Device-Reported Structural Failures of Implantable Venous Access Ports
A National Adverse Event Signal Analysis (2015–2025)

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Background

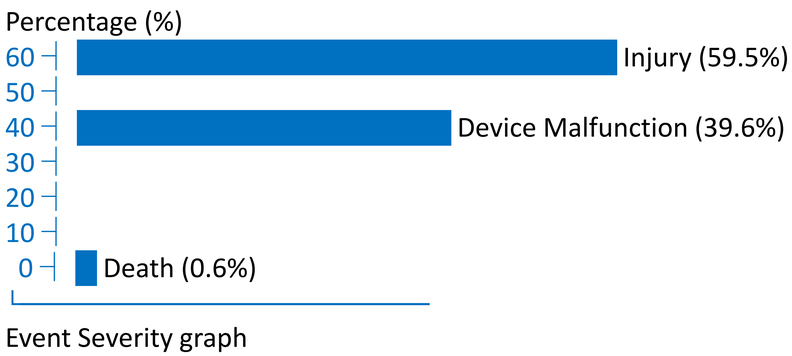
- Implantable venous access ports are essential in oncology care for long-term chemotherapy and IV therapy
- Structural device failures (fracture, embolization, leakage) remain underrecognized in routine surveillance
- We conducted a national adverse-event signal analysis to characterize structural failures of implantable ports and identify quality-of-care gaps amenable to prevention.

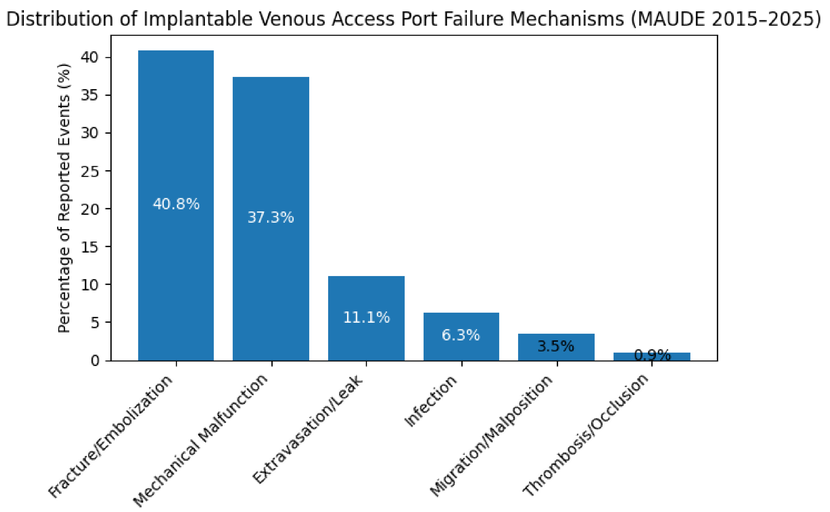
Methodology

- We performed a retrospective review of adverse event reports submitted to the FDA Manufacturer and User Facility Device Experience (MAUDE) database from January 2015 through January 2025
- Reports involving implantable venous access ports (n = 316) were independently reviewed by two investigators using a predefined hierarchical classification algorithm.
- Outcomes assessed:

→ Primary mechanism of injury: (fracture/embolization, extravasation/leak, mechanical malfunction, infection, migration/malposition, thrombosis/occlusion)

→ Event severity (injury, malfunction, death)





Results:

- 188 (59.5%) were associated with patient injury, 125 (39.6%) with device malfunction, and 2 (0.6%) with death
- Fracture or embolization was the most frequently reported failure mechanism (129 reports, 40.8%), followed by mechanical malfunction (118, 37.3%) and extravasation or leakage (35, 11.1%)
- Infectious events (6.3%), migration or malposition (3.5%), and thrombosis or occlusion (0.9%) were comparatively uncommon
- Reported clinical sequelae included intravascular catheter embolization, retained fragments requiring endovascular retrieval, and cardiopulmonary complications temporally associated with device failure
- Annual reporting peaked between 2017 and 2020

Conclusions:

- Our data provide a compelling rationale for an institutional review of implantation techniques, device selection, access practices, and post-placement monitoring within our patient population.
- Leveraging national safety signals to assess local outcomes can inform targeted quality improvement initiatives aimed at earlier detection of device compromise, prevention of avoidable complications, and improved patient safety.