

Evaluation of Screening Tests for Precancerous and Cancerous Lesions of the Cervix in a Resource-Limited Country: The Case of the Health District of Commune V of Bamako, Mali, 2024

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How to cite this paper: Oumar, T.S., Amadou, B., Ousmane, K.I., Mamadou, S., Aminata, K., Abdoulaye, S., Seydou, F., Alassane, T., Alou, S., Saoudatou, T., Saleck, D., Nouhoun, D., Fousseyni, D., Tioukany, T., Ibrahim, T., Youssouf, T. and Niani, M. (2025) Evaluation of Screening Tests for Precancerous and Cancerous Lesions of the Cervix in a Resource-Limited Country: The Case of the Health District of Commune V of Bamako, Mali, 2024. *Open Journal of Obstetrics and Gynecology*, 15, 2038-2048. <https://doi.org/10.4236/ojog.2025.1512171>

Received: November 23, 2025

Accepted: December 13, 2025

Published: December 16, 2025

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Abstract

Introduction: The validity of Visual Inspection with Acetic Acid (VIA) and Visual Inspection after Lugol's Solution (VIL), as well as cervical smears (CFS) or cervical-vaginal smears (CVS), in screening for cervical lesions of the uterus has been the subject of numerous studies worldwide. **The Objective** of this study was to evaluate the performance of these tests, comparing them to the results of biopsy/histology, for the detection of cervical lesions in the health district of Commune V of Bamako, Mali. **Methods:** This was a cross-sectional, descriptive, and analytical study with prospective data collection. The study aimed to evaluate the results of colorimetric tests (IVA/IVL) and cervical smears (Pap smears). We included sexually active women, aged 25 to 49 years, who were not pregnant, not menopausal, and had not undergone a total hysterectomy, who were undergoing their first screening for precancerous lesions with a positive IVA/IVL (one or both tests) and an abnormal Pap smear. Data analysis was performed using SPSS 20 software. **Results:** A total of 8,517 patients were screened, of whom 1,272 (14.90%) had abnormalities on the IVA/IVL smear, and 1,237 (14.50%) showed abnormalities on the urinalysis. Among these abnormalities, 88 (6.90%) were carcinomas. The mean age of the patients was 33.16 years, with an age range of 25 to 49 years. The majority of the women screened were married (69.18%), had had few pregnancies (35.14%), had

had few children (35.10%), were educated (67.25%), and were civil servants (35.43%). Regarding visual inspection tests, the IVA/IVL showed a sensitivity (Se) of 87%, a specificity (Sp) of 89%, a positive predictive value (PPV) of 89%, and a negative predictive value (NPV) of 87%, with an estimated true prevalence of the disease (PRM) of 50%. As for the cervical smear (FCU), we found a sensitivity (Se) of 87%, a specificity (Sp) of 90%, a positive predictive value (PPV) of 89%, and a negative predictive value (NPV) of 88%, with a true prevalence of the disease (PRM) of 48%. **Conclusion:** Visual inspection methods (VIA/VIA) demonstrate performance comparable to that of the cervical smear (CAP) in detecting precancerous and cancerous cervical lesions. These results suggest that VIA/VIA could be an effective alternative to the CAP for screening for cervical lesions, particularly in resource-limited settings.

Keywords

Screening, Cervical Lesions, Uterus, Visual Inspection, Cervical Smear, Cervical Cancer

1. Introduction

Globally, cervical cancer is the fourth most common cancer among women, with approximately 660,000 new cases in 2022. In the same year, approximately 94% of the 350,000 deaths from cervical cancer occurred in low- and middle-income countries [1] [2]. The highest incidence and mortality rates of cervical cancer are found in sub-Saharan Africa (SSA), Central America, and Southeast Asia [1] [2]. Regional differences in the burden of cervical cancer are linked to inequalities in access to vaccination, screening, and treatment services, risk factors, including HIV prevalence, and social and economic determinants [1] [2]. Modeling estimates suggest that 74 million new cases of cervical cancer could be prevented and 62 million deaths could be averted by 2120 if the elimination target is met [1] [2]. All countries have committed to eliminating cervical cancer as a public health problem. The WHO Global Strategy defines elimination as reducing the number of new annual cases to 4 or fewer per 100,000 women and sets three targets to be achieved by 2030 to put all countries on the path to elimination in the coming decades [1] [2]: 90% of girls vaccinated against HPV before the age of 15, 70% of women screened with a high-quality test before the age of 35 and 45, and 90% of women with cervical disease receive treatment.

