

## Sophy project: evidences intimate hygiene

A.R. GENAZZANI, B. PRATO

SUMMARY: Sophy project: evidences intimate hygiene.

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*The importance of intimate hygiene, pH and vaginal flora in keeping the vaginal ecosystem in good balance is known and widely described.*

*No systematic, nation-wide, current study is up to now available, on the correlation between vaginal pH and intimate hygiene in the different ages and condition of the woman, mainly considering the modified hygienic and clothing habits.*

*A project aimed to collect systematically data related to intimate hygiene, in a representative sample of the Italian gynaecological population has been realised, helped by a specific website to insert the data.*

*Lifestyle, vaginal pH, intimate hygiene compliance, presence of symptoms, gynaecological treatment stratified in different subgroups (prepubertal, fertile, pregnant, lactating, pre-menopause and menopause) have been recorded up to now on 1191 women.*

*The Study on pH and Hygiene (SOPHY) provides a strong educational impact, pushing doctors and women in considering pH and intimate hygiene an important moment of their professional and daily life.*

*Each natural plant extract used in intimate hygiene (Sage, Thyme and Chamomile) confirmed its clinical activity on protecting against bacteria, mycoses and inflammation.*

RIASSUNTO: Progetto Sophy

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*L'importanza di igiene intima, pH e flora vaginale nel mantenere l'ecosistema vaginale in buon equilibrio è nota e ampiamente descritta.*

*A tutt'oggi non sono disponibili studi sistematici, su scala nazionale, relative alla correlazione tra pH vaginale e igiene intima nelle differenti età e condizioni della donna, soprattutto in considerazione delle modificate abitudini igieniche e di abbigliamento.*

*È stato realizzato un progetto mirato a raccogliere sistematicamente dati correlati con l'igiene intima, in un campione rappresentativo della popolazione ginecologica italiana, con l'aiuto di uno specifico sito internet per inserire i dati.*

*Stile di vita, pH vaginale, igiene intima, presenza di sintomi, trattamento ginecologico stratificato in differenti sottogruppi (prepubere, fertile, gravidanza, allattamento, pre-menopausa e menopausa) sono stati registrati in 1197 donne.*

*Lo studio "Study on pH and Hygiene" (SOPHY) fornisce un forte impatto educativo, spingendo medici e donne a considerare pH vaginale e igiene intima un importante momento della loro vita quotidiana e professionale.*

*Ciascun estratto naturale vegetale usato nell'igiene intima (Salvia, Thymus e Camomilla) ha confermato la sua attività clinica nella protezione contro batteri, micosi e infiammazione.*

KEY WORDS: Intimate hygiene - Plant extracts - Vaginal pH - Bacterial vaginosis.  
Igiene intima - Estratti vegetali - pH vaginale - Vaginosi batterica.

### Introduction

Vaginal ecosystem is apparently an isolated and protected structure. The balance of this system is easily altered by anatomic contiguity with rectum and bladder, hormonal profile, pregnancy, traumas, sexual intercourse, and pharmacological therapies.

The importance of intimate hygiene, pH and vaginal flora in keeping the vaginal ecosystem in good balance is known and widely described. pH is a good

marker of the healthy condition of vaginal ecosystem and allows to early detect borderline situations for appropriate actions.

No systematic, nation-wide, current study is up to now available, on the correlation between vaginal pH and intimate hygiene in the different ages and condition of the woman, mainly considering the modified hygienic and life style habits.

A project aimed to collect systematically data related to intimate hygiene with the target to build a large and representative sample of the woman population in the different ages and/or physiological conditions, has been realised.

