# "A PROSPECTIVE INTERVENTIONAL STUDY BETWEEN CHEMICAL SPHINCTEROTOMY USING 0.2%TOPICAL GLYCERYL TRINITRATE AND SURGICAL INTERNAL SPHINCTEROTOMY IN THE MANAGEMENT OF CHRONIC FISSURE IN ANO"

Dissertation submitted to

THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERISTY CHENNAI

with partial fulfilment of the regulations for the Award of the degree **M.S. (General Surgery) -Branch I** 

**Reg No: 221711251** 



# DEPARTMENT OF GENERAL SURGERY, CHENGALPATTU MEDICAL COLLEGE & HOSPITAL CHENGALPATTU - 603001

MAY -2020

#### DECLARATION

I solemnly declare that the dissertation entitled "A PROSPECTIVE **INTERVENTIONAL** STUDY BETWEEN CHEMICAL USING **SPHINCTEROTOMY** 0.2%TOPICAL **GLYCERYL** TRINITRATE AND SURGICAL INTERNAL SPHINCTEROTOMY IN THE MANAGEMENT OF CHRONIC FISSURE IN Medical **ANO**" is done by me at Chengalpattu College and hospital, Chengalpattu during the period of JAN2018 - DEC2018 under the guidance and supervision of Dr. V.T ARASU, M.S., Professor, Department of General Surgery, Government Chengalpattu Medical College. This dissertation is submitted to The Tamilnadu Dr.M.G.R. Medical University, Chennai to wards the partial fulfilment of the requirements for the award of M.S GENERAL SURGERY.

Place: Chengalpattu Date:

Dr. ARULSAKTHI, M.S General Surgery Postgraduate Student, Department of General Surgery, Chengalpattu Medical College, Chengalpattu - 603001.

#### CERTIFICATE

This is to certify that this dissertation entitled, A PROSPECTIVE INTERVENTIONAL STUDY BETWEEN CHEMICAL SPHINCTEROTOMY USING 0.2% TOPICAL GLYCERYL TRINITRATE AND SURGICAL INTERNAL SPHINCTEROTOMY IN THE MANAGEMENT OF CHRONIC FISSURE IN ANO, submitted by Dr. ARUL SAKTHI ,in partial fulfilment for the award of the degree of M.S.(General surgery) by The Tamilnadu Dr. M.G.R. Medical University, Chennai is a bonafide record of the research work done by him , under the guidance of Dr. V.T. ARASU ,M.S., Professor , Department of General Surgery, Government Chengalpattu Medical College during the academic year 2017-20 in the Department of General Surgery, Chengalpattu Medical College, Chengalpattu-603001.

Dr.V.T Arasu ,M.S., Professor and Guide, Department Of General Surgery, surgery, Chengalpattu Medical College & Hospital, college, Chengalpattu – 603001 **Dr. Selvaraj ., M.S.,** Professor and HOD, Department of General

Chengalpattu medical

Chengalpattu – 603001.

Dr. G. Hariharan M.S. Mch., DEAN, Chengalpattu Medical College & Hospital Chengalpattu – 603001

#### **CERTIFICATE FROM GUIDE**

This is to certify that this dissertation work titled "A PROSPECTIVE **INTERVENTIONAL** STUDY BETWEEN CHEMICAL **SPHINCTEROTOMY** USING 0.2%TOPICAL **GLYCERYL** TRINITRATE AND SURGICAL INTERNAL SPHINCTEROTOMY IN THE MANAGEMENT OF CHRONIC FISSURE IN ANO" of the candidate DR. ARULSAKTHI., with registration Number 221711251 for the award of Degree of M.S in the branch of GENERAL SURGERY – BRANCH - I. I personally verified the urkund.com website for the purpose of plagiarism Check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows 6% percentage of plagiarism in the dissertation.

Guide & Supervisor sign with Seal.

#### INSTITUTIONAL ETHICAL COMMITTEE

#### CHENGALPATTU MEDICAL COLLEGE, CHENGALPATTU

Title of Work	<ul> <li>A Prospective Comparative study of Chemical and Surgical Management of Fissure in Ano in Chengalpattu Medical College.</li> </ul>
Principal Investigator	: Dr.S.Arulsakthi
Designation	: 1 <sup>st</sup> yr PG
Co-Investigators	: Dr.V.T.Arasu,M.S.,
	Associate Professor,
	Department of General Surgery
Department	: General Surgery

The request for an approval From the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 27.03.2018 at the Medical Education Unit, Government Chengalpattu Medical College, Chengalpattu at 11.00 AM.

The Members of the committee, the Secretary and the Chairman are pleased to inform you that your proposed project mentioned above is approved.

You should inform the IEC in case of any changes in study procedure, site, investigator investigation or guide or any other changes.

- 1. You should not deviate from the area of work for which you applied for ethical clearance.
- 2. You should inform the IEC immediately, in case of any adverse events or serious adverse reactions.
- 3. You should abide to the rules and regulations of the institution(s).
- 4. You should complete the work within the specific period and if any extension is required, you should apply for permission again and do the work.
- 5. You should submit the summary of the work to the ethical committee on complete of work.

MEMBER SECRETARY, IEC, CHENGALPATTU MEDICAL COLLEGE CHENGALPATTU. CHENGALPATTU MEDICAL COLLEGE CHENGALPATTU.

#### PLAGARISM CERTIFICATE

This is to certify that this dissertation work titled "A PROSPECTIVE INTERVENTIONAL STUDY BETWEEN CHEMICAL SPHINCTEROTOMY USING 0.2%TOPICAL GLYCERYL TRINITRATE AND SURGICAL INTERNAL SPHINCTEROTOMY IN THE MANAGEMENT OF CHRONIC FISSURE IN ANO" of the candidate DR. ARULSAKTHI for the award of degree of M.S. GENERAL SURGERY – BRANCH I. I personally verified the urkund.com website for the purpose of plagiarism check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows 6% of plagiarism in the dissertation.

Guide & Supervisor sign with Seal.



### **Urkund Analysis Result**

Analysed Document: Submitted: Submitted By: Significance: A DISSERTATION ON.docx (D57127207) 10/16/2019 3:59:00 PM arulsakthi.mbbs@gmail.com 6 %

Sources included in the report:

MAIN PLAGIARISM THESIS SHYAM.docx (D42532587) thesis plagiarism.docx (D42409390) https://nexusacademicpublishers.com/uploads/files/Nexus\_295.pdf https://www.jcdr.net/article\_fulltext.asp?id=2288 https://www.ijsr.net/archive/v8i2/ART20195257.pdf

Instances where selected sources appear:

11

#### ACKNOWLEDGEMENT

I wish to express my sincere thanks to Dr. Usha Sadasivan, Dean (Rt) and to the present Dean in charge Dr. Hariharan.G. M.S.,Mch ,Chengalpattu Medical College & Hospital, Chengalpattu, for having kindly permitted me to utilize the hospital facilities.

I wish to express my sincere thanks to our Head of the Department Dr.J.Selvaraj., M.S., sir for his keen interest and motivation.

I wish to express my heartfelt gratitude to My Guide Dr. V.T. Arasu, M.S., Professor of General surgery, Chengalpattu Medical College & Hospital, Chengalpattu for his immense help, encouragement, guidance and constant supervision.

I Am Greatly Thankful To Our Chief Dr. Vijayalakshmi , M.S., and Asst. Professors Dr.P.Pandiyan.M.S., Dr.KiranKumar.M.S., Dr.Velumurugan M.S. for their valuable suggestions and guidance and care and attention to complete this dissertation.

I owe great debt of gratitude to all the Assistant Professors and Tutors for their able help and support.

I Express my heartfelt gratitude to my senior postgraduates Dr.Arulselvan & Dr. Rajalakshmi for their training and guidance in preparation of this dissertation.

I can never forget the help of my junior postgraduates and House surgeons for their willing co-operation and assistance in assimilating the clinical material.

I thank all the Patients who took part in my study and their relatives.

# LIST OF CONTENTS

S.NO	TITLE	PAGE NO
1	INTRODUCTION	1
2	MATERIALS AND METHODS	5
3	METHODOLOGY	9
4	<b>REVIEW OF LITERATURE</b>	19
5	STATISTICAL ANALYSIS	46
6	DISCUSSION	75
7	SUMMARY	84
8	CONCLUSION	89
9	ANNEXURES	90
10	BIBLIOGRAPHY	
	CONSENT FORM	
	PROFORMA	
	MASTER CHART	
	INTRODUCTION	

#### **INTRODUCTION**

Fissure in ano is the most common painful condition of perianal region, characterized by longitudinal ulcers affecting the distal part of the anal canal. It's so common that it affects 1 in 10 people and causes very disabling symptoms such as severe cutting type perianal pain & bleeding per rectum making the diseased to suffer intense mental & physical agony inspite of rest and analgesics. Also the chronic fissures behave more differently in that way they are more persistent and relapsing than the acute fissures which are self-healing.

Much has been already discussed in the literature regarding the aetiology of Fissures though the Persistent Hypertonia of the anal sphincters is claimed to be the well-established cause. And so the available standard treatment options targets at relieving the spasm of the internal anal sphincter with surgical or chemical methods. Gold standard in the management of the chronic fissure in ano is the time proven, Lateral Internal Sphincterotomy with healing rates above 95%. But the need for the alternative is always been there to overcome the surgical stress and risk of incontinence. There are different chemicals which do the same job of relaxing the tone of internal sphincter by their special

properties. Of which, Glyceryl Trinitrate, a vaodilator and smooth muscle

1

relaxant with its unique profile of better healing rates and least side effects is been used in its topical form locally. Though many trials have already been done with 0.2% Topical Glyceryl Trinitrate in management of chronic fissure in ano, less emphasis has been paid to its methodology, dosage and compliance of usage which may be the reason for its higher recurrence rates and lesser cure rates.

The present study has been designed keenly taking all these into consideration and it compares the healing rates of chronic anal fissures using 0.2% Glyceryl Trinitrate(Chemical sphincterotomy) with that of the gold standard Surgical Lateral Internal sphincterotomy (Surgical sphincterotomy) as the primary objective. It also compares and analyses the other secondary objectives namely the recovery of Pain, Bleeding per Rectum, risk of Incontinence and the recurrence rates in both the methods.



# Fig1.1 A Prospective Interventional Study between Chemical Sphincterotomy using 0.2%Topical Glyceryl Trinitrate And Surgical Internal Sphincterotomy in the management of Chronic Fissure in Ano.

This clinical trial has been conducted in Chengalpattu Medical College and Hospital, Chengalpattu - 603001, with the patients suffering from chronic fissure in ano attending the Surgical Outpatient Department. Ethical committee approval was obtained priorly as per protocol. Present Study includes 183 patients of chronic fissure in ano treated over a period of 12 months (JAN 2018 to DEC 2018). Results has been analysed in both descriptive and statistical point of views and brought out in a simple understandable format for the readers.

Discussion of this study has been done with the review of literature and appropriate references.

### **AIM OF THE STUDY**

- 1) To find the **age and the sex incidence of fissure in ano.**
- To study the various modes of clinical presentation of fissure in ano and the various types of fissure in ano.
- To evaluate the effectiveness of topical 0.2% Glyceryl trinitrate in the symptomatic relief and healing of anal fissures.
- To compare the effectiveness of lateral anal sphincterotomy and chemical sphincterotomy in fissure in ano.
- **5**) To establish **the role of glyceryl trinitrate as the first line treatment** for both acute and chronic fissures.

#### MATERIALS AND METHODS

The study was conducted as a clinical trial at Chengalpattu medical college &Hospital, Chengalpattu - 603001, during the period between JAN 2018 to DEC 2018.

### SAMPLE AND SAMPLE SIZE DEFINITIONS

### **Population:**

The Patients diagnosed to have chronic anal fissure attending the Surgery Out Patient Department (OPD) of the Chengalpattu medical college & Hospital.

Diagnosis was based on history, clinical examination and Anoscopy (if tolerated by the patients).

History wise all patients had severe cutting type of pain during defecation & Bleeding per anum lasting for more than six weeks.

Clinical examination involved gentle separation of the buttocks and examination of the anus, to look for a linear ulcer in anoderm at the lower half of the anal canal with or without the sentinel pile.

### **INCLUSION CRITERIA**

Consenting patients between 16 to 65 years of age with symptomatic chronic fissure in ano among the population were included in the study. Extremes of age were not included due to possibility of age related bias.

### **EXCLUSION CRITERIA**

Patients with the following associated conditions were excluded from the study:

- a. Pregnant/lactating women,
- b. Inflammatory bowel disease, tuberculosis, malignancy and sexually transmitted diseases,
- c. Prior anal surgery,
- d. Previously Refractory to 0.2% Topical glyceryl Trinitrate,
- e. Associated haemorrhoids, fistula
- f. Patients with significant cardiovascular diseases,
- g. Patients opting for Specific Treatment(Chemical/surgery).

#### SAMPLE

With the above mentioned selection and exclusion criteria, the appropriate Sample was drawn from the population.

#### SAMPLE SIZE

In this Prospective Interventional trial- Parallel Study Design involving two groups, Sample size was calculated to be 183, with 90 in Group A and 93 in Group B.

### Formula:

 $N = Z^2 \{P1x (1-P1) + P2x (1-P2)\}/(P1-P2)^2$ 

Z- Involves the Power and significance of alpha & beta errors Power was kept as 90% and p value significant at 0.05

P1- Assumed success rate in Group A P2- Assumed success rate in Group B

It is observed from previous studies that the efficacy of Chemical Sphincterotomy using 0.2% Topical Glyceryl Trinitrates about 80% and that of Surgical Internal Sphincterotomy is about 95%. To estimate the difference with 95% confidence level & 80% power the minimum sample required is about 75 per arm (total of 150 patients for two arms).

