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# Attitudes and perceptions towards vulvar and vaginal atrophy in Italian post-menopausal women: Evidence from the European REVIVE survey

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ABSTRACT

*Objectives:* To achieve a deeper understanding of the attitudes and perceptions of Italian post-menopausal women (PMW) regarding vulvo-vaginal atrophy (VVA).
*Study design:* As part of the EU REVIVE study, an online survey was conducted in four European countries; the Italian arm comprised 1000 participants from representative regions of Italy.
*Main outcome measures:* The perceptions, experiences and needs of Italian PMW in relation to sexual and vaginal health.
*Results:* The most frequent VVA symptom was vaginal dryness (78%). Usually, the severity of symptoms was similar to or worse than when they first appeared. This was particularly true for dyspareunia, the most bothersome symptom (76%). VVA symptoms had a significant impact on Italian participants' ability to achieve pleasurable relations (74%) and spontaneity (70%). Although 75% of participants were still sexually active, their sex drive had been reduced by a third because of VVA. Women expected that doctors would start a discussion of menopausal symptoms and sexual health, but this was rarely the case (11%). Most women had been treated with a vaginal over-the-counter (OTC) product. Women who had discussed their condition with a physician were more likely (68%) to be under treatment for VVA than those who had not (36%). Low compliance was associated with symptom improvement (23%), not having annoying symptoms (22%), and the impossibility if restoring the vagina to normal (14%). Common reasons for treatment dissatisfaction were related to route of administration or discomfort. Lack of efficacy and fear of a hormone effect were perceived as the main limitations for OTC and local estrogen products, respectively.
*Conclusions:* Despite the commonness of VVA and its significant impact on quality of life, the condition remains underdiagnosed in Italy. Discussion of symptoms with doctors influences the diagnosis, and patients' satisfaction with available treatments is not high.


## 1. Introduction

Vulvar and vaginal atrophy (VVA), also known as Genital Syndrome of Menopause (GSM) [1,2] after a recent broader definition to include its global impact in uro-genital and sexual health, is a chronic and progressive post-menopausal condition associated with the reduction in estrogen levels that approximately affects 50% of all post-menopausal women worldwide [3–8].

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The VVA encompasses a complex cluster of symptoms that may vary according to age, duration of menopause, frequency of sexual intercourse, etc. The poor estrogenization in uro-genital and pelvic tissues mainly results in vaginal dryness, irritation, loss of elasticity, decreased lubrication, dyspareunia, and urinary symptoms [3–8]. Previous European research has shown that the impact of VVA symptoms in post-menopausal women is significant, since a growing percentage of the population is aging and achieving their last menopause period [9]. In addition to its impact on sexual function and relationship with the partner, VVA can have significant influence on many daily living activities as well as in women's quality of life [2,10–12].

As a consequence of the reported patient's embarrassment to ask for advice to healthcare professionals (HCP) [10,12,13], the VVA clinical diagnosis and treatment is still abridged despite the high prevalence and the considerable impact of the problem in post-menopausal women [6,14]. This under-diagnosis turns the disease into a chronic and progressive condition in many cases [15]. Recently, different cross-cultural surveys on the impact of VVA have been conducted on post-menopausal women [14,16–21], suggesting that VVA symptoms have a significant global negative effect on health, satisfaction, and sexual behavior, despite accounting for confounding factors due to population and cultural particularities like those co-existing in Europe [22].

The objective of the present analysis, based on the REal Women's VIews of Treatment Options for Menopausal Vaginal ChangEs-Europe (REVIVE-EU) survey, was to achieve a deeper understanding of the VVA problem knowledge by Italian women after menopause, together with their experiences and needs in terms of sexual and vaginal health, as well as the current nature of their interactions with HCP. This will help to gain better clinical and therapeutic approaches, avoiding the misconceptions and specific regrets on estrogen therapy that usually jeopardize the optimization of VVA management [6,23].

## 2. Methods

Following the same methodology of the original US REVIVE survey, an online interview was conducted in several European countries (Italy, Germany, Spain and United Kingdom) as described previously [24]. In Italy, of a total of 7284 women originally screened, 1000 women with VVA symptoms were included, being demographically representative of all the Italian geographic regions (North-East: 19%, North-West: 34%, Center: 21%, South 18%, Islands: 8%).

