

# Smart Scope® CX AI-enabled Test for Detection of Pre-Cancerous Lesions of the Cervix in Primary Screening: A Comparison with Cytology and VIA-VILI

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## Research Article

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# Abstract

**Introduction:** WHO's global initiative to eliminate cervical cancer, aims to screen 70% of women using a high-performance screening test at ages 35 and 45 years. Taking into account the various requirements of a screening test in low-resource settings, we aimed at an artificial intelligence (AI) based screening method, namely, the Smart Scope® CX AI-enabled test (SS-AI) to validate it against other screening tests to detect pre-cancerous lesions of the cervix. The SS-AI test results were compared with those of Pap smear, VIA and VILI.

**Material and methods:** This was a prospective observational study conducted in 2023 in the Department of Obstetrics and Gynaecology of a tertiary care hospital in a six month period. 200 sexually active women in the age group of 21 to 65 years were enrolled and screened for precancerous lesions of the cervix using Pap smear, followed by VIA and VILI, followed by SS-AI (smart scope – artificial intelligence) test. The patients detected positive in any of the screening tests underwent colposcopy and colposcopy-guided biopsy wherever needed.

**Results:** The mean age of the participants was  $40 \pm 8.3$  years and 86.6% of them belonged to the low-income group. 43.1% of them had their first pregnancy before 21 years of age. 76.1% of participants were multipara. 70.8% of participants had no history of any contraceptive measure. The presenting complaints were abnormal vaginal discharge (64.11%), abnormal uterine bleeding (48.8%), pelvic pain (34.92%). 179/200 women were detected positive on at least one of the screening tests and underwent colposcopic examination. 49/179 women had abnormal colposcopic findings underwent colposcopic guided biopsy. The histopathological examination was suggestive of CIN I in two cases, CIN II /CIN III in three women, and invasive cancer in six patients. Thirty-eight cases had benign changes.

On statistical analysis, Pap smear, VIA, VILI and SS-AI had sensitivity of 44.4%, 45.5%, 0%, 100% respectively, specificity was 100%, 55.3%, 63.2%, 81.6% respectively, NPV 85.7%, 77.8%, 68.6%, 100% respectively and a diagnostic accuracy 87.2%, 53.1%, 49%, 85.7% respectively.

**Conclusion:** The diagnostic accuracy of SS-AI is comparable to the standard Pap smear and superior to VIA and VILI. The SS-AI test has the potential to increase access to a quick screening without any on-site expert dependency. The study highlights the need for future studies on a larger cohort to standardize the results.

## Introduction

Globally, cervical cancer is one of the most common cancers among women. It is the fourth most common cancer, ranking after breast, colorectal, and lung cancer.<sup>[1]</sup> It is the second leading cause of cancer among women aged 15–44 years.<sup>[2]</sup> GLOBOCAN 2022 estimated that worldwide there were approximately 6,62,301 new cases with 3,42,000 deaths annually from cervical cancer. In India, approximately 1,23,907 new cases with 77,348 deaths are seen annually<sup>[3]</sup>. According to the Indian

statistics, carcinoma cervix is the second most common cancer after breast cancer and accounts for around 14% of cancer cases in women.

Almost 99.7% of cervical cancer is attributed to Human Papillomavirus (HPV)<sup>[4]</sup>. Around 150–200 HPV types can cause carcinoma of the cervix but the commonest among them are HPV 16 and 18, responsible for around 70% of cases of cervical cancer. Risk factors can be early marriage, early pregnancy, oral contraceptive usage, smoking, and HIV/STD history<sup>[5]</sup>. Cervical cancer patients generally present with post-menopausal bleeding, persistent pelvic pain, unexplained weight loss, intermenstrual bleeding, and a foul-smelling discharge per vaginum<sup>[6]</sup>.

