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Artificial Intelligence-Assisted Signal Detection of Medtronic Onyx Coronary Stent Complications: A Post-Market Analysis of the Manufacturer and User Facility Device Experience (MAUDE) Database

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Abstract

Background: Medtronic Onyx zotarolimus-eluting stents (ZES) are widely used in complex percutaneous coronary interventions (PCI), yet real-world safety signals remain underexplored outside of clinical trials. We conducted a focused case study leveraging the Food and Drug

Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database to characterize complications and technical failure modes specifically associated with Onyx platforms.

Methods: We applied a ChatGPT 5-assisted extraction and curation workflow to the 500 most recent MAUDE reports retrieved using the query Manufacturer = "Medtronic" AND Product = "Onyx" (as of September 30, 2025). The model accurately parsed free-text narratives to identify device problems, clinical outcomes, and event severity, guided by a standardized taxonomy, which were then summarized providing row counts and prevalence rates, with exact 95% confidence intervals. Notably, out of 30 randomly selected reports manually verified by two independent reviewers, no inaccuracies were evident for death (0 [0-11.6%]) and two for non-fatal events (6.7% [0.8%-22.1%]).

Results: We identified 499 reports (one was excluded because focusing on a non-coronary device), with death occurring in 21 cases (4.2% [2.8%-6.3%]). Devices were predominantly Onyx Frontier (n=419, 84.0% [80.5%-86.9%]), with Trucor (n=68, 13.6% [10.9%-16.9%]) and Trustar (n=12, 2.4% [1.4%-4.2%]). Leading issues included stent dislodgement/displacement (n=400, 80.2% [76.4%-83.4%]) and positioning failure (n=183, 36.7% [32.6%-41.0%]); balloon breakage/burst and balloon malfunction occurred in 58 (11.6% [9.1%-14.7%]) and 42 (8.4% [6.3%-11.2%]), respectively. Other reported outcomes included myocardial infarction in 19 (3.8% [2.5%-5.9%]), bleeding in 10 (2.0% [1.1%-3.6%]), and stroke in 3 (0.6% [0.2%-1.8%]).

Conclusions: This case study demonstrates the feasibility and accuracy of ChatGPT 5 in extracting structured safety signals from unstructured MAUDE narratives. Complications linked to Medtronic Onyx stents were predominantly procedural, centering on delivery and positioning challenges, with case fatality of 4.2%. These findings are promising and insightful, albeit hypothesis-generating. They underscore the need for procedural optimization and enriched linkage with clinical registries to contextualize risk.

Introduction

In current percutaneous coronary intervention (PCI) practice, the Medtronic (Minneapolis, MN, USA) zotarolimus-eluting stent (ZES) family—including the widely adopted Resolute Onyx platform—has been engineered to improve deliverability, radiopacity, and strut profile while maintaining favorable safety outcomes.(1) Its use in complex PCI — particularly in small-caliber vessels, bifurcation lesions, and high-bleeding-risk scenarios — has extended far beyond initial carefully selected trial populations.(2) Despite robust trial and registry data supporting its efficacy,

real-world complication patterns remain less well characterized, especially in uncontrolled procedural settings and among anatomically complex subgroups.

To address this gap, post-market surveillance systems like the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database offer a valuable, though underutilized, lens into rare or unexpected device-related events.(3-4) However, the unstructured nature of MAUDE narratives, inconsistent terminology, and lack of denominator data complicate traditional analyses and limit reproducibility.(5-6) Large language models (LLMs), particularly advanced versions such as ChatGPT 5 (OpenAI, San Francisco, CA, USA) now offer a novel pathway to extract structured insights from these free-text reports with high fidelity.(7-10)

In this focused case study, we applied a ChatGPT 5-assisted workflow to systematically curate and analyze MAUDE reports related to Medtronic Onyx coronary stents. By combining automated narrative parsing with human adjudication and standardized taxonomy mapping, we aimed to identify recurrent failure modes, procedural complications, and potential safety signals. Our approach illustrates the value of integrating AI tools into medical device surveillance and provides a replicable framework for translating unstructured adverse-event data into actionable procedural knowledge.

