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Review Article

Breaking barriers: the evolution of portable colposcopes in cervical health

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ABSTRACT

Global calls for cervical cancer elimination prompt urgent focus on low-income countries where screening challenges persist. While high-income nations utilize advanced methods like human papillomavirus (HPV) testing and colposcopy, many low-resource settings rely on cost-effective approaches like visual assessment with acetic acid (VIA) performed on the same day as screening and treatment. This review explores the feasibility of implementing improved visual assessment methods in low and middle-income countries (LMICs), considering challenges posed by systemic factors. Emphasizing the vital role of visual inspection, particularly in high-income countries where colposcopy guides biopsies and treatment decisions, the article advocates for tailored screening pathways. Unlike extensive multi-step processes in high-income countries, LMICs face limitations in clinic visits, making simple VIA crucial. The article evaluates the potential of cervical imaging devices for low-resource settings, aiming to enhance cervical cancer screening in line with global elimination goals.

Keywords: Cervical cancer, Low resource setting, Cervical imaging devices

INTRODUCTION

The World Health Organization's urgent plea for a globally coordinated effort to eradicate cervical cancer.[1] Recognizing the significant disparities in screening strategies between high- and low-income countries, it's imperative to address the unique challenges faced by low and middle-income countries (LMICs).[2] In LMICs, cost-effective methods such as visual assessment with acetic acid (VIA), coupled with same-day screening and treatment, often form the backbone of cervical cancer screening. Despite notable strides in cervical cancer screening techniques, including innovative molecular methods like human papillomavirus (HPV) testing, the indispensable role of visual assessment in detecting pre-cancerous lesions persists.[3,4] Colposcopy, a sophisticated visual inspection method, plays a pivotal role in high-income countries, guiding biopsies and treatment decisions through meticulous cervix assessment.[5] A comprehensive colposcopy examination, as outlined in the International Agency for Research on Cancer (IARC) manual, involves low- and high-magnification assessments, acetic acid application, Lugol's iodine staining, and examination under white and/or green light. In high-income settings, colposcopy not only directs biopsies but also informs treatment decisions, contributing to the success in reducing cervical cancer burden. However, the feasibility of extensive screening and treatment pathways requiring multiple clinic visits poses a significant challenge in LMICs.[6,7] Complex procedures such as colposcopy, HPV testing, Papanicolaou (PAP) smears, and histopathological confirmation are generally not practical.[8] Currently, many LMICs rely on naked-eye examination (VIA) for screening and treatment, despite VIA's sensitivity and specificity ranging from 41-78% and 14-98%, respectively.[9,10] Recognizing the need for enhanced visual assessment methods, this review explores cervical imaging devices tailored for low-resource settings, aiming to advance cervical cancer screening initiatives in line with global elimination objectives.

NATURAL HISTORY OF DISEASE

In the course of disease progression, the epithelium undergoes three distinct neoplastic states. Cervical intraepithelial neoplasia (CIN) of the first grade, or CIN 1, impacts one-third of the epithelium and is typically mild, often attributed to a transient HPV infection that is expected to clear naturally. CIN 2, affecting two-thirds of the epithelium, represents a moderate condition involving a combination of self-clearing and pre-cancerous lesions. CIN 3, deemed severe, involves the entire epithelium and is considered a pre-cancerous state due to the low likelihood of natural clearance. According to the Bethesda system, classifying cytological diagnosis and guiding treatment decisions, CIN 1 is categorized as a low-grade squamous intraepithelial lesion (LSIL), while CIN 2 and 3 are classified as high-grade squamous intraepithelial lesions (HSIL).

The progression to invasive cervical cancer is a gradual process, typically taking more than ten years to fully develop from the initial infection.[11-13] Notably, cervical neoplasia is not solely confined to epithelial changes but also involves alterations in stromal cells. Stromal changes precede and stimulate neoplastic progression, emphasizing the critical role of defective communication between the epithelium and the stroma in carcinogenesis. The deregulation of this communication pathway contributes to and promotes the development of cervical cancer.[14-16]

CERVICAL TESTING AND TREATMENT

The standard protocol for cervical cancer diagnosis involves liquid-based cytology (Pap test) along with DNA testing for high-risk HPV. If abnormal results are detected, additional steps such as colposcopy, biopsy, and histological confirmation are pursued, necessitating trained personnel and follow-up visits. Recognizing the challenges posed by this approach, the World Health Organization (WHO) advocates for a screen-and-treat strategy. According to WHO guidelines, the primary screening test should be HPV DNA detection every five to ten years after the age of 30.

Current screening practices encompass a combination of HPV testing, visual inspection with acetic acid (VIA), and cytology, followed by appropriate treatment. However, certain practices may not be universally applicable; for instance, VIA testing is deemed inappropriate for women older than 50, as the transformation zone, where lesions typically originate, shifts into the endocervical canal after menopause.

