



## RANDOMIZED TRIAL ON ELECTRIFIED TAMRA SHALAKA AGNIKARMA AND PUNARNAVASHTAKA GHANAVATI ON GARBHASHAYA GRIVAGATA VRANA (CERVICAL EROSION)

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### ABSTRACT

Health status of women is directly proportional to health of society. Cervical erosion is commonly found among the age group of 20-40 years, characterized by *Kandu*, *yoni srava* with red circular granular surface and the cervical os bathed in discharges. Etiological factors, signs and symptoms point towards *kaphapitta dosha prakopa* affecting *yoni* and *Garbhasaya Griva* leading to *samprapti* of cervical erosion. *Garbhashaya Grivagata Vrana* (GGV) is an abnormal proliferation of cervical epithelium which may produce abnormal discharge, alter the vaginal pH and cervical mucus plug. *Chikitsa* of GGV, can be *yoni prakshalana*, *yoni Pichudharana*, *yoni varti*, *agnikarma* and *ksharakarma*. Clinical trial carried out among 40 subjects with *agnikarma* with electrified, temperature regulated *tamra Shalaka* alone (Group A) once, and along with oral administration of *Punarnavashtaka ghanavati* 500mg Tab twice daily (Group B) for 30 days proved the efficacy on curative as well as prevention of recurrence of GGV among group A (**81.6%**) whereas the same in group B (**90.5%**) thus improving QOL of women of reproductive age. Reduction in discharges p/v, lower back ache, lower abdominal pain, cervical erosion too, were add-on benefits of therapy.

**Keywords:** Ayurveda, Agnikarma, Cervical erosion, Garbhashaya Grivagata Vrana, Tamra Shalaka.

## INTRODUCTION

Cervical Erosion is a characterized by the squamous epithelium of the ectocervix replaced by columnar epithelium, which is continuous with the endocervix.<sup>1</sup> Cervical erosion may be considered as *Garbhashaya Grivagata Vrana (GGV)*<sup>2</sup> based on its resemblance to the features of *Mamsaja vrana*. Management of *doshaja vrana* from the initial stage of *vrana shotha*<sup>3</sup> signifies the applicability of *Dahanopakrama*. *GGV* may predispose women to infertility and psychological upset. *Prakshalana, pichu, dhupana, varti, Avachurnana* are the commonly used local treatment in *yonirogas*<sup>4</sup>. In specific cases, *shodhana, shastra, kshara*<sup>5</sup>, *agnikarma*<sup>6</sup> are also the choice of treatment.<sup>7</sup> *Agnikarma* with *tamra shalaka* was selected in *GGV* as *tamra* alleviates *kapha dosha, sheeta* in *veerya* and is also useful in *mamsapradoshaja vikara*.<sup>8</sup> *Dahanakarma* also stimulates the immune response to wound healing which prevents the recurrence of infection as well as enhances cellular memory to defend the infections.

**Aim & Objective:** The primary objective was to evaluate the clinical efficacy of *agnikarma* with electrified *tamra shalaka* at uniform temperature and *Punarnavashtaka Ghanavati* in *Garbhashaya Grivagata Vrana* and thus to standardized the *Dahanakarma* in *GGV*.

### Material and method:

**Site:-** Subjects who fulfil the inclusion criteria, were selected from O.P.D and I.P.D of Department of PG Studies in Prasuti Tantra and Stri Roga, Parul Ayurveda Hospital, Parul Sevashram Hospital Limda, Vadodara.

**Sources of Drug:** *Punarnavashtaka ghanavati* was prepared at GMP certified pharmacy of Parul Institute of Ayurveda. Raw drugs were collected from the market sample of Vadodara, were identified and authenticated in Pharmacognosy Laboratory of PIA.

### METHOD OF COLLECTION OF DATA:

#### Study design

- Open labelled, randomized, comparative clinical study.
- Method of randomization – computer generated random table technique.
- 40 patients fulfilling the inclusion criteria were selected and randomly allocated in two groups.

#### Sample size, Grouping and Posology:

- Group A -Trial group of 20 patients – *agnikarma* with electrified *tamra shalaka* and oral medication of *punarnavashtaka ghanavati* (500mg BD before food with water for 30days)
- Group B - Control group of 20 patients – Only *agni karma* with electrified *tamra shalaka* at 110<sup>0</sup> F, until *samyak dagdha lakshana* followed by *yoniprakshalana* with warm water and *yonipichu* with *jatyadi taila* (15ml) OD for 7 days.

