HeartRhythm

The Official Journal of the Heart Rhythm Society, The Cardiac Electrophysiology Society, and The Pediatric & Congenital Electrophysiology Society

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Underreporting of complications following AF ablation: Comparison of the manufacturer and user facility device experience FDA database and a voluntary invitation-based registry: The POTTER-AF 3 study

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ABSTRACT

BACKGROUND The Manufacturer and User Facility Device Experience (MAUDE) database houses medical device reports of adverse events involving medical devices marketed in the United States submitted to the U.S. Food and Drug Administration (FDA) by mandatory and voluntary reporters. The MAUDE database is frequently used in clinical studies to report on device-related complications. Data about its efficacy are scarce.

OBJECTIVE We aimed to compare the mandatory MAUDE database (MAUDE group) with the invitation-based POTTER-AF study (POTTER-AF 1 group) regarding data quality, procedural characteristics, diagnosis, treatment, and survival.

METHODS The reports of esophageal fistula esophageal fistula following atrial fibrillation (AF) ablation in the MAUDE database were compared with those in the POTTER-AF study between August 1, 2009, and August 31, 2019.

RESULTS Esophageal fistulas were reported in 47 patients in the MAUDE group and in 81 in the POTTER-AF 1 group. Procedures were performed with radiofrequency, cryoenergy, or laser energy in 66.0%, 31.9%, and 2.1% (MAUDE group) and in 96.3%, 2.5%, and 1.2% (POTTER-AF 1 group). The median time to symptoms was 21 (14, 32.5) days (MAUDE group) and 18.0 (6.8, 22.3) days (POTTER-AF 1 group; $P = .031$). The diagnostic method was reported in 38.3% of patients in the MAUDE group and in 98.8% in the POTTER-AF 1 group, the treatment in 57.4% and 100%, and the outcome in all patients. In the MAUDE group, treatment was surgical (51.9%), endoscopic (37.0%), combined (3.7%), or conservative (7.4%), compared with 43.2%, 19.8%, 7.4%, and 29.6% in the POTTER-AF 1 group. Overall mortality was 76.6% in the MAUDE group and 61.7% in the POTTER-AF 1 group ($P = .118$).

CONCLUSION In the mandatory MAUDE database, fewer esophageal fistula cases were reported compared with an invitation-based study. The data quality in the MAUDE database was significantly poorer.

KEYWORDS Atrial fibrillation ablation; Esophageal fistula; Reporting complications; FDA; MAUDE

(Heart Rhythm 2025;22:1472–1479)

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https://doi.org/10.1016/j.hrthm.2024.09.060

Introduction

Medical device reports (MDRs) are one of the U.S. Food and Drug Administration's (FDA) several important postmarket surveillance data sources. According to the FDA website, the Manufacturer and User Facility Device Experience (MAUDE) database comprises MDRs submitted to the FDA by mandatory reporters including manufacturers, importers, and device user facilities as well as voluntary reporters such as health care professionals, patients, and consumers.[1,2] As mandated by FDA, the manufacturers and importers are required to submit any reports of adverse events involving medical devices marketed in the United States. Any event involving a medical device that might have caused or contributed to serious injury or death, as well as any malfunction of the devices that could have contributed to death or serious injury, must be reported, regardless of the country of origin.[1] The concept is similar in concept to the aviation safety reporting system.[3] It is important to note that the MAUDE database was used in numerous publications in prestigious journals to report on device-related complications.[4–7]

Catheter ablation for the rhythm control strategy of atrial fibrillation is extensively performed worldwide. Numerous new technologies and techniques have significantly improved the efficacy and safety profile of this therapeutic approach.[8–12]

Esophageal fistula represents a rare but probably the most dreadful complication of catheter-based atrial fibrillation (AF) ablation associated with high morbidity and mortality.[13,14] Its incidence is reported to range between .016% and .1%.[13–18]