Methods

We conducted a retrospective analysis of adverse-event reports involving Medtronic Onyx coronary stents using a LLM-assisted curation workflow. The protocol prespecified screening, coding, and synthesis steps to maximize reproducibility and minimize subjective variability. Two investigators oversaw data handling, with predefined adjudication procedures for discordant classifications. Because all information derived from a publicly available post-marketing surveillance database, this work did not constitute human-subjects research and required no institutional review board approval.

The data source was the MAUDE database.(5) We applied a strict query strategy—Manufacturer = “Medtronic” AND Product = “Onyx”—and included the most recent 500 reports entered as of September 30, 2025. Eligible records specifically referenced coronary use of Onyx stents; reports clearly pertaining to peripheral devices or unrelated products were excluded. Prior to analysis, we removed obvious duplicates and filtered out records with insufficient narrative content for classification.

Free-text narratives were processed through a prompting scheme designed to extract key entities, including device problem and clinical complication. The model outputs of 30 randomly selected reports were reviewed by two human adjudicators to estimate the risk of inaccurate data extraction. The overall workflow for data retrieval, AI-assisted classification, and eventual analysis is summarized in **Figure 1**.

Primary outcomes were the distributions of report categories—malfunction, patient injury, and death—and their corresponding clinical complications. Device-related failure modes were coded using a standardized taxonomy encompassing delivery failure, dislodgement, deformation/fracture, and entrapment.

Statistical analysis was based on providing counts and prevalence estimates for event categories and failure modes, and also accompanying exact 95% confidence intervals (95%CI), according to the Clopper-Wilson method.(11) The dataset used for the analysis and the prompts for data processing and extraction can be obtained contacting the corresponding author.

Results

Out of 500 screened reports, one was excluded because focusing on a non-coronary device (Onyx Liquid Embolic System, Medtronic), yielding 499 MAUDE reports suitable for analysis (**Table 1**). Out of the 30 randomly selected reports manually verified by two independent reviewers, no inaccuracies were evident for death (0 [0-11.6%]) and two for non-fatal events (6.7% [0.8%-22.1%]).

Event categories were distributed as follows: death in 21 (4.2% [95%CI, 2.8-6.3]), injury in 223 (44.7% [40.4-49.1]), and malfunction in 258 (51.7% [47.3-56.1]) (**Figure 2**). Notably, no mislabeling of fatal events occurred.

Most entries involved Onyx Frontier (n=419, 84.0% [80.5-86.9]), with smaller contributions from Onyx Trucor (n=68, 13.6% [10.9-16.9]) and Onyx Trustar (n=12, 2.4% [1.4-4.2]), indicating that signal profiles largely reflect Frontier-era devices. The leading device issue was stent dislodgement/displacement (n=400, 80.2% [76.4-83.4]), followed by positioning failure (n=183, 36.7% [32.6-41.0]). Balloon-related problems were also observed—balloon breakage/burst (n=58, 11.6% [9.1-14.7]) and balloon malfunction (n=42, 8.4% [6.3-11.2])—supporting a predominance of delivery/positioning-linked failure modes. These figures provide the framework for mapping technical issues to downstream clinical events.

Among records with outcome documentation, eventual procedural success was noted in most cases (n=358, 71.7% [67.6-75.5]). Non-fatal outcomes included myocardial infarction (n=19, 3.8% [2.5-5.9]), bleeding: (n=10, 2.0% [1.1-3.6]), and stroke (n= 3, 0.6% [0.2-1.8]).

Discussion

This case study demonstrates the feasibility of using a ChatGPT 5-assisted pipeline to accurately extract structured clinical insights from unstructured MAUDE narratives related to Medtronic Onyx coronary stents. Among the 499 curated entries, malfunction events predominated over patient injury, with death being the least frequent outcome. Delivery- and placement-related failures—specifically stent dislodgement and positioning issues—emerged as the dominant technical signals, while major adverse cardiac or cerebrovascular events were reported less frequently.

By combining high-fidelity AI extraction with manual adjudication, our approach enabled reliable identification of procedural complications across a heterogeneous set of real-world reports.(12) The clustering of delivery and positioning failures suggests that operator-device interaction and anatomic complexity likely contribute more to observed complications than fundamental flaws in stent design. Notably, 84% of all cases involved the Onyx Frontier generation, limiting inference across platform iterations but offering a focused snapshot of current-era device performance.