The EU REVIVE survey was originally translated and culturally adapted from the US REVIVE version (research agency: Eikon Europe; panel used: Toluna Group), as well as pre-tested in a subsample of 50 participants before the beginning of the study period. The comprehensive online questionnaire was approved by the corresponding accredited institutional review board. The survey participants were informed of the study procedures and gave informed consent to participate. The EU REVIVE survey lasted 35 min and was designed with a margin error of 3.1% at the 95% confidence interval. The invitation to participate was sent to the target population (post-menopausal women with at least one VVA symptom after the onset of menopause) by the panel (selected by age range). Participation was compensated with points that can then be redeemed for vouchers or gadgets (but not for products or money). Participants entered the secure online questionnaire portal and completed the survey between mid-June and mid-July of 2014. Prior to the completion of the questionnaire a three-step screening process was completed (see Fig. 1 for these details in the Italian participants). The information and variables collected from the participants included: knowledge about VVA and menopausal symptomatology, interactions with HCPs with respect to VVA symptomatology, impact of VVA symptoms on sexual life and daily living activities, current or previous use of OTC products prescription treatments for VVA, and patient's attitudes towards treatments.

Eligible patients were those who fulfilled all selection criteria and who had valid data for the considered variables. There was no imputation of missing data. The analysis consisted of a descriptive statistics report summarized by relative frequency distributions for categorical variables of the survey.

**Table 1**
Baseline characteristics of the Italian surveyed population.

| | |
|---|---|
| Women reporting VVA symptoms (n) | 1000 |
| Age (years), n (%) | |
| 45–50 | 99 (9.9) |
| 51–55 | 325 (32.5) |
| 56–60 | 309 (30.9) |
| 61–65 | 186 (18.6) |
| 66–70 | 60 (6.0) |
| 71–75 | 21 (2.1) |
| Marital status, n (%) | |
| Married | 673 (67.3) |
| Divorced | 85 (8.5) |
| Domestic partnership | 71 (7.1) |
| Single | 79 (7.9) |
| Widowed | 52 (5.2) |
| Separated | 40 (4.0) |
| Education/Employment, n (%) | |
| Employed | 430 (43.0) |
| University education or higher[a] | 271 (27.1) |
| Children, n (%) | |
| None | 186 (18.6) |
| One | 287 (28.7) |
| Two | 386 (38.6) |
| Three | 110 (11.0) |
| Four or more | 31 (3.1) |
| Children living at home, n (%) | 544 (67.0) |
| Prior treatment for VVA symptoms, n (%) | 787 (79.0) |
| OTC product | 651 (65.1) |
| Prescription medication | 26 (2.6) |
| Prescription and OTC in combination | 64 (6.4) |
| Current treatment for VVA symptoms, n (%) | 575 (58.0) |
| OTC product | 492 (49.2) |
| Prescription medication | 28 (2.8) |
| Prescription and OTC in combination | 1 (0.01) |

[a] Includes: trade training, degrees and master's degrees; OTC: over the counter.

## 3. Results

### 3.1. Population distribution

The baseline demographics and clinical characteristics of the final sample of 1000 Italian participants are summarized in Table 1. The 50–60 age range was the most represented demographic group in the sample (63%). Among the cohort of participants surveyed (Fig. 1), 442 (44%) had experienced VVA symptoms in the past month. At the beginning of the survey, 575 (58%) of all those included participants with VVA symptoms were receiving VVA treatment.