Based on this the sample size was calculated as 75 in each group with total of 150 patients. But the actual sample studied was 183 which is more than the needed volume.



Fig. 3.1 Selection of Sample.

### **SAMPLING METHOD**

Total 183 patients with Chronic Anal Fissure attending Surgical Out Patient Department were enrolled in the study. Odd no of patients starting 1,3,5,...183 were assigned to group A, who received treatment with 0.2% Topical Glyceryl Trinitrate and the remaining even no of patients starting from 2,4,6,....183 were assigned to group B (surgical sphincterotomy group). The B group patients were hospitalized for the surgery

### METHODOLOGY[<sup>1-10]</sup>

- \* The A group was treated with a 0.2% Topical Glyceryl Trinitrate ointment (chemical sphincterotomy). The subjects were specially taught to apply the ointment (about a size of 1.5cm) to the anoderm thrice daily for 6 consecutive weeks with proper hygiene and technique. (Using clean washed hands before and after application, nails properly trimmed to avoid trauma)
- In present Study the 0.2% Topical Glyceryl Trinitrate ointment was used.. Each tube weighed 30g and the dosage prescribed was 1.5cm for three times a day, measured in a small scale given with the ointment. It was found that each 30g tube on milking came up to 124.5cm length. The daily maximum requirement per day was 1.5 x 3= 4.5cm, and that for 6weeks (42 days) was 42 x 4.5 = 189 cm. So on an average 2 tubes were required for each patient to complete the course of the treatment. The cost of each tube was around 100 rupees, so the total cost of the treatment was 200 rupees only.



### Figure 3.2 0.2% Topical Glyceryl Trinitrate

The cases from the B group underwent open lateral internal sphincterotomy under spinal/general anaesthesia as inpatient in the hospital. In open method incision was made directly across the intersphincteric groove and the sphincter muscles are separated from the anal mucosa and then divided. The cost of the procedure could not be measured because in our setup the medical treatment was free of cost for the patients.



### **Fig3.3 Surgical sphincterotomy**

 $\bigstar$  During the course of the treatment, both the groups were asked to eat a high

fibre diet, use warm Seitz baths, mild analgesics & laxatives.

★ The patients were reviewed in the Outpatients Department at the

2nd, 4th, 6th, 8th &10th weekends during the course of the Treatment

\* At each visit, details on the fissure healing, pain relief and any side effects and

recurrence was documented.

\* Also, specific questions were asked regarding the leakage of flatus and faeces.

Incontinence was calculated based on Wexner's score.[Table3.1]

	Frequency				
Type of incontinen ce	Never	Rarely	Sometime s	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

## Table 3.1 Wexner incontinence score

0 –Perfect continence; 1-7 – Good continence

8-14Moderate incontinence 15-20 severe incontinence

★ The healing of the fissure was assessed visually. Healing was defined

as

the complete disappearance of the fissure on examination.

★ The intensity of Pain was assessed by Visual AnalogueScore.

Every patient was supplied with a pain score chart [fig3.4]. They were instructed to mark the level of the pain in it daily. These charts were graded from 0 to 10 and marked at one end-0 (no pain) and at the other end -10 (worst pain). 1-3(mild pain), 4- 7(moderate pain), 8-10(severe pain). Our target was to achieve a pain score less than 3, preferably near 0.



### Fig. 3.4 Visual analogue Pain scoring chart

- ★ Bleeding per rectum was also graded into the Following
  - 0- Nil bleeding
- 1- Occasional blood spotting in stools (<1/week) [Minimal]
  - 2- Blood stained stools [Mild]

3-Frank blood in stools[Moderate]

4 - Blood clots passing per rectum[Severe]

✤ Work resume time was defined as the time required by thepatients for

symptomatic pain relief and to resume with Daily routine work. It was

calculated in weeks.

- ☆ Recovery time was defined as the time taken for complete healing of the fissure. It was calculated in weeks.
- The disease was considered as recurrent if the fissure reappeared at the same site after 2 months of surgery or 6 weeks therapy of 0.2% Glyceryl Trinitrate
- ★ Drop outs were those patients who are quitting the trial before completion of 10 weeks/those who are switching over to other alternative methods before 10weeks.

\* Patients of Study Group A who have completed 10 weeks of follow up and found refractory to treatment were allowed to switch over to Surgical method and observed. They were considered as Failure cases of Group A. Similarly group B patients refractory to surgical treatment were allowed to convert to Chemical sphincterotomy as per the patients consent. But the data was not analysed within the Groups A or B of this study, but was included in the Conversion rate.

14 Screening Procedures / Visits: The subjects underwent clinical examination which included visual & digital Rectal Examination, a proctoscopic examination & fill up questionnaire.



Fig 3.5 Assessment of Chemical & Surgical Methods

### ANALYSIS

Assessments of following Parameters were made.

**PRIMARY:** Fissure Healing Rate

### **SECONDARY:**

- Recovery of Pain
- Recovery of Bleeding per rectum
- Recovery time
- Risk of Anal Incontinence
- Morbid aspects of thetreatment
- Recurrence rate
- Work resume time
- Conversion rate

# POPULATION

## HISTORY

 $\downarrow$ 

## **CLINICAL EXAMINATION**

↓

DIAGNOSED WITH CHRONIC FISSURE IN ANO

SAMPLE SELECTION AND SAMPLING

CONSENT

### **INCLUSION CRITERIA**

## **EXCLUSION CRITERIA**

**183 CASES DIAGNOSED & FULFILLED THE ABOVE CRITERIA** 

## **ODD – GROUP A EVEN – GROUP B**



#### **REVIEW OF LITERATURE**

An anal fissure is a longitudinal split in the anoderm of the distal anal canal, which extends from the anal verge proximally towards, but not beyond the dentate line.

### **EMBRYOLOGY:**

The distal part of hindgut known as cloaca is divided by urorectal septum into primitive anorectal canal posteriorly and vesicourethral canal anteriorly. Primitive anorectal canal forms the lower part of rectum and proximal part of anal canal. Distal part of anal canal is formed by the proctodeum.

Proximal part of anal canal constitutes upper 15 mm, above the pectinate line. Lower part below the pectinate line (15-8 mm) is formed from ectodermal invagination (i,e) proctodeum. Non continuity of the two parts result in imperforate anus.



#### ANATOMY

The anal canal is the terminal part of the large intestine .

## LOCATION:

Anal canal Is situated below the level of pelvic diaphragm. It lies in the anal triangle of perineum in between the right and left ischio anal fossa, which allow its expansion during passage of the feces. The sacculations and taeniae are absent here.

#### **EXTENT:**

It extends from the anorectal junction to the anus. It is 3.8 cm long, directed downwards and backwards. The anal canal is surrounded

by outer voluntary and inner involuntary sphincters. They keep the lumen closed in the form of an antero posterior slit.

The anorectal junction is marked by the forward convexity of the perineal flexure of the rectum. It lies 2-3 cms front of and slightly below the tip of the coccyx. Here the ampulla of the rectum suddenly narrows and pierces the pelvic diaphragm.

The anus is the surface opening of the anal canal situated about 4 cms below and in front of the tip of the coccyx in the cleft between the two buttocks. The surrounding skin is pigmented and thrown into radiating folds and contains a ring of large apocrine glands.





## **Relations of the Anal Canal**

## Anteriorly

In both sexes: perineal body.

In males: membranous urethra and bulb of penis.

In females: lower end of the vagina

## Posteriorly

- a. Anococcygeal ligament.
- a. Tip of the coccyx.

## Laterally

a) Ischioanal fossae.

### Allaround

Anal canal is surrounded by the sphincter muscles, the tone of which the canal is closed.

### **INTERIOR OF THE ANAL CANAL**

Interior of the anal canal shows many important features and can be divided into three parts: the upper part, about 15 mm long; the middle about 15 mm long; and the lower part about 8 mm long. Each part is lined by a characteristic epithelium and reacts differently various diseases of this region.



#### **UPPER MUCOUS PART**

1. This part is about 15 mm long. It is lined by mucous membrane, is of endodermal origin.

2. The mucous membrane shows:

- a. 6 to 10 vertical folds; these folds are called the anal columns of Morgagni.
- b. The lower ends of the anal columns are united to each other by short transverse folds of mucous membrane; these folds are called anal valve
- c. Above each valve there is a depression in the mucosa which is called the anal sinus.
- d. The anal valves together form a transverse line that runs all round the anal canal. This is the pectinate line. It is situated opposite the middle of internal anal sphincter, the junction of ectodermal and endodermal parts. Occasionally the anal valves show epithelial projections called anal papillae. These papillae are remnants of the embryonic anal membrane.

#### MIDDLE PART OR TRANSITIONAL ZONE OR PECTEN

The next 15 mm or so of the anal canal is also lined by mucous membrane, but anal columns are not present here. The mucosa has a bluish appearance because of a dense venous plexus that lies between it and the muscle coat. The mucosa is less mobile than in the upper part of the anal canal. This region is referred to as the pecten or transitional zone. The lower limit of the pecten often has a whitish appearance because of which it is referred to as the white line of Hilton. Hilton's line is situated at the level of the interval between the subcutaneous part of external anal sphincter and the lower border of internal anal sphincter.

It marks the lower limit of pecten or stratified squamous epithelium which is thin, pale and glossy and is devoid of sweat glands.

### LOWER CUTANEOUS PART

It is about 8 mm long and is lined by true skin containing sweat and sebaceous glands. The epithelium of the lower part resembles that of true skin in which sebaceous and sweat glands are present.

26

#### SURGICAL ANATOMY

The anal canal commences at the level where the rectum passes through the pelvic diaphragm and ends at the anal verge. The muscular junction between the rectum and anal canal can be felt with the finger as a thickened ridge – the anorectal 'bundle' or 'ring'.

### THE ANORECTAL RING

The anorectal ring marks the junction between the rectum and the anal canal.It is formed by the joining of the puborectalis muscle, the deep external sphincter, conjoined longitudinal muscle and the highest part of the internal sphincter. The anorectal ring can be clearly felt digitally, especially on its posterior and lateral aspects.

### THE PUBORECTALIS MUSCLE

Puborectalis, part of the funnel-shaped muscular pelvic diaphragm, maintains the angle between the anal canal and rectum and hence is an important component in the continence mechanism . The muscle derives its nerve supply from the sacral somatic nerves, and is functionally indistinct from the external anal sphincter. The position and length of the anal canal, as well as the angle of the anorectal junction, depend to a major extent on the integrity and strength of the puborectalis muscle sling. It gives off fibres that contribute to the longitudinal muscle layer.
### THE EXTERNAL SPHINCTER

The external sphincter forms the bulk of the anal sphincter complex and, although traditionally it has been subdivided into deep, superficial and subcutaneous portions, it is a single muscle which is variably divided by lateral extensions from the longitudinal muscle layer. Some of its fibres are attached posteriorly to the coccyx, whereas anteriorly they fuse with the perineal muscles. Being a somatic voluntary muscle, the external sphincter is red in colour and is innervated by the pudendal nerve.

#### THE INTERSPHINCTERIC PLANE

Between the external sphincter muscle laterally and the longitudinal muscle medially exists a potential space, the intersphincteric plane. This plane is important as it contains intersphincteric anal glands and is also a route for the spread of pus, which occurs along the extensions from the longitudinal muscle layer. The plane can be opened up surgically to provide access for operations on the sphincter muscles.

#### THE LONGITUDINAL MUSCLE

The longitudinal muscle is a direct continuation of the smooth muscle of the outer muscle coat of the rectum, augmented in its upper part by striated muscle fibres originating from the medial components of the pelvic floor. Most of the muscle continues caudally before splitting into multiple terminal septa that surround the muscle bundles of the subcutaneous portion of the external sphincter, to insert into the skin of the lowermost part of the anal canal and adjacent perianal skin. Milligan and Morgan named the most medial of these septa, passing around the inferior border of the internal sphincter, the 'anal intermuscularseptum'.

As it descends, however, it gives off fibers that pass medially across the internal sphincter to reach the submucosal space, and laterally across the external sphincter and ischiorectal space to reach the fascia of the pelvic side walls. As well as providing a supportive mesh for the anal canal and other muscular components, its ramifications provide potential pathways for the spread of infection. During defecation, its contraction widens the anal lumen, flattens the anal cushions, shortens the anal canal and everts the anal margin; subsequent relaxation allows the anal cushions to distend and thus contribute to an airtight seal.



### THE INTERNAL SPHINCTER

The internal sphincter is the thickened (2–5mm)distal continuation of the circular muscle coat of the rectum, which has developed special properties and which is in a tonic state of contraction. This involuntary muscle commences where the rectum passes through the pelvic diaphragmand ends above the analorifice , its lower border palpable at the intersphincteric groove, below which lie the most medial fibres of the subcutaneous external sphincter, and separated from intermuscular septum. When exposed during life, it is pearly-white in colour and its circumferentially placed fibres can be seen clearly.

Although innervated by the autonomic nervous system, it receives

intrinsic non-adrenergic and non-cholinergic (NANC) fibres, stimulation Of which causes release of the neurotransmitter nitric oxide ,which Induces internal sphincter relaxation.

Anatomical	Anal canal upper	Anal canal lower
distribution	2/3rd	1/3 <sup>rd</sup>
Embryological Origin	Endoderm	Ectoderm
Blood supply	Superior Rectal artery	Inferior Rectal artery
	(Portal)	(Systemic)
Lymphatics	Sacral & Internal Iliac	Superficial Inguinal
	nodes	nodes
Nerve supply	Autonomic Plexus	Inferior rectal branch
	(Pain Insensitive)	of Internal Pudendal
		Nerve(Pain Sensitive)
Epithelium	Columnar	Stratified Squamous
Haemorrhoids	Internal	External

# **FISSURE IN ANO**

An anal fissure is a linear ulcer usually found in the midline, distal to the dentate line . These lesions are typically easily seen by visual inspection of the anal verge with gentle spreading of the buttocks.

