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Post-Market Safety Signals for Pulsed Field Ablation Devices: An Artificial Intelligence-Augmented Analysis

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ABSTRACT

Background: Pulsed field ablation (PFA) is increasingly used for cardiac arrhythmias, yet uncommon complications and device-specific failure modes may remain undercharacterized after approval. We evaluated recent FDA MAUDE reports involving leading PFA platforms using an artificial intelligence-augmented safety-surveillance workflow.

Methods: MAUDE reports were queried using prespecified manufacturer, trade-name, and component terms for major PFA systems, including Affera/Sphere-9, FARAPULSE/FARAWAVE, PulseSelect, TRUPULSE/VARIPULSE, Volt/Current, and related catheters, generators, sheaths, and mapping components. Reports were screened, deduplicated, and parsed with ChatGPT-assisted extraction to identify event severity, clinical outcomes, procedural context, and technical failure modes. A standardized taxonomy was applied, and a random sample was manually verified by independent reviewers.

Results: A total of 2,063 unique pulsed field ablation (PFA)-related MAUDE reports were analyzed; malfunction reports predominated (59.8%), followed by injury (38.3%) and death (1.9%) reports. Overall, any device/use problem or malfunction was identified in 74.6% of reports, with frequent issues including power/software/sensing flaws (22.2%), air/gas bubbles (18.7%), and material deformation/kinking (15.6%). Clinical harm was absent or unreported in 61.0% of cases; however, the most common documented patient outcomes were hospitalization or prolonged stay (23.3%), arrhythmias (15.7%), and pericardial effusion or tamponade (10.1%). Distinct device-specific reporting patterns emerged, characterized by high rates of air/gas events in FARADRIVE (67.0%), material deformation in PulseSelect (52.2%), power/software issues in FARASTAR (67.1%), and cerebrovascular events in VARIPULSE (52.5%).

Conclusions: Real-world post-market safety reports for PFA systems are predominantly driven by technical malfunctions rather than direct clinical harm. However, distinct, platform-specific failure modes highlight the unique mechanical and workflow profiles of individual PFA designs. These findings also underscore the promising role of artificial intelligence-assisted surveillance in analyzing unstructured registries, providing targeted insights to guide ongoing operator education and iterative device development.

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Introduction

Pulsed field ablation (PFA) has emerged as one of the most important recent innovations in catheter-based treatment of cardiac arrhythmias, particularly atrial fibrillation [1]. Unlike conventional radiofrequency or cryothermal ablation, PFA relies on high-voltage electrical fields to induce irreversible electroporation, with relative myocardial selectivity and the theoretical potential to reduce collateral injury to adjacent structures such as the esophagus, phrenic nerve, and pulmonary veins [2]. This favorable biological profile has accelerated clinical interest and commercial development, leading to the introduction of multiple device platforms, including systems based on dedicated PFA catheters, generators, steerable sheaths, mapping integration, and software modules [3]. As these technologies move from controlled investigational settings into routine electrophysiology practice, their real-world performance requires careful and independent surveillance [4-6].

Although early clinical trials and registries of PFA have generally reported high procedural success and encouraging safety outcomes, several factors justify continued post-market evaluation [1,5,7]. First, uncommon complications of PFA may only become evident after exposure in large and heterogeneous patient populations [8]. Second, real-world PFA procedures often involve more complex anatomy, repeat ablations, concomitant mapping systems, challenging vascular access, and operator-dependent workflow variation [9]. Third, PFA introduces device-specific technical considerations, including waveform delivery, catheter positioning, generator–catheter communication, sheath interaction, and integration with electroanatomic mapping systems [10]. These features may generate safety signals specific to PFA that could differ substantially from those historically associated with thermal ablation, including not only clinical events such as stroke, tamponade, vascular complications, hemolysis, or coronary

spasm, but also technical malfunctions involving energy delivery, deployment, navigation, or system connectivity [11,12].

Post-market surveillance systems such as the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database offer a valuable source of information on rare, unexpected, or device-related events occurring after regulatory clearance or approval [13,14]. MAUDE reports are particularly relevant for device-intensive fields such as electrophysiology, where adverse outcomes may arise from the interaction between patient substrate, operator technique, ancillary equipment, and device behavior [15]. However, MAUDE analyses are methodologically challenging, especially because reports are unstructured, terminology is inconsistent, clinical detail is often incomplete, and duplicate or manufacturer-amended records may occur [16,17]. In addition, MAUDE does not provide the number of procedures performed, precluding accurate estimation of prevalence, incidence, or comparative risk; thus, analyses with this scope are best interpreted as descriptive and hypothesis-generating rather than definitive measures of safety [18].

Artificial intelligence (AI), and particularly large language models, may help address some of these barriers by converting free-text adverse-event narratives into structured variables suitable for reproducible analysis [14-19]. When coupled with predefined taxonomies and human adjudication, AI-assisted extraction can facilitate classification of event severity, clinical outcomes, suspected device involvement, procedural context, and technical failure modes across large numbers of safety reports [20].

In this study, we applied an artificial intelligence-augmented workflow to recent MAUDE reports involving leading PFA platforms for cardiac arrhythmias. We aimed to characterize reported clinical complications and device-performance signals, map recurring failure patterns across major device families, and illustrate a replicable framework for AI-enhanced post-market surveillance of emerging electrophysiology technologies.

