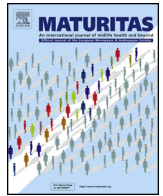




Contents lists available at ScienceDirect

Maturitas

journal homepage: www.elsevier.com/locate/maturitas



Vaginal atrophy of women in postmenopause. Results from a multicentric observational study: The AGATA study

F. Palma^{a,*}, A. Volpe^a, P. Villa^b, A. Cagnacci^{a,*}, as the writing group of the AGATA study¹

^a Obstetrics and Gynecology, University of Modena and Reggio Emilia, Italy

^b Obstetrics and Gynecology, Policlinico Gemelli of Rome, Italy

ARTICLE INFO

Article history:

Received 5 May 2015

Received in revised form 19 August 2015

Accepted 11 September 2015

Available online xxx

Keywords:

Genitourinary syndrome of menopause (GSM)

Postmenopausal women

Vaginal atrophy

Hormone therapy

Vaginal therapy

ABSTRACT

Objectives: Prevalence of vulvar-vaginal atrophy (VVA) has been always investigated by phone or web interview without any objective evaluation. Objective signs associated with symptoms of VVA are now termed genitourinary syndrome of menopause (GSM). This multi-centric study was performed in order to provide nation-wide data on the prevalence and management of GSM.

Methods: Nine hundred thirteen females, 59.3 ± 7.4 years old asking for a routine gynecological examination were recruited. Diagnosis of GSM was based on patient sensation of vaginal dryness, any objective sign of VVA and a pH > 5.

Results: A 722/913 (79.1%) women were diagnosed with GSM with a prevalence ranging from 64.7% to 84.2%, starting from 1 to 6 years after menopause. Sedentary women were at higher risk of GSM (OR 1.8, 95% CI: 1.3–2.5; $p = 0.0005$). Recent vaginal infection was more likely in women with GSM (OR 2.48, 95% CI: 1.33–4.62; $p = 0.0041$). Symptoms reported by women with GSM were vaginal dryness (100%), dyspareunia (77.6%), burning (56.9%), itching (56.6%) and dysuria (36.1%). Signs detected by gynecologists were mucosal dryness (99%), thinning of vaginal rugae (92.1%), pallor of the mucosa (90.7%), mucosal fragility (71.9%) and petechiae (46.7%). Only 274 (30%) of women had had a previous diagnosis of VVA/GSM. These were treated either with no therapy (9.8%), systemic hormone (9.2%), local hormone (44.5%) or local non-hormonal (36.5%) therapy. At the time of our investigation 266 of them (97.1%) still had the disorder.

Conclusions: GSM is a common, under-diagnosed and under-treated disorder. Measures to improve its early detection and its appropriate management are needed.

© 2015 Published by Elsevier Ireland Ltd.

1. Introduction

Vulvar and vaginal atrophy (VVA), resulting from the loss of estrogen stimulation, is characterized by thinning of the epithelial lining of the vagina and lower genitourinary tract, by loss of vaginal

elasticity, by vaginal dryness and by an increase of vaginal pH [1]. VVA is associated with a constellation of symptoms, such as vaginal dryness, burning and irritation, lack of lubrication, dyspareunia (pain at intercourse), dysuria, and urinary urgency that may affect daily activities, sexuality, relationships, and quality of life [1,2]. In 2012, an expert panel termed VVA with its associated symptoms, genitourinary syndrome of menopause (GSM) [3].

In contrast to vasomotor symptoms that often diminish over time, GSM is unlikely to resolve spontaneously, and if not treated, it often progresses [2]. Due to increasing longevity, women may now suffer from GSM for over one-third of their life [4,5]. The choice of a therapy depends on symptoms severity, on treatment effectiveness and safety, and on patient preference [2]. First-line therapies include vaginal moisturizers, continued sexual activity, and lubricants [2,6–9]. Estrogen therapy, either vaginal, in low doses, or systemic, remains the therapeutic standard for symptomatic women who suffer from moderate to severe GSM, and for

* Corresponding author at: Ginecologia e Ostetricia, Azienda Policlinico di, Modena, Via del Pozzo 71, 41124 Modena, Italy.

E-mail address: cagnacci@unimore.it (A. Cagnacci).

¹ Participants to the Atrophy of the vagina in woman in post-menopause in Italy (AGATA) study for the Italian Society for the Menopause (SIM): M. Bongiolotti (Gallarate); L. Cipolla (Milano); R. Chionna (Milano); G.M. Donvito (Peschiera del Garda); M. Bertezolo (Conegliano Veneto); C. Schrettenbrunner, S. Messini (Bolzano); A. Carrone, L. Riganelli, P. Benedetti-Panici (Roma); R. Lorefice (Chieti-Lanciano); M. Torella (Napoli); A. Chiacchio (Lagonegro); F. Zullo (Catanzaro); A. Cianci (Catania); R. Daguati, I. Bainsi (Milano); P. Villa, C. Moruzzi, L. Vacca, E. Tempestilli (Roma); C. Demetrio (Ferrara); A. Cagnacci, F. Palma, C. Romani (Modena); A. Becorpi (Firenze); N. Surico (Novara); C. Di Carlo (Napoli); P.G. Zampi (Brescia); M. Ciammella (Milano); A. Gambera (Brescia).

those who do not sufficiently improve with the use of lubricants or moisturizers [2,7].

