Comparison of Diagnostic Accuracy between Self-Collected and Physician-Collected Samples for HPV DNA Detection in Women

ISSN: 3059-9733
DOI: 10.3126/jobh.v1i2.80933

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ABSTRACT

Background

Cancer screening is critical for early detection and longer survival. While physician-collected samples are routine, self-sampling is more convenient, private, and accessible. This study compares the diagnostic performance and agreement of self- and physician-collected samples for cervical HPV detection.

Methods

A hospital-based cross-sectional study was conducted among 1,000 participants at BP Koirala Memorial Cancer Hospital, Bharatpur, Chitwan, Nepal, from July to December 2024. Ethical approval was obtained from the Nepal Health Research Council (Ref. No. 53_2024), and informed consent was taken from all participants. Both self-sampling and physician-collected cervical samples were obtained. Demographic data were gathered via structured questionnaires. The physician-collected sample served as the gold standard. Diagnostic performance metrics, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated for self-sampling. Agreement between methods was assessed using Cohen's Kappa coefficient, and associations were tested with the Chi-square test.

Results

Self-sampling exhibited high concordance with physician-collected sampling, with a Cohen's Kappa of 0.885, indicating almost perfect agreement. The Chi-square test ($\chi^2 = 786.068$, $p < 0.001$) confirmed a significant association between methods. The diagnostic performance of self-sampling was 95.29% sensitivity, 98.36% specificity, 84.38% positive predictive value (PPV), 99.56% negative predictive value (NPV), and 98.10% accuracy.

Conclusions

Self-sampling demonstrates excellent diagnostic accuracy and strong agreement with physician-collected samples for detecting cervical HPV. These results indicate that self-sampling is a reliable, accessible, and private alternative for cancer screening. Adoption of self-sampling could strengthen screening programs, especially in underserved regions. Further research is needed to assess scalability and long-term impact on early cancer detection.

Keywords: self-sampling; physician-sampling; cancer detection; diagnostic performance; Cohen's Kappa; sensitivity; specificity.

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INTRODUCTION

Globally, around 662,044 women developed cervical cancer, and approximately 348,709 died (GLOBOCAN 2022).[1] The disease also hampers quality of life, causing social and familial humiliation and isolation.[2] Such figures prompt consideration of optimal methods to reduce incidence; prevention lowers overall management cost.[3] Screening during the long latent period is key, as high-risk HPV is the causative agent.[4] HPV DNA detection is a primary screening tool, providing 60–70% more protection than cytology.[5,6] Traditionally, physicians collect HPV samples, but self-sampling shows comparable diagnostic accuracy.[7] Physician sample collection is costly and requires expertise, whereas many women report self-sampling as less painful, less embarrassing, and more convenient.[8] Some studies report higher HPV prevalence (10% vs. 8%) in self-samples.[8] Given equal diagnostic ability and greater acceptability, self-sampling expands screening coverage, especially in low-resource settings.[8-10] Our objective is to test diagnostic accuracy and acceptability of self-collected HPV DNA samples compared to physician-collected samples in the community.

METHODS

This hospital-based cross-sectional study was conducted with 1000 women at BP Koirala Memorial Cancer Hospital, Bharatpur, Chitwan, Nepal from July to December 2024. Ethical approval was obtained from Nepal Health Research Council (Ref No 53_2024), and informed consent was acquired from all participants. All participants provided written informed consent prior to their inclusion in the study. The primary objective of the study was to evaluate the diagnostic performance of self-sampling compared to physician-sampling in detecting HPV, using the physician-collected sample as the reference standard. The outcome variables were the results of the self-collected and physician-collected tests, which were categorized as either positive or negative for HPV DNA. A positive result indicated the presence of cancer-causing virus (HPV), while a negative result indicated the absence of cancer-causing virus (HPV). The physician-collected results were considered the gold standard for comparison. Data on different variables were collected through structured questionnaires administered to participants. The self-sample results were obtained by participants using a self-sampling kit, and the physician-sample results were collected by gynecologist, according to standard clinical procedures. Both sample results were analyzed in a laboratory for HPV detection. For data analysis, the collected data were carefully reviewed for completeness, and serial numbers were assigned to ensure confidentiality. The data were entered into Microsoft Excel for further processing and statistical analysis. Descriptive statistics, including frequency distributions and percentages, were used to summarize the demographic characteristics of the study population, as well as the results of the self-sampling and physician-sampling tests. The agreement between self-sampling and physician-sampling was evaluated using Cohen's Kappa to assess the level of agreement beyond chance. The Chi-square test was used to test for statistical significance in the association between the results of the self-sampling and physician-sampling methods. A p-value of less than 0.05 was considered statistically significant.

