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ORIGINAL ARTICLE

The LADY study: epidemiological characteristics of prevalent and new genitourinary syndrome of menopause cases in Greece

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ABSTRACT

Objective: The genitourinary syndrome of menopause (GSM) is often underdiagnosed and undertreated despite its significant impact on postmenopausal quality of life. We assessed the prevalence of GSM and associated symptoms in Greek perimenopausal/postmenopausal women attending gynecology clinics.

Methods: Four hundred and fifty women, aged 40–70 years (93.1% postmenopausal), attending three gynecology clinics at university hospitals completed a validated questionnaire and underwent pelvic examination.

Results: GSM was diagnosed in 87.6% of the women at the study visit, whereas only 16% of the overall sample had been previously diagnosed with the condition. Vaginal dryness (72.7%), vulvar burning sensation or itching (58.0%) and dyspareunia (52.7%) were the most prevalent symptoms. Pelvic signs consisted of vaginal dryness (89.1%), loss of vaginal rugae (80.6%) and vulvovaginal pallor (86.9%). However, only 31.3% of the participants had discussed genitourinary symptoms with their health-care professionals (HCPs). Regarding management, only 11.1% of women had prior experience with any form of therapy, and currently only 8.7% were receiving treatment.

Conclusion: GSM is highly prevalent in this Greek perimenopausal/postmenopausal population. Nevertheless, the majority of women remain undiagnosed and untreated. Education for both women and HCPs regarding GSM will lead to improved diagnosis and better management of this syndrome.

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Genitourinary syndrome of menopause; perimenopausal; postmenopausal; vaginal health

Introduction

The genitourinary syndrome of menopause (GSM) is a very common and bothersome consequence of estrogen decline during menopause transition [1,2]. The term vulvovaginal atrophy was long used to describe vaginal changes and complaints around menopause, but ever since the 2014 consensus conference of the International Society for the Study of Women's Sexual Health (ISSWSH) and the board of trustees of the North American Menopause Society (NAMS), the term GSM has been deemed more accurate and socially acceptable than vulvovaginal atrophy. GSM is defined as an ensemble of symptoms that includes vaginal dryness, burning and irritation, lack of lubrication, discomfort or pain during intercourse as well as urinary urgency, dysuria and recurrent urinary tract infections [3]. Nevertheless, there are no exact diagnostic criteria for GSM [4,5].

As women spend almost half of their life after menopause, GSM can significantly affect their quality of life for a considerable amount of time [6]. As we recently reported, more than half of postmenopausal women report at least one GSM-related complaint during their lifetime [7]. Moreover, genitourinary symptoms are chronic and progressive and do not resolve spontaneously [8]. The symptoms of poor vaginal health have been shown to impact functioning, well-being, body image, self-perception and sexual function [9]. Specific attention is warranted for women on treatment for or at risk of breast cancer, and there is a need for an individualized approach [10].

Nonetheless, the hesitation to discuss genitourinary health remains prominent for both patients and health-care professionals (HCPs) [9,11,12]. Only half of symptomatic women seek medical attention for vaginal discomfort, despite the significant influence on sexual function and quality of life [13]. Moreover, a lack of information on treatment options and fear of the consequences of hormonal treatment result in undertreatment [14,15]. The prevalence of genitourinary health at midlife and beyond, and women's understanding of it have been investigated in various countries [15–17], but not in the Eastern Mediterranean area. Therefore, this study estimated the prevalence of GSM and explored treatment awareness and patient–clinician interaction in Greece.

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Methods

Participants were recruited from three gynecology clinics at university hospitals in Greece (two in Athens and one in Thessaloniki). All women attending these clinics between November 2020 and June 2022 for their first routine consultation were invited to participate in the LADY study. The reason for attendance was routine gynecological examination and Pap smear for the majority of women, and consultation about menopause for a minority of the sample. Inclusion criteria were age 40–70 years and a reproductive stage of perimenopause or postmenopause. Perimenopause was defined as the presence of bothersome climacteric symptoms and evidence of irregular periods over the last 12 months. Postmenopause was defined retrospectively after at least 12 months of amenorrhea. GSM was defined as the experience of at least two bothersome symptoms concerning vaginal health or the presence of at least one bothersome symptom and one sign. Four hundred and fifty women agreed to participate, and signed an informed consent form. The protocol was approved by the University Ethics Committee of Aretaieion Hospital, National and Kapodistrian University of Athens (224/18-06-2020).