This analysis reinforces that MAUDE signals must be interpreted cautiously and descriptively.(5-6) The variability and occasional ambiguity of report narratives — despite mitigation via LLM-guided extraction — underscore passive nature and denominator-free design of this unique database.(7) Rather than estimating event incidence, our findings localize where complications are most likely to cluster, pointing to delivery and positioning stages as recurrent risk zones. When triangulated with data from randomized trials and prospective registries—where Onyx has shown favorable long-term outcomes—our results add procedural granularity to a broader safety profile.

Importantly, this study illustrates the added value of generative AI in post-market surveillance, in keeping with prior similar works on this novel take at clinical surveillance.(8-10). ChatGPT 5 enabled accurate parsing of technical complications, timing descriptors, and clinical outcomes that are typically buried in unstructured text, with human oversight ensuring precision.(13) This AI-human hybrid method provides a replicable template for future device-specific investigations across other platforms and specialties.(14)

The practical implications are clear: attention to lesion preparation, guide catheter support, and intraprocedural visualization is crucial to minimize stent misdelivery (e.g. embolization) and procedural failure, which can be quite eventful.(15) Future iterations of MAUDE should incorporate structured fields for procedural context, imaging use, and bailout strategies to expand analytic depth. Until then, narrative normalization—as applied here—can bridge data gaps and support procedural learning.

This work strengths include a nationally scoped dataset, systematic failure-mode taxonomy, dual-review validation, and proactive misclassification screening. Limitations remain intrinsic to MAUDE itself—underreporting, duplication, delayed entries, and missing contextual detail.(16) Nevertheless, our structured AI-assisted curation ensures interpretability and transparency, offering a methodological advance in how real-world device safety is analyzed. In addition, this work is not calling into question the safety and effectiveness of this DES, nor of DES in general, as a key limitation of MAUDE is the lack of any sort of denominator, limiting thus any accurate analysis on comparative safety and efficacy.(17-19)

Future directions include linking MAUDE reports to clinical datasets to enable adjustment for patient risk factors, antithrombotic regimens, or operator experience.(20) Assessing whether device iteration affects failure mode prevalence beyond the Frontier generation will be essential. Public release of our prompts, codebooks, and taxonomy mappings — as outlined in supplementary materials — can support reproducibility and prospective monitoring efforts.

In conclusion, a contemporary MAUDE analysis focusing on the Medtronic Onyx stent, complications were dominated by delivery/positioning-related failures. These descriptive, denominator-free signals are hypothesis-generating and highlight procedural risk clusters rather than estimating incidence. Technical optimization and richer, linkable data sources are needed to validate mechanisms and guide targeted mitigation.

Declarations

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This manuscript was drafted and illustrated with the assistance of artificial intelligence tools, such as ChatGPT 5 (OpenAI, San Francisco, CA, USA), Mage (Mage, New York, NY, USA), and Napkin AI (Napkin AI, Palo Alto, CA, USA), in keeping with established best practices (Biondi-Zoccai G, editor. ChatGPT for Medical Research. Torino: Edizioni Minerva Medica; 2024). The final content, including all conclusions and opinions, has been thoroughly revised, edited, and approved by the

authors. The authors take full responsibility for the integrity and accuracy of the work and retain full credit for all intellectual contributions. Compliance with ethical standards and guidelines for the use of artificial intelligence in research has been ensured.

Conflict of Interest

The authors declare there is no conflict of interest.

Disclosure

Giuseppe Biondi-Zoccai has consulted, lectured and/or served as advisory board member for Abiomed, Advanced Nanotherapies, Aleph, Amarin, AstraZeneca, Balmed, Cardionovum, Cepton, Crannmedical, Endocore Lab, Eukon, Guidotti, Innovheart, Meditrial, Menarini, Microport, Opsens Medical, Synthesa, Terumo, and Translumina, outside the present work. All other authors report no conflict of interest.

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Table 1

Summary features of included reports.