A scientific board was settled to agree on protocol and case report form and involved Genazzani A. R. Gynaecology and Obstetrics University Dept., University of Pisa; Bruni V. Obstetrics and Gynaecology Institute Pol. Careggi, Firenze; Di Nicola C. Physicians

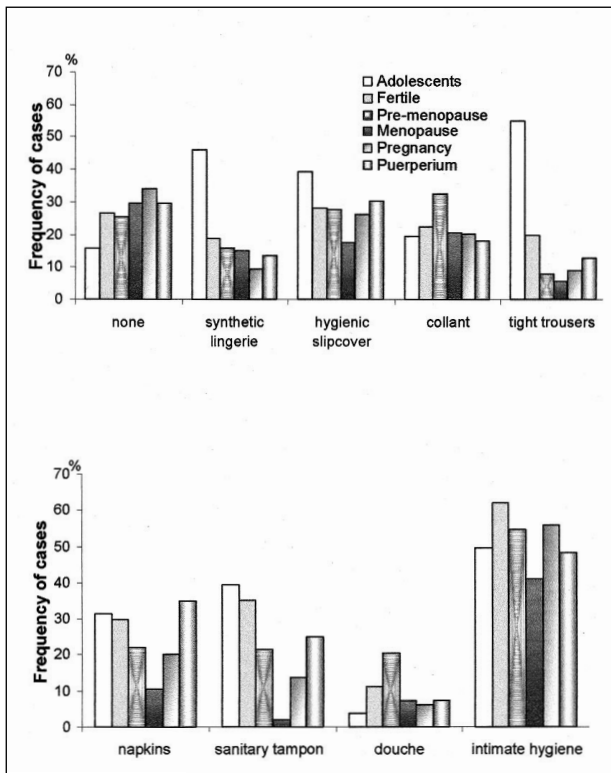


Fig. 1 - Life style: frequent use of clothing and specific hygienic actions.

Women Association, Roma; Cianci A. Gynaecology University Dept, Ospedale Santo Bambino, Catania; Graziottin A. Medical and Gynaecological Sexology, Osp. S. Raffaele Resnati, Milano; Guaschino S. Clinica Obstetrics and Gynaecology University Dept., Trieste; Nicoletti G. Microbiology and Gynaecological Sciences Dept., University of Catania; Novellino E. Pharmaceutical Chemistry, Pharmacy, University of Napoli; Schito G.C. Microbiology Istituto, University of Genova; Sismondi P. Oncological Gynaecology Chair, Ospedale Mauriziano, Torino.

Aim of the study is also to evaluate the impact of intimate hygiene carried out with specific natural plant extracts on the vaginal ecosystem balance. In fact, natural plant extracts, namely the ones derived by *Salvia officinalis*, *Thymus vulgaris*, and *Chamomila matricaria*, are endowed with pharmacological and microbiological activities, linked to their active principles corresponding to salviol and pinene (1-13), thymol and carvacrol (1, 2, 14-30) and bisabolol (1, 2, 12, 31).

## Material and methods

More than one thousand of Italian gynaecologists are participating to the standardised protocol, filling appropriate case report forms, with the help of a specific website to insert the data. Each investigator

