

**A RANDOMIZED OPEN LABELLED COMPARATIVE CLINICAL STUDY TO  
EVALUATE THE EFFICACY OF AGNIKARMA WITH PANCHDHATU SHALAKA AND  
CHANDRODAYA VARTI IN THE MANAGEMENT OF KARNINI YONIVYAPAD W.S.R.  
CERVICAL EROSION****\*<sup>1</sup>Dr. Sunita Kumari, <sup>2</sup>Prof. Dr. Jitesh Kumar Panda, <sup>3</sup>Prof. Dr. Suniti**<sup>1</sup>M.S. Scholar, <sup>2</sup>Professor & Chairperson, <sup>3</sup>Professor,  
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**ABSTRACT**

Cervical erosion is one of the most common gynecological conditions encountered in reproductive-aged women. It is characterized by the replacement of squamous epithelium of the ectocervix by columnar epithelium and may present with symptoms such as vaginal discharge, itching, contact bleeding, dyspareunia, and discomfort. Although benign in nature, untreated cervical erosion may predispose to chronic cervical pathology and requires timely management. In Ayurveda, cervical erosion can be correlated with *Karnini Yonivyapad* and *Garbhashaya Grivamukhagata Vrana* based on its symptomatology and pathogenesis. Conventional treatments such as cauterization, cryotherapy, and laser therapy may be associated with recurrence and adverse effects. Therefore, there is a need for a safe, effective, and economical treatment modality. *Agnikarma* is a well-established para-surgical procedure in Ayurveda and has shown promising results in managing cervical lesions. The present study is planned to evaluate the efficacy of *Agnikarma* with *Panchdhatu Shalaka* and *Chandrodaya Varti* in the management of *Karnini Yonivyapad* w.s.r. Cervical Erosion. A randomized open-labelled comparative clinical study will be conducted on 70 patients, divided equally into two groups of 35 patients each. Group A will receive *Agnikarma* with *Panchdhatu Shalaka* and Group B will receive *Chandrodaya Varti*. The study aims to provide scientific evidence regarding the comparative efficacy of these interventions and establish an effective Ayurvedic management protocol for Cervical Erosion. **Methodology:** 70 patients of *Karnini Yonivyapad* will be selected on the basis of inclusion and exclusion criteria. All patients will be divided into two groups. Each group having 35 patients. In group A patients will be receiving single sitting of *Agnikarma* with *Panchdhatu Shalaka* and in group B patients will be receiving single sitting of *Agnikarma* with *Chandrodaya Varti* after cessation of menses. Observations will be done on the basis of before, and after subjective and objective parameters.

**KEYWORDS:** *Karnini Yonivyapad*, Cervical Erosion, *Agnikarma*, *Panchdhatu Shalaka*, *Chandrodaya Varti*, *Garbhashaya Grivamukhagata Vrana*.**INTRODUCTION**

Women's health represents a delicate balance between physical, hormonal, and psychological factors that continuously interact throughout the life span. The reproductive phase, in particular, is marked by dynamic physiological changes that make women more susceptible to various gynecological disorders. These conditions not only affect the structural and functional

integrity of the reproductive system but also have a profound impact on overall well-being and quality of life. Cervical erosion is one of the most common gynecological conditions encountered in routine clinical practice. It is characterized by the replacement of the stratified squamous epithelium of the ectocervix by columnar epithelium, which is continuous with that of the endocervix.<sup>[1]</sup>In many cases, infections are

responsible for alterations in the epithelial lining. However, hormonal changes also play a significant role in these epithelial transformations. These changes are primarily associated with estrogen and are commonly observed during pregnancy and in women using oral contraceptive pills.

Cervical erosion has an incidence rate of 35–80% among women in the reproductive age group.<sup>[2]</sup> The condition remains asymptomatic in its early stages, however, as the condition progresses, it may manifest with symptoms such as vaginal discharge, itching, contact bleeding, dyspareunia, and related complaints. Although it is considered a benign condition, if left untreated, it may predispose to cervical malignancy. Therefore, early diagnosis and timely intervention are essential for effective management and prevention of complications.

