Diagnostic Accuracy of Artificial Intelligence Algorithm incorporated into MobileODT Enhanced Visual Assessment for triaging Screen Positive Women after Cervical Cancer Screening

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Abstract

Introduction : The goal of cervical cancer screening is to detect precancerous precursor lesions that can be treated in the preinvasive stage. Colposcopy is important for triaging of any abnormal cervical screening test. Scarcity of trained Colposcopists and colposcopy centres is a big hurdle to screening programs in lower and middle income countries.

Objectives of the study: The objective was to assess the performance of the Artificial Intelligence based incorporated into the MobileODT Enhanced Visual Assessment (EVA Visual Check) against physician colposcopic diagnosis and the gold standard of histopathology.

Material and Methods: A cross sectional observational study was conducted on women referred to our colposcopy clinic following an abnormal screening test. Colposcopic examination was performed by trained physicians using the mobile optical device technologies (ODT) Enhanced Visual Assessment (EVA) system and the images were saved. The physician colposcopic impression was recorded, biopsy performed if any acetowhite lesions were found. Images taken with the EVA system were uploaded on a cloud and analysed by the Visual Check algorithm. Correlation of Physician impression using the mobile ODT colposcope was compared with the Visual Check analysis. The sensitivity, specificity, positive predictive value, negative predictive value of physician's impression and Visual Check analysis was compared with the final histopathological analysis or cytology . Cases with normal cytology and normal colposcopy did not undergo biopsy and these were considered normal.

Result: We studied 147 women, EVA Visual check had a Sensitivity of 86.8% (75-95), Specificity 28.7% (20-39), Positive Predictive Value of 40.7% (32-50) and negative predictive value of 79.4% (62-91) and diagnostic accuracy of 49.7% (41-58) for CIN 1+ lesions. EVA visual check has sensitivity 89.3% (72-98),specificity 26.1% (18-35), PPV 22.1% (15-31), NPV 91.2% (76-98) and diagnostic accuracy of 38.1% (30-46) for CIN 2 + lesions. Physician impression had a sensitivity of 86.8% (75-95), specificity of 81.9% (73-89) positive predictive value(PPV) 73.0% (60-83) negative predictive value (NPV) 91.7% (84-97) and diagnostic accuracy 83.7% (77-89) as compared to histopathological diagnosis of CIN1+ lesions and sensitivity of 92.9% (76-99) ,specificity of 68.9% (60-77%) ,positive predictive value (PPV) 41.3% (29-54) ,negative predictive value (NPV) 97.6% (92-100) and diagnostic accuracy 73.5% (66-80) as compared to histopathological diagnosis of CIN 2 + lesions as the gold standard

Conclusion: Mobile ODT EVA colposcope with AI has sensitivity comparable to physician's diagnosis while specificity ,PPV and NPV was less than that of physician diagnosis. It is valuable for triage of screen positive women for further management.

Introduction:

In year 2020, an estimated 6,04,000 women were diagnosed with cervical cancer worldwide and about 3,42,000 women died from the disease (Globocan 2020) [1]. Incidence and mortality vary widely with geographic location, and ~ 90% of cervical cancers occur in low and middleincome countries [LMIC] that

lack organized screening and HPV vaccination programs [2]. WHO has called for Elimination of Cervical Cancer by the year 2030 by its multipronged approach of HPV vaccination of 90% adolescent girls by the age 15 years, screening of 70% of women between 30–50 years and treatment of 90% of precancerous lesions [3].

Colposcopy which is commonly used for triage of screen positive women has its own limitations in LMICs as it is expensive, sophisticated, requiring high maintenance and a skilled colposcopist all of which are scarce in LMICs [4]. There is an urgent need for point of care tests where screening, triage and treatment could be done in the same sitting as it may be the woman's only opportunity to contact the health care system. A triaging system is needed for screen positive women which has good diagnostic accuracy, is cost effective ,simple, user friendly and can be used by any health personnel with minimal training.

Incorporation of artificial intelligence in Digital colposcopy has generated a lot of interest in recent years to overcome these challenges [5]. MobileODT Enhanced Visual Assessment is one such system in which use of an inbuilt deep leaning algorithm (EVA Visual Check) in a mobile colposcopy device allows health personnel with minimal training to make a diagnosis and help in managing these patients effectively. It is based on the reviews of highly qualified colposcopists in various countries. It can evaluate input of an image of cervix captured during colposcopy and give output as risk assessment; normal or abnormal. It combines high-quality image capture with secure online data management and services. It allows providers to visualize the cervix, document examination and add annotations for appropriate site of biopsy. An added advantage is an option of further review, collaboration with fellow colposcopists for quality assurance, remote consultation and continued education [6, 7, 8]. The present study is an effort to assess the diagnostic accuracy of EVA Visual Check compared to physician diagnosis and histopathology.

