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Accuracy of Direct Visual Inspection Acetic Acid (VIA) and Smartphone-VIA (S-VIA) with Pap Smear in Cervical Cancer Screening in Low-Resource Setting: Cohort Retrospective Study

Düşük Kaynaklı Ortamlarda Serviks Kanseri Taramasında Asetik Asit ile Doğrudan Görsel İnceleme (VIA) ve Akıllı Telefon Destekli VIA (S-VIA) ile Pap Smear'in Karşılaştırmalı Doğruluğu: Kohort Retrospektif Çalışması

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ABSTRACT Objective: Cervical cancer is the 2nd most common cancer in Indonesia. Screening techniques can detect precancerous lesions, but direct visual inspection with acetic acid (VIA) can be subjective. Smartphones may assist healthcare providers in improving interpretation. This study aim to compare the accuracy of direct VIA, smartphone VIA (S-VIA) with 8-MP and 12-MP cameras, Pap smear, and biopsy in cervical cancer screening. **Material and Methods:** This cross-sectional diagnostic study follows the standards for the reporting of diagnostic accuracy studies (STARD 2015) guidelines. Each participant underwent screening and those with abnormal results proceeded to biopsy. The study included women aged 20-60 years who participated in the early detection cervical cancer program by the Yogyakarta Health Government from April to October 2017. **Result:** The study included 174 participants. Both direct VIA and S-VIA demonstrated low sensitivity but high specificity compared to the Pap smear. Direct VIA showed the highest accuracy relative to the Pap smear and the highest sensitivity to biopsy (100%), while the Pap smear had the highest specificity to biopsy (86.36%). The positive predictive values were low, whereas the negative predictive values were high. Direct VIA exhibited the highest positive likelihood ratio and the lowest negative likelihood ratio. The highest accuracy relative to biopsy was observed with the Pap smear, followed by direct VIA, S-VIA 12-MP, and S-VIA 8-MP. **Conclusion:** The highest accuracy was obtained from the Pap smear. VIA showed superior sensitivity and comparable specificity to the Pap smear. S-VIA with smartphone cameras offers a convenient alternative. Biopsy confirmation remains essential for accurate diagnosis and proper management.

Keywords: Cervical cancer; Pap smear; direct VIA; low-resource setting; smartphone-based VIA

ÖZET Amaç: Serviks kanseri, Endonezya'da en sık görülen ikinci kanserdir. Tarama yöntemleri prekanseröz lezyonları tespit edebilse de, asetik asit ile doğrudan görsel inceleme (VIA) öznel olabilmektedir. Akıllı telefonlar, sağlık çalışanlarının yorumlama becerilerini geliştirmelerine yardımcı olabilir. Bu çalışmanın amacı, serviks kanseri taramasında doğrudan VIA, 8 MP ve 12 MP kameralarla akıllı telefon VIA (S-VIA), Pap smear ve biyopsinin doğruluğunu karşılaştırmaktır. **Gereç ve Yöntemler:** Bu kesitsel tanısal çalışma, STARD 2015 kılavuzlarına uygun olarak yürütülmüştür. Her katılımcıya tarama yapılmış ve anormal sonuç saptananlara biyopsi uygulanmıştır. Çalışmaya, Nisan–Ekim 2017 tarihleri arasında Yogyakarta Sağlık Müdürlüğü tarafından yürütülen serviks kanseri erken tanı programına katılan, 20–60 yaş arası kadınlar dâhil edilmiştir. **Bulgular:** Çalışmaya 174 katılımcı dâhil edilmiştir. Hem doğrudan VIA hem de S-VIA, Pap smear ile karşılaştırıldığında düşük duyarlılık ancak yüksek özgüllük göstermiştir. Doğrudan VIA, Pap smear'e kıyasla en yüksek doğruluğu ve biyopsiye karşı en yüksek duyarlılığı (%100) ortaya koyarken, Pap smear biyopsiye karşı en yüksek özgüllüğe (%86,36) sahip olmuştur. Pozitif prediktif değerler (PPV) düşük, negatif prediktif değerler (NPV) ise yüksek bulunmuştur. Doğrudan VIA, en yüksek pozitif olasılık oranını (LR+) ve en düşük negatif olasılık oranını (LR-) sergilemiştir. Biyopsi ile karşılaştırıldığında en yüksek doğruluk Pap smear'de görülmüş, bunu sırasıyla doğrudan VIA, 12 MP S-VIA ve 8 MP S-VIA izlemiştir. **Sonuç:** En yüksek doğruluk Pap smear ile elde edilmiştir. VIA, Pap smear'e kıyasla üstün duyarlılık ve benzer özgüllük göstermiştir. Akıllı telefon kameraları ile yapılan S-VIA pratik bir alternatif sunmaktadır. Bununla birlikte, doğru tanı ve uygun yönetim için biyopsi doğrulaması temel önem taşımaktadır.

