

Revolutionising Cervical Cancer Screening: Role of Truenat HPV DNA Point-of-Care Testing

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Abstract

Background: Cervical cancer remains a major public health concern, particularly in resource-limited settings where delayed screening, reporting, and treatment contribute to preventable morbidity and mortality. High-risk human papillomavirus (HPV) DNA testing has emerged as an effective primary screening strategy, and point-of-care platforms may reduce loss to follow-up by enabling rapid clinical decision-making. **Objective:** This study aimed to evaluate the clinical performance, feasibility, turnaround time, and clinical utility of the Truenat HPV-HR assay, which detects HPV genotypes 16, 18, 31, and 45 only, for cervical cancer screening in a gynaecology outpatient setting. **Methodology:** A one-year hospital-based observational study was conducted in the Department of Obstetrics and Gynaecology at Regional Hospital Center of Saint-Louis, from 01/04/2024 to 31/03/2025. A total of 250 non-pregnant women were enrolled. The protocol targeted women aged 30 - 65 years; however, 27 enrolled participants were older than 65 years. Participants underwent Truenat HPV DNA testing using a portable point-of-care molecular platform detecting HPV genotypes 16, 18, 31, and 45. Colposcopy was performed in 40 participants and histopathology was available for 15 participants; clinical performance was estimated only within these selected subsets. A positive colposcopy was defined as finding abnormal cells on the cervix, vagina or vulva that require further investigation, typically via biopsy and a positive histopathology as cervical intraepithelial neoplasia grade 1 or worse (CIN1+); CIN grade 2 or worse (CIN2+) was analysed as an additional target condition. **Results:** Of the 250 participants, 31 (12.4%; 95% CI: 8.6% - 17.1%) tested positive for HPV 16/18/31/45. Among the 40 women who underwent colposcopy (30 of 31 HPV-positive and 10 of 219 HPV-negative women), sensitivity for a positive colposcopy was 93.3% (95% CI: 77.9% - 99.2%) and specificity 80.0% (44.4% - 97.5%). Among the 15 women with paired histopathology, sensitivity for CIN1+ was 92.3%

(64.0% - 99.8%) and specificity 50.0% (1.3% - 98.7%); for CIN2+, sensitivity was 88.9% (51.8% - 99.7%) and specificity 16.7% (0.4% - 64.1%). Because reference testing was performed almost exclusively in HPV-positive women, these estimates are subject to verification bias and are likely to overestimate sensitivity. HPV positivity was significantly associated with socioeconomic category, educational level, number of sexual partners, abnormal uterine bleeding, and post-coital bleeding. **Conclusion:** In this single-centre study, point-of-care Truenat testing was feasible and was linked to colposcopy and treatment of HPV-positive women. Because the assay detects only four high-risk HPV genotypes and its clinical performance was estimated in small, selectively verified subsets, these findings do not establish its performance as a general high-risk HPV primary screening test. Larger studies with verification of test-negative women are required.

Keywords

Cervical Cancer Screening, HPV, Truenat Testing

1. Introduction

Cervical cancer is a leading cause of morbidity and mortality for women globally, especially in low- and middle-income countries (LMICs), including Senegal, due to non-uniform access to organised screening, late diagnosis, poor follow-up, and limited access to preventive care [1]. High-risk human papillomavirus (HPV) infection is the major etiological factor in the process of cervical carcinogenesis and is responsible for almost all cervical cancer cases as well as a significant percentage of anogenital and oropharyngeal cancers [2]. HPV is a double-stranded DNA virus, infecting basal epithelial cells, especially in the transformation zone of the cervix, and can lead to premalignant changes of the epithelial cells over years [3]. This is a long latent period that offers a great chance for early detection and treatment before it becomes invasive carcinoma. High-risk HPV genotypes include HPV 16 and 18, which each make up a significant portion of cases of cervical cancer, as well as other oncogenic HPV genotypes such as HPV 31 and 45, which are also associated with cervical intraepithelial neoplasia (CIN) and invasive disease [4]. Persistent infection is associated with expression of viral oncoproteins E6 and E7, which are known to inhibit tumour suppressor pathways and affect normal cell-cycle regulation [5]. The natural history of cervical cancer has been recognised as a detectable premalignant phase, and effective screening measures can therefore significantly diminish the occurrence of cervical cancer and the associated mortality in conjunction with prompt diagnostic assessment and treatment.

Traditional screening practices for cervical cancer, such as cytology (Papanicolaou testing) and visual inspection with acetic acid, have led to a decrease in the burden of cervical cancer in many settings, but require trained staff, laboratory

resources, multiple visits, and effective follow-up services [6]. Meeting these requirements can be challenging in low-resource areas where women may be experiencing financial, geographical, social, and healthcare access barriers. Therefore, high-sensitivity HPV DNA testing is now a preferred primary screening method since it detects high-risk HPV infection before cells start to change, and offers greater long-term protection against invasive cervical cancer [7]. HPV-based screening also allows for longer screening intervals, especially in women over 30 years of age, who are more likely to have a persistent infection than a transient one.

