Connecticut Medicine

The Scientific, Peer-Reviewed Journal of the Connecticut State Medical Society, Published Since 1936

VOLUME 83 **FEBRUARY 2019** **NUMBER 2**

CONNECTICUT MEDICINE (ISSN 0010-6178), published monthly except June/July and November/December at 127 Washington Ave., East Building, 3rd Floor, North Haven, CT 06473. Subscription rate included in membership dues. Nonmembers: $60.00 per year. Periodicals postage paid at New Haven, Connecticut and at additional mailing offices. POSTMASTER: Send address changes to Connecticut Medicine, 127 Washington Ave., East Building, 3rd Floor, North Haven, CT 06473.

Reducing False-Positive Blood Cultures: Using a Blood Diversion Device

DAVID M. O'SULLIVAN, PhD, AND LEE STEERE, RN

ABSTRACT – Background: Determining if and when a patient receives antibiotic therapy can be a life-saving decision. If a person has an infection, starting antibiotics early is important; however, if a person does not need the antibiotics, starting them has significant financial and health-related consequences.

Objective: To evaluate if a minimal-risk blood diversion device could be used successfully to reduce the rate of false-positive blood cultures.

Methods: The false-positive blood culture rate (FPR) was compared for three months using a blood diversion device and three months not using a blood diversion device.

Results: There was a significantly lower rate of FPR during use of the blood diversion device (0.44%), compared with an average of 1.71% for the three months not used, an average reduction of 74.1%.

Key words: False positive, blood culture, device, antibiotic reduction, blood diversion

Introduction

In today's health care environment, hospitals face serious financial consequences from hospital-acquired infections (HAIs) and specifically with blood stream infections (BSIs). Many efforts have been made to impact the incidence of BSIs in acute care settings, including the implementation of insertion and maintenance bundles, intense focus on hand washing, and inventions like the needle port disinfecting cap technology. Hartford Hospital, an 869-bed level 1 trauma center, utilized these procedures in successfully decreasing its incidence of BSIs.

While efforts continue to reduce BSI rates and other HAIs in hospitals, a related critical issue is the accurate identification of patients with infections; the results of a blood-culture test must be accurate to effectively manage hospital resources. False-positive blood cultures (FPBCs) are a serious problem from several perspectives, including cost, antibiotic stewardship, and the impact on patients. The benchmark for US hospitals is 2% – 3%, with an incidence up to 10% in some emergency departments (ED),[1] with an associated cost of $4500 – $10 000 per event.[2,3] Using a benchmark rate of 3%, there are still over 1.2 million patients put at risk with false-positive results annually.[4]

A blood culture is a test that identifies patients with an infection, and a FPBC occurs when organisms not present in the blood are grown in cultures; the test shows they have an infection when they actually do not. False-positive results cost hospitals money (in drug use and resources), extend hospital stays, expose patients to unnecessary medications, contribute to a growing global problem of drug-resistant organisms, and may impact patient satisfaction scores. False positives occur for various reasons, but most of them occur before the blood is analyzed, during the collection and handling process.[5] One major factor is that contaminants are introduced into the sample during the collection of the blood.

David M. O'Sullivan, PhD, Research Administration, Hartford HealthCare, Hartford; Lee Steere, RN, CRNI, VA-BC, IV Therapy Services, Hartford Hospital, Hartford. Corresponding author: David M. O'Sullivan, PhD, david.osullivan@hhchealth.org

Determining if and when a patient receives antibiotic therapy is a critical and sometimes life-saving decision. If a person has an infection, starting antibiotics early is important; however, if a person does not need the antibiotics – either because they do not have an infection or the infection is viral and thus not susceptible to antibiotics – starting antibiotics has significant financial and health-related consequences for the hospital and the patient. According to the CDC, at least 30% of antibiotics prescribed in the US are unnecessary.[6] These 47 million excess prescriptions each year put patients at needless risk for allergic reactions or the sometimes deadly diarrhea, *Clostridium difficile*.[6]

An FPBC can occur with the inadvertent introduction of contaminants into the blood, many of which come from the patient. Human skin holds microbes, and clinicians are supposed to vigorously scrub the area before the venipuncture, but there are two challenges to this procedure. First, in a busy environment such as the ED, health care providers often do not take the time to properly scrub. Second, even if they do scrub properly, it is estimated that 20% of the microbes are just below the surface of the skin, and therefore missed during the surface disinfection process. When the needle is placed through the skin, these microbes are drawn up into the syringe with the blood, and thus these contaminants are part of the sample to be tested.