Location may vary; most fissures are identified in the posterior midline, and anterior midline fissures are still more common than lateral fissures.

### CLASSIFICATION

- 1. ACUTE FISSURE IN ANO.
- 2. CHRONIC FISSURE IN ANO.

### **ACUTE FISSURE IN ANO**

It is defined as a new onset fissure in ano which is extremely painful and resolve spontaneously within 6 weeks.

## **CHRONIC FISSURE IN ANO**

It is the one which persists for more than 6 weeks, which is characterized by the presence of chronic non healing ulcer, a skin tag or a hypertrophied anal papillae.



## ETIOLOGY

The cause of anal fissure is likely to be multi factorial. The passage of large and hard stools, low-fiber diet, previous anal surgery, trauma, and infection may be contributing factors. Increased resting anal canal pressures and reduced anal blood flow in the posterior midline have also been postulated as causes.

## PATHOPHYSIOLOGY

Initial minor tears in the anal mucosa due to a hard bowel movement probably occur often. In most people, these heal rapidly without long- term sequelae. In patients with underlying abnormalities of the internal sphincter, however, these injuries progress to acute and chronic anal fissures. Studies of the internal anal sphincter and of anal canal physiology have been performed with varied results, but at least one abnormality is likely present in the internal anal sphincter of many anal fissure patients. The most commonly observed abnormalities are hypertonicity and hypertrophy of the internal anal sphincter, leading to elevated anal canal and sphincter resting pressures. The internal sphincter maintains the resting pressure of the anal canal. Anal-rectal manometry can be used to measure this pressure. Most patients with anal fissures have an elevated resting pressure, which returns to normal levels after surgical sphincterotomy.

The posterior anal commissure is the most poorly perfused part of the anal canal. In patients with hypertrophied internal anal sphincters, this delicate blood supply is further compromised, thus rendering the posterior midline of the anal canal relatively ischemic. This relative ischemia is thought to account for why many fissures do not heal spontaneously and may last for several months. Pain accompanies each bowel movement as this raw area is stretched and the injured mucosa is abraded by the stool. The internal sphincter also begins to spasm when a bowel movement is passed. This spasm has two effects: First, it is painful in itself, and second, it further reduces the blood flow to the posterior midline and the anal fissure, contributing to the poor healing rate.

#### **CLINICAL FEATURES**

Although simple epithelial splits, acute anal fissures are, because of their location involving the exquisitely sensitive anoderm, characterised by severe anal pain associated with defaecation, which usually resolves spontaneously after a variable time only to recur at the next evacuation, as well as the passage of fresh blood, normally noticed on the tissue after wiping. Chronic fissures are characterized by a hypertrophied anal papilla internally and a sentinel tag externally (both consequent upon attempts at healing and breakdown), between which lies the slightly indurated anal ulcer overlying the fibres of the internal sphincter.

When chronic, patients may also complain of itching secondary to irritation from the sentinel tag, discharge from the ulcer or discharge from an associated intersphincteric fistula, which has arisen through infection penetrating via the fissure base.

Although most sufferers are young adults, the condition can affect any age, from infants to the elderly. Men and women are affected equally. Anterior fissures account for about 10% of those encountered in women (and many of these may occur postpartum) but only 1% in men. A fissure sited elsewhere around the anal circumference or with atypical features should raise the suspicion of a specific aetiology, and the inability to be able to conduct an adequate examination in the clinic should prompt early examination under anaesthesia, with biopsy and culture to exclude Crohn's disease, tuberculosis, sexually transmitted or human immunodeficiency virus (HIV)-related ulcers (syphilis, Chlamydia, chancroid, lymphogranuloma venereum, HSV, cytomegalovirus, Kaposi's sarcoma, B-cell lymphoma) and squamous cell carcinoma.

#### TREATMENT

Initial therapy for an anal fissure is medical in nature, and more than 80% of acute anal fissures resolve without further therapy. The goals of treatment are to relieve the constipation and to break the cycle of hard bowel movement, associated pain, and worsening constipation. Failure of medical therapy to resolve the acute fissure is an indication for surgical intervention. The presence of a symptomatic chronic fissure is also an indication for surgery because few of these heal spontaneously.

#### **MEDICAL THERAPY**

First-line medical therapy consists of therapy with stool-bulking agents, such as fiber supplementation and stool softeners. Laxatives are used as needed to maintain regular bowel movements. Mineral oil may be added to facilitate passage of stool without as much stretching or abrasion of the anal mucosa, but it is not recommended for indefinite use. Sitz baths after bowel movements and as needed provide significant symptomatic relief because they relieve some of the painful internal sphincter muscle spasm. Recurrence rates are in the range of 30-70% if the high-fiber diet is abandoned after the fissure is healed. This range can be reduced to 15-20% if patients remain on a high-fiber diet.

Second-line medical therapy consists of

- Local application of calcium channel blocker ointment (2% Diltiazem cream)
- Local application of Glycerol trinitrate ointment (0.2% nitroglycerin cream)
- 3. Botulinium toxin injection.

### **CALCIUM CHANNEL BLOCKERS**

Nifedipine is a L- type Calcium channel antagonist. L- type calcium channels are present in Intestinal smooth muscles. For anal fissures , Nifedipine 20 mg is given orally twice daily. It is effective in relieving the shincter spasm there by allowing faster healing. They have short duration of action and need to be administered 2-3 times daily. Side effects include headache, palpitations, flushing, dizziness, ankle edema, colicky abdominal pain, nausea and diplopia . Hence , it is not preferred nowadays. 2% Diltiazem ointments are commonly used.

Diltiazem belongs to Non Dihydropyridine (Non-DHP) group of calcium channel blockers. Diltiazem blocks voltage-sensitive calcium channels in the blood vessels, by inhibiting the ion-control gating mechanisms, thereby preventing calcium levels increase by other revenues. Alternatively, it has been suggested that this agent also Interferes with the release of calcium from the sarcoplasmic reticulum and inhibits the influx of extracellular calcium across both the myocardial and vascular smooth muscle cell membranes.

The overall low calcium levels leads to dilatation of the main coronary and systemic arteries and decreasing myocardial contractility, decreased peripheral arterial resistance, improved oxygen delivery to the myocardial tissue, and decreased cardiac output. When used topically it decreases the tone of internal anal sphincter and increases the blood supply to that region thereby augment fissure healing. Since the side effects are less compared to nifedipine and increased efficacy when used topically ,it is preferred.

#### **BOTULINUM TOXIN [BOTOX]**

It has been used to treat acute and chronic anal fissures. It is injected directly into the inter anal sphincter, in effect performing a chemical sphincterotomy. The effect lasts about 3 months, until nerve endings regenerate. This 3-month period may allow acute fissures (and sometimes chronic fissures) to heal and symptoms to resolve. Although botulinum toxin injection provides initial relief of symptoms but there is a recurrence after 3 months. Hence, it is lesspreferred.

### SURGICAL THERAPY

It includes,

1. Sphincterotomy.

Lord's Anal Dilatation
 Pneumatic Baloon Dilatation

4 .Fissurectomy

5. Ano Rectal AdvancementFlap

## SPHINCTEROTOMY

The purpose of the operation is to cut the hypertrophied internal sphincter,

thereby releasing tension and allowing the fissure to heal. It is of 2 types.

- 1. Posterior Sphincterotomy
- 2. Lateral sphincterotomy

#### **POSTERIOR SPHINCTEROTOMY**

It involves division of the internal sphincter fibres at posterior midline upto the dentate line . Due to adverse effects like frequent fecal soiling and key hole deformity it has been replaced by Lateral sphincterotomy.

### LATERAL SPHINCTEROTOMY

It involves division of internal anal sphincter at 3 or 9 O clock position . It can be done either by closed or open method. In a closed sphincterotomy, a No. 11 blade is inserted sideways into the intersphincteric groove laterally. It is then rotated medially and drawn out to cut the internal sphincter.

Care is taken not to cut the anal mucosa, because doing so could result in a fistula. After the knife is removed, the anal mucosa overlying the sphincterotomy is palpated, and a gap in the internal sphincter can be felt through it. The sphincterotomy is extended into the anal canal for a distance equal to the length of the anal fissure.

In an open sphincterotomy, a 0.5-to1-cmincisionis made in the Intersphincteric plane .The internal sphincter is then looped on a right angle and brought up into the incision. The internal sphincter is then cut under direct visualization. The two ends are allowed to fall back after being cut. A gap can then be palpated in the internal sphincter through the anal mucosa, as in the closed technique. The incision can be closed or left open to heal.

## **OPEN LATERAL INTERNAL SPHINCTEROTOMY**



# **CLOSED LATERAL INTERNAL SPHINCTEROTOMY**



#### LORD'S ANAL DILATATION

In the early 1990s, a repeatable method of anal dilatation proved to be very effective and showed a very low incidence of side effects. But it has fallen out of favour in recent years, primarily due to the unacceptably high incidence of fecal incontinence. In addition, anal stretching can increase the rate of flatus incontinence.



### PNEUMATIC BALLOON DILATATION

Anal dilatation was done with park's retractor opening upto 4.8 cms with a 40 mm recto sigmoid balloon. Similar to Lord's method, here pneumatic pressure is used to stretch the sphincter with lower incidence of fecal incontinence.



### FISSURECTOMY

It involves simple excision of fissure with indurated base along with the skin tag . The resultant raw area is closed primarily or with ano rectal v-y advancement flaps.

### ANO RECTAL V-Y ADVANCEMENT FLAPS

The recognition of the risk to continence following internal sphincterotomy has led some to advocate a different approach, especially in women and those with normal or low resting anal pressures, developed from the treatment of anal stenosis. After excision of the edges of the fissure and, if necessary, its base overlying the internal sphincter, an inverted house-shaped flap of perianal skin is carefully mobilised on its blood supply and advanced without tension to cover the fissure, and then sutured with interrupted absorbable sutures. The patient is maintained on stool softeners and bulking agents postoperatively, and usually also on topical sphincter relaxants minor breakdown of one anastomotic edge does not herald ultimate failure. The technique appears to work irrespective of sphincter hypertonicity or patient gender.



Mobilised skin flap prior to suturing intra-anally over the debrided and freshened Posterior fissure base

#### STATISTICAL ANALYSIS

#### **STUDY DEMOGRAPHY**

The study involved 183 patients diagnosed with Chronic fissure in ano attending the Surgery OPD, Chengalpattu medical college and hospital, Chengalpattu – 603001.<u>The</u> final sample was 183 patients with 90 in Group A and 93 in GroupB.

### AGE DISTRIBUTION

Age distribution of the Sample population ranged from 16 to 64 years, with an average age of 37 years.



Figure 5.1 Age Distribution Of The Sample

### **GENDER RATIO**

Females outnumbered the male subjects with the ratio of 5:4 in the study which included 83 Males and 100females.





### **CHRONIC FISSURE IN ANO**

All the patients in the study presented with the classical symptoms of

Chronic Fissure in ano i.e. bleeding per anum and Painful defecation.

Chronic Anal fissure were further classified according to their site of location into

 $\Sigma$ ANTERIOR(7%)

ΣPOSTERIOR (Most Common91.25%)

 $\Sigma$ ANTERIOR + POSTERIOR(1.64%)



**Figure 5.3 Locations Of Chronic Anal Fissures.** 

### **ANALYSIS OF GROUP A - (Chemical Sphincterotomy)**

In group A, total of 90 patients were treated with the Topical application of 2% Glyceryl TriNitrate ointment thrice daily for 6 consecutive weeks.

### **FISSURE HEALING**

Fissures started healing completely only by the  $4^{th}$  week and the final cure rate was 84.4 %( 76/90) at the  $10^{th}$  week.

FISSURE HEALING RATE								
2 <sup>nd</sup> Wk	4 <sup>th</sup> Wk	6 <sup>th</sup> Wk	8 <sup>th</sup> Wk	10 <sup>th</sup> Wk	Final Cure Rate			
0	38 (42.2%)	70 (77.78%)	76 (84.4%)	76 (84.4%)	76 (84.4%)			

 Table 5.1 Fissure Healing Rate in Chemical sphincterotomy.



Figure 5.4 Fissure Healing Rate In Chemical Sphincterotomy.

#### **AVERAGE RECOVERY TIME**

The average time taken for complete healing of Fissure was about 5.18 Weeks in GroupA.

#### PAIN RELIEF

The average initial pain score was 7.66 in Group A and the response to treatment in the form of immediate pain relief was achieved early in the treatment, right from the 2<sup>nd</sup> week itself. A drop in pain score from 7.66 to 3.93 occurred in first 2 weeks of treatment that is the pain was nearly halved in first 2 weeks, allowing the patients to resume their work sooner. Pain score of 3 and below (Mild) was considered to be target and was achieved by 6<sup>th</sup>week.

INITIAL	2 <sup>nd</sup> week	4 <sup>th</sup> week	6 <sup>th</sup> week	8 <sup>th</sup> week	10 <sup>th</sup> week
7.66	3.93	3.41	2.81	2.36	2.24

Table 5.2: Average pain Scoring in Group A



82

33

Figure 5.5 Mean Pain Score In Group A

### **RECOVERY OF BLEEDING PER ANUM**

The most apprehensive symptom of the patients, Bleeding per Anum was cured more faster than the Pain Relief. About 75% of patients were freed of this distressing symptom in first 2 weeks and by 10<sup>th</sup> week, 87.78% of patients were cured of this symptom.