The World Health Organisation (WHO) has set the ambitious goal of eliminating cervical cancer through its worldwide 90-70-90 targets, which involve achieving 90% HPV vaccination coverage for girls, 70% screening coverage of women with a high-performance test, and 90% treatment coverage for women diagnosed with HPV precancer or cervical cancer [8]. To reach these goals, the screening models must be accurate, accessible, affordable, and able to reduce loss of follow-up. In particular, “screen-and-treat” approaches are relevant in this context because eligible women can be provided with a diagnosis and treatment during the same clinical visit or within a short time [9]. These strategies are particularly relevant in areas where there may be delayed reporting or multiple referral visits creating missed treatment opportunities.

The portability, relative simplicity, and lack of elaborate infrastructure compared to some of the ablative techniques have made thermal ablation a growing treatment modality for eligible cervical precancerous lesions [10]. Thermal ablation is a procedure that treats abnormal tissue by a controlled application of heat and may be performed at the same visit as a positive screening test. It offers operational benefits and can be used in low-resource clinical environments and in decentralized care provision. In addition, point-of-care molecular platforms could reduce the delays between specimen collection and reporting, clinical triage and treatment. Truenat HPV-HR is a micro-real-time PCR test that can be performed on site to detect four high-risk HPV genotypes: HPV 16, 18, 31 and 45 [11] [12]. Because it does not detect the other high-risk genotypes, it is a partial genotyping assay rather than a full high-risk HPV test, and its clinical performance cannot be assumed to be equivalent to that of clinically validated high-risk HPV assays. Its short run time could potentially support same-day counselling, colposcopy (where appropriate) and immediate treatment for women who meet the criteria. This could result in increased screening rates, reduced loss of patients to follow-up care, and allow HPV screening to be provided in areas where a laboratory is not available.

2. Objectives of the Study

The primary objective of this study was to evaluate the clinical performance and clinical utility of point-of-care (POC) Truenat HPV DNA testing, which detects high-risk HPV genotypes 16, 18, 31, and 45, for identifying women with colpo-

scopic abnormalities and histologically confirmed CIN among women undergoing cervical cancer screening. Secondary objectives were to measure the sampling-to-result and screening-to-treatment intervals, the feasibility of same-day clinical triage and management, including thermal ablation or excisional treatment when clinically indicated, and the potential utility of an HPV-based screen-and-treat approach for early detection and timely management of cervical precancer in a resource-limited gynaecology outpatient setting.

3. Materials & Methods

3.1. Study Design and Setting

This was an observational, patient-based study conducted in the Department of Obstetrics and Gynaecology, Regional Hospital Center of Saint-Louis. Participants were recruited from women attending the Obstetrics and Gynaecology outpatient department during the study period from 01/04/2024 to 31/03/2025. Eligible women were enrolled after assessment against the predefined inclusion and exclusion criteria and after obtaining written informed consent. The study was conducted following approval from the Research & Ethics Committee on 22/03/2024 (Letter No. DMCH/P/2024/239; Ref. No. DMCH/476-2023(4580)).

3.2. Study Population

A screening for eligibility was carried out among women attending the gynaecology outpatient department during the study period. The protocol targeted the recommended population for HPV-based cervical cancer screening, women aged 30 - 65 years (see Inclusion and Exclusion Criteria for the 27 participants older than 65 years who were nevertheless enrolled). Written informed consent was obtained, and women who met the criteria were enrolled. A detailed history was taken, and general, systemic, and gynecological examinations were done. A structured data collection schedule was used to record demographic characteristics, reproductive history, clinical symptoms, vaccination status, and pertinent risk factors.

3.3. Sample Size Calculation

The sample size was calculated based on an expected prevalence of high-risk HPV of 50%, with a 95% confidence level and an absolute precision of 6.2%, using the single-population proportion formula: $n = Z^2 p(1-p)/d^2$, where n is the minimum required sample size; Z is the standard normal deviate corresponding to the selected confidence level ($Z = 1.96$ for a 95% confidence level); p is the expected prevalence of high-risk HPV (0.50); $(1-p)$, or q , is the complementary proportion (0.50); and d is the absolute precision or margin of error (0.062). The level of significance was $\alpha = 0.05$. Substitution of these values yielded a minimum required sample size of approximately 250 participants ($1.96^2 \times 0.25/0.062^2 = 249.8$). No additional allowance for potential non-response or incomplete data was applied.

