

CLINICAL EVALUATION OF IMPROVED ANOAC CREAM FOR EFFICACY AND ADVERSE DRUG REACTION IN PATIENTS WITH PERIANAL SYMPTOMS DUE TO ANAL FISSURE AND HEMORRHOIDS. A PROSPECTIVE OPEN LABEL STUDY¹*Dr. Ashwin Porwal, ²Dr. Deepak Kulkarni and ³Dr. Paresh Gandhi¹Consultant Colorectal Surgeon, Healing Hands clinic.²General Surgeon, Healing Hands Clinic.³General Surgeon, Healing Hands Clinic.***Corresponding Author: Dr. Ashwin Porwal**

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Article Received on 30/05/2018

Article Revised on 20/06/2018

Article Accepted on 10/07/2018

ABSTRACT

Anal fissure and hemorrhoids are painful and most common ailments found around the world. Common perianal symptoms include pain, bleeding, discharge, pruritus,^[8] inflammation, swelling, pricking sensations. These wounds result in significant morbidity, sometimes requiring prolonged hospital stay, hospital readmission, home-nursing care that increases significant medical costs. These wounds are painful, malodorous lesions requiring constant care and adversely affect the quality of life. Use of modern medicines sometimes came with serious unwanted effects that leads treatment discontinuation and continuation of sufferings. Anoac cream is a new improved Ayurvedic polyherbal cream used by all the participants who is having perianal wound or condition. In this Study safety and efficacy were evaluated with help of scale in which From day zero to day 30 mean score of overall symptoms was analyzed. Total 7 patients reported adverse events like fever, rashes, redness of skin, increase in itching and not continued the treatment. Total 90 participants from Day zero Mean (SD) symptoms score was 29.8(3.40) that after treatment showed a significant improvement was on 1st week 23.9(3.05), 2nd week 19.08(2.12), 3rd week 10.98(2.04), 4th week 5.5(2.02). It Showed the significant reduction of overall symptoms and efficacy is improved formula. Individual Symptom scores reduced from maximum 5 to min in the scale. Collection and use of symptoms in a scale found to be effective way to find the efficacy of this polyherbal formulation.

KEYWORDS: Fissure, Hemorrhoids, Anoac cream, Ayurvedic polyherbal.**INTRODUCTION**

Anal fissure and hemorrhoids are painful and most common ailments found around the world. It appears to the individuals with wrong lifestyles patterns,^[1] improper food habits results to constipation that leads to hard stool and passing out hard stool frequently causes fissure. Such trauma to anal canal is a primary cause, although 25% patients with chronic Anal Fissure have constipation.^[2,3] Perianal mean peripheral area near anus and Perianal wounds which are located around the anus near the opening of the rectum to the outside of the body.^[4] Causes Perianal wounds includes diseases like inflammatory bowel disease that includes Crohn's disease and ulcerative colitis,^[5,6] Abscess Anal fissure(19%), Hemorrhoids⁷(43%), Skin tags, Stricture. Common perianal symptoms include pain, bleeding, discharge, pruritus,^[8] inflammation, swelling, pricking sensations. These wounds result in significant morbidity, sometimes requiring prolonged hospital stay, hospital readmission, home-nursing care that increases significant medical costs. These wounds are painful, malodorous lesions requiring constant care and adversely affect the

quality of life.^[9] In modern medicine symptomatic treatments suggested that may include increase in dietary supplements in food, oral fluids to maintain hydration, non steroidal anti inflammatory (NSAIDS) drugs, sitz bath, rest,^[10] stool softener, topical analgesic gel, anesthetic gel, sometimes use the botulinim toxin injected to create a chemical sphincterotomy, allowing healing, glycerol trinitrate(GTN).^[11] Sometimes individuals using GTN complains about headache that leads to treatment discontinuation. Anoac cream is a new improved ayurvedic polyherbal cream used by all the participants who is having perianal wound or condition. The main objective of this study is to access safety and efficacy of Anoac cream. It is a polyherbal formulation in which all ingredients carefully taken together with the help of ayurveda literature. All the ingredients already proved their effectiveness as per these references.^[12,13,14,15,16,17,18,19]

AIM AND OBJECTIVE

1. To evaluate the safety & efficacy of anoac cream in patients with perianal symptoms due to anal fissure and haemorrhoids.
2. To evaluate the adverse events while taking treatment for perianal symptoms.

Study Drug

1. Tankan Powder-^[12]
2. Yasad Bhasm-^[13]
3. Sphatik Bhasm-^[14]
4. Jatyadi Oil-^[15]
5. Kasisadi Oil-^[16]
6. Shuddha Kapoor-^[17]
7. Neem Oil-^[18]
8. Menthol-^[19]
9. Cream Base.

Drug Dose: Small amount over finger as per affected area.

Usage Directions: Gently apply and massage on affected area.

Ethics committee approval and regulatory compliance

This study was conducted after getting approval from independent ethics committee and conducted as per schedule Y of drug and cosmetics rule 1945, ICMR national ethical guidelines for biomedical and Health research involving human participants. Every participant selected was informed and consent obtained before enrollment and initiation of the study. All information provided by the participant was studied and confidentiality was maintained.

