Vaginal pH: a self-measurement device for timely diagnosis of disorders

Disturbances of vaginal pH are associated with significant health problems in women, resulting in conditions such as bacterial vaginosis. Self-measurement devices have been suggested for the effective measurement of changes in vaginal pH allowing early intervention. This article describes a novel vaginal pH self-measurement device which is highly accurate and reliable as well as having good reproducibility compared to other pH self-measurement methods.

by Dr H. Maul and Dr C. Sohn

Background

Bacterial vaginosis, resulting from an imbalance of the normal vaginal microflora, is a common condition affecting millions of women annually [1]. It is associated with numerous health problems such as preterm labour and low birth weight (LBW) neonates [2, 3], pelvic inflammatory disease [4, 5], as well as increased susceptibility to infection with the human immunodeficiency virus [6, 7].

Malodorous vaginal discharge may be the only symptom of bacterial vaginosis, and many affected women are asymptomatic [8]. Therefore in the majority of women bacterial vaginosis is only diagnosed after occurence of the conditions described above, and early treatment (or even comprehensive counselling) comes too late. The authors believe that easy and cheap but reliable tools to aid in the diagnosis of bacterial vaginosis are needed to prevent a world-wide health problem from escalating.

Vaginal pH

Under normal conditions, the vaginal microflora prevents occurrence of bacterial vaginosis as well as other vaginal infections by maintaining suitably acidic conditions within the vagina; the vaginal pH ranges from around 4.0 to 4.4. This ensures that other bacterial species, such as those from the gastrointestinal tract which are usually not adapted to acidic pH levels, are not able to colonise the vagina. The main bacterial species maintaining the vaginal environment is *Lactobacillus acidophilus,* a species that produces lactic acid by catabolising the glucogen emanating from the vaginal surface epithelium. Lactobacilli are also found in high concentrations in dairy products such as yogurt. In addition lactobacilli produce other 'anti-bacterial' substances such as H_2O_2, biosurfactants and coaggregation molecules, which are particularly important for maintaining the vaginal biosystem [9]. It is well established that even slight disturbances of the vaginal environment may lead to changes in the concentration of *Lactobacillus* thus leading to decreased production of lactic acid and enabling bacteria from the gastrointestinal tract to colonise the vagina. Once a specific point is reached, it is almost impossible to reverse the situation unless treatment is commenced [Table 1]. The major clinical-pathological condition resulting is bacterial vaginosis (BV), with *Gardnerella vaginalis* being the most commonly identified pathogen causing BV [Figure 1].

Increasing physiological lactobacillus flora	Decreasing pathological flora
Lactobacilli preparations, i.e. Döderlein Med Vagiflor, Gynoflor	Antibiotics, i.e. Metronidazol (Clont, Arilin, Flagyl, Metronour, Vagimid), Clindamycin (Sobelin), Neomycin (Vagicillin)
Lactic acid preparations, i.e. Eubiolac Verla, Majorana Vaginalgel, Lactisan	Antiseptic preparations, i.e. Octenisept Vaginaltherapeutikum, Vagi-Hex, Fluomycin N
Other acidic preparations, i.e. Vitamin C (VagiC)	

Table 1. Various pharmacological strategies used for treatment of disturbances in the balance of the vaginal environment (based on the Rote Liste 2006).

Vaginal pH is an overall measure of disturbances to the balance of the vaginal environment and its flora. The reduction in lactobacilli results in an increase of vaginal pH to values greater than 4.4, the high vaginal pH leads to an increase in pathological flora, which affects conditions so that there are even fewer lactobacilli, resulting in a positive feedback situation.

High vaginal pH levels of > 4.4 are also associated with secondary phenomena such as an increase in the neutrophil count in the vaginal fluid indicative of inflammation [10], which is of clinical relevance since this finding is linked to preterm rupture of membranes resulting in preterm birth [11]. In addition, the combination of high vaginal pH and abnormal sialidase and prolidase activities in mid gestation were found to be associated significantly with LBW (<2500 g), very low birth weight (VLBW; <1500 g), and early preterm birth at <35 or <32 weeks' gestation, as well as being predictive of these outcomes [12].

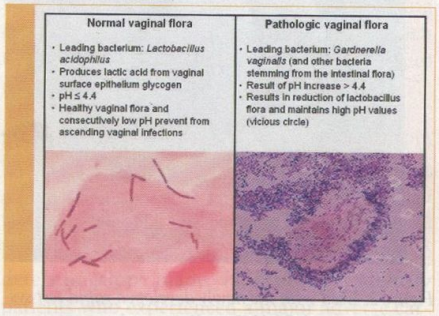

Figure 1. The normal and the abnormal vaginal microflora.

