



Original article

Evaluation of the impact, treatment patterns, and patient and physician perceptions of vasomotor symptoms associated with menopause in Europe and the United States

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ABSTRACT

Objectives: This study elicited the views of physicians and patients with vasomotor symptoms (VMS) associated with menopause on the impact of VMS and treatment patterns/perceptions.

Study design: Data from the Adelphi VMS Disease Specific Programme, a point-in-time survey conducted in 5 European countries and the United States in 2020, were used. Primary care providers (PCPs) and gynecologists seeing ≥ 3 patients/week with VMS associated with menopause completed a survey and chart review; their patients were invited to complete a survey and questionnaires.

Main outcome measures: Physicians reported treatment patterns and patient-specific symptoms and treatment preferences. Patients described symptoms, impact of VMS, and treatment satisfaction.

Results: Participants included 115 PCPs and 118 gynecologists. Physicians reviewed the charts of 1816 patients, 854 of whom completed surveys. Moderate/severe impact of VMS on sleep, mood, quality of life, and work/study was reported by 35.8 %, 31.6 %, 23.6 %, and 15.4 % of women, respectively. Based on chart review, 64.8 % of women were currently prescribed treatment for VMS, most commonly hormone therapy (HT; 73.1 %), followed by selective serotonin or serotonin-norepinephrine reuptake inhibitors (31.3 %). Most women (57.3 %) with VMS were eligible for HT but averse to using it. Despite 91.4 % of physicians finding HT to be effective, 62.7 % agreed (slightly–strongly) that their patients are generally reluctant to use it. One-third of women were dissatisfied with VMS control.

Conclusions: VMS can considerably impact daily life. Effective treatment options that are better accepted could potentially improve management of VMS and lead to better quality of life for women with VMS associated with menopause.

Clinical trial registration: None.

Abbreviations: BMI, body mass index; DSP, Disease Specific Programme; GYN, gynecologist; HT, hormone therapy; MENQOL, Menopause-Specific Quality of Life Questionnaire; MEPI, Menopause Epidemiology study; MHT, menopausal hormone therapy; PCP, primary care provider; QoL, quality of life; SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; VMS, vasomotor symptoms; WPAI:SHP, Work Productivity and Activity Impairment Specific Health Problem questionnaire.

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1. Introduction

Worldwide, more than half of women aged 40–64 years' experience vasomotor symptoms (VMS) associated with menopause (e.g., hot flashes, night sweats) [1]; prevalence varies widely between regions and over time [1–3]. Peak perimenopausal or postmenopausal prevalence of VMS among US women is even higher (~60%–80%) [4–6]. While some women experience mild or no postmenopausal VMS, about 32%–46% of US women and 40% of European women experience moderate to severe symptoms [3,5]. Severe VMS can interfere with sleep, concentration, mood, energy, work, leisure/social activities and sexual activity [7,8].

Treatment guidelines recommend hormone therapy (HT) for bothersome VMS associated with menopause in women aged <60 years or within 10 years of menopause who have no contraindications [9–12]; however, HT initiation declined after the Women's Health Initiative (WHI) trials based on potential health concerns [13] and may not be appropriate or acceptable for all women seeking treatment. Selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), gabapentin and clonidine are used off-label (except paroxetine) for VMS in women who require or prefer nonhormonal options [10,11,14].

Many women with bothersome VMS remain untreated or use nonprescription medications, herbal supplements or alternative therapies [15–17]. Factors influencing treatment decisions include safety and tolerability (e.g., breast cancer, stroke, venous thromboembolism, breast tenderness, vaginal bleeding) related to long-term HT use [18–22] and moderate efficacy of non-hormonal treatments [10]. Although previous studies have examined the burden of VMS associated with menopause [7,8], a more comprehensive understanding of VMS burden and patient/physician perspectives on its management is needed. This study elicited perspectives and data from US and European physicians and women with VMS associated with menopause to assess the impact of VMS, treatment patterns, and perceptions of treatment.

2. Methods

2.1. Study design and population

Data were collected from the Adelphi VMS Disease Specific Programme (DSP), a point-in-time survey of physicians and their patients, conducted in the United Kingdom, France, Germany, Italy, Spain, and United States February–October 2020 [23]. DSPs provide aggregated patient and physician data across health conditions [23].

2.1.1. Physician survey

Data were captured from an electronic survey and prospective chart review completed by primary care providers (PCPs) and gynecologists (GYNs). Physicians were identified from publicly available lists of healthcare providers (HCPs), recruited, and screened by field-based interviewers. Physicians were required to be responsible for treatment decisions and to see at least 3 patients with VMS per month. Physicians from geographically diverse regions were included.