Study Design

1. A Prospective, open label, Non Comparative, Single arm, single centre, Interventional

Inclusion Criteria

1. Patients having perianal symptoms or similar condition like fissure, hemorrhoids.
2. Follow the instructions as suggested while taking treatment.

Exclusion Criteria

1. Vulnerable person who is unable to understand the change in wound condition symptoms or adverse events after taking treatment.
2. Patients having age above 60years, diabetes, Sexually transmitted disease, fistula, anal abscess, received immunosuppressive treatment, allergic condition or allergic to herbal medications.

Intervention

The study protocol has been approved by ethics committee and written informed consent was obtained before initiation, complete understanding and after solving study related queries. This interventional study

was conducted at healing hands clinic, a leading proctology clinic and centre of excellence for training in proctology. Patients were identified by qualified physician who has examined them for perianal conditions. Voluntarily written informed consent of all the participants were taken before participation into the study. Total 107 patients were identified, 98 included in the study and of which 90 patients were completed the study after inclusion as per criteria. Participants were advised to apply anoac cream for 4 weeks before and after each defecation along with routine and standard care. Efficacy of this improved formula was noted using standard symptom assessment scale. All participants were analyzed using scale and scale were analyzed for all the participants for efficacy and adverse drug reactions were noted by taking further follow up.

Statistical Analysis

Symptoms assessment scale has been used. Collection of all the symptoms was done using online literature survey. All symptoms were analyzed from scale 0 to 5 for the severity and addition of it gives the overall severity of the present state of illness. This scale was applied to all the participants and mean of each symptom were calculated for 0 week to week 4 of the treatment.

RESULT

Total 98 participants in which male were 43(43.87%) and female were 55(56%) included in this study. Total 90 participants have completed the study of which 67 were of fissure and 23 of external hemorrhoids. Separate analysis was not done as we have focused on wound healing efficacy and adverse events. Age range of participants in this study found to be from 19 to 43Years. From day zero to day 30 mean score of overall symptoms was analyzed. On Day zero Mean (SD) symptoms score was 29.8(3.40) that after treatment showed a significant improvement was on 1st week 23.9(3.05), 2nd week 19.08(2.12), 3rd week 10.98(2.04), 4th week 5.5(2.02). It is showing the significant reduction of overall symptoms and efficacy is improved formula. Symptom scores reduced from maximum 5 to min1 in the scale. Weekly change in symptoms, improvements and ADRs were noted. Total 7 patients reported adverse events like fever, rashes, redness of skin, increase in itching and not continued the treatment. All the adverse events were non serious and due to polyherbal formulation assessment on causality was unable to confirm it.

DISCUSSION

Surgical treatment many a times advised for fissure and hemorrhoids but risk of incontinence cannot be neglected and availability of alternatives can give relief to great extent. In this study improved polyherbal formulation of Anoac cream were used and can be a good choice for such illness. Ingredients in it like kasisadi tail, jatyadi tail already proved its use for 1st 2nd degree hemorrhoids in clinical studies.^[20,21] Properties of neem oil includes

antiseptic, antifungal, antipyretic, antihistamine which reduces fever, itching, pain^[22] can also helpful in condition of fissure. In the treatment of wounds and inflammatory conditions yashad bhasm showed a good result due to its astringent and soothing properties. Sphatika (Kankshi) Bhasma is Vranashodhak (Cleanses wound), kanthya (useful for throat), Keshya (Hair tonic), Vishaghna (Anti poisonous), and Raktasthambak (clots blood).^[23] In one of the study Tankan bhasm showed good results in skin repaired and soft tissue in shortest time with reduction in pain and discomfort. Menthol gives cooling effect at site and its analgesic properties helps to reduce pain and burning.^[25] Use of camphor gives more cooling sensations on affected area.^[26] Overall this polyherbal formulation helped to heal and cure symptoms associated with anal fissure and hemorrhoids.

LIMITATIONS

It was very difficult to take answers from participants as per the scale. As some patients initially showed discomfort to discuss the problem. But later on after counseling agreed to be a part of study. It was difficult for participants to see the wound healing due to difficult site but by touch, individual feeling and reduction of other symptoms helped to give marking according to given scale. Some of the participants reported the adverse events which was found to be non serious but unable to assess the exact causality due to polyherbal formulation. Practice of reporting adverse drug reaction after taking medicine of ayurvedic or herbal or from natural source needs to be improved everywhere. It will be really helpful to make it safer to humans.

CONCLUSION

Collection and use of symptoms in a scale found to be effective way to find the efficacy of this polyherbal formulation but scale validation is needed. Further studies with multiple centers with bigger sample size definitely can give more safety and efficacy data. Inquiry on adverse events is really helpful to find adverse drug reaction. Participants many a times refuse to participate or giving information about efficacy due to anxiety or shyness of illness/ discomfort near anal region. Treating Physicians or counseling team needs to work in this area so that participants could comfortably share the study related information. In this study data collected, analyzed and found that this formulation is really helps to improve the symptoms related to anal fissure and hemorrhoids.

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