Short Communications

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Performance of a New Brazilian Self-Sampling Device for High-Risk Human Papillomavirus Screening

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Abstract

Objective: To evaluate the performance of a new Brazilian self-sampling device (COARI®) compared with clinician-collected samples for high-risk human papillomavirus (hrHPV) detection and partial typing. **Methods:** This diagnostic agreement study included 57 women who underwent routine cervical screening or follow-up at a private health center in Maringá, Brazil, between May and October 2023. Each participant provided two samples: a self-collected vaginal sample using the COARI® device (Kolplast, Brazil) and a clinician-collected cervical sample. Both were tested using the Cobas® HPV 4800 assay (Roche, USA), which detects HPV16, HPV18, and a pooled group of 12 other hrHPV types. **Results:** hrHPV detection was significantly higher in self-collected samples than in clinician-collected ones (52.9% vs. 37.2%; P = 0.008). The Overall agreement between sampling methods was 84.3%. All discordant cases (15.7%) were hrHPV-positive in self-collected samples and negative in clinician-collected specimens, suggesting potentially greater sensitivity for self-sampling. The COARI® device showed 100% sensitivity and a 100% negative predictive value, with an overall accuracy of 84.3%. **Conclusion:** The COARI® self-sampling device demonstrated reliable and effective performance for hrHPV detection and partial typing, showing strong potential to increase access to and coverage of cervical cancer screening in Brazil. Further studies with larger and more diverse populations are needed to validate these findings and inform public health implementation.

Keywords: Cervical cancer screening- High-risk human Papillomavirus- Self-sampling device- Diagnostic accuracy

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Introduction

Cervical cancer remains a preventable but highly prevalent disease, ranking as the fourth most common cancer and cause of cancer-related deaths among women worldwide. In 2020, there were an estimated 604,000 new cases and 342,000 deaths, with the majority occurring in low- and middle-income countries due to limited access to routine screening or inadequacies in existing screening programs [1]. In Brazil, it is the third most frequently diagnosed cancer among women and the fourth leading cause of female cancer mortality. Despite the availability of opportunistic screening via the Papanicolaou (Pap) test through the Unified Health System (SUS), many women remain unscreened, particularly those affected by healthcare access barriers, social inequalities, and psychosocial challenges [2, 3].

In response to these limitations, alternative strategies have been developed, including high-risk human papillomavirus (hrHPV) testing, which offers greater sensitivity and allows for extended screening intervals [4, 5]. Importantly, hrHPV testing can be performed on self-collected samples, with diagnostic performance comparable to clinician-collected samples [6, 7]. The World Health Organization (WHO) now recommends hrHPV-based primary screening, including self-sampling as a viable method [8].

To explore the potential of this approach in Brazil, the PREVINA-SE project compared adherence to traditional clinician-collected Pap testing, self-collected hrHPV

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testing using the "Just for Me" kit, and women's choice between the two. Self-collection showed notably higher adherence. Building on these results, the PREVINA-SE multicentric study was initiated across five regions of Brazil. Recently, the National Health Surveillance Agency (ANVISA) approved the COARI® self-sampling device (Kolplast, Brazil), designed to preserve dry vaginal samples. The preservation of self-collected samples in a dry state facilitates safe transport and storage, mitigating the risks associated with liquid-based media, such as leakage, partial or complete sample loss, and skin irritation [9]. This study aimed to assess the diagnostic performance of the COARI® device compared to clinician-collected samples using the Cobas 4800 test.

Materials and Methods

This diagnostic agreement study was part of the PREVINA-SE multicentric project. A total of 57 women, aged 20 to 69, were enrolled from a private healthcare facility in Maringá, Brazil, between May and October 2023. The sample included women with recent Pap test results both normal and abnormal to ensure an adequate number of hrHPV-positive cases. Women with abnormal results included those with atypical squamous or glandular cells, low-grade (LSIL), and high-grade squamous intraepithelial lesions (HSIL). Exclusion criteria included pregnancy, postpartum status, history of hysterectomy, current vaginal bleeding, sexual inactivity, and cancer treatment. All participants provided written informed consent, and the study received ethical approval.

Each participant was instructed on how to use the COARI® self-collection device, which consists of a falcon-type tube and soft-bristled brush, and stored samples at room temperature. Clinician-collected cervical samples were obtained using a cytobrush and preserved in ThinPrep PreservCyt® medium (Hologic, UK). Both sample types were tested for hrHPV using the Cobas 4800 test, which detects HPV16 and HPV18 separately and a pooled result of 12 other hrHPV types. Baseline demographic and behavioral data were collected through standardized clinic forms.

Concordance between self-collected and clinician-collected samples was assessed through descriptive statistics, accuracy measures, and Cohen's kappa coefficient. Additional comparisons were made across age groups and Pap cytology categories, using McNemar's test, t-tests, and chi-squared tests. A 95% confidence level and a significance threshold of $p<0.05$ were used.

