#### **ORIGINAL ARTICLE**



# Posterolateral versus lateral internal anal sphincterotomy in the treatment of chronic anal fissure: a randomized controlled trial

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#### **Abstract**

**Background** Lateral internal anal sphincterotomy (LIS) is considered the treatment of choice for chronic anal fissure. This study aimed to compare the outcome of standard LIS and posterolateral internal sphincterotomy (PLIS) at 5 o'clock position as regards healing of anal fissure, improvement in symptoms, and complications.

**Methods** Patients with chronic anal fissure were randomly allocated to one of two groups; group I underwent PLIS and group II underwent LIS. Patients were compared regarding the duration of healing of anal fissure, improvement in anal pain as recorded by visual analogue scale (VAS), complications, particularly fecal incontinence (FI) and changes in the anal pressures.

**Results** Eighty (49 females) patients were included to this trial. The mean age of patients was 35.5 years. The duration of healing was significantly shorter in group I than in group II ( $4.1 \pm 1.7 \text{ vs } 5.8 \pm 1.4 \text{ weeks}$ ; p < 0.0001). Group I achieved significantly lower pain score at 1 month postoperatively than group II ( $1.1 \pm 0.9 \text{ vs } 1.7 \pm 0.98$ ; p = 0.005). Two (2.5%) of group I patients and six (10%) of group II patients experienced minor FI postoperatively. The postoperative reduction in the mean resting anal pressure in group I was significantly higher than that in group II.

**Conclusion** Time to complete healing was significantly shorter and pain score was significantly lower after PLIS than after LIS which can be due to more reduction in the resting anal pressure after PLIS. Continence disturbances occurred after PLIS less frequently than after LIS; however, no significant differences between the two techniques were noted.

Trial registration www.clinicaltrials.gov NCT03426449

Keywords Internal sphincterotomy · Lateral · Posterolateral · Anal fissure · Chronic · Randomized trial

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#### Introduction

Anal fissure is a common anal condition that affects all age groups with an equal incidence in both sexes. If an anal fissure does not heal within 6 weeks, it can be recognized as chronic anal fissure [1]. Treatment of anal fissure aims to relieve the internal anal sphincter (IAS) spasm associated with chronic anal fissures. Conservative treatment could prove beneficial in some patients; however, several patients fail conservative treatment and surgery remains the gold standard in the treatment of chronic anal fissures.

Surgical techniques devised for the treatment of chronic anal fissure include anal dilatation, posterior midline sphincterotomy, lateral internal sphincterotomy (LIS), fissurectomy, and advancement flap repair. All surgical techniques carry a potential risk of postoperative fecal incontinence (FI) of variable degrees [2]. Internal anal



sphincterotomy helps reduce the resting anal pressure generated by the IAS which improves the blood supply to the fissure and hastens healing [3].

Posterior midline internal sphincterotomy has been one of the earliest surgical methods described for the treatment of chronic anal fissure as it attained satisfactory and quick relief of symptoms as reported in previous studies [4, 5]. Despite the simplicity of posterior midline sphincterotomy, it has been abandoned since it is associated with a unique complication that is the keyhole deformity where the incision heals leaving a gutter in the posterior midline which may lead to higher incidence of postoperative FI as compared to LIS [6].

On the other hand, LIS is now considered the "gold standard" treatment for chronic anal fissure as it achieved significant improvement in symptoms and high rates of healing with less than 10% long-term recurrence [7]. During LIS, the IAS fibers are divided laterally by using either an open or closed technique which helps decrease the spasm of the IAS [8].

The present study aimed to compare the standard LIS at 3 o'clock position with posterolateral internal sphincterotomy (PLIS) at 5 o'clock position as regards healing time, improvement in symptoms, postoperative recurrence, and complications, particularly FI. Since approximately 90% of anal fissures occur at the posterior midline which Schouten et al. [9] explained by lower perfusion of the anoderm at the posterior commissure secondary to higher anal pressure at the posterior anal canal quadrant, we hypothesized that performing internal sphincterotomy in a point midway between the standard lateral position and the posterior midline position would achieve more reduction in the resting anal pressure and therefore quicker healing and better relief of symptoms while avoiding the risk of keyhole deformity.

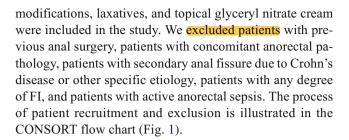
#### Patients and methods

## Study design and setting

This is a prospective randomized controlled trial on patients with chronic anal fissure who were admitted to the General Surgery Department and Colorectal Surgery Unit of Mansoura University Hospitals between January 2015 and July 2017. Ethical approval for the study was obtained from the institutional review board (IRB) of Mansoura Faculty of Medicine. The trial has been registered in www.clinicaltrials.gov with special identifier *NCT03426449*.

