

RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF PALASH PANCHANG EXTRACT OINTMENT IN DUSHTA VRANA W.S.R. TO POST FISTULECTOMY WOUNDS

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ABSTRACT

Ayurvedic texts provide cost-effective treatment options for managing wounds (Vrana). A common concern among patients with Vrana is delayed wound healing. According to Ayurvedic Samhitas, Vrana can result from both Nija (internal) and Agantuj (external) factors. The 'Palash Panchang Extract Ointment' may offer an ideal formulation due to its Shodhan (cleansing) and Ropana (healing) properties, potentially enhancing the healing process of post fistulectomy wounds. Numerous studies have been conducted on the management of infected wounds; however, a comprehensive solution remains elusive. This drug possesses notable properties, including astringent, antioxidant, and antiinflammatory effects, which could be beneficial in addressing these challenges. Given the local pathology associated with post-fistulectomy wounds, local application of an ointment presents a more effective treatment modality. The Palash Panchang extract ointment offers increased compliance and provides several benefits, including reduced local itching, inflammation, and pain. Additionally, the ingredients used in this ointment are readily available and easy to prepare. Despite these advantages, no studies have yet been conducted on the Palash Panchang extract ointment. Therefore, we have decided to investigate this topic to explore its potential benefits and applications.

KEYWORDS: vrana, wound, Palash.

INTRODUCTION

In medical practice, the rapid healing of wounds (vrana) is a crucial factor. In contemporary settings, we frequently encounter patients with a variety of wounds. Sometimes, wounds do not heal properly, and it can take a considerable amount of time for the skin to return to its natural state. Although wound healing is a natural process of the body, it is essential to protect the wound from dosha imbalances and infections, which can impede the natural healing rate. Palash (*Butea monosperma*) plays a significant role in the management of wounds (vrana). According to Bhavaprakash, it is described as "vranagulmajit" meaning it possesses qualities that can heal wounds and masses. The Dhanvantari Nighantu also acknowledges its effectiveness in wound healing. Modern science supports its efficacy in managing both chronic and infected wounds. Research indicates that its chemical composition, including flavonoids, steroids, tannins, phenolic compounds, and alkaloids, enhances cellular proliferation and collagen synthesis at the wound site. This is evidenced by increased DNA, total protein, and collagen content in granulation tissues. Wounds treated with Palash extracts heal faster, as demonstrated by improved rates of epithelialization and wound contraction, which are further confirmed by histopathological examinations. Additionally, 4 modern studies highlight its antioxidant properties, particularly its ability to reduce lipid peroxidation. Today, Betadine (povidone iodine) is commonly used for cleaning and dressing wounds due to its effectiveness as a germicide. It is widely employed in wound care; however, its frequent use is discouraged due to its insolubility, staining properties, and potential to cause irritation. In contrast, Ayurveda offers Palash (*Butea monosperma*) as a valuable alternative. Palash is known for its anti-inflammatory, antioxidant, and antibacterial properties, which support skin healing. When used as an ointment, Palash extract can be particularly beneficial in treating infected wounds, offering a natural and potentially less irritating option for wound management. A systematic and scientific study is needed to evaluate the effects of such drugs on wound bed preparation, including their impact on granulation tissue formation, epithelialization, and wound contraction. This research is crucial for advancing current understanding and treatment practices in wound care. To investigate the role of Palash Panchang extract ointment in treating Dusta Vrana, with a specific focus on its application to post-fistulectomy wounds. This study aims to explore and assess novel Ayurvedic procedures for local administration in the management of these wounds^[1,5].

AIM

To Evaluate the efficacy of Palash Panchang extract ointment in the treatment of post fistulectomy wounds i.e. dushta vrana

OBJECTIVE

- 1) To assess the efficacy of Palash Panchang extract ointment in the treatment of post fistulectomy wounds i.e. dushta vrana using BATES-JENSEN ulcer assessment tool.
- 2) To compare the efficacy of betadine with Palash Panchang extract ointment in the treatment of post fistulectomy wounds i.e. dushta vrana wound using BATES-JENSEN ulcer assessment tool.

