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PILOT STUDY TO EVALUATE PERFORMANCE OF A LOW-COST, LOCALLY DEVELOPED DIGITAL PORTABLE COLPOSCOPE AND CONVENTIONAL COLPOSCOPE IN CERVICAL CANCER SCREENING

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Abstract

Introduction: Cervical cancer is the second most common cancer observed in women. The majority of cases occur in resource-poor countries where there is inaccessibility to effective screening methods. Numerous effective screening methods are available, including Pap smear, LBC (liquid-based cytology), VIA (visual inspection of the cervix with acetic acid), VILI (visual inspection of the cervix with Lugol's iodine), HPV (human papillomavirus) testing, digital cervicography, and colposcopy. Colposcopy is a reliable and precise method for identifying and treating pre-malignant cervical lesions. However, conventional colposcopes are costly, and they require a well-equipped setup with trained personnel, making them unfeasible for community-based screening of cervical cancer. Considering this, we designed and developed a low-cost, locally manufactured, and portable digital colposcope suitable for community-based screening. We conducted a pilot study to assess the diagnostic accuracy, sensitivity, and specificity of the locally developed colposcope for screening cervical cancer in comparison with the conventional colposcopes.

Methods: This study was conducted at Jawaharlal Nehru Medical College, Sawangi (M), Wardha, from June 15 through December 15, 2021. Initially, a low-cost, locally developed, and portable digital colposcope was designed, and a prototype was created. We enrolled women between 25 and 65 years of age who met the inclusion criteria and voluntarily consented. Colposcopy was performed using both a conventional colposcope and the low-cost, Images captured, Swede scoring, and marking of biopsy sites by both colposcopes were compared by a reviewer blinded to the device assignments. Cervical lesions were biopsied and evaluated using gold-standard histopathological methods to confirm diagnoses.

Results: The mean age of the study participants was 41.1 years. There was substantial concordance between the devices, with a Cohen's kappa coefficient of 0.999 (95% CI: 0.998, 1.000) ($p < 0.0001$) suggesting that the low-cost colposcope can perform on par with the conventional colposcope. The sensitivity was 100% (95% CI: 90.26-100%), while the specificity was 8.33% (95% CI: 0.21-38.48%). The accuracy was 77.08% (95% CI: 62.69-87.97%). The locally developed colposcope performed better in terms of the visibility of the cervix, sharpness, and brightness of the image, with mean scores of 4.6, 4.8, and 4.9, respectively, vs. 4.1, 3.6, and 3.8 for the conventional colposcope on a 5-point scale.

Conclusions: This pilot study assessed the performance of a newly developed, low-cost, locally manufactured, and portable digital colposcope and compared it with a conventional colposcope. The findings will serve as the foundation for conducting large-scale, multicenter trials to determine whether the low-cost colposcope can enhance cervical cancer screening at the community level in low- and middle-income countries, thus facilitating the achievement of the World Health Organization's target of screening 70% of women by the age of 45.

INTRODUCTION

Cervical cancer poses a significant public health concern in low- and middle-income countries (LMICs). Annually, 342,000 cervical cancer deaths are anticipated, with approximately 90% occurring in LMICs [1]. The World Health Organization (WHO) has developed a global strategy to eliminate cervical cancer by 2030 [2]. Effective screening is essential to achieving this goal. For women with abnormal initial screening results, colposcopy is a vital step in diagnosing and treating pre-invasive lesions [3]. The WHO recommends either a "screen and treat" or a "screen, triage, and treat" approach in its revised guidelines for screening and treating pre-malignant cervical lesions in LMICs [3]. The

screen-and-treat strategy allows women who test positive for pre-malignant cervical lesions via cytology, HPV (human papillomavirus) testing, or VIA (visual inspection with acetic acid) to be treated immediately with ablation (such as thermal or cryotherapy) or excision using LEEP (loop electrosurgical excision procedure). This approach bypasses the need for a cervical biopsy and histological diagnosis, enabling single-visit treatment, which reduces loss to follow-up and the reliance on often scarce pathology and gynecology services in LMICs [4]. However, the drawback of the screen-and-treat strategy is the potential for overtreatment, as the majority of women with HPV infection (between 50% and 70%) do not and will not develop high-grade cervical disease [5]. For women living with HIV, the screen, triage, and treat approach is recommended. This involves a positive primary screening test followed by a positive second ("triage") test, with or without histological confirmation, to guide treatment. Point-of-care techniques are crucial for effectively screening, triaging, and treating women who test positive, allowing for treatment in a single visit.

