

## Initial international multicenter human experience of a Novel Epicardial Access Tuohy Needle embedded with a Real Time Pressure/Frequency Monitoring to facilitate Epicardial Access: Feasibility and Safety

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### Abstract

**Introduction:** Epicardial (epi) ablation is often necessary for the treatment of challenging arrhythmias refractory to endocardial ablation. The subxiphoid approach is the most used method for epi access. However, major and minor complications may occur even in experienced centers with reported rates of 4-7%. We evaluated the feasibility and safety of the EpiAccess™ Needle by EpiEP, Inc., a novel “tuohy” epi access needle in a multicenter study.

**Methods:** 25 patients with a clinical need for epi access were enrolled. Epi access was obtained with the EpiAccess Needle whose tip is embedded with a pressure sensor able to report the pressure waveform in real time. Successful epi access was assessed through the device and confirmed by fluoro and contrast injection.

**Results:** Patients were male (92%) with a mean age of 65.6±13.9. Epi access due to VT ablation occurred in 84% of the patients. Successful epi access was obtained in all cases. Mean access time was 280 secs ± 98.9 secs. Mean pericardial pressure/pulsation was 4.72 ±1.7 mmHg. Pressure monitoring identified pericardial wire access in 100% of the cases. In 2 cases (8%) the needle sensor suggested tenting of the pericardial space but not access to pericardial space as evidenced by an increased pressure to 11 mmhg. Unintended RV perforation occurred in 1 pts (4%) and was detected by the device (figure). No drainable hemopericardium was reported. No acute or late complications were observed.

**Conclusion:** Epicardial access with the novel EpiAccess™ tuohy needle and real time pressure monitoring is feasible and safe. The pressure monitoring identifies successful epi access and minimizes complications. This has relevant clinical implications.

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- The subxiphoid approach is the most used method for epi access.
- However, major and minor complications may occur even in experienced centers with reported rates of 4-7%.
- We evaluated the feasibility and safety of the EpiAccess™ Needle by EpiEP, Inc., a novel “tuohy” epi access needle in a multicenter study.

### Disclosures

Dr. Di Biase is a consultant for Hansen Medical Biosense Webster, St Jude Medical and received speaker honorarium/travel reimbursement from Biotronik, Aticure and Epi EP. Dr. Natale received speaker honorariums from Boston Scientific, Biosense Webster, Medtronic and St. Jude. All the remaining authors have no disclosures.

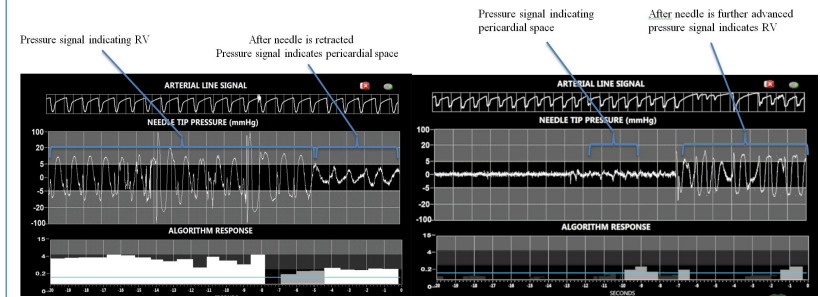
### Methods

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### Figures



### Conclusions

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