



Comparison of controlled-intermittent anal dilatation and lateral internal sphincterotomy in the treatment of chronic anal fissures: A prospective, randomized study

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ABSTRACT

Aim: The results of controlled-intermittent anal dilatation (CIAD) or lateral internal sphincterotomy (LIS) in the treatment of chronic anal fissures are presented.

Material and methods: Forty patients who were randomized to two groups underwent CIAD or a LIS. The pre- and post-operative mean anal canal resting pressures (MACRPs) and symptoms were recorded and the results were compared.

Results: Two months post-operatively, 18 patients in the CIAD group and 17 patients in the LIS group had healed completely, and had no anal incontinence or other complications. The post-operative improvement in pain, bleeding, and constipation did not differ significantly between the two groups. In the CIAD and LIS groups, the pre-operative MACRPs were 89.7 ± 16.5 and 87.6 ± 12.3 mmHg, respectively; 2 months post-operatively, the MACRPs had significantly decreased to 76.9 ± 13.7 and 78.1 ± 11.3 mmHg in the CIAD and LIS groups, respectively. No statistical difference existed in the pre- or post-treatment MACRPs between the groups.

Conclusion: CIAD applied with a standardized technique reduced anal canal resting pressure and provided symptomatic healing that was equivalent to a LIS. Since there were no findings of incontinence, or situations which resulted in sphincter damage, we conclude that CIAD is suitable for patients with chronic anal fissures because it is less invasive than LIS, with equivalent efficacy and safety. In addition, the CIAD method may be an alternative procedure in older and multiparous women who has a higher risk of incontinence.

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1. Introduction

Patients with anal fissures present with pain, bleeding during defecation, and constipation; anal fissures are one of the most common medical conditions encountered in proctology.¹

The etiology of anal fissures is not known. Anal fissures generally arise with local trauma caused by difficult defecation due to hard stools and internal sphincter hypertonia caused by persistence of these conditions, which in turn reduces blood flow of the

posterior wall and results in a higher anal canal pressure, even at rest. Thus, anal fissures often become chronic.²

Studies on the methods of treatment of chronic anal fissures range from medical applications to surgery; there is no general agreement on ideal therapy for chronic anal fissures.³

In a meta-analysis, it was concluded that medical applications did not achieve a satisfactory result, whereas manual anal stretch methods resulted in a high-degree of sphincter damage.³

Lateral internal sphincterotomy (LIS) is a surgical procedure which is performed routinely in the treatment of chronic anal fissures, especially in cases that have failed traditional medical modalities. The results of open and closed LIS techniques are similar.³ Because of reports of the high incidence of incontinence (66%)¹ with these techniques, alternative methods have been investigated.

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Controlled anal dilatation methods have been found to be promising, but these methods should be supported with prospective randomized studies.^{3,4}

Controlled application of a Park's retractor was found to be an alternative method⁵ and with standardization, 88% healing with a 12% recurrence were achieved in a large series.⁶

In this prospective, randomized study, with the idea that a Park's speculum can reduce sphincter damage, the effectiveness of controlled-intermittent application (rather than continuous) on the treatment of chronic anal fissures was analyzed by comparison with a standard LIS method.

2. Patients and methods

Between January 2004 and December 2005, 40 patients with posterior chronic anal fissures between 18 and 50 years of age who were treated in our clinic were included in our study. Chronic anal fissure was defined as "an ulcer in the lower portion of the anal canal which involve sentinel pile and hypertrophic anal papilla". These 40 patients did not have inflammatory bowel disease, AIDS, tuberculosis, sexually transmitted diseases, or medically related conditions (i.e., gestation or the puerperium), and did not take anticoagulation/immunosuppression medications. The patients had no history of anorectal surgery and obstetric trauma and pre- and peri-operative rectoscopy showed that these patients did not have any other conditions affecting the anus (tumor, incontinence, stenosis, abscesses, fistulas, or hemorrhoids).

The study protocol was approved by the Ethics Committee of our hospital and was carried out in accordance with the principles of the Helsinki Declaration. The methods were explained to the patients and informed consent was obtained from all patients under study.

This was a prospective, randomized, double-blind study. The randomization was done using sealed envelopes, which were opened by the operating room nurse upon the patient's arrival for the procedure. Patients were randomized to two groups, which had 20 patients in each group.

