Section: Biochemistry

Original Research Article

TO DETERMINE WHETHER VAGINAL PH CAN REPLACE SERUM FSH AS A MARKER FOR MENOPAUSE

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ABSTRACT

Background: Menopause is diagnosed retrospectively since its confirmation occurs 12 months after cessation of menstruation. The diagnosis of menopause is confirmed by serum FSH levels ≥ 40 IU/L. Studies have focused on vaginal pH ≥ 4.5 to be diagnostic of menopause, as it is a simple, non-invasive and inexpensive test. **Objective:** To determine whether vaginal pH can replace serum FSH level as a marker for menopause.

Materials and methods: This cross sectional descriptive study was conducted in randomly selected 200 females with menopausal symptoms. Vaginal pH was measured with a pH strip and blood was assayed for serum FSH levels using chemiluminescence technique. Statistical tests were used to determine the correlation between both in diagnosing menopause.

Results: The study was conducted on 200 females with menopausal symptoms. Vaginal pH value ≥ 4.5 had a sensitivity of 100%and FSH ≥ 40 IU/L had a sensitivity of 99.36% in detecting post menopausal status. Vaginal pH and FSH were positively associated by Pearson Chi-Square test ($p<0.001$) and McNemer test ($p=0.180$). Pearson's correlation coefficient and Spearman's rho testshowed that these two parameterswere positively correlated.

Conclusion: It was concluded that vaginal pH is simple, accurate and cost effective tool that can be used as an alternative to serum FSH level in diagnosing menopause.

Keywords: Menopause, vaginal pH, serum follicle stimulating hormone.

INTRODUCTION

Menopause is a natural phenomenon occurring because of the reduction of ovarian function and onset of the last menstrual period and is generally diagnosed in retrospect since confirmation occurs only after a 12-month cessation of menstrual periods[1].The most common and severe symptoms are memory loss, recurrent fatigue, exhaustion and dry skin in women at menopause period. Mild depression, may also be present[2].

The average age of menopause in Indian women is 46.8 years.[3]With increasing life expectancy, women spend 1/3rd of life in this phase.[4] Severe menopausal symptoms compromise overall quality of life for those experiencing them. Moreover, there is under-reporting of symptoms among Indian women due to socio-cultural factors.[5]

There occurs loss of ovarian follicles, 1-3 years after menopause, the FSH and LH increase occurs, and during 1-3 years it reaches to a maximum level. Clinicians commonly identify perimenopausal women by their age, menstrual history, symptoms, and by their FSH and serum estradiol hormone levels to confirm the diagnosis.[6].The diagnosis of menopause is confirmed by FSH levels >40 IU/L.[7]

The normal vaginal pH of reproductive aged woman is 3.9-4.5. During premenopausal years, vaginal pH ranges between 4.5 and 6, whereas lack of estrogen after the menopause is associated with alkalization to about 6.5 to 7.[8]

Menopause can be diagnosed by elevated serum FSH level but this is an expensive test and according to the patient's socio-economic status, it is reasonable to choose a more cost-effective, simple and non-invasive method. Some authors suggested

the evaluation of proposed vaginal pH as a good and cheap method. They reported that in the absence of vaginitis, a vaginal pH of 6-7.5 strongly suggests menopause.[9]

The purpose of our study is to determine whether vaginal pH can replace serum FSH as initial screening test for menopause.

Aims and Objectives

To determine whether vaginal pH can replace serum FSH as a marker for menopause.

MATERIALS AND METHODS

This cross sectional descriptive study was conducted in the postgraduate department of Obstetrics and Gynaecology SMGS Hospital Jammu over a period of one year i.e. October 2018 to September 2019. 200 females, 40 - 65 years of age with menopausal symptoms attending the OPD menopausal clinic or admitted in ward were selected randomly. Pregnant females, females in post partum period, on hormone replacement therapy, with history of sexual intercourse within previous 3 days, having vaginitis and on vaginal medications and douches were excluded from the study. A complete menstrual, sexual, medical and family history of menopause was obtained. Vaginal pH was measured with a pH strip. After insertion of a non-lubricated sterile vaginal speculum, the pH strip was applied directly to the lateral vaginal wall at the outer third of the vagina until it became wet. Colour change of the strip was immediately compared with colorimetric scale and the measurement recorded. Care was taken to avoid cervical mucus, blood, or other substances as lubricating jelly, known to affect vaginal pH. Blood sample was obtained by venipuncture and assayed for serum FSH levels. Serum Follicle Stimulating Hormone (FSH) levels were determined by chemiluminescence technique and reported in International Units per Litre (IU/L) from Central Laboratory SMGS Hospital. At the end of the study, all the data was compiled and analysed with the help of computer software MS EXCEL and SPSS version 21.0 of Windows. The data was reputed as proportion and mean (±Standard Deviation) for qualitative and quantitative variables. McNemer and Pearson Chi-square tests were used to analyse the convergence of two methods for diagnosis of menopause. Pearson's Correlation coefficient and Spearman's rho test were used to determine the correlation between FSH and vaginal pH in diagnosing menopause.

