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A randomized controlled clinical trial to study the efficacy of *Yavakshara Madhu Pratisarana* in *Garbhashayagrivagata Vrana* (Cervical Erosion)

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ABSTRACT

Woman has to go through many functions like conception, childbirth resulting in different physiological changes, some pathological conditions also. Not all life threatening but some are troublesome. Cervical erosion is one among them, condition where squamous epithelium of ectocervix is replaced by columnar epithelium, which is continuous with endocervix.^[1] It needs special concern if left untreated may leads to infertility and predisposes to malignancy. The treatment in modern medicine cauterization, cryosurgery and laser vaporization are having side effects like secondary infertility, bleeding per vagina, stenosis, accidental burns, infections, etc. So, there is need of safe and effective treatment keeping this in mind, A randomized controlled clinical trial was conducted to study the efficacy of *Yavakshara Madhu Pratisarana* in *Garbhashayagrivagata Vrana* (Cervical Erosion) on 60 patients selected from *Streeroga-Prasutitantra* OPD of Government Ayurvedic Hospital, Osmanabad in two groups. Trial Group A - *Yava Kshara Madhu Pratisarana* & Control Group B - *Triphala Kashaya Yonidhavana* for 7 days starting from 7th day of menstrual cycle for 2 consecutive menstrual cycle. The effect of treatment has showed statistically highly significant results in both the groups Trial group has shown better effect in reducing the symptoms than control group.

Key words: *Yavakshara, Pratisarana, Yonidhavana, Cervical Erosion, Cauterization.*

INTRODUCTION

Ayurveda divided into eight branches, many points of *Streeroga* has been mentioned under *Kaumarabhrtya* and further, the diseases of women has been mentioned under the chapter of *Yonivyapada*.^[2] *Maharshi Charaka* explained female as the base of human race. Female is having all four important factors for the conception like *Rutu, Kshetra, Ambu* and *Beej*

and known to be *Kshetrapradhana*, having *Garbhashaya* where the *Garbha* resides and growth-development takes place. Any diseases causing harm to these factors will create problems of fertility. Women undergoes different physiological changes and some pathological conditions.

Cervical Erosion is one among the common complaints in Gynaecology OPD which can be correlated to *Garbhashayagreevagata Vrana*. It is benign lesion in which squamous covering of ectocervix is replaced by columnar epithelium which is continues with that lining the endo cervix shows symptoms like *Yonigata Strava* (white discharge) *Katishula* (backache), *Yonikandu* (itching), cervical tenderness, and white discharge are the most common findings. Most commonly used treatment according to modern science is cryosurgery and diathermy to destruct the columnar epithelium and facilitate the growth of new healthy stratified squamous epithelium.^[3] These treatments are costly and also various side effects like excessive mucoid discharge per vagina, sometimes cervical stenosis

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vaginal bleeding and recurrence of disease are associated with these treatments. So, to minimize these complications and to get good results the *Yavakshara* and *Madhu Pratisarana* which is having *Vrana Shodhana* and *Ropana* properties has been selected for trial here.

In Ayurveda classics *Kshara Karma* is said to be superior among both parasurgical and surgical procedures.^[4] *Kshara* has properties of *Katu Rasa*, *Katu Vipaka*, *Ushna Virya*, *Kaphahara*, *Laghu*, *Tikshna*, *Pachana*, *Vilayana*, and *Kaphavatshamak Karma*. Honey is hygroscopic, prevents colonization and bacterial growth and has antibacterial and wound healing properties. So, *Yavakshara Madhu Pratisarana* does the *Samprapti Vighatana* of disease and this treatment is very much cost effective, less invasive, with negligible side effects.

MATERIALS AND METHODS

Plan of Study

Ethical Clearance: Clearance from the Institutional Ethical Committee was obtained.

Consent: A consent explaining about the clinical study and a written consent was taken from the patients in the language best understood by them, before their participation in the trial.

Selection of patients: Patient who will report to the OPD, Clinically diagnosed cases of *Garbhashya Grivagata Vrana* (Cervical erosion) were selected on the basis of inclusion and exclusion Criteria.

Study Population: Women suffering from *Garbhashya Grivagata Vrana* (Cervical erosion) between the age group of 20-45 years.