2.1.2. Patient chart review

Each physician completed the survey and electronic patient record form based on charts for 8 consecutive patients aged 40–65 years with clinically confirmed VMS associated with menopause.

2.1.3. Patient survey

Women evaluated in the chart review were invited to take a paper-based survey and complete questionnaires. Surveys were developed in English and translated by a local fieldwork agency into French, German, Italian, and Spanish; translations were validated by an independent UK-based translation agency.

2.2. Data collection

Data collected via physician surveys included the number of patients with VMS associated with menopause seen over a 10-day period; physician characteristics; and treatment beliefs, approaches, attribute importance, and treatment satisfaction.

Patient information collected by physicians via chart review included demographics, symptoms/symptom control, treatments prescribed for VMS, reasons for treatment choice, patient risk factors/concomitant conditions, and physician-rated VMS severity (mild, moderate, or severe).

Patient surveys collected information on demographics, symptoms, VMS impact on daily life, productivity, quality of life (QoL), perceptions of treatment, and satisfaction with symptom control. In addition, patients completed the validated Menopause-Specific Quality of Life (MENQOL) Questionnaire and the Work Productivity and Activity Impairment Specific Health Problem (WPAI:SHP) questionnaire adapted to hot flashes/night sweats. The MENQOL comprises 29 questions in vasomotor, physical, psychosocial and sexual functioning domains; users rate symptoms (yes/no) and their bothersomeness (scale: 0–6) in the past month [24,25]. Responses are converted to 1 = not experienced in the past month, 2 = experienced but not bothered, through 8 = extremely bothered [24,25]. Domain scores are calculated as the mean of the individual questions in that domain, and total scores as the mean of the domain scores [24,25]. The WPAI questionnaire [26] comprises 6 questions about employment history, time dedicated to work, time missed due to VMS or non-VMS reasons, impact on productivity (scale: 0 = no effect on work, 10 = hot flashes/night sweats completely prevented me from working), and how much VMS affects performance of daily non-work activities [27]. Scores are percentages of scheduled work hours missed (absenteeism), impairment while working (presenteeism), overall work impairment (absenteeism and presenteeism), and general activity impairment [28].

2.3. Ethical considerations

The survey received ethical exemption by the Western Institutional Review Board (work order number 1-1258281-1). Physicians and patients provided informed consent via tick boxes on their surveys, data were collected anonymously, and responses were collected and de-identified by local fieldwork partners before receipt by Adelphi. Data were analyzed in aggregate so survey responses remained anonymous in accordance with data protection laws.

2.4. Descriptive statistics

Descriptive statistics were generated for each variable. The electronic physician survey and patient record form did not allow for missing responses. Since the patient questionnaire was voluntary, not all physician-completed patient record forms had matching patient questionnaires. Data completeness depended on patients completing the survey fully and correctly. All available responses were analyzed.

Based on the chart review and patient survey, patients were divided into 5 subgroups: (1) eligible and nonaverse to using HT, (2) eligible but averse to using HT, (3) HT contraindicated, (4) caution required with HT initiation and (5) prior HT users who had discontinued HT for any reason. Women were considered eligible for HT associated with menopause if approved by a physician and they had no known medical history precluding its use. Patients were included in all applicable categories except 1 and 2, which were mutually exclusive. Determination of HT nonaverse vs HT averse categorization was based on patients' responses to the question: "How would you describe your attitude about hormone replacement therapy (HRT) for your symptoms?" (scale: 1 = extremely negative, 7 = extremely positive); scores of 5–7 were considered non-averse and 1–3 were considered averse. For patients with a score of 4 or who declined the survey, determination was based on physician

response to the question: “How concerned is this patient about the potential safety risks associated with HRT?” (answer choices: not at all concerned, slightly concerned, moderately concerned, very concerned, extremely concerned); an answer of not at all concerned was categorized as HT nonaverse, whereas all other responses were categorized as HT averse. Contraindications to HT included vaginal bleeding, metastatic solid tumor, tumor without metastasis, angina pectoris, myocardial infarction, thrombosis, coagulated blood clotting disorder or liver disease; these were selected based largely on contraindications in guidelines from the North American Menopause Society [9,29] and The Endocrine Society [30], as well as representative oral and transdermal HT product labels [31,32] but do not match exactly because of practicalities of extracting relevant information during chart review. Conditions necessitating caution were those requiring breast cancer or cardiovascular benefit-risk assessment before prescribing (including current smoking, body mass index >29.9 kg/m², elevated cholesterol/hyperlipidemia or history of diabetes) or history of migraine [29–32]. Because the physician chart review included a combined check box for “personal and family history of breast cancer,” patients who checked the box were included in the HT caution rather than contraindication group.