The selection of screening techniques is heavily influenced by local resources. Nevertheless, WHO's latest recommendations strongly endorse transitioning from traditional methods to HPV DNA screening due to the test's objectivity and efficacy.[17]

HPV DNA TESTING, CYTOLOGY, COLPOSCOPY, AND BIOPSY

Cervical screening in India involves a multi-stage process. The initial steps for cervical cancer diagnosis include HPV DNA co-testing and cytology (Pap smear). HPV DNA testing is employed to identify the presence of high-risk HPV, demonstrating a specificity of 55.6%, an accuracy of 75.8%, and a positive predictive value of 84.8%.[18] Following a positive Pap smear result, the next stage in cervical screening is colposcopy. This involves a visual inspection by trained physicians, utilizing a colposcope—a clinical microscope with 3–15 times magnification—to closely examine the uterine cervix.

VISUAL INSPECTION

Visual inspection with acetic acid (VIA) involves applying a 3–5% acetic acid solution to the ectocervix, causing abnormal cells to turn opaque white (acetowhite), indicating a VIA-positive result. The positive predictive value of VIA is 16.7%, with a negative predictive value of 99%, and specificity and sensitivity of 79.4% and 71.8%, respectively.[19,20] However, VIA results in numerous false positives, leading to overdiagnosis and overtreatment. Visual inspection with Lugol's iodine (VILI) includes applying Lugol's iodine to the cervical epithelium, reacting with glycogen in normal tissue (turning black) and highlighting neoplastic tissue (turning yellow). VILI's positive predictive value is 16.8%, with a negative predictive value of 99.7%, and specificity and sensitivity of 86% and 88%, respectively.[21] Despite its advantages, VILI also yields many false positives. Visual inspection methods for cervical screening exhibit low reproducibility and subjectivity-dependent variation in results. Factors such as age, parity, menopause, and HPV presence influence outcomes, emphasizing the importance of healthcare provider training. Visual inspection, cost-effective and providing real-time results, is suitable for low-resource settings and a screen-and-treat approach, especially in areas with high cervical cancer incidence and limited medical resources. Raifu et al recommends improved training for personnel on the definition and interpretation of acetowhite lesions in such settings.[22-24] For cervical neoplasia, recommended treatments focus on removing or destroying the transformation zone and abnormal cervical areas. Ablative treatments involve thermal coagulation or cryotherapy, while excisional approaches include large loop excision of the transformation zone (LLETZ) or cold knife cone (CKC), also known as conization of the cervix.[16]

HPV VACCINES

Three HPV vaccines have been available since 2006, demonstrating close to 100% efficacy for young adolescents aged 9–15 years.[25] These vaccines target infections in anatomical areas beyond the cervix, such as the vulva, penis, and anus. While HPV vaccination has contributed to reducing infections in women, it does not

cover all 15 high-risk HPV types.[26] However, its implementation in developing countries faces challenges due to cost and complexity, emphasizing the continued importance of screening and treating precancerous lesions as primary preventive measures.[27] Given the slow progression of cervical cancer, its anatomical accessibility, and the potential treatment of precancerous lesions, early screening remains an effective management strategy.[11] Traditional cervical screening procedures are costly, prompting the development of devices to enhance accessibility in low-resource settings. However, screening-positive women often face challenges in being triaged for colposcopy, particularly in low-middle-income countries. The use of portable colposcopes has the potential to address these challenges, reduce referrals, and facilitate a single-visit approach.

CERVICAL IMAGING TARGETED FOR NEOPLASTIC DETECTION

Callascope

The Callascope, a speculum-free cervix imaging device, was developed at Duke University, featuring a Calla Lily-shaped silicone introducer and a slender camera with a hydrophobic window.[28-31] The introducer allows easy insertion into the vagina, equipped with a light source and a rotating asymmetric tip for optimal cervix viewing. The camera, set at a working distance of 25-30 mm, provides a 35mm field of view with 4x magnification.

Clinical testing in the United States and Ghana involved healthy females aged 18 or older.[28] Participants preferred the Callascope over a standard speculum, with over 60% finding it easy to insert and use for self-imaging. Image quality assessment revealed positive outcomes, with over 75% expressing a higher preference for the Callascope. Discomfort and pain were minimal, indicating its potential for efficient and user-friendly cervix examination.

High-resolution microendoscope (HRME)

The high-resolution microendoscope (HRME), developed at Rice University, Houston, TX, is a fluorescence optical imaging system for cervical cancer screening. It employs high-resolution fiber optic microscopes, allowing direct visualization of neoplastic indicators. The system utilizes a 455 nm LED light source to excite proflavin, a fluorescent DNA label, providing optical contrast. The HRME, inserted through a speculum, offers real-time morphology and epithelial architecture, with a field of view of 720 μm and a lateral resolution of 4 μm. Weighing 2.3 kg (reduced to 0.91 kg in a new iteration), the device is portable.[32-34]