Thus, for screening, women should be screened for cervical cancer every 5 to 10 years starting at age 30. Women living with HIV should be screened every 3 years starting at age 25. The global strategy encourages a minimum of two screenings during a woman's lifetime with a high-performing HPV test before age 35, and then again before age 45 [1] [2]. The validity of visual inspection tests after application of acetic acid (VIA), visual inspection after application of Lugol's io-

dine (VI), and cervical smears (CFS) or cervical-vaginal smears (CVS) in the screening for precancerous and cancerous lesions of the cervix has been the subject of several studies [3]-[5]. In Mali, few studies have focused on the validity of these screening tests. Thus, in this study, we evaluated the performance of VIA/VIS and CVS tests, after biopsy/histology, in the detection of cervical lesions in the health district of Commune V of Bamako, Mali.

2. Patients and Method

Background: Before the start of the activity, two gynecologists and about ten midwives from the health district of Commune V in Bamako were trained in screening methods for precancerous and cancerous lesions of the cervix using IVA/IVL, but also, and especially, in the locally available treatment techniques for precancerous lesions. For cervical smears, which were not available at the department, an agreement was signed with a private clinic that performed this examination for a flat fee of three thousand francs (3000 CFA francs).

Study setting: The study was conducted in the health district of Commune V. It is one of the six health districts in Bamako, the capital of Mali. The health district of Commune V, along with that of Commune VI, is one of the two health districts of Bamako located on the right bank of the Niger River.

Study type: This was a descriptive and analytical cross-sectional study with prospective data collection. The study aimed to evaluate the results of colorimetric tests and cervical smears (CSP).

The study focused on women aged 18 to 65 who were consulted in the health district of Commune V between January 2021 and December 2022. We included in the study sexually active women aged 25 to 49, who were not pregnant or menopausal, and who were undergoing their first screening for precancerous lesions with a positive IVA/IVL (one or both) and an abnormal Pap smear. Pregnant women, women with vaginal bleeding, women already being monitored for precancerous lesions, menopausal women, and women unable to have a Pap smear were excluded from this study.

Study procedure:

The women (patients) first underwent a **cervical smear** (CSP). The CSP was performed by directly spreading the collected cells onto slides using an Ayre spatula and a cytobrush, then fixed immediately, and sent to the histology laboratory for reading by an anatomopathologist.

-Visual inspection after application of acetic acid (VA):

VIA involves applying a 3% - 5% acetic acid solution to the cervix and then examining it with the naked eye using a bright light source.

When acetic acid is applied to an epithelium containing high amounts of cellular proteins, coagulation is maximal and masks the red color of the stroma. This acidophilic reaction results in a noticeable whitening of the epithelium compared to the usual pinkish color of the surrounding normal squamous cervical epithelium.

Any well-defined area of acidophilic abnormality near the transformation zone

indicates a positive test. This abnormality was biopsied, the specimen was fixed in formalin, and sent to the pathology laboratory.

For the categorization of the IVA results, we used the criteria reported by Sankaranarayanan R [6] from 2003 (**Table 1**).

Table 1. IVA test result.

Test result	Criteria
Negative (-)	<ul style="list-style-type: none"> No acidophilic lesions Acidophilia associated with endocervical polyps and Nabothian cysts Marked acidophilic effect in line with the squamo-cylindrical junction
Positive with a cross (+)	<ul style="list-style-type: none"> lesions with low acidophilicity on the cervix. Geographic, angular and well-defined acidophilic lesions, far from the squamo-cylindrical junction.
Positive with two crosses (++)	<ul style="list-style-type: none"> Opaque, dense, dull, well-defined acidophilic lesions affecting the squamo-cylindrical junction or near the external opening. Large, dense, circumferential, well-defined, thick acidophilic lesions. The mass on the cervix becomes acidophilic

-Visual inspection after application of strong Lugol's solution (IVL):