A direct description of cervical erosion is not available in Ayurvedic classics, however, it can be correlated with conditions such as *Karnini Yonivyapad* and *Garbhashaya Grivamukhgata Vrana* based on similarities in clinical presentation, etiopathogenesis, and treatment principles. On the basis of its features, cervical erosion can be understood as a *Nija* or *Agantuja* condition, predominantly involving *Twaka* and *Mamsa Dhatu*, presenting as a *Karnikakara Granth*.<sup>[3]</sup> at the *Garbhashaya Mukha*.

In Ayurvedic classics, most gynecological disorders are described under the category of *Yonivyapad*,<sup>[4]</sup> which comprises twenty distinct conditions. Although certain conditions, such as *Karnini Yonivyapad*, are not life-threatening, they can markedly affect a woman's quality of life due to ongoing discomfort. According to *Acharya Charaka*, when a woman strains excessively during labour in the absence of proper labour pains, *Vata* becomes obstructed by the fetus. This disturbed *Vata*, along with *Kapha* and vitiated *Rakta*, leads to the formation of a *Karnika*<sup>[5]</sup> in the *Yoni*, which obstructs the normal flow of *Raja* and which is described as a *Granthi* resembling a *Mamsakanda*.<sup>[6]</sup> The condition is characterized by symptoms such as *Picchila*, *Kandu*, *Sheetala Yonistrava*.

From a modern perspective, cervical erosion is often associated with the non-healing of cervical ulcers during the postnatal period. In such conditions, the columnar epithelium of the endocervix extends over and replaces the squamous epithelium of the infra vaginal portion of the cervix. This results in a characteristic bright red appearance of the cervix, frequently accompanied by thick, mucoid vaginal discharge and pruritus.<sup>[7]</sup> Clinically, patients may present with symptoms such as profuse, offensive, and irritant vaginal discharge, Nabothian follicle formation, contact bleeding, dyspareunia, intermenstrual bleeding, pelvic pain, and bowel irritability. When associated with cervicitis, it may also manifest as low backache.<sup>8</sup> In addition, the condition may contribute to infertility and general debility, and can

significantly affect the psychological well-being of the patient. Considering the similarities in etiopathogenesis and clinical presentation, *Karnini Yonivyapad* can be reasonably correlated with cervical erosion.

In modern medicine, treatment modalities such as cauterization,<sup>[9]</sup> cryosurgery,<sup>[10]</sup> diathermy,<sup>[11]</sup> and laser therapy are commonly used for the management of cervical erosion. However, these procedures may be associated with certain complications, including per vaginal bleeding, cervical perforation, sepsis, menstrual disturbances, and even secondary infertility. Hence, there is a need for safe, cost-effective, and holistic treatment approaches that not only manage the condition effectively but also prevent recurrence. So present study is planned to evaluate the effect of *Agnikarma* with *Panchdhatu Shalaka* and *Chandrodaya Varti* locally.

## AIM AND OBJECTIVES

### AIM

To compare the efficacy of *Agnikarma* with *Panchdhatu Shalaka* and *Chandrodaya Varti* in the management of *Karnini Yonivyapad* w.s.r. Cervical Erosion.

### PRIMARY OBJECTIVE

To evaluate the comparative efficacies of *Agnikarma* with *Panchdhatu Shalaka* and *Chandrodaya Varti* in managing *Karnini Yonivyapad*.

### SECONDARY OBJECTIVE

To Study the *Karnini Yonivyapad* in the view of both ancient and modern literature.

To evaluate the efficacy of *Agnikarma* on symptoms of *Karnini Yonivyapad* by assessing through used parameters.

### Research Question

Is there any Difference in Efficacy of *Agnikarma* with *Panchdhatu Shalaka* and *Chandrodaya Varti* in the management of *Karnini Yonivyapad*?

### Hypothesis

Null Hypothesis (H<sub>0</sub>)

There is no difference in the efficacy of *Agnikarma* with *Panchdhatu Shalaka* and *Chandrodaya Varti* in the management of *Karnini Yonivyapad*.

Research Hypothesis (H<sub>1</sub>)

There is a significant difference in the efficacy of *Agnikarma* with *Panchdhatu Shalaka* and *Chandrodaya Varti* in the management of *Karnini Yonivyapad*.

