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Case Series

An open-label pilot study to evaluate the efficacy and safety of BC caps for women with abnormal vaginal discharge due to microbial infections: case series

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ABSTRACT

Herbal therapeutics advancement demand in management of abdominal vaginal discharge is increasing in women as it serves as an important housekeeping function in the reproductive system. This case series study evaluates the safety and effectiveness of birth control contraceptives capsules (BC caps) in women suffering from abnormal vaginal discharge. We conducted an open label interventional study of 15 female patients with in the age of 18-45 years (mean 33.7 years) with a history of abnormal vaginal discharge. Patients were asked to administer two BC caps (neem seed oil) capsule of 500 mg manually to vagina daily at night for 15 days followed by treatment assessment as per each schedule visit. Primary outcome includes change in microbiological parameters. Secondary outcomes included monitoring of adverse event (AE) and serious adverse event (SAE), changes in clinician's assessment of symptoms and change in Subject's global assessment of symptoms. The study showed the 93.33% and 87.5% improvement in abnormal vaginal discharge and cervical abnormalities. Microbiological cure rate found was 100% for pathogens. A constant decline was seen in the mean values of all the associated symptoms. Significant results in whiff and pH test were observed after treatment. The vaginal discharge was observed to be clear in 100% of the participants. Subject's assessment of symptoms which were low back pain, vulval itching, general weakness, foul discharge, and burning sensation were improved. All results were significant at p value <0.05. The study found that BC caps is highly effective and safe in a treatment for abnormal vaginal discharge. It also showed improvements on associated symptoms with minimal to zero side effects.

Keywords: Open label, Vaginal discharge, Treatment

INTRODUCTION

Vagina secretes healthy vaginal fluid in the normal functioning of the body. Physiological vaginal discharge varies with the menstrual cycle. There are no related symptoms such as vulva itching, swelling, redness, bad odour with normal vaginal discharge.[1] Some factors like vaginal infection, aging, change in vaginal pH cause abnormal discharge.[2] It is characterized by colour change, variation in consistency, volume and fishy odour. Vaginal mucosa causes inflammation and leads to symptomatic vaginal discharge and vaginitis condition. Various factors like age, monthly cycle, contraception usage has an impact on vaginal and cervical discharge.[3] Vaginal discharge prevalence in India is approximately 30% in the reproductive age group. It is reported that almost 90% vaginal discharge occurs due to infection of sexually transmitted diseases (STD).[4,5] If vaginitis condition is left untreated it may lead to infertility, urethral syndrome, and endometriosis.[6] Monitoring of vaginal discharge throughout the menstrual cycle is the important follow up question.[7] Evaluation of vaginal discharge pathologically

helps in early detection of serious complication in women.[8] The main cause for vaginal discharge is microbial infection. 70% cases are connected to bacterial vaginosis (BV), vulvovaginal candidiasis (VVC) or trichomoniasis (TV).[9] Approximately 50% infection are through bacterial vaginosis.[2,10] Amsel criteria is recommended for the diagnosis of BV infection (vaginal discharge measurment, vaginal pH test, fishy odour whiff test, and microscopy pathogen test as gold standard.[11] Vaginal pH value plays an important role in normal functioning of vagina.[7] Vaginal swabs obtained from the lateral walls and applied on pH strips.[12] Many chemical based soaps used for vagina causes vaginal pH imbalance and other infections. Plant medicine intake is increasing as compared to synthetic drugs for bacterial infection treatment.[13] Various side effects such as itching, chills, and rashes occurs due to the excessive use of antifungal and antibacterial antibiotics like metronidazole, fluconazole. Further, Antibiotics harms the natural flora of the vagina which leads to repeated infections and increases the duration of the treatment.[14] Metronidazole is the most common drug used against *Trichomoniasis* infection.[15] Herbal medicine balances the normal functioning of the body. Side effects and adverse effect are low in herbal medicine.[16] Herbal products like oil, leaves, seed, bark are the good source of antioxidant and has the healing properties, apoptotic activities through p53 induction and chemopreventive property.[17,18] *Azadirachta indica* (neem) is a Meliaceae family member and has various therapeutic importance in preventing, control and treating the diseases. Neem extracts shows the antimicrobial and antifungal properties against various strains of pathogens and fungi.[19,20] Various studies showed the nutraceuticals significance as a medicinal compound for curing various life threatening diseases like cancer. Neem compositions show an effective role in treating diseases.

