International Research Journal of Ayurveda & Yoga

An International Peer Reviewed Journal for Ayurveda & Yoga





Clinical Study To Evaluate The Efficacy Of *Triphaladi Ghrita Yonipichu* In *Paripluta Yonivyapat* With Special Reference To Pelvic Inflammatory Disease.

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VOLUME 4 ISSUE 8

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Article received on 2nd July 2021

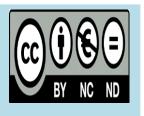
Article Accepted 20th August 2021

Article published 31st August 2021

ABSTRACT: -

Pelvic inflammatory disease is a major problem to the health of young maiden. PID may be asymptomatic or subclinical. The incidence varies from 1-2% per year among sexually active women. About 85% are spontaneous infection in sexually active females of reproductive age. The 15% follow procedures, which favors the organism to ascend up. PID affects one woman in 10 during her reproductive year 25% will have serious sequels including infertility, pelvic pain, ectopic pregnancy, Hysterectomy, Oophorectomy. In our classics *Paripluta* is one among *yonivyapat* explained with dominancy of *Pitta- Vata* predominance as mentioned in *Bhavaprakash* in *Yonirogadhikar*, so mentioned above herbal preparation has been trial here.

KEYWORDS: Paripluta Yonivyapat, Pelvic Inflammatory disease, Yoni pichu, Triphaladi Ghrita.



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How to cite this article: Mathapati P, Rawal P, Shiraguppi S, Clinical Study To Evaluate The Efficacy Of *Triphaladi Ghrita Yonipichu* In *Paripluta Yonivyapat* With Special Reference To Pelvic Inflammatory Disease". IRJAY. [Online] 2021;4(8): 29-37. Available from: http://irjay.com; DOI:https://doi.org/10.47223/IRJAY.2021.4803

INTRODUCTION

In the developing countries, Pelvic inflammatory disease is a major health issue which affects more than 1 million maiden population and also hampers the personal, interpersonal relationship between the couples. It also affects the economy of family and national economic burden. Pelvic inflammatory disease is one of the common gynecological disorders or disease in maiden of the reproductive age group. Moreover, many maiden have clinically silent spread of the infection to the upper genital tract which results in the subclinical PID.

The incidence varies from 1-2% per year among sexually active women. About 85% are spontaneous infection in sexually active females of the reproductive age^[1], Recurrent chances of PID in the duration of 84 months is 21.3%.^[2] Two third are restricted to young women of less than 25 years and the remaining one-third limited among 30 years or old.^[3]

PID is a common health problem encountered in gynecological, infertility, post natal, legal abortions and sterilization clinics India and abroad.^[4]It can also result in the long term reproductive disability and there is more recurrent chances and progressive organ damage too.

In classics, *Paripluta* is one among the twenty yonivyapat. The Paripluta yonivyapat^[5,6] can be characterized by Shunatva, Sparsha Asahatva, Nila-Pita vedana yukta srava, Jwara, Shula in sroni, Prusta, Vankshana.^[7] Aggravated pittadosha associated with Vata reaches yoni and causes shopha in yoni. Here, similar manifestation as seen in PID so, Paripluta can be correlated with PID.

In the normal condition, the vagina having the pH of 3.8-4.4 and colonized by bacteria which may have a role in the defense infection. Any factor

which trigger the vaginal pH including feminine hygiene products, repeated douching, IUCD and very frequent change of sexual partners which altered the vaginal defense causing upper genital tract infections.

In *Paripluta yonivyapat* there is a vitiation of *Vata- Pitta dosha*, hence on the basis of *doshahara* property *Triphaladi ghrita* has been selected for this study.

Considering the above factors, this study is planned to evaluate the efficacy of *Triphaladi Ghrita yoni pichu* in *Paripluta yoni vyapat*.