DRUG FORMULATION DETAILS

Dravya	Latin name	Family	Ras	Virya	Vipa k	Ingredients	PROPERTIES
Palash	<i>Butea Monosperma</i>	<i>Legumiosae</i>	<i>Katu, tikta, kashay</i>	<i>ushna</i>	<i>katu</i>	Kinotanic Acid, Palasonin, palmitic, lin oceric, oleic acid	antimicrobial and antiviral anti inflamma tory, antioxidant, ntidiabetic

PALASH**SCIENTIFIC CLASSIFICATION**

Kingdom: Plantae Family: Legumiosae (Fabaceae) Genus: Butea Species: Butea monosperma Botanical name: Butea Monosperma Sushrutokta gana: Rodhradi, Muskakadi, Ambasthadi and Nyagrodhadi Gana. Chemical constituents: Kinotanic Acid, Palasonin, palmitic, linoceric, oleic acid Synonyms: Kimshuk, Vakrapushpa, Bhramavruksha, Raktapushpa

Rakta Palash

- Description: Refers to the variety of Palash with reddish or orange flowers.
- Uses: This variety is primarily used in treating skin conditions, bleeding disorders, and for its purifying properties. The bright flowers are often used in traditional medicine.

Pita Palash

- Description: Refers to the Palash plant when the flowers are more yellowish.
- Uses: Although less common, this variety may also have medicinal uses, but specific references in classical texts are less detailed compared to Rakta Palash. Other varieties:- Lata Palash, Shwet Palash, Neela Palash Parts used:- Panchang Properties[80]: Rasa:- Katu, tikta, kashay Guna- Laghu, Snigdha Properties:- anti-microbial and anti-viral anti inflammatory, antioxidant, antidiabetic Doshaghnata:- Kaphaghna and vataghna

POVIDONE IODINE

It was discovered in 1955.

1. Aerosol Spray

- Brand Names: Wokadiene, Pyodiene, Betadiene
- Formulation: Contains Povidone-Iodine USP 5% per ml of spray.
- Uses: Typically used for topical antiseptic applications to prevent infection in minor cuts, wounds, and burns.

2. Mouthwash & Gargles

- Brand Names: Wokadiene, Pyodiene, Betadiene
- Formulation: Povidone-Iodine USP 1% with alcohol 8% per ml.
- Uses: Used for oral hygiene to reduce bacteria and treat throat infections.

3. Ointment

- Brand Names: Wokadiene, Pyodiene, Betadiene
- Formulation: Povidone-Iodine USP 10% in a water-soluble polyethylene glycol ointment base.
- Uses: Applied topically to minor wounds and infections.

4. Solution

- Brand Names: Wokadiene, Pyodiene, Betadiene
- Formulation: Povidone-Iodine USP 10% per ml.
- Uses: Used as a topical antiseptic for skin disinfection before surgeries or minor wounds.

5. Surgical Scrub

- Brand Names: Wokadiene, Pyodiene, Betadiene
- Formulation: Each ml contains Povidone-Iodine USP 7.5%.
- Uses: Used for scrubbing hands and forearms before surgeries to ensure a sterile environment.

MATERIALS AND METHODS

The topic received approval from the ethical committee, and permission was granted. Following this, clinical trials were conducted. Patients of post fistulectomy wounds were randomly assigned to two groups based on the sample size for this study. Group A received Palash Panchang Extract ointment for local application during wound dressing, while Group B was treated with Betadine ointment. The dose of Palash Panchang Extract ointment was determined based on the size of the infected wound. Patients were instructed to follow up regularly for 21 days. The ointment was prepared using parts of the Palash plant and manufactured according to standard protocols in the Rasashastra department, under the supervision and guidelines of the Head of the Department.

