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ORIGINAL RESEARCH ARTICLE

A RCT ON THE EFFICACY OF NIMBADI YONI VARTI ON ABNORMAL VAGINAL DISCHARGE IN REPRODUCTIVE AGED WOMEN

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ABSTRACT

Background: *Shwetapradara* (Vaginal discharge), in female is a most common complaint encountered everyday both by gynaecologists and general practitioners. **Objectives:** The present study was designed to evaluate the comparative efficacy of the "*nimbadi yoni varti"* with that of clingen vaginal suppository. **Methods:** Total 104 diagnosed Patients of abnormal vaginal discharge confirmed by vaginal smear & gram staining were selected for randomized control trial, out of them 50 patients each were divided in two groups (excluding drop outs) named Group A & group B. Group A received *Nimbadi yoni varti* as trial drug & Group B received Clingen vaginal suppository as standard control drug. **Results:** Complete remission was found in 4% patients, 78% were found markedly improved and 18% patients were moderately improved in trial group while in Clingen vaginal suppository group, complete remission was found only in 2% patients, 66% were observed with marked improvement, 32% moderately improved & no any patients remain unchanged or mild improved. **Conclusion:** It was observed that *Nimbadi Yoni Varti* gave better results in both subjective and objective variables in comparison with the control group. Therefore, *Nimbadi Yoni varti* has proved to be an effective therapy in the management of *Shwetapradara* (vaginal discharge), and will also help in deriving new conclusion and axioms.

Keywords: Bacterial vaginitis, Abnormal Vaginal Discharge, vaginal suppository.

Key Message: Administration of *Nimbadi yoni varti* is effective and safe to cure Abnormal Vaginal Discharge.

INTRODUCTION

Vaginal discharge is caused by inflammation due to infection of the vaginal mucosa. It occurs in 1-14% of all women in the reproductive age group and is responsible for 5-10 million OPD visits per year throughout the world. The prevalence of vaginal discharge in India is estimated to be 30%[1].

Abnormal vaginal discharge also predisposes to significant morbidity in the form of pelvic inflammatory diseases, infertility, endometriosis, cuff cellulitis, urethral syndrome, pregnancy loss, preterm labour, to enumerate a few. Most common cause of symptomatic vaginal discharge is bacterial vaginosis (33-47%)[2], followed by candidiasis (20-40%) and trichomoniasis (8-10%)[3],[4].These three conditions account for 90% of all aetiologies of abnormal vaginal discharge. Multiple infections can also coexist.

Shwetapradara is not mentioned as a separate clinical entity in classics, but it can be

considered as a symptom in many stree roga. Mostly all Aacharyas described white vaginal discharge as *Shwetapradara*. However, the word "*Shwetapradara"* was firstly mentioned by Acharya Vrinda Madhava on 9th century A.D. Later on Commentator Chakrapani has explained the word [5] *Swetapradar* in very brief. Therefore this study has been designed to analyse and evaluate the efficacy of *Nimbadi yoni varti*, as a whole in light of Ayurvedic and modern concepts.

AIMS AND OBJECTIVES

To evaluate the comparative efficacy of the trial drug (*Nimbadi yoni varti*) with clingen vaginal suppository.

MATERIALS AND METHODS

Study Design: Single blind randomized Comparative Clinical Trial.

Trial Drug details:

Reference- *Nimbadi Yoga*[6] (*Nimba Patra, Triphala Yavakuta, Sphatika* and *Madhu*) in the form of duly prepared *yoni varti* had been selected for trial study. Pharmacognostical, analytical & antimicrobial study (including antimicrobial activity and microbial load) of drug has been carried out for this research work.

