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# Portable Colposcopy a promising means for cervical cancer screening for low- and middle-income countries: A review

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**Abstract**
Cervical cancer is a prevalent cancer, particularly affecting women in LMICs nations due to limited access to screening and diagnostic services. This gap in healthcare accessibility necessitates the development of affordable and accurate screening methods. This review explores the challenges faced by LMICs in cervical cancer screening and the potential of portable colposcopy technologies to address these limitations. Various screening methods, including Pap smears, HPV genotyping, visual inspection with acetic acid (VIA), and colposcopy, were developed, each with its advantages and limitations. Recent advancements in portable colposcopy, such as the Pocket colposcope, Gynocular colposcope, SmartScope, Enhanced Visual Assessment (EVA), and Gyneye, offer promising solutions with portability, affordability, and comparable diagnostic accuracy to traditional colposcopes. Integration of artificial intelligence (AI) and machine learning further enhances diagnostic capabilities. Despite progress, challenges such as awareness, infrastructure, and economic constraints persist. Collaborative efforts are needed to address these challenges and ensure the widespread adoption of portable colposcopes, ultimately decreasing the global weight of cervical cancer and saving lives.

## Introduction

Cervical cancer is a malignant carcinoma that develops in the cervix region. It is the fourth most prevalent cancer in women worldwide and remains the leading cause of female death, importantly in developing countries [1]. The incidence of cervical cancer was approximately 660,000 new cases in 2022 globally. Low and middle income countries (LMIC) accounted for approximately 94% of the 350,000 cervical cancer deaths in 2022. LMIC's have the highest incidence and death rate from cervical cancer [2]. Cervical cancer is the primary cause of death from cancer in 36 nations, including sub-Saharan Africa, Latin America, and India [1]. This indicates significant disparities due to the unavailability and inaccessibility of cervical screening, treatment programs, and national HPV vaccination, as well as social and economic factors. A key etiological agent of cervical cancer is contact with precarious Human Papillomavirus [3]. Persistent infection with the human papillomavirus (HPV) leads to cervical cancer. Studies revealed that women with HIV can have an incidence of cervical cancer 6 times higher compared to others [2].

Cervical cancer screening and prevention measures include HPV vaccination, screening testing, and early diagnosis of suspicious cervical lesions. HPV vaccines can prevent up to 90% of cervical cancers if given before sexual debut and HPV infection [4]. Screening requires detecting and treating cervical dysplasia, which can lead to invasive carcinoma [5]. Various screening procedures are used globally, like liquid-based cytology and high-risk HPV genotyping. The Pap test and the HPV test are the two most used cervical cancer detection methods [6]. In certain countries the diagnosis, screening, and prevention of early cervical cancer can help, says WHO's 90-70-90. The World Health Organization has set 3 targets (90-70-90) to eliminate cervical cancer: vaccinate 90% of girls against HPV by 15, screen 70% of women at key ages, and treat 90% of women with invasive cancer or pre-cancer. Achieving these by 2030 can put countries on track to eliminate cervical cancer in the coming century [7].

Cervical cancer screening techniques include visual inspection with acetic acid (VIA), Papanicolaou smear (Pap), HPV DNA testing, liquid-based cytology (LBC), and combinations of these tests. HPV-based modalities, such as HPV DNA testing, are more affordable and more accurate in detecting true positives than LBC-based techniques [8]. Combining HPV testing with cytology is now the most recommended method for cervical screening, while distinct HPV testing is seen to be the most promising [9]. Colposcopy is the primary approach for detecting cervical pathology, with cervical biopsy and histopathological examination necessary [10]. HPV DNA

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testing has been shown to have higher sensitivity than traditional cytology. VIA has also demonstrated great sensitivity when compared to Pap smears [11]. Overall, HPV-based testing and VIA have shown significant cost-effectiveness and sensitivity for cervical cancer screenings.

