

# Effect of Trayodashanga Guggul Followed by Lodhra, Arjun, Haridra Kashaya Yoni-Dhavan And Paribhadra Taila Yoni-Pichoo on Yonigat Dushta Vrana With Special Reference to Premalignant Lesion of Cervix.

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**Abstract:** Women are the source of health care of their family. Because of negligence towards health causes many undesirable disorders in woman. Among them cervical erosion occupies the vast area. Its prevalence is between 50-85% of all the gynecological conditions<sup>1</sup>. Cervical erosion itself is not life threatening, but has a profound impact on the quality of life of women and may result into serious consequences like cervical intraepithelial neoplasia and cervical cancer<sup>2</sup>.

Cancer of the cervix is the second most common cancer among women in the world. It accounts for 12% of all cancers in females. In developing countries, including India carcinoma of the cervix is the major cause of morbidity and mortality. Incidence and mortality of cervical cancer in India is 134,420 and 72,825, respectively per year<sup>3,4</sup>. Premalignant or precancerous lesions are the epithelial changes of female genital track, which are left without treatment, could progress into carcinoma. Considering this principle and rising incidence of cervical cancer in India, the topic was selected as management of premalignant lesion of cervix leading to cervical cancer. Ayurvedic treatment was comprised of oral Ayurvedic treatment and local treatment in the form of vaginal douche (yoni-dhavan) and vaginal tampon soaked with medicated oil (pichoo-dharana). These treatment modalities have given symptomatic relief in patients.

**Keywords:** Yonigata Dushta Vrana, Yonidhavana, Yoni pichoo, Cervical erosion dysplasia, Nimb Tail, precancerous lesion

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## 1. Introduction:

Ayurved, an ancient medical science is based on 'Triskandha Ayurved', which comprises knowledge of Hetu, Linga and Aushadha as 3 Skandha of Ayurved. Hetu and Linga are two essential components of diagnosis of any disease. In Ayurvedic system of medicine, though the name of particular disease is not known, the methodology of diagnosing disease on the basis of Vikaraprakruti (etiopathology), Adhisthanantara (site of disease) and Sthanantaravishesha (signs and symptoms) is described distinctively.

विकारानामाकुशलो न जिन्हीयात् कदाचन ।  
न हि सर्व विकाराणा नामतोऽस्ति धृवा स्थितिः ॥च.सू.

The word 'cancer' doesn't have any Ayurvedic synonym, in olden texts. But it is possible to understand the disease with help of Panchnidan&sampraptividyan. Ayurved mentions various diseases similar to cancer like DushtaVrana, DushtaGranthi, DushtaArbuda, DushtaVidradhi etc.

Charakacharya mentioned a concept of Purvarupavastha in Nidanpanchak, which is the stage when disease can be diagnosed in early stage. Sushutacharya has mentioned this stage as Sthanasamskraya.

It is clearly said that vitiation of doshas if controlled in early stage then manifestation of disease can be prevented.

चय एव जयेत् दोषं, कुपितं तुऽविरोधयन् ।  
संचयेऽपहृता दोषाः लभते नोत्तरा गतिः ।  
तेऽतुत्तरासु गतिषु भवन्ति बलवत्तरः ॥ सुश्रुत संहिता

In Ashtanga Ayurved, Gynecological diseases are incorporated in Kayachikitsa. Charakacharya has emphasized on gynecological disorders by describing a separate chapter 'Yonivyapadchikitsa Adhyaya', the last chapter of Chikitsasthana. In this chapter he mentions various causative factors and various signs and symptoms of diseases of female genital organs.

Because of change in lifestyle, food habits & stress, females have stressful life now a days. Due to such stressful life many women suffer from various gynecological disorders mentioned as Vinshati Yonivyapad, PCOD, DUB and cancers of female genital organs like breast cancer, uterine cancer, cervical cancer etc. Though cervical cancer ranks second most common cancer in India, its prevalence is significantly reduced due to awareness and early detection by screening methods.

WHO GUIDELINES of National Cancer Control Programme (NCCP) states PREVENTION as first principle of the programme.

Ayurved also describes similar principle about prevention and control of disease.

Premalignant or precancerous lesions are the epithelial changes of female genital track, which are left without treatment, could progress into carcinoma.

General features of precancerous cells:

- 1) Loss of stratification: Loss of normal arrangement of epithelial cells into layers
- 2) Distorted cells; with enlarged hyper chromatic regular nuclei.
- 3) Increased Nuclear/Cytoplasm ratio (N/C Ratio)
- 4) Nuclear mitosis is present at high level at top layer more than the basal layer.

Types of precancerous lesions:

- 1) Epithelial, endometrial and cervical hyperplasia.
- 2) Leucoplakia-adherent white patch on mucous membrane. (Patches of keratosis)
- 3) Parakeratosis
- 4) Cervical dysplasia
- 5) Endometrial polyp
- 6) Cervical intraepithelial neoplasm (CIN)

Precancerous lesions;

To know the precancerous lesion, let us revise anatomy of cervix in brief.