Inclusion Criteria

- Age: 20-45 years, Married Women.
- Clinically diagnosed cases of *Garbhashya Grivagata Vrana* having symptoms of
 - *Yonigata Strava*.
 - *Yoni Kandu*.
 - *Katishul*

- Cervical Hypertrophy
- Cervical tenderness

Exclusion Criteria

- Unmarried Women.
- Pregnant women.
- Other systemic disorder like Hypertension, Diabetes, HIV, HbsAg, coagulation disorders. etc.

Investigations

Blood - Hb%, BSL-R, HIV, HbsAg.

Urine - Routine and microscopic.

So as to assess the general condition of patient and to exclude any form of abnormalities.

Intervention

Group A - 30 Patient - *Yavakshara Madhu Pratisarana*

Group B - 30 Patient - *Triphala Kashaya Yonidhavana*

Duration - Starting after 7th day of menstruation, every day for 7 days, Follow up on every 8th day. Duration of drug intervention is 2 consecutive menstrual cycle. Total duration of study is 18 months.

Criteria for Assessment

Table 1: Yonigata Strava (White Discharge)

SN	Yonigata Strava	Grades
1.	Normal - No discharge	0
2.	Mild - Occasional discharge	1
3.	Moderate - on p/v examination white discharge	2
4.	Severe - excessive vaginal discharge	3

Table 2: Yonikandu (Itching at vulval region)

SN	Yonikandu	Grades
1.	Absent	0
2.	Mild - Occasional	1

3.	Moderate - Disturb daily routine	2
4.	Severe - No relief after taking medicine	3

Table 3: Katishula (Backache)

SN	Katishula	Grades
1.	No pain	0
2.	Mild - No interference with daily routine	1
3.	Moderate - Backache during any effort	2
4.	Severe - Excessive	3

Table 4: Cervical Tenderness

SN	Cervical Tenderness	Grades
1.	Absent	0
2.	Only with compression	1
3.	Rubbing with swab	2
4.	Severe – patient resist during examination of cervix	3

Table 5: Appearance of Cervix

SN	Appearance	Score
1.	Whitish pink	0
2.	Pink	1
3.	Red	2
4.	Deep red	3

OBSERVATIONS

Age - In present study maximum i.e., 60% patients are of 20-30 year. While 33.33 % are of 31-40 year and 6.67% patients are of 41-50 year. **Occupation** - Maximum number of patients i.e., 55% were House Wife, 28.33% Teacher, 16.67% Government servants.

Diet - 53.33% were consuming mixed type of diet and 46.67% vegetarian diet. **Contraception** - 36.67% not using contraception, 28.33% intake OC Pill whereas 21.67% IUCD insertion and 13.33% Tubal Ligation done. **Vaginal discharge** - 43.33% Mucoid Discharge, 20% watery Discharge, 16.67% Milky Discharge, 15% Curdy Discharge and 5% of Yellowish Discharge. **Tenderness** - 100% had cervical tenderness. **Hypertrophy** - 100% had Hypertrophy of cervix. **Site** - 53.33% Around OS, 28.33% Lower lip of cervix and 18.33% erosion on Lower Lip of cervix. **Type** - 58.33% of simple type and 41.67% (25) had papillary type cervical erosion.

Statistical Analysis of Observations

Group A (Yavakshara Madhu Pratisarana)

Table 6: Wilcoxon Signed Ranks Test to symptoms in the Group A

Symptom	BT/AT	N	Mean	SD	W	P	Significance
Yonigata Srava	BT	30	2.56	0.50	151	<.00001	HS
	AT	30	0.63	0.49			
Yoni Kandu	BT	30	1.73	0.94	91	<.00001	HS
	AT	30	0.33	0.48			
Katishula	BT	30	1.77	0.89	110	<.00001	HS
	AT	30	0.3	0.46			
Cervical Tenderness	BT	30	2.06	0.52	151	<.00001	HS
	AT	30	0.2	0.41			
Appearance	BT	30	2.4	0.37	151	<.00001	HS

	AT	30	0.49	0.49			
HS - Highly Significant, S - Significant, NS - Non Significant							

Group B (Triphala Kashaya Yonidhawana)