All participants had a structured face-to-face interview, and their anthropometric and demographic parameters, lifestyle, and personal and reproductive history were documented. Participants had the chance to discuss their gynecological history, and the self-reported presence and severity (absent, mild, moderate, severe) of genitourinary symptoms (vaginal dryness, irritation, burning sensation, pruritus of vulva or vagina, reduced lubrication during sexual activity, dyspareunia, postcoital bleeding, dysuria, urinary urgency/frequency). We also documented whether the woman had had any prior consultation concerning vaginal health, a pre-existing GSM diagnosis and treatment for GSM (currently or previously). All women were then requested to complete a paper version of the Vulvovaginal Symptoms Questionnaire (see later) [18]. Finally, a trained gynecologist assessed the participant clinically for the presence and severity of the following signs: decreased vaginal moisturization/vaginal mucosa dryness, loss of vaginal rugae, vaginal mucosa pallor, decreased elasticity, fragility/fissures/petechiae, loss of hymenal remnants, labia minora atrophy, introital retraction, prominence urethral meatus and urethral prolapse.

Vulvovaginal Symptoms Questionnaire

This written, validated questionnaire quantifies genitourinary complaints in perimenopausal and postmenopausal women. It comprises four distinct scales – namely emotions, life impact, sexual impact and symptoms – and consists of 21 questions in total, which focus on symptoms over the last 7 days. The respondent answers the questions either positively or negatively [18].

Statistical analysis

Statistical analysis was performed using R version 4.2.2. The analysis included all patients who had signed the informed consent form, and for whom an electronic case report form was registered or who had responded to the Vulvovaginal Symptoms Questionnaire.

Descriptive statistics provide an overview of all study data. Categorical variables are reported as absolute and relative frequencies, while continuous variables are reported as means with the standard deviation. All tests for significance are two-sided with $\alpha = 0.05$.

The relationship between demographic and baseline characteristics and the presence of GSM was assessed using the χ^2 statistical test with continuity correction for categorical variables and the independent-samples *t*-test for continuous variables. The main analysis focused on the investigation of independent factors affecting GSM symptoms (vaginal dryness, irritation, burning sensation, pruritus of the vulva or vagina, reduced lubrication during sexual activity, dyspareunia, bleeding after intercourse and dysuria). A multivariate logistic regression model was used for each symptom. The dependent variable of each model was the severity of each symptom (classified as absent/mild versus moderate/severe). The parameters tested for inclusion in the model were age, educational level (none or primary, secondary, or higher, tertiary or postgraduate), area of permanent residence (urban, rural), marital status (single, married, divorced/widowed), employment status (unemployed/household, working, retired), body mass index (BMI), smoking status (non-smoker, current/ex-smoker), alcohol consumption (none, low, moderate/high), age of menarche, age of menopause, number of pregnancies, number of abortions, osteoporosis treatment (yes, no), treatment for thyroid disease (yes, no), treatment for cardiovascular disease (yes, no) and statin treatment (yes, no). The selection of the final independent variables for each model was based on the Akaike information criterion and a backward selection procedure with a threshold of 0.05. The magnitude of association between the independent variables and each GSM symptom is expressed as an odds ratio (OR) with 95% confidence interval (CI) and standard error.

Results

Study population

The demographic characteristics of the study population are presented in Table 1 and details of their gynecological history are presented in Supplementary Table 1a. The mean (standard deviation) age of participants was 58.25 (6.8) years and the majority (93.11%) were postmenopausal. Most of the women resided in an urban area (88.7%) and were married (76.0%). Thirty-eight percent had a secondary level of education and 51% had a higher or tertiary level. Almost half (46.0%) of the study population was working. The mean scores of the Vulvovaginal Symptoms Questionnaire are presented in Supplementary Table 1b.

Prevalence of GSM

Of the 450 participants, 394 were diagnosed with GSM at the study visit, corresponding to a prevalence of 87.56%. The prevalence of individual GSM-related symptoms is presented in Figure 1. The most commonly reported symptoms were vaginal dryness (72.67%) and reduced lubrication during sexual activity (64%). Irritation, burning sensation, pruritus of

vulva or vagina, dyspareunia and urinary urgency/frequency were present in more than half of the women (58.0%, 52.7% and 51.6% respectively).

Table 1. Characteristics of the population of the LADY study ($N = 450$).