**Diagnostic criteria:** Diagnosis was made based on per speculum examination and pap smear. More than 50% of ectocervix if eroded was considered for the study.

**STUDY DURATION:** 2 months.

**INCLUSION CRITERIA:** Married women aged between 20-35 years, diagnosed with cervical erosion with inflammatory papsmear, with chronicity of six months or more up to one year and willing for the trial and ready to give informed written consent were incorporated for the trial.

**EXCLUSION CRITERIA:** Women of the age <20 years and >45 years, pregnant women, known cases of Tuberculosis, cervical carcinoma, HIV, VDRL, HBsAg positive, with second and third degree of uterine prolapse, with coagulation disorders, with IUCD, high risk of cautery like patient with metallic implant or heart disease were excluded from the trial.

#### CRITERIA FOR ASSESSMENT

##### Subjective parameters

**Per vaginal discharge:** Absent (0), Mild (persistent vulva moistening only) (1), Moderate (persistent staining of undergarments) (2), Severe (profuse/heavy and needs applying of vulval pads) Severe

(profuse/heavy and needs applying of vulvar pads) (3). **Vulvar itching (Pruritus Vulvae):** Absent (0), Itching occasionally (1), Itching during day and night with disturbed sleep (3). **Lower Backache:** Absent (0), Pain increase on exertion and relieved by rest (1), Pain present during day and night and relieved by painkillers and rest (2), Pain increased on exertion and not relieved by rest (3). **Odour of Discharge:** - Absent (1), Present (1). **Burning Micturition:** Absent (0), Present (1). **Lower Abdomen Pain:** Absent (0), Mild Pain throughout the day but gets relief by rest (1), Moderate Pain interfering physical activities and not relieved by rest (2), Pain interfering physical activities and relieved by taking analgesics (3).

#### Objective criteria

**Erosion on cervix (The area of cervix is divided into four halves each considered as 25%):**

0-25% (0), 26-50% (1), 51-75% (2), 76-100% (3). **Appearance of Cervix:** Normal Colour (0), Pink to Red Colour (1), Red Colour (2), Deep Red Colour (3). **Discharge from cervix:** Absent (0), Present (1), Moderate (persistent staining of Undergarments) (2), Severe (profuse/heavy and needs applying of vulvar pads) (3). **Offensiveness:** - Absent (0), Present (1). **Colour of discharge:** Whitish (0), Yellowish (1), Greenish (2), Brownish Blood Stained (3). **Bleeding**

**on application of electric cauterization:** Absent (0), No pain (1), Mild Pain (2), Moderate Pain (3).

#### Procedure of Agnikarma:

**Purva karma:** After taking informed written consent at the time of registration of the patient for study, prerequisite investigation was carried out to rule out any systemic illness. Distilled water, gauze pieces, gloves were assembled. The temperature of shalaka was maintained at 110° F. Part preparation, positioning in dorsal lithotomy and draping was done.

**Pradhana karma:** Cautery was applied as *bindu* (dotted) or *rekha*<sup>9</sup>. In cervical erosion cauterization was done at the most painful site at affected mouth of cervix. Signs of *mamsa dagdha* – pigeons colour, a little swelling and pain along with dry and constricted wound were observed as *samyak lakshana*. *Yoni pichu* of *jatyadi taila* was administered after the procedure once daily for 7 days.

**Paschat karma:** *Yoni prakshalana* with lukewarm water once daily for seven days followed by *yoni pichu* with *jatyadi taila* once daily. After 15 days of *agnikarma*, p/s examination was done for observing healing process, colour and discharge and any other findings. Follow up study of the patients was carried out on 30<sup>th</sup> day, 45<sup>th</sup> day and 60<sup>th</sup> Day. *Agnikarma* was carried out as I.P. basis only.