RESULTS

The study was conducted on 200 females with menopausal symptoms, age ranging from 40 to 65 years with a mean age of 51.59 years. 156 out of 200 women were post menopausal rest 44 were premenopausal. The mean age of menopause in our study was 48.48 ± 2.29 years. In our study, out of 200 patients, 180 had FSH ≥40 IU/L out of which 7 had pH < 4.5 and 173 had pH ≥4.5. Showing that the sensitivity of vaginal pH to be 96.11 % with respect to FSH. Rest 20 had FSH < 40 including 18 with pH < 4.5 and 2 with pH ≥ 4.5. We calculated that in post menopausal patients pH value ≥ 4.5 had a sensitivity of 100%, specificity of 45.45%, a Positive Predictive Value (PPV) of 86.67% and a Negative Predictive Value (NPV) of 100%[Table 1]. Similarly in post menopausal patients FSH ≥ 40 IU/L in detecting post menopausal status of the patient had a sensitivity of 99.36%, specificity of 54.55%, a Positive Predictive Value (PPV) of 88.57% and Negative Predictive Value (NPV) of 96%.[table 2]The classifications over vaginal pH and FSH were positively associated by Pearson Chi-Square test, i.e. p < 0.001. And the changes were equally likely by McNemer test (p=0.180). Their agreement by Kappa statistic was also good and significant (value = 0.775 and p < 0.001). Pearson's correlation had value of r = 0.86. Spearman's rho had a correlation coefficient of 0.879 and p < 0.001, showing that the two parameters serum FSH and vaginal pH were positively correlated. Neither any correlation between age of menarche and age of menopause, nor between parity and age of menopause was seen.

Table 1: Comparison of sensitivity of pH and Serum Follicle Stimulating Hormone(FSH) for predicting menopause

Serum FSH	Vaginal pH<4.5	Vaginal pH ≥4.5	Total number of patients	Sensitivity of vaginal pH with FSH
≥40	7	173	180	**96.1%**
<40	18	2	20	
	25	**175**	**200**	

Table 2: FSH as a predictor for menopause

Serum FSH	Post menopausal	Pre menopausal	Total	
≥40	155	20	175	Sensitivity 99.36% Specificity 54.55% Positive Predictive value 88.57% NPV 96%
<40	1	24	25	
	156	44	200	

Table 3: Distribution of subjects according to groups

Groups	Number of subjects	Percent
FSH<40 and pH <4.5	18	9.0

FSH<40 and pH ≥ 4.5	2	1.0
FSH≥40 and pH <4.5	7	3.5
FSH≥ 40 and pH ≥ 4.5	173	86.5
Total	200	100.0

The classifications over the vaginal pH and FSH were positively associated by Pearson Chi Square Test i.e P Value < 0.001(Pearson correlation had value of r = 0.86).

DISCUSSION

Two factors influence vaginal pH during menopause, i.e. menopausal status and the presence of pathogenic organisms. In normal fertile women, lactobacilli maintain the normal acidic pH that protects the vagina against colonization.[10]Exclusion of vaginitis is essential for the vaginal pH to reflect the state of menopausal vagina, as some strains of lactobacilli produce hydrogen peroxide that prevent vaginal colonization with uropathogens.[11]In assessing the status of the vaginal ecosystem, the vaginal pH is perhaps the most significant predictor of its status and can be done on office basis.With the commencement of menopause and loss of functioning follicles, the most significant change in the hormonal profile is the dramatic decrease in the circulating oestrogen levels.[12]In our study, with the cut off value of vaginal pH taken as ≥4.5, the sensitivity and positive predictive value of vaginal pH in diagnosis of menopause was 100% and 86.67% respectively.According to the study conducted by Cailloutte, elevated pH level in the range of 5 to 6.5 suggests a diagnosis of bacterial pathogen or decreased serum estradiol, and in absence of bacterial agents, ph range of 6 – 7.5 strongly suggests menopause.[9] They reported that the sensitivity of vaginal pH in predicting estradiol status was 88% and positive predictive value was 96% which is in accordance with our results.Roy S conducted a review article study analyzing 16 studies and reported that in absence of vaginitis, a vaginal pH > 4.5 indicated menopause with a sensitivity of 74%.[13] Our study is in agreement with this study.According to the study conducted by Panda S, sensitivity of vaginal pH > 4.5 for menopausal diagnosis was 84.9%.[14]The results in studies mentioned above are consistent with our results. In our study, the sensitivity of serum FSH to diagnose menopause was 99.36% when the cut off level of serum FSH was taken as 40IU/L.In the study conducted by Panda S, the sensitivity of serum FSH ≥ 40IU/L as diagnostic of menopause was 77.4%.[16]Roy S observed that the sensitivity of serum FSH in diagnosing low estradiol status in menopausal women was 68%.[13]The above mentioned studies show results consistent with those of ours. However, in the study conducted by Khadum TJ, with cut off serum FSH ≥ 20 IU/L, which is lower than the cut off point of serum FSH used in our study, the sensitivity of FSH to predict low estradiol status in postmenopausal females was 98%.[15]In our study, with serum FSH ≥ 40IU/L taken as a cut off point for the diagnosis of menopause, a vaginal pH ≥ 4.5 showed a sensitivity of 96.11% in diagnosing menopause.The classifications over vaginal pH and FSH are positively associated by Pearson Chi-Square test, i.e. p < 0.001. And the changes are equally likely by McNemer test (p=0.180). Their agreement by Kappa statistic was also good and significant (value = 0.775 and p < 0.001). Spearman's rho had a correlation coefficient of 0.879 and p < 0.001, showing that the two parameters serum FSH and vaginal pH are positively correlated. Similar to our study, in a study conducted by Kadhum TJ**,**it was observed that the sensitivities of vaginal pH and serum FSH were comparable (p = 0.516) denoting their similarity for diagnosing estradiol value < 40 pg / ml, which is one of the markers for menopause.[17] The correlation between vaginal pH and FSH and estradiol levels were seen. Serum estradiol showed a significant negative correlation with vaginal pH (r = 0.166, p= 0.069) and FSH (r=0.372, p=0.000), whereas serum FSH showed a significant positive correlation with vaginal pH (r=0.351, p=0.001).