Characteristic	*Value*
Mean (SD) age (years)	58.25 (6.8) (range 40–70)
Mean (SD) BMI (kg/m^2)	27.3 (4.9) (range 17.7–46.7)
Educational level, *n* (%)	
None/primary education	52 (11.55%)
Secondary education	169 (37.56%)
Higher education/tertiary education/ postgraduate	229 (50.88%)
Area of permanent residence, *n* (%)	
Urban	399 (88.67%)
Rural	51 (11.33%)
Marital status, *n* (%)	
Single	34 (7.56%)
Married	342 (76.00%)
Divorced	41 (9.11%)
Widowed	33 (7.33%)
Race, *n* (%)	
White	448 (99.56%)
Other	2 (0.44%)
Employment status, *n* (%)	
Working	207 (46.00%)
Unemployed/household	106 (23.55%)
Retired	137 (30.44%)
Cigarette use, *n* (%)	
Non-smoker	293 (65.11%)
Current smoker	115 (25.56%)
Ex-smoker	42 (9.33%)
Alcohol consumption, *n* (%)	
None	306 (68.00%)
Low	132 (29.33%)
Moderate	11 (2.44%)
High	1 (0.22%)
Medical history of other disease(s)[a], *n* (%)	
Yes	331 (73.56%)
No	119 (26.44%)

[a]Includes osteoporosis (11.8%), breast cancer (4.4%), thyroid disease (26.0%), cardiovascular disease (29.8%), thromboembolism (2.4%), dyslipidemia (36.7%) or other chronic disease (30.4%).
BMI, body mass index; SD, standard deviation.

The severity of GSM-related symptoms is described in Supplementary Table 2. Mild vaginal dryness was present in 31.33%, moderate in 27.11% and severe in 14.22%. Similarly, mild and moderate reduced lubrication during sexual activity was reported by 29.33% and 21.56% of the women, respectively, while 14.22% experienced severe reduced lubrication.

The prevalence of GSM clinical signs is presented in Table 2**.** The vast majority of participants presented decreased vaginal moisturization/vaginal mucosa dryness (89.09%), loss of vaginal rugae (80.62%) and vaginal mucosa pallor (86.86%). Decreased elasticity, loss of hymenal remnants and labia minora atrophy were present in more than half of the study population. The severity of GSM clinical signs is presented in Supplementary Table 3.

Awareness and treatment of GSM

Of the 394 patients who were diagnosed with GSM at the study visit, only 72 had been previously given a diagnosis for the condition, corresponding to 18.3% of the sample. Of the overall sample, 68% had never had a discussion about GSM-related symptoms with a HCP despite that fact that 60.4% reported that these symptoms seriously affected their quality of life.

Only 8.7% of the overall sample were currently receiving at least one treatment for GSM, with over-the-counter (OTC) products (i.e. vaginal lubricants and moisturizers) being the most popular. Fifty women (11.1%) had tried at least one treatment in the past but had discontinued therapy. OTC products were again the most frequently used (by 68% of those who had received past treatment), while topical estrogens had been prescribed to only 18% of the women who had previously received treatment (Figure 2). The main reason for discontinuation of all treatment options was the perception of a lack of effectiveness (Table 3).