3. Results

3.1. Analysis population

Participating physicians (N = 233) included 115 PCPs and 118 GYNs. The majority (>70.4 %) were in practice for 15–37 years. Compared with PCPs, GYNs treated more patients aged 40–65 years with VMS (10-day mean: 31.0 vs 21.1) and saw a larger percentage of women with VMS (17.7 % vs 12.6 %).

Physicians provided data on 1816 patients; 854 patients completed questionnaires. Patients whose records were reviewed had a mean age of 53.9 years, and most were white (82.5 %); demographics varied slightly by region (Table 1). Demographics were similar among women who did and did not complete the survey (data not shown).

3.2. Impact of VMS

Based on patients' survey responses, VMS had a substantial impact (rated moderate, severe, or “problem as bad as it can be”) on sleep in 35.8 %, mood in 31.6 %, QoL in 23.6 %, and work/study in 15.4 % of women over the past week (Fig. 1). A larger percentage of European vs US women (30.5 % vs 14.4 %) reported at least a moderate impact on overall QoL (Fig. 1). Women experiencing moderate/severe vs mild VMS reported greater impact on sleep, mood, QoL, work/study, social activities, self-confidence, leisure activities, concentration, relationships, sexual intimacy and enjoyment in life (Supplementary Table S1).

Mean (SD) overall MENQOL score was 2.5 (1.3) (higher score [maximum: 8] = greater bother). The highest mean (SD) domain score was in the vasomotor domain (3.5 [1.8]). Overall and domain scores were higher among women with moderate/severe vs mild VMS (Supplementary Fig. S1A).

WPAI results demonstrated that women rarely missed work because of VMS (mean: 1.3 % [SD: 8.4 %] absenteeism [higher score = greater effect]) but had more impairment while working (20.1 % [20.8 %] presenteeism); overall work impairment (absenteeism and presenteeism) was 20.6 % (21.4 %), and non-work activities were impaired by 23.6 % (22.9 %). Greater work and activity impairments were observed in women with moderate/severe vs mild VMS (Supplementary Fig. S1B).

3.3. Treatments prescribed to ameliorate VMS

Based on physicians' chart review, 1158 women (63.8 %) were currently prescribed therapy for VMS, 156 (8.6 %) were formerly prescribed medication and 502 (27.6 %) were never prescribed medication. There were 847 women currently prescribed HT (46.6 % of total sample

Table 1

Demographic characteristics of women with clinically confirmed VMS associated with menopause (from physician-reported chart review).

| | Overall (N = 1816) | Europe ^a (n = 1177) | United States (n = 639) |
|-----------------------------|--------------------|--------------------------------|-------------------------|
| Age, years | N = 1816 | n = 1177 | n = 639 |
| Mean (SD) | 53.9 (5.4) | 53.4 (5.2) | 54.6 (5.6) |
| Race/ethnicity, n (%) | N = 1816 | n = 1177 | n = 639 |
| White | 1499 (82.5) | 1065 (90.5) | 434 (67.9) |
| Black | 99 (5.5) | 16 (1.4) | 83 (13.0) |
| Hispanic/Latina | 89 (4.9) | 40 (3.4) | 49 (7.7) |
| Asian | 85 (4.7) | 33 (2.8) | 52 (8.1) |
| Other or mixed race | 44 (2.4) | 23 (2.0) | 21 (3.3) |
| BMI, kg/m ² | N = 1815 | n = 1176 | n = 639 |
| Mean (SD) | 25.6 (4.6) | 25.1 (4.2) | 26.6 (5.1) |
| Smoking status, n (%) | N = 1756 | n = 1133 | n = 623 |
| Current | 242 (13.8) | 209 (18.5) | 33 (5.3) |
| Former | 399 (22.7) | 270 (23.8) | 129 (20.7) |
| Never | 1115 (63.5) | 654 (57.7) | 461 (74.0) |
| Employment status, n (%) | N = 1783 | n = 1156 | n = 627 |
| Full-time | 962 (54.0) | 586 (50.7) | 376 (60.0) |
| Part-time | 254 (14.3) | 181 (15.7) | 73 (11.6) |
| Not currently employed | 567 (31.8) | 389 (33.7) | 178 (28.4) |
| Age at menopause, years | N = 1544 | n = 1015 | n = 529 |
| Mean (SD) | 49.6 (5.7) | 49.6 (4.8) | 49.7 (7.2) |
| Age at VMS diagnosis, years | N = 1541 | n = 1003 | n = 538 |
| Mean (SD) | 50.3 (5.7) | 50.2 (4.8) | 50.6 (7.1) |
| VMS symptom severity, n (%) | N = 1816 | n = 1177 | n = 639 |
| Mild | 732 (40.3) | 417 (35.4) | 315 (49.3) |
| Moderate | 796 (43.8) | 535 (45.5) | 261 (40.8) |
| Severe | 288 (15.9) | 225 (19.1) | 63 (9.9) |

BMI, body mass index; SD, standard deviation; VMS, vasomotor symptoms.

