Observational Retrospective Study Confirms Safety, Performance and Utility of an Antimicrobial/Antithrombogenic Peripherally Inserted Central Catheter in Adults and Pediatric Patients

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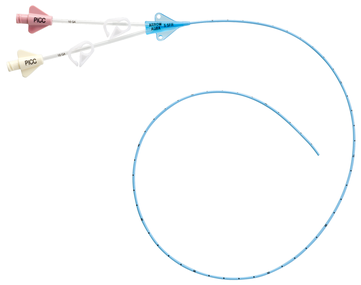
Background and Objectives

Arrowg+ard Blue Advance™ (AGBA) Pressure Injectable Peripherally-Inserted Central Catheters (PICC) are treated with antimicrobial (AM) and antithrombogenic (AT) agent—chlorhexidine. They are indicated for short-term or long-term vascular access for patients requiring central venous access. To meet EU Medical Device Regulation requirements, a study examining the safety and performance of these PICCs when used for adult and pediatric patients was conducted.

Methods and Materials

- Primary endpoint was successful completion of treatment using the AGBA PICCs (Teleflex, Morrisville, NC, USA) without elective removal due to complications/adverse events (AE).
- Secondary endpoint was the rate of specific AEs.
- Study protocol was reviewed by a central IRB and determined to be exempt from consent/continued review.
- The study was conducted in US, UK, Spain and Italy by clinicians collecting data for consecutive cases in which device was used within the previous 30 days.



Results (Index Study: Adults and Pediatrics)

- For index study (adults and pediatrics) investigators at 49 sites collected data for 316 cases in which the AGBA PICCs were used; 55% male and 78% adult patients
- Duration of use ranged from <1 day to 731 days (mean 46±77 days)
- Successful use without removal due to complications/AEs in 91% of cases
- 11% cases with potentially device-related AEs: occlusion (17), suspected infection (12), phlebitis (2), arrhythmia (1), exit site infection (1), skin inflammation (1); also:
  - One confirmed CRBSI (0.3%, 0.07/1000 catheter days)
  - One reported case of anaphylaxis (0.3%)
- Pressure injection of contrast media performed in 65 cases without incident.

Results (Pediatric Subset)

- Pediatric subset included cases from index study and additional cases from Phase II pediatric-only data collection (N=175)
- Duration of use ranged from <1 day to 253 days (mean 24±42 days)
- Successful use without removal due to complications/AEs in 90% of cases
- 10% cases with potentially device-related AEs: occlusion (8), suspected infection (5), occlusion and suspected infection (2), occlusion and phlebitis (1), suspected infection and phlebitis (1), hematoma (1)
  - No confirmed CRBSI, thrombus, or anaphylaxis reported
- Pressure injection of contrast media performed in 65 cases without incident.

Limitations

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

Conclusions

- This real-world evidence study of AM/AT treated PICCs showed positive outcomes for adult and pediatric patients
- Performed as intended with few AEs, including one confirmed CRBSI and one anaphylaxis
- Observed outcomes included sustained catheter dwell, successful pressure-injectable use, and a low frequency of device-related adverse events.
- Findings support continued use of AM/AT PICCs in routine clinical practice under approved indications.

Disclosures: All authors were, or are, employees of Teleflex Incorporated, the parent company of the manufacturer of the AGBA PICC device used in the study described herein. The study was funded by Teleflex Incorporated.