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Homoeopathic Observational Study in the Treatment of Anal Fissure

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Abstract
Introduction: Anal fissures are an extremely common disease with a severe impact on patients quality of life. The main goal of anal fissure treatment is rapid pain relief and long-lasting healing.
Aim: Controversies and disagreement exist on conventional treatment strategies of Anal fissures due to relapse, inefficacy, and complications. We intend to evaluate the role of individualized homeopathic treatment in Anal fissures.
Materials and Methods: In this prospective, open level, observational trial, Anal fissures patients were treated using standardized scales measuring complaints severity from REALISE score. It was conducted at homeopathic hospitals in RBTSGHMCH Bihar India, during from mid-feb 2023 to mid-Nov 2023. Patients were intervened as per individualized homeopathic principles and followed up every fortnight up to 3 months.
Results: Total 40 were screened, 34 enrolled, 30 completed, 4 dropped out. Intention to treat population (n: = 30) was analyzed in the end. A 'paired t-test' was conducted to compare the effect of Individualized Homeopathic medicine at "0" month (Baseline) and after "3" months. The mean was reduced from 23.26 (SD 3.638) to 5.33 (SD 4.513). The reduction [t(29)=22.119, p<0.001, 2 tailed which less than p<0.05]. The 95% confidence interval for the mean difference ranges from 16.27516 to 19.59151. Here p values much less than P<0.01, Hence statistically highly significant.
Conclusion: Under classical homeopathic treatment, Anal fissures patients improved considerably in symptoms severity in REALISE scores. However, being observational trial, our study cannot provide efficacy data. Controlled studies are required. This study was approved by institutional ethics committees were obtained (IEC no. R.B.T.S ETHICS-53/21-24), and was not registered in CTRI.

Keywords: Homoeopathy, observational study, REALISE score, Anal fissure

Introduction

Anal fissures (ICD-11. DB50.0) [1] have a severe impact on patients' quality of life [2]. An anal fissure, also known as *fissure-in-ano*, refers to a longitudinal split in the skin within the lower part of the anal canal. This split extends from the outer edge of the anus towards the dentate line but does not surpass it [3]. The main symptom is anal pain, which can be acute or chronic, recurrent and extremely disabling. The most common sign is anal bleeding, due to delayed healing of the fissure or local trauma, mostly occurring during bowel movements. The main goal of anal fissure treatment is rapid pain relief and long-lasting healing of the fissure. It also aims to avoid evolution towards an abscess or perianal fistula, through effective healing and appropriate timing of the treatment, as well as to reduce indications for surgery, notwithstanding the recent introduction of less invasive procedures [4]. Anal fissures are extremely common worldwide and are estimated to account for 10% to 15% of all proctologic consultations [5]. In India, approximately 17.8% population suffer from Anal fissure at any given point in time [6].

Fissure-in-ano (Figure-1) is of two types - acute and chronic. Acute fissure presents within 3–6 weeks of onset of symptoms [7]. Anal fissures can be divided into two main categories, depending on the duration of symptoms: Acute anal fissure, where symptoms arose in the last 6 weeks, and chronic anal fissure, for symptoms of a longer duration. Within the group of chronic fissures, however, the objective features of the wound must also be carefully evaluated, as it may sometimes be complicated by the presence of sentinel skin tags, anal papillae, anal polyps and indurated margins [8, 9].

