

# Urogenital Atrophy in 40–75 Years Women Assessed with Different Scoring Systems at Tertiary Care Hospital of India

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ABSTRACT

**Objective:** The present study was conducted to assess the validity of symptom score and Genital Health Clinical Evaluation (GHCE) score as diagnostic tools for urogenital atrophy in females of 40–75 years of age group. **Materials and Methods:** A cross-sectional study including 600 females in the age group of 40–75 years attending gynecology outpatient department was conducted. They were given a symptom score based on their history. GHCE score and smears for vaginal maturation index (VMI) were taken and percentages of superficial cells were counted. Statistical tests of significance such as Karl Pearson's coefficient of correlation were applied. Sensitivity, specificity, positive predictive value, negative predictive value, accuracy of GHCE score, and symptom score with VMI score were calculated. **Results:** The prevalence of urogenital atrophy in females of 40–75 years of age group using VMI scoring was 38.1%. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of total symptom score for diagnosing urogenital atrophy were 66.4%, 75.3%, 56.3%, 82.4%, and 72.5%, respectively. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of GHCE score for diagnosing urogenital atrophy were 43.4%, 80.7%, 75.3%, 51.3%, and 59.3%, respectively. **Conclusion:** Both symptom score and GHCE score can be used as valid alternatives to VMI as diagnostic tools for urogenital atrophy in females of 40–75 years of age group at least in resource-poor settings.

**KEYWORDS:** Females, Genital Health Clinical Evaluation score, India, symptom score, urogenital atrophy, vaginal maturation index

## INTRODUCTION

Menopause is a transition phase from the reproductive to the nonreproductive phase in a woman's life. It can be considered as a nature's protective phenomenon against reproductive morbidity and mortality in the aging population.<sup>[1]</sup> Evidence supports the clinical importance of the transition for many women as a period of temporal changes such as vasomotor symptoms and sleep disturbance and long-term changes in several health outcomes such as urogenital symptoms.<sup>[2]</sup>

There is a gradual loss of estrogen during the perimenopausal period, with reduction in the amount of estradiol. Changes in tissue composition are seen in the genital tract as well as the urinary tract. Urogenital

tissues show profound degenerative and inflammatory changes which are described as urogenital atrophy.<sup>[3]</sup> This gives rise to symptoms such as vaginal dryness, irritation, soreness, dyspareunia with urinary frequency, urgency, and urge incontinence.

Studies published in 2009 in the USA showed that the prevalence of urogenital atrophy symptoms in postmenopausal women is approximately 40%–50%.<sup>[3,4]</sup> In Indian women, these symptoms have been shown to increase progressively in the perimenopausal

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**How to cite this article:** Shah M, Khandelwal A, Patel S. Urogenital atrophy in 40–75 years women assessed with different scoring systems at tertiary care hospital of India. J Mid-life Health 2018;9:191-4.

Access this article online	
Quick Response Code: 	Website: <a href="http://www.jmidlifehealth.org">www.jmidlifehealth.org</a>
	DOI: 10.4103/jmh.JMH_15_18

period reaching an incidence of more than 40% after menopause.<sup>[5]</sup> The prevalence of vaginal dryness and urinary incontinence showed a linear decrease with increasing age according to J. M. van Geelen *et al.*<sup>[6]</sup>

The present cross-sectional study is an attempt to find the actual prevalence of urogenital atrophy with the help of simpler methods such as symptom score and Genital Health Clinical Evaluation (GHCE) score in females of 40–75 years of age group. It also assesses the validity of symptom score and GHCE score as compared to vaginal maturation index (VMI) which is a standard diagnostic tool for urogenital atrophy.

## MATERIALS AND METHODS

This was a cross-sectional study conducted at the tertiary care hospital of Western India. The study protocols were approved by the Scientific Ethics and Research Committee of the institute. All females of 40–75 years of age group attending gynecology outpatient department were recruited to participate in the study after obtaining their written informed consent.

Considering 40% prevalence of urogenital atrophy<sup>[1]</sup> and relative allowable error of its 10%, sample size was calculated which came out to be 600. Those females on any oral, vaginal, or transdermal medication containing estrogens, androgens, or progestins within 8 weeks of screening; women who had used vaginal moisturizers, lubricants, jellies, ointments, douches, herbal medications, over-the-counter preparations, home remedies, or natural estrogen products (i.e., soy products) for the treatment of menopausal symptoms; and those with history of significant medical problems such as cardiac disease, diabetes mellitus, renal disorder, gallbladder or hepatic disorder, or history of urogynecological surgeries except hysterectomy were excluded from the study.

