14] to haemorrhoidectomy did not result in significant increase in the magnitude of drop in resting anal pressure. The resting anal pressure in both the pile suture and ligation excision groups significantly decreased after surgery indicating that both methods are effective in dealing with the haemorrhoidal mass.

The increase in the squeeze anal pressure in patients with haemmorhoidal disease, which is produced by the external anal sphincter is also reduced after surgery.[15,16] Several attempts at explaining the increase in squeeze anal pressure have been presented ranging from sustained tonic contraction secondary to anal irritation or fear from soiling from anal discharge[17] to an increase or predominance of fatigue resistant muscle fibres known as type I muscle

fibre.[18] However, the effect of surgery on the squeeze anal pressure is variable and depends on the technique used in dealing with the haemorrhoidal mass. This study has clearly shown that ligation excision results in a significant sustained drop in squeeze anal pressure while pile suturing only results in an insignificant drop. It seems that ligation excision not only removes the mass of veins and overlying mucosa, but also a component of the external anal sphincter, most probably the subcutaneous fibres. This is strongly supported by the findings of this study where a significant decrease in the vector symmetry index of the anal canal was found among patients undergoing ligation excision and not among patients undergoing pile suture.

The clinical implications of the destructive nature of ligation excision in comparison to pile suture are evident in the postoperative period. Patients who have undergone ligation excison, significantly, suffered from more pain, required more narcotic analgesia, required more time to open their bowels and had a longer hospital stay. These findings can not be considered minor as they present a considerable morbidity to the patients and are sustained in a percentage of patients in the postoperative period in the form of soiling and inability to control liquid stools. These findings are not unique to our study or technique of ligation excison as they have been previously reported from expert centers where minor problems with anal control have affected a quarter of the patients after discharge from hospital.[19] Not to mention, that the stormy postoperative period asociated with ligation excison is avoidable when other less destructive and as efficient procedures such as pile suture are offered to patients with haemorroidal disease.

The pile suture technique leaves the external sphincter intact as it is not associated with a significant drop of squeeze anal pressure in the postoperative period. Whether the sustained increase in squeeze anal pressure, in comparison to control patients, will decrease by time or have adverse clinical effects in the long-term is yet to be determined. However, the pile suture technique which was first introduced by Farag[2] in the seventies offers an attractive alternative to pile ligation procedures which are currently considered by many authorities worldwide to be the preferred method in the initial management of patients with haemorrhaidal disease.[20,21,22] It is safe as there is no stripping or excison of the mucosa and sphincters, not to mention, that it is simple, easy to learn, cheap and does not require any special instruments.

In view of the results of this randomized controlled study we would like to draw the attention of the destructive nature of the ligation excison operation which is widely used in our surgical practice and recommend the use of less traumatic operations such as pile suture in the management of patients with haemorrhoidal disease and strongly recommend the inclusion of the pile suture technique in the training programmes of Egyptian surgeons.

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