Visual inspection of the cervix with VIA is a low-cost screening technique to detect cervical cancer that is simple and quick to perform, making it suitable for environments with limited resources [12]. Digital-aided VIA is the use of digital colposcopy using a smartphone to capture and evaluate images of the cervix during VIA [13]. Colposcopy, on the other hand, is a more complex technique that necessitates training and experience. It requires the use of a colposcope, which provides a magnified image of the cervix, allowing for a more comprehensive examination [14]. Colposcopy is considered to be a better diagnostic method than VIA since it detects abnormal results more accurately. However, colposcopy is expensive and not portable, making it difficult to use in low-resource situations [15]. Digital colposcopy based on a smartphone has the potential to address these limitations because it is less expensive and can be used for telemedicine and data exchange [16].

Portable point-of-care devices for the screening of cervical cancer have emerged to meet the requirements of LMIC's with limited resources and infrastructure. A possible approach is the development of C-ColAur, a colorimetric technology that detects malignancy by combining gold nanoparticles with cervicovaginal secretions [17]. Another possibility is to employ a paper-based device that combines proteomics and lateral flow immunochromatography technologies to detect high-risk pre-cancer and invasive cervical cancer [18]. Also, a multimodal mobile colposcope (MMC) has been developed to diagnose precancerous cervical lesions at the point of treatment without the need for biopsy by integrating widefield imaging and high-resolution fiber optic microendoscopy [19]. These advances in portable point-of-care devices have the potential to improve cervical cancer screening and early detection in low-resource settings.

**Disease progression from HPV infection to Ca Cx**

One of the main risk factors for the development of cervical cancer (Ca Cx) is persistent infection with high-risk strains of the HPV. As the neoplastic process progresses in Ca Cx, the expression of HOXB2 and HOXB13 proteins rises, and this elevated expression is linked to HPV infection [20]. Patients with weakened immune systems, namely people affected with HIV, are likely to develop condyloma acuminata (CA), a skin lesion linked to HPV that can quickly proceed to aggressive anogenital squamous cell carcinoma [21]. High enduring infection with increased-risk HPV, mainly HPV-16, induces the expression of CD39 and CD73 in patients with grade 1 cervical intraepithelial neoplasms (CIN-1), which creates an immunosuppressive milieu and aids in the progression of CIN-1 to Ca Cx. Both HIV infection and the development of Ca Cx are influenced by inflammatory pathways and immunological modulation [22].

**HPV Vaccination**

Vaccination against HPV is a reliable way to stop the spread of the human papillomavirus (HPV) and avoid malignancies that are linked to it. Six prophylactic HPV vaccines are licensed; there are two quadrivalent, three bivalent, and one nonavalent vaccine. HPV types 16 and 18, which cause more than 70% of cervical cancer cases, are prevented by these immunizations [23]. Macroeconomic considerations, vaccine supply chain management, cold chain storage, lack of awareness, and vaccine delivery to remote locations make immunization programs in low and middle-income nations vulnerable. This makes it challenging to implement national awareness programs and make them affordable and accessible [24].

**Pap Smear/Liquid-based cytology (LBC)**

Liquid-based cytology and PAP smears are two efficient screening methods for the early identification of cervical cancer. PAP smears have been used extensively for a long time and have demonstrated 82% to 91% specificity and sensitivity of 50% to 66%. LBC was presented as a substitute method in the middle of the 1990s, and results indicate that it has a sensitivity of 61% to 66% and a specificity of 82% to 91% [25]. Compared to traditional PAP smears, LBC has benefits like fewer air-drying artifacts and a lower percentage of unsatisfactory smears [26]. However, their accessibility is limited in LMIC.

**HPV Genotyping**

When it comes to cervical cancer screening and diagnosis, HPV genotyping is essential. HPV genotyping offers a better sensitivity in identifying precursor lesions making it adopted as the principal screening method for cervical cancer in low- and middle-income countries [27]. It can be difficult to distinguish between a newly discovered primary tumor and metastatic cervical cancer, although routine HPV molecular genotyping testing can be helpful in these situations. Cervical cancer screening using primary high-risk HPV (hrHPV) screening is now widely established,

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and research has been done to identify potential biomarkers by examining the relationship between HPV genotypes and cellular epigenetic alterations [28]. Further research is necessary to determine the significance of undeclared HPV genotypes in screening programs and vaccination, as they have also been examined about cervical lesions [29]. Cervical cancer prevention and management can be significantly enhanced by an understanding of HPV's molecular biology and the application of HPV genotyping in clinical care [30].

