Advances in Bioresearch
Adv. Biores., Vol 17 (1) January 2026: 60-67

Print ISSN 0976-4585; Online ISSN 2277-1573
Journal's URL:http://www.soeagra.com/abr.html
CODEN: ABRDC3
DOI: 10.15515/abr.0976-4585.17.1.6067

Advances in Bioresearch

ORIGINAL ARTICLE

Randomized Controlled Clinical Trial to Check the Efficacy of Agnikarma (Thermal Cauterization) with Panchdhatu Shalaka Versus Surgical Excision in the Management of Kadara (Corn)

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ABSTRACT
Kadara (Corn) is a painful, hyperkeratotic lesion commonly affecting the plantar surface of the foot. Its management in modern medicine includes topical keratolytic agents and surgical excision; however, recurrence is a common concern. In Ayurveda, Agnikarma (thermal cauterization) is described as a superior treatment modality to prevent recurrence. This study aims to compare the efficacy of Agnikarma using Panchdhatu Shalaka with surgical excision for the treatment of Kadara. A randomized clinical trial (RCT) was conducted on 40 patients with Kadara at Parul Ayurved Hospital. Patients were randomly allocated into two groups: Group A (Agnikarma) and Group B (Surgical Excision). Outcomes were assessed based on pain relief, quality of life, wound healing, and recurrence over a 21-day follow-up. Agnikarma showed superior pain relief immediately post-procedure, better quality of life improvement, and lower recurrence rates. Surgical excision had a higher incidence of postoperative pain and longer recovery periods. Agnikarma with Panchdhatu Shalaka is a safer, cost-effective, and superior alternative to surgical excision for Kadara, with minimal recurrence.
Keywords: *Kadara, Corn, Agnikarma, Thermal Cauterization, Kshudra Roga, Surgical Excision.*
CTRI No: CTRI/2019/05/019114

Received 24.07.2025 Revised 01.09.2025 Accepted 30.12.2025

How to cite this article:
Nikhil G, Parikshit S, Nitin P. Randomized Controlled Clinical Trial to Check the Efficacy of Agnikarma (Thermal Cauterization) with Panchdhatu Shalaka Versus Surgical Excision in the Management of Kadara (Corn). Adv. Biores. Vol 17 [1] January 2026. 60-67

INTRODUCTION

Kadara is painful condition appearing as knotty hard growth elevated at its center and depressed at its margins, appears at the soles and has the shape of an Indian plum (*kola*). [1] *Kadara* occurs as a result of vitiation of local blood and fat caused by deranged doshas due to incidental injuries like thorn pricking etc. [2] few authorities like *Bhojas* explain appearance of *Kadara* on palm.[3] *Kadara* can be correlated with Corn as explained in modern surgery. A corn is a localized, hyperkeratotic lesion characterized by a dense accumulation of dead epidermal cells, typically forming on glabrous or thin plantar skin. It develops primarily as a result of chronic mechanical stress, such as repeated pressure or friction, often due to ill-fitting footwear or minor penetrating trauma like thorn injuries. The lesion is distinguished by a central keratinous core that extends into the deeper layers of the dermis, contributing to localized pain. Corns generally present with a white, yellow, or grey discoloration and are more frequently observed in females. While most corns are of the hard type and form over pressure-bearing areas, soft corns tend to develop in interdigital spaces where moisture is retained [4] Though excision of symptomatic corn is the choice of treatment, conservative management with anti-inflammatory medicines salicylic acid corn caps are also in trend according to the modern medicine. [5] Corns tend to recure after excision [6] according to *Acharya Sushrut*, to prevent recurrence of *kadara, Agnikarma* with oil should be performed immediately after *Utkartan* (excision) of *Kadara*.[7]. As described in Sushrut Samhita Agnikarma simply means application of therapeutic heat (Agni) to the affected part. There is no chance of recurrence of

disease which is treated with *Agnikarma*. Even *Agnikarma* can effectively cure the diseases which cannot be treated successfully with medicine, surgery and *Kshar Karma* (chemical cauterization). [8] It is also included in *Anushastra* i.e. Para-surgical procedures. [9] *Agnikarma* can be correlated to Thermal Cauterization.

