Colli-Pee™

Microbiological evaluation of medical grade PP in the development of a midstream collector

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Background & objectives

Standardized collection of midstream urine is needed to detect urinary tract infections (UTIs). However, the current Clean Catch Method has several drawbacks (Figure 1a).
Therefore a newly developed midstream collector could have an added value for all stakeholders involved (Figure 1b).

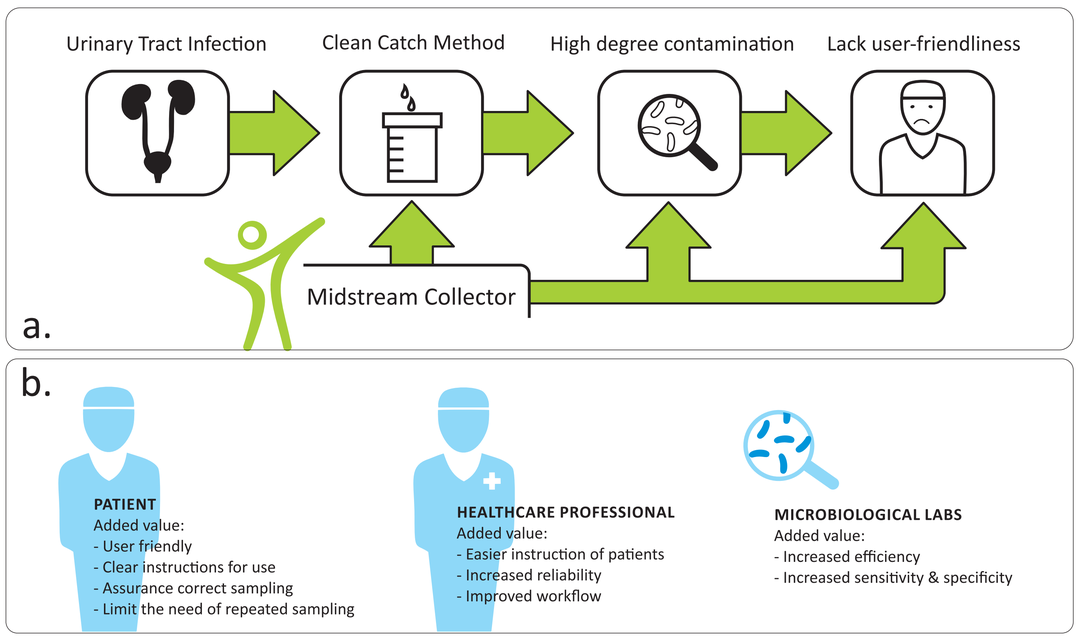

Figure 1: Importance of a midstream collector. a) related drawbacks of the current golden standard, the Clean Catch Method, compared to a newly developed midstream collection device. b) added value for patients, healthcare professionals, and microbiological labs.

Novosanis' current urine sampling device, Colli-Pee™, allows for standardized first-void (FV) urine (first 20 ml) collection. To extend the collection device platform, collection of midstream urine is investigated.

The aim of this research project was therefore threefold:

(i) to assess bacterial adhesiveness related to medical grade polypropylene (PP) funnel, and
(ii) to assess transmission of microorganisms in subsequently collected fractions, and
(iii) to assess if incorrect handling of the device affects the outcome of the collected sample.

Materials & Methods

This study was conducted in three steps:

(i) Bacterial adhesiveness related to medical grade PP funnel:

Suspensions with known concentrations (10^3, 10^5, and 10^7 CFU/ml) of *Escherichia coli* (ATCC 700928) and *Staphylococcus epidermidis* (ATCC 12228) were poured through the Colli-Pee™ device (Figure 2a). Adhesiveness of the funnel, i.e. differences in bacterial load, was investigated using the viable plate count (VPC) method prior and post pouring, corresponding with first-void (FV) collection (n=7).

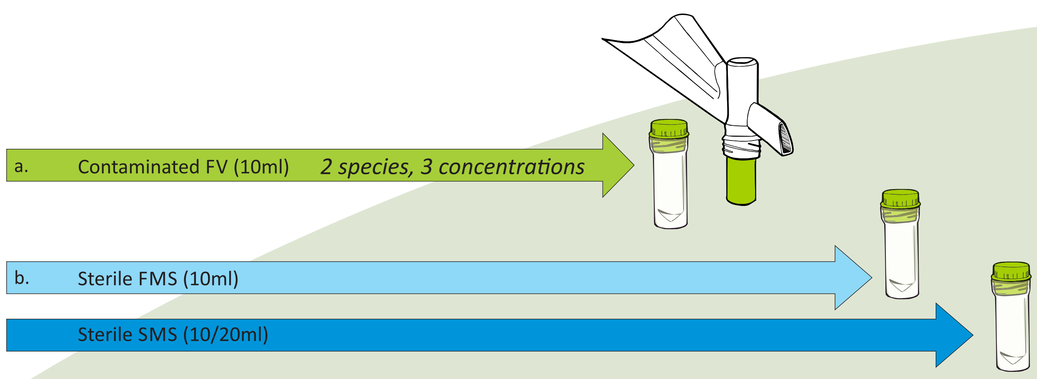

Figure 2: Method for the investigation of a) bacterial adhesiveness related to the medical grade polypropylene (PP) funnel: the bacterial concentration difference in sample and first-void (FV) collection determined using the viable plate count method (VPC), and b) transmission of microorganisms in subsequently collected fractions, being first midstream (FMS) and second midstream (SMS), which originated as sterile tryptic soy broth (TSB).