^a UK, France, Germany, Italy, and Spain.

[US: 46.6 %; Europe: 45.5 %] and 73.1 % of those given any prescription medication) (Fig. 2). Another 75 women (4.1 % overall; 6.5 % of those prescribed treatment) were prescribed bioidentical HT. HT use was slightly more common in Europe than the United States (Fig. 2). PCPs and GYNs reported prescribing HT for a mean (SD) of 41.0 % (28.3) and 48.6 % (24.8) of patients with VMS, respectively.

SSRIs/SNRIs were prescribed for VMS for 363 women (20.0 % of total sample; 31.3 % of women receiving prescription medication). SSRI/SNRI use was more common in the United States than Europe (Fig. 2). PCPs and GYNs prescribed SSRIs/SNRIs for a mean (SD) of 30.8 % (23.0) and 22.8 % (15.0) of patients with VMS, respectively.

Most (57.3 %) of the 1802 women with VMS associated with menopause had been advised by their HCP that they were eligible for HT (i.e., they had no medical history precluding HT use) but were averse to using it, and nearly half had medical conditions warranting caution and regular follow-up if HT were prescribed (Table 2). Regional differences were observed: the United States had the highest proportion of patients who were eligible and nonaverse, and Spain, France and the United Kingdom had the highest proportion of patients eligible but averse (Table 2). German HCPs had the smallest percentage of patients who had used and discontinued HT.

3.4. Physician and patient perceptions of prescription treatments for VMS

While 91.4 % of physicians believed HT to be effective, 62.7 % agreed (slightly–strongly) that their patients were generally reluctant to use HT, most commonly owing to long-term safety concerns (Table 3). Physicians reported that prescription of SSRIs/SNRIs for VMS was limited by insufficient efficacy, patient avoidance of prescription therapy, and long-term safety or short-term tolerability concerns (Table 3). Physicians' primary reasons for selecting patients' current treatments

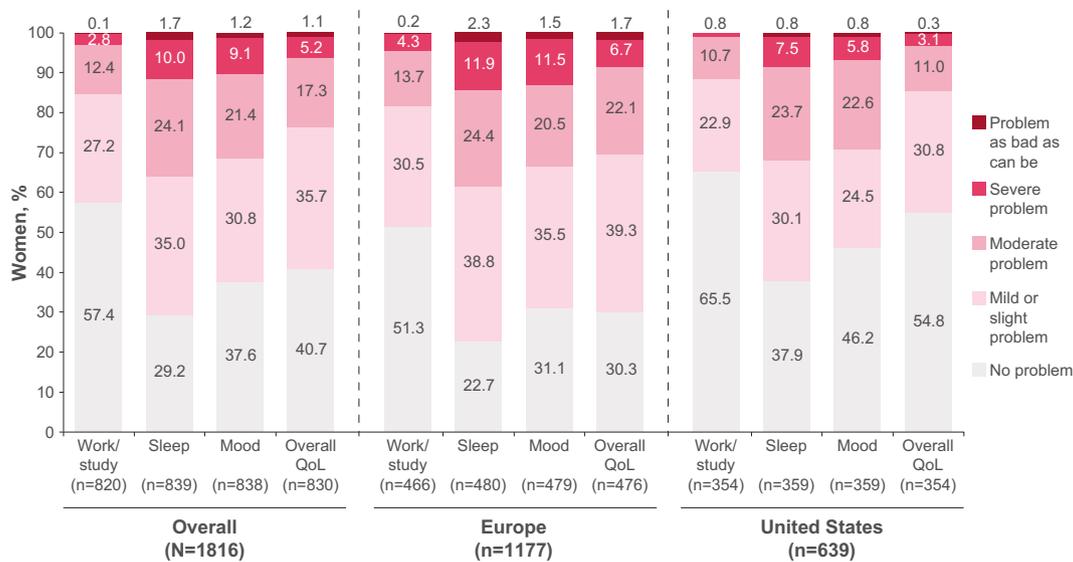


Fig. 1. Patient-reported impact of VMS on work/study, sleep, mood, and overall QoL (patient survey data).

Survey question: Over the past week, how problematic have your hot flashes/night sweats been in terms of frequency and severity for the following aspects of your day to day life?

QoL, quality of life; VMS, vasomotor symptoms.