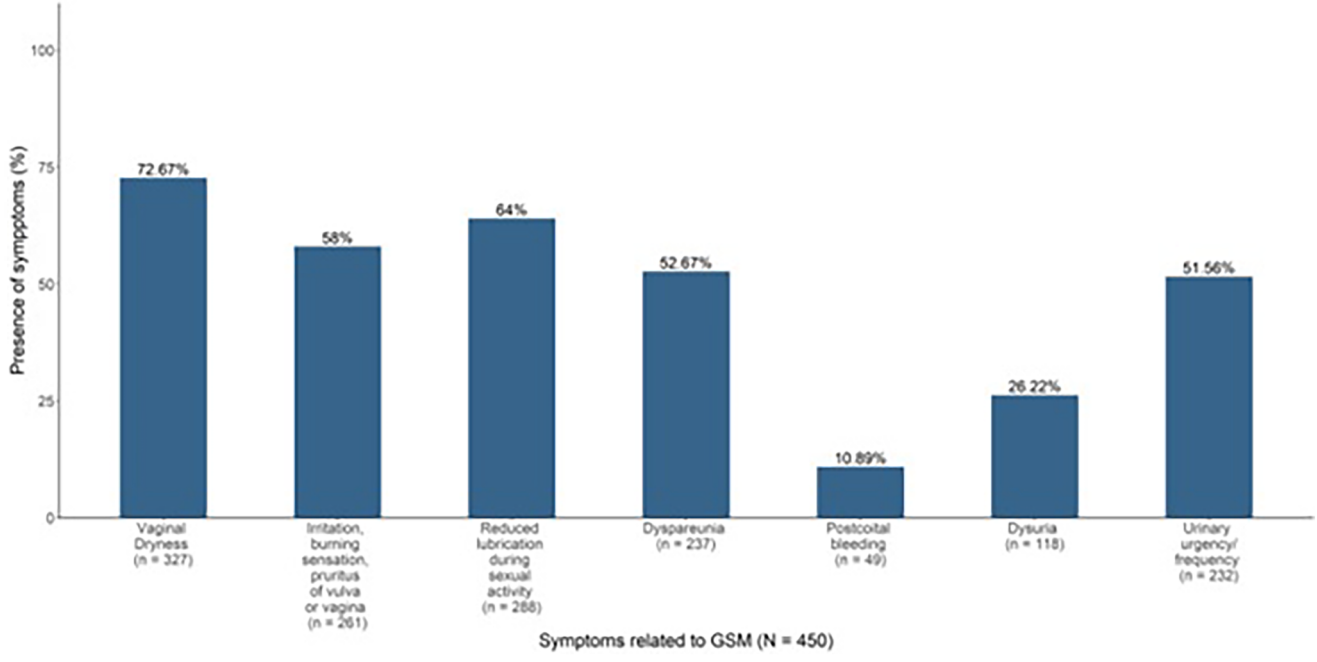

Figure 1. Prevalence of symptoms related to genitourinary syndrome of menopause (GSM) in 450 perimenopausal and postmenopausal women routinely attending gynecology clinics in Greece.

Factors associated with GSM

Older age, higher BMI and postmenopausal status were strongly associated with the presence of GSM (Table 4). Women on treatment for cardiovascular disease had an increased risk of vaginal dryness (OR 1.7; 95% CI 1.077, 2.683; $p=0.022$). Women receiving statins were at a lower risk of experiencing vaginal dryness (OR 0.593; 95% CI 0.379, 0.928; $p=0.022$). Irritation, burning sensation and pruritus of the vulva or the vagina were associated with higher BMI (OR 1.044; 95% CI 1.001, 1.088; $p=0.043$). The number of pregnancies appeared to be significantly related to urinary symptoms such as dysuria (OR 1.169; 95% CI 1.013, 1.349; $p=0.032$) and urinary frequency/urgency (OR 1.223; 95% CI 1.089, 1.374; $p<0.001$) (Table 5).

Discussion

The LADY study is the first to assess the prevalence of GSM in the Greek middle-aged population. We found that GSM is highly prevalent in Greek perimenopausal and postmenopausal women, affecting around 88% of the assessed population. The most common symptoms were vaginal dryness, reduced lubrication during sexual activity and vulvar burning or irritation, followed by dyspareunia. The most common signs were vaginal dryness and vulvovaginal pallor. Despite the fact that women reported that these symptoms were important for their quality of life, only 32.0% had discussed their concerns with their HCP and only 11.1% had previously used some form of treatment.

Table 2. Clinical signs of GSM at gynecological examination ($N=450$).

Clinical sign	n *(%)*
Decreased vaginal moisturization/vaginal mucosa dryness, *n* (%)	400 (89.09%)
Loss of vaginal rugae, *n* (%)	362 (80.62%)
Vaginal mucosa pallor, *n* (%)	390 (86.86%)
Decreased elasticity, *n* (%)	287 (63.92%)
Fragility/fissures/petechiae, *n* (%)	219 (48.78%)
Loss of hymenal remnants, *n* (%)	256 (57.02%)
Labia minora atrophy, *n* (%)	248 (55.23%)
Introital retraction, *n* (%)	168 (37.42%)
Prominence urethral meatus, *n* (%)	75 (16.70%)
Urethral prolapse, *n* (%)	55 (12.25%)

GSM, genitourinary syndrome of menopause.

