

Results of the VALYD* study

A multicenter, epidemiological, observational, prospective study of vaginal atrophy and quality of life in menopausal women

** Vaginal Dryness and Quality of Life in Menopausal Women*

By Milena Mincigrucci*, Costante Donati Sarti**, Angelamaria Becorpi***, Massimo Milani°, and Gianluca Botta°

* “Menopause Space” consultation department, Health Agency of Umbria, USL no. 2

** Physiopathology Center for Menopause and the Elderly, Obstetrics and Gynecology Consultation Department, Perugia Hospital Facility

*** Department of Gynecology, Perinatology, and Human Reproduction, “Careggi” University Hospital Facility, Florence

° Mipharm R&D SpA, Milan

Abstract

As a result of an estrogen deficiency caused by the onset of menopause, substantial modifications of the hormone-dependent tissues and the urogenital tract occur, including a rise in vaginal pH, decreased or discontinued production of glycogen, a reduction in the elasticity and thickness of the vaginal wall, and reduced blood flow and secretions in the vagina. Vaginal atrophy, which occurs in 40% of postmenopausal women, may occur with characteristic symptoms such as itching, dryness, dyspareunia, and dysuria, and with repercussions on the woman’s quality of life. Vaginal atrophy can be treated with hormonal therapy either topically or systemically. When these treatments are poorly tolerated or contraindicated (history of cancer, thromboembolism, etc.), local, non-hormonal therapies with a moisturizing and/or lubricating action, such as crèmes or gels, may be a valid alternative. The VALYD (Vaginal Dryness and Quality of Life in Menopausal Women) study conducted under the auspices of the SIGITE (Italian Society of Elderly Gynecology) was aimed at evaluating the epidemiology of the signs and symptoms related to vaginal atrophy in postmenopausal women and, at the same time, evaluating the effects of local, non-hormonal therapies and systemic therapies on the symptomatic and clinical evolution of vaginal atrophy. The results show that the use of a special, non-hormonal vaginal therapy with moisturizing and lubricating action, either alone or in combination with a systemic hormone replacement therapy, is accompanied by a significant and clinically relevant improvement in the VHIS and symptoms associated with vaginal atrophy.

Introduction

The female urogenital tissue is characterized by an abundant presence of estrogen receptors involved in maintaining the nutrition of the female reproductive organs (1).

An estrogen deficiency related to the onset of menopause brings about substantial modifications of the urogenital tract, including a rise in the vaginal pH, decreased or discontinued production of glycogen, a reduction in the elasticity and thickness of the vaginal wall, and reduced blood flow and secretions in the vagina, in addition to being a situation that favors vulvovaginal infections (6). In this context, vaginal atrophy, a condition present among 40% of

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postmenopausal women (2, 3), may occur with characteristic symptoms such as itching, dryness, dyspareunia, and dysuria and with repercussions for the woman's quality of life.

Vaginal atrophy is characterized by a thinning of the mucous membrane epithelium, a reduction in gland secretions (with an attendant decrease in hydration), and a loss of vaginal elasticity. Vaginal atrophy can be treated rationally with either topical or systemic hormonal therapies, or alternatively, when these treatments are poorly tolerated or contraindicated (history of cancer, thromboembolism, etc.), with local, non-hormonal treatments having a moisturizing action, such as crèmes or gels (1-2, 4, 5, 7-10).

Purpose of the study

The VALYD (Vaginal Dryness and Quality of Life in Menopausal Women) study conducted under the auspices of the SIGITE (Italian Society of Elderly Gynecology) was aimed at evaluating the epidemiology of the signs and symptoms related to vaginal atrophy in postmenopausal women and, at the same time, verifying the effects of non-hormonal vaginal therapies and systemic hormonal therapies on the symptomatic and clinical evolution of vaginal atrophy by means of the Vaginal Health Index Score (7).

