COMPARATIVE EFFECTIVENESS OF INTRAVENOUS CONNECTORS

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Introduction

Four pathogens are responsible for 60% of intraluminal catheter-related bloodstream infections (CR-BSIs): *Staphylococcus epidermidis and aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*.

Cost is $225 million/year and 200,000 ICU days/year. Manufacturers of positive displacement intravenous (IV) connectors received a FDA *Alert & Notification* letter in July (2010) regarding the need to prove that positive displacement IV connectors do not cause bloodstream infections.

Research has shown that both positive and negative displacement IV connectors are associated with CR-BSIs (Field et al, 2007; Jarvis et al, 2009; Maragakis et al, 2006). Additionally, negative displacement IV connectors are associated with increased occlusions that lead to a CR-BSI (Rummel et al., 2001).

Theoretically, the new silver-coated and ion-engineered technologies of needleless IV connectors promote antibacterial activity. However, once blood contacts the silver coating, loss of antibacterial effectiveness may occur, which may not happen with the ion engineered IV connector.

Therefore, researching comparative technologies for bacterial growth patterns is necessary to refine nursing care and decrease CR-BSI incidence, particularly with immuno-compromised patients.

Purposes

1. Evaluate *in-vitro* differences in colony forming units (CFUs) with 4 different bacteria over 4 days using 5 different needleless IV connectors:
   - One positive displacement connector: CareFusion/Medegen MaxPlus® Clear
   - Three negative displacement connectors: ICU Medical MicroClave®, B-D Q-Syte™, and Hospira Lifeshield™ TKO™/Clave®
   - One zero displacement connector: RyMed Technologies InVision-Plus® with Neutral Advantage™
2. Evaluate the best IV connector's occlusion rates in multiple clinical settings.
3. Compare 2 antibacterial needleless IV connectors [Baxter V-Link™(silver coated); RyMed Technologies InVision-Plus® CS™ (chlorhexidine/silver ion engineering)], and the best non-antibacterial needleless IV connector (RyMed Technologies InVision-Plus®) using 4 different bacteria.

Methods

An independent laboratory, Nelson Laboratories, Inc. (UT), tested the different needleless IV connectors, 20 connectors of each type with 6 controls, each day for 4 days under identical laboratory conditions. Each connector was swabbed, inoculated with a minimum of 10^5 of a pooled specimen of 4 different bacterial organisms *(Staphylococcus epidermidis and aureus*, *Pseudomonas aeruginosa*, *Escherichia coli)*.

See table below for details. Appropriate equipment, reagents, media and safety were employed. Repeated measures ANOVA was used to examine differences between connectors over time (level of significance = 0.05; Bonferroni post hoc testing determined specific group differences).

DAY	HOUR	TIME	INTERVENTION
1	0	0600	1, 2, 3, 4
1	6	1200	2, 1, 2, 3, 4
1	12	1800	2, 1, 5, 3, 4
2	24	0600	2, 1, 2, 3, 4
2	30	1200	2, 1, 2, 3, 4
2	36	1800	2, 1, 5, 3, 4
3	48	0600	2, 1, 2, 3, 4
3	54	1200	2, 1, 2, 3, 4
3	60	1800	2, 1, 5, 3, 4
4	72	0600	2, 1, 2, 3, 4
4	78	1200	2, 1, 2, 3, 4
4	84	1800	2, 1, 5

Intervention Steps

Step 1: Flush = attach 10mL saline syringe, draw up bovine blood, flush 10mL of saline.

Step 2: Disinfection = 70% IPA pad applied with downward thumb pressure for 3 rotations.

Step 3: Administration = Give 1mL of saline.

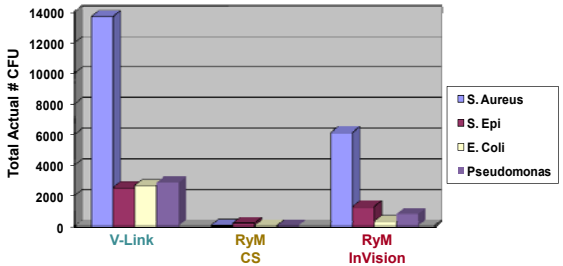
Step 4: Inoculation = Septum's inoculated with pooled suspension of all 4 organisms.