It has been demonstrated that not using the first sample (aliquot) of blood results in a cleaner sample and lower FPBC rates.[7,8] This concept is well-established; as an example, rejecting the first aliquot of blood is standard practice during the blood donation process.[9] An invention that seamlessly eliminates the first aliquot in the blood culture arena could have a significant impact on these FPBC rates. While eliminating this first aliquot can be accomplished in various ways, clinicians must have a product that does not require a change in their normal process. Anything that requires a change in behavior, or requires more time and manipulation, will result in poorer compliance and less effective outcomes, in addition to having negative consequences for the patients from whom the blood is being drawn.

Kurin, Inc., has invented a new product, Kurin Lock™, specifically to address the relatively high (≥ 3%) incidence of FPBCs. The device is FDA 510(k) cleared and is considered a nonsignificant risk (NSR) device. It is a sterile plastic porous plug, which is placed inline with blood draw tubing. It does not allow for backflow and does not add time or burden to the blood collection process. The device requires no expertise or skills beyond the training already possessed by a phlebotomist or nurse. Additionally, the device poses no risk to patients and causes no delay in providing/receiving care.

Methods/Procedures

After receiving institutional review board approval (HHC-2016-0203), blood was collected using the Kurin Lock device on all patients visiting the Hartford Hospital ED between April and June, 2017, inclusive, from whom blood cultures were ordered. Blood samples were sent to the Microbiology laboratory for standard analysis. The false-positive rate (FPR) for each month is a standard report, providing the number of blood samples analyzed and the number of false-positive findings.

Blood cultures were obtained from two direct venipunctures, one in each arm, using a butterfly set that had the integrated Kurin Lock device. Determination of a FPBC using the Kurin Lock device used the same process and criteria as was done prior to its implementation.

The FPR for the three months using the Kurin Lock device was compared with the historical FPR rate from the most recent three-month period preceding implementation of the device (January – March, 2017, inclusive). Statistics comprised chi square tests, and were conducted with SPSS v. 21 (IBM, Armonk, NY).

Results

Table 1 shows the FPR rate for the most recent three months in which the Kurin Lock device was not used, and most recent three months when the Kurin Lock device was used. There was a statistically significant lower rate of FPR, with reductions ranging from 65% to 82%, in all nine comparisons. For the three most recent months in which the Kurin Lock was used, the false-positive rate was 0.44%, compared with an average false-positive rate of 1.71% for the three most recent months during which the Kurin Lock device was not used, an average reduction of 74.1%. This reduction in the absolute risk also yields a number needed to treat (NNT) equal to eight, meaning that use/implementation of the device would save one person from the ramifications of a FPBC for every eight times the diversion device was used. If we apply a conservative estimate of $5000 per FPBC (based on the low end of the estimated range[2,3]) and include the $15.00 cost of the device, the monthly savings are shown in Table 2.

Discussion

It long has been recognized that sepsis arising from the transfusion of bacterially contaminated platelet components is a serious transfusion complication. Skin organisms are implicated in a number of these septic episodes. As early as 2000, a model system was

Table 1. FPR Rates, % reductions and P values comparing months with Kurin Lock™ device vs months without

with Kurin Lock device (false positive rate)	*without Kurin Lock device (false positive rate)*		
	March, 2017 (1.4%)	February, 2017 (1.6%)	January, 2017 (2.1%)
June, 2017 (0.4%)	-67.8% / *P* = .028	-71.4% / *P* = .013	-79.0% / *P* = .001
May, 2017 (0.5%)	-64.8% / *P* = .028	-68.8% / *P* = .012	-77.0% / *P* = .001
April, 2017 (0.4%)	-72.1% / *P* = .012	-75.3% / *P* = .005	-81.8% / *P* < .001

Table 2. Estimated monthly cost savings at $5,000/FPBC

with Kurin Lock device (number of false positives)	*without Kurin Lock device (number of false positives)*		
	March, 2017 (20)	February, 2017 (24)	January, 2017 (33)
June, 2017 (4)	$80,000	$100,000	$145,000
May, 2017 (5)	$75,000	$95,000	$140,000
April, 2017 (4)	$80,000	$100,000	$145,000

used to investigate if a skin organism's bioburden in blood components could be reduced by diverting the first few milliliters of whole blood away from the primary container.[9] Authors of this study concluded that development of a diversion system for collection of blood may reduce the bioburden of subsequently prepared components and thereby the frequency of sepsis due to skin organisms.[9] More recently, similar blood diversion products have been developed that claim to show as much as a 37% reduction in vancomycin days of therapy.[10] One such device, an initial specimen diversion device (ISDD), has demonstrated positive predictive values for sepsis approaching 97% and reductions in blood contamination rates in the ED.[11]

The Kurin Lock device does not allow the backward flow of fluid as fluid dynamics force blood to the distal end of the tubing, so from a patient perspective, this device is no different than butterfly sets currently in use.