CASE SERIES

This is an open label study conducted on 15 patients at Rajalakshmi Hospital, Bangalore from 23 April 2021 to 14 May 2021. The subjects were included based on the following criteria during screening the study: women with reproductive age group of 18-45 years; diagnosed with the presence of signs and symptoms such as irritation, soreness, dysuria, vulvo vaginal inflammation (edema, erythema), and abdominal pain; and confirmed laboratory diagnosis of abnormal vaginal discharge. The exclusion criteria depend on: allergy to neem products; pregnant or lactating females; patients who had taken antifungal medicines intravenously or orally within 4 weeks or taken topical antifungal vaginal drugs before enrolment of 1 week; patients suffering from serious or uncontrolled medical conditions such as cardiac, hypertension, cancer, and kidney failure; and patients who have participated in any other clinical trial study in previous 3 months. Each participant signed the voluntary written informed consent before the recruitment. Based on inclusion and exclusion criteria, 15 subjects were recruited for the test product of birth control contraceptives capsules (BC caps) (neem seed oil) capsules (developed by Nutra grace, Hyderabad) of 500 mg as per each schedule visit. Each woman was asked to insert two capsules in the vagina at night for seven days. Treatment evaluation was based on ease of symptoms reported by women, speculum examination and by microbiological investigations. No concomitant treatments were given along with the study product.

Patient disposition, demographics, and baseline characteristics

Total 15 subjects were enrolled in the study and received treatments. All the study subjects were females, having the mean age of 33.7 years. Among them 93.33 % of subjects were living with family and 88.6% were married. The mean height and weight of the subjects was 162.27 m and 71.78 kg, respectively. None of the study participant was a smoker. 26.6% of women were carrying degree qualification, where 60% of females were having income between 50,000-1,00,000 as shown in Table 1.

Table 1: Baseline demographics details of all the study subjects.

S. no	Clinical characteristics	Variable (%) (n=15)
1	Age	33.7
2	Height	162.27
3	Weight	71.78
4	Married	13 (86.66)
5	Not married	2 (13.33)
6	Smoker	0
7	Non-smoker	15 (100)
8	Ethnicity (Indian)	15 (100)
9	Income status	
	0-10000	0
	10,000-20,000	0
	20,000-30,000	0
	30,000- 40,000	2 (13.3)
	40,000-50,000	4 (26.6)
	50,000- 1,00,000	9 (60)
	Above 1,00,000	0
10	Highest level of education	
	Intermediate	5 (33.33)
	High school	5 (33.33)
	Degree	4 (26.6)
	Professional degree	1 (6.6)
11	Living with family	14 (93.3)

Vital signs of the subjects at the screening

The mean values of the vital signs at the time of screening were recorded. In the screening of participants, the mean body temperature observed was 98.3±0.08 ^{0}C, the mean systolic blood pressure was 118.80±7.43 mmHg and mean diastolic blood pressure recorded was 80.53±4.86 mmHg, the mean respiratory rate and mean pulse rate at screening

visit was 17.47±0.83 and 78.4±6.33 beats per minute (bpm) respectively.

Collection of samples

Swabs from vagina were collected for wet mount test, whiff test (fishy odour) and vaginal pH measurement. Vagina lateral wall swab was taken for evaluating vaginal pH with the narrow range of pH strips (4-7). Normal pH is considered as 4.5 or less and abnormal pH value is more than 4.5.[21] Vaginal wet mount is a pathogen test to diagnose the cause of vaginitis. Smear of vaginal discharge is placed onto the glass slides and few drops of salt solution (isotonic NaCl) were added. The slide is seen under the microscope for bacterial, yeast, trichomoniasis (trichomonads), and white blood cells growth for infection in vagina.[22] Wet mount test is advantageous in terms of early prevention, diagnostic and treatment action required. Whiff test is a fishy odour test which is conducted on vaginal smear. Few drops of potassium hydroxide were added with smear of vaginal discharge. Positive test consist of a fishy odour and considered as abnormal.[23]