The concomitantly published POTTER-AF 2 (The PrOgnosis following oesophageal fisTula formaTion in patients undergoing cathetER ablation for AF) study analyzed all the esophageal fistula and esophageal injury cases reported in the MAUDE database between August 1, 2009, and August 31,2019. The study identified and investigated 47 esophageal fistula cases (78.3%) and 13 esophageal injury cases (21.7%), examining factors such as reporting modality, energy source, catheter type and manufacturer, clinical manifestations, lesion type, diagnostic methods, treatment approaches, and patient survival.[19]

The recently published POTTER-AF study is an international, multicenter, anonymized registry study. It was conducted on a voluntary, invitation-based basis to evaluate the incidence, management, and outcomes of postprocedural esophageal fistula following catheter ablation for AF. Between 1996 and 2022, 138 cases of esophageal fistula were reported, with an incidence of .038% among RF-based procedures and of .0015% among cryoballoon-based ablations.[13]

The aim of the current study was to compare the FDA mandatory and voluntary reports on esophageal fistula with the results of the worldwide, voluntary, invitation-based POTTER-AF registry. The comparison focused on data quality, procedural details, symptoms, diagnosis, treatment, and outcomes.

Abbreviations

AF: atrial fibrillation

AFL: atrial flutter

AT: atrial tachycardia

CT: computed tomography

FDA: Food and Drug Administration

MAUDE: Manufacturer and User Facility Device Experience

MDR: medical device reports

RF: radiofrequency

SD: standard deviation

Methods

The methods of the POTTER-AF and POTTER-AF 2 studies were published earlier.[13,19]

Briefly, the POTTER-AF study is a retrospective, worldwide, multicenter, anonymized, invitation-based registry conducted at the Department of Rhythmology of the University Heart Centre Lübeck, Germany, under the auspices of the Working Group of Cardiac Electrophysiology of the German Cardiac Society (AGEP, DGK). The study investigated the incidence, management, and outcome of esophageal fistula following catheter-based ablation for the treatment of AF. A total of 609 experienced electrophysiological centers received invitations to participate, of which 214 centers from 35 countries completed the survey. Each center provided general data regarding the number of patients treated by means of catheter ablation for AF or atrial tachycardia (AT) as well as specific data for the patients exhibiting esophageal fistula, such as baseline characteristics, periprocedural characteristics, and follow-up data using a standardized online questionnaire survey (SurveyMonkey). Patients with esophageal fistulas (which included atrioesophageal, esophagopericardial fistula, or esophageal perforation) after catheter ablation for AF and atrial tachycardia between 1996 and 2022 were included. [13]

In the POTTER-AF 2 study, the MAUDE database was searched for adverse events related to AF and atrial flutter (AFL) ablation procedures reported between August 1, 2009, and August 31, 2019. The searched product class was Catheter, Percutaneous, Cardiac Ablation, For Treatment of Atrial Fibrillation, and Atrial Flutter. All reports were manually reviewed, and adverse events associated with esophageal fistula formation and esophageal injury were included. Data regarding the report modality, location, energy source, catheter type and manufacturer, manifestations, type of lesion, diagnosis methods, treatment, and survival were collected. All events were classified either as "Death" or "Injury." All suspected or diagnosed esophageal fistulas, atrioesophageal fistula, esopericardial fistulas, and esophageal perforations were classified as esophageal fistula.[19]

Considering that the study period in the POTTER-AF 2 study was shorter, only the patients in the POTTER-AF study developing esophageal fistula in this period (August 1, 2009, and August 31, 2019) were included in the analysis. The 2 populations were analyzed in terms of procedural data, symptoms, diagnosis methods, treatment, and survival (Figure 1).

Statistical analysis

Categorical variables are reported as absolute and relative frequencies, n (%) and were compared using the χ^2 test or the Fisher's exact test. The Shapiro-Wilk test was used to test the

normal distribution of the continuous variables. They are reported as mean ± standard deviation (SD) and compared by means of the Student *t* test in case of normal distribution and reported as median and interquartile range (Q1, Q3) and compared by means of the Mann Whitney *U* test otherwise.