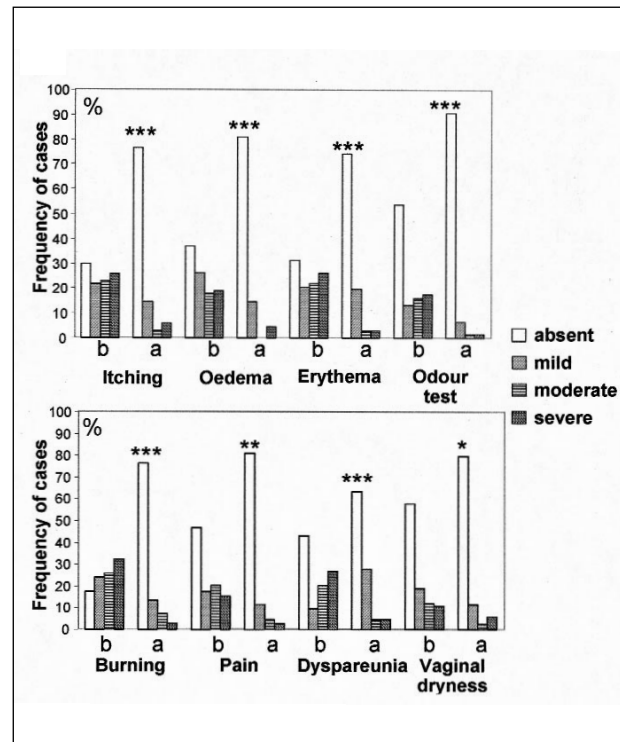


Fig. 2 - Signs and symptoms in Bacterial vaginosis before and after 4 weeks of Thyme extract daily use for intimate hygiene (b = before, a = after; \* p < 0.05; \*\*\* p < 0.0001 vs baseline at  $\chi^2$  2x4 test).

receives individual login and password to have a protected access to the website.

**Selection criteria.** The investigators collect the data on 12 consecutive women referring to the doctor's observation, 2 for each of the following physiological conditions: 2 adolescents (from menarche+following 6 yrs), 2 fertile, 2 pregnant, 2 lactating, 2 pre-menopause, 2 menopause.

To achieve an unbiased interpretation of the data, the sample has not be "chosen", but collected following the random order of the woman referring to the doctor's observation.

**Evaluation criteria.** The investigator fills the CRF inserting data on history, lifestyle and diet, vaginal pH (a standard set for pH determination is given to each doctor), presence of signs/symptoms at start, or the ones appeared during the treatment, stratified in different subgroups - adolescents, fertile, pregnant, lactating, pre-menopause and menopause - possible diagnosis of bacterial vaginosis, current pharmacological therapies.

**Treatments.** The investigator, beside the possible pharmacological prescription required by the current clinical conditions, recommends the woman the most appropriate product for a correct intimate hygiene, according to the following scheme: Sage extract detergent for adolescents, fertile and pre-menopause,

TABELLA I - CHARACTERISTICS OF THE POPULATION STUDIED (MEAN ± SD)

	Adolescents	Fertile	Pre-menopause	Menopause	Pregnancy	Puerperium
n	109	360	126	228	225	149
Age (years)	17.3 ± 3.0	32.7 ± 7.9	47.8 ± 5.4	56.4 ± 10.5	30.7 ± 4.8	31.6 ± 6.1
BMI (kg/m <sup>2</sup> )	20.6 ± 2.9	22.3 ± 4.0	23.6 ± 3.4	25.6 ± 4.4	24.3 ± 4.4	24.2 ± 6.2
Bacterial Vaginosis (%)	14.7	19.2	18.3	11.8	12.9	16.1
Candida (%)	28.4	21.9	15.9	8.3	20.9	11.4

TABELLA II - PH BEFORE AND 4 WEEKS AFTER DAILY USE OF PLANT EXTRACTS (SAGE, THYMUS AND CHAMOMILE) FOR INTIMATE HYGIENE IN DIFFERENT AGES AND PATHOPHYSIOLOGIC GROUPS: ADOLESCENT (A), FERTILE (F), PRE-MENOPAUSE (PM), MENOPAUSE (M), PREGNANCY (P), PUERPERIUM (Pu), BACTERIAL VAGINOSI (BV) AND CANDIDA (C) (MEAN ± SD).

	Sage			Chamomile	Thymus			
	A	F	Pm		M	P	Pu	BV
%	4.88	4.88	4.94	5.04	4.91	5.17	5.35	5.2
before	± 0.84	± 0.76	± 0.60	± 0.85	± 0.66	± 0.8	± 0.70	± 0.89
after	4.48	4.59	4.58	4.96	4.62	4.60	4.61	4.57
	± 0.55	± 0.61	± 0.50	± 0.67	± 0.55	± 0.72	± 0.79	± 0.64
P t test	< 0.01	< 0.01	< 0.01	NS	< 0.01	< 0.01	< 0.01	< 0.01

Thyme extract detergent for pregnancy and lactation, Chamomile extract detergent for menopause.

