



Research Article

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THE EFFECT OF ANOAC TOPICAL CREAM IN THE TREATMENT OF PERIANAL SYMPTOMS DUE TO ANAL FISSURE AND HEMORRHOIDS

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Received on: 27/06/15 Revised on: 20/07/15 Accepted on: 18/08/15

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DOI: 10.7897/2277-4343.066146

ABSTRACT

The purpose of this study was to evaluate the safety and efficacy of ANOAC topical cream in the management of perianal symptoms due to anal fissure and hemorrhoids. Adult patients with perianal symptoms were enrolled in the study. Patient applied Anoac cream twice a day for 60 days. Perianal symptoms like anal pain, swelling, itching, burning and pricking sensation were evaluated on the visual analog scale (VAS) and patient's quality of life on SF-36 questionnaire. A total of 197 patients enrolled in the study out of which 135 (68.53%) were males and 62 (31.47%) were females. Mean age was 39.47 ± 12.22. A significant ($p < 0.0001$) reduction in anal pain from 8.06 ± 2.17 to 0.28 ± 0.74 and in burning sensation from 7.61 ± 2.00 to 0.18 ± 0.54 were observed at the end of the therapy. Also, there was significant reduction in pricking sensation from 1.44 ± 2.62 to 0.03 and swelling in the anal region from 1.65 ± 2.83 to 0.05 ± 0.32. On day 30 there were significant improvements in mean SF-36 scores over baseline in five items, while on day 60 there were improvements in all items over baseline, but not significant. There was no adverse event observed during the study and the therapy was well tolerated in all patients. Topical application of ANOAC cream demonstrated a significant beneficial effect when applied to patients suffering from perianal symptoms due to anal fissure and piles and also improved quality of life.

Key words: Hemorrhoid, Anal fissure, Visual analog scale.

INTRODUCTION

Perianal problems are most common presentation in the general practice setting. Perianal problems often accompanied by hemorrhoids (43%), rectal bleeding (24%) and anal fissure/perianal abscess (19%).¹ Common symptoms are a combination of one or more of pain, lumps, bleeding, burning, discharge or itch.² Hemorrhoid is a lifestyle disease and caused by lack of adequate physical activity, no exercise, smoking, consumption of alcohol and irregular lifestyle patterns.³ First degree hemorrhoids can be managed with conservative treatment. Commonly, conservative treatments are based on increasing dietary fiber, oral fluids to maintain hydration, non-steroidal anti-inflammatory drugs (NSAIDs), sitz baths and rest.⁴ Patients who experience mild symptoms of hemorrhoid that can be treated with topical preparations. Several topical agents and suppositories are available in the market for the treatment of hemorrhoids, however, there are fewer evidences to support their use.⁵ Primarily, acute anal fissures heals spontaneously or with conservative therapy. Conservative treatment includes a high fiber diet, fecal softeners, topical local anesthetic gel and glycerol trinitrate (GTN) ointment.² Common side effect of topical GTN is headache, which in some case is severe to treatment leading to treatment discontinuation.⁶ Therefore, many

patients prefer herbal and safe topical drug as an alternative treatment of fissure and hemorrhoids. Hence, our study was planned to investigate efficacy and safety of Anoac cream in perianal symptoms due to fissure and hemorrhoids.

Aim and objectives: Objective of the study was to evaluate the safety and efficacy of "ANOAC cream" in perianal symptoms. Efficacy was evaluated by assessing perianal symptoms like anal pain, swelling, itching, burning and pricking sensation on a VAS and patients' quality of life on SF-36 questionnaire. Safety was evaluated by assessing adverse events.

MATERIAL AND METHOD

Study design and participants: An open-label, non-comparative, prospective, single-arm, single-center, interventional study. A total of 197 patients who were between 18 and 70 old with with perianal symptoms due to anal fissure and hemorrhoids were included in the study. The exclusion criteria included sexually transmitted diseases, substance abuse and other anorectal diseases (hemorrhoids, anal fistulae, and anal abscesses). Also, patients who had previously undergone anal surgery, pelvis radiotherapy or chemotherapy and received

immunosuppressive drugs or had any drug sensitivities were excluded from this study.

Ethics aspect: The study was approved by ethics committee and the study was conducted accordance with schedule Y of drug Drugs and Cosmetics act, India and ICMR ethical guidelines for biomedical research on human participants.

Study drug: Anoac cream contains Kasisadi oil, Jatyadi oil, Neem oil, Guava extract, Yashad bhasam, Menthol, Camphor. The cream was prepared under sterile conditions.

Intervention: This study was carried out at the Healing Hands clinic, Pune under Dr Ashwin Porwal, one of the leading Proctology clinics in India. After written informed consent, the patient was recruited in the study if patient fulfilled all the eligibility criteria. Patients applied Anoac cream twice a day for 60 days. Patient followed on Day 15, Day 30 and Day 60.

Statistical analysis: Measurement data would be expressed as means with SD (mean±SD). Categorical data and discrete data would be expressed as numbers in percentages (proportions). All data were coded and analyzed using the paired t-test, and Wilcoxon Signed Rank. p<0.05 was considered a significant difference.

RESULT

Total 197 patients enrolled in the study out of that 135 (68.53%) were male and 62 (31.47%) were female patients. Mean age was 39.47 ±12.22 yrs.