Methods

We conducted a retrospective analysis of adverse-event reports involving leading PFA systems for cardiac arrhythmias using an artificial intelligence-assisted curation workflow. The protocol prespecified data retrieval, screening, coding, adjudication, and statistical synthesis steps to enhance reproducibility and reduce subjective variability. Two investigators supervised report eligibility assessment and data handling, with predefined procedures for resolving discordant classifications. Because all information was obtained from a publicly available, deidentified post-market surveillance database, this work did not constitute human-subjects research and did not require institutional review board approval.

The data source was the MAUDE database [21]. We applied a prespecified query strategy using manufacturer names, trade names, generic product descriptors, and component terms for major PFA platforms and related electrophysiology equipment. For Boston Scientific devices, search terms included FARAWAVE, FARAWAVE NAV, FARASTAR, FARADRIVE, FARAVIEW, INTELLANAV STABLEPOINT and FARAPOINT; for Medtronic devices, PulseSelect, Sphere-9, Affera, and Flex Cath Contour; for Johnson & Johnson devices, MedTech/Biosense Webster VARIPULSE, TRUPULSE, and CARTO pulsed field ablation integration; for Abbott devices, Volt, Current, Sensor Enabled, TactiCath Sensor Enabled and Agilis NxT; for Biotronik devices, Centauri, Centauri Connect, Ivy cardiac monitor, and THERMOCOOL SMARTTOUCH; and for MicroPort devices, Pulse Magic.

For each query, the number of available records was documented, including zero-yield searches, to preserve transparency in device-term sensitivity. When a query yielded more than 500 records, the most recent 500 reports were retained for focused analysis, consistent with the approach used in the reference MAUDE case-study framework. The queries were last updated on December 31, 2025.

Eligible reports were those that plausibly involved PFA use, attempted PFA use, or PFA-related system components in the treatment of cardiac arrhythmias. Reports were excluded when they clearly referred to non-cardiac applications, unrelated electrophysiology or ablation technologies without evidence of PFA involvement, peripheral or nonvascular devices, training or packaging issues without procedural relevance, or records lacking sufficient narrative content for classification. Obvious duplicates, manufacturer follow-up reports referring to the same event, and repeated submissions with identical event dates, device identifiers, and narrative content were consolidated. When uncertainty persisted regarding whether a report represented PFA exposure or an adjacent non-PFA electrophysiology device, the record was retained for sensitivity classification but flagged as indeterminate.

Free-text narratives were processed using a ChatGPT 5-assisted extraction workflow based on standardized prompts. The model was instructed to identify the manufacturer, device family, specific component, report type, event severity, patient outcome, procedural context, suspected mechanism, device problem, and clinical complication. Extracted outputs were mapped to a predefined taxonomy and reviewed for internal consistency before analysis. A randomly selected subset of reports was independently reviewed by two human adjudicators to estimate the frequency of AI-extraction inaccuracies. Discrepancies were resolved by consensus, and errors were categorized according to whether they involved event severity, clinical outcome, device attribution, or failure-mode classification. The full workflow for database querying, AI-assisted extraction, manual adjudication, and final coding has been detailed previously [14].

The primary outcomes were the distributions of MAUDE event categories, including death, patient injury, and malfunction. Clinical complications were coded using a taxonomy encompassing stroke or transient ischemic attack, pericardial effusion or tamponade, hemolysis, vascular access complications, coronary spasm, phrenic nerve injury, esophageal injury, conduction disturbance, arrhythmia induction, and other reported adverse outcomes. Device-performance signals were classified as catheter malfunction, positioning or deployment difficulty, generator or software failure, energy-delivery interruption, mapping or system-communication failure, sheath-related difficulty, catheter entrapment, device deformation or fracture, and procedural abandonment or conversion. Statistical analysis was descriptive. Categorical variables were summarized as counts and prevalence estimates, with exact 95% confidence intervals calculated using the Clopper–Pearson method. Findings were stratified by device family and interpreted as post-market safety signals rather than incidence estimates, given the absence of procedural denominators in MAUDE. The curated dataset, classification taxonomy, and extraction prompts are available from the corresponding author upon reasonable request.

Results

A total of 2,063 unique PFA-related MAUDE reports were analyzed (Table 1). The largest device strata were FARADRIVE, FARAWAVE, and PulseSelect, each with 500 reports, followed by Affera (307) and VARIPULSE (162) (Figure 1). Patient-level characteristics were rarely documented: anticoagulant therapy was the most commonly captured feature, while sex, age, chronic kidney disease, diabetes, antiplatelet therapy, frailty, and prior revascularization were infrequently reported. Nearly all reports involved an EP/cardiac ablation context, and explicit AF/flutter or pulmonary vein isolation was noted in 942 reports (45.7%).

