EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 6
Issue: 6
326-330
Year: 2019

EFFECT OF LODRA SUPPOSITORIS IN MANAGEMENT OF KAPHAJA YONI VYAPATH W.S.R MIXED VAGINITIS

***[1]Dr. Usha D. T. and [2]Dr. Satish Pai**

[1]Assistant Professor Dept. Obstetric and Gynecology, JSS Ayurveda Medical College and Hospital Mysuru.
[2]Associate Professor Dept. Pharmocology, JSS Ayurveda Medical College and Hospital, Mysuru.

***Corresponding Author: Dr. Usha D. T.**
Assistant Professor Dept. Obstetric and Gynecology, JSS Ayurveda Medical College and Hospital Mysuru.

Article Received on 16/04/2019 **Article Revised on 06/05/2019** **Article Accepted on 27/05/2019**

ABSTRACT

Introduction: Vagintis is defined as inflammation of vagina and it is the probably most common reason where a woman seeks help of gynaecologist. The common causative factors are candida albicans, Bacteria and thricomoniliasis. Potential treatment has been explained in ayurveda but it needs an standardization of drug and mode of application to have a better result in present scenario. In the present study a sincere effort has been made to prepare a vaginal suppositories to treat vaginitis. **Purpose**: The purpose of this study was to evaluate the effect of lodra suppositories in treating vaginitis. **Methods:** Study design: A prospective clinical study was performed to study the effectiveness of lodra suppositories in vaginal inflammation. 100 patients were identified with vaginitis mainly of Candid albicans, Thricomonaliasis and bacterial vaginosisthrough clinical examination and vaginal smear. These patients were instructed to administer vaginal suppositories contains lodra for consecutive 7 days. **Discussion and Results:** A significant reduction in signs and symptoms noted both subjectively and objectively The drug lodra which used in the form suppository gives promising local action without any side effect noted. Invitro study of lodra churna also proved with antifungal and antimicrobial effect. **Conclusion:** the drug lodra can be effectively used in treating vaginal inflammation and vaginal route is fast, easy,cost effective, and safe method of administration.

KEYWORDS: vaginitis, Lodra, Suppository.

INTRODUCTION

Vaginitis is a common gynecological problem in women that is associated with substantial discomfort and frequent medical visits. Research in recent years has increased our understanding of the disease process and its potential sequel[1] and resulted in improved diagnostic and treatment modalities.[2-6] The initial evaluation of vaginal discharge requires an understanding of physiologic vaginal discharge and what differentiates it from abnormal, pathologic discharge. Substances from the vulvar, sebaceous, sweat, Bartholin's and Skene's glands, as well as exfoliated cells, cervical mucus, and secretions of the endometrial cavity and fallopian tubes constitute the normal physiologic secretions of the vagina. These secretions pool in the posterior fornix and do not adhere to the vaginal walls.[7] The pH of normal vaginal secretions in women of childbearing age is between 3.8 and 4.5. The presence of sperm, blood, amniotic fluid, or cervical mucus raises the vaginal pH.[7] The amount and fluidity of the discharge can vary over the menstrual cycle. Cervical mucus becomes more fluid around ovulation, and women frequently mistake this change in consistency for an abnormal discharge. Stress increases the rate of vaginal desquamation and thus the amount of discharge, which patients can also mistake for a pathologic discharge.[8]

In contrast, a pathologic discharge adheres to the vaginal walls and is often accompanied by irritation, pruritus, odor, or urinary symptoms such as dysuria or frequency[6] The discharge can be thick to watery and frothy, and white to yellow, gray, or green.[7] Main Causes of an abnormal discharge include infectious causes of vaginitis such as yeast infection, bacterial vaginosis, and trichomonas infection. The description of vaginitis in ayurveda is explained in yoni vyapath(genital pathology) as Kaphaja yoni vyapath. The kaphaja yoni vyapath is characterized with abnormal vaginal discharge varies from watery to thick in consistency, high incidence of purities, and vaginal irritation.[8]

Adequate treatment of vaginitis in the OPD setting often is problematic for practitioners. Even drug resistance is a major concern in developing new medication. Potential treatment has been explained in ayurveda but it needs an standardization of drug and mode of application to have

a better result in present scenario. Ayurveda classics give wide range of drugs to combact lower genital tract infections among them the drug Lodra (Symplocus racemosa) selected for present study. A sincere effort has been made to prepare a vaginal suppositories to treat vaginitis.

