

“Evaluate the efficacy of *Kareeradi Kwatha* versus *Panchvalkal Kwath* (as *Yoni Prakshalan*) in the management of *Shweta Pradara* (leucorrhoea)"A randomized controlled trial

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Abstract

Background :-One of the most prevalent and serious issues that face women worldwide is Shweta Pradara. There is no woman who is immune to this sickness. Shweta pradara is a common gynaecological illness that, if left untreated, can cause ascending infections that can affect overall health and cause other problems. All gynaecological problems are frequently alluded to as yonivyapada in Ayurveda. Astaangsangraha and Astaanghridaya utilised Shweta Srav rather than Shweta Pradara to describe white vaginal discharge in Brihatrayee i.e. Charak Samhita, Shushrut Samhita, Astaangsangraha, and Astaanghridaya. However, Bhavaprakash Samhita and Yogaratnakar Shweta Pradara have since been described in Sharangdhara Samhita. Many medications have been reported in Ayurveda for the treatment of Shweta Pradara. Therefore, it is crucial to choose a treatment that is appropriate without interfering with other systems. The goal of the current study is to support the Nidana and Samprapti, Samprapti Vighantana of Shweta Pradara and provide alternative method of therapy those who have Shweta Pradara . Considering the side effects of untreated Shweta Pradara, such as infertility, etc. Therefore, it is essential that this ailment receive active treatment and that the quality of life be improved. Drugs in Kareeradi kwath is having sothahar (anti-inflammatory),

jantughan(antibacterial) ,kandughana (helpful in itching), varana sodhana property which is helpful in Shweta pradara .Paired ‘t’ test will be proved statistically significant in kandu , srav , and also in excoriation of skin of vulval regions and signs of discharge . As the outcome of this study will be positive i.e, the drug has vital action in remission of the symptom like yonisrav , katischoola and kandu . Thus the study will give the best curative effect of Kareeradi kwath Yoni prakshalan in Shweta Pradara.**Aim And Objectives** :-Comparison of the efficacy of Kareeradi Kwatha versus Panchvalkali Kwath (Yoni Prakshalana) in the management of Shweta Pradara (Leucorrhoea) and To compare of the efficacy of Kareeradi Kwath vs Panchvalkali Kwath as Yoni-Prakshalana in in the management of Shweta Pradara.**Methodology** :-In the planned study, 60 participants will be randomised into two groups at random, with 30 patients in each group. Group A (Panchvalkali kwath) will receive a daily dose of 500 ml administered yoni prakshalan for 7 days. Group B (kareeradi kwath) will receive a daily dose of 500 ml administered yoni prakshalan for 7 days. At day zero, eighth day , and after day sixteenth day for follow-up, an assessment record will be taken.**Results** :-Improvement in results will be recorded according to the Objectives. Changes in objective results will be seen.**Conclusion**:-It may be predicted that the study's parameters will improved in Shweta Srav , kati schoola, and yoni kandu.

Key Words:- Shweta Pradara , Yoni Vyapad ,

INTRODUCTION

According to Ayurveda

The famous trios Charaka, Susruta, and Vagbhata Samhita do not contain the word Shweta Pradara. Raktpradara and Asrgdara have been used for bleeding from the vagina, and Shwetasarav or Yonisarav have been used for white discharge.¹ The term "Shweta Pradara" for white vaginal secretions is used by commentator Chakrapani as well as the works Sarngadhara Samhita, Bhawaparakasha, and Yogaratnakara². Acharya Chakrapani has provided the following explanation: || (30/116)

Aastang sangrah³ claims.

