

Epidemiological and Clinical Aspects of Women Infected with High-Risk Human Papillomavirus Genotypes in Mbuji mayi, Democratic Republic of the Congo

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Abstract

Original Research Article

Introduction: The human papillomavirus (HPV) is a major cause of cervical cancer, a leading cause of mortality particularly in low-income countries. Late diagnosis of cervical cancer often leads to the discovery of disease at an advanced stage, accompanied by a poorer prognosis and higher mortality, highlighting the crucial need for effective screening methods. The objective of this study was to determine the epidemiology and clinical characteristics associated with high-risk human papillomavirus (Hr-HPV) infection in women in Mbuji mayi, Democratic Republic of the Congo (DRC). **Methods:** Between January and May 2025, samples from the cervix of women aged 30 to 65 who visited care units were collected using the Cervex-Brush® and the heads of the Cervex-Brush® were placed in PreservCyt® medium. The analysis was carried out by multiplex polymerase chain reaction (PCR) detecting 14 genotypes of Hr-HPV in a single analysis. **Result:** The age group of 40-49 years was the most affected mainly by all types of Hr-HPV, primarily types 52/58 grouped in P4 at 52.9%. Vaginal itching was the most reported symptom (44.2%) and cervicitis was the most frequent physical sign (11.16%). Genital bleeding during sexual intercourse was found to be a clinical symptom predictive of Hr-HPV infection. **Conclusion:** In Mbuji mayi, adult women aged between 40-49 are the most affected by Hr-HPV infection; and genital bleeding during sexual intercourse is a predictive sign of this infection. The implementation of an effective screening program is necessary to reduce the morbidity and mortality associated with cervical cancer.

Keywords: Hr-HPV, Clinique, Epidemiologie, Mbuji mayi, Democratic Republic of Congo.

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1. INTRODUCTION

The human papillomavirus (HPV) is one of the most common sexually transmitted infections in the world [1]. About 75 to 80% of sexually active individuals are infected at some point in their lives. Genital warts are the classic clinical manifestation of HPV, which is caused by non-oncogenic or low-risk (Lr-HPV) subtypes. Only a small proportion of infections progress to precancerous and cancerous lesions. These are caused

by oncogenic or high-risk (Hr-HPV) types, such as HPV 16 and HPV 18 [2].

Sub-Saharan Africa is the most affected region (24% prevalence). Women living with the human immunodeficiency virus (HIV), immunocompromised individuals, and those who do not have access to testing are the most vulnerable [3].

In the DRC, HPV infection is a major concern, particularly due to the high prevalence of oncogenic

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types such as HPV 16 and 18, which are responsible for the majority of cervical cancer cases worldwide. Despite the burden, genotyping and systematic screening for HPV are rarely performed, especially in rural and underserved areas. Cytological screening programs are limited, with most diagnoses being made at advanced stages of the disease, contributing to high mortality rates [4].

According to the WHO, cervical cancer is a major public health issue, particularly in low- or middle-income countries. In 2022, it caused approximately 660,000 new cases and 350,000 deaths worldwide, representing over 90% of HPV-related cancers in women [5,6]. The inequality in access to vaccination and care exacerbates the situation, leading to a high mortality rate that could be preventable [7].