The approach to intravenous lupus iodine (IVL) is similar to Schiller's iodine test, advocated in the 1930s, which involved applying Lugol's iodine solution to the cervix and visually examining it for mustard-yellow areas. IVL relies on the interaction between iodine and glycogen. Normal, mature squamous epithelium is characterized by an abundance of glycogen, whereas abnormal epithelium contains relatively little or no glycogen. Applying iodine solution to normal squamous epithelial cells will produce a dark brown, almost black, mahogany stain; while columnar and abnormal epithelial cells, as well as immature metaplasia, both of which contain little or no glycogen, remain relatively unstained and exhibit colorless, pale, or mustard-yellow areas. These areas of abnormality indicate positive Lugol's iodine tests. These areas were biopsied, and the samples were sent to the pathology laboratory after fixation in formalin.

For the categorization of the IVA results, we used the criteria reported by Sankaranarayanan R [6] 2003 (**Table 2**).

Table 2. IVL test results.

IVL test results	Criteria
Negative (-)	<ul style="list-style-type: none"> The normal cervix where the squamous epithelium becomes mahogany brown or black and where the columnar epithelium does not change color and remains pale. Uneven, indistinct, poorly defined, colorless or partially brown areas in the transformation zone. Leopard skin appearance. Areas of non-absorption of Lugol, irregular and poorly defined on the cervix, with or without extension onto the vagina.

Continued

- Thin, yellow, iodine-free absorption zones with angular or finger-like margins, resembling geographic zones, located far from the squamo-cylindrical junction
 - Well-defined, dense, thick, shiny, mustard yellow or saffron yellow areas with no iodine absorption, touching the squamo-cylindrical junction
- Positive (+)**
- Circumferential lesion, well defined, thick, dense, yellow, occupying a large part of the cervix.
 - The mass on the collar turns yellow.

Data entry and analysis: we have do a seizure simple of the texts, of the paintings on THE Word software. Data analysis was performed using SPSS software. 20. Statistical analyses were carried out using R software version 3.1.0. Thus, the results obtained by the IVA/IVL and FCU tests were compared to the results obtained by histology, which was used as the reference test. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and the true prevalence of the disease were calculated to evaluate the performance of the IVA/IVL and FCU tests.

3. Results**3.1. Number of Screenings**

We performed 8517 IVA/IVL and IVA/IVL cervical smears. The overall results of the screening tests are reported in **Table 3**. IVA combined with IVL revealed 1272 (14.90%) abnormalities, and the Pap smear identified 1237 (14.50%) abnormalities.

Table 3. Screening tests and overall results.

Results	Screening test	
	IVA/IVL E (%)	FCU E (%)
Normal	7245 (85.10)	7280 (85.50)
Abnormal	1272 (14.90)	1237 (14.50)
Total	8517 (100)	8517 (100)

3.2. Result of Pathological Anatomy

Among the 1272 cases of abnormalities on the IVA/IVL smear, histology revealed 21% CIN1, 11.55% CIN2, and 3.85% CIN3. Of the 1237 cases of abnormalities on the smear, the main lesions found were HSU-US (15.50%), HSIL (11.40%), and indeterminate smear (2.90%). In both screening methods, histology of the biopsy specimens revealed 6.90% carcinoma (88 cases). These results are shown in the table.

Table 4. Anatomical pathology results.

Histology	Screening test	
	IVA/IVL	FCU
	E (%)	E (%)
Non-dysplastic lesions	792 (62.26)	792 (62.30)
CIN1	267 (21.00)	-
CIN2	147 (11.55)	-
CIN3	49 (3.85)	-
HSU-US	-	210 (16.50)
HSIL	-	145 (11.40)
Undetermined	-	37 (2.90)
Carcinoma	-	88 (6.90)
Total	1272 (100)	1272 (100)

CIN1 = low-grade cervical intraepithelial neoplasia (grade 1); CIN2 and 3 = high-grade cervical intraepithelial neoplasia (grade 2 and grade 3, respectively).

ASC-US (atypical) squamous cell of undetermined significance) refers to atypia of squamous cells of undetermined significance.

HSIL (High grade squamous intraepithelial Lesions) refers to high-grade squamous intraepithelial lesions.

