

# Prospective Trial of a Passive Diversion Device to Reduce Blood Culture Contamination

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**Background.** Blood culture contaminants can lead to inappropriate antibiotic use, prolonged length of stay, and additional hospital costs. Several devices have been developed to reduce the risk of blood culture contamination by diverting a portion of the initial blood sample from the blood culture bottle. We assessed the effectiveness of 1 blood diversion device (BDD) in a prospective trial performed at the 2 separate emergency departments (EDs) of an academic medical center.

**Methods.** A multiphase prospective crossover trial was performed with the BDD in use at 1 ED and standard equipment at the other ED for 10 weeks, and a second 10-week study phase was conducted with the use of the BDD and standard equipment in the EDs reversed. Contaminants were identified both by standard clinical microbiology lab criteria and by independent retrospective review by 3 infectious disease (ID) physicians. The primary analysis was performed based on intention-to-use data using the physician review of positive blood cultures.

**Results.** A total of 5637 blood samples were obtained, with 5625 samples analyzed after 12 blood culture results were deemed inconclusive by the ID physician review. The University ED had a higher blood culture contamination rate of 2.9% compared with the Memorial ED at 1.4%. In an intention-to-use analysis, the overall contamination rates were 2.0% and 2.9% in the BDD and standard equipment periods, respectively ( $P = .03$ ), and in an actual-use analysis the contamination rates were 1.2% and 3.0% for the BDD and standard equipment, respectively ( $P < .001$ ).

**Conclusions.** The BDD was associated with significantly lower blood culture contamination rates at the institution's 2 EDs, with a stronger effect noted at the campus caring for higher acuity patients.

**Keywords.** bacteremia; blood cultures; contaminants; infection control and hospital epidemiology ; blood diversion device.

Blood cultures are critically important for detecting bacteremia in patients. However, as with any test, false-positive results (blood culture contaminations [BCCs]) are inescapable and can lead to inappropriate antibiotic use, prolonged length of stay, and additional hospital costs [1–3]. While target rates for contamination have been set at 1% per newer recommendations (prior target of 2%–3%), actual rates seem to vary widely between institutions, from as little as 0.6% to >6% [3–5]. Contamination of blood cultures can occur even when precise techniques for collection and processing are used. This has been linked to bacteria present below the skin surface in pores and hair follicles that

enter the bore of the needle as it passes through the skin [5]. Given this concern, an additional approach has been developed to discard an initial portion of blood drawn through the collection needle, either by filling and discarding a blood collection tube or by utilizing collection devices designed to divert the first volume of blood. A recent single-site study of 1 such blood diversion device (BDD), Steripath from Magnolia Medical Technologies, that diverts the first 1.5–2.0 mL of blood before collection of blood for culture found a reduction in blood culture contamination rates (from 1.78% to 0.22%) without reducing the sensitivity for detection of true bacteremia and candidemia [6]. An alternative Food and Drug Administration–approved passive BDD, named Kurin Lock from Kurin Inc., diverts the initial 0.15 mL of the blood specimen, and initial clinical trials indicate that it can produce a similar reduction in contaminated blood cultures [7, 8]. However, all of these studies have had design limitations including before-and-after trial designs and lack of concurrent control groups. The availability of 2 separate emergency departments (EDs; University and Memorial) at UMass Memorial Medical Center, a tertiary care 3-campus academic medical center with recent BCC rates of 3.3% and 2.6%, respectively, has allowed for the performance of a prospective crossover

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control trial comparing BCC rates with a passive BDD vs standard blood culture collection equipment in the ED setting.

## METHODS

All blood culture samples obtained from the 2 EDs during the study period of September 16, 2019, through February 16, 2020, were included in the trial. Pediatric blood culture samples were excluded from the study as there was dedicated pediatric staffing on only 1 of the campuses. The study period was divided into 2 study phases, with the passive 0.15-mL BDD (Kurin) initially used at the Memorial ED and standard blood culture equipment at the University ED for 10 weeks, followed by a 2-week washout period, and then a second study period where the use of the BDD and standard equipment was reversed between the 2 campuses for another 10-week period. The University Campus is the site of a level 1 trauma center, a stroke center, interventional cardiology/cardiac surgery centers, a pediatric intensive care unit, and transplant services, while the Memorial Campus has general medical/surgical services, elective orthopedic surgical services, and obstetrical/gynecologic services.