Table: 1: Ingredients of *Nimbadi Yoni Varti*-

	Ingredients				**For 1 tab. of 3 gm.**
1.	*Kwatha* of *Nimba* and Triphala	**Drug**	**Latin Name**	**Part used**	3.33ml
		Nimba	*Azadirachta indica* A. Juss.	Leaf	
		Amalaki	*Emblica officinalis* Linn.	Fruit	
		Haritaki	*Terminalia chebula* Retz.	Fruit	
		Bibhitaki	*Terminalia bellirica* Roxb.	Fruit	
2.	*Madhu*		*Apis cerana Fabr.*(source) Apidae[7]		0.16ml
3.	*Sphatika*				0.11gm
4.	Gelatine powder				1.3gm
5.	Methyl-P-Hydroxy Benzoate				0.01gm
6.	Paraffin Liquid				as lubricant

Procedure for preparation of *Varti*:

Nimbadi (*Nimba Patra*: *Triphala Yavakuta*- 3:1) *Kwatha* (decoction) had prepared by *Kwatha Vidhi* (1/8 reduction of water) then filtered it & evaporated by mild heating to made it semi solid. Then Gelatine powder had added in *kwatha*, stirring by help of spatula & heated till melt into a homogeneous mixture. Then *Su.Sphatika*, *Madhu* & preservative added to it and the whole mixture became poured into lubricated mould and allowed to set in refrigerator. Finally the *Varti* had packed in Aluminium foil. Weight of each *varti* About 3 gm. Shape: Oviform shape. Size: About 1.5" x 0.5" cm Dark Green in colour with specific odour, Smooth in touch. Storage: kept in well closed polythene bags and stored in refrigerator.

Study sample- The woman affected with *Shwetapradara* (Abnormal vaginal discharge) with age limit of 20 to 50 years attending the outpatient and inpatient unit of department of stree roga and prasuti tantra IPGT & RA, Gujarat Ayurveda University, Jamnagar, Special medical camps and other referrals were the research population of the study. Simple Random sampling was followed in the study. Selected subjects were randomly divided into two groups, group A and group B by using Table of Random Number.

Sample Size- As per the inclusion criteria, total 104 woman affected with *Shwetapradara* (Abnormal vaginal discharge) were thoroughly interrogated, history and facts were noted in a specially designed clinical proforma. It included past illness, physical findings, clinical manifestations and treatment history.

Study Settings- Study was started on aug 2012 and completed by jan 2013.

Ethical clearance & CTRI registration

The Institutional Ethical Committee of the IPGT&RA Hospital, Gujarat Ayurveda University, Jamnagar, approved the study. This study had also been registered in CTRI (Clinical Trial Registry-India) and their registration no. is CTRI/2012/08/002902. An informed written consent was taken from each patient willing to participate before the commencement of the trial. The patients were free to withdraw their name from the study at any time without giving any reason.

Criteria for diagnosis

- Patients were selected on the basis of wet vaginal smear & Gram staining.
- If any one of the following i.e. Trichomonas Vaginalis/ Fungal Hyphae / pus cells / Gram negative organism were present in the wet vaginal smear & Gram staining then those patients were registered.

Inclusion criteria

- Married woman aged 20 years to 50 years having clinical sign & symptoms of *Shwetapradara.*
- The patient having positive microorganism diagnosed by wet vaginal smear test & Gram staining.

Exclusion criteria

- Unmarried women.
- Pregnant women.
- Patients suffering from Tuberculosis, Sexually Transmitted Diseases like VDRL, HIV, Gonorrhoea, etc. and genital malignancy, Congenital and any other pathologies of reproductive tract.

Intervention:

Table 2: Posology

Group	Drug	Dose and Route of administration	Time of administration	Duration
A.	*Nimbadi Yoni Varti*	Locally (in vagina) 1varti (3gm) O.D.	At Bed time	15 days
B.	Clingen vaginal suppository[8]	Locally (in vagina) 1 tab(1gm) O.D	At Bed time	7days

Method of administration of Yoni Varti:

Patient was advised to empty the bladder. Then asked to lie on her back with thighs flexed and Yoni Varti was inserted deep in vagina (Posterior Fornix).

Advice:

To avoid intercourse during the course of treatment.

To avoid spicy, fried, bakery items and fermented items and over eating.

To avoid mental stress.