Step 5: Collection = Collect flush for plating.

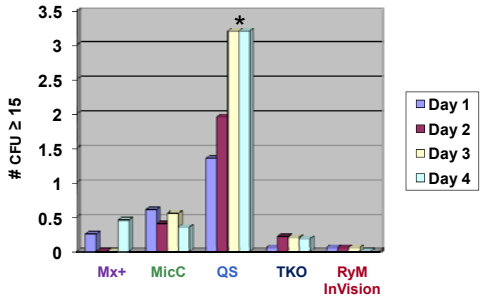
Results

Repeated Measures ANOVA
Number of Types Bacteria with CFU >=15 (infection potential)

Device Type	Adjusted Least Square Mean	SE of Mean	F	p-value
CareFusion/ Medegen MaxPlus Clear®	0.18	0.13	56.10	< .0001
ICU Medical MicroClave®	0.48	0.13		
B-D Q-Syte™	2.43	0.13		
RyMed Technologies InVision-Plus®	0.04	0.13		
Hospira Lifeshield™ TKO™+Clave®	0.43	0.13		



Total actual number of CFUs per individual pathological organism for 2 antibacterial connectors (Baxter V-Link ™ and RyMed Technologies InVision-Plus® CS™) and 1 non-antibacterial connector (RyMed Technologies InVision-Plus®).



Mean CFU count per day for the 5 types of connectors; * p < .0001
Note: CFU ≥ 15 causes CR-BSI (Maki, 1977)
MaxPlus® Clear (positive)
MicroClave®, Q-Syte™, & Lifeshield™ TKO™/Clave® (negative)
InVision-Plus® (zero)

Occlusion Incidence in Oncology

Replacing the B-D Q-Syte™ negative displacement split septum (3,984 connectors; 92 connector days) with the RyMed Technologies InVision-Plus® zero displacement connector (6,024 connectors; 121 connector days).

	ICU	Pediatric Inpatient	Pediatric Outpatient
Q-Syte™ Split Septum:	15.3	8.3	4.7
Invision-Plus® Zero Fluid Displacement:	12.25	4.5	0.75
Reduction %:	20%	46%	84%

Conclusions

- RyMed Technologies InVision-Plus® (non-antibacterial) had the best overall performance at reducing the number of CFUs for all the pathological organisms compared to the other IV connectors; B-D Q-Syte™ had the worst overall performance.
- CareFusion/Medegen MaxPlus® Clear™ and ICU Medical MicroClave® were both inconsistent in the number of CFUs between growth days; Hospira Lifeshield™ TKO™/Clave® had consistently high CFU amounts.
- The silver-coated Baxter V-Link™ (antibacterial) IV connector produced up to 200 times more bacteria than RyMed Technologies InVision-Plus® (non-antibacterial) and RyMed Technologies InVision-Plus ® CS™ with Chlorhexidine/Silver Ions (antibacterial) IV connectors regardless of bacteria type. These findings demonstrate that antibacterial and non-antibacterial needleless IV connectors differ on CFU counts *in-vitro,* which increases the probability for CR-BSIs in patients.
- The positive and negative displacement, plus the one silver-coated needleless IV connectors were not effective in controlling bacterial growth. Only the RyMed Technologies InVision-Plus® (non-antibacterial) & RyMed Technologies InVision-Plus CS™ with Chlorhexidine/Silver Ion Engineering (antibacterial) zero displacement needleless IV connectors exhibited no consistent CFU counts for all 4 bacteria over all 4 days.
- The RyMed Technologies InVision-Plus® (non-antibacterial) needleless IV connector in oncology clinical settings decreased occlusion rates between 20 -84% without other changes made to patient care methods.

References

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