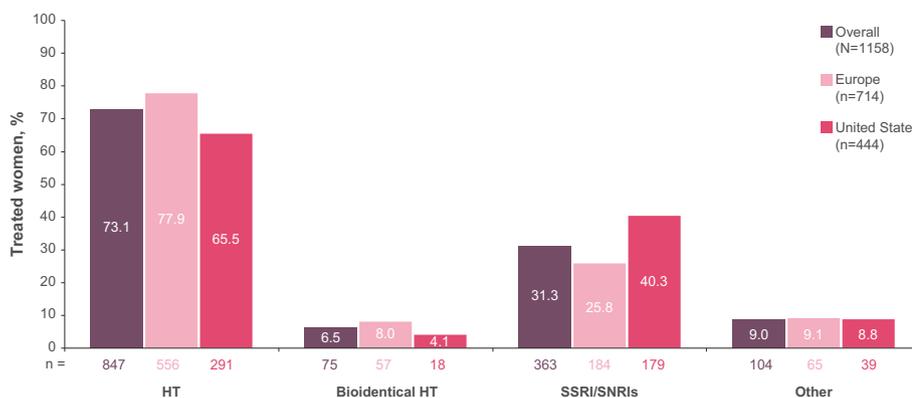


Fig. 2. Current prescribed treatments for VMS among women who received any prescription VMS therapy (based on chart review).

Percentages were calculated using the number of patients prescribed treatment as the denominator, and their sums are >100 % because some patients had >1 prescribed treatment and therefore were counted in multiple categories.

HT, hormone therapy; SSRIs/SNRIs, selective serotonin reuptake inhibitors/serotonin norepinephrine reuptake inhibitors; VMS, vasomotor symptoms.

Table 2

Women with VMS categorized by eligibility for, interest in, and use of HT,^a overall and by country.

| | Overall (N = 1802) | USA (n = 634) | France (n = 215) | Germany (n = 240) | Italy (n = 237) | Spain (n = 239) | UK (n = 237) |
|--|--------------------|---------------|------------------|-------------------|-----------------|-----------------|--------------|
| Eligible and nonaverse to use HT, n (%) | 534 (29.6) | 225 (35.5) | 51 (23.7) | 69 (28.8) | 77 (32.5) | 44 (18.4) | 68 (28.7) |
| Eligible but averse to using HT, n (%) | 1033 (57.3) | 337 (53.2) | 139 (64.7) | 118 (49.2) | 136 (57.4) | 163 (68.2) | 140 (59.1) |
| HT contraindicated, n (%) | 214 (11.9) | 67 (10.6) | 22 (10.2) | 51 (21.3) | 23 (9.7) | 25 (10.5) | 26 (11.0) |
| Caution required at HT initiation, n (%) | 887 (49.2) | 325 (51.3) | 85 (39.5) | 120 (50.0) | 116 (48.9) | 133 (55.6) | 108 (45.6) |
| Discontinued HT, n (%) | 149 (8.3) | 59 (9.3) | 14 (6.5) | 8 (3.3) | 26 (11.0) | 28 (11.7) | 14 (5.9) |

BMI, body mass index; HT, hormone therapy; MHT, menopausal hormone therapy; VMS, vasomotor symptoms.

^a Based on the chart review and patient questionnaire, patients were categorized into 5 subgroups: HT eligible and nonaverse; HT eligible and averse; HT contraindicated (vaginal bleeding, metastatic solid tumor, tumor without metastasis, angina pectoris, myocardial infarction, thrombosis, coagulated blood clotting disorder, or liver disease); caution required at HT initiation (i.e., conditions requiring a cardiovascular or breast cancer risk evaluation before HT initiation: current smoking, BMI >29.9 kg/m², personal or family history of breast cancer, patient history of migraine, diabetes, and elevated cholesterol/hyperlipidemia); and prior HT users who discontinued HT for any reason. Women were included in all applicable categories with the exception of HT eligible and nonaverse and HT eligible and averse, which were mutually exclusive.

were consistent with areas they cited as needing improvement (e.g., symptom relief; Fig. 3).

Based on the patient survey, women with more severe VMS and those currently receiving treatment were more likely than those with mild VMS and those who never received treatment to have a favorable perception of HT (Supplementary Fig. S2).

3.5. Symptom control and physician and patient satisfaction with symptom control

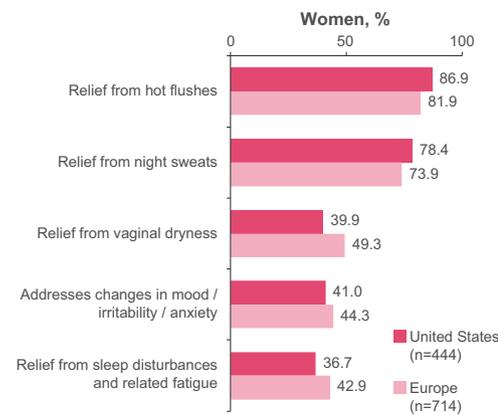
According to physicians, 22.8 % of their patients with VMS (irrespective of treatment status) had no control of hot flashes, 53.2 % had partial control and 24.0 % had full control. Similarly, they reported that