Vaginal pH - self measurement

Although vaginal pH measurement by trained health professionals may be more accurate, self measurement provides many advantages. Firstly women can check their vaginal pH immediately and do not need appointments with professionals. Therefore self measurement saves both time and money if it is correctly performed. Moreover more regular and frequent measurements can take place when self measurement is carried out. Secondly, self measurements encourage women to be responsible for their own health, bringing the desire to understand the underlying medical problem. The authors believe that this form of collaboration between patient and health professional leads to better patient outcome. Thirdly, women can learn which factors influence their vaginal pH, which facilitates changes of habits in order to promote vaginal health. Such habits include omitting vaginal douching, use of condoms during sexual intercourse, and an understanding of how to prevent secondary vaginal infections after antibiotic treatment for another condition.

The largest study on vaginal pH self measurement is the Erfurt prematurity prevention trial by Saling *et al* as summarised in various articles [13]. Although the two investigations do not fulfil the criteria of a randomised controlled trial, and the protocol resulted in some discussion, the effectiveness of the self care programme for prematurity prevention developed by Saling was investigated. In these studies pregnant women in Erfurt, Germany, were offered the possibility of performing self measurements of their vaginal pH twice a week. A pH test glove was used in order to screen for any disturbances of the vaginal environment. If vaginal pH was abnormal (>4.4), participants in the trial were instructed to see their physician immediately. If the findings were confirmed *Lactobacillus acidophilus* therapy, or in case of bacterial vaginosis treatment with clindamycin cream applied intravaginally, was commenced. A major drawback of the study was that patients who were not interested in the programme served as a control group; the implication is that women in this group may not be comparable concerning responsibility for their own health. Therefore a variety of factors was not taken into account in the analysis of the data. Nevertheless the results of the trial were impressive. Seventy-three out of 381 women in the test group were identified as high risk cases. Fifty-eight of them were treated with a lactobacillus preparation, and 24 with clindamycin cream; three patients refused to have any therapy. In this study, the prematurity rate was 8.1% in the self measurement/intervention group versus 12.3% in the control group ($P < 0.05$, $n = 2341$). 0.3% versus 3.3% of the neonates were very premature with a gestational age of $<32 + 0$ ($P < 0.01$). Preterm rupture of membranes was registered in 22.8% versus 30.8% ($P < 0.001$), respectively.

A similar statewide study was performed by Saling *et al* in the State of Thuringia, Germany. Although the treatment and control groups did not fulfill all requirements for trials, a significant reduction of early preterm births from 1.58 to 0.99% was seen ($P < 0.001$). Even if Saling's conclusions from this study may be too robust, the study did demonstrated that women are able to monitor their vaginal pH, and that a significant reduction of a serious global health problem might be reduced by means of a cheap, easy to handle and time-saving procedure.

Vaginal pH - self measurement devices

Currently there are two devices available for vaginal pH self measurement, the Merck pH indicator test strip or use of a vaginal pH glove (Care Plan vaginal pH test glove, Selfcare GmbH, Oberhaching, Germany). Women reportedly found use of the Merck pH indicator test strip problematic. Moveover the plastic matrix is relatively sharp and may lead to lesions of the vaginal epithelium if the test is not used properly.

The vaginal pH glove, mainly introduced and promoted by Saling's team, utilises the Merck pH indicator test strip paper attached to the index finger of the glove. Although the pH glove has been used in several clinical studies it has not been tested in a user study as required for CE certification as a self test. Moreover measurement with the glove does not ensure pH determination at the right position in the vagina (usually between the middle and the lower third of the vagina, i.e. 3 cm above the hymen). Ideally the pH should be measured at the 6 o'clock position within the vagina. This is not possible unless the glove is used by left handed women. Therefore standardisation between different measurement techniques appears to be low. In addition, and from our own experience, about half of all women are hesitant to insert their finger into their vagina in order to perform self measurement using the glove.

For these reasons DIMA has developed a self measurement device that attempts to overcome

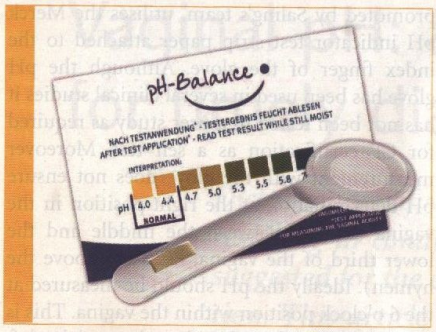

Figure 2. The DIMA pH Balance vaginal pH self-measurement device.

the drawbacks of the two currently available devices [Figure 2]. The applicator contains the Merck pH indicator test strip within a polypropylene probe. The probe does not have sharp edges and is relatively soft and smooth. At the end of the probe a flat, circular handpiece enables the device to be held properly and to be inserted into the vagina at the correct position (6 o'clock position) and depth. The DIMA pH Balance pH self-measurement test is therefore the first pH test that enables measurement in a standardised manner providing reliable results. In addition, a lay study has been performed using the device in collaboration with the authors at the Department of Obstetrics and Gynecology of the University of Heidelberg (approved by the local Ethics committee). The aim of the study was to test if women who were not health care professionals were able to read and interpret the self measurement correctly. This study was part of the CE certification of the pH Balance test as a device for self measurement. In their study DIMA in cooperation with the authors were the first to demonstrate that women who are not health care professionals are able to use the test properly and interpret the results of measuring the pH of various buffer solutions as well as their own vaginal pH.