Anahtar Kelimeler: Serviks kanseri; Pap smear; doğrudan VIA; kaynak kısıtlı ortam; akıllı telefon destekli VIA

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Cervical cancer is the 4th most prevalent cancer among women globally. The primary cause of cervical cancer is human papillomavirus (HPV).[1] Approximately 90% of the 342,000 cervical cancer-related deaths occurred in low and middle-income countries.[2] Eighty percent of cases were reported in developing countries.[3] In Indonesia, cervical cancer was the 2nd most common cancer with 36,633 newly diagnosed cases in 2020. The incidence rate was 24.4 per 100,000 people. The mortality rate was 14.4 per 100,000 people.[4] The majority of cases of cervical cancer are preventable.[1] The best strategies for reducing the cost of healthcare and mortality from cervical cancer are primary prevention and screening.[1] The HPV vaccine has been available to prevent cervical cancer since 2006. Cervical cancer is preventable, and by focusing on education, screening, and prevention.[1]

The progression of cervical cancer is gradual, with a prolonged preinvasive period. Appropriate screening, early detection, and treatment can often lead to a cure if the disease is identified in its early stages, ultimately reducing healthcare costs.[5] Cervical screening techniques can detect precancerous lesions in the cervix of asymptomatic women who appear healthy. These techniques include liquid-based cytology, HPV testing, visual inspection with acetic acid (VIA), and traditional cytology (Pap smear).[6] The World Health Organization's (WHO) goals require investments in cost-effective interventions for low- and middle-income countries, where health systems often face budgetary constraints. Therefore, it is essential to optimize resource allocation in these regions and integrate available evidence.[7]

For early cervical lesions, VIA is a simple and low-cost screening technique with acceptable sensitivity and specificity. It can be used in combination with simple treatment protocols.[8] Healthcare professionals can be trained to perform the test, and the results are available immediately. In many low-resource settings where maintaining high-quality cytology programs is challenging, VIA is a practical option.[8] However, the direct VIA assessment remains a highly subjective test with low performance and minimal quality control.[9] Smartphones can assist healthcare providers in identifying the distribution, morphology, and type of the transformation zone, as well as the aceto-whitening properties.[10] This study aims to compare the accuracy of direct VIA, VIA with an 8-MP smartphone, and VIA with a 12-MP smartphone against the Pap smear and biopsy in cervical cancer screening.

MATERIAL AND METHODS

STUDY DESIGN

This observational analytic study used a cross-sectional diagnostic design and was conducted at Dr. Sardjito Hospital from 1st April to 31st October 2017. Informed consent was obtained from all participants. The study adhered to the principles of the Helsinki Declaration and received ethical approval from the Ethics Committee of the Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada/Dr. Sardjito General Hospital, Yogyakarta, Indonesia (date: September 20, 2017; no: KE/FK/025/EC/2017).

STUDY POPULATION

The study included women aged 20-60 years who participated in the early cervical cancer detection program by the Yogyakarta Health Government. Inclusion criteria were women aged 20-60 years, married, and able to provide informed consent. Exclusion criteria included pregnancy, a diagnosis of cervical cancer, a history of hysterectomy, or an unclear cervical appearance. Each participant underwent direct VIA, smartphone (S-VIA), and a Pap smear test. Participants with abnormal results underwent a biopsy examination for definitive diagnosis.

Abnormal VIA and S-VIA results were defined as the presence of well-defined acetowhite lesions in the transformation zone, leukoplakia, or an abnormal growth suggestive of malignancy. Abnormal Pap smear results included atypical squamous cells of undetermined significance, low-grade squamous intraepithelial lesions, high-grade squamous intraepithelial lesions, atypical glandular cells, or findings suggestive of carcinoma.

