

# Local application of Nifedipine versus calibrated lateral internal sphincterotomy for treatment of chronic anal fissure

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## INTRODUCTION

- Anal fissure (AF) is a longitudinal tear or crack in the skin of the anal canal.
- AF is a common disorder which affects all age groups with an equal incidence in both sexes  
*(Dykes and Madoff, 2007).*

- -Anal fissure usually self-heal within a few weeks but some anal fissures become deep and do not heal.
- If an AF does not heal in at least six weeks, it may be recognized as chronic AF *(Wollina, 2008)*.
- Anal fissure is one of the most common causes of anal pain *(Sailer et al., 1999)*.

- All treatment modalities, including surgery, aim to reduce the spasm Of the internal anal sphincter *(Collins and Lund, 2007)*.

- **-Calcium channel blockers (CCBs) relax the internal anal sphincter by blocking the influx of calcium into the cytoplasm of smooth muscle cells.**
- **It has been shown that both nifedipine (0.2-0.5 % gel) and diltiazem (2 % Cream) promote fissure healing by decreasing mean anal resting pressure** *(Bhardwaj et al., 2000).*

- **Surgical internal sphincterotomy is recommended as the first therapeutic approach in those with anal hypertonia** *(Arroyo et al., 2005).*
- **It achieves permanent reduction of hypertonia with relief of symptoms and is very successful causing healing of chronic AF** *(Liratzopoulos et al., 2006).*

## **AIM OF STUDY**

- **To compare local application of Nifedipine with tailored closed lateral internal sphincterotomy for treatment of chronic anal fissure.**

## **PATIENTS & METHODS**

- The study was conducted at Colorectal Surgery Unit, Mansoura University Hospital in the period from September, 2014 through December, 2015.

**A-patients:**

- Fifty-six patients with chronic anal fissure were informed and agreed to participate in our study.

**- Exclusion criteria:**

Pregnant ladies, patient with inflammatory bowel disease, patient with recurrent anal fissure, patient with hemorrhoid, and those not willing for participation.

## **B. Methods**

All patients were subjected to the following:

Full history taking evaluating the patient conditions for suspected etiology, disease duration and history of previous anal trauma in the form of previous anal operations or vaginal delivery and episiotomy.

- **Thorough clinical examination:** including both general and local examination.
- **Routine laboratory investigations:** as complete blood count, random blood sugar, liver and kidney functions.
- **Ano-rectal Manometry**

## ■ Interventions:

Patients were randomly assigned into one of the equal treatment groups listed below.

1. Group I: 28 patients were subjected to local application of Nifedipine gel (0.5%) every 8 hours daily for 3 weeks.
2. Group II: 28 patients were managed with closed lateral internal sphincterotomy.

The patients were Followed up for 6 months.

## Outcome measures

### A. Primary outcome:

- By clinical improvement.

### B. Secondary outcome:

1. Hospital stay
2. Operative complications
3. Pain assessment:
  - Using the visual analog scale.

#### **4. Symptoms persistence and treatment complications**

- These included constipation, bleeding, headache, flushing and anal irritation.

#### **5. Wound healing after 8 weeks.**

#### **6. Assessment of anal sphincter dysfunction**

- Using anal manometry

#### **7. Incontinence**

- Incontinence was assessed using Wexner score.

#### **8. Patients satisfaction**

- Patients were asked if they were satisfied with the results or not.

# RESULTS

**Table-1 Comparison between the studied groups regarding the demographic data**

		Group I (n=28)	Group II (n=28)	Student t test	
				t	p
Age (years)		41.5 ± 11.7	42.2 ± 12.7	-0.17	0.87
				Chi-square test	
				X <sup>2</sup>	P
Gender	Male	18 (64.0 %)	14 (50.0 %)	0.2	0.17
	Female	10 (36.0 %)	14 (50.0 %)		

**Table-2 Comparison between the studied groups regarding the clinical data**

		Group I (n=28)	Group II (n=28)	Student t test	
				t	p
Symptoms duration (m)		5.3 ± 2.2	5.4 ± 2.1	-0.08	0.94
Pain score (VAS)		7.0 ± 1.3	6.3 ± 1.6	6.3	0.14
				Chi-square test	
				X <sup>2</sup>	P
Constipation		24 (86.0 %)	25 (89.0 %)	0.36	0.55
Bleeding		21 (75.0 %)	20 (71.0)	0.63	0.43
Position	Anterior	3 (11.0 %)	4 (14.5 %)	0.49	0.78
	Posterior	20 (71.0 %)	20 (71.0 %)		
	Combined	5 (18.0 %)	4 (14.5 %)		

**Table-3 Comparison between the studied groups regarding manometry results**

		Group I (n=28)	Group II (n=28)	Student t test	
				t	p
Resting pressure	Preoperative (mmHg)	102.7 ± 5.8	106.7 ± 9.8	-0.67	0.45
	Postoperative (mmHg)	70.3 ± 7.3	65.9 ± 6.0	2.09	0.044*
	Reduction (mmHg)	32.5 ± 10.2	40.9 ± 12.2	-2.3	0.024*
Student t test *	t	203.2	223.7		
	p	0.0001*	0.0001*		
Squeezing pressure	Preoperative (mmHg)	183.6 ± 22.4	180.2 ± 29.9	0.4	0.69
	Postoperative (mmHg)	153.7 ± 15.6	154.2 ± 14.9	-0.11	0.91
	Reduction (mmHg)	29.9 ± 18.3	26.0 ± 32.4	0.47	0.64
Student t test *	t	52.9	12.8		
	p	0.0001*	0.002*		

**Table-4 Comparison between the studied groups regarding the operative outcome**

		Group I (n=28)	Group II (n=28)	Student t test	
				t	p
Pain	Pain in 1 <sup>st</sup> day	3.05 ± 1.6	5.6 ± 1.1	3.29	0.002*
	Pain in 7 <sup>th</sup> day	1.1 ± 1.3	0.9 ± 0.1	2.74	0.011*
				Chi-square test	
				X <sup>2</sup>	P
Healing (8 weeks)		19 (68.0 %)	25 (89.0 %)	5.6	0.018*
Clinical improvement at 8 weeks					
• Improved		21 (75.0 %)	24 (86.0 %)	5.6	0.018*
• Not improved		7 (25.0 %)	4 (14.0 %)		
Clinical improvement at the end of follow up					
• Improved		13 (46.0 %)	25 (89.0 %)	13.8	0.0001*
• Not improved		15 (54.0 %)	3 (11.0 %)		

**Table-5 Comparison between the studied groups regarding the postoperative complications**

		Group I (n=28)	Group II (n=28)	Chi-square test	
				X <sup>2</sup>	P
Headache		4 (14.0 %)	-	4.4	0.035*
Flushing		4 (14.0 %)	-	4.4	0.035*
Anal irritation		3 (11.0 %)	3 (11.0 %)	3.1	0.77
Incontinence	None	28 (100.0 %)	25 (89.0 %)	0.22	0.15
	Mild	-	3 (11.0 %)		

## **Conclusions**

**In spite of superiority of surgical sphincterotomy, local application of Nifedipine is a good alternative to surgery for treatment of chronic anal fissure where continence is in jeopardy.**