<b>BLEEDING PR RECOVERY</b>								
2 <sup>nd</sup> Wk	4thWk	6thWk	8thWk	10thWk				
67 (74.4%)	79 (87.78%)	79 (87.78%)	79 (87.78%)	79 (87.78%)				



## Figure 5.6 Bleeding Per Anum Recovery Rate

### WORK RESUME TIME

Work resume time correlated directly with the relief of Pain and Bleeding per anum symptoms which was about 3.37Weeks in Group A. In other words patients in group A resumed their day to day productive life in 3.37 weeks on an average.

### **MORBIDITY OF TREATMENT**

Among the Group A involving the chemical Sphincterotomy using 2% Topical Glyceryl Trinitrate, the major adverse effects were Headache & Itching. The incidence of itching and headache was 15.6% and 22.22% respectively. Anal Incontinence was reported to be very low i.e. only 2 out of 90 patients (2.22%) which was temporarily.



**Figure 5.7 Morbidity Of Chemical Sphincterotmy** 

#### **RECURRENCE & CONVERSION RATE**

The Recurrence rate in group A was 6.67% that is 6 patients developed Fissures at the same site after complete healing of the Fissure within 2 months past the treatment.

Similarly patients who didn't respond to chemical methods and those who had recurrences were allowed to undergo the standard surgical Sphincterotmy. They were 15 patients in this category leading to the conversion rate of 16.67%.

RECURRENCE	CONVERSION
RATE	RATE
6(6.67%)	15(16.67%)

### Table 5.4 Recurrence & Conversion Rate

### **ANALYSIS OF GROUP B**

### (SURGICAL SPHINCTEROTOMY)

Group B patients were admitted as inpatient and treated with the standard Surgical method of Lateral Internal Sphincterotomy under spinal anaesthesia. There were 93 patients in this Group.

### **FISSURE HEALING**

Healing rates with the Gold Standard Surgical method was about 97.85%. Healing started by 4<sup>th</sup> week and completed by 8weeks.

	FISSURE HEALING RATE – GROUP B							
2nd Wk	4th Wk	6th Wk	8th Wk	10th Wk				
0	54 (58.06%)	88 (94.62%)	91 (97.85%)	91 (97.85%)				

Table 5.5 Fissure Healing Rate In Group B



Figure 5.8 Fissure Healing Rates In Group B

### AVERAGE RECOVERY TIME

The average recovery time in Group B was 4.84 weeks by which the complete healing of Fissure was achieved.

## PAIN RELIEF

Pain relief was evident starting from the  $2^{nd}$  week and the scoreless than 3 was achieved by  $4^{th}$  week itself. The final average Pain score was 0.55 indicating complete pain relief in the patients.

AVERAGE PAIN SCORE						
Initial	2nd week	4th week	6th week	8th week	10th week	
7.92	3.4	2.17	1.41	0.83	0.55	

## Table 5.6 Pain Relief Rate In Group B



## Figure 5.9 Pain Relief Rate In Group B

## **RECOVERY OF BLEEDING PER ANUM**

Bleeding per anum was relieved in 68% of patients by second week and by 10<sup>th</sup> week, 98.92% of patients had no bleeding per anum.



### **Table 5.7 Recovery of Bleeding Per Anum In Group B**

Figure 5.10 Recovery Of Bleeding Per Anum In Group B

### WORK RESUME TIME

Patients resumed their normal work by 3.19 weeks on an average in Group B after undergoing the Surgical sphincterotomy.

## **MORBIDITY OF TREATMENT**

Immediate post-surgical complications included Post-operative Pain, Bleeding from Sphincterotomy site, surgical site Infection and Faecal Incontinence.



### Figure 5.11 Morbidity Of Surgical Sphincterotomy In Group B

MORBIDITY	PATIENTS	PERCENTAGE
Post-OP pain	40	43.01%
Post-OP bleeding	21	22.58%
Surgical Site Infection	3	3.23%
Faecal Incontinence	27	29.03%

### **Table 5.8 Morbidity Of Surgical Sphincterotomy**

Faecal Incontinence was the most distressful problem in the post- surgical patients, which was temporary in 88.89% cases, that is among the affected 27 patients, 24 had recovered from the problem in 10 weeks and 3 patients had permanent Faecal incontinence.

#### **RECURRENCE AND CONVERSION RATE**

In Group B involving the Surgical sphincterotomy method there was nil recurrence and the conversion rate was 2.15% (2 out of 93), proving the reliability of this Gold Standard method.

RECURRENCE	CONVERSION
RATE	RATE
0	2(2.15%)

**Table 5.9 Recurrences And Conversion In Group** 

#### STATISTICAL COMPARISON OF BOTH GROUP A & B

### **Statistical analysis**

In the above study, the statistical methods were, for quantitative data, descriptive statistics was presented by N, Mean, Standard Deviation and Range. For qualitative data, frequency count N and percentage were displayed in a tabular manner.

To analyze the data, an appropriate statistical tests were applied suchas to compare the two groups Independent Samples Test- t test for Equality of Means by using statistical software SPSS (version 16.0) and Other data displayed by various tables and charts by using Microsoft excel (windows 2010).

\*Significant at p < 0.05

\*\* very significant p <0.01

\*\*\* highly significant p < 0.001,\*\*\* highly significant p < 0.000

	t-test for Equality of Means						C I of erence
PARAMETE RS	Mean Differen ce	t	df	p value	Std. Error Differen ce	Lowe r	Uppe r
INITIAL PAIN	-0.18	- 1.44 1	18 1	0.151	0.125	0.427	0.06 7
PAIN SCORE 2ndweek	0.546	2.42	18 1	0.016*	0.226	0.101	0.99 2
PAIN SCORE 4thweek	1.239	5.49 4	18 1	0.0001* **	0.226	0.794	1.68 4
PAIN SCORE 6thweek	1.413	5.69 4	18 1	0.0001* **	0.248	0.923	1.90 3
PAIN SCORE 8thweek	1.528	6.44	18 1	0.0001* **	0.237	1.06	1.99 6
PAIN SCORE 10thweek	1.739	7.12	18 1	0.0001* **	0.244	1.257	2.22 1
BPR2ndWk	-0.067	- 0.99 7	18 1	0.32	0.067	-0.2	0.06 6
BPR4thWk	0.079	1.96 3	18 1	0.051*	0.04	0	0.15 9
BPR6thWk	0.134	3.03	18 1	0.003**	0.044	0.047	0.22 1
BPR8thWk	0.123	3.04 8	18 1	0.003**	0.04	0.043	0.20 2
BPR10thWk	0.123	3.04 8	18 1	0.003**	0.04	0.043	0.20 2
FH4thWk	-0.158	- 2.15 8	18 1	0.032*	0.073	0.303	- 0.01 4

FH6thWk	-0.168	-	18	0.001**	0.05	-	-
		3.40 3	1			0.200	1
FH8thWk	-0.134	- 3 28	18 1	0.001**	0.041	- 0.215	- 0.05
		5. <b>2</b> 0 6	1			0.213	4
FINAL CURE	-0.123	-	18	0.002**	0.04	-	-
KAIE		3.09	1			0.201	0.04 5
INCONTINEN	-0.268	-	18	0.0001*	0.051	-	-
CE		5.50 8	1			0.308	0.16 8
INC –TEMP	-0.236	-	18	0.0001*	0.049	-	-
		4.82 7	1	ጥጥ		0.332	0.13 9
INC-	-0.033	-	18	0.085	0.019	-	0.00
PERMANENT		1.73	0			0.07	5
Work Resume	0.182	0.74	16	0.455	0.242	-	0.66
time		9	5			0.297	
RECOVERYTI ME	0.391	2.06	16 6	0.041*	0.19	0.016	0.76 5
RECURRENCE	0.056	1.98	18	0.049*	0.028	0	0.11
		2	1				2
CONVERSION	0.16	3.89 6	17 8	0.0001* **	0.041	0.079	0.24
		Ŭ	Ŭ				

# Table 5.10 Statistical Analysis of the Study

## { Df- degree of freedom.BPR- Bleeding per rectum, FH- Fissure healing, INC- Incontinence.}
## FISSURE HEALING RATES OF GROUP A & B

The overall healing rates were better in Group B with 97.85% of cure rates when compared to the Group A (84.4%). Also response was quicker in Group B starting from 4<sup>th</sup> week.

FISSURE HEALING RATE								
Group	2 <sup>nd</sup> wk	4 <sup>th</sup> wk	6 <sup>th wk</sup>	8 <sup>th wk</sup>	10 <sup>th</sup> wk	Success Rate		
А	0	38 (42.2%)	70 (77.78%)	76 (84.4%)	76 (84.4%)	76 (84.4%)		
В	0	54 (58.06%)	88 (94.62%)	91 (97.85%)	91 (97.85%)	91 (97.85%)		

## Table 5.11 Comparison Of Healing Rates In Group A &B



## Figure 5.12 Comparison Of Healing Rates In Group A & B

The p value was found to be significant right from the 4<sup>th</sup> week (0.032\*) and the final cure rate was statistically very significant with a p value of 0.002\*\*. Thus Group B patients undergoing Surgical sphincterotomy had a better cure rate than the Group A patients with Chemical Sphincterotomy.

### AVERAGE RECOVERY TIME

The average recovery time was earlier in Group B (4.84Weeks) than in

Group A (5.18Weeks). The p value 0.041\* was statistically significant.

 Table 5.13 Comparison Of Average Recovery Time

	INDEPENDENT SAMPLE TEST								
	t-test	t-test for Equality of Means 95% C I of the Difference							
Fissure Healing over Weeks	Mean Difference	t	df	p value	Std. Error Difference	Lower	Upper		
4thWeek	-0.158	- 2.158	181	0.032*	0.073	-0.303	-0.014		
6thWeek	-0.168	- 3.403	181	0.001**	0.05	-0.266	-0.071		
8thWeek	-0.134	- 3.286	181	0.001**	0.041	-0.215	-0.054		
Final Cure Rate 10 <sup>th</sup> week	-0.123	- 3.093	181	0.002**	0.04	-0.201	-0.045		



## Figure 5.13 Comparison Of Average Recovery Time

#### PAIN RELIEF

On comparison the Pain relief was much better and faster in Group B compared to Group A. Pain score less than 3 was achieved in Group B by 4<sup>th</sup> week, whereas it was only in the 6<sup>th</sup> week with Group A. The final pain scores were 0.55 in Group B and 2.24 in GroupA, indicating that ultimate pain relief was better in Group B.

PAIN SCORE MEAN							
Group	Initial	2nd week	4th week	6th week	8th week	10th week	
А	7.66	3.93	3.41	2.81	2.36	2.24	
В	7.92	3.4	2.17	1.41	0.83	0.55	



Figure 5.14 Comparisons Of Pain Scores In Group A And B

From Statistical point of view the Pain relief was significant from the  $2^{nd}$  week itself (p=0.016\*) and then onwards it was very much significant (p=0.0001\*\*\*), clearly depicting that the Pain Relief in Group B was certainly better than Group A.

## Table 5.15 Statistical p Value For Pain Relief

	INDEPENDENT SAMPLE TEST							
	t-tes	99 Conf Int	5% ïdence erval					
Pain Score	Mean Difference	t	df	p value	Std. Error Difference	Lower	Upper	
Initial Pain	-0.18	- 1.441	181	0.151	0.125	-0.427	0.067	
2ndweek	0.546	2.42	181	0.016*	0.226	0.101	0.992	
4thweek	1.239	5.494	181	0.0001***	0.226	0.794	1.684	
6thweek	1.413	5.694	181	0.0001***	0.248	0.923	1.903	
8thweek	1.528	6.44	181	0.0001***	0.237	1.06	1.996	

## **RECOVERY OF BLEEDING PER ANUM**

Bleeding per anum became nil for 87.78% of patients in Group A and 98.92% of patients in Group B by the end of 10<sup>th</sup> week, which correlated with the Fissure healing rates. Recovery was actually better in Group B but appeared to be little faster in Group A during the early course of treatment i.e. first 2 weeks.

	<b>BLEEDING PR RECOVERY</b>						
Group	2nd Wk	4thWk	6thWk	8thWk	10thWk		
A	67 (74.4%)	79 (87.78%)	79 (87.78%)	79 (87.78%)	79 (87.78%)		
В	63 (67.74%)	89 (95.7%)	92 (98.92%)	92 (98.92%)	92 (98.92%)		

Table 5.15 Comparison Of Recovery Of Bleeding Per Anum In Group A&B



## Figure 5.15 Comparison Of Recovery Of Bleeding Per Anum In Group A &B

The recovery of Bleeding per anum was statistically significant from the 4<sup>th</sup> week onwards with p value of  $0.051^*$ . In the subsequentweeks (6<sup>th</sup>th , 8<sup>th</sup>& 10<sup>th</sup>week) the p value was verysignificant(p=0.003\*\*), showing that the recovery was better in Group B.

	Independent Samples Test							
	t-tes	ns	9 Con Int	95% fidence terval				
Pain Score	Mean Difference	t	df	p value	Std. Error Difference	Lower	Upper	
2ndWk	-0.067	- 0.997	181	0.32	0.067	-0.2	0.066	
4thWk	0.079	1.963	181	0.051*	0.04	0	0.159	
6thWk	0.134	3.03	181	0.003**	0.044	0.047	0.221	
8thWk	0.123	3.048	181	0.003**	0.04	0.043	0.202	
10thWk	0.123	3.048	181	0.003**	0.04	0.043	0.202	

# Table 5.17 Comparison Of Recovery Of Bleeding Per Anum In<br/>Group A& B

#### WORK RESUME TIME

Work resuming Time was little better with Group B (3.19Weeks) over Group A(3.37Weeks) with p value of 0.455, suggesting not much of statistical significance.

#### **MORBIDITY OF TREATMENT**

Each group had its own specific morbid aspects such as Headache & Itching in Group A and Post-operative pain, Surgical site bleeding & Infection in Group B, which could not be compared.