HPV infected cervical cells exhibit certain cyto-morphological changes called Cervical Intraepithelial Neoplasia (CIN) for many years before developing into an invasive carcinoma<sup>[7]</sup>. These precancerous changes in the cervix provide a basis for cervical cancer screening. With the help of an effective screening method, the cytomorphological changes can be detected well before the appearance of malignancy thereby, reducing cervical cancer burden and treatment-related morbidity. An ideal screening method is the one which is cost-effective, readily available, safe, easy to interpret, with 100% sensitivity and specificity.

FIGO (International federation of Gynaecology and Obstetrics) includes cervical cytology (Pap smear or liquid-based cytology i.e., LBC), HPV testing and visual inspection with acetic acid and Lugols' iodine (VIA/VILI) as the cervical cancer screening methods<sup>[8]</sup>. The adoption of a particular strategy depends on the specific settings. The cytology-based screening is effective but beyond the reach of health services in rural and backward areas, where cytologists are not readily available. In addition, sometimes patients are noncompliant and do not report for follow up. VIA/VILI are simple low-cost screening methods having limitations like extreme subjectivity in interpreting tests, lack of a permanent record, low reproducibility, overestimation, and overtreatment. Although HPV-DNA detection serves as a reliable marker for carcinoma cervix but high cost of testing makes it prohibitive in poor Indian setting.

Considering the Indian population, where majority of the women hail from rural areas with a limited access to education and health, there is a need to adopt a robust screening test that is easily available, low-cost, and yet accurate enough to detect the precancerous changes in cervix. In the present study we aimed to evaluate the effectiveness of an artificial intelligence (AI) based screening method, namely, the Smart Scope® CX AI-enabled test (SS-AI).

## Materials and Methods

This prospective observational study was conducted at the Obstetrics and Gynaecology Out- patient Department of a tertiary care hospital for a period of six months in 2023.

Sexually active women in the age group of 21 to 65 years were counselled regarding screening for cervical cancer and were enrolled after obtaining informed written consent. Women having obvious

growth on the cervix, those who had undergone procedures like cryotherapy, excision biopsy, conization in the last six months, hysterectomy, those with ongoing pregnancy were excluded from our study.

Detailed demographic data, menstrual, obstetrical, family, personal, and past history was recorded. All the patients were screened for precancerous lesions of the cervix using Pap smear, followed by VIA (visual inspection with acetic acid) with application of 3% acetic acid, VILI (visual inspection with lugol's iodine) with application of 95% Lugol's iodine followed by SS-AI (smart scope – artificial intelligence) test.

As per Bethesda classification of Pap smear, ASCUS, ASC-H, LSIL, and HSIL were taken as screen positive. Presence of acetowhite area (AWA) on VIA and a distinct yellow or faint patchy yellow area on VILI was considered positive. On the SS-AI test, high-risk-amber (HRA) and red were considered as screen positives. Probable low- or high-grade lesions and carcinoma were taken as positives on colposcopy. On histology, CIN 1 + was considered positive.

The SS-AI test involves the use of a newly designed handy digital portable device “Smart Scope® CX” that can be easily carried to any remote location, that is non-invasive and easy to use (Fig. 1). Smart Scope® CX is a battery operated and once fully charged, the device works for about six to eight hours. Anterior and posterior vaginal walls are retracted using Cusco's speculum. Smartscope is then inserted into the vaginal cavity. The images of ecto-cervix were captured as done in colposcopy i.e., using green filter, on application of acetic acid and Lugol's iodine. The SS-AI test results are interpreted in a color-coding system using cloud-based AI software as green, amber, high-risk amber (HRA) and red.

Smart Scope® CX is integrated with a Tablet having an inbuilt software “Net4Medix®” that stores the patient medical history and cervix images. As the software Net4Medix® keeps a digital log of the images, it becomes useful at the time of follow-up visits. Also, the images can be easily accessed at the higher center for expert analysis.

The images of the cervix are assessed by a cloud-based AI model, and the results are given in four colour codes. Green indicates a normal cervix. Amber indicates any benign condition such as cervicitis, infection, inflammation, etc. High risk amber (HRA) indicates a probable low lesion, while red colour indicates a probable high lesion or cancer.