Treatment details

A. Group A: Used *Palash Panchang* Extract ointment for local application on post-fistulectomy wounds.

B. Group B: Used Betadine ointment for local application on post-fistulectomy wounds.

Points	GROUP A	GROUP ' B'
No .of patients	33	33
Route of administration	Patient of group A treated with Ointment Of Ethanolic Extract Of <i>Palash</i> (Butea	Patient of group B treated with Betadine topically after dressing with NS on once in
	Monospermae) topically after dressing with NS on once in alternate day for 21 days	alternate day for 21 days
Duration of treatment	21 days	21 days
Follow up to	O,3rd,5th,7th& 15th,21 day	O,3rd,5th,7th& 15th,21 day

PREPARATION OF PALASH PANCHANG EXTRACT

The kalka of Palash Panchang was stored in a closed container with proper labeling for future use. The air-dried plant material was subjected to continuous hot extraction using a Soxhlet apparatus with ethanol as the solvent. The extract was then concentrated under reduced pressure at 40°C to obtain a syrupy mass and stored in an amber-colored glass jar at 2-8°C for further investigation and evaluation.

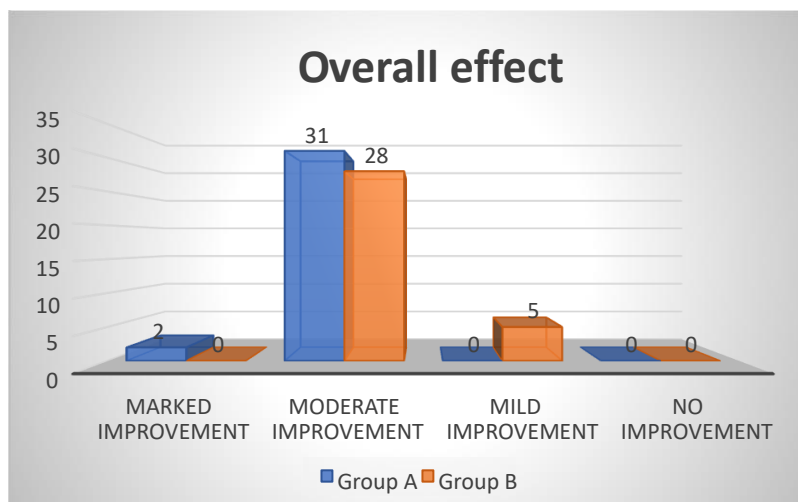
OBSERVATION & RESULTS

A total of 66 patients were randomly selected and evenly divided into two groups, regardless of age, sex, occupation, religion, or wound site.

Group A (Experimental Group) – *Palash Panchang* Extract Ointment used for dressing in patients of Post fistulectomy wound i.e. *Dushta Vrana*.

Group B (Control Group) - Betadine Ointment used for dressing in patients of Post fistulectomy wound i.e. *Dushta Vrana*.

Overall effect	Group A		Group B	
	Frequency	Percentage	Frequency	Percentage
Marked improvement	2	6	0	0
Moderate improvement	31	94	28	85
Mild improvement	0	0	5	15
No improvement	0	0	0	0



Interpretation: Above table and graph reveal that, 6% patients in group A showed marked improvement, 94% showed moderate improvement. In group B, 0% patients showed marked improvement, 85% showed moderate and 15% showed mild improvement. No patient in both groups with no improvement.

So, it is clear that group A is more effective than group B.

Before fistulectomy image and post fistulectomy wound image which treated with *Palash Panchang* extract ointment



DISCUSSION

The study was Randomized clinical Trial, entitled as; “Randomized controlled clinical study to evaluate the efficacy of palash panchang extract ointment in dushta vrana w.s.r. to post fistulectomy wounds.” In this study, we evaluated the effectiveness of Palash Panchang Extract Ointment versus Betadine Ointment in treating post fistulectomy wounds. Both the trial and control groups consisted of 66 patients each. The trial group received Palash Panchang Extract Ointment for 21 days, while the control group was treated with Betadine Ointment for the same duration. Data collected from both groups were analyzed, classified, and presented through tables and graphs. Statistical analysis was conducted to draw inferences and determine whether to accept or reject the hypothesis. Below, we present a discussion and critical analysis of the findings.