Blood cultures were obtained when clinically indicated in patients presenting to the 2 emergency rooms. Each blood draw consisted of 2 separate “sticks,” yielding 2 sets of cultures (4 bottles in total). Each blood culture result was counted independently when calculating the BCC rate. All blood culture samples were obtained by the nursing staff in the respective EDs regardless of whether they were collected with the BDD or standard equipment. Before venipuncture, standard skin disinfection was performed using 2% chlorhexidine gluconate and 70% alcohol for 30 seconds with adequate time allowed for drying. The blood culture bottles drawn with the BDD were labeled with a yellow tag, and the UMass Memorial Medical Center Microbiology lab recorded the BDD use and processed the blood cultures following standard procedures. Positive blood cultures considered likely to have contaminants were determined both according to standard laboratory definitions [9] and by chart review by 3 independent infectious disease physicians considering the patient’s reported clinical history, physical findings, laboratory and imaging findings, number of positive blood cultures out of the total number performed, clinical course, and response to therapy. In practice, a positive blood culture was more likely to be considered to have a contaminant if it consisted of 1 or more of the typical skin bacteria growing in 1 of 4 culture bottles, in the absence of fever and a clear identifiable source, occasionally accompanied by chart documentation of a difficult blood draw. Standard lab practice defined blood culture contamination as any culture where low-virulence organisms typical of normal mucocutaneous flora are isolated from a single culture of all blood culture sets obtained from 1 patient on the same day (eg, coagulase-negative staphylococci, alpha-hemolytic streptococci, *Micrococcus* species, *Cutibacterium*

[*Propionibacterium*] species, *Corynebacterium* species, and *Bacillus* species) [9]. The primary analysis was performed based on physician categorization of false-positive results using an intention-to-use model. Additional secondary analyses included (1) a comparison of BCC rates based on the actual observed use of the BDD (“actual-use analysis”), (2) a comparison of BCC rates based on microbiology laboratory classification of contamination, and (3) a comparison of the true-positive blood culture rates. Chi-square tests using a significance level of 5% were used for these analyses.

## RESULTS

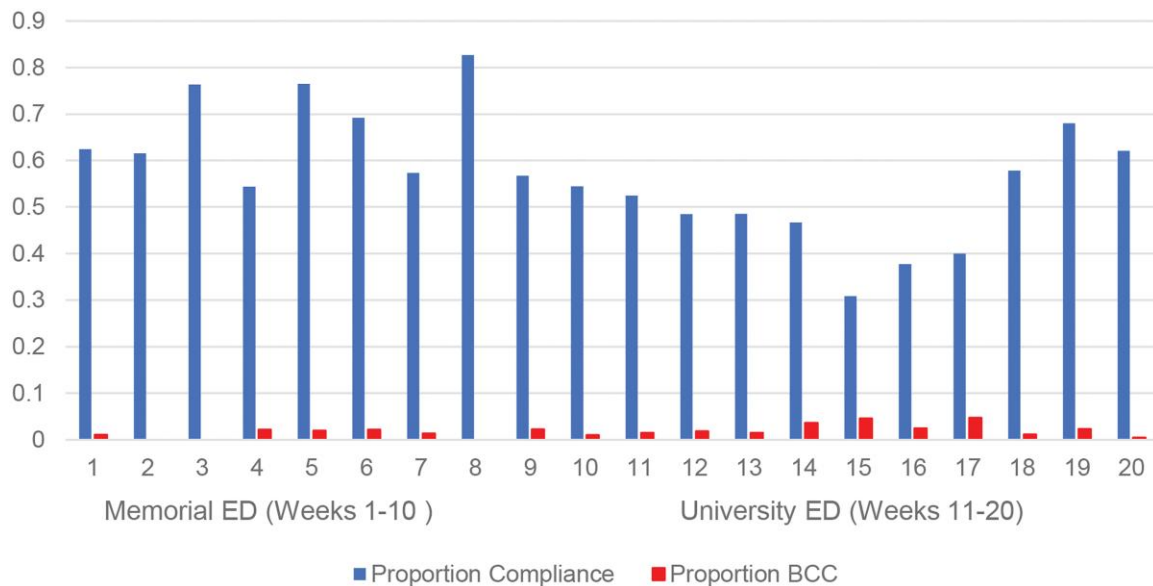
There were 5637 individual blood culture bottles collected, with 624 having microbial growth. Twelve samples with bacterial growth were excluded from analysis as ID physician review could not determine conclusively if results represented true bacteremia or contaminants. Among 159 samples that met lab criteria for BCC, ID physician review identified 27 (17%) that were clinically considered to represent a true infection; among 453 samples identified as a true pathogen by lab criteria, only 6 (1%) were deemed to be a BCC by ID physician review. The overall BCC rate across both EDs combined was 2.4%.