Primary outcome

Speculum examination

Speculum examination of vaginal discharge and cervical abnormalities were done before and after treatment with BC caps for 7 days and 14 days as shown in Table 2.[25] Abnormal vaginal discharge considered as a white, thin watery discharge with characteristics of mucoid, odourless and no itching. All the study participants had abnormal vaginal discharge before receiving the treatment. It is recorded that 80% and 93.3% of subjects had normal vaginal discharge after the treatment with BC caps for 7 days and 14 days respectively. Similarly, total 53.3% subjects had cervical abnormalities at the baseline. After the treatment with BC caps, 86.6% and 93.33% of subjects had normal cervical examination in 7 days and 14 days respectively.

Global assessment of symptoms

A constant significant decline was observed in the mean values of all the symptoms that are low back pain, vulval itching, general weakness, foul discharge, and burning sensation during the treatment from day 1 to day 14 as shown in the Figure 1.

Secondary outcome

Laboratory tests values

All the participants had abnormal vaginal discharge problem: 11 subjects for 6 months duration, 3 subjects for 6 to 12 months duration and 1 subject for more than period of 12 months. Vaginal inflammation with discharge can be caused by bacterial vaginosis, *Candida* species, or *Trichomonas vaginalis*, *Bacterial vaginosis* (n=3); *C. albicans* (n=3); *T. vaginalis* (n=2); *bacterial vaginosis* and *C. albicans* (n=4); *bacterial vaginosis and T. vaginalis* (n=2); *C. albicans and T. vaginalis* (n=1).[26] The 100% overall cure rate was observed for single pathogens. The overall cure rate for multiple pathogens *Candida albicans* and *T. vaginalis*, *bacterial vaginosis* and *C. albicans*, and *bacterial vaginosis* and *T. vaginalis* were 66.67, 75.00, and 100%, respectively. It has been observed that cure rate for single pathogen was higher than for multiple pathogens. There was improvement in percentage of subjects having pathogens in the vaginal discharge and it was observed that BC caps is 100% effective against the pathogens (*bacterial vaginosis* (100%), *Candida albicans* (100%), *Trichomonas vaginalis* (100%), *bacterial vaginosis* and *Candida albicans* (100%) and *bacterial vaginosis* (100%) but only the *Candida albicans* and *Trichomonos vaginalis* was 66.6% cured after the course of treatment.

Whiff test

A whiff test was done for odour analysis of the specimen sample as shown in Figure 3. Significant difference (p=0.0001) was noted in the whiff test before (100% women with fishy odour positive) and after (100.0% women with no fishy odour) treatment with BC caps.

Vagina pH test

A significant change (p=0.000051) was observed in the vaginal pH measurement before (20% of women having normal pH of below or equal to 4.5) and after (93.33% women with normal pH of below or equal to 4.5) the treatment with BC caps.

Associated symptoms

All the associated symptoms (lower abdominal pain, abnormal vaginal bleeding, dysuria, vaginal soreness, vaginal dryness and vulval edema) with their severity (none, mild, moderate, severe) were assessed from baseline to day 14 as shown in Table 3.[27] The significant decline was observed in the severity of all the symptoms after the treatment with BC caps for 14 days. Abnormal vaginal bleeding and vulval edema symptoms were completely cured in all the patients at day 14. Dysuria, vaginal soreness and vaginal dryness were cured in 93.3% patients and lower abdominal pain symptom was cured in 80% of patients at day 14.

Other assessment parameters

Table 4 indicates the baseline and follow-up data of the assessment parameters related with abnormal vaginal discharge. After the treatment with BC caps, the vaginal discharge was observed to be clear in 100% of the participants, the consistency of vaginal discharge was thin in 66.6% of the subjects whereas 80% of the participants had non-offensive odour after the treatment with BC caps.

Table 2: Patient's response to treatment assessed on day 0, day 7 and day 14 in speculum examination.

