



## Research Article

# Effect of aqueous extract of Neem (*Azadirachta indica* a. Juss) patra pichu in Karnini Yoni Vyapada (Cervical erosion) – A randomised controlled clinical trial

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## Abstract

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**Background:** *Karnini Yoni Vyapada*, correlated with cervical erosion in modern gynecology, presents with symptoms such as excessive vaginal discharge, inflammation, and cervical ectopy. *Neem (Azadirachta indica* A. JUSS) is known in Ayurveda for its antimicrobial, anti-inflammatory and wound-healing properties. **Objective:** To evaluate the clinical efficacy of using aqueous *Neem* leaf extract *pichu* in *Karnini Yoni Vyapada*. **Materials and Methods:** A randomized controlled clinical trial was conducted on 120 women (aged 18–50) diagnosed with *Karnini Yoni Vyapada*. Participants were divided into two groups (n=60). Group - A received *pichu* (tampon) soaked in fresh aqueous *Neem* extract for 7 days after menstruation, over three consecutive cycles. Group - B (control) received standard local Ayurvedic treatment *Yonidhavana* with *Triphala kashaya* followed by *Jatyadi taila pichu*. Clinical symptoms (discharge, itching, and backache) cervical findings were monitored, along with pre- and post-treatment pap smears. **Observations and Results:** Group – A showed statistically significant improvement ( $p<0.01$ ) in symptoms and cervical healing compared to the Group – B (control group) with notable reductions in discharge, inflammation and cervical erosion. No adverse effects were observed. **Conclusion:** *Neem based Patra Pichu* is a safe, effective, and accessible Ayurvedic intervention for managing *Karnini yoni vyapada*. Its promising results warrant further validation through larger, multicentre trials with long-term follow-up for broader clinical integration.

**Keywords:** *Karnini Yoni Vyapada, Cervical erosion, Azadirachta indica* A. JUSS, *Neem, Patra Pichu, Ayurveda, Randomized clinical trial*

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## Introduction

Cervical erosion, also referred to as cervical ectropion or cervical ectopy, is a common benign gynaecological condition characterized by the anomalous replacement of the normal squamous epithelium of the ectocervix, the part of the cervix that extends into the vagina with columnar epithelium, which is typically confined to the lining of the endocervical canal. Epithelial transformation results in a noticeable reddish appearance around the external OS of the cervix, often presenting as bright red or pink lesions during a pelvic examination (1).

The incidence of cervical erosion is particularly high among women of childbearing age, with progressive parity being a significant contributing factor. It is infrequently observed in postmenopausal women (2). The condition is more prevalent

among women using hormonal contraceptives, as the hormone fluctuations can influence the epithelial transformation (3). In most cases, cervical erosion is asymptomatic and is frequently discovered incidentally during routine gynaecological examinations (4). When symptoms do arise, common manifestations include an increase in vaginal discharge, typically characterized as mucoid or yellowish-white and thicker in consistency post-coital or contact bleeding stemming from the vulnerability of the exposed columnar epithelium, as well as intermenstrual bleeding or signs indicative of cervicitis, which denotes inflammation of the cervix (1),(5).

Despite its name, "erosion" in this context does not denote actual ulceration or loss of cervical tissue; rather, it signifies a physiological change in the epithelial lining type (6). Cervical erosion is not categorized as a premalignant condition; however, it is essential to note that chronic instances may, albeit rarely, undergo malignant transformation (7).

The condition can be correlated with the Ayurvedic concept of *Karnini Yoni Vyapada*, where *Acharya Sushruta* elaborated in his work, *Uttartantra*, that it exhibits similar characteristics to cervical erosion (8). For instance, features such as the *karnika*, which resembles an auricle-shaped growth, unctuousness

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(*Paichilya*), increased mucoid discharges (*Yoni srava*), and itching (*Yoni kandu*) align with the manifestations of cervical erosion. This condition may also be linked to the vitiation of *rakta* (blood) combined with *kapha* (mucus), resulting in reddened appearance and potentially blood-stained discharge (9).

