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RESEARCH ARTICLE

Comparison of Portable Colposcope with Visual-based Screening and Cytology for Observational Study: Cervical Cancer Screening in a North Indian Tertiary Care Hospital: A Prospective

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ABSTRACT

Précis: Comparison of PC with other cervical cancer screening tests and determine its diagnostic accuracy in the detection of premalignant lesions of the cervix.

Objective: To determine and compare the diagnostic accuracy of the portable colposcope device with other tests of cervical cancer screening, namely the visual-based test VIA VILI and the Pap test. Also, to administer its use in outreach areas with sparse healthcare facilities.

Methods: A total of 80 women attending the Gynaecology Outpatient Department (OPD) AIIMS Rishikesh, Uttarakhand, underwent all tests of screening, namely Pap smear, visual inspection with acetic acid (VIA), visual inspection with Lugol's iodine (VILI), and portable colposcope (PC) test, followed by standard colposcopy examination. Biopsies were taken based on standard colposcopy findings. Results of all parameters were compared according to their sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) and diagnostic accuracies were calculated.

Results: Among the study participants, 34 (42.5%) were screened positive in the PAP test, 42 (52.5%) in the VIA and 37 (46.2%) in the VILI. PC identified precancerous lesions in 27 patients (33.8%). After statistical analysis, pap test had a sensitivity of 60%, a specificity 60.9%, a PPV 26.5% and an NPV was 100%. VIA had a sensitivity of 100%, a specificity 57.8%, a PPV 35.7%, and an NPV of 100%. VILI had a sensitivity of 93.3%, a specificity 64.1%, a PPV 37.8% and an NPV of 97.6%. PC had a sensitivity of 100%, specificity 81.2%, PPV 55.6% and NPV of 100% and a diagnostic accuracy of 84.8%. About 35 patients had abnormal colposcopy findings and a total of 39 biopsies were taken, including an additional 4 biopsies of patients with suspicious cervix. Histopathology (HPE) reports of 36 patients were available; 3 were loss to follow-up. PC detected all 11 patients with HPE findings of precancerous and cancerous lesions.

Conclusion: PC is comparable to other tests of screening and has shown good diagnostic accuracy.

KEYWORDS
Pap test, Visual inspection with acetic acid, Visual inspection with Lugol's iodine, Portable colposcope, Histopathology.

INTRODUCTION

Cervical cancer is the fourth most common cancer among women worldwide, whilst it is the second leading cause of mortality among female cancers in India.[1] According to World Health Organization Global Cancer Observatory (WHO GLOBOCAN) 2020 data, there were an estimated 6,04,127

cervical cancer cases and 3,41,831 deaths per year in the world. In India, it is the 2nd most common cause of female cancer among women aged 15 to 44 years, with 1,23,907 new cases and 77,348 deaths reported per year.[2] In LMICs such as India, the traditional approach of cervical cancer screening fails to reach subpopulations of women who live in remote, medically poor areas. This makes cervical cancer strongly related to socioeconomic, geographic, and racial disparities. The WHO cervical cancer elimination strategy 2030 has emphasized the importance of continued and enhanced cervical cancer surveillance and monitoring.[2]

Due to the advent of newer technologies like digital colposcopes used to visualize the cervix in a magnified view. One such scope discussed in this study is the enhanced visual assessment (EVA) device. In this study, the potency of the EVA Mobile ODT device was assessed for screening of precancerous lesions in the cervix. This device improves the screener's ability to visualize the cervix with magnification and a polarized bright light that reduces glare. In addition to this, the application installed in this device, namely "visual check," allows clinicians to document their examination findings using image capture and simple data entry forms. From a patient's point of view, the examination results can be shown to the patient, which helps them understand their clinical condition better.[3]

With this background, the present study was designed to compare the diagnostic accuracy of this portable colposcope device with other tests of cervical cancer screening, namely visual-based and pap tests, in this population. And to incorporate the use of portable colposcope in the social and outreach programs of the remote areas with limited resources for cervical cancer screening.

MATERIAL & METHODS

The present study was a prospective observational study carried out in the OPD and social and outreach camps of the Department of Obstetrics and Gynecology, All India Institute of Medical Sciences (AIIMS), Rishikesh, in a tertiary care teaching hospital between January 2021 and March 2023. The study protocol was approved by the Institutional Ethics Committee (Letter No: IEC/22/85). All consenting sexually active women between the ages of 25 and 65 years of age were included in the study. Exclusion criteria include refusal to consent, women with already diagnosed with cervical cancer or have a history of surgery for cervical cancer or pelvic radiation therapy, hysterectomized women without a cervix, and pregnant women. After an explanation of the study, clinical procedures involved, and the basics of cervical cancer and screening, the participants signed an informed consent document in either English or Hindi.

Each participant completed a demographic questionnaire according to the cervical cancer screening proforma. Each participant underwent Pap smear test, VIA, VILI and examination by PC followed by standard colposcope. All these tests were performed by a single gynecologist. In patients with abnormal colposcopy findings based on individual swede score, cervical punch biopsies were taken and sent for histopathology. The results of the pap smear test and HPE were followed up on. Pap smears were read based on the Bethesda Classification with a 6-point scale classification: normal, atypical squamous cells of undetermined significance (ASCUS), high-grade atypical squamous cells (ASC-H), low-grade and high-grade squamous intraepithelial lesion (LSIL and HSIL), and cancer. Visual inspection with acetic acid and Lugol's iodine was classified on a 2-point scale: negative and positive. Histologic classification (criterion standard) was as follows: normal, LSIL, HSIL, or cancer. The results of PC were reported as normal or abnormal, interpreted by the artificial intelligence (AI) application installed in the device. Statistical analysis was done using SPSS, version 23. Descriptive statistics were used for demographic and clinical data and summarized. The diagnostic accuracy of each test was compared with that of other tests by calculating the sensitivity, specificity, PPV and NPV using the standard contingency table. A *p-value* of <0.05 was considered significant where applicable. Means were compared using an independent t-test and proportions were compared using a chi-square test.