Moreover, independently from the physiological condition, Thyme extract detergent is recommended

for intimate hygiene in presence of suspected or ascertained bacterial vaginosis, mycosis or attendance of environments at risk and Chamomile extract detergent is advised for itching and vulvar burning due to hyperacidity

Each detergent is used 1 or 2 times/day for 4 weeks.

*Statistical analysis.* Chi square test and Student's t test were applied when appropriate to calculate the statistical significance of the 4-week effect compared to baseline values.

*Timing of the study.* The observational study started with the delivery of login and password. The study is currently running and the preliminary results are here presented.

## Results

The characteristics of the 1197 women studied are reported in Table I. Body Mass Index (BMI) is positively correlated with increasing age, as expected, bacterial vaginosis is more frequent in fertile age and Candida in adolescents.

The frequent use of clothing at risk of vaginal infections was generally by far more linked to adolescents and less in menopause. Intimate hygiene is reported more frequently in fertile age and is lower in menopausal women (Fig. 1).

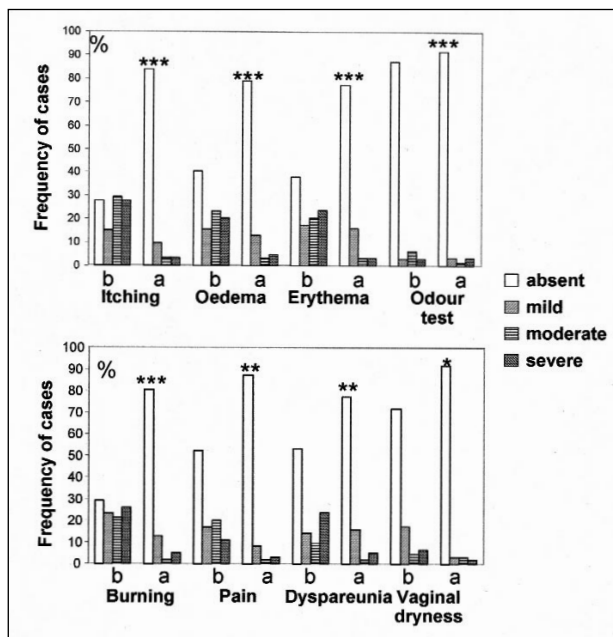


Fig. 3 - Signs and symptoms in Candida infection before and after 4 weeks of Thyme extract daily use for intimate hygiene (b = before, a = after; \* p < 0.05, \*\* p < 0.01, \*\*\* p < 0.0001, vs baseline at  $\chi^2$  2x4 test).

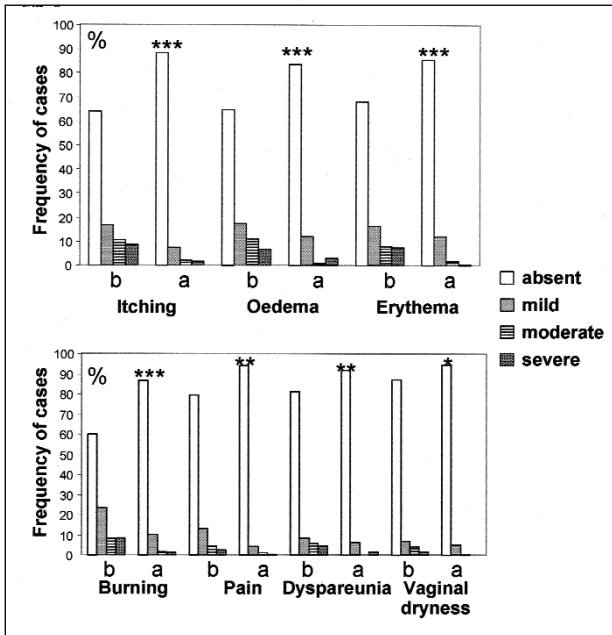


Fig. 4 - Signs and symptoms in Pregnancy before and after 4 weeks of Thyme extract daily use for intimate hygiene (b= before, a=after; \* p < 0.05, \*\* p < 0.01, \*\*\*p < 0.0001, vs baseline at  $\chi^2$  2x4 test).