MATERIALS AND METHOD

Research methodology

- Single center interventional study
- Quantitative research –Questionnaires
- Sampling- Convenience
- Sample size-100

4. Preparation of suppositories

- The lodra suppositories were prepared by fusion method 9 by melting cocoa butter or the obromo oil in different ratios and then drug was dispersed. Cocoa butter suppositories were prepared by melting cocoa butter on water bath, and then the drug was incorporated.
- Firstly, nickle coated brass molds of 1g capacity was calibrated. The displacement value of lodra powder was found to be 2.42. Based on the displacement value the final quantities of lodra powder and suppository base was calculated.
- Secondly, the moulds were thoroughly cleaned, mildly lubricated with coconut oil and kept inverted on a filter paper for 10 minutes to drain off excess oil.
- Thirdly, the exact quantities of lodra powder and cocoa butter were kept ready by weighing on a digital balance. Cocoa butter was then transferred into the china dish with brief exposure to mild heating or held over a steam with continuous agitation till a clear molten mass forms.
- Finally lodra was incorporated by maintaining the temperature at 30°C into cocoa butter melt and mixed thoroughly. The molten mass was bought to the pourable consistency by mildly heating the china dish and poured in excess into previously calibrated molds of 1g and allowed to set in a freezer or on the ice tray. After15 minutes, the solidified mass above the mould was trimmed off using a sharp blade dipped in hot water.
- The moulds were unscrewed, separated and carefully removed the fully formed suppositories from the holes of the mould by pushing gently from the bottom. All the suppositories were free from pits, fissures and cracks. The longitudinal section of the suppositories was turbid and denser. The resultant suppositories were stored in a double wrapped butter paper in an air tight container.
- Note: Temperature maintenance at exactly 30°C is highly crucial in order to prevent polymorphism of cocoa butter.

5.Methodolgy: The present study was conducted in the department of prasuti tanta and stree roga of the JSS AyurvedaMedical institute and included assessment of 100 participants with chief problem of White discharge per vagina2016 to 2018. Ethical approval was obtained from the institutional ethical committee and written consent was obtained after explaining in detail the entire research protocol. Complete physical examination of the patients was done before starting the treatment therapy of the patients.

6.Inclusion criteria

- AGE-20-40years
- Married
- Symptom- white discharge p/v and Itching p/v

7. Exclusion criteria

- Unmarried
- Known case PID
- Known case of systemic disease
- PID
- Malignant conditions

8.Diagnostic criteria:

- Subjects with white discharge P/V associated with p/v itching
- Nature, amount of discharge
- Vaginal wet mouth test for candid albican,thricomoniliasis and bacteria

9.Preparation of wet smear: Women were asked to take the lithotomy position. A sterile speculum was inserted into their vagina, and then two sterile cotton swabs were rolled in the posterior fornix for 10 s to collect discharge. Swabs were immediately put into a sterile tube containing 3 mL of normal saline solution and transferred to the microbiology laboratory to be examined by an expert, who was blind to the patients' data. The secretion on the first swab was mixed with a drop of normal saline on a glass slide and a cover slip was placed on the glass slide. The saline wet mount was investigated by direct microscopy to determine any sign of yeast.

TREATMENT PLAN-Patients were asked to place one Lodra vaginal suppository approximately 4–5 cm into their vagina for seven consecutive nights. Patients were instructed not to take any medicines during menstruation and return for re-examination 7–10 d after the start of treatment. Patients were contacted by phone every 2 d to check for any side effects and compliance. At the final visit, subjects were re-examined.

