

A needleless closed system device (Clave[®]) protects from intravascular catheter tip and hub colonization: a prospective randomized study

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PURPOSE

As an immunocompromised population, cardiac surgical patients are vulnerable to complications from infections such as catheter-related bloodstream infection (CRBSI) arising from the multitude of intravascular devices and jugular insertions required for their care. Catheter tip and hub colonization accounts for 29%–38% of catheter-related colonization (CRC) and 60% of CRBSI. The purpose of this study was to determine the effectiveness of a needleless closed system device (Clave, ICU Medical, San Clemente, CA) in preventing CRC compared to a conventional open system device (COS). The study was conducted in the intensive care cardiac unit of the University of Madrid Hospital, Madrid, Spain, a 1750-bed teaching institution that admits 50,000 patients per year.

MATERIALS AND METHODS

A prospective, randomized, comparative clinical trial was conducted for 11 months. High-risk cardiac patients admitted to the Heart Surgery ICU were randomly assigned to the Clave or COS group. Both the Clave and COS were disinfected before and after each use with 2% chlorhexidine. Cultures were taken from the skin-insertion site and catheter hubs when catheters were in place for more than five days. The Clave connectors were changed every seven days per manufacturer's instructions; the COS systems were changed every three days in accordance with Nosocomial Infection Prevention Committee Guidelines. Study end points were colonization of the catheter hub, tip, and skin; incidence of CRBSI; and number of accidental needlesticks.

RESULTS

Three hundred fifty-two patients (178 Clave, 174 COS) completed the study. Data were evaluated from 1708 catheters (838 Clave, 870 COS). Results from surveillance samples of catheters in place for more than five days showed significantly less catheter tip, hub, and skin colonization when the Clave system was used. One needlestick incident was reported. Clave patients also experienced 46% less CRBSI than COS patients; however, the difference was not statistically significant because of sample size.

CONCLUSION

The authors found that the Clave connector created “an independent protective factor from catheter tip and hub colonization” and “offered significant protection from catheter tip and hub colonization.” Additionally, the reduced hub colonization associated with the Clave system led to reduced colonization at the insertion site. Other authors have found skin colonization to be independently associated with increased risk of hub contamination. The lower incidence of CRBSI in Clave patients may be attributed to the less frequent change protocol. It is also notable that the only cases of accidental needlestick and endocarditis associated with valvular prosthesis occurred in the COS group.

TABLE

Clave vs. COS: surveillance skin and hub cultures	Clave	COS
Number of patients	178	174
Number of catheters	838	870
Tip colonization*	10.9%	17.2%
Skin colonization**	23.7	33.9
Hub colonization*	4.3%	14.2
Episodes of CRBSI***	3.4%	6.3
Needlestick	0	1

*P=0.001; **P=0.002; ***Not statistically significant due to sample size.