The other results of the Histology were non-dysplastic lesions including 33 cases of Nabothian cyst, 47 cases of ectropion, 712 cases of inflammation.

3.3. Socio-demographic Characteristics

The mean age of the patients was 33.16 years, with a range of 25 to 49 years. Women with few pregnancies and women with few children represented 35.14% and 36.10%, respectively. Civil servants comprised 35.43% of the sample, and married women 69.18%, as shown in **Table 5**.

3.4. Analytical Results

For IVA/IVL, the sensitivity (se) was 89%, the specificity (sp) was 87%, the positive predictive value (PPV) was 100%, the negative predictive value (NPV) was (87%) for a true prevalence of the disease (PRM) of 50%.

For FCU the sensitivity (se) was 87%, the specificity (sp) was 90%, the positive predictive value (PPV) was 89%, the negative predictive value (NPV) was 88% for a true prevalence of the disease (PRM) of 48% (**Table 6**).

Table 5. Distribution according to socio-demographic characteristics.

Age Range	Number	Percentages
25 - 29	945	11.10
30 - 34	1018	11.95
35 - 39	2018	23.70
40 - 44	2303	27.27
45 - 49	2233	25.98
Total	8517	100

Continued

Gravidity	Number	Percentages
Nulligestes	567	6.65
Primigestes	2254	26.46
Paucigestes	2993	35.14
Multi-gestures	2703	31.75
Total	8517	100
Parity	512	6.00
Nulliparous	2239	26.92
First-time mothers	3073	36.10
Pauci pares	2693	30.98
Multiparous	8517	100
Total	512	6.00
Occupation	Number	Percentages
Housewives	1817	21.33
Students	2510	29.47
Civil Servants	3017	35.43
Shopkeepers/saleswomen	1173	13.77
Total	8517	100
Marital status	Staff	Percentages
Married	5892	69.18
Singles	2625	30.82
Total	8517	100

Table 6. Validity test values for IVA/IVL and FCU.

Test	Sensitivity	Specificity (Sp)	VVP	VPN	PRM
IVA/IVL	87%	89%	89%	87%	50%
FCU	87%	90%	89%	88%	48%

4. Discussion

4.1. Limitations and Considerations

Although these tests are useful, they have some important limitations:

- **Variable sensitivity and specificity:** A test may have high sensitivity, but its specificity may sometimes be lower, which can lead to false positives or false negatives. This can affect the accuracy of the diagnosis.
- **Observer dependence:** The effectiveness of tests relies heavily on the experience and training of medical personnel. Therefore, the quality of results can vary depending on the observer's skills, which can introduce inconsistencies, especially in settings where training resources are limited.
- **Need for follow-up:** A positive test requires further investigations, such as a colposcopy or biopsy, to confirm the diagnosis. However, in some settings, this follow-up can be difficult to provide due to limited access to care and resources, which complicates management.

4.2. Local Context and Socio-Demographic Data of the Women Screened

In Mali, screening and treatment of precancerous and cancerous lesions of the

cervix constitute an essential component of Minimum Package of Activities (MPA) in the majority of healthcare facilities. This strategy is primarily based on visual inspection after the application of acetic acid (VA). at 3 - 5% and on Visual Inspection after Lugol's iodine application (VIL). Two screening approaches are implemented: screening mass or organized and screening individual or opportunistic.

In total, 8,517 women were detected, among which 1,272 anomalies were identified, namely a prevalence of 14.90%. All patients with an abnormality benefited from a biopsy followed by Histological examination. The age range 40 - 44 years old was the most represented (27.27%). The extreme ages observed were 25 years old and 49 years old, with an average age of 33.16 years.

These results are comparable to those reported by M' Piga E *et al.* [4] in Gabon, who observed that 34% of women screened belonged to the age group of 40 to 49 years old. Similarly, Guèye I [7] in Senegal reported an average age of 37 ± 8.09 years, while Somé OR [8] found an average age is 30.5 years. In Morocco, the target age for cervical cancer screening is between 30 and 49 years old [9].

From a socio-demographic perspective, the majority of women screened were married (69.18%), paucigestes (35.14%), pauciparous (35.10%), educated (67.25%) and civil servants (35.43%). These figures partially agree with those of Guèye I [7], who reported a higher proportion of married women (87%) but a higher rate of uneducated women (45%).