### 3.2. VVA knowledge and awareness

In Italy, within the cohort of participants that were aware of its VVA condition, this knowledge and information came through active internet searching (40%), newspaper/journal paper reading (21%), talks with family or friends (20%), and direct discussions with their HCP/pharmacist (17%). In the overall sample, 21% of the Italian participants had been clinically diagnosed with VVA and formally

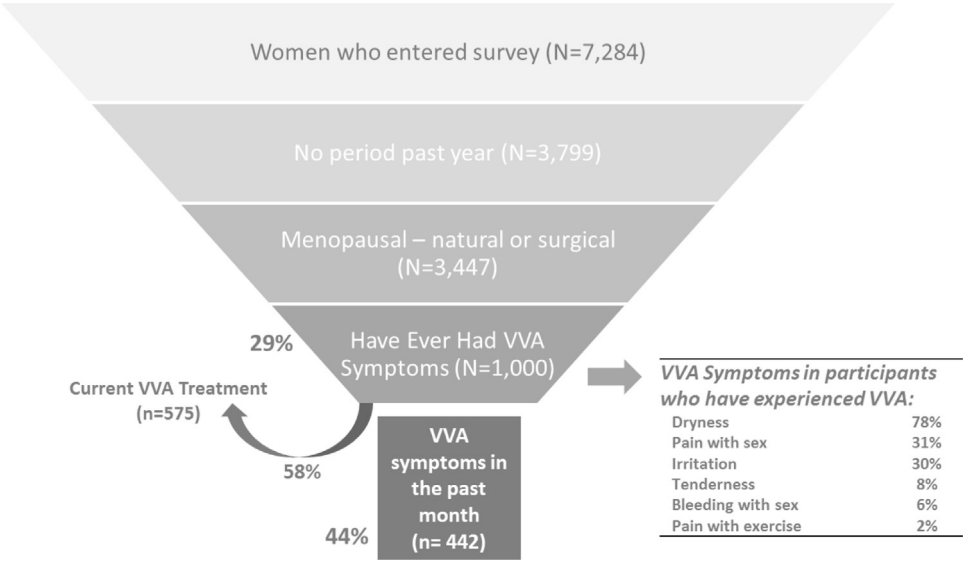


**Fig. 1.** Characteristics of the Italian surveyed participants.

communicated that way by its HCP, although this rate varied geographically reaching almost 30% in the center but less than 14% in the northeast region ($\chi^2$ test, $p < 0.005$).

### 3.3. VVA symptoms and impact on life

The most frequent symptom of the VVA condition in surveyed Italian post-menopausal women at the moment of the inclusion was vaginal dryness (78%), followed by dyspareunia (pain during intercourse) (31%), vaginal irritation (30%) and vaginal/vulvar tenderness (8%), with no significant differences among regions. A retrospective summary of the onset of symptoms associated or linked with VVA is presented in Fig. 2. Most participants (58% or more) reported the onset of symptoms during the post-menopausal period, although it varied considerably across menopause stages depending on the specific symptomatology. Vaginal irritation was the most likely symptom to occur before menopause (16%), while vaginal dryness and tenderness were the most likely symptoms to begin within the first year after menstrual cessation (27% and 26%, respectively). The onset of pain with intercourse occurs across all the menopause and post-menopause period, although it is most common at the exact moment of menopause (28%) or during the subsequent year (23%).

The majority of the cohort acknowledged that at the time of the survey the severity of symptoms was similar or worse than when it first appeared (about 2/3 of cases), with particular reference to pain during intercourse (75%), and without differences among country regions. Pain associated with sex was rated as the most bothersome symptom (76% participants set it as bothersome or extremely bothersome), although all VVA symptoms were rated as quite bothersome. Participants also stated that VVA made them feel aging (45%), uncomfortable (37%), less feminine (16%), frustrated (15%), worried (11%), anxious (11%) and depressed (10%). The most concerning facet on mind reported as a result of VVA symptoms were “losing sexual intimacy” (47%) and “youth” (17%). The higher interference of VVA symptoms was acknowledged by participants on sexual satisfaction (74%), followed by sexual spontaneity (70%), intimacy (69%), and relationship with the partner (66%), respectively (Fig. 3).

Italian participants who have a partner (81%) were cohabitating in 85% of cases. The survey shows that 75% of Italian post-menopausal women with VVA were sexually active during the last year. The analysis showed that the strength of sexual drive was diminished around 33% overall ($\chi^2$ test, $p < 0.01$) as a direct result of VVA symptomatology (30% in women with partner and 49% in women without partner).