Results

The study population had a mean age of 31.7 years, with the majority of participants aged between 25 and 34 years. Most women reported early sexual debut (between 17 and 19 years), a limited number of sexual partners in the previous year, and low smoking rates. Demographic and behavioral characteristics were similar between women with normal Pap results and those with abnormalities (Table 1).

Out of the 57 women enrolled, 51 paired samples (89.5%) were valid for hrHPV analysis. Six self-collected samples were invalid due to failure in the β-globin internal control amplification, although their corresponding clinician-collected samples tested negative for hrHPV. These invalid results may be attributed to incorrect self-sampling.

Among the valid sample pairs, the overall prevalence of hrHPV was higher in self-collected samples than in clinician-collected ones (52.9% vs. 37.2%, respectively), with the difference being statistically significant ($p = 0.008$). Of the 51 valid pairs, 43 (84.3%) showed concordant hrHPV results, including 24 cases where both methods yielded negative results and 19 where both tested positive. In 8 cases (15.7%), discordant results were observed—all of which were positive in self-collected samples but negative in the clinician-collected ones. Among these discordant cases, 5 women had previously normal Pap tests, while 3 had prior HSIL diagnoses, indicating that some clinically relevant cases may be detected exclusively through self-sampling (Table 2).

Analysis of hrHPV types revealed that HPV16 was identified in 18.5% of hrHPV-positive self-collected samples and in 26.3% of clinician-collected ones. The pooled 12 hrHPV types were detected in 88.9% of hrHPV-positive self-collected samples and in 84.2% of clinician samples, either alone or with HPV16. HPV18 was not detected in any sample. In all 19 cases where both methods tested positive, the same hrHPV types were found.

In terms of diagnostic performance, self-sampling using the COARI® device showed 84.3% accuracy, 100% sensitivity, 75% specificity, 70.4% positive predictive value (PPV), and 100% negative predictive value (NPV) compared to clinician-collected samples. The Cohen's kappa coefficient was 0.69, indicating good agreement (Table 2). These results remained consistent across different age groups (data not shown).

When analyzing the subgroup of women with normal cytological findings (NILM), the prevalence of hrHPV detected by self-sampling was higher than that of clinician-collected samples (38.9% vs. 11.1%), although this difference was not statistically significant ($P = 0.062$). Among these women, only 2 had concordant positive results across both methods, while 5 were positive only in the self-sampling. In this subgroup, self-sampling yielded 72.2% accuracy, 100% sensitivity, 68.8% specificity, 28.6% PPV, and 100% NPV, with a κ of 0.32, indicating fair agreement (Table 2).

In contrast, among women with prior abnormal cytological findings, self-sampling again showed a higher prevalence of hrHPV detection compared to clinician-collected samples (60.6% vs. 51.5%). Seventeen women had concordant positive results, while three were positive only through self-sampling. For this subgroup, the diagnostic accuracy of self-sampling reached 90.9%, with 100% sensitivity, 81.3% specificity, 85% PPV, and 100% NPV. The κ value was 0.82, indicating excellent agreement (Table 2).

Discussion

This study evaluated the performance of the Brazilian

Table 1. Characteristics of 57 Women Included in the Study According to Cytological Findings

Characteristics	Cytological findings		
	Overall (n = 57)	*NILM (n = 22)	Abnormal (n = 35)
Age mean (SD)	31.7 ± 10.3	31.4 ± 8.8	31.9 ± 11.5
	n (%)	n (%)	n (%)
Age ranges (years)			
20-24	15 (26.3)	6 (27.3)	9 (25.7)
25-34	26 (45.6)	9 (40.9)	17 (48.6)
35-44	9 (15.8)	4 (18.2)	5 (14.3)
45-69	7 (12.3)	3 (13.6)	4 (11.4)
Age of first sexual intercourse (years)			
13-16	17 (29.8)	5 (22.7)	12 (34.3)
17-19	28 (49.1)	12 (54.6)	16 (45.7)
≥20	12 (21.1)	5 (22.7)	7 (20)
Sexual partners in the last year (n)			
0	9 (15.8)	3 (13.6)	6 (17.1)
1-2	46 (80.7)	17 (77.3)	29 (82.9)
≥3	2 (3.5)	2 (9.1)	0 (0.0)
Pregnancies (n)			
0	32 (56.1)	13 (59.1)	19 (54.3)
1-3	24 (42.1)	8 (36.4)	16 (45.7)
≥4	1 (1.8)	1 (4.5)	0 (0)
Use of hormonal contraceptive			
No	26 (45.6)	9 (40.9)	17 (48.6)
Yes	31 (54.4)	13 (59.1)	18 (51.4)
Smoking			
No	53 (93)	20 (90.9)	33 (94.3)
Yes	4 (7)	2 (9.1)	2 (5.7)

SD, mean ± standard deviation; *NILM, negative for intraepithelial lesion or malignancy; Abnormal , include atypical glandular cells (AGC), squamous intraepithelial lesions (SIL) of low (LSIL) or high (HSIL) grade, and atypical squamous cells (ASC) of undetermined significance (ASC-US) or not possible exclude HSIL (ASC-H).