All the *P* values are 2-sided, and a $P < .05$ was considered significant. The statistical analysis was conducted using the SPSS software, version 29 (SPSS Statistics, IBM, Armonk, NY).

Results

Patient population

The POTTER-AF 2 study identified 47 patients developing esophageal fistulas reported between August 1, 2009, and August 31, 2019 (MAUDE group). For 3 patients, the date of event was not available, but the year of report was 2014 and 2017, respectively. In the POTTER-AF study, a total of 138 patients developed esophageal fistulas between 1996 and 2022. The date of procedure leading to esophageal fistula was available in 116 patients. Of them, 81 developed esophageal fistula between August 1, 2009, and August 31, 2019 (POTTER-AF 1 group).

Information on the location of events was available in 33 (70.2%) patients in the MAUDE group and in all patients in the POTTER AF 1 group. In the former group most esophageal fistulas were reported in the United States (66.7%), France (12.1%), and Australia (12.1%), whereas in the latter group, most esophageal fistulas were reported in France (34.6%), Germany (22.2%), and the United States (8.6%) (Figure 2). The median age was 61 (49, 68) years in the MAUDE group and 63 (54, 70) years in the POTTER-AF 1 group ($P = .435$).

Incidence

According to the Asia Pacific Heart Rhythm Society White Book, a total of 674,734 ablation procedures for AF were performed in this region between 2010 and 2019 (Asia Pacific White Book 2013-2023 [https://www.aphrs.org/publications/the-aphrs-white-book]). A publication from Innovative-Health.com reported a total of 2,162,600 ablation procedures in the United States from 2010 to 2019. It is noted that, in 2020, the AF ablation procedures accounted for more than two-thirds of all ablation procedures, whereas the percentage steadily increasing over time. Assuming that two-thirds of all ablation procedures were AF ablations, the total number of AF ablations in the USA during this period would be approximately 1,441,733 (https://innovative-health.com/wp-content/uploads/2014/10/EP-Single-Use-Device-Reprocessing-by-the-Numbers_ART0139-Rev.-1.pdf).

For the European space, the European Heart Rhythm Association White Book is available until 2017, reporting the number of ablation procedures until 2016. Between 2010 and 2016, a total of 488,264 AF ablations were performed. Assuming an increase of 10% each year, the number of AF ablation procedures between 2017 and 2019 was estimated at 411,826 procedures (https://www.escardio.org/Subspecialty-communities/European-Heart-Rhythm-Association-(EHRA)/Research-and-Publications/The-EHRA-White-Books).

Accounting for all reports, the number of AF ablations performed between 2010 and 2019 was 3,016,557. Considering the total number of esophageal fistulas reported in the MAUDE database, the incidence of this complication between 2010 and 2019 was .00155%. In the POTTER-AF study, the incidence of esophageal fistulas was .025% between 1996 and 2022.

Energy type

Of the 47 patients in the MAUDE group, 31 (66.0%) were radiofrequency (RF)-based procedures, 15 (31.9%) cryoballoon-based procedures, and 1 (2.1%) laser balloon-based procedure. In comparison, 78 (96.3%), 2 (2.5%), and 1 (1.2%) procedure in the POTTER-AF 1 group were performed using RF, cryoballoons, and laser balloons, respectively (Figure 3).