□□□□□ □□□□□□□□□□ (As.Sa.Ut 39/51)

In accordance with As.Sa.Ut. 39/51,

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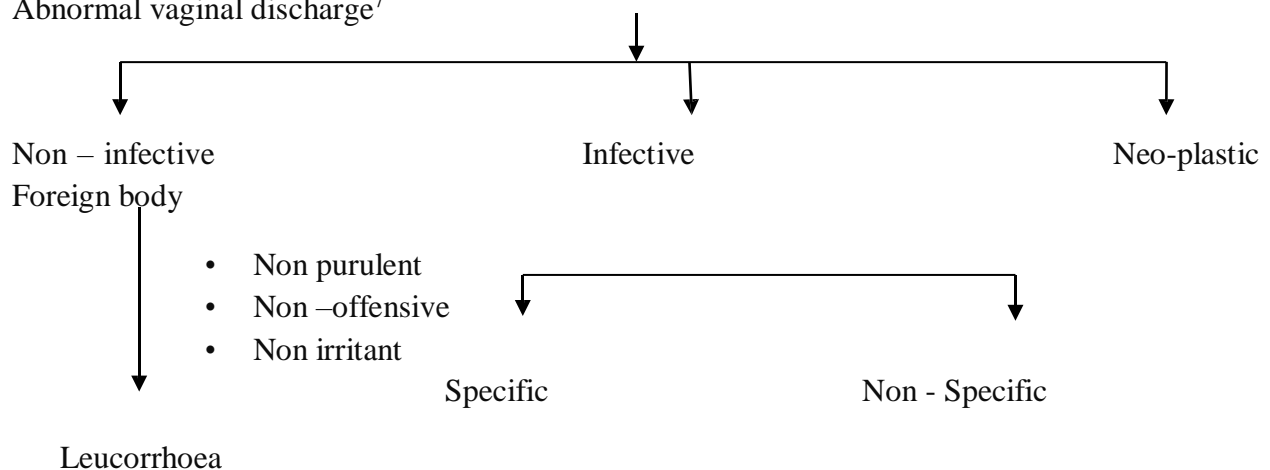
Since Shweta Pradara is a symptom rather than a disease, its etiopathogenesis would likewise be that of the main disease⁴

However, based on its clinical characteristics, it appears to be a disease of kapha viability, hence its etiopathogenesis may be thought of in the following manner:

The aggravated kapha, which is brought on by its own vitiating factors, influences or vitiates the rasa dhatu of the reproductive system, which was previously influenced by excessive coitus, abortions, a bad way of living, and poor dietetics, because of the dominance of its liquid property before Ritukala. White, painless vaginal discharge is the consequence.⁵

Leucorrhoea is currently understood to be an excessive amount of typical vaginal discharge. The excessive symptom is a subjective one with individual variance, and it requires clinical and laboratory tests to determine whether it is normal and not infectious.⁶

Abnormal vaginal discharge⁷



The physiologic basis involved in normal vaginal secretion is dependent on the endogenous estrogen level, there is abundant secretory activity of the endocervical glands and the superficial vaginal epithelium becomes rich in glycogen.⁸

The cervical glands typically secrete only a tiny amount of mucoid. The glycoprotein mucin's carbohydrate radicle is separated and fermented into lactic acid. However, if too much mucus is secreted, it spills out at the vulva.⁹

Concept of *Trividh Chikitsa*¹⁰

Antah Parimarjana - Antah is the Arabic word for inside, and parimarjana is the verb to cleanse or purify, therefore Anath Parimarjan literally translates as to cleanse, purify, or heal from

When combined in equal proportions, they create "Panchvalkal kwath," which possesses astringent and cleansing properties.

Panchvalkal Kwath advantage

The uterus can be thoroughly cleaned with panchvalkal kwath.

purifies the blood and body

Anti-bacterial

Anti-fungal

treats fallopian tube blockage

carefully treats wounds and infections.

Even though Panchvalkal powder is widely accessible in drug stores, if you don't take it frequently as directed by your doctor, you won't get any benefits from it. You won't be able to reap all of its advantages unless you have been consuming it consistently for a while.

Need of Study :

- In India, 61% of women from low socioeconomic backgrounds and 39% from high socioeconomic backgrounds reported having vaginal discharge due to leucorrhoea.
- *Shweta Pradara* (Leucorrhoea) may arise and affects the female genital health.
- The outcome of *Kareeradi Kwath* will be more effective than *Panchvalkal kwath* in combating the signs and symptoms of *Shweta Pradara*(Leucorrhoea).
- It will be cost effective than the *Panchvalkal kwath for Yoni Prakshalan*.
- It will generate new clinical evidences .