Table 3
Physicians' stated reasons for not prescribing HT and SSRIs/SNRIs for treatment of VMS.

| | Reasons for not prescribing HT n (%) | | | Reasons for not prescribing SSRIs/SNRIs n (%) | | |
|--|--------------------------------------|-------------|------------------|---|-------------|------------------|
| | Overall (N = 233) | US (n = 81) | Europe (n = 152) | Overall (N = 233) | US (n = 81) | Europe (n = 152) |
| Patient concern with long-term risk of treatment | 128 (54.9) | 55 (67.9) | 73 (48.0) | 79 (33.9) | 31 (38.3) | 48 (31.6) |
| Symptoms not severe enough to warrant treatment | 99 (42.5) | 39 (48.1) | 60 (39.5) | 84 (36.1) | 39 (48.1) | 45 (29.6) |
| Comorbid condition | 96 (41.2) | 33 (40.7) | 63 (41.4) | 59 (25.3) | 22 (27.2) | 37 (24.3) |
| Physician concern with long-term risk of treatment | 91 (39.1) | 36 (44.4) | 55 (36.2) | 40 (17.2) | 13 (16.0) | 27 (17.8) |
| Patient refusal of prescription drugs | 83 (35.6) | 34 (42.0) | 49 (32.2) | 82 (35.2) | 40 (49.4) | 42 (27.6) |
| Contraindicated with other treatment | 80 (34.3) | 30 (37.0) | 50 (32.9) | NA | NA | NA |
| Concern of short-term side effects | 53 (22.7) | 14 (17.3) | 39 (25.7) | 60 (25.8) | 19 (23.5) | 41 (27.0) |
| Patient prefers non-prescription treatment | 46 (19.7) | 26 (32.1) | 20 (13.2) | 60 (25.8) | 35 (43.2) | 25 (16.4) |
| Treatment not efficacious enough | 41 (17.6) | 15 (18.5) | 26 (17.1) | 84 (36.1) | 31 (38.3) | 53 (34.9) |
| Medication not covered by patient's insurance | 37 (15.9) | 31 (38.3) | 6 (3.9) | 29 (12.4) | 23 (28.4) | 6 (3.9) |
| Patient already taking too many tablets for other conditions | 29 (12.4) | 11 (13.6) | 18 (11.8) | 39 (16.7) | 17 (21.0) | 22 (14.5) |
| Patient cannot afford prescription drugs | 25 (10.7) | 20 (24.7) | 5 (3.3) | 29 (12.4) | 23 (28.4) | 6 (3.9) |
| Treatment only affects VMS and not other menopausal symptoms | 19 (8.2) | 9 (11.1) | 10 (6.6) | 37 (15.9) | 13 (16.0) | 24 (15.8) |
| Fear of addiction/physical dependence | NA | NA | NA | 65 (27.9) | 18 (22.2) | 47 (30.9) |

HT, hormone therapy; NA, not applicable; SSRIs/SNRIs, selective serotonin reuptake inhibitors/serotonin and norepinephrine reuptake inhibitors; VMS, vasomotor symptoms.

A. Reasons for choice



B. Areas for improvement

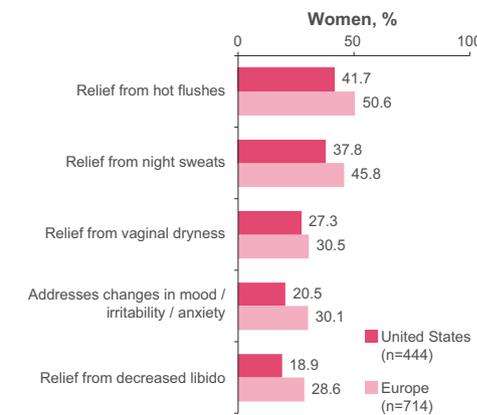


Fig. 3. Top 5 physician-stated reasons for A) treatment choice and B) areas in which improvement in VMS treatment is needed. Survey question: Please indicate the following for the patient's current prescription treatment for VMS: i) The primary reasons which influenced your choice of therapy for this patient. ii) The most important areas of improvement for this treatment that would benefit this patient. Twenty-eight response options were provided, and physicians were instructed to select all that applied. VMS, vasomotor symptoms.

23.8 %, 48.9 % and 27.3 % of patients had no, partial, and full control of night sweats, respectively. Of women currently prescribed treatment for VMS, only 31.1 % had full control of hot flashes and 33.7 % had full control of night sweats, whereas 16.0 % and 16.8 % had no control of hot flashes and night sweats, respectively, based on physician report. As expected, even fewer untreated women had symptom control (Supplementary Fig. S3).

