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Urinary Sample Collection Methods in Ileal Conduit Urinary Diversion Patients

A Randomized Control Trial

Markku H. Vaarala

ABSTRACT

PURPOSE: The purpose of this study was to compare bacteriological urinalysis findings using 3 urinary sample collection methods (clean stoma catheterization, urine dripping from the stoma, urine collected from the clean urostomy pouch) in ileal conduit urinary diversion patients.

DESIGN: Randomized controlled trial.

SAMPLE AND SETTING: Twenty-seven patients with ileal conduit urinary diversion from an outpatient urology clinic were enrolled; 9 patients were seen twice, for a total of 36 subjects and comparisons.

METHODS: Data were collected during a clinic visit by a trained research nurse. Patients were randomized into 2 groups: group A had the first urine sample collected by clean stoma catheterization, followed by sample collection by urine dripping from the stoma; group B had the first urine sample collection by urine dripping from the stoma, followed by sample collected by clean stoma catheterization. All patients had a third urine sample collected from a factory-clean urostomy pouch. Bacteriological urinalysis findings were compared among methods. Descriptive analyses were summarized using mean, percentage, and frequency. The mean ages of the patients between the groups were compared with the *t* test. Other between-group comparisons were performed using the Fisher exact test. Urinary culture finding differences among the same patients were evaluated using the McNemar test. Sensitivity and specificity of the different urine sample collection methods were calculated assuming urine sample collection by catheterization as a reference method.

RESULTS: Uropathogen bacteria were detected in urinary culture in 16 of 36 samples (44%) collected by clean stoma catheterization, 15 of 36 samples (42%) collected by urine dripping directly from the stoma, and 13 of 35 samples (37%) collected from the clean urostomy pouch. Significant differences among the urine collection methods were not detected. Assuming catheterization as the most reliable method of sample collection, the sensitivity and specificity of the urine dripping from stoma collection method were 81.3% and 90.0%, respectively. The sensitivity and specificity of the urostomy pouch collection method were 73.3% and 90.0%, respectively. Among the same patients, there were no significant differences in the incidence of uropathogen bacteria when clean stoma catheterization was compared with urine dripping from the stoma and urostomy pouch methods.

CONCLUSION: This study provides clinically relevant information regarding urine collection methods in ileal conduit patients. Urinary sample collection by urine dripping directly from the stoma or collected from a clean urostomy pouch provided similar uropathogen bacteria findings compared with sample collection by clean stoma catheterization.

KEY WORDS: Ileal conduit, Randomized controlled trial, Urinary tract infection, Urine collection methods, Urine culture, Urine sample, Urostomy.

INTRODUCTION

Cutaneous urinary diversion is commonly used for cancer patients requiring radical cystectomy[1] or those with neurogenic urinary bladder disorder when other therapies have not been successful.[2] The most commonly used cutaneous urinary diversion method is ileal conduit.[3] Other widely used methods include ureterocutaneostomy.[4] Patients with a urinary diversion require regular follow-up due to potential complications even years after the diversion operation.[1] Usually, this follow-up includes urinalysis.[1] Particularly after ileal conduit urinary diversion, asymptomatic bacteriuria is common[5] and does not require treatment.[5,6] Urinary samples may be collected by catheterization,[7] by dripping the urine directly from the stoma,[8] or from a fresh urostomy pouch after stoma care.[9]

Urine sample collection by catheterization is regarded historically as the most reliable method for urine culture sample collection.[7,10] The other 2 methods, namely, dripping the urine directly from the stoma[8] and collecting the urine from a fresh urostomy pouch after stoma care,[9] were compared to this method with respect to uropathogen bacteria findings on urine culture. The purpose of this study was to compare bacteriological urinalysis findings using 3 urinary sample collection methods (clean stoma catheterization, urine dripping from the stoma, and urine collected from the clean urostomy pouch) in ileal conduit urinary diversion patients. The presence of 10^4 or more uropathogen bacteria in urine culture was regarded as clinically significant finding.[11] A secondary aim was to

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determine sensitivity and specificity for the different urine collection methods compared with clean stoma catheterization. As well, the presence or absence of uropathogen bacteria in urine culture between different urine collection methods among the same patients was evaluated.

METHODS

This study used a randomized controlled trial design. Eligible patients followed up at Oulu University Hospital (Oulu, Finland) urology outpatient department were informed by a research nurse about the study, and written informed consent was obtained. Inclusion criteria were patients with an ileal conduit urinary diversion, aged 18 years and older, and cognitively intact. Exclusion criterion was patients with signs of symptomatic urinary tract infection (fewer, gross hematuria, and/or back pain). The research was approved by the Ethics Council of the Northern Osthrobothnia Hospital District, Oulu.