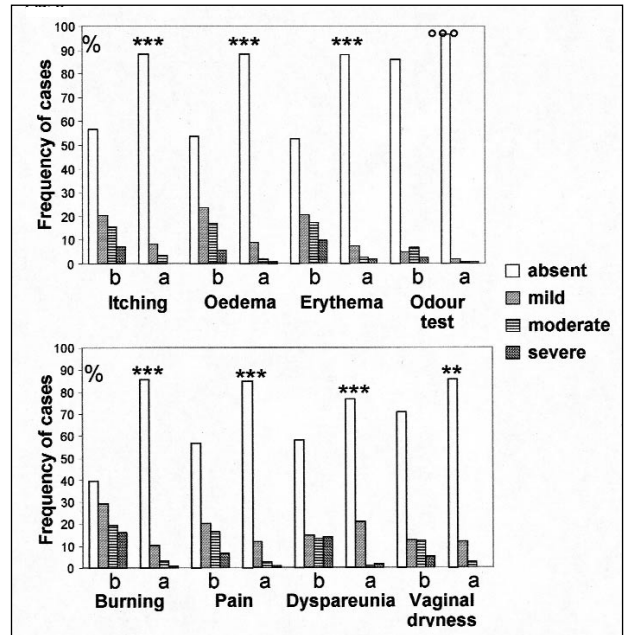


Fig. 5 - Signs and symptoms in Puerperium before and after 4 weeks of Thyme extract daily use for intimate hygiene (b= before, a=after; \*\* p < 0.01, \*\*\* p < 0.0001, vs baseline at  $\chi^2$  2x4 test).

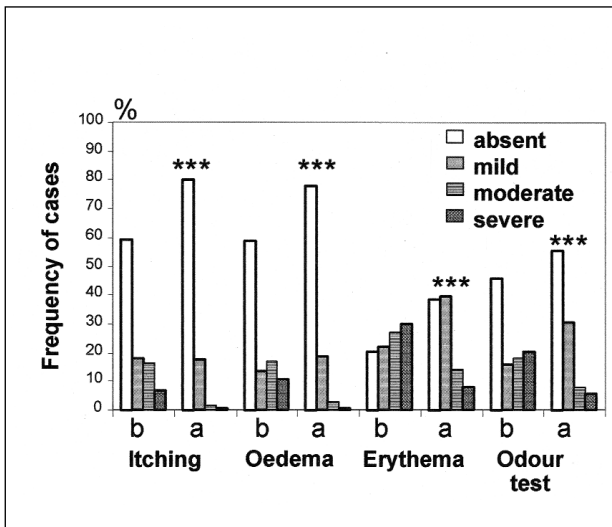


Fig. 6 - Signs and symptoms in Menopause before and after 4 weeks of Chamomile extract daily use for intimate hygiene (b= before, a=after; \*\*\* p < 0.0001 vs baseline  $\chi^2$  2x4 test).

Contraceptive methods were more used in fertile age (52.8%) than in adolescents (42.2%) pre-menopause (32.5%) and puerperium (26.9), being oral contraceptive (OC) the preferred by adolescents and fertile women (30%) versus condom (C), and no difference between the two methods in pre-menopause (7.9% OC, 11.1% C) and puerperium (11.4% OC, 8.1% C). As concomitant treatment that could interact with the results, only less than 1% of local antimycotics in thyme treated group