Treatment group	Symptomatic response (%) (n=15)			
	Vaginal discharge		Cervical abnormalities	
	Abnormal	Normal	Abnormal	Normal
Untreated (day 0)	15 (100)	0 (0)	8 (53.3)	7 (46.6)
Treatment (day 7)	3 (20)	12 (80)	2 (13.3)	13 (86.6)
Treatment (day 14)	1 (6.6)	14 (93.3)	1 (6.6)	14 (93.3)

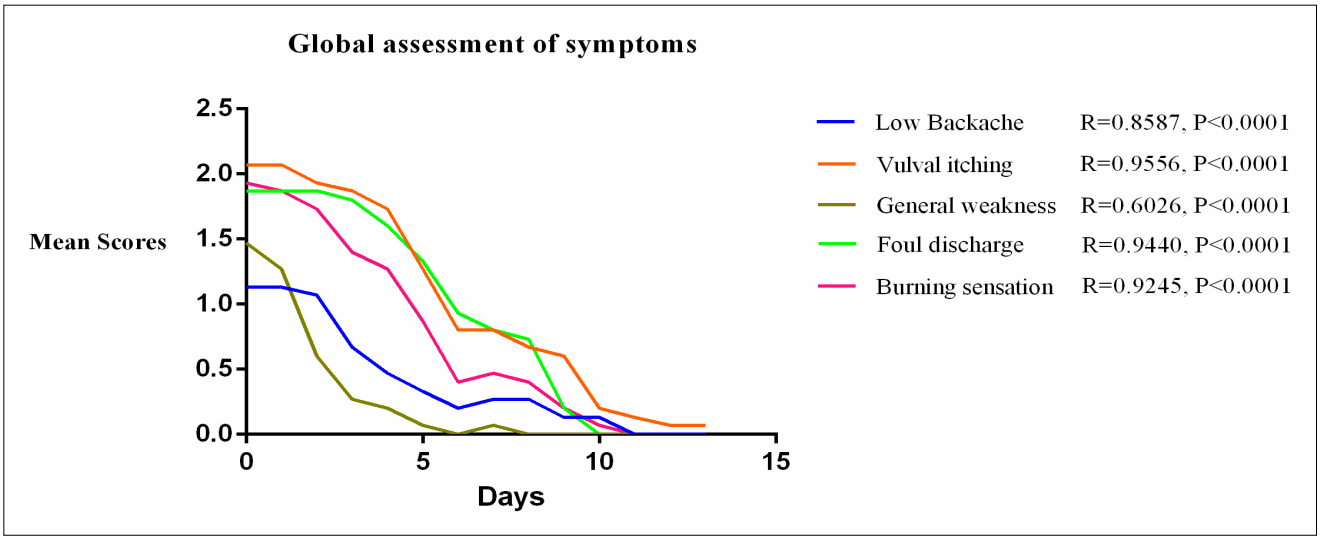

Figure 1: Global assessment of symptoms during the treatment (n=15).

Table 3: Number of subjects having associated symptoms at baseline, day 7 and day 1; n=15.

Associated symptoms	Category	Baseline (%)	Day 7 (%)	Day 14 (%)
Lower abdominal pain	None	2 (13.333)	9 (60)	12 (80)
	Mild	11 (73.333)	6 (40)	3 (20)
	Moderate	2 (13.333)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)
Abnormal vaginal bleeding	None	10 (66.6)	12 (80)	15 (100)
	Mild	5 (33.3)	3 (20)	0 (0)
	Moderate	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)
Dysuria	None	0 (0)	7 (46.6)	14 (93.3)
	Mild	13 (86.6)	8 (53.3)	1 (6.6)
	Moderate	2 (13.3)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)
Vaginal soreness	None	0 (0)	10 (66.6)	14 (93.3)
	Mild	7 (46.6)	5 (33.3)	1 (6.6)
	Moderate	8 (53.3)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)
Vaginal dryness	None	0 (0)	10 (66.6)	14 (93.3)
	Mild	2 (13.3)	5 (33.3)	1 (6.6)
	Moderate	13 (86.6)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)
Vulval edema	None	4 (26.6)	14 (93.3)	15 (100)
	Mild	11 (73.3)	1 (6.6)	0 (0)
	Moderate	0 (0)	0 (0)	0 (0)
	Severe	0 (0)	0 (0)	0 (0)

Table 4: Other assessment parameters (n=15).