Faecal incontinence was the factor specially measured in both groups. Group A patients had better continence profile than the Group B

FAECAL INCONTINENCE						
GROUP	+/-	ТЕМР	PERMANENT			
А	2(2.22%)	2	0			
В	27(29.03%)	24(25.80%)	3(3.22%)			

#### Table 5.18 Faecal Incontinence Comparison

And that p value was very much significant(0.0001\*\*\*), suggesting that the incidence of Faecal incontinence in Group A was very rare, while it was common with (GroupB) Post-surgical patients.

INDEPENDENT SAMPLE TEST							
	t-test for Equality of Means Interval						
	Mean Differenc e	t	df	p value	Std. Error Differenc e	Lowe r	Uppe r
Incontinenc e	-0.268	- 5.30 8	18 1	0.0001** *	0.051	- 0.368	- 0.168

 Table 5.19 Faecal Incontinence Comparison p Value.

#### **RECURRENCE AND CONVERSION RATE**

Recurrence with the Surgical method was nil and its conversion rate due to failure was only 2.15% (2/93). Whereas in Group A , the Recurrence was 6 out of 90(6.67%) and the conversion rate was 16.67% (15 out of 90, including both failures and recurrence cases). The statistical analysis showed that the Recurrence in Group A was significant ( $p=0.049^*$ ) and the conversion rate was very much significant( $p=0.0001^{***}$ ).

INDEPENDENT SAMPLE TEST							
	t-tes	95% Cor Inte	nfidence erval				
	Mean Difference	t	D f	p value	Std. Error	Lower limit	Upper limit
Recurrence rate	0.056	1.982	181	0.049*	0.028	0	0.112
Conversion rate	0.16	3.896	178	0.0001***	0.041	0.079	0.24

 Table 5.20 Statistical p Values Of Recurrence & Conversion Rates.

#### DISCUSSION

The analysis of the study between both the treatment groups was done and the results were compared with literature for establishing its significance. Starting from the primary objective of Fissure healing rates to the secondary objectives of recovery of Pain, Bleeding Per anum, Morbidity of the treatment & Recurrence rate were analysed and discussed in a detailed manner.

#### **Fissure Healing Rate**[71-76]

In the present study the overall healing rates were better in Group B with 97.85% of cure rates when compared to that of the Group A(84.4%). Healing of fissure was completed by 4 to 8 weeks in both the groups. But response was quicker in Group B starting from 4<sup>th</sup>week.

When compared with the previous similar studies in the literature the healing rate of chemical method with 2% Topical Glyceryl Trinitrate were ranging from 60 to 89%. The Fissure healing rate in the present study is comparable with most of the studies.

Study	Healing rate with 0.2% Glyceryl Trinitrate
Rithin Suvarna Et al 2012	69.23%
<u>Giridhar C. M</u> Et al 2014	88.4%
Ansar Latif Et al 2013	74%
Manjunath S Kotennava Et al2012	60%
Rajan vaithyanathan Et al 2015	71%
Madhusudhan M. Et 2014	89.36%
Nelson et al. 2012	80%
Sanei et al. 2009	67%
Present study	84.4%

# Table 6.1 Healing Rates with 0.2% Glyceryl Trinitrate in<br/>Chronic Fissure in Ano.

The healing rates with Surgical method was constantly high(>95%) in all the above trials including the present study.

## Recovery time [71-76]

The average Recovery time with Topical Glyceryl Trinitrate was 5.18 weeks which is one of the lesser recovery time as compared to literature(Table6.2) and is very close to that of the Surgical method(4.84 weeks in the present study).

Study	Average recovery time with topical 0.2% Glyceryl Trinitrate
<u>Sanei et al. 2009</u>	7.58±2.01
Abd Elhady et al. 2009	5.1±1.13 weeks
Manjunath S Kotennavar et al2012	7.2 weeks
<u>Giridhar C. M</u> et al 2014	5.04 weeks
PRESENT STUDY	5.18 weeks

# Table 6.2 Average Recovery Time with 0.2% TopicalGlycerylTrinitrate

## Pain Recovery[71-76]

On comparison the Pain relief was much better and faster in Group B compared to Group A. Pain score less than 3 was achieved in Group B by 4<sup>th</sup> week, and in group A by 6<sup>th</sup> week. The final pain scores were 0.55 in Group B and 2.24 in Group A, indicating that ultimate pain relief was better in Group B. The total percentage of pain recovery was 84% in Group A, which is comparable with the literature(Table6.3).

Study	Final Pain Score	% Of Recovery With Glyceryl Trinitrate
Madhusudhan M. et al 2014	-	89.4%
Rajavaithyanathan et al 2015	3.38	-
<u>Giridhar C. M</u> et al 2014	-	78.26%
PRESENT STUDY	2.24	84%

## Table 6.3 Pain Recovery with 2 % Glyceryl Trinitrate

#### **Recovery of Bleeding per Anum**

The total recovery rate by the 10<sup>th</sup> week in group A was 87.78% and that of Group B was 98.92%. Not much of the studies give data regarding the recovery of bleeding per anum. But the available literature suggests that the recovery of bleeding peranum is one of the earliest response to the treatment along with the Pain recovery (Table6.4). In our study the response was quicker in both groups. The cure of bleeding per anum was achieved by 2weeks in nearly 75% patients of both Groups, which is faster as compared to that achieved by Manjunath S Koteennavaret al.

Study	Early response time
Manjunath S Kotennavar et al2012	3weeks
Present Study	2 weeks

## Table 6.4 Recovery of Bleeding per rectum with GlycerylTrinitrate.

### **MORBIDITY OF THE TREATMENT[71-76]**

#### **I.Faecal Incontinence rate**

Faecal incontinence was analysed based on the duration and separately classified as Temporary (<10 weeks) and Permanent (>10weeks).

The Temporary incontinence was initially reported to be in 2.22% patients of Group A and 29.03% patients in Group B. The permanent incontinence was nil in Group A and was about in 3.22% in Group B which correlates with the data available in the literature (Table6.5).

STUDY	2% Glyceryl Trinitrate	Surgical Sphincterotomy
Madhusudhan M. et al 2014	Nil	2.1%
Ansar Latif et al 2013	Nil	6%
Rithin Suvarna et al 2012	Nil	9.27%
Majid Aziz et al 2009	Nil	3.33%
Present Study	Temporary- 2.22% Permanent- Nil	Temporary-29.03% Permanent- 3.22%

## Table 6.5 Faecal Incontinence Rate in Surgical and GlycerylTrinitrate Groups

## **II.Headache**

The headache was specifically associated with Group A and its incidence was 22.22% with that of Glyceryl trinitrate (67%) as reported by Rithin Suvarna et al.

STUDY	Incidence of Headache
Manjunath S Kotennavar et al 2012	5.71%
Rithin Suvarna et al 2012	5.49%
Present Study	22.22%

### Table 6.6 Headache in Glyceryl Trinitrate group

## **III.Itching**

Local itching was reported to be in 15.6% patients of Group A, which was higher than that reported by madhusudhan M et al(4.3%). But it was mostly temporary which lasted few minutes after application of theOintment.

Study	Incidence of Itching
Madhusudhan M et al 2014	4.3%
Present Study	15.6%

## Table 6.7 Incidence of Itching in Glyceryl Trinitrate group

### **IV.Post-operative Pain, Surgical Site Bleeding &Infection**

In the Surgical group the specific drawbacks were Post-operative pain (43.01%), Surgical site bleeding (22.58%) & Infection (3.23%).

Study	Infection Rate	
Rajan Vaithianathan et al 2015	4.44%	
Present Study	3.23%	

## Table 6.8 Infection rate in Surgical group.

## **Recurrence Rate**[71-76]

In the present study the recurrence rate in Group A (0.2% Glyceryl Trinitrate) was 6.67%, whereas it was nil with surgical method. The recurrence rate in the current Study was much lower than that reported in the literature. The data suggests Chemical sphincterotomy can definitively be used as an alternative to surgery when used with proper methodology and compliance.

Study	Recurrence rate
Nelson et al. 2012	12.5%
Abd Elhady et al. 2009	65%
Samim et al. 2012	17.6%
Suvarna et al. 2012	10.43%
Cevik et al. 2011	11.1%
Madhusudhan M et al 2014	2.1%
<u>Ansar Latif</u> et al 2013	25%
Rithin Suvarna et al 2012	10.43%
Present Study	6.67%

**Table 6.9 Recurrence Rate in Glyceryl Trinitrate Groups** 

The final inference drawn from these observations is that the Chemical Sphincterotomy using 0.2% Glyceryl Trinitrate has better side effect profile and good comparable healing rates in the treatment of Chronic Anal Fissures. The drawbacks that could be mentioned are the slower response, longer duration of treatment and more chances of recurrence. Considering all these parameters it could be recommended that 0.2% Topical Glyceryl Trinitrate is the best available alternative for Surgical method in treatment of chronic fissure in ano.. And surgery can be reserved for Non-responders alone.

#### SUMMARY

The current study was an interventional study which compared the Chemical Sphincterotomy (using 0.2% Topical Glyceryl Trinitrate gel) with Surgical Sphincterotomy (Open Lateral Internal Sphincterotomy). The sample was selected from the population with specific Inclusion & Exclusion criteria. The total sample size was 183 patients in this trial of which 90 belonged to Group A (Chemical Sphincterotomy) and 93 belonged to Group B (Surgical Sphincterotomy). The following parameters were compared between the twogroups.

- Fissure Healing Rate
- Pain Recovery Rate
- Bleeding per Anum RecoveryRate
- Work ResumeTime
- Morbidity of theTreatment
- Faecal incontinence
- RecoveryTime
- Recurrence Rate
- Conversion
- Rate

The study was done in Chengalpattu Medical College & Hospital, Chengalpattu between JAN2018 to DEC 2018. The findings were interpreted as below

#### **Fissure Healing Rate:**

The final cure rate at 10<sup>th</sup> week for both the Groups was 84.4% in Chemical sphincterotomy and 97.85% in surgical sphincterotomy. The complete Fissure healing was documented from 4<sup>th</sup> week in both the Groups. The Surgical sphincterotomy had better healing than the Chemical method which was also statistically very significant.

## **Pain Recovery Rate:**

The pain recovery was evident from the 2<sup>nd</sup> week in both the groups with the initial pain being halved. The final average pain score by 10<sup>th</sup> week in Group A (chemical Sphincterotomy) was 2.24, which was acceptable. Whereas in Group B (Surgical sphincterotomy) the final pain average was 0.55 (very negligible) showing complete resolution of symptoms. The rate of recovery was also faster in Group B than Group A.

#### **Bleeding Per Anum Recovery Rate:**

The recovery of Bleeding per anum also occurred early in the treatment by 2<sup>nd</sup> week in both the groups. The final recovery rates by 10<sup>th</sup> week were 87.78% in Group A and 98.92% in Group B, which correlates with Fissure healingrates.

#### Work Resume Time:

The average work resuming time were 3.37 weeks in Group A (Chemical Sphincterotomy) and 3.19 weeks in Group B which correlated with the recovery of Pain and Bleeding per anum. The work resuming time was not statistically significant.

#### **Recovery Time**:

The recovery time showed the average Fissure Healing time. It was better in group B (Surgical Sphincterotomy) with about 4.84 weeks as its average recovery time while it was 5.18 weeks with Group A (Chemicalsphincterotomy).

#### **Morbidity of Treatment**

Each group had its unique drawbacks. Group A had headache (22.22%) and itching (15.6%) as its unique side effects. Group B patients had Post-operative Pain (43.01%), Surgical site bleeding (22.58%) and Surgical site infections (3.23%).

#### **Faecal incontinence**

Faecal incontinence was mostly experienced by the Group B (Surgical sphincterotomy) patients in about 29.03% of them. Whereas it was only 2.22% in Group A Patients (ChemicalSphincterotomy), that too only temporarily. Also out of the 27 patients only 3 had permanentincontinence.

#### **Recurrence Rate & Conversion Rate**

There was nil recurrence in Surgical limb (Group B) re- establishing that it is the Gold Standard in the treatment of Chronic fissure in ano. In group A (chemical Limb) the recurrence rate was 6.67%.

The conversion rate was about 16.67% in Group A and 2.15% in group B reflecting that failure rates were higher in Group A so that patients needed to shift to the Gold standard treatment.

The final inference from the study was that Group B (Surgical sphincterotomy) patients definitely had better recovery & response to the treatment than the Group A (Chemical Sphincterotomy) patients. The only notable major drawback was the higher faecal incontinence rate in Group B. On the other hand group A patients also had significantly good recovery and response to the Chemical sphincterotomy method with lesser morbidity.

#### CONCLUSION

In present study it was observed that Chemical sphincterotomy with 0.2% Topical Glyceryl Trinitrate in the management of Chronic fissure in ano in comparison with surgical sphincterotomy has :-

- I. Significant fissure healing rate
- II. Early recovery of bleeding per anum and pain with lesser recovery time
- III. Least side effect profile including risk of faecal incontinence
- IV. Significant recurrence rate requiring surgical modality for nonresponders
- V. Needs proper patient education, motivation and a compliance

Thus the present study concludes that the Chemical sphincterotomy with 0.2% Topical Glyceryl Trinitrate gel should be used as the primary treatment of choice in the management of Chronic fissure in ano, while the surgical method must be kept reserved for the non- responders.