In the patient survey, approximately one third of women reported dissatisfaction with their level of VMS control. Women with severe vs mild VMS were more commonly dissatisfied with VMS control (43.3 %

vs 22.2 %) (Fig. 4). Physicians were somewhat less satisfied with VMS control than their patients were (Fig. 4).

4. Discussion

This survey provides perspectives on VMS and related treatments from patients and physicians in Europe and the United States and advances the established body of literature reporting substantial bothersomeness and impact of VMS on QoL and daily activities.

Findings regarding the burden of VMS are consistent with those from

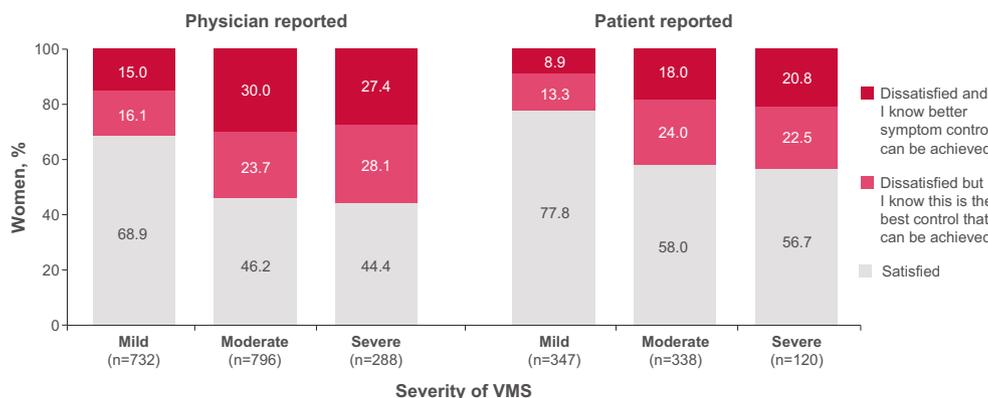


Fig. 4. Physician- and patient-reported satisfaction with control of VMS by VMS severity (survey results). Physician survey question: How satisfied are you with the current control of this patient's VMS? Patient survey question: How satisfied are you with the current control of your hot flashes/night sweats? VMS, vasomotor symptoms.

previous surveys showing sleep interruptions and adverse effects on mood, concentration/memory, personal and sexual relationships, perceptions of work productivity, social and leisure activities and health-related QoL [7,8,33]. A survey in 5 European countries, the United States, and Japan found that VMS had a greater impact on daily activities than work on the WPAI, although impact on both was generally low [3]. Overall WPAI results in the current study showed similarly low impacts on overall work impairment and activity impairment. However, the current study demonstrates that the impact of VMS on daily life worsens with greater symptom severity. Similarly, a survey in 5 European countries showed greater absenteeism, presenteeism and activity impairment on the WPAI with severe vs mild VMS postmenopause [34].

HT is the standard of care for bothersome VMS but may not be appropriate or acceptable for all women. We sought to quantify actual HT use and openness to using HT among eligible women who brought their VMS to the attention of a HCP. To our knowledge, this is only the second study to categorize and evaluate women based on eligibility for and openness to HT use for VMS. In a previous study, HT was contraindicated in 8 %–12 % of women across countries [3], which is generally consistent with current results (overall 12 % had contraindications [10 %–21 % across countries]). That study also reported that 11 %–25 % were “HT willing” and 54 %–79 % were “HT-averse” [3], consistent with our findings that a majority of HT-eligible women are averse to it. Moreover, nearly half of the women had comorbid conditions necessitating caution during initiation and monitoring during use, as per treatment guidelines and product labels [29–32].

In the current study, despite physicians' largely positive perceptions of HT, many patients expressed negative attitudes toward the use of HT. Patient concern with long-term risk was the most common reason physicians cited for not prescribing HT, which is consistent with published evidence of declines in HT use following reports of safety concerns from the WHI trials [13,21].

In the current study, women prescribed treatment for VMS had a more favorable impression of HT than those not treated. Similarly, a survey of postmenopausal European women found that those receiving HT had a more favorable impression of it than those receiving other treatments [35].

Despite the concerns, 46.6 % of women with VMS under physicians' care (PCPs, 41.0 %; GYNs, 48.6 %) were currently prescribed HT. This rate is higher than that in the general population of women with VMS, including those choosing not to seek medical care for VMS. An online survey of women who were postmenopausal and had moderate/severe VMS within the past year found that only 17 % in Europe and 19 % in the United States had ever used HT [3]. In the 2005 population-based Menopause Epidemiology (MEPI) study of randomly selected US women aged 40–65 years of any menopausal status, 19 % were current HT users and about 49 % had used HT at some point [16]. About 31.3 % of women in the current study who were prescribed treatment for VMS received a prescription for SSRIs/SNRIs, despite 36.1 % of physicians citing lack of efficacy for not prescribing SSRIs/SNRIs.