A direct comparison of the prevalence rates of GSM across studies is hindered by differences in the definition of GSM. Our results are comparable to the Spanish GENISSE study, where 70% of the population presented with GSM. The GENISSE study defined GSM as the presence of at least two symptoms or one symptom and one sign [9]. A recent study from Thailand reported a prevalence rate of 87.2% when GSM was defined as the presence of at least one genitourinary symptom [19]. In the Italian AGATA study, women were diagnosed with GSM if they reported vaginal dryness, had any objective sign and had vaginal pH > 5. GSM affected 79% of these Italian participants (average age 60 years) [20]. A prevalence of GSM of almost 98.27% was recently described in a large sample of Chinese women, aged on average 50 years [21]. In a study of Turkish women, 71.5% of participants (aged 43–75 years) were affected by GSM, which was defined as the presence of both urinary and vaginal symptoms or at least one vaginal symptom, and after exclusion of urogenital pathologies [22]. Studies which assessed GSM based on self-reported symptoms have reported a prevalence of 40–60% [11,15,16,23,24]. These disparities between studies highlight the need for uniform and reliable techniques and diagnostic criteria.

A surprisingly high number of women were newly diagnosed with GSM at the study visit, the vast majority of whom had never previously been assessed for or questioned about

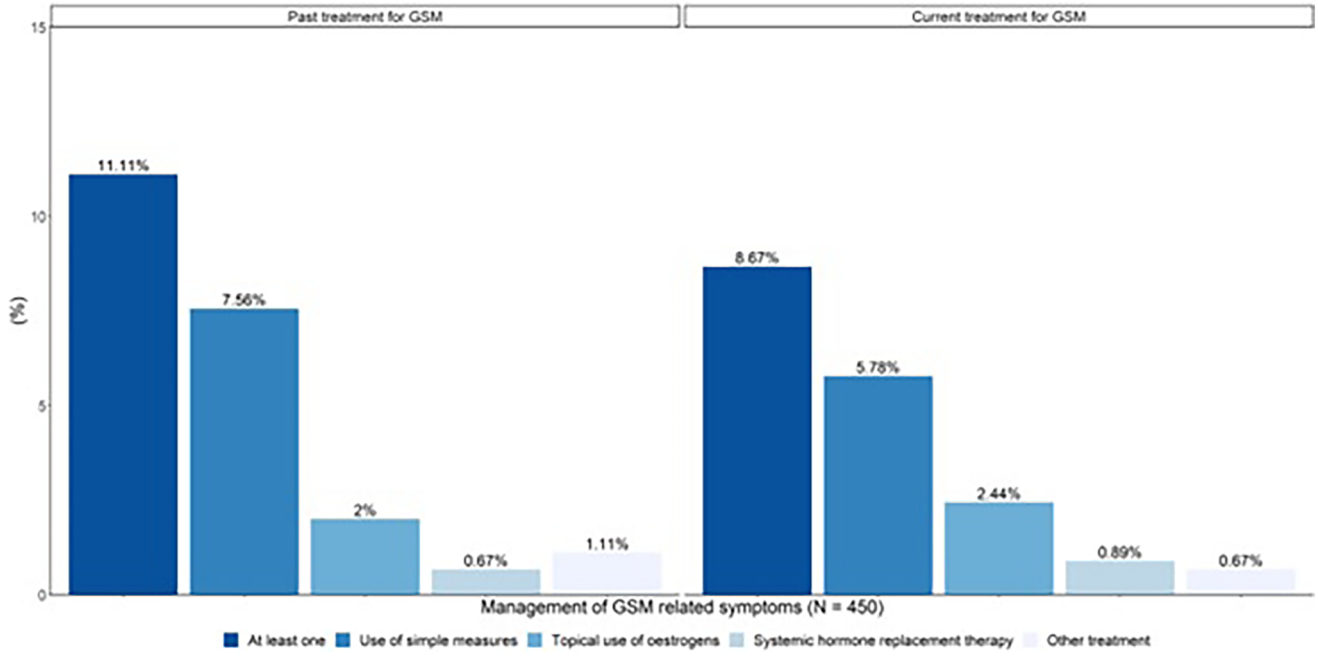

Figure 2. Previous and current treatment of symptoms related to genitourinary syndrome of menopause (GSM) in 450 perimenopausal and postmenopausal women routinely attending gynecology clinics in Greece.

Table 3. Previous and current treatment of GSM-related symptoms ($N = 450$).

