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ORIGINAL ARTICLE

**RANDOMISED SINGLE BLIND PLACEBO CONTROL STUDY ON
THE EFFICACY OF CALCAREA FLUORICA 6X IN FISSURE-IN-ANO**

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Abstract

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Key Word- Fissure-in-ano,
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Anal fissure is a most common anorectal disorder which affects both genders. Fissures may be acute or chronic and usually occur as a liner tear in the anoderm in the posterior midline. Adults with anal fissures usually present with pain during or after defecation, passage of bright red blood per rectum, perianal swelling, and occasional anal pruritus.

Objectives: 1) To understand the various presentations of fissure-in-ano. 2) To study the changes in suffering in individuals with fissure-in-ano with administration of biochemic medicine Calcarea fluorica 6x. 3) To study the efficacy of biochemic medicine Calcarea fluorica 6x in individuals with fissure-in-ano with the comparison with placebo control.

Methodology: Single blind, Prospective Interventional Placebo Control Trial

Active drug ingredient: Biochemic Calcarea fluorica 6x. Placebo: Identically white

colour, shape & size of sugar of milk tablets as looking like active drug. **Method of Study:** After diagnosis, patient would be enrolled for the study with consent sign. As per enrolment, patients would be divided into two groups (active and placebo), as per computerised randomisation. Both groups would be received identical tablets but Calcarea fluor 6x would be given to active group while identical placebo tablets would be given to placebo group. For local or external application, both groups would be advised for vaseline/ coconut oil only, as a softener. Each patient would be advised for fibrous diet, plenty of water, avoids fasting, not to postpone defecation, avoid spicy or outer food & sitz bath. **Sample size:** 100 (50 in Active group & 50 in Placebo group). **Sampling:** Computerized Randomization Sampling **Conclusion:** Biochemic medicine Calcarea fluorica 6x has significant efficacious role in treatment in fissure-in-ano.

INTRODUCTION

Anal fissure is a most common anorectal disorder which affects both genders. Fissures may be acute or chronic and usually occur as a liner tear in the anoderm in the posterior midline. Adults with anal fissures usually present with pain during or after defecation, passage of bright red blood per rectum, perianal swelling, and occasional anal pruritus. The passage of a large fecal bolus through the anal canal may result in direct trauma to

the anoderm and produce a fissure. Most patients with anal fissure do not have a history of constipation prior to the development of a fissure but often become constipated after fissure development secondary to fear of defecation. However, questions still exist with respect to the classical midline position of anal fissure and the finding that some acute fissures heal whereas others become chronic. The external anal sphincter is not a true circle, but rather a band of muscle fibers that run

from anterior to posterior around the anal orifice. The anoderm is therefore supported best laterally and worst posteriorly.^[1,2,3,4,5,6,7,8,9]

Most recurrent fissures resolve with medical therapy. Short term morbidity of urinary retention, hematoma, and incontinence have been reported in up to 36% of patients. As with anal dilatation, incontinence is the most serious long-term complication after lateral internal anal sphincterotomy.^[1,2,4]

While in homoeopathy, various fissure cases have been treated successfully. Lots of homoeopathic materia medicas also suggest various medicines in anal fissure cases.^[10,11,12,13,14] Calcarea fluorica one of the commonly used biochemic medicine, which is used to treat anal fissures.^[12,14] So, this research work would justify the significant role of Calcarea fluorica in different kind of fissures and may be give alternate way of surgeries or postpone it.

This study was conducted during my Ph.D. (Hom.) course.

AIMS & OBJECTIVES

AIM: To study the efficacy of Calcarea fluorica 6x in Fissure-in-ano

OBJECTIVES:

- To understand the various presentations of fissure-in-ano
- To study the changes in suffering in individuals with fissure-in-ano with

administration of biochemic medicine Calcarea fluorica 6x.

- To study the efficacy of biochemic medicine Calcarea fluorica 6x in individuals with fissure-in-ano with the comparison with placebo control.

MATERIAL & METHODOLOGY

Study Type: Prospective Experimental Interventional Trial

Masking: Single Blind

Control: Placebo Control

Follow ups duration: 2 weeks

Route of drug administration: Oral tablet (1grain)

Active drug ingredient: Biochemic Calcarea fluorica 6x white tablets of 1 grain from GMP certified company.