Additionally, diagnostic performance metrics such as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated to evaluate the performance of self-sampling compared to physician-sampling. Sensitivity was calculated as the proportion of true positives (HPV DNA detection correctly identified by self-sampling), specificity as the proportion of true negatives, PPV as the likelihood that a positive self-sampling result corresponds to a true positive HPV case, and NPV as the likelihood that a negative result corresponds to the absence of HPV DNA. Diagnostic accuracy was calculated as the overall percentage of correct diagnoses (true positives and true negatives) made by the self-sampling method.

RESULTS

In a survey of 1,000 participants, the majority (91.5%) had not heard of HPV self-sampling, while only 8.5% were aware of it. When asked about the

ease of performing the self-sampling, a significant portion found the process manageable: 39.0% of participants rated it as very easy, and 51.2% found it relatively easy. However, 8.1% felt it was somewhat difficult, and a smaller group (1.5%) found it very difficult, with 0.2% describing it as hard to describe. Regarding confidence, 90.5% of participants believed they could sample correctly on their own. However, 17.2% felt embarrassed, and 16.9% reported feeling uncomfortable or in pain during the process. When it came to the regular and correct sampling by doctors, a vast majority (99.0%) trusted physicians, with only 1.0% expressing doubt. Although 31.1% reported feeling embarrassed during the doctor's sampling, 21.6% found the process uncomfortable or painful. In terms of preferences, 68.2% preferred physician-collected samples, while 23.2% favored self-sampling, and 8.6% had no strong preference. Those who preferred self-sampling primarily valued privacy protection (13.7%), the convenience of doing it at home without the need to travel (9.7%), and the absence of medical personnel (9.9%). On the other hand, those who preferred doctor-collected samples cited the belief that results are more reliable when conducted by a doctor (61.8%). Despite this, 85.7% indicated they would choose self-sampling if a doctor were unavailable, with 9.3% uncertain and only 4.2% rejecting the idea (Table 1).

Table 2 presents the key performance metrics of self-sampling and physician-sampling in detecting cancer causing virus (HPV). The sensitivity of both sampling methods is 95.29%, indicating a high ability to correctly identify true positive cases (HPV present). The specificity of 98.36% reflects a strong capacity of both methods to correctly identify true negative cases (HPV negative). The positive predictive value (PPV) for self-sampling is 84.38%, which means that among all positive results from self-sampling, 84.38% are true positives. Similarly, the negative predictive value (NPV) is 99.56%, suggesting that self-sampling has a very high accuracy in correctly predicting negative cases. Diagnostic accuracy, which reflects the overall correct classification rate of both methods, stands at 98.10%, emphasizing the high reliability of self-sampling compared to physician-sampling for HPV detection.

Table 1. Awareness and perceptions of HPV self-sampling among participants.

Variable	Frequency (%)
Heard about HPV self-sampling	
Know	85(8.5)
Don't know	915(91.5)
Easiness	
Very easy	390(39.0)
Relatively easy	512(51.2)
Somewhat difficult	81(8.1)
Very difficult	15(1.5)
Hard to describe	2(0.2)
I can sample correctly (yes)	905(90.5)
Feel embarrassed (yes)	172(17.2)
Uncomfortable and pain full (yes)	169(16.9)
Doctor can take samples regular and correctly	
Yes	990(99.0)
No	10(1.0)
Feel embarrassed during (yes)	311(31.1)
Sampling process unconformable and painful	216(21.6)
Preferences	
Self-sampling	232(23.2)
Physical sampling	682(68.2)
All acceptable/Don't know	86(8.6)
Prefer self-sampling because	
Protect privacy	137(13.7)
It can be done at home without travelling long distance	97(9.7)
No need for medical personal more convenient	99(9.9)
Others	2(0.2)
Prefer doctor sampling	
Completed by a doctor no need to do my self	158(15.8)
Results are more reliable when doctor takes samples	618(61.8)
Would you choose self-sample if no Doctor	
Yes	857(85.7)
May be	93(9.3)
No	42(4.2)
Don't know	8(0.8)