After obtaining consent, patients were randomized 1:1 into 2 groups using a computer-generated block randomization method with randomly varying block lengths of 2 and 4. Randomization was performed in order to exclude an influence of the sequence of sample collection on outcome. The same patients were allowed to be randomized more than once to the trial with the requirement that the randomization was performed at different prescheduled follow-up visits for the underlying disease. The minimum interval between consecutive randomizations of the same patients was 3 months. Randomized, sequentially numbered, opaque, sealed envelopes were generated. A research nurse opened envelopes consecutively after each patient consented, and the patient was assigned to either of the groups. Study procedures were performed during the same clinic visit.

A trained research nurse removed the urostomy pouch and cleansed the stoma with sterile gauze moisturized with sterile saline, using a circular motion from stoma opening outward. Group A had the first urine sample collected by clean stoma catheterization, followed by urine sample collection by dripping urine from the stoma. Group B had the first urine sample collection by dripping urine from the stoma, followed by urine sample collected by clean stoma catheterization. Subsequently, all patients had a third urine sample collected from a factory-clean urostomy pouch. Urine sample was collected from the urostomy pouch immediately after there was approximately 20 mL of urine present in the pouch. Sample collection from the urostomy pouch was the last sample collection method for all study participants in order to minimize expenses to the patients (ie, the cost of the urostomy pouch). The flowchart of the study is presented in the Figure. All urine samples were collected immediately after one another without further stoma cleansing. Each urine sample was evaluated by urine culture. Patient age and reason for diversion were recorded. Primary outcome measure was the incidence of uropathogen bacteria (ie, gram-negative rod or gram-positive cocci) in urinary culture following 2 different sample collection methods (dripping urine from the stoma method and urine from the urostomy pouch) compared with sample collection by clean stoma catheterization. Urine samples were collected into sterile transfer tubes and were plated by laboratory personnel within 2 hours at Oulu University Hospital Diagnostic Laboratory among clinical samples.

Urine cultures were plated using a 10-μL loop on a chromogenic plate (CHROMagarTM Orientation; CHROMagar Microbiologics, France) and on a chocolate agar plate

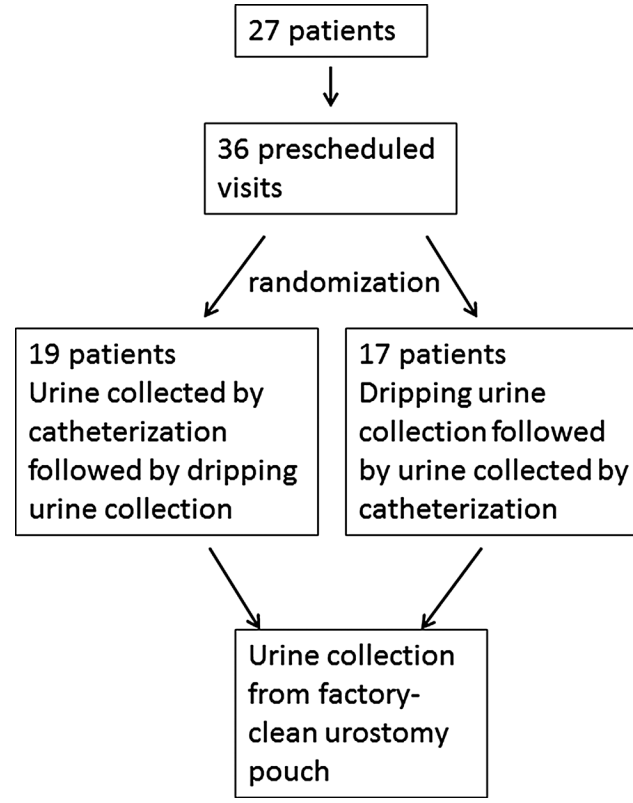

Figure. Study flowchart.

(self-made at Oulu University Hospital, Oulu, Finland). The chromogenic plates were incubated a maximum of 72 hours in ambient air at 35°C, and chocolate agar plates were incubated a maximum of 72 hours in a 5% CO2 atmosphere at 35°C. Identification of bacteria was performed using the MALDI-TOF (matrix-assisted laser desorption/ionization time-of-flight mass spectrometry) method (VitekMS, bioMerieux, France). For statistical analyses, urine cultures with uropathogen bacteria (ie, gram-negative rod or gram-positive cocci) showing 10^4 colony forming units (CFUs) or more/mL of urine were regarded as positive. Low polymicrobial bacterial count cultures were considered to be probable contamination.[11] To describe detected bacteria, urine cultures showing more than 10^2 CFUs/mL of urine[11] are separately shown in Table 2. In Table 2, urine cultures with 10^2 or fewer CFUs/mL of urine were recorded as negative.[11]

