GSM/VVA: Advances in Understanding and Management

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23.1 Introduction

There has been considerable debate whether the terms vulvovaginal atrophy (VVA), vaginal atrophy (VA) and atrophic vaginitis (AV) are entirely appropriate. The terms are not entirely accurate from a medical perspective and have limitations from a public perspective. From the medical point of view, (vulvo)vaginal atrophy does not necessarily lead to symptoms and does not include the urinary tract. From the public point of view, there is a reluctance to use the terms "vulva" and "vagina", and atrophy is associated with negative connotations. A working group was convened by the International Society for the Study of Women's Sexual Health (ISSWH) and North American Menopause Society (NAMS) in order to discuss the nomenclature with a view to developing new terminology [1]. The term genitourinary syndrome of menopause (GSM) was agreed as it encompasses both genital and urinary tracts, which are often both affected, the symptoms are multiple (hence syndrome) and there is avoidance of use of the term vagina which many women find embarrassing.

23.2 Impact of VVA/GSM on Quality of Life (QOL)

The impact of VVA/GSM on the quality of life of many women continues to be underestimated. Although the reasons for this are multiple and complex, it is clear that many women are reluctant to complain about the problem for risk of personal

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embarrassment and cultural reasons. Healthcare providers do not proactively raise the issue in consultations because they are uncomfortable discussing sexual issues and for fear of opening a "can of worms", with limited time to deal with the consequences. There is lack knowledge as to the available effective treatment options, both hormonal and alternative [2, 3].

Even though we have an ageing population where more than 50% of postmenopausal women suffer with VVA, the subject is avoided both in social conversation and in the media. In a recent European survey, 54% of respondents said they discussed their sexual health concerns only when the healthcare professional asks. Thirty-three percent said they were too shy to discuss their sexual health concerns [4]. Women and their sexual partners are in effect, suffering in silence. The issue is particularly frustrating because treatment is often simple and safe and can transform a woman's quality of life.

23.3 Pathophysiology

With declining oestrogen, the mucosa of the cervix and the epithelium of the vagina and vulva thin and become susceptible to injury. The vaginal rugae diminish, leading to a smoother-appearing vaginal wall accompanied by diminished blood flow and a rise in pH (6–8). Together, these changes result in a pale appearance which may contain small petechiae and/or other signs of inflammation. The proportion of superficial to parabasal cells decreases with loss of glycogen and loss of lactobacilli. The loss of secretions leads to vaginal dryness and irritation.

23.4 Symptoms

Symptoms most commonly complained about include vaginal dryness (75%), pain during intercourse (40%) and vulval and vaginal pruritus and discharge. However, the urinary tract is also commonly affected leading to urinary frequency and urgency, nocturia, dysuria and incontinence in 15–35% of women greater than 60 years of age. Recurrent urinary tract infections occur in up to 20% of postmenopausal women due to atrophy of the urothelium in response to oestrogen deficiency. Women with lower urinary tract infections have a sevenfold greater risk for sexual pain disorders and a fourfold increased risk for sexual arousal disorders [5]. In a recent European survey, 66% of women stated that vulval and vaginal symptoms interfered with their ability to enjoy sexual intercourse [4].

23.5 Diagnosis

Women experiencing sexual and urinary symptoms due to vaginal atrophy should be diagnosed and treated without delay in order to avoid a cascade of events which do not resolve spontaneously. The diagnosis of VVA/GSM is often made on symptoms alone—many healthcare professionals avoid examination of the patient, which is a mistake. There are other vulval and vaginal conditions which can lead to similar

symptoms such as vulval dermatoses, e.g. lichen sclerosis and vulval/vaginal malignancy. The diagnosis has been largely subjective with few objective measures used to confirm the diagnosis and monitor progression and response to treatment. The measurement of vaginal pH and the vaginal maturation index from vaginal smears provides some objective evidence. Although these measurements are commonly used in VVA/GSM studies, they are rarely used in day-to-day clinical practice.

