ORIGINAL RESEARCH PAPER

Gynaecology

Evaluation of different diagnostic methods of bacterial vaginosis in a TeritiaryHospital, Chennai.

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ABSTRACT

Bacterial vaginosis (BV) is an ecological disorder of the vaginal microbiota that affects millions of women annually, and is associated with numerous adverse health outcomes including pre-term birth and the acquisition of sexually transmitted infections. This study aimed to determine the incidence rate of bacterial vaginosis among women and aimed to compare between the different methods of BV diagnosis. The results revealed that from the 314 patients, the prevalence of bacterial vaginosis is 18% in women at active labour. There is significant association of various factors like socio economic status, maternal weight, birth weight and neonatal complications with bacterial vaginosis. The association of bacterial vaginosis with preterm labour is quiet significant. Maternal age and parity lacked significant association with bacterial vaginosis.
Amsel's criteria has almost perfect agreement with Nugent's scoring system. But clue cells alone or clue cells combined with amine test can replace the cumbersome three parameters Amsel's scoring system or technically demanding Nugent's scoring system.

Introduction:

Bacterial vaginosis (BV) is a polymicrobial syndrome with acquisition of several fastidious bacteria, concurrent with a decrease of lactobacilli, the dominant constituents in normal vaginal flora [1]. It is a condition characterized by replacement of vaginal lactobacilli with predominantly anaerobic micro-organisms such as Gardnerella vaginalis, Prevotella, Peptostreptococcus and Bacteroides spp. [2]. Although BV is often asymptomatic, it still is, along with vulvovaginal candidiasis, the most common cause of vaginitis, and hence among the commonest reasons for women to seek medical help [3]. BV is common in low social economic groups where the reported incidence is 20-49%. Its reported rate is 45-55% in African American, 20-30% in Asian women and 5-15% in Caucasian women [4].

There is an evidence that BV, whether it is asymptomatic or symptomatic, is an independent risk factor for severe reproductive tract and obstetric sequelae, including pre-term delivery, pre-term labor, low birth weight, post abortion endometritis, post-partum endometritis [5], development of Pelvic inflammatory disease (PID) as reported by [6], acquisition of sexually transmitted diseases (STIs) as proved by [7], acquisition and transmission of HIV [8]. Due to these serious complications, there has been an increase of interest in bacterial vaginosis during the last decade, regarding its diagnosis and treatment [9].

The diagnosis for bacterial vaginosis remained difficult and controversial due to lack of diagnostic tools. Clinically, BV can be identified by the presence of at least three of the four Amsel criteria: an elevated vaginal PH, an increased vaginal discharge, the presence of clue cells and an amine odor after the addition of potassium hydroxide [10].

Diagnostic Considerations

Bacterial vaginosis can be diagnosed by the use of clinical criteria (i.e., Amsel's Diagnostic Criteria) or Gram stain (Nugent's scoring).Amsel's clinical criteria include four parameters namely characteristic vaginal discharge, presence of clue celss, high vaginal Ph and positive amine test. Presence of at least three parameters establishes Bacterial vaginosis A Gram stain (considered the gold standard laboratory method for diagnosing bacterial vaginosis) is used to determine the relative concentration of lactobacilli (i.e., long Gram-positive rods), Gram-negative and Gram-variable rods and cocci (i.e., G. vaginalis, Prevotella, Porphyromonas, and peptostreptococci), and curved Gram-negative rods (i.e., Mobiluncus) characteristic of bacterial vaginosis.

Culture of G. vaginalis is not recommended as a diagnostic tool because it is not specific because of polymicrobial nature of bacterial vaginosis. Cervical Pap tests have no clinical utility for the diagnosis of bacterial vaginosis because of their low sensitivity and specificity.

OBJECTIVE:

1.To assess the Cohen's Kappa agreement of Amsel's criteria and its components against the golden standard Nugent's criteria.

Results and Discussion.

Table: 1

AMSEL'S CRITERIA VS NUGENT'S SCORING

	Nugent's Score+	Nugent's Score-	Total
Amsel's Criteria+	49	4	53
Amsel's Criteria-	7	254	261
	56	258	314

Amsel's criteria misses 7 cases of bacterial vaginosis as detected by Nugent's scoring.

Amsel's criteria makes diagnosis of bacterial vaginosis in 4 case in whom Nugent's Criteria failed to do so.

But there is high degree of agreement between these two scoring system.

Estimation of Cohen's kappa

Null Hypothesis	The extent of agreement is same as random (kappa=0)
Kappa score	0.878
S.E	0.0360
95% CI	0.807 to 0.949
Judgment	"Almost Perfect Agreement"

Table:2

VAGINAL DISCHARGE

	Bacterial Vaginosis+	Bacterial Vaginosis-	Total
Vaginal Discharge+	41	42	83
Vaginal Discharge-	15	216	231
	56	258	314

Although the characteristic vaginal discharge is the most observed component in Amsel's Criteria , it is not sensitive in detecting bacterial vaginosis (Positive Nugents's Score). But it has got high Negative Predictive Value.