#### **BIBLIOGRAPHY**

- 1. Gott, M. D.; Peter, H. (5 March 1998). "New Therapy Coming for Anal Fissures". The Fresno Bee (Fresno, CA: McClatchy Co). p. E2, "Life"section.
- Collins, E. E.; Lund, J. N. (September 2007). "A Review of Chronic Anal Fissure Management". Techniques in Coloproctology11 (3): 209– 223.doi:10.1007/s10151-007-0355-9.PMID17676270.
- 3. Best Practice. British Medical Journal. Apr 23, 2012. Retrieved 30 June2012.
- 4. Basson, Marc D. (28 January 2010). "Constipation". eMedicine.New<u>York, NY: WebMD.</u> Retrieved 5 April2010.
- 5. Nelson RL, Thomas K, Morgan J, Jones A (2012). "Non surgical therapy for anal fissure". Cochrane Database of Systematic Reviews2:CD003431.doi:10.1002/14651858.CD003431.pub3.PMID 22336789.
- Haq., Z.; Rahman, M.; Chowdhury, R.; Baten, M.; Khatun, M. (2005). "Chemical Sphincterotomy—First Line of Treatment for Chronic Anal Fissure". Mymensingh Medical Journal 14 (1): 88–90.PMID15695964.
- 7. Shao,WJ;Li,GC;Zhang,ZK(September2009)."Systematic review and meta-analysis of randomized controlled trials comparing botulinum toxin injection with lateral internal
  - a. sphincterotomy for chronic anal fissure". International journal of colorectal disease 24(9): 995–1000. <u>doi:10.1007/s00384-009-0683-5.PMID 19266207</u>.
- 8. <u>Anal Fissure Treatment Overview".</u> WebMD. Retrieved27 September2011.
- 9. Poritz, Lisa Susan.<u>"Anal Fissure Treatment & Management".</u> Medscape. Retrieved 27 September2011.
- Loder, P.; Kamm, M.; Nicholls, R.; Phillips, R. (1994). "'Reversible Chemical Sphincterotomy' by Local Application of Glyceryl Trinitrate". British Journal of Surgery 81 (9): 1386–<u>1389.doi:10.1002/bjs.1800810949. PMID7953427.</u>
- 11. Lockhart Mummery JP (1934) Diseases of the rectum and colon and their surgical treatment. (MacMillan,Toronto)
- 12. Pescatori M, Interisano A (1995) Annual report of the Italian coloproctology units. Tech Coloproctol3:29-30
- 13. Klosterhalfen B, Vogel P, Rixen H, ef al. (1989) Topography of the inferior rectal artery: a possible cause of chronic, primary analfissure. Dis Colon

Rectum32:43-52.

- 14. Prohm P, Bonner C (1995) Is manometry essential for surgery of chronic fissure-in-ano? Dis ColonRectum38:735-738.
- 15. Schouten WR, Briel JW, Auwerda JJ (1994) Relationship betweenanalpressureandanodermalbloodflow.Thevascular
  - a. pathogenesis of anal fissures. Dis Colon Rectum 37:664-669.
- 16. Minguez M, Tomas-Ridocci M, Garcia A, ef al. (1992) Pressure of the anal canal in patients with haemorrhoids or with anal fissure. Effect of the topical application of an anaestheticgel.
  - a. Rev Esp Enferm Dig 81:103-107.
- Rosen L, Abel ME, Gordon PH, ef al. (1992) Practice parameters for the management of anal fissure. The Standards Task Force AmericanSocietyofColonandRectalSurgeons.DisColon
  - a. Rectum 35:206-208.
- 18. Notaras MJ (1969) Lateral subcutaneous sphincterotomy for analfissure—a new technique. Proc R Soc Med6
- 19. Khubchandani IT, Reed JF (1989) Sequelae of internal sphincterotomyforchronicfissureinano.BrJSurg76:431-434.
- 20. Pernikoff BJ, Eisenstat TE, Rubin RJ, ef al. (1994) Reappraisal of partial lateral internal sphincterotomy. Dis Colon Rectum 37:1291-1295.
- 21. Sultan AH, Kamm MA, Nicholls RJ, ef al. (1994) Prospective study of the extent of internal anal sphincter division during lateral sphincterotomy. Dis Colon Rectum37:1031-1033.
- 22. Garcia-Aguilar J, Belmonte Montes C, Perez JJ, ef al. (1998) Incontinence after lateral internal sphincterotomy: anatomic and functional evaluation [see comments]. DisColon Rectum 41:423-427. 23
- 23. Garcia-Aguilar J, Belmonte C, Wong WD, ef al. (1996) Open vs closed sphincterotomy for chronic anal fissure: long-term results. Dis Colon Rectum39:440-443.
- 24. Jensen SL, Lund F, Nielsen OV, ef al. (1984) Lateral subcutaneous sphincterotomy versus anal dilatation in the treatment of fissure in ano in outpatients: a prospective randomised study. BMJ289:528-530.

- 25. Abcarian H (1980) Surgical correction of chronic anal fissure: results of lateral internal sphincterotomy vs fissurectomy-midline sphincterotomy. Dis Colon Rectum 23:31-36.
- 26. (1980) Classic articles in colonic and rectal surgery. Stretching, massage and rhythmic percussion in the treatment of muscular contractions: Joseph-Claude-Anthelme Recamier (1774-1852).
  - a. Dis Colon Rectum 23:362-367.
- 27. Lord PH (1968) A new regime for the treatment of haemorrhoids. Proc R Soc Med 61:935-936. Weaver RM, Ambrose NS, Alexander-Williams J, ef al. (1987) Manual dilatation of the anus vs lateral subcutaneous sphincterotomy in the treatment of chronic fissure-in-ano. Results of a prospective, randomized, clinical trial. Dis Colon Rectum30:420-423.
- 28. Sohn N, Eisenberg MM, Weinstein MA, ef al. (1992)Precise anorectal sphincter dilatation—its role in the therapy of analfissures. Dis Colon Rectum35:322-327.
- 29. Marby M, Alexander-Wlliams J, Buchmann P, ef al. (1979) A randomized controlled trial to compare anal dilatation with lateral subcutaneous sphincterotomy for anal fissure. Dis Colon Rectum22:308-311.
- 30. Giebel GD, Horch R (1989) Treatment of anal fissure: a comparison of three different forms of therapy. Nippon Geka Hokan58:126-133.
- 31. Saad AM, Omer A (1992) Surgical treatment of chronic fissure- in-ano: a prospective randomised study. East Air Med J 69:613- 615.
- 32. Oliver DW, Booth MW, Kernick VF, ef al. (1998) Patient satisfaction and symptom relief after anal dilatation. Int J Colorectal Dis13:228-231.
- 33. Speakman CT, Burnett SJ, Kamm MA, ef al. (1991) Sphincter injury after anal dilatation demonstrated by anal endosonography. Br J Surg78:1429-1430.
- Nielsen MB, Rasmussen OO, Pedersen JF, ef al. (1993) Risk of sphincter damage and anal incontinence after anal dilatation forfissure-inano.Anendosonographicstudy.DisColonRectum

   36:677-680.
- 35. Collopy B, Ryan P (1979) Comparison of lateralsubcutaneous
  - a. sphincterotomy with anal dilatation in the treatment of fissure in ano. Med J Aust ii:461-462, , 487..

- 36. RattanS, SarkarA, ChakderS (1992) Nitricoxidepathwayin
- 37. rectoanal inhibitory reflex of opossum internal anal sphincter. Gastroenterology 103:43-50
- 38. O'Kelly T, Brading A, Mortensen N (1993) Nerve mediated relaxation of the human internal anal sphincter: the role of nitric oxide. Gut34:689-693.
- 39. Stebbing JF (1998) Nitric oxide synthase neurones and neuromuscular behaviour of the anorectum. Ann R Coll Surg Engl80:137-145
- 40. Loder PB, Kamm MA, Nicholls RJ, ef al. (1994)"Reversible chemical sphincterotomy" by local application of glyceryl trinitrate. Br J Surg81:1386-1389.
- 41. Guillemot F, Leroi H, Lone YC, ef al. (1993) Action of in situ nitroglycerin on upper anal canal pressure of patients with terminalconstipation.Apilotstudy.DisColonRectum36:372
  - a. 376.45. Carapeti EA, Kamm MA, McDonald PJ, ef al. (1999) Randomised controlled trial shows that glyceryl trinitrate heals anal fissures, higher doses are not more effective, and there is a high recurrence rate. Gut 44:727-730.
- 42. Langman's Medical Embryology 12<sup>th</sup> edition:chapter15:pg229.
- 43. Majid Aziz, Faran Kiani, Shahzad Ahmed Qasmi:Journal of SurgeryPakistan(International)17(1)January-March2012;
- 44. Medscape : Management of Anal Fissures: onlinecontents.
- 45. Lysy J, Israelit-Yatzkan Y, Sestiere-Ittah M, ef al.(1998)
  - a. Treatment of chronic anal fissure with isosorbide dinitrate: long- term results and dose determination. Dis Colon Rectum 41:1406- 1410.
- 46. Hallan Rl, Wlliams NS, Melling J, ef al. (1988) Treatment of anismus in intractable constipation with botulinum A toxin. Lancef i i:714-717.
- 47. Schouten WR, Briel JW, Boerma MO, ef al. (1996) Pathophysiological aspects and clinical outcome of intra-anal application of isosorbide dinitrate in patients with chronic anal fissure. Gut39:465-469.
- 48. Bacher H, Mischinger HJ, Werkgartner G, ef al. (1997)Local
  - a. nitroglycerin for treatment of anal fissures: an alternative to lateral sphincterotomy? Dis Colon Rectum 40:840-84
- 49. Watson SJ, Kamm MA, Nicholls RJ, ef al. (1996) Topical glyceryl trinitrate in the treatment of chronic anal fissure. Br J Surg83:771-775.

- 50. Gunn J, Varma A, Monson J, ef al. (1998) The dose response of the internal anal sphincter to topical application of glyceryl trinitrate cream [abstract]. Dis Colon Rectum41.
- 51. Dorfman G, Levitt M, Platell C (1999) Treatment of chronic anal fissure with topical glyceryl trinitrate. Dis Colon Rectum 42:1007-1010.
- 52. Lund JN, Scholefield JH (1997) A randomised, prospective, double-blind, placebo-controlled trial of glyceryltrinitrate
- 53. ointment in treatment of anal fissure [see comments] [published erratum appears in Lancet 1997;349:656]. Lancef
- 54. Lund JN, Parsons SL, Scholefield JH (1996) Spasm of the internal anal sphincter in anal fissure—cause oreffect?
- 55. Jost WH, Schimrigk K (1993) Use of botulinum toxin in anal fissure [letter]. Dis Colon Rectum36:974.
- 56. Maria G, Cassetta E, Gui D, ef al. (1998) A comparison of botulinum toxin and saline for the treatment of chronic anal fissure [see comments]. NEnglJ Med338:217-220.
- 57. Jost WH, Schimrigk K (1994) Therapy of anal fissure usingbotulintoxin[seecomments].DisColonRectum37:1321-1324.
- 58. Espi A, Melo F, Minguez M, ef al. (1998) Therapeutic effects of different doses of botulinum toxin in chronic analfissure [abstract]. Dis Colon Rectum41:A16.
- 59. Jost WH (1997) One hundred cases of anal fissure treated with botulin toxin: early and long-term results [see comments]. Dis Colon Rectum40:1029-1032
- 60. Jost WH, Schrank B (1999) Repeat botulin toxin injections in anal fissure: in patients with relapse and after insufficient effect of first treatment. Dig Dis Sci44:1588-1589.
- 61. Mason PF, Watkins MJ, Hall HS, ef al. (1996) The management of chronic fissure in-ano with botulinum toxin [see comments]. J R Coll Surg Edinb41:235-238.
  - a. 60. Boquet J, Moore N, Lhuintre JP, ef al. (1986) Diltiazem for proctalgia fugax [letter]. Lanceti:1493.
- 62. Jonard P, Essamri B (1987) Diltiazem and internal anal sphincter [letter]. Lanceti:754.

- 63. Carapeti EA, Kamm MA, Evans BK, ef al. (1998) Diltiazem lowers resting anal sphincter pressure. A potential low side-effect alternative to glyceryl trinitrate (GTN) for fissures [abstract]. Gut 42 (suppl 1)A97.
- 64. Cook TA, Humphreys MM, Mortensen NJ (1999) Oral nifedipine reduces resting anal pressure and heals chronic anal fissure. BrJ Surg86:1269-1273
- 65. Brisinda G, Maria G, Bentivoglio AR, ef al. (1999) A comparison of injections of botulinum toxin and topical nitroglycerin ointment for the treatment of chronic anal fissure [see comments]. N EnglJ Med341:65-69.
- 66. Bhatia KP, Munchau A, Thompson PD, ef al. (1999)Generalised
  - a. muscular weakness after botulinum toxin injections for dystonia: areportofthreecases.JNeurolNeurosurgPsychiatry67:90-93.
- 67. Latimer PR, Hodgkins PR, Vakalis AN, ef al. (1998) Necrotising fasciitis as a complication of botulinum toxin injection. Eye 12:51-53.
  - a. 67. Fiacchino F, Grandi L, Soliveri P, ef al. (1997) Sensitivity to vecuronium after botulinum toxin administration. J Neurosurg Anesthesiol9:149-153.
- 68. Truong DD, Cullis PA, O'Brien CF, ef al. (1997) BotB (botulinum toxin type B): evaluation of safety and tolerability in botulinum toxin type A-resistant cervical dystonia patients (preliminary study). Mov Disord12:772-775.
- 69. Mezaki T, Kaji R, Brin MF, ef al. (1999) Combined use of type A and F botulinum toxins for blepharospasm: a double-blind controlled trial. Mov Disord14:1017-1020
- 70. Ansar Latiff, Anila Ansar Muhammad, Pak J Med Sci.2013, 29(5):1230-1235.
- 71. Rithin Suvarna, Panchami, Guruprasad Rai D. Chemical Sphicterotomy versus Surgical Sphicterotomy in theManagement of Chronic Fissure in ANO: A Prospective, Randomized Trial. DOI:JCDR/2012/4386:0000
- 72. JP Garner, M McFall, DP Edwards group.bmj.com J RArmy Med Corps 2002; 148:230-235
- 73. Rithin Suvarna, Hanumanthappa MB \* , Panchami , Guruprasad Rai, Int J Biol Med Res. 2012; 3(2):1747-1750
- 74. Madhusudhanan et al JEMDS2014: june: vol 3: issue22:6243-6251

- 75. 1Dr. Manjunath S Kotennavar\*, 1Dr. Arvind K Patil, 1Dr. Amit Mand1Dr.GururajP.InternationalJournalofCurrentResearch
- 76. Vol. 4, Issue, 12, pp.029-031, December, 2012
- 77. K Mc Callion et al progression in the understanding & treatment of Chronic fissure in ano, JCDR/2014/10480.4925.

