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Evaluation of the Bacteriuria Detection Device

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The ability of the Bacteriuria Detection Device (BDD) (Marion Laboratories, Kansas City, Mo.) to detect significant bacteriuria was evaluated. Quantitative plating and BDD results were compared for 513 clinical specimens, 188 of which were voided. Eighty-seven specimens (17%) could not be tested because of clogging or excessive pigmentation. Specimens were considered positive if they contained more than 10^4 bacteria per ml. Thirteen specimens gave false-negative BDD results; 10 of these contained gram-positive cocci. The sensitivity of the BDD test was calculated to be 89%; the specificity, 65%. The predictive value of a negative test was 94%; that of a positive test was 49%. The efficiency of the BDD test was 71.6%. The BDD has the potential for providing rapid detection of bacteriuria, but requires further improvement before it can reliably be substituted for urine culture.

Quantitative urine culture is the most frequently ordered bacteriological test and often accounts for more than half of the work load of a bacteriology laboratory. Results are dependent upon the growth of bacteria and consequently require at least 18 h for completion. False-negative results may be obtained for specimens from patients receiving antimicrobial drugs or for specimens containing less than 10^3 bacteria per ml. False-positive results may occur for specimens that have been improperly obtained or that have been stored for prolonged periods before plating.

Recently, the Bacteriuria Detection Device (BDD) (Marion Laboratories, Kansas City, Mo.), a device utilizing a simple colorimetric test for the rapid detection of bacteriuria, has been described (5). The test does not require bacterial growth and is unaffected by residual antibiotics in the urine (5). The method is based upon the passage of a small volume of urine through a bacteria-retaining filter, followed by the sequential passage of dye and decolorizer through the same filter. The depth of color of the stained filter is related to the quantity of bacteria on the filter surface and can therefore give an indication of the bacterial density in the urine specimen. The filter is decolorized with urine specimens containing less than 10^5 CFU/ml; the filter remains pink when specimens containing 10^5 CFU/ml or more are processed.

The present paper describes the evaluation of this device with clinical specimens of urine and compares the results to those obtained by a conventional cultural technique.

MATERIALS AND METHODS

Approximately half of the urine specimens were obtained from inpatients of The Presbyterian Hospital and the remainder from clinic outpatients. The majority of specimens came from adult patients and included both voided and catheterized urines. Specimens were transported in sterile plastic tubes without any preservative and were received in the laboratory within 2 h after voiding or catheterization. Specimens arriving during the day were processed for detection of significant bacteriuria by culture methods and by the BDD within minutes of each other; specimens arriving during evening hours were cultured immediately and were stored at 5°C for BDD processing the following day.

Culture method. The specimens were mixed by inversion, and 0.01 ml of urine was delivered to the surface of each of three plates by means of a calibrated loop. The media used were MacConkey agar, colistin-nalidixic acid agar with 5% sheep blood, and Columbia agar with 5% sheep blood (Scott Laboratories, Fiskeville, R.I.). The urine was spread uniformly over the surface of each plate with an L-shaped glass rod that had previously been flamed and cooled. Plates were incubated under 5% CO_2 at 35°C for 18 to 24 h, at which time colony counts were performed. This method cannot accurately detect bacteria in numbers fewer than 1,000/ml or in concentrations greater than 20,000/ml. Gram-positive species were tested for catalase production, coagulase, and growth on bile-esculin medium; gram-negative organisms were speciated by a microdilution method (American MicroScan Co., Mahwah, N.J.) that also provided antimicrobial susceptibility data.

BBD procedure. The apparatus consisted of a central processing unit equipped with two "barrels," each having its own dispenser cap and filter slot, bottles of reagents, a vacuum pump, and a reservoir for waste. Filter cards containing a printed color scale were also

provided. After inserting a filter card in the slot beneath barrel no. 1, 1.0 ml of the mixed urine specimen was pipetted into that barrel, the dispenser cap was replaced, and the automatic sequence was activated. This caused the sequential addition of 14.5% acetic acid to the urine, the successive filtering of the diluted urine, followed by 0.01% safranine and, finally, 2.4% acetic acid through the filter card. The filter card was then transferred to the slot beneath barrel no. 2, and 3.0 ml of 2.4% acetic acid was added manually to that barrel and suctioned through the filter card. The filter card was removed and the central portion was visually compared with the printed color scale to determine the extent of the reaction. Filter cards were read immediately after processing while still wet and reread again several days after they were dry. Reactions were read as 0, ±, 1+, 2+, 3+, or 4+, based upon the intensity of the color. The manufacturer recommended that reactions of ± or greater should be considered to indicate counts of 10^5 CFU/ml or greater. It was observed that the color of the filter card became lighter after drying. The time required for BDD processing was estimated and compared with the time needed to detect bacteriuria by conventional plating methods.