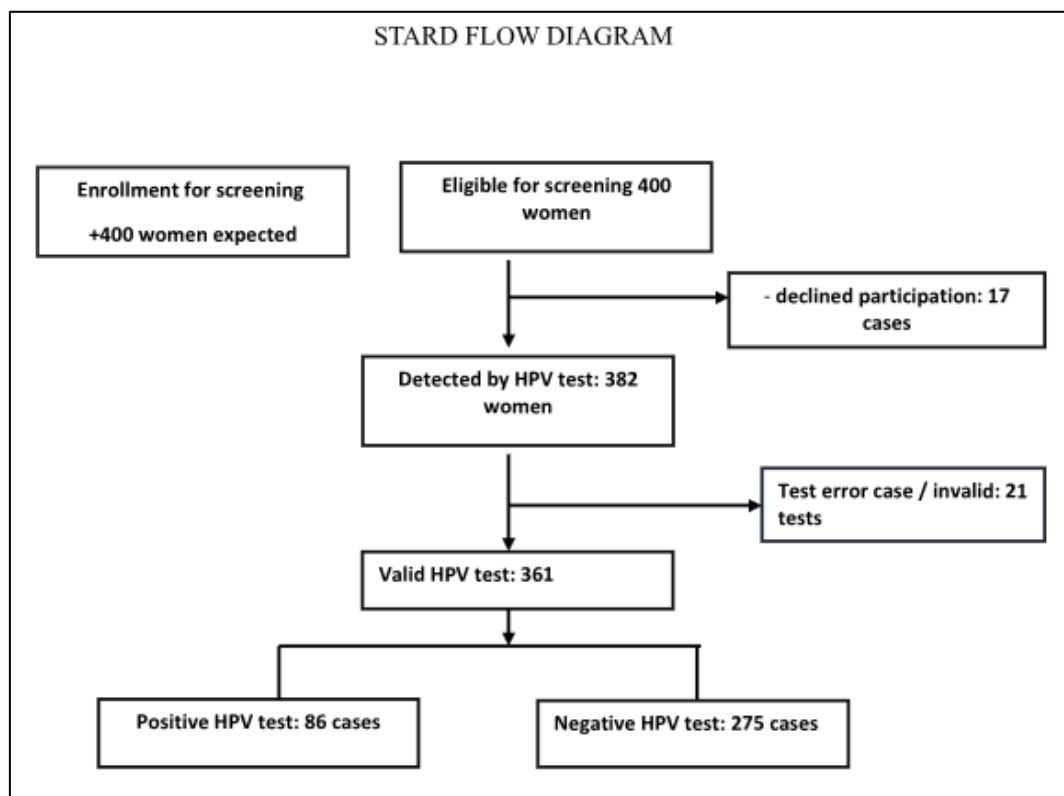
Indeed, although cervical cancer is the easiest to prevent, it remains the fourth most common malignant

tumor among women worldwide after breast, colorectal, and lung cancers. More than 85% of cervical cancer deaths occur in low- and middle-income countries [5].

In the Democratic Republic of Congo, cervical cancer is the most common cancer among women, with an estimated rate of 30-35 per 100,000 inhabitants. In this same region of the world, partial studies show high prevalences of HPV, with 28.2% in Kinshasa and 29% in South Kivu [5,8].

Given the high prevalence of HPV in the DRC and its importance for public health, this study was initiated to determine the epidemiology and clinical characteristics associated with Hr-HPV infection in the city of Mbujimayi in Kasai Oriental (DRC).

2. METHODS



• 2.1 Framework, type and study period

The study was conducted in Mbujimayi, the capital of the Kasai-Oriental province in the center of the DRC, in 3 hospital structures namely the Valentin Disashi Hospital, Mégumi Hospital Center, and the Pediatric and Maternity Clinic of Mbujimayi. The study was cross-sectional and analytical and took place over a period of 5 months, from January 20, 2025, to May 20, 2025. This duration includes the training of physicians, data collection, and the analysis of biological samples by PCR.

• 2.2 Study population and minimum sample size

We included non-pregnant women aged 30 to 65, regardless of their screening history, but with no history of invasive cervical cancer or total hysterectomy. The minimum sample size was calculated using Schwartz's formula, based on the prevalence of CIN2+ at 20% found in South Kivu by Olivier Nyakio (10), in the DRC. By adding 10% as a non-response rate, the minimum sample size of the study should be 270 cases.

• 2.3 Data Collection

Recruitment was conducted after a one-week awareness campaign. Women were contacted and invited to participate in the study based on the token number assigned upon their arrival at the hospital. The HPV test was conducted within 24 hours after obtaining the cervical sample, and the test results were available 48 hours later.