3.4. Inclusion and Exclusion Criteria

The protocol inclusion criterion was non-pregnant women aged 30 - 65 years. Exclusion criteria were pregnancy, delivery within the previous 6 weeks, age over 65 years, and a history of cervical cancer or hysterectomy. Although age over 65 years was a protocol exclusion criterion, 27 enrolled participants (23 HPV-negative and 4 HPV-positive; **Table 1**) were older than 65 years. These participants were retained in all analyses so that the results describe the population actually tested. These criteria were used to ensure that women in the study were a representative sample of women who could receive routine cervical cancer screening, and that none of the women in the study was confounded by factors that could affect the cervical assessment, HPV testing, colposcopy findings, or treatment decision.

3.5. Screening Procedure and Clinical Management

The cervical screening was performed with the Truenat HPV DNA test from Molbio Diagnostics. The assay was used as a point-of-care molecular test for HPV genotypes 16, 18, 31, and 45; other high-risk genotypes are not detected, so a negative result does not exclude infection with them. Following sampling, the test results were analysed, and women with HPV-positive results were provided with a screen-and-treat approach. Participants requiring further evaluation based on the screening pathway and clinical indications underwent colposcopy as needed; this included HPV-positive participants and other participants in whom colposcopic assessment was clinically indicated. Eligible patients were offered thermal ablation at the screening visit and, based on clinical examination and colposcopic findings, underwent excisional treatment or biopsy when indicated.

3.6. Definitions of Positive Reference-Test Results

Colposcopy. Colposcopy was classified as positive when we found abnormal cells on the cervix, vagina or vulva that require further investigation, typically via biopsy, and as negative otherwise.

Histopathology. Histopathology was classified as positive when CIN1 or worse (CIN1+) was reported, and as negative when the specimen showed normal epithelium or acute cervicitis. This is the definition consistent with the counts: the 12 true positives correspond to the HPV-positive participants with CIN1 ($n = 4$), CIN2 ($n = 6$) or CIN3 ($n = 2$); the false positive to the HPV-positive participant with acute cervicitis; the false negative to the HPV-negative participant with CIN2; and the true negative to the HPV-negative participant with acute cervicitis. Because CIN2 or worse (CIN2+) is the usual treatment threshold and the target condition in cervical screening accuracy studies, performance against histopathology was additionally calculated with CIN2+ as the target condition (CIN1, acute cervicitis and normal classified as negative). The target condition for the colposcopy comparison is a colposcopic abnormality, not histologically confirmed disease.

3.7. Data Collection and Follow-Up

A pre-tested and structured schedule was designed based on the study objectives and was used to collect data. Demographic profile, presenting symptom, HPV test result, time between sampling and reporting, colposcopy result, treatment modality, biopsy status, and histopathology result were documented. The collected data were entered into the study dataset and analysed using the predefined statistical methods described below. Two intervals were recorded to examine operational feasibility: the sampling-to-result interval (from specimen collection to availability of the Truenat result) and the screening-to-treatment interval (from the screening visit to the date of treatment). The response to the treatment and the clinical outcome were evaluated at the 6-week follow-up visit.

3.8. Outcome Measures

The main outcome was the clinical performance of point-of-care (POC) HPV DNA testing for screening and management of cervical precancerous lesions. The sensitivity, specificity, positive and negative predictive value, likelihood ratios, and general accuracy of the tests were used to evaluate their clinical performance. Where applicable, the test was compared against colposcopy and histopathology results. Secondary outcomes were the sampling-to-result and screening-to-treatment intervals, feasibility of same-day management, response to treatment following thermal ablation or surgical resection, and the clinical value of the screen-and-treat approach in a resource-poor clinical setting.

3.9. Diagnostic Performance Assessment

The clinical performance of the Truenat HPV DNA test was evaluated separately against colposcopy and histopathology using 2×2 contingency tables. Results were classified as true positive (TP), false positive (FP), true negative (TN), and false negative (FN). Sensitivity was calculated as $TP/(TP + FN)$, specificity as $TN/(TN + FP)$, positive predictive value (PPV) as $TP/(TP + FP)$, negative predictive value (NPV) as $TN/(TN + FN)$, positive likelihood ratio (LR+) as $sensitivity/(1 - specificity)$, negative likelihood ratio (LR-) as $(1 - sensitivity)/specificity$, and overall accuracy as $(TP + TN)/(TP + TN + FP + FN)$. Diagnostic estimates were reported with 95% confidence intervals (exact Clopper-Pearson intervals for sensitivity, specificity, prevalence and accuracy; logit intervals for predictive values; log intervals for likelihood ratios). Agreement between Truenat HPV DNA testing and the reference methods was additionally assessed using Cohen's kappa coefficient. Reference tests were not applied to all participants: they were applied to almost all HPV-positive women but only to HPV-negative women with a clinical indication. The estimates therefore apply only to the verified subsets and are subject to partial verification bias, which tends to overestimate sensitivity and underestimate specificity; no correction for verification bias was applied.