It was determined based on a diagnostic test formula with a 95% confidence interval, assuming an expected sensitivity of 85% for S-VIA. The required

sample size for the inter-rater agreement study on VIA test interpretation for cervical cancer screening using digital images was derived from prior literature, which reported a kappa value ranging from 0.28 to 0.43.[11,12] Therefore, at least 83 to 96 subjects were needed. This cross-sectional study utilized a consecutive sampling technique and analyzed clinical data from 174 patients.

STUDY OUTCOME

Demographic data were collected through interviews and questionnaires before the test. Participants provided informed consent prior to undergoing the Pap smear, VIA, and S-VIA tests. All images collected were used exclusively for research, with confidentiality strictly maintained.

After applying acetic acid to the cervix, a healthcare provider performed the initial assessment, followed by an on-site gynecologist, and the findings were recorded on the research form. Cervical images were captured by the on-site team using smartphone cameras (8-MP and 12-MP). These images were labeled with subject ID numbers and later reviewed by an off-site gynecologist. Each S-VIA test (8-MP and 12-MP) was interpreted by 3 gynecologists, with the final diagnosis determined when at least 2 agreed.

Pap smear samples were fixed in an alcohol solution and sent to the pathology laboratory at the Faculty of Medicine, Nursing, and Public Health, Gadjah Mada University, for expert evaluation. Participants with abnormal screening results were contacted for further examination, including a biopsy.

DATA ANALYSIS

Statistical analyses were performed using SPSS version 25 (IBM, New York, USA). Univariate analysis included calculations of the mean, standard deviation, percentage, and frequency. Categorical variables were presented as proportions. Normally distributed data were described as means with standard deviations, whereas non-normally distributed data were summarized as medians with interquartile ranges. In the univariate analysis, variables were categorized as either continuous or categorical data. Diagnostic tests were conducted to compare biopsy and Pap smear results with direct VIA and S-VIA, assessing sensitivity, specificity, positive predictive value (PPV), negative predictive values (NPV), positive likelihood ratio (LR+), negative likelihood ratio (LR-), and accuracy.

RESULTS

A total of 174 participants were included in the study. Table 1 presents the participants' characteristics, including age, parity, age at menarche and age at 1st sexual intercourse. The mean age of the participants was 41.46±7.72 years, with a mean menarche age of 14.09±1.48 years. The mean age at 1st sexual intercourse was 23.04±4.50 years. Among the participants, 74 (42%) were nulliparous, while 100 (58%) were multiparous. The mean number of children was 2.22±0.82.

The overall accuracy of the methods comparing to Pap smear was comparable, with direct VIA achieving 91.38%, S-VIA 8-MP at 87.36%, and S-VIA 12-MP at 90.23%. The PPV was highest for direct VIA (23.08%), followed by S-VIA 12-MP (9.09%) and S-VIA 8-MP (6.25%), suggesting that direct VIA is more likely to correctly identify true positives among those with positive screening results. NPV were consistently high across all methods, highlighting their effectiveness in accurately identifying true negatives. Likelihood ratios further illustrated the diagnostic performance of these methods. Direct VIA had the highest LR+ of 6.23, indicating a moderate increase in the probability of a positive result in individuals with abnormal findings on Pap smear. In

TABLE 1: Characteristics of the study

Variables	n (%)	$\bar{X}$±SD	Median (minimum-maximum)
Age (years)	174 (100)		
20-30 years old	22 (13)		
31-40 years old	71 (40)	41.46±7.72	42 (23-58)
41-50 years old	50 (29)		
51-60 years old	31 (18)		
Age at menarche		14.09±1.48	14 (10-18)
Age at 1st sexual intercourse		23.04±4.50	23 (21-37)
Parity/number of children	174 (100)		
Nullipara	74 (42)	2.22±0.82	2 (1-5)
Multipara	100 (58)		

SD: Standard Deviation

comparison, S-VIA 8-MP and 12-MP had lower LR+ values (1.38 and 2.08, respectively), reflecting lesser diagnostic accuracy. Direct VIA also demonstrated the lowest LR- of 0.67, indicating a moderate reduction in the probability of a negative result in individuals with normal findings on Pap smear (Table 2).

The overall accuracy of the screening methods compared to biopsy was similar, with direct VIA achieving 81.25%, S-VIA 8-MP at 77.08%, S-VIA 12-MP at 79.17%, and Pap smear at 83.33%. Direct VIA had the highest sensitivity to biopsy (100%), demonstrating its strong ability to detect abnormalities confirmed by biopsy. In contrast, lower sensitivity values were observed for S-VIA 8-MP (75%), S-VIA 12-MP (50%), and Pap smear (50%).