Table 1: Patient and Procedural Features

Domain	Measure	All PFA devices	Affera mapping/ ablation system	Affera system / Sphere-9 catheter	FARADRIVE steerable sheath	FARASTAR generator/ cables	FARAWAVE catheter	PulseSelect PFA system	TRUPULSE generator	VARIPULSE catheter
Patient features	Age ≥65/ elderly	2/2063 (0.1%; 0.0–0.4)	0/307 (0.0%; 0.0–1.2)	0/6 (0.0%; 0.0–39.0)	0/500 (0.0%; 0.0–0.8)	0/79 (0.0%; 0.0–4.6)	1/500 (0.2%; 0.0–1.1)	1/500 (0.2%; 0.0–1.1)	0/11 (0.0%; 0.0–25.9)	0/162 (0.0%; 0.0–2.3)
	Female sex	25/2063 (1.2%; 0.8–1.8)	0/307 (0.0%; 0.0–1.2)	0/6 (0.0%; 0.0–39.0)	3/500 (0.6%; 0.2–1.7)	0/79 (0.0%; 0.0–4.6)	6/500 (1.2%; 0.6–2.6)	2/500 (0.4%; 0.1–1.4)	0/11 (0.0%; 0.0–25.9)	14/162 (8.6%; 5.2–14.0)
	Anticoagulant on board	63/2063 (3.1%; 2.4–3.9)	4/307 (1.3%; 0.5–3.3)	0/6 (0.0%; 0.0–39.0)	10/500 (2.0%; 1.1–3.6)	1/79 (1.3%; 0.2–6.8)	18/500 (3.6%; 2.3–5.6)	4/500 (0.8%; 0.3–2.0)	0/11 (0.0%; 0.0–25.9)	26/162 (16.0%; 11.2–22.5)
	Antiplatelet on board	4/2063 (0.2%; 0.1–0.5)	0/307 (0.0%; 0.0–1.2)	0/6 (0.0%; 0.0–39.0)	0/500 (0.0%; 0.0–0.8)	1/79 (1.3%; 0.2–6.8)	2/500 (0.4%; 0.1–1.4)	0/500 (0.0%; 0.0–0.8)	0/11 (0.0%; 0.0–25.9)	1/162 (0.6%; 0.1–3.4)
	CKD/ renal insufficiency/ dialysis	12/2063 (0.6%; 0.3–1.0)	2/307 (0.7%; 0.2–2.3)	0/6 (0.0%; 0.0–39.0)	0/500 (0.0%; 0.0–0.8)	0/79 (0.0%; 0.0–4.6)	7/500 (1.4%; 0.7–2.9)	1/500 (0.2%; 0.0–1.1)	0/11 (0.0%; 0.0–25.9)	2/162 (1.2%; 0.3–4.4)
	Diabetes	8/2063 (0.4%; 0.2–0.8)	2/307 (0.7%; 0.2–2.3)	0/6 (0.0%; 0.0–39.0)	0/500 (0.0%; 0.0–0.8)	0/79 (0.0%; 0.0–4.6)	3/500 (0.6%; 0.2–1.7)	0/500 (0.0%; 0.0–0.8)	0/11 (0.0%; 0.0–25.9)	3/162 (1.9%; 0.6–5.3)
	Frailty/ poor functional status	0/2063 (0.0%; 0.0–0.2)	0/307 (0.0%; 0.0–1.2)	0/6 (0.0%; 0.0–39.0)	0/500 (0.0%; 0.0–0.8)	0/79 (0.0%; 0.0–4.6)	0/500 (0.0%; 0.0–0.8)	0/500 (0.0%; 0.0–0.8)	0/11 (0.0%; 0.0–25.9)	0/162 (0.0%; 0.0–2.3)
	Prior CABG or PCI	0/2063 (0.0%; 0.0–0.2)	0/307 (0.0%; 0.0–1.2)	0/6 (0.0%; 0.0–39.0)	0/500 (0.0%; 0.0–0.8)	0/79 (0.0%; 0.0–4.6)	0/500 (0.0%; 0.0–0.8)	0/500 (0.0%; 0.0–0.8)	0/11 (0.0%; 0.0–25.9)	0/162 (0.0%; 0.0–2.3)