To take green leafy vegetables, simple food and milk.

ADR: No any adverse drug reaction was reported during or after the treatment.

Criteria for assessment: both subjective and objective criteria were implemented to find out the efficacy of trial drug as follows:

Subjective criteria:

The improvement in the patient was assessed mainly on the basis of relief in cardinal features and associated symptoms of the disease.

To assess the effect of therapy, a dully prepared scoring system was composed depending upon their rigor

Scoring pattern for sign & symptoms:

Gradation on Yonigata Lakshana

1. Yonitah Srava (White discharge per vagina)
2. Smell
3. Consistency
4. Yoni Kandu (Itching in vulva) 5. Yoni Daha (pain in vagina)
6. Yoni Vedana (Burning sensation in vagina)

Gradation on associated symptom

7. Katishoola (Low backache)
8. Udara Shoola (Pelvic pain)
9. Mutradaha (Burning micturition)
10. Local tenderness during examination
11. Vulvitis
12. Vaginitis
13. Cervicitis

Criteria for the assessment of overall effect of the therapy: The total effect of treatment was assessed in the terms of complete remission, markedly improvement, moderate improvement, mild improvement and no change.

Gradation on gynaecological examination

Objective criteria:

Assessment of the therapy was also carried out by comparing the B.T. and A.T., values of routine hematological, routine and microscopic examination of Urine.

Scoring pattern of wet vaginal smear & Gram staining was prepared.

Wet vaginal smear & Gram staining reading pattern:

Based on cellular (Pus cell / Epithelial cell)

Based on Gram negative organism

Based on Mycology

Based on Trichomonas vaginalis organism

Assessment criteria of overall effect of therapy

No change: < 25% changes in the signs and symptoms

Mild improvement: 26-50% changes in the signs and symptoms

Moderate improvement: 51-75% relief in the signs and symptom

Marked improvement : 76-99% relief in the signs and symptoms

Complete cure: 100% relief in the signs and symptoms

Follow up after the trial: After completion of course patients were advised to report every 15 days for follow up study, which was carried out for 1 month. During the follow up study, further recurrence in the signs & symptoms were recorded.

Statistical Estimation of results: The obtained data was analysed for statically significance by using paired and unpaired students 't' test. 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. If the calculated 't' value was more than 0.05 (P>0.05) results were taken as insignificant. Insignificant P > 0.05, Significant P < 0.05, Highly Significant P < 0.01 & 0.001.