A total of 610 women who were found to be eligible were screened for enrollment into the study. They were counseled about the methods in details and their roles in the study. Ten women out of them refused to give consent, so remaining 600 women were included in the study. After taking their detailed history, all of them were asked about the following symptoms related to urogenital atrophy and were given a symptom score which is defined as the following: A baseline composite score rated for each symptom as: 0 – no complaint, 1 – mild, 2 – moderate, and 3 – severe for four symptoms of: (1) vaginal dryness, (2) itching, (3) burning, and (4) dyspareunia.<sup>[3]</sup>

Following this, all of them were subjected to per-speculum examination for GHCE scoring which is

a tool used to evaluate six parameters scored on a scale of 1–4:

(a) vaginal pH, (b) fluid secretion, (c) moisture, (d) vaginal rugosity (e) mucosal color, and (f) epithelial mucosa.<sup>[3]</sup>

Smears for VMI were taken and percentages of superficial cells were counted for all of them. In this study, we have kept VMI as the gold standard.

Urogenital atrophy was defined as the following: a baseline composite score (at the initial screening visit) of at least 5 (1 = mild, 2 = moderate, 3 = severe, and None = No symptoms present); total score of 15 or less on the GHCE score (scored on a scale of 1–4); vaginal pH of at least 5; and 0% to 5% superficial cells on vaginal cytologic smear.<sup>[3]</sup>

Participation was voluntary and women were given the right to get any services from the facilities even if they declined to participate in the study. Women had the right to decline participation at any time during the course of the study. Information collected from the subjects and the data entered were kept confidential.

Baseline demographic information was collected from the participants at the time of first visit. All the data were entered into a Microsoft Excel Sheet and analyzed by Epi\_Info Version 7.2.0.1 software (Atlanta, Georgia, USA) and statistical test of significance such as Karl Pearson's coefficient of correlation between the different scores was applied, wherever applicable.

Sensitivity, specificity, positive predictive value, negative predictive value, accuracy of GHCE score, and symptom score with VMI score were calculated in order to compare their diagnostic accuracies.

## RESULTS

### Baseline characteristics and demographic profile of all subjects

Out of 600 women, 52.1% were of 40–45 years of age group, 21.1% were in 46–50 years of age group, while only 1.5% women were above 70 years of age group. Out of 600 women, 172 were postmenopausal. Majority of the women (84.1%) resided in urban areas. Only 15.8% of women were of rural area. There were no women from tribal or urban slum area. Almost three-fourths (77.5% out of 600) women were illiterate, 17.1% were educated up to primary school class, and 4.3% till middle school. One woman was educated till high-school class [Table 1].

**Prevalence of urogenital atrophy according to Symptom score, Genital Health Clinical Evaluation score, and vaginal maturation index**

The prevalence of urogenital atrophy in females of 40–75 years of age group was 38.1% using symptom score, 33.3% according to the GHCE score, and 32.6% based on VMI score. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of total symptom score for diagnosing urogenital atrophy were 66.4%, 75.3%, 56.3%, 82.4%, and 72.5%, respectively.

Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of GHCE score for diagnosing urogenital atrophy were 43.4%, 80.7%, 75.3%, 51.3%, and 59.3%, respectively [Table 2].

**Validity and predictive values of different clinical parameters compared with vaginal maturation index**

As compared to VMI score (gold standard), sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of total symptom score were 66.4%, 75.3%, 56.3%, 82.4%, and 72.5%, respectively.

Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of GHCE score were 43.4%, 80.7%, 75.3%, 51.3%, and 59.3%, respectively.

The correlation coefficient *r* between total symptom score and VMI was  $-0.1757$  (95% confidence interval [CI] for  $r = -0.2522$ – $-0.09706$ ). There is a weak negative correlation between total symptom score and VMI, which is statistically significant ( $P < 0.0001$ ). This indicates that as the VMI score increases and total symptom score decreases.

Correlation coefficient *r* between GHCE score and VMI was  $0.4620$  ( $P < 0.0001$ ) (95% CI for  $r = 0.3966$ – $0.5227$ ). There was a moderate correlation between GHCE score and VMI. This correlation is statistically significant with  $P = 0.0001$  [Table 3].

