

# Farewell to fissure: Marigold suppositories

Ingale Komal Prabhakar<sup>1</sup>, Rai Shalini Dhirendra<sup>1</sup>

<sup>2</sup>-Assistant Professor, Saraswati Institute of Pharmacy, Kurtadi, Tq. Kalamnuri Dist. Hingoli  
431701.

## Abstract:-

Globally, anal fissure poses a persistent and serious injuries on the lining of anal mucosa, with its incidence steadily increasing. Traditional medicinal plants marigold (*calendula officinalis*) offer promising potential for treatment. Our review evaluates traditional knowledge and use of medicinal plants for the anal fissure treatment. In ano-rectal disorders, incidences fissures are increasing in Indian population due to western lifestyle. In surgery many methods are available for curing ano-rectal disorders but nowadays demand of Ayurveda and herbal preparation are increasing in society.

*Calendula officinalis* (marigold) was characterized in respect to its chemical composition, antioxidant potential and antimicrobial activities. Which has healing and antiseptic properties with actions that are sudorific and analgesic, anti-inflammatory, antiviral and anti-emetic and tone the skin with vasodilation. A tincture of 5% *calendula* positively influences the generation of new cells involved in wound healing, and provides more satisfactory healing than other treatments applied to wounds. Because of it having numerous activities the marigold (*calendula officinalis*) suppositories help to treat anal fissure. Suppositories are the conventional and suitable way to treat anal fissure.

Marigold medicinal plants hold potential as wound healing against anal fissure; However, most studies lack validation and rely on anecdotal evidence. Further research is required to establish their mechanism and therapeutic relevance.

**Keywords** :- Herbal suppository, wound healing, Anal fissure, Marigold (*calendula officinalis*).

## Introduction:-

Fissure are a common and painful condition affecting millions of people worldwide. It may be small in size and characterized by tears in the mucosa. Fissure can cause significant discomfort, bleeding and decrease quality of life conventional treatments often involve topical creams, ointments. However, these can have limitations. Such as side effects. The marigold suppositories can provide targeted delivery of marigold's bioactive compounds directly to the affected area, and reducing side effects.

Flavonoids, Terpenoids, Carotenoids, Essential oils and phenolic acids these are bioactive compounds isolated from the marigold. It having numerous activities including Anti-inflammatory, promotes tissue repair, antioxidant, improves capillary function, promotes skin regeneration, wound healing and antimicrobial properties.

## Objective:-

To explore the therapeutic potential of marigold-based suppositories in the treatment of anal fissure, evaluating their efficacy, safety and potential outcomes as a natural alternative to conventional treatment.

## **Fissure in Anus:-**

Fissure is longitudinal ulcer in the lower end of anal canal called as the fissure and it is mostly because of constipation. It is a painful condition in anal region and mostly seen in adults[13].

Fissure → Hard stool → Absorption of water → constipation → spasm of sphincters → pain

### **Investigation:-**

- 1) On examination fissure, is visible in midline.
- 2) Digital examination → In acute condition per-recta examination is painful but in chronic condition fissure is observed as spasm of sphincter.

In humans the rectum comprises the last 12-19cm of the colon and the rectal epithelium is formed by a single layer of columnar or cuboidal cells and goblet cells; its surface area is about 200-400 cm<sup>2</sup>. The absorbing surface area of the rectum is considerably smaller than that of the small intestine, as the former lack villi and microvilli. However, the epithelium in the rectum and the upper intestinal tract are histologically similar, giving them comparable abilities to absorb drugs.

Anorectal disorder fissure is among the most common affliction of people in India, negatively impacting the 'quality of life' of the patient. Clinicians observe that the prevalence of anorectal disorders in the general population is probably much higher than what is seen in clinical practice, and most of the patients hesitate to seek medicinal care unless the symptoms become too bothersome[10].

It is usually caused by minor trauma at defecation and accounts for about 40% of the annual visits to a coloproctology unit.

Progress in developing treatments based on internal sphincter relaxant agents. But still there is debate about what constitutes optimal treatment is. In fact, anal fissure treatment is one of the issues most frequently studied and documented in the literature, which is an indication of the clinical relevance of the problem with and the awareness that the available treatment options are still unsatisfactory.

Anal fissure affects both men and women and are common in all age groups, especially young people. Despite advancement and extensive research, the exact etiology of anal fissure is still unknown. The possible reasons include trauma to the anus caused during the defecation of hard stool. Food habits such as a low fiber diet are also considered to be contributing factors for the occurrence of anal fissures. A study by Chaudhary et al. (2019) found that the prevalence of anal fissures among patients with anorectal complaints was around 18%[10].