RESULTS

Figure 1: Vaginal findings during per speculum

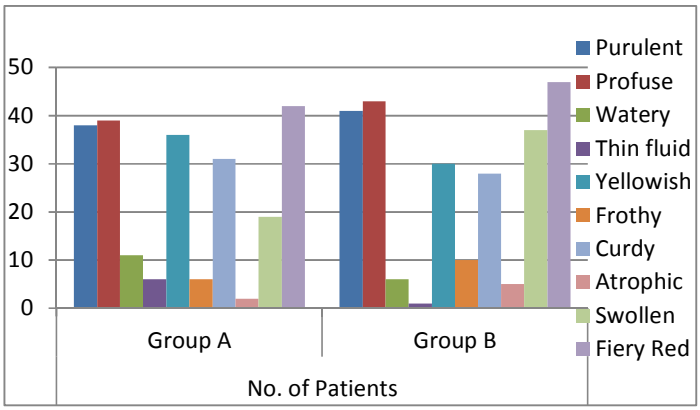


Figure 2: Finding of cervix during per speculum examination

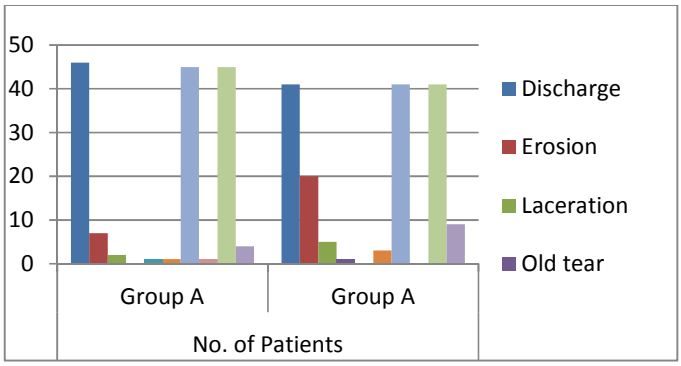


Figure 3: Characteristics of Yoni Srava during per speculum examination

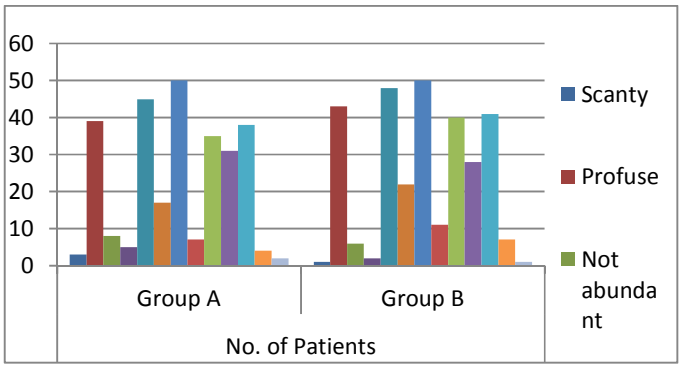


Figure 4: Uterine findings during per vaginal examination

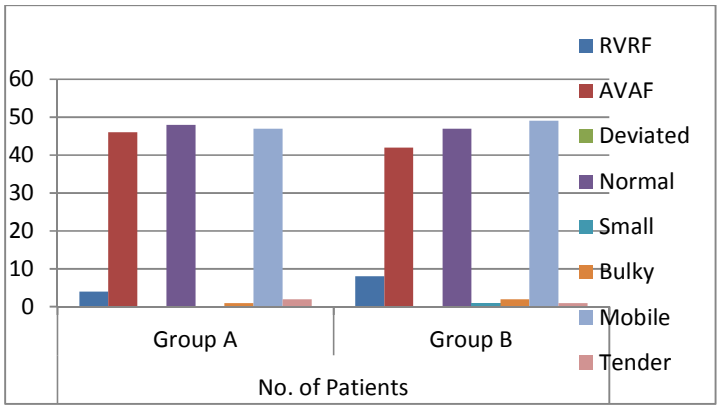


Figure 5: Cervical findings during per vaginal examination

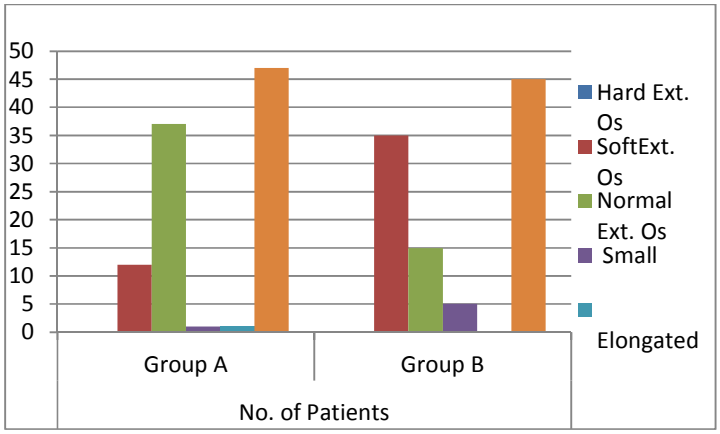
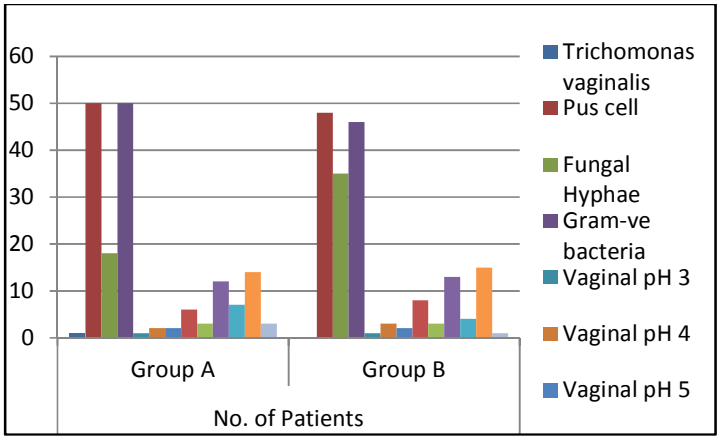


