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Cervical Cancer Screening Using HPV and Cytology Co-Testing in Senegal: Epidemiological Profile and Diagnostic Performance

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Abstract **Original Research Article**

Introduction: Cervical cancer remains the second most common cancer among women worldwide and the leading cause of cancer death. Depending on the center and the screening policy in place, primary screening may involve HPV testing, cervical smear testing, or both in a "co-testing" approach. The objective of our study was to describe the results obtained after primary co-testing screening. More specifically, we sought to report the epidemiological profile of patients, describe the cytology results and the results for HPV viruses detected, and correlate the type of HPV virus with the precancerous lesions detected. ***Materials and methods:*** This was a retrospective, descriptive, and analytical study involving 99 patients. The parameters studied concerned epidemiological data, cytological aspects of smears, and HPV test results. Performance indicators [sensitivity, specificity, PPV, NPV, accuracy, Youden's index], concordance [Cohen's kappa], and McNemar's test were calculated. The analyses were performed using R. ***Results:*** Ninety-nine women were included. The mean age was 44.3 ± 10.2 years. HPV positivity was 24%, dominated by high-risk genotypes [76%]. The prevalence of cytological abnormalities was 8.1%. The HPV test had a sensitivity of 12.5% and a specificity of 74.7%, with a high NPV [90.7%] and low concordance with cytology [kappa = −0.07]. ***Conclusion:*** Co-testing shows good exclusion capacity but limited concordance in this context. Standardization of techniques and integration of molecular typing could improve performance.

Keywords: Cervical cancer, HPV, cytology, co-testing, Senegal.

INTRODUCTION

Cervical cancer remains a major public health problem, particularly in low- and middle-income countries, where it is one of the leading causes of cancer mortality in women [1]. Persistent infection with high-risk oncogenic human papillomavirus [HPV] is recognized as the etiological factor necessary for the development of precancerous lesions and invasive cervical cancer [2]. Globally, more than 95% of cervical cancers are attributable to oncogenic HPV genotypes, mainly types 16 and 18, although the distribution of genotypes varies by region [3]. In sub-Saharan Africa, the incidence and mortality of cervical cancer remain particularly high due to limited access to organized screening and early management of precancerous lesions [4]. The Pap smear, long considered the gold standard, has led to a significant reduction in the incidence of cervical cancer in countries with structured screening programs [5]. However, its moderate sensitivity and dependence on the quality of the sample and cytological reading have led to the emergence of HPV testing as a more sensitive alternative for primary screening [6]. Co-testing, combining cytology and HPV testing, aims to combine the specificity of cytology with the high sensitivity of HPV testing, thereby improving the early detection of significant lesions while strengthening the power of exclusion [7]. This strategy is recommended in several countries and recognized by the World Health Organization as a relevant option, particularly in contexts where resources and infrastructure allow it [8]. In Senegal, despite the existence of opportunistic screening campaigns, there is still no structured national program clearly defining the respective roles of HPV testing, cytology, and co-testing in primary screening [9]. Local

data on the performance of co-testing remain limited. This study aims to contribute to this literature by describing the epidemiological, cytological, and virological profile of women screened at the Elisabeth Diouf Health Center in Diamniadio, and by evaluating the diagnostic performance and concordance of HPV/cytology co-testing in this context.

MATERIALS AND METHODS

Type and period of study

This is a retrospective, descriptive, and analytical study. Screening was carried out during October 2023, during a free screening day as part of Pink October, which aims to screen for gynecological cancers, particularly breast and cervical cancer.

This study was conducted in collaboration with the Elisabeth Diouf Health Center in Diamniadio and the Histology, Embryology, and Cytogenetics Laboratory of the Faculty of Medicine, Pharmacy, and Dentistry at Cheikh Anta Diop University in Dakar.

Inclusion criteria

We included in our study all women who came for cervical cancer screening and who underwent both HPV typing and a cervical smear.

