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# Effect of *Darvyadi Yoni Varti* in the management of *Garbhasaya Mukhagata Vrana* (Cervical erosion) - An Open label clinical trial

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## ABSTRACT

Cervical erosion is a common condition seen in most women of all the age groups. About 85% women suffer from the cervical erosion i.e. benign condition of female genital tract during their lifetime. Cervical cancer is one of the most common cancers in women worldwide about 493 000 new cases each year resulting in 274 000 deaths globally. Cytology (Pap test) screening has been very successful in lowering cancer incidence and mortality in countries where good-quality screening is available. For the present study open label single arm clinical study was planned to evaluate the efficacy of *Darvyadi Yoni Varti* in the management of cervical erosion. Total 43 patients with cervical erosion diagnosed by Pap smear test were selected from out patient department of *Prasutitantra* and *Streeroga*, out of which two patients discontinued. The treatment protocol comprised of *Darvyadi Yoni Varti* of 3gm once at bed time for 21 days. The assessment was done with subjective criteria and Pap-smear after 45 days. The results were observed highly significant in clinical features of disease like in *Yoni Srava* (68.75%), *Yoni Kandu* (70.83%), *Kati Shoola* (56.94%), *Udara Shoola* (70%), *Mutra Daha* (74.07%), *Daurbalya* (63.83%), area of erosion (85.96%), appearance of erosion (69.32%) and significant result was observed in *Yoni Daha* (76.92%). *Darvyadi Yoni Varti* was effective management of cervical erosion.

**Key words:** Cervical erosion, Cervical cancer, Cytology, *Darvyadi Yoni Varti*, Pap-smear.

## INTRODUCTION

Cervical erosion is a common condition seen in most women of all the age groups. About 85% women suffer from the cervical erosion i.e. benign condition of female genital tract during their lifetime.<sup>[1]</sup> It is asymptomatic in initial stage but later on it progresses to show many symptoms like white discharge, itching

vulva, dyspareunia etc. It adversely affects the physiological and psychological health of women and even interferes in their professional life. It may even lead to infertility.<sup>[2]</sup> It can show malignant changes in chronic stage.<sup>[3]</sup> Cervical cancer is one of the most common cancers in women worldwide with about 5,28,000 new cases in 2012 resulting in 2,66,000 deaths from cervical cancer worldwide in 2012, accounting for 7.5% of all female cancer deaths. Almost nine in ten (87%) cervical cancer deaths occur in less developed regions.<sup>[4]</sup> Cervical cancer is ranked as the most frequent cancer in women in India. The current estimates indicate approximately 132,000 new cases diagnosed and 74,000 deaths annually in India; accounting to nearly 1/3<sup>rd</sup> of the global cervical cancer deaths.<sup>[5]</sup> High-quality screening with cytology (Pap smear) has markedly reduced mortality from squamous cell cervical cancer, which comprises 80% to 90% of cervical cancers. Cytology (Pap test)

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screening has been very successful in lowering cancer incidence and mortality in countries where good-quality screening is available.<sup>[6]</sup>

While going through the *Ayurvedic* literature it becomes evident that all the gynaecological disorders are included in *Yonivyapad* and *Streeroga*. Direct reference regarding the cervical pathology cannot be traced in *Ayurvedic Classics*. However, considering the pathology and main symptoms of that is discharge and erosion, it can be correlated with *Garbhashayagrivagata Vrana*. The present study is aimed to find out a method of treatment, which was impart a permanent, easy, effective cure and was with normal side effect, which was accepted by the patient. Some of the drugs like *Darvi* (*Barberies aristata* DC.), *Lodhra* (*Symplocos recemosa* Roxb.), *Haridra* (*Curcuma longa* Linn), *Sphatika* (alum) and *Gairika* (red ochre) has been mentioned in *Upadansha Chikitsa*<sup>[7]</sup> were selected for *Yoni Varti* (vaginal suppository). Drugs like *Sphatika*, *Darvi*, *Haridra* and *Lodhra* having *Vranashodhana*, *Ropana* and *Prasadhana* properties were selected for *Yoni Varti* preparation.