5. Outcome measures:

Subjectively- Subjects were asked to score the intensity of burning and itching on a 5-point Likert scale (not at all (0), slightly (1), moderately (2), quite a bit (3), extremely (4)) in the first and following visits. The other symptoms like vaginal discharge, purities are graded(not at all(0)mild(1), moderate(2), severe(3)).

Objectively- Vaginal smear repeated after 7 days to determine any sign of yeast.

Also, patients were asked to rate their satisfaction with the therapy on a 'yes or no' basis.

OBSERVATIONS

Table-1, Age distribution.

Age group	Frequency	Percent
21-25	16	16
26-30	38	38
31-35	30	30
36 and above	16	16
Total	100	100.0

Table 2: Socioeconomic status.

SE	Frequency	Percent
L	3	3
LM	15	15
M	67	67
UM	15	15
Total	100	100.0

Table 3: Occupation.

Occupation	Frequency	Percent
engineer	6	6
Housewife	63	63
lecturer	7	7
office work	10	10
Teacher	15	15
Total		100.0

Table 4: Education.

Education	Frequency	Percent
High school	38	38
Degree	34	34
Academic degree	28	28

2.CLINICAL COMPLAINTS

Table 1 Per Vaginal discharge.

WD	Frequency	Percent
Present	100	100.0%

Table 2: itching per vagina.

Complaints	Frequency	Percent
Absent	24	24%
Present	76	76%
Total	100	100.0%

Table 3: Abnormal odour.

Complaints	Frequency	Percent
Absent	57	57%
Present	43	43%
Total	100	100.0%

Table 4: Organism Detected.

	Frequency	Percent
Candida	57	57%
Trichomonas	21	21%
Bacterial	23	23%
Total	100	100.0%

12. Detailed analysis of results.

1. Lodra as suppository: the action of drug lodra as suppository is evaluated with following points.

A) Local tolerability: local tolerability of lodra suppository was been evaluated through cumulative sum of local or vaginal symptoms rated by patients for each patients after every application.

SCALE EVALUATION EVENTS

- burning - 2 points,
- dryness - 1 point,
- painful symptom- 3 points,
- itching - 1 point,
- bleeding - 5 points,

Two subjects were complained vaginal burning after insertion of suppository and relived by itself after an hour. This shows local tolerability of lodra suppository can be consider as good.

B)safety: As no adverse effect was been reported by patients hence the usage of drug lodra in vagina can be consider as safe.

2. Efficacy of lodra suppositories

In this trail around 300 subjects were screened, 100 patients were underwent the treatment. All the participants completed the study. Three patients complained of severe burning and itching after using the lodra vaginal suppositories, which did not lead to her withdrawal from the trial. The prevalence of Leucorrhoea was 100% in the study, the prevalence of itching was 76% in the study and the Prevalence of organism detected in the was candida albicans 56%, Thrichomoniliasis 21%, Bacterial vaginosis 23%. After treatment a significant result observed as improved in 61% of vaginal discharge with statistical significance of p-0.001,purities P value0.001.In the present study the action of drug lodra on organism was establish as over candida albicans 64% of improvement, over thricomoniliasis 50% of improvement and over bacterial vaginosis 41% improvement.

Statistical analysis of each criteria for assessment was done and presented below.

1. PURITIS

PURITIS	Condition		Total	Chi	P
	Before Treatment	After treatment			
Absent	24 (24.2)	75 (75.8)	99 (49.0)	76.36 df = 3	0.001
Mild	17 (43.6)	22 (56.4)	39 (19.3)		
Moderate	40 (90.9)	4 (9.1)	44 (21.8)		
Severe	20	0	20		
Total	101	101	202		

2. Quantity of discharge

Quantity of discharge	Group		Total	Chi	P
	Before Treatment	After treatment			
Absent	0	61	61 (30.2)	117.13 df= 3	0.001
Mild	30 (46.9)	34 (53.1)	64 (31.7)		
Moderate	44 (88.0)	6 (12.0)	50 (24.8)		
Severe	27	0	27 (13.4)		
Total	101	101			