At Day 1 patients experienced anal pain, itch, burning sensation, swelling and pricking sensation based on the VAS standard. Anal pain significantly (p<0.0001) reduced from 8.06±2.17 to 3.59 ± 2.29, 1.45±1.85 and 0.28±0.74 on Day 15, Day 30 and Day 60 respectively. Burning sensation reduced from 7.61 ±2.00 to 3.31± 2.21, 1.44±1.81 and 0.18 ±0. 54 on Day 15, Day 30 and Day 60 respectively. The itch was significantly reduced from 7.75±2.26 to 3.24±2.22 on Day 15, 1.39± 1.82 on Day 30 and 0.13 ±0. 74 on Day 60.

Also, there was a reduction in pricking sensation from 1.44 ± 2.62 to 0.37±0.93, 0.1±0.42, and 0.03±0.17 on Day 15, Day 30 and Day 60 respectively, and swelling in the anal region reduced from 1.65 ±2. 83 to 0. 5±1.36,0.24±0.98 and 0.05 ±0. 32 on Day 15, Day 30 and Day 60 respectively.

The SF-36 questionnaires were completed by 197 patients before treatment. On Day 30 after treatment there was improvement in mean score over baseline, the difference observed were significant for five dimensions in physical, social activity, freedom of pain and mental health. On Day 60 after treatment, there were improvement in mean scores over baseline for all items, but only significantly improvement in mental health. (Table 1)

There were no adverse events observed during the study and treatment was well tolerated in all patients.

Table 1: Quality of life on SF-36 questionnaire

Dimensions	Pre-treatment, On Day 1	On Day 30	p	On Day 60	p
Physical functioning (PF)	59.87 ± 2.30	63.6 ± 3.40	0.03	61.12 ± 5.20	0.07
Role limitation due to physical problem (RP)	66.80 ± 13.20	64.6 ± 11.20	0.64	62.9 ± 10.50	0.59
Body pain (BP)	60.50 ± 3.31	63.6 ± 6.50	0.03	62.4 ± 7.00	0.07
General health (GH)	75.80 ± 3.90	76.5 ± 6.70	0.52	75.7 ± 6.57	0.54
Vitality (VT)	69.70 ± 11.50	70.2 ± 10.76	0.01	68.9 ± 12.30	0.09
Social functioning (SF)	73.90 ± 6.20	76.6 ± 5.64	0.05	75.1 ± 7.40	0.06
Role limitation due to emotional problem (RE)	60.6 ± 3.10	59.0 ± 5.60	0.09	64.9 ± 4.40	0.09
Mental health (MH)	72.0 ± 2.70	73.8 ± 2.00	0.01	73.5 ± 5.20	0.04

DISCUSSION

Anal fissures and hemorrhoids are a very common problem across the world. They cause considerable morbidity and adversely affect quality of life; therefore, appropriate treatment is mandatory. Traditionally, surgical treatments, such as hemorrhoidectomy, manual anal dilatation, internal sphincterotomy and, hemorrhoidectomy have been used for this condition. Because of the long recovery associated with surgery and the risk of incontinence, medical alternatives to surgery have been required. Our study demonstrated that application of a Anoac topical cream provided significant perianal symptoms relief to patients with hemorrhoids and anal fissures.

A clinical study was conducted to find effect of Kasisadi taila in the management of 1st and 2nd degree haemorrhoids and study result prove that *Kasisadi taila* as local application is effective and relieves the symptoms.⁷ Jatyadi

oil gives symptomatic relief of 1st and 2nd degree hemorrhoids.⁸ Neem oil has antiseptic, antifungal, antipyretic and antihistamine properties which help to reduce itching and pain.⁹ Guava has analgesic, anti-inflammatory activity and antipyretic properties.^{10,11} In Haiti country traditionally, Guava is used for itch and piles.¹² Yashad bhasma (Zinc Oxide) has astringent and soothing properties. It is used in the treatment of wounds and inflammatory conditions of the skin.¹³ Menthol topical application, causes a feeling of coolness due to stimulation of 'cold' receptors by inhibiting Ca⁺⁺ currents of neuronal membranes and it has analgesic properties which helps to reduce pain and burning.¹⁴ Camphor gives the cold sensation.¹⁵ Anoac cream has antimicrobial, anti-inflammatory, antipyretic, cooling effect properties. The ingredient showed effective management of perianal symptoms due to hemorrhoids and anal fissure.

CONCLUSION

In this study, a topical cream Anoc decreased perianal symptoms. Topical Anoc cream is an effective and safe form of treatment and represents a new therapeutic avenue towards treating perianal symptoms.

ACKNOWLEDGEMENT

The author's would like to thank all the contributing clinicians and Healing Hands Herbs Pvt Ltd. for their contribution.

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Cite this article as:

Porwal Ashwin, Gandhi Pares, Maheshwari Jaya, Deepak Kulkarni. The effect of ANOAC topical cream in the treatment of perianal symptoms due to anal fissure and hemorrhoids. Int. J. Res. Ayurveda Pharm. 2015;6(6):785-787 <http://dx.doi.org/10.7897/2277-4343.066146>

Source of support: Nil, Conflict of interest: None Declared

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