Exclusion criteria

The following were excluded from our study:

- smears that were uninterpretable according to Bethesda criteria
- smears taken from pregnant women during the first trimester of pregnancy.

The sample collection:

It must be performed 48 hours after sexual intercourse, outside the menstrual period, without any local treatment, without any local infection, and after estrogen treatment in postmenopausal patients.

The sample is taken in the gynecological position; vaginal examination and the use of lubricant are prohibited. The cervix is exposed using a properly positioned speculum. Using a cytobrush, the long bristles are inserted into the endocervix and the brush is gently rotated clockwise. The external os of the cervix is scraped with the spatula. The samples are spread on two different slides and immediately fixed by spraying fixative at a right angle from a distance of 20 cm.

Papanicolaou staining:

Papanicolaou staining is performed according to the different steps in Table I. However, to reduce the risk of toxic exposure to toluene, the cost and duration of cytodiagnostic staining techniques, a new approach to Papanicolaou staining is used by the Histology-Embryology and Cytogenetics Laboratory [Table II]. The results are reported according to the Bethesda 2001 classification.

HPV viral typing:

This was performed using the Bioperfectus Tech test, a real-time PCR technique with amplification of HPV-HR viral DNA [E6/E7 region], which can detect 17 types of HR-HPV or high-risk oncogenic HPV [HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 73, and 82] and 3 low-risk oncogenic HPV types [HPV 6, 11, and 81].

Data collection and analysis

The data were recorded on individual survey forms that included the various variables studied:

- Socio-epidemiological data: age, address, marital status;
- Gynecological and obstetric history [gestation, parity, age at first sexual intercourse, period of genital life];
- Use of contraception;
- Type of contraception;
- Indications for cervical smear;
- Macroscopic appearance of the cervix;
- Cervical smear results;
- HPV typing
- Calculation of the diagnostic performance of the HPV test compared to cytology [reference], concordance analyses, and statistical tests [threshold $p < 0.05$].

The data were analyzed using R software.

Results:

Sociodemographic data

Ninety-nine [99] women were included. The mean age was 44.29 ± 10.21 years, ranging from 22 to 73 years. The most represented age group was 35–44 years [36%], followed by 45–54 years and 25–34 years [Figure 1]. The ajority of patients resided in Diamniadio [76%]. In terms of marital status, 88% were married, 7% were divorced, and 5% were widowed.