3. Type of discharge

TYPE OF DISCHARGE	Group		Total	Chi	P
	Before Treatment	After treatment			
Negligible	13 (21.0)	49 (79.0)	62 (30.7)	47.45 df= 4	0.001
Curdy	34 (46.6)	39 (53.4)	73 (36.1)		
Purulent	27 (75.0)	9 (25.0)	36 (17.8)		
Mucopurulent	25 (86.2)	4 (13.8)	29 (14.4)		
Watery	2	0	2 (1.0)		
Total	101	101	202		

4. Abnormal odour

ABNORMAL ODOUR	Group		Total	Chi	P
	Before Treatment	After treatment			
Absent	57 (37.3)	96 (62.7)	153 (75.7)	40.92 df=1	0.001
Present	44 (89.8)	5 (10.2)	49 (24.3)		
Total	101	101	202		

5. OVERALL ASSEMENT

Improvement	Frequency	Percent
No improvement	9	8.9
Mild improvement	20	19.8
Moderate improvement	22	21.8
Marked improvement	50	49.5
Total	101	100.0

DISCUSSION

Vaginitis is a common gynecological problem in women that is associated with substantial discomfort and frequent medical visit. Research in recent years has increased our understanding of disease process and its potential sequel nevertheless adequate treatment of vaginitis in the outpatient setting often is problematic for practitioners. As though much promising treatments like yoni praksalana , pichhu of various drugs in different conditions of vaginal inflammation is available still treating needs inpatients facility. Hence there is need of standardization of available treatments.

Here the drug lodra(symplocus racemosa) was selected for study, since the thousand of years Lodra has been used safely to treat gynecological disorders. Due to the property of rodaka(arresting) it also named as rodra , and widly using for abnormal vaginal discharge.the drug lodra as kasaya rasa ,laghu ruksa guna hence probably it acted on atisrava in kaphaja yoni.lodra suppositories can be used in vaginal epithelium easily due to its sheeta virya .in the present study lodra suppositories effectively acted on kaphaja yoni vyapath.

The phytochemical screening showed that of symplocus racemosa contains higher amount of carbohydrate, glycoside, saponin, terpenoid glycoside, phytoestrol and stroid. the result of preliminary antibacterial evolution showed that ethanolic extract of symplocus roxb posses good antibacterial activity. Hence the approach of vaginitis with lodra had given a promising result.

Mode of action of drug also depends on route of administration in the present study lodra suppositories were administered to vagina ,a target organ of study. It is one of potential route of drug delivery and dense network of blood vessel.candida albicans, Thrichomoniliasia, bacterial vaginitis were been selected in present study based on study the higher efficacy was proven in bacterial vaginosis and canadia vaginitis where as mild efficacy in Thrichomoniliasis.

CONCLUSIONS

In this single arm clinical trail lodra had significant reducing effect on vaginal discharge. And effective in making the wet smear results negative. lodra was effective in the treatment of candidiasis and bacterial vaginosis symptoms and could be used as an alternative or adjuvant for other antifungal drugs in the treatment of vaginitis.

ACKNOWLEDGEMENT

I Thank Ragiv gandhi university of health sciences, Banglore, Karnataka, for funding the clinical research study and also thank for theie support and guidance.

REFERENCES

1. Vaginitis. American College of Obstetricians and Gynecologists FAQS. http://www.acog.org/Patients/FAQs/Vaginitis. Accessed Aug. 11, 2017.
2. Edmonds D, Dewhurst J. Dewhurst's Textbook of Obstetrics & Gynaecology. 7th ed. Oxford: Wiley-Blackwell, 2012; 364.
3. Hill lvh Embil JA. Vaginitis: current microbiological and clinical concepts. Can Med assoc J.1986:134:321-31
4. Friendrich EG .vaginitis. Am J obstet Gyececol, 1985; 152: 247-51.
5. Shastry, J.L.N. Dravya Guna Vignana. (3rdedn.). Varanasi: Chowkamba, 2003.
6. Devmurari, V.P. Antibacterial Evaluation and Phytochemical Screening of Symplocos racemosa Roxb. International Journal of Pharm Tech Research, 2010; 2(2): 1359-1363.