OBJECTIVES

- 1. To study the efficacy of *Triphaladi Ghrita Yoni Pichu* on *Paripluta Yonivyapat*.
- 2. To study in detail concept of *PariplutaYonivyapat*.

MATERIAL AND METHODS

The clinical study entitled "Clinical Study To Evaluate The Efficacy Of *Triphaladi Ghrita Yoni Pichu* In *Paripluta Yonivyapat* With Special Refrence To Pelvic Inflammatory Disease" was carried out on 30 patients who attended the OPD sections of *PrasootiTantra and StreeRoga* Department, SDMT'S Ayurvedic medical College, Danigond Post Graduation Centre,Terdal, Bagalkot.

Study Design:

 \checkmark Single group Open clinical study.

- ✓ It is a clinical study with a Pre test and Posttest design, where 30 Patients suffering from *Paripluta Yonivyapat* were selected.
- \checkmark The duration of treatment was for 07 days
- ✓ The parameters of signs and symptoms were scored on the basis of standard method of Statistical Analysis.

Inclusion Criteria:

- Married women in between the age group of 18-45 years.
- 2. Subject presenting with the symptoms like *Shuntava of Yoni, Vedana in Sroni ,Vankshana, Prustha* (pain in pelvic, inguinal, lower back region and bilateral lower abdomen).
- 3. *SparshAsahatva* (adnexal tenderness , cervical motion tenderness).
- 4. *Gramyadharma Vedana*(Dyspareunia, post coital pain/ discomfort).
- 5. Abnormal vaginal discharges
- 6. Subjects presenting with symptoms of Vaginitis, cervicitis will be selected.

Exclusion Criteria:

- 1. Pregnant Women.
- 2. PID associated with peritonitis, Tubo-ovarian abscess and reproductive malignancy.
- 3. PID associated with infections like diagnosed cases of Actinomycosis , TB,HIV.
- 4. Diagnosed cases of Endometriosis / Chocolate cyst, Pelvic Abscess.
- 5. Patients who require surgical line of management
- 6. PID when associated with prolapsed uterus
- 7. PID associated with senility and menopause.

Investigations

Hb%,

Total leukocyte count

Differential leukocyte count

ESR

RBS

Pelvic scan

Interventions

The Subjects fulfilling above criteria are selected and assigned in a group for administration of *Triphaladi Ghrita Yoni Pichu*.

Duration of Treatment-07 days.

Follow Up After 15 days.

Informed consent:

The subject undergoing this study was informed about the nature & purpose of study & written consent for each patient was taken, essential pathological investigations were done and studied accordingly.

Standard operative procedure for yoni pichu

- 1. Definition
- 2. Pre-operative procedures
- 3. Operative procedure
- 4. Post-operative Procedure
- 5. Safety measures

1. Definition:

Yoni pichu is one among sthanika chikista. Pichu means sterile swab/Tampon .yonipichu is the application of sterile swab soaked in medicated *Ghrita* in the vagina/ pottali prepared with drugs.this procedure is indicated in mahayonivyapat, Prasravasini yonivyapat, pittaja yonivyapat, Kaphaja yonivyapat, Karnini yonivyapat.

2. Pre-operative procedure:

- I. Collection of Instruments:
 - a) Cotton
 - b) Gauze piece
 - c) Surgical Gloves
 - d) Hole towel
 - e) Betadine
 - f) Sponge holding forcep
 - g) Autoclaved Ghrita
- II. Preparation of patient Laboratory Investigations
 - a) Hb%
 - b) Total leukocyte count
 - c) Differential leukocyte count
 - d) ESR
 - e) RBS
 - f) USG (Pelvic scan)

- g) Well informed consent
- h) Monitoring of vitals- Record Pulse and Blood pressure
- i) Part preparation
- 3. Operative procedure
- 1. Positioning of the patient Patient should be taken in lithotomy position on the table.
- 2. Sterile Tampon is taken
- 3. The autoclaved *Ghrita* is heated indirectly by keeping the container containing the *Ghrita* in hot water.
- 4. The sterile *pichu* is dipped in the heated *ghrita*
- 5. The vulva and vagina cleaned with antiseptic solution
- 6. Then the *pichu* is inserted in to the vagina.