Age - Age wise distribution of 66 patients with post fistulectomy wound in the clinical study was as follows, Based on age factors, the total number of patients is divided into four groups. In Experimental group (Group A), 40% belong to the 51-60 age group, followed by 30% from 41-50, 27% from 21-30, and only 3% from 31-40. In Control group (Group B), 37% are from the 31-40 age group, with 24% from both 41-50 and 51-60, and 15% from 21-30. The highest incidence of post-fistulectomy wounds occurs in the 40 to 60 age group. This may be attributed to the fact that individuals in this age range are often the primary earners in their families, which can lead to neglect of personal health and anal hygiene due to their daily work commitments. Additionally, this group tends to have specific dietary habits that contribute to the development of anal fistulas, making them more likely to undergo surgery for this condition.

Sex - The sex distribution of 66 patients with post-fistulectomy wounds in the clinical study is as follows: The patients were divided into two gender groups: male and female. The data indicates that male patients outnumber female patients in both groups. In Experimental group (Group A), 67% of the patients are male, while in Control group (Group B), the percentage of male patients is 64%. The number of males was found to be higher than females, possibly because women may be more hesitant to seek treatment for the conditions they are experiencing.

Diet – The patients were divided into two groups based on their diet: vegetarians and non-vegetarians. In both groups, the majority of patients preferred a nonvegetarian diet. In the experimental group (Group A), 79% of patients chose non-vegetarian options, while in the control group (Group B), this figure rose to 91%. The remaining patients in both groups were vegetarian. The number of non-vegetarians was found to be higher than that of vegetarians, likely because non-vegetarians are more prone to developing anal fistulas, leading to a greater number of fistulectomy surgeries.

Occupation – The total number of patients in both groups was 66, and their distribution by occupation is as follows: In Experimental group (Group A), the occupational distribution is as follows: 25% of patients are housewives, 18% hold private jobs, 12% are farmers, 9% are students, and 6% are mechanics and shop owners, respectively. Additionally, 25% are in other professions.

In Control group (Group B), the distribution is: 21% are housewives, 12% are teachers and shop owners, 9% are students and drivers, and 6% are farmers and individuals in private jobs, respectively. Again, 25% are in other professions. The incidence of post-fistulectomy wounds was found to be higher among housewives, likely due to their continuous work at home. Additionally, both laborers and housewives often show a lack of awareness regarding their health issues.

Prakriti - The 66 patients in the study were categorized into 5 groups in Experimental group (Group A) and 6 groups in Control group (Group B) based on their prakritis. In Group A, the distribution of patients by prakriti is as follows:

45% with Vata-Pitta, 18% with Pitta-Vata, 15% with Pitta-Kapha, and 6% with VataKapha. In Group B, the distribution is: 43% with Vata-Pitta, 18% with Pitta-Vata and Kapha-Pitta, 15% with Pitta-Kapha, 6% with Vata-Kapha, and 3% with KaphaVata.

Marital Status - 66 Patients of post fistulectomy wound distributed in two categories i.e. married and unmarried on basis of marital status. In Experimental group (Group A), 97% of patients are married, while in Control group (Group B), 91% are married. The remaining patients in both groups are unmarried. Married people are seem to be more prone to the get fistula in ano because of stressful life and workload. They are also quantitatively huge to get operated for fistulectomy surgery.

Residence - The distribution of the 66 patients with infected wounds, based on their residence, in the clinical study is as follows: Patients were categorized into two groups based on residence: Urban and Rural. In the experimental group (Group A), 76% are from urban areas, while 24% are from rural areas. Similarly, in the control group (Group B), 82% are from urban areas, and 8 patients (21%) are from rural areas. People in urban areas are found to be more prone to infected wounds than those in rural areas. However, it's important to note that this study was conducted primarily in an urban setting.