23.6 Global Assessment Scales

Assessment tools have been developed to facilitate the formal diagnosis and classification of the severity of GSM. One of the most commonly used tools for assessing vaginal health has been the vaginal health index. The user is asked to rate both the appearance of the vaginal mucosa and production of secretions on a scale from 1 to 5 (Fig. 23.1) [6]. The drawback of this scale is that it does not take into account the impact on the vulva or the urinary tract. The absence of a vulval assessment tool was recently addressed by development of the vulval health index (Palacios S, 2015, The vulval health index (personal communication)) which assesses the appearance of the labia majora and minora, clitoris and introitus, colour of the tissues and the presence of other pathological features. There has also been an attempt to introduce a quality-of-life impact modality (pain on intercourse) in this tool although the value of assessing only one modality is limited (Fig. 23.2). A more comprehensive tool has recently been developed following the consensus group development of the term GSM [1]. The GSM assessment tool consists of three general categories of elasticity, lubrication and tissue integrity, an anatomical section which includes vulval, vaginal and urethral anatomy and two objective measures, vaginal pH and vaginal maturation. Each one of these seven components is scored from 0 to 3 according to severity (Fig. 23.3) to provide a semi-objective measure of vulval and vaginal atrophy. A numeric score is calculated by adding each one of the scores to give a total out of

Score	1	2	3	4	5
Elasticity	None	Poor	Fair	Good	Excellent
Fluid Volume (Pooling of Selection)	None	Scant amount, vault not entirely covered	Superficial amount, vault entirely covered	Moderate amount of dryness (small areas of dryness on cotton tip applicator)	Normal amount (fully saturates on cotton tip applicator)
pH	≥ 6.1	5.6 - 6.0	5.1 - 5.5	4.7 - 5.0	≤ 4.6
Epithelial Integrity	Petechiae noted before contact	Bleeds with light contact	Bleeds with scraping	Not friable - thin epithelium	Normal
Moisture (Coating)	None, surface inflamed	None, surface not inflamed	Minimal	Moderate	Normal

Table 1: Gloria Bachmann Vaginal Health Index (VHI).

Fig. 23.1 Vaginal health index [6]

Vulva health index

	Normal (0)	Mild (1)	Moderate (2)	Severe (3)
Labia Majora	Normal	Mild loss	Moderate loss	Severe loss or disappeared
Labia Minora	Normal	Mild loss	Moderate loss	Severe loss or disappeared
Clitoris	Normal size	Mild decrease in size	Moderate decrease in size	Severe decrease or undetected
Introitus & elasticity	Normal	Mild decrease or stenosis	Moderate decrease or stensis	Severe decrease or stenosis
Color	Normal	Mild pallor	Moderate pallor	Severe pallor
Discomfort & pain	None	Mild during intercourse	Moderate during intercourse	Severe during intercourse and any discomfort intensity beyond intercourse
Other findings (petechiae, excoriation, ulceration, etc)	None	Mild	Moderate	Severe

* This physical and clinical examination assessment tool assists in the classification of vulva health and atrophy.

** A numeric score can also be calculate by multiplying each catagory total by 1-3 depending on the category and totalling up the scores. From 0 to 21. 0-7 mild vulva atrophy 7-14, Moderate vulva atrophy. >14 severe vulva atrophy.

Fig. 23.2 Vulva health index (Palacios S, 2015, The vulval health index (personal communication))

21 (0–7 = mild atrophy, 7–14 = moderate atrophy and >14 = severe atrophy). There is some inaccuracy in that there is overlap between the categories, and even though the tool assesses GSM, the score refers to degree of "atrophy" rather than the "syndrome" itself. It should be noted that both the vulva health index and the GSM tool still require validation and publication of outcomes from clinical trial usage.

23.7 Impact of VVA/GSM on Quality of Life

Despite the development of these assessment tools, the formal evaluation of impact of VVA/GSM on quality of life (QOL) remains a poorly addressed issue both in research and clinical practice. In the absence of specific VVA/GSM QOL rating scales, sexual QOL scales have been used as "surrogate rating scales" to assess the impact of GSM symptoms; but what about the impact in women who are not sexually active? There has been some recent progress in this area through adaptation of a dermatology quality-of-life scale [7]. By the admission of the authors of this paper, there was considerable work still to be done. However, a recently developed multidimensional vaginal ageing questionnaire (the day-to-day impact of vaginal ageing questionnaire DIVA) [8] could be a major step forward in the development of a practical, validated questionnaire which accurately assesses the impact of VVA/GSM on personal, social and professional aspects of QOL. Data from a recent European survey showed positive correlation between vulval, vaginal and urinary