## **Eligibility criteria**

Adult patients of both genders with chronic anal fissure who failed previous conservative treatment including dietary



# Random sequence generation and allocation

Patients were randomly allocated to one of two equal groups: group I (LIS) and group II (PLIS). Randomization was undertaken by special computer software (www.randomization.com). The trial was single blinded as patients gave informed consent about the nature of the study and the potential benefits and complications of each technique; however, they were not aware about the type of internal sphincterotomy they will undergo.

## **Preoperative assessment**

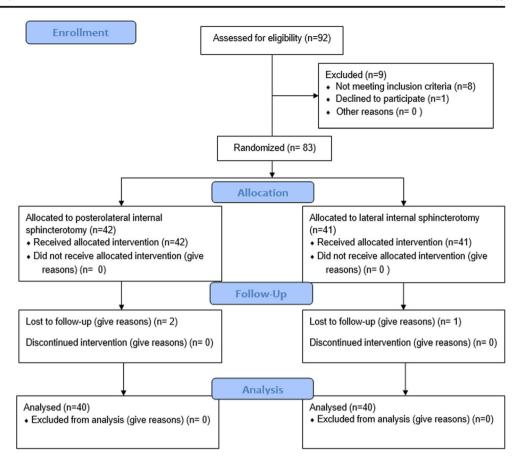
All patients were subjected to preoperative assessment including careful history taking with special attention to symptoms of anal fissure and duration of these symptoms, and medical comorbidities. Patients who had previous anal surgery were excluded from the study during the initial assessment. The degree of anal pain was assessed using visual analogue scale (VAS) from 0 to 10 where 0 indicated the absence of pain and 10 implied the worst severe pain. The continence state was assessed using Wexner continence score [10].

Each patient was examined carefully in the left lateral position. Inspection of anal verge, perineal skin, and anal canal confirmed the diagnosis of anal fissure. Palpation and digital rectal examination (DRE) were done to confirm the presence of anal sphincter spasm and to exclude any other pathology. Chronic anal fissure was defined based on the persistence of symptoms for more than 6 weeks [1, 11] and the diagnosis was confirmed during clinical examination by detection of the signs of chronicity as indurated edges, visible IAS fibers through the base of the fissure, hypertrophic anal papilla, and sentinel pile.

Anorectal manometry was done by a trained nurse to measure the mean resting and squeeze anal pressures before and after the procedures. Conventional manometry was performed using a standard, low-compliance water perfusion system and eight channel catheters with a pressure transducer connected to a 5.5-mm probe with spirally located ports at 0.5 cm intervals; the ports measure the pressure along the length of the anal canal. We followed the stationed pull-through technique as reported in a previous publication [12]. Normal ranges of mean resting anal pressure and mean squeeze anal pressure were 40–80 mmHg and 80–160 mmHg, respectively.



Fig. 1 CONSORT flow chart illustrating the process of patient recruitment and exclusion



# Technique of internal anal sphincterotomy

The procedures were performed under spinal anesthesia with the patients lying in the lithotomy position. One gram of cefotaxime was administered intravenously on induction. Gentle anal dilatation was performed, then an anal retractor was inserted for clear visualization of the anal fissure, then skin tag (if present) was excised.

In group I The anal mucosa was grasped gently using a pair of forceps, and after excision of the skin tag, the IAS was identified by its white fibers and was separated from anal mucosa using a dissecting scissor, then tailored internal anal sphincterotomy was performed at 5 o'clock position (Fig. 2) by dividing 8–10 mm of the IAS fibers using coagulative diathermy, then the wound was left open to allow drainage.

In group II The intersphincteric groove was identified, then a 2-cm incision was made into the perineal skin just lateral to the border of IAS at 3 o'clock position. The medial edge of the incision was held by small forceps and a pair of dissection scissors was used to separate the anal mucosa from IAS. The IAS was identified by its white fibers and then tailored internal anal sphincterotomy was performed at 3 o'clock position (Fig. 3) by dividing 8–10 mm of the IAS fibers using coagulative diathermy, then the wound was left open to allow drainage.

Patients in both groups were discharged the day next to surgery on a high-fiber diet, laxatives, and analgesics (nonsteroidal anti-inflammatory drugs).