Objectives

- To compare post-operative pain in the management of *Kadara* in *Agnikarma* and excision.
- To compare the efficacy of wound healing in post *Agnikarma* and excision in the management of *Kadara*.

Hypothesis:

NULL HYPOTHESIS {Ho}:

- *Agnikarma* by *Panchdhatu Shalaka* is not effective in the management of *Kadara*.

ALTERNATIVE HYPOTHESIS {H_1}

- H1: *Agnikarma* by *Panchdhatu Shalaka* is less effective than excision in the management of *Kadara*.
- H2: *Agnikarma* by *Panchdhatu Shalaka* is equally effective as excision in the management of *Kadara*.
- H3: *Agnikarma* by *Panchdhatu Shalaka* is more effective than excision in the management of *Kadara*.

MATERIAL AND METHODS

Study Design

This study was a parallel-group, randomized controlled clinical trial conducted at Parul Ayurved Hospital.

Participants

Inclusion Criteria:

- Patients aged 18-70 years with clinically diagnosed *Kadara.*
- Patients willing to participate and provide informed consent.

Exclusion Criteria:

- Patients with uncontrolled diabetes, immunocompromised status (HIV, TB, Hepatitis), or pregnancy.
- Patients with palmar corns or systemic infections

Randomization and Blinding

Patients were randomly assigned to Group A (Treated with *Agnikarma*) or Group B (Treated with Surgical Excision) using computer-generated randomization.

Group A (*Agnikarma* with *Panchdhatu Shalaka*)

Procedure: *Panchdhatu Shalaka* was heated till red-hot and applied to the lesion until *Samyak Dagdha Lakshana* (optimal cauterization signs) appeared.

Table 1: Procedure of *Agnikarma* with *Panchdhatu Shalaka*

Pre-Operative	Operative	Post Operative
• *Pandhatu Shalaka*, *Yastimadhu Ghrita*, Gas stove, Dressing Forceps, Sterile gauze, Povidone–Iodine solution, Sponge holding forceps. • All pre-operative investigations were done. • Informed written consent was taken prior to the procedure. • Injection T.T. (0.5ml) intra muscular was given ½ hour before the procedure. • *Snigdha* and *Picchila Annapana Sevana* prior to procedure was advised.	• Patient was given comfortable position. • Painting and draping done. • *Panchdhatu Shalaka* was kept on gas stove till red hot and applied it on corn tissue with firm pressure till *Samayak dagdha lakshan* appeared and burned till root of corn. • Then *Yashtimadhu Ghrita* was applied over the wound to relieve burning pain. • During procedure patient was kept assured by encouraging words all the time.	• Patient was made to rest for 30 minutes after the procedure. • After *Agnikarma* with *Panchdhatu Shalaka*, *Yasthimadhu Ghrita* was applied and lastly dressing and bandaging done on first day. • Patient was advised to avoid water contact for next 2 days.