Patients and methods

A total of 18 Menopause Centers participated in this multicenter, epidemiological, observational, prospective study. Between December 2002 and October 2004, 509 women (average age (SD): 56.4 (6) years) being seen as outpatients for routine visits were enrolled (see Table). The 24-week study called for a clinical checkup and filling out a quality-of-life questionnaire at the baseline, after 12 weeks, and after 24 weeks, while a determination of the vaginal trophic condition using the Vaginal Health Index Score (VHIS) was called for at the baseline and after 24 weeks. Women experiencing natural or surgical menopause with and without hormone replacement therapy with a VHIS at the baseline visit of 14 or less (maximum score 25, minimum 5) who consented to participate in the study after an oral informed consent, were enrolled. The exclusion criteria consisted of the presence of ongoing uterine bleeding, the use of vaginal douches within 24 hours preceding the visit, and the use of topical antibiotics and/or antifungal agents within 2 weeks preceding the baseline visit. The VHIS evaluated the following vaginal parameters: elasticity, secretion volume, vaginal pH, integrity of the epithelium, and lubrication of the vaginal wall. A semi-quantitative score was used for each parameter (from 1 to 5) with the higher values indicating a normal situation (maximum possible value of the VHIS: 25) and the lower values indicating an abnormal situation (minimum possible value of the VHIS: 5). The objective of the study was to evaluate the impact of vaginal atrophy among menopausal women and the corresponding symptoms, and to check the effects of the non-hormonal vaginal therapies and the systemic hormonal therapies on the symptomatic and clinical evolution of the vaginal atrophy.

Results

At the initial visit, 97 women out of 509 were using HRT (15%) [sic.]. During the study, this percentage rose to 33% and 34% after 12 and 24 weeks, respectively. Only 9% of the women were using non-hormonal vaginal treatments: the percentage rose to 94% during the study. The vaginal gel based on polycarbophil-carbophol (Replens®) was the most widely used topical treatment (90%).

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At the baseline, the vaginal symptoms and disorders were present in a high percentage of women: the presence of vaginal itching, vaginal burning, and dyspareunia was reported in 59%, 77%, and 80% of the cases, respectively (Figure 1).

In the course of the study, the percentage of women complaining of vaginal burning and itching gradually dropped significantly compared to the baseline: from 77% to 17% by week 24, and from 59% to 5% by week 24, respectively (Figures 2 and 3).

By the end of the study, a significant drop in the percentage of women complaining of dyspareunia was observed: only 13% reported the presence of this problem (Figure 4). This reduction was observed in both women receiving hormone replacement therapy (HRT) and those using non-hormonal topical preparations, as well as women being treated solely with a non-hormonal topical therapy: 9% and 16% complained of dyspareunia in week 24, respectively.

The presence of vaginal discharges was reported by 54% of the enrolled women at the baseline: by the end of the study this percentage had dropped to 9%.

The Vaginal Health Index Score was 11.7 ± 2 at the baseline visit. In the women receiving HRT, the value was 12.4, while among the untreated subjects it was 11.6 ($p = 0.04$). By the end of the study in week 24, the VHIS had increased significantly to values of 18.2 ± 3 ($p = 0.0001$: T-test), representing a rise of 55% compared to the baseline (Figure 5).

The increase was observed both in women receiving HRT and also using a non-hormonal topical treatment (VHIS = 19.1 ± 3), as well as in women being treated solely with a non-hormonal topical therapy (VHIS = 18.3 ± 2) (Figure 6).

Discussion and conclusions

The VALYD (Vaginal Dryness and Quality of Life in Menopausal Women) is the first prospective multicenter Italian trial of a large population conducted with the aim of verifying the extent of disorders related to vaginal atrophy and determining the role of hormonal and non-hormonal therapies. The study confirms that atrophy, dyspareunia, and other vaginal symptoms are commonly found among menopausal women. The use of a special non-hormonal vaginal therapy with moisturizing and lubricating action, either alone or in combination with HRT, brings about a significant and clinically relevant improvement in the Vaginal Health Index Score and symptoms related to vaginal atrophy.

In particular, significant reductions of itching, burning, and vaginal discharges were observed. Dyspareunia dropped by 84%: this reduction occurred both in women taking a hormonal therapy in conjunction with a non-hormonal vaginal therapy, and among women receiving only non-hormonal vaginal therapy.

