AVA 2024
September 28-30 Denver, Colorado
This poster was presented at the AVA Annual Scientific Meeting

Retrospective Observational Study of a New ECG-Guided Tip Positioning Device for Central Venous Catheter Placement

Thomas Philbeck, PhD, MBA; Amy Bardin, EdD, EMBA, RRT, FAARC, VA-BC
Nick Potochick, MS; John McDonald, PhD
Teleflex Incorporated Clinical & Medical Affairs

Background and Objectives

The Arrow™ VPS Rhythm™ DLX Device with TipTracker™ Technology is indicated for the positioning of central venous access devices, including peripherally-inserted central catheters (PICCs), as an alternative to chest X-ray/fluoroscopy for confirmation of catheter tip placement in adults. Introduced in 2022, a retrospective study was performed to collect real-world evidence to substantiate performance and safety of the device.

Methods and Materials

- Primary endpoint was the success rate for catheter tip location (proportion of cases in which the catheter was successfully placed using the patient's ECG p-wave).
- Secondary endpoint was the rate of device related adverse events.
- Study protocol was reviewed by a central IRB and determined to be exempt from consent/continued review.
- The study was conducted in US by clinicians who had used the device.



Results

- Investigators at two sites collected data for 85 cases
- In most cases (56.5%), the patients were male and 87.1% were >55 years old.
- In 65 (76.4%) and 20 (23.5%) cases, the NaviCurve™ Stylet and the VPS TipTracker™ Stylet were used, respectively

Disclosures: Arrow™ VPS Rhythm™ DLX with TipTracker™ Technology, NaviCurve™ Stylet and VPS TipTracker™ Stylet are manufactured by Teleflex and the authors are employed by Teleflex. This study was funded by Teleflex.

Results

- All PICCs placed and ready to use between 5 and 30 minutes after initiation of placement procedure
- 6 cases disqualified from analysis due to patients experiencing atrial fibrillation
- In 100% of qualifying cases (N=79), catheter tip navigation and placement confirmation were successful
- No malpositioned catheters; no adverse events.

Limitations

- Data was collected retrospectively from charts with no monitoring or control data for comparison. The were only two study sites, limited to patients needing a PICC. No placements of other types of CVAD were examined and there was an unequal distribution of cases for the two PICC stylets.

Conclusions

- In first study describing Arrow™ VPS Rhythm™ DLX, the device showed positive outcomes regarding performance and safety.
- Device performed as intended with a high level of success and no adverse events
- For all patients who qualified for ECG guided insertion, the device consistently facilitated successful placement of a PICC, determined by the ECG P-wave deflection
- Demonstrated ability to safely place PICCs at the bedside and immediate use of the catheter
- Avoided X-ray exposure and the associated time and costs
- Study confirmed general safety and performance of the device