In Ayurveda, *Sthanika Chikitsa* (local therapies) holds significant relevance, with its efficacy attributed to the absorption of therapeutic agents through the vaginal mucosa (10). The vaginal route offers distinct advantages over oral administration, such as the avoidance of first-pass hepatic metabolism, prevention of enzymatic degradation in the gastrointestinal tract, a larger absorption area, and rich vascularisation of the vaginal tissue.

Theoretically, targeting cervical erosion through *Sthanika Chikitsa* may provide protective effects against the incidence of cervical cancer. The local therapies employed generally possess antiseptic, antimicrobial, antifungal, antiulcer, anti-inflammatory, and analgesic properties. Practices such as *Prakshalana* (vaginal douching) have notable cleansing, bactericidal, and healing attributes, especially when using formulations like *Triphala* and *Panchavalkala*, known for their free radical scavenging capabilities (11).

*Pichu* (tampon) therapy enhances tissue strength, flexibility, nourishment, and wound healing, exemplified by *Jatyaditaila*, a formulation rich in flavonoids, tannins, steroids, alkaloids, and glycosides, which collectively promote rapid wound healing (12).

Moreover, the diverse therapeutic principles derived from the bark, leaves, seeds, and other parts of the *Neem* plant are recognized for their immunomodulatory, antiseptic, diuretic, antipyretic, anti-parasitic, antimicrobial, analgesic, contraceptive, antiulcer, anti-mutagenic, and anticancer effects. The ingredients in the aqueous extract of *Neem* leaves are generally easier to procure, cost-effective, and often less adulterated when compared to more complex formulations like, which consists of numerous components. Consequently, this study aims to rigorously assess and validate the therapeutic impact of the aqueous extract of *Neem* leaves in the treatment of cervical erosion, providing insights into its efficacy and potential benefits for patient management.

The study's objectives were to assess the efficacy of Aqueous Extract of *Neem Patra Pichu* and to compare the effectiveness of Aqueous Extract of *Neem Patra Pichu* with *Jatyadi Taila Pichu* in the treatment of *Karnini Yoni Vyapada* (Cervical Erosion).

## Materials and methods

**Trial Design:** An open-label randomized controlled clinical trial was conducted at KLE Ayurveda Hospital & Medical Research Centre, Shahapur, Belagavi, to assess the efficacy of *Neem Patra Aqueous Extract Pichu* with *Jatyadi taila pichu* in *Karnini Yoni Vyapada* (cervical erosion). A total of 120 women (aged 18–50) from OPD and IPD, who met the inclusion criteria and gave informed consent, were enrolled. The trial was ethically approved and registered CTRI (CTRI/2023/05/066992). Participants were randomly divided into two groups. Both received *Yoni Dhavana* (vaginal douche) with *Triphala kashaya* for 7 days. Group- A received *pichu* soaked in aqueous *Neem* leaf extract, while Group - B was treated with *Jatyadi taila pichu*.

**Trial Setting:** The study was carried out in a specialized hospital unit ensuring proper procedural care and follow-up during the 7 day treatment course.

**Inclusion Criteria:** Women aged 18–50 years presenting with vaginal discharge, low backache, or recurrent /chronic vaginitis, and who provided informed consent.

**Exclusion Criteria:** Pregnant women, menopausal women, and those with congenital gynecological anomalies, carcinoma of the cervix, systemic illnesses (e.g., TB, diabetes), STDs, dysmenorrhea, or dyspareunia were excluded.