For their part, M' Piga E *et al.* [4] observed approximately 45% multi-gesture and 28% of civil servants are women, while noting a significant proportion of educated women (65%) having a secondary or university level of education. Ardahan M *et al.* [10] They also point out that the proportion of married women varies, according to studies, between 74% and 100%. However, the same study of M' Piga E *et al.* [4] highlighted a larger proportion of singles (42.4%), as well as a relatively high rate of educated women (65%), a result comparable to those of Ardahan M [10], who reports proportions of educated women ranging between 59% and 79% depending on the contexts studied.

In summary, this data highlights the socio-demographic diversity of women participating in cervical cancer screening in the sub-region, with a general trend towards a predominance of married, educated women in the 30 - 49 age group.

4.3. Validity of Cervical Lesion Screening Tests

In our study, the diagnostic performance of visual tests was evaluated based on sensitivity (Se), specificity (Sp), and positive predictive values (PPV) and negative predictive values (NPV). The results obtained for visual inspection after application of acetic acid (IVA and visual inspection after application of Lugol's iodine (IVL) show a sensitivity of 87%, a specificity of 89%, a VPP of 89% and one VPN with 87%, for an actual prevalence of the disease (PRM) estimated at 50%. Regarding the cervical smear (FCU), performance was comparable, with a sensitivity of 87%, a specificity of 90%, a VPP of 89% and one VPN with 88%, for a PRM of

48%.

Similar results were reported at Gabon by M' Piga E *et al.* [4], who observed for visual tests (IVA/IVL) a 100% sensitivity, a specificity of 92%, a VPP of 90% and one 100% VPN. In the same study, the performance of FCU were identical with a 100% sensitivity, a specificity of 92%, a VPP of 90% and a 100% VPN [4]. In other African works, the sensitivity of the IVA/IVL test varies between 79% and 97%, and the specificity between 87% and 96% [11] [12]. In Ivory Coast, Horo AG [13] reported a sensitivity of 72.9% and one specificity of 95.2% for visual tests. For the FCU, the reported values were 45.4% for sensitivity and 99.2% for specificity. For its part, Bennis S [14] found a specificity of FCU of 81.8%.

The conventional cervical smears, although inexpensive, have a longer turn-around time for results. Nevertheless, they remain a feasible technique in Mali and are widely used in healthcare facilities [4] [17] [18]. A systematic review including 11 studies showed that the sensitivity of smears ranged from 33% to 100%, while their specificity fluctuated between 60% and 97%. Combined estimates showed a mean sensitivity of 84% (95% CI: 76 - 90%) and a mean specificity of 88% (95% CI: 79 - 93%) [15]. Similarly, Mustafa RA [16] reported a sensitivity of smears ranging from 33% to 100% and a specificity ranging from 60% to 97%. The high performance observed for visual tests in our study can be explained by the quality of the human resources involved. Indeed, the IVA/IVL tests are carried out by an experienced team, active for over 20 years, benefiting from ongoing supervision by a national trainer and program focal point. Screening activities have been conducted daily for over 10 years, from Monday to Friday, sometimes even on Saturdays, which guarantees excellent technical expertise and standardized procedures. These results support the data in the literature and suggest that the Visual tests (IVA/IVL) constitute a reliable, sensitive and economically viable method for screening for precancerous lesions of the cervix in resource-limited countries such as Mali.

5. Conclusion

Precancerous and cancerous lesions of the cervix remain prevalent in the Commune V health district of Bamako. Visual inspection methods (IVA/IVL) have shown comparable performance to those of the cervical smear, confirming their relevance and adaptability in resource-constrained contexts.

Thanks

We would like to express our sincere thanks to all those who contributed to the completion of this study.

First of all, we would like to warmly thank the staff of the gynecology-obstetrics department of the Health District for their constant support and valuable collaboration throughout this study.

We also wish to express our deep gratitude to our colleagues for their wise advice and expertise. Their academic support was crucial to the completion of this

work.

We also thank the patients who agreed to participate in this study; without them, this work would not have been possible. Their trust and cooperation were essential.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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