Table 2. Concordance and Overall Agreement for High-Risk HPV Detection (Any Type) between Self-Collected Samples Using COARI and Clinician-Collected Samples According to Cytological Findings (n = 51)

Self-sampling	Clinician-collected samples								
	Overall cytological findings (n = 51)			*NILM cytological findings (n = 18)			Abnormal cytological findings (n = 33)		
hrHPV test	[a]hrHPV+	[b]hrHPV-	Total	[a]hrHPV+	[b]hrHPV-	Total	[a]hrHPV+	[b]hrHPV-	Total
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
ahrHPV+	19 (37.2)	8 (15.7)	27 (52.9)	2 (11.1)	5 (27.8)	7 (38.9)	17 (51.5)	3 (9.1)	20 (60.6)
bhrHPV-	0 (0)	24 (47.1)	24 (47.1)	0 (0)	11 (61.1)	11 (61.1)	0 (0)	13 (39.4)	13 (39.4)
Total	19 (37.2)	32 (62.8)	51 (100)	2 (11.1)	16 (88.9)	18 (100)	17 (51.5)	16 (48.5)	33 (100)
p-value		0.008			0.062			0.25	
Performance variables (%)									
Accuracy		84.3			72.2			90.9	
Sensibility		100			100			100	
Specificity		75			68.8			81.3	
**PPV		70.4			28.6			85	
***NPV		100			100			100	
[c] κ		0.69			0.32			0.82	

*NILM, negative for intraepithelial lesion or malignancy; hrHPV, high-risk human papillomavirus; [a]hrHPV+, types 16, 18, and/or other high risk type (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68); [b]hrHPV-, hrHPV negative; Abnormal cytological findings, include ASC-US (atypical squamous cells of undetermined significance), atypical glandular cells (AGC), LSIL (low-grade squamous intraepithelial lesion), ASC-H (atypical squamous cells, cannot exclude a high-grade), and HSIL (high-grade squamous intraepithelial lesion); **PPV, positive predictive value; ***NPV, negative predictive value; [c] κ, Cohen's kappa coefficient.

COARI® self-sampling device for hrHPV detection in comparison to clinician-collected samples using the Cobas 4800 assay. The results demonstrate that the COARI® device offers high diagnostic accuracy and substantial agreement with traditional methods, particularly among women with clinically significant cytological abnormalities. Invalid results in 10.5% of self-samples suggest potential user difficulties in performing the procedure correctly. This issue is consistent with literature noting challenges in self-sampling due to anatomical differences and lack of training [10]. For safety, it may be advisable to treat invalid self-sampling results as potentially positive, ensuring follow-up testing or clinical evaluation.

Interestingly, the study showed that self-sampling detected a greater number of hrHPV cases than clinician collection, particularly in women with prior HSIL. Similar findings have been reported with other dry self-sampling devices. [11-13]. This may be due to the absence of dilution in dry samples and the lack of chemical preservatives, which could enhance DNA concentration and extraction efficiency [12].

Self-sampling achieved 100% sensitivity and NPV across all subgroups, confirming its potential for use in primary screening strategies. While specificity and PPV were lower, this is less critical in initial screening where sensitivity is prioritized [14].

Cohen's kappa coefficients showed excellent agreement for women with abnormal cytology, while agreement was only fair for those with normal Pap results. This suggests that self-sampling is particularly effective for detecting hrHPV in higher-risk individuals.

Overall, the findings support the use of the COARI® vaginal self-sampling device as a reliable and accurate tool for hrHPV detection. The device demonstrated good overall performance, with particularly strong results in women with abnormal cytological findings. Given its ease of use, high sensitivity, and potential to increase screening coverage, COARI® may be a valuable component of cervical cancer prevention strategies in Brazil. Further research with larger and more diverse populations is recommended to confirm these results and support its broader implementation in public health programs.

Author Contribution Statement

MELC conceived the idea, study design and procured funding; CBD carried patients intervention; MVFS, GCC, DMGS, ED carried HPV diagnostic; DMGS, SMP, VCAM, CMC, RGA, JCOCF, KRS, data collection and analysis; VRSS, supervised the conduct of the study. All authors discussed the results and contributed to the final manuscript.

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General

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Ethical Declaration

All participants provided voluntary consent for both vaginal self-sampling and physician-collected cervical-vaginal samples for hrHPV-DNA detection. The study adhered to ethical guidelines outlined in The Code of Ethics of the World Medical Association (Declaration of Helsinki) and received approval from the Ethics Committee for Studies Involving Human Beings (COPEP) of the State University of Maringá/PR/Brazil under the number CAAE 43750621.9.1001.0104.

Conflict of Interest

Kolplast/Brazil for supplying the COARI® devices used in this study and the authors declare that there is no conflict of interest.

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