Treatment	n *(%)*
Patients who had used at least one treatment for GSM in the past	50 (11.11%)
Use of simple measures (e.g. vaginal lubricants, moisturizers)[a]	34 (7.56%)
Reason for therapy cessation[b]	
Ineffectiveness	22 (4.89%)
Cost	3 (0.67%)
Adverse effects	2 (0.44%)
Other	8 (1.78%)
Topical use of estrogens (e.g. suppositories, gel)	9 (2.00%)
Reason for therapy cessation	
Ineffectiveness	5 (1.11%)
Adverse effects	2 (0.44%)
Other	2 (0.44%)
Systemic hormone replacement therapy	3 (0.67%)
Reason for therapy cessation	
Adverse effects	1 (0.22%)
Comorbidities	1 (0.22%)
Other	1 (0.22%)
Other treatment	5 (1.11%)
Reason for therapy cessation	
Ineffectiveness	2 (0.44%)
Other	3 (0.67%)
Patients currently receiving at least one treatment for GSM	39 (8.67%)
Use of simple measures (e.g. vaginal lubricants, moisturizers)[c]	26 (5.78%)
Topical use of estrogens (e.g. suppositories, gel)	11 (2.44%)
Systemic hormone replacement therapy	4 (0.89%)
Other treatment	3 (0.67%)

[a]Previous treatments are not mutually exclusive categories.
[b]Different reasons for therapy cessation are not mutually exclusive categories.
[c]Current treatments are not mutually exclusive categories.
GSM, genitourinary syndrome of menopause.

Table 4. Comparison of demographic and anthropometric characteristics according to GSM diagnosis.

Characteristic	*GSM*		p-*Value*
	Yes (n = *394*)	*No* (n = *56*)	
Mean (SD) age (years)	58.70 (6.45)	55.13 (8.09)	**0.001**
Educational level, *n* (%)			0.083
None/primary education	46 (11.68%)	6 (10.71%)	
Secondary education	155 (39.34%)	14 (25.00%)	
Higher education/ tertiary education/ postgraduate	193 (48.98%)	36 (64.29%)	
Area of permanent residence, *n* (%)			0.050
Urban	345 (87.56%)	54 (96.43%)	
Rural	49 (12.44%)	2 (3.57%)	
Marital status, *n* (%)			0.073
Single	26 (6.60%)	8 (14.29%)	
Married	306 (77.66%)	36 (64.29%)	
Divorced	33 (8.38%)	8 (14.29%)	
Widowed	29 (7.36%)	4 (7.14%)	
Race, *n* (%)			>0.9
White	392 (99.49%)	56 (100%)	
Other/mixed	2 (0.51%)	0 (0.00%)	
Professional status, *n* (%)			0.085
Working	174 (44.16%)	33 (58.93%)	
Unemployed/ household	98 (24.87%)	8 (14.29%)	
Retired	122 (30.96%)	15 (26.79%)	
Mean (SD) BMI (kg/m^2)	27.44 (4.7)	26.30 (5.6)	**0.018**
Final menstrual period, *n* (%)			**0.002**
Less than 12 months ago	21 (5.33%)	10 (17.86%)	
More than 12 months ago	373 (94.67%)	46 (82.14%)	

BMI, body mass index; GSM, genitourinary syndrome of menopause; SD, standard deviation. Bold indicates statistical significance which was set at the level of p-value < 0.05.

genitourinary health. According to the EMPOWER study from the USA, most women diagnosed with GSM are hesitant to talk about vulvovaginal discomfort with their HCP. The primary reasons for this reluctance were the belief that these symptoms are a natural part of menopause, that they are not worth reporting during a consultation and that women feel embarrassed and uneasy to talk about them [16]. Earlier studies from Finland and Scandinavia showed that women from these countries were more comfortable discussing GSM-related symptoms, and were more aware of the condition and available treatments than were participants from the UK, the USA and Canada [15,25]. Gynecological issues appear taboo for many Asian women, whereas in Latin America the majority of women feel comfortable reporting such concerns [17,24]. Despite the hesitation to talk about GSM-related symptoms, women are more inclined to discuss them if their doctor initiates the conversation [4]. These findings should make HCPs aware of their crucial role in bringing sexual health issues to light, in breaking the taboos around vaginal health and in offering women a higher quality of life and better sexual health after menopause [4].