**Visual Inspection with Acetic acid (VIA)**

In low- and middle-income countries VIA has been used as a cervical cancer screening method. VIA was found to have a low sensitivity, ranging from 13% to 70.8%, to detect cervical intraepithelial neoplasia grade 2/3 (CIN2/CIN3+) [31]. On the other hand, the World Health Organization (WHO) has suggested VIA as a cost-effective screening method for LMIC's [32].

However, there are several benefits and drawbacks to VIA. VIA's affordability and ease of use make it a valuable tool for environments with limited resources. Additionally, it has a high sensitivity, which enables it to precisely identify early-stage cancer and premalignant cervical lesions [33]. Because VIA yields results quickly, positive patients can be treated right away, lowering the chance of loss to follow-up [34]. But VIA is not without its restrictions. The procedure is subjective and depends on healthcare practitioners' visual perception, which may cause variations in the outcomes. Additionally, its sensitivity is lower than that of other screening techniques, such as the Pap smear, which increases the likelihood of false-positive results. Furthermore, VIA might not be appropriate for identifying cervical cancer in more advanced stages.

**Colposcopy**

Colposcopy is a diagnostic procedure used in oral oncology and gynecology to identify abnormalities of the mouth and cervical region. Among its many benefits is that colposcopy is a reasonably easy, painless, non-invasive treatment that doesn't require anesthetic [35]. It can help in the early detection of malignant and possibly malignant tumors by precisely identifying representative biopsy sites. Colposcopy's sensitivity ranges from 70% to 98%, indicating that it can identify changes in the mucosa with excellent precision. It is contingent upon the amount of biopsies obtained and the proficiency of the colposcopist [36]. When HPV-positive women underwent colposcopy, the outcomes were superior to those of VIA-positive women. However, the most unreliable test for determining non-neoplastic diseases frequently seen in women who are VIA-positive and/or HPV-positive was colposcopy [37]. The use of pap smear is inaccessible in LMIC nations due to its cost. In situations when resources are scarce and access to alternative screening techniques may be restricted, colposcopy is seen as a useful tool.

All the diagnosis methods including liquid-based cytology, HPV genotyping, pap smear, VIA, and colposcopy have advantages and disadvantages. The common problem faced in LMIC is lack of awareness, accessibility, economics, and mobility. The situation can be turned to produce better results with the help of portable colposcopy, and other mobile devices that are powered with AI, deep learning, and machine learning.

**Evolution of portable colposcopes**

Portable colposcopes have emerged to address challenges in cervical cancer screening in LMIC. Studies have demonstrated that portable colposcopes, such as the Pocket colposcope and Gynocular colposcope, perform similarly compared to traditional video colposcopes in terms of Swede score agreement and diagnostic accuracy. These portable colposcopes have the potential to minimize referrals and provide a one-time approach, increasing access to colposcopy in resource-limited conditions [38]. A multimodal mobile colposcope (MMC), which combines a colposcope and a high-resolution fiber-optic microendoscope (HRME), has been developed to diagnose precancerous cervical lesions at the point-of-care without the need for biopsy [39].

Gynocular colposcopes is one of the portable colposcopes designed to give healthcare staff a handheld, battery-operated, and low-cost colposcope. This allows utilization in any situation, including outreach screening programs and mobile camps [40]. High-resolution microendoscopy (HRME) is a technique for visualizing cervical epithelium at the subcellular level. It can be used with portable colposcopes to diagnose precancerous cervical lesions at the point of care, eliminating the need for a biopsy. The combination of HRME and widefield imaging enables the high-resolution imaging of uncertain areas as well as the identification of abnormal cervical regions [39]. A pocket colposcope is a portable small device used to screen for cervical cancer. When used following a VIA test, the Pocket colposcope can greatly enhance the detection and evaluation of high-grade cervical intraepithelial neoplasia (CIN2+) lesions, lowering overtreatment and referral rates. The Pocket colposcope is incredibly lightweight and portable, making it ideal for field use. Overall, the Pocket colposcope shows potential as a low-cost, easily accessible