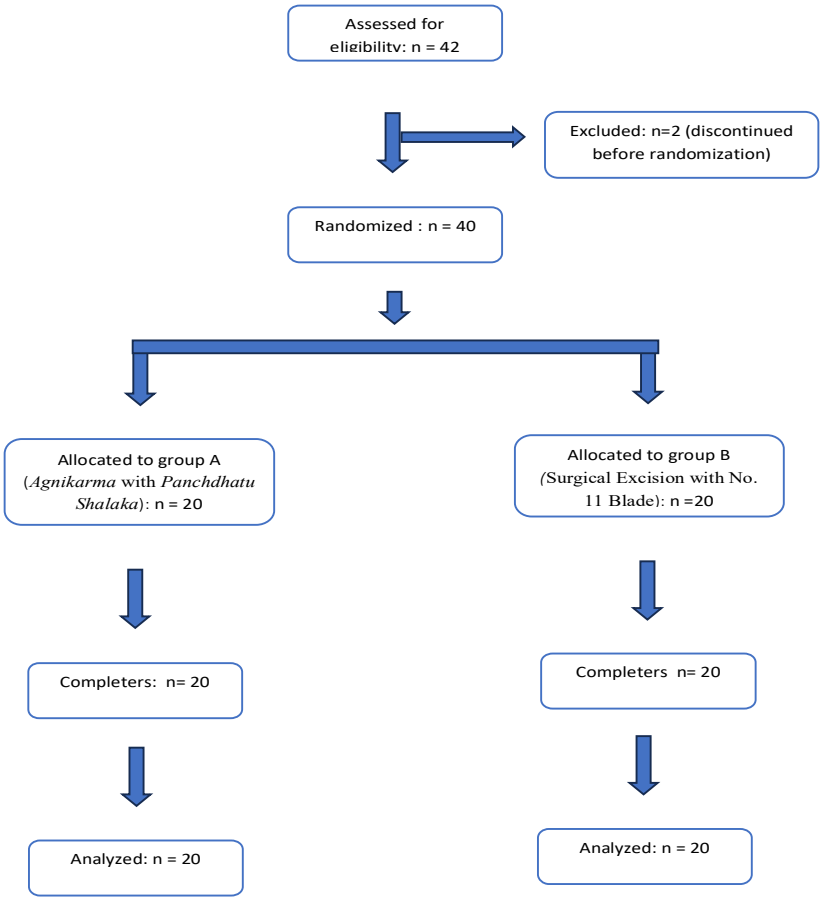

Figure No.1: Consort Flow Diagram

Interventions

Group B (Surgical Excision with No. 11 Blade)

Procedure: Under local anesthesia (Xylocaine 2%), the lesion was excised up to the dermis and hemostasis achieved.

Table 2: Procedure of Surgical Excision

Pre-Operative	Operative	Post Operative
• No.11 surgical blade, B.P. handle, dressing forceps, Artery forceps, Sponge holding forceps, sterile gauze piece, Disposable syringe with needle, Injection Xylocaine 2%, Drape sheet, Povidone–Iodine solution, H_2O_2, Spirit, *Yastimadhu Ghrita*. • All pre-op investigations were done. • Informed written consent was taken prior to the procedure. • Injection T.T. (0.5ml) intra muscular was given ½ hour before the procedure. • Inj Xylocaine 2% sensitivity test subcutaneous was given to the patient ½ hour before procedure was done.	• Patient shifted to operative room; Patient was given supine position. • Painting and draping done. • Injection Xylocaine 2% infiltrate at local part, Anesthesia effect was confirmed. • A circumscribed incision was taken with no 11 surgical blade around the corn and extended up to base i.e. dermal layer and excised. • Hemostasis was achieved. • Dressing with *Yasthimadhu Ghrita*. • Pressure bandaging was done.	• Patient was shifted to post-operative room. • Patient was kept under observation for one hour and was checked for bleeding and soakage. • Patient was advised to avoid water contact at the wound site. • Patient was advised to take proper rest with concerned lower limb elevation.

Pathya – Apathya

***Pathya:*(Do's)**

Patients were instructed to wear soft shoes, eat food that is light (easy to digest), not too chilly, food that encourages the creation of blood, and food that is either mildly sour or not at all sour.

- ***Apathya*:(Don't)**

Following the treatment, patients were instructed to refrain from wearing hard shoes, engaging in severe activity, chilly breezes, sleeping during the day, using alkalis, eating harsh foods, being upset, talking a lot, and experiencing indigestion until they were strong enough. Steer clear of barefoot walking and *Vata vardhaka ahara.*

CONCOMITANT MEDICINE BOTH GROUPS

1. Tablet *Triphala Guggle* 2BD after food
2. Tablet *Gandhak Rasayan* 1BD after food
3. *Yastimadhu Ghrita* for local application

RESCUE MEDICINE

Tablet Zerodol P 1 BD (Sos Whenever intolerable pain at operation site occurs)

Outcome Measures

Primary and secondary outcomes were assessed at baseline, post-procedure, and at weekly intervals for 21 days.

Primary Outcomes:

- Pain (VAS Scale)
- Quality of Life (QoL) Scale

Secondary Outcomes:

- Wound healing time (granulation, discharge, and peri-wound skin changes)
- Recurrence at 21 days
- Cost-effectiveness

RESULTS

This study conducted a comparative analysis of *Agnikarma* (therapeutic heat treatment) and excision (surgical removal) for the management of *Kadara* (corns on the feet). The efficacy of these interventions was assessed based on pain alleviation, quality of life enhancement, wound healing (granulation tissue formation), wound discharge, and Peri wound skin condition.

Baseline Characteristics

The study enrolled 42 patients, of which 40 completed the study (20 per group). The demographic distribution was balanced across groups.