Data Analysis

Descriptive analyses were performed using mean, percentage, and frequency. The mean ages of patients in each group was compared with the *t* test. Other between-group comparisons were performed using the Fisher exact test. A *P* value less than .05 was regarded as statistically significant. Sensitivity and specificity of the different urine sample collection methods were calculated assuming urine sample collection by clean stoma catheterization as a reference method. Number needed to treat was calculated for missed uropathogen findings in urine cultures from urinary sample collection by the urine dripping method compared with the reference method (clean stoma catheterization). Urinary culture finding differences among the same patients were evaluated comparing urine cultures of uropathogen bacteria showing 10^4 CFUs or more/mL of urine from urinary sample collection by the urine dripping method

or from the urostomy pouch method with the reference method (clean stoma catheterization) using the McNemar test. Analyses were performed with SPSS version 23 (IBM SPSS Statistics for Windows, IBM Corp, Armonk, New York).

RESULTS

Twenty-seven patients were enrolled, with 9 patients enrolled twice, resulting in 36 subjects and comparisons. Patient demographics (age and gender distribution) are shown in Table 1. Indications for ileal conduit urinary diversion were urinary bladder cancer (n = 24; 89%), painful bladder (n = 1; 4%), urethrocutaneous fistula after femoral-femoral bypass operation (n = 1; 4%), and severe urinary incontinence (n = 1; 4%).

Urine culture findings are presented in Table 2. Uropathogen bacteria showing more than 10^2 CFUs/mL of urine were detected in urinary culture in 16 of 36 samples (45%) collected by clean stoma catheterization, 18 of 36 samples (50%) collected by urine dripping from the stoma method, and 13 of 35 samples (36%) collected from the clean urostomy pouch. Among samples collected by urine dripping from the stoma method, uropathogen bacteria were detected in 2 of 20 patients who had no uropathogen bacteria in the sample obtained by clean stoma catheterization. Among samples collected from the clean urostomy pouch, uropathogen bacteria were detected in 2 of 19 patients who had no uropathogen bacteria in the sample obtained by catheterization.

Comparison of the number of the samples with detected uropathogen bacteria showing 10^4 CFUs/mL of urine between the groups is presented in Table 3. There were no statistically significant differences between the groups. Samples with uropathogen bacteria showing 10^4 CFUs/mL of urine were most commonly detected in the first sample regardless of the group (Table 3). Of note, due to the small sample size, the observed differences were small (1-patient difference in group A and 2-patient difference in group B) despite the low *P* values.

Among 19 patients randomized to group A, uropathogen bacteria were detected in 7 samples collected by clean stoma catheterization (37%). The second sample collected by urine dripping from the stoma method had uropathogen bacteria detected in 6 of these 7 cases ($P = 1.0$). The third sample collected from the urostomy pouch had uropathogen bacteria in 5 of these cases (26%) ($P = 1.0$). In 1 case, there were uropathogen bacteria identified in the sample collected from the urostomy pouch in a patient with no uropathogen in the first or second sample.

Among 17 patients randomized to group B, there were uropathogen bacteria detected in 9 samples collected by urine dripping from the stoma (53%). The second sample collected by clean stoma catheterization had uropathogen bacteria in 7 of these 9 cases ($P = 1.0$). The third sample collected from the urostomy pouch had uropathogen bacteria detected in 7 cases (41%) ($P = .5$). One urostomy pouch sample was lost after sample collection in this group. There were no uropathogen bacteria identified in samples collected from the urostomy pouch in patients with no uropathogen bacteria on the first or second sample.

Assuming sample collection by clean stoma catheterization as the most reliable method, in 1 patient, uropathogen bacteria were not detected by urine dripping from the stoma method (group A). Based on this, 19 (number needed to treat) sample collections have to be performed by clean stoma catheterization in order to detect all uropathogen bacteria, compared with urinary sample collection by urine dripping from the stoma method.

Assuming clean stoma catheterization as the most reliable method of sample collection, the sensitivity and specificity of the urine dripping from the stoma collection method were 81.3% and 90.0%, respectively. The sensitivity and specificity of the urostomy pouch collection method were 73.3% and 90.0%, respectively. Among the same patients, there were no significant differences in the incidence of uropathogen bacteria when clean stoma catheterization was compared with the dripping ($P = 1.0$) and urostomy pouch ($P = .7$) samples.