	Count (%)	95% Confidence Interval of %
Reports	499	-
Event type		
Death	21 (4.2%)	2.8-6.3%
Injury	223 (44.7%)	40.4-49.1%
Malfunction	258 (51.7%)	47.3-56.1%
Device		
Onyx Frontier	419 (84.0%)	80.5-86.9%
Onyx Trucor	68 (13.6%)	10.9-16.9%
Onyx Trustar	12 (2.4%)	1.4-4.2%
Issue(s)		
Balloon malfunction	42 (8.4%)	6.3-11.2%
Balloon breakage/burst	58 (11.6%)	9.1-14.7%
Deployment failure	183 (36.7%)	32.6-41.0%
Dislodgement/displacement	400 (80.2%)	76.4-83.4%
Patient outcomes		
Procedural success	358 (71.7%)	67.6-75.5%
Bleeding	10 (2.0%)	1.1-3.6%
Myocardial infarction	19 (3.8%)	2.5-5.9%
Stroke	3 (0.6%)	0.2-1.8%

Figure 1

Workflow for large language model-based analysis of Manufacturer and User Facility Device Experience (MAUDE) reports.

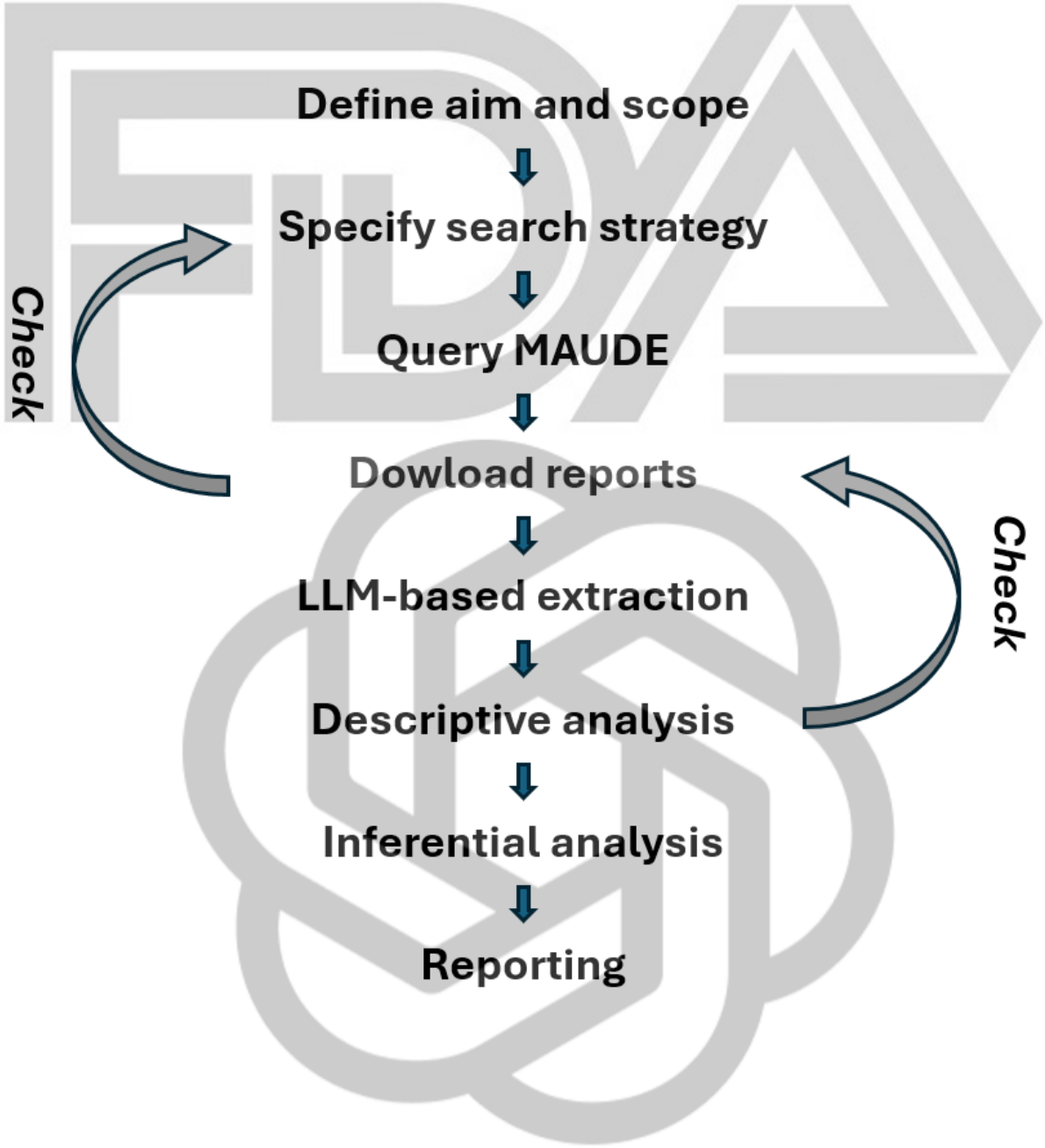
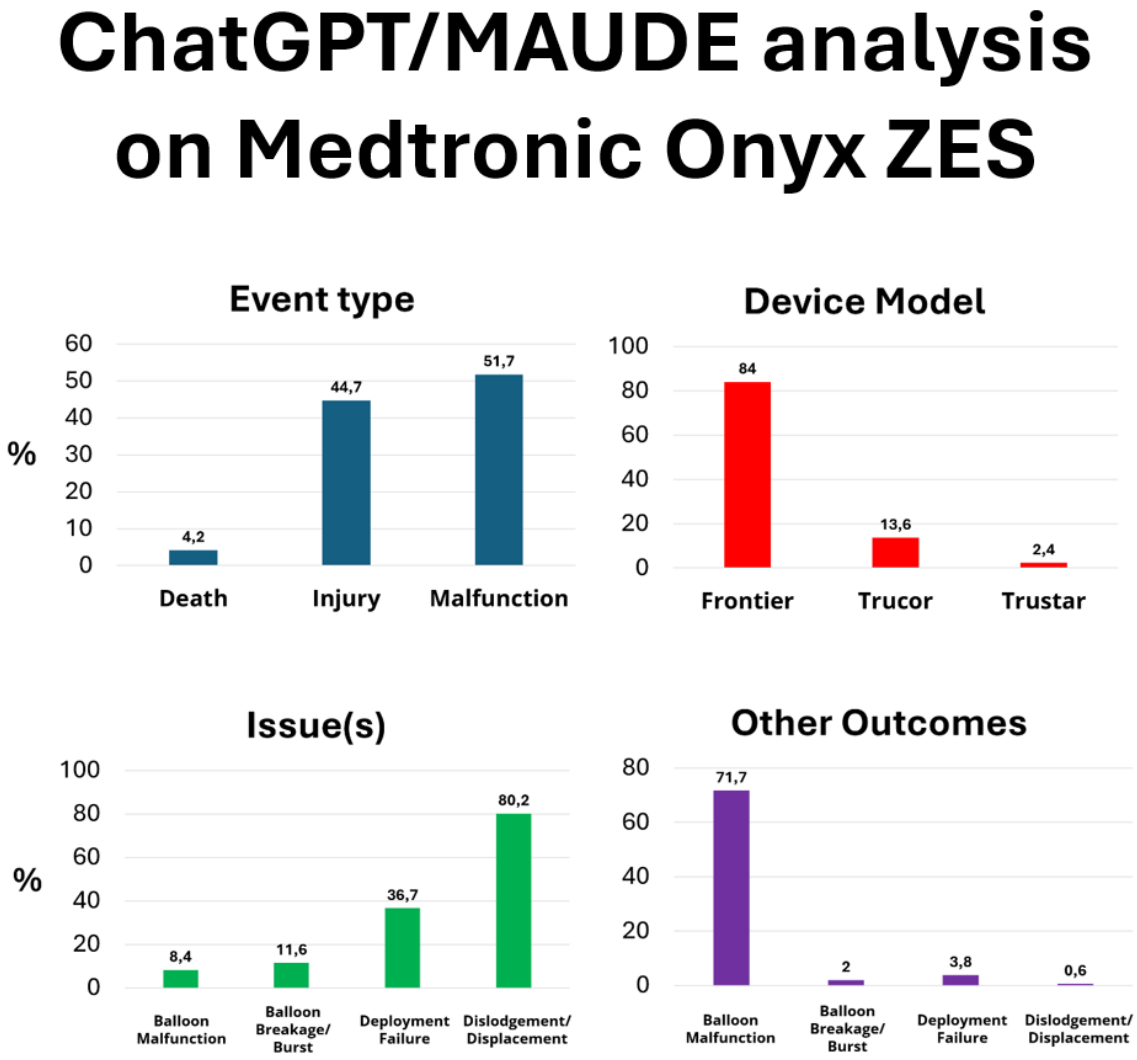


Figure 2

Main findings of a ChatGPT-based analysis of recent Manufacturer and User Facility Device Experience (MAUDE) reports on the Medtronic Onyx zotarolimus-eluting stent, as of September 30, 2025.



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