Aims And Objectives

The objective was to compare the performance of EVA Visual Check with physician colposcopic diagnosis using histopathology as the gold standard.

Material And Methods:

This was a cross sectional observational study conducted at tertiary care teaching hospital from north India after approval by the institutional ethical committee [IRB : IEC/VMMC/SJH/Project/2019-09/]. The study was registered on Clinical Trial Registry of India (CTRI Ref /2021/07/045475). Women aged 25–65 years with an abnormal cervical screening test (Pap, HPV or VIA) referred for colposcopy were included in the study after informed consent. Pregnant women, women who were treated for CIN or cervical cancer were excluded. A sample for cytology was taken for all women who did not have a Pap smear earlier. All Colposcopic examination were carried out by four trained colposcopists using the MobileODT EVA system. Images were taken serially after applying normal saline, 5% acetic acid and lugol's iodine. A colposcopic impression of low-grade lesion or high-grade cervical intraepithelial lesion [CIN] was made

by the colposcopist; guided biopsy was taken from any acetowhite lesion and sent for histopathological examination. Images taken with the EVA system were later uploaded on a cloud with the AI algorithm [EVA Visual Check] which gave the diagnosis in the form of “normal “or “abnormal “image. Colposcopic correlation of “physician diagnosis “using EVA digital colposcope was compared with Visual Check analysis. The sensitivity, specificity, positive predictive value [PPV], negative predictive value [NPV] of physician diagnosis and EVA Visual Check were compared with the final histopathology or cytology. Women who had normal colposcopic impression by the physician and normal cytology were considered normal and did not undergo biopsy.

Statistical analysis

SPSS v23 (IBM Corp.) was used for data analysis. Descriptive statistics for categorical variables (Physician, PAPS, HPE diagnosis etc) were elaborated in the form of frequencies, percentages and the 95% CI for these percentages. Chi-Squared test was used to explore the association between EVA Visual check impression and diagnoses by different modalities. Fisher's exact test was where > 20% of the cells contained an expected count of < 5. Sensitivity, specificity, PPV, NPV and diagnostic accuracy for various modalities was calculated by taking histopathological evaluation or cytology as the gold standard. Statistical significance was kept at $p < 0.05$.

Results:

For the final analysis to results 147 women were considered; three women were dropped from the analysis since they did not consent for biopsy. A total of 90 women had a biopsy and histologically proven diagnosis. Following are the results of the study.

The mean age of the participants was 38.81 ± 10.78 years. Table 1 depicts the association between EVA Visual Check impression and physician’s diagnosis in 147 women.

Table 1
Association Between EVA Visual Check Impression and Physician Diagnosis (n = 147).

Physician Diagnosis	EVA Visual Check Impression			Chi-Squared Test	
	Normal	**Abnormal**	**Total**	**χ2**	**P Value**
Normal	27 (79.4%)	23 (20.4%)	50 (34.0%)	46.125	< 0.001
Ectropion	0 (0.0%)	22 (19.5%)	22 (15.0%)		
Squamous Metaplasia	0 (0.0%)	5 (4.4%)	5 (3.4%)		
Cervicitis	0 (0.0%)	7 (6.2%)	7 (4.8%)		
Low Grade Lesion	7 (20.6%)	26 (23.0%)	33 (22.4%)		
High Grade Lesion	0 (0.0%)	27 (23.9%)	27 (18.4%)		
Cancer	0 (0.0%)	3 (2.7%)	3 (2.0%)		
Total	34 (100.0%)	113 (100.0%)	147 (100.0%)		

Out of 50 cases which were normal according to physician diagnosis, EVA Visual check reported 27 (79.4%) as normal and 23 (20.4%) as abnormal. All case of ectropion, squamous metaplasia and cervicitis were diagnosed as abnormal on EVA Visual Check. Out of 33 (22.4%) low grade lesion as per physician diagnosis, 7(20.6%) were diagnosed as normal on EVA Visual Check. However, all high-grade lesions and cancer were diagnosed as abnormal by EVA Visual Check (100% specificity for high grade and cancer).
Table 2 describes the association between histopathological diagnosis with EVA Visual Check and physician impression.