### Outcome of the study

The primary outcome of the study was the duration of healing of anal fissure in each group. Healing was defined as complete epithelization of the anal wound (Fig. 4). Secondary outcomes included improvement in symptoms, particularly anal pain as recorded by the decrease in the VAS, complications including



Fig. 2 Posterolateral internal anal sphincterotomy at 5 o'clock position





Fig. 3 Lateral internal anal sphincterotomy at 3 o'clock position

FI, recurrence of anal fissure, and degree of reduction in the anal pressures.

## Follow-up

All patients were instructed to visit the outpatient clinic at 1 and 4 weeks after discharge then every 3 months for 1 year. During each visit, a surgical resident who was unaware about the nature of the study assessed the healing of the anal wound by careful examination of the anus and the time of complete healing was recorded.

Pain was evaluated using VAS from 0 to 10 and the continence state was assessed by Wexner continence score. Patients were asked about complications including rectal bleeding, infection, urine retention, and FI. DRE was performed to assess the tone of the anal sphincters and anorectal manometry was done at 3 months postoperatively to measure the resting and squeeze anal pressures. Recurrence of anal fissure was assessed by careful clinical examination.

## Statistical analysis

The sample size was calculated using sample size and study power calculation software (www.clincalc.com). Based on the primary endpoint of the study (duration of healing of anal



Fig. 4 Complete healing of anal wound after posterolateral internal anal sphincterotomy with no evidence of keyhole deformity



fissure in each group) and in light of previous literature [13, 14] that reported complete healing of anal fissure within  $6\pm 2$  weeks after LIS (group II), we assumed the mean duration of healing after PLIS (group I) to be within 4.5 weeks, and accordingly, a sample size of 56 patients equally divided on both groups was estimated to be necessary to have a study power of 80% with alpha level set at 5%. In order to compensate for loss to follow-up and dropouts, a sample size of 80 patients was finally included.

Data was analyzed using SPSS (Statistical Package for Social Science software, Chicago, IL, USA) version 23.0 under Microsoft Windows. The description of data was in the form of mean  $\pm$  standard deviation (SD) for quantitative data and frequency and proportion for qualitative data. Student's t test was used for the analysis of quantitative data. Fisher's exact test and chi-square tests were used for analysis of qualitative data. Statistical significance was assumed for p < 0.05.

## **Results**

#### Patients' characteristics

Eighty patients were included in this prospective trial and were randomly divided into two equal groups: group I comprised 40 patients who underwent PLIS at 5 o'clock position and group II comprised 40 patients who underwent LIS at 3 o'clock position.

Patients were 49 (61.2%) females and 31 (38.8%) males of a mean age of  $35.5 \pm 11.2$  years. Pain was the most common presenting symptom as 77 (96.2%) patients complained of anal pain preoperatively. Seventy-one (88.7%) patients reported chronic constipation, 16 (20%) reported slight rectal bleeding, 13 (16.2%) complained of anal discharge, and 16 (20%) had pruritus ani. None of the patients complained of FI or soiling before surgery. The mean duration of symptoms was  $5.5 \pm 2.4$  months. Anal fissure was located posteriorly in all patients included. Six patients in group I and five in group II had normal preoperative resting anal pressure (range, 71–80 mmHg). There were no significant differences between the two groups regarding the preoperative characteristics and duration of symptoms as shown in Table 1.

## Postoperative outcome

At 3 months of follow-up, all patients in both groups achieved complete healing of the surgical wound. The average duration of healing was significantly shorter in group I than in group II  $(4.1 \pm 1.7 \text{ vs } 5.8 \pm 1.4 \text{ weeks}; p < 0.0001)$ . Group I achieved significantly lower pain score at 1 month postoperatively than group II  $(1.1 \pm 0.9 \text{ vs } 1.7 \pm 0.98; p = 0.005)$ .

The incidence of complications and recurrence of anal fissure were comparable in both groups (Table 2). Eight (10%)

**Table 1** Preoperative patients' characteristics in both groups

Variable  Age in years (mean ± SD)		Group I $(n = 40)$	Group II $(n = 40)$ 35.6 ± 10.02	<i>p</i> value 0.93
		$35.4 \pm 12.2$		
Male/female		16/24	15/25	0.81
Complaint	Pain (%)	39 (97.5)	38 (95)	1
	Constipation (%)	37 (92.5)	34 (85)	0.48
	Bleeding (%)	7 (17.5)	9 (22.5)	0.78
	Discharge (%)	8 (20)	5 (12.5)	0.54
	Pruritus (%)	9 (22.5)	7 (17.5)	0.78
Duration of complaint in months (mean $\pm$ SD)		$5.1\pm2.37$	$5.8\pm2.5$	0.2
Presence of skin tag (%)		35 (87.5)	37 (92.5)	0.71

patients experienced FI postoperatively, two (2.5%) of whom were in group I and six (10%) were in group II. All patients had mild incontinence to flatus except one patient in group II who complained of fecal soiling of his underwear; the median Wexner score of the patients was 3, ranging from 2 to 6. None of the patients in both groups developed keyhole deformity on follow-up. The mean duration of follow-up was  $12.2 \pm 2.7$  (range, 6-18) months.