Bibliography

[All in English]

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VALYD study – Enrolled population

Age, average (SD) in years	56.4 (6)
Weight, kg, average (SD)	63.9 (4)
BMI, average (SD)	25 (3.8)
Age at menopause, average (SD) in years	49 (4)
Natural menopause, %	86
Surgical menopause, %	14
Pregnancies, yes	77%
Smoker, %	19
Alcohol consumption, %	41

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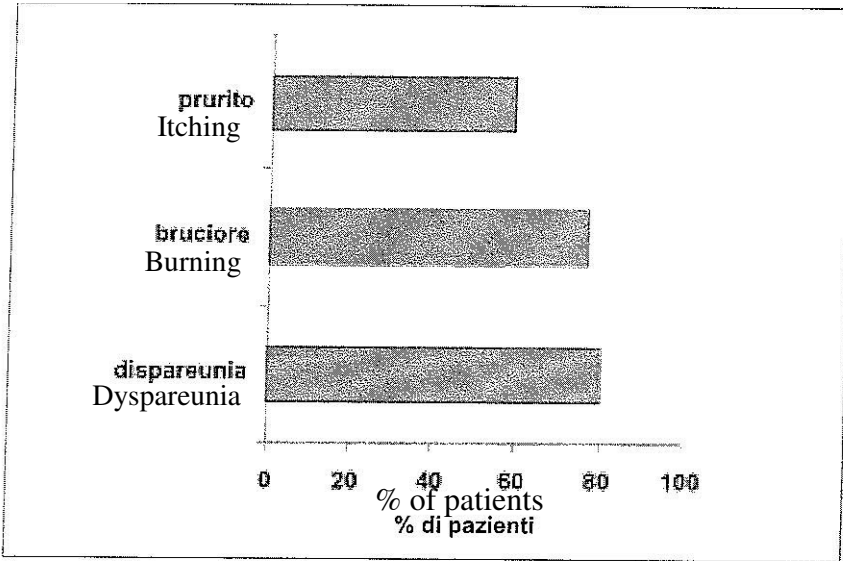


FIGURA 1. Presenza di disturbi vaginali al basale
Figure 1. Presence of vaginal disorders at the baseline