S. no	Assessment	Parameter	Baseline (%)	Day 7 (%)	Day 14 (%)
1	Color of the vaginal discharge	Clear	0 (0)	3 (20)	15 (100)
		White	14 (93.3)	11 (73.3)	0 (0)
		Yellow	1 (6.66)	1 (6.66)	0 (0)
		Brown	0 (0)	0 (0)	0 (0)
		Green	0 (0)	0 (0)	0 (0)
2	Consistency of the vaginal discharge	Thick white	4 (26.6)	4 (26.66)	5 (33.3)
		Thin	0 (0)	11 (73.3)	10 (66.6)
		Mucoid	10 (66.6)	0 (0)	0 (0)
		Frothy	1 (6.66)	0 (0)	0 (0)
3	Odour of vaginal discharge	Non offensive	0 (0)	7 (46.6)	12 (80)
		Offensive	0 (0)	6 (40)	2 (13.33)
		Fishy	2 (13.3)	2 (13.33)	1 (6.66)
		others	13 (86.6)	0 (0)	0 (0)
4	Symptoms experienced by partner	Recurrent dysuria	0 (0)	4 (26.66)	-
		Soreness	2 (13.33)	3 (20)	-
		Soreness recurrent dysuria	13 (86.6)	3 (20)	-
		Nil	0 (0)	5 (33.3)	-

Safety evaluation

Adverse event

1 subject recorded a temporary burning sensation in the vagina for first 2 days of treatment with BC caps. However, all 15 subjects completed the prescribed treatment duration (14 days) of capsules. No serious adverse events were reported during the whole study.

DISCUSSION

Vaginal discharge is the most common concern worldwide among women. It is made by the made by the cells of the vagina and cervix under the influence of female estrogen harmone.[28] Only physical evaluation and history examination are critical for diagnosing the infection in vagina. Therefore, laboratory examination, symptoms assessment and non-specific associated symptoms are required to target therapy.[29] Fluconazole is the FDA approved drug for treating bacterial vaginosis and vulvovaginal candidiasis infection in women but this treatment is unsuccessful in reducing the relapse rate of disease. Therefore use of traditional drugs are widely accepted for the disease.[30] Praneem polyherbal capsules is one of the treatment evaluated the healing rate for *bacterial vaginosis*, *C. albicans* and *T. vaginalis*, as 65, 70 and 100%, respectively.[31] The healing rate is also observed for chlamydial infection.[32] Efficacy of praneem polyherbal pessary is higher than complementary and alternative medicine (CAM) with symptomatic improvement of 72%.[33] Neem has variety of medicinal uses reported till date due to its anti-fungal anti-bacterial properties.[34] Neem oil doesn't have any side effects and easily available in the market.[35] This study was a single center study carried out among female participants (n=15) within the age group of 18 to 45 years. The speculum examination (gynecological examination) was done in order to fulfil the primary efficacy evaluation parameter. Speculum examination determines the condition of vaginal discharge before and after treatment with BC caps for both 7 days and 14 days. Before treatment 100 % of study subjects had abnormal vaginal discharge, and after the treatment with BC caps for 7 days and 15 days 12/15 (80%) and 14/15 (93.33%) of subjects had normal vaginal discharge. And, the cervical abnormalities were observed in 8/15 (53.3%) of subjects at the baseline, and after the treatment with BC caps for 7 days and 15 days, 13/15 (86.6%) and 14/15 (93.33%) of subjects had normal cervical examination.

Also, the significant decline was noted in all the associated symptoms and, the vaginal discharge was observed to be clear in 100% of the participants. The 100% improvement was noted in eradication of microbial pathogens. Further, microbiology test revealed that the cure rate for single microbe is superior to multiple microbes. The highly significant improvement was observed in the pH (<4.5) and odour of vaginal sample (which was confirmed by whiff test). A constant decline was seen in the mean values of all the symptoms during the treatment. The acceptability of test product was 100%. All subjects like the shape/size of the capsule. This clinical trial study results showed that 98% of women were cured and felt relieved in their symptoms.

CONCLUSION

The study fulfilled the goal of BC caps which shown huge improvements in subsiding symptoms and proven to be safe and effective as a treatment for abnormal vaginal discharge and adding to that treatment showed improvements on associated symptoms with minimal to zero side effects.