# Changes in the resting and squeeze anal pressures

The mean preoperative resting and squeeze anal pressures were comparable in both groups. At 3 months postoperatively, both groups showed a significant decrease in the mean resting and squeeze anal pressures. The postoperative reduction in the mean resting anal pressure in group I was significantly higher than that in group II ( $45.2 \pm 4.7$  vs  $56.9 \pm 7.02$ ; p < 0.0001) whereas both groups showed comparable reduction in the mean squeeze anal pressure (Table 3).

#### Discussion

In the present study, we compared the outcome of posterolateral internal sphincterotomy at 5 o'clock position and the standard LIS at 3 o'clock position in 80 patients with chronic anal fissure. The mean age of patients was 35 years in line

**Table 2** Postoperative outcome in both groups

Variable	Group I $(n = 40)$	Group II $(n = 40)$	p value
Mean duration of healing in weeks	4.1 ± 1.7	5.8 ± 1.4	< 0.0001
Preoperative pain VAS (mean $\pm$ SD)	$5.9\pm1.3$	$5.8 \pm 1.7$	0.77
Postoperative pain VAS at 1 month (mean $\pm$ SD)	$1.1\pm0.9$	$1.7\pm0.98$	0.005
Postoperative bleeding (%)	1 (2.5)	5 (12.5)	0.2
Infection (%)	1 (2.5)	1 (2.5)	1
Fecal incontinence (%)	1(2.5)	4 (10)	0.36
Recurrence (%)	2 (10)	6 (15)	0.26
Follow-up in months (mean $\pm$ SD)	$12.4\pm2.6$	$12.1\pm2.3$	0.58

with previous studies which implied that anal fissure commonly affects young and middle-aged individuals [15].

We aimed to investigate the impact of changing the position of internal anal sphincterotomy to become at 5 o'clock, midway between LIS at 3 o'clock and posterior midline IS, on the outcome of anal fissure. Although some investigators reported quick and satisfactory improvement in symptoms after posterior midline sphincterotomy [4, 5], it has been reported to be associated with delayed healing and guttering of posterior midline scar which is known as the keyhole deformity. In addition, posterior midline sphincterotomy may cause further compromise of anal continence than LIS as Barisone et al. [16] implied. Hence, we thought that performing internal sphincterotomy at the posterolateral position would attain lower recurrence and quicker healing than LIS and in the same time would avoid the complications of posterior midline sphincterotomy such as keyhole deformity and the risk of continence disturbance.

The primary outcome of the trial was the duration of healing of anal fissure after each technique. PLIS attained significantly shorter time to complete healing than LIS. Similarly, pain relief was significantly better after posterolateral sphincterotomy compared to LIS. These observations may be explained by better alleviation of IAS spasm after PLIS which was supported by comparing the anal pressures in both groups before and after the procedure. Both techniques resulted in a significant reduction in the resting anal pressure postoperatively which has been already documented in



**Table 3** Changes in the resting and squeeze anal pressures in both groups

Variable	Group I ( <i>n</i> = 40)	Group II ( <i>n</i> = 40)	p value	
variable	Group 1 (n = 40)	Group II (n = 10)	p varue	
Preoperative MRP (mmHg)	$86.2 \pm 9.3$	$84.6 \pm 7.9$	0.41	
Postoperative MRP (mmHg)	$45.2\pm4.7$	$56.9 \pm 7.02$	< 0.0001	
p value	< 0.0001	< 0.0001	_	
Preoperative MSP (mmHg)	$146.9 \pm 18.53$	$146.8\pm16.2$	0.97	
Preoperative MSP (mmHg)	$130.5\pm16.4$	$135.4 \pm 15.8$	0.17	
p value	< 0.0001	0.002	_	

MRP mean resting anal pressure, MSP mean squeeze anal pressure

previous studies [17–19]; however, the available data are still insufficient to determine the extent of this decrease as stated by Peker et al. [20].