Research Question: -

Whether *Yoni – Prakshalan* of *Kareeradi Kwath* is more efficacious than *Yoni – Prakshalan* of *Panchvalkal kwath* in the management of *Shweta Pradara*?

Hypothesis:-**Alternative Hypothesis (H1)**

- There is significance difference in the effect of *Kareeradi Kwatha (Yoni-Prakshalana)* and *Panchvalkal Kwatha (Yoni-prakshalan)* in the management of *Shweta-Pradara*.

Null Hypothesis (H0)

- There is no significant difference in the effect of *Kareeradi Kwatha (Yoni-Prakshalana)* and *Panchvalkal Kwatha (Yoni-prakshalan)* in the management of *Shweta-Pradara*.

Population	• Participants suffering from <i>Shweta Pradara</i> .
Intervention	• <i>Kareeradi Kwatha in Yoni - prakshalan</i>
Comparison	• <i>Panchvalkal Kwatha in Yoni - prakshalan</i>
Outcome	• Reduction of symptoms of <i>Shweta Pradara</i> .

AIM AND OBJECTIVES**Aim: -**

Comparison of the efficacy of *Kareeradi Kwatha versus Panchvalkaldi Kwath (Yoni Prakshalana)* in the management of *Shweta Pradara (Leucorrhoea)*.

Objectives:

- To evaluate the efficacy of *Kareeradi Kwath as Yoni-Prakshalana* in the management of *Shweta Pradara*.
- To evaluate the efficacy of *Panchvalkal Kwath as Yoni-Prakshalana* in the management of *Shweta Pradara*.
- To compare of the efficacy of *Kareeradi Kwath vs Panchvalkal Kwath as Yoni-Prakshalana* in the management of *Shweta Pradara*.

Research Gap Analysis

Sr. No.	Name Of Research	Name Of Researcher	Conclusion Of Author	Time (In Year)	REMARK OF SCHOLAR
1.	<i>Madhumeha Roga Par Kareeradi Choorna Evam Panchatikta Nirooha Basti ki Karmukata Ka Chikitsatmaka Adhyayana.</i>	Jain A.K National Institute Of Ayurveda , Jaipur.	Basti is used for vata chikitsa.and is one of the type of vatajh parmeha and kariradi churna is kashaya guna yukta so it will directly used in vata chikitsa.	2001	Used in madhumeha roga as kareeradi churna but kwath is not used yet
2.	Pharmaceutical And Clinical Evaluation Of Vanga Bhasma And Ashwagandhadi Yog in the Management Of ShwetaPradar.	Ahuti Rai Rajiv Gandhi Govt. Post – Graduate Ayurvedic College, Paprola	-	2010	For Prakshalana Kareeradi Kwath not used yet
3.	A clinical study on effect of yoni prakshalan with pancha valkal kwatha in the management of kaphaja yonivapada w.s.r. to candida albicans.		2013	Triphala Kwath is used as Yoni Prakshalana but comparative In this article, the sample size is very less , so the chances of error will be more.study in not done.	
4.	Grishma Solanki, Role of Nimbadi yoni prakschalan on Shweta Pradaraa(Leucohorrea)		2019	This formulation not done for Shweta Pradaraa.	

<p>5. Sheela Mallikarjun , ,Management of <i>Sweta Pradara with sthanik chikitsa – A case study.</i></p> <p>WORLD JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH</p>	2021	<p><i>Shweta Pradaraa</i> can be put parallel to Leucorrhoea in modern medicine on the basis of different symptom</p> <p>Treatment of <i>Sweta pradara</i> is mainly based on the use of drugs which are having predominance of <i>Kashaya rasa</i> and <i>Kapha-shamak</i> property.</p>	<p>No drug is used and not compare with <i>Kareeradi kwath.</i></p>
<p>6. <i>Akanksha Sharma,Management of Sweta pradara (Leeucorrhoea) Through Ayurveda – a case series</i> International Journal of Ayurveda and Pharma Research.</p>	2022	<p>The whole treatment combination of Jeevak plus capsule, Gynae vin syrup, <i>Haritaki churna</i> for <i>Anulomana</i>, and <i>Triphala kwatha</i> for <i>Yoni prakshalan</i>, Himtone forte as <i>Rasyana</i> and <i>Balya aushadhi</i> when used in patients of <i>Shweta Pradaraa.</i></p>	<p><i>Triphala Kwath</i> is used as <i>Yoni Prakshalana</i> but comparative</p>

- Many studies have been carried out on *Shweta Pradaraa* with different internal formulations.
- Many *Kwath* are also available in market but few studies have been done for *Yoni Prakshalana* in *Shweta Pradaraa*.
- Drugs of *Panchvalkal kwath* for *Yoni – prakshalan* endangered. So, availability of *Panchvalkal* drugs in market is less.