Figure 6: Distribution according to wet vaginal smear & vaginal pH examination



Effect of Therapy: In subjective parameters, viz. *Yonitah Srava* (White discharge per vagina), *Yoni Daurgandhya (*Smell), *Srava (*consistency*), Yoni kandu* (Itching vulva),*Yoni Vedana* (pain in vagina) better response was observed in trial group 'A' receiving *Nimbadi Yoni Varti*. (Table-5) It may be due to *Kashaya* (astringent), *Tikta* (bitter), *Katu* (spicy) *Rasa, Laghu* (easy to digest), *Ruksha* (dry)

Guna & *Kapha-Kleda hara*,*Kapha Pitta Shamaka, Yoni Shodhak* (vaginal purifier) *& Daurgandhaya Nashaka* (anti noisome) property of *Nimbadi yoni varti*.

Table 3: Comparative Effect of *Nimbadi Varti* & Clingen suppository on General symptoms

Vaginal symptomps	% of relief		Mean difference		Unpaired "t" test	"P"
	Group A	Group B	Group A	Group B		
Yonitaha *Srava*	94.57	82.95	2.44	2.14	2.54	< 0.02
Yoni Daurgandhya	97.53	88.29	1.92	1.81	0.88	>0.05
Consistency	90.56	78.31	1.92	1.66	2.56	< 0.02
Yoni Kandu	93.47	82	1.91	1.67	2.73	< 0.01
Yoni Vedana	96.29	69.05	1.18	1.03	1.18	>0.05

Table 4: Comparative Effect of *Nimbadi Varti* & Clingen suppository on associated symptoms

Generalised symptoms	% of relief		Mean difference		Unpaired "t" test	"P"
	Group A	Group B	Group A	Group B		
Katishoola	73.63	61.91	1.36	1.08	1.25	>0.05
Udarashoola	72.5	41.67	0.88	0.4	2.35	< 0.05
Mutradaha	80.00	47.06	0.76	0.45	1.38	>0.05

A significant relief in all General symptoms was noticed by the end of the trial in compare to control group.

In relieving local symptoms viz. Vaginitis, Cervicitis, Vulvitis and Local tenderness better response was observed in trial group 'A' & the revealed data proves the anti inflammatory property (*Shothahara*) of *Nimbadi yoni varti* drugs. (Table-7)

Table 5: Comparative Effect of *Nimbadi Varti* & Clingen suppository on gynaecological examination

Gynaecological examination	% of relief		Mean difference		Unpaired "t" test	"P"
	Group A	Group B	Group A	Group B		
Vaginitis	90.29	74.07	1.86	1.6	2.13	< 0.05
Cervicitis	88.61	69.74	1.52	1.23	2.11	< 0.05

Vulvitis	86.12	77.53	1.63	1.51	0.84	>0.05
Local Tenderness	90.77	72.31	1.75	1.31	1.70	>0.05

A significant relief in gynaecological complains was noticed by the end of the trial in compare to control group

Table 6: Comparative Effect of *Nimbadi Varti* & Clingen suppository on Wet vaginal smear

Investigations	% of relief		Mean difference		Unpaired "t'' test	"P"
	Group A	Group B	Group A	Group B		
Trichomonas Vaginalis	50	00	2	0.0	50	< 0.001
Fungal Hyphae	91.83	94.87	2.5	2.11	2.34	< 0.05
Pus cells	86.72	87.82	2.48	2.02	2.96	< 0.005
Gram-ve organism	85.22	91.59	2.42	2.36	0.44	>0.05
Vaginal pH	29.54	16.96	2.52	1.34	1.45	>0.05