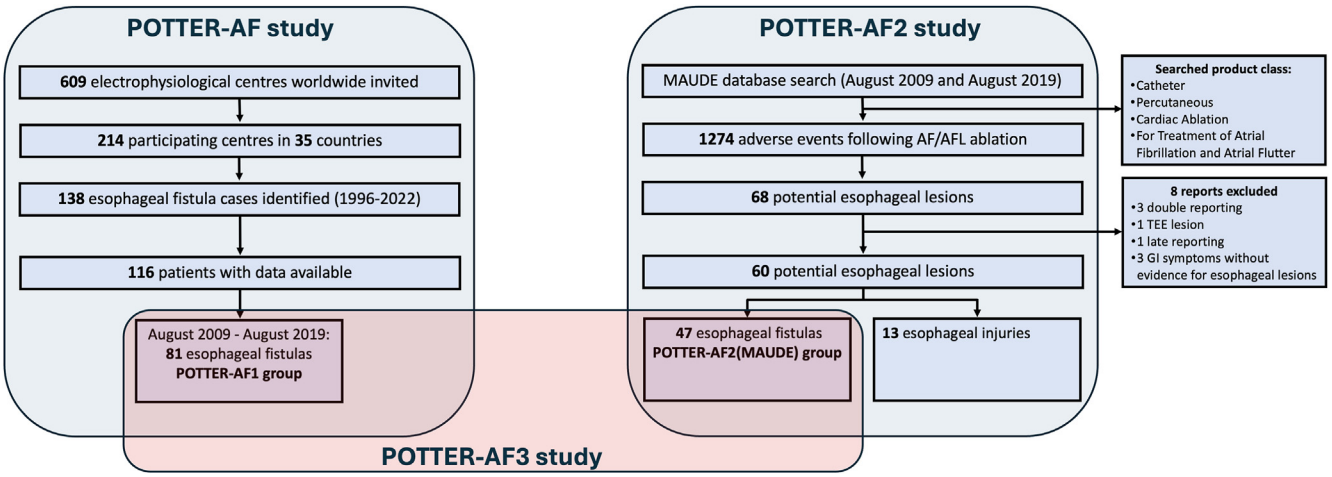

Figure 1
Study flowchart. AF = arial fibrillation; AFL = atrial flutter.

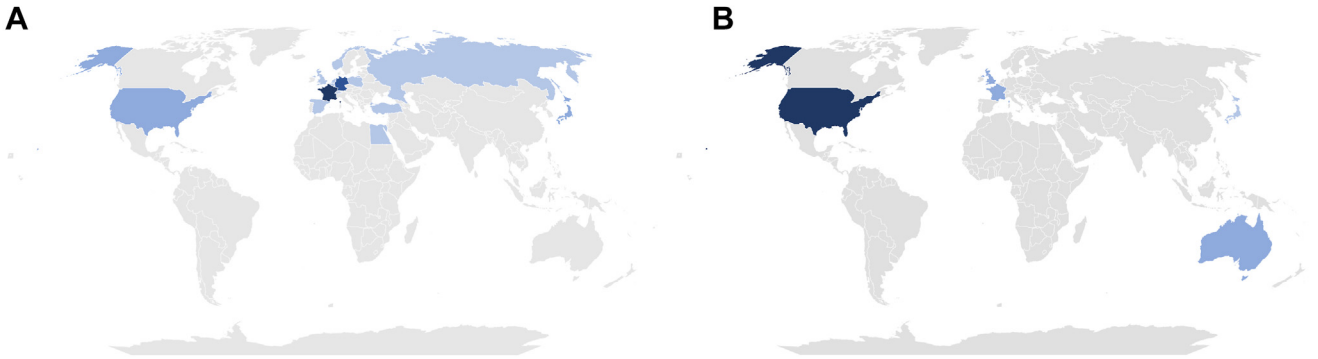

Figure 2
Distribution of the reports. Distribution of the reports in the POTTER-AF 1 group (**A**) and MAUDE group (**B**) (*gray* = no reports, scale of blue: *light blue* = fewer reports, *dark blue* = more reports). (Figure powered by Bing [Australian Bureau of Statistics, GeoNames, Microsoft, Navinfo, Open Places, OpenStreetMap, TomTom, Zenrin])

Presentation and symptoms

The time to symptoms was available in 21 (44.7%) patients in the in the MAUDE group and 78 (96.3%) patients in the POTTER-AF 1 group. The median time to symptoms onset was 21 (14, 32.5) days in the former group and 18.0 (6.8, 22.3) days in the latter group ($P = .031$).

The initial symptoms were reported in 30 (63.8%) patients in the MAUDE group and in all patients in the POTTER-AF 1 group. The most common form of presentation of the patients in the MAUDE group was with neurologic events (66.7%), followed by fever (46.7%), thorax pain (36.7%), and dysphagia (10%). Thirteen (43.3%) patients exhibited other symptoms. In the POTTER-AF 1 group, 54.3% patients showed fever, whereas 55.6% of them exhibited chest pain or odynophagia, and 49.4% neurologic events. Other symptoms were reported in 54 (66.7%) patients (Figure 4).