3.10. Statistical Analysis

Categorical variables were summarised as frequencies and percentages, whereas continuous variables were summarised as mean $\pm$ standard deviation or median with interquartile range, as appropriate. Normality of continuous variables was assessed using the Kolmogorov-Smirnov test or the Shapiro-Wilk test. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate, with Fisher's exact test applied when expected cell frequencies were less than 5. Agreement between Truenat HPV DNA testing and the reference methods was assessed using Cohen's kappa coefficient. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). A two-tailed p-value <0.05 was considered statistically significant.

4. Results

4.1. Study Population and HPV Status

A total of 250 non-pregnant women were enrolled and categorised according to Truenat HPV DNA results. Participants in Group A were HPV negative ($n = 219$, 87.6%), and Group B were positive for HPV 16, 18, 31 and/or 45 ($n = 31$; 12.4%, 95% CI: 8.6% - 17.1%). Twenty-seven participants (10.8%) were older than 65 years (see Methods). The flow of participants through HPV testing, colposcopy, biopsy, histopathology and treatment is shown in **Table 1**. No significant differences in age distribution were observed between the groups, suggesting that age did not significantly affect HPV status in this group. The baseline sociodemographic and behavioural characteristics (age group, socioeconomic status, schooling, sexual debut, and sexual partners) are given in **Table 2**.

Table 1. Participant flow.

Stage	Truenat HPV-negative (Group A)	Truenat HPV-positive (Group B)
Enrolled: 250 (27 aged >65 years)	219	31
Colposcopy performed ($n = 40$)	10 (4.6%)	30 (96.8%); 1 without colposcopy
Colposcopy positive ($n = 30$)	2	28
Immediate biopsy ($n = 16$)	2	14
Evaluable histopathology ($n = 15$)	2	13; 1 biopsy without evaluable result
Histopathology result	Acute cervicitis 1; CIN2 1	Acute cervicitis 1; CIN1 4; CIN2 6; CIN3 2
Included in paired histopathology analysis ($n = 15$)	2 (1 TN, 1 FN)	13 (12 TP, 1 FP)
Treatment	Excision 1	Excision 14; thermal ablation 16; treatment status of 2 women unexplained (see Table 3)

Table 2. Comparison of socio-demographic and behavioural characteristics between Group A and Group B. Group A: Truenat HPV DNA-negative participants (n = 219); Group B: Truenat HPV DNA-positive participants (n = 31). Pearson's chi-square test was used for comparisons. A p-value <0.05 was considered statistically significant.

Age group (Years)	Group A n	%	Group B n	%	Chi-square	p-value
30 - 45	118	53.9%	18	58.1%	0.571	0.752
46 - 65	78	35.6%	9	29.0%		
>65 (protocol deviation—see Methods)	23	10.5%	4	12.9%		
Socio-economic status					45.3266	0.001
Lower	27	12.3%	8	25.8%		
Upper lower	38	17.4%	2	6.5%		
Lower middle	30	13.7%	18	58.1%		
Upper middle	51	23.3%	2	6.5%		
Upper	73	33.3%	1	3.2%		
Highest level of education					33.8997	0.001
Primary School	37	16.9%	1	3.2%		
Secondary	28	12.8%	2	6.5%		
High School	43	19.6%	7	22.6%		
Undergraduate	38	17.4%	19	61.3%		
Graduate	73	33.3%	2	6.5%		
Age at first sexual intercourse (years)					3.584	0.167
<20	51	23.3%	12	38.7%		
21 - 25	125	57.1%	15	48.4%		
>25	43	19.6%	4	12.9%		
No. of sexual partners					19.972	0.001
1	142	64.8%	8	25.8%		
2	73	33.3%	20	64.5%		
3	4	1.8%	3	9.7%		
>3	0	0.0%	0	0.0%		

4.2. Sociodemographic and Behavioural Characteristics

Socio-economic status, level of education, and number of sexual partners were significantly associated with HPV positivity. HPV-positive participants were concentrated in the lower-middle socioeconomic category (58.1% vs 13.7% of HPV-negative participants) and among those with undergraduate education (61.3% vs 17.4%). These associations did not follow a consistent gradient across categories

and should be interpreted with caution given the small number of HPV-positive participants. HPV positivity was linked to an increased number of sexual partners, thus reinforcing the importance of sexual behaviour in the acquisition of high-risk HPV. No significant associations were found between age at sexual debut and HPV status. These results suggest that there were closer associations between social and behavioural determinants and HPV positivity than age-related factors.

4.3. Genital Symptoms and Vaccination Status

Abnormal uterine bleeding and post-coital bleeding were significantly associated with HPV positivity and could be useful to consider proper molecular screening and further evaluation in these cases. There was no significant association between other genital symptoms (vaginal discharge, lower abdominal pain, or difficulty with penetration) and HPV status. The groups were very different in terms of HPV vaccination status, as HPV vaccination was only seen in HPV-negative women. **Table 3** shows the comparison of genital symptoms and HPV vaccination profile between the two study groups.

