

FRD Versus Via-Vil: An Alternative to Colorimetric Tests in the Screening of Precancerous Lesions of the Uterus Cervix

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Abstract

The screening of precancerous lesions of the uterus cervix by VIA and VIL colorimetric assays is the main way in the prevention of uterus cervical cancer in Africa. The introduction on the market of new colorimetric tests such as the FRD encourages a comparison to determine its sensitivity and specificity.

Patients and Methods: This was a prospective, double-blind, comparative study conducted in the Medical Oncology Department of the University Hospital of Brazzaville, which involved 100 women who underwent cervical-uterine Pap smears as a discriminatory test.

Results: The mean age was 39.21 years with extremes ranging from 23 to 64 years old. The VIA and VIL test was positive in 7 women; the sensitivity compared to this test was 85.7% with a specificity of 96.8%. The FRD test applied to women with a VIA-VIL positive test confirmed the positivity of these women and highlighted two other women with positive test among women who had a negative VIA-VIL test. The sensitivity was 100% with a specificity of 98.9%.

Conclusion: The effectiveness of the FRD is evident in our study. Its sensitivity similar to the Pap smear is much higher than the VIA-VIL.

Keywords: Screening; Cancer; Cervix; VIA-VIL; FRD; University Hospital of Brazzaville

Introduction

Cervical cancer is the second most common cancer in women in African countries after breast cancer. With nearly 493,000 new cases a year, and 273,000 annual deaths [1]. The global burden of cervical cancer makes it a major public health problem, including within the WHO African Region [2]. Most cancers occur in women at an age when their role is central to family support, the economy and social cohesion including education and children's health [2]. Over the last 60 years, extensive screening and treatment programs have resulted in a sharp reduction in cervical cancer figures in industrialized countries, while in sub-Saharan Africa more than 95% of women have never been screened; the mortality of cervical cancer is constantly increasing [2]. A comprehensive strategy combining primary prevention with vaccination, screening for precancerous lesions, early diagnosis and treatment is essential to reverse the situation; action is needed to give girls and women everywhere in Africa better access to new technologies [2].

In sub-Saharan Africa and Congo in particular, the insufficiency of the technical equipment's the quality of human resources, the precariousness of the populations and the late diagnoses make the screening the main way of fighting against this plague. VIA-VIL colorimetric testing for its simplicity and affordability is an effective alternative to cytology testing in low-income regions [3].

Its sensitivity and specificity, although high, do not reach 100% according to several analyzes, which encourages us to evaluate other tests. Several new and easier to use tests are available including the FRD. The purpose of our study was to determine the efficacy of FRD in detecting pre-cancerous cervical lesions by comparing it to VIA-VIL colorimetric tests.

Patients and Methods

This study was conducted over a period of 4 months from April 1st to August 1st2018.

The selection of women took place at the University Hospital of Brazzaville, in the department of Medical Oncology. This was a prospective, double-blind comparative study. To be included in the study, women should be:

- In sexual activity:
- Screened at University Hospital of Brazzaville in the Department of Medical Oncology.
- Having performed a pap smear from.

A sample of 100 women was selected based on the number of tests available. The pap smear was previously performed in these women to distinguish negative (non-sick) and positive (high-grade lesion). The FRD is a test that has the same principle as the VIA-VIL. It consists of using an electronic colorimeter or an abacus, to read the color of an applicator previously soaked with a specific solution and placed in contact with the cervical orifice.

For all these women, the two tests FRD and VIA-VIL were successively performed. The study variables were:

- Age
- Origin
- Sensitivity (Se): ability to identify patients when the test is positive.
- Specificity (Sp.): Ability to eliminate the disease when the test is negative.
- TP: true positives (patients with positive test).
- FP: false positive (not sick to positive test)
- TN: true negative (healthy subject to negative test)
- FN: false negatives (patients with negative test).
- Positive Predictive Value (PPV): The test's ability to express the truth. This is the number of patients actually identified.

- Negative Predictive Value (NPV): ability of the test to identify truly healthy subjects Sensitivity and specificity are calculated according to standard formulas.
- $Se = TP / TP + FN$
- $Sp = TN / TN + FP$.
- $PPV = TP / TP + FP$.
- $NPV = TN / TN + FN$

The calculations were done using Excel 2010 software.