Estimation of Cohen's kappa

Null Hypothesis	The extent of agreement is same as random (kappa=0)
Kappa score	0.479
S.E	0.058
95% CI	0.365 to 0.593
Judgment	"Moderate Agreement"

Table:3
VAGINAL pH

	Bacterial Vaginosis+	Bacterial Vaginosis-	Total
High Vaginal pH+	38	11	49
Normal Vaginal pH	18	247	265
	56	258	314

Estimation of Cohen's kappa

Null Hypothesis	The extent of agreement is same as random (kappa=0)
Kappa score	0.669
S.E	0.0569
95% CI	0.557 to 0.78
Judgment	"Substantial Agreement"

Vaginal Ph offers high degree of specificity (96%) among the all components of Amsel's criteria.It has also produced high Positive Likelihood ratio(15.92).

Table:4
AMINE TEST

	Bacterial Vaginosis+	Bacterial Vaginosis-	Total
Amine Test+	46	5	51
Amine Test-	10	253	263
	56	258	314

Estimation of Cohen's kappa

Null Hypothesis	The extent of agreement is same as random (kappa=0)
Kappa score	0.831
S.E	0.0422
95% CI	0.748 to 0.914
Judgment	"Almost Perfect Agreement"

Positive amine test offers high degree of sensitivity and specificity (82% and 98%). It has very high Positive Likelihood Ratio (42.39).

Table:5
CLUE CELLS

	Bacterial Vaginosis+	Bacterial Vaginosis-	Total
Clue Cells+	51	6	57
Clue Cells-	5	252	257
	56	258	314

Estimation of Cohen's kappa

Null Hypothesis	The extent of agreement is same as random (kappa=0)
Kappa score	0.881
S.E	0.0351
95% CI	0.813 to 0.95
Judgment	"Almost Perfect Agreement"

Clue cells are very sensitive and specific in reflecting in Nugent's Scoring (91% and 98%). High positive predictive value makes it a very important parameter among all other components of Amsel's Criteria.Post test prevalence is almost the same(18%).

Table:6
Amine Test and Clue Cells

	BacterialVaginosis+	BacterialVaginosis-	Total
Amine Test+ and Clue Cells+	45	4	49
Absence of positive amine test and Clue Cells	11	254	265
	56	258	314

Estimation of Cohen's kappa

Null Hypothesis	The extent of agreement is same as random (kappa=0)
Kappa score	0.829
S.E	0.0428
95% CI	0.745 to 0.943
Judgment	"Almost Perfect Agreement"

When Amine test and clue cells are combined together, the sensitivity has increased to 80% which is the highest among the dual criteria test. The post test prevalence is about 16 % which comes close to True Prevalence (18%).

Among the two criteria tests, the combination of amine test and clue cells is coming close to the Amsel's Criteria.

- 314 women in active labor were included in the study. Of these, 102 women belonged to preterm labor group.
- The prevalence bacterial vagiosis is 18% as detected by gold standard Nugent's scoring.
- Women in class 5 of socio economic status had higher prevalence of bacterial vaginosis than women in class 4. (p=0.02047)
- Neonatal complications like prematurity, birth asphyxia and sepsis are more common in women with bacterial vaginosis than in women without bacterial vaginosis. (p=0.00002)
- Bacterial vaginosis is more commonly associated with preterm labour than term labour. (p=0.003387)
- Birthweight of babies born to mother with bacterial vaginosis is lesser than birth weight of babies born to mother without bacterial vaginosis. (difference in mean=160g, p=0.041)
- Average weight of mothers with bacterial vaginosis is lesser than that of women without bacterial vaginosis. (difference in mean=1.9 kg , p=0.009232)
- The amsel's scoring system has almost perfect agreement with Nugent's scoring criteria. (cohen's kappa=0.8779).
- Among the individual components of Amsel' criteria, clue cells alone has the best sensitivity (91%) and specificity (98%) and better positive likelihood ratio (39.16).
- When two components of Amsel's criteria is considered , combination of positive amine test and clue cells has the best sensitivity (80%) and better specificity (98%) and positive likelihood ratio (51.83).
- Combination of amine test and clue cells has also perfect agreement with Nugent's scoring. (cohen's kappa=0.8286).

Conclusion:

The prevalence of bacterial vaginosis is 18% in women at active labour. The association of bacterial vaginosis with preterm labour is quiet significant. Maternal age and parity lacked significant association with bacterial vaginosis.

Amsel's criteria has almost perfect agreement with Nugent's scoring system using Cohen's Kappa Agreement. But clue cells alone or clue cells combined with amine test can replace the

cumbersome three parameters Amsel's scoring system or technically demanding Nugent's scoring system.

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