STUDY SUMMARY

Differences in bacterial transfer and fluid path colonization through needlefree connector-catheter systems in vitro

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PURPOSE

The purpose of this study was to compare six needlefree connectors in terms of bacterial transfer and colonization over a 96-hour period. This study measured the difference among connectors in the passage rate of bacteria from the connector surface through the catheter and into the bloodstream over time; the amount of biofilm formation within the connector, catheter hub, and catheter lumen; and the amount of biofilm bacteria within the connector at 72 compared to 96 hours. The six connectors tested were the ICU Medical MicroClave®, RyMed® InVision-Plus®, CareFusion® MaxPlus® and Smart-Site®, Baxter® ClearLink®, and BD® Q-Syte™.

MATERIALS AND METHODS

An in vitro model was designed to simulate clinical use with a four times daily antibiotic infusion utilizing the saline, administer medication, saline, heparin (SASH) method. At the start of each day, the surface of each connector was inoculated with approximately 106 CFU of Staphylococcus aureus ATCC# 6538 overnight culture and dried for 30 minutes. After inoculation of the connectors, each connector was attached to a hub and catheter (5 Fr, single lumen, 60 cm PICC). Each connector-catheter set was placed in a sterile 15 mL conical vial for storage at room temperature (in between flushes) in order to maintain sterility.

After the 30-minute inoculation dry time, each connector-catheter set was flushed with 3.0 mL of sterile saline. The flush was collected and plated. The catheter-connector sets were flushed two more times with 3.0 mL sterile saline and locked with 2.0 mL sterile BrainHeart Infusion Broth (BHI) for one hour. After one hour, the catheter connector sets were flushed three more times with 3.0 mL sterile saline. The last flush was collected and plated. After the last flush, the catheter-connector sets were reinoculated and dried for 30 minutes, and the entire procedure of flushing and locking was repeated so that the connector-catheter sets were flushed for a total of 15 flushes (three flushes x five times per day) and were locked with sterile BHI after the first, third, and fourth set of flushes for one hour for a final total of 18 flushes per day.

The entire inoculation, lock, and flush procedure was repeated daily for five days (96 hours). On day three (72 hours) and day four (96 hours), two of the connector-catheter sets for each type of connector were removed from the test and destructively sampled. A total of nine experimental runs were performed. The MicroClave was tested in all nine runs. All others were tested in three runs.

RESULTS

The risk of transfer of bacteria from a contaminated connector surface through the hub and catheter lumen and into the bloodstream is dependent on the type of connector used (see Table 1). The MicroClave had a significantly lower bacterial transfer rate than all other connectors. Also, when analyzing the amount of bacterial formation over a 96-hour period, it was found that the ICU Medical MicroClave had the lowest bacterial log density of all connectors measured, while the CareFusion MaxPlus, BD Q-Syte, and RyMed InVision-Plus maintained the highest bacterial counts during the 72-96–hour period (see Table 2). These results also suggest that the common classification of split septum and mechanical valve is an oversimplification and an unreliable approach for device selection.

RESULTS (cont'd.)

TABLE 1

Connector	Overall Mean Log (CFU/Flush)*	p Value
MicroClave	2.5	≤0.0001
SmartSite	3.6	≥0.0677
ClearLink	3.6	≥0.0677
InVision-Plus	3.8	≥0.0677
Maximus	4	≥0.0677
Q-Syte	4.8	≤0.0001

*calculated as the Least Squares Mean

TABLE 2

Connector	Connector Log Density	Hub Log Density	Catheter Log Density
MicroClave	2.123	1.871	1.011
ClearLink	2.591	2.368	1.101
Maximus	3.432	2.398	1.980
SmartSite	2.878	2.629	1.386
InVision-Plus	3.306	3.046	1.391
Q-Syte	3.348	3.159	2.223

SUMMARY

In all three phases of testing—bacteria transfer, biofilm formation, and biofilm bacteria formation—the ICU Medical MicroClave outperformed all connectors tested. It proved to provide an effective barrier to bacterial transfer and colonization. The MicroClave's ability to provide clinicians with an enhanced level of protection from bacteria being transferred from external surfaces into the patient's bloodstream can be an important benefit in their fight to eliminate catheter-related bloodstream infections (CRBSIs). Biofilm formation in the catheter hub and internal lumen can result from bacteria transferred through a needlefree connector, and that biofilm formation within the connector is the best predictor of the number of bacteria flushed into the bloodstream. Also, the frequency of connector exchange may be dependent on the bacterial transfer potential of each device design, which brings into question the 72-hour Centre for Disease Control (CDC) exchange recommendation.

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