Anal fissures are tears in the anal canal accompanied by pain, bleeding and spasms. Many patients may not require surgery; hence they can be treated with non-surgical options such as sitz baths, local anaesthetics, topical nitrates, oral fiber, calcium channel blockers, etc[8]. Topical nitrates have side effects such as severe headaches, while topical calcium channel blockers can cause itching. There is a need to explore alternative treatments with fewer or no side effects. A study by Gopalkrishna et al. (2023) evaluated more success.

## **Marigold (calendula officinalis)**

*Calendula officinalis* Linn. Commonly known as pot calendula or marigold, is one of the traditionally used medicinal plants in India, China, Europe and the US and has been of therapeutic importance since the beginning of 12<sup>th</sup> century[7]. It belongs to the Asteraceae family. The colour of the petals of yellow and orange varieties originated from carotenoid pigments. It has been evidenced to portray

several promising benefits, for instance, it has role in fissure, treatment. Considering pot marigold contains a wide range of phytochemicals, includes quinines, terpenoids, lipids, fatty acids, carotenoids, flavonoids and coumarins. It has received widespread recognition for its medicinal benefits. It is widely utilized in traditional medicinal treatment to address a wide range of illness, including ulcer, sacs, frostbite, cuts, herps, blood purification and skin damage.



**Fig 1: *Calendula officinalis* (Marigold)**

**Biochemistry and Pharmacology:-**The plants gives us different types of biologically active compounds such as terpenoids, flavonoids, carotenoids, luteins, coumarins, quinines, volatile oils, Amino acids, carbohydrates, lipids, etc.[6]

**Pharmaceuticals properties:-** Experimental and clinical trials on *c. officinalis* extracts have demonstrated a broad spectrum of pharmacological properties. Thus beings could potentially lead to the development of new therapeutic strategies for managing various disorders in both humans and animals. The plant exhibits notable anti-inflammatory, antioxidant, antimicrobial and wound healing effects. Largely attributed to its rich content of flavonoids, terpenoids, carotenoids, lupeol, rutin, narcissi, umbelliferone, etc[12]. These compounds contribute to its efficacy in treating skin condition, promoting wound healing and alleviating symptoms of various inflammatory disorders. Additionally its, use in traditional medicine as a remedy for digestive issues, menstrual discomfort and various issues which underscores its broad therapeutic potential.

**Phytochemistry:-** Every part of the *calendula officinalis* plant contains on incredible source for various phytochemical components as well as exhibiting different amount of each component with regard to both quality and quantity found in different plant regions.[12]

The yellow or orange flowers from the plant serve a purpose for required treatment properties from ancient days to novel chemical constituents that it is widely employed for treating external laceration wounds which have bleedind, open wounds and skin inflammation and manymore. Themedicinalpropertiesofplantsareoftenlinkedtothesecondarymetabolitesor bioactive compounds.[11]

**Traditional uses:-**The extract of the plants can be used internally as well as externally. In india the flowers of *calendula* have culinary uses. The can be used as an additive for coloring the food or flavoring the food. The dried flowers are used as insect repellents. The oils obtained from the flowers have vaterinary uses, it can be used for treatment of wounds, diarrhea and sore stomach.

**Biological activity:-** The animal studies of the flower extract shown its effectiveness as a potent anti-inflammatory and wound healing agents.

### **Calendula suppositories:-**

Drugs or medication are administered through a variety of routes ,the most common being the oral and parenteral route. While rectal route is less commonly used in routine practice, in proctological disorder it is being used effectively since long. Drugs mixed with various adjuvant and administered through the rectal route do provide satisfactory pharmacokinetics with acceptable local tolerance.

**Defination:-**The latin root of the word “suppository” is “to place under”. Suppositories are solid dosage forms of medication meant to be put into body orifices[2]. Suppositories are solid dosage forms inserted into a bodily orifice to melt, soften, or dissolve, causing local or systemic effects. Suppositories are intended to be put into body cavities or orifices, where they dissolve and melt at body temperature, causing a local impact on the body.

The ano-rectal physiology provides a sufficiently adequate surface area for drug absorption. The surface area is also permeable to non-ionized drugs. Suppositories formulations are rather efficient in variety of different bases to increase absorption and reduce complications. The osmosis process allows the drug to transfer from the vehicle in the suppositories across the membrane of the rectum. The higher the concentration and the greater the solubility, The more efficient is the transfer of medication.