Among the included samples, 1710 were obtained from the Memorial ED and 3915 from the University ED; 2815 samples were drawn during periods randomized to use standard blood collection methods, and 2810 were drawn during periods randomized to use the BDD. Weekly compliance with the use of the BDD in the assigned EDs varied throughout the study period, ranging from 31% to 83% (Figure 1), with an average of ~56%.

The intention-to-use analysis showed that the overall BCC rate was significantly lower overall during the BDD-assigned intervals vs during intervals using standard methods (2.0% vs 2.9%, respectively), as well as in both EDs individually (Table 1). There was a general correlation between the intention-to-use BCC and the weekly compliance with BDD usage (Figure 1). The effectiveness of the BDD was greater in the actual-use analysis, with a BCC rate of 1.2% using the BDD vs 3.0% using standard equipment ( $P < .001$ ) (Table 1). The Memorial ED had a lower BCC rate (1.4% overall) compared with the University ED (2.9% overall), and the reduction in BCC rates associated with use of the BDD was greater in the University ED. A secondary analysis of the effectiveness of the BDD based on the microbiology laboratory classification of contaminants had similar results (Supplementary Tables 1 and 2). The true-positive blood culture rates were not significantly different between the use of the BDD and the use of standard equipment (Table 2; Supplementary Table 3).

## DISCUSSION

The results of this prospective controlled trial affirm that the BDD did lead to a decrease in BCC rates in busy ED settings



**Figure 1.** BDD compliance—the bar graph displays the proportion of blood samples collected using the BDD in the emergency department randomized to use the BDD each week during the study period as well as the ITU blood culture contamination rate in that ED. Abbreviations: BDD, blood diversion device; ED, emergency department; ITU, intention-to-use.

in both the intention-to-use and actual-use analyses. Multiple approaches have been developed to try to limit BCCs including the use of blood collection kits, skin antisepsis techniques, blood culture bottle disinfection techniques, collection site location, use of a single needle as opposed to 2 needles to inoculate the culture bottles, use of sterile gloves, intensified multimodal educational programs, and use of phlebotomy teams for culture collection [4, 5, 10–16]. While all of these approaches are beneficial and generally recommended for institutional protocols, even with their implementation many institutions have found it difficult to achieve the prior recommended target of a blood culture contamination rate of <3% [17, 18]. A newer approach has been the additional use of a BDD to prevent contamination from the introduction of bacteria into the lumen of the collection needle as it passes from the skin surface to the vein.

There was a significant difference in the blood culture contamination rates between the 2 Eds, such that a direct comparison of the effectiveness of the BDD could not be assessed in each of the 2 intervention time periods. This difference in contamination rates between the 2 EDs was likely related to major differences in the volume of patients [19], the acuity of presentation, and the patient populations (immunosuppressed, transplant, cardiac/neurologic emergency patients) [20]. However, it is notable that the effectiveness of the BDD in lowering the contamination rate was greater in the University ED, which had a higher baseline contamination rate. This is significant, as the use of a BDD at an institution with a low contamination rate may not necessarily capitalize on its effectiveness.