Cervix is tubular structure composed of stromal tissue, which is lined by squamous epithelium in the vagina (ectocervix) and columnar epithelium within cervical canal (endocervix). Meeting of these two types of epithelium is called as squamo-columnar junction (SCJ). This is usually at ectocervix. At puberty and during pregnancy, position of SCJ extends outwards as cervix enlarges. And in adult age, it returns to the ectocervix through the process of metaplasia. Metaplasia is a physiological process whereby columnar epithelium is replaced by squamous tissue in response to the acid environment of vagina.

The Transformation Zone-TZ, (area where original SCJ was to the current SCJ and it includes area of metaplasia), is the site where pre-malignancy and malignancy develop.

The abnormalities near cervix;

- a) Dysplasia-Histological term, describing architectural abnormalities within the tissue.
- b) Dyskaryosis-Cytological term, describing the nuclear abnormalities.
- c) CIN-Cervical Intraepithelial Neoplasia. CIN is condition characterized by new cell growth. Once CIN is diagnosed, this alarms us about abnormal tissue in the cervix of woman. CIN is essential precursor of invasive cervical cancer.

Risk factors for cervical cancer:

- I. HPV –Most important causative factor. In 80% of sexually active women, HPV virus is essential pre requisite for development of malignant changes at cervix.

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- II. Incidence of genital warts, is a marker with 15% prevalence of oncogenic HPV TYPE 16 AND 18.  
 III. Smoking reduces cervical immunity.  
 IV. Multiple sexual partners along with STD.  
 V. Presence of STD like infections and genital herpes.  
 VI. Long term contraceptive pills.  
 VII. Immunosuppressant

**Aim:**

Evaluation of vaginal douche (Yonidhavan) and medicated tampon (Yoni pichoo) with internal use of Trayodashaang Guggulu in Yonigat Dushta Vrana with special reference to premalignant lesions of cervix

**Objectives:**

- a) To assess the effect on precancerous lesions like dysplasia, dyskaryosis, leucoplakia, CIN in cervix of decided management as-  
 b) Comparison of experimental group with control group  
 c) To observe the etiopathogenesis of inflammatory conditions in female genitalia with special reference to cervix.

**2. Material and Methods****I. Sources of data:-**

Classical Ayurved Texts.

Modern system of medicine, books, and articles.

Related source from authentic websites.

**II) Clinical Data:-**

Patients were recruited for study after CTRI registration number (CTRI REGISTRATION NUMBER: **CTRI/2023/07/055011**)

Computerised randomisation was done to enroll subjects in two groups-Study group and Control group

Control group of Yonigat Dushta Vrana will be given oral tablets of vitamin C and vitamin E together one tablet each daily for 30 days.

Study group was given vaginal douche (Yonidhavan) with Lodhra-Arjun-Haridra kwath – medicated tampon (pichoo dharana) with Paribhadra oil along with Abhyantar Chikitsa with Trayodashaang Guggulu.

Both groups will be guided with same dietary advice.

Patients were registered at Khemdas Ayurved Hospital, Parul Institute of Ayurved and Research, At Ishwarpura, Post Limda, Taluka Waghodiya, District Vadodara. Gujarat.

All patients underwent PAP smear test and laboratory tests such as CBC ESR RBS and Urine routine and microscopic examinations. Follow ups were taken after treatment.

**Management of Protocol: -**

For Study Group:

No.	Procedure	Selected drugs	Dose & duration	Frequency & period of administration
1	Vaginal Douche (Yonidhavan)	Lodhra-Arjun-Haridra	One liter decoction (kwath)	Daily once for 7 days
2	Tampon (Pichoo Dharana)	Paribhadra Tail	Soaked Tampon for 6 hrs. for 7 days	Daily once for 6hrs. / day
3	Internal Medicine (Abhyantar Chikitsa)	Trayodashaang Guggulu	500mg BD After Lunch and after dinner	30 days

**For Control Group:**

**Vitamin E and Vitamin C** together one tablet each daily for 30 days.

**Selection of drugs**

For Yonidhavan i.e. vaginal douches.

Lodhra, Arjun & Haridra Kwath was used.

Drug	Rasa	Guna	Veerya	Vipak
Lodhra	Kashay	Laghu sheet	Sheet	Katu
Arjun	Katutikt	Ruksha, Ushna	Ushna	Katu
Haridra	Kashay	Sheet teekshn	Sheet	Katu

**Method of preparation of medicine:-**

Trayodashaang Guggulu was purchased from Dhootpapeshwar Company and Paribhadra tail and mixture of Lodhra Haridra Arjun was purchased from authentic certified Ayurvedic shop.

**Methodology -**

The patient having following symptoms were checked with Ashtavidha Pariksha.