The specificity of direct VIA, S-VIA, and Pap smear was comparable, ranging from 79.55% to 86.36%. Direct VIA also had the highest PPV compared to S-VIA (8-MP and 12-MP) and Pap smear, suggesting that it may be more reliable in identifying patients who require further diagnostic evaluation and intervention. All screening methods exhibited high NPV, indicating their effectiveness in ruling out the need for further investigation or treatment in negative cases.

Direct VIA also had higher LR+ values compared to S-VIA and Pap smear, signifying a moderate increase in the likelihood of a positive biopsy result among individuals with abnormal screening findings. Additionally, direct VIA had an LR- of zero, suggesting a superior ability to rule out abnormal biopsy findings in individuals with negative screening results compared to S-VIA and Pap smear (Table 3).

TABLE 2: Diagnostics tests to Pap smear

		Pap smear								
		(+) (n=8)	(-) (n=166)	Sn	Sp	PPV	NPV	LR+	LR-	Accuracy
Direct VIA	(+)	3	10	37.50%	93.98%	23.08%	96.89%	6.23	0.67	91.38%
	(-)	5	156							
S-VIA 8-MP	(+)	1	15	12.50%	90.96%	6.25%	95.57%	1.38	0.96	87.36%
	(-)	7	151							
S-VIA 12-MP	(+)	1	10	12.50%	93.98%	9.09%	95.71%	2.08	0.93	90.23%
	(-)	7	156							

Sn: Sensitivity; Sp: Specificity; PPV: Positive predictive value; NPV: Negative predictive value; LR+: Positive likelihood ratio; LR-: Negative likelihood ratio; VIA: Visual inspection acetic acid; MP: Megapixel

TABLE 3: Diagnostics tests to biopsy

		Biopsy								
		(+) (n=4)	(-) (n=44)	Sn	Sp	PPV	NPV	LR+	LR-	Accuracy
Direct VIA	(+)	4	9	100.00%	79.55%	30.77%	100.00%	4.89	0.00	81.25%
	(-)	0	35							
S-VIA 8-MP	(+)	3	10	75.00%	77.27%	23.08%	97.14%	3.30	0.32	77.08%
	(-)	1	34							
S-VIA 12-MP	(+)	2	8	50.00%	81.82%	20.00%	94.74%	2.75	0.61	79.17%
	(-)	2	36							
Pap smear	(+)	2	6	50.00%	86.36%	25.00%	95.00%	3.67	0.58	83.33%
	(-)	2	38							

Sn: Sensitivity; Sp: Specificity; PPV: Positive predictive value; NPV: Negative predictive value; LR+: Positive likelihood ratio; LR-: Negative likelihood ratio; VIA: Visual inspection acetic acid; MP: Megapixel

DISCUSSION

Cervical cancer is a major global health concern, and effective screening methods are essential for early detection and prevention. In 2020, the WHO launched a global strategy to eliminate cervical cancer by 2030. This strategy includes the 90-70-90 targets: 90% of girls under 15 should receive the HPV vaccine, 70% of women aged 35 and 45 should undergo screening with a high-performance test, and 90% of women with precancerous lesions should receive treatment, while 90% of those diagnosed with invasive cancer should receive appropriate management.[13]

The Indonesian Ministry of Health developed a National Action Plan for Cervical Cancer Eradication (2023-2030). The primary focus of the NAP is cervical cancer screening, with a target coverage of 75% of all women aged 30-69 years using HPV DNA testing.[14] The national program for cervical cancer screening in Indonesia began in 2007, employing VIA testing. However, according to a study by Wahidin et al., the screening coverage in Indonesia has only reached 9.8%, which accounts for 3,664,625 of 37.4 million women aged 30-50 years, with significant variations between provinces. The 3 provinces with the highest coverage are West Nusa Tenggara (34.08%), South Sumatra (33.49%), and Bangka Belitung Islands (27.77%).[15]

Various modalities for cervical cancer screening include cytology examination, VIA, HPV DNA testing, and colposcopy. The Indonesian Gynecological Oncology Association (HOGI) issued cervical cancer screening and follow-up algorithms for abnormal findings in 2023. These algorithms are based on screening methods such as VIA-DoIVA/TeleDoIVA, Pap smear (cytology), and HPV DNA testing (High Risk or Partial Genotyping). The ideal target age for screening is 25-65 years or starting 3 years after the onset of sexual activity.[16]

