Abstract #3731
Poster P 13-6

IMPACT OF VAGINAL SELF-SAMPLES SUSPENSION VOLUME ON HUMAN PAPILLOMAVIRUS (HPV) TESTING

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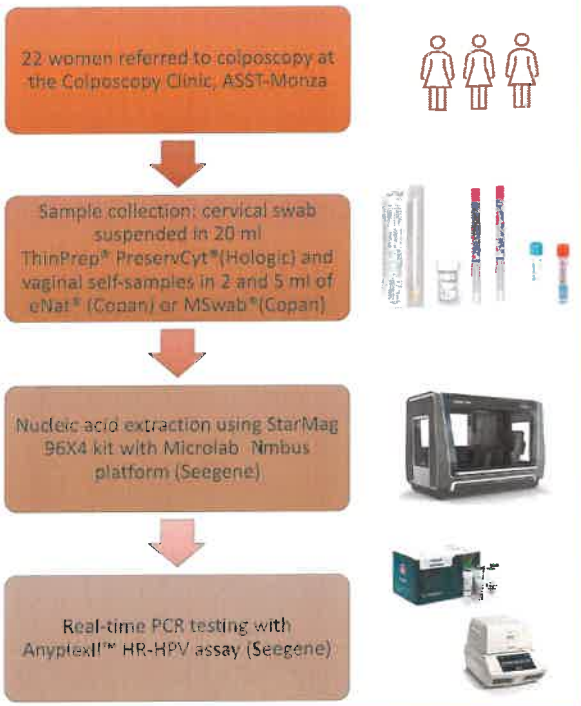
Background/Objectives:

Validation of Human Papillomavirus (HPV) testing in combination with self-collection devices offers the possibility to improve cervical cancer screening coverage rates, reaching women who do not attend screening programs. Moreover, the possibility of performing HPV testing on vaginal self-samples eluted in alternative media and suspension volumes as compared to the methanol-based media, presently used routinely to perform cervical cytology (Pap test) for the triage of women HPV-positive, may further reduce screening costs.

This ongoing study aims to evaluate the performance of HPV detection on self-collected vaginal samples suspended in two different non-alcohol-based media, eNat® and MSwab® (Copan), using two different resuspension volumes (2 ml and 5 ml).

Methods:



Results (1):

Preliminary results showed **HR-HPV positivity rates of 77.3%** (17/22), **81.8%** (18/22) and **81.8%** (18/22) respectively **in cervical swabs, vaginal self-samples resuspended in 2 ml and in 5 ml** of women enrolled.

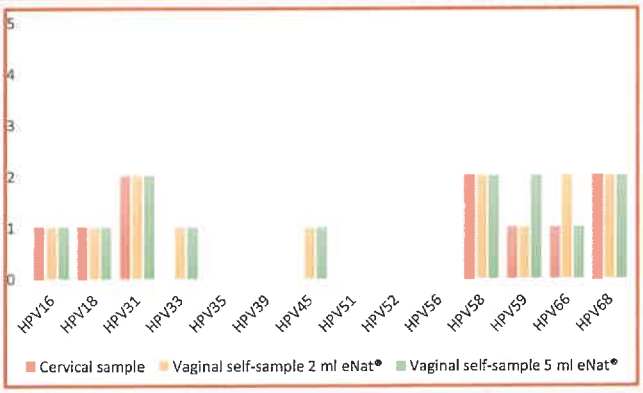
Percentages of positivity for HR-HPV in the group of women with vaginal-self samples suspended in eNat® and those from specimens suspend in MSwab® are reported in *Table 1a* and *1b*; while genotypes distribution in the two groups of women are reported in *Figure 1a* and *1b*.

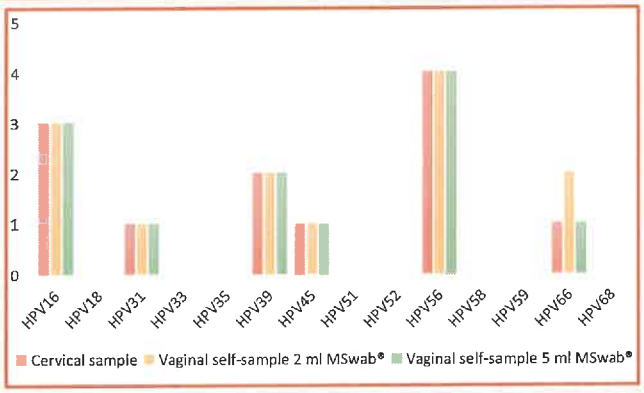
	HR-HPV positivity rate % (n)
Cervical sample 20 ml ThinPrep® PreservCyt®	72,7% (8/11)
Vaginal self-sample 2 ml eNat®	81,8% (9/11)
Vaginal self-sample 5 ml eNat®	81,8% (9/11)

	HR-HPV positivity rate % (n)
Cervical sample 20 ml ThinPrep® PreservCyt®	81,8% (9/11)
Vaginal self-sample 2 ml MSwab®	81,8% (9/11)
Vaginal self-sample 5 ml MSwab®	81,8% (9/11)

Table 1: HR-HPV positivity rate in cervical swabs and vaginal self-samples suspend in eNat® (*1a*, left) and MSwab® (*1b*, right).

Figure 1*: HR-HPV genotypes distribution in* cervical and vaginal specimens suspended in 2 and 5 ml of eNat® (*1a*, left) and MSwab® (*1b*, right).





Results (2):

Independently from the suspension volume, the percentage of agreement between cervical and vaginal swabs was **95.45% (21/22)**.

Data regarding agreement rates of cervical and vaginal specimens suspended in 2 and 5 ml of eNat® and MSwab® are shown respectively in *Table 2a* and *Table 2b*.

	Cervical sample	
	Concordance n (%)	Kappa (95% CI)
Vaginal self-sample 2 ml eNat®	10 (90.91%)	0.774 (0.282 - 1.000)
Vaginal self-sample 5 ml eNat®	10 (90.91%)	0.774 (0.282 - 1.000)

	Cervical sample	
	Concordance n (%)	Kappa (95% CI)
Vaginal self-sample 2 ml MSwab®	11 (100.00%)	1.000 (1.000-1.000)
Vaginal self-sample 5 ml MSwab®	11 (100.00%)	1.000 (1.000-1.000)

Table 2*:* agreement rates of cervical and vaginal specimens suspended in 2 and 5 ml of eNat® (*2a*, left) and MSwab® (*2b*, right).

Conclusions:

These preliminary data demonstrated a **good agreement in HPV detection between cervical and vaginal self-collected samples independently from the suspension medium and/or volume used**, supporting the possibility of introducing alternative safer and more cost-effective media for the implementation of vaginal self-sampling in cervical cancer screening programs. Studies on a larger set of samples could confirm these findings.