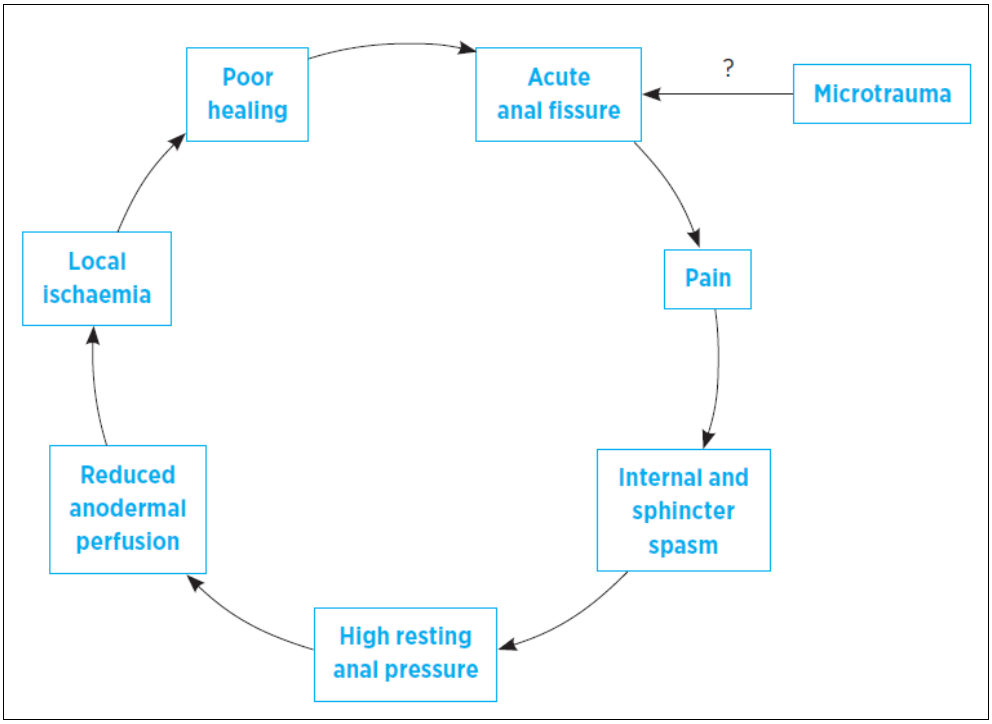

Fig 1: Anal fissure pathophysiology

In recent decades, various conservative (local ointments) management have been proposed to reduce anal pressure and/or to control anal pain, as well as to enable the fissure to heal through the application of active substances [10] and improvement of the blood supply. The aim of this study is to evaluate the efficacy of a individualized homoeopathic medicine in potentized form, each with a specific goal, on anal fissure in terms of pain control, symptoms resolution, healing time and patient satisfaction.

Material and Method

This study was conducted in the medicine and surgery outpatients of Govt Homoeopathic Hospital of Bihar, India, R.B.T.S Govt Homoeopathic Medical college and Hospital Muzaffarpur Bihar. The study was started in 16-Feb-2023, enrollment continued until November 2023 and ended in mid-Feb 2024. In this prospective single blind, open level observational trial, patients were included consecutively on their first consultation with the participating physicians and followed up for 3 months using standardized scales. Before enrollment, written informed consent and approval by institutional ethics committees were obtained (IEC no. R.B.T.S ETHICS-53/21-24), and each patient was provided with a patient information sheet in local vernacular language in Hindi detailing the objectives, methods, risks and benefits of participating, and confidentiality issues. The study protocol was not registered with the Clinical Trials Registry, India. The study was performed under the constant supervision of the independent ethics committees of the respective institutions.

Inclusion and Exclusion Criteria

Inclusion criteria were male and female patients between 15 and 40 years suffering from Anal fissure presenting with any of the symptoms, namely, bleeding, pain (including discomfort and tenesmus during defecation or any other time). Patient willing to take homoeopathic medicine, of all religion and socioeconomic status. Patient who have already had other method of treatment but now intend to undergo homoeopathic treatment, after providing a gap of six weeks as a washout periods.

Exclusion criteria were gross pathology as co-morbidity developed, chronic alcoholism, and suffering from a systemic illness and / or a life threatening character, who have not given written consent for the trial.

Aim and scope

Before treatment (at baseline), patients independently rated their, The scoRing systEm for AnaL fIsSurE Score (REALISE) combines the five items of most commonly reported symptoms of Anal fissure. The pain, was scored from 0 – 10 using a visual analogue scale, their severity on 10 cm visual analog scales (VAS; 0 = no complaints; 10 = maximum severity) measuring intensity of symptoms of Anal fissure – bleeding, pain, and discomfort on examination by the treating physicians. the remaining four (quality of life duration of the pain, pain killers pill intake and bleeding) were scored from 1 to 5 points using a Likert-scale questions. The REALISE score was the sum of all points, with a maximum possible of 30 points and a minimum of 4 points. Patient was asked to encircle the digits according to the severity of symptoms which he/she feels. We planned to measure the outcomes at baseline, up to 3 months, with regular follow up at fortnight.

We postulated the null hypothesis (H_0) as pre-treatment score = post-treatment score; and alternative hypothesis (H_A) was pre-treatment score ≠ post-treatment score. The study design was open-label, observational, single arm, non-randomized, non-controlled, and interventional. We targeted to achieve a sample size around 40 conveniently within the stipulated time frame of 1 year, from mid-Feb 2023 to mid-Nov 2024.

Treatment protocol

Interventions were planned as administering indicated remedies in centesimal potencies as appropriate. In

centesimal scale, each dose consisted of four cane sugar globules medicated with a single drop of the indicated medicine, preserved in 88% v/v ethanol. All medicines were procured from a Good Manufacturing Practice-certified firm.