Clinical testing in Botswana, Brazil, the United States (Texas), and El Salvador demonstrated its efficacy.[35-39] In Botswana, HRME achieved 86% specificity and 87% sensitivity for high-grade neoplastic lesions (CIN2+). A Brazilian study reported an average specificity and sensitivity of 48% and 92%, respectively, for identifying CIN2+ compared to histopathology. The HRME system has also been applied in oral and esophageal cancer diagnosis.[40-43]

Snapshot Mueller matrix polarimeter

The Snapshot Mueller Matrix Polarimeter, introduced in 2020, is a portable optical imager utilizing Mueller matrix polarimetric imaging.[44] It employs a ring illuminator to create four polarization states at 633 nm, using two Savart plates for a snapshot approach. The unique polarization information is analyzed by a 45-degree polarizer forming the polarization state analyzer (PSA) and detected on a CMOS camera. The polarimetric approach provides quantitative cervix information through Mueller matrix decomposition, capturing distinctions between healthy and unhealthy cervix responses to incident polarized light. With a 30 mm field of view, the device allows a complete cervix view in a single snapshot. Although non-invasive, a speculum is required for cervix visualization.

Clinical testing at the Public Health Research Institute of India (PHRII) in Mysore involved 22 patients, with six excluded due to image quality issues. The device accurately imaged healthy cervices, showcasing high depolarization values. An exception was noted in one patient diagnosed with a polyp, displaying lower depolarization values than expected.[45]

Enhanced visual assessment (EVA) system

The enhanced visual assessment (EVA) System by MobileODT in Tel Aviv, Israel, is a portable colposcope designed for enhanced VIA analysis. Utilizing a speculum, the system augments VIA results by providing necessary lighting, magnification, and facilitating image and information logging. Weighing 605 g, the portable system features a 3 W LED light source, lasting up to ten hours with battery power. Equipped with a cellphone, it offers optical and digital zoom capabilities of 4x and 16x, respectively. The onboard software allows real-time analysis and patient follow-up tracking, using an application to control the smartphone and a cloud-based portal for image storage and viewing.[46,47]

In clinical testing, the EVA system was employed for primary screening co-testing with cytology by the Fronteras Unidas Pro-Salud outreach program. A hospital-based study in Mumbai, India, showed agreement between EVA and cytology in 157 out of 471 cases, with most disagreements related to cervicitis misclassification. EVA demonstrated comparable performance to naked eye visualization in a screening camp, capturing challenging information such as age and socioeconomic status. However, image quality assessment revealed that 73% of images were of poor quality, prompting ongoing efforts to implement real-time image quality determination using machine learning methods.[48]

Gynocular

The Gynocular, a small monocular colposcope from Gynius Plus AB in Stockholm, Sweden, provides colposcope functionality in a pocket-sized, 480 g device. It utilizes a self-holding speculum for cervix access, offering optical magnification of 5x, 8x, and 12x with a field of view ranging from 20 to 40 mm. The light source features a 3 W/3.6 V warm white LED, with an optional 530 nm green filter. The onboard battery allows at least two hours of use, and the device is portable, and usable as a handheld or tripod-mounted tool. Coupling with a cellphone for image capture is also possible, with an approximate cost of $3000.[49-53]

In clinical testing across Uganda, India, Bangladesh, and Sweden, the gynocular was compared to a standard colposcope. In a study involving VIA-positive women in Uganda, visual scores for cervix state were in 70.1% agreement between both modalities.

Another study in Bangladesh reported a gynocular sensitivity of 83.3% and specificity of 23.6%, with positive and negative predictive values of 88.6% and 16.6%, respectively. No significant differences were found between the gynocular and colposcope in identifying CIN2+ lesions across all clinical trials.[54,55]

Table 1: Overview of the introduced portable devices for cervical imaging.

Device	Company	Magnification	Illumination	Speculum needed	Software present
Callascope	Duke University	4x	White ring LED	No	Yes
HRME	Rice University	10x	455 nm LED	No	Yes
Snapshot Mueller matrix polarimeter	FIU	None	633 nm LEDs	Yes	Yes
EVA	Mobile ODT	4x,16x	3 W LED	Yes	Yes
Gynocular	Gynius	5x,8x,12x	3 W LED	Yes	Yes

CONCLUSION

This overview outlines a range of colposcopes used in cervical imaging within low-resource settings (Table 1). Devices such as callascope, EVA, and gynocular offer cervix images for examination, while HRME and snapshot Mueller matrix polarimeter provide quantitative data through fluorescence and polarimetry. Except for callascope, speculum assistance is required for image capture. Priced between $2000–$8200 and weighing 480–2300 g, these devices support portability. Deployed clinically, they address challenges in low-resource settings, where cultural, social, and infrastructural limitations impede cervical cancer testing. These portable, low-cost devices, supplemented with machine learning, enhance image quality, interpretation, and testing outcomes, bridging healthcare gaps in both developing and developed regions with remote populations. User-friendly devices like the callascope contribute to accessibility, mitigating current limitations in interpretation errors, result timelines, and workforce scarcity.

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