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tool for cervical cancer screening in LMIC's [38]. A digitalized screening test, called the Smart Scope® visual screening test (SS test), was introduced. The SS assisted visual screening tool was used to detect different cervical lesions. SS is a non-invasive, portable device that is easy to operate [41]. The smartphone-enabled colposcope known as Enhanced Visual Assessment (EVA), developed by Mobile ODT in Israel, was able to distinguish between CIN II+ and CIN I lesions with high accuracy [42]. The EVA System improves the VIA technique in two major ways. The software enables real-time workflow support and procedure logging for monitoring and assessment, while the hardware offers magnification and a dependable, suitable light source for visibility [43]. Gyneye is a comprehensive system for observing, documenting, and maintaining patient records, which include comprehensive images of the cervix. It uses medical-grade, high-definition cameras that provide clear imagery even at high optical zooms while minimizing glare. Gyneye's cameras can detect variations in tissue texture, shape, and color at higher magnification levels. These variations would be missed with a normal stationary colposcope **[44]**.

Portable colposcopes have evolved significantly over the years, with novel models such as Gynocular, Pocket Colposcope, EvaColpo, SmartScope, and Gyneye being released. These devices are designed to be affordable and simple to use, making cervical cancer screening more accessible, especially in low-resource settings.

**Sensitivity, specificity, and diagnostic accuracy of these portable devices:**

**Pocket colposcopy**

When detecting high-grade cervical intraepithelial neoplasia (CIN2+) lesions, the Pocket colposcope has been found to have equal sensitivity, specificity, and diagnostic accuracy to regular colposcopes. The Pocket colposcope yielded similar Swede scores to the video colposcope in 99.20% of participants in a trial carried out in LMIC, with agreement scores of 0.9969 [38][45]. As a result, the sensitivity, specificity, and diagnostic accuracy of the Pocket colposcope for identifying high-grade cervical lesions have demonstrated promise.

**Gynocular colposcopy**

Gynocular colposcopy is another type of pocket colposcopy. The gynocular colposcopy used for identifying cervical intraepithelial neoplasia (CIN) 2+ lesions has been compared to that of a standard colposcope. Gynocular colposcopy was shown to have diagnostic accuracy comparable to that of a normal colposcopy [40]. The Swede scores from the regular colposcope and the gynocular colposcope showed a good degree of agreement. The portability, affordability, and battery-powered nature of gynocular colposcopy render it a viable option for use in outreach screening initiatives. Gynocular colposcope was found to have a 95 percent specificity at a Swede score of 5 [46]. The sensitivity of gynocular colposcopy was found to be comparable to that of the regular colposcope.

**Smartscope**

To identify low-grade squamous intraepithelial lesions or worse plus (LSIL+), the improved SmartScope demonstrated a sensitivity of 96.6% (95% CI, 91.6-99.1), specificity of 12.9% (CI 95%, 8.06-19.2), and diagnostic accuracy of 49.7% (41-58). The study found that the diagnostic accuracy for high-grade squamous intraepithelial lesions plus (HSIL+) was 81.0% (CI 95%, 0.75-0.85), 85.4% of specificity (95% CI, 79.9-90.0), and sensitivity was 67.6% ( CI 95%, 55.2-78.5) [47]. To identify cervical lesions, the Smart Scope® visual screening test (SS test) showed 100% sensitivity and negative predictive value (NPV) for each, 36.8% specificity, and 49.7% diagnostic accuracy [41].

**Enhanced visual assessment (EVA)**

In a different pilot study conducted using enhanced visual assessment, 85% of pathologically proven CIN I+ instances were found when 20 individuals with aberrant cervical cytology were used to diagnose pre-cancer using a smartphone. Different studies have demonstrated differing levels of sensitivity, specificity, and diagnostic accuracy with enhanced visual assessment (EVA) of colposcopy. Research in academic and teaching hospitals at the tertiary level in Italy revealed a sensitivity of 73.7% and specificity of 87.7% for the identification of CIN2+ lesions overall [48]. A different study that used the EVA Visual Check algorithm found that for CIN1+ lesions, 86.8% of sensitivity and 28.7% of specificity, while for CIN2+ lesions, 89.3% of sensitivity and 26.1% of specificity. The accuracy of colposcopies varied in a Swedish screening program, and the judgment was not significantly impacted by the experience of the colposcopists [49].

