STUDY SUMMARY

The in vivo evaluation of the flushing efficiency of the NanoClave™ low-profile neutral displacement connector compared to two other connectors commonly used on central and PICC lines

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PURPOSE

This study was designed to determine how much fluid volume of saline is required to flush a connector completely free of blood or blood constituents. The ability to effectively and completely clear a connector of blood residual helps reduce the possibility of residual buildup, which can result not only in potential occlusions, but can also form the basis of a growth medium for microorganisms that can lead to infection.[1-3] Connectors that facilitate minimal flush volumes can help clinicians effectively manage patient fluids in certain patient populations such as neonates and pediatric. For the purposes of the study, three different types of needlefree IV connectors with clear housings were chosen—two positive displacement connectors (CareFusion MaxPlus® Clear and B. Braun CARESITE®) and one neutral displacement needlefree IV connector (ICU Medical NanoClave™).

MATERIALS AND METHODS

Three separate sheep were used in this analysis with repeated blood samples obtained through indwelling catheters placed percutaneously and remaining indwelling for three days, allowing each needlefree connector to be accessed over several days. A baseline blood sample was drawn to determine the CBC: Red Blood cells/uL (RBC-s), Hematocrit (Hct), and Hemoglobin (Hgb). The connectors were then pulled free of the bandage and the samples were collected as follows:

- Flush each connector with 5 mL normal saline to ensure patency.
- Disinfect each needlefree connector and attach a sterile 3 mL syringe.
- Aspirate 3 mL of blood from lumen and discard.
- Remove blood-saturated connector from catheter lumen port, place a new connector onto the catheter lumen port, and proceed to flush the removed blood-saturated connector as follows:
  - Attach 12 mL syringe filled with 10 mL 0.9% sterile saline to needlefree connector.
  - Infuse 0.5 mL increment of saline through connector into uniquely labeled flush capture vessels.
- Analyze each flush capture for hemoglobin concentration.

Two connector types (CARESITE and NanoClave) were flush tested five times, whereas the third connector (MaxPlus Clear) clotted and was only flush tested four times. An accurate sample flush volume was ensured by weighing the capture vessel while empty and following the addition of 0.5 mL of flush volume.

Samples that contained appreciable amounts of blood (visible to the naked eye) were run at the BioSurg Clinical Pathology Laboratory on an Advia clinical analyzer. The range of reliable and reproducible detection for hemoglobin by the Advia unit is 0.5 g/dL (500 mg/dL). In addition to the hemoglobin, each sample was analyzed for total erythrocyte count and hematocrit. All samples below the 0.5 g/dL threshold were sent to Equine Laboratories (Houston, TX) for analysis. Equine Laboratories employs a spectrophotometric method (TMB method) to determine total hemoglobin concentration and is reproducible and sensitive to 0.05 mg/dL.

RESULTS

All of the ICU Medical NanoClave low-profile neutral displacement connectors were blood free after 3.5 mL of flush volume. Initial flushes of the NanoClave were also found to contain lesser blood components when compared to the other connectors tested. By contrast, all of the CareFusion MaxPlus Clear devices tested showed residual blood after 10 mL of saline flush, as did three out of the five B. Braun CARESITE connectors.

TABLE

Raw data of the samples. Measured hemoglobin in mg/dL. Blue indicates values measured on the Advia 120 clinical analyzer. All others measured by Equine Labs by spectrophotometry using a proven TMB colorimetric assay.

Hemoglobin retention (mg/dL): Considered blood free at less than 1.0 mg/dL.