### Ingredients, Rasapanchaka and Proportion of Punarnavashtaka Ghanavati<sup>10</sup>:

#### PUNARANAVAAHTAKA GHANA VATI

Drug	Botanical Name	Rasa	Rasa	Guna	Veerya	Vipaka	Parts Used	Proportion
Punarnava <sup>11</sup>	<i>Boerhavia diffusa</i>	Madhura, Tikta, Kashaya	Madhura, Tikta, Kashaya	Laghu, Ruksha	Ushna	Madhura	Mula	1 part
Nimba <sup>12</sup>	<i>Azadirachta indica</i>	Tikta, Kashaya	Tikta, Kashaya	Laghu	Sheeta	Katu	Twak	1 part
Patola <sup>13</sup>	<i>Trichosanthes dioica</i>	Tikta	Tikta	Laghu, Ruksha	Ushna	Katu	Samoola	1 part
Shunti <sup>14</sup>	<i>Zingiber officinale</i>	Katu	Katu	Laghu, Snigdha, Guru, Ruksha, Tik-	Ushna	Madhura	Kanda	1 part

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Katuki <sup>15</sup>	<i>Picorrhiza kurroa</i>	Tikta	Tikta	Ruksha, Laghu	Sheeta	Katu	Moola	1 part
Guduchi <sup>16</sup>	<i>Tinospora cordifolia</i>	Tikta, Kashaya	Tikta, Kashaya	Snigdha, Guru	Ushna	Madhura	Kanda	1 part
Devdaru <sup>17</sup>	<i>Cedrus deodara</i>	Tikta	Tikta	Laghu, Snigdha	Ushna	Katu	Kandasara	1 part
Haritaki <sup>18</sup>	<i>Terminalia chebula</i>	Pancharasa Lavanavarjita Kashayapradhana	Pancharasa Lavanavarjita Kashayapradhana	Laghu, Ruksha	Ushna	Madhura	Phala	1 part

**INVESTIGATIONS:** CBC, Urine routine and microscopic examination, Cervical Cytology (Pap smear) was done to observe the changes in Cervical Epithelium at Squamo-Columnar Junction both Before and after trial.

**PATHYA AHARA VIHARA**<sup>19</sup>

- Plenty of liquid diet, green leafy vegetables, fresh seasonal fruits were advised.
- Vitamin C rich diet, salad.
- *Suryanamaskara* and *pranayama* daily in the morning.
- Maintain vaginal hygiene.

**APATHYA:**<sup>20</sup>

- Avoid coitus during the treatment.
- Avoid junk food, fermented food preparations and cold drinks.
- Avoid awakening in the night and sleeping in the daytime.
- Avoid excessive exercise.

**Statistical estimation of results:**

- Friedman’s test<sup>21</sup> applied for subjective and objective criteria for appearance of cervix, bleeding p/v, burning micturition, colour of discharge, discharge p/v, erosion of cervix, lower backache, lower abdomen pain, odour of discharge, offensiveness, pruritus vulvae, discharge p/v.
- The Wilcoxon test<sup>22</sup> followed by Post hoc analysis with Bonferroni correction applied for subjective and objective criteria.
- Mann-Whitney U test<sup>23</sup> was applied to see the difference between the Group A and Group B.

- The level of ‘P’ between 0.05 to 0.01, and P<0.001 was considered as statistically significant and highly significant respectively. The level of significance was noted and interpreted accordingly.

**Observation & Results:**

**Appearance:** Among 21 patients, in Gp.A, 13(61.9%) patients had pink to red colour,6(28.6%) had red colour and 1(4.8%) patient had deep red colour, which improved to(n=20) patients,18(85.7%) patients with healthy appearance of cervix and 2(9.5%) had pink to red colour appearance of the cervix. **In Gp.B,** (n=21),13(61.9%) patients had dark red colour,6(38.1%) had red colour improved to (n=20),18(85.7%) patients had healthy appearance of cervix and 1(4.8%) patient had pink to red appearance, and 1(4.8%) had red colour appearance of the cervix. In Gp. A, BT, 61.9% patients had dark red colour, and AT 85.7% patients had healthy appearance of the cervix, it may be due to *pitta shamaka* property of *punarnavashtaka ghanavati* and *agnikarma* with *tamra Shalaka*. **Cervical discharge:** **Gp.A, BT:** n=21, 14(66.7%) had moderate cervical discharge,7(33.3%) had mild cervical discharge which got improved to (n=20), 17(81.0%) with no cervical discharge and only 3(14.3%) with mild cervical discharge p/v. **Gp.B, BT:** n=21; 11(52.4%) had moderate cervical discharge,10(47.6%) had mild cervical discharge.**Gp.B.AT:** n=20, 15(71.4%) had no cervical discharge p/v, only 5(23.8%) had mild cervical discharge p/v. Gp. A: 66.7% patients had moderate cervical discharge and after treatment 81.0% patients got complete relief from cervical discharge, it may be due to *kapha shamaka*<sup>8</sup> property of

*punarnavashtaka ghanavati*, as evidenced from earlier studies that cervical discharge increased from Day 1-Day 15 after the procedure due to altered healing action of tissue and metabolic activity of cells after *agnikarma*.