TABLE 1.
Demographics of the Randomized Patients

	Group A (n = 19)	Group B (n = 17)	*P*
Age, mean (range), y	69.6 (57-84)	72.3 (46-86)	.39
Gender (female), n (%)	2 (10.5)	3 (17.6)	.65

TABLE 2.
Urine Culture Findings of 3 Urine Sample Collection Methods[a]

Technique	Pathogen	$>10^2$CFUs, n (%)	$\geq 10^4$CFUs, n (%)
Catheter (n = 36)	Gram-negative rod	15 (41.7)	15 (41.7)
	Gram-positive cocci	1 (2.8)	1 (2.8)
	Staphylococci	2 (5.6)	1 (2.8)
	Low polymicrobial bacterial count	13 (36.1)	0 (0)
	Negative	5 (13.9)	19 (52.8)
Dripping (n = 36)	Gram-negative rod	17 (47.2)	14 (38.9)
	Gram-positive cocci	1 (2.8)	1 (2.8)
	Staphylococci	1 (2.8)	1 (2.8)
	Low polymicrobial bacterial count	14 (38.9)	0 (0)
	Negative	3 (8.3)	20 (55.6)
Pouch (n = 35)	Gram-negative rod	11 (30.6)	11 (30.6)
	Gram-positive cocci	2 (5.6)	2 (5.6)
	Staphylococci	1 (2.8)	0 (0)
	Low polymicrobial bacterial count	16 (44.4)	0 (0)
	Other	1 (2.8)	1 (2.8)
	Negative	4 (11.1)	21 (58.3)

Abbreviation: CFU, colony forming unit.
[a]Urine cultures showing more than 10^2 and 10^4 or more CFUs/mL of urine.

DISCUSSION

Asymptomatic bacteriuria among patients with ileal conduit urinary diversion is common, and there is no evidence to support treatment of asymptomatic bacteriuria in this patient group.[5,6] The recommended urine sample collection method after noncontinent urinary diversion is clean stoma catheterization of urostomy.[8] Sample collection from clean urostomy pouch may be an option,[9] although it is not widely recommended.[10]

TABLE 3.
Comparison of Urine Culture Findings Between the Groups[a]

	Group A, n (%)	Group B, n (%)	*P*
First sample with uropathogen bacteria $>10^4$			.50
Catheterization	7 (36.8)		
Dripping urine		9 (52.9)	
Second sample with uropathogen bacteria $>10^4$			.31
Dripping urine	6 (31.6)[b]		
Catheterization		9 (52.9)[c]	
Third (from the urostomy pouch) sample with uropathogen bacteria $>10^4$	6 (31.6)[d]	7 (43.8)[e]	.50

[a]Group A (n = 19) had the first urine sample collected by catheterization, followed by urine sample collection by dripping urine from the urostomy pouch. Group B (n = 17) had the first urine sample collection by dripping urine from the urostomy pouch, followed by urine sample collected by catheterization. Subsequently, all patients had a third urine sample collected from a factory-clean urostomy pouch. One group B urostomy pouch sample was lost after sample collection.
[b]$P < .001$ when compared to the first sample in group A.
[c]$P = .057$ when compared to the first sample in group B.
[d]$P = .01$ when compared to the first sample in group A.
[e]$P = .003$ when compared to the first sample in group B.

Previously, the influence of collection technique on urine culture findings was studied among 13 asymptomatic patients with ileal conduit.[9] Urine samples were collected from the urostomy pouch in situ, aseptically from the conduit using a catheter, or from a fresh urostomy pouch applied after stoma care. Most samples (61%) from the urostomy pouch in situ were infected ($>10^5$ bacteria/mL), whereas only 6% of samples obtained by the catheter were infected. Of the samples from the fresh urostomy pouch, 19% were infected. The authors concluded that urine collection technique other than aseptic catheterization led to overestimation of significant infection. However, when catheterization is not possible, a fresh pouch may be used for urine sample collection.[9] Our results presented here support this strategy.

The criterion for defining significant bacteriuria is commonly the presence of more than 10^5 CFUs/mL of urine,[12-14] but a colony count limit of 10^4 CFUs/mL is expected to increase the sensitivity of the test without making the test impractical for clinicians and laboratories to use.[11] In this trial, a limit of 10^4 or more was used for statistical analysis, as this sensitivity reporting limit is used at our institution for urinary cultures from urologic and nephrologic patients.

LIMITATIONS

Limitations of the present study include the small number of enrolled patients. As patients with suspected symptomatic urinary tract infection were excluded, these results may not be directly applicable for patients with suspected urinary tract infection. Furthermore, individual laboratory sensitivity criteria for urinary culture result reporting may affect the usefulness of these results in daily practice.

CONCLUSION

With available techniques, asymptomatic bacteriuria is a common finding among patients with ileal conduit urinary diversion. In this study, urine sample collection technique had a minor effect on the detection of potential uropathogen bacteria. Significant differences between the study groups were not detected. Among the same patients, there were no significant differences in the incidence of uropathogen bacteria when clean stoma catheterization was compared with urine dripping from the stoma method and the clean urostomy pouch method. Patients in our study were asymptomatic. Our results suggest that urinary samples collected by urine dripping from the stoma method or from a clean urostomy pouch would, in most cases, provide similar clinically significant uropathogen bacteria findings compared with sample collection by clean stoma catheterization. Treatment should only be considered if accompanied by clinically relevant symptoms.

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