CONCLUSION

Based on the above study it can be concluded that vaginal pH is simple, accurate and cost effective tool that can be suggested as a suitable alternative to serum FSH level in diagnosing age- related hormonal changes of menopause. However, further studies are required in appropriate design to evaluate the method of vaginal pH measurement for diagnosing menopause as a reliable and better alternative than serum FSH level estimation.

REFERENCES

1. Boskey ER, Telsch KM, Whaley KJ et al. Acid production by vaginal flora in vitro is consistent with the rate and extent of vaginal acidification. Infect Immun 1999; 67:5170–75.
2. Brinton RD, Yao J, Yin F et al. Perimenopause as a neurological transition state. Nat Rev Endocrinol 2015; 11(7):393-405.
3. Caillouette JC, Sharp CF, Zimmerman GJ et al. Vaginal pH as a marker for bacterial pathogens and menopausal status. Am J Obstet Gynecol 1997; 176:1270-77.
4. Han MJ, Lee JH. Factors influencing self-identity and menopausal symptoms on level of depression in middle aged women. Korean J Women Health Nurs 2013; 19:275-84.
5. Kadhum TJ, Al-Khafagy ZH. Vaginal pH as a marker for vaginitis and menopausal status. Thi-Qar Medical Journal 2011; 5(1):84-91.
6. Kahwati LC, Haigler L, Rideout S et al. What is the best way to diagnose menopause? J Fam Pract 2005; 54:1000–02.

7. Kapur P, Sinha B, Pereira BM. Measuring climacteric symptoms and age at natural menopause in an Indian population using the Greene Climacteric Scale. Menopause 2009; 16:378-84.
8. Klebanoff SJ, Hillier SL, Eschenbach DA et al. Control of the microbial flora of the vagina by H_2O_2-generating lactobacilli. J Infect Dis 1991; 164(1): 94–100.
9. Manea M, Popescu CF, Mitrut P et al. Correlations between gonadotropins level, vaginal cytology and menopause vessel-active phenomena. Rom J Morphol Embryol 2009; 50(4):631-37.
10. Mishra N, Mishra VN, Devanshi. Exercise beyond menopause: Dos and don'ts. J Midlife Health 2011; 2:51-56.
11. Panda S, Das A, Singh AS et al. Vaginal pH: A marker for menopause. Journal of Mid-Life Health 2014; 5(1):34-37.
12. Redondo-Lopez V, Cook RL, Sobel JD. Emerging role of lactobacilli in the control and maintenance of the vaginal bacterial microflora. Rev Infect Dis 1990; 12:856–72.
13. Roy S, Caillouette JC, Roy T et al. Vaginal pH is similar to follicle-stimulating hormone for menopause diagnosis. Am J Obstet Gynecol 2004; 190:1272–77.
14. Shen CJ, Yang CY, Chen HY, Chen WC, Chang TC, Cheng CM. Clinical Evaluation of a Self-Testing Kit for Vaginal Infection Diagnosis. J Healthc Eng. 2021 Aug 6; 2021:4948954. doi: 10.1155/2021/4948954. PMID: 34394891; PMCID: PMC8363453.
15. Smith KE, Judd HL. Menopause and postmenopause. In: Decherney AH, Pernoll ML, (eds.) Current Obstetric and gynecologic Diagnosis and Treatment. 8th ed, Appleton and Lange, University of California. 1994; pp. 1030-50.
16. Vaze N, Joshi S. Yoga and menopausal transition. J Midlife Health 2010; 1:56-58.