• 2.4 Collection of cervical samples

After providing their informed consent to participate, all eligible women underwent a gynecological examination. While the woman was lying in the lithotomy position on the examination table, a trained health worker inserted a Collin speculum into the vagina to visualize the cervix. The cervical sample was taken using the Cervex-Brush® (Rovers Medical Devices) with gentle rotational movements clockwise and then counterclockwise. The heads of the Cervex-Brush® were then transferred into a vial containing 20 ml of PreservCyt® (Hologic, Marlborough, MA) and stored for 24 hours at room temperature between 15 °C and 30 °C, according to the manufacturer's protocol. All collected samples were sent within 24 hours to the provincial public health laboratory for HPV testing.

• 2.5 HR HPV Screening Test

The HPV screening test was performed using the Xpert HPV IV gene by Cepheid®. The Xpert HPV test by Cepheid® is a qualitative in vitro test designed to detect the E6/E7 region of the viral DNA genome from high-risk human papillomavirus (HPV) in patient samples. The test performs a multiplex amplification of the target DNA through real-time polymerase chain reaction (PCR) for 14 types of HPV in a single analysis. The final categorical results were recorded as follows: "HPV 16; Primary" for HPV 16, "HPV18_45; Primary" for the grouped result of HPV types 18 or 45, "P3; Primary" for the grouped result of HPV types 31, 33, 35, 52 or 58, "P4; Primary" for the grouped result of HPV types 51 or 59, and "P5; Primary" for the grouped result of HPV types 39, 56, 66 or 68. The presence of a unique copy human gene and the adequate number of human cells have been detected to perform a qualitative assessment of HPV status. The processing of cervical samples was done in batches of 4 samples following these steps: first vortex the samples for 5 seconds at intermediate speed continuously. Then, transfer a 1 ml aliquot of the cervical sample directly into the Xpert cartridge while ensuring there are no air bubbles in the pipette.

• 2.6 Statistical Data Analysis

Statistical analyses were performed using R software version 4.5.1 (<https://cran.r-project.org/bin/windows/base/>). Categorical variables were summarized as frequencies and percentages. Calculations of the mean with standard deviations and the median with extremes were performed for

quantitative variables. To identify clinical characteristics associated with the risk of Hr-HPV infection, a multivariate logistic regression model was conducted. For the interpretation of statistical tests, a $p\text{-value} \leq 0.05$ was considered statistically significant.

• 2.7 Ethical considerations

This study was approved by the Ethics Committee of the University of Mbujimayi under number 001/CEI/UM/2025. Informed consent was obtained, and an identifier was assigned to all participants. The study was conducted in accordance with the requirements of good clinical practices and the principles of the Helsinki Declaration (2013) of the World Medical Association and relevant subsequent amendments.

3. RESULTS

3.1 Socio-demographic and anamnesis characteristics

During the 5-month screening period in Mbujimayi, a total of 382 women were screened. However, only 361 were retained after excluding cases of withdrawal from the study and invalid test cases. Table 1 presents the socio-demographic and anamnesis data of the screened women. The results show that more than half of the screened women (69.81%) were married and had attained secondary education level (67.04%). The majority of married women (60.32%) were in monogamous marriages. The average age of the participants was 47.15 ± 9.08 years, and the age group of 40-49 years was the most represented (39.89%). The anamnesis of the screened women showed that the majority of these women (54.85%) were grand multiparas and had had sexual intercourse with a single partner (59.56%).