Material and Method :-

Place of study or Source of Data: -

The clinical materials required for *Shweta Pradara* will be screened and enrolled from OPD and IPD of Dept of Stree and Prasuti MGACH&RC Salod (H.), Wardha and AVBRH.

Sample size : 60

Group A :- Control Group (30)

Group B :- Standard Group (30)

Sampling Procedure :- Randomization computer generated table

Type of Study: Interventional study

Study design : Randomized standard control single blind superiority clinical trial.

Grouping And Posology

Group	Sample size	Intervention	Dose and Frequency	Duration	Follow-up
Group A	n =30	<i>Panchvalkal kwath</i> in <i>Yoni prakshalan</i>	500ml once in a day for <i>Yoni Prakshalan</i>	16 days	0 th ,8 th ,16 th Days
Group B	n =30	<i>Kareeradi kwath</i> in <i>Yoni</i>	500ml once in a day for <i>Yoni</i>	16 days	0 th ,8 th ,16 th Days

		<i>prakshalan</i>	<i>prakshalan</i>		
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Study Duration :- 2 years

Drug Collection And Authentication :-

Raw materials would be obtained from trustworthy sources , identified and authenticated by the department of Dravyaguna , Mahatma Gandhi Ayurved College , Hospital & Research Centre , Salod(Hirapur) , Wardha .

Case definition: Patient with classical symptoms of *Shweta Pradara* on the basis of examination will be selected for the study.

Data collection tools and process

Eligibility Criteria

7.1 Inclusion criteria:

- Female patients (Age 18 year -55 year) in reproductive period of life will be included in this study irrespective of marital status.
- Married/unmarried female's patients will be taken for this study.
- Female patients having signs and symptoms of *Shweta Pradara* will be included.

7.2Exclusion criteria:

- Female patients having signs and symptoms of abnormal Vaginal Bleeding such as Menorrhagia, metrorrhagia .
- Female patients having pregnancy will be excluded from this study.
- Female patients having Hormonal disbalance, diabetes, HTN. Those patients who are having carcinoma or other severe systemic illness.

Detail of drug preparation

Sr.no.	Name of <i>Dravya</i>	Botanical name	Family	Part used

1	<i>Kareer</i>	<i>Capparis decidua</i>	<i>Capparidaceae</i>	<i>Mool twak</i>
2	<i>Dhav</i>	<i>Anogeissus latifolia</i>	<i>Combretaceae</i>	<i>Twak</i>
3	<i>Nimbha</i>	<i>Azadirachta indica</i>	<i>Meliaceae</i>	<i>Twak</i>
4	<i>Aark</i>	<i>Calotropis procera</i>	<i>Asclepiadaceae</i>	<i>Pushp</i>
5	<i>Venu</i>	<i>Bambusa arundinacea</i>	<i>Graminae</i>	<i>Patra</i>
6.	<i>Koshaamra</i>	<i>Schleichera oleosa</i>	<i>Sapindaceae</i>	<i>Twak</i>
7.	<i>Jambu</i>	<i>Syzygium cumini</i>	<i>Myrataceae</i>	<i>Twak</i>
8.	<i>Jingini</i>	<i>Lannea coromandelica</i>	<i>Anacardiaceae</i>	<i>Mool</i>
9.	<i>Aarush</i>	<i>Adhatoda vasica Nees</i>	<i>Acanthaceae</i>	<i>Mool</i>
10.	<i>Draksha(sura)</i>	<i>Vitis vinifera</i>	<i>Vitaceae</i>	<i>Phal</i>