Group A showed better effect to alleviate Trichomonas vaginalis because absence of organism in the 50 enrolled patients in group B. Highly significant result (P < 0.001) in both the group sin relieving pus cells, fungal hyphae and Gram-ve organism in wet vaginal smear & Gram staining but in Inter group comparison, trial drug *Nimbadi Yoni Varti*

Table 7: Comparative effect of *Nimbadi Varti* & Clingen suppository on laboratory parameters

Investigations	% of relief		Mean difference		Unpaired "t" test	"P"
	Group A	Group B	Group A	Group B		
Hb%	9.15	4.99	0.99	0.56	2.36	< 0.05
TLC	8.55	10.36	640.64	792	0.73	>0.05
N	4.42	3.72	2.62	2.22	0.24	>0.05
L	9.08	5.15	3.1	1.9	0.69	>0.05
E	14.89	19.81	0.56	0.82	0.69	>0.05
M	9.48	2.62	0.26	0.08	0.77	>0.05
ESR	12.55	24.83	3.72	6.9	1.23	>0.05

Trial drug *Nimbadi Yoni Varti* is just effective in raising the Hb% than control drug Clingen suppository. Better relief was observed in the Total leukocyte count, Eosinophil count & ESR in

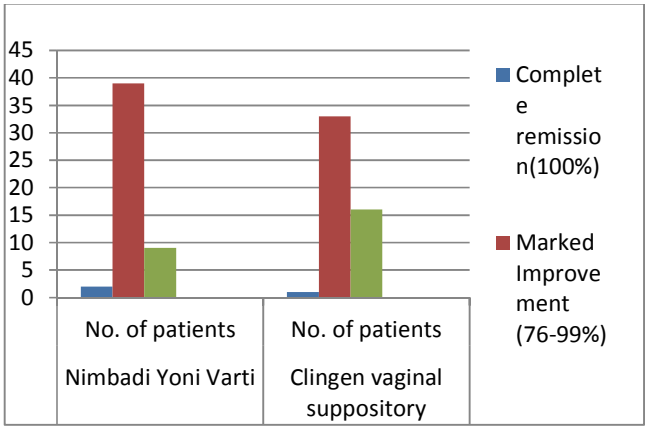
Clingen suppository treated group in comparison to *Nimbadi Yoni varti* group.

Table 8: Comparative effect of *Nimbadi Varti* & Clingen suppository on laboratory parameters

Investigations	% of relief		Mean difference		Unpaired "t" test	"P"
	Group A	Group B	Group A	Group B		
Urine pus cell	37.72	53.79	1.26	1.74	0.66	>0.05
Epithelial Cell	25.49	27.06	0.52	0.47	0.19	>0.05
RBC	33.34	44.45	0.4	1	1.26	>0.05
Calcium Oxlate	22.23	43.75	0.57	1	0.82	>0.05

Other parameter of urine routine & microscopic examination viz. Urine pus cell, Epithelial Cell, RBC & Calcium oxalate, better results has been found in Clingen suppository group.

Figure 7: Overall Effect of Therapies



On analysing the Overall effect of therapy, in the *Nimbadi Yoni Varti* Group, 2 patients (4%) got complete remission and 39 patients (78%) were found markedly improved, While 9 patients (18%) were found moderately improved. In the Clingen vaginal suppository group, complete remission was found only in 1 patients (2%) and 33 patients (66%) observed marked improvement and 16 patient (32%) was moderately improved & no any patients remain unchanged or mild improved.

Table 9: Clinical observations of patients after follow-up

Recurrence	Number of patients		Total	%
	Group A	Group B		
Follow up of 1 month	00	00	00	00.00
Follow up of 2-3 month	01	09	10	10.00

In follow up study no patient had complaint of recurrence of symptoms within 1 month. While after 2 to 3 months of follow up one patient in Group A (Nimbadi Yoni Varti Group) & after 1 to

2 months of follow up 9 Patients in Group B (Clingen Group) had complained of recurrence.