There are no known or foreseeable risks to patient safety or adverse events from using this product. The only adverse events to be expected are those from venipuncture – namely a small (< 5% of patients) risk of bruising at the site(s) of venipuncture, bleeding, and lightheadedness – are all temporary and would be the same if the device were not being used.

Reducing FPBCs has several significant advantages. FPBCs are costly; one study with 8000 ED yearly samples compared annual net savings of two interventional strategies, a sterile kit and phlebotomy team, with usual care and calculated a savings of $483 219 and $288 980, respectively.[12] Using a conservative estimate of $5000 per FPBC, and making an assumption that March's FPR without the Kurin Lock device would remain constant, an average savings for the three months using the Kurin Lock device would result in a yearly savings of more than $900 000, or more than $750 000 after adjusting for device costs. Obviously, a greater reduction in the FPR rate would increase the cost savings. In fact, the hospital's FPBC rate of 1.4% in March (ie, before use of the Kurin Lock device) was lower than either of the two preceding months (1.6% and 2.1%, respectively) and still well below the threshold of 3%.

Another advantage to reducing the FPR is avoiding use of unnecessary antibiotics. The key issue is that as we use antibiotics, bacteria evolve to become resistant to them. Reducing FPBCs means that we help individual patients in the acute sense by saving those patients from unnecessary procedures and medication, which is of direct benefit, and by not prolonging their discharge from the hospital. In the longer term, avoiding prescription of unnecessary antibiotics prevents contributing to (or exacerbating) a potential problem (eg, antibiotic resistance, medication side effects, and drug interactions) for these patients later in life.

Acknowledgments

The authors wish to acknowledge: Rosemary Renouf and the phlebotomy team at Hartford HealthCare; Dr. Jaber Aslanzadeh, Director of Microbiology, Hartford HealthCare; Pamela Hamilton, manager, Clinical Laboratory Partners (CLP) microbiology; Laurie Jacobsen, cytology manager; Yanice Maldonado, Technician, CLP microbiology.

Financial Sources/Disclosures: This study was supported by an investigator-initiated grant from Kurin, Inc. (San Diego, CA). However, neither the company nor any of its personnel had any influence in the design or the analysis of the study, nor drafting of the manuscript.

None of the authors has any disclosures.

REFERENCES

1. Snyder SR, Favoretto AM, Baetz RA, et al. Effectiveness of practices to reduce blood culture contamination: a laboratory medicine best practices systematic review and meta-analysis. Clin Biochem. 2012;45(13-14): 999–1011.
2. Gander RM, Byrd L, DeCrescenzo M, et al. Impact of blood cultures drawn by phlebotomy on contamination rates and health care costs in a hospital emergency department. J. Clin. Microbiol. 2009;47(4):1021–4.
3. Garcia RA, Spitzer ED, Beaudry J, et al. Multidisciplinary team review of best practices for collection and handling of blood cultures to determine effective interventions for increasing the yield of true-positive bacteremias, reducing contamination, and eliminating false-positive central line–associated bloodstream infections. Am J Infect Control. 2015;43(11):1222–37.
4. Plumhoff EA, Masoner D, Dale JD. Preanalytic laboratory errors: identification and prevention. Mayo Clinic Communique, 2008;33(12):1–7.
5. Binkhamis K, Forward, K. Effect of the initial specimen diversion technique on blood culture contamination rates. J Clin Microbiol. 2014;52(3):980–1.
6. Fleming-Dutra KE, Hersh AL, Shapiro DJ, et al. Prevalence of inappropriate antibiotic prescriptions among US ambulatory care visits, 2010-2011. JAMA. 2016;315(17):1864–73.
7. Patton RG, Schmitt T. Innovation for reducing blood culture contamination: initial specimen diversion technique. J Clin Microbiol. 2010;48(12): 4501–3.
8. Liumbruno GM, Catalano L, Piccinini V, et al. Reduction of the risk of bacterial contamination of blood components through diversion of the first part of the donation of blood and blood components. Blood Transfus. 2009;7(2):86–93.
9. Wagner SJ, Robinette D, Friedman LI, et al. Diversion of initial blood flow to prevent whole-blood contamination by skin surface bacteria: an in vitro model. Transfusion. 2000;40(3):335–8.
10. Chang D, Nielsen L, Ager E, White BK. Impact of blood culture diversion device and molecular pathogen identification on vancomycin use. Society of Healthcare Epidemiology of America (SHEA) Conference April, 2017 (poster).
11. Rupp ME, Cavalieri RJ, Marolf C, et al. Reduction in blood culture contamination through use of initial specimen diversion device. Clin Infect Dis. 2017;65(2):201–5.
12. Self WH, Talbot TR, Paul BR, et al. Cost analysis of strategies to reduce blood culture contamination in the emergency department: sterile collection kits and phlebotomy teams. Infect Control Hosp Epidemiol. 2014;35(8):1021–8.