### 3.4. Interaction with HCP

Overall, 96% of participants reported visiting a HCP for their main gynecological needs (91% of them having a gynecologist/obstetrician and 17% a general/family practitioner). Over half of HCPs were female physicians (54%). During the last year, 71% of the participants consulted their main HCP, with the higher rate in the south (76%) and the lower in the islands and the north-east region (68%, in both cases). Only 41% of the participants with an HCP for gynecological needs acknowledged that their HCP usually asked about that participant’s sexual activity during routine check-up visits. Two thirds of Italian participants (67%) had discussed VVA symptoms with their physician. Italian women in islands were the participants who less discuss symptoms with their HCP (60%) and those in the north-west the ones who do more (71%). Three quarters (75%) of participants reported that they expect their HCP to specifically ask about menopause-related symptoms, although only 11% of them said that the HCP themselves had initiated the conversation (ranging between 8% in the south and 13% in the north-west region).

The most commonly reported reasons for never discuss VVA symptoms with HCP were beliefs that the condition was a natural part of the aging phenomenon (36%), followed by the statement that symptoms were not bothersome enough to warrant discussion with their HCP (25%) and that they will go away in time (24%). Almost 53% of the participants had received advice/support from their partner about VVA treatment. Usually, depending on the specific symptom, between 62% (vaginal/vulvar dryness) and 76% (tenderness) of participants discussed the problem with a HCP during the first 6 months experiencing it. Italian participants reported overall satisfaction with how HCP handled the first discussion about VVA symptoms (70%), the received information (67%) and the treatment options proposed by the physician (64%).

