NOVEL POLYMER FOR DAIGNOSIS OF BACTERIAL VAGINOSIS AND TRICHOMONIASIS INFECTIONS

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Abstract

Objective: Traditional methods for diagnosis of bacterial vaginosis (BV) and Trichomonas(TV) are subjective and some requires expert personnel. As a result the diagnosis is often inaccurate and the treatment is frequently inappropriate. The association between BV/TV and serious health effect, including PID, cervicitis, postoperative infection, preterm delivery, and HIV infection are well documented. An accurate diagnosis will reduce those complications. Lately, a novel polymer indicator has been developed to improve these diagnoses. It comprises a mixture of polymer, plasticizer, wetting agent, ion-balance reagent and an indicator; applied on a substrate. The indicator changes color from yellow to blue at pH>5.1 and in presence of vaginal watery discharge with buffer capacity lower than 20mM at pH 4.3-5.1. The polymer is used as a swab impregnated within an indicator for ob/gyn office (VS-SENSE™ PRO) and for home use (VS-SENSE™ OTC). The present study compared the results of this indicator to "Gold-Standard methods". **Study Design:** 236 Women with abnormal vaginal discharge were enrolled in multi-center studies and were examined with the VS-SENSE™ PRO. Amsel criteria and Nugent scoring were used for BV diagnosis, cultures for Candida species and InpouchTMTV for Trichomonas. The results were compared to the performance of VS-SENSE™ swab. **Results:** The sensitivity and specificity of VS-SENSE™ were 91.8% and 92.9% (PPV=91.8%, NPV=92.9%), respectively. **Conclusion:** VS-SENSE™ was found to be superior to traditional tests (Whiff Test, pH paper, speculum examination) in diagnosis of vaginal infections. The new polymer gives extra sensitivity in diagnosing of abnormal vaginal discharge, and is beneficial for physicians and patients in fast and easy diagnosis of vaginal infection.

Study Objectives

To evaluate the ability of VS-SENSE™ swab, (Common Sense Ltd.) to rule in or rule out BV and/or TV. In addition to show an agreement between the swab results reading when read by the patient and by the clinician.

Background

- Only 33.7% of self OTC antifungal treatment is correct (1).
- Clinical diagnosis is inaccurate in 40-50% of the cases (2).
- BV was found to be associated with serious health effects, including PID, cervicitis, postoperative infection, preterm delivery, and HIV infection.

The Innovation: New polymer – indicator

One step test - results can be interpreted within 10 seconds. No need for colors scale.

Changes in acidity parameters of vaginal secretion induces color changes of the VS-SENSE™ polymer.

Positive result: present a blue-green stain over a yellow contrast, when vaginal pH > 5.1, and when vaginal pH between 4.3-5.1 and low buffer capacity (i.e. watery vaginal discharge).

Development of new diagnostic applications:

VS-SENSE™ PRO (Professional version)

VS-SENSETM OTC (Self Test Version)

Study Design

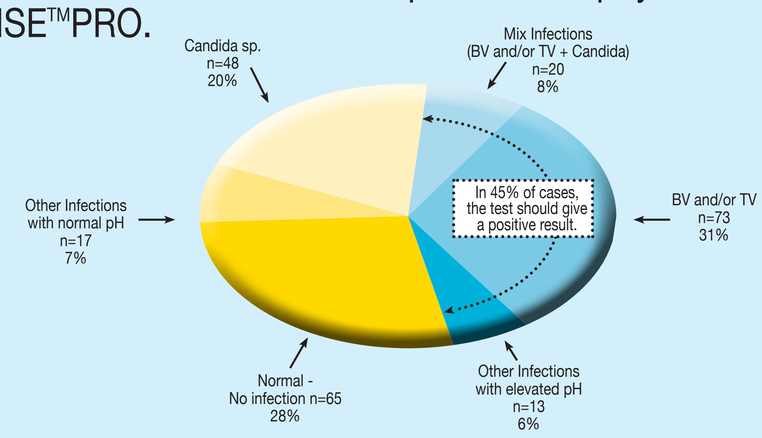
Study population: 286 women with vaginal symptoms complains (236 in the performance study and 50 in the self test study), ages 18-60. The studies conducted in U.S and Israel.

Results of the VS-SENSE™ were compared to the clinical diagnosis:
Amsel criteria and the Nugent scoring for BV, cultures for Candida sp. and Trichomonas.

Patient result reading of the VS-SENSE™ OTC were compared to the physician result reading of the VS-SENSE™PRO.

Results

Final Diagnosis Defined by Clinical and Laboratory Tests (n=336)



VS-SENSE™ Vs. Final Diagnosis Defined by Clinical and Laboratory Tests

		Gold Standard Clinical Diagnosis		
		Positive	Negative	Total
VS-SENSE™ Swab	Positive	101 True Positive	9 False Positive	110
	Negative	9 False Negative	117 True Negative	126
	Total	110	126	236
Sensitivity=	91.8%		Specificity=	92.9%
PPV=	91.8%		NPV=	92.9%

The VS-SENSE™ **sensitivity is 91.8%** with a 95% exact binomial CI:[85.04%,96.16%] and its **specificity is 92.9%** with its respective 95% exact binomial CI:[86.87%, 96.68%].

Comparison between Patients and Clinicians Results Reading (n=50):

VS-SENSE™ Patient Result Reading Vs. Doctor Result Reading			
VS-SENSE™ Patient Result	VS-SENSE™ Doctor Result		Total
Frequency	Yellow	Blue/Green	
Yellow	31	1	31
Blue/Green	3	15	18
Total	34	16	50

The overall agreement between the patient reading and the clinician reading is 92% (46/50).

Conclusions

- The VS-SENSE™ has high accuracy compared to the clinical diagnosis, sensitivity and specificity of 91.8%, and 92.9% respectively.
- All the participants complained about vaginal symptoms. 28% of them had no vaginal infection.
- Actually there is a 92% agreement (kappa=0.822) between the patient and physician results reading.
- One step test - test results can be interpreted by simply looking at the indicator strip within 10 seconds.

References

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2) Wiesenfeld HC, Macio I. The infrequent use of office-based diagnostic tests for vaginitis. Am J Obstet Gynecol. 1999 Jul;181(1):39-41.