Any patient detected positive on anyone of the screening tests underwent colposcopy and colposcopy-guided biopsy wherever needed.

Statistical analysis was carried out with the help of SPSS version 23 for windows package (SPSS Science, Chicago, IL, USA). Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the curve (AUC) were calculated for the tests where histopathology was available as a gold standard. Chi-square test was used to examine the association between histopathology and screening tests. A p-value of less than 0.05 was considered significant.

## Results

A total of 200 women were enrolled in the study. The demographic data is described in Table 1. The mean age of the participants was  $40 \pm 8.3$  years, with a range of 21–80 years. Around 86.6% of the women belonged to the low-income group. The majority (80.9%) of the participants were homemakers.

Table 1  
Demographic profile of study participants (N = 200)

| Demographic profile  |                                                        | Number | Percentage |
|----------------------|--------------------------------------------------------|--------|------------|
| Age Group (Years)    | 21–40                                                  | 111    | 55.50      |
|                      | 41–60                                                  | 85     | 42.50      |
|                      | 61–80                                                  | 4      | 2.00       |
| Annual family income | < ₹ 300,000 p.a.<br>(Low Income)                       | 172    | 86.0       |
|                      | ₹ 300,001 p.a. to<br>₹ 600,000 p.a.<br>(Middle Income) | 18     | 9.0        |
|                      | > ₹ 600,000 p.a.<br>(High Income)                      | 10     | 5.0        |
| Occupation           | Working                                                | 39     | 19.50      |
|                      | Homemaker                                              | 160    | 80.00      |
|                      | Student                                                | 1      | 0.50       |
| Parity               | Nulligravida                                           | 10     | 5.00       |
|                      | Primipara                                              | 40     | 20.00      |
|                      | Multipara                                              | 150    | 75.00      |
| Contraceptive use    | Yes                                                    | 61     | 30.50      |
|                      | No                                                     | 139    | 69.50      |

43.1% of the participants had their first pregnancy before the age of 21 years. Around 76.1% of participants were multipara. In 70.8% of participants, no history of usage of any contraceptive method was found. The most common symptom was abnormal vaginal discharge (64.11%) followed by abnormal uterine bleeding (48.8%) followed by pelvic pain (34.92%). Around 60% of participants had abnormal cervical findings on per speculum examination i.e, congestion, erosion, ulcers, nabothian follicles.

All the 200 participants underwent four screening tests (Pap smear, VIA, VILI, SS-AI). Pap smear test detected pre-cancerous lesions in 7 women (3.34%) (ASCUS = 3, ASC-H = 1, LSIL = 1, and HSIL = 2) (Table 2). The maximum number of women (110/200, 55%) had inflammatory smears, followed by 51 (25.5%) with normal cytology, and the rest had unsatisfactory findings (32/200, 16%).

Table 2  
Frequency distribution of test results (N = 200)

| Test                  | Assessment                         | Frequency | Percent | Valid Percent |
|-----------------------|------------------------------------|-----------|---------|---------------|
| <b>PAP</b>            | Negative (Normal+Benign)           | 161       | 80.5    | 95.8          |
|                       | Positive<br>(HSIL/LSIL/ASCH/ASCUS) | 7         | 3.5     | 4.2           |
|                       | NA (Unsatisfactory finding)        | 32        | 16.0    | 100.0         |
|                       | Total                              | 200       | 100.0   |               |
| <b>VIA</b>            | Negative                           | 100       | 50.0    | 50.0          |
|                       | Positive                           | 100       | 50.0    | 50.0          |
|                       | Total                              | 200       | 100.0   | 100.0         |
| <b>VILI</b>           | Positive                           | 116       | 58.0    | 58.0          |
|                       | Negative                           | 84        | 42.0    | 42.0          |
|                       | Total                              | 200       | 100.0   | 100.0         |
| <b>SS-AI</b>          | Negative (Green+Amber)             | 137       | 68.5    | 68.5          |
|                       | Positive (HRA + Red)               | 63        | 31.5    | 31.5          |
|                       | Total                              | 200       | 100.0   | 100.0         |
| <b>Histopathology</b> | Benign                             | 38        | 19.0    | 77.6          |
|                       | CIN I                              | 2         | 1.0     | 4.1           |
|                       | CIN II & CIN III                   | 3         | 1.5     | 6.1           |
|                       | Invasive cancer                    | 6         | 3.0     | 12.2          |
|                       | Total                              | 49        | 24.5    | 100.0         |
|                       | NA (not applicable)                | 151       | 75.5    |               |
|                       | Total                              | 200       | 100.0   |               |