Assesment Criteria

Subjective Criteria

- *Shweta Srava*(vaginal discharge)
- *Katishoola*
- *Yoni kandu*

Sr. No.	YONIGHAT SARAV (DISCHARGE)	GRADE
1.	No discharge	0

2.	Mild discharge (rarely) wetting under clothing, a mild discharge, and moistness in the vulva	1
3.	Moderate discharge (wetting of under garments)	2
4.	Heavy discharge (Heavy discharge which needs vulva pads)	3

Sr. No.	<i>KATISULA (BACKACHE)</i>	GRADE
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1.	No backache	0
2.	Mild (can withstand pain & can manage routine work)	1
3.	Moderate (cannot manage routine work & need to take rest)	2
4.	Dependent on painkiller (cannot withstand pain & bed ridden)	3

Sr. No.	<i>YONI KANDU (ITCHING)</i>	GRADE
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1.	<i>No Kandu</i>	0
2.	Mild itching (Slight rub)	1
3.	Moderate itching (Instant rub causes redness)	2

4

Heavy itching (continuous rub causing redness)

3

Objective Criteria: - Vaginal pH, Pap smear

Drug Analysis :- Raw materials would be obtained from trustworthy sources , identified and authenticated by the department of Dravyaguna , Mahatma Gandhi Ayurved College , Hospital & Research Centre , Salod(Hirapur) , Wardha .

Statistical Method:- According to objective criteria,both paired and unpaired, fssor subjective criteria , non parametric.

Observation And Results :- The result will be created using various charts , graphs and tables based on data from the follow up charts and observations.To determine the relevance of findings do the following . Improvement in range of katishoola , srav and yoni kandu.

Discussion :-Shweta pradara (Leucorrhoea) in accordance with ayurveda, is caused by kapha dosa vitiation. However, according to modern science, pathological leucorrhoea is caused by Doderlein lactobacilli while physiological leucorrhoea is caused by an increase in estrogen hormone under various conditions. It is a gram-positive lactobacillus that originates from the colon and enters the vagina after adolescence and then leaves after menopause. It turns glycogen into lactic acid to maintain an acidic vaginal PH. This stops the development of infectious organisms in the vagina. This is the vagina's built-in defence system. If the vagina's local hygiene is impaired for whatever reason, So local hygiene will be maintained or will be treated properly by using Kareeradi kwath and the Kapha vitiation will be improved by using kareeradi kwath locally. Other contents in Kareeradi kwath is also having sothahar (anti-inflammatory), jantughan(antibacterial) ,kandughana (helpul in itching), varana sodhana. The vaginal tract is kept clean and healthy by douching with lukewarm decoction. Kareer , dhav , nimbha, jambhu,,vasa, Ark,Venu, koshaamra, jigini ,arush, Draksha all 10 drugs contains the kashaya rasa as predominance . The kashaya rasa is nothing but the astringent and having property of Sthambhan . The astringents are the tropically anti-inflammatory , can be used for all the inflammations of the skin and mucous tropically.

Scope of Implications of the proposed study

- This study will generate data for the effect of *Kareeradi kwath* in *Shweta Pradaraa*.

- ❑ It is recommended that the study will be carried out in large number of patients to confirm findings on wider scale.
- ❑ As *Kareeradi kwath* is mentioned for all *yonisaras*, its efficacy can be tested in other *yonivyapad*
- ❑ Increases the wide range of availability of the drugs.
- ❑ Future patent can be filed for *Kareeradi Kwath* if found more effective than *Panchvalkal Kwath*.

Implications of the proposed study

- *Kareeradi kwath* will be cost effective for the social well being.
- Availability of drugs of *kareeradi kwath* is more in market.
- According to ayurvedic property of *kareeradi kwath dravyas* will be used in some skin diseases .
- If the the *kareeradi kawath* will be effective in *Shweta Pradara* it will be maintain the hygiene of the female genital tract and it also prevent the complicated disease.

Conclusion: -Conclusion will be followed by the thoughtful and analytical facts.

Ethical consideration:-

The study will be initiated only after the ethical approval from IEC (MGACH & RC) followed by the prospective registration in CTIRI (Clinical trial registry India).

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