RESULTS

Out of the study population of 80, the maximum number of women were in the age group of 36 to 45 years (46.2%) with a mean age of 42.39 ± 10.33 years. Table 1 shows the sociodemographic details of the study population. As shown in Figure 2, out of 80, 34 (42.5%) were screened positive on the pap test, 42 (52.5%) on VIA and 37 (46.2%) on VILI. PC identified precancerous lesions in 27 patients (33.8%). Among 80 participants, 46 had normal cytology findings (57.5%). In the present study, pap smear could detect 11 ASC-US, 9 ASC-H, 9 HSIL, 4 AGC, and 1 LSIL. On standard colposcopy, the swede score of the study population ranged from 1–7. The mean (SD) swede score was 3.48 (1.79). The median (IQR) of the Swede Score was 3.50 (2-5). For the feasibility of statistical analysis and comparison, the swede score impression was taken as positive (swede score >/= 5) and negative (swede score <5). As shown in Table 2, it was inferred that there was a significant association between the results obtained by the PC test and HPE ($p = 0.001$) by Fisher's exact test. A larger proportion of Participants with a negative impression on portable colposcope had HPE reports suggestive of normal findings or Chronic cervicitis. A larger proportion of participants with a positive impression of the PC had HPE reports suggestive of precancerous and cancerous lesions. After statistical analysis, the sensitivity of pap test was calculated to be 60% with a specificity of 60.9%, PPV of 26.5% and NPV of 100%. VIA had

a sensitivity of 100%, specificity of 57.8%, PPV of 35.7% and NPV of 100%. VILI had a sensitivity of 93.3%, specificity of 64.1%, PPV of 37.8% and NPV of 97.6%. PC had a sensitivity of 100%, specificity of 81.2%, PPV of 55.6% and, and NPV of 100% and a diagnostic accuracy of 84.8% as shown in Table 3.

DISCUSSION

Cervical cancer can be prevented if detected at an early stage by various modalities of screening techniques used. Pap smear has been the traditional method for cervical cancer screening.[5] The use of pap smear as a screening test is limited in low-resource settings due to its high cost, requirement of cytology laboratories, a pathologist and loss to follow-up. It has the lowest sensitivity when compared to other screening tests. Visual-based screening tests (VIA and VILI) are the least expensive, with high sensitivity. Limitations of these tests include subjectivity in the interpretation of results and low reproducibility due to a lack of permanent records. With the advent of newer technologies, portable handheld devices were developed over many years to obtain a magnified view of the cervix. One such device discussed in this study is the EVA system mobile ODT. After adequate validation in large trials, it has been proposed that the EVA scope can be used as one of the tests for screening cervical cancer. This device fulfills the criteria of an ideal screening test in the sense that it is easy to administer and less expensive. The results are reproducible, valid, and detect disease before its critical point. The usefulness of a screening test is evaluated by its sensitivity and specificity and analysis in the present study shows that EVA has a good sensitivity as well as specificity.[6] According to the literature, many studies conducted on EVA were based on screening in health camps, and the diagnostic accuracy of EVA, as well as its comparison with other tests, were not analysed in them. The EVA device tested in the present study has the advantage of an Artificial Intelligence (AI) feature over other scopes available. With the help of this AI feature installed in the EVA device, it offers its use in outreach settings by the paramedical staff, even in the absence of an expert colposcopist.

The purpose of this study was to define the efficacy of portable in terms of sensitivity, specificity, PPV, and NPV to use it as one of the screening modalities of choice in social and outreach settings, which are devoid of laboratory facilities, where PAP is not possible. It also enhances NE examinations in VIA and VILI due to its high resolution and magnification. The data in the present study offer a strong representation of verified precancerous and cancerous cases (11 out of 80). Taking the sensitivity and NPV to 100%, the PC test was able to identify all verified precancerous cases, thus carrying high sensitivity than traditional methods of screening, namely PAP smear and is similar to that of visual-based screening tests (VIA, VILI). The EVA scope fulfils the criteria of an ideal screening test as it is easy to administer, less expensive, the results are reproducible, valid, and have good sensitivity and specificity.The limitation of the present study was that all the screening tests and interpretations were performed by a single expert.

CONCLUSION

The PC used in this study, the EVA mobile ODT device, is a handheld battery-based portable device. It does not require a laboratory setting and gives input of its own in the form of normal and abnormal impressions based on images of the cervix.

When compared to the standard of care colposcopy, it is cheaper, portable and does not require expertise of a gynaecology doctor. It has a diagnostic accuracy comparable to that of a standard colposcope. Images captured can be uploaded to the image portal online and help from experts can be taken in case of doubt. This study compared the efficacy of PC with other screening tests like PAP, VIA, and VILI, taking standard colposcopy as the gold standard. After reviewing the statistical analysis, it is concluded that the PC is one of the best screening methods for cervical cancer in a resource-restricted setting with a high sensitivity and NPV.

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CONFLICT OF INTEREST

All authors agree with the content of the manuscript.

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