Patients were asked to fill out a questionnaire that queried their symptoms. Anal pain was assessed before beginning treatment and at follow-up visits using a linear visual analog pain score. Rectal bleeding and constipation were assessed subjectively at baseline and at the end of treatment. Anal incontinence was assessed by means of a validated scoring and grading system, as previously reported by Pescatori et al.⁷

The mean anal canal resting procedure (MACRP) was measured pre-operatively in all patients, and these measurements were repeated 8 weeks post-operatively. One hour prior to the procedure, the rectum was evacuated with a Fleet enema; the manometry probe with 8 channels (Fig. 1) was placed in the lower rectum with the pressure sensitive sensor at the level of the anal verge. The computerized program reset the system, excluding the basal pressures of the internal and external sphincters. The resting pressure was measured while the patient was relaxed and when the monitor tracing was flat. The ranges of resting pressures were recorded by the computerized system as "cm H₂O" and afterwards the change were recorded in "mmHg".

2.1. Controlled-intermittent anal dilatation (CIAD) group

Under general anesthesia, the anal speculum, which is capable of being adjusted for CIAD, was placed in the anal canal; the anal speculum was gradually dilated to a diameter of 4.8 cm, and then gradually relaxed⁵ in 20 s. The dilation-relaxation sequence was repeated 15 times during a 5 min period. We performed this intermittent procedure to avoid ischemic and traumatic sphincter

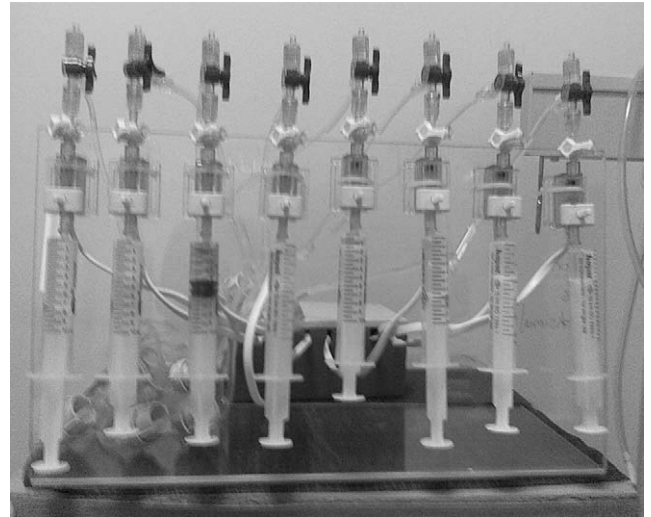


Fig. 1. The manometry equipment with 8 channels used in the measurement of sphincter pressures.

rupture due to continue pressure. The same surgical team participated in all applications. The patients were discharged from the hospital after a day of analgesia, sitz baths, and observation. Two months later, the resting anal canal pressures were measured, scar healing was assessed, and improvement in symptoms and complications were recorded. After one year, symptoms, healing, and complications were recorded via telephone calls. A questionnaire-form was prepared to record the telephone long-term follow-up data.^{8–10}

2.2. Lateral internal sphincterotomy (LIS) group

Under general anesthesia, a LIS with an open method was applied to patients in the lithotomy position. The internal sphincter was separated from the mucosa just under the dentate line; the distal part of the sphincter was dissected and cut with a scalpel. The surgeon who carried out the study attended all the surgical procedures. The patients were discharged from the hospital after a day of analgesia, sitz baths, and observation. Two months later, the MACRP was measured again, scar healing was assessed, and improvement in symptoms and complications were recorded. After one year, symptoms, healing, and complications were recorded through telephone calls. A questionnaire-form was prepared to record the telephone long-term follow-up data.^{8–10}

The data were analyzed with SPSS for Windows 10.0. Student's *t*-test for parametric comparisons, and χ^2 , Fisher's exact, and Mann-Whitney *U* tests for non-parametric comparisons were used.

For comparison of values of the groups before and after the treatment, the Kolmogorov-Smirnov test and paired *t*-test were used. As a significant difference, $p < 0.05$ value was accepted.

3. Results

No significant difference was detected between gender and the age distributions of the patients and the values are given in Table 1.

The distribution of pain, rectal bleeding, and constipation, which were the presenting symptoms of the patients, were not significantly different between the groups and, these values are given in Table 2.

Following CIAD, the complaints of 17 of 18 patients ($p < 0.001$) with pain, all of the 13 patients with rectal bleeding, and 8 of 10

Table 1
Distributions of gender and age of the groups.

	CIAD ^a	LIS ^b	<i>p</i>
Gender	10 female, 10 male	13 female, 7 male	NS ^c
Means of ages (ranges)	28.7 ± 7.5 (19–43)	32.3 ± 7.9 (18–49)	NS ^c

^a CIAD: controlled-intermittent anal dilatation.