Healthcare professionals now have access to affordable, handheld, battery-operated colposcopes that can be used in outreach screening programs and mobile camps, thanks to the development of portable devices such as the Gynocular, Evacolpo, and Smart Scope [6-8]. Although these colposcopes are portable, they have drawbacks, such as cost-effectiveness and the invasive nature of the procedure, making them less suitable for LMICs [9]. The need for further research was underscored by a recent meta-analysis of portable colposcopes [10]. A study by Shamsunder et al., which assessed the artificial intelligence-based Smart Scope, identified a need to enhance their automation technique for diagnosing cervical lesions, as they failed to diagnose two malignant lesions with their device [11] [12]. We developed a low-cost portable colposcope and aimed to evaluate how well it, relative to conventional colposcopes, detects pre-invasive and invasive lesions of the cervix. This study aimed to determine if our portable, domestically developed digital colposcope could be comparable to a conventional colposcope in screening for pre-invasive and invasive cervical lesions. Our objective was to compare the specificity and sensitivity of a conventional colposcope with the locally developed colposcope. We also analyzed secondary outcomes, including the visibility of the cervix, image quality, and the time required to perform colposcopy procedures with both devices.

MATERIALS AND METHODS

Low-cost, locally developed, and portable digital colposcope

A low-cost portable colposcope was designed, developed, and patented by the researchers. The device comprises a control panel with built-in battery switches and a keypad to control illumination, along with a mounting body attached perpendicularly to the control panel with a smartphone holder. The mounting body features a capsule-shaped aperture aligned with the smartphone camera. A light-controlled, conical chamber is attached to the back of the aperture. Four sets of LEDs (light-emitting diodes) are placed in the four quadrants of this chamber. A smartphone with a 48-megapixel primary camera, 4 GB of RAM, and 64 GB of memory was used to capture images. The smartphone was mounted on the mounting body and secured by a holder.

Designed and developed by a gynecologist with the ergonomics of the operator in mind, this device is a point-of-care diagnostic and screening tool. It is non-invasive, featuring a portable light-controlled chamber and a built-in light source with adjustable intensity and a four-quadrant illumination system. The low-cost colposcope is powered by rechargeable lithium-ion batteries and is integrated with an Android device meeting specific requirement, such as a 48-megapixel camera, 4 GB of storage space, and 8 hours of battery life. Images are captured from 5 to 10 cm away from the cervix, creating a darkroom effect by resting the conical chamber on a Cusco speculum. A key feature of this device is its user-friendliness; it can be operated with minimal training by primary-level healthcare providers.

Study Procedure

This interventional diagnostic study was conducted in outpatient department of Obstetrics and Gynecology, Jawaharlal Nehru Medical College, Sawangi(M), Wardha India, from June 15 through December 15, 2021, following clearance from the relevant institutional ethical committee (IEC/Dec-2020/8661). We invited 48 women who consented to participate in the study, adhering to the following inclusion criteria: women aged 25 to 65 years with a history of sexual cohabitation, presenting with complaints of vaginal discharge mixed with blood, foul-smelling discharge, postcoital bleeding, postmenopausal bleeding, intermenstrual bleeding, lower abdominal pain, or lesions on the cervix visible after application of acetic acid. An abnormal Pap smear report indicating ASCUS (atypical squamous cells of undetermined significance), ASC-H (atypical squamous cells-cannot exclude HSIL), LSIL (low-grade intraepithelial lesion), HSIL (high-grade intraepithelial lesion), or cancer was considered positive. The exclusion criteria were as follows: lactating and pregnant women, those with active vaginal bleeding, visible growth on the cervix, active infection, Pap smear indicative of organism growth such as Trichomonas vaginalis, Candida, bacterial vaginosis, cytological changes from cytomegalovirus, herpes simplex virus, non-neoplastic pathology, post-hysterectomy status, previous treatment for CIN (cervical intraepithelial neoplasia) or cervical cancer, a history of systemic malignancies or other major systemic terminal diseases, and individuals who declined participation or informed consent. All participants provided written informed consent. For each patient, a comprehensive clinical history, demographic details, and obstetric history were documented, followed by a physical evaluation. Colposcopy was performed using both the locally developed digital colposcope (Figure 1) and a conventional colposcope during the same consultation. Colposcopy was performed by a gynecologist trained for the procedure. Images were captured after clearing mucus and following the application of acetic acid and Lugol's iodine, ensuring that the entire cervix was visible and the light intensity was optimal. The conventional colposcopy procedures adhered to the protocols outlined in the International Agency for Cancer Research and WHO training manual [4]. The duration of each procedure was also documented.