On VIA, 100 women (50%) were screen positive and 100 (50%) were screen negative whereas 116 (58%) were screen positive and 84 (42%) were screen negative on VILI (Table 2).

On SS-AI test, results in 64 (32%) women showed green colour suggestive of normal cervix, 73 (36.5%) showed amber colour suggestive of benign conditions or infections, 22 (11%) were in HRA category indicating low grade lesions and 41 (20.5%) showed red colour suggesting suspicion of high grade or cancerous lesions (Table 2).

On analysis the data, 179 women were detected positive on at least one of the four screening tests. They were advised to have a colposcopy. Out of these, only 49 women had abnormal colposcopic findings i.e., suspicious lesions, therefore they underwent Colposcopic guided biopsy. The histopathological examination was suggestive of CIN I in two cases, CIN II /CIN III in three women, and invasive cancer in six patients. Thirty-eight cases had benign changes on histopathology. (Table 2). Table 3 shows the distribution of patients (n = 49) who underwent colposcopic directed biopsy with respect to their histopathologic result and screening test (Pap smear, VIA, VILI, SS-AI) findings.

Table 3  
Correlation of histopathology outcome and screening results on four tests.

| <b>Histopathology (49)</b> |               |              |                        |           |              |
|----------------------------|---------------|--------------|------------------------|-----------|--------------|
|                            | <b>Benign</b> | <b>CIN I</b> | <b>CIN II<br/>-III</b> | <b>CA</b> | <b>Total</b> |
| <b>Pap (49)</b>            |               |              |                        |           |              |
| NILM                       | 10            | 1            | 0                      | 0         | 11           |
| Inflammation               | 20            | 1            | 0                      | 3         | 24           |
| HSIL/mild dysplasia        | 0             | 0            | 2                      | 2         | 4            |
| Unsatisfactory findings    | -             | -            | -                      | -         | -            |
| Total                      | 30            | 2            | 2                      | 5         | 39           |
| <b>VIA (49)</b>            |               |              |                        |           |              |
| Negative                   | 17            | 1            | 0                      | 4         | 22           |
| Positive                   | 21            | 1            | 3                      | 2         | 27           |
| Total                      | 38            | 2            | 3                      | 6         | 49           |
| <b>VILI (49)</b>           |               |              |                        |           |              |
| Negative                   | 14            | 0            | 0                      | 0         | 14           |
| Positive                   | 24            | 2            | 3                      | 6         | 35           |
| Total                      | 38            | 2            | 3                      | 6         | 49           |
| <b>SS-AI (49)</b>          |               |              |                        |           |              |
| Green                      | 10            | 0            | 0                      | 0         | 10           |
| Amber                      | 21            | 0            | 0                      | 0         | 21           |
| HRA                        | 0             | 1            | 2                      | 1         | 4            |
| Red                        | 7             | 1            | 1                      | 5         | 14           |
| Total                      | 38            | 2            | 3                      | 6         | 49           |

Table 4 gives the statistical analysis of the data from all four screening tests in comparison with the gold-standard histopathological examination.