- I) Shwetpradar leucorrhoea quantity & consistency of discharge.
- II) Vaginal itching
- III) Vaginal burning
- IV) Ulcer at cervix
- V) P/V bleeding- quantity & consistency of discharge/bleed
- VI) Urgency micturition
- VII) Backache
- VIII) Abdominal pain
- IX) Fatigue

Gradation of signs & symptoms was done as follow:-

P/V discharge :	Grade 1 watery profuse Grade 2 mucous profuse curd like discharge Grade 3 purulent discharge Grade 4 mucopurulent discharge e foul smell Grade 5 profuse foul discharge with maggots' formation.
P/V bleeding :	Grade 1 bleeding for more than 5 days Grade 2 bleeding for eight days with 5 pads per day. Grade 3 Profuse bleeding with clots n backache Grade 4 Patient unable to do regular work Grade 5 Patient needs hospitalization.
Fatigue:	Grade 1 Mild fatigue over baseline Grade 2 Moderate – causing difficulty in routine Grade 3 Severe – need bed rest Grade 4 Disability
Abdominal Pain:	Grade 1 Mild pain not interacting with routine Grade 2 Pain subsiding with analgesics. Grade 3 severe pain not subsiding e analgesics Grade 4 Disabilities – need hospitalization
Backache:	Grade 1 Mild pain not interacting with routine Grade 2 Pain subsiding with analgesics. Grade 3 Severe pain not subsiding e analgesics Grade 4 Disabilities – need hospitalization
Vaginal burning :	Grade 1 Mild burning for some time Grade 2 Moderate burning sensation, patient can tolerate

Grade 3 Severe burning sensation, needs medication

Vaginal itching;

Grade 1 Mild-itching for some time

Grade 2 Moderate-itching sensation, patient can tolerate

Grade 3 Severe-itching sensation, needs medication

Similar as above gradation was done for other symptoms also

### Sample size and Methods

Sample size 15 cases each in study and experimental group

Duration of treatment

Control group	Vitamin C and Vitamin E one tablet each	30days
Experimental group	Vaginal douche(Yonidhavan)	7days
	Tampoon soaked with medicated oil	7days
	Trayodashaanga Guggulu capsule (120 capsules) 1Cap – 500mg	30 days

**Design of study** Composite, Open labelled control Clinical study

### Criteria for inclusion

Female patients complaining of symptoms like leucorrhoea, backache, urgency micturation, vaginal burning(yoni daha), vaginal itching(yoni kandu) along with Yonigatdushta Vrana.

Female with PAP smear study having precancerous lesions like

- Epithelial hyperplasia
- Cervical hyperplasia
- Endometrial hyperplasia
- Leucoplakia
- Parakeratosis and dyskaryosis
- Cervical dysplasia
- Cervical intraepithelial neoplasm

Female age 21 years to 50 years having complaints of shwetpradar, backache, burning micturation, altered menstruation etc.

### Criteria for exclusion

- Woman with pregnancy & lactation.
- Unmarried woman (sexually inactive woman)
- Age below 21 years & above 50 years.
- Woman having uterine growth, Cancers of genital organs.
- Endocrine disorders
- Patients taking hormonal therapy for any illness,
- Any systemic disorder which influences menstrual cycle.
- Case undergoing treatment for any serious disease.

### Criteria for withdrawal

- If the condition worsens.
- Development of any serious illness
- Patient's failure to report for follow up or irregular medication [Missing 10 or more doses]

The one case was withdrawn from the study group since she conceived after treatment of Yonidhavan and pichoo. She was a case of primary infertility since 15 years.

**Informed consent form process**

Informed consent was taken before treatment.

**Adverse event reporting**

No adverse event happened during study

**Routine examination and assessment**

Patients were clinically evaluated per speculum before treatment and after 8<sup>th</sup> and 30<sup>th</sup> day. Required laboratory investigations like CBC URINE BSL exam PAP smear study were done

**Criteria for assessment of results**

The premalignant conditions like dysplasia, dyskeratosis, Leucoplakia, CIN were compared before and after treatment with the help of PAP smear.

After PAP smear testing no such abnormalities were observed before treatment also still there were symptoms of Yonigat Dushta Vrana Symptomatic relief was assessed with signs and symptoms, clinical examination and per vaginal examination.

**Statistical analysis**

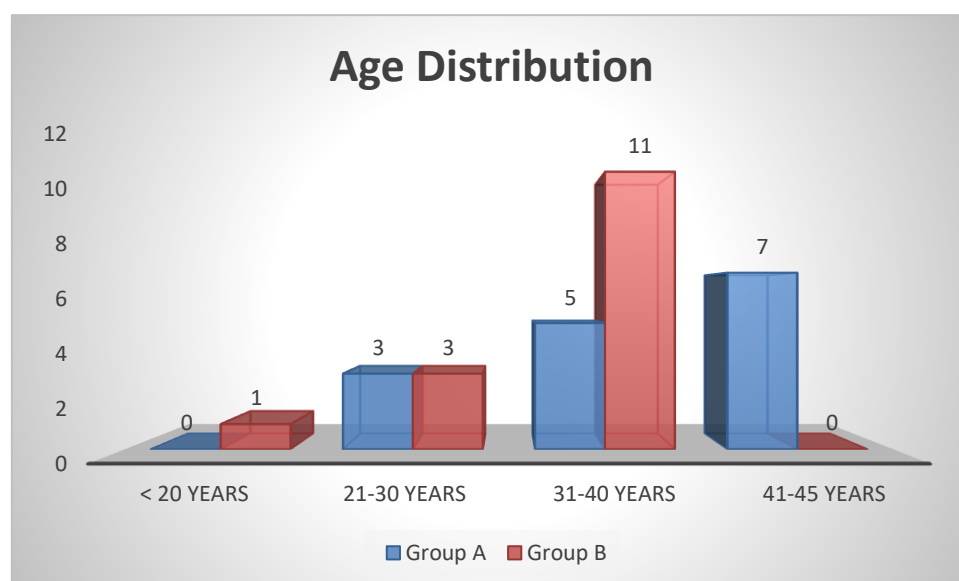
Since the study design was comparative analysis, Nominal parameters were converted to numerical parameters and tabulated and analyzed using appropriate statistical methods. Level of significance or confidence level was taken into consideration. Wilcoxon Signed Rank Test applied in this type of study design.