**Cervical erosion: Gp. A, BT n=21,15(71.4%)** was having 26-50% of cervical erosion, 5(23.8%) patients were having 76-100% of cervical erosion and 1(4.8%) patient had 51-75% size of cervical erosion. **Gp.A.AT: n=20**, 19(90.5%) patients were having 0-25% of cervical erosion only 1(4.8%) patient had 26-50% of cervical erosion. **Gp. B, BT,n=21,17(81.0%)** were having 26-50% of cervical erosion,2(9.5%) patients were having76-100% of cervical erosion and 2(9.5%) patient had 51-75% of cervical erosion. **AT, n= 20**, 19(90.5%) patients were having 0-25% of cervical erosion only 1(4.8%) patient had 26-50% of cervical erosion. It was observed that in group A, 71.4% patients had 26-50% eroded area but after treatment 90.5% patients eroded area reduced to 0-25%, it may be due to *tridoshashamaka* property of *punarnavashtaka ghanavati*, healing property of *agnikarma*, the area of the cervical erosion reduced. *Agnikarma* with *tamra shalaka* was selected in *garbhashaya Grivagata vrana* as *tamra* alleviates *kapha dosha*, *ushna in guna*, *Vranashodhana-ropana* and is also useful in *mamsa-pradoshaja vikara* and *vrana*.

**Lower backache: In Gp. A BT, n= 21**, 16(76.2%) patients had mild lower backache, 3 (14.3%) patients had no lower backache, and 2(9.5%) had severe lower backache.AT, n=20 got relief from lower backache. In Gp.B., BT, n=21, 15(71.4%) patients had mild lower backache, 5 (23.8%) patients had no lower backache, and 1(4.8%) had severe lower backache.AT, n=20 all got relief from lower backache. 76.2% had mild lower backache BT, after treatment 100% patients got relief from lower backache, it may be due *ushna veerya* of *punarnavashtaka ghanavati* and *ushna guna* of *agnikarma*, *vata dosha* diminishes and pain was relieved.

**Lower abdomen pain: In Gp.A.n=21**, 13(61.9%) had mild lower abdomen pain, and 8(38.1%) had no

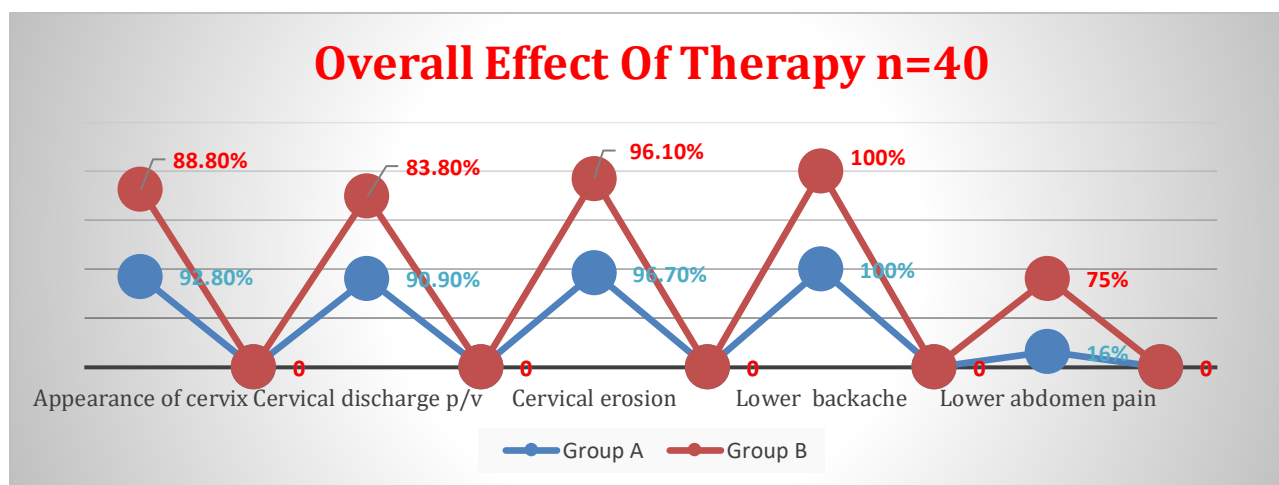
lower abdomen pain. AT, n=20, 19(90.5%) patients had no lower abdomen pain only 1(4.8%) patient had mild lower abdomen pain. In **Gp. B, BT, n= 21**, 17(81.0%) had mild lower abdomen pain, and 2(9.5%) had no lower abdomen pain and 2(9.5%) had moderate lower abdomen pain. AT, n=20,15(71.4%) patients had no lower abdomen pain only 5(23.8%) patient had mild lower abdomen pain. 61.9% had mild lower abdomen pain and after treatment 90.5% relieved from lower abdomen pain, it may be due to *vata shamaka*, *nirameekarana* property of *punarnavashtaka ghanavati* and *ushna guna* of *agnikarma* also pacifies *vata dosha*, thus reduces lower abdomen pain.