Table 4  
Statistical analysis of screening tests data against the gold standard histopathological examination.

| <b>Statistics</b>          | <b>Pap</b>    | <b>VIA</b>    | <b>VILI</b>   | <b>SS-AI</b>  |
|----------------------------|---------------|---------------|---------------|---------------|
| <b>N</b> (No. of patients) | 39            | 49            | 49            | 49            |
| <b>Sensitivity</b>         | 44.4          | 45.5          | 0             | 100           |
| <b>Specificity</b>         | 100           | 55.3          | 63.2          | 81.6          |
| <b>PPV</b>                 | 100           | 22.7          | 0             | 61.1          |
| <b>NPV</b>                 | 85.7          | 77.8          | 68.6          | 100           |
| <b>Accuracy</b>            | 87.2          | 53.1          | 49            | 85.7          |
| <b>AUC</b>                 | 0.722         | 0.504         | 0.316         | 0.908         |
| <b>AUC Range</b>           | (0.498–0.947) | (0.308–0.699) | (0.163–0.469) | (0.827–0.989) |

## Discussion

Screening for cervical cancer just once in a lifetime, after the age of 35 years, decreases the chances of dying from it by 70%. The probability of dying further decreases by 85% if screening is done every 5 years<sup>[9]</sup>. It is of utmost importance to identify precancerous lesions of the cervix, as it takes many years for CIN to progress to malignancy. Early detection of pre-cancerous of cervix will aid in timely management through less radical approach that will significantly reduce patient morbidity and mortality. The existing screening tests for the early detection of cervical lesions have their limitations like subjectivity, cost, resources, infrastructure and availability of pathologist. Considering the Indian scenario where majority of the population is residing in rural areas with limited access to healthcare, we need to design an effective screening test that is capable of mitigating these limitations.

A lot of research has been done and is still on-going to design an effective screening method and to compare the existing screening tests in poor-resource countries. Salehiniya et al<sup>[10]</sup> found that the pap smear test used for the detection of early-stage cervical cancer, reduces the mortality by 70–80% in all developed countries and by approximately 90% in the developing countries. In developing countries, meta-analyses of cytology-based screening have demonstrated sensitivity ranges as low as 11%, and specificity as low as 14% for detecting high grade lesions (CIN2 or greater)<sup>[10]</sup>.

In 2005, the Government of India and WHO (world health organization) had laid the guidelines for community-based screening using VIA and VILI. Sankaranarayanan et al reported the sensitivity and specificity of VIA approximately in the range 67% – 79% and 49% – 86% respectively and that of VILI was found to be in the range of 78–98% and 73-91.3% respectively<sup>[11]</sup>. The study by Yagnik et al.<sup>[12]</sup> demonstrated that VILI had higher sensitivity (99.47%), NPV (98.17%) but lower specificity (92.53%) as compared to pap smear. However, visual screening tests have limitations like extreme subjectivity in

interpretation of results, lack of permanent record, low reproducibility, overestimation and overtreatment. In the present study the specificity of Pap smear was 100% as compared to VIA and VILI (55.3%, 63.2%) and the NPV (85.7%) was also more as compared to visual screening tests (77.8, 68.6%).

Shamsunder S et al. <sup>[13]</sup> has conducted a pilot study in 2023 to assess the effectiveness of Smart Scope® CX AI in comparison to histology and found its sensitivity to be 90.3%, specificity 75.3% and accuracy as 84.81%. In the present study, the artificial intelligence based Smart Scope had a sensitivity of 100%, specificity 81.6% and NPV 100%. SS-AI was comparable to Pap smear in terms of accuracy (85.7% vs. 87.2%) and more accurate in comparison to VIA, VILI (85.7% vs. 53.1% vs. 49%). SS-AI offered additional advantage of being user-friendly, record maintenance and standardized results.

Another study by Tanaka et al. <sup>[14]</sup> used a smartphone to assess its diagnostic performance for CIN 1 or worse and CIN 2 or worse in comparison to standard colposcopy. They found it to be a viable alternative to colposcopy with respect to histologic diagnosis with a kappa value of 0.67 (95% confidence interval, 0.43-.90). It is important to highlight the role of screening in cervical cancer, as screening usually detects pre-cancerous or non-invasive cancers. The results of this study should be interpreted in light of this study's limitation, which is a small sample size of 75 women.