Table 7: Wilcoxon Signed Ranks Test to symptoms in the Group B

Symptom	BT/AT	N	Mean	SD	W	P	S or NS
Yonigata Srava	BT	30	2.53	0.51	151	<.00001	HS
	AT	30	0.9	0.48			
Yoni Kandu	BT	30	1.67	0.96	91	<.00001	HS
	AT	30	0.6	0.56			
Katishula	BT	30	1.6	0.93	151	<.00001	HS
	AT	30	0.5	0.51			
Cervical Tenderness	BT	30	2	0.52	151	<.00001	HS
	AT	30	0.9	0.61			
Appearance	BT	30	2	0.74	151	<.00001	HS
	AT	30	0.83	0.74			
HS - Highly Significant, S - Significant, NS - Non Significant							

Statistical Analysis in between the Group A and B (By Mann Whitney’s U Test)

Table 8: Yonigata Srava

Group	N	Mean	SD	U	P
Group A	30	1.93	0.52	331.5	0.0409
Group B	30	1.63	0.49		

p is <0.05, significant difference was observed between the mean of difference of Group A and B mean of Group A is greater so, Group A is more effective than Group B.

Table 9: Yoni Kandu

Group	N	Mean	SD	U	P
Group A	30	1.4	0.81	330	0.03836
Group B	30	1.06	0.691		

p is <0.05 significant difference Between group A and B, mean of Group A is greater so, Group A is more effective than Group B

Table 10: Katishula

Group	N	Mean	SD	U	P
Group A	30	1.467	0.73	321	0.0287
Group B	30	1.1	0.712		

p is <0.05, significant difference was observed, mean of Group A is greater so, Group A is more effective than Group B

Table 11: Cervical Tenderness

Group	N	Mean	SD	U	P
Group A	30	1.86	0.35	105	<0.00001
Group B	30	1.1	0.305		

p is <0.00001, Highly significant difference was observed, mean of Group A is greater so, Group A is more effective than Group B

Table 12: Appearance

Group	N	Mean	SD	U	P
Group A	30	2.03	0.61	135	<0.00001
Group B	30	1.16	0.38		

p is <0.00001, Highly significant difference was observed, mean of Group A is greater so, Group A is more effective than Group B

Effect of therapy according to Percentage Relief in Symptoms

Table 13: Relief in Symptoms of Group A

SN	Symptom (Group A)	B.T.	A.T.	Relieved	% Relief
1.	Yonigata Strava	77	19	58	75.32
2.	Yoni Kandu	52	10	42	80.77
3.	Katishula	53	9	44	83.02
4.	Cervical Tenderness	62	6	56	90.32
5.	Appearance	72	11	61	84.72
Average Relief (A)					84.28%

Table 14: Relief in Symptoms of Group B

SN	Symptom (Group B)	B.T.	A.T.	Relieved	% Relief
1.	Yonigata Srava	76	27	49	64.47
2.	Yoni Kandu	50	18	32	64
3.	Katishula	48	15	33	68.75
4.	Cervical Tenderness	62	27	33	55
5.	Appearance	60	25	35	58.33
Average Relief (B)					63.44%

Table 15: Average Relief in Symptom score

SN	Group	Avg. % Relief in Symptom score
1.	Group A	84.28
2.	Group B	63.44

Average percentage Relief in Symptoms of Group A is 84.28% and in Symptoms of Group B is 63.44%.

Table 16: Total effect of therapy in patients

S N	Improvement Grade	Criteria	No. of patients	
			Group A	Group B
1.	Marked	> 75%	24	5

2.	Moderate	50% - 75%	6	20
3.	Mild	25% - 50%	0	5
4.	Poor	< 25%	0	0

Table 17: Overall effect of therapy as per Statistical analysis

SN	Subjective Parameters	Within Groups (Wilcoxon test)		Comparison (Mann-Whitney's test)
		Group A	Group B	
1	Yonigata Strava	HS	HS	S (A > B)
2	Yoni Kandu	HS	HS	S (A > B)
3	Katishula	HS	HS	S (A > B)
4	Cervical Tenderness	HS	HS	HS (A > B)
5	Appearance	HS	HS	HS (A > B)
HS - Highly Significant, S - Significant, NS - Non Significant				

DISCUSSION

Garbhashya Grivagata Vrana is not directly explained In *Ashtang Sangraha* we get the reference of "Yoni Vranekshana Yantra" where, we get the word as "Yoni Vrana" and in our *Samhita* we get detailed explanation of Vrana, Lakshanas and Chikitsa. Vrana *Gatravichurnana* is ultimately responsible for the "Gatravivarnana"^[5] i.e., change in the normal colour of the part of the body and "Vrana Vastu Na Nashyati"^[6] which correlates to scaring of cervical tissue even after the healing of erosion, depending upon *Lakshana* it can be correlated to *Vatakaphaja Vrana*, *Mamsaja Vrana*, present at *Garbhashya Griva*.