According to their physicians, only 31.1 % and 33.7 % of currently treated women had complete control of hot flashes and night sweats, respectively. One third of women reported dissatisfaction with their level of VMS control. This points to potential unmet needs for better symptom control among women who desire relief from VMS. However, the fact that two thirds of women were satisfied with their level of VMS control suggests that treatment-related reductions in symptoms are appreciated even when full control is not achieved. In the MEPI survey, women reported that only 21.3 % of HT medications used primarily for VMS produced complete symptom resolution [16]. In a survey of women who were postmenopausal, 47 %–67 % from 5 European countries reported good symptom relief from treatment and 22 %–60 % were satisfied with treatment, and HT provided better symptom relief and treatment satisfaction than other prescription and nonprescription therapies [35].

This study had several limitations. Women with VMS under a HCP's

care may have more severe/bothersome symptoms than the general population of women with VMS [34,35]. Women under medical care are presumably less averse to prescription therapies. Physician inclusion was likely influenced by willingness to participate and practical considerations such as geographic location (potential selection bias). Physicians enrolled consecutive patients with VMS, which was not a true random sample of all patients with VMS. No formal auditing of electronic medical records was performed to assess completeness or accuracy of physician-completed patient record forms. It is unknown whether perspectives on impact and treatment of VMS would have differed between women who chose to participate in the survey and those who declined; however, demographic characteristics were similar between these groups. Although over 200 HCPs participated and provided data on over 1800 patients, the sample size is relatively small especially considering they were spread across 6 countries. Although we adhered as closely as possible to standard HT contraindications in clinical practice guidelines and product labels, practicalities of extracting relevant data from medical charts prevented an exact match to these contraindication lists. Physician and patient responses were subject to potential recall bias. Finally, this study did not assess frequency, completeness, or quality of communication about VMS and related treatment options between physicians and patients.

A strength of this survey is that data were collected in Europe and the United States, allowing exploration of patient and physician perspectives across regions. Analysis of patient-reported outcomes and the use of validated MENQOL and WPAI questionnaires in the current study facilitate our understanding of the impact of VMS associated with menopause.

5. Conclusions

Despite availability of prescription treatments for VMS associated with menopause, many women with VMS, particularly those with moderate/severe symptoms, continue to experience detrimental effects of VMS on daily activities and QoL. A significant proportion of women with VMS were averse to using or dissatisfied with current VMS prescription treatment options, and many had persistent VMS while being treated. These findings suggest a need for greater patient and physician education about menopausal VMS. Physicians need to appreciate the reasons patients who report bothersome VMS may be hesitant to take VMS treatments and address their questions and concerns. The full range of empirically supported VMS treatment options should be offered to those who are eligible for them. Furthermore, it is necessary to understand patients' treatment goals to set realistic expectations and improve patient satisfaction with VMS treatment. Lastly, results of this study could be used as a foundation for follow-up studies to further investigate the barriers to the receipt of treatment for bothersome VMS for women who experience these symptoms and seek relief from them.

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Contributors

Petra Stute participated in the interpretation of data and review of the manuscript.

Antonio Cano participated in the interpretation of data and review of the manuscript.

Rebecca C. Thurston participated in the interpretation of data and review of the manuscript.

Mark Small contributed to study design and acquisition of data, and participated in the interpretation of data and review of the manuscript.

Lauren Lee contributed to study design and acquisition of data, and participated in the interpretation of data and review of the manuscript.

Megan Scott contributed to study design and acquisition of data, and participated in the interpretation of data and review of the manuscript.

Emad Siddiqui contributed to study design and acquisition of data,

and participated in the interpretation of data and review of the manuscript.

Neil M. Schultz contributed to study design and acquisition of data, and participated in the interpretation of data and review of the manuscript.

All authors reviewed and approved the final version.

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Ethical approval

The survey received ethical exemption by the Western Institutional Review Board (work order number 1-1258281-1). Physicians and patients provided informed consent via a tick box on their surveys, data were collected anonymously, and responses were collected and identified by local fieldwork partners before receipt by Adelphi. Data were analyzed in aggregate so survey responses remained anonymous in accordance with data protection laws.

Provenance and peer review

This article was not commissioned and was externally peer reviewed.

Research data (data sharing and collaboration)

There are no linked research data sets for this paper. The datasets generated during and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

Declaration of competing interest

Petra Stute: Consulting, Advisory Board, Research grant; Astellas Pharma, Dr. Kade/Besins Pharma, Labatec, Jenapharm.

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