#### PATIENT CONSENT FORM

## STUDY DETAIL: <u>A PROSPECTIVE COMPARATIVE STUDY OF</u> <u>CHEMICAL AND SURGICAL MANAGEMENT OF</u> <u>FISSURE IN ANO IN CHENGALPATTU MEDICAL</u> <u>COLLEGE</u>

#### <u>STUDY CENTER:</u> CHENGALPATTU MEDICAL COLLEGE & HOSPITAL, CHENGALPATTU

#### PATIENT NAME: IDENTIFICATION NUMBER:

#### PATIENT AGE:

I confirm that I have understood the purpose of procedure for the above study.

I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at anytime without giving any reasons, without my legal rights being affected.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to the current study and any further research that may be conducted in relation to it, even if withdraw from the study, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperative with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or wellbeing or any unexpected or unusual symptoms.

I hereby give consent to participate in this study.

I hereby give permission to undergo complete clinical examination and diagnostic test.

Signature/Thumb impression:	Place:	Date:
Patient name and address:		

Signature of the investigator: Study investigator's name: Place: Date:

#### **INFORMED CONSENT FORM**

## Title of the Study :: A PROSPECTIVE COMPARATIVE STUDY OF CHEMICAL AND SURGICAL MANAGEMENT OF FISSURE IN ANO IN CHENGALPATTU MEDICAL COLLEGE

Name of the Participant :

Name of the Principal (Co-

Investigator):\_\_\_\_\_

Name of the Institution :Government Chengalpattu medical college and Hospital

Name and address of the sponsor / agency(ies) (If any) :

Documentation of the informed consent :

I \_\_\_\_\_\_have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give

#### my consent to be included as a participant in :: A PROSPECTIVE COMPARATIVE STUDY OF CHEMICAL AND SURGICAL MANAGEMENT OF FISSURE IN ANO IN CHENGALPATTU MEDICAL COLLEGE

- 1. I have read and understood this consent form and the information provided to me.
- 2. I have had the consent document explained to me.
- 3. I have been explained about the nature of the study.
- 4. I have been explained about my rights and responsibilities by the investigator.
- I have been informed the investigator of all the treatments I am taking or have taken in the past \_\_\_\_\_\_ months including any native (alternative) treatment.
- 6. I have been advised about the risks associated with my participation in this study.\*
- I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.\*

- I have not participated in any research study within the past \_\_\_\_\_\_month(s).\*
- I have not donated blood within the past \_\_\_\_\_ months----add if the study involves extensive blood sampling.\*
- 10. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.\*
- 11. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.
- 12. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.
- 13. I have understand that my identity will be kept confidential if my data are publicly presented .
- 14. I have had my questions answered to my satisfaction.
- 15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.
#### சுயஒப்புதல்படிவம்

ஆய்வுசெய்யப்படும்தலைப்பு :

## A PROSPECTIVE COMPARATIVE STUDY OF CHEMICAL AND SURGICAL MANAGEMENT OF FISSURE IN ANO IN CHENGALPATTU MEDICAL COLLEGE

ஆய்வுசெய்யப்படும் இடம்:

பங்குபெறுபவரின் பெயர்:

பங்குபெறுபவரின் வயது:

பங்குபெறுபவரின் எண் :

மேலேகுறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கபட்டுள்ளது.நான்

இவ்வாய்வில்தன்னிச்சையாகபங்கேற்கின்றேன்.எந்தகாரணத்தினாலோ,எந்தசட்டசிக்கலுக் கும்உட்படாமல்நான்இவ்வாய்வில்இருந்துவிலகிக்கொள்ளலாம்என்றும்அறிந்துகொண்டே ன்.

இந்தஆய்வுசம்பந்தமாகவோ,இதைசார்ந்துமேலும்ஆய்வுமேற்கொள்ளும்போதும்இந் தஆய்வில்பங்குபெறும்மருத்துவர்,என்னுடையமருத்துவஅறிக்கைகளைபார்ப்பதற்குஎன்அ னுமதிதேவைஇல்லைஎனஅறிந்துகொள்கிறேன்.இந்தஆய்வின்மூலம்கிடைக்கும்தகவலை யோ,முடிவையோபயன்படுத்திக்கொள்ளமறுக்கமாட்டேன்.இந்தஆய்வில்பங்குகொள்ளஒப் புக்கொள்கிறேன்.இந்தஆய்வைமேற்கொள்ளும்மருத்துவஅணிக்குஉண்மையுடன்இருப்பே ன்என்றுஉறுதியளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம்:		சாட்சியாளரின்கை யொப்பம்:
இடம்:	இடம்:	
தேதி:	தேதி :	

பங்கேற்பவரின் பெயர் மற்றும் விலாசம்:

ஆய்வாளரின்கையொப்பம்:

இடம்:

தேதி:

#### PROFOMA

Name :

Age: Sex:

IP.NO:

Address:

Date of admission: Date of operation : Date of discharge : Duration of hospital stay:

## SYMTPOMS:

### Pain:

Assoc symptoms if any:

### **PAST HISTORY**

Associated diseases :

Any operations:

### CLINICAL EXAMINATION

#### General examination: Any positive finding

Weight:

Abdomen:

Other systems:

#### DIAGNOSIS

#### PREOPERATIVE INVESTIGATION

- RBS Urea SrCreatinine
- LFT BT CT

ECG Chest x ray

Any other relevant investigations

Consent for the study

# **OPERATIVE DETAILS**

Duration of surgery

Antibiotics

Name:

Dosage:

Duration:

## **Problems encountered**

Bleeding

Cause Source Management

Others

# **POST OPERATIVE PERIOD**

## Analgesia

## Antibiotics

Drugs used:	Drugs used:	
Dosage:	Dosage:	
Duration:	Duration:	

Oral feeds when started Ambulation Hospital stay Complications Early Haemorrhage Wound infection Pulmonary complications Others

Follow up:

S NO	NAME	AGE/SEX	ON di	PAIN	BLEEDING	SWELLING	PRURITIS	CONSTIPATION	POSITION	SURGERY	POSTOP PAIN	BLEEDING	INFECTION	INCONTINENCE	RECURRENCE
1	KARPAGAMMAL	40/F	461	Y	Y	Y	N	N	Р	IS	Y	N	N	N	N
2	MUNIYAMMAL	50/F	1217	Y	Y	Y	Y	Y	Р	IS	Y	Y	N	Y	N
3	RENUGA	37/F	2216	Y	Y	Y	Ν	Y	Р	LIAS	Y	Ν	Ν	N	Ν
4	VENKATESAN	34/M	3981	Y	Y	Y	Ν	Y	Р	LIAS	Ν	Ν	Ν	N	N
5	KALA	43/F	5172	Y	Ν	Y	Ν	Υ	Р	LIAS	Y	Ν	Ν	Ν	Ν
6	MOHAN	42/M	6442	Y	ΥY	Υ	Ν	Υ	Р	LIAS	Y	Y	Ν	Ν	Ν
7	JANAKI	27/F	7117	Y	Y	Υ	Ν	Υ	Р	LIAS	Ν	Ν	Ν	Ν	Ν
8	NANDHINI	23/F	7992	Y	Y	Y	Ν	Υ	Р	LIAS	Y	Ν	Ν	Ν	Ν
9	PALANI	47/M	8780	Y	Y	Υ	Ν	Υ	А	LIAS	Y	Y	Ν	Ν	Ν
10	ROSE	60/F	9476	Y	Y	Y	Υ	Y	Р	LIAS	Y	Y	Ν	Y	Ν
11	KALA	37/F	10076	Y	Y	Υ	Ν	Υ	Р	LIAS	Y	Y	Ν	Ν	Ν
12	PACHAIYAPPAN	45/M	10711	Y	Y	Y	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
13	DEVI	38/F	11077	Y	Y	Y	Ν	Υ	Р	LIAS	Y	Ν	Ν	Ν	Ν
14	KULSAMBI	60/F	1678	Y	Y	Y	Ν	Y	Р	LIAS	Y	Ν	Ν	Y	Ν
15	PRABHU	35/M	12179	Y	Ν	Ν	Ν	Y	Р	LIAS	Y	Ν	Ν	Ν	Ν
16	TULASIDASAN	33/M	12976	Y	Y	Y	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
17	ARJUNAN	47/M	13327	Y	Y	Y	Ν	Υ	Р	LIAS	Y	Ν	Ν	Ν	Ν
18	DHANASEKAR	30/M	14166	Y	Y	Y	Ν	Υ	Р	LIAS	Ν	Ν	Ν	Ν	Ν
19	GUNASUNDARI	60/F	14999	Y	Ν	Y	Υ	Υ	А	LIAS	Y	Y	Ν	Y	Ν
20	THANTHONI	50/M	15788	Y	Y	Y	Ν	Υ	Р	LIAS	Y	Ν	Ν	Ν	Ν
21	SUGUNA	34/F	16529	Y	Y	Υ	Ν	Υ	Р	LIAS	Y	Y	Ν	Ν	Ν
22	RAMASAMY	41/M	17469	Y	Y	Υ	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
23	SARASWATHY	65/F	18168	Y	Y	Ν	Ν	Υ	Р	LIAS	Y	Y	Ν	Y	Ν
24	PALANI	21/M	18878	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
25	KEERTHIGA	19/F	19646	Y	Y	Ν	Ν	Υ	Р	LIAS	Y	Y	Ν	Ν	Ν
26	ELUMALAI	48/M	20118	Y	Y	Ν	Ν	Υ	Р	LIAS	Y	Ν	Ν	Ν	Ν
27	USHA	36/F	20789	Y	Y	Υ	Ν	Ν	Р	LIAS	Y	Ν	Ν	Y	Ν
28	DHANALAKSHMI	45/F	21168	Y	Y	Ν	Υ	Υ	Р	LIAS	Ν	Y	Ν	Y	Ν
29	MADHAN	21/M	21869	Y	Y	Ν	Υ	Υ	Р	LIAS	N	Ν	Ν	Ν	Ν
30	PATTU	50/F	22178	Y	Y	Ν	Ν	Υ	Р	LIAS	Y	Y	Ν	Y	Ν
31	USHA	48/F	22976	Y	Y	Ν	Ν	Υ	Р	LIAS	Ν	Ν	Ν	Y	Ν
32	AMUDHA	30/F	23106	Y	Ν	Ν	Ν	Υ	Р	LIAS	Ν	Y	Ν	N	Ν
33	КОТТІ	45/M	23979	Y	Y	Ν	Ν	Ν	Р	LIAS	Ν	Ν	N	Y	N
34	KOWSALYA	19/F	24768	Y	Y	Ν	Ν	Ν	Р	LIAS	Y	Ν	N	N	N
35	KARTHIKEYAN	42/M	25107	Y	Y	Ν	Ν	Y	А	LIAS	Ν	Ν	N	Ν	N
36	KANNAGI	45/F	25989	Y	Y	Ν	Ν	Y	Р	LIAS	Y	Y	Ν	Y	Ν

