COMPARING HAY'S CRITERIA AND NUGENT'S SCORING SYSTEM FOR DIAGNOSING BACTERIAL VAGINOSIS IN VIETNAM: A 2023 STUDY

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SUMMARY

Objective: This study aimed to assess the simplicity and diagnostic effectiveness of the Hay et al. method in comparison to the Nugent scoring system for diagnosing Bacterial Vaginosis (BV).

Method: A cross-sectional analysis was conducted on 290 women who sought medical consultation for abnormal vaginal discharge at the National Hospital of Dermatology and Venereology between September 2022 and June 2023.

Results: According to Nugent's scoring system, 62 patients (21.4%) were diagnosed with BV, 20 patients (6.9%) exhibited intermediate flora, and 208 patients (71.7%) had normal vaginal flora. The diagnostic performance of the Hay/Ison criteria demonstrated a sensitivity of 98.4%, specificity of 98.2%, a positive predictive value of 93.8%, and a negative predictive value of 99.6%, with a Kappa coefficient of 0.95. A significant correlation was observed between the presence of clue cells and both Hay's grade III ($p < 0.001$) and Nugent's score of 7–10 ($p < 0.001$).

Conclusion: The Hay classification system proved to be a highly effective diagnostic tool, allowing clinicians to evaluate BV based on the relative quantities of Lactobacilli and Gardnerella morphologies. This simplified method offers a practical and reliable alternative to Nugent's scoring system, making it particularly suitable for use in hospitals and healthcare facilities.

Key word: *Bacterial vaginosis, Nugent's score, Hay/Ison criteria.*

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INTRODUCTION

The syndrome of vaginal discharge is a common medical condition in women of reproductive age.[1] This is a common manifestation of lower genital tract infections in women. According to Javed (2019), it was estimated that approximately 21.1 million women worldwide were currently suffering from Bacterial Vaginosis (BV).[2] A recent study by Anh et al. (2024) examined the prevalence of bacterial vaginosis (BV) in Vietnam. Out of 885 pregnant women, 435 (49.1%) had a normal BV score, 352 (39.8%) displayed intermediate vaginal microbiota, and 98 (11.1%) were diagnosed with BV. Of the 98 women with BV, 71 (72.4%) were also found to have a fungal infection.[3] Lower genital tract infections affect health, quality of life, work capacity, and, notably, reproductive health.[4–6] If not detected early and treated promptly, they can lead to severe consequences such as pelvic inflammatory disease, ectopic pregnancy, infertility, cervical cancer, and an increased risk of HIV transmission.[7–9]

According to the 2018 guidelines issued by the International Union Against Sexually Transmitted Infections (IUSTI) and the World Health Organization (WHO) for the management of vaginal discharge, the most reliable diagnostic methods for Bacterial Vaginosis (BV) are the Nugent score and the Hay/Ison criteria, with the Nugent score regarded as the gold standard.[10–12] However, the application of the Nugent score requires substantial expertise, time, and technical skill.[13] Numerous studies have indicated that the Hay/Ison criteria are currently preferred in clinical practice for diagnosing BV due to their simplicity and rapid application.[12]

The etiological factors causing the syndrome of abnormal vaginal discharge are highly diverse, including *Candida*, *Trichomonas vaginalis*, anaerobic bacteria, *Gonorrhea*, *Chlamydia trachomatis*, and others.[14] Furthermore, the recurrence rate after treatment is high.[14,15] This necessitates identifying the causative agent to provide the most appropriate diagnostic and treatment guidelines. Hence, the aim of the study was to evaluate the simplicity of the Hay et al. diagnostic method in comparison to the Nugent scoring system and to assess their effectiveness in diagnosing Bacterial Vaginosis.

MATERIALS AND METHODS

Participants

The study included women who sought examination for abnormal vaginal discharge at the National Hospital of Dermatology and Venereology between September 2022 and June 2023.

