DOI: 10.7860/JCDR/2025/77107.21991

Original Article

Ayurveda Section

# Comparative Evaluation of the Healing Effect of Topical *Jayanti* (*Tridax procumbens*) Cream versus Topical Lignocaine and Nifedipine Cream in *Parikartika* (Acute Fissure in Ano): A Randomised Controlled Trial

SHUBHAM BOBADE[1], SHEETAL ASUTKAR[2]




## ABSTRACT

**Introduction:** Fissure in ano is a common anorectal disorder, often characterised by the presence of an ulcer and increased anal sphincter spasm. The primary treatment goals focus on promoting wound healing and reducing sphincter spasm. Conservative management, including a fiber-rich diet and sitz baths, is effective in healing most cases. The disease typically presents with an ulcer in the anal canal as a key symptom.

**Aim:** To evaluate the efficacy of topical *Jayanti (T. procumbens)* cream vs lignocaine and nifedipine cream in healing of *Parikartika* (acute fissure in ano).

**Materials and Methods:** The present single-blind, double-arm, randomised controlled trial involved 70 patients with acute fissure in ano, and was conducted from April 2023 to November 2024. The patients were divided into two groups: Group A (Lignocaine 1.5% w/w and Nifedipine 0.3% w/w cream), and Group B (*Jayanti (T. procumbens)* cream), with 35 patients in each group. Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) statistical software v 29.0. A p-value of less than 0.05 was considered statistically significant. The evaluation parameters, including wound healing, anal spasm, per rectal bleeding, pain, and itching, were assessed.

**Results:** In group A (n=35), the mean score for wound healing improved from 2.40 on Day 0 to 0.46 on Day 30, while in group B (n=35), the score reduced from 2.37 to 0.31 over the same period, both showing statistical significance with p=0.0001. Spasm scores in group A (n=35) decreased from 0.86 on Day 0 to 0.14 by Day 30, and from 0.74 to 0.14 in group B (n=35), with p=0.0001. Per rectal bleeding in group A (n=35) dropped from 2.00 on Day 0 to 0.29 on Day 30, and from 1.57 to 0.23 in group B (n=35), with p=0.0001. For group A (n=35), improvement in itching after treatment showed a reduction from 23 to five patients, and for group B (n=35), from 25 to 7. The Chi-square ($\chi^2$) values were 19.28 for group A (n=35) and 16.64 for group B (n=35). However, a p-value of 0.751 indicated no statistically significant difference between the two groups at the 95% confidence level after treatment.

**Conclusion:** Lignocaine and Nifedipine cream (Group A) and *Jayanti (T. procumbens)* cream (Group B) on the symptoms of *Parikartika* (acute fissure in ano) were found to be equally efficacious, with both treatments showing statistically significant improvements across the overall assessment criteria.


**Keywords:** Anal fissure, Anal sphincter, Anus disease, Ayurveda, Surgery

## INTRODUCTION

In surgical practice, fissure in ano is a benign, painful proctological ailment that affects well-being [1]. The probable understanding is a collective consequence of internal anal sphincter spasm, hard stools and susceptible factors alike: a high-fat diet, alcohol consumption, a non-vegetarian diet, smoking, etc., but the cause of fissure in ano is yet to be determined [2]. Typically, it ends above the dentate line, occurring more commonly in the midline posteriorly in males and anteriorly in females. In males, 95% of anal fissures are posterior and 5% are anterior, while in females, 80% are posterior and 20% are anterior [3]. The conservative approach is the initial line of management for fissures, with aim of normalising the bowel movements through local medications that reduce the local pain and exasperation, laxatives, stool softeners, and a high-fiber diet. The optimal approach for addressing the hypertonicity of the anal sphincter is a matter of debate, with potential options including medical or surgical intervention [4]. But the majority of anal fissures respond to conservative management. One of the treatment approaches may be to achieve analgesia, and wound healing may help to reduce the hypertonicity of the anal sphincter [5]. Lateral internal sphincterotomy stands out as the most efficient and well-established surgical method for managing fissure in ano, despite having a recurrence rate that varies from 90 to 100% [6]. A notable drawback associated with lateral internal sphincterotomy is potential onset of anal incontinence, primarily related to flatus [7]. Given the intricate nature of this condition, it becomes essential to find effective, safe, and promising treatment modalities within alternative sciences to facilitate early recovery and prevent recurrence. Though most of the studies suggest that for acute fissure in ano standard treatment remained the use of local application of nifedipine and lignocaine cream [8]. Given the current scenario in India, where no comparative studies are accessible, the present study seeks to compare the newer medicine, *Jayanti (T. procumbens)* cream, with standard Lignocaine 1.5% w/w and Nifedipine 0.3% w/w cream. This study aims to evaluate the efficacy of topical *Jayanti (T. procumbens)* cream and Lignocaine and Nifedipine cream in promoting healing of *Parikartika* (acute fissure in ano). The primary objectives are to assess the healing effects of each cream individually. Additionally, the study seeks to compare the relative efficacy of these treatments to identify the more effective option for managing acute fissure in ano.

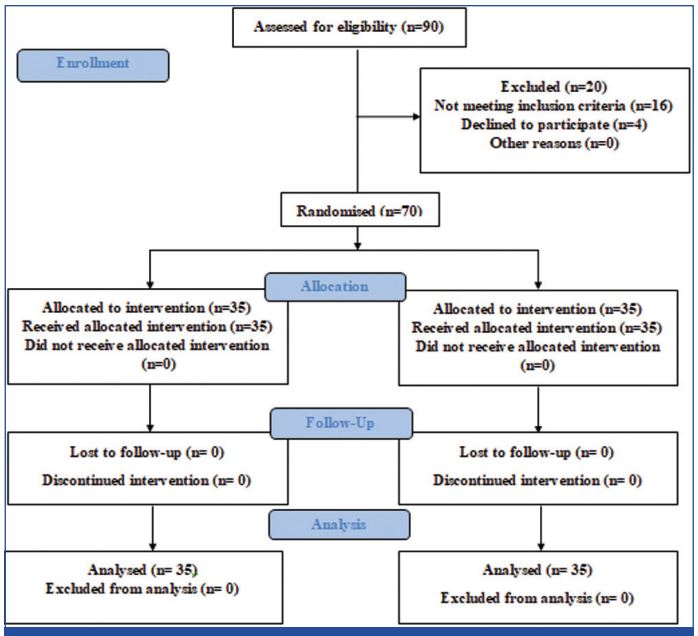
**Null hypothesis:** Topical *Jayanti (T. procumbens)* cream is not more efficacious than topical Lignocaine and Nifedipine cream in the management of *Parikartika* (acute fissure in ano).