To evaluate the level of agreement between self-collected and physician-collected samples for HPV detection, we calculated Cohen's Kappa. The observed agreement (Po) was calculated as the proportion of times both methods agreed. The agreement on

Table 2. Sensitivity, specificity, positive predictive value, and negative predictive value of self-collected samples and physician sample.

Self-Sampling	Physician sample	
	Positive	Negative
Positive	True Positive (TP) = 81	False Positive (FP) = 15
Negative	False Negative (FN) = 4	True Negative (TN) = 900

Table 3. Diagnostic accuracy of test result.

Calculated value	Percentage (%)
Sensitivity	95.29%
Specificity	98.36%
Positive Predictive Value (PPV)	84.38%
Negative Predictive Value (NPV)	99.56%
Diagnostic Accuracy	98.10%

positive results (True Positives) was 81, and the agreement on negative results (True Negatives) was 900, leading to a total of 981 agreements out of 1000 samples. Therefore, the observed agreement (Po) was 0.981, or 98.1%. To assess the expected agreement (Pe), which is based on chance, we calculate it using the formula that accounts for the number of positive and negative results expected by random chance. The Cohen's Kappa (κ), which accounts for the agreement beyond chance, was found to be approximately 0.885, indicating almost perfect agreement between self-collected and physician-collected samples for HPV detection. This high value suggests that the self-sampling method is highly consistent with the physician-collected method.

Result of Agreement between Self-Collected and Physician-Collected Samples for HPV Detection

a = 81 (Agreement on positive)

d = 900 (Agreement on negative)

b + c = 15 + 4 = 19 (disagreement)

$$\text{Observed Agreement (Po)} = \frac{a+d}{N} = \frac{981}{1000} = 0.98$$

$$\text{Expected Agreement (Pe)} = \frac{(Row1 * Col1)}{N^2} + \frac{(Row2 * Col2)}{N^2}$$

$$\text{Pe} = \frac{(96 * 85)}{1000 * 1000} + \frac{(904 * 915)}{1000 * 1000} = 0.8353$$

$$\text{Cohen's Kappa (K)} = \frac{Po - Pe}{1 - Pe} = \frac{0.981 - 0.8353}{1 - 0.8353} = 0.8847$$

There is an almost perfect agreement (K≈ 0.885) between self-collected and physician-collected samples for HPV detection.

The Chi-square test was used to examine this relationship, and the results are shown in the table. For the self-collected positive test results, 81 were also positive according to the physician (84.4%), and 15 were false positives (15.6%). For the self-collected negative results, 4 were false negatives (0.4%) and 900 were correctly identified as negative by the physician (99.6%). The Chi-square value was found to be 786.068, with a p-value of <0.001, indicating that the results are statistically significant. This suggests a very strong association between the two methods, as the two test results are not independent. The low p-value (<0.001) rejects the null hypothesis, supporting the claim that there is a significant association between self-collected and physician-collected test results for HPV detection.

Table 4. Comparison of self-collected and physician collected sample.

Self-Report	Physician Positive	Physician Negative	χ^2 value	p-value
Positive	81 (84.4)	15 (15.6)	786.068	<0.001
Negative	4 (0.4)	900 (99.6)		