## OBJECTIVES OF THE STUDY

To evaluate the efficacy of *Darvyadi Yoni Varti* on cervical erosion.

## MATERIALS AND METHODS

It was an open label single arm clinical study conducted at *Streeroga* and *Prasutitantra* Out Patient Department (OPD), I.P.G.T. and R.A. Jamnagar.

### Patients

Patients (N=43) attending the out patient department of *Prasutitantra* and *Streeroga*, fulfilling the criteria for the selection were selected for the study. A detailed history was taken according to the proforma specially prepared for this purpose.

### Drugs

The raw drugs of *Yoni Varti* (vaginal suppository) were collected from the Pharmacy of Gujarat Ayurved University and authenticated in the Pharmacognosy Laboratory, I.P.G.T. and R.A. Jamnagar. Vaginal

suppository was prepared in the department of *Rasashashtra* and *Bhaishajya Kalpana*. Table 1 shows the ingredients of *Yoni Varti*.

**Table 1: Ingredients of Darvyadi Yoni Varti**

| SN | Ingredients   | For 1 tab. of 3 gm. |
|----|---|---------------------|
| 1. | <i>Kwatha</i> ( <i>Darvi</i> , <i>Lodhra</i> , <i>Haridra</i> ) | 2.5ml               |
| 2. | <i>Madhu</i>  | 0.16ml              |
| 3. | <i>Shu. Sphatika</i>  | 0.06gm              |
| 4. | <i>Shu. Gairika</i>   | 0.05gm              |
| 5. | Gelatin powder  | 1.3gm               |
| 6. | Propyl Para Ben Sodium Salt                                     | 0.01gm              |

### Ethical clearance

The study was cleared by the Institutional Ethics Committee (PGT/7-A/Ethics/2012-2013/3532) and registered in Clinical Trial Registry of India (CTRI) No. CTRI//2014/01/00623. Prior to initiation of the study, informed written consent was taken from each patient. Patients were asked to withdraw their name from the study at any time without giving any reason if they wish.

### Inclusion criteria

Married patients of aged between 20 to 60 years with clinical signs and symptoms of cervical cell pathology including white discharge, contact bleeding, backache, erosion, hypertrophy, Acute and Chronic Cervicitis, Cervical intraepithelial neoplasia (CIN) I and II (As per CIN classification) in Pap smear test were enrolled in the study.

### Exclusion criteria

Patients with Tuberculosis of uterus, *Procedentia*, CIN Grade III (As per Bethesda classification), TB, DM, S.T.D., H.I.V., Pregnant and lactating women, aged <20 and > 60 years were excluded from study.

**Posology**

The treatment protocol comprised of *Darvyadi Yoni Varti* of 3 gm once at bed time for 21 days. The assessment was done with subjective criteria and pap-smear after 45 days.

**Criteria for assessment**

Assessment was done on the basis of improvement in signs and symptoms of the disease, Changes in Pap smear report, improvement in other investigatory parameters. A special scoring pattern was adopted for the signs and symptoms.

**OBSERVATION AND RESULTS**

In this clinical study, total 43 patients were registered, out of which 41 patients completed the treatment, whereas two patients discontinued. In the present study, maximum number of patients, i.e. 41.86% belonged to age group of 20-30 years, 46.51% were from lower middle class, 53.49% were multipara, 62.79% were from rural area, 100% had *Yoni Srava* (vaginal discharge) and 41.86% had been suffering for 1-2 year.

Pap-smear report shows that 24 patients had chronic cervicitis while 7 patients had acute cervicitis, 7 had acute on chronic cervicitis, 3 had benign hypertrophy and 1 patient had CIN-1 respectively.