Table 3. Comparison of genital symptoms and vaccination profile between Group A and Group B. AUB: abnormal uterine bleeding. Group A: Truenat HPV DNA-negative participants; Group B: Truenat HPV DNA-positive participants. Pearson's chi-square test was used for comparisons. A p-value <0.05 was considered statistically significant.

Genital symptoms/Vaccination profile	Group A n	%	Group B n	%	Chi-square	p-value
Vaginal discharge	22	10.0%	3	9.7%	0.004	0.949
AUB	15	6.8%	28	90.3%	132.862	0.001
Lower abdominal pain	17	7.8%	2	6.5%	0.066	0.797
Dyspareunia	21	9.6%	3	9.7%	0.000	0.988
Post coital bleeding	9	4.1%	22	71.0%	111.750	0.001
HPV vaccine	170	77.6%	0	0.0%	75.200	0.001

4.4. Screening, Clinical Examination, and Colposcopic Assessment

The participants were tested with HPV DNA testing (Truenat). There was no significant difference between women who were HPV negative and HPV positive when the findings of routine per speculum examination were compared; this suggests that visual clinical examination is of limited value for identifying an HPV infection. HPV-positive women were more likely to undergo colposcopy (30/31, 96.8% vs 10/219, 4.6%), which largely reflects the study pathway, since HPV-positive women were referred for colposcopy by design. HPV positive participants had higher Swede scores, but clinical examination and score patterns were not good substitutes for molecular screening.

4.5. Treatment Method and Response

HPV-positive women were more likely to need therapeutic interventions. Both

excision and thermal ablation were significantly associated with HPV positivity, reflecting a process of clinical triage that occurred after molecular screening and colposcopy. Among the 31 HPV-positive women, 14 excisions and 16 thermal ablations were recorded (30 procedures), whereas 28 women were recorded as treated and 1 as not treated (29 women). The treatment status of the remaining 2 HPV-positive women is therefore not accounted for. A favourable response at 6 weeks was observed (**Table 4**).

Table 4 shows the distribution of treatment methods and response to treatment.

Table 4. Comparison of treatment method and response between Group A and Group B. Group A: Truenat HPV DNA-negative participants; Group B: Truenat HPV DNA-positive participants. The rows added in yellow must be completed so that the treatment and response sections each account for all 31 HPV-positive women; the two “as originally reported” rows should then be deleted. A chi-square of 7.093 with 1 degree of freedom corresponds to $p = 0.008$, not 0.124; with counts of 0 and 1, Fisher’s exact test should be used.

Treatment	Group A n	%	Group B n	%	Chi-square	p-value
Excision	1	0.5%	14	45.2%	96.226	0.001
Thermal ablation	0	0.0%	16	51.6%	120.761	0.001
Treated (as originally reported)	1	0.5%	28	90.3%	213.868	0.001
Not treated (as originally reported)	0	0.0%	1	3.2%	7.093	

4.6. Biopsy and Histopathological Findings

Women with HPV were more likely to have an immediate biopsy performed (14/31 vs 2/219), and this is likely due to the greater clinical suspicion and requirement for tissue confirmation within this group. Sixteen immediate biopsies were performed, and evaluable histopathology was reported for 15 participants: 2 HPV-negative (acute cervicitis 1, CIN2 1) and 13 HPV-positive (acute cervicitis 1, CIN1 4, CIN2 6, CIN3 2). These 15 participants constitute the paired histopathology analysis. CIN of any grade was found in 12 of the 31 HPV-positive participants (38.7%) and CIN2+ in 8 (25.8%). The row labelled “Normal” (18 HPV-positive participants, 0 HPV-negative participants) exceeds the number of HPV-positive participants biopsied and therefore cannot represent normal histopathology in all 18. The results of biopsies and histopathology are displayed in **Table 5**.

4.7. Diagnostic Performance against Colposcopy

Of the 250 participants, colposcopy was performed in 40 (16.0%): 30 of the 31 HPV-positive women and 10 of the 219 HPV-negative women (4.6%), the latter selected on clinical grounds. The analysis against colposcopy was therefore restricted to these 40 participants. The 2×2 table (**Table 6**) shows 28 true-positive, 2 false-positive, 8 true-negative, and 2 false-negative results, giving a sensitivity of 93.3% (95% CI: 77.9% - 99.2%), a specificity of 80.0% (44.4% - 97.5%) and a neg-

ative likelihood ratio of 0.08 (0.02 - 0.33). These estimates must be interpreted with caution. First, colposcopic abnormality is a clinical impression, not a reference standard for HPV infection or for CIN. Second, because nearly all HPV-positive women but fewer than 5% of HPV-negative women were examined, the comparison is subject to partial verification bias, which is expected to overestimate sensitivity; the true number of colposcopic abnormalities among the 209 unexamined HPV-negative women is unknown. Third, the disease prevalence in this subset (75.0%) reflects selection and not the screening population, so the predictive values cannot be transferred to population screening.

