Evaluating the specificity of a new type of urine collection bag for infants

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Abstract  Objective: For diagnosing urinary tract infection (UTI) in infants, the urine collection bag is a common sampling method. It has several advantages versus other methods but a high risk of contamination makes culture results difficult to evaluate. Previous studies report a specificity ranging from 14% to 84%. The objective of this study was to evaluate the specificity of a new type of urine collection bag.

Method: Urine samples were collected from healthy infants with a new type of collection bag. As the urine is expected to be sterile, any bacterial growth would be considered a contamination.

Results: Forty-four samples were included: 40 samples showed <10,000 cfu/ml of mixed growth or no growth at all, three samples showed <10,000 cfu/ml of single-strain growth and one sample showed >10,000 < 100,000 cfu/ml of single-strain growth. No samples showed any growth >100,000 cfu/ml.

Conclusion: According to Kass criteria, 97.7% of the samples would exclude a UTI and 2.3% would be considered inconclusive. None of the samples had a contamination level that, falsely, would be interpreted as positive. Further studies will be valuable as a specificity of 97.7% suggests that this collection device could give the clinician a non-invasive option for diagnosing UTI in infants.

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Introduction

Urinary tract infection (UTI) is a rather common and potentially serious condition, particularly in young children. The diagnosis is primarily based on the result from urine culturing. Some of the most commonly used methods for obtaining a urine sample from children in this age group are collection bags, catheter and supra-pubic aspiration (SPA), the latter being considered as the 'gold standard'.

Previous studies [1] indicate that the preferred method by many clinicians is to use collection bags. The main reasons for this are, most likely, that this method is non-invasive for the patient and simple to work with for the staff. Another important advantage of the collection bags, that almost certainly affects the clinicians’ preferences, is that in general has a sensitivity of 100%, which means that a negative result effectively rules out UTI.

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A positive culture result is, however, not reliable. In previous studies, the reported specificity of collection bags ranges from 14% to 84% [2]. Low specificity due to high rate of contamination [3] often results in uncertainty and diagnostic difficulties. There will in many cases be a bacterial count that cannot be interpreted as either a positive or a negative result, but also a majority of those positive results that actually can be interpreted most likely will be falsely positive. Consequently, new samples often need to be collected, carrying a risk of delayed diagnosis, incorrect clinical decisions and potential adverse effects. Hence, most recommendations and practice guidelines favour the use of more invasive methods like SPA and catheterization, despite the obvious drawbacks of such methods. The objective of this study is to evaluate the specificity of a new type of urine collection bag.

Material and method

Description of collection bag

The studied collection bag has been developed to eliminate the drawbacks of the present bags, while maintaining their advantages. The main difference between the bags commonly used today and the studied bag is that the latter is specifically designed to reduce the amount of irrelevant bacteria in the sample, preferably to a point where it is possible for the clinician to distinguish contamination from a possible UTI.

This is a difficult task to accomplish since contaminating bacteria not only enter the bag through contact between the skin and the inside of the bag, but also are washed along with the urine on its path to the bag. A third source of contamination, in most of the bags used today, is when the urine is allowed to back flow after it has entered the bag, and wash back and forth over the perineum. The studied bag is designed so that it yields a mid-stream sample which, theoretically at least, should reduce the level of contamination. It does not allow any direct contact between the sample and the skin of the patient, and is supplied with a one-way valve that prevents the urine from back flowing once it has reached the container.

Fig. 1 shows a partly disassembled prototype of the studied bag, as it would be seen from the doctor’s point of view. This prototype is similar to the test bags in all functional parts. The red marker is pointing at the entrance opening (1) from the patient’s direction. The mid-stream effect is achieved in the following manner. When the urine passes the entrance opening (1), it first enters a compartment surrounded by an absorbing material (2) (this material has been tested for medical use and does not contain any chemicals or other substances that could have any effect on the sample). Since the funnel (4) that leads into the container (6) initially is effectively sealed by the construction combined with the adhesive properties of the material, the first portion of urine is absorbed almost instantly. The rising pressure on the second aperture (3) then opens the funnel (4). This allows the remaining urine to enter the container (6) without any resistance, where a simple one-way valve (5) keeps it from re-fluxing back through the funnel.