**Alternate hypothesis:** Topical *Jayanti (T. procumbens)* cream is more efficacious than topical Lignocaine and Nifedipine cream in the management of *Parikartika* (acute fissure in ano).

## MATERIALS AND METHODS

The present study was a single-blind, double-arm, randomised controlled trial conducted at Mahatma Gandhi Ayurveda College, Hospital, and Research Centre (MGACHRC), Salod Hirapur (H), Maharashtra, India, from April 2023 to November 2024. The participants were unaware of their group allocation and the treatment they received. To ensure single blinding, this was achieved by providing identical, unlabeled treatment packaging to all participants, irrespective of their group assignment. Randomisation was performed using a computer-generated randomisation table, which ensured an unbiased allocation of participants into two groups. The allocation sequence was concealed in Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). Approval from Institutional Ethics Committee, were taken before initiating the study (vide letter no. MGACHRC/IEC/July–2022/568). The study was registered with the Clinical Trials Registry-India (CTRI) under the number CTRI/2023/03/050428. Informed written consent was obtained from the patients prior to their enrollment in the study.

**Sample size calculation:** Cochran's formula was used for sample size estimation, with a confidence level of (Z=1.67) and a margin of error (e=0.117), using a prevalence (p=0.1781) [9]. The sample size for this study was calculated to be 35 in each group. Simple randomisation was used as the sampling technique. A total of 70 patients with a diagnosis of acute anal fissure were enrolled in this study, consisting mostly of the rural and suburban population of Wardha, Maharashtra, India [Table/Fig-1].



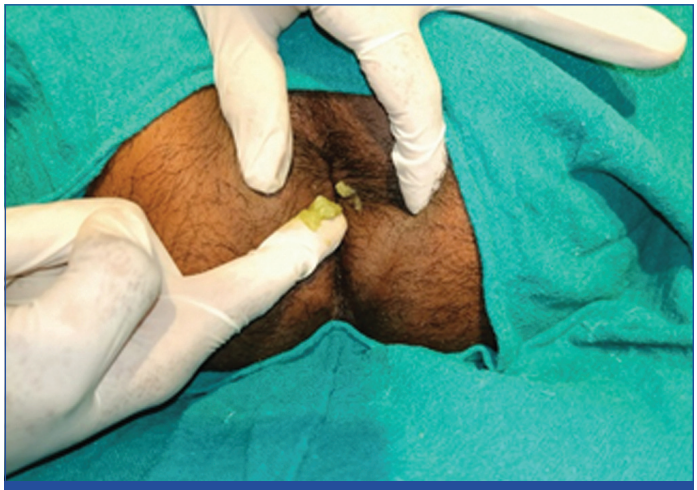

**[Table/Fig-1]:** CONSORT flow diagram.

**Inclusion criteria:** Patients presenting with acute fissure in ano, diagnosed through rectal examination within a timeframe of less than six weeks from onset. Patients aged between 20 and 50 years, regardless of gender, occupation, and socioeconomic status were included. Diagnosed patients with fissure in ano exhibiting grade 0 or 1 anal spasm were considered eligible [10]. Additionally, patients with fissure in ano who had controlled cases of diabetes mellitus (with random blood sugar levels between 80 mg/dL and 140 mg/dL) and known cases of immunocompromised conditions such as tuberculosis, Human Immunodeficiency Virus (HIV), hepatitis B, or sexually transmitted diseases, who were receiving standard treatment, were included. Participants were required to provide informed consent and be prepared to adhere to clear instructions.

**Exclusion criteria:** Patients outside the age range of 20 to 50 years, particularly those over 50, were excluded. Additionally, individuals with chronic fissures lasting more than six weeks, especially those with a sentinel tag, were not included. Patients with grade 2 anal spasm, haemorrhoids, fistula in ano, or anorectal carcinoma were also excluded. Furthermore, those with uncontrolled diabetes mellitus (random blood sugar levels >140 mg/dL) and known cases of anaemia, bleeding disorders, Crohn's disease, or ulcerative colitis were omitted from the study.

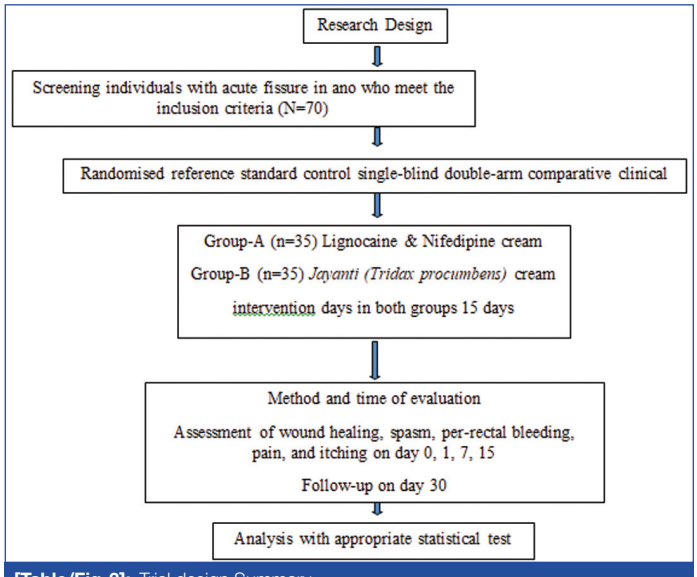
### Study Procedure

A total of 70 patients were divided into two groups: group A and group B, with 35 patients in each group. In group A, Lignocaine 1.5% w/w and Nifedipine 0.3% w/w cream and in group B, *Jayanti (T. procumbens)* cream was applied over anal fissure [Table/Fig-2] for 15 days twice a day. Additionally, subjects in both groups received a hot sitz bath twice a day before the application of the cream, along with *Panchasakara Churna*, 5 grams taken orally at bedtime with lukewarm water.



**[Table/Fig-2]:** Application of *Jayanti (T. procumbens)* cream in group B.

Evaluation of patients for overall assessment criteria was done in the Outpatients Department at day 0, 1, 7, 15 during the course of the treatment and follow up after treatment on day 30. At each visit, details on the fissure healing, pain relief and any side-effects and recurrence were noted down [Table/Fig-3].




**[Table/Fig-3]:** Trial design Summary.

The assessment scales were as follows: wound healing: Assessed on a 0 to 3 scale- 0: completely healed with healthy scar, 1: partially

healed with granulation tissue, 2: clean wound without slough/discharge, 3: wound with discharge [11].