**Specifications of different portable colposcopy**

The Pocket Colposcope is a handheld, portable, and digital colposcope developed by Calla Health Technologies and Duke University. The key specifications include compactness and length similar to a smartscope. Additionally, it is a trans-vaginal digital device, equipped with a telemedicine facility, affordable, portable, and enabled with m-Health allowing it to work in remote areas.

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The Pocket Colposcope is designed like a tampon and is able to be inserted and positioned so that it is 5-50 mm away from the cervix.. Images taken are transmitted instantly to a smartphone, tablet, or laptop [50].

The Gynocular is a versatile mobile colposcope that is entirely optical, utilizing the latest technology to capture high-quality images. The optical magnification has three distinct levels (5x, 8x, and 12x) with a 300 mm of focal length o. An optical green filter that enhances the contrast of vascular structures, an anti-glare function that reduces reflections for clearer viewing, and the dimensions of the colposcope ( depth x height x width) 5.0 cm x 16.6 cm x 8.3 cm [51].

The Smart Scope colposcopy is a compact and portable device developed by Periwinkle Technologies Pvt. Ltd. The key specifications include: compactness that can fit even in an A4 size bag, the total length of the SmartScope only is 220mm, the device has AI-enabled risk evaluation of obtained images and generates a color-coded report immediately. It is convenient and simple to use [52].

The EVA COLPO is a digital solution for cervical visualization, documentation, and teleconsultation. The key specifications of the instrument include a: CMOS sensor, 13 MP resolution with a working distance of 250mm - 400mm, and a zooming ability of 4.0x optical / 16x with digital zoom. The EVA System also includes a digital green filter designed to optimize the contrast of vascular structures and blood [53].

The Gyneye colposcope is a smart, portable, and user-friendly device developed by Gyneye. Their key specifications include a camera resolution of 108MP f/1.8, Wide Angle, and a 48 MP f/3.5 Telephoto camera, AI assistance, telemedicine, and lightweight. It's a comprehensive solution for observing, recording, and storing patient records, including detailed images of the cervix. Whether you're in a low-resource setting or an advanced medical center, Gyneye has got you covered [54].

The Dr. Cervicam Series is a range of handheld colposcopes designed for cervical cancer screening and visualization of the cervix. Key feature is a13.0 Megapixel CMOS Image Sensor installed to express the texture and color of the real cervix. It is a wireless cervical camera that enables seamless transmission of images using 2.4GHz and 5GHz Wi-Fi. Intentionally designed to ensure data security and is equipped with an LCD touch screen for an intuitive environment.

**Key Findings**

Portable Devices: Several portable colposcopes, such as the Gynocular™ and the Pocket Colposcope, have been evaluated for cervical cancer screening in LMICs1 2.

Diagnostic Accuracy: Studies have reported varying diagnostic accuracy for these devices. While some show promising sensitivity and specificity, others highlight limitations due to partial verification and classification bias.

**Challenges and Opportunities:**

Cost-Effectiveness: Portable colposcopes offer cost-effective alternatives to traditional colposcopy, making them suitable for LMICs.

Immediate Results: Real-time visualization and image capture allow for immediate assessment, reducing the need for multiple visits.

Training and Capacity Building: Ensuring proper training and capacity building for healthcare providers is crucial for successful implementation.

Patient Outcomes: Future studies should focus on patient-relevant outcomes, including missed cases, overtreatment, and long-term follow-up.

**Conclusion**

In conclusion, cervical cancer remains a significant global health challenge, particularly in low and middle-income countries. Various methods for screening and diagnosis, including Pap smears, HPV genotyping, VIA, and colposcopy, have been developed to address this issue. Recent advancements in portable colposcopy, such as the Pocket colposcope, Gynocular colposcope, SmartScope, and Enhanced Visual Assessment, have shown promising results in improving the approach to screening of cervical cancer in resource-limited settings. Integrating artificial intelligence (AI) into portable colposcopes may further enhance diagnostic accuracy and streamline decision-making. However, despite these advancements, challenges such as lack of awareness, limited infrastructure, and economic constraints persist and must be addressed through concerted efforts by governments, healthcare organizations, and advocacy groups. By harnessing the power of technology and expanding access to screening services, we can make meaningful progress toward reducing the global burden of this preventable disease and saving countless lives.

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