Procedural features	EP/ cardiac ablation context	2061/2063 (99.9%; 99.6–100.0)	307/307 (100.0%; 98.8–100.0)	6/6 (100.0%; 61.0–100.0)	500/500 (100.0%; 99.2–100.0)	79/79 (100.0%; 95.4–100.0)	500/500 (100.0%; 99.2–100.0)	500/500 (100.0%; 99.2–100.0)	11/11 (100.0%; 74.1–100.0)	160/162 (98.8%; 95.6–99.7)
	Pulsed-field ablation context	2063/2063 (100.0%; 99.8–100.0)	307/307 (100.0%; 98.8–100.0)	6/6 (100.0%; 61.0–100.0)	500/500 (100.0%; 99.2–100.0)	79/79 (100.0%; 95.4–100.0)	500/500 (100.0%; 99.2–100.0)	500/500 (100.0%; 99.2–100.0)	11/11 (100.0%; 74.1–100.0)	162/162 (100.0%; 97.7–100.0)
	AF/ flutter or PVI target	942/2063 (45.7%; 43.5–47.8)	49/307 (16.0%; 12.3–20.5)	1/6 (16.7%; 3.0–56.4)	375/500 (75.0%; 71.0–78.6)	27/79 (34.2%; 24.7–45.2)	295/500 (59.0%; 54.6–63.2)	61/500 (12.2%; 9.6–15.4)	8/11 (72.7%; 43.4–90.3)	127/162 (78.4%; 71.4–84.0)
	Femoral/ groin access	70/2063 (3.4%; 2.7–4.3)	10/307 (3.3%; 1.8–5.9)	0/6 (0.0%; 0.0–39.0)	32/500 (6.4%; 4.6–8.9)	0/79 (0.0%; 0.0–4.6)	14/500 (2.8%; 1.7–4.6)	11/500 (2.2%; 1.2–3.9)	0/11 (0.0%; 0.0–25.9)	3/162 (1.9%; 0.6–5.3)
	Transseptal/ Brockenbrough access	235/2063 (11.4%; 10.1–12.8)	30/307 (9.8%; 6.9–13.6)	0/6 (0.0%; 0.0–39.0)	77/500 (15.4%; 12.5–18.8)	1/79 (1.3%; 0.2–6.8)	44/500 (8.8%; 6.6–11.6)	30/500 (6.0%; 4.2–8.4)	0/11 (0.0%; 0.0–25.9)	53/162 (32.7%; 26.0–40.3)
	Reposition/ retrieval/ snare/ bailout	100/2063 (4.8%; 4.0–5.9)	5/307 (1.6%; 0.7–3.8)	0/6 (0.0%; 0.0–39.0)	16/500 (3.2%; 2.0–5.1)	8/79 (10.1%; 5.2–18.7)	50/500 (10.0%; 7.7–12.9)	20/500 (4.0%; 2.6–6.1)	0/11 (0.0%; 0.0–25.9)	1/162 (0.6%; 0.1–3.4)
	Procedure/ case completed	1082/2063 (52.4%; 50.3–54.6)	148/307 (48.2%; 42.7–53.8)	0/6 (0.0%; 0.0–39.0)	313/500 (62.6%; 58.3–66.7)	16/79 (20.3%; 12.9–30.4)	199/500 (39.8%; 35.6–44.2)	372/500 (74.4%; 70.4–78.0)	3/11 (27.3%; 9.7–56.6)	32/162 (19.8%; 14.4–26.6)
	Procedure stopped/ aborted/ not completed	214/2063 (10.4%; 9.1–11.8)	58/307 (18.9%; 14.9–23.6)	0/6 (0.0%; 0.0–39.0)	35/500 (7.0%; 5.1–9.6)	40/79 (50.6%; 39.8–61.4)	31/500 (6.2%; 4.4–8.7)	37/500 (7.4%; 5.4–10.0)	2/11 (18.2%; 5.1–47.7)	11/162 (6.8%; 3.8–11.7)
	Conversion/ need for surgery	42/2063 (2.0%; 1.5–2.7)	5/307 (1.6%; 0.7–3.8)	0/6 (0.0%; 0.0–39.0)	5/500 (1.0%; 0.4–2.3)	0/79 (0.0%; 0.0–4.6)	12/500 (2.4%; 1.4–4.1)	9/500 (1.8%; 0.9–3.4)	0/11 (0.0%; 0.0–25.9)	11/162 (6.8%; 3.8–11.7)