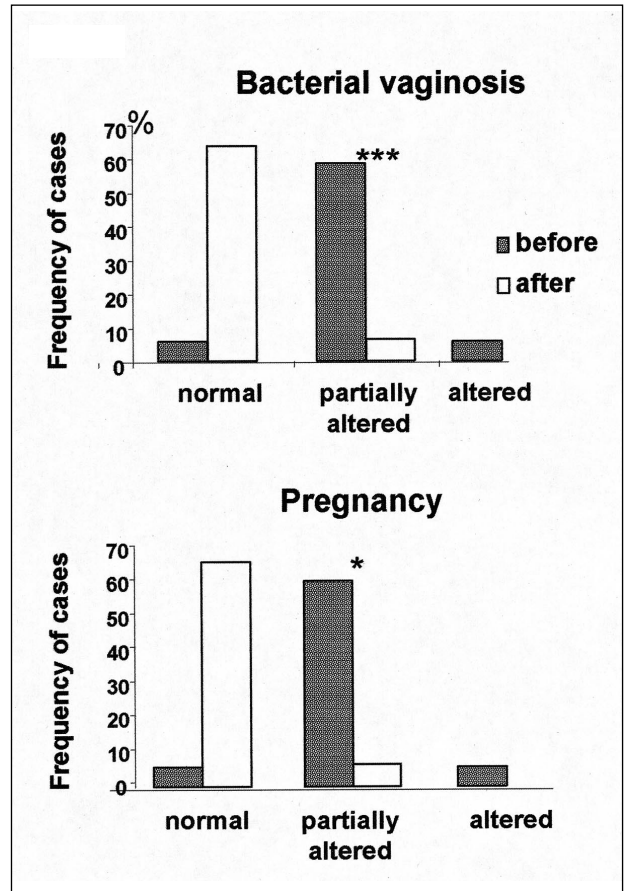


Fig. 7 - Microbiological evaluation in Bacterial vaginosis and Pregnancy before and after 4 weeks of Thyme extract daily use for intimate hygiene (b= before, a=after; \* p < 0.05; \*\* p < 0.01 \*\*\* p < 0.0001 vs baseline at  $\chi^2$  2x3 test).