As compared with other recent studies, our trial is unique in its approach of having the positive blood cultures reviewed by 3 independent ID physicians. This helps in part validate true positives in some bacteremia cases with traditionally labeled “skin contaminants” growing from the cultures. Determination by lab criteria and ID physician clinical review yielded similar results. Importantly, there was no significant difference in the rate of detecting true bacteremia between the 2 modes of blood draw, something that was both reassuring and expected. In addition, the crossover trial design assisted in minimizing confounders that could arise from having different ED staff drawing blood cultures, different patient risk factors (such as immunocompromised, cardiac, neurological emergencies), and different volumes of patients, all of which can affect the need and quantity of blood cultures drawn [20]. The study did not use a randomized trial design, so the application of the intention-to-use principle helped yield unbiased and more accurate results compared with an as-treated analysis, even though it may have underestimated the magnitude of the intervention effect in appropriate (compliant) BDD use cases.

Other studies have shown a reduction in BCC rate down to 0.8% using Steripath from Magnolia Medical Technologies [6, 21]. Prior work suggests that optimal reduction in BCC can be achieved with a diverted volume of 0.5 mL to 2.0 mL [22]; however, studies using the Kurin Lock from Kurin Inc. similarly showed excellent reduction in BCC rates by diverting 0.15 mL [8, 23, 24]. It is difficult to ascertain if the difference in BCC rate reduction is solely due to diverted blood volume,

**Table 1. Blood Culture Contamination Rates**

Analysis	Overall, No. (%)	BDD, No. (%)	Standard, No. (%)	P Value
Both EDs	138/5625 (2.45)	56/2810 (1.99) <sup>a</sup> 19/1597 (1.19) <sup>b</sup>	82/2815 (2.91) <sup>a</sup> 119/4028 (2.95) <sup>b</sup>	.03 <sup>a</sup> <.001 <sup>b</sup>
Memorial ED	23/1710 (1.35)	11/885 (1.24) <sup>a</sup> 5/584 (0.86) <sup>b</sup>	12/825 (1.45) <sup>a</sup> 18/1126 (1.60) <sup>b</sup>	.70 <sup>a</sup> .21 <sup>b</sup>
University ED	115/3915 (2.94)	45/1925 (2.34) <sup>a</sup> 14/1013 (1.38) <sup>b</sup>	70/1990 (3.52) <sup>a</sup> 101/2902 (3.48) <sup>b</sup>	.03 <sup>a</sup> .001 <sup>b</sup>

<sup>a</sup>Intention-to-Use Analysis<sup>b</sup>Actual-Use Analysis

especially with the contrast in study design and BDD compliance rates.

Blood culture contamination rates have profound clinical and financial impacts as contamination can lead to longer inpatient lengths of stay and expose patients to additional unnecessary therapies. Multiple studies performed before 2010 showed that ~40% of patients with false-positive blood cultures received unnecessary antibiotic therapy, with median courses of 6 to 7 days [2, 25–27]. Additionally, multiple studies have also shown a significant financial impact related to blood culture contamination, with older studies documenting increases in hospital charges or costs ranging from \$4100 to \$8756 primarily related to increases in lengths of hospitalization and antimicrobial therapy [1, 28–30]. A more recent single-center retrospective study of blood culture contamination performed between 2014 and 2018 found that each blood contaminant was associated with an increase in hospital length of stay (1.3 days), antibiotic exposure (1 day), acute kidney injury, echocardiogram orders, and increased hospital charges of \$7132 [31]. A second retrospective review performed in both Dutch and US hospitals between 2016 and 2019 found that blood culture contamination was associated with 1.6–1.7 additional days of antibiotic use, higher use of blood cultures, and a 3.36-day longer length of stay in the Netherlands [32]. It is probable that the lower impact of the false-positive blood culture on hospital length of stay and antibiotic usage in these 2 newer studies is due to the increasing use of newer rapid diagnostic approaches such as multiplex polymerase chain reaction assays and matrix-assisted laser desorption ionization–time of flight mass spectroscopy (MALDI-TOF MS) identification [33–35].