Addiction - Four groups were established based on the addiction habits of the patients. In the experimental group (Group A), 9% are alcoholics, 9% are tobacco chewers, 3% having addiction of smoking and 79% of patients report no addictions. In the control group (Group B), there are 15% who are alcoholics, 9% who are tobacco chewers, 6% having smoking addiction and 70% with no addictions. Thus, the comparison suggests that addiction does not have a significant effect on disease formation.

PROBABLE MECHANISM OF ACTION OF PALASH PANCHANG EXTRACT OINTMENT IN AYURVEDIC POINT OF VIEW

In Ayurveda according to Bhavaprakash, Palash (*Butea Monosperma* Retz. Family: Fabaceae), also referred to as "Kimshuk," is described as "vranagulmajit," which implies that it is a cure-all for vrana i.e. wound and gulma i.e. swelling. The Dhanvantari Nighantu recognizes *Butea monosperma* for its effectiveness in wound healing. Modern science also supports its efficacy in managing both chronic and infected wounds. Palash is considered a miracle medication due to its diverse pharmacological effects and numerous health benefits. With Katu, tikta, kashaya ras its vipak is Katu, Veerya is Ushna and Laghu, Snigdha gunas. Due to these benefits, the plant exhibits various pharmacological properties, including Deepan (appetizer), Vrushya (aphrodisiac), Sara (strengthening), Kaphaghna (Kapha-reducing), and Vataghna (Vata-reducing). Katurasa aids in Vrana Avasadana and inhibits vitiated Kapha, while Tiktarasa assists in Kleda and Puyashoshana, helping to reduce Kandu. Additionally, Kashayarasa contributes to Kledashoshana, promoting the reduction of excess moisture. Additionally, it possesses qualities that promote cell renewal, ultimately aiding in Vranropan (wound healing). Palash Panchang Extract Ointment contains various parts of the Palash tree. Recent studies have identified its pharmacological properties and chemical constituents, highlighting its therapeutic potential. Kinotanic Acid, Palasonin, palmitic, linoceric, oleic acid are the primary phytochemicals found in Palash. In addition to its antimicrobial properties, it also possesses anti-viral anti inflammatory, antioxidant, antidiabetic properties. The astringent properties of this medication promote the contraction of skin cells, making an ointment containing palash panchang extract beneficial for wound healing. It aids in wound contraction and accelerates

epithelialization during the granulation formation stage, as well as the scar remodeling phase. Therefore, an ointment formulated with palash panchang extract can effectively support the wound healing process.

CONCLUSION

This topic entitled as “Randomized Controlled Clinical Study to Evaluate the Efficacy of Palash Panchang Extract Ointment in Dushta Vrana with special reference to Post-Fistulectomy Wounds.” was studied in detail and conclusions are drawn on the basis of it, as follows:

- Palash Panchang Extract ointment has more efficacies to reduce grades of Bates & Jenson than Betadine ointment.
- Palash Panchang Extract ointment is equally effective as that of Betadine ointment to reduce the grades of pain.
- Palash Panchang Extract ointment is more effective to reduce grades of Itching than Betadine ointment.
- Palash Panchang Extract ointment is more effective to reduce treatment duration of post fistulectomy wound i.e. dushta vrana.
- Pitta-vataj or Vata-pittaj prakruti people are found more prone for developing infected wound.
- The trial was found to be safe for all patients, with no side effects reported during the study.
- The trial group demonstrated good results, while the control group showed moderate results.
- Therefore, the drug in the trial group exhibited a significantly greater effect than the control group.
- As a result, H1 is accepted and H0 is rejected.
- Thus, the use of Palash Panchang Extract Ointment for 21 days is more effective for managing Post fistulectomy wound i.e. Dushta Vrana compared to Betadine ointment administered for the same duration.

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