RESULTS

A total of 513 urine specimens were received; 188 of these were voided specimens and the remainder were obtained by catheter.

A total of 426 specimens were processed by both culture and BDD methods (Table 1). Eighty-seven specimens (17%) could not be compared by the BDD because of clogging of the filter or excessive pigmentation that interfered with the reading. For the purpose of this study, specimens containing more than 10^4 CFU/ml were considered positive, the criterion presently employed by this laboratory.

One hundred and eighteen specimens had counts greater than 10^4 CFU/ml; 89% of these gave positive BDD results when the filter cards were read wet, and 79% were positive when reread dry. Three hundred and eight specimens showed either no growth or less than 10^4 CFU/ml; 65% of these gave negative BDD results when read wet, and 82% gave negative results when reread dry (Table 2).

Of the 13 false-negative reactions, 10 were associated with specimens containing gram-positive cocci. Conversely, about half of the false-positive reactions were in specimens that showed no growth when cultured.

TABLE 2. BDD results obtained for 426 urine specimens

Culture results	No.	No. with following BDD result:			
		Positive (± or greater)		Negative (0)	
		Wet	Dry	Wet	Dry
Positive (>10^4 CFU/ml)	118	105	93	13	24[a]
Negative (no growth or <10^4 CFU/ml)	308	108	56	200	252

[a] One filter card was lost and could not be read dry.

Twelve of the 17 specimens that clogged the filter and 10 of the 70 specimens with excessive pigment were found to contain more than 10^4 CFU/ml.

The time required to process a urine specimen by the BDD method was approximately 3.3 min.

DISCUSSION

The detection of significant bacteriuria remains an essential factor in the diagnosis of urinary tract infections. The rapid determination of bacteriuria can have a profound effect on patient care as well as laboratory economics; in the former case by avoiding unnecessary antimicrobial treatment in patients who have normal urine and in the latter situation by eliminating perhaps 70% of the cost of labor and materials associated with the quantitative culture of negative urine specimens.

Microscopic examination of Gram-stained unspun urine can detect bacteriuria at a level of 10^5 CFU/ml (1), but unfortunately, this technique is too labor intensive to be utilized for this purpose in laboratories processing high volumes of urine specimens. Chemical methods for detecting bacteriuria have been shown to be unreliable (2), and so-called rapid methods requiring 4 to 6 h seldom affect clinical practice since the physician and patient rarely remain together for that period of time. Two approaches to the detection of bacteriuria within a 30-min period are the ATP-dependent bioluminescence technique (4)

TABLE 1. BDD readings and colony counts obtained with 426 urine specimens

Colony count (CFU/ml)	No. with following BDD reading:											
	0		±		1+		2+		3+		4+	
	Wet	Dry	Wet	Dry	Wet	Dry	Wet	Dry	Wet	Dry	Wet	Dry
No growth	126	161	48	14	9	7	6	6	0	1	0	0
<10^3	37	46	13	6	5	3	1	1	1	1	0	0
10^3–10^4	37	46	12	7	8	3	0	1	2	2	3	3
>10^4	13	24	18	20	27	17	22	16	22	25	16	15

and the colorimetric BDD method described here.

In theory, the BDD is rapid and simple. On the basis of the criterion of 10^4 CFU/ml, we have calculated the sensitivity of the BDD to be 89%, the specificity to be 65%, and the efficiency to be 72% when the filter cards are read wet and 81% when the filters are read dry. The predictive value of a positive BDD test in detecting significant bacteriuria was calculated to be 49%; the predictive value of a negative test was 94%.

In actual practice, significant problems were encountered with the BDD. These included the inability to process 17% of the specimens because of clogging of the filters or excessive pigmentation; a false-negative rate of 2.5 to 4.7% (depending upon whether the filter cards were read wet or dry), and a false-positive rate of 10.7 to 21%. Positive specimens were detected more efficiently by wet readings, whereas negative specimens were best eliminated by reading the dried filter card. Many of the false-negative results were associated with specimens containing gram-positive cocci; false-positive results were due to increased filter color values possibly caused by soluble proteinaceous material in the specimen.

It has recently been shown that 30% of female patients with symptomatic urethritis have urine counts of less than 10^4 CFU/ml; often as low as 10^2 CFU/ml (3). Urine cultures with 10^5 CFU/ml as the critical value for these patients have a sensitivity of 51% and a specificity of 99%. Lowering the critical value to 10^2 CFU/ml would raise the sensitivity to 95% while the specificity would become 85% (3).

It is obvious from this study that the BDD in its present form lacks sufficient sensitivity to be reliably substituted for culture methods. If the sensitivity could be increased and the problem of clogging and pigmentation resolved, the method could be extremely valuable in clinical laboratories especially if it could be automated.

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