Table 2
Association between Histopathological Diagnosis with EVA Visual Check and Physician impression

HPE Diagnosis		**EVA Visual Check**		**Physician impression**	
	Total	**Normal**	**Abnormal**	**Normal**	**Abnormal**
Normal	83 (56.5%)	26 (76.5%)	57 (50.4%)	44 (88.0%)	39 (38.1%)
Cervicitis	11 (7.5%)	1 (2.9%)	10 (8.8%)	1 (2.0%)	10 (10.3)
CIN-I	25 (17.0%)	4 (11.8%)	21 (18.6%)	4 (8.0%)	21 (21.6%)
CIN-II	14 (9.5%)	2 (5.9%)	12 (10.6%)	1 (2.0%)	13 (13.4%)
CIN-III	8 (5.4%)	1 (2.9%)	7 (6.2%)	0 (0.0%)	8 (8.2%)
Carcinoma	6 (4.1%)	0 (0.0%)	6 (5.3%)	0 (0.0%)	6 (6.1%)
Total	147 (100.0%)	34 (100.0%)	113 (100.0%)	50 (100.0%)	97 (100%)

For EVA Visual Check , strength of association between the two variables that is Histopathological diagnosis and EVA Visual Check diagnosis is low (Cramer's V = 0.23) (Bias Corrected Cramer's V = 0.14).

For physician diagnosis, strength of association between the two variables that is physician impression and Histopathological diagnosis is moderate (Cramer's V = 0.45 (Moderate Association) (Bias Corrected Cramer's V= 0.41).
Table 3 summarise the prediction of CIN 1 + lesions by various modalities.

Table 3
Summary of prediction of CIN 1 + lesions

Variable	Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
Physician Impression	86.8% (75–95)	81.9% (73–89)	73.0% (60–83)	91.7% (84–97)	83.7% (77–89)
PAP'S Impression	22.6% (12–36)	95.7% (89–99)	75.0% (48–93)	68.7% (60–77)	69.4% (61–77)
EVA Visual Check Impression	86.8% (75–95)	28.7% (20–39)	40.7% (32–50)	79.4% (62–91)	49.7% (41–58)

Table 4 summarise the prediction of CIN2 + lesions by various modalities.

Table 4
Summary of prediction of CIN2 + lesions

Variable	Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
Physician Impression	92.9% (76–99)	68.9% (60–77)	41.3% (29–54)	97.6% (92–100)	73.5% (66–80)
PAP'S Impression	35.7% (19–56)	95.0% (89–98)	62.5% (35–85)	86.3% (79–92)	83.7% (77–89)
EVA Visual Check Impression	89.3% (72–98)	26.1% (18–35)	22.1% (15–31)	91.2% (76–98)	38.1% (30–46)

Table 5 evaluates the diagnostic parameters in the form of likelihood ration and Youden Index for diagnosing CIN.

Table 5
Diagnostic Parameters : Likelihood ration and Youden Index for diagnosis of CIN

Variable	LR+	LR-	Youden Index
Physician Impression	4.80 (3.08–7.47)	0.16 (0.08–0.32)	68.7
PAP'S Impression	5.32 (1.81–15.67)	0.81 (0.69–0.94)	18.4
EVA Visual Check Impression	1.22 (1.03–1.44)	0.46 (0.22–0.98)	15.5

Discussion:

In recent years AI has been utilised in various fields for phonetic recognition, image recognition ,face recognition and automated driving etc [8]. Many medical disciplines are also successfully utilising Artificial intelligence including detection of skin cancer, diabetic retinopathy, predicting stroke, assessing bone health and diagnostic mammograms [9, 10, 11, 12]. Most of the methods of cervical cancer screening like cytology, VIA and colposcopy depend upon visual interpretation by a trained health care provider which is subjective and depends upon the level of training. Automation helps to reduce inter-operator variability, improves diagnostic accuracy and reproducibility. Artificial intelligence (AI) is a proposed method to mitigate such variations in visual interpretation and for improvising performance of learners [13]. Digital colposcopy built around a smartphone with incorporated artificial intelligence has the potential to revolutionize the cervical screening program [14].

The results of the present study reveal that MobileODT EVA colposcope with an inbuilt AVE [Automated visual evaluation] algorithm “EVA Visual Check” has sensitivity and negative predictive value comparable to physician diagnosis though having a lower specificity and diagnostic accuracy for cervical intraepithelial neoplasia [CIN].

CIN 2 + lesions are true precursors for cervical cancer and we found EVA visual check had better sensitivity ,specificity, PPV, NPV and diagnostic accuracy of for CIN 2 + lesions as compared to CIN 1 + lesions. EVA Visual Check falsely diagnosed 20.4% of normal cervices, 19.5% of ectropion, 4.4% of squamous metaplasia, and 6.2% of cervicitis in present study. Similar observation was made in another multinational study which noted a high prevalence of cervicitis in images collected from India which interfered with decision making of Automated Visual Evaluation [AVE] algorithm and commented that AVE algorithm needs to be trained to deal with such regional variations [14, 15].