Inclusion Criteria

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- Female patients aged 15 to 49, either married or sexually active, presenting with clinical manifestations of vaginal discharge syndrome, including abnormalities in the quantity, color, or odor of vaginal discharge, vaginal itching, painful urination, pain during sexual intercourse, or mucous cervicitis.

- Patients who consented to participate in the study.

Exclusion Criteria

- Patients who were menstruating or pregnant.

- Patients who had used antibiotics or antifungal medications within the past 4 weeks.

- Patients who were uncooperative or lacked sufficient behavioral capacity to participate in the research.

Study Design

This was a cross-sectional descriptive study.

Sample Size

The sample size was determined using the formula for descriptive study sample estimation. From the data, the calculated sample size was n = 260. In this study, a sample of 290 participants was collected.

Measurements/Sample collection

The patient presented to the outpatient department with symptoms of vaginal discharge syndrome, which included abnormal vaginal discharge, vaginal itching, painful urination, and pain during sexual intercourse, among others. Vaginal fluid samples were collected for testing. The specimens were stained using the Gram method and scored according to Nugent's and Hay/Ison criteria. Smears prepared from the vaginal fluid were air-dried. Once the slides had dried, they were fixed by gently passing them through a flame with moderate heat to preserve the bacterial and cellular structure. A violet dye solution (Genital/Crystal violet) was applied to cover the slide and left for 60 seconds. The slide was then gently rinsed under water. Iodine solution was applied for approximately 2 minutes, followed by a gentle rinse under water. The slide was quickly exposed to 96% alcohol for 10 seconds and rinsed with water. A Fuchsin/Safranine red solution was applied for around 10 seconds, and the slide was rinsed gently under water before being left to dry. All smears were assessed using the grading systems developed by Nugent et al. and Hay et al.[17–19]

For the diagnosis of bacterial vaginosis, the Gram-stained vaginal smear was examined under a microscope with an oil immersion objective at a magnification of 1000x. Coffee bean-shaped or kidney-shaped Gram-negative diplococci, both inside and outside cells, were observed.

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The Nugent score used a system based on bacterial morphology of the Gram-stained vaginal fluid to diagnose bacterial vaginosis. The large Gram-positive rod morphology was characteristic of *Lactobacillus*. The small Gram-negative rod morphology (with variable forms) included *Gardnerella* and anaerobic bacteria. The curved Gram-negative rods, larger than *Gardnerella*, with more intensely stained ends, were indicative of *Mobiluncus*.[20]

Data management and analysis

Data were recorded and tracked using Excel, and subsequently analyzed with SPSS software (version 20.0). Qualitative variables were summarized in terms of frequency and percentage, and sensitivity was computed. The Kappa coefficient, along with sensitivity, specificity, and both positive and negative predictive values, were determined using Hay's method.

Ethical considerations

The confidentiality of patient information was maintained throughout the study, with the exception of cases involving suicidal or homicidal ideation. All patient and treatment data were kept secure. The research was approved by the Science Council. Additionally, the study received approval from the Preventive Medicine & Public Health Institute and the National Hospital of Dermatology and Venereology under decision No. 70/HĐĐĐ-BVDLTW, dated 01/09/2022. Patients were thoroughly informed about the research details and were assured that there were no associated risks. Furthermore, they were fully informed of their right to withdraw from the study at any time without consequence.

RESULTS

The study conducted on 290 patients diagnosed with vaginal discharge syndrome at the National Hospital yielded the following results:

According to Nugent's scoring system, 62 patients (21.4%) were diagnosed with bacterial vaginosis (BV), 20 patients (6.9%) had intermediate flora, and 208 patients (71.7%) had normal vaginal flora. Among the 62 smears with a Nugent score of ≥7 (indicating BV), 61 were classified as grade III (BV) according to Hay's grading method. For the smears with a Nugent score of 4–6 (indicating intermediate or mixed flora), 16 were classified as grade II, and 4 were categorized as grade III (BV) using Hay’s method (Table 1).

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Table 1. Comparison of Hay's Criteria with Nugent's Scoring in diagnosing Bacterial vaginosis (n=290).