AF = Atrial Fibrillation
CABG = Coronary Artery Bypass Grafting
CKD = Chronic Kidney Disease
EP = Electrophysiology
PCI = Percutaneous Coronary Intervention
PFA = Pulsed Field Ablation
PVI = Pulmonary Vein Isolation

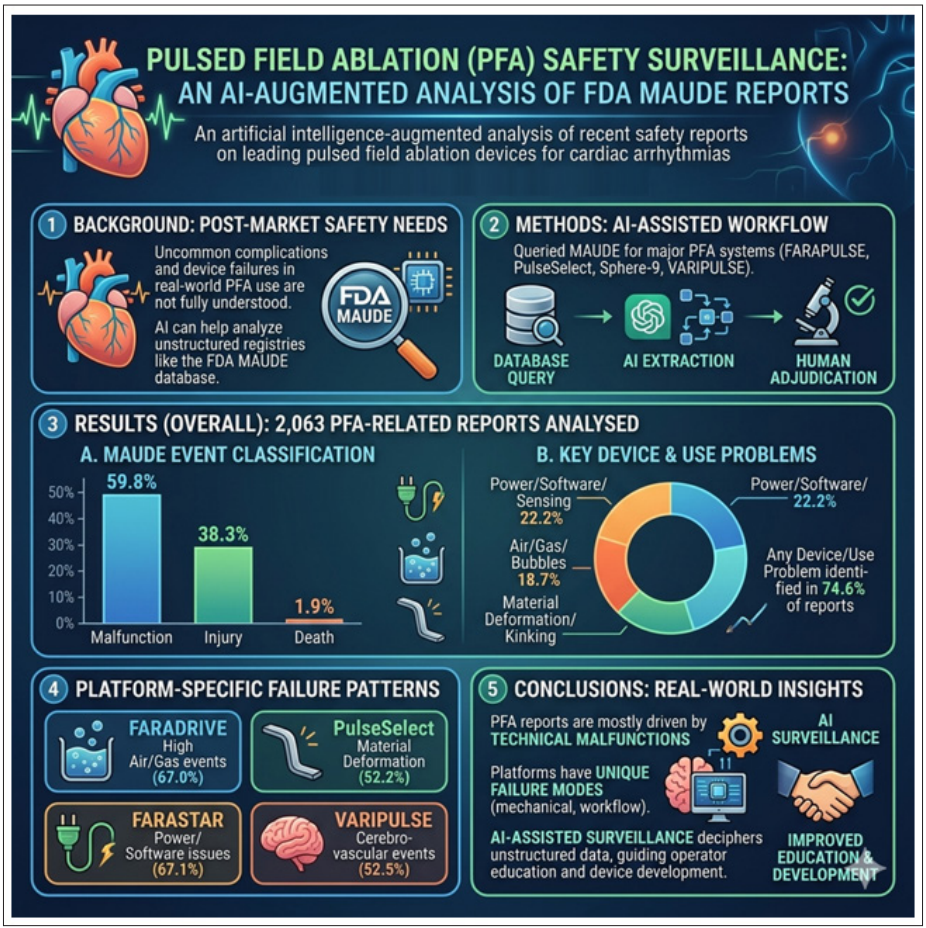

Figure 1: Graphical Summary of Pulsed Field Ablation (PFA) Adverse Reports
AI = Artificial Intelligence
FDA = Food and Drug Administration
MAUDE = Manufacturer and User Facility Device Experience Database

MAUDE event-type classification showed that malfunction reports predominated, accounting for 1,233/2,063 reports (59.8%; 95% CI, 57.6–61.9), followed by injury reports (791/2,063 [38.3%; 95% CI, 36.3–40.5]) and reports categorized as death events (39/2,063 [1.9%; 95% CI, 1.4–2.6]) (Table 2). Overall, any device/use problem or malfunction was identified in 1,538 reports (74.6%; 95% CI, 72.6–76.4). The most frequent issue categories were problems with power, software, display, alarm, or sensing; those associated with air, gas, or bubbles; material deformation or kinking; and use error, off-label use, or patient-device interaction. Device-specific patterns differed, with air and gas events concentrated in FARADRIVE, deformation and kinking in PulseSelect, power and software issues in FARASTAR/TRUPULSE, and use-error coding in VARIPULSE.

Table 2: Event and Issue Types MAUDE = Manufacturer and User Facility Device Experience Database

Domain	Measure	All PFA devices	Affera mapping/ ablation system	Affera system/ Sphere-9 catheter	FARADRIVE steerable sheath	FARASTAR generator/ cables	FARAWAVE catheter	PulseSelect PFA system	TRUPULSE generator	VARIPULSE catheter
Event	MAUDE event type: Malfunction	1233/2063 (59.8%; 57.6–61.9)	84/307 (27.4%; 22.7–32.6)	6/6 (100.0%; 61.0–100.0)	430/500 (86.0%; 82.7–88.8)	72/79 (91.1%; 82.8–95.6)	258/500 (51.6%; 47.2–56.0)	344/500 (68.8%; 64.6–72.7)	11/11 (100.0%; 74.1–100.0)	29/162 (17.9%; 12.8–24.5)
	MAUDE event type: Injury	791/2063 (38.3%; 36.3–40.5)	219/307 (71.3%; 66.0–76.1)	0/6 (0.0%; 0.0–39.0)	64/500 (12.8%; 10.2–16.0)	6/79 (7.6%; 3.5–15.6)	221/500 (44.2%; 39.9–48.6)	149/500 (29.8%; 26.0–34.0)	0/11 (0.0%; 0.0–25.9)	132/162 (81.5%; 74.8–86.7)
	MAUDE event type: Death	39/2063 (1.9%; 1.4–2.6)	4/307 (1.3%; 0.5–3.3)	0/6 (0.0%; 0.0–39.0)	6/500 (1.2%; 0.6–2.6)	1/79 (1.3%; 0.2–6.8)	21/500 (4.2%; 2.8–6.3)	7/500 (1.4%; 0.7–2.9)	0/11 (0.0%; 0.0–25.9)	1/162 (0.6%; 0.1–3.4)
Issue	Any device/ use problem or malfunction	1538/2063 (74.6%; 72.6–76.4)	143/307 (46.6%; 41.1–52.2)	6/6 (100.0%; 61.0–100.0)	459/500 (91.8%; 89.1–93.9)	74/79 (93.7%; 86.0–97.3)	322/500 (64.4%; 60.1–68.5)	364/500 (72.8%; 68.7–76.5)	11/11 (100.0%; 74.1–100.0)	160/162 (98.8%; 95.6–99.7)