3.2 The distribution of Hr-HPV types by age group among the participants

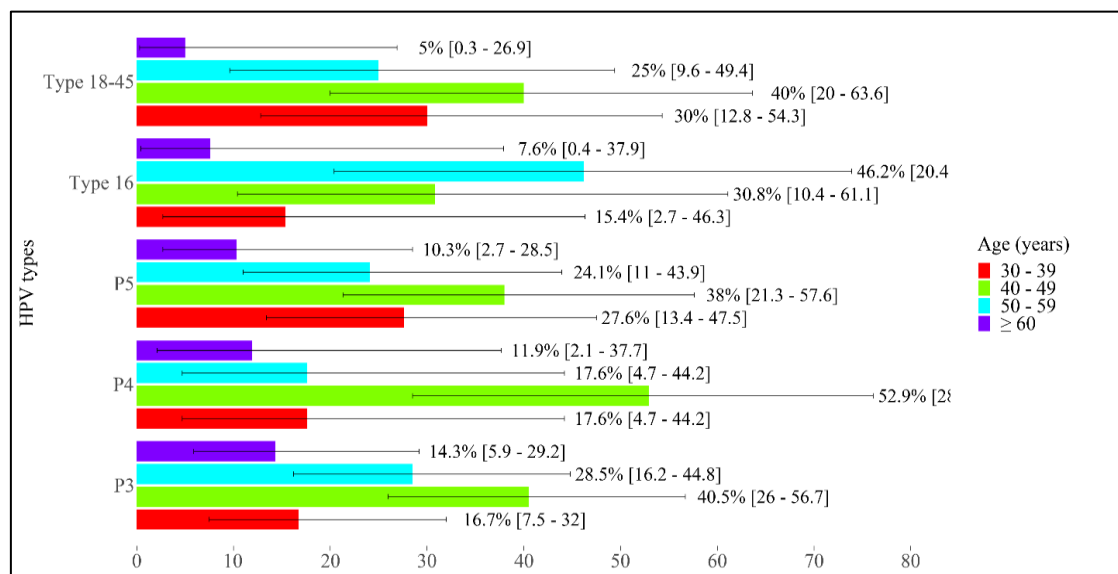
The age group of 40-49 years was the most affected by all types of Hr-HPV except for type 16, with types 51/59 (grouped in P4) at 52.9%; types 31/33/35/52/58 (grouped in P3) at 40.5%; types 18-45 at 40%; and types 39/56/66/68 (grouped in P5) at 38% (figure 1).

3.3 Clinical characteristics associated with Hr-HPV infection and the regression of infection based on age

As shown in figure 2, we observed a non-significant decrease starting at age 45 between HPV-HR infection and age. Among the symptoms, vaginal itching was the most reported symptom (44.2%) and cervicitis the most frequent physical sign (11.16%). Only contact bleeding during sexual intercourse was found to be a predictive clinical sign of Hr-HPV infection (OR at 95% 3.0 [1.3 – 6.9] 0.012) (table 2 and figure 3).

Table 1: Socio-demographic and anamnesis characteristics

Characteristics	N	%
Marital Status		
Single	3	0,83
Common-law union	17	4,71
Divorced	28	7,75
Widow	61	16,89
Married	252	69,81
Type of marriage		
Polygamous	100	39,68
Monogamous	152	60,32
Level of education		
None	2	0,55
Primary	94	26,04
Secondary	242	67,04
University	23	6,37
Profession		
Housewife	82	22,65
Non-liberal	128	35,36
Liberal	152	41,99
Age (year)		
30-39	79	21,88
40-49	144	39,89
50-59	94	26,04
≥ à 60	44	12,19
Average ± Standard deviation 47.15 ± 9.08		
Parity		
Nulliparous	17	4,71
Primiparous	12	3,32
Paucipare	20	5,54
Multiparous	114	31,57
Grand multiparous	198	54,85
Median number of children (Min - Max) 6 (0 - 14)		
Age at first birth (in years)		
Before 18 years	97	28,12
Old From 18 years old	248	71,88
Median (Min - Max) 20 (12 - 48)		
Number of partners in a lifetime		
1 partner	215	59,56
More than 1 partner	146	40,44
Median (Min - Max) 2 (1 - 8)		