**Spasm:** Assessed on a 0 to 2 scale- 0: normal (one finger can pass): 1: finger can pass with severe pain; 2: no finger can pass [12].

**Per rectal bleeding:** Assessed on a 0 to 3 scale- 0: no bleeding, 1: mild (<5 drops), 2: moderate (5-10 drops), 3: severe (>10 drops) [13].

**Pain:** Assessed on the Visual Analogue Scale (VAS) (0-10)- 0: no pain, 10: worst pain [14,15]. Scores: 0: no pain, 1-3: mild, 4-6: moderate, 7-9: severe, 10: unbearable.

**Itching:** Assessed on the Numerical Rating Scale (0-10)- 0: no itch, 10: worst imaginable itch [16].

## STATISTICAL ANALYSIS

The data were collected and analysed statistically using the SPSS software v 29.0. Results were calculated using Wilcoxon's signed rank test and the Chi-square test for the overall assessment of each symptom separately. A One-way Analysis of Variance (ANOVA) test was applied within the groups for the gradations of each variable.

## RESULTS

Total number of 70 (N=70) patients were divided in to three age groups. The youngest patient had been of 20 years while the eldest patient had been of 50 years. The study indicates that the incidence of acutes fissure in ano was highest 27 (38.57%) in the age group of 40-50 years, while it was lowest 19 (27.14%) in the age group of 20-29 years. The age group of 30-39 years comprised 24 (34.28%). The study found a slightly higher incidence of fissure in ano among males 45 (64.28%) compared to females 25 (35.71%), resulting in a male-to-female ratio of 1.8:1. This suggests that the condition is more common in males [17]. The study observed that a higher percentage of patients 39 (55.71%) with a non-vegetarian diet experienced fissure in ano compared to those following a vegetarian diet 31 (44.28%). The non-vegetarian diet, often low in fiber and roughage and high in spicy foods, contributes to frequent constipation, which is a known factor in the aggravation of this condition [18]. The study indicated that the majority of patients 47 (67.14%) had a fissure located at the 6 o'clock position, which was the most common occurrence [19]. Fissures at the 12 o'clock position were observed in 6 (8.57%) of cases, while multiple fissures at both the 6 and 12 o'clock positions were present in 17 (24.28%) of patients. The study revealed a strong correlation between bowel habits and the occurrence of constipation in patients with acute fissure in ano. A majority of the patients 54 (77.14%) had irregular bowel habits, which are often associated with episodes of constipation, while only 16 (22.85%) reported having regular bowel habits. Constipation can lead to hard stools and straining during defecation, increasing the risk of developing anal fissures [20].

**Effect of group A (lignocaine and nifedipine cream) on wound healing:** The initial Before Treatment (BT) mean score for wound healing was 2.40 on Day 0 and remained the same at 2.40 on Day 1. A notable improvement was observed by Day 7, with the mean score reducing to 1.57, further decreasing to 1.00 on Day 15, and reaching 0.46 by Day 30. The effectiveness of the treatment in promoting wound healing was statistically significant, with a p-value 0.0001 (p=<0.05) [Table/Fig-4].

**Effect of group B {*Jayanti* cream} on wound healing:** The initial (BT) mean score for wound healing was 2.37 on Day 0, slightly improving to 2.29 by Day 1. The healing continued with a reduction to 1.54 on Day 7, 1.03 on Day 15, and a substantial decrease to 0.31 by Day 30. The effectiveness of the treatment in wound healing [Table/Fig-5,6] was statistically significant, with a p-value 0.0001 (p<0.05) [Table/Fig-7].

**Effect of group A (lignocaine and nifedipine cream) on spasm:** The initial (BT) mean score for the spasm parameter was 0.86 on Day 0, which decreased to 0.77 on Day 1. A more notable reduction was observed by Day 7, with the mean score dropping to 0.23. By Day 15, the spasm had resolved, reaching a mean score of 0.00, and remained at 0.14 on Day 30. The effectiveness of the treatment in reducing spasm was statistically significant, with a p-value 0.0001 (p=<0.05) [Table/Fig-8].

**Effect of group B {*Jayanti* cream} on spasm:** The initial (BT) mean score for the spasm parameter was 0.74 on Day 0, which improved to 0.60 by Day 1. Further improvement was observed with a reduction to 0.31 on Day 7, and a near-complete resolution with a score of 0.06 by Day 15. By Day 30, the mean score was 0.14. The effectiveness of the treatment in reducing spasm was statistically significant, with p-value=0.0001 (p=<0.05) [Table/Fig-9].

**Effect of group A (lignocaine and nifedipine cream) on per rectal bleeding:** The initial (BT) mean score for per rectal bleeding was 2.00 on Day 0, which slightly decreased to 1.91 by Day 1. A more significant reduction was observed by Day 7, with the mean score dropping to 1.17. By Day 15, the mean score further decreased to 0.54, and on Day 30, it was 0.29. The effectiveness of the treatment in reducing per rectal bleeding was statistically significant, with a p-value 0.0001 (p=<0.05) [Table/Fig-10].

**Effect of group B (*Jayanti* cream) on per rectal bleeding:** The initial (BT) mean score for per rectal bleeding was 1.57 on Day 0, which improved to 1.49 by Day 1. By Day 7, the mean score decreased to 0.80, and by Day 15, it further reduced to 0.63. On Day 30, the mean score was significantly lower at 0.23. The effectiveness of the treatment in reducing per rectal bleeding was statistically significant, with a p-value 0.0001 (p=<0.05) [Table/Fig-11].

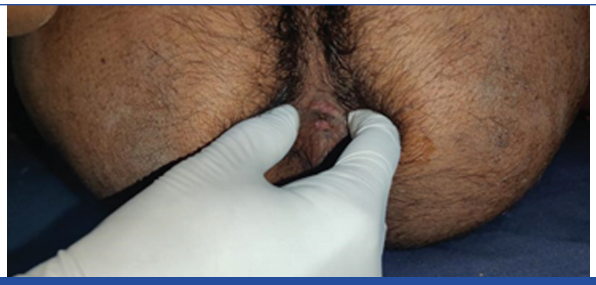
**Effect of group A (lignocaine and nifedipine cream) on pain:** The initial (BT) mean score for pain was 2.11 on Day 0, which slightly decreased to 2.00 by Day 1. A more significant reduction was observed by Day 7, with the mean score dropping to 1.17. By Day 15, the mean score further decreased to 0.49, and on Day 30, it was 0.23. The effectiveness of the treatment in reducing pain was statistically significant, with a p-value 0.0001 (p=<0.05) [Table/Fig-12].