Figure 1: Low-cost, locally developed, and portable digital colposcope

Images captured by the low-cost colposcope (group A) and the conventional colposcope (group B) were organized into two separate folders and sent to an external gynecologist with expertise in colposcopy. Before sending the images to the expert, we ensured that they contained no identifying information that could reveal which device was used for their capture, thus maintaining the expert's unbiased perspective during image analysis and diagnosis. Patient confidentiality was preserved by employing patient codes. The expert gynecologist was provided with a form to evaluate the following: image quality grading, lesion scoring using the Swede score, and biopsy site marking. The images were assessed, and Swede scoring was conducted to categorize lesions into CIN grades 1, 2, and 3, as well as carcinoma [13]. For all patients presenting with cervical lesions, the researcher conducted a punch biopsy at the designated biopsy site. Additionally, in instances of a type 3 transformation zone, endocervical curettage was performed. These procedures were carried out irrespective of the patients' Swede scores to secure histopathological verification of the lesion type. Histopathological confirmation served as the gold standard. A simple sampling method was employed to enroll patients in the study. Data entry was facilitated using SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). Statistical associations were tested using Pearson's chi-square test. The concordance between Swede scores obtained by two devices and colposcopy interpretations of lesion grade were tested for significance using the Wilcoxon signed-rank test due to non-normal distributions. The agreement of colposcopy findings by two methods was evaluated using Cohen's kappa coefficient. The sensitivity and specificity of the test device as compared to histopathology in diagnosing CIN was determined. The statistical significance was evaluated at 5% level

Statistical Methods

Data entry was facilitated using SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). Statistical associations were tested using Pearson's chi-square test. The concordance between Swede scores obtained by two devices and colposcopy interpretations of lesion grade were tested for significance using the [8]Wilcoxon signed-rank test due to non-normal distributions. The agreement of colposcopy findings by two methods was evaluated using Cohen's kappa coefficient. The sensitivity and specificity of the test device as compared to histopathology in diagnosing CIN was determined. The statistical significance was evaluated at 5% level.

RESULTS

Table *1* presents the age distribution of the study participants, who had a mean age of 41.4 years. The analysis revealed a statistically significant association between age and histopathological findings, with a significantly higher proportion of positive cases occurring in the 30- to 40-year age group ($\chi 2$: 30.07; DF: 16; Pearson chi-square p=0.018).

Table 1: Distribution of patients according to age and histopathological findings

Age in years	Histopathology					Total
	Positive				Negative	
	Cancer	CIN I	CIN II	CIN III	Inflammation	
30-35	0	11	2	0	3	16
36-40	0	6	4	0	4	14
41-45	0	5	1	1	2	9
46-50	0	2	0	1	1	4
> 50	2	1	0	0	2	5
Total	2	25	7	2	12	48

CIN- Cervical intraepithelial neoplasia ($\chi 2$: 30.07; DF: 16; p=0.018)

A comparison of associated Swede scores was conducted for both colposcopy devices. The mean Swede scores for group A and group B were 4.75 and 4.73, respectively ($\chi 2$: 5.26; DF: 3; p=0.564) (Table *2*). However, Cohen's kappa coefficient was 0.999, indicating a significant level of intergroup concordance between the Swede scores.