S NO	NAME	AGE/SEX	ON di	PAIN	BLEEDING	SWELLING	PRURITIS	CONSTIPATION	POSITION	SURGERY	POSTOP PAIN	BLEEDING	INFECTION	INCONTINENCE	RECURRENCE
37	SANKARI	29/F	26698	Y	Ν	Ν	Ν	Ν	Р	LIAS	Ν	Ν	Ν	Ν	Ν
38	KARTHIKAYINI	45/F	27762	Y	Υ	Ν	Ν	Y	Р	LIAS	Y	Ν	Y	Y	Ν
39	DILLIKUMAR	38/M	28878	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
40	KAVIDASS	19/M	29684	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Y	Ν	Ν	Ν
41	SENTHAMIZH	30/F	30701	Y	Υ	Ν	Ν	Ν	Р	LIAS	Ν	Ν	Ν	Ν	Ν
42	REKHA	34/F	32169	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Y	Ν
43	SARAVANAN	30/M	33767	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Y	Ν	Ν	Ν
44	REVATHY	30/F	36868	Y	Υ	Ν	Ν	Y	Р	LIAS	Y	Ν	Ν	Ν	Ν
45	ALAMELU	35/F	35589	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Y	Ν	Ν	Ν
46	MANJULA	45/F	38298	Y	Υ	Ν	Ν	Y	Р	LIAS	Y	Ν	Ν	Υ	Ν
47	SATHYAMOORTHY	35/M	30177	Y	Y	Ν	Ν	Ν	Р	LIAS	Ν	Ν	Ν	Ν	Ν
48	JANARTHANAN	42/M	39586	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Y	Ν
49	VINOTH	28/M	39046	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	N	Ν	Ν	Ν
50	JAGADEESH	36/M	40192	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	N	Ν	Ν	Ν
51	KANNIYAMMAL	41/F	41687	Y	Υ	Ν	Ν	Ν	Р	LIAS	Y	Y	Ν	Y	Ν
52	EGAMBARAM	70/M	43218	Y	Υ	Ν	Ν	Y	Р	LIAS	Y	Ν	Y	Y	Ν
53	SUBRAMANI	44/M	46219	Y	Ν	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
54	BHAGYARAJ	48/M	46327	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	N	Ν	Y	Ν
55	BHUVANESHWARI	32/F	48121	Y	Υ	Ν	Ν	Y	Р	LIAS	Y	Y	Ν	Ν	Ν
56	MOHAN	40/M	48412	Y	Υ	Ν	Ν	Ν	Р	LIAS	Ν	N	Ν	Ν	Ν
57	RASU	34/M	49211	Y	Υ	Ν	Ν	Y	Р	LIAS	N	Ν	Ν	Ν	Ν
58	LAKSHMI	38/F	50942	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
59	AMSA	48/F	51964	Y	Υ	Ν	Y	Y	Р	LIAS	Y	Y	Ν	Y	Ν
60	BABU	28/M	52621	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
61	MAHALAKSHMI	29/F	53007	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
62	VINOTH	34/M	53918	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Y	Ν
63	ΚΑνγα	28/F	54876	Y	Υ	Ν	Ν	Y	Р	LIAS	Y	Y	Ν	Ν	Ν
64	ISHWARYA	27/F	55977	Y	Y	Ν	Ν	Ν	Р	LIAS	Ν	Ν	Ν	Ν	Ν
65	ROOBAN	40/M	56578	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
66	DANIEL	42/M	57462	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
67	TITUS	49/M	58876	Y	Υ	Ν	Ν	Y	Р	LIAS	Y	Y	Ν	Y	Ν
68	BRINDHA	28/F	60487	Y	Υ	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
69	MAHESHWARI	32/F	61797	Y	Y	Ν	Ν	Ν	Р	LIAS	Ν	Ν	Ν	Ν	Ν
70	PANDIYAN	45/M	62977	Y	Y	Ν	Ν	Y	Р	LIAS	N	N	Ν	Y	Ν
71	MUSTAFA	32/M	63667	Y	Y	Ν	Ν	Y	Р	LIAS	Y	Y	Ν	Ν	Ν
72	NISHA	34/F	64176	Y	Y	Ν	Ν	Ν	Р	LIAS	Ν	Ν	Ν	Y	Ν
73	SOUNDARYA	30/F	65027	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
74	MONISHA	26/F	65528	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν

S NO	NAME	AGE/SEX	ON di	PAIN	BLEEDING	SWELLING	PRURITIS	CONSTIPATION	POSITION	SURGERY	POSTOP PAIN	BLEEDING	INFECTION	INCONTINENCE	RECURRENCE
75	GANESH	22/M	66148	Y	Y	Ν	Ν	Υ	Р	LIAS	Υ	Ν	Ν	Ν	Ν
76	PAVITHRA	26/F	66926	Y	Y	Ν	Ν	Υ	Р	LIAS	Ν	Ν	Ν	Ν	Ν
77	MANI	44/M	67477	Υ	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
78	INDRANI	45/F	68176	Y	Y	Ν	Ν	Ν	Р	LIAS	Y	Ν	Ν	Y	Ν
79	MALLIGA	29/F	68972	Y	Y	Ν	Ν	Υ	Р	LIAS	Ν	Ν	Ν	Ν	Ν
80	VARUN	26/M	69477	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
81	PUSHPA	36/F	70121	Y	Y	Ν	Ν	Υ	Р	LIAS	Ν	Ν	Ν	Ν	Ν
82	VALLI	40/F	71862	Y	Y	Ν	Ν	Υ	Р	LIAS	Υ	Υ	Ν	Υ	Ν
83	SHANTHI	36/F	72771	Y	Y	Ν	Ν	Ν	Р	LIAS	Ν	Ν	Ν	Ν	Ν
84	MEGANATHAN	45/M	74774	Υ	Y	Ν	Ν	Ν	Р	LIAS	Ν	Ν	Ν	Y	Ν
85	UDHAYA	28/M	75471	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
86	KANNAN	34/M	76129	Y	Y	Ν	Ν	Y	Р	LIAS	Y	Ν	Ν	Ν	Ν
87	HEMA	26/F	76648	Υ	Y	Ν	Ν	Υ	Р	LIAS	Ν	Ν	Ν	Ν	Ν
88	KOWSALYA	28/F	77429	Y	Y	Ν	Ν	Y	Р	LIAS	Ν	Ν	Ν	Ν	Ν
89	VIGNESH	18/M	77976	Y	Y	Ν	Ν	Υ	Р	LIAS	Υ	Υ	Ν	Ν	Ν
90	ILAKIYA	28/F	78409	Y	Y	Ν	Ν	Ν	Р	LIAS	Ν	Ν	Ν	Ν	Ν
91	VICKY	18/M	79562	Y	Y	Ν	Ν	Y	Р	LIAS	Y	Ν	Ν	Ν	Ν
92	KUMAR	48/M	79770	Y	Y	Ν	Ν	Y	Р	LIAS	Y	Ν	Ν	Ν	Ν
93	SAMPATH	50/M	79962	Y	Y	Ν	Ν	Y	Р	LIAS	Y	Ν	Y	Y	Ν

S NO	NAME	AGE/SEX	ON di	PAIN	BLEEDING	SWELLING	PRURITIS	CONSTIPATION	POSITION	OINTRMENT APPLICATION	HEADACHE	POST APP. ITCHING	INCONTINENCE	RECURRENCE
94	RATHNA	45/F	192	Y	Y	Ν	Ν	Ν	A+P	Y	Ν	Ν	Ν	Ν
95	OVIYA	26/F	1471	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
96	KOUSHIK	19/M	3472	Y	Y	Ν	Ν	Ν	Р	Y	N	Ν	Ν	Y
97	CHANDRA	40/F	5684	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	Ν
98	SOWMIYA	29/F	7971	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
99	SUNDAR	46/M	9671	Y	Y	Ν	Y	Ν	А	Y	Y	Ν	Y	Ν
100	MEENA	26/F	11721	Y	Ν	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
101	BABY	40/F	14421	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	Ν
102	MUBARAK	36/M	17371	Y	Y	Ν	Ν	Ν	Р	Y	Y	Y	Ν	Ν
103	JESSY	19/F	18116	Y	Y	Ν	Y	Ν	Р	Y	Ν	Ν	Ν	Ν
104	MURALI	46/M	19416	Y	Y	Ν	Ν	Ν	А	Y	Ν	Ν	Ν	Ν
105	SHEELA	34/F	20717	Y	Ν	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Ν
106	KARTHICK	34/M	22412	Y	Y	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Ν
107	MURALI	45/M	23716	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
108	RAKSHITHA	26/F	25542	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
109	MADHUMITHA	19/F	26747	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
110	BALA	36/M	27262	Y	Ν	Ν	Y	Ν	Р	Y	Y	Ν	Ν	Ν
111	CHITHRA	38/F	28119	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
112	KRISHNAN	44/M	29719	Y	Y	Ν	Ν	Y	А	Y	Ν	Y	Ν	Ν
113	PREM	32/M	31332	Y	Ν	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Y
114	PRITHIKA	28/F	32271	Y	Y	Ν	Y	Ν	Р	Y	Ν	Ν	Ν	Ν
115	ARCHANA	30/F	33441	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
116	VIJAY	29/M	34717	Y	Ν	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
117	PRIYA	26/F	35912	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
118	IBRAHIM	34/M	37112	Y	Y	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Ν
119	SOUNDARYA	32/F	38296	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
120	JOHN	34/M	39916	Y	Ν	Ν	Ν	Ν	А	Y	Ν	Ν	Ν	Ν
121	DEEPAN	28/M	41133	Y	Y	Ν	Y	Ν	Р	Y	Y	Ν	Ν	Ν
122	KAVITHA	36/F	42277	Y	Y	Ν	Ν	Ν	А	Y	Ν	Ν	Ν	Ν
123	MALVIKA	35/F	43771	Y	Y	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Ν
124	DINESH	28/M	45116	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
125	AARTHI	34/F	47716	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν

S NO	NAME	AGE/SEX	ON di	PAIN	BLEEDING	SWELLING	PRURITIS	CONSTIPATION	POSITION	OINTMENT APPLICATION	HEADACHE	POST APP. ITCHING	INCONTINENCE	RECURRENCE
126	SASHA	16/F	48167	Y	Ν	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	N
127	SATHISH	36/M	49961	Y	Y	Ν	Ν	Ν	А	Y	Ν	Ν	Ν	Ν
128	SABARI	38/M	50771	Y	Y	Ν	Y	Ν	Р	Y	Ν	Ν	Ν	N
129	PREM	22/M	51163	Y	Y	Ν	Ν	Ν	Р	Y	Y	Ν	N	N
130	SABREENA	40/F	53636	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	N
131	SAMYUKTHA	18/F	54451	Y	Ν	Ν	Ν	Ν	А	Y	Ν	Ν	Ν	Ν
132	DANIEL	36/M	57781	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
133	DIVAKAR	30/M	58816	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
134	JENNIFER	28/F	59716	Y	Y	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Y
135	SUNDARAM	45/M	61173	Y	Y	Ν	Y	Y	A+P	Y	Ν	Ν	Ν	Ν
136	RATHIMA	48/F	64432	Y	Y	Ν	Ν	Y	Р	Y	Ν	Y	Ν	Ν
137	MOHANA	26/F	67736	Y	Ν	Ν	Ν	Ν	А	Y	Ν	Ν	Ν	Ν
138	SILAMBARASAN	34/M	69932	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
139	AISHWARYA	40/F	71177	Y	Y	Ν	Ν	Y	Р	Y	Y	Ν	Ν	Ν
140	SNEHA	36/F	74471	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
141	PRITHVIRAJ	28/M	76659	Y	Ν	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Y
142	VISHAL	19/M	79769	Y	Y	Ν	Y	Ν	Р	Y	Ν	Ν	Ν	Ν
143	SANJANA	18/F	84821	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Y	Ν	Ν
144	KASTHURI	45/F	86769	Y	Y	Ν	Ν	Y	А	Y	Ν	Ν	Ν	Ν
145	KAVIN	33/M	87469	Y	Ν	Ν	Ν	Ν	Р	Y	Ν	Ν	Y	Ν
146	MANOHAR	38/M	89978	Y	Y	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Ν
147	KAVITHA	40/F	91767	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
148	MUTHU	45/M	94463	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	Ν
149	RAMESHWARI	49/F	96672	Y	Y	Ν	Ν	Y	Р	Y	Y	Ν	Ν	Ν
150	RAMU	55/M	97749	Y	Y	Ν	Y	Y	Р	Y	Y	Ν	Ν	Ν
151	ESHWARI	53/F	98869	Y	Y	Ν	Ν	Y	А	Y	Ν	Ν	Ν	Ν
152	LINGAM	47/M	99979	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
153	CHITHRA	52/F	100212	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	N	N
154	RANI	48/F	101361	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	Ν
155	DEVIKA	45/F	104563	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	Ν
156	VIJAY	40/M	107861	Y	Ν	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
157	SHAFNA	34/F	109967	Y	Y	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Ν

S NO	NAME	AGE/SEX	ON di	PAIN	BLEEDING	SWELLING	PRURITIS	CONSTIPATION	POSITION	OINTMENT APPLICATION	HEADACHE	POST APP. ITCHING	INCONTINENCE	RECURRENCE
158	SANGEETHA	48/F	113212	Υ	Y	Ν	Y	Ν	Р	Y	Y	Ν	Ν	Ν
159	KUMAR	40/M	115513	Y	Y	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Ν
160	STELLA	36/F	119612	Y	Y	Ν	Ν	Ν	А	Y	Ν	Ν	Ν	Ν
161	VIKRAM	28/M	121172	Υ	Ν	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	N
162	MALA	49/F	124563	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	Y
163	SHANMUGAM	52/M	129763	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	Ν
164	JAYA	50/F	131143	Υ	Y	Ν	Ν	Y	Р	Y	Ν	Y	Ν	Ν
165	VELU	36/M	134562	Υ	Ν	Ν	Ν	Ν	Р	Y	Y	Ν	Ν	Ν
166	RAJA	48/M	137741	Υ	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	N
167	AMBIKA	45/F	139976	Y	Y	Ν	Ν	Ν	А	Y	Ν	Ν	Ν	Ν
168	NANDHA	40/M	144571	Υ	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	N
169	AMUTHA	38/F	147951	Υ	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
170	JESICA	21/F	149761	Υ	Ν	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	N
171	ABDUL	45/M	155768	Υ	Y	Ν	Ν	Y	Р	Y	N	Ν	Ν	Ν
172	MALATHY	28/F	159678	Υ	Ν	Ν	Ν	Y	Р	Y	N	Ν	Ν	Ν
173	MUNIYAMMAL	55/F	164698	Y	Y	Ν	Ν	Ν	A+P	Y	Ν	Ν	Ν	N
174	SAKTHI	29/M	169218	Υ	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
175	PRABHA	26/F	173219	Y	Ν	Ν	Y	Ν	Р	Y	Ν	Ν	Ν	N
176	LAVANYA	35/F	179319	Υ	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
177	CHAKRAVARTHY	54/M	86371	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	Ν
178	SUBASHINI	32/F	191172	Υ	Y	Ν	Ν	Ν	Р	Y	N	Y	Ν	Ν
179	RAJALAKSHMI	45/F	194672	Υ	Y	Ν	Ν	Ν	Р	Y	N	Ν	Ν	N
180	PANDIYAN	48/M	199773	Y	Y	Ν	Ν	Y	Р	Y	Ν	Ν	Ν	N
181	MINU REKHA	34/M	201762	Y	Y	Ν	Ν	Ν	А	Y	Ν	Ν	Ν	Ν
182	ABINAYA	32/F	204763	Y	Ν	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	Ν
183	RAJESH	34/M	208861	Y	Y	Ν	Ν	Ν	Р	Y	Ν	Ν	Ν	N