**Effect of group B (*Jayanti* cream) on pain:** The initial (BT) mean score for pain was 2.03 on Day 0, which improved to 1.91 by Day 1. By Day 7, the mean score decreased to 1.20, and by Day 15, it further reduced to 0.77. On Day 30, the mean score was significantly lower at 0.31. The effectiveness of the treatment in reducing pain was statistically significant, with a p-value 0.0001 (p=<0.05) [Table/Fig-13].

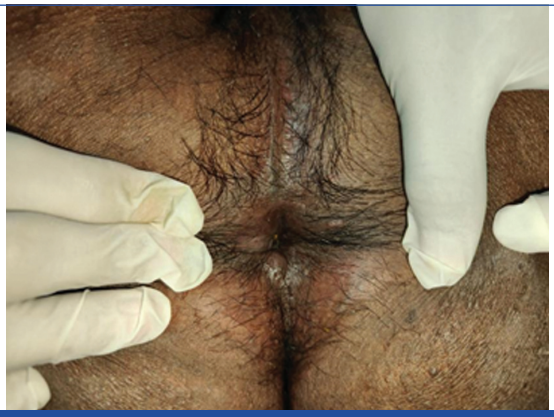
**Effect of group A (lignocaine and nifedipine cream) on itching:** The initial (BT) assessment revealed that 23 patients experienced present itching, which reduced to 5 at the follow-up assessment After Treatment (AT). The Chi-square ($\chi^2$) value calculated was 19.28, with a p-value of 0.751 (p>0.05) [Table/Fig-14].

| Follow-up duration | Mean wound healing score | SD | Source of variation (wound healing) | Degree of freedom (df) | Sum of squares | Mean sum of squares | F ratio | p-value | Result |
|---|---|---|---|---|---|---|---|---|---|
| Day 0 | 2.40 | 0.497 | Between the groups | 4 | 102.937143 | 25.73429 | 94.98697 | 0.0001 | Significant (p=<0.05) |
| Day 1 | 2.40 | 0.497 | | | | | | | |
| Day 7 | 1.57 | 0.608 | Error | 170 | 46.0571429 | 0.270924 | | | |
| Day 15 | 1.00 | 0.485 | | | | | | | |
| Day 30 | 0.46 | 0.505 | Total | 174 | 148.994286 | | | | |

**[Table/Fig-4]:** ANOVA table for wound healing in group A (Lignocaine and Nifedipine cream).



**[Table/Fig-5]:** Depiction of acute fissure in ano in group B before treatment on Day 0.



**[Table/Fig-6]:** Effect of *Jayanti (T. procumbens)* cream in group B after treatment on Day 30.

**Effect of group B (*Jayanti cream*) on itching:** The initial (BT) assessment showed that 25 patients reported itching, which reduced to seven at the follow-up assessment (AT). However, the Chi-square ($\chi^2$) value for this group was 16.64, with a p-value of 0.751 (p>0.05) [Table/Fig-14].

Mean difference of group A is less than mean difference of group B and p-value is greater than the significance level alpha=0.05, we should accept the null hypothesis H0 and reject the alternate hypothesis Ha, i.e., *Jayanti (T. procumbens)* cream (Group B) is not significant than Lignocaine and Nifedipine cream (Group A) for wound healing, spasm, per rectal bleeding and pain [Table/Fig-15,16].

The calculated Chi-square ($\chi^2$) value was 0.10 with a p-value of 0.751. The degrees of freedom (df) are 1. Since the p-value 0.751 is much higher than 0.05, the result is not statistically significant at the 95% confidence level. This suggests that there is no significant difference between group A and group B in terms of itching after treatment [Table/Fig-14].

## DISCUSSION

The present study indicates that both treatment with Lignocaine and Nifedipine cream in group A and *Jayanti (T. procumbens)* cream in group B significantly improved wound healing, spasm, per rectal bleeding, and itching. Group B demonstrated superior wound healing, with mean scores reducing from 2.37 (Day 0) to 0.31 (Day 30), compared to 2.40 (Day 0) to 0.457 (Day 30) in group A. Spasm resolution was faster in group A, where mean scores

| Follow-up duration | Mean wound healing score | SD | Source of variation (wound healing) | Degree of freedom (df) | Sum of squares | Mean sum of squares | F ratio | p-value | Result |
|---|---|---|---|---|---|---|---|---|---|
| Day 0 | 2.37 | 0.546 | Between the groups | 4 | 105.222857 | 26.30571 | 88.52885 | 0.0001 | Significant (p=<0.05) |
| Day 1 | 2.29 | 0.518 | | | | | | | |
| Day 7 | 1.54 | 0.610 | Error | 170 | 50.5142857 | 0.297143 | | | |
| Day 15 | 1.03 | 0.568 | | | | | | | |
| Day 30 | 0.31 | 0.471 | Total | 174 | 155.737143 | | | | |

**[Table/Fig-7]:** ANOVA table for wound healing in group B *(Jayanti (T. procumbens)* cream).

| Follow-up duration | Mean spasm score | SD | Source of variation (spasm) | Degree of freedom (df) | Sum of squares | Mean sum of squares | F ratio | p-value | Result |
|---|---|---|---|---|---|---|---|---|---|
| Day 0 | 0.86 | 0.35 | Between the groups | 4 | 21.0857143 | 5.271429 | 42.84836 | 0.0001 | Significant (p=<0.05) |
| Day 1 | 0.77 | 0.42 | | | | | | | |
| Day 7 | 0.23 | 0.42 | Error | 170 | 20.9142857 | 0.123025 | | | |
| Day 15 | 0.00 | 0.00 | | | | | | | |
| Day 30 | 0.14 | 0.35 | Total | 174 | 42 | | | | |

**[Table/Fig-8]:** ANOVA table for spasm in group A (Lignocaine and Nifedipine cream).

| Follow-up duration | Mean spasm score | SD | Source of variation (spasm) | Degree of freedom (df) | Sum of squares | Mean sum of squares | F ratio | p-value | Result |
|---|---|---|---|---|---|---|---|---|---|
| Day 0 | 0.74 | 0.44 | Between the groups | 4 | 12.0571429 | 3.014286 | 17.79266 | 0.0001 | Significant (p=<0.05) |
| Day 1 | 0.60 | 0.49 | | | | | | | |
| Day 7 | 0.31 | 0.47 | Error | 170 | 28.8 | 0.169412 | | | |
| Day 15 | 0.06 | 0.23 | | | | | | | |
| Day 30 | 0.14 | 0.35 | Total | 174 | 40.8571429 | | | | |