(ii) Transmission of microorganisms in subsequently collected fractions:

To elaborate on part (i), transmission of contamination in FV samples towards subsequent first midstream (FMS) and second midstream samples (SMS) was investigated by pouring previously described contaminated FV into the device, followed by sterile volumes of tryptic soy broth (TSB) (Figure 2b). FMS volumes consisted of 10 ml (n=3) or 20 ml TSB (n=2). Bacterial concentrations were assessed using the VPC method and evaluated according to the Kass criterium (10^5 CFU/ml), which is the international standard to diagnose UTIs.

(iii) Effect of incorrect handling of the device:

The effect of hand contamination was studied by letting healthy volunteers touch the internal area of the funnel with unwashed hands (Figure 2) and evaluated by (1) swabbing the funnel with a PBS-wetted swab, swabs were vortexed in 10 ml TSB (1min) (n=2), and (2) pouring 10 ml TSB through the device (n=8, 3♂ | 5♀). Bacterial concentrations were determined immediately after pouring using the VPC method. All samples were additionally incubated overnight at 37°C and visually inspected for bacterial growth. Negative control (NC) consisted of opening the pouch in a sterile environment and preventing any contact with the internal area of the funnel (n=4).

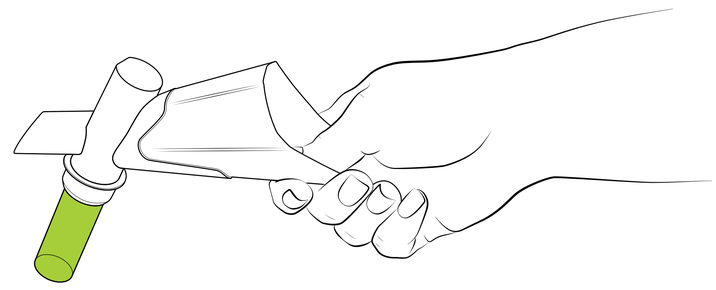

Figure 3: Instructions for hand contamination, touching the internal area of the Colli-Pee™ funnel

Results

Bacterial adhesiveness related to medical grade PP funnel

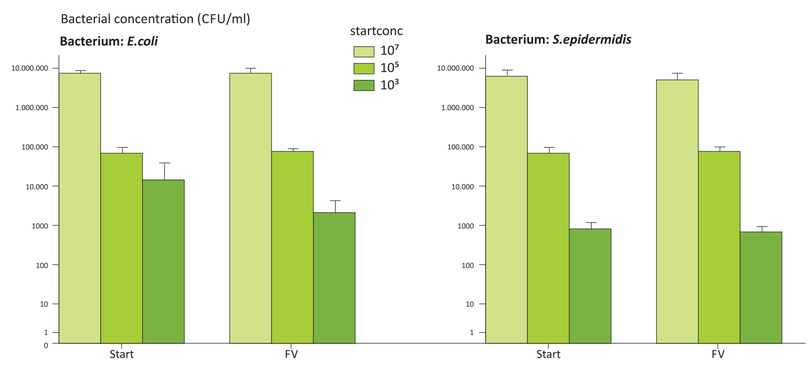

Figure 4: Bacterial concentration prior and post pouring, to determine the adhesiveness of Colli-Pee's™ medical grade polypropylene funnel. Start concentrations and concentrations in first-void (FV) samples do not differ significantly, p=0.770 and p=0.098, for E. coli and S. epidermidis, respectively. Error bars of + 2 SE are shown (n=7).

Transmission of microorganisms to subsequently collected fractions

No significant influence of FMS volume on SMS bacterial concentrations was found (Mann-Whitney U Test, p=0.623). Data were therefore compiled.

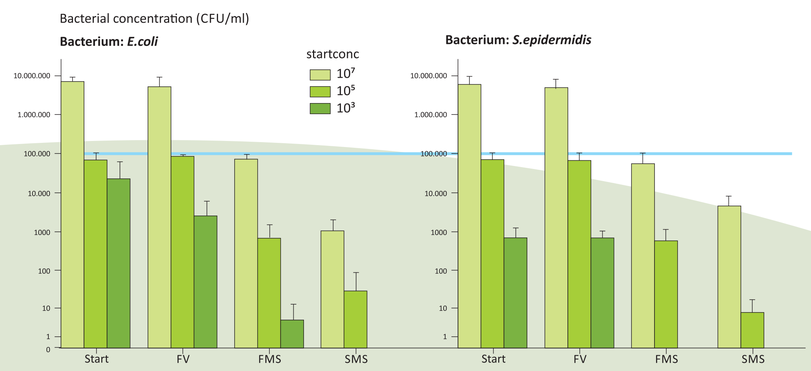

Figure 5: Transmission of contamination to subsequent fractions, being first-void (FV), first midstream (FMS), and second midstream (SMS). Start and FV concentration did not significantly differ, whereas all other fractions significantly differed from each other (Wilcoxon Signed Ranks Test, p<0.0001). In blue, the Kass criterium is visualized (10^5 CFU/ml), the current standard for detection of urinary tract infections. Error bars of + 2 SE are shown (n=5).

Hand contamination

Microbiological growth was observed in TSB samples collected from all 8 volunteers, showing as presence of turbidity after 24 hours of incubation. However, the bacterial concentration of this contamination was not detectable using the VPC method, indicating that it is lower than its sensitivity threshold (200 CFU/ml) and will not significantly influence the diagnostic outcome, based on the Kass criterium.

Conclusion

These findings indicate feasibility of developing a device allowing for both first-void and midstream urine collection. Based on these results, a new generation of Colli-Pee™ prototypes can be developed and tested in a healthy and diseased population.

Disclaimer: *This research was conducted by FC, mandatory assistant and PhD student from LMPH. Resources were provided by Novosanis.*

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Come and see us at Booth 83-84 for more information

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