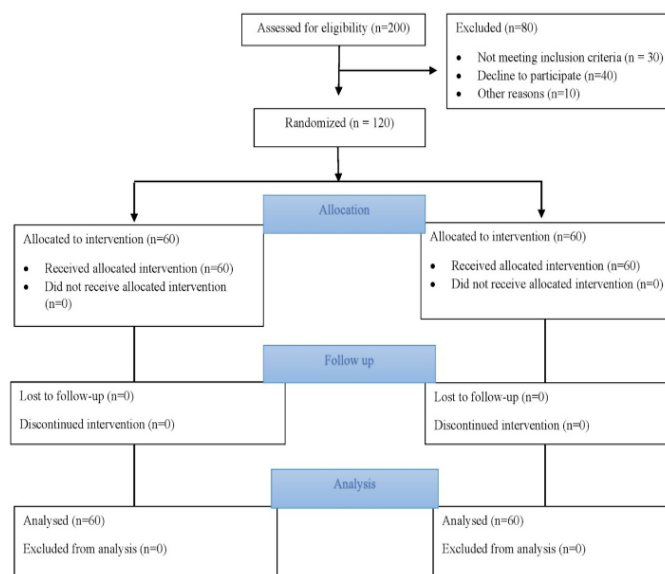
**CTRI Registration No:** CTRI/2023/05/066992.

**Clinical Intervention:** Participants in both groups underwent *Yoni Dhavana* (vaginal douching) with *Triphala kashaya* for 7 consecutive days. Before the procedure, patients emptied their bladders and were positioned comfortably, either lying on their backs with legs apart or seated. The decoction was pre-heated using a water bath to a safe, comfortable temperature. A sterile nozzle or catheter attached to a rubber pipe was used to administer the lukewarm liquid, allowing it to flow gently into the vagina for 10–15 minutes. Following douching, Group A received *Jatyadi taila pichu*, while Group B received *Neemextract pichu*.

**Pichu Dharana Procedure:** The procedure was performed in the lithotomic position, ensuring comfort and accessibility. Prior to insertion, the patient emptied her bladder and the genital area was cleaned. A *Pichu* was prepared using 2–3 cotton swabs wrapped in gauze, tied with a thread for easy removal, and soaked in *Neem Patra Kwatha* (Group 1) and *Jatyadi Taila* (Group 2), kept warm before application. Using sterile, aseptic techniques, the medicated *Pichu* was gently inserted into the vagina, with the thread left outside. It remained in place for the therapy duration and was administered for 7 consecutive days post-menses. Patients were monitored for safety and comfort. The *Pichu* was removed when the patient felt the urge to urinate, marking the end of the session. A short rest period of 15 minutes was advised post-procedure.

**Allocation and Blinding Procedure:** After obtaining informed consent, 120 Subjects aged 18–50 years diagnosed with *karnini yonivyapada* were enrolled. Symptom severity was assessed using a self-graded scale. Random allocation into two equal groups was performed using an online random number generator ([www.random.org](http://www.random.org)).

Figure 1: CONSORT flow chart



**Table 1: Group specific interventions**

| Group                | Treatment plan                                                                       | Timing/Duration                                                                        |
|----------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| A<br>(Trial group)   | <i>Triphala kwatha Yoni dhawana</i> followed by <i>Neem Patra pichu dharana</i> .    | 30 mins /7 days. (10-15 minutes <i>Yoni dhawana</i> 15 minutes <i>pichu dharana</i> ). |
| B<br>(Control Group) | <i>Triphala kwatha Yoni dhawana</i> followed by <i>Jatyadi taila pichu dharana</i> . | 30 mins /7 days. (10-15 minutes <i>Yoni dhawana</i> 15 minutes <i>pichu dharana</i> ). |

Patients of both groups were advised to rest for 10 minutes after the procedure.