It is found that, most commonly seen in 20-30 age group. Women of these age group are more emotionally influenced, nervous, tensed, faulty habits, anxiety, marital upsets and stress strain etc and they also have oestrogenic effect so, the incidence is high. Who are sexually active without proper contraception are more prone. Most of them are housewives of shy nature, and do not reveal the problem to the family

members. And also, stressful life, self-negligence, wrong dietary habits make them susceptible. mucoid discharge is found more due to *Kapha Dosha Pradhanata*.

Since long time specific therapies like diathermy cautery, laser, cryosurgery and some topical applications also available but none of these therapies are satisfactory in curing the cervical erosion and most of the times causing side effects like excessive vaginal discharges, cramping pain, spotting, bleeding per vagina, stenosis, accidental burns, infections, secondary infertility

Yavakshara is having common *Kshara* properties of *Ushna Virya*, *Tikshana Guna*, *Dushtavrana Shodhaka*, *Shuddhavrana Ropaka*, *Vranashothadi Pachaka*, does *Lekhana* of *Kathin Unnat Mamsa*, *Kapha-Krimi-Kushta-Medvridhi Nashaka* and having specific properties like *Laghu*, *Dipana*, *Pachana*, *Kaphavata Shamak*, *Gulma*, *Shul*, *Udarahara* and also does the *Phalashotha Nivarana*^[7] (anti-inflammatory) Specially mentioned under *Shodhanadi Gana*^[8] of *Sushruta Samhita* mainly helps in *Kapha Vilayana*, act as *Kaphavatanashak*, *Vrana Shodhak* and *Ropaka*. *Madhu* has *Vrana Ropak* properties as per the principles of the sixty *Upakramas* explained for *Vrana* management defined in the *Sushruta Samhita*. *Madhu* is commonly used as *Anupana*. *Madhu* is supposed to act by 'pacifying' the 3 vitiated *Doshas*.^[8]

Kshara Karma, instead of destruction of tissue, scrapping of unhealthy tissue done. This action gives the upper edge of *Kshara Karma*. Because in *Kshara Karma* tissue scrapping is done by medicines/ alkalis and hence chances of cervical stenosis etc is almost nil.^[9] This may be the reason, immediately after procedure in *Ksharakarma* patients do not complaint profuse vaginal discharges. And also have added advantage of wound healing, anti-inflammatory actions. *Madhu* helps in De-sloughing of unhealthy tissue, cleanse the wound surface and removes foul smell from wounds by destroying the bacteria helping wound for healing Thus, the combination of *Yavakshara - Madhu* brings a best combination of wound purificatory and healing medicine with very

minimal or nil side effects compared to the many modern invasive techniques. It will be patient friendly, easy to administer and the drugs are easily available, non-invasive and does the *Samprapti Vighatana*.

CONCLUSION

The symptomatology of the cervical erosion resembles with the *Kaph-Vata Vrana*. Hence, in this study the cervical erosion is considered as *Kapha Vata Vrana* situated in *Garbhashayamukha*. When we compare the effect of overall therapy in both the groups and statistical tests are applied, it is found that in relieving the symptoms of *Yonigata Strava*, *Yonikandu* and *Katishul* a significant difference was observed between both the groups which indicate that even though both groups are effective in treating these symptoms and in treating the cervical tenderness and appearance of erosion. Highly significant difference was observed between both groups where group A is more effective than group B. Thus, *Yavakshara Madhu Pratisarana* is having much more significant results compared to *Triphala Kashaya Yonidhavana*. The combination of *Yavakshara-Madhu* brings a best combination of wound purificatory and healing medicine with very minimal or nil side effects, easy to administer, patient friendly and non-invasive compared to the many modern invasive techniques.

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