In another study AVE algorithms on images taken by MobileODT EVA were found to be at par with human evaluation by a gynaecologist in predicting the precancerous lesions [14]. AVE algorithms strongly predicted CIN 2 + or worse lesions proven on histopathology. We second their suggestion that it is essential to train AVE algorithms for broader use with larger sample sized studies with rigorously defined cases of histologically proven CIN 2 + lesions in association with HPV testing [14].

A large prospective epidemiological study was done in Guanacoste Cohort, Costa Rica where another Automated Visual Evaluation detection algorithm was developed from 9406 subjects .It compared cytology, VIA and HPV testing with trained algorithm using data with a long natural history dating from 1990 ,and reported that trained algorithm using digitalised cervicogram had excellent sensitivity for detection of CIN 2 + lesions. This performance was found to be better than colposcopist's interpretation of the same image and had high agreement with cytology and HPV testing. The sensitivity ,specificity, of automated visual evaluation was found to be 97.7% and 84% for the age group 25–49 years [16]. However, this study used archived then digitized cervical images from screening, taken with a fixed-focus camera ("cervicography") instead of much upgraded mobile digital camera used now.

In a recent study, a set of researchers from Japan compared impression of 100 images of colposcopy by a panel of 32 colposcopists versus Artificial Intelligence Supported Diagnosis [AISD]. Artificial intelligence was found to have accuracy of 57.8% for normal, 35.4% for CIN 1, 40.5% for CIN 2 & 3 and 44.5% for invasive cancer as compared colposcopist's diagnosis of 54.4% for CIN 1, CIN 2 & 3 and 38.9% for invasive cancer. After learning from AISD even diagnosis of gynaecologist improved to 58.0% for CIN 2 & 3 lesions and 48.5% for invasive cancer. They reported that assistance from AI significantly improves diagnostic accuracy of Gynaecologist for invasive cancer ($p < 0.1$) and for CIN 2&3 ($p = 0.14$) [17].

In the present study MobileODT EVA visual check had good sensitivity and NPV but lower specificity, PPV ,and diagnostic accuracy as compared to physician diagnosis. However, it can help in quicker triage of screen positive women by healthcare workers who can apply this algorithm at the peripheral centres. Moreover sensitivity, specificity and diagnostic accuracy of EVA visual check is higher for CIN 2 + lesions as compared to all CIN 1 + lesions .Trainees in colposcopy could also use it for triage of screen positive women before colposcopy by an expert. The images marked abnormal could be reviewed by an expert even situated remotely. This can reduce the load on expert colposcopists who can review only the "abnormal ones", thereby reduce waiting times for colposcopy and treatment. Quicker triage can also reduce loss to follow up and help in achieving the 90% treatment goal of WHO. Efficient data collection by incorporation of AI will pave the way for an organised cancer registry as well as deep learning and evidence-based care for health care providers [7] .

Conclusion:

Present study revealed MobileODT EVA Visual Check helps quicker triage of abnormal screening as it has good sensitivity comparable to physician diagnosis for precancerous lesions and invasive cancer. Though it cannot replace an expert colposcopist, it has great potential as a point of care triage system following a positive screening test in peripheral health centres, minimising number of women travelling to colposcopy and treatment clinics thus making effective usage of limited resources in LMICs. The results of this study suggest that potential modifications are needed in the AI system to improve the specificity and larger multicentric studies including different levels of health care workers like doctors , nurses and midwives is needed for further improvising algorithms.

Limitations Of Present Study:

It was a single centre study and the population was hospital based instead of community screening. We recommend future multicentre studies on triage incorporating WHO recommended primary HPV testing in all participants.

Strength of present study : As compared to most retrospective studies , our study was a cross sectional study which provided the results of physician's diagnosis , EVA Visual Check and histopathology which paves the way for future follow up and review of EVA Visual Check's performance. Study was performed on a random sample of women who were screened for the first time and our definition of precancer was robust as it was proven by histopathology.

Abbreviations:

LMIC : Low and middle Income countries

A I : Artificial Intelligence

O D T : Optical Device Technology

E V A : Enhanced Visual Assessment

C I N : Cervical intraepithelial neoplasia

WHO : World Health Organisation

HPV : Human Papilloma Virus

PPV : Positive predictive value

NPV : Negative predictive value

VIA : Visual inspection with acetic acid

AVE : Automated visual evaluation

ASID : Artificial intelligence supported diagnosis

HPE : Histopathological Evaluation

L R : Likelihood Ration

Declarations:

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