Highly significant relief was observed in the *Yonitah Srava* (Vaginal discharge) (68.75%, p<0.001), *Yoni Kandu* (Itching vulva) (70.83%, p<0.001), *Kati Shoola* (Backache) (56.94%, p<0.001), *Udara Shoola* (Lower abdominal pain) (70%, p<0.001), *Mutra Daha* (Burning micturition) (74.07%, p<0.001), *Daurbalya* (Weakness) (63.83%, p<0.001). Significant relief was observed in *Yoni Daha* (Burning sensation in vagina) (76.92, p<0.05). (Table-2)

**Table 2: Effect of therapy on clinical features**

| N  | Chief complaints     | Mean Score |       | % of relief | 'W' | P      |
|----|----------------------|------------|-------|-------------|-----|--------|
|    |                      | B.T.       | A.T.  |             |     |        |
| 41 | <i>Yonitah Srava</i> | 2.341      | 0.731 | 68.75       | 861 | <0.001 |

|    |                     |       |       |       |     |        |
|----|---------------------|-------|-------|-------|-----|--------|
| 30 | <i>Yoni Kandu</i>   | 1.6   | 0.466 | 70.83 | 465 | <0.001 |
| 10 | <i>Yoni Daha</i>    | 1.3   | 0.3   | 76.92 | 55  | <0.05  |
| 35 | <i>Kati Shoola</i>  | 2.057 | 0.885 | 56.94 | 630 | <0.001 |
| 13 | <i>Udara Shoola</i> | 1.538 | 0.461 | 70    | 91  | <0.001 |
| 15 | <i>Mutradaha</i>    | 1.8   | 0.466 | 74.07 | 120 | <0.001 |
| 28 | <i>Daurbalya</i>    | 1.678 | 0.607 | 63.83 | 406 | <0.001 |

N= number of pairs in Wilcoxon's signed-rank test

**Table 3: Effect of therapy on per speculum finding**

| N  | Per speculum finding | Mean Score |       | % of relief | 'W' | P      |
|----|----------------------|------------|-------|-------------|-----|--------|
|    |                      | B.T.       | A.T.  |             |     |        |
| 41 | % Area of Erosion    | 1.195      | 0.195 | 83.67       | 820 | <0.001 |
| 41 | Appearance           | 1.707      | 0.536 | 68.57       | 861 | <0.001 |

N= number of pairs in Wilcoxon's signed-rank test

Table 3 shows the statistically highly significant relief in the % area of cervical erosion and appearance in per speculum finding.

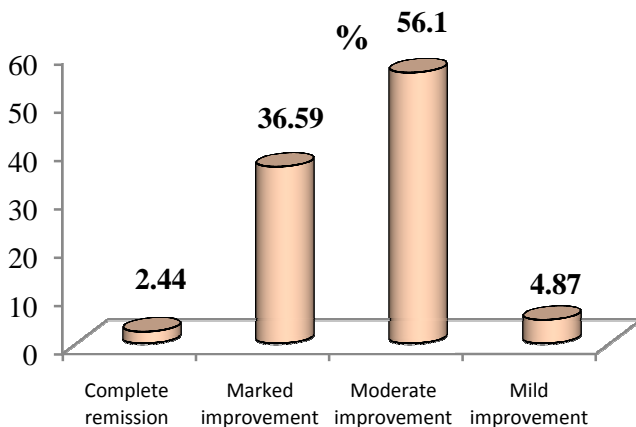
Effect of therapy on cytology reports shows after treatment normal cytology was observed in 6 patients of chronic cervicitis, 3 patients of acute cervicitis, 1 patient of acute on chronic cervicitis and 2 patients of benign hypertrophy. Decrease in infection with repair changes was observed in 10 patients of chronic cervicitis, 3 patients of acute cervicitis, 5 patients of acute on chronic cervicitis. No change was observed in 5 patients of chronic cervicitis, 1 patient of acute cervicitis. Infection was increased in 3 patients of chronic cervicitis, 1 patients of benign hypertrophy and 1 patient of normal cytology report. (Table 4)

**Table 4: Effect of therapy on cytology**

| Before treatment cytology report | Total | After treatment cytology report |                |            |                     |
|----------------------------------|-------|---------------------------------|----------------|------------|---------------------|
|                                  |       | Normal                          | Repair changes | No changes | Increased infection |
| Chronic cervicitis               | 24    | 6                               | 10             | 5          | 3                   |
| Acute cervicitis                 | 07    | 3                               | 3              | 1          | -                   |
| Acute on chronic cervicitis      | 06    | 1                               | 5              | -          | -                   |
| Benign hypertrophy               | 03    | 2                               | -              | -          | 1                   |
| Normal                           | 01    | -                               | -              | -          | 1                   |