## MATERIAL AND METHODS

To fulfil the aim and objectives, the study plan is divided into two sections.

Literary Review

Clinical Study.

## STUDY DESIGN

Type of Trial: Interventional

Design: Randomized clinical trial

Purpose: Treatment  
 Masking: No, Open Label  
 Timing: Prospective  
 Endpoint: Efficacy and safety  
 Duration of trial: 18 months  
 Phase of trial: Phase 2  
 Subjects: 70 (35 in each group)  
 Statistical tool: Appropriate tool will be applied.

**Selection of Patients:** A total of 70 patients meeting the inclusion criteria were selected for the study from OPD & IPD of Prasuti Tantra Evam Stree Roga Department. These patients were randomised into two groups, each consisting of 35 patients.

#### INCLUSION CRITERIA

- Married women of reproductive age group (21-45) years of age.
- Patients with symptoms related to *Karnini Yonivyapad*.
- Per speculum examination - bright red area surrounds the external os in the ectocervix with clearly demarcated outer edge.
- Patients who are willing to go for relevant investigations.
- Pap smear grading 1,2.
- Cervical Erosion present after three months of delivery or three months after the stoppage of contraceptive pills.
- Recurrence case of electro-cauterization after three months of treatment.
- Suitable for *Agnikarma*.

#### EXCLUSION CRITERIA

- Female patient of age < 21 years and > 45 years / Pt age > 40 years with history of menopausal symptoms.

#### INTERVENTIONS

S. No.	Group	Instrument/ Drug	No. of Patients	Kaal of <i>Agnikarma</i>	Duration of <i>Agnikarma</i> therapy
1.	Group A (Trial group)	<i>Panchdhatu Shalaka</i>	35	<i>Agnikarma</i> done after cessation of menses (within 10 day)	Single sitting
2.	Group B (Trial group)	<i>Chandrodaya Varti</i>	35	<i>Agnikarma</i> done after cessation of menses (within 10 day)	Single sitting

**Route of Administration:** Local application

**Method of Preparation:** *Panchdhatu Shalaka*<sup>[12]</sup> will be made by local blacksmith in appropriate dimensions and under all precautions.

*Chandrodaya Varti*<sup>[13]</sup> will be made according to the *Varti Kalpana*<sup>[14]</sup> method mentioned in *Sharangdhar Samhita*.

#### Method of *Agnikarma* Application

The whole procedure will be done in three steps after taking informed written consent, proper examination and investigations of patient.

***Agnikarma* procedure divided into 3 parts**

- Patients with any diagnosed uterine pathology like Sub-mucosal pedunculated fibroid, Adenomyosis, Endometrial Polyp, Cervical Polyp etc.
- Patients with coagulopathy.
- Patients with pregnancy, history of last delivery in duration of three months.
- Pap smear grading 3,4,5
- Diagnosed Systemic illness like genital T.B, Malignancy, Uncontrolled Hypertension, Diabetes mellitus etc.
- Known case of sexually transmitted diseases like VDRL, HIV, Gonorrhoea etc.
- Unsuitable for *Agnikarma*.

#### INVESTIGATIONS

Several investigations were performed to monitor the patients health status and evaluate the efficacy of the treatment.

**Haematological study:** Complete blood count, Random blood sugar, BT, CT, ESR. Viral Markers.

**Urinary study:** Routine and Microscopic urine examination.

**Specific investigations:** Pap Smear

#### Sources of Data

**Literature Source:** The literature related to disease, and the formulation will be reviewed from *Samhitas*, contemporary system of medicine textbook, published articles, research journals and relevant websites.

**Clinical Source:** Daily OPD, IPD patients of Institute for Ayurved Studies & Research Hospital, Kurukshetra & patients diagnosed as Cervical Erosion will be considered for the study after obtaining written informed consent.

**Experimental Source:** This was a human clinical study, no animal experimentation was conducted.

1. *Purva karma*
2. *Pradhana karma*
3. *Pashchata karma*

#### 1. *Purva Karma*

**Prerequisites:** Patient will be explained about the *Agnikarma* Procedure & after that Informed and Written Consent will be taken.

