**Sophy project: evidences intimate hygiene**

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**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 lifestyle 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 1197 women.

The Study on pH and Hygiene (SOPHY) provides a strong educational impact, pushing doctors and women in considering pH vaginale 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.

**KEY WORDS:** Intimate hygiene - Plant extracts - Vaginal pH - Bacterial vaginosis.

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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 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,
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, mycosis or attendance of environments at risk and Chamomile extract detergent is advised for itching and vulvar burning due to hyperacidity.

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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.
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 (Figg. 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 antymycotic 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-
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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References

2. BENVENUTI C., CAMANA M.G., MORTARA E., PORTALUPPI P., SETNIKAR I.: Natural compounds from plant extract in gynaecology. 12th World Cong Hum Reprod, 10-13 March, Venice, Italy, 2005.
7. MEJHLHOLM O., DALGAARD P.: Antimicrobial effect of essential oils on the seafood spoilage micro-organism Photobacterium phosphoreum in liquid media and fish products. Lett Appl Microbiol 34:


