

ORIGINAL

Urine sample collection using a perineal bag without replacement in infants with suspected urinary tract infection: implications of a change in the Emergency Department protocol

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Abstract

Introduction: Urine sample collection using a collection bag is considered the initial screening method for suspected urinary tract infection (UTI) in non-toilet-trained patients. As the contamination rate is high, it was traditionally recommended to change the bag every 30 minutes; however, the latest recommendations advise not to replace the bag until the sample is collected, as it will not be sent for culture. In addition, a recent study concludes that the rate of positive urinalysis results also decreases, leading to a lower need for urinary catheterization. Therefore, in September 2021 our Pediatric Emergency Department (PED) stopped carrying out bag replacement.

Objective: To assess in our PED whether urine sample collection using the perineal bag without replacement modifies the contamination rate and the number of urinary catheterizations.

Methodology: This descriptive-observational study included patients < 2 years of age with suspected UTI in the PED whose urine sample was obtained using a collection bag in July-August (period 1: hourly bag replacement) and October-November (period 2: no bag replacement) in 2021.

Results: 404 cases were included in period 1 and 359 in period 2. Urethral catheterization was performed in 35 (8.7%) patients in period 1 vs. 38 (10.6%) in period 2 ($p=0.368$). The contamination rate was 40.0% vs. 28.9%, respectively ($p=0.320$).

Conclusions: The change of method did not lead to a significant change in the contamination rate and the number of urinary catheterizations. Given the advantages of collecting the sample using a collection bag without replacement (lower nursing care burden, less discomfort for the patient, and less use of material), it will continue to be the method of choice.

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OBTENCIÓN DE MUESTRA DE ORINA A TRAVÉS DE BOLSA PERINEAL SIN RECAMBIO EN LACTANTES CON SOSPECHA DE INFECCIÓN URINARIA: IMPLICACIONES DEL CAMBIO DE PROTOCOLO EN URGENCIAS

Resumen

Introducción: La obtención de muestra de orina por bolsa perineal es el método de despistaje inicial ante la sospecha de infección del tracto urinario (ITU) en pacientes no continentales. Dada su elevada tasa de contaminación, clásicamente se aconsejaba el recambio de bolsa cada 30 minutos. Sin embargo, las últimas recomendaciones abogan por no realizar recambio hasta la recogida de muestra ya que no se enviará a cultivar. Además, un estudio reciente concluye que también disminuye la frecuencia de uroanálisis alterados, implicando la realización de menos sondajes. En base a ello, en septiembre-2021 en nuestro Servicio de Urgencias (SU) se dejó de realizar recambio de bolsa.

Objetivo: Evaluar si la obtención de muestra de orina a través de bolsa perineal sin recambio modifica el número de sondajes y la tasa de contaminación.

Metodología: Estudio descriptivo-observacional. Se incluyeron los pacientes < 2 años con sospecha de ITU en el SU con recogida de muestra de orina por bolsa en julio-agosto (período-1: recambio horario) y octubre-noviembre (período-2: sin recambio) de 2021.

Resultados: Se incluyeron 404 casos en el período-1 y 359 en el período-2. Se realizó sondaje a 35 (8,7%) pacientes en el período-1 vs. 38 (10,6%) en el período-2 ($p=0,368$). La tasa de contaminación fue 40,0% vs. 28,9%, respectivamente ($p=0,320$).

Conclusiones: El cambio de método no representa una variación significativa en el número de sondajes ni en la tasa de contaminación. Dadas las ventajas de la recogida de muestra por bolsa sin recambio (menor carga asistencial de enfermería, molestias para el paciente y gasto en material) se mantiene como método de elección.

INTRODUCTION

When urinary tract infection (UTI) is suspected in non-toilet-trained patients, urine sampling using the perineal collection bag is considered the initial screening method⁽¹⁾. As the method is associated with a high contamination rate (around 50%), it was traditionally recommended to change the collection bag every 30 minutes in order to minimize contamination and false positive cultures^(2,3).

Recent recommendations advise not to replace the perineal bag until the sample is collected, as it will not be cultured. It was suggested that regular changes of the perineal collection bag, as was the common procedure, may alter the results of the urinalysis⁽⁴⁾ and lead to iatrogenesis (need for catheterization), unnecessary diagnostic tests, and an increased workload for the nursing staff. A study by Lorente *et al.*⁽⁵⁾ confirmed that the change in the method did not modify in the contamination rate, supporting the recommendation. The authors also observed that that keeping the perineal urine collection bag in place beyond 30 minutes in non-toilet-trained patients reduced the rate of positive results thereby decreasing the need for catheterization, which is an additional advantage to those mentioned above.

Therefore, at the Pediatric Emergency Department (PED) of our center we decided to implement this change of method in September 2021. Given that in our hospital the method differed from that used in other centers (the bag was changed every hour instead of every 30 minutes and in

addition to urinalysis, sediment analysis was also performed in all samples), we assessed whether the modification of the technique led to substantial changes in the results and, subsequently, to variations in the maneuvers.

The aim of our study was to evaluate in our PED whether urine sample collection using a perineal bag without replacement modified the contamination rate and the number of catheterizations performed.

MATERIAL AND METHODS

A retrospective, descriptive-observational study was conducted in the PED of a tertiary-level maternity and children's hospital, with an average of 120,000 PED visits per year.

Patients who underwent urine analysis during their visit to the PED between July and November 2021 were identified from the hospital's electronic records. All patients younger than 2 years in whom the urine sample was collected using the perineal bag were included. The patients were divided into two groups according to the period in which they were seen, either before or after the change in the sample collection protocol: period 1, between 1-7-2021 and 31-8-2021 (hourly perineal bag replacement) and period 2, between 1-10-2021 and 30-11-2021 (no replacement). Cases seen in the month of September 2021 (transitional period), those with anatomical defects of the anogenital area, and those who had a positive result from the collection bag and did

not have a sterile urine culture confirming infection were excluded.

For both cohorts, the clinical and epidemiological features, as well as the results of the urinalysis of the sample collected using the perineal bag, catheterization and urine culture, if applicable, and the time to urine sample collection were analyzed.

For this study, contamination rate was defined as the percentage of urine samples with a negative urine culture by catheterization of the samples collected using the perineal bag with abnormal urine sediment findings (e.g. presence of germs, leukocyturia, or significant hematuria).

The collected data were stored and processed in a specific Microsoft Access® relational database. Quantitative and categorical variables were included. Subsequently, the data were analyzed with the statistical program SPSS® v25.0 for Windows. Data are presented as counts and percentages for categorical and median and interquartile range (IQR) for quantitative variables. The Kolmogorov-Smirnov test was used to verify the normality of distribution and the student's t test and the Mann-Whitney U test for the comparison of quantitative data. 95% confidence intervals for proportions were calculated using the Wilson's score method. P values less than 0.05 were considered significant. The study was approved by the Ethics Committee of the Hospital where the study was performed. The data were extracted from the Hospital records and the information obtained was anonymized. No intervention was performed in the patients. Informed consent was not required.

RESULTS

A total of 961 patients were included, of whom 196 patients seen during the month of September 2021 (transition period) and two with a positive result by perineal bag who did not have a sterile urine culture were excluded, resulting in a sample of 763 patients: 404 in period 1 and 359 in period 2. The clinical and epidemiological characteristics of both groups are detailed in Table 1.

The perineal bag was kept in place for more than 60 minutes in 229 (56.7%) patients (required bag replacement) in period 1 vs. 225 (62.7%) in period 2 ($p=0.092$). The median time to urine collection was 70 (IQR, 33-108) minutes vs. 79 (IQR, 41-144) minutes, respectively ($p=0.002$).

In period 1, 35 (8.7%) patients had an abnormal sediment of the urine collected using the bag and all of them underwent subsequent catheterization, compared to 38 (10.6%) in period 2 ($p=0.368$). In 14/35 of these patients in period 1 and in 11/38 in period 2 the urine culture obtained by catheterization was negative (contamination rate 40% vs. 28.9%, respectively; $p=0.320$).

When specifically analyzing patients in whom the perineal bag was kept in place for more than 60 minutes, 229 in period 1 and 225 in period 2, the samples were positive in 20 (8.7%) and 22 (9.8%) patients, respectively ($p=0.701$). In 9/22 (45%) positive bag samples in the first period and in 9/22 (40.9%) in the second period, catheterization did not confirm the suspected infection ($p=0.789$) and the samples were therefore considered to be contaminated.

TABLE 1. Clinical and epidemiological characteristics of the sample.

	Period-1 (n= 404)	Period-2 (n= 359)	p
Sex (boys)	199 (49.3)	191 (53.2)	0.276
Median age (months)	7.2 (2.2-13.2)	8.4 (3.6-14.6)	0.002
Healthy	350 (86.6)	306 (85.2)	0.579
Previous UTI	28 (6.9)	38 (10.6)	0.073
Fever	275 (68.1)	268 (74.7)	0.045

Categorical variables are reported as absolute frequency (percentage) and continuous variables as median (interquartile range). UTI: urinary tract infection.

DISCUSSION

This study shows that urine sample collection using a perineal bag without replacement does not lead to significant changes in the contamination rate compared to the technique with hourly replacement. In agreement with the study by Lorente *et al.*⁽⁵⁾, we procured that the samples were comparable in terms of the time elapsed until the collection of the urine sample from the perineal bag, and we specifically analyzed those cases with a bag time of more than 60 minutes. This analysis was performed in order to eliminate possible bias derived from including patients without bag replacement in period 1, as up to 60 minutes no bags were replaced in either of the two periods and thus, contaminated samples that were found in these cases could not be attributed to the change in protocol.

Both when considering the overall sample and when specifically analyzing patients in whom it took longer than 60 minutes to replace the bag, the false positive rate was found to be similar in the two groups.

On the other hand, the change of the method did not lead to a decrease in the number of catheterizations as described by Lorente *et al.*⁽⁵⁾. They observed a strikingly high initial rate of positive urine cultures from perineal bag collection (26%), which was reduced by more than 10% after the change of the protocol, accounting for the decrease in catheterizations reported by the authors. As mentioned in the introduction, Piñeiro *et al.*⁽⁴⁾ suggest this may be explained by the manipulation of the urogenital area every 30 minutes, which may lead to abnormal results of the systematic urine and sediment tests, if only because of the irritation that the bag changes cause on the skin of the perineal area. The fact that from the beginning the time to bag replacement was longer in our center (every hour instead of every 30 minutes) would have decreased this possibility and thereby the likelihood of positive urinalysis results due to excessive manipulation. Nevertheless, in our study the rate of positive bag samples was much lower, making it more difficult to find statistically significant differences. The urine sediment examination with Gram staining in all samples with a positive urine dipstick test would largely explain the differences in the rates between both studies, since the sensitivity and specificity of this technique for the diagnosis of UTI is superior to that of the dipstick test alone⁽⁶⁾.

Among the limitations of this study are those inherent to its retrospective design; there may have been some loss of information that may have influenced the sample selection. On the other hand, and related to this first limitation, it is not possible to verify whether there were any patients in whom the bag was not changed in the first period (e.g., due to carelessness) or in whom the bag was changed in the second (e.g., due to stool contamination or because the collection bag was separated from the perineal area). Lastly, the study was conducted in a tertiary-care hospital with its own laboratory and therefore extrapolation of the results to all settings may not be possible.

CONCLUSIONS

In conclusion, a similar contamination rate was found in the two groups. Although the change in protocol did not result in a decrease in the number of catheterizations in non-toilet-trained infants with suspected UTI or a reduction in the time to obtain the sample, urine sampling using the perineal bag without replacement remains the method of choice because of the lower nursing workload and reduced patient discomfort and material costs.

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