4. Post operative procedure

Remove *pichu* after 3-4 hours or before going to urination.

Clean the vagina.

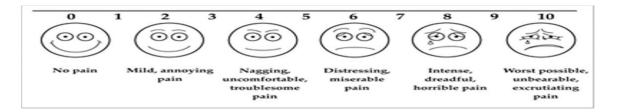
5. Safety measures

Ensure patient safety by asking any allergic reactions (pain, itching and belb formation) after procedure.

ASSESSMENT SCORING

- I. Subjective parameters
 - 1. *Maithuna asahishnuta* 0
 - Mild discomfort during coitus 1
 - Pain during coitus but tolerable-2
 - Severe pain during coitus but subsides later- 3
 - Intolerable pain during coitus and continues even after coitus-4
 - 2. Yoni srava
 - No discharge-0
 - Vulval moisture-1
 - Moderate discharge, wetting of undergarments-2
 - Heavy discharge, needs pads-3
 - 3. Kati shoola
 - No pain -0
 - Mild pain-1
 - Moderate pain -2
 - Severe pain-3

Will be assessed as per VAS scale



I have used VAS scale (visual analogue scale) for **II.** pain gradation. Pain intensity 0= No pain,1-3=Mild pain (pain present but does not disturbs the routine), 4-6=Moderate pain (pain present which disturbs the routine), 7-10=Severe pain (patients rolls on the bed due to pain).

Objective parameters

- 1. Sparsha asahathva
- No tenderness-0
- Just wines on comptression-1
- Feels pain on compression-2

- Severe pain on just touching the cervix-3
- 2. Inflammatory changes of vagina
- Absent 0
- Present 1
- 3. Inflammatory changes of cervix
- Absent-0
- Present -1

OBSERVATIONS AND RESULTS

In this Clinical Study 30 Subjects of Paripluta yonivyapat were registered, and zero drop outs. This study was single group open clinical study. Here TRIPHALADIGHRITA YONI PICHU is administered the subjects of to PARIPLUTAYONIVYAPAT (PELVIC INFLAMMATORY DISEASE) at the dose of 25-30ml of Triphaladi Ghritayoni pichuis done once daily for a period of 7 days. And here in this section obtained data pre and post study was analyzed using Friedman's test and Wilcoxon signed rank test. The results are presented in table Number[1,2,3,4,5,6,7,8,9,10,11,12].

DISCUSSION

Probable Mode Of Action Of Triphaladi Ghrita

Triphaladi ghrita is mentioned by *Bhavaprakasha* in *Yonirogadikar*, it is best for *yonirogas*.

Main ingredients are, *triphala*, *punaranava*, *dwisahachar*, *rasna*, *ghrita*, *ksheera*. *Ghrita* may have reduces *Daha* in vagina, thus producing *snehana*, *Bruhmana* and hence increases the strength of the vaginal barrel. This is in *ghrita* form so this might have strengthened the nerve endings innervating the region and increases the pain withholding threshold.

Rationality of selection of Yonipichu

In *Pariplutayonivyapat* there is inflammatory changes due to *vata pitta dosha*, there fore *yonipichu* was advised, due to which *snehana* of *apatyapatha* and does the *vataanulomana, snehana* and leads to *sukhamaithuna*.

The *akruti* aong with *sneha* and retention at a single site for 3-5 hours, may alter the local pathology by dilation of vagina, reduction of *rukshana*, strengthening of vaginal muscles, strengthening of inverting nerves, increases the vascular by entering the *suskhmasrotas*, establishing the normal flora maintain the vaginal pH.