Points	Normal = 0	Mild = 1	Moderate = 2	Severe = 3
Elasticity	Stretchable, elastic tissue	Slightly diminished elasticity	Moderately diminished	Absent, fibrotic
Lubrication	Normal secretions, moisture	Slightly decreased moisture	Mostly dry, some moisture	Very dry
Tissue integrity	Intact epithelium, no friability or petechiae	Some friability with vigorous contact, no petechiae	Moderate friability or petechiae with some contact	Significant friability, bleeding, petechiae with minimal contact
Anatomy				
Introitus	3-Dimensional	Mostly 3-dimensional	Some contraction, stenosis, rather flat	Mostly contracted, stenotic, flat
Labia majora, minora	Normal for parity, coital activity, and anatomic variation	Most definition present	Some resorption, especially inferior aspect of labia minora	Significantly decreased size; minora mostly resorbed
Urethra	Normal size and position	Normal to slightly prominent	Moderately prominent urethral meatus	Eversion present; inner aspect protruding
Rugae	Normal	Present to slightly diminished	Moderately diminished but visible	Significantly diminished to absent
Color	Normal	Some faint pallor	Moderate pallor	Complete pallor
Supportive				
pH	<5		5-6.5	
Maturation index	No parabasal cells	Decrease in number of superficial cells, increase in number of parabasal cells	Fewer superficial cells, more parabasal cells	Few to no superficial cells, many parabasal cells

Fig. 23.3 Genitourinary syndrome of the menopause assessment tool [1]

symptom severity and DIVA scores, i.e. the more severe the symptoms the higher the DIVA scores indicating impairment of QOL [9].

In order to derive meaningful information from quality-of-life scales, we need to be clear about which questions we ask women and why we ask them. Women are

often confused by the meaning of terms such as “vaginal dryness”; to them, this could mean “lack of normal discharge”, “absence of lubrication during intercourse” or both. The “most bothersome symptom” question, now mandatory in FDA-approved studies, attempts to individualise the assessment of the magnitude and severity of GSM but runs the risk of devaluing the other less bothersome symptoms which still impact on overall wellbeing and quality of life [10].

23.8 Improving Information to Women and Healthcare Providers

Whilst social and cultural taboos are difficult to deal with, we believe there are a number of action points which the wider medical profession (doctors, pharma companies, health departments and regulators) should urgently address to improve the situation. Firstly, formal research into VVA/GSM should be expanded to confirm the scale of the problem and the impact it has on quality of life. Although highly informative, all VVA/GSM surveys such as VIVA [3] are unavoidably biased by the type and size of study population selected, and information is limited by the choice of questions asked. Is the scale of the VVA/GSM problem even larger than we think because women are reluctant to admit to having symptoms? Guidelines issued by the International Menopause Society and other societies [11, 12] are vitally important to improve awareness of VVA/GSM and in promoting the evidence-based management. Finally, it is imperative that menopause societies and pharma companies work with the regulators to change the labelling of vaginal oestrogen preparations, which currently carry precisely the same contraindications as systemic hormone therapy even though local oestrogen is not absorbed systemically.

23.9 The Need for New Products

The development of novel efficacious and safe interventions is essential to expand our armamentarium for managing VVA symptoms to provide approaches which suit all needs and desires. For instance, there will be some women who do not wish to use oestrogen or in whom oestrogen is genuinely contraindicated. Other women may find it uncomfortable or may not want, due to personal or cultural reasons, to use vaginal products. Emerging interventions include safe new laser treatments which avoid pharmacologically active agents [13], vaginally active oral selective oestrogen receptor modulators [10] and vaginal androgens such as DHEA [14]. Technological advances in nonhormonal physiological vaginal moisturisers should banish the use of vaginal lubricant gel to the examination couch [15]. It is vital that a wide armamentarium of treatment options exists to facilitate individualised management [16].

Conclusion

VVA/GSM has been neglected for too long by sufferers, their partners, society, the medical profession and the regulators. With an ageing population, it is likely that the problem will only grow as women live nearly half of their lives in a post-menopausal state. The development of the new GSM nomenclature, new tools for assessing the severity and impact of the condition and the new intervention modalities such as laser, SERMS and androgens will facilitate the understanding and management of this distressing condition.

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