	Air/ gas/ bubbles/ air embolism	386/2063 (18.7%; 17.1–20.5)	7/307 (2.3%; 1.1–4.6)	0/6 (0.0%; 0.0–39.0)	335/500 (67.0%; 62.8–71.0)	0/79 (0.0%; 0.0–4.6)	27/500 (5.4%; 3.7–7.7)	10/500 (2.0%; 1.1–3.6)	0/11 (0.0%; 0.0–25.9)	7/162 (4.3%; 2.1–8.6)
	Material deformation/ twist/ bend/ kink	322/2063 (15.6%; 14.1–17.2)	0/307 (0.0%; 0.0–1.2)	0/6 (0.0%; 0.0–39.0)	14/500 (2.8%; 1.7–4.6)	2/79 (2.5%; 0.7–8.8)	40/500 (8.0%; 5.9–10.7)	261/500 (52.2%; 47.8–56.5)	0/11 (0.0%; 0.0–25.9)	5/162 (3.1%; 1.3–7.0)
	Component fracture/ break/ rupture/ tear	118/2063 (5.7%; 4.8–6.8)	8/307 (2.6%; 1.3–5.1)	0/6 (0.0%; 0.0–39.0)	19/500 (3.8%; 2.4–5.9)	5/79 (6.3%; 2.7–14.0)	23/500 (4.6%; 3.1–6.8)	54/500 (10.8%; 8.4–13.8)	0/11 (0.0%; 0.0–25.9)	9/162 (5.6%; 3.0–10.2)
	Dislodgement/ detachment/ migration/ embolization	131/2063 (6.3%; 5.4–7.5)	3/307 (1.0%; 0.3–2.8)	0/6 (0.0%; 0.0–39.0)	8/500 (1.6%; 0.8–3.1)	0/79 (0.0%; 0.0–4.6)	37/500 (7.4%; 5.4–10.0)	77/500 (15.4%; 12.5–18.8)	0/11 (0.0%; 0.0–25.9)	7/162 (4.3%; 2.1–8.6)
	Delivery/ advance/ position/ deploy/ remove failure	114/2063 (5.5%; 4.6–6.6)	0/307 (0.0%; 0.0–1.2)	0/6 (0.0%; 0.0–39.0)	49/500 (9.8%; 7.5–12.7)	1/79 (1.3%; 0.2–6.8)	59/500 (11.8%; 9.3–14.9)	6/500 (1.2%; 0.6–2.6)	0/11 (0.0%; 0.0–25.9)	0/162 (0.0%; 0.0–2.3)
	Power/ software/ display/ alarm/ error/ sensing issue	458/2063 (22.2%; 20.5–24.0)	94/307 (30.6%; 25.7–36.0)	4/6 (66.7%; 30.0–90.3)	5/500 (1.0%; 0.4–2.3)	53/79 (67.1%; 56.1–76.4)	51/500 (10.2%; 7.8–13.2)	188/500 (37.6%; 33.5–41.9)	10/11 (90.9%; 62.3–98.4)	53/162 (32.7%; 26.0–40.3)
	Leak/ splash/ fluid/ blood leak	168/2063 (8.1%; 7.0–9.4)	5/307 (1.6%; 0.7–3.8)	0/6 (0.0%; 0.0–39.0)	112/500 (22.4%; 19.0–26.3)	0/79 (0.0%; 0.0–4.6)	49/500 (9.8%; 7.5–12.7)	2/500 (0.4%; 0.1–1.4)	0/11 (0.0%; 0.0–25.9)	0/162 (0.0%; 0.0–2.3)
	Contamination/ packaging/ sterility issue	165/2063 (8.0%; 6.9–9.2)	10/307 (3.3%; 1.8–5.9)	0/6 (0.0%; 0.0–39.0)	49/500 (9.8%; 7.5–12.7)	18/79 (22.8%; 14.9–33.2)	54/500 (10.8%; 8.4–13.8)	25/500 (5.0%; 3.4–7.3)	0/11 (0.0%; 0.0–25.9)	9/162 (5.6%; 3.0–10.2)
	Use error/ off-label/ patient-device interaction	287/2063 (13.9%; 12.5–15.5)	45/307 (14.7%; 11.1–19.1)	0/6 (0.0%; 0.0–39.0)	10/500 (2.0%; 1.1–3.6)	8/79 (10.1%; 5.2–18.7)	86/500 (17.2%; 14.1–20.8)	6/500 (1.2%; 0.6–2.6)	0/11 (0.0%; 0.0–25.9)	132/162 (81.5%; 74.8–86.7)
	Entrapment/ stuck/ trapped device	168/2063 (8.1%; 7.0–9.4)	11/307 (3.6%; 2.0–6.3)	0/6 (0.0%; 0.0–39.0)	6/500 (1.2%; 0.6–2.6)	1/79 (1.3%; 0.2–6.8)	88/500 (17.6%; 14.5–21.2)	52/500 (10.4%; 8.0–13.4)	0/11 (0.0%; 0.0–25.9)	10/162 (6.2%; 3.4–11.0)

Clinical harm was absent or not reported in 1,258 reports (61.0%; 95% CI, 58.9–63.1) (Table 3). The most frequent patient outcomes were hospitalization or prolonged stay (23.3%), arrhythmia or conduction disturbance (15.7%), pericardial effusion or tamponade (10.1%), reintervention (8.6%), and cerebrovascular events (8.1%). Death as a patient outcome was coded in 47 reports (2.3%; 95% CI, 1.7–3.0). Device-level signals included high cerebrovascular event reporting with VARIPULSE (52.5%) and higher death reporting in FARAWAVE (4.6%), though these findings should be interpreted as reporting patterns rather than comparative safety rates.