Demographic data in this study align with previous literature. This study showed mean age of 41.46±7.72 years, with a mean menarche age of 14.09±1.48 years and a mean age of 1st sexual intercourse of 23.04±4.50 years. These findings align with Sharma et al., who reported that 34-41% of participants were aged 41-60 years. Menarche at 13 to 14 years old occurred in 59.3% of cases [odds ratio (OR)=4.295, 95% confidence internal (CI): 2.067-8.924, p<0.001], while 72.5% had early sexual debut (OR=8.534, 95% CI: 4.810-15.142, p<0.001).[17] Early sexual activity, especially before 18, increases the risk of HPV infection due to the immature cervix, making it more susceptible to cervical dysplasia and other abnormalities.[18] Among the participants, 74 (42%) were nulliparous, while 100 (58%) were multiparous, with a mean number of children of 2.22±0.82. These findings align with Sharma et al., who reported multiparity in 44-47.3% of participants.[17] Tekalegn et al. found that high parity increased cervical cancer risk 2.65 times (OR=2.65, 95% CI: 2.08-3.38). This may be due to hormonal changes during pregnancy, particularly in the third trimester, which affect the transformation zone and increase squamous metaplasia.[19]

The results of direct VIA compared to digitalized-based approaches have been variable across different studies. Tonui et al. in Kenya reported the sensitivity, specificity, PPV, and NPV of direct VIA at 28.1%, 97.8%, 79.8% and 80.4%, respectively. For VIA with digital cervicography were higher at 69.3%, 87.9%, 77.6% and 80.3%.[20] Similarly, Ricard-Gauthier et al. demonstrated that smartphone-based imaging could complement conventional visual inspection with acetic acid (VIA) or Lugol's iodine (VILI) for detecting cervical intraepithelial neoplasia in precancerous lesions, particularly high-grade lesions (HSIL), classified as CIN2 or higher lesions, particularly in low-resource settings. Notably, 95.6% of the images were rated as acceptable or very good for interpretation.[21] Digital VIA demonstrated a sensitivity of 84% and specificity of 58% for detecting CIN2+, compared to cytology, which showed a sensitivity of 61% and the same specificity of 58%.[22] In Thailand, digital VIA's sensitivity, specificity, and PPV for detecting CIN2+ were 72.41%, 97%, and 84%, respectively, comparable to Pap smear performance.[23]

One possible reason for the improved detection using smartphone images is their high pixel resolution, allowing users to zoom in on suspicious areas or transformation zones. Additionally, smartphone imaging enables side-by-side comparison of native,

post-VIA, and post-VILI images, which is not feasible in standard clinical practice where the cervix cannot be reassessed once VILI has been performed. Digital imaging also allows revisiting native or VIA images, potentially enhancing interpretation accuracy.[21]

However, the differences in outcomes observed in this study may be attributed to challenges in using smartphone cameras for VIA testing. These challenges include inadequate phone specifications leading to poor-quality digital images, difficulties in photo transmission due to weak network signals, limitations in the phone's capability for remote image sharing, and reduced image quality resulting from alterations in format or size when shared via social media platforms.

Despite direct VIA demonstrating superior sensitivity to biopsy, it's crucial to consider the overall accuracy of each screening method in this study. Direct VIA had varying levels of accuracy across different metrics, including sensitivity, specificity, PPV, NPV, and likelihood ratios. S-VIA with 8-MP and 12-MP cameras and Pap smear also showed moderate to good accuracy, although with some limitations in sensitivity and specificity compared to direct VIA.

LIMITATIONS

The magnification and shooting length of the obtained images were not standardized between images. Therefore, we recommend training for image capture in future research to ensure optimal image quality, enabling better interpretation and more consistent results.

CONCLUSION

Direct VIA showed superior sensitivity and comparable specificity to the Pap smear, making it a valuable screening tool for cervical cancer detection, particularly in resource-limited settings where access to cytology-based methods may be restricted. While S-VIA with smartphone cameras offers a convenient alternative, its lower sensitivity indicates the need for further refinement or complementary use with other screening methods for optimal effectiveness. Biopsy confirmation remains essential for cases with detected abnormalities to ensure accurate diagnosis and proper management.

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Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

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