## Conclusion

This study provides a better understanding of the risk assessment for cervical cancer. The Smart Scope® CX is a superior alternative to the pre-existing traditional cervical cancer screening methods i.e. Pap, VIA, and VILI. While traditional tests are being used widely, they are subjective, require training, and have variable sensitivity and specificity. In contrast, the SS-AI test provides an objective assessment and is user-friendly. The SS-AI test has the potential to increase access to a quick screening without any on-site expert dependency. The high sensitivity, specificity, and NPV of the SS-AI test may help to reduce the referral rate. The SS-AI test produces results immediately, and can be used easily at the periphery, even by minimally trained health workers. The real-time digital imaging, and colour coding system enhances its usability, offering the advantage of treating the low-grade lesions in the same sitting.

## Abbreviations

AI

Artificial Intelligence

AUC

Area under curve

ASC H

Atypical squamous cells cannot exclude high-grade squamous intraepithelial lesion

ASCUS

Atypical squamous cells of undetermined significance

CIN

Cervical Intraepithelial Neoplasia  
FIGO  
International federation of Gynaecology and Obstetrics  
HIV  
Human immunodeficiency virus  
HSIL  
High squamous intraepithelial malignancy  
HPV  
Human Papilloma Virus  
HRA  
High risk amber  
LBC  
Liquid based cytology  
LSIL  
Low squamous intraepithelial malignancy  
NILM  
Negative for intraepithelial lesion or malignancy  
NPV  
Negative Predictive Value  
PPV  
Positive Predictive value  
PAP Smear  
Papanicolaou smear  
SS  
Smartscope  
STD  
Sexually transmitted disease  
VIA  
Visual inspection on acetic acid  
VILI  
Visual inspection on Lugol's iodine  
WHO  
World Health Organisation

## Declarations

### ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

The institutional ethical committee – All India Institute of Medical Sciences, Bathinda has approved the present study. The IEC approval number is: **IEC/AIIMS/BTI/337 dated 14.03.2023**

All the participants were enrolled in the study after obtaining written informed consent to participate in the study.

All the Authors (Dr. Lajya Devi Goyal, Dr. Balpreet Kaur, Dr. Yukta Dhingra, Dr. Manjit Kaur) have declared their consent to participate.

The study adhered to the Declaration of Helsinki to this effect.

## **CONSENT FOR PUBLICATION**

A written informed consent for publication of the study has been taken from all the participants.

All the Authors (Dr. Lajya Devi Goyal, Dr. Balpreet Kaur, Dr. Yukta Dhingra, Dr. Manjit Kaur) have declared their consent for publication.

## **AVAILABILITY OF DATA AND MATERIALS**

The data and material related to the present study has been recorded in the case sheets.

## **COMPETING INTERESTS**

There are no competing interests among the authors related to the present study.

## **FUNDING**

The present study did not receive any funding

## **AUTHORS' CONTRIBUTIONS**

Dr.Lajya Devi Goyal: Concept designing, data collection, patient management,

Dr. Balpreet Kaur: Data collection, Manuscript editing,

Dr. Yukta Dhingra: Manuscript writing,

Dr. Manjit Kaur: Cytology and Histopathology

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**Institutional ethical committee approval** IEC/AIIMS/BTI/337 dated 14.03.2023

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## Authors contribution

Dr.Lajya Devi Goyal: Concept designing, data collection, patient management,

Dr. Balpreet Kaur: Data collection, Manuscript editing,

Dr. Yukta Dhingra: Manuscript writing,

Dr. Manjit Kaur: Cytology and Histopathology

## Conflict of interest statement

None of the authors has any conflict of interest.

## Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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Smartscope was provided by NASSCOM centre of excellence for conducting the study. As such no funding was provided.

The manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work.

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## Figures



Figure 1

Smart Scope® CX device