Probable mode of action of yonipichu

- *Karya* by *rasa*: *Triphaladi ghrita* is *madhur rasa pradhana* which in turn does the *bruhmana, snehana* to *yoni*.
- Karya by guna:Pitta vata shamaka, vrunaropana, Shotagna.
- *Karya* by *akruti*: Shape of *pichu* acts as a dilator and thus helps in improving the structure of *yoni*.

CONCLUSION

Paripluta yoni vyapat is common problem which affects women of reproductive age characterized by Shunatva, Sparsha – asahatva, Nila-Pita vedanayuktasrava, Jwara.Shoola in Shroni.Prusta. Vankshana. This can be correlated to Pelvic inflammatory disease as there is close resemblance in etiology and symptomatology exhibited by paripluta *yonivyapat* which was explained by *acharyas*. The mode of action of Triphaldighrita is like shulagna, shophahara, tridoshahara, yoni

vrunashodana, ropana, ghrita having property

like *yogavahi*, and *sanskarasyaanuvartana* facilitates absorption and delivery of the active principles to the target organs the hypoliphic action of the ghee facilitates the transportation of the fungal, antibacterial, anti inflammatory action thus *Triphaladi ghrita* will act on symptoms as well as the pathology of the disease.

Efficacy of the*Sthanika chikista* lies in the fact that, it helps in *lakshana upashamana* and easy to administer. The topical application of the drug has the advantages of targeting drug on local tissue. There is high drug concentration near the tissue, and high flux through membrane is thus achived.

Thus, *Triphaladi Ghrita yonipichu* showed significant effect locally in the management of *Paripluta yonivyapat*.

Acknowledgment: Nil. Financial Support: Nil. Conflict of Interest: Nil

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TABLE NO : 01:-Showing Results Of Friedman Test For Effect Of Thriphaladi Ghrita Yonipichu On Maithun Asahishnuta

Variable	Ν	Mean Rank	χ^2	Р	Remarks
BT (Day 0)		2.92			
AT(Day 10)	30	2.03	54.591	< 0.001	S
FU (Day 15)		1.05			

BT-Before treatment; AT-After treatment; FU-Fallow up; S-Significant; Freidman's test; (χ^2)-Chi squre; N- Number of subjects; P-Probability

TABLE NO : 02; Showing Results Of Wilcoxon Signed Rank Test On The Symptom Maithuna Asahishnuta

Bonferroni Correction: 0.016

Parameter	Neg	ative ra	ive ranks		Positive ranks			Ν	Z	Р	Remarks
	Ν	MR	SR	Ν	MR	SR			value	value	
BT-AT	27	11.50	394.50	1	11.50	11.50	2		-4.638	< 0.001	S
AT-FU	28	.00	406.00	0	.00	.00	2	30	-5.070	< 0.001	S
BT-FU	29	.00	435.00	0	.00	.00	1		_4.851	< 0.001	S

BT-Before treatment; AT-After treatment; FU-Fallow up; S-Significant; MR-Mean rank; SR-Sum of ranks; N- Number of subjects; Bonferroni correction: p<0.001, P-probability, Z-Wilcoxon signed rank value.

TABLE NO : 03; Effect Of Triphaladi Ghrita Yonipichu On The Symptom Yonisrava

Variable	Ν	Mean Rank	χ^2	Р	Remarks
BT (Day 0)		2.98			
AT(Day 10)	30	1.90	56.482	< 0.001	S
FU (Day 15)		1.12			

TABLE NO : 04:-Wilcoxon Signed Rank Test On The Symptom Yonisrava

Parameters	Negat	tive Ran	ıks	ks Positive Ra		ks	Ties	Ν	Z	Р	Remarks
	Ν	MR	SR	Ν	MR	SR			value	value	
BT-AT	29	15.00	435.00	0	.00	.00	1	30	-5.23	< 0.001	S
AT-FU	23	12.00	276.00	0	.00	.00	7		-4.70	< 0.001	S

