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Adverse Events Associated with the Cook-Swartz Implantable Doppler Probe for Free Flap Monitoring – a MAUDE Database Review

Maximilian Hemmrich MD, Joseph Meleca MD, Hassan Arshad MD, Nishant Agrawal MD

University of Chicago Medical Center, Department of Surgery, Section of Otolaryngology-Head&Neck Surgery

BACKGROUND

- Implantable Doppler probes are frequently used to monitor blood flow to free flaps after microvascular head and neck oncologic reconstruction
- Continuous free flap monitoring may aid in earlier detection of vascular compromise, which could improve flap salvage rates compared to clinical monitoring alone[1]
- The Cook-Swartz probe developed by Cook Medical is the most frequently used Doppler probe[2]

PURPOSE

- Identify adverse event reports associated with the Cook-Swartz Implantable Doppler probe submitted to the United States Food and Drug Administration Manufacturer and User Device Facility Experience (MAUDE) database[3]

METHODS

- The FDA MAUDE database was searched for the terms:
  - Product code “ITX” (Transducer, Ultrasonic, Diagnostic)
  - Product code “JOP” (Transducer, Ultrasonic)
  - Brand name “Cook-Swartz”
  - Brand name “Doppler probe”
  - Manufacturer “Cook”
- Reports manually reviewed and data extracted
  - Date of event, event type, reporter occupation, device operator, device problem, patient problem due to device, interventions required

RESULTS

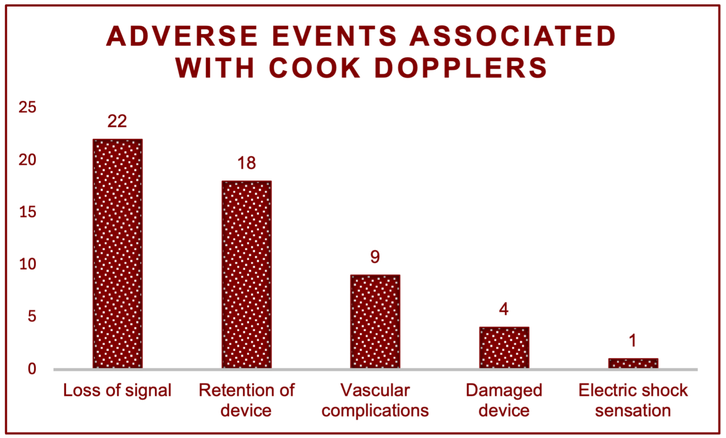
A total of 58 adverse events filed with the MAUDE database between August 2015 and March 2024 were identified. Of these, 56 had complete data used for analysis.

Adverse events reported in decreasing frequency:

- Loss of signal requiring return to operating room (OR) (n = 22)
- Fragmentation of device at time of removal resulting in retention of portion of device (n = 18), of which 5 (28%) required removal in OR
- Vascular complications (n = 9), of which 7 (78%) were damage to the arterial anastomosis requiring return to OR. Venous occlusion attributed to device removal occurred once (11%), as did injury to the venous pedicle from removal.
- Damaged device in package (n = 4)
- Electric shock sensation while in situ (n = 1)

Overall, 32 (65%) of reported complications required revision in the operating room.

Reporter occupation was listed in 45 reports. Most reporters were either physicians (n = 20, 44%) or other healthcare professionals (n = 10, 22%).



DISCUSSION

- While implantable Doppler probes after free flap reconstruction may aid in detection of early vascular compromise, their use may lead to additional complications
- The most common adverse events per the US FDA MAUDE database are loss of signal, retention of portion of device at time of removal, and injury to the vascular pedicle
- Most reported complications required return to the operating room for revision surgery
- This database only captures malfunctions reported to the FDA; further studies are needed to better quantify the absolute risk associated with use of implantable Doppler probes

REFERENCES

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