Following recruitment, selection of the single individualized medicine was based on the presenting symptom totality, repertorization and consultation with Materia Medica, and individualized dose on the judgment of susceptibility of the patients. As per individual requirement of the cases, aid of different repertories (ZOMEO software, Mind Technologies, Mumbai India) was taken with due consultation of Materia Medica. Overall decision making was influenced by consensus among the physicians. Subsequent prescriptions were generated according to Kent's observations and second prescription. Thus results of this study adhered to the criteria for reporting individualization in homeopathy.

All the participants were encouraged to maintain local hygiene, correct constipation, and unhealthy defecation habits such as ignoring the need to pass stools, irregular meals, spending a long time in the lavatory, straining, and lack of exercise. They were also advised about the importance of a fiber-rich diet in health and encouraged to consume food rich in natural fiber such as unpeeled fruits, vegetables, and whole-grain bread and will be prohibited from high consumption of spices.

Statistical analysis

Statistical analysis followed the intention-to-treat (ITT) approach; i.e., every included patient entered final analyses. Descriptive data (categorical and continuous) were presented in terms of absolute values, percentages, mean, and standard deviations (SD) as appropriate. Missing values were replaced by the last value carried forward method. To compare longitudinally obtained data measured repeatedly in the same patients at different points of time, paired *t*-test was performed comparing baseline data with that recorded after 3rd month. The significance level was set at $P < 0.05$ two-tailed. For within-subjects studies, dependence among means was corrected to make direct comparisons to effects size from between-subjects studies.

Results

Total 40 patients suffering from Anal fissure were screened for the project; 34 satisfied the pre-specified eligibility criteria; 6 were excluded for varied reasons. Since enrollment, each patient received classical homeopathic treatment for a period of 3-month. Total 30 continued till the end, 4 dropped out. Finally, the ITT population, i.e. 30 patients entered the analysis

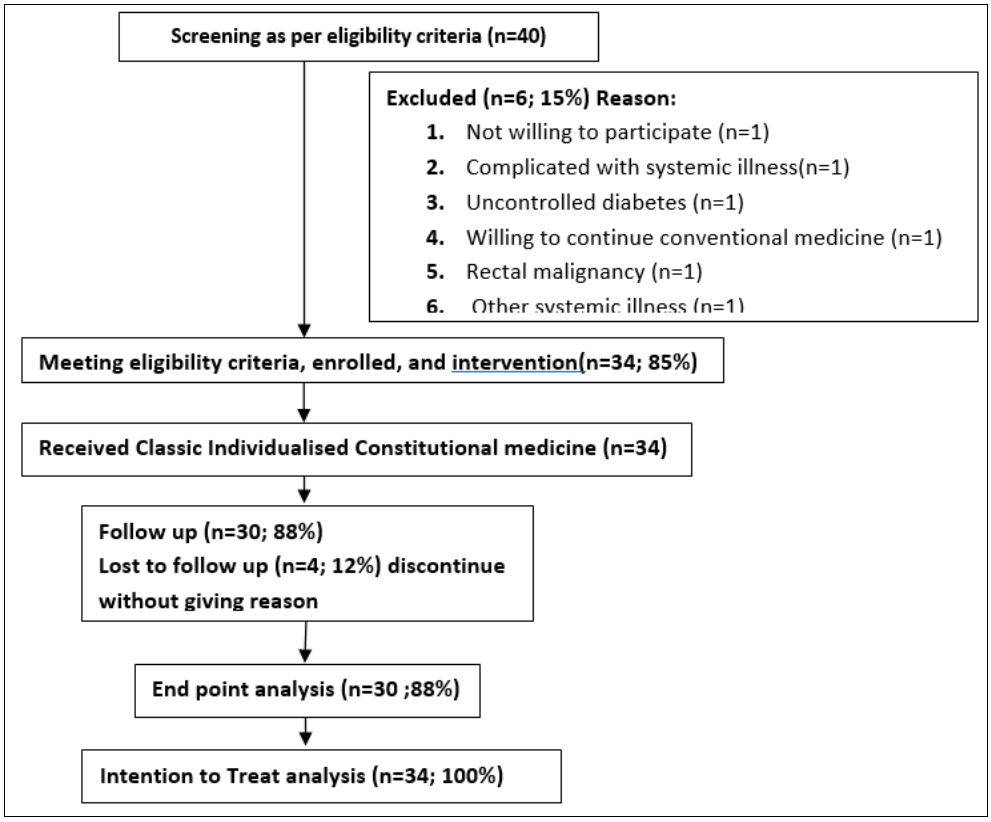

Fig 2: Study flow Diagram

Baseline Characteristics

Mean age of the patients was 31.8years (SD 5.4years); spanned all age groups, but majority belongs to the group of 30-35years (n=11; 37%), Most of the patient were male (n=21; 70%) their habitat were urban (n=22; 73%). Majority of patient physical activity sedentary habit affected (n=17; 57%), with profession teachers were affected (n=8; 25%) but having the low income people were affected more(n=14; 47%).