**DISCUSSION**

According to the STRAW 10+ Criteria, early postmenopausal period last for 5–8 years after the final menstruation period. However, symptoms of vaginal dryness and urogenital atrophy become increasingly prevalent in late postmenopausal period. The STRAW 10+ model does not use age as a criterion for determining reproductive staging.<sup>[2]</sup> Many studies till date have evaluated the prevalence of urogenital atrophy in different populations. Most of them have used self-reported symptom scores in response to various questionnaires to assess prevalence rate. Pal *et al.*, from Maharashtra, India, in 2013, conducted a study on perimenopausal and postmenopausal

**Table 1: Demographic profile of participants**

	Number of participants (%)
Occupation	
Homemaker	437 (72.8)
Teacher	2 (0.3)
Laborer	161 (26.8)
Residence	
Rural	95 (15.8)
Urban	505 (84.1)
Religion	
Hindu	487 (81.1)
Muslim	88 (14.6)
Others	25 (4.16)
Education	
Illiterate	465 (77.5)
Primary school	103 (17.1)
Middle school	26 (4.3)
High school and above	6 (1)

**Table 2: Prevalence of urogenital atrophy according to symptom score, Genital Health Clinical Evaluation score, and vaginal maturation index**

	Total (n=600), n (%)
Symptom score	
≥5	229 (38.1)
<5	371 (61.8)
GHCE score	
≤15	200 (33.3)
>15	400 (66.7)
VMI (percentage superficial epithelial cells)	
≤5	196 (32.6)
>5	404 (67.3)

GHCE: Genital Health Clinical Evaluation, VMI: Vaginal maturation index

**Table 3: Karl Pearson’s correlation coefficient for total symptom score and Genital Health Clinical Evaluation score with vaginal maturation index**

	Correlation between total symptom score and VMI	Correlation between GHCE score and VMI
Sample size	600	600
Correlation coefficient ( <i>r</i> )	$-0.1757$	$0.4620$
Significance level ( <i>P</i> )	$<0.0001$	$<0.0001$
95% CI for <i>r</i>	$-0.2522$ – $-0.09706$	$0.3966$ – $0.5227$

GHCE: Genital Health Clinical Evaluation, VMI: Vaginal maturation index, CI: Confidence interval

women with the help of menopausal rating scale and concluded that prevalence of urogenital atrophy is 53% in postmenopausal women.<sup>[4]</sup> Mac Bride *et al.*, in 2010, found out 4% prevalence in early premenopausal

age group and 47% in postmenopausal age group.<sup>[5]</sup> In general, the prevalence rate in menopausal females is estimated to be around 50% based on the symptoms reported. It has been observed that very few women discuss these problems and seek treatment from their practitioners because of societal and cultural taboos. Of approximately 40% of postmenopausal women experiencing vaginal atrophy, only 20%–25% seek medical attention.<sup>[3]</sup>

Physical signs of urogenital atrophy are variable and include a change from moderately acidic range (pH 3.5–5.0) to a neutral range (pH 6.0–8.0) in vaginal pH and a shift in the VMI. The modalities of evaluation range from basic pelvic examination, examination of the vulva, and laboratory tests.<sup>[7]</sup> In the present study, we have used all these modalities to evaluate urogenital atrophy in 40–75 years age group. According to our study, the prevalence of urogenital atrophy was 38% using symptom score, it turned out to be 33.3% using GHCE score, and with VMI score, it was 32.6%.

In this study, keeping VMI SCORE as the gold standard, we analyzed the accuracy and correlation of different clinical parameters such as GHCE score and total symptom score with VMI score. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of total symptom score for diagnosing urogenital atrophy were 66.4%, 75.3%, 56.3%, 82.4%, and 72.5%, respectively. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of GHCE score for diagnosing urogenital atrophy were 43.4%, 80.7%, 75.3%, 51.3%, and 59.3%, respectively.

There was a statistically significant positive correlation between GHCE score and VMI score and negative correlation between total symptom score and VMI score. VMI correlates well with other parameters such as symptom score and GHCE score. Hence, symptom score and GHCE score can also be used for diagnosis of urogenital atrophy where facilities for VMI are not available. Health-care personnel at peripheral health level can diagnose urogenital atrophy on this basis and timely reference can be done.

Using standard definitions, we have tried to make this evaluation more objective which can help to frame guidelines in the future. We did not find any similar study in the available literature.

## CONCLUSION

Prevalence of urogenital atrophy using VMI scoring was 31.8%. As VMI correlates well with other parameters such as symptom score and GHCE score, these can be used as valid alternatives to VMI as diagnostic tools for urogenital atrophy in females of 40–75 years of age group at least in resource-poor settings. This study can be considered as one of the interim studies of its kind and further studies including a larger sample size with diverse group of participants are needed for its validity.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

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