



CASE REPORT

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## A Unique Polyherbal Wide Spectrum Microbicide BASANT Maintains Healthy Vagina and has Capability of Eliminating HPV-16 from Infected Cervical Cells Preventing Carcinoma of Cervix

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### Introduction

Besides pleasure, vagina enables the propagation of mankind. It is also the gateway to a variety of infections inflicting woman. We recapitulate in this brief review a marvellous Polyherbal formulation that we developed some years back to protect women from getting undesirable infections from the partner and in the same breadth not pass on the same to him [1].

The formulation consists of 95% pure curcumin (diferuloyl methane) from *curcuma longa*, purified extracts of Amla (*Emblca officinalis*), Aloe vera, and Neem (*Azadirachta indica*) leaves. These ingredients were formulated along with pharmacologically approved excipients and preservatives, such as citric acid, sodium alginate, xanthan gum, lactic acid, potassium sodium tartarate, benzoic acid, glycerol, Rose water. The Formulation was named as BASANT, which in Hindi (Indian language), is a pleasant colour. It is also the Spring season in India.

### Action of Basant on Genital Pathogens

Basant inhibits all strains of *N. gonorrhoeae* tested, amongst which were all WHO strains and clinical isolates of *Neisseria gonorrhoeae*, including strains resistant to Penicillin, Tetracycline, Nalidixic acid and Ciprofloxacin (1). It is effective against *Candida glabrata*, *Candida albicans* and *Candida tropicalis* including multi-drug resistant strains.

Of great interest is its ability to prevent infection by HIV, the virus that causes AIDS. This has been tested not only in India, but also in USA. Manoj Pastey et al of the University of Oregon, have reported

its efficacy against all strains of Human Immunodeficiency virus-1, whether entering human cells via CCR5 or CXCR4 receptors [2].

Aruna Mittal et al from the Institute of Pathology, Indian Council of Medical Research, have reported the ability of BASANT to prevent another major infection, that of *Chlamydia trachomatis* by sexual route [3].

### Abnormal Vaginal Discharge

A fairly large percentage of women coming to Obstetrics and Gynaecology Department of the All India Institute of Medical Sciences and Sir Gangaram Hospital, have abnormal vaginal discharge, caused by a variety of infections [4]. Even in USA, 29% of women suffer from it [5].

It is worth recalling that while the pH of the human body is 7.4, which is rigorously maintained at 7.4, the pH of healthy vagina is around 4.5. This is made possible by co-existence of a family of Lactobacilli residing on the endometrium of vagina. Lactobacilli make and secrete lactic acid locally, which renders the pH of healthy vagina around 4.5. The pH of the vagina goes above 4.5 with the demise of Lactobacilli, which enables many infections to occur in the vagina.

We isolated around 200 strains of Lactobacilli from vagina of healthy women with their consent and characterized these [6]. All lactobacilli do not make the same amount of lactic acid. On basis of meritorious properties, we selected 3 strains of Lactobacilli. These have been patented and deposited in the International Depository. These are *L. salivarius* TRF # 30, *L. fermentum* TRF

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# 36, and *L. gasseri* TRF # 8. In order to make these available to those in need, these have been passed on to M/s Microbax (India) Ltd Hyderabad. Vikas Rajurkar can be contacted to procure these selected meritorious strains of lactobacilli, which will be supplied in lyophilized form along with stabilizers.

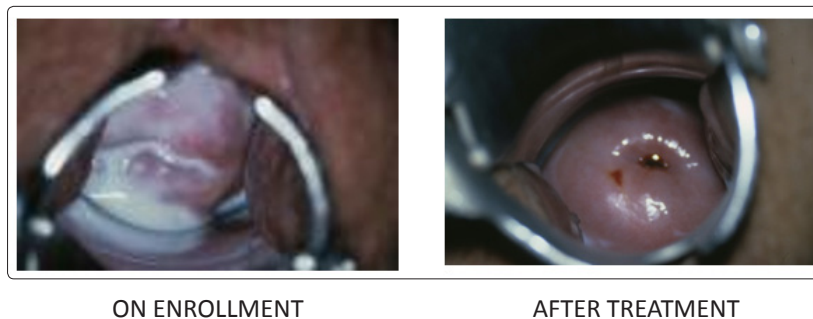
Antibiotics in the market relieve only up to 65% of these women from vaginitis. However employing BASANT along with 3 selected Probiotics, *L. salivarius* TRF # 30, *L. fermentum* TRF # 36, and *L. gasseri* TRF # 8, clears abnormal vaginal discharge in 95% of women as shown in Table 1 and Figure 1.