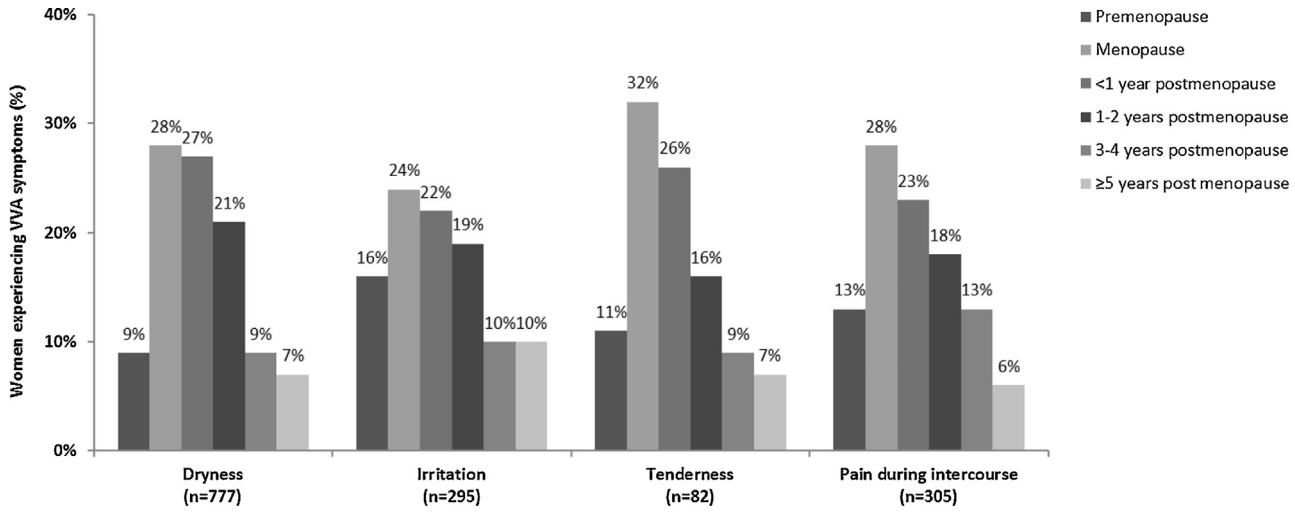


**Fig. 2.** Onset of VVA symptoms in Italian women currently suffering from VVA.

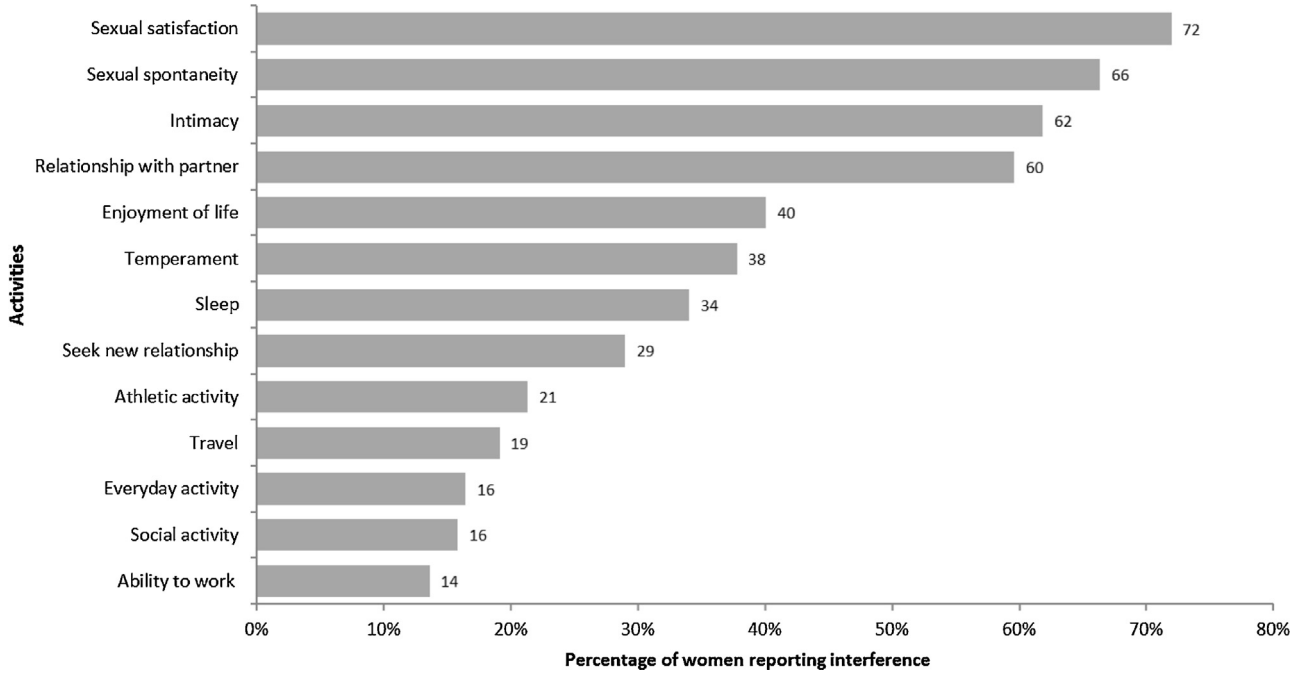


**Fig. 3.** VVA symptom interference with sexual life and other activities in Italy.

### 3.5. Experiences with VVA treatments

Among the total Italian cohort, 58% of participants were currently using a VVA-specific treatment (Fig. 4). The overall incidence of women naïve to any treatment was 21% (lower in the north than in the south regions, $\chi^2$ test, $p < 0.05$) and another 21% had lapsed from their treatment schedule when the survey started. VVA treatments were mainly administered vaginally without prescription (83% of current users, mostly benzocaine and calendula extract), while vaginal prescription therapies were uncommon (3%), and an 8% of participants were using both kinds of products (Fig. 4). Women who have discussed their VVA symptoms with an HCP were more likely to be under current medication (68% vs. 36% for those who had not discussed symptoms), as well as those who have been diagnosed for VVA (94% vs. 75%). Participants started their VVA treatment in different manners: (1) 23% through a HCP prescription and the recommendation of an OTC product to be used together; (2) 15% started using an OTC product through a HCP before receiving specific prescription; (3) 12% began treatment through a HCP prescription without precious OTC recommendation; (4) another 12% started using an OTC product before talking to a HCP.

An overall ratio of 40% of current participants abandoned their medication at some point in the past. The most frequent reasons for this low compliance were the relief from VVA symptoms (23%), not consider symptoms bothersome enough (22%), the belief that symptoms would diminish with time (15%), the inability of treatment to reverse the vaginal changes (14%) and the price of the product (13%). In patients who completed or were currently taking an OTC medication, 60% reported overall satisfaction. By contrast, in patients who completed their local estrogen prescription or who were currently taking it, 51% showed global satisfaction.

