CSIRO PUBLISHING

LETTER
https://doi.org/10.1071/SH21149

SEXUAL HEALTH

Diagnostic concordance between Amsel's criteria and the Nugent scoring method in the assessment of bacterial vaginosis

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Handling Editor:
Christopher Fairley

ABSTRACT

Bacterial vaginosis (BV) is diagnosed by the microbiological Nugent scoring method or clinical Amsel's criteria. Assessment of 404 vaginal samples (293 women) identified 110 (27.2%), 108 (26.7%) and 161 (39.9%) samples to be BV-positive using Nugent's method, standard Amsel's criteria and simplified Amsel's criteria respectively. The sensitivity, specificity, and kappa statistic (κ) for standard and simplified Amsel's criteria were 71.8% (95% CI = 62.4–80.0), 90.1% (95% CI = 62.4–86.1), 0.62 (95% CI = 0.53–0.72) and 88.2% (95% CI = 80.6–93.6), 78.2% (95% CI = 73.1–82.8), 0.58 (95% CI = 0.49–0.67), respectively. A combination of vaginal pH and clue cells exhibited the highest concordance (κ = 0.64, 95% CI = 0.54–0.74) with Nugent's method and may be used for simplified BV diagnosis.

Keywords: Amsel's criteria, bacterial vaginosis, diagnostics, Nugent scoring method, reproductive health, sexual and reproductive health, vaginal dysbiosis, vaginal ecology, vaginal microbiota, women.

Bacterial vaginosis (BV) is a clinical syndrome associated with altered vaginal ecology and a spectrum of vulvovaginal symptoms, including malodorous discharge and elevated pH. It is common among pre-menopausal women and has been implicated in adverse sexual and reproductive outcomes.[1–3] Traditionally, BV has been diagnosed by Amsel's clinical criteria or laboratory-based Nugent scoring method. However, due to realistic constraints in clinical practice, either syndromic case management is favoured or modified clinical criteria are used, leading to misdiagnosis and unfavourable health outcomes. We therefore sought to evaluate the concordance between the standard diagnostic tests – Amsel's criteria and the Nugent scoring method. Additionally, we evaluated the accuracy of individual and combinations of two Amsel's criteria for BV diagnosis.

A prospective, longitudinal study was conducted from August 2018 to February 2021 in the Sexually Transmitted Diseases (STD) and Obstetrics and Gynaecology out-patient departments at the All India Institute of Medical Sciences, New Delhi, India. Women who were pregnant, lactating, menstruating, or had received oral antibiotics in the preceding 4 weeks were excluded. The study was approved by the Institute Ethics Committee, All India Institute of Medical Sciences, New Delhi and informed consent was obtained from all participants.

A total of 293 participants were enrolled in the study and vaginal swabs were collected. Additionally, BV-positive women were treated and repeat swabs were collected at week 1, week 4 and thereafter quarterly till relapse. Finally, 404 vaginal samples were evaluated using the Nugent scoring method and a score of 0–3 was considered negative, 4–6 as intermediate, and 7–10 as BV-positive. Clinical diagnosis was based on the following signs: (1) thin homogenous vaginal discharge; (2) vaginal pH > 4.5; (3) positive whiff test; and (4) presence of clue cells. A positive diagnosis using standard Amsel's criteria was made when any three of the four signs were present and for simplified criteria, the presence of any two of the signs were considered. Using the Nugent score as the gold standard, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and kappa statistic (κ) for standard, simplified, and individual Amsel's criteria were calculated. All statistical tests were performed using STATA ver. 12 (StataCorp LLC).

Received: 4 August 2021
Accepted: 13 September 2021
Published: 17 December 2021

Cite this:
Challa A *et al.* (2021)
Sexual Health, **18**(6), 512–514.
doi:10.1071/SH21149

Table 1. Diagnostic concordance between standard, individual and simplified Amsel's criteria and the Nugent scoring method in Indian women.