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BT-FU	30	15.00	465.00	0	.00	.00	0	-4.99	< 0.001	S

Table No: 05:-Effect Of Triphaladi Ghrita Yonipichu On The Symptom Katishoola

Variable	Ν	Mean Rank	χ^2	Р	Remarks
BT (Day 0)		2.92			
AT(Day 10)	30	1.15	53.226	< 0.001	S
FU (Day 15)		1.93			

Table No: 06;-Wilcoxon Signed Rank Test On The Symptom Katishoola

Parameters	Negative Ranks		Positive Ranks			Ties	Ν	Z	Р	Remarks	
	Ν	MR	SR	Ν	MR	SR			value	value	
BT-AT	27	14.00	378.00	0	.00	.00	3	30	-5.03	< 0.001	S
AT-FU	23	12.00	276.00	0	.00	.00	7		-4.79	< 0.001	S
BT-FU	30	14.50	406.00	28	14.50	.00	0		-4.84	< 0.001	S

Table No : 07:-Effect Of *Triphaladi Ghrita Yonipichu* On The Symptom Inflammatory Changes On Vagina

Variable	Ν	Mean Rank	χ^2	Р	Remarks
BT (Day 0)		2.98			
AT(Day 10)	30	1.90	56.482	< 0.001	S
FU (Day 15)		1.12			

Table No: 08:-Wilcoxon Signed Rank Test On The Symptom Inflammatory Changes On Vagina

Parameters	Neg	Negative Ranks		Positive Ranks		Ties	Ν	Ζ	Р	Remarks	
	Ν	MR	SR	Ν	MR	SR			value	value	
BT-AT	20	10.50	210.00	0	.00	.00	10	30	-4.47	< 0.001	S
AT-FU	7	5.00	35.00	2	.00	10.00	21		-1.66	< 0.096	S
FU-BT	25	13.00	325.00	0	.00	.00	5		-5.00	< 0.001	S

Table No :09:-Effect Of Triphaladi Ghrita Yonipichu On The Symptom Inflammatory Changes On Cervix

Variable	N	Mean Rank	χ^2	Р	Remarks
BT(Day 0)		2.85			
AT(Day 10)	30	1.65	43.800	<0.001	S
FU (Day 15)		1.50			

Friedman test showed statistically significant difference in Inflammatory changes on Cervix with $\chi 2=43.800$, p<0.001.

Table No :10:-Wilcoxon Signed Rank Test On The Symptom Inflammatory Changes On Cervix

Parameters	Neg	Negative Ranks		Pos	Positive Ranks			Ν	Ζ	Р	Remarks
	Ν	MR	SR	Ν	MR	SR			value	value	
BT-AT	24	12.50	300.00	0	.00	.00	6	30	-4.89	< 0.001	S
AT-FU	6	5.00	30.00	3	.00	15.00	21		-1.00	< 0.317	S
FU-BT	27	14.00	378.00	0	.00	.00	3		-5.19	< 0.001	S

Table No: 11:-Effect Of Triphaladi Ghrita Yonipichu On The Symptom Sparsha Asahatva

Variable	Ν	Mean Rank	χ^2	Р	Remarks
BT (Day 0)		2.98			
AT(Day 10)	30	1.98	58.513	< 0.001	S
FU (Day 15)		1.03			

Table No : 12:-Wilcoxon Signed Rank Test On The Symptom Sparsha Asahatva

Parameters	Negative Ranks			Positive Ranks			Ties	Ν	Ζ	Р	Remarks
	Ν	MR	SR	Ν	MR	SR			value	value	
BT-AT	29	15.00	435.00	0	.00	.00	1	30	-5.38	< 0.001	S
AT-FU	28	14.50	406.00	0	.00	.00	2		-520	< 0.001	S
FU-BT	30	15.50	465.00	0	.00	.00	0		-5.20	< 0.001	S