Hay/Ison Criteria	**Nugent's score**			
	Normal (0-3)	Intermediate (4-6)	Positive (≥7)	Total n (%)
I	208	0	0	208 (71.7)
II	0	16	1	17 (5.9)
III	0	4	61	65 (22.4)
Total, n (%)	208 (71.7)	20 (6.9)	62 (21.4)	290

The Hay/Ison criteria demonstrated a sensitivity of 98.4%, specificity of 98.2%, positive predictive value of 93.8%, and negative predictive value of 99.6%, with a Kappa index of 0.95. This high Kappa value indicated excellent interobserver agreement. When compared to Nugent's method, the Hay/Ison approach was found to offer superior diagnostic accuracy for bacterial vaginosis (Table 2).

Table 2. The sensitivity, specificity, positive predictive value, and negative predictive value of the Hay/Ison criteria, with Nugent's score serving as the standard for the diagnosis of BV.

Hay/Ison Standard		**Nugent's score**		
		Bacterial vaginosis (≥7)	Normal (0-3) and intermediate (4-6)*	Total (%)
Group III		61	4	65
Group I, II*		1	224	225
Total		62	228	290
Sensitivity	***Specificity***	***Predictive value of positive result***	***Predictive value of negative result***	***Kappa index***
98.4	98.2	93.8	99.6	0.95

The results presented in Table 3 indicated a significant association between the presence of clue cells and both Hay's grade III ($p < 0.001$) and Nugent's score of 7–10 ($p < 0.001$).

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Table 3. The presence of associated clue cells was evaluated using the Nugent scale and the Hay/Ison criteria.

Criteria	n	Clue cells		p-value Odds ratio
		Positive	Negative	
Nugent Scale				
7-10	62	55	7	0.000[y]
4-6	20	5	15	290[*]
0-3	208	1	207	
Hay/Ison Standard				
III	65	58	7	0.000
II	17	2	15	613.14[*]
I	208	1	207	

[y] *Chi square test*

DISCUSSION

Bacterial vaginosis (BV) represents a significant, albeit often overlooked, public health issue. The global prevalence of BV varies considerably, with rates ranging from 23% to 29% in developed nations, and rising to 61% in less-developed regions.[2,21] The condition also imposes a substantial economic burden. The annual worldwide cost associated with the treatment of symptomatic BV is estimated at approximately US$4.8 billion (95% CI: 3.7 -6.1 billion).[2,21] Although the accurate diagnosis of bacterial vaginosis (BV) presents certain challenges, it is essential for preventing further complications. [22,23] Therefore, selecting an appropriate diagnostic method necessitates precision and thorough consideration. [24,25]

Hay's Criteria and Nugent's Score are two commonly used diagnostic methods for Bacterial Vaginosis (BV), each with distinct advantages and limitations. Hay's Criteria, introduced in the early 1990s, is based on clinical signs and symptoms, such as vaginal pH, the presence of clue cells, and a fishy odor on amine testing.[20] This method is simple and cost-effective but may lack sensitivity and specificity compared to laboratory-based techniques. In contrast, Nugent's Score, a microscopic method, involves the assessment of the vaginal flora through Gram stain, categorizing the presence of different bacterial morphotypes

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(*Lactobacillus, Gardnerella,* and *Mobiluncus*).[26] It provides a more objective and precise diagnosis, offering higher sensitivity and specificity for BV detection (Nugent et al., 1991).[27] Studies suggest that Nugent's Score is superior in terms of diagnostic accuracy, especially in asymptomatic women.[28] However, the requirement for laboratory facilities and expertise limits its widespread use, making Hay's Criteria a practical alternative in low-resource settings. Additionally, while Nugent's Score has been validated in multiple populations, Hay's Criteria still remains useful in clinical practice due to its ease of implementation. In conclusion, while Nugent's Score is generally considered the gold standard, Hay's Criteria can still be valuable in primary care or resource-limited settings.[27,29,30]