^b LIS: lateral internal sphincterotomy.

^c NS: not significant.

patients ($p < 0.02$) with constipation were significantly reduced (Table 2).

Following LIS, the complaints of 14 of 17 patients with pain ($p < 0.001$), 11 of 13 patients with rectal bleeding ($p = 0.003$), and 8 of 11 patients ($p < 0.03$) with constipation were significantly reduced (Table 2).

The decreased pain, rectal bleeding, and constipation after treatment did not differ between the two groups (Table 2).

The fissures healed after 2 months in 18 of 20 patients who underwent CIAD. In one of these two patients, the pain diminished, but the constipation continued; this patient was one of six multiparous female included in this study. In the other patient, the pain and constipation persisted. These patients refused the surgical approach, left the study, and were designated as recurrences. No anal incontinence or other complications were detected in the group of patients who underwent CIAD.

In the LIS group, the anal fissures healed by 2 months post-operatively in 17 of 20 patients. In all of these three patients, pain and constipation persisted, and in two of these patients, the complaints of rectal bleeding continued. Because of the persistent symptoms despite supportive treatment for one month, re-operation was offered. These three patients were designated as a recurrence; two of the patients did not undergo a second operation, but in the other patient, a contralateral LIS was performed successfully and healing was observed within the first post-operative month. No incontinence or other complications existed in this group.

Based on the telephone call follow-ups at the end of the first year, except for the 4 patients (4/40 [10%]) who had been excluded from the study and designated as recurrences, no symptoms, recurrences, or complications occurred in the remaining the patients in both groups.

The results and statistical evaluation of MACRP values are shown in Table 3 and Fig. 2. No statistical differences were observed in the pre- or post-treatment MACRP values between the groups.

4. Discussion

In the pathogenesis of anal fissures, which is a painful ulceration of the anal canal mucosa, internal sphincter spasm is an accepted cause as a result of the traumatizing effect of hard and large stools which develops secondary to constipation. It is well-accepted that

Table 2
Healing of symptoms of the groups and comparisons.

Symptom	Time	CIAD ^a (n = 20)	LIS ^b (n = 20)	<i>p</i>
Pain	Pre-operative	18	17	NS ^c
	Post-operative	1	3	
Bleeding	Pre-operative	13	13	d
	Post-operative	0	2	
Constipation	Pre-operative	10	11	NS ^c
	Post-operative	2	3	
Fissure	Pre-operative	20	20	NS ^c
	Post-operative	2	3	

^a CIAD: controlled-intermittent anal dilatation.

^b LIS: lateral internal sphincterotomy.

^c NS: not significant.

^d Not suitable for comparison.

Table 3
Mean anal canal resting pressures of the groups and comparisons.

MACRP ^a	CIAD ^b (n = 20)	LIS ^c (n = 20)	<i>p</i>
Pre-operative	89.7 ± 16.5 mmHg	87.6 ± 12.3 mmHg	NS ^d
Post-operative	76.9 ± 13.7 mmHg	78.1 ± 11.3 mmHg	NS ^d
Difference (%)	14.0 ± 5.5	10.8 ± 4.6	NS ^d

^a MACRP: mean anal canal resting pressure.

^b CIAD: controlled-intermittent anal dilatation.

^c LIS: lateral internal sphincterotomy.

^d *t*-Test.

ischemic events are effective in poor healing and recurrence of anal fissures.²

In studies, a higher anal canal resting pressure was measured in patients with anal fissures compared to the control group, and it was shown that this situation existed in the entire anal canal.²

It was found that even in the patients with full paralysis in the external sphincter muscles, the anal canal resting pressure could be higher.^{11,12} High resting pressures were found in all our patients pre-operatively.

The most common complaints observed in patients with anal fissure were pain, rectal bleeding, and constipation,¹ occurring in 35 (87.5%) of the patients with perianal pain, 26 of the patients (65%) with rectal hemorrhage, and in 20 (50%) of the patients with constipation.

In the patients with anal fissure, anal dilatation, LIS or effective medical treatment decrease the anal canal resting pressure and treat the pain.^{13–15} The decrease in the anal canal resting pressure and the cessation of pain after the effective treatment supported the ischemic theory of Gibbons and the increase in anal sphincter tonus has become a cause, rather than the result, of an anal fissure.¹⁶

In our study, pre- and post-treatment anal canal resting pressures of each patient were measured with an anal manometer device and it was found that in both groups, anal canal resting pressures significantly decreased after treatment.