A direct consequence of the low level of awareness of GSM and the related health implications is the fact that, in the present study, only a few of the patients had sought therapeutic options to alleviate their symptoms, reflecting the limited information and discussion of vaginal health. The proportion of women receiving GSM treatment in Greece is at the lower end of the international spectrum. In many international studies, 13–78% of the participants used either OTC or prescription medication [7]. OTC products are the first choice of Greek patients, reflecting the low level of patient and HCP awareness of treatment options [14,24]. Indeed, patients frequently feel they are not made aware of their treatment options and the benefits and risks of hormone therapy [4]. In the EMPOWER study, women with bothersome symptoms reported that they would be inclined to use hormone therapy after being thoroughly educated if their doctor strongly suggested it. Nevertheless, one-third of the interviewees would never consider using hormonal therapies [16].

GSM is a chronic and progressive condition, in contrast to the vasomotor symptoms associated with menopause, which most often subside within 5 years of the final menstrual period [26]. Age and time since menopause are well documented factors associated with the development of GSM. In accordance with our findings, multiple studies have found that the prevalence as well as the number and severity of symptoms increase as age and menopausal status progress [7,9,12].

In terms of modifiable risk factors, BMI is an established risk factor for urinary symptoms [27]. In our study, apart from an association with urinary frequency/urgency, we also found that increased BMI is positively associated with

Table 5. Logistic regression analysis for the presence of independent factors affecting the severity of GSM symptoms (absent/mild vs. moderate/severe).

Factor	*OR*	*SE*	*95% CI*	p-*Value*
Vaginal dryness				
Smoking status				
Never smoked	—	—	—	
Former/current smoker	1.427	0.202	0.960, 2.122	0.078
Treatment for cardiovascular disease				
No	—	—	—	
Yes	1.700	0.232	1.077, 2.683	**0.022**
Statin use				
No	—	—	—	
Yes	0.593	0.227	0.379, 0.928	**0.022**
Irritation, burning sensation, pruritus of the vulva or the vagina				
BMI (kg/m^2)	1.044	0.021	1.001, 1.088	**0.043**
Reduced lubrication during sexual activity				
Smoking status				
Never smoked	—	—	—	
Former/current smoker	1.431	0.202	0.961, 2.130	0.077
Dyspareunia				
Marital status				
Single	—	—	—	
Married	0.858	0.377	0.409, 1.800	0.7
Divorced/ widowed	0.286	0.494	0.108, 0.757	**0.011**
Post-coital bleeding				
Smoking status				
Never smoked	—	—	—	
Former/current smoker	0.278	0.766	0.062, 1.253	0.095
Dysuria				
Age of menarche	1.242	0.111	0.998, 1.545	0.051
Number of pregnancies	1.169	0.073	1.013, 1.349	**0.032**
Treatment for cardiovascular disease				
No	—	—	—	
Yes	2.100	0.241	1.308, 3.372	**0.040**
Urinary frequency/urgency				
BMI (kg/m^2)	1.049	0.023	1.003, 1.097	**0.035**
Employment status				
Working	—	—	—	
Unemployed/ household	2.247	0.272	1.316, 3.837	**0.003**
Retired	0.870	0.281	0.501, 1.511	0.6
Age of menarche	1.229	0.077	1.057, 1.430	**0.007**
Number of pregnancies	1.223	0.059	1.089, 1.374	**<0.001**

BMI, body mass index; CI, confidence interval; GSM, genitourinary syndrome of menopause; OR, odds ratio; SE, standard error. Bold indicates statistical significance which was set at the level of p-value < 0.05.

irritation, burning sensation and pruritus of the vulva or the vagina. We observed an interesting association between the severity of vaginal dryness and active treatment for cardiovascular disease. The effects of vaginal health on cardiovascular health are a matter of great debate [28]. In particular, poor sexual function has been reported in women with cardiovascular or coronary heart disease, but the evidence is still sparse [29]. However, we could not explore this association further as details of cardiovascular health were outside the scope of the study.

Our study has certain other limitations as well. The study sample comprised outpatients of gynecology clinics in university hospitals, and therefore might not reflect the general postmenopausal population. In addition, the cross-sectional design does not allow the detection of causality. Finally, our study did not exclude women with surgical menopause, which has been shown to affect the development of GSM.

In conclusion, our study highlights that GSM is a highly prevalent condition that remains an uncomfortable and neglected topic for many women. Ignorance and embarrassment lead to underdiagnosis and undertreatment. It is the role of HCPs to focus on urogenital health, and to inform and counsel patients to combat undertreatment and misinformation.

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Data availability statement

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

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