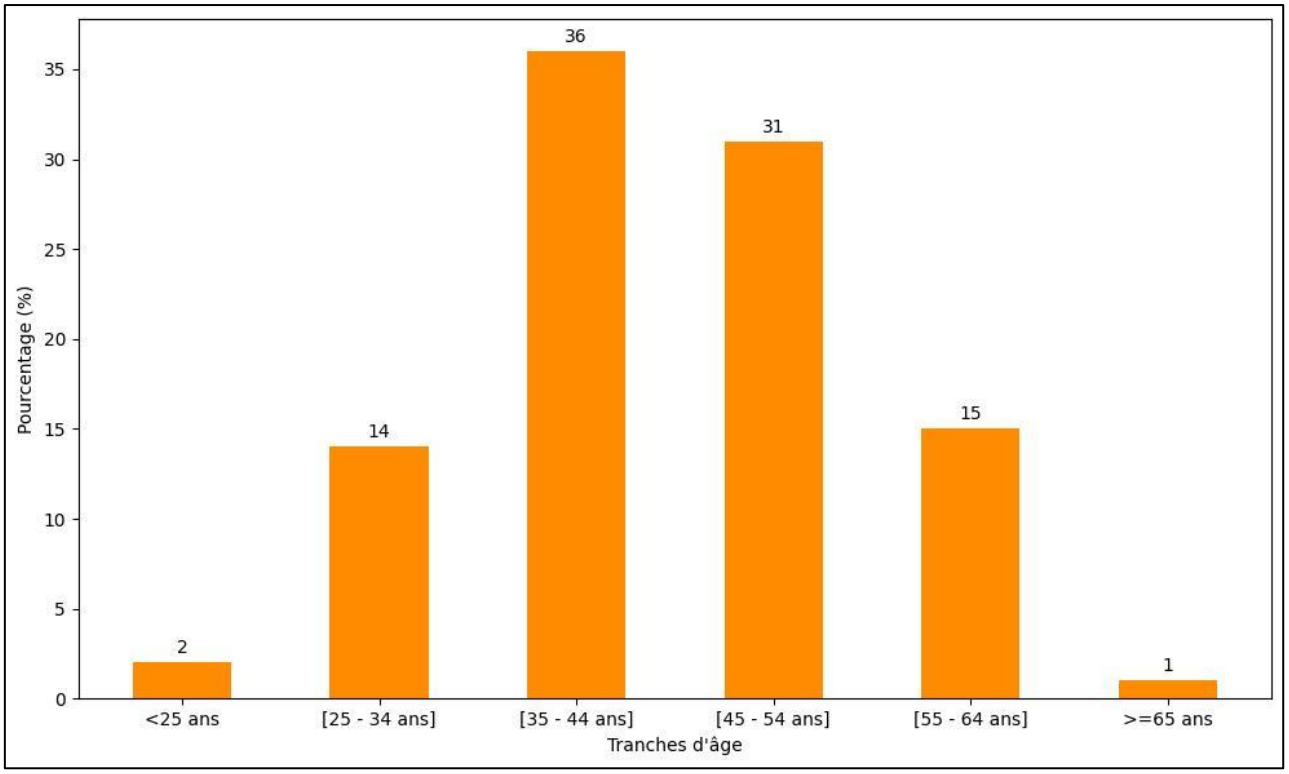

Figure 1: Distribution of patients by age group

Gynecological and obstetric history

The average age at first sexual intercourse was 22.95 ± 5.22 years [range: 11–39 years]. The majority of women were sexually active [64%], while 35% were postmenopausal. Women who had given birth multiple times accounted for 57.8% of patients, with an average of 4 ± 2 pregnancies. The average parity was also 4 ± 2, and 52% of women were multiparous.

Contraception

Sixty percent of patients did not use any method of contraception. Among those using contraception [40%], the pill and injectable methods were the most commonly used [32% each].