**Table 1: Summary of results of treatment with either Probiotics, BASANT or a combination of BASANT and Probiotics to cure Vaginosis and restore Healthy Vagina**

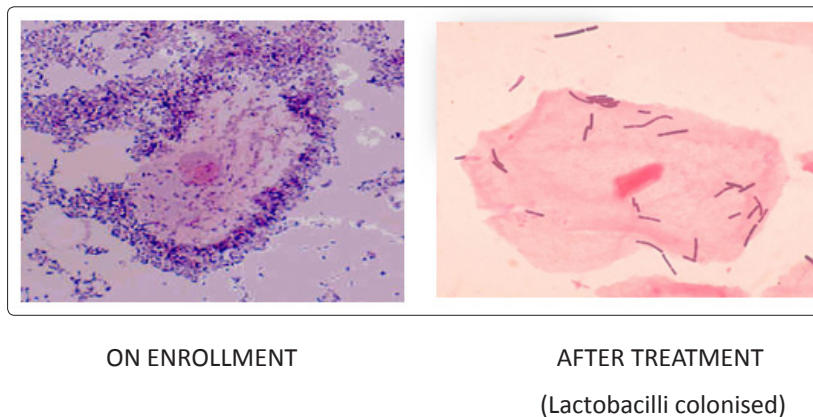
Group Name	Women enrolled	Improved (%)	P value Comparison with Placebo	P value Comparison with BASANT+Probiotics
Probiotics	20	65%	P<0.001	P = 0.04
BASANT	20	70%	P<0.001	P = 0.09
BASANT+Probiotics	20	95%	P<0.001	-
Placebo	20	5%	-	P<0.001

Comparison with Fisher’s exact test

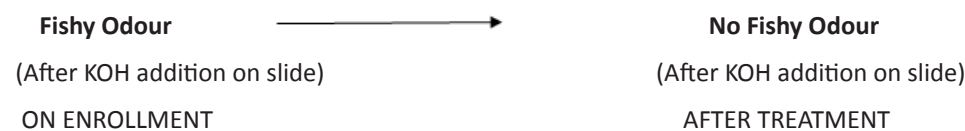
**(a) Relief from abnormal vaginal discharge**



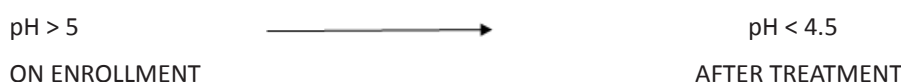
**(b) Disappearance of Clue cells**



**(c) Healing of fishy odour**



**(d) pH of vagina restored to acidic range**



**Figure 1:** An illustrative representation of a typical woman receiving the treatment with combination of BASANT plus Pro-vag-Health (7).

### Expulsion of HPV-16 from Infected Cervical Cells

Carcinoma of cervix is the second largest cancer of women in the world. More than half million cases occur every year and 2,88,000 women die of this cancer annually. In India too, its toll is high, 74,000 women die of cervical cancer every year.

The cancer is caused by a virulent form of virus, the Human Papilloma virus (HPV), a discovery for which Nobel Prize was given to Harald zur Hausen. Several variant strains of HPV, are observed to exist, amongst which HPV-16 and HPV-18, are observed to cause this cancer. The progression of HPV-16 or HPV-18 infected cervical cells to cancer is slow and goes through stages of intraepithelial neoplasia CIN-1, CIN-2 and CIN-3. Pap smear is carried out to diagnose the virus infected cervical cells progressing to cancer. Two good vaccines, 'Gardasil' (Merck) and 'Cervarix' (GlaxoSmithKline), are in the market. These generate antibodies that are effective in preventing the entry of the virus, hence require immunization of healthy women before they are exposed to HPV infection. These are of no avail if the woman is already infected. On the other hand, BASANT is effective not only to prevent the occurrence of infection of the cervical cells by HPV, but what is amazing is that it is also effective to eliminate HPV from already infected cervical cells.

A clinical trial was conducted along with Prof. Rajyashree Sharma, Head of the Department of Obstetrics and Gynaecology, Jawaharlal Nehru Medical College, Aligarh. A total of 159 women were examined clinically and by staining with acetic acid. Cervical scraps were collected using Ayres spatula to prepare Pap smears. On the basis of inflammatory cervix and abnormal Pap smear, 35 subjects were enrolled for the trial. Amongst these 19 patients were found positive for HPV-16. However only 11 out of 19, agreed to undergo intravaginal treatment with BASANT. All eleven HPV-16 positive cases became HPV negative (Table 2).

**Table 2: Pre and Post Treatment with BASANT of HPV-16 Positive Patients (8).**

S.No.	Age	Parity	HPV-16 Pre-treatment	HPV-16 Post-treatment
1.	42	3+0	+VE	NEGATIVE
2.	27	4+0	+VE	NEGATIVE
3.	35	3+0	+VE	NEGATIVE
4.	28	1+1	+VE	NEGATIVE
5.	45	3+0	+VE	NEGATIVE
6.	35	4+0	+VE	NEGATIVE
7.	30	2+1	+VE	NEGATIVE
8.	45	2+0	+VE	NEGATIVE
9.	38	5+2	+VE	NEGATIVE
10.	35	3+1	+VE	NEGATIVE
11.	38	3+1	+VE	NEGATIVE

Number of patients screened for HPV DNA: 159; Number of patients positive for HPV-16: 19; Intravaginal BASANT given with written consent to 11 HPV positive patients accepting to take BASANT; HPV-16 turning negative after intravaginal BASANT in all.

BASANT has been licensed to M/s Bipha Drug Laboratory Pvt Ltd, Kerala. The Managing Director, Mr. Ajay George Varghese can be approached for the requirements of BASANT.

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