It was notable that the reduction in the resting anal pressure after PLIS was significantly higher than after LIS which can be explained in light of the observation made by Taylor and colleagues [21] that the resting pressure exerted at the posterior quadrant of the anal canal is higher than the other three quadrants; hence, it may be understandable why the division of the IAS within the posterior quadrant would achieve more reduction in the resting anal pressure.

As we examined the efficacy of each technique with regard to healing time and symptom improvement, we also opt to examine the safety of each technique, particularly its impact on the continence state. It is known that FI is the most dreaded complication of surgery for anal fissure as it can occur in 20% of cases after anal dilatation and up to 14% of patients treated with internal sphincterotomy [22, 23].

In the present study, minor FI was reported in 2.5% of patients after PLIS and 10% of patients after LIS in agreement with other studies [22–26] that reported continence disturbance, particularly flatus incontinence, in 10–14% of patients after LIS. Nelson et al. [27] documented that minor FI is still considered a significant risk of LIS in comparison to nonsurgical treatments.

Although the postoperative resting anal pressure after PLIS was significantly lower than that after LIS, FI was more frequently recorded after LIS. This phenomenon may be attributable to the mechanism of FI which is usually a multifactorial process that may not be explained by the decline in the resting anal pressure after sphincterotomy alone. Other factors such as anorectal sensation, rectal capacity and adaptation, and pudendal nerve conduction may also contribute to the development of continence disturbances postoperatively even when resting anal pressures are within normal range as previous investigators highlighted [6, 28].

FI in both groups was transient and improved spontaneously without permanent residual damage within few weeks after surgery in line with other investigators who reported spontaneous improvement in minor FI after internal sphincterotomy [5, 23]. A privilege of PLIS that may have contributed to the lower incidence of postoperative FI is the ability to perform

controlled division of the IAS fibers under direct vision similar to midline posterior sphincterotomy as Memon et al. [5] highlighted.

Recurrence of anal fissure was comparable in both groups as 10% of patients in group I and 15% of patients in group II experienced recurrence of anal fissure. The incidence of recurrence after both techniques is within the range of 10–20% reported by Arroyo et al. [29] and Chen et al. [30]. Other postoperative complications, including bleeding and infection, occurred in 10% of patients overall with no significant difference between the two groups.

None of the patients who underwent PLIS developed keyhole deformity, since in PLIS, the sentinel pile is excised in the midline posterior position whereas the division of the IAS is done more laterally at 5 o'clock position; hence, only the cutaneous wound is present in the midline posterior position whereas the defect or gap in the IAS is present at a more lateral position. The keyhole deformity is caused by "scarring and epithelization of the gap created by the separation of the edges of the divided internal and subcutaneous external anal sphincter muscles which may result in a characteristic posterior midline furrow deformity" as Notaras implied [31], and since the gap in the IAS is not at the posterior midline, development of keyhole deformity was avoided.

In summary, both PLIS and LIS achieved satisfactory outcome with regard to healing of anal fissure and symptom improvement. PLIS showed some advantages including quicker healing of anal wound, better symptom improvement, and less incidence of FI. These advantages may be attributed to the location of internal sphincterotomy that was within the posterior quadrant of the anal canal, yet away from the posterior midline, thus avoiding keyhole deformity formation.

Limitations of the present study include the short-term follow-up which warrants longer follow-up to exclude recurrence and long-term disturbance in the continence state which can occur several months after IAS as Garg et al. [26] highlighted. Although we used standard methods to assess anal pain and the continence state, no assessment of the quality of life of patients before and after each procedure was made which may have better supported the conclusions of the study.



## **Conclusion**

Both posterolateral and lateral internal anal sphincterotomy achieved satisfactory outcome in the treatment of chronic anal fissure. Time to complete healing was significantly shorter and pain scores were significantly lower after PLIS than after LIS which can be due to more reduction in the resting anal pressure after PLIS. Continence disturbances occurred after PLIS less frequently than after LIS; however, no statistically significant differences between the two techniques were noted.

Authors' contributions Mohamed Farid introduced the concept of and designed the study. Sameh Emile and Mohammed Alawady collected the required data. Mohammed Alawady, Sameh Emile, Mahmoud Abdelnaby, and Hosam Elbanna conducted the procedures and the analysis of data. Mohamed Farid conducted interpretation of the results. Sameh Emile, Mohammed Alawady, and Hosam Elbanna wrote the manuscript. Mohamed Farid, Mahmoud Abdelnaby, and Hosam Elbanna drafted and critically revised the manuscript.

# **Compliance with ethical standards**

Ethical approval for the study was obtained from the institutional review board (IRB) of Mansoura Faculty of Medicine.

Conflict of interest The authors declare that they have no conflict of interest

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