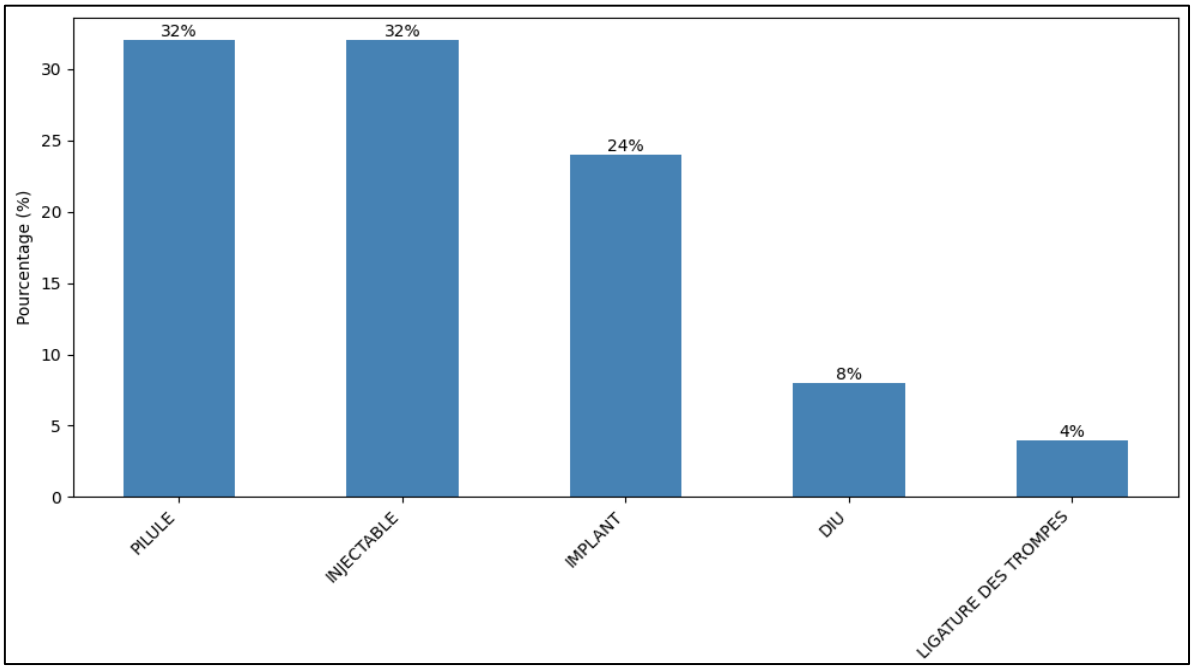

Figure 2: Distribution of patients according to the contraceptive method used

The macroscopic appearance of the cervix was predominantly inflammatory in 55% of cases, or 54 patients.

The microscopic appearance of the FCV showed no signs of malignancy in 92% of cases, with 5 ASC-H cases and 3 LSIL cases.

The viral test was positive in 24% of cases. In patients with a positive HPV test, there was a predominance of high-risk HPV types, with a prevalence of 76% in 19 patients. Among the high-risk HPV types, type 26 was predominant with 42.11% [8 patients], followed by type 33 with 26.32% [5 patients] [Table I]. Among the low-risk HPV types, type 81 was noted in one patient.

Table I: Distribution of high-risk HPV types among patients

Type With High Risk of Malignancy	Number	Percentage [%]
HPV type 26	8	42.11
HPV type 33	5	26.32
HPV type 58	4	21.05
HPV type 82	4	21.05
HPV type 66	3	15.79
HPV type 51	3	15.79
HPV type 18	3	15.79
HPV type 16	2	10.53
HPV type 52	2	10.53
HPV type 59	1	5.26
HPV type 31	1	5.26
HPV type 45	1	5.26

The HPV test positivity rate was higher in patients under the age of 25 and between the ages of 45 and 54. Belonging to these age groups appeared to influence viral test positivity [P-Value = 0.01].

The majority of patients with high-risk HPV [79.17%] had smears with no signs of malignant lesions.

Epidemiological profile of HPV+ patients:

The epidemiological profile of patients with positive tests took into account gestation, parity, genital life span, and age at first sexual intercourse.

More than half of patients with a positive HPV test were multiparous [62.5%]; gestation was found to contribute to HPV test positivity [P = 0.045].

More than half of patients with positive HPV tests were multiparous [54.1%]; there is a statistically significant relationship between parity and positive HPV tests [P-Value = 0.003].

More than half of patients with positive HPV tests were sexually active [58.33%]; there is a statistically significant relationship between sexual activity and positive HPV tests [P-Value = 0.007].

More than half of patients with positive HPV tests had their first sexual intercourse between the ages of 18 and 25 [60.8%]; the age of first sexual intercourse may contribute to positive HPV test results [P-Value = 0.02].

Performance analyses

The prevalence of cytological abnormalities was 8.1%. The HPV test had a sensitivity of 12.5% [95% CI 2.2–47.1] and a specificity of 74.7% [95% CI 64.9–82.5]. The predictive values were 4.2% CI 95% [0.007; 0.202] for the positive predictive value [PPV] and 90.7%, CI 95% [0.820; 0.954] for the negative predictive value [NPV]. These results are shown in Figure 3. Accuracy was 69.7% and Youden's index was –0.13. Kappa [–0.07] and McNemar's test [p = 0.006] indicate low agreement between tests.