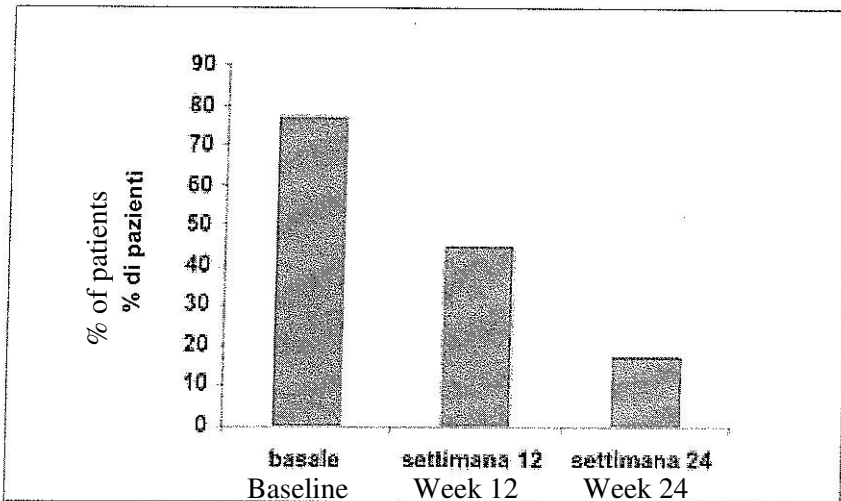


FIGURA 2. Presenza di bruciore vaginale
Figure 2. Presence of Vaginal burning

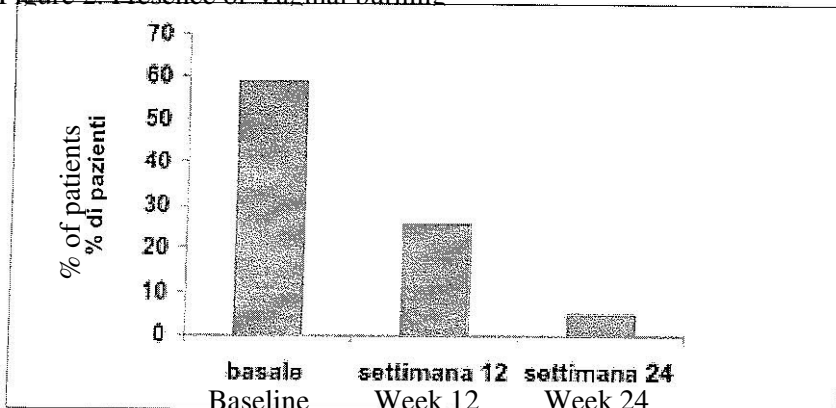


FIGURA 3. Presenza di prurito vaginale
Figure 3. Presence of vaginal itching

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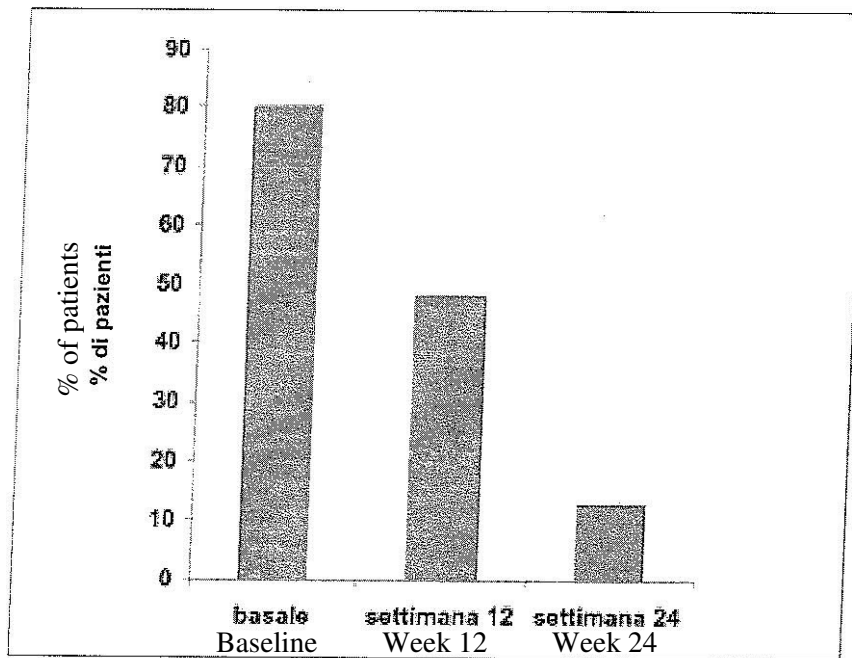


FIGURA 4. Presenza di dispareunia
Figure 4. Presence of dyspareunia

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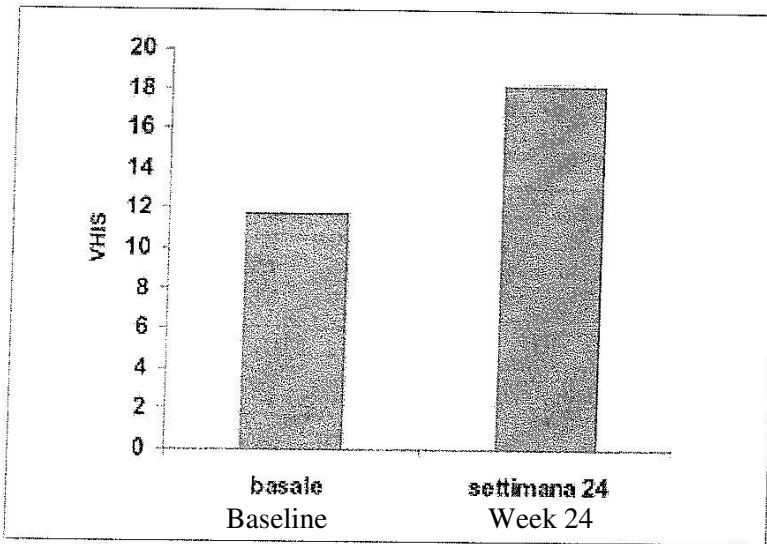