**Figure 1: prevalence of high-risk HPV types by age group**

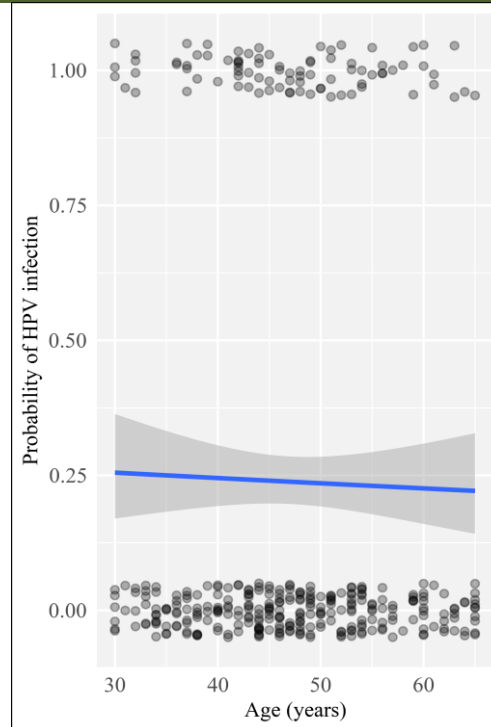


Figure 2: Regression of HR HPV based on age

Table 2: Prevalence of Clinical characteristics in Cases of Hr-HPV Infection (n=86)

Characteristics	N	%	
Symptoms			
Leukorrhea	38	44.2	
Vaginal pruritus	30	34.9	
Dyspareunia	29	33.7	
Bleeding during intimate bathing	11	12.8	
Bleeding during intercourse	9	10.5	
Physical signs			
Cervicitis	10	11.6	
Ectropion	8	9.3	
Nabothian eggs	4	4.7	
Condyloma	3	3.5	
Cervical polyp	2	2.3	
Prolapse	1	1.2	

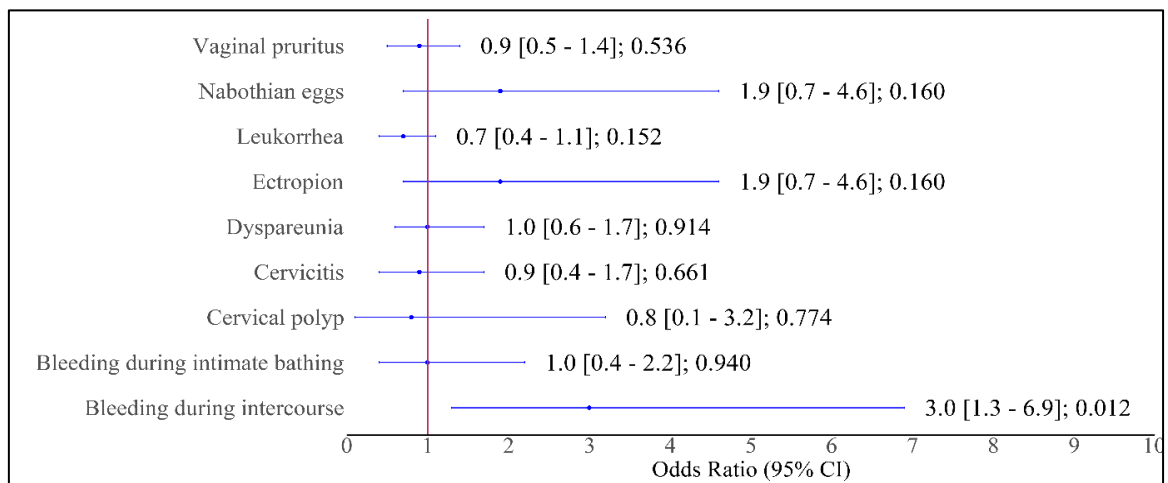


Figure 3: Clinical characteristics associated with Hr-HPV infection

4. DISCUSSION

The aim of this study was to determine the epidemiology and clinical characteristics associated with Hr-HPV infection in women aged 30-65 years in Mbuji mayi, DR Congo. This is the first study conducted in this city on high-risk HPV infection, with its strength lying in the test used for HPV detection, which is PCR.

