Abstract:

Background: Transfusion of bacterially contaminated platelet concentrates (PCs) can result in serious health consequences for the affected patient. Before being released from blood banking facilities, PCs are routinely screened for bacterial contamination by culture-based tests. However, culture-based PC screening methods require extended holding and incubation periods and are prone to false-negative results due to sampling error. Screening PCs closer to the time of transfusion using rapid point-of-issue tests represents an alternative approach; however, FDA-approved assays generally suffer from a lack of sensitivity.

Study Design and Methods: Presented herein is the feasibility of a novel approach toward rapid, sensitive, and universal detection of bacterially contaminated PCs via selective measurement of microbial DNA polymerase activity. This approach is achieved using a differential cell lysis procedure in combination with enzymatic template generation and amplification (termed ETGA-PC assay).

Results: Serial dilution spiking experiments revealed an approximate sensitivity of 30 to 200 colony-forming units (CFUs)/mL (mean, 85 CFUs/mL) for Staphylococcus epidermidis,
Staphylococcus aureus, Escherichia coli, and Klebsiella pneumoniae. An additional 22 clinically relevant strains of bacteria were also detected below 200 CFUs/mL after spiking into PC aliquots. Furthermore, the ETGA-PC assay was able to accurately monitor the presence and growth of seven clinically relevant bacterial species that were spiked into PC units.

Conclusion: Together, the data presented here demonstrate that the ETGA-PC assay is a feasible approach for rapid and sensitive detection of bacterially contaminated PCs. Experiments, aimed at simplification and/or automation of the assay procedure, are under way.