**Linen:** Sterile gloves, draping sheet, Cut sheet, Sterile gauze pieces, Sterile *Pichu*, Betadine.

**Instruments:** Autoclaved *Panchdhatu Shalaka*, sponge holder, Cusco's speculum, Vulsellum, Spirit lamp.

**Others:** Autoclaved *Chandrodaya Varti*, *Jatyadi Tail*, *Triphala kwatha* wash.

### 2. Pradhana Karma

The approximation of Cusco's will be done properly for proper visualization of cervix. Then *Agnikarma* by red heated *Panchdhatu Shalaka* & *Dagdha Chandrodaya Varti* will be performed in clockwise direction in customized *Vinduvat Agnikarma* manner on ectocervical eroded region. *Agnikarma* will be considered complete after the appearance of sign of *Dagdha* that is *Twakasankochta* and *Kapotavarnata*<sup>[15]</sup> and bluish brown color marked.

### 3. Pashchata karma

- After completion of *Agnikarma Jatyadi Tail Picchu* will be inserted high in vaginal canal till *Amutra kaal*.
- Patient will be advised for *Jatyadi Tail Picchu* high in vaginal canal at bed time till *Amutra kaal* continue for seven days.

### Post Procedure Precautions

- Marital relationship should be avoided during treatment period.
- Patient will be informed that there will be excessive mucinous discharge p/v after *Agnikarma* till fifteen days due to shedding of the necrosed epithelium.

**Follow up:** 7<sup>th</sup>, 15<sup>th</sup>, 25<sup>th</sup>, 35<sup>th</sup> day

### Assessment Criteria

#### Subjective Parameters

- *Yonigatasrava* (Amount of white discharge per vaginum)
- *Udarashula* (Lower abdominal pain -VAS Scale)
- *Katishula* (Lower backache-VAS Scale)

### OBJECTIVE PARAMETERS

- Erosion on cervix
- Grade of erosion

### Outcomes

#### Primary

Reduction in area of erosion with respect to that of cervix.

To improve the sign and symptoms associated with *Karnini Yonivyapad*.

#### SECONDARY

Changes in other associated clinical features related to *Karnini Yonivyapad*.

### Sample Size

The observation and result will be analyzed and presented on the basis of respective and applicable statistical tests.

Sample Size Calculation:

Sample Size at 90% Power

Sample size is calculated on the basis of expected cured % with trial drugs in cases of *Karnini Yonivyapad* using the formula:

$$n = \frac{(z_{\alpha} + z_{\beta})^2}{[\ln(1-e)]^2} \left[ \frac{1-p_1}{p_1} + \frac{1-p_2}{p_2} \right]$$

$P_1 = 1.00$  (100%) the proportion of *Karnini Yonivyapad* before applying the trial drug

Where  $p_2 = 0.35$  (35%) the proportion of *Karnini Yonivyapad* after applying the trial drug (equal to the incidence in general population)

(Ref: Akanksha Mahesh Naik\*, Seema Chandrakant Mehre.

AYURVEDIC MANAGEMENT OF CERVICAL EROSION THROUGH YONIDHAVAN WITH TRIPHALA AND DARUHARIDRA KWATH, APAMARGA KSHAR PRATISARAN WITH JATYADI TAILPICHU – A CASE STUDY.

Ayushdhara [Internet]. 2020Feb.2 [cited 2024Apr.25];6(6):2477-9.)

$e = 0.9(p_1 - p_2)$ , the proportion difference considered to be clinically significant

Type I error,  $\alpha=5\%$

Type II error  $\beta=10\%$  for detecting results with power of study 90%

The sample size is  $n = 32$  each group

Sample size according to this formula come out to be 32, but considering the drop out factor of the patient, 35 cases in each group will be taken

### Ethical clearance & CTRI Registration

The study was registered with the Clinical Trials Registry of India (CTRI) with **CTRI NO. CTRI/2024/077097**.

### OBSERVATIONS AND RESULTS

The results were evaluated based on the predefined assessment criteria and statistically analysed for significance.

### DISCUSSION

The obtained results will be discussed on the basis of Ayurvedic concept and modern parameters.

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