Amsel's criteria	*n* (%)	Sensitivity (95% CI)	Specificity (95% CI)	PPV (%)	NPV (%)	Accuracy (%)	Kappa (95% CI)
Standard criteria	108 (26.7)	71.8 (62.4–80.0)	90.1 (62.4–86.1)	73.1	89.5	85.1	0.62 (0.53–0.72)
Simplified criteria	161 (39.9)	88.2 (80.6–93.6)	78.2 (73.1–82.8)	60.2	94.7	80.9	0.58 (0.49–0.67)
Vaginal discharge	157 (38.9)	64.5 (54.9–65.2)	70.7 (65.2–75.9)	45.2	84.2	69.0	0.31 (0.22–0.41)
Vaginal pH	230 (56.9)	81.8 (73.3–88.5)	52.4 (46.5–58.2)	39.1	88.5	60.4	0.26 (0.17–0.34)
Whiff test	122 (30.2)	70.9 (61.5–79.2)	85.0 (80.4–88.9)	63.9	88.7	81.2	0.54 (0.44–0.64)
Clue cells	117 (30.0)	80.9 (72.3–86.5)	90.5 (86.5–93.6)	76.1	92.7	87.9	0.70 (0.60–0.80)
Vaginal discharge + pH	103 (25.4)	52.7 (43.0–62.3)	84.7 (80.1–88.6)	56.3	82.7	76.0	0.38 (0.28–0.48)
Vaginal discharge + whiff test	80 (19.8)	50.0 (40.3–59.7)	91.5 (87.7–94.4)	68.8	83.0	80.2	0.45 (0.36–0.55)
Vaginal discharge + clue cells	82 (20.3)	54.5 (44.8–64.1)	92.5 (88.9–95.3)	73.2	84.5	82.2	0.51 (0.42–0.61)
Vaginal pH + whiff test	102 (25.2)	63.6 (53.9–72.6)	89.1 (85.0–92.4)	68.6	86.8	82.2	0.54 (0.44–0.64)
Vaginal pH + clue cells	100 (24.7)	70.0 (60.5–78.4)	92.2 (88.5–95.0)	77.0	89.1	86.2	0.64 (0.54–0.74)
Whiff test + clue cells	91 (22.5)	61.8 (52.1–70.9)	92.2 (88.5–95.0)	74.7	86.6	83.9	0.57 (0.48–0.67)

PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval.

The Nugent score diagnosed 110 (27.2%), Amsel's criteria detected 108 (26.7%), and simplified Amsel's criteria identified 161 (39.9%) women as BV-positive (Table 1). The overall sensitivity, specificity, PPV, NPV, and accuracy for standard Amsel's criteria were 71.8% (95% CI = 62.4–80.0), 90.1% (95% CI = 62.4–86.1), 73.1%, 89.5%, and 85.1%, whereas for simplified Amsel's criteria, the parameters were 88.2% (95% CI = 80.6–93.6), 78.2% (95% CI = 73.1–82.8), 60.2%, 94.7%, and 80.9% respectively (Table 1). The overall concordance between standard Amsel's criteria and the Nugent scoring method was substantial (κ = 0.62; 95% CI = 0.53–0.72), but decreased on using the simplified Amsel's criteria (κ = 0.58; 95% CI = 0.49–0.67) (Table 1). Clue cells were the single most valuable marker of BV with highest concordance (κ = 0.70; 95%,CI = 0.60–0.80) and accuracy (87.9%). Although vaginal pH had the highest sensitivity (81.8%; 95% CI = 73.3–88.5), a noteworthy observation is its fair concordance (κ = 0.26; 95% CI = 0.17–0.34) when the Nugent scoring method is used. This finding holds relevance in busy clinical settings where pH is often used as a standalone tool for BV diagnosis.[4] As vaginal pH is subject to fluctuations in the presence of semen or blood, un-aided by other criteria, it may lead to over-diagnosis and subsequently over-treatment. In our study, vaginal pH > 4.5 (specificity 52.4%; 95% CI = 46.5–58.2) and abnormal vaginal discharge (sensitivity 64.5%; 95% CI = 54.9–65.2) were the least reliable predictors of BV. Vaginal pH in combination with clue cells, however, had the highest concordance (κ = 0.64; 95% CI = 0.54–0.74) when using the Nugent scoring method (Table 1).

Amsel's criteria may be simplified using a combination of vaginal pH and clue cells with high diagnostic accuracy. A combination of vaginal pH and a whiff test may be useful when microscopic facilities are unavailable, however, with a considerable loss to sensitivity.

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Data availability. The data that supports this study may be shared upon reasonable request to the corresponding author.

Conflicts of interest. Somesh Gupta is a Joint Editor of *Sexual Health* but was blinded from the peer-review process for this paper.

Declaration of funding. The work was supported by grants from Intramural Collaborative Research Award (Grant number: 8-06/AC-06/2018-RS) by the All India Institute of Medical Sciences, New Delhi, India.

Acknowledgements. The authors acknowledge the Indian Council of Medical Research, Government of India, for a research fellowship award (5/3/8/35/ITR-F/2019-ITR) to Ms Apoorva Challa.

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