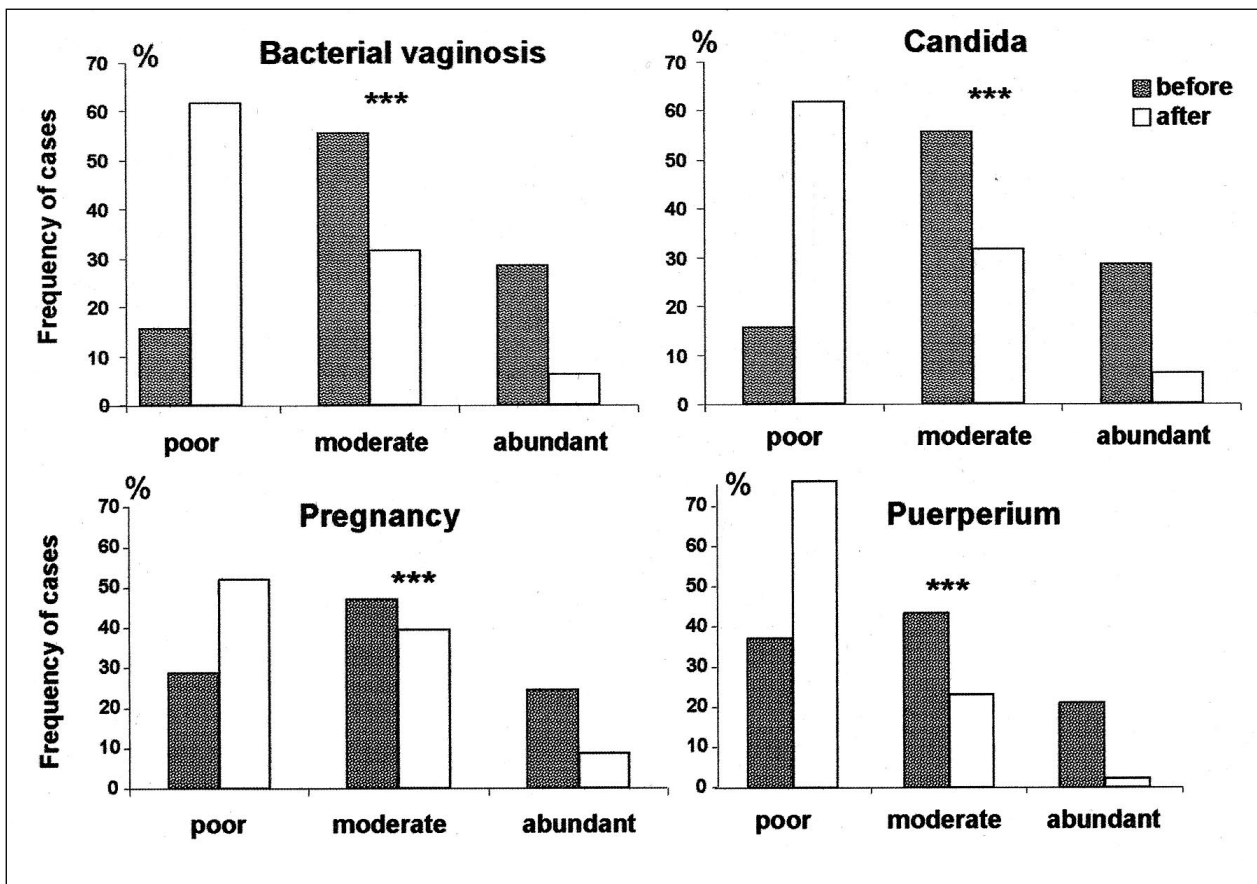


Fig. 8 - Leucorrhoea in Bacterial vaginosis, Candida, Pregnancy and Puerperium before and after 4 weeks of Thyme extract daily use for intimate hygiene (b= before, a=after; \*\*\* p < 0.0001; NS statistically not significant vs baseline at  $\chi^2$  2x3 test).

was reported.

Vaginal pH responded to the action of the different plant extracts, showing that in all the stratified ages, but menopause, pH was statistically reduced after 4 weeks use of Sage extract in adolescents, fertile age and pre-menopause, and Thyme extract in bacterial vaginosis, candida, pregnancy and puerperium (Tab. II).

Signs and symptoms in bacterial vaginosis, candida, pregnancy, puerperium and menopause were significantly reduced as severity and frequency (Fig. 2-6).

Microbiological evaluation showed a statistically significant normalisation in bacterial vaginosis, pregnancy, puerperium and in candida too, even if not significantly (Fig. 7). Leucorrhoea determined as quantity was significantly reduced in bacterial vaginosis, candida, pregnancy and puerperium (Fig. 8).

The physician's judgment on treatment and the overall conditions of the woman vs pre-treatment confirmed the positive results on the natural extract

daily use for intimate hygiene (Fig. 9-10).

## Conclusions

The Study on pH and Hygiene (SOPHY) is providing a strong educational impact. The study protocol, beyond the data on the activity of natural plant extracts in intimate hygiene, achieved the goal to push doctors and women in considering pH and intimate hygiene an important moment of their professional and daily life.

Each natural plant extract used (Sage, Thyme and Chamomile) confirmed clinically the experimental data of activity on bacteria, mycoses and inflammation.

As consequence of the antibacterial and antimycotic action expressed at vulvovaginal level by the active principles contained in Thyme and Sage extract, mean vaginal pH was reduced to normal values.