Placebo: Identically white colour, shape size 1 grain sugar of milk tablets as looking like active drug.

Inclusion Criteria:

- Diagnosed fissure-in-ano cases would be included (single fissures or multiple fissures)
- Age group: 18 years to 50 years
- Sex: All sexes
- 1grain piles/ internal polyp with clinically non-significant cases along with fissure-in-ano can be included.

Exclusion Criteria:

- Other rectal disorder/ diseases e.g., abscess, haemorrhoids 2 degree or above, fistula, carcinoma (CA),

Levator ani syndrome (LAS), and proctalgia fugax etc.

- Previous anal surgeries
- Coccygodynia, tension myalgia of the pelvic floor
- Rectal foreign body
- Crohn's Disease
- Sexual Transmitted Disease [HIV]
- Human Papillomavirus (HPV)
- Hepatitis B
- Uncontrolled Diabetes Mellitus/ uncontrolled high blood glucose level
- Heart diseases with anti-coagulant therapy
- Pregnant women and Lactating mothers
- Homosexual practices (sodomy, fisting and the use of anorectal sex toys etc.)

Method of Study:

- Diagnosis of fissure-in-ano would be based on clinical history, physical examination especially per-rectal (PR) examination.
- Investigations would be ordered

i. Compulsory Investigations:

- Complete Blood Count (CBC),
- Blood sugar level (BSL): Fasting/ PP/ Random,
- HbA1C,
- HIV,
- HPV,
- HBsAg

ii. Optional/Additional

Investigations:

- Liver Function Test (LFT)
- Kidney Function Test (KFT)
- Lipid Profile
- Endoscopy: Proctoscopy/ Colonoscopy/ Gastroscopy
- Ultra-Sonography (USG) - Abdomen/ Trans-rectal
- Electro-cardiography (ECG)
- Urine Pregnancy Test (UPT)
- Rectal Doppler flow study
- Other investigation(s) may be useful to rule out other causes/ factors/ illnesses.
- After diagnosis, patient would be enrolled for the study with consent sign.
- As per enrolment, patients would be divided into two groups (active and placebo), as per computerised randomisation (chart given above).
- Both groups would be received identical tablets but Calcarea fluor 6x would be given to active group while identical placebo tablets would be given to placebo group.
- For local or external application, both groups would be advised for vaseline/ coconut oil only, as a softener.
- Each patient would be advised for
 - fibrous diet
 - plenty of water

- avoid fasting
- not to postpone defecation
- avoid spicy or outer food
- sitz bath

Sample size: 100 (50 in Active group & 50 in Placebo group)

Sampling: Computerized Randomization Sampling

OBSERVATION & RESULTS

In order to reach a valid conclusion from the result obtain from the study to understand the efficacy of Biochemic medicine Calcarea fluorica 6x in 100 individuals with fissure-in-ano; a prospective experimental interventional single blind placebo control trial was conducted with computerized randomization (50 cases in Active Group + 50 cases in Passive Group). I am obliged to discuss some of the findings which have been evolved out of this study.

Age Group: The maximum number of patients were found under 36-40 years age group (24%) then 26-30 years age group (20%), 18-25 years age group (19%), 31-35 years age group (16%), 41-45 years age group (14%) & 46-50 years age group (7%). As per literature, Fissures occur at any age but are most common in young and middle-aged adults.[2]

Sex ratio: The male sex constituted a major section of the study forming 73% of

the total. Which may suggest males are more prone to fissure-in-ano.

Religion Ratio: In this study, 91% Hindus, 8% Muslims & 1% Sikha were found. As per 2011 census, the religion distribution of the district was 90.7% Hindus, 4.3% Muslims & 2.6% Sikh were calculated. This study also justifies the religion ratio distribution in the community^[15]

Occupation/ Job Type: This study found that sitting job is more prone for fissure in ano with 41% of cases were found in this category while moderate labor work jobs were also near to this with 38% of cases. Heavy labor work jobs were found less affective with 21% of cases.