**[Table/Fig-9]:** ANOVA table for spasm in group B *(Jayanti (T. procumbens)* cream).

| Follow-up duration | Mean per rectal bleeding score | SD | Source of variation (per rectal bleeding) | Degree of freedom (df) | Sum of squares | Mean sum of squares | F ratio | p-value | Result |
|---|---|---|---|---|---|---|---|---|---|
| Day 0 | 2.00 | 0.84 | Between the Groups | 4 | 84.6057143 | 21.15143 | 40.15667 | 0.0001 | Significant (p=<0.05) |
| Day 1 | 1.91 | 0.85 | | | | | | | |
| Day 7 | 1.17 | 0.71 | Error | 170 | 89.5428571 | 0.526723 | | | |
| Day 15 | 0.54 | 0.66 | | | | | | | |
| Day 30 | 0.29 | 0.52 | Total | 174 | 174.148571 | | | | |

**[Table/Fig-10]:** ANOVA table for per rectal bleeding in group A (Lignocaine and Nifedipine cream).

| Follow-up duration | Mean per rectal bleeding score | SD | Source of variation (per rectal bleeding) | Degree of Freedom (df) | Sum of squares | Mean sum of squares | F ratio | p-value | Result |
|---|---|---|---|---|---|---|---|---|---|
| Day 0 | 1.57 | 0.65 | Between the groups | 4 | 46.1714286 | 11.54286 | 34.27146 | 0.0001 | Significant (p=<0.05) |
| Day 1 | 1.49 | 0.61 | | | | | | | |
| Day 7 | 0.80 | 0.63 | Error | 170 | 57.2571429 | 0.336807 | | | |
| Day 15 | 0.63 | 0.55 | | | | | | | |
| Day 30 | 0.23 | 0.43 | Total | 174 | 103.428571 | | | | |

**[Table/Fig-11]:** ANOVA table for per rectal bleeding in group B {*Jayanti (T. procumbens)* cream}.

| Follow-up duration | Mean per rectal bleeding score | SD | Source of variation (per rectal bleeding) | Degree of Freedom (df) | Sum of squares | Mean sum of squares | F ratio | p-value | Result |
|---|---|---|---|---|---|---|---|---|---|
| Day 0 | 2.11 | 0.83 | Between the groups | 4 | 102.571429 | 25.64286 | 53.53509 | 0.0001 | Significant (p=<0.05) |
| Day 1 | 2.00 | 0.77 | | | | | | | |
| Day 7 | 1.17 | 0.75 | Error | 170 | 81.4285714 | 0.478992 | | | |
| Day 15 | 0.49 | 0.61 | | | | | | | |
| Day 30 | 0.23 | 0.43 | Total | 174 | 184.000000 | | | | |

**[Table/Fig-12]:** ANOVA table for pain in group A (Lignocaine and Nifedipine cream).

| Follow-up duration | Mean per rectal bleeding score | SD | Source of variation (per rectal bleeding) | Degree of Freedom (df) | Sum of squares | Mean sum of squares | F ratio | p-value | Result |
|---|---|---|---|---|---|---|---|---|---|
| Day 0 | 2.03 | 0.71 | Between the groups | 4 | 75.4057143 | 18.85143 | 43.88341 | 0.0001 | Significant (p=<0.05) |
| Day 1 | 1.91 | 0.78 | | | | | | | |
| Day 7 | 1.20 | 0.58 | Error | 170 | 73.0285714 | 0.42958 | | | |
| Day 15 | 0.77 | 0.69 | | | | | | | |
| Day 30 | 0.31 | 0.47 | Total | 174 | 148.434286 | | | | |

**[Table/Fig-13]:** ANOVA table for pain in group B {*Jayanti (T. procumbens)* cream}.

| Itching | Group A | | | Group B | | | Chi square ($\chi^2$) value | p-value | Result |
|---|---|---|---|---|---|---|---|---|---|
| | BT | AT | Chi-square ($X^2$) value and result | BT | AT | Chi-square ($\chi^2$) value and result | | | |
| Present (10) | 23 | 5 | 19.28 Significant in group A | 25 | 7 | 16.64 Significant in group B | 0.1 | 0.751 | Non-significant between group A and group B (p>0.05) |
| Absent (0) | 12 | 30 | | 10 | 28 | | | | |
| Total (n) | 35 | 35 | | 35 | 35 | | | | |

**[Table/Fig-14]:** Statistical analysis for itching in group A and group B.

| Follow-ups | Wound healing | | | | | |
|---|---|---|---|---|---|---|
| | Mean | | SD | | t-value | p-value (t test) |
| | Group A | Group B | Group A | Group B | | |
| Day 0 | 2.40 | 2.37 | 0.497 | 0.546 | 0.22 | 0.82 |
| Day 1 | 2.40 | 2.29 | 0.497 | 0.518 | 0.94 | 0.35 |
| Day 7 | 1.57 | 1.54 | 0.608 | 0.610 | 0.19 | 0.84 |
| Day 15 | 1.00 | 1.03 | 0.485 | 0.568 | -0.22 | 0.82 |
| Day 30 | 0.46 | 0.31 | 0.505 | 0.471 | 1.22 | 0.22 |
| Follow-ups | Spasm | | | | | |
| | Mean | | SD | | t-value | p-value (t test) |
| | Group A | Group B | Group A | Group B | | |
| Day 0 | 0.86 | 0.74 | 0.35 | 0.44 | 1.19 | 0.23 |
| Day 1 | 0.77 | 0.60 | 0.42 | 0.49 | 1.54 | 0.12 |
| Day 7 | 0.23 | 0.31 | 0.42 | 0.47 | -0.79 | 0.42 |
| Day 15 | 0.00 | 0.06 | 0.00 | 0.23 | -1.43 | 0.16 |
| Day 30 | 0.14 | 0.14 | 0.35 | 0.35 | 0.00 | 1.00 |
| Follow-ups | Per rectal bleeding | | | | | |
| | Mean | | SD | | t-value | p-value (t test) |
| | Group A | Group B | Group A | Group B | | |
| Day 0 | 2.00 | 1.57 | 0.84 | 0.65 | 2.38 | 0.020 |
| Day 1 | 1.91 | 1.49 | 0.85 | 0.61 | 2.41 | 0.018 |
| Day 7 | 1.17 | 0.80 | 0.71 | 0.63 | 2.32 | 0.023 |
| Day 15 | 0.54 | 0.63 | 0.66 | 0.55 | -0.59 | 0.555 |
| Day 30 | 0.29 | 0.23 | 0.52 | 0.43 | 0.50 | 0.616 |
| Follow-ups | Pain | | | | | |
| | Mean | | SD | | t-value | p-value (t test) |
| | Group A | Group B | Group A | Group B | | |
| Day 0 | 2.11 | 2.03 | 0.83 | 0.71 | 0.46 | 0.64 |
| Day 1 | 2.00 | 1.91 | 0.77 | 0.78 | 0.46 | 0.64 |
| Day 7 | 1.17 | 1.20 | 0.75 | 0.58 | -0.18 | 0.86 |
| Day 15 | 0.49 | 0.77 | 0.61 | 0.69 | -1.83 | 0.07 |
| Day 30 | 0.23 | 0.31 | 0.43 | 0.47 | -0.80 | 0.43 |

