CHAPTER 4

DISCUSSION AND CONCLUSIONS

Discussions

Performance of vaginal fluid pH in screening for vaginitis was determined. The pH was obtained by using pH paper tested with vaginal fluid and apply the pH value of 4.5 as the cutoff point. The gold standard test for vaginitis apply at least one of the positive result of the following test: three out of four clinical criteria for bacterial vaginosis, ELISA for chlamydia, culture for GBS., G.C., and wet smear for T.V., and fungus.

A total of 256 consecutive pregnant women at the first visit of ANC were studied. The prevalence of vaginitis documented by the gold standard test was 31.3% (80/256). Among these 80 cases, vaginal fluid pH can correctly detect 51 cases resulting the sensitivity of 63.8%. From a total of 176 who were non vaginitis, the vaginal fluid pH can classified as so for 159 cases, resulting the specificity of 90.3%. Among 68 cases of those who have positive test result (pH $>$ 4.5) have positive gold standard test of 51 cases resulting the positive predictive value of 75.0%. Also from 188 cases of negative test result (pH $<=$ 4.5) have negative gold standard test result leading to the negative predictive value of 84.6%.

The performance of the test for BV giving the sensitivity and specificity of 100.0% and 77.7% respectively whereas for non-BV, the test has the sensitivity and specificity of 50.0% and 77.3% respectively. It is also found that the proportion of non-BV which is resulting in elevating the vaginal fluid pH is 14.1% (36/256) and that of BV is 5.5% (14/256). Since the proportion of non-BV is 2.6 times greater than that of BV at the study setting, this could be the reason for the low sensitivity of the vaginal fluid pH test as a screening test for vaginitis. Therefore, in the setting that the non BV presents in higher proportion than that of the BV, vaginal fluid pH test is not recommended. This is because the BV, if present, will increase the vaginal fluid pH whereas vaginitis which caused by fungus, GBS, and Chlamydia, the vaginal pH may be or may be not increase. The mechanism of infection of these organisms is different from the vaginitis caused by bacterial vaginosis.

The results also revealed that the prevalence of asymptomatic cases of vaginitis is 75.0% (60/80). From these, the vaginal fluid pH can detect for 61.7% (37/60). Using both the vaginal fluid pH and clinical symptoms and signs as the parallel test can identify 71.3% (57/80) of the total cases of vaginitis.

As noted earlier that vaginitis is mostly asymptomatic which lead to an attempt to find a screening test of high sensitivity. The study results also confirmed this condition, 75.0% (60/80) of all cases are asymptomatic.

The sensitivity of vaginal fluid pH test in detecting vaginitis was found to be low, 63.8%, but a high specificity, 90.3%, is observed. This findings is inconsistent with previous study such as the study by Minkoff H. et al.(1987)[33] shown the sensitivity of an alkaline pH (pH $>=$ 4.4) in identifying most pathogens was very

high (85 - 97%) while the specificity was lower (40 - 52%). This inconsistency could be due to the difference of the proportion of vaginal pathogens which usually did not elevate vaginal fluid pH. That is, the proportion of the pathogens in the study by Minkoff H. et al.(1987)[33] which increased vaginal fluid pH was approximately 40% whereas it was 5.5% in this study. However, when only the pathogens involved increasing of vaginal fluid pH is examined, the performance of the test of this study is more or less the same as that of the study by Minkoff H. et al.(1987)[33] . That is, the sensitivity of the test is 100.0% and the specificity of 77.7%.

The sensitivity of the vaginal fluid pH of more than 4.5 in identifying carrier of BV was high since the test has a high sensitivity in detecting BV. But the test has a moderate to low sensitivity in detecting GBS., fungus, and Chlamydia. Hence patient with pH of greater than 4.5 would be an appropriate choice to be ordered for further investigation to document infection of BV. For chlamydia, GBS, and fungus, it may require another tests which has higher sensitivity than the pH. The explanation of the study results is related to the mechanism of inflammatory reaction. The host responds to the different organisms differently. Detail for the host response in specific organisms are given in Appendix 4.