To the best of our knowledge, this represents the first study conducted in Vietnam to compare Hay et al.'s simple reading scheme with the scoring method of Nugent et al. Our findings revealed a significant association between Nugent's score ≤ 3 and Hay grade I flora, while a Nugent score ≥ 7 correlated with Hay grade III classification. Among the 62 Nugent specimens from the BV group, 61 were classified as Hay grade III, and 1 was classified as Hay grade II. Conflicting results were observed in 5 patients (1.7%), with 4 showing Nugent's intermediate group and Hay grade III, and 1 showing Nugent's BV group and Hay grade II. More women were diagnosed with BV using Hay's method compared to Nugent's method. Furthermore, we observed high levels of agreement in sensitivity, specificity, positive predictive value, negative predictive value, and the Kappa index for Hay's criteria when compared to Nugent's method. These findings are consistent with the results of Chawla (2013).[20] A study by PG Larsson and colleagues in Sweden (2003) also demonstrated a Kappa index of 0.88 between the two methods. These results suggest that when time or experience is limited, the Hay/Ison method may serve as an effective alternative to Nugent's score for diagnosing BV.[31] María et al. (2011) assessed discordant specimens using the Ison and Hay method.[32] Vaginal microbiota was classified as normal in 58% and 68% of samples according to Nugent and Spiegel criteria, respectively. Thirty percent and 32% of samples were identified as bacterial vaginosis (BV) by Nugent and Spiegel, respectively. Concordance between both criteria was found in 88.5% of samples. The remaining 11.5% (40 samples) were discordant, categorized as intermediate microflora by Nugent but normal or BV by Spiegel. The Ison/Hay method further classified these specimens into four microbiota categories: 25% as grade II (intermediate by Nugent), 15% as grade III (BV by Spiegel), 32.5% as a non-categorized type, and 11 samples could not be classified due to limitations in distinguishing bacterial morphotypes. The findings suggest that the diagnostic systems of Spiegel, Nugent, and Ison/Hay are comparable for

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BV identification.[32] Rutuj et al. (2022) similarly reported that bacterial vaginosis (BV) diagnoses based on Amsel's and Nugent's criteria were comparable to those obtained using the Hay/Ison method, reinforcing the consistency of these diagnostic approaches in BV identification.[33]

The presence of Clue cells was strongly associated with bacterial vaginosis (BV) in this study. Among the 62 women diagnosed with BV using the Nugent method, 88.7% exhibited positive Clue cells, while 89.2% of the 65 women diagnosed based on the Hay/Ison method also had Clue cells. Antonucci (2017) examined 100 Gram-stained vaginal fluid specimens, finding that all patients diagnosed with BV had Clue cells, thereby supporting the association between Clue cell presence and BV.[13] Our findings also demonstrated a significant correlation between Clue cells and Hay grade III ($P<0.001$) as well as Nugent scores of 7-10 points ($P<0.001$). In a similar study by Tamonud Modak and colleagues (2011) in Kolkata, India, a significant relationship was observed between Clue cell presence and Nugent positivity ($P<0.001$).[34] These results suggest that Clue cells may serve as an important indicator in the diagnosis of bacterial vaginosis.

CONCLUSION

The study, conducted on 290 patients diagnosed with vaginal discharge syndrome at the National Hospital, revealed that 62 patients (21.4%) were diagnosed with bacterial vaginosis (BV), 20 patients (6.9%) exhibited intermediate flora, and 208 patients (71.7%) had normal vaginal flora, based on Nugent's scoring system. According to the Hay/Ison criteria, the diagnostic performance demonstrated a sensitivity of 98.4%, specificity of 98.2%, positive predictive value of 93.8%, and negative predictive value of 99.6%, with a Kappa coefficient of 0.95. The results showed a significant correlation between the presence of clue cells and both Hay's grade III ($p < 0.001$) and Nugent's score of 7–10 ($p < 0.001$). The Hay classification system proved to be effective, enabling clinicians to diagnose based on the relative quantities of Lactobacilli and Gardnerella morphologies. This simplified approach offers a viable alternative to Nugent's score and is particularly suitable for use in hospitals and healthcare facilities.

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