**3. Discussion and Results:**

Observations of data collected were divided into – 1. Demographic data 2. Clinical data (includes observations on symptoms and biochemistry)

Age: Enrolled candidates' data statistically analyzed. There was frequency of symptoms was more in age group 31-40 years.

Age Group	Group A	Group B	Total	Percentage
< 20 Years	0	1	1	3.33%
21-30 Years	3	3	6	20.00%
31-40 Years	5	11	16	53.33%
41-45 Years	7	0	7	23.33%
TOTAL	15	15	30	100.00%

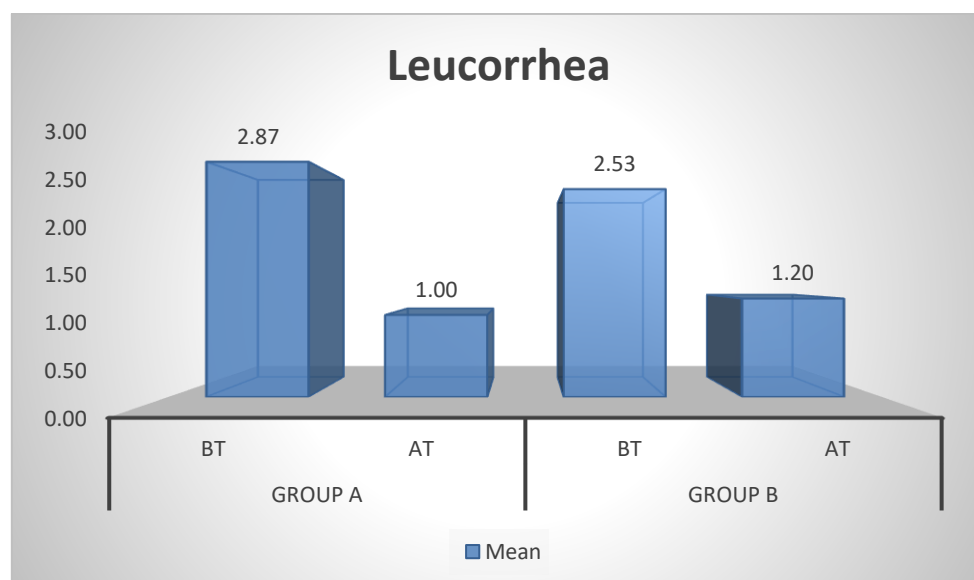


The symptoms were analysed as follows:

1) Leucorrhea:

Leucorrhea		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	2.87	3.00	1.06	0.27	-2.958 <sup>b</sup>	0.00310	65.12	Sig
	AT	1.00	1.00	0.76	0.20				
Group B	BT	2.53	3.00	1.13	0.29	-2.724 <sup>b</sup>	0.00646	52.63	Sig
	AT	1.20	1.00	1.37	0.35				

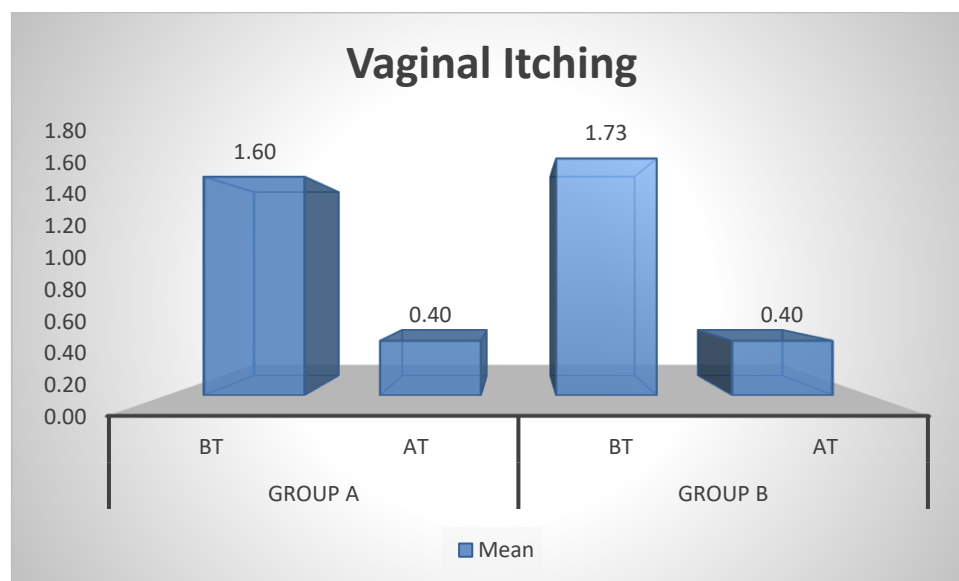
Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group A and Group B. From above table, we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.