Conclusion

Self measurement of the vaginal pH is effective in detecting disturbances, and thus allowing early treatment for imbalances of the vaginal environment. Although studies of vaginal pH (self) measurements have not lead to significant reductions in secondary outcomes such as preterm birth, low birth weight, and transmission of HIV, one main reason for this 'lack of evidence' may be the fact that these adverse outcomes are relatively common in low risk populations on the one hand and relatively rare in high risk populations on the other hand. In other words the adverse outcomes occur late after the causal event (i.e. vaginal douching preconception, resulting in bacterial vaginosis leading to preterm delivery at 32 weeks, after several weeks of treatment of symptoms of preterm labour) and can be additionally influenced by a great variety of other factors, such as genetic predisposition, succeptibility to infections (i.e. immunological reasons), other risk factors (i.e. vaginal bleeding - preterm birth, HIV infection - i.v. drug abuse etc.). If one looks at the immediate result of vaginal pH changes the relationship becomes or remains more evident, namely the colonisation of the vagina with bacteria stemming from the gastrointestinal tract, resulting in bacterial vaginosis in a high percentage of cases.

However pH self-measurements can contribute to a woman's understanding of her vaginal environment and may lead to changes in 'bad habits' (i.e. vaginal douching) and to learning about how to prevent and treat problems. Current methods of measurement do not seem to fulfil the requirements of high reliability and quality. The DIMA pH Balance aims to overcome several problems posed by these methods, and is easy to use as proven by the lay study. The authors believe that this test would allow timely and easy diagnosis of a significant health problem.

References

1. Wang J. Bacterial vaginosis. Prim Care Update Ob Gyns 2000; 7: 181-5.
2. Leitich H, Bodner-Adler B, Brunbauer M, Kaider A, Egarter C, Husslein P. Bacterial vaginosis as a risk factor for preterm delivery: a meta-analysis. Am J Obstet Gynecol 2003; 189: 139-47.
3. Hillier SL, Krohn MA, Cassen E, Easterling TR, Rabe LK, Eschenbach DA. The role of bacterial vaginosis and vaginal bacteria in amniotic fluid infection in women in preterm labor with intact fetal membranes. Clin Infect Dis 1995; 20: Suppl 2:S276-S278.
4. Peipert JF, Ness RB, Blume J *et al.* Clinical predictors of endometritis in women with symptoms and signs of pelvic inflammatory disease. Am J Obstet Gynecol 2001; 184: 856-63.
5. Hillier SL, Kiviat NB, Hawes SE *et al.* Role of bacterial vaginosis-associated microorganisms in endometritis. Am J Obstet Gynecol 1996; 175: 435-41.
6. Martin HL, Richardson BA, Nyange PM *et al.* Vaginal lactobacilli, microbial flora, and risk of human immunodeficiency virus type 1 and sexually transmitted disease acquisition. J Infect Dis 1999; 180: 1863-8.
7. Moodley P, Connolly C, Sturm AW. Interrelationships among human immunodeficiency virus type 1 infection, bacterial vaginosis, trichomoniasis, and the presence of yeasts. J Infect Dis 2002; 185: 69-73.
8. Klebanoff MA, Schwebke JR, Zhang J, Nansel TR, Yu KF, Andrews WW. Vulvovaginal symptoms in women with bacterial vaginosis. Obstet Gynecol 2004; 104: 267-72.
9. Saling E, Schreiber M. The lactobacilli-protection system of pregnant women--efficient prevention of premature births by early detection of disturbances Z. Geburtshilfe Neonatol 2005; 209(4): 128-34.
10. Simhan HN, Bodnar LM. Prepregnancy body mass index, vaginal inflammation, and the racial disparity in preterm birth. Am J Epidemiol 2006; 163(5): 459-66.
11. Simhan HN, Caritis SN, Krohn MA, Hillier SL. The vaginal inflammatory milieu and the risk of early premature preterm rupture of membranes. Am J Obstet Gynecol 2005; 192(1): 213-8.
12. Cauci S, McGregor J, Thorsen P, Grove J, Guaschino S. Combination of vaginal pH with vaginal sialidase and prolidase activities for prediction of low birth weight and preterm birth. Am J Obstet Gynecol 2005; 192(2): 489-96.
13. Hoyme UB, Saling E. Efficient prematurity prevention is possible by pH-self measurement and immediate therapy of threatening ascending infection. Eur J Obstet Gynecol Reprod Biol 2004; 115(2): 148-53.

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