

The CLAVE[®] NeedleFree System

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Objective To evaluate a closed needlefree system – The CLAVE by:

1. Ascertaining its efficacy when microbiologically challenged.
2. Assessing its performance technically.
3. Assessing its ease of use in both professional and patient groups.

Description

The CLAVE NeedleFree Connector is believed to be the simplest system on the market due to its one-piece design and its compatibility to any IV administration set and or syringe. The system functions by attaching the CLAVE directly to the peripheral cannula, midline, PICC or atrial catheter. The IV set or syringe is then placed directly into the CLAVE, opening the fluid path. The Internal slit in the silicone allows separation over the internal piercing element thus allowing the fluid path to operate. The CLAVE is a two-way closed connector, which also allows aspiration.

Model The CLAVE was used as an access device on the following patient populations:

1. Fifteen Adult and Pediatric Haematology
2. Inpatient and Outpatient
3. Profoundly immunocompromised.

Setting Dayward / Outpatient department in a teaching hospital.

Method of Use

- **Venous Access Device.** CLAVE was used on atrial, midline and peripheral catheters.
- **Dwell Time.** The aim was to have the CLAVE in use for seven days after which they were removed, placed in a sterile container and sent for culture.
- **Disinfectant.** Prior to access the silicone dome was disinfected with 0.2% chlorhexidine and 70% isopropyl alcohol.
- **Access and Infusates.** The number of access and accompanying infusates was documented.
 - IV Fluids
 - Blood Products
 - Chemotherapy Agents
 - Antibiotics
 - Anti-virals
 - Anti-emetics
- **Flow Rates.** Irrespective of viscosity, infusates flowed unimpeded. No incidence of haemolysis occurred.
- Neutropenic state of each patient was documented.

Microbiological Culture Method

1. The CLAVE was received in the laboratory in a sterile urine container.
2. The CLAVE was then secured using sterile forceps in a vertical position over a blood agar plate and the silicone dome and threaded area of the CLAVE was disinfected using a sterile alcohol prep.
3. Approximately 0.1mL of liquid medium, Brain Heart Infusion, was then flushed through the CLAVE.
4. The flush was captured on the blood agar plate and streaked over its surface using a disposable sterile loop. The plate was then incubated at 36°C and checked daily for growth for three days.
 - Colonized device = semiquantitative culture method MAKI (≥ 15 colony forming units).

TABLE 1

UPN	Diagnosis	Catheter Type	CLAVE Number	Total Days	Access Number	CLAVE Culture	Blood Culture
001	MYELOMA	HICKMAN	10	66	134	NEG	NEG
002	ALLO-BMT	HICKMAN	8	116	298	NEG	NEG
003	ALLO-BMT	HICKMAN	6	32	22	NEG	NEG
004	NHL	MIDLINE	1	2	14	NEG	NEG
005 ¹	CLL-FLUDARA	7D-H20 GEL-P	2	12	79	NEG	1
006 ²	HIV, FIX DEF.	7D-H20 GEL-P	6	34	225	1	NEG
007 ³	ALLO-BMT	HICKMAN	12	82	273	4	1
008	MYELOMA	PICC	1	2	6	NEG	NEG
009	ALL, NEUTROP.	GROSHONG	4	26	70	NEG	NEG
010	AUTO-BMT	GROSHONG	27	240	142	NEG	NEG
011	NHL-FLUDARA	7D-H20 GEL-P	1	5	25	NEG	NEG
012	T CELL-NHL	HICKMAN	2	10	22	NEG	NEG
013	CLL, NEUTROP.	7D-H20 GEL-P	1	5	15	NEG	NEG
014	MUD-BMT, GVHD	MIDLINE	2	13	103	NEG	NEG
015	CLL-FLUDARA	7D-H20 GEL-P	3	22	57	NEG	NEG
TOTALS			96	669	1485	5	2

¹ Patient returned a positive blood culture from one lumen of a double lumen atrial catheter. Coagulase Negative Staphylococcus was identified. The CLAVE on this lumen returned a negative culture.

² After study completed, "substitute nurse" admitted not disinfecting CLAVE prior to access. Coagulase Negative Staphylococcus probable contaminant.

³ Patient had two previously infected catheters. Third catheter placed with subsequent exit site purulence. Coagulase Negative Staphylococcus positive culture with positive peripheral blood culture prior to CLAVE attachment. Therefore, the positive colonization and device blood cultures probably due to previously infected catheter.

CONCLUSIONS

- *No significant complications associated with the use of the CLAVE occurred in this group of profoundly immunocompromised patients.*
- Quality of care given to the CLAVE may be more important than the number of times the device is accessed. This is particularly relevant for self care patients. Example: *One MUD transplant patient accessed the CLAVE 80 times in seven days. The CLAVE returned a negative culture.*
- CLAVE is simple to use with IV fluids, blood products, chemotherapy agents, antibiotics, anti-virals, anti-emetics, etc. No technical problems were reported with the exception of one of the 96 CLAVES used did not accept a luer slip, but would accept a luer lock syringe.
- Needlestick injuries eliminated, especially in home care patients.
- Generated feeling of security for those handling catheters as CLAVE performs like a clamp by closing the system.
- Since CLAVE remained on the catheter for up to seven days or longer, catheter hub exposure was reduced during multiple access for aspiration of blood, infusion of fluids and flushing.

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