Italian participants also expressed their perception on VVA treatment difficulties (Table 2). Users of OTC moisturizers were mainly worried about the impossibility to restore the vagina into

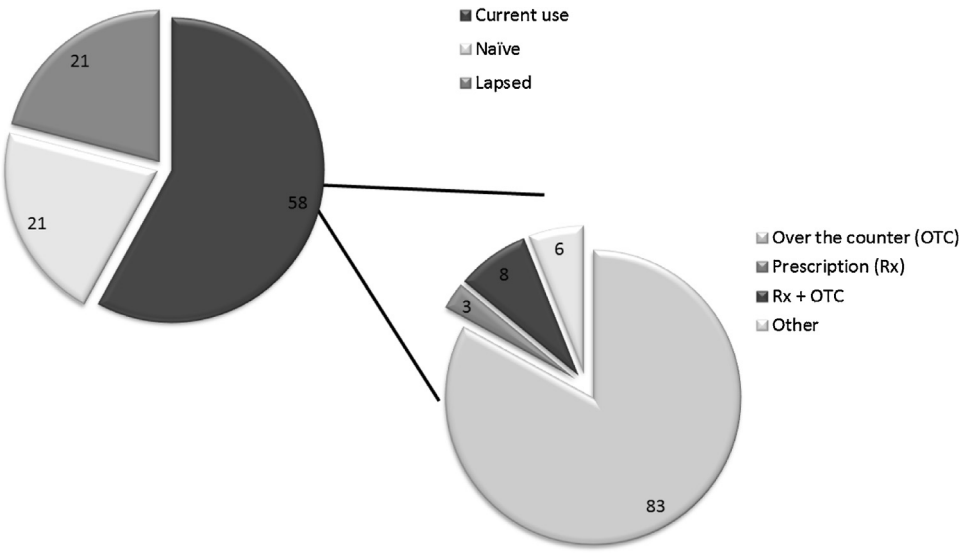


**Fig. 4.** Participant's treatment use.

**Table 2**
Views of VVA therapies in Italian participants currently using treatment.

| | OTC personal vaginal moisturizer (n = 333) | OTC vaginal lubricant (n = 77) | Prescription vaginal product (n = 32) |
|---|---|---|---|
| Issues related to route of administration, n (%) | | | |
| Messy | 36 (10.8) | 8 (10.4) | 4 (12.5) |
| Not discrete | 12 (3.6) | 0 (0.0) | 1 (3.1) |
| Not an oral pill | 24 (7.2) | 3 (3.9) | 2 (6.3) |
| Do not like touching body | 10 (3.0) | 1 (1.3) | 0 (0.0) |
| Issues related to convenience, n (%) | | | |
| Interrupts my daily activities/life | 5 (1.5) | 1 (1.3) | 0 (0.0) |
| Inconvenient to administer | 26 (7.8) | 5 (6.5) | 6 (18.8) |
| Cannot be sexually spontaneous | 45 (13.5) | 5 (6.5) | 1 (3.1) |
| Difficult dosing schedule | 10 (3.0) | 2 (2.6) | 0 (0.0) |
| Procedure of administering treatment | 13 (3.9) | 0 (0.0) | 2 (6.3) |
| Issues related to side effects/safety, n (%) | | | |
| Concern about breast cancer | 15 (4.5) | 1 (1.3) | 9 (28.1) |
| Concern about hormone exposure | 18 (5.4) | 2 (2.6) | 12 (37.5) |
| Concern about long-term use safety | 35 (10.5) | 8 (10.4) | 12 (37.5) |
| Vaginal discharge | 21 (6.3) | 9 (11.7) | 4 (12.5) |
| Concern about other side effects | 30 (9.0) | 4 (5.2) | 11 (34.4) |
| Experienced side effects | 7 (2.1) | 2 (2.6) | 1 (3.1) |
| Partner absorbing estrogen | 9 (2.7) | 1 (1.3) | 3 (9.4) |
| Issues related to efficacy, n (%) | | | |
| Vagina not restored to natural state | 86 (25.8) | 19 (24.7) | 10 (31.3) |
| Not enough relief of symptoms | 36 (10.8) | 4 (5.2) | 1 (3.1) |
| Takes a long time to start working | 25 (7.5) | 7 (9.1) | 3 (6.3) |
| Other, n (%) | | | |
| Expensive | 38 (11.4) | 8 (10.4) | 1 (3.1) |
| Negative impact on intimacy | 12 (3.6) | 1 (1.3) | 1 (3.1) |