**Table 2: Assessment Criteria for Vaginal Health**

| Sl. No. | Symptom or Sign                       | Severity Grade | Description                                        |
|---------|---------------------------------------|----------------|----------------------------------------------------|
| 1       | Foul Odor ( <i>Yoni Gandha</i> )      | 0              | No foul smell detected                             |
|         |                                       | 1              | Foul smell present                                 |
| 2       | Vaginal Itching ( <i>Yoni Kandu</i> ) | 0              | No itching sensation                               |
|         |                                       | 1              | Moderate itching                                   |
|         |                                       | 2              | Persistent or constant itching                     |
| 3       | Pain ( <i>Vedana</i> )                | -              | Rated on a Visual Analog Scale (VAS) for intensity |
| 4       | Extent of Vaginal Erosion             | 1              | Erosion affecting 1-25% of the area                |
|         |                                       | 2              | Erosion affecting 26-50% of the area               |
|         |                                       | 3              | Erosion affecting 51-75% of the area               |
|         |                                       | 4              | Erosion affecting 76-100% of the area              |

## Observations and Results

**Table 3: Representing the demographic data of participant's variables in %**

| Sl. No. | Particulars           | Variables                | Percentage                | Graph |
|---------|-----------------------|--------------------------|---------------------------|-------|
| 1       | Age                   | 18-34<br>35-50           | 66%<br>44%                |       |
| 2       | Education             | Literate<br>Illiterate   | 83.33%<br>16.77%          |       |
| 3       | Socio-economic status | Lower<br>Middle<br>Upper | 0.83%<br>95.83%<br>3.33%  |       |
| 4       | Dwelling status       | Urban<br>Rural<br>Slum   | 50.00%<br>49.17%<br>0.83% |       |

**Table 3: Contd.....**

|   |          |                                                                              |                                                                |  |
|---|----------|------------------------------------------------------------------------------|----------------------------------------------------------------|--|
| 5 | Diet     | Vegetarian<br>Mixed                                                          | 14.66%<br>84.14%                                               |  |
| 6 | Prakriti | Vata<br>Pitta<br>Kapha<br>Vatapitta<br>Vatakapha<br>Pittakapha<br>Tridoshaja | 0.00%<br>1.67%<br>9.17%<br>10.00%<br>65.83%<br>13.33%<br>0.00% |  |
| 7 | Hygiene  | Maintained<br>Not Maintained                                                 | 18.33%<br>81.67%                                               |  |

**Table 4: Per speculum wise % of eroded area distribution of participants**

| Sl. No. | Per speculum examination | Percentage | Graph |
|---------|--------------------------|------------|-------|
| 1       | Present                  | 85.83%     |       |
| 2       | Absent                   | 14.17%     |       |

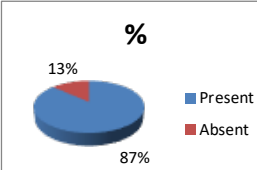
Chi-Square test is carried out to test independence. From above table, we can observe that P-Value is greater than 0.05. Hence, we can conclude that, distribution of patients in trial group and control group is independent.

**Table 5: Congestion wise distribution of participants**

| Sl. No. | Congestion | Percentage | Graph |
|---------|------------|------------|-------|
| 1       | Present    | 87.50%     |       |
| 2       | Absent     | 12.50%     |       |

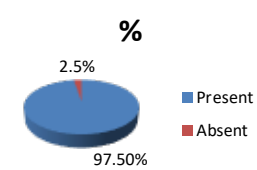
Chi-Square test is carried out to test independence. From above table, we can observe that P-Value is greater than 0.05. Hence, we can conclude that, distribution of patients in trial group and control group is independent.

**Table 6: Cervical motion tenderness (CMT) wise distribution of participants**

| Sl. No. | CMT               | Percentage       | Graph                                                                             |
|---------|-------------------|------------------|-----------------------------------------------------------------------------------|
| 1<br>2  | Present<br>Absent | 86.67%<br>13.33% |  |

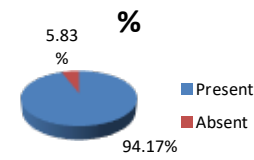
Chi-Square test is carried out to test independence. From above table, we can observe that P-Value is greater than 0.05. Hence, we can conclude that, distribution of patients in trial group and control group is independent.

