Performance of a new first-void urine collection device

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Introduction and objectives:

Importance of collecting the first part of a urine void (first void) and adequately preserving the DNA has been reported previously.[1] In this study we evaluate a prototype of a new first-void urine collection device (Colli Pee™, Novosanis) and a self-sampling method using urine collection vials (Multi-Collect™, Abbott).

Methods

Group A: 32 women, ever positive for HPV16 and/or 18 at earlier testing (HPV DNA on cervical sample);

Group B: 155 healthy volunteers (50 ♂/ 105 ♀), HPV status not know. Participants group A and B enrolled to test each device (Figure 1) at home on two consecutive days; all participants completed online questionnaire.

Transport of samples: Group A received and returned the sampling devices by mail. For group B specific collect and drop-off sites at the university were organized.

HPV and hDNA detection:

Group A urine samples (obtained through both collection systems): HPV DNA and hDNA were quantified by real-time PCR and all samples were tested by Multiplex HPV genotyping kit, DiaMex, Heidelberg, Germany.

Group B urine samples (obtained through Colli-Pee™): hDNA and HPV quantification as well as HPV detection and genotyping by Multiplex HPV genotyping kit was performed. Prior to automated DNA extraction the total DNA, i.e. cell associated, viral and free DNA was recovered using ultra-filtration.

Statistical analysis was done in SPSS 20.

Figure 1: Two different urine collection methods

Discussion and conclusion

In women, urine collected by the Colli-Pee™ method provided more copies hDNA than the Multi-Collect™ from Abbott. Although the difference was not significant, a similar trend was observed for HPV DNA.

Urine may not be the most appropriate sample for detecting HPV infection in men. Significant less hDNA copies and HPV DNA were observed in the male urine.

Impact of vaccination on HPV DNA presence in urine was not observed. This could be due to the fact that the current cohort of women was vaccinated after contracting HPV infection. Further research is needed to confirm this.

Results

All samples including the samples of group A arrived at the lab in good condition. Figure 2 shows that in group A a significant better recovery of hDNA was obtained by the Colli-Pee™; no significant difference was observed for detection of HPV DNA copies.

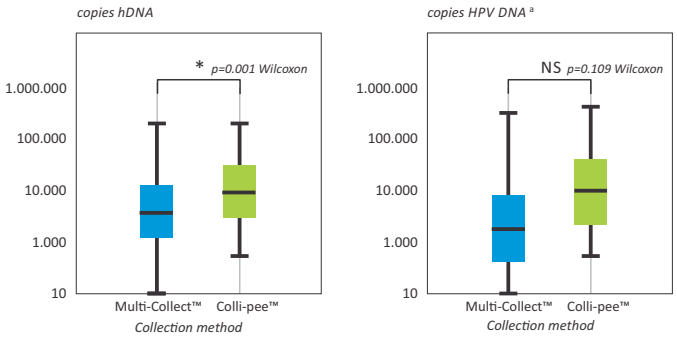

Figure 2: Group A: comparison of HPV DNA copies (n=16) and hDNA (n=32) found in urine samples collected through Multi-Collect™ or Colli-Pee™

* *a: 15 of the Colli-Pee™ samples and 14 of the Multi-Collect™ collected samples were HPV 16 DNA positive. Samples negative for both methods are not included in boxplot; NS not significant; * significant.*

Participants reported that the Colli-Pee™ device was more reliable and hygienic. Overall, appreciation for Colli-Pee™ was higher when the device was used standing in front of the toilet and no urine was spilled. Of note, 27% of the Multi-Collect™ vials were filled incorrectly.

Table 1 shows that 20% of the women in group B was positive for one or more of the HPV genotypes detected by the Multiplex HPV genotyping kit. Only 4% of the men had detectable HPV DNA. The amount of hDNA detected in the male urine, 1597 copies/µl DNA extract, was significantly less than in women, 40414 copies/µl DNA extract (p=0.001; T-test).

Table 1: Group B: HPV DNA positivity determined by Multiplex HPV genotyping kit in Colli-Pee™ collected urine samples from 155 healthy volunteers.

	Men[a]	Women
HPV DNA neg	48 (96%)	84 (80%)
HPV DNA pos	2 (4%)	21 (20%)

a: significant difference between HPV positivity in females and males. (p= 0.008, Fisher's exact test).

Table 2: Group B: HPV DNA status in vaccinated and non-vaccinated women <27y.

	Not vaccinated[b]	Vaccinated
HPV DNA neg	50	24
HPV DNA pos	6	9
HPV DNA neg	40	29
HPV DNA pos	1	4

b: Vaccination status was self reported, 2 women did not know their vaccination status and are not included in the table. They were both HPV DNA negative.

Table 2 shows the HPV DNA and vaccination status in women under 27 years in group B. 33 (43.4%) of the 76 women reported to be vaccinated. No significant impact of the reported vaccination status was observed on the presence of HPV DNA. Of note, 7 of the 36 men under 27y were not aware of their vaccination status.

Disclosure

Novosanis is a spin-off company of the University of Antwerp.
VA, VKV, BK, and VDP are co-founders of Novosanis.

Reference:

1. A. Vorsters, J. Van den Bergh, I. Micalessi, S. Biesmans, J. Bogers, A. Hens, I. De Coster, M. Ieven, P. Van Damme. Optimization of HPV DNA detection in urine by improving collection, storage, and extraction. Eur J Clin Microbiol Infect Dis. 2014; available online, DOI 10.1007/s10096-014-2147-2.

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