Anal dilatation is a method that has been used for a long time in fissure treatment and it is advantageous as it is easily applied, does

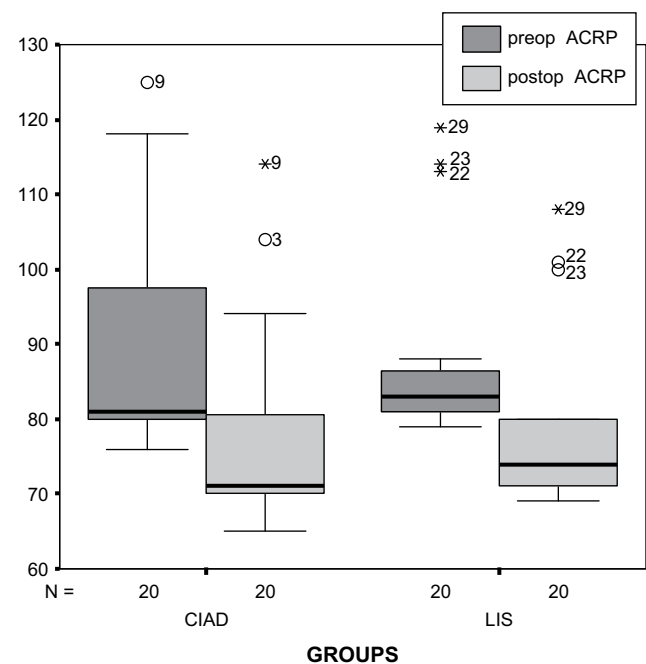


Fig. 2. Comparison of pre-operative and post-operative MACRP among CIAD and LIS groups. *Extremes; O: outliers; MACRP: mean anal canal resting pressure, CIAD: controlled anal dilatation, and LIS: lateral internal sphincterotomy.

not require much equipment, and allows patients to be discharged from the hospital one day later.^{5,13,17–19}

However, relapse and the anal incontinence ratio after manual anal dilatation have always been controversial. In literature, healing rate of this method is reported as 83–89%, but recurrence (17%), sphincter damage (50%), and anal incontinence (12.5%) values are represented as serious disadvantages.^{5,17,18}

The shortcomings can be due to uncontrolled approaches in the application of anal dilatation, and it has been stressed that the application should be standardized.³ In the meta-analysis report, in controlled anal dilatation, acceptable results were obtained, but prospective randomized studies were required.³

In our study, the significant decrease in anal canal resting pressures of our patients were obtained by anal dilatation with an anal speculum applied by a controlled-intermittent manner; 90% healing and satisfactory improvement in symptoms (94.4% of pain, 100% of rectal bleeding, and 80% of constipation) were considered sufficient to support this method. In addition, no episodes of incontinence as a result of sphincter damage existed after this application. After review of the results, the intermittent controlled dilatation appeared to be effective.

Currently, LIS is a common surgical method which is utilized for the treatment of chronic anal fissure.³ In the studies of Arroyo et al. after LIS, minor incontinence was found in 5% of patients, healing occurred in 93–100% of patients, recurrence occurred in 0–25% of patients, and incontinence occurred in 0–38% of patients.²⁰ In recent studies, regarding to healing and recurrence, LIS has been found better than Lord's method,²¹ nitroglycerine¹⁰ and glyceryl trinitrate²²; nifedipine has been shown an alternative to LIS.²³

In our study, it was observed that the anal canal resting pressure was reduced effectively after LIS; the healing rate, and improvement in pain, rectal bleeding, and constipation was 85, 82.4, 84.6, and 72.7%, respectively, by the 3rd post-operative month; post-operative anal incontinence did not occur in any patients.

Although it not statistically significant, our results indicated the slight superiority of CIAD. It was also concluded that CIAD applied with a standardized technique reduced the anal canal resting pressure and provided symptomatic healing that was equivalent to LIS. Even with slightly better ratios, CIAD is a successful, reliable, and less invasive method in the treatment of chronic anal fissure. In addition, there were no findings of incontinence, or situations which led to sphincter damage in the patients after the application of CIAD. Besides the CIAD method may be an alternative procedure in older, multiparous women who has a higher risk of incontinence.

A further study should be planned with a larger series of patients, including the comparison with continuous pressures and ultrasonographic control.

Conflict of interest statement

There are no any conflicts of interest.

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Ethical approval

None declared.

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