**Table 7: Discharge wise distribution of participants**

| Sl. No. | Discharge         | Percentage      | Graph                                                                             |
|---------|-------------------|-----------------|-----------------------------------------------------------------------------------|
| 1<br>2  | Present<br>Absent | 97.50%<br>2.50% |  |

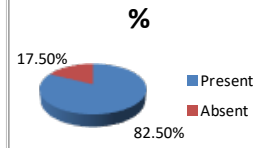
Chi-Square test is carried out to test independence. From above table, we can observe that P-Value is greater than 0.05. Hence, we can conclude that, distribution of patients in trial group and control group is independent.

**Table 8: Low back ache wise distribution of participants**

| Sl. No. | Low Back Ache     | Percentage      | Graph                                                                               |
|---------|-------------------|-----------------|-------------------------------------------------------------------------------------|
| 1<br>2  | Present<br>Absent | 94.17%<br>5.83% |  |

Chi-Square test is carried out to test independence. From above table, we can observe that P-Value is greater than 0.05. Hence, we can conclude that, distribution of patients in trial group and control group is independent.

**Table 9: Per vaginal examination wise distribution of participants for discharge**

| Sl. No. | Per vaginal Examination | Percentage       | Graph                                                                               |
|---------|-------------------------|------------------|-------------------------------------------------------------------------------------|
| 1<br>2  | Present<br>Absent       | 82.50%<br>17.50% |  |

Chi-Square test is carried out to test independence. From above table, we can observe that P-Value is greater than 0.05. Hence, we can conclude that, distribution of patients in trial group and control group is independent.

**Table 10: Showing % of Eroded area of Cervix**

| % of Eroded Area of Cervix |          | Mean  | N  | SD    | SE   | t -value | p- value |
|----------------------------|----------|-------|----|-------|------|----------|----------|
| Trial                      | Baseline | 76.42 | 60 | 11.20 | 1.45 | 40.360   | <0.001   |
|                            | Day 7    | 13.58 | 60 | 5.05  | 0.65 |          |          |
| Control                    | Baseline | 85.00 | 60 | 12.55 | 1.62 | 45.042   | <0.001   |
|                            | Day 7    | 15.00 | 60 | 7.87  | 1.02 |          |          |

% of Eroded area of Cervix within the Groups shows statistically significant result at “p” value less than 0.001

**Table 11: Showing % of Eroded area of Cervix between the Group**

| % of Eroded Area of Cervix | N  | Mean  | SD    | SE   | t-value | p-value |
|----------------------------|----|-------|-------|------|---------|---------|
| Trial                      | 60 | 62.25 | 11.95 | 1.54 | -1.800  | 0.0745  |
| Control                    | 60 | 70.00 | 12.04 | 1.55 |         |         |

% of Eroded area of Cervix in between the Groups shows statistically no significant difference at “p” value =0.0745

**Table 12: Showing VAS within the Group**

| VAS     |          | Median | SD   | SE   | Wilcoxon W | p –value |
|---------|----------|--------|------|------|------------|----------|
| Trial   | Baseline | 7.00   | 1.00 | 0.13 | -6.801     | <0.001   |
|         | Day 7    | 1.00   | 0.56 | 0.07 |            |          |
| Control | Baseline | 7.00   | 0.86 | 0.11 | -6.814     | <0.001   |
|         | Day 7    | 1.00   | 0.34 | 0.04 |            |          |

VAS within the Groups shows statistically significant result at “p” value less than 0.001

**Table 13: Showing VAS between the Groups**

| Variable | Group   | N  | Mean Rank | Sum of Ranks | Mann-Whitney U | p- value |
|----------|---------|----|-----------|--------------|----------------|----------|
| VAS      | Trial   | 60 | 52.73     | 3164.00      | 1334.0000      | 0.06     |
|          | Control | 60 | 68.27     | 4096.00      |                |          |

VAS in between the Groups shows statistically no significant difference at “p” value 0.06