However, vaginal fluid pH screen test still requires further evaluation for applying in clinical practice. Issues to be investigated include- what appropriate gestational age, how often the test should be repeated considering the nature of the different vaginal pathogens, for example, G.C. usually found in early pregnancy while chlamydial infection usually found in late pregnancy, and what is the optimal cutoff point to screen for vaginitis by a quantitative diagnostic study.

The women's history of previous vaginitis, STD, and their husband's STD were determined if they were significant predictor of vaginitis. It was found that the women's history of STD, and their husband's STD were statistically significant associated with vaginitis (p-value = 0.027 and 0.020 respectively). Logistic regression analysis was performed to adjust for the effect of the three selected factors. The adjusted odds ratio indicated that there were moderately strong association between vaginitis and the women's history of STD, and their husband's STD separately with the odds ratio of 2.4 (95% CI: 0.6-10.1) and 2.5 (95%CI : 0.8-8.4) respectively (Table 16). Although there were no statistically significant of such association due to insufficient sample size, the confidence interval still showed substantially high association. Thus the women's history of STD, and their husband's STD could probably used in combination with vaginal fluid pH test in screening for vaginitis.

Table 16. Adjusted odds ratio between selected factors and vaginitis

Factors	n	Vaginitis	Odds Ratio(OR)	95% Confidence Interval
1. Previous experience of vaginitis				
No.....	208	62	0	-
Yes.....	47	17	1.0	0.5 - 2.2
2. Previous history of STD				
No.....	243	72	0	-
Yes.....	13	8	2.4	0.6 - 10.1
3. Husband's history of STD				
No.....	234	69	0	-
Yes.....	15	9	2.5	0.8 - 8.4

In summary, concerning the previous studies, the vaginal pathogens have different mechanisms of inflammatory reaction involving elevation of vaginal pH. Thus the vaginal pH level can be varied depending on vaginal pathogens. Therefore, all vaginal pathogens were included in this study. Moreover, vaginal pH is aimed to be as a screening test which is not specific to any pathogens. This study interested in screening for pathogens of vaginitis which usually elevate vaginal pH and also asymptomatic. These pathogens is initially assessed to be common cause of

vaginitis in several previous study. This is the reason for not excluding the pathogens which usually not involve vaginal fluid pH which is believed to be low prevalence in the study setting.

The diagnostic performance of vaginal fluid pH in screening for non Bacterial vaginosis were analyzed in consideration of incorporation bias. Because pH test which we used to screen for vaginitis is a criteria to document BV. Anyhow we still assess the test performance with some bias (underestimation) of excluding BV cases since they were, in fact, vaginitis cases that we want to screen. Aside from this, the study setting have quite a low prevalence of each type of vaginitis that the result of the test performance may missed leading. So we should have more data to assess the vaginal fluid pH to screen for vaginitis.

Conclusion

Vaginal pH has a sensitivity 63.8%, specificity 90.3%, PPV 75.0%, NPV 84.6%, and accuracy 82.0% in detecting vaginitis in pregnant women.

Limitations & obstacles

As the process of the study is outlined in Fig.2, the study requires a careful physical examination to take adequate specimens from the appropriate sites and identify various organisms that cause vaginitis. Because some organisms are fastidious and difficult to identify.

The most important issue to assess a diagnostic test performance is the gold standard test. The appropriate gold standard to identify the various organisms of vaginitis in this study should have been the culture for all organisms. According to the limitation of funding support, we have to choose some alternative methods rather than culture to identify organisms. The method we selected may not be the best to be used as the gold standard. However, we have carefully selected the method that have been used practically to identify the causative organisms. For example, trichomoniasis, we do not have enough budget to do culture. So we identified it by using clinical symptoms and signs and wet mount examination.

Recommendations

The vaginal fluid pH test has quite low sensitivity in screening for vaginitis in the situation that the proportion of vaginal pathogens involving the low vaginal pH (pH $<=$ 4.5) is relatively higher than that of those involving the high vaginal pH (pH $>$ 4.5). However, such proportion may not be predetermined in the usual practice. Therefore, vaginal fluid pH test alone may not be appropriate to be used as a screening test for vaginitis in such circumstance. However using clinical symptoms and signs combined with the vaginal fluid pH test can detect substantial proportion of vaginitis in pregnant women.