2) Vaginal Itching:

Vaginal Itching		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.60	2.00	0.63	0.16	-2.972 <sup>b</sup>	0.00296	75.00	Sig
	AT	0.40	0.00	0.51	0.13				
Group B	BT	1.73	2.00	0.70	0.18	-3.115 <sup>b</sup>	0.00184	76.92	Sig
	AT	0.40	0.00	0.51	0.13				

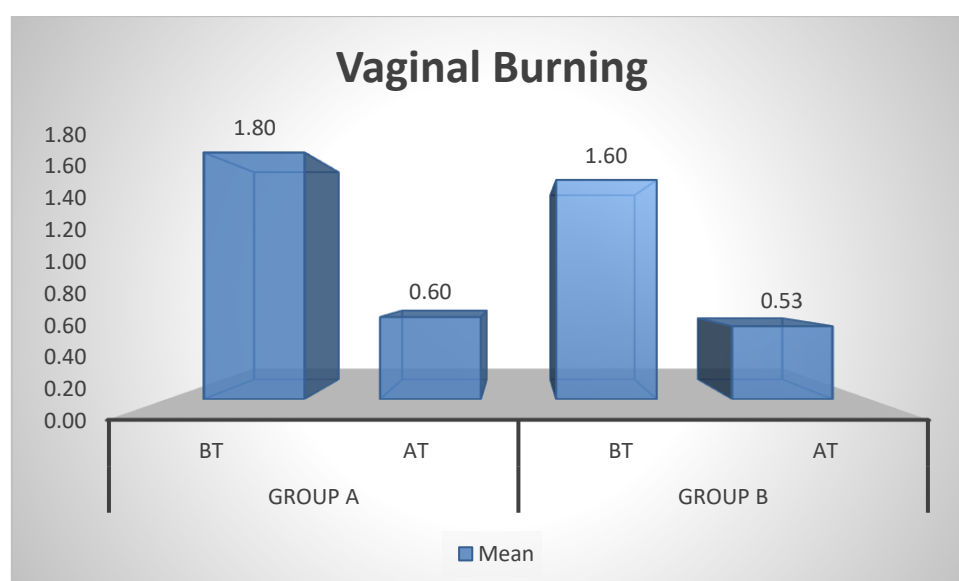
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## 3) Vaginal burning:

Vaginal Burning		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.80	2.00	0.68	0.17	-3.145 <sup>b</sup>	0.00166	66.67	Sig
	AT	0.60	1.00	0.63	0.16				
Group B	BT	1.60	1.00	0.74	0.19	-3.025 <sup>b</sup>	0.00249	66.67	Sig
	AT	0.53	1.00	0.52	0.13				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group A and Group B. From above table, we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

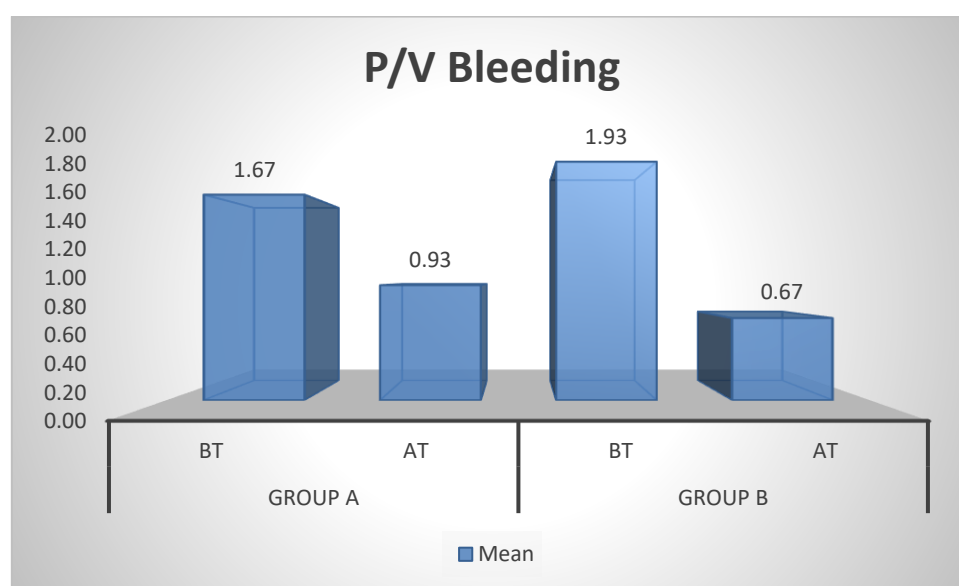




## 4) Per vaginal bleeding:

P/V Bleeding		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.67	2.00	0.72	0.19	-2.351 <sup>b</sup>	0.01874	44.00	Sig
	AT	0.93	1.00	0.96	0.25				
Group B	BT	1.93	2.00	0.70	0.18	-3.094 <sup>b</sup>	0.00198	65.52	Sig
	AT	0.67	1.00	0.62	0.16				

