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Use of Smartphones as Adjuvant Tools for Cervical Cancer Screening in Low-Resource Settings

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Objectives: Our aim was to evaluate the feasibility and performance of smartphone digital images for the detection of cervical intraepithelial neoplasia of grade 2 or worse (CIN2+) as an adjunct to a conventional visual inspection approach with acetic acid (VIA) and Lugol's iodine (VILI), in comparison with detection by histopathologic examination.

Methods: Three hundred women were primarily screened for human papillomavirus (HPV) using self-collected vaginal specimens. Human papillomavirus–positive women were then invited for VIA and VILI, which were interpreted as (i) nonpathological, (ii) pathological or, (iii) inconclusive. Cervical smearing, endocervical brushing, and cervical biopsies were performed. Digital images of the cervix were taken with a smartphone and evaluated offsite by experienced health care providers. Sensitivity and specificity for CIN2+ were compared between on-site and off-site observers, using histopathological diagnosis as the criterion standard.

Results: Eighty-eight HPV-positive women were screened for cervical cancer. Overall, 7 cases of CIN2+ (8.0%) were diagnosed using biopsy specimens. The on-site physician obtained a sensitivity of 28.6% (95% confidence interval [95% CI], 3.7–71) and a specificity of 87.2% (95% CI, 77.7– 93.7). The off-site physicians obtained a sensitivity ranging between 42.9% (95% CI, 9.9–81.6; p = 1) and 85.7% (95% CI, 42.1–99.6; p = .13) and a specificity between 48.1% (95% CI, 36.5– 59.7; p < .001) and 79.2% (95% CI, 68.5–87.6; p = .10). Comparison between observers did not reach significance. Observers assessed 95.6% of all images as very good or acceptable for interpretation purpose.

Conclusion: Smartphone images may be a useful adjunct to conventional VIA and VILI for the detection of CIN2+ and improve cervical cancer screening in low-resource settings.

Key Words: human papillomavirus, cervical cancer screening, smartphone photography, digital

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According to the latest statistics of the International Agency for Research on Cancer (IARC),[1] cervical cancer is the most commonly diagnosed cancer among Malagasy women and the deadliest one, accounting for 29.2% of total cancer-related deaths. These numbers are shared by all developing countries, which, combined together, account for more than 85% of death caused by cervical cancer in the world.[2] This high mortality rate can be explained by the lack of efficient cervical cancer screening programs in these countries.[3] As a result, cervical cancer is usually identified in advanced stages, at which point no effective treatment is available. Early detection and treatment of cervical lesions would reduce the number of deaths by at least half associated with this cancer.[4]

Visual inspection approach with acetic acid (VIA) and Lugol's iodine (VILI) are recommended by the Alliance for Cervical Cancer Prevention for cervical cancer screening in low-income countries.[5] Nonetheless, a VIA-based screening approach is associated with a large variability in cervical intraepithelial neoplasia of grade 2 or worse (CIN2+) detection rate, which may be a major drawback in the implementation of this approach in Madagascar.[6,7] Human papillomavirus (HPV) screening increases the sensitivity of a VIA and VILI screening method by selecting a high-risk population.[8] In addition, the prevalence of CIN2+ in an unscreened population is low and estimated at 2.3%.[6] This means that the physicians should be able to recognize among a large spectrum of benign and precancerous cervical lesions those corresponding to CIN2+. Therefore, further training and quality control can potentially lead to a reduction of the interobserver variability and improve the detection of CIN2 +.

Progress in imaging devices as well as in transfer and quality of images has allowed the use of cervical imaging for cervical cancer screening in low-resource settings.[9] Moreover, digital cervical imaging has acceptable performance, supporting its use as an adjunct to VIA-based screening[10–12] and improving the decision-making process and quality assurance of VIA.[9,13] More recently, smartphones have become a major communication tool, having multiple computer applications such as mailing and Internet accessibility combined with high-definition cameras.[14] Owing to its accessibility, technical capabilities, and user-friendliness, this technology has great promises for quality assurance and telemedicine. Smartphone applications have already been developed in anesthesiology, dermatology, neurosurgery, plastic surgery, orthopedic surgery, urology, and infectious diseases to improve quality assurance and reduction of observer variability.[15]

The aim of our study was to evaluate, in the context of cervical cancer screening with VIA/VILI, the feasibility and performance of smartphone images for CIN2+ identification, compared to standard on-site examination.

MATERIALS AND METHODS

Setting and Study Population

The study took place between July 2013 and November 2013, in the Saint-Damien Health-Care Centre, in Ambanja, Madagascar. Three hundred women had been recruited during

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Conflicts of interest: None.

This study has been approved by the Ethics Committee of Ambanja, Madagascar.

the cervical cancer screening campaign organized in July 2013. During this first study phase, the women carried out a self-vaginal sampling on their own with a sterile, flocked swab after reading a flyer with written instructions. The samples were then forwarded to Switzerland (Unilabs, Lausanne, Switzerland) where an Anyplex II HPV28 Detection test was performed as recommended by the manufacturer (Seegene, Seoul, South Korea). This test simultaneously detects 19 high-risk HPVs (including types 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73 and 82) and 9 low-risk HPVs. The 19 high-risk HPVs detected in the test include HPV types from group 1 of IARC (carcinogenic to humans), group 2A of IARC (probably carcinogenic to humans), and group 2B of IARC (possibly carcinogenic to humans). Participants in this study were HPV-positive women having at least one high-risk HPV and aged between 30 and 65 years. The choice of including women infected with HPV types of group 2A and 2B was made to avoid missing precancerous lesions in a population with little access to health care and no regular screening programs, therefore preventing potential cancer development.

Among the 300 women who participated, 122 were HPV positive and were invited to the Saint-Damien Health-Care Centre for further investigation. Upon arrival at the consultation site, they were invited to participate in the present study after having signed an informed consent. The study was approved by the Ethics Committee of Ambanja, Madagascar.

Study Design

This was a diagnostic accuracy cross-sectional study, including assessment of interobserver reliability. During the consultation, a physician examined the native cervix followed by VIA and VILI. At the end of the examination, a cervical smear and an endocervical sample were collected for each woman, followed by a biopsy of the cervix at 6 o'clock when no lesion was visible, or of the pathological area when present. In some cases, when there was a suspicion of several distinct precancerous lesions, a biopsy sample was collected at each site. The samples were all sent to the laboratory Cytopath-Unilabs, Geneva. When needed and possible, treatment was provided to the women, following a "see and treat" approach. A minimum of 3 pictures were taken for all participants with a smartphone (Samsung Galaxy S4, Samsung Electronics, 2013, Seoul, South Korea) during the examination: one of the native cervix, one after application of acetic acid (1 minute after application) and one after application of Lugol's iodine.

Cervical Liquid-based Cytology

Cervical specimens were collected using a broomlike device and fixed in BD SurePath liquid medium. The results were interpreted according to the Bethesda classification.

Endocervical Sample and Cervical Biopsies

Endocervical samples were collected using an endocervical brush, and cervical biopsy forceps were used for biopsy collection. Both were fixed in liquid formalin. The diagnoses were given by histopathologic examination and classified as negative; CIN1, CIN2, or CIN3; or invasive carcinoma. When discrepancies occurred between cytologic and histopathologic results, the histopathologic results were used as the standard for the statistical analysis.

Photography Technique

Photos were taken at a distance of 15 cm, with 2× optical zoom and in flash mode. The smartphone used for the study was chosen for its high-quality camera (13-megapixel with autofocus and flash), allowing highly precise and detailed visualization of the cervix after zooming in on the photo. Privacy and security of images were protected by transmitting them to a secure server and assuring that they would not be unknowingly duplicated or shared. The smartphone was used solely for the purpose of this study and the follow-up study.

On-site and Off-site Diagnosis

An experienced gynecologist in VIA and colposcopy was asked to visualize the cervix with a colposcope and classify the VIA and VILI as nonpathological, pathological, or inconclusive. The gynecologist in Madagascar did not use the smartphone photos on site to establish their diagnoses. Later, in Geneva, 3 other physicians analyzed the smartphone photos of every participant's cervix on computer screens (22 inches measured diagonally, with a resolution of 1680 × 1050 pixels) and had to determine whether the VIA and VILI were nonpathological, pathological, or inconclusive. Three months after the study in Ambanja, the images were also reanalyzed on a tablet computer screen (7.9 inches measured diagonally, with a resolution of 2048 × 1536 pixels) by the gynecologist who graded the cervical lesions on site. This allowed comparison between the on-site evaluation based on colposcopy and the off-site image-based interpretation. All physicians were blind to the histopathologic and cytologic diagnoses as well as to the on-site gynecologist's appreciation while giving their interpretations. Women who were diagnosed with CIN2+ by histopathologic examination but not treated on site will receive treatment in the follow-up study.

Statistical Analysis

Based on information obtained during the Self-HPV study, means and percentages of epidemiological characteristics for the 88 participants remaining in our study were calculated (Broquet et al., unpublished data, 2015). For every specialist who had graded the photos, sensitivity and specificity were calculated for VIA and VILI. The same was done for the on-site physician's evaluations. The McNemar test was used to determine equality of sensitivity and specificity between the on- site observer and each off-site observer. Quantitative variables are expressed as means and standard deviations, and qualitative variables are expressed as percentages, unless otherwise stated. Data were analyzed with a statistical analysis software package (StataCorp 2009. Stata Statistical Software: Release 11.College Station, TX, USA).

RESULTS

Participants' Photos

Among the 122 women meeting the inclusion criteria who were asked to participate in the study, 88 (72.1%) of them showed up at the consultation site, in Saint-Damien Health-Care Centre, Ambanja. A total of 576 photos were taken on site. Only 2 sets of photos for 2 participants were excluded from the study: one was excluded because no photo after VIA had been taken, the other one because of a large cervical fibroma covering the totality of the cervix, which could therefore not be visualized. Therefore, 86 sets of photos (570 single photos) of the 88 originally obtained photos remained in the study. Before being analyzed by the specialists, photos were sorted by a gynecologist, so that there would be a total of 3 photos per woman (258 photos analyzed altogether).

Participants' Epidemiological Characteristics

Epidemiological characteristics of the participants are shown in Table 1.

TABLE 1. Characteristics of Study Participants (n = 88)

Variable	n (%)
Age, mean ± SD, y	43.0 ± 9.1
Age groups, y	
29–39	32 (36.4%)
40–49	31 (35.2%)
50–59	21 (23.9%)
≥ 60	4 (4.5%)
Marital status	
Single	40 (45.5%)
Married/with a partner	44 (50%)
Separated/Divorced	1 (1.1%)
Widowed	3 (3.4%)
Habitation	
Urban area	49 (55.7%)
Rural area	39 (44.3%)
Religion	
Catholic	40 (45.4%)
Protestant	16 (18.2%)
Muslim	16 (18.2%)
Others	16 (18.2%)
Education	
Unschooled	3 (3.4%)
Primary education	37 (42.1%)
Secondary education	45 (51.1%)
Tertiary education	3 (3.4%)
Age of first sexual intercourse, mean ± SD, y	16.9 ± 2.4
Number of sexual partners, median (IQR)	4 ± 3
Number of pregnancies, mean ± SD	3.9 ± 3.1
Contraception	
Pill	5 (5.7%)
Injectable	8 (9.1%)
Condom	1 (1.1%)
Coitus interruptus	74 (84.1%)

IQR indicates interquartile range; y, years; SD, standard deviation.

On-site Activity and Laboratory Results

On site, 12 patients were evaluated as pathologic after VIA and received treatment when possible. Cervical cancer was diagnosed in 1 woman but could not be treated owing to the advanced invasion and the lack of adequate material on site. Sample analysis results positive for precancerous lesions are shown in Table 2. Of 86 patients, 9 of them had pathologic results: CIN1, 2; CIN2, 3; CIN3, 2; and invasive carcinomas, 2, were found. P16ink4a immunohistochemistry demonstrated a strong nuclear and cytoplasmic staining for all CIN2 lesions. Histopathologic result was negative for precancerous lesions for the 77 remaining patients. Result of the cytologic analysis was positive for 6 women: atypical squamous cells—cannot exclude high-grade squamous intraepithelial lesion, 1; low-grade squamous intraepithelial lesion, 1; high-grade squamous intraepithelial lesion, 2; and invasive carcinomas, 2, were reported. Additionally, two of the samples analyzed with cytology showed atypical squamous cells of undetermined significance. Three of the 9 lesions identified by histopathologic examination (1 CIN1 and 2 CIN2) were missed by cytological analysis. The remaining 75 patients were tested negative by cytologic analysis. Table 3 summarizes all the results of sample analysis by histopathology and cytology. Of 7 CIN2+, only 2 have been detected by the on-site health care provider (1 CIN3 and 1 invasive carcinoma). Thus, 5 CIN2+ were missed and 9 healthy women were unnecessarily treated on site. Women with pathologic lesions (CIN2+) not treated on site will receive treatment in the follow-up study.

Diagnostic Accuracy

Statistical results after VIA and VILI combined are shown in Figure 1. With photo analysis, sensitivity ranged from 42.9% (95% confidence interval [CI], 9.9–81.6; $p = 1$) to 85.7% (95% CI, 42.1–99.6; $p = .13$) and specificity ranged from 48.1% (95% CI, 36.5–59.7; $p < .001$) to 79.2% (95% CI, 68.5–87.6); $p = .10$). Moreover, the gynecologist who performed analysis on site had a sensitivity of 71.4% (95% CI, 29.0–96.3) on photo versus 28.6% (95% CI, 3.7–71.0) on site ($p = .25$), and a specificity of 70.7% (95% CI, 59.0–80.6) on photo versus 87.2% (95% CI, 77.7–93.7) on site ($p = .005$). Overall, specificity was higher on site than on photo. However, sensitivity was much better on photo than on site.

TABLE 2. Positive Cytology and/or Histopathology Found in 9 Patients

				VIA/VILI evaluation off site			
Patient no.	Cytology	Histopathology	VIA/VILI evaluation on site	No. 1[b]	No. 2[b]	No. 3[b]	No. 4[b]
1	CA INV[a]	CA INV[a]	Pathological	Pathological	Yes	Pathological	Pathological
2	CA INV[a]	CA INV[a]	Nonpathological	Pathological	Pathological	Pathological	Pathological
3	HSIL[a]	CIN3[a]	Pathological	Pathological	Pathological	Pathological	Pathological
4	HSIL[a]	CIN3[a]	Nonpathological	Pathological	Nonpathological	Pathological	Pathological
5	ASC-H[a]	CIN2[a]	Nonpathological	Pathological	Nonpathological	Nonpathological	Pathological
6	NEG[a]	CIN2[a]	Nonpathological	Pathological	Nonpathological	Pathological	Nonpathological
7	NEG[a]	CIN2[a]	Nonpathological	Nonpathological	Nonpathological	Pathological	Nonpathological
8	LSIL[a]	CIN1[a]	Nonpathological	Nonpathological	Nonpathological	Nonpathological	Nonpathological
9	NEG[a]	CIN1[a]	Pathological	Pathological	Nonpathological	Pathological	Pathological

Concurrent VIA/VILI evaluation on site and delayed VIA/VILI evaluation on smartphone photo, off site.

[a] HSIL indicates high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; CA INV, invasive carcinoma; ASC-H, atypical squamous cells—cannot exclude high-grade squamous intraepithelial lesion; NEG, negative.

[b] No. 1 is photo-based evaluation by specialist No. 1; No. 2, photo-based evaluation by specialist No. 2; No. 3, photo-based evaluation by specialist No. 3; No. 4, photo-based evaluation by specialist No. 4, same as on-site specialist 3 months after original assessment in Ambanja.

TABLE 3. Histopathologic and Cytologic Results for Collected Cervical Samples (n = 86)

		Histopathologic results				
		CA INV	CIN3	CIN2	CIN1	NEG
Cytologic results	CA INV	**2**	0	0	0	0
	HSIL	0	**2**	0	0	0
	ASC-H[a]	0	0	**1**	0	0
	LSIL	0	0	0	**1**	0
	ASC-US[a]	0	0	0	0	**2**
	NEG	0	0	**2**	**1**	**75**

Boldface represents patients who tested positive with histopathology or cytology.

[a]ASC-US indicates atypical squamous cells of undetermined significance.

Diagnostic Inter-Rater Reliability

Variation in reliability among off-site observers was substantial, leading to a poor Cohen kappa coefficient (0.29; 95% CI, 0.20–0.38).

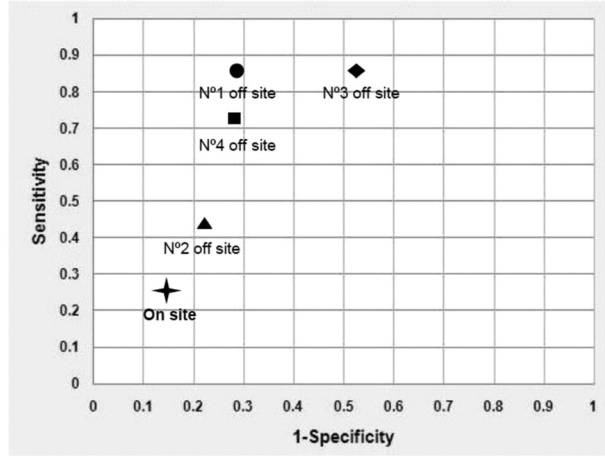
Photo Quality Evaluation

The 4 specialists evaluated the quality of the selected smartphone photos. The quality was graded as bad, acceptable, or excellent for each photo individually, resulting in a total of 258 photos per analyst and thus 1,032 evaluations overall. Only a minor percentage of photos were graded as bad (4.9% native photos, 4.7% photos after acetic acid, and 3.8% photos after Lugol), whereas most photos were graded as acceptable or excellent (85.1% native photos, 95.3% photos after acetic acid, and 96.2% photos after Lugol). Overall, 4.5% of the photos were evaluated as bad, 42.6% as acceptable, and 52.9% as excellent.

Figures 2, 3, and 4 show examples of smartphone photos respectively of a noncancerous cervix, a cervix with CIN3, and a cervix with an invasive carcinoma, taken natively (A), after application of acetic acid (B) and Lugol's iodine (C).

DISCUSSION

Primary HPV screening is a promising method for low-resource settings, as it is very sensitive and allows longer screening intervals for HPV-negative women. In the future, we can expect the development of user-friendly and less expensive HPV tests, permitting large use in low-resource settings. However, in a population having a high prevalence, which is the case in Madagascar, management of HPV-positive women becomes a critical step, as most of them do not have CIN2+. To avoid or reduce overtreatment, a triage step for HPV-positive women is necessary.[16] Visual inspection approach with acetic acid is probably the most cost-effective approach adapted for low- resource settings such as Madagascar, which is why our strategy was to perform a visual assessment of all HPV-positive women to identify possible CIN2+ and the type of treatment required. These steps followed one of the World Health Organization guidelines options for screening and treatment of precancerous lesions in the context of cervical cancer prevention,[17] which recommends that women be primarily screened with an HPV test before getting triaged with VIA and treated. To have quality control and continuous education, digital imaging has progressively become an adjunct to the visual inspection method.[9,11,12] Smartphone digital imaging is a low-cost method, providing magnified and easily interpretable images. However, its use in this context remained to be established.[18] To our knowledge, our study is the first to assess the feasibility and accuracy of smartphone images



Observer	N°*	Sensitivity % (95% CI)	P-value	N°*	Specificity % (95% CI)	P-value
On site*	2/7	28.6 (3.7 to 71.0)		68/78	87.2 (77.7 to 93.7)	
N°1 off site*	6/7	85.7 (42.1 to 99.6)	0.13	56/79	70.9 (59.6 to 80.6)	0.006
N°2 off site*	3/7	42.9 (9.9 to 81.6)	1	61/77	79.2 (68.5 to 87.6)	0.1
N°3 off site*	6/7	85.7 (42.1 to 99.6)	0.13	37/77	48.1 (36.5 to 59.7)	< 0.0001
N°4 off site*	5/7	71.4 (29.0 to 96.3)	0.25	53/75	70.7 (59.0 to 80.6)	0.005

* On site, results of evaluation by specialist on site; N°1 off site, results of photo-based evaluation by specialist N°1; N°2 off site, results of photo-based evaluation by specialist N°2; N°3 off site, results of photo-based evaluation by specialist N°3; N°4 off site, results of photo-based evaluation by specialist N°4, same as on-site specialist 3 months after original assessment in Ambanja.

** Sensitivity (N), number of correctly identified cervical lesions CIN2+; Specificity (N), number of correctly identified non-pathological cervices.

FIGURE 1. Specificity and sensitivity calculated after VIA and VILI combined.

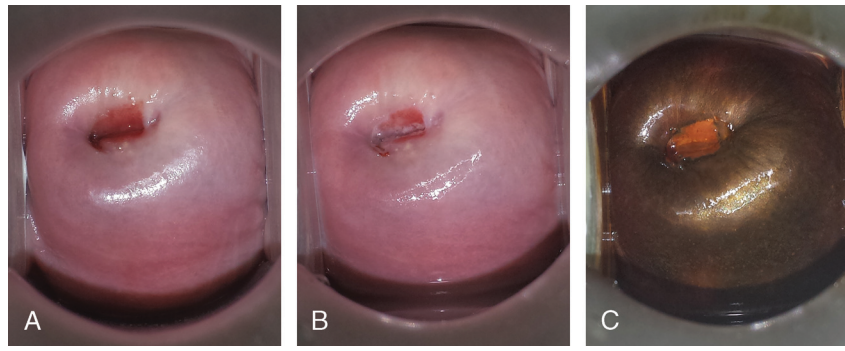


FIGURE 2. Smartphone photos of noncancerous cervix with metaplasia. A, Native. B, After application of acetic acid. C, After application of Lugol's iodine.

in detecting CIN2+ using a VIA-based cervical cancer screening approach.

Although comparison of sensitivities between different observers did not reach significance, our exploratory study results reveal that the use of smartphone images may improve the detection rate of CIN2+ compared to direct on-site appreciation. Indeed, 2 off-site physicians accurately identified 6 of 7 lesions (sensitivity of 85.7%) compared to 2 (sensitivity of 28.6%) by the on-site physician (p = .13). Analysis of the smartphone images 3 months later by the same physician, blinded to their initial interpretations, improved their sensitivity with a correct finding of 5 lesions (71.4% on the smartphone versus 28.6% on site; p = .25) and decreased their specificity from 87.2% to 70.7% (p = .005). Owing to the small sample size, these results could be obtained by chance, although they are clearly suggestive.

A potential explanation for improved detection through smartphone images may stem from the fact that the high-pixel smartphone images can be manipulated to zoom in on suspicious regions or transformation zones, as well as from the possibility to simultaneously compare native, post-VIA, or post-VILI images. In clinical practice, once VILI has been done, VIA or the native cervix cannot be interpreted again. Digital imaging offers the opportunity to come back to VIA or native images, which may contribute to improve interpretation accuracy. The overall quality of the smartphone digital images, particularly the light exposition, color fidelity, and resolution, was reported to be very good. In fact, only 4.5% of images were considered of poor quality by observers and inadequate for interpretation.

Overall specificity with on-site evaluation (87.2%) compared to smartphone images' specificity (highest, 79.2%), suggests

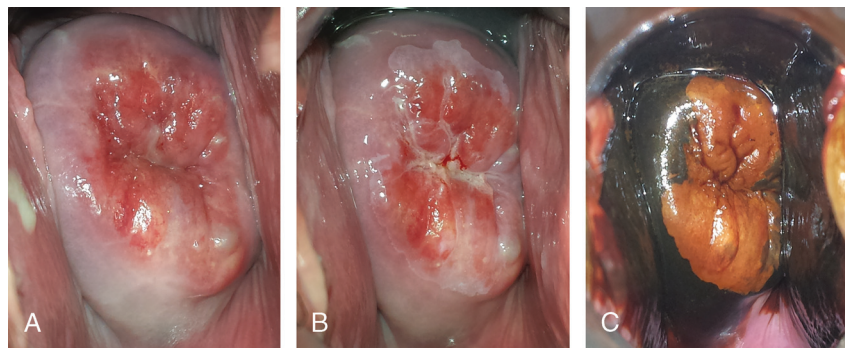


FIGURE 3. Smartphone photos of cervix with CIN3 lesion. A, Native. B, After application of acetic acid. C, After application of Lugol's iodine.

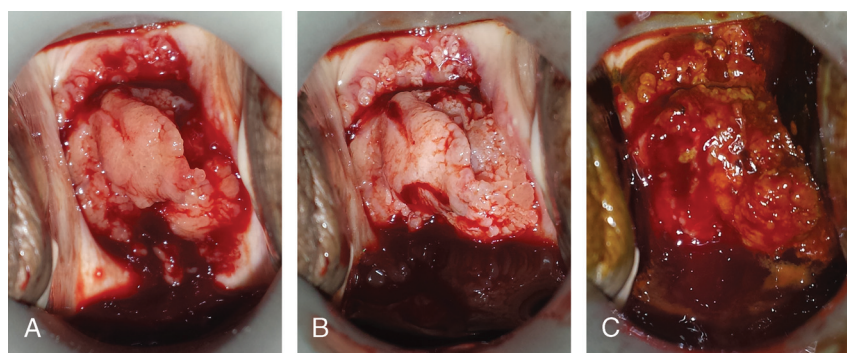


FIGURE 4. Smartphone photos of cervix with invasive carcinoma. A, Native. B, After application of acetic acid. C, After application of Lugol's iodine.

fewer healthy women being treated unnecessarily ($p = .10$). Our results substantiate a previous study using digital images obtained by an older mobile phone for cervical cancer screening subsequent to VIA staining.[19] The aim of the latter study was to compare the on-site evaluation made by a trained midwife with the one she would give 3 months later by analyzing digital images. The study was able to show a good concordance proving the usefulness of mobile phones for cervical cancer screening in remote areas. However, biopsies were not systematically performed, so no definitive diagnosis was established to corroborate the findings and images were of much lower quality. With our research, we supplemented the study by determining the accuracy of the images' performance by comparing them to the histopathologic criterion standard. The current trend is to produce high-quality images and develop applications that might help to improve screening strategies in developing countries, where access to specialists is restricted. This requires assuring privacy and security of the obtained images, on the original photographic device, during transmission and storage.

The limitations of our study include the small sample size, which will increase with further projects. Moreover, an important number of women (27.9%) were lost to follow-up. However, it is unlikely that our results have been considerably skewed by the latter. Indeed, the characteristics of women who did not show up for the second visit were similar to those who participated with regard to sociodemographic variables and HPV genotypes (data not shown).

The strengths of our study are that consecutive cases have been included and no exclusion has been made because of insufficient image quality. Furthermore, all HPV-positive women had a biopsy and endocervical brushing to determine CIN2+ cases.

CONCLUSIONS

In summary, our study supports the feasibility and reliability of smartphone images in the context of an enhanced visual approach in cervical cancer screening. Smartphones may be used as an adjunct to VIA/VILI and for quality control in remote areas such as Madagascar, improving cervical cancer screening.

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