DISCUSSION

Our study revealed that self-sampling for HPV detection showed excellent diagnostic agreement with physician-collected samples with a Cohen's Kappa of 0.885, sensitivity of 95.29%, specificity of 98.36%, positive predictive value (PPV) of 84.38%, negative predictive value (NPV) of 99.56%, and overall diagnostic accuracy of 98.10%. These results align closely with findings from institutions reporting strong agreement, such as a study documenting 93.8% concordance and κ = 0.76, with sensitivity 82.5%, specificity 93.6%, PPV 52.4%, and NPV 98.4% for self-collected sample[11], underscoring our larger sample size. In contrast, the result of Phoolcharoen et al., found only moderate agreement with a κ value of 0.46, [12] and another investigation reported good but lower concordance with κ value of 0.62.[13] Similarly, a Nigerian study showed moderate agreement with κ value of 0.47[14], highlighting that

smaller sample sizes or differing protocols may contribute to reduced kappa values. Conversely, a study in Ghana among both HIV-positive and HIV-negative women reported strong agreement with a κ value of 0.88 [15], comparable to our results despite their smaller sample size. A 2007 meta-analysis by Petignat et al., further supports self-sampling's reliability for HPV transmission and vaccine trials.[16] However, some studies have noted lower sensitivity and specificity for self-sampling[17], this may be due to variations in sampling design, laboratory workflows, or participant instruction. A meta-analysis reported self-sampling sensitivity of 99% and specificity of 85%[18], while other studies showed good to strong agreement (κ = 0.65–0.78) for HPV detection via self-collected methods.[19-21] This indicates that, despite methodological variations, self-sampling methods have acceptable diagnostic performance. Regarding women's knowledge and acceptability, 91.5% of participants in our study had not previously heard of HPV self-sampling. Once introduced, 39% reported the procedure as "very easy," and 51.5% as "relatively easy." Only 8.1% found it "somewhat difficult," and 1.5% said it was "very difficult," with a mere 0.2% unable to categorize the difficulty. These findings align with a meta-analysis in which 75–97% of participants found self-sampling easy and 60–90% considered it painless.[22] In Cameroon, 90% of women felt confident undertaking self-sampling, and 96.7% found it easy. Similarly, 96.5% reported no embarrassment versus 62.5% for physician-collected sampling, and 90.7% experienced no pain compared to 26.5% with physician sampling.[23] Such findings suggest that, across diverse contexts, self-sampling is generally perceived as user-friendly and less intimidating, reinforcing its potential to overcome barriers related to discomfort, pain, and stigma. Similarly, physician-collected sampling showed high trust among participants, 99% believed that physicians would obtain the most accurate HPV specimens. However, 31.1% felt embarrassed during physician-collected sampling, and 21.6% reported discomfort or pain. These findings are similar to those from other studies documenting greater confidence but increased anxiety and physical discomfort with physician sampling.[23] Regarding preference, 61.8% indicated they would choose physician sampling because of its reliability, while 23.2% stated they preferred self-sampling for privacy protection, reflecting similar findings from a Minnesota based study.[24] Furthermore, 85.7% of participants said they would choose self-sampling if a physician were not available, which aligns with findings from Minnesota, where a majority expressed a willingness to self-sample in the absence of a healthcare provider.[24] Statistical analysis showed a highly significant association between self and physician collected results ($\chi^2 < 0.001$), similar results from multiple studies.[11,14,25,26] This strong association supports the conclusion that self-sampling can function as an alternate primary screening modality for cervical cancer, particularly in resource-constrained settings where access to clinical providers is limited.

CONCLUSIONS

The analysis of the results obtained from self-collected and physician-collected samples detection reveals a strong and statistically significant association between the two methods. The Chi-square test confirmed that the two sampling methods are not independent. This suggests that self-sampling is highly consistent with physician-sampling, making it a reliable alternative for HPV detection. The Cohen's Kappa value further supports the conclusion of almost perfect agreement between the two methods. Given these findings, self-sampling demonstrates promising feasibility and effectiveness, which may offer advantages in terms of privacy, convenience, and accessibility, potentially improving cancer screening rates. Therefore, the use of self-sampling for HPV detection could be considered a valuable complement or alternative to traditional physician-collected methods, particularly in settings where access to healthcare professionals is limited.

Conflict of interest: None

Funding: Yes

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Citation: Acharya BC, Subedi H, Gurung SR, Upadhyay HP. Comparison of Diagnostic Accuracy between Self-Collected and Physician-Collected Samples for HPV DNA Detection in Women. JoBH, Nepal. 2025; 1(2): 74-80.