Flush Vol (mL)	ICU Medical NanoClave™					B. Braun CARESITE®					CareFusion MaxPlus®			
	D1	D2	D3	D4	D5	E1	E2	E3	E4	E5	F1	F2	F3	F4
0.5	517.8	214	476.7	343.5	366.6	2600	2800	2800	3000	2800	5000	5700	4500	1200
1.0	2	2	18.3	16.2	10.4	215	200	100	300	200	800	800	600	600
1.5	0.0	0.0	0.2	2.2	1.4	63.8	101.0	189.5	189.4	115.7	241.32	118.2	321.4	119.5
2.0	0.0	0.0	0.0	1.0	0.0	34.8	63.0	49.2	108.8	54.8	171.51	75.3	161.3	86.0
2.5	0.0	0.0	0.0	0.5	0.0	17.5	28.4	27.1	67.0	37.7	86.82	20.2	97.1	48.3
3.0	0.0	0.0	0.0	0.3	0.0	8.1	18.9	18.0	31.0	20.2	79.81	16.6	69.2	28.8
3.5	0.0	0.0	0.0	0.0	0.0	2.6	16.2	11.5	33.3	18.0	28.12	17.0	47.2	19.9
4.0	0.0	0.0	0.0	0.0	0.0	2.1	15.4	9.8	22.0	14.0	33.9	12.8	37.6	12.6
4.5	0.0	0.0	0.0	0.0	0.0	1.0	8.2	7.3	13.2	6.8	22.4	9.8	31.9	10.8
5.0	0.0	0.0	0.0	0.0	0.0	0.6	4.9	3.2	7.4	4.1	19.94	8.7	25.7	5.3
5.5	0.0	0.0	0.0	0.0	0.0	1.3	5.4	3.9	23.6	3.1	10.84	6.0	19.1	3.5
6.0	0.0	0.0	0.0	0.0	0.0	0.6	2.6	8.4	7.4	4.8	21.69	3.8	18.8	2.1
6.5	0.0	0.0	0.0	0.0	0.0	1.2	2.8	2.7	5.1	1.7	8.05	2.3	21.4	2.2
7.0	0.0	0.0	0.0	0.0	0.0	0.3	2.3	1.8	4.0	1.5	20.98	1.8	15.7	2.0
7.5	0.0	0.0	0.0	0.0	0.0	0.8	1.9	0.0	2.6	2.0	1.63	0.7	13.9	1.7
8.0	0.0	0.0	0.0	0.0	0.0	0.2	1.6	0.0	0.8	0.5	1.71	0.8	13.4	1.3
8.5	0.0	0.0	0.0	0.0	0.0	0.0	1.8	0.0	1.9	0.9	1.14	0.6	13.2	1.2
9.0	0.0	0.0	0.0	0.0	0.0	0.0	1.5	0.0	0.7	0.7	1.46	0.5	11.6	1.6
9.5	0.0	0.0	0.0	0.0	0.0	0.0	1.4	0.0	1.0	0.6	0.15	0.5	13.5	1.7
10.0	0.0	0.0	0.0	0.0	0.0	0.0	1.2	0.0	1.3	0.7	1.38	0.4	12.8	0.8

CONCLUSION

In summary, the ICU Medical NanoClave low-profile neutral displacement connector is superior to the positive displacement CareFusion MaxPlus Clear and B. Braun CARESITE connectors as determined by the total flush volume needed to clear the connectors of blood elements. In addition, the flush volume to clear the NanoClave had a much narrower range of variability across flush volume increments.

Previous studies have demonstrated that the more proteinaceous material (including small blood clots) that resides in the connector hub, the greater the chance of infection.[1-3] Infection is a major concern in the hospital environment and especially so given the issues of antibiotic resistance and hospital-acquired infection. Prevention of such issues is of great concern. The NanoClave shows a definite advantage in this environment, while demonstrating an uncommonly efficient ability to be completely free of blood constituents with exceedingly low flush volumes.

A second potential negative consequence of blood retention within a connector is the loss of catheter patency as occurred with the MaxPlus Clear connector prior to the final test flush. A compromised catheter necessitates placement of a new catheter, resulting in additional expense and discomfort for the patient.

References

1. Jarvis W.R., et al. Increased bloodstream infection rates in surgical patients associated with variation from recommended use and care following implementation of a needlefree device. Infect Control Hosp Epidemiol. 1998 Jan;19(1):23-7.
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3. Centers for Disease Control and Prevention. Draft guideline for the prevention of intravascular catheter-related infections. Federal Register 74:211 (Nov. 3, 2009): 56843.