Table 1: Socio Demographic and Baseline status (n=30)

Feature	Description
Age Mean± SD	31.8±5.4
Age group (year) n(%)	
15-20years	1 (3.33%)
20-25 years	3(10%)
25-30 years	5(16.67%)
30-35 years	11(36.67%)
35-40 years	10(33.33%)
Gender n(%)	
Male	21(70%)
Female	9(30%)
Habitat n(%)	
Urban	22(73%)
Physical activity n(%)	
Sedentary	17(57%)
Economic Status n(%)	
Lower Middle Upper	14(47%) 10(33%) 6(20%)
Profession (Employment) n(%)	
Teacher Student Labour	8(25%) 6(18%) 5(15%)

(SD: Standard Deviation)

Realise Score

For REALISE Score, a 'paired t-test' was conducted to compare the effect of Individualized Homeopathic medicine at "0" month (Baseline) and after "3" months. The mean was reduced from 23.26 (SD 3.638) to 5.33 (SD 4.513). The reduction [t(29)=22.119, $P<0.001$, 2 tailed which less than $P<0.05$]. Here p values much less than $P<0.01$, Hence statistically highly significant. A graphical representation of the means and adjusted 95% Confidence interval is displayed in figure 2.

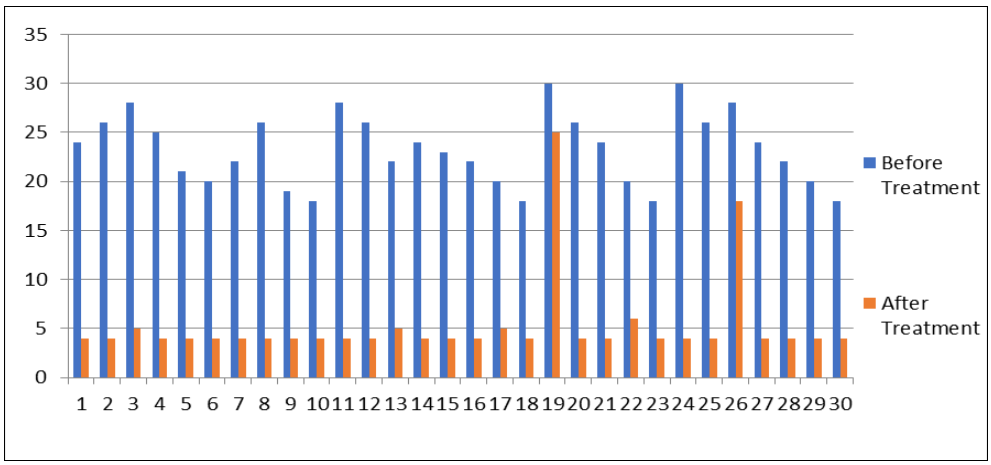

Fig 3: Bar diagram shows comparison of REALISE Score before and after treatment

Medicine Prescribed

The most frequently prescribed medicines were sulfur (n=9;30%), Nitric acid(n=8;27%), Aesculous Hip(n=5;17%), Arsenic alb, Ratanhia, Thuja(n=2;6%) Other prescribed medicines and their indications are enlisted in Table 2, Calcarea cab, Graphites were used in centesimal potencies (30C and 200C) remedies as and when required. Baseline prescriptions contained both centesimal potencies 30C n=24 (80%) and 200C n=6(20%).

Table 2: Table showing distribution of people according to the remedies used.

Sl. no.	Remedies	No. of people (%)
1.	Thuja	02(6%)
2.	Sulphur	09(30%)
3.	Ratanhia	02(6%)
4.	Nitric acid	08(27%)
5.	Graphites	01(3%)
6.	Calc carb	01(3%)
7.	Ars alb	02(6%)
8.	Aesculous hip	05(17%)