The threshold of significance was $p < 0.05$

Results

During the survey period, 263 women were received for screening. 153 of them met the inclusion criteria; we selected the first 100 that met the inclusion criteria in relation to the number of tests available.

The mean age was 39.21 years \pm 11.64 with extremes ranging from 23 to 64 years (Table 1).

Age Range (Years)	Number	(%)
[0 - 25]	2	2
[25 - 50]	63	63
[50 - 75]	35	35
Total	100	100

6 women or 6% came from rural areas

Table 1: Age Distribution of Women

Type of Test	Positive	Negative	Total
VIA-VIL	6(TP)	1(FN)	7
Total	6	1	7

Table 2: IVA-IVL results on positive Pap smear women (Patients)

Type of Test	Negative	Positive	Total
VIA-VIL	90(TN)	3(FP)	93
Total	90	3	93

Table 3: Results of VIA-VIL on negative Pap smear women (non-sick)

	Patients	Non-Sick	Total
VIA-VIL	TP(6) FN(1)	FP(3) TN(90)	9 91
Total	7	93	100

- Sensitivity= $TP/TP + FN = 6/7 = 85,7\%$
- Specificity= $TN/TN + FP = 90/93 = 96,8\%$
- $PPV = TP / TP + FP = 6/9 = 66,7\%$
- $NPV = TN/TN + FN = 90/91 = 98,9\%$

Table 4: Sensitivity, Specificity and Predictive values of VIA-VIL

Type of test	Positive	Negative	Total
FRD	7(TP)	0(FN)	7
Total	7	0	7

Table 5: Results of FRD to women with positive Pap smear (patients)

Type of test	Negative	Positive	Total
FRD	91(TN)	2(FP)	93
Total	91	2	93

Table 6: Results of FRD to women with negative Pap smear (non-sick) du FRD

	Patients	Non sick	Total
FRD+	TP(7)	FP (2)	9
FRD-	FN(0)	TN(91)	91
Total	7	93	100

- Sensitivity = $TP / TP + FN = 7 / 7 = 100\%$
- Specificity = $TN / TN + FP = 91 / 93 = 97,8\%$
- PPV = $TP / TP + FP = 7 / 9 = 88,8\%$
- NPV = $TN / TN + FN = 91 / 92 = 98,9\%$

Table 7: Sensitivity, Specificity and predictive values of the FRD

Test Results

Pap smear previously performed on 100 women was negative in 93 women and positive in 7 of them.

Discussion

This study is the first conducted in our working condition, the anonymity of the women was respected; Informed consent was obtained from all women who agreed to participate in the study. The authorization of the ethics committee was obtained before the completion of this work. The size of our sample of 100 women sets the limits, because it does not make it possible to extrapolate the results to the general population; but several conclusions emerge clearly. The mean age of 39.21 years at screening was found by several authors the low percentage of women from rural areas reflects the lack of awareness and may be precarious.

Of the 100 preselected women, the VIA-VIL showed sensitivity and specificity respectively of 85.7% and 96.3% with positive and negative predictive values of 66.7% and 98.9%.

These values are close to those found by several authors and account for the effectiveness of this test [4,5] even if they do not reach 100%, which is the ideal value for a test. This sensitivity is much greater than that of Doh A S [6] and EKALAKSANAN [7] probably because of the experience in the practice of screening service personnel since he is a dependent operator. Recalling that the service has a cancer prevention unit and screening has been practiced by oncologists for several years. Akinola and al in a reduced sample, find a sensitivity of 100% [8]. The inferiority of our sensitivity could be explained by the fact that the light sources we used were not always of good quality; we used the electric power, subjected to variations of the tensions; still not meeting standard conditions.

The FRD, in view of the calculated indicators, appears to be much more effective than the VIA-VIL. In addition, due to a preselection of the women by the Pap smear, whose effectiveness of 100% is widely documented, the FRD gives a similar efficiency. Despite its cost, although affordable, but higher than that of the VIA-VIL, the FRD is a serious alternative as a colorimetric test.

Conclusion

This preliminary study confirms the effectiveness of the FRD in screening precancerous cervical lesions compared to VIA-VIL tests in our series. Its sensitivity identical to the Pap smear is much higher than that of the VIA-VIL. Conducting a study on a larger sample would consider it an alternative to VIA-VIL.

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