its normal conditions (25.8%), but they also had concerns related to its impact on sexual spontaneity (13.5%), the price of the product (11.4%), the limitation on symptom relief (10.8%) and the messy administration (10.8%). Participants that used OTC lubricants were mostly worried by the limitations of the product in restoring the natural state of the vagina (24.7%), the side effects of vaginal discharge (11.7%), its messiness (10.4%), its cost (10.4%) and the safety of a long-term use (10.4%). Finally, women that were taking VVA prescription products were most worried about safety issues including the long-term safety (37.5%), hormone exposure (37.5%), other side effects (34.4%) and breast cancer risks (28.1%), as well as with the ability of the product to restore the vagina to its natural condition (31.3%).

## 4. Discussion

The post-hoc analysis of the Italian branch of 1000 post-menopausal women with recognizable VVA symptomatology included in the European version of the REVIVE study – the largest survey of this nature to date (n = 3768) – highlighted the still significant lack of awareness of the VVA condition by subjects in Italy and the consequences for its effective clinical and therapeutic management. A previous analysis of the REVIVE survey has detected significant socio-cultural barriers in Europe for the exact VVA impact in relation with post-menopausal women's sexual satisfaction and spontaneity, as well as with their interaction with HCP's [22]. These observations tally other previous evidence about the fact that female sexual dysfunctions occur along a continuum from dissatisfaction to complete dysfunction linked with socio-

cultural factors that may modulate the expression and complaining modalities [20,25]. Significantly, this health variation occurs not only at a country level, but also at a regional level with significant cultural or social differences like those existing for Italian regions more central-European driven in the north and others more Mediterranean driven in the south [26].

As previously reported in other backgrounds, the role of vaginal dryness as one of the most significant VVA symptoms associated with menopause has been proved also here in Italian postmenopausal women [10,14,21,24]. Symptoms generally appeared early after the onset of menopause and usually did not resolve over time or even worsened, even for Italian women that expressed higher treatment satisfaction than other European countries as evidenced by the overall EU REVIVE survey [21,24]. The fact that only 1/5 of the surveyed women in Italy were formally diagnosed with VVA and that usually they last for more than six months to discuss symptoms with a HCP, evidenced that VVA is still underrecognized in this country. This occurs in spite of being directly associated with extreme burden and with progressive bothersome symptomatology like pain during sexual intercourse and vaginal discomfort that extremely compromises sexual pleasure and spontaneity [12,14,20,27]. The trend towards an underdiagnose was also depicted recently in Italy by the AGATA study group under the more wide perspective of the GSM condition [28]. In fact, although ¾ of post-menopausal Italian women in our survey have acknowledged being sexually active, our results showed that, after VVA symptoms manifestation, sexual drive fall down a percentage of 30% in women with partner and almost a 50% in those without partner. This observation is likely related mainly with the reduction of sexual satisfaction through aging also reported in Italy [29], as well as with the demonstrated association of sexual function in Italian women with occurrence of pain during sex and with symptoms after sexual intercourse [30].

The European REVIVE survey has indicated that the effective discussion of symptoms and communication with an HCP has a significant impact both on the incidence of the diagnosis of VVA and the therapeutic approach. This pattern has been also observed specifically for the Italian post-menopausal women. In this sense, the data in Italy proves that women who have consulted a gynecologist discuss more easily VVA and menopausal symptoms, and start sooner a medical treatment. Concretely, in this country, among participants who have discussed their VVA symptoms with physicians, the percentage of women under treatment almost double that observed on those who did not discuss symptoms. Furthermore, although 2/3 of Italian participants acknowledged that have discussed VVA with their HCP, they still expect their HCP to initiate proactive discussion on symptoms (75%), a fact that very rarely happens (only one in ten cases, a similar rate than for the overall EU REVIVE survey). Despite these observations prove the need for an improved awareness by HCPs regarding VVA and its impact, both the percentage of women who discuss symptoms with an HCP and the percentage of symptomatic participants formally diagnosed are higher for Italian post-menopausal women that for the overall EU REVIVE cohort [24]. This is in agreement with previous results of the CLOSER survey, which also showed significantly higher worries in Southern European postmenopausal women with long-term vaginal discomfort and its impact on their sexual relationships [20].