The positive physician's judgment on treatment and favourable response of the overall conditions of the woman vs pre-treatment were in agreement with the results observed on signs and symptoms respecti-

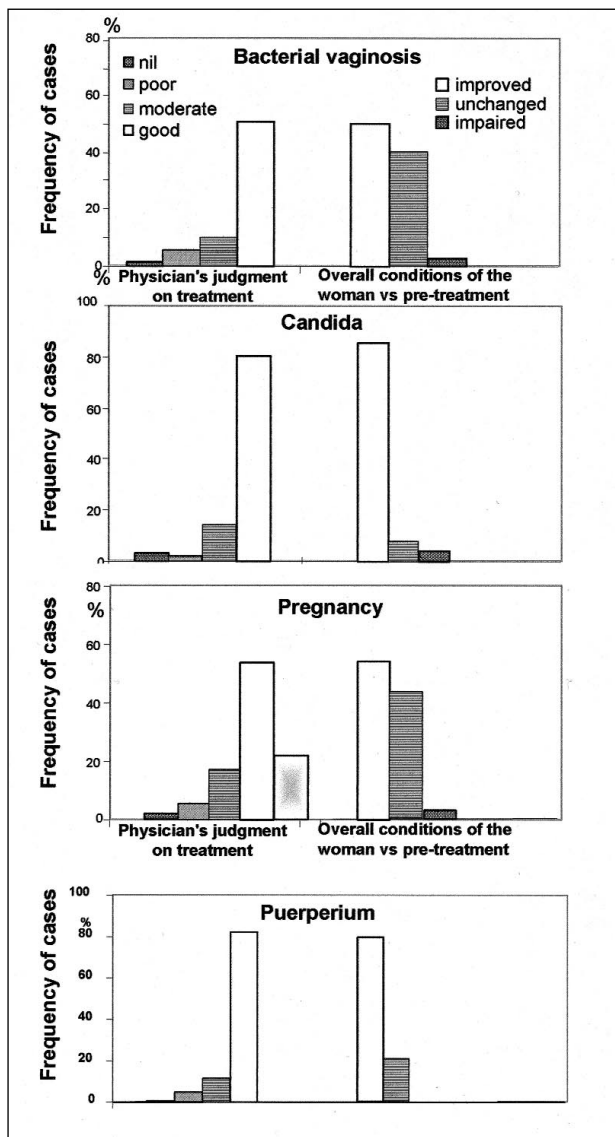


Fig. 9 - Physician's judgment on treatment and Overall conditions of the woman vs pre-treatment in Bacterial vaginosis, Candida, Pregnancy and Puerperium before and after 4 weeks of Thyme extract daily use for intimate hygiene.

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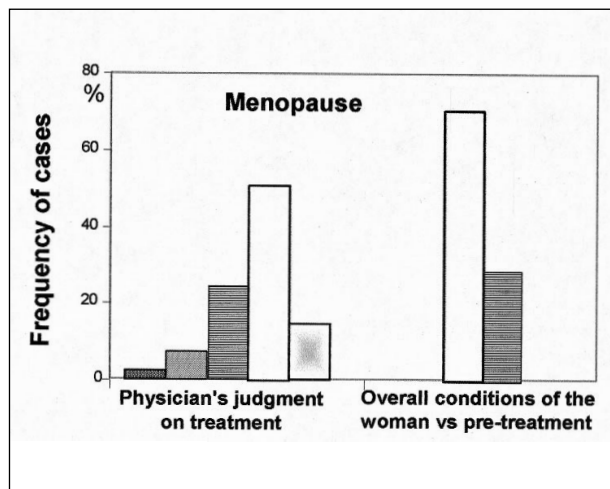


Fig. 10 - Physician's judgment on treatment and Overall conditions of the woman vs pre-treatment in Menopause before and after 4 weeks of Chamomile extract daily use for intimate hygiene.

vely in Bacterial vaginosis, Candida, Pregnancy and Puerperium before and after 4 weeks of Thyme extract daily use and in menopause before and after 4 weeks of Chamomile extract daily use.

These data confirm the usefulness to practice intimate hygiene with appropriate active principles aimed to protect against vulvovaginal infections.

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