**Table 14: Showing results on Yoni Kandu Within the Group**

| Yoni Kandu |          | Median | SD   | SE   | Wilcoxon W          | p-Value |
|------------|----------|--------|------|------|---------------------|---------|
| Trial      | Baseline | 1.00   | 0.56 | 0.07 | -7.171 <sup>b</sup> | <0.001  |
|            | Day 7    | 0.00   | 0.38 | 0.05 |                     |         |
| Control    | Baseline | 2.00   | 0.72 | 0.09 | -7.071 <sup>b</sup> | <0.001  |
|            | Day 7    | 0.00   | 0.45 | 0.06 |                     |         |

Yoni Kandu within the Groups shows statistically significant result at “p” value less than 0.001

**Table 15: Showing results on Yoni Kandu Between the Group**

| Variable   | Group   | N  | Mean Rank | Sum of Ranks | Mann-Whitney U | P-Value |
|------------|---------|----|-----------|--------------|----------------|---------|
| Yoni Kandu | Trial   | 60 | 62.24     | 3734.50      | 1784.5000      | 0.9098  |
|            | Control | 60 | 58.76     | 3525.50      |                |         |

Yoni Kandu in between the Groups shows statistically no significant difference at “p” value 0.9

**Table 16: Showing results on Yoni Gandha Within the Group**

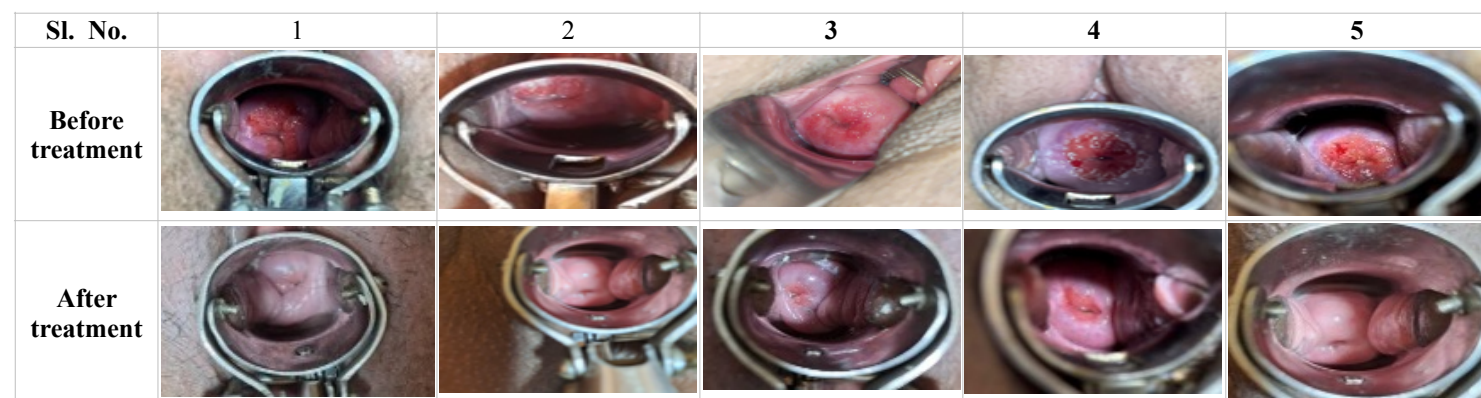
| Yoni Gandha |          | Median | SD   | SE   | Wilcoxon W | P-Value |
|-------------|----------|--------|------|------|------------|---------|
| Trial       | Baseline | 1.00   | 0.49 | 0.06 | -7.345     | <0.001  |
|             | Day 7    | 0.00   | 0.36 | 0.05 |            |         |
| Control     | Baseline | 1.00   | 0.56 | 0.07 | -7.273     | <0.001  |
|             | Day 7    | 0.00   | 0.42 | 0.05 |            |         |

Yoni Gandha within the Groups shows statistically significant result at “P” value less than 0.001

