Study Protocol

Comparative evaluation for the efficacy of collecting sample by using vaginal atrophy screening combistick (VAS combistick) as against the traditional method of collecting sample for screening of vaginal atrophy in perimenopausal women

Abstract

Background: Genitals and sexuality is an essential element of healthy and happily aging in perimenopausal women with their partners. Vaginal atrophy (VA) of menopause is a condition associated to physiological, histological and anatomical changes noticed in the genital and urinary tracts in peri and postmenopausal women. Vaginal atrophy is the sequel of the decease levels of estrogens in plasma, which are symptoms of menopause

Objectives: 1. To evaluate the baseline data for vaginal maturation index (VMI) & pH in perimenopausal women. **2**. To evaluate and compare the method of collecting sample by using VAS combistick & traditional method. **3.** To evaluate and compare the accuracy of VMI score & pH using VAS combistick & traditional method. **4.** To evaluate and compare the feasibility & acceptability using survey based analysis in VAS combistick method and traditional method.

Methodology: Women who will come to Acharya Vinobha Bhave Rural Hospital (Obstetric and Gynaecology) OPD with at least one symptoms of vaginal atrophy and will take self sampling by using VAS combistick will be included in 'sampling A' (self sampling) while samples of same group of patients will be taken by traditional method included in 'sampling B' (clinician sampling).

Results: In this study we hypothesized that there vaginal sampling by vaginal atrophy screening (VAS) combistick will be better when compared to traditional method of sampling for screening of vaginal atrophy in terms of adequacy, feasibility and acceptability.

Conclusion: VAS combistick may be considered as elective best examining strategy which gives a reproducible and equivalent to screening of vaginal atrophy to that of traditional sampling methods.

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Keywords: vaginal atrophy, perimenopausal women, screening, combistick, vaginal maturation index

Introduction:

Genitals and sexuality is an essential element of healthy and happily aging in perimenopausal women with their partners. One in two postmenopausal women experience a collection of symptoms and signs known as vaginal atrophy (VA) of menopause.[1] Vaginal atrophy (VA) of menopause is a condition associated to physiological, histological and anatomical changes noticed in the genital and urinary tracts in peri and postmenopausal women. Vaginal atrophy is the sequel of the decease levels of estrogens in plasma, which is symptoms of the menopause.[1,2] Oestrogen levels play a primary role in helping to regulate the density and wetness of uro-genital region. Because of hypo estrogenic nature, the vaginal epithelium cells becomes thin, squamous and stratified, the vagina drops its elasticity and lowers the blood flow. Addition changes seen in vaginal flora and increases the vaginal pH by 5. Although these symptoms are annoying, they are often considered by perimenopausal women as the normal effect of age and menopausal state, which disappoints women for consulting their health-care provider.[3-6] In present days the screening method for vaginal atrophy in clinical research is limited, however, because sampling requires a vaginal speculum examination by using a tool called a spatula, some doctors use device called a cytobrush, which is a combination brush and spatula. This requires specially trained personnel and might be uncomfortable to participants. It's been seen that invasion of privacy women is the most important cause behind dropping to screening in India additionally barriers to screening includes shame and phobia, especially when it involves unnecessarily exposure of genial organ in front of male health care providers, which can negatively affect women's self-assurance. Women also want to be confirmed that their privacy

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is maintained. Most of the settings where resource is limit, so women do not have health policy and health care expenses are usually paid out of pocket.

Manifestations of genitourinary syndrome in menopause (GSM) are troublesome to perimenopausal women, and affect their quality life, sexual relations, and daily life's activities. Untreated, symptoms of vaginal atrophy can not only cause discomfort but can also negatively impact quality of life of women, including sex relationships and emotional wellbeing.[7-10] Late detection of vaginal atrophy may affect other quality-of-life aspects, includes clothing choices, exercise options, and general comfort of pelvic floor. The proposed VAS combistick device will not only help women to collect samples of their own for the screening of Vaginal cytology but also they can check their vaginal ph by using vaginal atrophy screening (VAS) combistick so that they can do it easily and preferable to traditional collection of samples of vagina. Although it is not the only and initial study of self vaginal collection sample, but it will be the first study of self collected sampling for screening of vaginal atrophy. In so many other settings, includes screening of sexually transmitted disease and cervical cancer, women are able to collect self vaginal samples while compare to physician-collected samples. Self-collected sample is also feasible to implement and accepted by women.

Rationale:

Self-sampling might be encouraged screening participation in under diagnosed populations. Although screening for vaginal atrophy, visiting physician is usually sensitive, self-sampling can allow for screening without undergoing pelvic examination. Attempt to spread awareness of right of privacy should be directed at both clinicians and women. Other benefits of self-sampling for screening of vaginal atrophy include superior clinical performance thereby self-collected vaginal testing will be more cost effective than clinician collected sampling so that women can have better Quality of life and are able to perform different roles efficiently in personal and social life. Self-sampling as an alternative to other screening programs for prevention of vaginal atrophy is a significant and reasonable act of beneficence. Hence we aim to conduct this study in order to determine vaginal sampling by using vaginal atrophy screening (VAS) combistick will be better when compared to traditional method of sampling for screening of vaginal atrophy.

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Methods:

The study will be conducted after approval from the institutional ethical committee. This will be an interventional-cross sectional comparative study performed on cases who will come to the OPD with at least one complaint of vaginal atrophy. The study subject will be oriented to use VAS combistick to collect self sample. The sample of study subjects will be collected by clinician as per traditional method. The sample from both group will be sent to pathology lab for evaluation of VMI, hormonal level. The pH recorded by VAS combistick during self collection of sample will be compared with clinician collected pH value and compare the findings of results in both groups, evaluate the feasibility and acceptability of VAS combistick by using a questionnaire.

Inclusion Criteria:

1. Perimenopausal women (45-60 years of age).
2. Women reporting at least one vulvo-vaginal atrophy symptom (itching, burning and pain during sex).

Exclusion Criteria:

1. Vaginal infection.
2. Intercourse history of last 2 days.

Statistical Analysis:

The findings of Correlation between physician-collected and self-collected by VAS combistick samples for VMI will be calculated using Pearson's correlation coefficient to test the linear relationship between the samples and Cronbach's α to assess consistency between the samples.

Expected Outcomes/Results:

In this study we hypothesized that there vaginal sampling by vaginal atrophy screening (VAS) combistick will be better when compared to traditional method of sampling for screening of vaginal atrophy in terms of adequacy, feasibility and acceptability.

Discussion:

In this study we will be discussing the findings of feasibility and acceptability in self vaginal sampling by using vaginal atrophy screening (VAS) combistick and traditional method of

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sampling as well as adequacy of samples for vaginal atrophy in perimenopausal age group. This will be an interventional study performed on cases who will come to the OPD with at least one complaint of vaginal atrophy, will be included in this study after obtaining informed consent. Patients will be excluded with infection and intercourse history of 2 days.

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