Lesion type

The type of lesion was available for all patients in both groups. In the MAUDE group, the lesion types were reported as follows: 26 (55.3%) atrioesophageal fistulas, 16 (34.0%) esophageal fistulas, 4 (8.5%) esophageal perforations, and 1 (2.1%) esophageal-pericardial fistula. A total of 77 (95.1%) patients in the POTTER-AF 1 group exhibited atrioesophageal fistulas, whereas 4 (4.9%) showed esophageal-pericardial fistulas.

Diagnostic method

The diagnostic method was reported in 18 (38.3%) patients in the MAUDE group and in 80 (98.8%) patients in the POTTER-AF 1 group. In the first population, the diagnostic method was computed tomography (CT) in 14 (77.8%) patients, reported as thorax CT in 9 (50.0%) patients and cranial CT in 3 (16.7%) patients, magnetic resonance imaging (MRI) in 3 (16.7%) patients, echocardiography in 3 (16.7%) patients, and endoscopy in 2 (11.1%) patients. Other diagnostic methods were reported in 12 (66.7%) patients. In the POTTER-AF 1 group the most common diagnostic method was thorax CT in 62 (77.5%) patients, followed by cranial CT or MRI in 31 (38.8%) patients, echocardiography in 26 (32.5%) patients, and endoscopy in 16 (20%) patients, whereas other diagnostic modalities were reported in 15 (18.8%) patients.

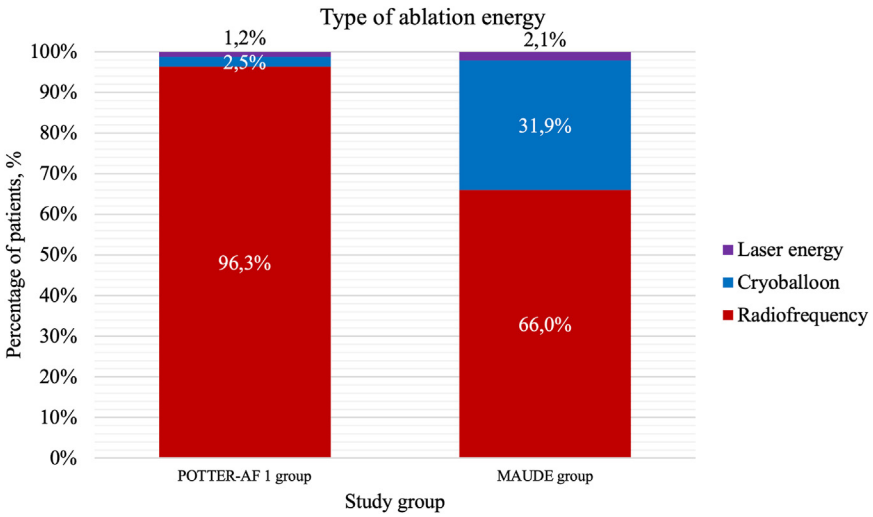

Figure 3
Energy source. Energy source used in the POTTER-AF 1 group (*left*) and in the MAUDE group (*right*).