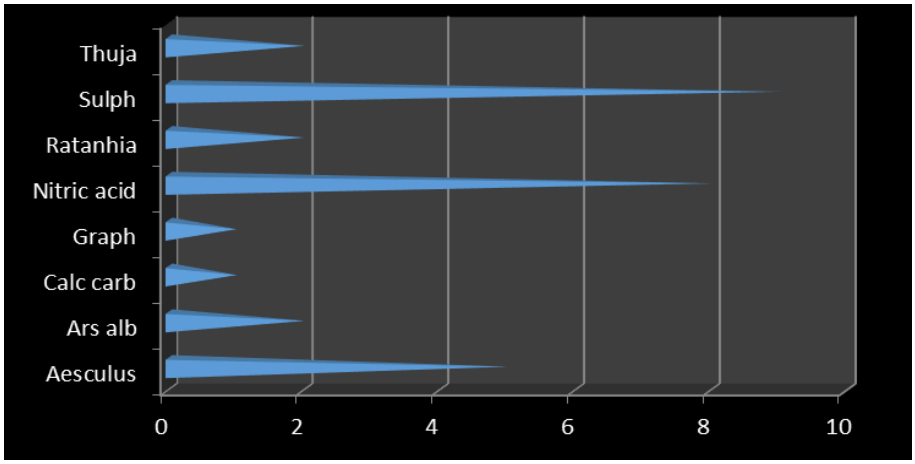

Fig 4: Distribution according to Remedy

Discussion

After individualized homeopathic treatment of the patients suffering from symptomatic anal fissure there was statistically significant lowering of mean REALISE Score intensity measures of bleeding and pain score over 0th and 3rd months. The discharge REALISE Score also reduced but that was statistically non-significant. Improvement was also observed in likert scale REALISE Score but over a 3rd month only. Assessments of disease severity clearly showed substantial improvements, even though the disease was long-standing, chronic, and primarily pre-treated. These remarkable results may be influenced by placebo effects and regression to the mean; however, our study's design did not focus on controlling for these factors. Additionally, while there is a possibility of overestimating the treatment effect or the use of undisclosed concurrent therapeutic modalities, we are confident in the validity of our findings.

This prospective observational study was aimed to reflect the contemporary homeopathic health care in real practice settings and its outcome in 30 adult anal fissure patients. The methodological strengths of our study include the consecutive patient enrollment, the participation of qualified Post graduate Homoeopathic Scholar and experienced homeopathic Associate professor of RBTS GHMCH schooled in and practicing “classical” homeopathy, and use of standardized and already validated outcome scales. This study is representative of individualizing (“classical”) homeopathy only. In a broader interpretation of the law of similar, remedies are selected for symptoms both typical of the diagnoses and outside the predominating pathologies (“constitutional”). In contrast to randomized trials, our study describes patients from everyday practice with a large variety of life styles. This ensures a high degree of external validity that allows extrapolation to usual medical care. We used REALISE score that are validated, often used and allowed for assessments of a specific complaint as well as for generalization and interpretation across various diagnoses.

Randomised controlled trials (RCTs) are known to be the gold standard for medical research investigating the efficacy of new interventions. While randomised controlled trials (RCTs) have advantages, they also face limitations, such as low external validity and potential recruitment challenges. In these situations, well-designed observational studies can provide valuable insights without systematically overestimating treatment effect [11].

Both RCTs and observational studies can complement each other, as observational studies help test hypotheses and reflect real-life scenarios more accurately. Together, they enhance the understanding of evidence and support informed clinical decision-making. Including both in meta-analyses often leads to more comprehensive evaluations of intervention [12].

Comparing A Case series study published by Dixit A K, Yadav M S. Reducing Pain and Promoting Healing in Acute Anal Fissure with Individualized Homoeopathic Treatment: A Case Series, on 2023. All seven cases here showed a significant reduction in VAS Score from base line to 3 month. In this study of case series showed that, effectiveness of Individualized homeopathic medicine in pain removing and healing in cases of anal fissure [13].

Another study, Giani I, Cioppa T, Caminati F, Linari C, Dreoni P, Rossi G, *et al*. Acute and Chronic Anal Fissure: The Role of a New Multitarget Ointment, An observational study published in 2023. Here use of REALISE score was used for assessment of conventional management of Anal fissure [14].

In this study a significant improvement in REALISE score, the effectiveness of the homeopathic remedies because no methodology for this purpose (control group, randomization, blinding, etc.) was built into its design. The aim of the investigation was to explore the effects of homeopathic medical care in treating some forms of anal fissures. Any improvement observed in this study should not be extrapolated to other forms of anal fissures. The data may also be helpful in the planning of further research projects on homeopathy. It would require specific instruments for more detailed assessment and effect size comparability, and a longer observation period.

Conclusion

Under “classical” or “individualized” homeopathic treatment of 3 months, the severity of anal fissure symptoms – pain, bleeding, improved substantially; however, there was significant improvement. Overall, homeopathic treatment appeared promising but needs further rigorous exploration in different designs for arriving at a confirmatory conclusion.

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Conflict of interest: None

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