1. Pain management

- Both treatments significantly reduced pain over time ($P < 0.05$, Friedman test).
- Group A (*Agnikarma*):
- Showed immediate pain relief after the procedure.
- No significant changes in pain grades (ranging between grade 1 to grade 0) on Day 7 and 14.
- Significant improvement noted on Day 21 compared to Day 0.
- Group B (Excision):
- Initial increase in pain on Day 0 due to the surgical wound.
- Slight pain reduction on Day 7, followed by significant relief on Days 14 and 21.
- Comparison:
- *Agnikarma* provided faster and more effective pain relief than excision.
- On Day 7, pain was significantly lower in *Agnikarma* group compared to Excision group ($P < 0.05$).

2. Enhancement of Quality of Life

- Both treatments significantly improved quality of life over time ($P < 0.05$, Friedman test).
- Group A (*Agnikarma*):
- Immediate improvement in quality of life after the procedure due to symptom relief.
- No significant changes on Days 7 and 14.
- Significant improvement again by Day 21.
- Group B (Excision):
- Initial drop in quality of life on Day 0 and Day 7 due to pain and healing process.
- No significant change on Day 14.
- Significant improvement observed on Day 21.
- Comparison:
- *Agnikarma* provided faster and greater improvement in quality of life than excision.
- Just after the procedure, quality of life was significantly better in the *Agnikarma* group than in the excision group.

3. Wound Healing and Granulation Tissue Formation

- The Wilcoxon sign-rank test analysis revealed that both *Agnikarma* (Group A) and Excision (Group B) showed statistically significant results in granulation.
- Group A (*Agnikarma*):
- From Day 0 to Day 7, granulation was not significant due to scald formation after *Agnikarma*.
- From Day 7 to Day 21, significant granulation was observed as the scald naturally detached, allowing normal wound healing.
- Group B (Excision):
- Showed significant granulation from the beginning since an open wound was created.
- Comparison:
- On Day 7, Group B had better granulation than Group A.
- On Day 21, Group A showed superior granulation compared to Group B.
- The difference in granulation between the two groups was statistically significant ($P < 0.05$) on Day 7 and Day 21.

4. Wound Discharge

- Both treatments significantly reduced wound discharge over time ($P < 0.05$, Friedman test).
- Group A (*Agnikarma*):
- No discharge from Day 0 to Day 7 due to no open wound.
- Some patients experienced discharge after Day 7 due to auto-removal of the scab.
- Significant reduction in discharge after scab removal and continued healing.
- Group B (Excision):
- Discharge was present from Day 0 due to the open wound from surgery.
- Gradual reduction in discharge as the wound contracted over time.
- Comparison:
- *Agnikarma* had significantly less discharge on Days 0, 7, and 21 compared to excision.
- Excision resulted in more initial discharge, while *Agnikarma* controlled discharge better overall.

5. Peri wound Skin Condition

- Both treatments showed significant improvement in peri wound skin condition over time ($P < 0.05$, Friedman test).
- Group A (*Agnikarma*):
- Showed a statistically higher improvement in peri wound skin condition compared to Group B.
- Significant improvement observed from the day of the procedure itself.
- Group B (Excision):
- Also showed improvement, but at a slower rate compared to *Agnikarma*.
- Comparison:
- On Day 0, the mean peri wound skin condition in Group A was better than in Group B.
- *Agnikarma* resulted in better peri wound skin healing overall.

DISCUSSION

Kadara, classified as a *Kshudra Roga* in Ayurvedic texts such as *Sushruta Samhita* [1], *Astanga Hridaya, Astanga Sangraha, Bhavaprakash,* and *Sharangadhar*a, is described as a localized thickening and induration of the skin due to continuous pressure or friction [9,10,11]. The etiopathogenesis involves the vitiation of *Vata* and *Kapha* doshas along with Rakta dushya, leading to hyperkeratosis, pain, and central induration. Modern medical science correlates *Kadara* with Corn, a localized hyperkeratosis characterized by a conical mass of keratinized cells causing deep-seated pain and discomfort. Conventional treatments, including corn caps and surgical excision [13], often result in recurrence, whereas *Agnikarma*, a therapeutic cauterization technique described in Ayurveda, has shown promising outcomes in effectively managing *Kadara*. [14].