CIN: Cervical Intraepithelial Neoplasia

The total effect of therapy shows that 2.44 % of the patients had got complete remission, 35.69% patients got marked improvement, 56.10% patients got moderate improvement and 4.87% patients had got mild improvement. (Figure 1)



**Figure 1: Total effect of therapy**

**DISCUSSION**

In the present study, majority of patients i.e. 41.86% belonged to age group of 20-30 years which indicates that this disease is common problem of reproductive life. The sexual life is most active during this period

making the genitals more prone to infection and laceration causing cervical cell pathology. 46.51% were from lower middle class. The increased risk with low socioeconomic status is attributed to a lack of screening, failure to treat precancerous conditions, and lack of knowledge about prevention of human papilloma virus (HPV) infection.<sup>[8]</sup> 53.49% were multipara which progressive rise of dysplasia with increasing parity. Previous most of studies<sup>[9]</sup> have documented multiparity as a risk factor. 62.79% were from rural area which reveals that nutrition and hygiene are the most crucial factors responsible for preventing vaginal. 41.86% had been suffering for 1-2 year. Chronicity of a disease provides knowledge of its severity and is helpful to decide the prognosis of the disease. Patients do not consult the physician until it creates major vaginal discomfort or other associated problems like severe backache, bodyache, burning micturition, infertility etc. So, this negligence converts the disease into chronic state.

Result was observed highly statistically significant in most symptoms. Properties of *Darvyadi Yoni Varti* like *Tridoshashamaka*, *Shothahara*, *Kushthaghna* and *Kandughna* normalized *Tridosha* and relief in symptoms. Abnormal vaginal discharge, pruritus vulvae is mainly due to trichomonas, monilial and bacterial infection which is reduced by drugs due to its Antipyretic, Anti protozoal, Antimicrobial, Anti-inflammatory and Antifungal action.

**Probable mode of action of *Darvyadi Yoni Varti***

The drugs of *Darvyadi Yoni Varti* have mainly *Kashaya Rasa*. *Kashaya Rasa* by asset of its *Guna* restrains *Srava*.<sup>[10]</sup> Acharya Charaka has mentioned that *Kashaya Rasa* is having pharmacological properties like *Samshamana*, *Shoshana*, *Sangrahi*, *Stambhana*, *Ropana* and *Kaphanashaka*. It has also quality of drying *Kleda*. The other dominant *Rasa* in *Yoga* are *Tikta*, *Madhura* and *Katu Rasa*. *Tikta Rasa* is having *Kandughna*, *Kleda*, *Puya* and *Kapha Shoshana* pharmacological properties.<sup>[10]</sup> While *Madhura Rasa* which is *Vata* and *Pitta Shamaka* and also has *Prinana*, *Jeevana* property etc.<sup>[11]</sup> *Balya*, *Poshana Karma* of *Madhura Rasa* helped in promotion of

healing by *Dhatuwardhana*<sup>[11]</sup> (re-growth of the tissue) leading to minimal inflammation.

The modern technology has proved that drugs of *Darvyadi Yoni Varti* has anti-inflammatory, antimicrobial, anti-bacterial, hypoglycaemic, anti-fungal, antifutigal and immunomodulatory pharmacological properties<sup>[12],[13]</sup> by which it kills the causative microorganism, reduces inflammation and also supports the vaginal defense mechanism.

## CONCLUSION

The present study is aimed to find out a method of treatment, which was impart a permanent, easy, effective cure and was with normal side effect, which was accepted by the patient. The study is overall concluded that the *Darvyadi Yoni Varti* is highly effective in reducing subjective and objective variables of *Garbhashaya Mukhagata Vrana* (cervical erosion) and will also help in deriving new conclusion and axioms in the management of *Garbhashaya Mukhagata Vrana* (cervical erosion). No Adverse Drug Reaction (ADR) and side effects were reported in the present study.

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