



Research Article

A RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE ANTIMICROBIAL EFFECT OF PETROLEUM ETHER EXTRACT OF *ARKADIGANA* FOR SURGICAL SITE PREPARATION WITH SPECIAL REFERENCE TO LOW ANAL FISTULA

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ABSTRACT

Ayurveda, the ancient Indian medical science, provides extensive guidance on wound management *Vrana Chikitsa*. *Sushruta Samhita*, considered the foundational text of Ayurvedic surgery, outlines principles of *Purvakarma*, *Pradhana Karma*, and *Paschat Karma* in operative procedures. Various groups of herbs *Ganas* described under *Dravyasangraha Niyama Adhyaya* are indicated for *Vrana Shodhana* wound cleansing and may be used for skin preparation. Ayurvedic literature also mentions several lotions and chemical formulations later validated as potent antimicrobial agents. Although detailed descriptions of surgical site preparation are not explicitly stated in *Sushruta Samhita*, this step is implied under *Purvakarma* and aligns with modern surgical practices. *Arkadigana* is a unique herbal formulation described in Ayurveda with potent antiseptic, antimicrobial, and antifungal properties. Topical application of *Arkadigana* is considered safe and beneficial in promoting wound hygiene and reducing microbial contamination. Present study evaluates the antimicrobial effect of petroleum ether extract of *Arkadigana* for surgical site preparation with special reference to low anal fistula.

INTRODUCTION

The prevalence of surgical site infection SSI has been reported as 24.6, out of which 10 develop deep-site infection, 9.2 organ-space infection, and 5.2 superficial-space SSI. Surgical site infections are defined as infections occurring up to 30 days after surgery or up to one year in patients receiving implants and affecting either the incision or deeper tissues at the operative site.^[1] The incidence of SSIs may be as high as 20, depending on the surgical procedure^[2]. The most commonly isolated organisms include *Staphylococcus aureus*, coagulase-negative staphylococci, *Enterococcus* spp., and *Escherichia coli*.^[3]

A wound is defined as a disruption in the normal anatomical integrity of the body caused by physical injury.^[4]

Terms such as erosion, ulcer, and fissure are commonly used while describing wound pathology. Erosion refers to focal epidermal loss that does not extend into the dermis. Fissure indicates vertical cracks involving loss of tissue that may affect the epidermis and dermis. Ulcers are focal wounds involving loss of epidermis with extension into the dermis and underlying tissues.^[5] Ulcers may become chronic and often present a therapeutic challenge for clinicians.^[5] Wound healing is influenced by several factors, including the patients general health, the cause and depth of the wound, primary wound care, tissue involvement, and adequacy of circulation. Wounds are broadly classified as acute and chronic. Acute wounds result from trauma or surgical excision, whereas wounds that fail to heal within six weeks are considered chronic.^[6]

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Inadequate blood supply is the most common underlying cause in all chronic wounds. Infection, trauma, burns thermal, chemical, or electrical, foreign bodies, postoperative wound dehiscence, diabetic ulcers, pressure sores, and trophic ulcers following spinal injury are common etiologist.^[7] The wound-healing process consists of regeneration and tissue repair involving numerous molecular and cellular events. Healing proceeds through three phases-exudative, proliferative, and extracellular matrix remodelling. These phases involve soluble mediators, blood cells, and parenchymal cells. Tissue oedema develops immediately after injury, followed by fibroplasia, myofibroblast contraction, angiogenesis, and re-epithelialization during the proliferative phase.^[8] Endothelial cells may differentiate into mesenchymal components, and several signalling proteins play an essential role in this cascade.^[9] Chronic wounds represent a significant global health problem. Their management requires coordinated interdisciplinary care.^[10] Accurate wound assessment is crucial for evaluating the effectiveness of treatment strategies and relies on consistent clinical observation combined with quantitative assessment tools. *Arkadigana* is a unique herbal formulation described in Ayurveda with potent antiseptic, antimicrobial, and antifungal properties. It is known to neutralize various microbial toxins and pacify disorders related to the skin and blood.^[11] Topical application of *Arkadigana* is considered safe and beneficial in promoting wound hygiene and reducing microbial contamination.^[12]

AIMS

1. To evaluate the antimicrobial effect of the petroleum ether extract of *Arkadigana* in surgical site preparation.
2. To compare the efficacy of the petroleum ether extract of *Arkadigana* with povidone-iodine solution.