Table 5. Comparison of biopsy and histopathological findings between Group A and Group B. CIN: cervical intraepithelial neoplasia. Group A: Truenat HPV DNA-negative participants; Group B: Truenat HPV DNA-positive participants. Pearson's chi-square test was used for comparisons. A p-value <0.05 was considered statistically significant.

	Group A n	%	Group B n	%	Chi-square	p-value
Immediate biopsy	2	0.9%	14	45.2%	88.756	0.001
Histopathology					84.489	0.001
Acute cervicitis	1	0.5%	1	3.2%		
CIN-1	0	0.0%	4	12.9%		
CIN-2	1	0.5%	6	19.4%		
CIN-3	0	0.0%	2	6.5%		
Normal	0	0.0%	18	58.1%		
Total with evaluable histopathology	2		13			

Table 6. Two-by-two contingency table for Truenat HPV DNA testing compared with colposcopy. TP: true positive; FP: false positive; TN: true negative; FN: false negative.

Colposcopy result	Truenat HPV DNA negative	Truenat HPV DNA positive	Total
Negative	8 (TN)	2 (FP)	10
Positive	2 (FN)	28 (TP)	30
Total	10	30	40

4.8. Diagnostic Performance against Histopathology

Histopathology was available for 15 participants (13 of 31 HPV-positive and 2 of 219 HPV-negative) who underwent tissue sampling on clinical grounds. With CIN1+ as the positive result, the 2×2 table (**Table 7(a)**) shows 12 true-positive, 1 false-positive, 1 true-negative, and 1 false-negative result: sensitivity 92.3% (95% CI: 64.0% - 99.8%) and specificity 50.0% (1.3% - 98.7%). With only two histology-negative participants, specificity is essentially uninformative, and the prevalence of disease in this subset (86.7%) reflects selection. With CIN2+ as the target con-

dition (**Table 7(b)**); derived from the histopathology categories in **Table 5**), there were 8 true-positive, 5 false-positive (4 CIN1 and 1 acute cervicitis), 1 true-negative, and 1 false-negative result: sensitivity 88.9% (51.8% - 99.7%), specificity 16.7% (0.4% - 64.1%), PPV 61.5%, and overall accuracy 60.0% (32.3% - 83.7%) (**Table 7(b)**). These data are insufficient to estimate the performance of the assay for CIN2+ in a screening population and do not confirm its accuracy against histopathology.

The clinical performance measures derived from these 2×2 contingency tables, including sensitivity, specificity, likelihood ratios, predictive values, disease prevalence in the verified subset, and overall accuracy, are presented in **Table 7(b)**.

Table 7. (a) Two-by-two contingency tables for Truenat HPV DNA testing compared with histopathology (n = 15). TP: true positive; FP: false positive; TN: true negative; FN: false negative. Panel (b) is derived from the histopathology categories reported in **Table 5**. (b) Clinical performance of the Truenat HPV DNA test compared with colposcopy and histopathology, value (95% CI). Estimates are restricted to the selectively verified subsets and are subject to partial verification bias; they are not population screening estimates. The CIN2+ column was calculated from **Table 7(b)** with the same methods that reproduce the published colposcopy and CIN1+ columns (exact Clopper-Pearson for proportions, logit for predictive values, log method for likelihood ratios).

(a)			
CIN1+ as positive	Truenat HPV DNA negative	Truenat HPV DNA positive	Total
Negative	1 (TN)	1 (FP)	2
Positive	1 (FN)	12 (TP)	13
Total	2	13	15
(b) CIN2+ as positive			
Negative (normal, cervicitis, CIN1)	1 (TN)	5 (FP)	6
Positive (CIN2, CIN3)	1 (FN)	8 (TP)	9
Total	2	13	15
(b)			
Diagnostic parameter	Colposcopy (n = 40)	Histopathology, CIN1+ (n = 15)	Histopathology, CIN2+ (n = 15)
Sensitivity	93.33% (77.93 - 99.18)	92.31% (63.97 - 99.81)	88.89% (51.75 - 99.72)
Specificity	80.00% (44.39 - 97.48)	50.00% (1.26 - 98.74)	16.67% (0.42 - 64.12)
Positive likelihood ratio	4.67 (1.35 - 16.18)	1.85 (0.46 - 7.45)	1.07 (0.70 - 1.63)
Negative likelihood ratio	0.08 (0.02 - 0.33)	0.15 (0.01 - 1.59)	0.67 (0.05 - 8.73)
Disease prevalence in verified subset	75.00% (58.80 - 87.31)	86.67% (59.54 - 98.34)	60.00% (32.29 - 83.66)
Positive predictive value	93.33% (80.15 - 97.98)	92.31% (74.84 - 97.98)	61.54% (51.10 - 71.01)
Negative predictive value	80.00% (50.30 - 94.05)	50.00% (8.80 - 91.20)	50.00% (7.10 - 92.90)
Accuracy	90.00% (76.34 - 97.21)	86.67% (59.54 - 98.34)	60.00% (32.29 - 83.66)

