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Retrospective Observational Study Demonstrates Safety and Performance of Antimicrobial Central Venous Catheters

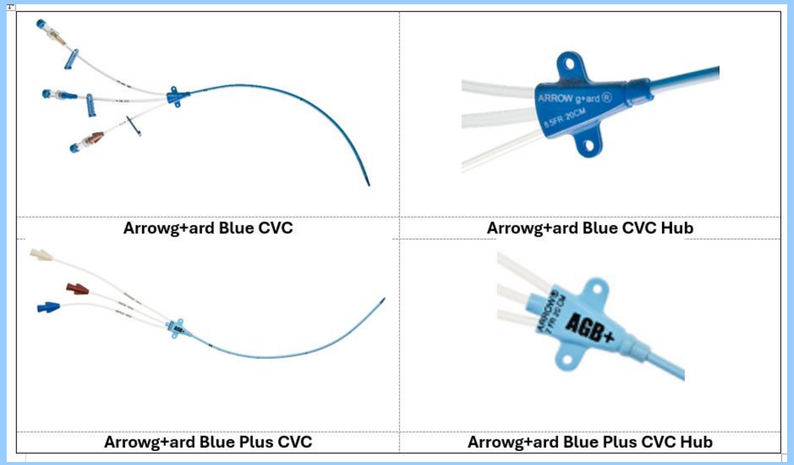
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Background and Objectives

Arrowg+ard Blue™ (AGB) and Arrowg+ard Blue Plus™ (AGB+) Central Venous Catheters (CVC) are treated with chlorhexidine and silver sulfadiazine antimicrobials (AM). AGB CVC are treated externally; AGB+ CVC are treated externally and internally. Both are indicated for short-term (<30 day) vascular access for patients requiring central venous access and intended to provide protection against catheter-related bloodstream infections. A retrospective study was performed to collect real-world evidence to substantiate performance and safety of the devices.

Methods and Materials

- Primary endpoint was successful completion of treatment using the AGB/AGB+ CVC without pre-defined device-related adverse events (AE).
- Secondary endpoints were the rates of specific AEs experienced during device placement, use, and removal.
- Study protocol was reviewed by a central IRB and determined to be exempt from consent/continued review.
- The study was conducted in US, UK and Germany by clinicians collecting data for consecutive cases in which device was used within previous 30 days.



Results

- Investigators at 43 sites collected data for 384 cases
- In most cases (74%) patients were >35 years old; 5% were pediatric (<18 years old)
- 99.2% (95% CI of 97.7% - 99.8%) of cases were successful
- Mean dwell time was 9.8 (SD: 6.8) days
- AEs included one case each cardiac tamponade, vessel erosion and dysrhythmia
- 4 CVCs removed due to suspected infection but not reported as AEs.

Results

- The 4 infections were adjudicated as potentially non-recognized CLABSI; resulting in CLABSI rates of
  - AGB CVC: 1.35/1000 catheter days
  - AGB+ CVC: 0.65/1000 catheter days
- Devices were used for infusions in 73% of cases; In roughly 1/3 of cases was also used for TPN administration, blood sampling, blood transfusion and CVP monitoring
- Used for contrast media injection in 51 (13%) cases; all successful, no extravasations

Limitations

- Observational study; no control group
- Data not monitored
- Findings not necessarily applicable or restricted to specified cohort, such as in an RCT

Conclusion

- This real-world evidence study of AM treated CVCs showed positive outcomes; perform as intended with few AEs
- Suspected CLABSI rate 52% lower with externally/internally treated CVCs as compared to those treated externally only
- Catheters indicated for pressure injection performed successfully with no extravasation or other AE

Disclosure: Arrowg+ard Blue™ and Arrowg+ard Blue Plus™ CVCs are manufactured by Teleflex and the authors are employed by Teleflex. This study was funded by Teleflex.