**Table 17: Showing results on Yoni Gandha Between the Group**

| Variable    | Group   | N  | Mean Rank | Sum of Ranks | Mann-Whitney U | P-Value |
|-------------|---------|----|-----------|--------------|----------------|---------|
| Yoni Gandha | Trial   | 60 | 62.58     | 3755.00      | 1745.0000      | 0.6409  |
|             | Control | 60 | 58.42     | 3505.00      |                |         |

Yoni Gandha in between the Groups shows statistically no significant difference at “P” value 0.6

**Photo plate 1: Images showing the cases before treatment and after treatment of 5 cases**

## Discussion

*Karnini Yoni Vyapada* is one of the *Ashta Yoni Vyapada*, is characterized by a *Karnika Sannibha Granthi* (polyp-like growth) in the vaginal canal, resembling cervical erosion. Symptoms include pain, itching, foul-smelling discharge, and occasional inter menstrual bleeding. It is primarily caused by vitiated *Vata* and *Kapha doshas*, affecting the *Rasa, Rakta*, and *Mamsa dhatus* of the *Artavavaha srotas*. Contributing factors include trauma, poor

lifestyle, suppression of natural urges, and improper sexual activity.

Treatment in Ayurveda emphasizes both *Shodhana* (purificatory) and *Shamana* (palliative) therapies. Local interventions like *Yonidhavana* with *Triphala* or *Neem* decoctions, and *Patra Pichu* with *Jatyadi Taila* and *Neem* aqueous extract, support healing. Internal use of herbs like *Triphala*, *Daruharidra*, and *Guduchi* help reduce infection, inflammation, and discharge.

This randomized controlled clinical trial demonstrated that *Patra Pichu* with *Neem* leaf extract significantly improved symptoms of cervical erosion, including discharge, inflammation, and erosion, with no adverse effects. *Neem*'s antimicrobial and anti-inflammatory properties aid in mucosal healing and may prevent complications. The study reinforces the value of localized Ayurvedic therapies (*Sthanika Chikitsa*) and highlights the safety and efficacy of *Neem* in gynecological care.

While results are promising, limitations include a small sample size and short follow-up. Further studies with larger, diverse populations are needed. This research supports integrating Ayurvedic treatments into modern gynecology, offering holistic and effective care for conditions like cervical erosion.

A seven day Ayurvedic protocol consisting of yonidhavana with *Triphala kashaya* followed by *Neem Patra Pichu*, applied post menstrual consistently alleviated symptoms of *Karnini Yoni Vyapada*, notably *Yoni Srava*, *Yoni Kandū*, and local inflammation. A 15 days follow-up confirmed no recurrence of abnormal discharge or cervical erosion and any adverse events, indicating high safety and tolerability.

Modern pharmacological studies substantiate *Neem*'s effectiveness: aqueous and methanolic extracts of *Neem* leaves and bark have demonstrated anti-inflammatory, antimicrobial, and immunomodulatory effects, along with apoptosis inducing and cell cycle arrest activity in cervical cell lines, including HeLa cells (13, 14, and 15).

These results align seamlessly with Ayurvedic principles, where localized therapies (*Sthanika Chikitsa*) address both symptom relief and *Vata Kapha dosha* imbalances. *Neem*'s biologically active constituents such as *Nimbin*, *Azadirachtin*, *Nimbolide*, and *Quercetin* provide mechanistic plausibility for its healing effects.

**Outcome of study:** Primary outcomes were reduction in Visual analogue scale (VAS) for pain. Secondary outcomes were improvement in *Yoni gandha* (Foul smell), *Yoni Kandū* (Vaginal itching) and extent of vaginal erosion. All outcomes were measured before and after intervention using validated scales.

## Conclusions

This randomized clinical trial demonstrated that *Neem Patra Pichu* with aqueous extract significantly outperformed standard local treatments in promoting vaginal discharge resolution, inflammation reduction, and cervical tissue healing, while maintaining an excellent safety profile.

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