**[Table/Fig-15]:** Day wise mean table for wound healing, spasm, per rectal bleeding and pain.

decreased from 0.857 (Day 0) to 0.142 (Day 30), while group B showed a reduction from 0.742 (Day 0) to 0.142 (Day 30). Per rectal bleeding improved more in group B, with mean scores dropping from 1.57 (Day 0) to 0.22 (Day 30), compared to 2.00 (Day 0) to 0.28 (Day 30) in group A. Itching relief was also better in group B, where mean scores declined from 2.11 (Day 0) to 0.228 (Day 30), while group A reduced from 2.02 (Day 0) to 0.31 (Day 30).

A study conducted by Elgendy HM et al., showed that the topical metronidazole 10% combined with 0.2% Glyceryl Trinitrate (GTN) treatment group had faster healing compared to the 0.2% GTN treatment group in acute anal fissure [21]. In a recent

| Wound healing | | Mean | Median | SD | SE | Wilcoxon W | % Effect | p-value |
|---|---|---|---|---|---|---|---|---|
| Group A | BT | 2.40 | 2.0 | 0.49 | 0.08 | 630 | 86.75 | <0.0001 |
| | AT | 0.46 | 0.0 | 0.50 | 0.08 | | | |
| Group B | BT | 2.37 | 2.0 | 0.54 | 0.09 | 630 | 80.95 | <0.0001 |
| | AT | 0.31 | 0.0 | 0.47 | 0.07 | | | |
| **Spasm** | | | | | | | | |
| Group A | BT | 0.86 | 1.0 | 0.35 | 0.06 | 325 | 83.33 | <0.0001 |
| | AT | 0.14 | 0.0 | 0.35 | 0.06 | | | |
| Group B | BT | 0.74 | 1.0 | 0.44 | 0.07 | 231 | 80.77 | <0.0001 |
| | AT | 0.14 | 0.0 | 0.35 | 0.06 | | | |
| **Per rectal bleeding** | | | | | | | | |
| Group A | BT | 2.00 | 2.0 | 0.84 | 0.14 | 561 | 85.71 | <0.0001 |
| | AT | 0.29 | 0.0 | 0.51 | 0.08 | | | |
| Group B | BT | 1.57 | 2.0 | 0.65 | 0.11 | 496 | 85.45 | <0.0001 |
| | AT | 0.23 | 0.0 | 0.42 | 0.072 | | | |
| **Pain** | | | | | | | | |
| Group A | BT | 2.11 | 2.0 | 0.70 | 0.11 | 595 | 84.51 | <0.0001 |
| | AT | 0.23 | 0.0 | 0.47 | 0.07 | | | |
| Group B | BT | 2.03 | 2.0 | 0.83 | 0.14 | 630 | 89.19 | <0.0001 |
| | AT | 0.31 | 0.0 | 0.42 | 0.072 | | | |

**[Table/Fig-16]:** Statistical analysis for wound healing, spasm, per rectal bleeding and pain.

study conducted by Manu S et al., it was shown that fixed-dose preparations containing 7% sucralfate and 1% metronidazole are almost as effective as 2% diltiazem, which is considered quite effective in the treatment of acute fissure in ano [22]. Based on the findings of an in-vitro study, Turmocin Plus demonstrated significant potential in reducing inflammation, inhibiting inflammatory cell migration, and suppressing VEGF expression, as assessed using cell viability assay, western blot analysis, wound migration assay, immunofluorescence studies, and immunohistochemical analysis of anorectal specimens. It has a therapeutic role in managing the symptoms of acute anal fissure in ano, along with other anorectal diseases [23]. Meanwhile, past studies have shown that the use of topical 0.2% GTN treatment was often associated with adverse effects such as headaches, dizziness, and postural hypotension, hence limiting its use [24]. Research also suggested that headaches were common, and rarely, perianal dermatitis and hypotension had been reported in subjects treated with topical 2% diltiazem [25]. Although topical Nifedipine was suggested to be better tolerated by subjects, exhibiting a lower incidence of adverse effects compared to diltiazem [26].

In the present study, topical Lignocaine 1.5% w/w and Nifedipine 0.3% w/w cream was used as the standard treatment in the control group A. Anal fissures are often associated with compromised blood supply to the anoderm due to elevated anal pressure. Nifedipine is a calcium channel blocker that addresses this issue by dilating blood vessels, thereby enhancing blood flow to the injured tissues. It also helps lower the pressure in the internal anal sphincter, reducing pain and promoting healing. Lignocaine is primarily used for its anaesthetic properties in combination with Nifedipine [27,28].

The recent study suggested that the deficiency of Nitric Oxide Synthase (NOS) in the internal anal sphincter might have contributed to anal spasm in anal fissure, and the release of Nitric Oxide (NO) could have been a potential treatment to alleviate this spasm [29]. In line with this, an in-vivo study indicated that *T. procumbens* extract promotes endothelial NO release, enhancing smooth muscle relaxant activity, primarily through L-type calcium channel blocking, inhibition of prostaglandin release or synthesis, and partly through inhibitory muscarinic receptor activity [30]. The statistically significant effectiveness of reducing spasm in group B treated with *Jayanti (T. procumbens)* cream, with a p-value of 0.0001 ($p<0.05$), can be attributed to its hypotensive activity. Additionally, the warm sitz bath given in both group A and group B can help reduce spasm, as supported by clinical literature.