Several local host factors may influence absorption in the rectum: the mucus layer, the variable volume of rectal fluid, the basal cell membrane, the tight junctions and the intracellular compartments may each constitute local barriers to drug absorption; depending on histological factors and on the molecular structure of the administration drug.

Given the limitations of conventional treatments, there has been a growing interest in alternative and complementary therapies, particularly those involving herbal ingredients. Herbal medicine offers a promising avenue due to its potential to provide symptomatic relief with fewer side effects. Several herbal ingredients, such as calendula officinalis ( marigold) have demonstrated anti-inflammatory, analgesic, and antioxidant, wound healing properties, making them suitable conditions for managing anal fissure.[1]

The development of new rectal suppository formulation incorporating the herbal ingredients is justified by the need to enhance therapeutic efficacy and improves patient convenience. Rectal suppositories offers several advantages over oral administration, including direct delivery to the prostate region, bypassing the gastrointestinal tract, and reducing systemic side effects[1]. Additionally, this route of administration can enhance the bioavailability of active compounds, ensuring more effective relief from symptoms.

The importance of developing new formulations lies in addressing the unmet needs of fissure patients. Improved formulations can lead to better adherence to reduce incidence of side effects, and overall enhance quality of life. By exploring novel delivery systems and integrating scientifically validated herbal ingredients, it is possible to create more effective and patient friendly therapeutic options for fissure. The current study is a continuation of our previous work aimed at improving fissure herbal treatment[1].



**Fig 2: Suppository**

### **Advantages:-**

- 1.The suppositories can utilize with unconscious patients.
- 2.Suppositories are compact dose forms.
- 3.They have a lower risk of side effects.
- 4.It can be administration to people who are experiencing acute nausea and vomiting
- 5.Suppositories are appropriate for children and elderly individuals who are unable to swallow tablets.

### **Preparation of marigold suppositories:-**

Medline (1950-2006) was searched for all published reports using the key words “suppositories, anal, fissure, rectum and proctology”. This study sum up various suppositories used in proctological practice, which either are in vogue and have been used with a proven degree of success, or suppositories which are described in the literature but are no more in use.

**Selection of excipients:-** The composition of the excipients was selected taking into account the compliance of the main indicators of the quality of suppositories (disintegration, dissolution, uniformity of dosage).

The excipients incorporated into the formulated product are selected based on stringent criteria to ensure compatibility, safety, and efficacy. These criteria include: non-interaction with active substances, ensuring that the specific pharmacological activity of the primary packaging, or the technological equipment used in the manufacturing process. This prevents any adverse effects on the product's stability and efficacy. These selected excipients must be non-toxic, ensuring the overall safety of the product for human use. The physicochemical and technological characteristics of the excipients should be such that they provide the desired therapeutic effect with the minimal required quantity. Excipients must meet stringent chemical and microbiological purity.

**Standards:-** They should also comply with the specified physicochemical indicators outlined in the quality control methods for pharmaceutical formulations. Excipients must be stable under storage conditions, ensuring the product shelf life and efficacy over time.

Herbal suppositories formulation containing the main product marigold extract which is the main active pharmaceutical ingredient (API) in the herbal suppository formulation for fissure treatment with this cocoa butter is used as a base for the suppositories. Also in this several natural excipients are added such as ghee as a lubricant, vitamin E for antioxidant activity and lavender oil as a preservative agent.

In the suppository formulation base is most important.



**Fig 3 :Marigold Extraction preparation**



**Fig 4 :Adding excipients**



**Fig 5 : Suppository preparation**

### **Ideal properties of suppository Base:-[4]**

It should be non-irritant and non-reactive

- It should melt at body temperature.
- It should maintain the proper shape and size.
- It should be stable in storage conditions.
- It should shrink sufficiently to remove mold.
- It should not interfere in the release or absorption of the drug.

### **Evaluation test of suppository:-[5]**

1. Uniformity of weight
2. Content uniformity test
3. Melting point determination test General appearance test
4. Assay of active contents Liquefaction time
5. Breaking test
6. Distegrationtest
7. Dissolutiontest.

### **Conclusion:-**

The present study indicates the wound healing and antioxidant activities of calendula officinalis(marigold)for the treatment of fissure. The development of new products aiming to correct several key points of the pathophysiology of anal fissure has made it possible to transversely treat any type of patient suffering from anal fissure. Our study underline the capability of calendula officinalis and its impact on anal fissure. Its key components achieved all their objectives: Wound healing, antioxidant, anti-inflammatory, skin regeneration reducing pain and burning. This study helps to successfully designed, developed, and evaluated novel herbal suppository formulation for the treatment of anal fissure.

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