Our study has several limitations. First, even with expert clinical review, there is still a lack of a gold standard definition for blood culture contamination, as illustrated by the need to exclude a small number of observations due to an inability to classify a culture as being a true- or false-positive result. Second, compliance with the use of the BDD was not uniform across the span of the study, with a decrease in compliance noted around weeks 15 and 16 when the BDD was in use at the University ED. This coincided with a holiday period when

**Table 2. Intention-to-Use Analysis of True-Positive Culture Rates**

Analysis	Overall, No. (%)	BDD, No. (%)	Standard, No. (%)	P Value
Both EDs	474/5625 (8.43)	231/2810 (8.22)	243/2815 (8.63)	.58
Memorial ED	149/1710 (8.71)	76/885 (8.59)	73/825 (8.85)	.85
University ED	325/3915 (8.30)	155/1925 (8.05)	170/1990 (8.54)	.58

Abbreviations: BDD, blood diversion device; ED, emergency department.

there were likely to have been changes in the department staffing as well as coverage by staff with less experience with the use of the BDD. Furthermore, even though training for the use of the BDD was done at different time slots, some nursing staff members were not able to attend training sessions due to shift variabilities. Additionally, some nurses reported that it took longer to collect a blood culture using the BDD as compared with standard equipment and may have elected to not use the device. This could have been more evident in the case of patients deemed to have “difficult sticks.” Other potential lapses could have occurred if ED staff failed to tag the cultures drawn with the BDD, and there could have been errors in recording the yellow-tagged cultures by the microbiology lab upon receipt of specimens. Third, the patients were not randomized given the difficulty in application in a real-world scenario in the ED and the need for prior consent. Fourth, while statistical analyses were not performed until all the physician review data had been completed, the physicians were not blinded as to whether samples had been collected with the BDD—although the similar results noted based on standard clinical microbiology lab criteria indicated that this did not impact the overall findings. Fifth, although it was not standard practice, we do not know if during the standard collection time periods ED staff may have occasionally obtained blood cultures while starting a peripheral intravenous catheter, which could have increased the BCC rate. Sixth, our institution did not have a formal hospital-wide effort to reduce blood culture contamination before the BDD project. As part of the nurse training for the use of the BDD focused on standard antiseptic procedures, it is possible that the added training helped potentiate the effect from the use of the BDD.

In conclusion, the use of the BDD led to an overall reduction in blood culture contamination rates by 1% at our institution’s 2 Eds, with a stronger effect noted in the ED at the campus with higher patient acuity. The absolute impact of the BDD would likely have been notably greater with more consistent use of the device, which would be achieved by integration of its use in the Standard Operating Procedure for Blood Culture Collection used by the EDs. Assuming that the cost of a false-positive blood culture was \$4000, at the low end of reported costs, the use of the BDD at our institution would potentially decrease the cost of contaminated blood cultures by \$1 million annually. Equally important at a time when there is a nationwide concern with hospital overcrowding and patient flow,



the use of the BDD could potentially save our institution 187–343 hospital-days annually and be an important addition to ongoing practices to minimize BCCs. However, as new guidelines push for the more stringent 1% BCC rate benchmark, the use of a BDD alone may not be enough, and achieving that goal will certainly require more effort in training staff on standard approach and antiseptic techniques.

### Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

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**Author contributions.** Ellison, Greenough, and Arnaout conceived of the study and were involved in writing and editing the manuscript. Stock and Clifford handled the data management, statistical analysis, and edited the manuscript. Wedig collected and organized the data and helped with management of the study. Mitchell oversaw the microbiology data and provided guidance on the appropriate reference guidelines.

**Patient consent.** The study design was approved by the local institutional review board. The study did not include factors necessitating patient consent.

**Potential conflicts of interest.** None of the authors had any conflicts of interest.

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