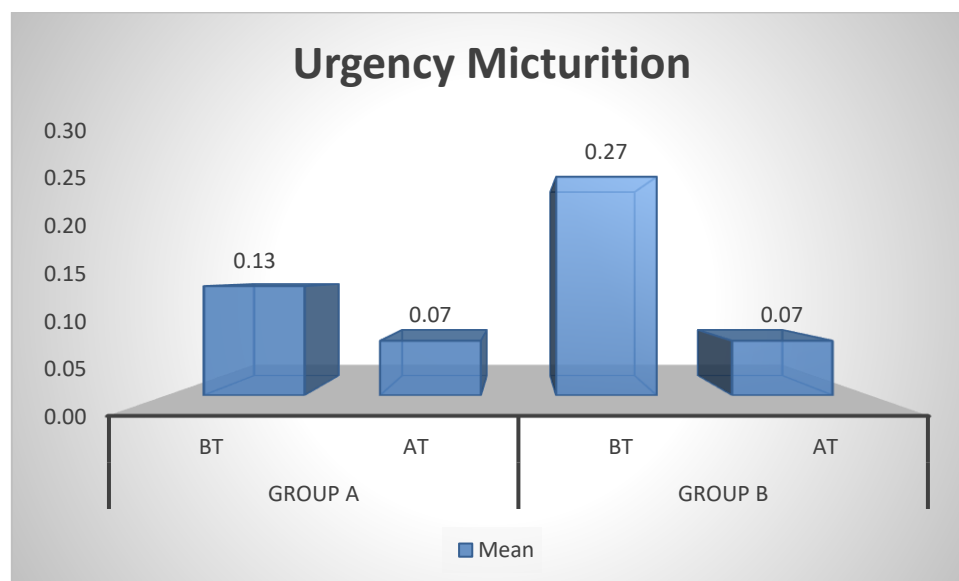
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## 5) Urgency micturation:

Urgency Micturition		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	0.13	0.00	0.35	0.09	-2.000 <sup>b</sup>	0.04317	50.00	Sig
	AT	0.07	0.00	0.26	0.07				
Group B	BT	0.27	0.00	0.46	0.12	-2.132 <sup>b</sup>	0.04326	75.00	Sig
	AT	0.07	0.00	0.26	0.07				

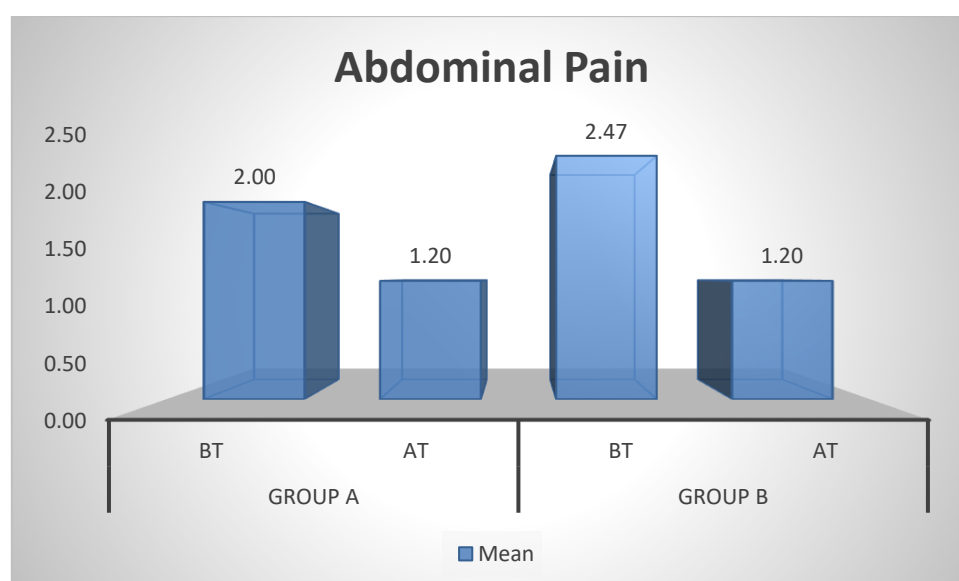
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## 6) Abdominal Pain:

Abdominal Pain		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	2.00	2.00	0.76	0.20	-2.762 <sup>b</sup>	0.00575	40.00	Sig
	AT	1.20	1.00	1.08	0.28				
Group B	BT	2.47	2.00	1.19	0.31	-2.701 <sup>b</sup>	0.00691	51.35	Sig
	AT	1.20	1.00	1.08	0.28				

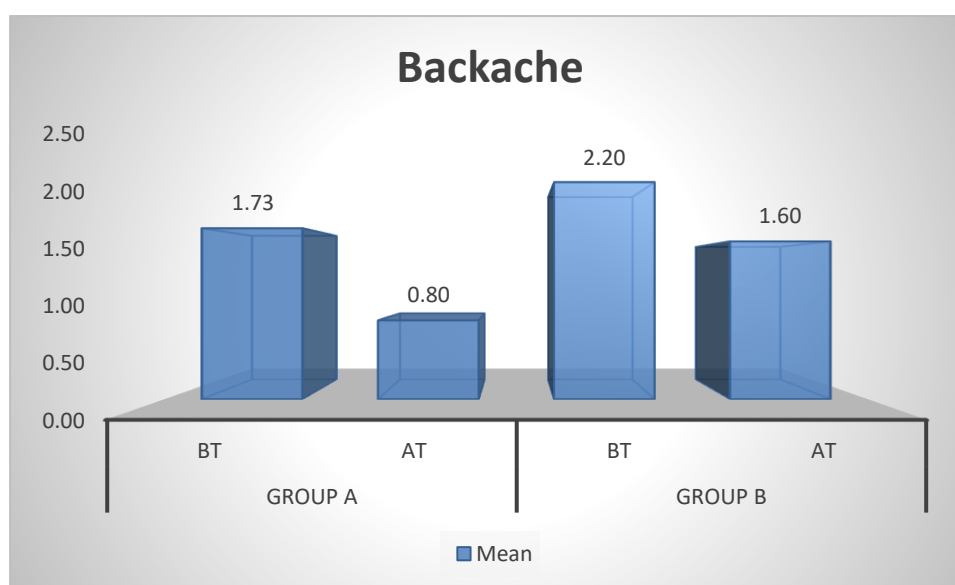
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## 7) Backache:

Bachache		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.73	2.00	0.70	0.18	-3.500 <sup>b</sup>	0.00047	53.85	Sig
	AT	0.80	1.00	0.86	0.22				
Group B	BT	2.20	2.00	0.86	0.22	-2.714 <sup>b</sup>	0.00666	27.27	Sig
	AT	1.60	1.00	1.24	0.32				

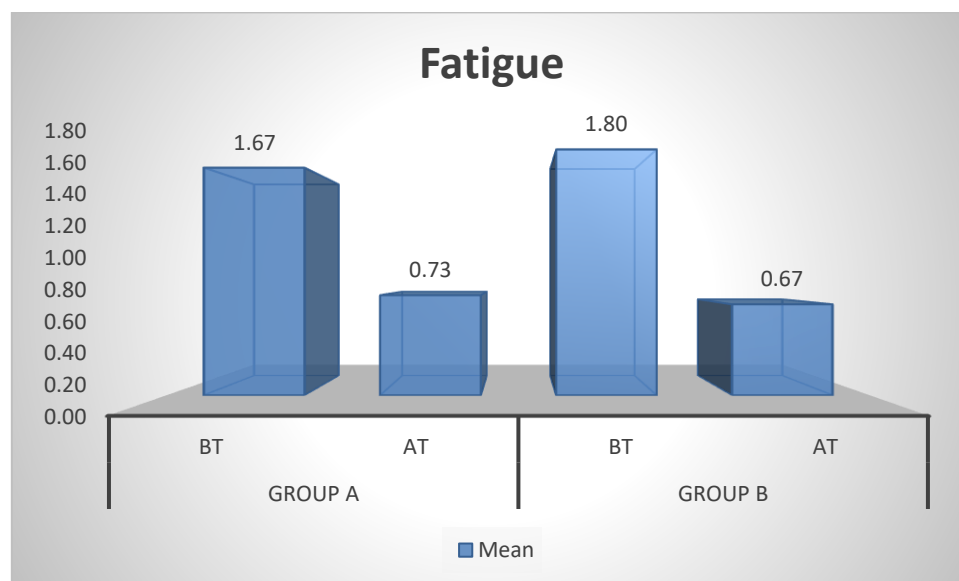
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## 8) Fatigue:

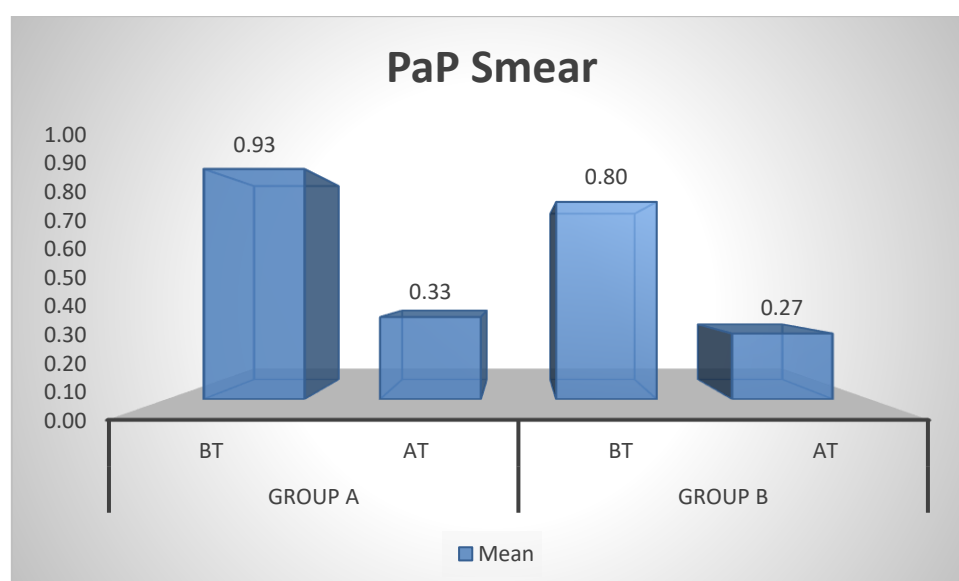
Fatigue		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	1.67	2.00	0.49	0.13	-3.276 <sup>b</sup>	0.00105	56.00	Sig
	AT	0.73	1.00	0.70	0.18				
Group B	BT	1.80	2.00	0.56	0.14	-3.314 <sup>b</sup>	0.00092	62.96	Sig
	AT	0.67	1.00	0.62	0.16				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group A and Group B. From above table, we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.