Due to the design of the bag and the properties of the absorbent, the first, potentially contaminated, portion of fluid will remain in the absorbing material and will not enter the container (6). This function not only discards the first portion but does also block the remaining fluid from passing through the absorbent on its way to the container, which possibly could have a filtering effect on the sample. The bags are manufactured in a clean but non-sterile environment and partly assembled manually by a medical device manufacturer in Sweden. The materials mainly consist of polyethylene and unbleached cellulose.

Study design

The study group comprised 50 healthy children, aged 0–2 years. This number was chosen for practical reasons. Since the urine samples only could be collected when the nurses had some spare time, the study would have spanned over too long a time period if we had chosen a larger number. Partly for the same reason, there was no control group included.

The public child health clinics (care-centres) in the local region were asked to assist in the study. Three of these clinics agreed to participate. Eligible participants were children visiting the clinics as scheduled in the regular healthcare program. Whenever the staff had time to manage both the test and their routine tasks, they informed the parents about the study and they were asked to participate. All the children whose parents gave their (written) consent were included. No other instructions were given regarding the selection.

Exclusion criteria were a history of UTI and any current symptoms of infection, regardless of organ system, in order to include only children that most likely had sterile urine. As there are no plausible methods for predicting if a child
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There are no commonly accepted criteria for defining the significance of different levels of bacterial growth. We found the criterion defined by Kass [4] to be used more frequently than any other, even though it has been criticized in several studies for not being precise enough to detect low counts of bacteria in the urine. According to this criterion any growth \( \geq 100,000 \text{ cfu/ml} \) should be regarded as a definite UTI and any growth \( \geq 10,000 < 100,000 \text{ cfu/ml} \) as inconclusive.

**Statistical analysis**

With this material, hypothesis testing based on statistical calculations would be difficult to perform validly given the study design. We did not have a control group for direct comparison, and historical controls are in general problematic, particularly in this case, as we elected to study healthy children for specific reasons. In our opinion the specificity stands on its own as a result, with the specificity range mentioned above (14%–84%) as a reference.

**Limitations**

For reasons partly stated above, the number of samples is rather small, which should be taken into consideration when interpreting the results. Another limitation is the lack of a control group. However, a control group using a different collection bag would have been difficult to perform without a risk of bias, as it would have been obvious for the nurses which bag they were testing. There are also factors that potentially can contribute to a false low specificity, e.g. proliferation of bacteria in the time frame between sampling and culturing.

**Results**

Fifty samples were collected during the period from 2004 to 2006. Six of the samples were, in accordance with general clinical practice, excluded due to obvious stool contamination. This type of ‘contamination’ could, however, be regarded as more of an accident (like e.g. a dropped bag), and should not be confused with the problem of ‘actual’ contamination, which is the issue here.

The remaining 44 samples were sent to the laboratory for urine culturing. These samples were all collected from white children, 24 boys and 20 girls, ranging from 1 to 18 months of age. The mean age of the population was 11 months and the median was 4 months. There were no uncircumcised boys in the study.

Forty of the 44 included samples (90.9%) showed \( <10,000 \text{ cfu/ml} \) of mixed growth or no growth at all. Three samples (6.8%) were reported as having \( <10,000 \text{ cfu/ml} \) of single-strain growth (E. coli). One sample (2.3%) was reported as having \( \geq 10,000 < 100,000 \text{ cfu/ml} \) of single-strain growth (E. coli). No sample was reported as having \( \geq 100,000 \text{ cfu/ml} \).

**Discussion**

The interpretation of the results from a study like this is, of course, dependent upon the definitions of the criteria that are used. Since there are no generally established criteria, we have selected to interpret the results using Kass criteria, which we believe represent a fair image of the
most commonly used definitions. However, we do recognize and agree that these criteria can be questioned.

In practice, the clinician will have to interpret the results and, based on this interpretation, sort them into one of three categories: negative, inconclusive or positive. According to the results of this study, 97.7% of the samples would exclude an UTI and 2.3% would be considered inconclusive using Kass criteria. None of the samples had a contamination level that, falsely, would be interpreted as positive.

In conclusion, the new collection device in this study, reached a specificity of 97.7% applying Kass criteria. Further studies would be valuable to confirm these results, which in our opinion suggest that this collection device could be a useful tool, giving the clinician a non-invasive option in the difficult diagnosing of UTI in infants.

References