Table 2: Comparison of Swede scores between two groups

	Group	n	Mean	Standard Deviation	Median	P-value
Swede score	Low cost Colposcope	48	4.75	1.23	5.00	0.564
	Conventional colposcope	48	4.73	1.23	5.00	

n- Total number of study participants

There was a strong intergroup concordance in the colposcopy findings, with a Cohen's kappa statistic of 0.999, indicating high reliability in identifying pre-invasive and invasive lesions. In our study, 7 women were diagnosed with CIN 1, 36 with CIN 2, 2 with CIN 3, 1 had ectropion, and 2 participants were suspected of having cervical cancer (Table *3*).

Table 3: Agreement of colposcopy findings by two methods

Colposcopy finding – Low cost colposcope	Colposcopy finding – Conventional colposcope					Total
	Ca Cervix	CIN 1	CIN 2	CIN 3	Ectropion	
Ca Cervix	2	0	0	0	0	2
CIN 1	0	7	0	0	0	7
CIN 2	0	0	36	0	0	36
CIN 3	0	0	0	2	0	2
Ectropion	0	0	0	0	1	1
Total	2	7	36	2	1	48

CIN- Cervical intraepithelial neoplasia
Ca- Carcinoma

Cohen's Kappa coefficient: 0.999 (95% CI: 0.998, 1.000), p < 0.0001

Table *4* illustrates the association between colposcopy findings and histopathological results. Two patients with colposcopy findings suggestive of cervical cancer were histopathologically confirmed to have squamous cell carcinoma. Of the seven women diagnosed with CIN 1 via colposcopy, three were histopathologically positive for CIN 1. Among the 36 women diagnosed with CIN 2 through colposcopy, 22 were confirmed to have CIN 1, and six had CIN 2 upon histopathological examination. Of the two diagnosed with CIN 3 via colposcopy, one was confirmed to have CIN 3. The overall sensitivity of colposcopy was 100% (95% confidence interval [CI]: 90.26-100%), while the specificity was 8.33% (95% CI: 0.21-38.48%). The overall accuracy was calculated to be 77.08% (95% CI: 62.69-87.97%).

Table 4: Association of colposcope finding with histopathology

Type of lesion	Histopathology				
	Negative	Positive			
	Inflammation	Cancer	CIN I	CIN II	CIN III
Ca Cervix	0	2	0	0	0
CIN 1	4	0	3	0	0
CIN 2	7	0	22	6	1
CIN 3	0	0	0	1	1
Ectropion	1	0	0	0	0

Ca- Carcinoma
CIN- Cervical intraepithelial neoplasia
$\chi 2$: 8.78; DF: 4; P-value: 0.067 using Pearson's Chi-square test

Table *5* compares the image quality parameters of the investigated colposcopes, with each parameter graded on a 5-point scale. The mean score for the visibility of the cervix in group A was 4.60, compared to 4.13 in group B (p=0.001). The mean scores for the brightness of the image were 4.48 in group A and 3.65 in group B (p=0.001). The mean scores for image sharpness were 4.92 in group A and 3.81 in group B (p=0.001).

Table 5: Comparison of image quality parameters between two groups

Parameters	Group	n	Mean	Standard Deviation	Median	P-value
Visibility of Cervix	A	48	4.60	0.49	5.00	< 0.0001
	B	48	4.13	0.44	4.00	
Brightness score	A	48	4.48	0.58	5.00	< 0.0001
	B	48	3.65	0.84	4.00	
Sharpness of Image	A	48	4.92	0.28	5.00	< 0.0001
	B	48	3.81	0.64	4.00	

n- Number

Table *6* indicates the mean time required for colposcopy procedures: for group A, the mean time was 6.02 ± 1.22 minutes, with a median of 6 minutes. In contrast, group B required a mean time of 9.48 ± 1.45 minutes, with a median of 9 minutes (p < 0.0001).