**Laboratory Investigation:**

PAP Smear		Mean	Median	SD	SE	Wilcoxon W	P-Value	% Effect	Result
Group A	BT	0.93	1.00	0.59	0.15	-2.714 <sup>b</sup>	0.00666	64.29	Sig
	AT	0.33	0.00	0.49	0.13				
Group B	BT	0.80	1.00	0.77	0.20	-1.999 <sup>b</sup>	0.04558	66.67	Sig
	AT	0.27	0.00	0.46	0.12				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group A and Group B. From above table, we can observe that, P-Value for Group A and Group B is less than 0.05. Hence, we can conclude that, effect observed in Group A and Group B is significant.



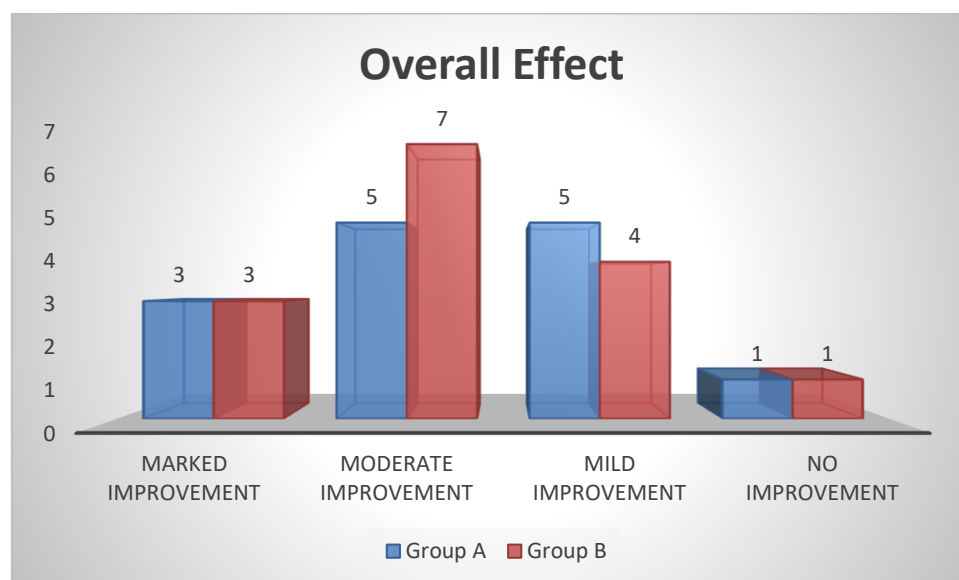
**Intergroup Analysis:**

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Leucorrhea	Group A	15	17.03	255.50	89.500	0.322
	Group B	15	13.97	209.50		
	Total	30				
Vaginal Itching	Group A	15	15.17	227.50	107.500	0.827
	Group B	15	15.83	237.50		
	Total	30				
Vaginal Burning	Group A	15	16.40	246.00	99.000	0.551
	Group B	15	14.60	219.00		
	Total	30				
P/V Bleeding	Group A	15	13.03	195.50	75.500	0.099
	Group B	15	17.97	269.50		
	Total	30				
Urgency Micturition	Group A	15	14.50	217.50	97.500	0.291
	Group B	15	16.50	247.50		
	Total	30				
Abdominal Pain	Group A	15	14.40	216.00	96.000	0.470
	Group B	15	16.60	249.00		
	Total	30				
Backache	Group A	15	17.83	267.50	77.500	0.087
	Group B	15	13.17	197.50		
	Total	30				
Fatigue	Group A	15	14.27	214.00	94.000	0.370
	Group B	15	16.73	251.00		
	Total	30				
PAP Smear	Group A	15	15.70	235.50	109.500	0.893
	Group B	15	15.30	229.50		
	Total	30				

Mann Whitney U Test is carried out for comparison between Group A and Group B. From above table, we can observe that, P-Value for almost parameters is greater than 0.05. Hence, we can conclude that, there is no significant difference between Group A and Group B.

Overall Effect	Group A		Group B	
	N	%	N	%
Marked Improvement	3	20.00%	3	20.00%
Moderate Improvement	5	33.33%	7	46.67%
Mild Improvement	5	33.33%	4	26.67%

No Improvement	1	6.67%	1	6.67%
TOTAL	15	100.00%	15	100.00%



#### 4. Conclusion:

The treatment protocol was followed successfully. There is marked improvement in 3 patients of both study and control group. Also no improvement found in one patient of each group and sent for further gynaecological management. There were not significant changes found in pathological parameters. The Ayurvedic management has helped the patients in symptoms and there were no recurrence found in study group. In short, Ayurvedic treatment modalities are equally effective in management of Yonigat Dushta Vrana. During this small study,

#### Scope for the study:

There was no change in PAP smear after the treatment. Perhaps more days of treatment may require to get the change. Such project if funded further, can be executed with large scale campaigning for such procedures that can prevent the occurrence of cervical cancer. Prevention is better than cure. Its efficacy shows preventive aspect so it can be executed as a preventive measure in National policy for cervical cancer prevention by Department of Ayush Ministry Government of India

PAP smear evaluation after every 3 years (from the age of 21 years) is advisable as per Indian government. So large scale campaigning and execution can be done to help society.

#### 5. References:

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