4.1 Socio-demographic and anamnesis data of screened women

The analysis of socio-demographic and anamnesis data was a crucial aspect for understanding the difference in prevalence found in this study compared to those conducted by other researchers. More than half of the screened women (69.89%) were married. Most of them (67.13%) had achieved a secondary education level. The average age of the participants was 47.15 ± 9.08 years, and the age group of 40-49 years was the most represented (40.06%). The anamnesis of the screened women showed that the majority of the screened women (54.97%) were grand multiparas and that most women (59.67%) had sexual relations with a single partner. Our results are different from those of Traoré in Bobo-Dioulasso, Burkina Faso, regarding the average age of women (35.3 years) and the number of sexual partners (90.6%) in his series [9]. This difference could be explained by the fact that his study focused on the general population of sexually active women, whereas ours focuses on the target population for HPV screening according to WHO recommendations [6]. Nevertheless, our results are similar to those of Mutombo indicating an average age of 46 years (± 11.4 years), married women 64.1%, secondary education level 54%, and grand multiparous women 47% [5]. The similarity in education level could be explained by the fact that these two studies were conducted in cities where girls are encouraged to study, and for marriage status and the number of children by the fact that these studies are conducted in the same country where communities share almost the same cultural habits.

4.2 The distribution of HPV-Hr types by age group among participants

This study, based on a population of women aged 30 to 65 years, showed that the age group 40-49 was the most affected by the majority of Hr-HPV types, except for type 16, which affected the 50-59 age group in 46.2% of cases. These high prevalences, with a slight decline in the Hr-HPV infection rate with age, may reflect cumulative exposure over a lifetime and the vulnerability of the immune system to the persistence or reactivation of latent infection [10, 11, 12]. The high prevalences in the adult female population in this study may also raise the question of other factors associated with HPV infection in this study. The role of several risk factors is known in the transmission of HPV infection. In Jing Yang's study, the risk factors that contributed to the HPV infection rate included a low level of education, low income, smoking, age at first sexual intercourse under 23 years, and having three or more births [13]. In addition

to these factors, Gilbert Doh also found a significant relationship between HPV infection and having more than two partners in his series [14]. In the present study, this relationship was not investigated in order to explain these high prevalences according to age group.

Due to their strong association with cervical cancer and other anogenital cancers, HPV types 16, 18, and 45 are considered high-risk [15]. These strains contribute significantly to the global burden of HPV-related diseases, making them a major public health concern [16]. HPV16 and 18 infections account for 71% of cervical cancer cases, and this prevalence rises to 94% when HPV 45 is also included [17].

4.3 Clinical characteristics associated with Hr-HPV infection

According to clinical results, vaginal discharge, vaginal itching, and dyspareunia were the most common symptoms (44.2%, 34.9%, 33.7% respectively). While Bahadoran found frequent symptoms in his series to be bleeding during sexual intercourse and dyspareunia (36.5% and 34.9%) [15]. Precancerous and inflammatory lesions of the cervix explain this observation. In our study, only contact bleeding during sexual intercourse was found to be a predictive clinical sign of Hr-HPV infection (OR at 95% 3.0 [1.3 – 6.9] 0.012), increasing the positivity of the HPV test by 3 times. Indeed, Gadelha found that bleeding after sexual intercourse and dyspareunia were the most reported symptoms, showing a strong correlation with HPV infection. Positive PCR tests were 2.5 times more frequent in women suffering from dyspareunia and bleeding (RR 2.55, 95% CI 2.48-2.84, $P = 0.003$) [2]. The existence of bleeding is closely linked to the presence of high-grade intraepithelial lesions, which can be explained by the high degree of cellular changes [18,19]. Thus, in the presence of these signs, in low-income countries or in institutions where resources do not allow for screening, the implementation of a routine gynecological examination with visual inspection using acetic or Lugol's solution seems crucial from our perspective. Several studies have already shown in the past a positive correlation between positive PCR and positive visual inspection, cervical cytology, and reported symptoms [18,20]. The visual inspection test may be a useful alternative method for low-income populations in the poorest regions [2,15].

5. CONCLUSION

This study reports high prevalences of Hr-HPV infections in the adult female population, clearly indicating a health risk for women in the city of Mbuji mayi in the DRC. A positive correlation between Hr-HPV and genital bleeding during sexual intercourse highlights the need for a screening test tailored to local particularities and adversities. Therefore, it is crucial and urgent to implement a more effective program for the diagnosis of HPV, follow-up, and treatment of women with precancerous lesions of the cervix, as well as regular

prevention and health promotion actions for the population of the city of Mbujimayi.

Notes

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