Background

The issue the research addressed: When physicians suspect that a patient has a serious infection, they normally order a special test of the patient’s blood called a “blood culture.” But under current protocols, blood cultures can be unreliable for diagnosing these infections, with contamination rates that range from 1.1 percent to 6 percent.

These percentages may seem small, but they represent a significant number of patients and have major clinical and cost implications. Contamination can lead to false-positive blood cultures. These can in turn lead to unnecessary and inappropriate antibiotic treatment, potentially harmful clinical consequences and substantial health care costs. Over 1 million patients annually in the U.S. have contaminated blood cultures.

The alternative solution that researchers were investigating: The study was undertaken to determine if blood culture contamination could be reduced through the use of an innovative new product referred to as the initial specimen diversion device (ISDD, known as SteriPath®). This proprietary, novel device is a “vein-to-bottle” closed sterile system that mechanically diverts and sequesters the initial 1.5 to 2 milliliters of blood in a blood draw before creating a new, second sterile blood flow path into the culture bottles.

The rationale behind the SteriPath design. Before a patient’s blood is drawn, the health care practitioner applies antiseptic to the patient’s skin to kill surface microorganisms. The anatomy of skin is such that it can be disinfected but not completely sterilized, so some microorganisms and bacteria can survive the antiseptic (in the keratin layer, for example), and are captured when the phlebotomy needle first pierces the skin. These dislodged contaminants can then cause a contaminated blood sample.
Blood culture contamination can also be caused by numerous other circumstances related to standard blood draw procedures in the hospital environment. The self-contained, pre-assembled, sterile system design of the ISDD addresses these challenges, as well.

The study concluded that the ISDD (SteriPath) dramatically reduced blood culture contamination rates. “The study by Rupp et al. is valuable, as it provides us with a better understanding of an effective tool for reducing blood culture contamination,” said an accompanying editorial by Alexander J. McAdam, M.D., Ph.D., of the Department of Laboratory Medicine, Boston Children’s Hospital.

Study Details

Methodology. This was a prospective, controlled, open label trial conducted with patients and personnel in the Emergency Department of the University of Nebraska Medical Center. The study was led by Mark Rupp, M.D., a nationally recognized researcher and infectious disease expert. The research was designed to compare the accuracy of blood culture results collected with the ISDD to blood cultures collected with standard phlebotomy procedures.

Research subjects were patients who required blood cultures due to clinical suspicion of serious infection and who gave consent to be included in the study. Two cultures were collected from each patient using separate venipunctures drawn by phlebotomists. One draw was performed using standard procedures and the other draw was performed with the ISDD. The study involved 904 non-duplicative subjects and 1,808 blood cultures.

Key results included:

* A statistically significant (p=0.001), 88 percent reduction in blood culture contamination was seen with the SteriPath ISDD. When blood cultures were performed with standard phlebotomy procedures, there were 16 contaminated samples in 904 cultures, a contamination rate of 1.78 percent. When the ISDD was used, there were 2 contaminated samples in 904 cultures, a rate of 0.22 percent. The contamination rate with SteriPath was 88 percent lower than for standard phlebotomy procedures.

* More accurate blood cultures. Looking at the false positive issue another way, a positive culture was a true positive 97 percent of the time (65/67) with SteriPath and 81 percent of the time (69/85) with standard procedures. The ratio of true positive to false positive cultures for SteriPath was 33:1 (65/2). For standard procedure, the ratio was 4.3:1 (69/16). “So in other words, the standard cultures give you an awful lot of false signal or noise compared to the diversion device,” said Dr. Rupp.

* Significant projected cost savings. Using a conservative cost estimate of $4,850 per blood culture contamination incident, researchers calculated that the study institution would save $1.8 million per year (373 prevented instances of contamination at $4,850/contamination) if it could achieve the low contamination rate obtained in the study with the ISDD.
* No compromise in sensitivity. True septicemia was noted in 65/904 cultures (7.2 percent) with SteriPath and 69/904 cultures (7.6 percent) with standard procedures.

* No compromise in caregiver safety. No needlestick injuries or potential bloodborne pathogen exposures were reported.

* Widespread user satisfaction. Researchers conducted a post-study, anonymous survey about SteriPath. The 73 percent of phlebotomists who returned the survey felt the ISDD was easy to use and had several widely perceived advantages over standard procedures, including “the ability to easily draw additional tubes of blood in addition to the sample for culture” and “the lack of need to transfer blood from a syringe to blood culture vials.”

* Post-Hoc Analysis. The rate of contamination was significantly decreased among phlebotomists (who used the ISDD) but not for nurses (who did not use the ISDD). This indicates there were no confounding changes in clinician practice that might have influenced the study findings.

Study Conclusion: “Use of the ISDD was associated with a significant decrease in blood culture contamination in patients undergoing blood cultures in an Emergency Department setting.”

Clinical Implications

Blood culture contamination rates with SteriPath were 80 percent lower than the best published rate with phlebotomy best practices. A meta-analysis published in 2012 in Clinical Biochemistry reviewed studies of phlebotomy best practices used to reduce blood culture contamination rates. In those studies the lowest contamination rate achieved was 1.13 percent. The 0.22 percent rate in the current study is 80.5 percent lower than this rate. “We were using all of the recognized appropriate techniques and we had a low baseline level of contamination, but we were able to decrease that very significantly through the use of this device,” said Dr. Rupp.

Study supports SteriPath use to help hospitals meet requirements for antimicrobial stewardship. The Joint Commission now requires all accredited institutions to have an antimicrobial stewardship program. Lower contamination rates contribute to more accurate test results and more appropriate use of antibiotics.

Cost Impacts and Implications

Blood culture contamination is costly. A 2016 study published in Infection Control & Hospital Epidemiology found the annual cost to the U.S. health care system for blood culture contamination was $6.64 billion. Dr. Rupp: “Although only a few percent of blood cultures are
contaminated when using standard techniques, when you multiply it by the millions of blood cultures that are done, it actually ends up having a very big impact.”

_The ISDD is a cost-effective solution._ Dr. Rupp: “If you can cut your blood culture contamination rate from somewhere in the neighborhood of almost 2 percent to 0.2 percent, that is a substantial decrease. It’s clear even without rigorous cost analysis that this device can pay for itself pretty easily.”

**Implications for Future Research**

Researchers wrote: “The very low rate of contamination observed in our study may justify abandonment of the current practice of performing two separate venipunctures (in order to better rule out contamination) which would result in improved patient satisfaction and health care provider safety (fewer venipunctures).”

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