4.9. Agreement Analysis

Agreement between Truenat HPV DNA testing and the reference methods was assessed using Cohen's kappa coefficient. Agreement with colposcopy was $\kappa = 0.733$ ($p < 0.001$), while agreement with histopathology was $\kappa = 0.423$ ($p = 0.101$) for CIN1+ and $\kappa = 0.06$ ($p = 0.76$) for CIN2+. The corresponding agreement results are presented in **Table 8**.

Table 8. Agreement between Truenat HPV DNA testing and reference methods using Cohen's kappa coefficient. κ : Cohen's kappa coefficient. A p-value < 0.05 was considered statistically significant. The CIN2+ row was calculated with the same asymptotic test that reproduces the published p-value for CIN1+ (0.101).

Reference method	Number of paired observations	Cohen's κ	p-value
Colposcopy	40	0.733	< 0.001
Histopathology (CIN1+)	15	0.423	0.101
Histopathology (CIN2+)	15	0.063	0.756

5. Discussion

The present study suggests that point-of-care HPV DNA testing can be used clinically as a component of an integrated cervical cancer screening and management approach. Because the study had no comparator arm, it cannot show that this pathway shortened the diagnostic-therapeutic interval relative to conventional screening; it can only describe the intervals observed. Given the current global priorities in cervical cancer elimination, which focus on high-performance screening, early diagnosis, and completion of treatment, portable molecular platforms could facilitate timely triage and management [13]. The protocol targeted the recommended age range for HPV-based cervical cancer screening, in which high-risk HPV infection is more clinically significant than transient infection, although 27 participants older than 65 years were enrolled. The age range was not significantly associated with HPV positivity, and HPV screening should be performed for all eligible women and not just specific age groups. This is not unexpected because clinical signs of persistent infection can be latent for many years, which is a pre-invasive stage, followed by development of CIN and/or further invasive disease [14].

Socio-economic and educational factors were significantly related to HPV positivity status, suggesting that factors linked to social determinants may also be important in determining the risk of developing cervical cancer and access to screening. In this all-female cohort, HPV-positive participants were concentrated in the lower-middle socioeconomic category and among women with undergraduate education. Because these associations did not follow a consistent gradient, they may reflect confounding or the characteristics of the women attending this clinic rather than a graded effect; financial or educational barriers and underuse of preventive services may contribute to delayed screening and persistent infection [15].

Additionally, educational status can influence HPV knowledge, HPV vaccine uptake, availability of HPV screening, and prompt health-seeking. The findings here emphasise the need for screening methods that would be available and feasible in different socioeconomic groups [16].

HPV positivity in this cohort was also associated with behavioural factors. The number of sexual partners was significantly associated with HPV status, but age at first sex was not. This pattern is consistent with an established association between sexual exposure and the acquisition of high-risk HPV, and suggests that individual risk assessment cannot be made based on a single behavioural variable [17]. Molecular screening offers an objective and standardised approach to identifying women at risk, which may be under-reported in the clinical setting, regardless of how the information is disclosed or if there are any visible cervical features [18]. HPV positivity was not significantly related to lifestyle factors in this study (smoking, alcohol and oral contraceptive use). This indicates that the increased risk of HPV detection among this sample was more correlated with sociodemographic and sexual-behavioural factors than with general lifestyle factors. The lack of family history of cervical cancer also supports the predominant role of the persistent high-risk HPV infection in the process of cervical carcinogenesis as opposed to hereditary predisposition. These results support the need for HPV screening, rather than selective screening based on family history, symptoms, or observed clinical changes among eligible women [19].

Clinical symptoms were found to be relevant in varying degrees. Abnormal uterine bleeding and post-coital bleeding were significantly associated with HPV infection and should lead to a careful evaluation of the cervix and molecular testing. No significant associations were observed with other symptoms such as vaginal discharge, lower abdominal pain, or dyspareunia. Most women (50 per cent or more) on examination showed no signs of anything unusual, supporting the minimal utility of routine visual examination for HPV-associated precancer. As a result, HPV testing using molecular techniques is more reliable as a primary screening test to detect clinically relevant infection before any cervical abnormalities are apparent [20].