Background

The prevalence of surgical site infection (SSI) is reported to be 24.6%, of which 10% develop deep-site infection, 9.2% organ-space infection, and 5.2% superficial-space infection. SSIs are defined as infections occurring within 30 days after surgery- or up to one year in patients with implants- and involve the incision or deep tissues at the operative site. The incidence may reach up to 20% depending on the surgical procedure, with the most commonly isolated organisms being *Staphylococcus aureus*, coagulase-negative staphylococci, *Enterococcus* species, and *Escherichia coli*.^[13]

MATERIALS AND METHODS

The study was conducted in the operation theatre premises of the National Institute of Ayurveda (Deemed to be University), Jaipur, in collaboration with the Department of Pathology/Microbiology and the Drug Discovery and Development Unit (DDDU). This was an open, randomized comparative clinical trial. Total 60 patients diagnosed with low anal fistula in ano, attending the outpatient and inpatient Department of Shalya Tantra, NIA, Jaipur were registered randomly irrespective of their age, sex, religion, caste, occupation etc.^[13] This is an open randomized control trial. Study was approved by Institutional Ethics Committee, wide letter no. IEC/ACA/2023/ 3-70 This clinical trial is registered under CTRI. (Reference No./2024/04/083423).

A total of 60 patients were randomly allocated to two groups:

Painting Group A: Petroleum ether extract of *Arkadigana*

Painting Group B: Povidone-iodine solution

Swabs from the surgical site were collected before and after painting and sent for microbiological analysis.^[14]

Group A (*Arkadigana* Extract)

Two swabs were taken before painting and two after painting. One swab was taken 3cm from the anal verge, and the second swab was taken 3cm from the first site.^[15]

Group B (Povidone-Iodine)

Sampling method was identical to Group A.

Swabs were incubated at 37°C for 48 hours. Bacterial colonies were identified using standard microbial load count techniques.^[16]

Follow-up was done for 1 month.

Assessment Criteria

- Microbial load (before and after painting)
- Clinical assessment of surgical site infection for 30 days post-operatively.^[17]

Swab Collection and Culture Protocol

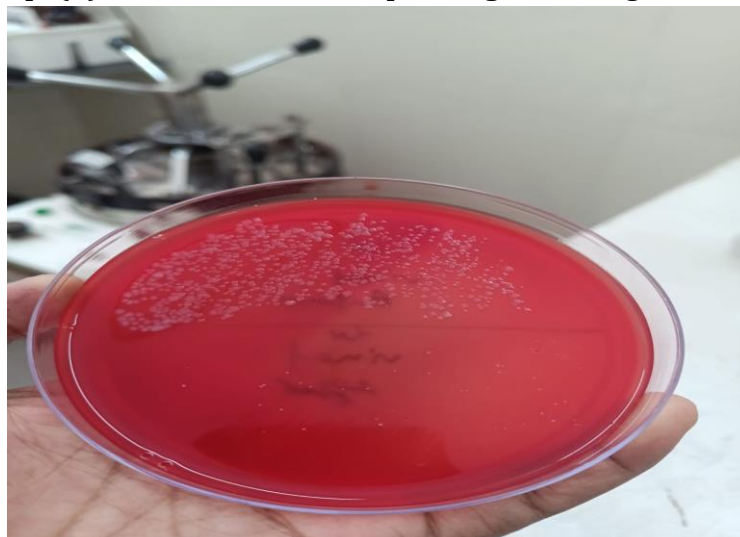
Sterile cotton swabs were collected from the perianal region 3cm from the anal verge, rotated in a circular manner, and immediately placed in transport medium. Samples were incubated at 37°C for 24–48 hours on standard culture media including blood agar, MacConkey agar, nutrient agar, and selective media as required. Bacterial growth was assessed by colony morphology, Gram staining, biochemical tests was done following CLSI guidelines. Common isolates included *Escherichia coli*, *Klebsiella* spp., *Staphylococcus aureus*, and *Enterococcus* spp. Results were reported as growth after 48 hours of incubation

in Group A and almost nil growth seen in Group B after same incubation period of 48 hours.

Colony count, or organism identification with sensitivity profile.



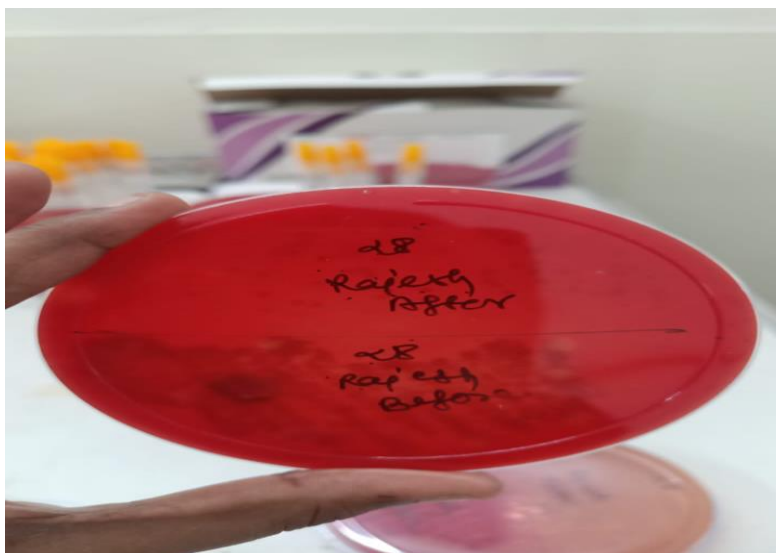
Group: (A) Swab Culture before painting of Arkadigana Extract