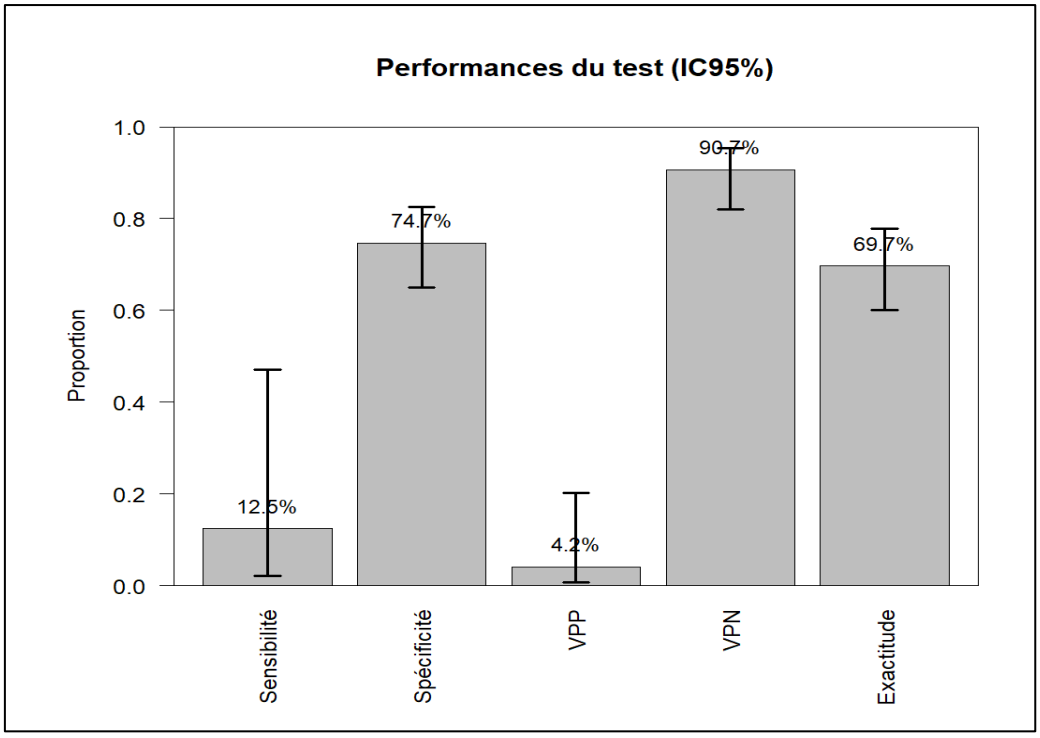

Figure 3: Diagnostic performance of the HPV test [95% CI] in patients screened

DISCUSSION

Epidemiological aspects

Thirty-six patients [36%] were between 35 and 44 years old. Our results are similar to those of Diop [10], whose average age was 43.35 years. However, they are lower than those of Arechkick [11] in Morocco, where the average age was 49.31 ± 6.3 years. This delay in screening in our population is due to women's lack of knowledge about cervical cancer [12]. The WHO recommends cervical cancer screening from the age of 30 for the general population [25 for women living with HIV] [13].

In our series, the average age of first intercourse was 22.95 ± 5.22 years, with extremes of 11 and 39 years. This result is higher than that of Kabibou [14] in Benin, where the average age of first intercourse was 17.54 ± 2.45 years. In Senegal, the median age of first sexual intercourse among women is estimated at 19 years, which is relatively close to the estimated age of marriage, estimated at 20 years [15].

According to the study conducted by Sylla et al [16], multiple pregnancies increase the risk of precancerous lesions; among our patients, 57.8% had had multiple pregnancies. The average number of pregnancies was 4 ± 2, with extremes of 0 and 10 pregnancies.

Among our patients, the average parity was 4 ± 2, with extremes of 0 and 10. The majority of patients were multiparous, representing 52% of the sample. In our series, 25 patients [40%] were using contraception, 32% of whom were using the pill. Our results are lower than those of Yazghich [17], in which 58.4% of patients used oral contraception.

Cytological aspects

In 91.92% of cases, cytological analysis revealed no lesions suspected of malignancy, and low-grade lesions were in the minority [3%] with no high-grade lesions. Our results are similar to those of Véronique [18], with a minority of low-grade lesions [2.4%] and no high-grade lesions. However, in the study conducted by Ndiadé *et al.,* in Diourbel [19], high-grade lesions were present.

Pap smears are the oldest primary screening method and the only method that has been shown to reduce the incidence of cervical cancer when adopted as a screening method. Cervical cancer is declining in most European countries where screening exists, whether spontaneous or organized [81].

In Senegal, improving geographical and financial access to screening through a national prevention program could effectively contribute to reducing the number of cervical cancer cases [20].

The high proportion of smears classified as NIL/M and the low prevalence of low-grade lesions are consistent with screening studies in the general population in sub-Saharan Africa [21]. The absence of high-grade lesions can be explained by the moderate sample size, but also by the opportunistic nature of screening, which was carried out on women who were mostly asymptomatic. Similar results have been reported

in community screening campaigns using cytology as the reference test [22].

HPV typing results

In our series, 24% of HPV tests were positive, of which 76% were high-risk, 4% were low-risk, and 20% were other HPV types. Our results are similar to those of Dumont [23], whose HPV tests were positive in 24.8% of cases. As human papillomavirus is a major risk factor for cervical cancer, HPV testing is preferred to cytology because it is more sensitive for detecting precursors of cancer and also allows for accurate risk stratification [24]. It also has a good negative predictive value compared to cytology. In fact, a negative HPV test is more reassuring than a negative cytology test, as the cytology test is more likely to be false negative [25]. However, the HPV test is not 100% specific, meaning that a positive HPV test does not necessarily indicate cervical lesions [26]. Hence the advantage of combining it with cytology for optimal screening of cervical lesions, an approach adopted in the United States as the standard screening option [27]. In Senegal, the SY study [28] demonstrated the importance of co-testing [Pap smear and HPV test] in screening for cervical lesions.

In our study, among HPV types with a high risk of malignancy, type 26 was predominant at 42.11%, followed by type 33 at 26.32%. This contrasts with data in the literature, where types 16 and 18 are predominant, as in the study conducted at the Pasteur Institute in Dakar [9].

The majority of our patients with precancerous lesions had a negative HPV test. This was not the case in the study by Karray et al., in which HPV tests in women with normal smears were positive but without oncogenic genotypes [29].

Diagnostic performance and concordance

The low sensitivity of the HPV test observed in our study contrasts with the high performance reported in high-income countries, where the HPV test is often used as a primary screening method [6]. Several hypotheses may explain this discrepancy: low prevalence of cytological lesions, transient HPV infections, sampling conditions, cervical inflammation, and intrinsic limitations of the test used [30].

On the other hand, the high negative predictive value gives the HPV test excellent exclusion power, a major advantage already highlighted in the WHO recommendations for resource-limited countries [8]. The low or even negative concordance between cytology and HPV testing highlights the complementary rather than substitutable nature of these two methods in our context, as observed in other African co-testing studies [21].

Implications for practice and public health

In a country such as Senegal, where there is not yet a clearly defined national strategy for primary screening, these results argue in favor of an integrated approach combining cytology and HPV testing, at least in pilot contexts. Standardization of procedures, training of operators, and improving the affordability of HPV testing are essential conditions for optimizing the impact of co-testing.

Limitations

The sample size is limited due to the single-center nature and one-off nature of the screening [screening and awareness campaign], the lack of longitudinal follow-up, and the lack of assessment of HPV persistence. The lack of independent cytological review and the use of a single HPV test are limiting factors. Clinical and behavioral factors were not taken into account [smoking, history of STIs, vaccination status].

CONCLUSION

From an epidemiological perspective, multigestation, multiparity, period of genital activity, and age at first sexual intercourse contribute to HPV test positivity. Co-testing is an effective primary screening alternative when available, even reducing the number of colposcopy referrals. The performance of the HPV test in terms of its maximum HR detection capacity plays a crucial role in primary screening in order to avoid false negatives. A randomized multicenter study could contribute to national health decision-making in order to propose it as a national screening strategy.

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