**Pruritus vulvae: Gp.A,BT, n=21,14(66.7%)** had vulval itching occasionally,4(19.0%) had no vulval itching and 2 (9.5%) had severe vulval itching with disturbed sleep.AT, 100% cure was observed. In **Gp. B, BT, n=21**, 13(61.9%), patients had vulval itching occasionally,8(38.1%) had no vulval itching. AT, 100% relief was observed in the symptom. Gp. A, 66.7% had vulval itching initially, which completely subsided after intervention. This may be attributed to the bio purification property of *punarnavashtaka ghanavati* and proper maintenance of vaginal hygiene and antimicrobial property of *tamra* ions of *tamra shalaka* used for *agnikarma*. Most of the drugs have antimicrobial activity, so prevent secondary infection.

**Per vaginal discharge: In Gp. A, BT, n=21**, 12(57.1%) patients had moderate p/v discharge and 9 (42.9%) had mild p/v discharge. AT, n=20, 12(57.1%) patients had no p/v discharge, 8(38.1%) patients had mild p/v discharge. In Gp.B, BT, n=21, 11(52.4%) patients had moderate p/v discharge and 10(47.6%) had mild p/v discharge. AT, n=20, 17(81.0%) patients had no p/v discharge, 3(14.3%) patients had mild p/v discharge. In Gp.A., 57.1% patients had moderate discharge p/v, 57.1% had no discharge p/v which may be due to the *laghu* and *ruksha*<sup>7</sup> property of *punarnavashtaka ghanavati* and also due to *kapha shamaka* property of *agnikarma* with *tamra shalaka*. *Yoni prakshalana* was done for cleansing the *yoni marga* and cervix.

**Overall effect of therapy in group A and group B:**

Sr. No.	Sign and symptoms	Mean % of relief in group A	Mean % of relief in group B
1.	Appearance	92.8%	88.8%
2.	Cervical discharge	90.9%	83.8%
3.	Cervical erosion	96.7%	96.1%
4.	Lower backache	100%	100%
5.	Lower abdomen pain	16%	75%
6.	Pruritus vulvae	100%	100%
7.	P/v discharge	75%	90.3%



**Overall effect of therapy:**

Based on the above assessment parameters the overall percentage of improvement in group A was **81.6%** whereas the same in group B was **90.5%**. The difference in percentage of both the groups is 9%. This proves that group B is more effective than group A in management of *garbhashaya grivagata vrana* (cervical erosion).

**Probable mode of action of agnikarma by tamra shalaka:**

*Tamra* alleviates *kapha dosha* due to its *vranaropana, lekhana, tridoshahara, varnya, garahara, krimihara, rasayana* and *vishaghna* properties. It alleviates excessive vaginal discharge, foul smell, itching, redness, inflammation and prevents infections and *agnikarma* due to *ushna guna* pacifies *vata – kapha dosha*. *Tamra shalaka* has anti cancerous and rapid healing property which repairs the damaged epithelium by rejuvenative action, thus reduces pain, increases cellular activity, neo-vascularization and

metabolism<sup>10</sup>. It reduces inflammation and helps in quick healing of cervical erosion.

**CONCLUSION**

- Among women aged between 36-45 years diagnosed with cardinal features of *garbhasaya grivagata vrana* oral administration of *punarnavashta ghanavati* and *agnikarma* with *tamra shalaka* alleviated the cervical erosion through antimicrobial activity of *tamra* ions and statistically highly significant result (P<0.001) were observed.
- Thus *agnikarma* with *tamra shalaka* with oral medication of *punarnavashtaka ghanavati* is effective management in *garbhasaya grivagata vrana*(Cervical erosion).

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