Few surveys have tried to provide insights on issues related to VVA, now termed GSM [10–14]. The Revealing Vaginal Effects At MidLife (REVEAL) study, was conducted in the United States and consisted in a telephone survey of 1006 postmenopausal women, combined with a 10-min online survey of 602 health care providers [10]. The Vaginal Health: Insights, Views, & Attitudes (VIVA) study, was an online survey of 500 postmenopausal women from each of the following 7 countries: United States, Great Britain, Canada, Sweden, Denmark, and Finland, and Norway [11]. The Healthy Women was an online survey of 1043 postmenopausal women conducted in the United States [12]. The REVIVE (Real Women's Views of Treatment Options for Menopausal Vaginal ChangEs), was an online survey of 3046 participants, conducted in the United States [13], and the CLOSER (Clarifying Vaginal Atrophy's Impact on Sex and Relationships), was an online survey of postmenopausal women with VVA symptoms and of their partners, that was conducted in nine countries (United Kingdom, Finland, Norway, Sweden, Denmark, Italy, France, Canada, and the United States) [14]. All these surveys were based on an online interview without any clinical evaluation. All surveys concluded that, despite the prevalence and associated burden, VVA is often inadequately identified or addressed in medical practice.

The aim of this multi-centric study is to provide nation-wide data on the prevalence and management of GSM. GSM diagnosis is performed both on symptom perception and objective genital evaluation.

2. Methods

The AGATA survey is a multicentre observational study conducted between December 2013 and March 2014 in 22 Italian gynecological centres (13 in the north, 4 in the centre, and 5 in the south of Italy).

Eligible participants were all Italian women in post-menopause, defined as the presence of amenorrhea for at least 12 months, who consulted an outpatient gynecological service for a routine gynecological examination. Among eligible women, only those who signed an informed consent were enrolled into the study. The ethics committee of all the involved centres approved the study, and no financial incentive was offered to any of the participants.

Each woman underwent a medical interview where basic demographic information, personal and family history, and comorbidities were collected. Presence of subjective symptoms of VVA/GSM was recorded and an experienced gynecologist performed an objective evaluation of the vagina. Subjective symptoms considered were: vaginal dryness, itching, burning, dysuria and dyspareunia. Objective signs taken into considerations were: thinning of vaginal rugae, mucosal dryness, pallor of the mucosa, mucosal fragility and presence of petechiae. Both objective and subjective symptoms were scored in a 0–3 scale with 0 = absent; 1 = slight; 2 = moderate; 3 = severe.

2.1. The coexistence of 3 parameters was necessary in order to perform the diagnosis of GSM

(1) A vaginal pH > 5; (2) the subjective perception of vaginal dryness (of any intensity); (3) one objective sign of VVA/GSM (of any grade). These 3 parameters were selected because: a vaginal pH > 5 is a clear indicator of reduced estrogen stimulus at the vagina [15]; the subjective sensation of vaginal dryness is the symptom most frequently associated with VVA/GSM [16]; the objective signs taken into consideration are those more frequently associated with

VVA/GSM [17]. We considered that the concomitant association of the 3 signs would have furnished a robust indication of VVA/GSM.

Women who reported a previous diagnosis of VVA/GSM were asked to complete an additional questionnaire (questionnaire 1) investigating the eventual use of therapies and their effectiveness. Data were entered into a single database. Descriptive statistic, contingency tables with the chi squared test for comparing prevalence and Student's *t* test for comparing means, were used for statistical analyses.

Risk factors associated with VVA/GSM were evaluated by means of logistic regression analysis, where presence of VVA/GSM was entered as dependent variable, and age, weight, years since menopause, lifestyle (sedentary or not), use of alcohol (yes or no), of smoking (yes or no), previous use (yes or no) of vaginal and systemic therapies for VVA/GSM, were entered as independent variables.

Analyses were performed by the statistical package StatView 5.01 (SAS Institute Inc., Cary, NC). All results are expressed as the means and standard deviations. A *p* value < 0.05 was considered as statistically significant.

2.2. Sample size calculation

On the basis of previous studies [18] we considered the prevalence of VVA of 40.3% (95% confidence interval +3.5%), and calculated that 753 women were necessary to obtain a reliable estimate of VVA.

3. Results

3.1. Full study cohort

Among 927 eligible women, 913 gave their informed consent to participate to the study. Enrolled women had a mean age of 59.3 ± 7.4 years. Their characteristics are presented in Table 1.

Table 1
Baseline characteristics of the population under survey.

Age, year (mean \pm SD)	59.3 \pm 7.4
Weight, kg (mean \pm SD)	68.0 \pm 12.2
Height, cm (mean \pm SD)	161.1 \pm 6.2
Years since menopause, year (mean \pm SD)	10.3 \pm 8.8
Systolic blood pressure (SBP), mmHg (mean \pm SD)	124.9 \pm 12.6
Diastolic blood pressure (DBP), mmHg (mean \pm SD)	78.2 \pm 9.0
Heart rate, bpm (mean \pm SD)	75.1 \pm 7.5
Race/ethnicity, n (%)	
White, non-hispanic	904 (99.0)
Black	0 (0.0)
Hispanic	4 (0.4)
Other	5 (0.6)
Menopausal status, n (%)	
Physiological menopause	761 (83.3)
Surgical menopause	92 (10.1)
Non-physiological menopause	60 (6.6)
Smoking status, n (%)	
Never	583 (63.9)
Former	161 (17.6)
Current	169 (18.5)
Alcohol intake, n (%)	
No	772 (84.6)
Yes	141 (15.4)
Sedentary lifestyle, n (%)	
No	405 (44.4)
Yes	508 (55.6)
Ever used treatment for VVA/GSM, n (%)	
No therapy	666 (73.0)
Local therapy	222 (24.4)
Systemic therapy	25 (2.6)

Download English Version:

<https://daneshyari.com/en/article/8284505>

Download Persian Version:

<https://daneshyari.com/article/8284505>

[Daneshyari.com](https://daneshyari.com)