Panchadhatu Shalaka, a specialized cauterization tool composed of copper, iron, zinc, silver, and tin in a 4:3:1:1:1 ratio, was employed for *Agnikarma*. This instrument retains heat for a prolonged duration, ensuring optimal cauterization and controlled tissue destruction. *Agnikarma* induces local tissue necrosis and prevents recurrence by pacifying *Vata* and *Kapha* doshas, thereby addressing the root pathology of *Kadara*.

Demographic Analysis: The study, conducted on 42 subjects, demonstrated a higher incidence of *Kadara* in the 18-30 age group, likely due to increased physical activity and foot trauma. Both sexes were equally affected. Socioeconomic and dwelling status influenced disease occurrence, with a higher prevalence among rural and middle-class individuals due to lifestyle and occupational factors. Effect on Pain:

Postoperative pain relief in Group A (*Agnikarma*) was 45.4%, whereas Group B (excision) initially exhibited an increase in pain, followed by significant relief after 21 days. *Agnikarma* provided immediate pain reduction due to its *Vata-Kapha* pacifying properties and deep tissue penetration. Quality of Life Improvement: Statistically significant improvements in the quality of life were observed in both groups; however, Group A showed better outcomes immediately post-procedure due to minimal post-treatment discomfort. Wound Discharge and Healing: *Agnikarma* effectively controlled wound discharge due to its *Sandhana* and *Skandhana* properties, promoting faster wound contraction. Group B exhibited discharge post-excision, resolving as the wound healed. Granulation tissue formation was significantly enhanced in Group A due to the vasodilatory effect of *Agnikarma*, promoting neo angiogenesis. Peri wound Skin Integrity: Group A exhibited transient discoloration due to eschar formation, which subsequently resolved as normal tissue regenerated. In contrast, Group B maintained peri-wound integrity unless secondary infection occurred.

Effect of *Agnikarma* on *Kadara*

Agnikarma exerts its therapeutic action through *Vyavayi, Vikashi, Sukshma, and Laghu Gunas*, allowing deeper penetration into the dermis and targeting hyperkeratotic cells via *Chedana and Lekhana* properties. This results in controlled aseptic necrosis, followed by phagocytosis of necrotic debris. The *Ushna-Tikshna Guna* counteracts *Sheeta-Sthira Gunas* of *Vata-Kapha*, stabilizing *Rakta and Meda Dhatu*. The outcome is complete eradication of hyperkeratotic tissue, preventing recurrence, and facilitating regeneration of normal epithelial cells with restored structural integrity and pigmentation. *Agnikarma* with *Panchdhatu Shalaka* is a superior treatment modality for *Kadara* compared to surgical excision. It offers faster pain relief, better quality of life, minimal recurrence, and cost-effectiveness. Future studies with larger sample sizes and longer follow-up durations are recommended to further validate these findings.

PROCEDURE (Excision of *Kadara*) from Figure No. 2-6

BEFORE EXCISION
FIGURE N0 02

LOCAL ANAESTHESIA
FIGURE N0 03

EXCISION OF CORN
IGURE N0 04

AFTER EXCISION
FIGURE N0 05

AFTER TREATMENT
FIGURE N0 06

PROCEDURE (*Agnikarma* of *Kadara*) FROM FIGURE N0.07 TO FIGURE NO.12

PANCHADHATU SHALAKA
FIGURE NO.07

RED HOT *PANCHADHATU SHALAKA*
FIGURE NO.08

BEFORE *AGNIKARMA*
FIGURE NO.09

AGNIKARMA OF *KADARA* WITH *PANCHADHATU SHALAKA*
FIGURE NO.10

APPLICATION OF *YASTIMADHU GHRUTA*
FIGURE NO.11

AFTER *AGNIKARMA*
FIGURE NO.12

ETHICAL CONSIDERATIONS

- Ethical approval obtained from Institutional Ethics Committee, Parul institute of *Ayurved*, Parul university Limda, Vadodara, Gujrat, India. (IEC No: PU/PIA/IECHR/2019/41)
- Informed consent was acquired from all participants.

LIMITATIONS

- Short follow-up period (21 days) limits long-term recurrence assessment.
- Sample size was relatively small; larger multi-center studies are needed.

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