Table 3: Patient Outcomes

Measure	All PFA devices	Affera mapping/ ablation system	Affera system/ Sphere-9 catheter	FARADRIVE steerable sheath	FARASTAR generator/cables	FARAWAVE catheter	PulseSelect PFA system	TRUPULSE generator	VARIPULSE catheter
No clinical signs/ symptoms or no patient harm	1258/2063 (61.0%; 58.9–63.1)	119/307 (38.8%; 33.5–44.3)	5/6 (83.3%; 43.6–97.0)	428/500 (85.6%; 82.3–88.4)	73/79 (92.4%; 84.4–96.5)	249/500 (49.8%; 45.4–54.2)	345/500 (69.0%; 64.8–72.9)	11/11 (100.0%; 74.1–100.0)	29/162 (17.9%; 12.8–24.5)
Death	47/2063 (2.3%; 1.7–3.0)	5/307 (1.6%; 0.7–3.8)	0/6 (0.0%; 0.0–39.0)	8/500 (1.6%; 0.8–3.1)	1/79 (1.3%; 0.2–6.8)	23/500 (4.6%; 3.1–6.8)	9/500 (1.8%; 0.9–3.4)	0/11 (0.0%; 0.0–25.9)	2/162 (1.2%; 0.3–4.4)
Cardiac arrest/ CPR/ resuscitation	76/2063 (3.7%; 3.0–4.6)	13/307 (4.2%; 2.5–7.1)	0/6 (0.0%; 0.0–39.0)	7/500 (1.4%; 0.7–2.9)	1/79 (1.3%; 0.2–6.8)	37/500 (7.4%; 5.4–10.0)	14/500 (2.8%; 1.7–4.6)	0/11 (0.0%; 0.0–25.9)	4/162 (2.5%; 1.0–6.2)
Stroke/ CVA/ TIA	168/2063 (8.1%; 7.0–9.4)	32/307 (10.4%; 7.5–14.3)	0/6 (0.0%; 0.0–39.0)	6/500 (1.2%; 0.6–2.6)	1/79 (1.3%; 0.2–6.8)	22/500 (4.4%; 2.9–6.6)	22/500 (4.4%; 2.9–6.6)	0/11 (0.0%; 0.0–25.9)	85/162 (52.5%; 44.8–60.0)
Myocardial ischemia/ MI/ ST elevation MI	68/2063 (3.3%; 2.6–4.2)	12/307 (3.9%; 2.2–6.7)	0/6 (0.0%; 0.0–39.0)	13/500 (2.6%; 1.5–4.4)	0/79 (0.0%; 0.0–4.6)	29/500 (5.8%; 4.1–8.2)	10/500 (2.0%; 1.1–3.6)	0/11 (0.0%; 0.0–25.9)	4/162 (2.5%; 1.0–6.2)
Pericardial effusion/ tamponade/ pericardiocentesis	209/2063 (10.1%; 8.9–11.5)	31/307 (10.1%; 7.2–14.0)	0/6 (0.0%; 0.0–39.0)	28/500 (5.6%; 3.9–8.0)	1/79 (1.3%; 0.2–6.8)	76/500 (15.2%; 12.3–18.6)	47/500 (9.4%; 7.1–12.3)	0/11 (0.0%; 0.0–25.9)	26/162 (16.0%; 11.2–22.5)
Bleeding/ hematoma/ hemorrhage	87/2063 (4.2%; 3.4–5.2)	14/307 (4.6%; 2.7–7.5)	0/6 (0.0%; 0.0–39.0)	26/500 (5.2%; 3.6–7.5)	0/79 (0.0%; 0.0–4.6)	20/500 (4.0%; 2.6–6.1)	20/500 (4.0%; 2.6–6.1)	0/11 (0.0%; 0.0–25.9)	7/162 (4.3%; 2.1–8.6)
Vascular injury/ perforation/ pseudoaneurysm/ dissection	98/2063 (4.8%; 3.9–5.8)	9/307 (2.9%; 1.5–5.5)	0/6 (0.0%; 0.0–39.0)	23/500 (4.6%; 3.1–6.8)	0/79 (0.0%; 0.0–4.6)	28/500 (5.6%; 3.9–8.0)	30/500 (6.0%; 4.2–8.4)	0/11 (0.0%; 0.0–25.9)	8/162 (4.9%; 2.5–9.4)
Arrhythmias	323/2063 (15.7%; 14.2–17.3)	118/307 (38.4%; 33.2–44.0)	0/6 (0.0%; 0.0–39.0)	23/500 (4.6%; 3.1–6.8)	1/79 (1.3%; 0.2–6.8)	105/500 (21.0%; 17.7–24.8)	58/500 (11.6%; 9.1–14.7)	0/11 (0.0%; 0.0–25.9)	18/162 (11.1%; 7.1–16.9)

Hypotension	160/2063 (7.8%; 6.7–9.0)	27/307 (8.8%; 6.1–12.5)	0/6 (0.0%; 0.0–39.0)	23/500 (4.6%; 3.1–6.8)	5/79 (6.3%; 2.7–14.0)	62/500 (12.4%; 9.8–15.6)	37/500 (7.4%; 5.4–10.0)	1/11 (9.1%; 1.6–37.7)	6/162 (3.7%; 1.7–7.8)
Unplanned intervention	177/2063 (8.6%; 7.4–9.9)	36/307 (11.7%; 8.6–15.8)	0/6 (0.0%; 0.0–39.0)	18/500 (3.6%; 2.3–5.6)	2/79 (2.5%; 0.7–8.8)	58/500 (11.6%; 9.1–14.7)	40/500 (8.0%; 5.9–10.7)	0/11 (0.0%; 0.0–25.9)	23/162 (14.2%; 9.7–20.4)
Prolonged stay	481/2063 (23.3%; 21.5–25.2)	125/307 (40.7%; 35.4–46.3)	0/6 (0.0%; 0.0–39.0)	31/500 (6.2%; 4.4–8.7)	2/79 (2.5%; 0.7–8.8)	101/500 (20.2%; 16.9–23.9)	56/500 (11.2%; 8.7–14.3)	11/11 (100.0%; 74.1–100.0)	156/162 (96.3%; 92.2–98.3)