Another in-vivo study investigated the wound-healing effect of *T. procumbens* using an excision wound model, which exhibited dose-dependent pro-healing properties, with higher doses triggering inflammatory reactions [31]. The statistically significant effectiveness of wound healing in group B treated with *Jayanti (T. procumbens)* cream, with a p-value of 0.0001 ($p<0.05$), can be justified in the treatment of acute anal fissure. An in-vivo study showed that *Tridax procumbens* extracts possessed significant analgesic, anti-inflammatory, and antipyretic activity [32]. The statistically significant effectiveness in pain relief in group B treated with *Jayanti (T. procumbens)* cream, with a p-value of 0.0001 ($p<0.05$), can be associated in anal fissure. Anal fissures are caused by a vicious cycle involving anal spasm, pain, hard stool, constipation, and ulcers in the anal canal [33]. In the present study, *Panchasakara Churna* was used as a laxative in both group A and group B to treat constipation, a primary factor associated with fissure in ano [34].

Present study suggests that a combined approach, addressing pain reduction, anal sphincter hypertonicity, faster ulcer healing, and constipation, offers more effective management of acute fissure in ano. The findings highlight the safety and potential of *T. procumbens* in promoting wound healing, providing analgesia, reducing anal spasm, and its non-toxic nature, making it a promising therapeutic option for advanced cases. None of the patients experienced adverse effects related to the use of topical *Jayanti (T. procumbens)* cream, while only two patients reported mild headaches as side-effects after using Lignocaine and Nifedipine cream. Future studies should focus on longer follow-up periods to assess recurrence rates and further investigate the long-term safety and efficacy of both treatments in diverse populations.

### Limitation(s)

The primary limitation of this study was the brief duration of follow-up, which precluded the collection of data on long-term recurrence rates. Consequently, any potential recurrence beyond the study period could not be assessed or analysed.

## CONCLUSION(S)

This study demonstrated that both topical *Jayanti (T. procumbens)* cream and topical Lignocaine 1.5% w/w and Nifedipine 0.3% w/w cream are equally efficacious in providing symptomatic relief for acute fissure in ano. Both topical treatments are viable, non-invasive options and can act as effective first-line therapies for the management of acute fissure in ano.

## REFERENCES

[1] Gardner IH, Siddharthan RV, Tsikitis VL. Benign anorectal disease: Hemorrhoids, fissures, and fistulas. Ann Gastroenterol. 2020;33(1):09-18. Available from: https://doi.org/10.20524/aog.2019.0438. Epub 2019 Nov 29. PMID: 31892792; PMCID: PMC6928486.
[2] Kad AM, Akhtar M, Sonarkar R, Saxena D, Kumar K, Keswani S. A comparison of segmental internal sphincterotomy versus lateral internal sphincterotomy in management of chronic fissure in ano. Int Sur J. 2017;4(9):3044-48. Available from: https://doi.org/10.18203/2349-2902.isj20173884.
[3] Sriram Bhat M. SRB's manual of surgery, rectum and anal canal, New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2013. Pp. 1046.
[4] Lund JN, Scholefield JH. Aetiology and treatment of anal fissure. Br J Sur. 1996;83(10):1335-44. Available from: https://doi.org/10.1002/bjs.1800831006.
[5] Zaghiyan KN, Fleshner P. Anal fissure. Clin Colon Rectal Surg. 2011;24(1):22-30. Available from: https://doi.org/10.1055/s-0031-1272820.
[6] Jonas M, Scholefield JH. Anal fissure. Gastroenterol Clin North Am. 2001;30(1):167-81. Available from: https://doi.org/10.1016/s0889-8553(05)70172-2. PMID: 11394029.
[7] Rather SA, Dar TI, Malik AA, Rather AA, Khan A, Parray FQ, et al. Subcutaneous internal lateral sphincterotomy (SILS) versus nitroglycerine ointment in anal fissure: A prospective study. Int J Surg. 2010;8(3):248-51. Available from: https://doi.org/ 10.1016/j.ijsu.2010.01.013. Epub 2010 Feb 13. PMID: 20156605.