Group: (A); Swab Culture After painting of Arkadigana extract



Group: (B) Swab Culture before Painting of Povidone Iodine extract



Group: (B) Swab Culture after Painting of Povidone Iodine extract

OBSERVATIONS

Most participants in both groups were male, primarily labourers and private-sector workers. All patients presented with perianal boils as the chief complaint, along with pain, burning, and pus discharge. No patient reported past illness or previous surgery. Irregular bowel habits were common, and chronic constipation was universal in Group A and highly prevalent in Group B. Burning sensation, hyperaemia, and oedema were slightly more common in Group A. Before treatment, *E. coli* and *Klebsiella* spp. were the most common organisms after treatment, Group B showed a much higher proportion of "no growth" results than Group A, indicating better microbiological clearance.

RESULTS

Group B showed significantly better outcomes than Group A across most parameters, including VAS pain score, dysesthesia, hyperaemia, oedema, local temperature, APSEPSIS score, pus discharge, hospital stay, and microbial colony count ($p < 0.05$), with most differences being highly or extremely significant. Wound-healing days were the only parameter showing no significant difference ($p > 0.05$). Overall, Group B demonstrated superior clinical and microbiological improvement.

Local Temperature

Group A showed a higher local temperature (98.23 ± 0.504) compared to Group B (97.83 ± 0.461), with a significant difference ($U = 293.5$, $p = 0.0032$).

Asepsis Score

Group A demonstrated a much higher ASEPSIS score (11.13 ± 2.825) than Group B (6.233 ± 2.086). The difference was extremely significant ($t = 7.747$, $p < 0.0001$).

Pus Discharge

Pus discharge was more frequent in Group A (0.533 ± 0.507) than in Group B (0.133 ± 0.345), with a significant difference ($U = 270$, $p = 0.0022$).

Wound-Healing Days

No significant difference was observed between Group A (26.13 ± 4.032 days) and Group B (25.23 ± 4.546 days) ($p = 0.4206$).

Hospital Stay

Hospital stay was same in both Group A (2.73 ± 0.449 days) than Group B (2.76 ± 0.434 days).

Colony Count

Group A showed a markedly higher microbial colony count ($12,653,711 \pm 33,405,257$) compared to Group B ($64,233 \pm 1,887,004$). The difference was extremely significant ($U = 119$, $p < 0.0001$).

DISCUSSION

Betadine (Group B) demonstrated superior antimicrobial efficacy compared to the petroleum ether extract of *Arkadigana* (Group A). Betadine's broad-spectrum action, due to sustained iodine release, rapidly reduces microbial load, lowers inflammation, and minimizes post-operative symptoms such as pain, hyperaemia, oedema, and pus discharge. This leads to better asepsis and shorter hospital stay. *Arkadigana* extract possesses Ayurvedic properties such as *Shothahara*, *Krimighna*, and *Vranashodhana-Ropana*, which contribute to wound cleansing and healing. However, its slower onset of action and milder antimicrobial potency resulted in reduced effectiveness in acute surgical settings. Comparable wound-healing duration in both groups may be attributed to the natural healing-supportive

phytoconstituents in *Arkadigana*. Overall, while *Arkadigana* is safe and beneficial, Betadine remains superior for rapid infection control and improved post-operative outcomes.

CONCLUSION

Group B demonstrated significantly better clinical and microbiological outcomes than Group A, indicating greater effectiveness in reducing infection, inflammation, and associated postoperative complications. Although extract of *Arkadigana* was found significant in reducing post operative inflammatory signs and microbial load after surgical site preparation but on comparison from Betadine; Batadine was found more significantly more effective than the petroleum ether extract of *Arkadigana* in reducing microbial load and improving postoperative clinical outcomes. ^{7,8,15} It provided better control of pain, inflammation, hyperaemia, oedema, dysesthesia, pus discharge, and hospital stay duration. Although wound-healing time was similar in both groups, betadine ensured faster symptomatic relief and superior asepsis. *Arkadigana* may still serve as a safe natural alternative with moderate wound-healing benefits.

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