Regarding the therapeutic management of VVA in Italy, VVA treatments were administered mainly vaginally without prescription (OTC), although the efficacy and safety of minimally absorbed local vaginal estrogen as VVA therapy has been extensively proven [31,32]. Italy is one of the European countries studied with higher rate of current users since only an overall 1/5 of Italian participants remained naïve to any treatment (32% in EU REVIVE) and 2/5 has left it at least once previously (23% in EU REVIVE). Main reasons that explain why women have had still a relatively low level of compliance with vaginal treatments were the result of a complex spectrum of cultural elements (perception of improvement and of not enough annoying symptoms) and skeptical views on the reversibility of vaginal changes [22]. In Italy, effectiveness was perceived as the main limitation for OTC products while for local estrogen was the fear of hormone effect. For all therapeutic options the most frequent reason for dissatisfaction was related to the route of administration or discomfort [22].

The main limitations of this analysis are a direct consequence of the original survey nature, mainly the fact that data came from an electronically self-reported questionnaire that could be affected from recall bias effect and from respondent bias when reporting subjective symptoms. On the other side, the overall Italian sample included in the REVIVE survey represents the largest one never included before about VVA symptomatology, being representative of the current age stratification of the Italian postmenopausal women population, as well as of the condition and its management in different regions in Italy with very diverse culture in terms of sexual health [29].

Our results demonstrated that, despite the commonness of VVA symptoms after menopause and its significant impact on quality of life and sexual enjoyment, this condition remains underdiagnosed and undertreated in Italy. Discussion of symptoms with a doctor has a significant impact on the incidence of VVA diagnosis, while the rate of dissatisfaction with currently available treatments remains relatively important. To effectively promote a change of behavior and of VVA perception in Italian women, both policy-makers and clinicians should consider the way to solve the dispute between expectations and experiences with treatments [33], together with a balanced educational program for patients about real risk-benefit profile of the currently available products.

## Contributors

REN and MP designed the study.
REN, MP, NB, AC, CDC, SL and AMP developed the methodology.
REN, NB, AC, CDC, SL and AMP supervised the collection of data managed by a third party.
MP performed the analysis.
REN wrote the manuscript.
MP, NB, AC, CDC, SL and AMP critically revised the manuscript.
All authors gave final approval of the version to be published.

## Conflict of interest

Rossella E. Nappi had a financial relationship (lecturer, member of advisory boards and/or consultant) with Bayer HealthCare AG, Boehringer Ingelheim, Ely Lilly, Endoceutics, Gedeon Richter, HRA Pharma, Merck Sharpe & Dohme, Novo Nordisk, Pfizer Inc., Procter & Gamble Co., Shionogi Limited and TEVA Women's Health Inc.

Martire Particco is an employee of Shionogi Italy.

Nicoletta Biglia had a financial relationship (lecturer, member of advisory boards and/or consultant) with Gedeon Richter, Shionogi Limited and Italfarmaco.

Costantino Di Carlo had a financial relationship (lecturer, member of advisory boards and/or consultant) with Bayer HealthCare AG, Gedeon Richter, HRA Pharma, Merck Sharpe & Dohme, Shionogi Limited and TEVA Women's Health Inc.

Angelo Cagnacci, Stefano Luisi and Anna Maria Paoletti declare no conflict of interest.

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## Ethical approval

The comprehensive online questionnaire was approved by the corresponding accredited institutional review boards at the respective institutions (University of Pavia, University of Torino School of Medicine, University of Modena, University of Naples Federico II, University of Siena and University Hospital of Cagliari). All survey participants were appropriately informed of the nature of the study and gave informed consent to participate before completing the online questionnaire.

## Provenance and peer review

This article has undergone peer review.

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