Types of Fissures: In the study 36.99% (n = 27) males were suffering from acute fissure-in-ano while 63.01% (n = 46) males were suffering from chronic fissure-in-ano, in which 82.61% (n = 38) males suffering from chronic fissure-in-ano had sentinel piles while 17.39% (n = 8) males suffering from chronic fissure-in-ano had no sentinel piles. 11.11% (n = 3) females were found suffering from acute fissure-in-ano and 88.89% (n = 24) females were found suffering from chronic fissure-in-ano, in which 12.5% (n = 3) females had no sentinel piles while 87.5% (n = 21) females had sentinel piles with chronic fissure-in-ano.

Fissure Positions in Males: In the study 6 o'clock position was found more prone for acute 40.74% (n = 11) as well as for chronic 69.56% (n = 32) fissure-in-ano. As per literature, the posterior midline is the most common site for fissure-in-ano in males.^[2]

Fissure Positions in Females: In the study 6 o'clock position was found more prone in chronic fissure-in-ano with 41.67% (n = 10) females, than two fissures at 12 & 6 o'clock positions were found second more prone in females with chronic fissure-in-ano with 37.5% (n = 9). Only 12.5% (n = 3) females were found chronic fissure-in-ano at 12 o'clock position.

Change of Treatment: In the study only 2% (n = 1) case was needed to change the plan of treatment from Active group while in Passive group, 48% (n = 24) cases were needed to change the treatment plan to

active action due to lack of expected significant relief of the patients.

Changes in Sentinel piles: There were no change in sentinel piles noticed in both active as well a passive group.

There were two groups: Active Group & Passive Group. Both groups were evaluated by Visual Analog Scale (VAS) for pain and Face Pain Rating Scale (PRS) before and after the homoeopathic treatment (2 weeks). Weekly follow ups were evaluated with the criteria of Pain (intensity & duration), bleeding (type of bleeding), Itching (intensity) & sentinel piles (length).

Stool frequency, stool consistency, unsatisfactory stool and appetite were common response of ancillary measures in both groups. So, these are excluded for the analysis.

STATISTICAL ANALYSIS

Active Group VAS Paired t-test (pair 1) and Face PRS (Pair 2) result:

		Paired Samples Test					t	df	Significance	
		Paired Differences			Lower	Upper			One-Sided p	Two-Sided p
		Mean	Std. Deviation	Std. Error			95% Confidence Interval of the Difference			
Pair 1	Baseline VAS - Post Hom. VAS	4.600	1.884	.266	4.064	5.136	17.261	49	<.001	<.001
Pair 2	Baseline Face PRS - Post Hom. Face PRS	2.100	.839	.119	1.862	2.338	17.697	49	<.001	<.001

P values are found significant in both pair, which suggest there are significant changes in baseline VAS with Face PRS and Post Homoeopathy VAS with Face PRS.

Active Group Pain PR follow ups analysis by Paired t-test:

		Paired Samples Test							Significance	
		Paired Differences							One-Sided	Two-Sided
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	p	p
					Lower	Upper				
Pair 1	Pain PR intensity Baseline - Pain PR intensity 1st Follow up	1.061	.517	.074	.913	1.210	14.376	48	<.001	<.001
Pair 2	Pain PR intensity 1st Follow up - Pain PR intensity 2nd Follow up	.367	.487	.070	.227	.507	5.279	48	<.001	<.001
Pair 3	Pain PR duration Baseline - Pain PR duration 1st Follow up	2.449	1.100	.157	2.133	2.765	15.579	48	<.001	<.001
Pair 4	Pain PR duration 1st Follow up - Pain PR duration 2nd Follow up	.939	.922	.132	.674	1.204	7.126	48	<.001	<.001

P value in every pair is found < 0.001 ; which suggest significant changes/ relief in pain intensity and duration in 1st week and 2nd week also.

Active group bleeding PR follow up analysis by Paired t-test:

		Paired Samples Test							Significance	
		Paired Differences							One-Sided	Two-Sided
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	p	p
					Lower	Upper				
Pair 1	Bleeding PR Baseline - Bleeding PR 1st Follow up	.571	.612	.087	.396	.747	6.532	48	<.001	<.001
Pair 2	Bleeding PR 1st Follow up - Bleeding PR 2nd Follow up	.286	.456	.065	.155	.417	4.382	48	<.001	<.001

P value in both pair is < 0.001 ; suggested that Calcareo fluorica 6x gives significant changes in first week as well as in second week also.