Table 6: Comparison of time required to perform procedures

Parameter	Device	Mean time in minutes	Standard Deviation	P-value
Time required for procedure (minutes)	Low cost colposcope	6.02	1.22	< 0.0001
	Conventional colposcope	9.48	1.45	

DISCUSSION

Cervical cancer remains a significant public health issue in resource-poor countries, including India. Many of these nations have struggled to implement effective cytology-based screening programs due to a variety of challenges, such as inadequate infrastructure, a shortage of skilled personnel, inconsistent patient follow-up, and healthcare that is inaccessible in remote areas, among other logistical challenges. VIA emerged as a promising alternative to cytology-based diagnostic tools. Nonetheless, its reliance on the observer's experience led to high false-positive rates, while concerns about under-diagnosis and over-treatment persisted. Several studies have indicated that HPV testing is associated with a decrease in the incidence of advanced malignancies [14,15]. Despite this, costs and the availability of skilled personnel remain significant barriers. In 2005, the Tamil Nadu Health Systems Project (TNHSP), under the Government of Tamil Nadu, initiated a World Bank-funded non-communicable disease intervention program across all districts [16]. This program revealed a considerable dropout rate in the multi-step approach, highlighting the failure to treat a large screen-positive population. This observation, among others, underscored the need for an effective single-visit screen-triage-treat strategy. Recent studies have investigated the role of portable colposcopes in facilitating this approach [8,17,18]. With this context in mind, we developed a low-cost, locally manufactured, and portable digital colposcope and investigated its efficacy. The primary aim of this pilot study was to evaluate the diagnostic efficiency of the newly developed colposcope compared with conventional colposcopes in detecting pre-malignant and malignant lesions of the cervix. Additionally, this pilot study was conducted to establish a protocol for larger-scale studies.

In our study, 48 participants who met the inclusion criteria were enrolled. The mean age of the participants was 41.1 years, with a notably higher proportion of positive cases found in the 30- to 40-year age bracket. Two cases of squamous cell carcinoma were identified, both within the 50- to 60-year age range. Both colposcopy devices demonstrated equivalent performance in lesion identification and Swede score assessment. The high level of concordance, indicated by a Cohen's kappa coefficient of 0.999, suggests that the low-cost colposcope is comparable to the conventional colposcope. The overall sensitivity was 100% (95% CI: 90.26-100%), while the specificity was 8.33% (95% CI: 0.21-38.48%). The overall accuracy stood at 77.08% (95% CI: 62.69-87.97%). These results may be attributable to the study's small sample size, pointing to the need for further large-scale, multicenter studies for comprehensive evaluation.

The low-cost colposcope outperformed the conventional colposcope in terms of visibility of the cervix, sharpness, and image brightness, with mean scores of 4.6, 4.8, and 4.9,

respectively, compared with 4.1, 3.6, and 3.8 on a 5-point scale. The use of a 48-megapixel smartphone camera with a light-controlled enclosure and an integrated light source significantly enhanced image quality. The distance from which images were captured, ranging from 5 to 10 cm depending on the depth of the cervix, optimized image sharpness without the need for zoom functionality, which could compromise image quality. The mean time required to perform procedures with the locally developed colposcope was 6.02 minutes, compared to 9.48 minutes with the conventional colposcope. The longer duration associated with the conventional colposcope was due to the need for adjustments, such as height, focal length, and lighting conditions, to capture glare-free images. Additionally, the lack of a footswitch necessitated constant assistance for image capture, further extending the time required. In contrast, the newly developed device required significantly less time, as it simply rests on a Cusco speculum, and images are captured by adjusting the light intensity on the control panel.

LIMITATIONS

The study's major limitations were its small sample size and the fact that it was conducted in an ideal colposcopy clinic setup. Future studies should aim to evaluate the device in primary healthcare centers, mobile vans, and screening camps to determine its efficacy in more varied and realistic settings.

CONCLUSIONS

This study evaluated a locally developed and portable digital colposcope with the goal of determining its efficacy, feasibility, and potential for widespread application. The low-cost, locally developed colposcope and the conventional colposcope demonstrated equal capability in diagnosing cervical lesions. In evaluating cervical lesions, Swede scores, and cervix assessment, the locally developed colposcope matched the performance of the conventional colposcope, as confirmed by the definitive histopathology results. Furthermore, the low-cost colposcope outperformed the conventional colposcope in terms of image quality and the time efficiency of colposcopic procedures. Conducted on a small sample of patients, this pilot study aimed to establish a protocol for larger-scale clinical trials. Further extensive studies are necessary to thoroughly evaluate the diagnostic accuracy, sensitivity, and specificity of this newly developed, low-cost colposcope before it can be implemented in the field for cervical cancer screening.

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