[8] Perrotti P, Bove A, Antropoli C, Molino D, Antropoli M, Balzano A, et al. Topical nifedipine with lidocaine ointment vs. active control for treatment of chronic anal fissure: Results of a prospective, randomized, double-blind study. Diseases of the colon & rectum. 2002;45(11):1468-75. Available from: https://doi.org/10.1007/s10350-004-6452-1.
[9] Chaudhary R, Dausage CS. Prevalence of anal fissure in subjects with anorectal disorders: A single-centre experience. J Clin Diagn Res. 2019;13(2):PC05-PC07. Available from: https://www.doi.org/10.7860/JCDR/2019/38478/12563.
[10] Dudhamal TS, Baghel MS, Bhuyan C, Gupta SK. Comparative study of Ksharasutra suturing and Lord's anal dilatation in the management of Parikartika (chronic fissure-in-ano). Ayu. 2014;35(2):141-47. Available from: https://doi.org/10.4103/0974-8520.146219.
[11] Bobade S, Asutkar S. Efficacy of the healing effect of topical jayanti (Tridax procumbens) cream versus topical lignocaine with nifedipine cream in parikartika (acute fissure-in ano): A protocol for randomised controlled trial. J Clin Diagn Res. 2025;19(1):YK01-YK04. Available from: https://www.doi.org/10.7860/JCDR/2025/71373/20478.
[12] Badwe Y, Pendam K. Study the effect of chandanbalalakshadi taila pichu in parikartika with special reference to fissure-in-ano: A pilot study. Ayushdhara. 2020;7(1):2545-52. Available from: https://doi.org/10.47070/ayushdhara.
[13] Shinde J, Mugave B, Badwe Y. Pilot study on efficacy of Sarjarasa malahara local application in Parikartika with special reference to Fissure-in-ano. International Journal of Ayurvedic Medicine. 2022;13(1):254-57. Available from: https://doi.org/10.47552/ijam.v13i1.2408.
[14] Chen X, Yuan R, Chen X, Sun M, Lin S, Ye J, et al. Hypnosis intervention for the management of pain perception during cataract surgery. J Pain Res. 2018:1921-26. Available from: https://doi.org/10.2147/JPR.S174490.
[15] Heller G, Manuguerra M, Chow R. How to analyze the Visual Analogue Scale: Myths, truths and clinical relevance. Scand J Pain. 2016;13(1):67-75. Available from: https://doi.org/10.1016/j.sjpain.2016.06.012.
[16] Ikoma A, Ebata T, Chantalat L, Takemura K, Mizzi F, Poncet M, et al. Measurement of nocturnal scratching in patients with pruritus using a smart watch: Initial clinical studies with the itch tracker app. Acta DermVenereol. 2019;99(3):268-73. Available from: https://doi.org/10.2340/00015555-3105. PMID: 30523352.
[17] Mapel DW, Schum M, Von Worley A. The epidemiology and treatment of anal fissures in a population-based cohort. BMC Gastroenterology. 2014;14:01-07. Available from: https://doi.org/10.1186/1471-230X-14-129.
[18] Basava AH, Irkal YN. Demography, epidemiology, clinical presentations, diagnoses and management of various anorectal diseases: An article review. J Univer Surg. 2019;7(3):7. Available from: https://doi.org/10.36648/2254-6758.7.1.112.
[19] Trilling B, Pflieger H, Faucheron JL. Decreased blood flow to the posterior anal canal shown during Doppler-guided hemorrhoidal artery ligation explains anodermal ischemia in anal fissure. Tech Coloproctol. 2017;21(5):411-12. Available from: https://doi.org/10.1007/s10151-017-1636-6.
[20] Klein JW. Common anal problems. Med Clin North Am. 2014;98(3):609-23. Available from: https://doi.org/10.1016/j.mcna.2014.01.011.
[21] Elgendy HM, AbdelMawla A, Hussein AF. Efficacy of local metronidazole with glyceryl trinitrate versus topical glyceryl trinitrate alone in the treatment of acute anal fissure: A randomized clinical trial. The Egyptian Journal of Surgery. 2024;43(1):304-08. Available from: https://doi.org/ 10.4103/ejs.ejs_284_23.
[22] Manu S, Ray R, Baruah TD, Samal S. Sucralfate plus Metronidazole ointment is as effective as Diltiazem ointment for treatment of acute fissure in ano – an open label randomized clinical trial. Ro Med J. 2024;71(1):05-11. Available from: https://doi.org/10.37897/RMJ.2024.1.1.
[23] Porwal A, Kundu G, Bhagwat G, Nimma R, Chowdhury J. Turmocin plus suppresses vascular endothelial growth factor (vegf) and macrophage infiltration in the management of perineal wounds, anal fistula, acute anal fissures and haemorrhoids. Journal of Natural Remedies. 2024;24(2):283-91. Available from: https://doi.org/10.18311/jnr/2024/33298.
[24] Lu Y, Kwaan MR, Lin AY. Diagnosis and treatment of anal fissures in 2021. JAMA. 2021;325(7):688-89. Available from: https://doi.org/10.1001/jama.2020.16705.
[25] Kujur ADS, Paul Ekka NM, Chandra S, Lal S, Malua S. Comparative study to assess the effectiveness of topical nifedipine and diltiazem in the treatment of chronic anal fissure. J Family Med Prim Care. 2020;9(11):5652-57. Available from: https://doi.org/10.4103/jfmpc.jfmpc_986_20.
[26] Patel JR, Dudhamal TS. A comparative clinical study of Yashtimadhu Ghrita and lignocaine-nifedipine ointment in the management of Parikartika (acute fissure-in-ano). Ayu. 2017;38(1-2):46-51. Available from: https://doi.org/10.4103/ayu.AYU_93_17.
[27] Cook TA, Humphreys MS, Mortensen NM. Oral nifedipine reduces resting anal pressure and heals chronic anal fissure. Br J Surg. 1999;86(10):1269-73. Available from: https://doi.org/10.1046/j.1365-2168.1999.01292.x.
[28] Singh B, Khichy S, Kumar A, Singh S, Neki NS. Comparative study to observe effects of topical nifedipine with lignocaine and topical sucralfate with lignocaine in acute anal fissure. J Adv Med Dent Scie Res. 2016;4(6):81-85. Available from: https://doi.org/ 10.21276/jamdsr.2016.4.6.18.
[29] Lund JN. Nitric oxide deficiency in the internal anal sphincter of patients with chronic anal fissure. Int J Colorectal Dis. 2006;21(7):673-75. Available from: https://doi.org/10.1007/s00384-005-0757-y.
[30] Salami SA, Salahdeen HM, Anidu BS, Murtala BA, Alada AA. Preliminary mechanistic study on the trachea smooth muscle relaxant activity of aqueous leaf extract of tridax procumbens in male wistar rats. J Pharmacopuncture. 2022;25(3):209. Available from: https://doi.org/10.3831/KPI.2022.25.3.209.
[31] Yaduvanshi B, Mathur R, Mathur SR, Velpandian T. Evaluation of wound healing potential of topical formulation of leaf juice of tridax procumbens L. In mice. Indian J Pharm Sci. 2011;73(3):303-06. Available from: https://doi.org/10.4103/0250-474X.93523. PMID: 22457556; PMCID: PMC3309652.
[32] Kamila S, Sravani K. Study of a drug (TLB) containing tridax procumbens, lawsonia inermis and bougainvillea spectabilis for the effect of analgesic, antiinflamatory and antipyretic action in rat. Current Traditional Medicine. 2018;4(4):305-14. Available from: https://doi.org/10.2174/2215083804666180607104804.
[33] Emile SH, Elgendy H, Elfeki H, Magdy A, Abdelmawla AA, Abdelnaby M, et al. Does the duration of symptoms of anal fissure impact its response to conservative treatment? A prospective cohort study. Int J Surg. 2017;44:64-70. Available from: https://doi.org/10.1016/j.ijsu.2017.06.044.
[34] Ashok Kumar BS, Saran GS, Banu F, Harshada R, Archana PG. In vitro antioxidant and α-amylase inhibition activities of panchsakar churna. Acta Medica Medianae. 2013;52(4):12-14. Available from: https://doi.org/10.5633/amm.2013.0402

**PARTICULARS OF CONTRIBUTORS:**
1. Junior Resident, Department of Shalyatantra, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India.
2. Professor, Department of Shalyatantra, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India.

**NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:**
Shubham Bobade,
Junior Resident, Department of Shalyatantra, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India.
E-mail: drbobade9@gmail.com

**PLAGIARISM CHECKING METHODS:** [Jain H et al.]
- Plagiarism X-checker: Dec 03, 2024
- Manual Googling: May 06, 2025
- iThenticate Software: May 08, 2025 (5%)

**ETYMOLOGY:** Author Origin

**EMENDATIONS:** 7

**AUTHOR DECLARATION:**
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Dec 02, 2024**
Date of Peer Review: **Jan 25, 2025**
Date of Acceptance: **May 10, 2025**
Date of Publishing: **Nov 01, 2025**