Active Group Itching PR Follow up Analysis by Paired t-test:

		Paired Samples Test					t	df	Significance	
		Paired Differences							One-Sided	Two-Sided
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				p	p
					Lower	Upper				
Pair 1	Itching PR Baseline - Itching PR 1st Follow up	.224	.511	.073	.078	.371	3.076	48	.002	.003
Pair 2	Itching PR 1st Follow up - Itching PR 2nd Follow up	.367	.487	.070	.227	.507	5.279	48	<.001	<.001

As per paired sample test, the P value in Pair 1 (itching PR in 1st week) is < 0.005 but > 0.001 ; while in pair 2 (itching PR in 2nd week), P value is < 0.001 ; suggested that, Tab. Calcarea fluorica 6x significantly work on itching PR but more in second week of treatment than first week.

Passive Group VAS and Face PRS analysis by Paired t-test:

		Paired Samples Test					t	df	Significance	
		Paired Differences							One-Sided p	Two-Sided p
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference					
					Lower	Upper				
Pair 1	Basline VAS - Post Hom. VAS	1.280	1.750	.248	.783	1.777	5.172	49	<.001	<.001
Pair 2	Basline Face PRS - Post Hom. Face PRS	.520	.814	.115	.289	.751	4.516	49	<.001	<.001

As per P value in both pair (Pair 1: Baseline VAS & Post Hom. VAS; Pair 2: Baseline Face PRS & Post Hom. Face PRS) in Passive group (Placebo with ancillary measure) is < 0.001 ; suggested significant changes in pre & post treatment.

Passive Group Pain PR intensity & duration follow ups analysis by paired t-test:

		Paired Samples Test					t	df	Significance	
		Paired Differences							One-Sided p	Two-Sided p
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference					
					Lower	Upper				
Pair 1	Pain PR intensity Baseline - Pain PR intensity 1st Follow up	.277	.498	.073	.130	.423	3.808	46	<.001	<.001
Pair 2	Pain PR intensity 1st Follow up - Pain PR intensity 2nd Follow up	.085	.545	.079	-.075	.245	1.071	46	.145	.290
Pair 3	Pain PR duration Baseline - Pain PR duration 1st Follow up	.553	1.212	.177	.197	.909	3.128	46	.002	.003
Pair 4	Pain PR duration 1st Follow up - Pain PR duration 2nd Follow up	.383	.709	.103	.175	.591	3.705	46	<.001	<.001

Pain PR changes in intensity in Pair 1 is highly significant ($P < 0.001$), while in second week in Pair 2, the Pain PR changes is non-significant ($P = 0.145$, one sided); suggested that ancillary measures can help in pain PR intensity in first week while no further improvement happens.

While in Pain PR Duration in Pair 3 (1st follow up), P value is 0.002; which suggests that changes are significant in first week; while in 2nd week/ follow up in Pair 4, the changes

are highly significant ($P < 0.001$) which suggests; ancillary measures can reduce the pain duration from first week and more in second week.

Passive Group Bleeding PR follow up analysis by Paired t-test:

		Paired Differences					t	df	Significance	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				One-Sided p	Two-Sided p
					Lower	Upper				
Pair 1	Bleeding PR Baseline - Bleeding PR 1st Follow up	.064	.385	.056	-.049	.177	1.137	46	.131	.261
Pair 2	Bleeding PR 1st Follow up - Bleeding PR 2nd Follow up	.128	.448	.065	-.004	.259	1.953	46	.028	.057

There is no significant change in Placebo with Ancillary measures in passive group in first week of bleeding PR follow up ($P = 0.131$) while in second week, very low significance is noticed ($P = 0.028$).

Passive Group Itching PR follow up analysis by Paired t-test:

		Paired Differences					t	df	Significance	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				One-Sided p	Two-Sided p
					Lower	Upper				
Pair 1	Itching PR Baseline - Itching PR 1st Follow up	.191	.449	.066	.060	.323	2.923	46	.003	.005
Pair 2	Itching PR 1st Follow up - Itching PR 2nd Follow up	.149	.416	.061	.027	.271	2.455	46	.009	.018

There are significant changes have been found with ancillary measure & placebo in itching PR in first week ($P = 0.003$) as well as in second week ($P = 0.009$).