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REFERENCES

1. Alzohairy MA. Therapeutics Role of Azadirachta indica (Neem) and Their Active Constituents in Diseases Prevention and Treatment. Evid Based Complement Alternat Med. 2016;7382506.
2. Bahmani M, Saki K, Shahsavari S, Rafieian-Kopaei M, Sepahvand R, Adineh A. Identification of medicinal plants effective in infectious diseases in Urmia, northwest of Iran. Asian Pac J Trop Biomed. 2015;5(10):858-64.
3. Bates CK, Carroll N, Potter J. The challenging pelvic examination. J Gen Intern Med. 2011;26(6):651-7.
4. Becker M, Stephen J, Moses S, Washington R, Maclean I, Cheang M, Isac S, Ramesh BM, Alary M, Blanchard J. Etiology and determinants of sexually transmitted infections in Karnataka state, south India. Sex Transm Dis. 2010;37(3):159-64.
5. Bhowmik D, Yadav J, Tripathi KK, Sampath Kumar KP. Herbal Remedies of Azadirachta indica and its Medicinal Application. J Chem Pharm Res. 2010.
6. Charonis G, Larsson PG. Use of pH/whiff test or QuickVue Advanced pH and Amines test for the diagnosis of bacterial vaginosis and prevention of postabortion pelvic inflammatory disease. Acta Obstet Gynecol Scand. 2006;85(7):837-43.
7. Egan ME, Lipsky MS. Diagnosis of vaginitis. Am Fam Physician. 2000;62(5):1095-104.
8. Mitra A. Evaluation of Contraceptive Properties of Neem Oil-A Prospective Study. Science and Culture. 2018;84(1-2).
9. Frobenius W, Bogdan C. Diagnostic Value of Vaginal Discharge, Wet Mount and Vaginal pH - An Update on the Basics of Gynecologic Infectiology. Geburtshilfe Frauenheilkd. 2015;75(4):355-66.
10. García-Closas M, Herrero R, Bratti C, Hildesheim A, Sherman ME, Morera LA, Schiffman M. Epidemiologic determinants of vaginal pH. Am J Obstet Gynecol. 1999;180(5):1060-6.
11. Giri RP, Gangawane DAK, Giri DSG. Neem the Wonder Herb: A Short Review. Int J Trend in Scientific Res Develop. 2019.
12. Oxfordshire Clinical Commissioning Group Investigation and Management of Vaginal Discharge in Adult Women. NHS Oxfordshire. 2017. Available at: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwi0jqq47732AhWtS2wGHQx9BpAQFnoECAcQAQ&url=https%3A%2F%2Fwww.oxfordshirecg.nhs.uk%2Fprofessional-resources%2Fdocuments%2Fclinical-guidelines%2Fgynaecology%2Finvestigation-and-management-of-vaginal-discharge-in-adult-women-2016.pdf&usg=AOvVaw1L3Xp-NGerOyXBJDyPuuhF. Accessed on 15 May 2021.
13. Hemalatha R, Ramalaxmi BA, Swetha E, Balakrishna N, Mastromarino P. Evaluation of vaginal pH for detection of bacterial vaginosis. Indian J Med Res. 2013;138(3):354-9.
14. Himalaya D. Pengaruh Pemberian Ekstrak Biji Manjakani (Quercus Infectoria Gall) Terhadap Bakteri Vaginosis Dan Candida Penyebab Keputihan (Leukorrhea). J Midwifery. 2017;5(1).
15. Ilankoon P, Goonewardena CSE, Fernandopulle RC, Perera PPR. Vaginal discharge: women's health seeking behaviours and cultural practices. Int J Curr Res. 2015;7(6):17473-9.
16. Institute on Aging. NIA Adverse Event and Serious Adverse Event Guidelines.Available at: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwiduaeU8L32AhWlS2wGHQ8MCuAQFnoECAcQAQ&url=https%3A%2F%2Fwww.nia.nih.gov%2Fsites%2Fdefault%2Ffiles%2F2018-09%2Fnia-ae-and-sae-guidelines-2018.pdf&usg=AOvVaw3VsIpZiGm4dpr96pXyK17j. Accessed on 15 May 2021.
17. Jabeen K, Hanif S, Naz S, Iqbal S. Antifungal Activity of Azadirachta Indica Against Alternaria Solani. Journal of Life Sciences and Technologies, 2013;89-93.
18. Kelly KG. Tests on Vaginal Discharge. In: Walker HK, Hall WD, Hurst JW, editors. Clinical Methods: The History, Physical, and Laboratory Examinations, 3rd Edition, Butterworths, Boston. 1990;833-5.
19. Khalilzadeh S, Eftekhar T, Rahimi R, Mehriardestani M, Tabarrai M. An Evidence-Based Review of Medicinal Plants Used for the Treatment of Vaginitis by Avicenna in "the Canon of Medicine". Galen Med J. 2019;8:e1270
20. Owen MK, Clenney TL. Management of vaginitis. Am Fam Physician. 2004;70(11):2125-32.
21. Mittal A, Kapur S, Garg S, Upadhyay SN, Suri S, Das SK, Gupta S, Talwar GP. Clinical trial with praneem polyherbal cream in patients with abnormal vaginal discharge due to microbial infections. Aust N Z J Obstet Gynaecol. 1995;35(2):190-1.
22. Moga MA, Bălan A, Anastasiu CV, Dimienescu OG, Neculoiu CD, Gavriș C. An Overview on the Anticancer Activity of Azadirachta indica (Neem) in Gynecological Cancers. Int J Mol Sci. 2018;19(12):3898.
23. Mullick S, Watson-Jones D, Beksinska M, Mabey D. Sexually transmitted infections in pregnancy: prevalence, impact on pregnancy outcomes, and approach to treatment in developing countries. Sex Transm Infect. 2005;81(4):294-302.