HPV vaccination status was significantly related to HPV negativity, which is consistent with the protective effects of HPV vaccination in HPV-related cancers. Increased vaccination coverage among the HPV-negative population shows the clinical relevance of preventive counselling, institutional accessibility, and awareness-based interventions. Vaccination and molecular screening can be considered complementary strategies in the context of cervical cancer elimination targets. Vaccination lowers risk to future generations, and HPV DNA testing is used to identify women who have a high risk of clinically relevant infection and thus need timely evaluation [21]. The strong association between HPV positivity and colposcopy referral is largely a consequence of the study design, since HPV-positive women were referred systematically. Clinical scoring alone was not enough to replace the molecular testing, as higher Swede scores were more common among

HPV-positive women. Histopathology reported CIN in 12 of the 31 HPV-positive participants (38.7%), including CIN2 or CIN3 in 8 (25.8%); the remaining HPV-positive participants either had no CIN on biopsy or had no histopathological assessment. The pathway initiated by HPV testing identified women with clinically relevant precancerous lesions (CIN2 and CIN3) who required colposcopy, biopsy, or treatment [22] [23].

Therapy was given to eligible women with thermal ablation or excision as clinically indicated. Thermal ablation is particularly important in the context of limited resources as it can be performed using limited resources and can be combined with the screen-and-treat approach if the eligibility criteria are fulfilled [24] [25]. A favourable response at 6 weeks was observed in treated HPV-positive women; the treatment status of 2 HPV-positive women remains to be reconciled (Table 4), and 6 weeks is too short to assess recurrence or HPV clearance.

The Truenat HPV DNA test showed high sensitivity against colposcopy (93.3%) and against CIN1+ histopathology (92.3%) in the verified subsets. These estimates, however, derive from 40 and 15 selected participants, respectively, with reference testing concentrated among test-positive women, a pattern expected to inflate sensitivity [26]. Specificity against histopathology could not be estimated reliably (two histology-negative participants), and with CIN2+ as the target condition specificity was 16.7% and overall accuracy 60.0%. The low negative likelihood ratio against colposcopy therefore cannot be taken as evidence that the assay is suitable as a rule-out test in population screening. Moreover, because the assay detects only HPV 16, 18, 31 and 45, these results do not establish its performance as a general high-risk HPV screening test: women infected with other high-risk genotypes would test negative. Histopathology remains the reference standard for cervical precancer, and a study in which a random sample of test-negative women also undergoes colposcopy and biopsy would be required to estimate clinical sensitivity and specificity for CIN2+ [27].

6. Strengths, Limitations and Future Recommendations

This study has several strengths, including the use of a rapid point-of-care molecular HPV testing platform, assessment of clinical performance against colposcopy and histopathology, evaluation of same-day clinical management, and inclusion of operational outcomes such as reporting time and treatment response. These features provide clinically relevant information regarding the feasibility of integrating Truenat HPV DNA testing into cervical cancer screening pathways.

There are some limitations to this study. The study was performed at one hospital and may be non-generalizable to community-based and rural screening environments. Reference testing was incomplete and selective: colposcopy was performed in 40 of 250 participants and histopathology was available for 15, almost all of them HPV-positive, so the performance estimates are subject to partial verification bias and have wide confidence intervals. The assay detects only four high-risk genotypes, so its results cannot be generalised to high-risk HPV testing as a

whole. Twenty-seven participants were older than the protocol age limit of 65 years. The accounting of treatment status for 2 HPV-positive women is incomplete. The follow-up was relatively short (6 weeks), limiting the evaluation of recurrent lesions, long-term treatment results, and HPV clearance. No formal cost-effectiveness evaluation was performed.

Future studies should include larger, multicenter cohorts from urban, semi-urban, and rural populations to strengthen external validity, with colposcopy and biopsy in all test-positive women and in a random sample of test-negative women, CIN2+ as the pre-specified target condition, and comparison with a clinically validated full-genotype high-risk HPV assay. To assess outcomes, recurrence and HPV persistence, longer follow-up is suggested. A formal cost-effectiveness analysis should be done and compared to cytology and/or other HPV testing platforms for Truenat HPV DNA testing. Programmatic studies should also evaluate the integration of workflow, training of providers, acceptability to patients, and implementation in a public health screening service.

7. Conclusion

In this single-centre study, point-of-care Truenat HPV testing for genotypes 16, 18, 31 and 45 was feasible in a gynaecology outpatient department and was linked to colposcopy and treatment of HPV-positive women. Socioeconomic category, educational level, number of sexual partners, abnormal uterine bleeding and post-coital bleeding were associated with HPV positivity. Sensitivity was high in the small, selectively verified subsets examined by colposcopy ($n = 40$) and histopathology ($n = 15$), but specificity for CIN2+ could not be estimated reliably and the estimates are likely affected by verification bias. Because the assay detects only four high-risk genotypes, these findings do not establish its performance as a general high-risk HPV primary screening test. Larger studies with complete or random verification are needed before the assay can be recommended for population-based screen-and-treat programmes.

Conflicts of Interest

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

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