Combined (Active & Passive):

Active & Passive Groups Post Intervention VAS Unpaired t-test:

Independent Samples Test					
	Mean Difference	Std. Error Difference	t	df	Sig. (2-tailed)
Equal variances assumed	-3.600	.580	-6.211	98.000	<.001
Equal variances not assumed	-3.600	.580	-6.211	97.159	<.001

Hartley test for equal variance: $F = 1.205$, Sig. = 0.2559

Both active as well as passive group have showed significant changes in statistical analysis. Passive group had been received ancillary measures, so that, passive group showed

significant changes. While active group had been received same ancillary measures along with homoeopathic intervention. Both groups are independent and not same sample but quantity and group of illnesses are same. So, as per Independent Sample t-test, there are significant (<0.001) changes are noticed. Which suggest there are significant difference between only ancillary measures and ancillary measures with homoeopathic intervention in VAS scale.

Active & Passive Post Intervention Face PRS Unpaired t-test:

Independent Samples Test					
	Mean Difference	Std. Error Difference	t	df	Sig. (2-tailed)
Equal variances assumed	-1.700	.268	-6.345	98.000	<.001
Equal variances not assumed	-1.700	.268	-6.345	92.781	<.001

Hartley test for equal variance: F = 1.622, Sig. = 0.0452

Both active as well as passive group have showed significant changes in statistical analysis. Passive group had been received ancillary measures, so that, passive group showed significant changes. While active group had been received same ancillary measures along with homoeopathic intervention. Both groups are independent and not same sample but quantity and group of illnesses are same. So, as per Independent Sample t-test, there are significant (<0.001) changes are noticed. Which suggest there are significant difference between only ancillary measures and ancillary measures with homoeopathic intervention in Face PRS scale.

DISCUSSION

- As per this study, middle aged adults are more affected.
- Males are more prone than females.
- As per population distribution, fissure-in-ano is not dependent on religion. Fissure-in-ano can affect person of any religion equally.
- Persons with sitting jobs are more prone for fissure-in-ano.
- Posterior midline (6 o'clock) position is more common site for fissure-in-ano in males.
- Along with posterior midline (6 o'clock) position, anterior midline (12 o'clock) position is second most common site for fissure-in-ano in females.
- Calcarea fluorica 6x can significantly reduce pain PR from first week, and significant improvement in second

- week also, in intensity as well as duration of pain also.
- Calcarea fluorica 6x can significantly reduce bleeding PR from the first week or treatment, and continuous significant improvement in second week also.
 - Calcarea fluorica 6x can significantly act on itching PR on first week of treatment while continuous administration of Calcarea fluorica 6x for second week can reduce more itching than previous week administration.
 - With above mentioned ancillary measures, intensity of pain PR can significantly be reduced in first week while reduction in intensity pain PR in second week is non-significant. While duration of pain PR can be mildly significant reduced in first week of treatment but highly significantly reduced in second week of treatment.
 - Bleeding PR in fissure-in-ano cannot be improved in first week with ancillary measures while very mild significant changes can be found in second week of treatment.
 - As per statistical analysis, itching PR can be reduced mild significantly with ancillary measures in first week of treatment while non-significant changes can be found in second week of treatment.
 - As per VAS and Face PRS, Calcarea fluorica 6x gives significant relief in patients with fissure-in-ano as well as ancillary measures also show significant relief in patients with fissure-in-ano. But when we compare responses of Calcarea fluorica 6x and ancillary measures, there are significant changes noticed. It means ancillary measures can help to reduce suffering of patients with fissure-in-ano but ancillary measures along with Calcarea fluorica 6x help to reduce more significant relief to the patients with fissure-in-ano.
 - Patients with fissure-in-ano, who did not get specific relief in pain, were required to change the line of treatment. In active group, only 1 case out of 50 was required to change the line of treatment while in passive group 24 cases out of 50 were required to change the line of treatment.
 - Calcarea fluorica 6x as well as ancillary measures have no role in sentinel piles. Sentinel piles are irreversible pathological changes, which required surgical intervention. But with Calcarea fluorica 6x, suffering of patient with fissure-in-ano can be reduced, even with sentinel piles.

CONCLUSION

Biochemic medicine Calcarea fluorica 6x has significant efficacious role in treatment of fissure-in-ano.

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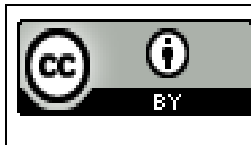
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