24. Nasseri A. Vaginal Discharge. Decision Making in Medicine. 2010;576-7.
25. Neal CM, Kus LH, Eckert LO, Peipert JF. Noncandidal vaginitis: a comprehensive approach to diagnosis and management. Am J Obstet Gynecol. 2020;222(2):114-22.
26. Patel Y, Gopalan S, Bagga R, Sharma M, Chopra S, Sethi S. A randomized trial comparing a polyherbal pessary (a complementary and alternative medicine) with Ginlac-V pessary (containing clotrimazole, tinidazole and lactobacilli) for treatment of women with symptomatic vaginal discharge. Arch Gynecol Obstet. 2008;278(4):341-7.
27. Patient education: Vaginal discharge in adult women (Beyond the Basics) - UpToDate. Available at: https://www.uptodate.com/contents/vaginal-discharge-in-adult-women-beyond-the-basics#!. Accessed on 10 February 2021.
28. Prasad D, Parween S, Kumari K, Singh N. Prevalence, Etiology, and Associated Symptoms of Vaginal Discharge During Pregnancy in Women Seen in a Tertiary Care Hospital in Bihar. Cureus. 2021;13(1):e12700.
29. Sharma RS, Mathur AK, Chandhiok N, Datey S, Saxena NC, Gopalan S, et al. Phase II clinical trial with Praneem polyherbal tablets for assessment of their efficacy in symptomatic women with abnormal vaginal discharge (an ICMR task force study). Transactions of the Royal Society of Tropical Medicine and Hygiene. 2009;103(2):167-72.
30. Singh K. Integrated Approach to Obstetrics and Gynaecology. In Integrated Approach to Obstetrics and Gynaecology. World Scientific. 2016.
31. US20130108599A1 - Herbal Vaginal Compositions - Google Patents. Available at: https://patents.google.com/patent/US20130108599A1/en. Accessed on 10 February 2022,
32. Paladine HL, Desai UA. Vaginitis: Diagnosis and Treatment. Am Fam Physician. 2018;97(5):321-329.
33. Vaginitis - an overview. ScienceDirect Topics. Available at: https://www.sciencedirect.com/topics/nursing-and-health-professions/vaginitis. Accessed on 10 February 2022.
34. Zemouri C, Wi TE, Kiarie J, Seuc A, Mogasale V, Latif A, Broutet N. The Performance of the Vaginal Discharge Syndromic Management in Treating Vaginal and Cervical Infection: A Systematic Review and Meta-Analysis. PLoS One. 2016;11(10):e0163365.

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