CPR = Cardiopulmonary Resuscitation
CVA = Cerebrovascular Accident
MI = Myocardial Infarction
TIA = Transient Ischemic Attack

Discussion

In this retrospective analysis of more than 2,000 unique MAUDE reports, we successfully implemented an artificial intelligence-augmented safety-analysis approach to characterize the real-world performance of leading PFA platforms. The principal finding of our study is that post-market safety reports for PFA systems are overwhelmingly driven by technical and device-related malfunctions (59.8%) rather than direct or immediate clinical harm, which was absent or unreported in 61.0% of cases. When clinical complications did arise, they were most frequently characterized by hospitalization or prolonged stay, arrhythmias, and pericardial effusion or tamponade. Crucially, our analysis identified distinct, platform-specific reporting patterns, linking specific device designs to unique failure modes, such as high rates of air/gas events in FARADRIVE, material deformation in PulseSelect and power/software issues in FARASTAR.

The high prevalence of technical malfunctions relative to clinical injuries underscores a critical aspect of early-generation PFA adoption. Key problems involving power, software, display, and sensing errors, as well as material deformation and kinking, suggest that, although the biological profile of PFA may provide a theoretical safety cushion against severe collateral tissue damage, the mechanical and electronic delivery systems remain prone to early-stage engineering vulnerabilities [4]. The fact that the majority of these technical disruptions did not result in documented patient harm indicates that operators are often able to recognize system errors, abort or modify procedures, and troubleshoot hardware issues before they escalate into serious clinical events [9]. However, these frequent technical interruptions carry economic and operational burdens, potentially prolonging procedure times and contributing to the documented 23% proportion of prolonged stays [22].

The emergence of highly differentiated safety signals across different manufacturer platforms highlights how variations in catheter architecture, sheath mechanics, and generator software dictate real-world vulnerability profiles [1]. For instance, the marked concentration of air/gas bubble events in the FARADRIVE system points toward specific fluid-dynamic or flushing challenges inherent to its steerable sheath workflow, requiring meticulous operator technique to mitigate microembolic risks [23,24]. Conversely, the high reporting proportion of material deformation and kinking in the PulseSelect platform likely reflects distinct structural limitations in catheter flexibility or deployment mechanics when navigating complex cardiac anatomies [25].

The notable clustering of cerebrovascular events within the VARIPULSE cohort, while limited by the descriptive nature of the database, warrants close scrutiny regarding specific energy-delivery waveforms or baseline patient selection, underscoring that PFA should not be treated as a single, uniform technology [26].

Indeed, some reported failure modes may be influenced by procedural and workflow-related factors, including device preparation and handling practices, whereas others may be more directly related to intrinsic mechanical or software-related device performance [27]. As such, certain reported events may be amenable to mitigation through increased operator experience and ongoing refinement of procedural workflows [9].

From a methodological perspective, the present work demonstrates the usefulness of large language models for data extraction to improve and automate post-market medical device surveillance [14,19,20]. Unstructured, spontaneous reporting registries such as the FDA MAUDE database have historically been underutilized because dense narrative text, inconsistent terminology, and duplicate records make manual curation of thousands of records logistically prohibitive [28]. By applying a standardized taxonomy via an AI-augmented pipeline, we converted heterogeneous free-text data into reproducible, structured variables efficiently. When paired with independent human adjudication to identify occasional model hallucinations, this framework provides a scalable and rigorous methodology for real-time safety tracking, offering a blueprint for monitoring other rapidly evolving, device-intensive fields in electrophysiology and interventional cardiology, as well as similar biomedical fields [29].

Despite the insights provided by this AI-augmented framework, several inherent limitations of the MAUDE database must be acknowledged. First, because MAUDE lacks a denominator, that is, the total number of procedures performed globally or per device is unknown, it is impossible to calculate true clinical incidence rates or establish definitive comparative safety rankings among the platforms [16]. The data are subject to reporting biases, underreporting of minor events, and incomplete documentation of baseline patient demographics or clinical context [6]. Consequently, these findings must be interpreted as hypothesis-generating safety signals rather than definitive evidence of comparative risk. While PFA systems exhibit a favorable clinical safety profile in the real world, platform-specific technical failure modes persist, and these insights should directly inform targeted operator education, catalyze iterative manufacturing refinements, and guide the design of prospective, mandatory clinical registries to optimize this emerging ablation modality [30].

In conclusion, AI-assisted extraction, when combined with predefined taxonomies and human adjudication, may offer a scalable approach for structuring unstructured post-market safety narratives. However, such methods should be viewed as an adjunct to, rather than a replacement for, expert clinical review and prospective surveillance.

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Data Sharing Statement
Original data are available from the corresponding author upon reasonable request.

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