FIGURA 5. Andamento del Vaginal Health Index Score

Popolazione globale

Figure 5. Change in the Vaginal Health Index Score. Overall population

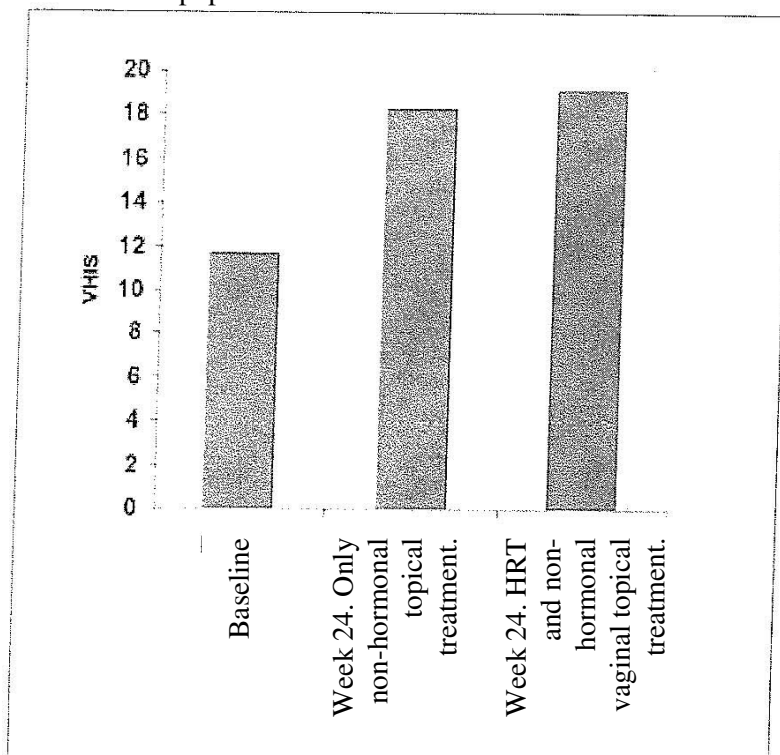


FIGURA 6. Andamento del Vaginal Health Index Score

Tipologia del trattamento

Figure 6. Change in the Vaginal Health Index Score. According to type of treatment

STUDIO VALYD

CENTRI PARTECIPANTI

- Maria Rosa Della Sala
Osp. Civ. Bergamo
- Stefano Quaranta
Osp. S. Carlo - Milano
- Raffaele Ponticelli
Centro per la Menopausa ASL Napoli 1 Distretto 52 - Napoli
- Giuseppe Tomasillo
Centro per la Menopausa Osp. "San Paolo" - Napoli
- Carla Chirico
Div. Ginecologia Osp. SS. Annunziata Cento (FE)
- Enzo Esposito
Div. Ginecologia Osp. Civile Lugo di Romagna - (RA)
- Maurizio Morelli
Div. di Ost. e Gin. Osp. S. Maria delle Croci - (RA)
- Arcangelo Cordopatri
Centro per la Menopausa Osp. "Papardo" - Faro Superiore (ME)
- Ottavia Favi
Consultorio Via Enrico Rossi 46 Livorno
- Corrado Baj
Clinica Ost. e Gin. Osp. Maggiore della Carità - Novara
- Vittorio Le Rose
AIED Via Toscana 30 - Roma
- Giuseppe Casarella
Centro per la Menopausa "Diagnostica Medica" - Mercogliano (AV)
- Massimo Di Liberto
Ospedale di Mazara del Vallo - (TP)
- Pierluigi Tartaglino
Osp. S. Croce - Moncalieri (TO)
- Aurelio Sorace
Div. Ginecologia Osp. Galliera - Genova
- Domenico Costa
Centro per la Menopausa Consultorio "C.I.F." ASL 1 - Agrigento
- Claudio Angeloni
Centro per la Menopausa Osp. "S. Liberatore" - Atri (TE)
- Riccardo Arienzo
- Maria Grazia Nitti
Centro per la Menopausa Osp. "Annunziata" - Napoli