Table 10: Adverse reaction during course of treatment

ADR	Number of patients		Total	%
	Group A	Group B		
Burning sensation in vagina	00	04	04	04.00

In *Nimbadi Yoni Varti G*roup, neither any complications was found during treatment nor during follow up period but in Clingen vaginal suppository group 4 patients had slight burning sensation in vagina during the treatment.

DISCUSSION

This study showed a higher incidence of vulvitis, vaginitis and cervicitis during per speculum examination and tenderness in posterior, lateral & anterior fornix which suggests high prevalence rate of active lower reproductive tract infection. Wet vaginal smear examination shows that 98% patients had pus cells, 53% patients had fungal hyphae, 96% patients had Gram-ve bacteria organism while 1% patients had Trichomonas vaginalis present in wet vaginal smear. The revealed data is similar with most of the recent theories which stated that most common cause of symptomatic vaginal discharge is bacterial vaginosis (33-47%)[9], followed by candidiasis (20-40%) and trichomoniasis (8-10%)[10],[11].These three conditions account for 90% of all aetiologies of abnormal vaginal discharge. Multiple infections can also coexist[12].

Vaginal pH examination suggests that bacterial vaginosis was found in maximum patients which also supports many studies whose revealed that the most common cause of vaginal discharge among women in reproductive age[13]. It is characterized by an increased vaginal pH and the replacement of vaginal lactobacilli (particularly those that produce hydrogen peroxide) with *Gardnerella vaginalis* and anaerobic Gram negative rods [14].

On analysing comparative Effect of *Nimbadi Varti* with Clingen suppository on General symptoms better response was observed in trial group 'A' receiving *Nimbadi Yoni Varti*. It may due to *Kashaya* (astringent), *Tikta* (bitter), *Katu* (spicy) *Rasa, Laghu* (easy to digest)*, Ruksha* (dry) *Guna* & *Kapha-Kleda hara*,*Kapha Pitta Shamaka, Yoni Shodhak* (vaginal purifier) *& Daurgandhaya Nashaka* (anti foul smellers) property of *Nimbadi yoni varti*. Due to *Tridoshahara* and *Rasayana* properties of ingredients, *Nimbadi yoni varti* it shows better relief in all associated symptoms in compare to Clingen suppository.

In relieving gynaecological complains viz. Vaginitis, Cervicitis, Vulvitis and Local tenderness better response was observed in trial group 'A' & the revealed data proves the anti-inflammatory property (*Shothahara*) of *Nimbadi yoni varti* drugs. Highly significant result ($P < 0.001$) in both the group sin relieving pus cells, fungal hyphae and Gram-ve organism in wet vaginal smear & Gram

staining but in Inter group comparison, trial drug *Nimbadi Yoni Varti*on basis of laboratory investigations is less effective than control drug Clingen suppository. The revealed data concludes that the therapeutic effect *Nimbadi Varti* is nearer to Clingen suppository in their antibacterial property.

Trial drug is more effective than control drug in maintaining vaginal pH. As already proved that trial drug significantly reduces the vaginal discharge and allow the vagina floral environment to be healthy by their *Srotoshodhak* (channel purifier) property and also due to *Kashaya* (astringent), *Tikta* (bitter), & *Amla* (sour) rasa it is very helpful in maintaining the vaginal pH. Better relief was observed in the Total leukocyte count, Eosinophil count & ESR in Clingen suppository treated group in comparison to *Nimbadi Yoni varti* group.

CONCLUSION

The present study concluded that *Nimbadi yoni varti* is safe, potent, cost effective remedy for the management of *Shwetapradara* (abnormal vaginal discharge), it is well proved by this study that this health hazard can be well managed with *Nimbadi yoni varti* in better way compare to modern medicine.

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