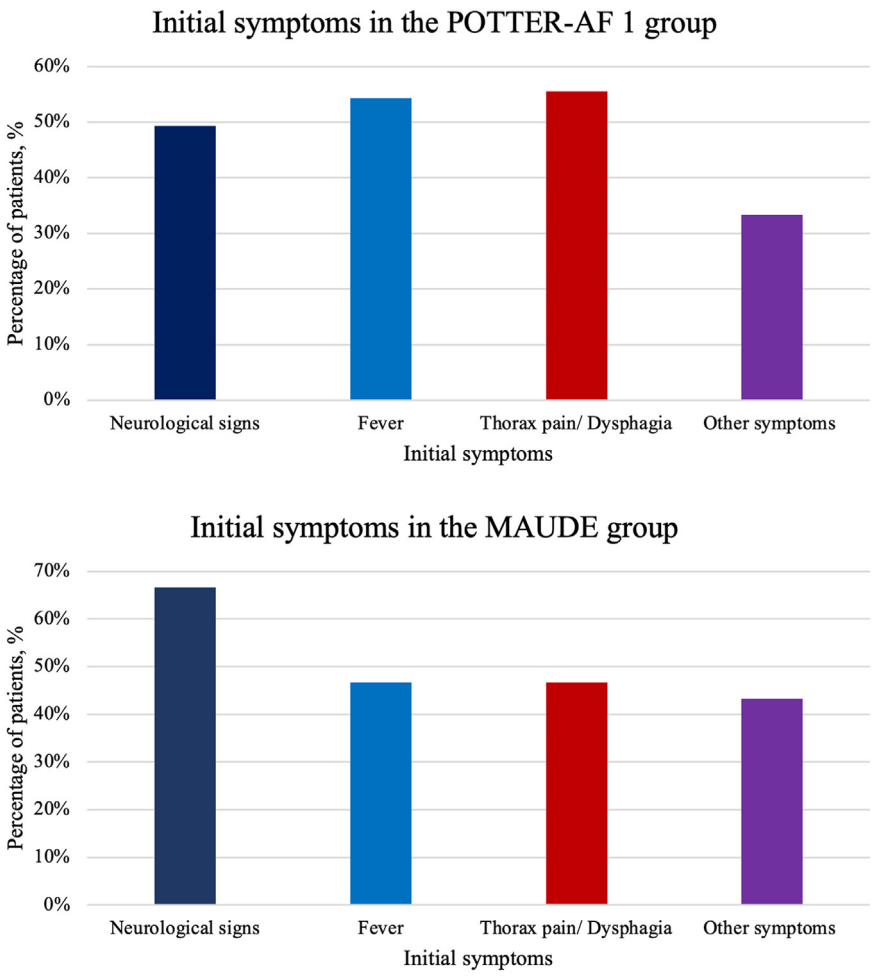

Figure 4
Symptoms. Initial symptoms reported in the POTTER-AF 1 group (*upper panel*) and in the MAUDE group (*lower panel*).

Treatment

The treatment modality was available for 27 (57.4%) patients in the MAUDE group and for all the patients in the POTTER-AF 1 group. In the MAUDE group, 14 (51.9%) patients underwent surgical treatment only, 10 (37.0%) patients received interventional treatment only, 1 (3.7%) patient received a combination of surgical and interventional treatment, and 2 (7.4%) patients were treated conservatively (1 patients did not require intervention, and 1 patient had severe anoxic brain injury and received no further treatment). In comparison, the POTTER-AF 1 group reported 35 (43.2%) patients undergoing surgery only, 16 (19.8%) undergoing interventional treatment only, 6 (7.4%) patients undergoing a combined treatment, and 24 (29.6%) patients who were treated conservatively (Supplemental Figure S1).

Survival

Information regarding the survival was available for all the patients in both populations. In the MAUDE group, the overall mortality was 76.6%, compared with 61.7% in the POTTER-AF 1 group ($P = .118$; Supplemental Figure S2). When stratifying by treatment, the mortality in the MAUDE group was 80% among patients undergoing surgery, 80% among those undergoing interventional treatment only, and 100% among those treated conservatively ($P = .782$), whereas in the POTTER-AF 1 group, it was 51.2%, 50.0%, and 87.5%, respectively ($P = .002$).

Discussion

The current study is the first one to compare the mandatory and voluntary reports of the MAUDE FDA database with a concomitant, invitation-based registry on esophageal fistula complicating catheter-based AF ablations. The main findings are as follows:

1. In the same timeframe, substantially fewer patients were reported in the mandatory and voluntary FDA database compared with the invitation-based POTTER-AF study. This may be because of a massive underreporting of complications in the FDA database.
2. The quality of the data in the MAUDE database was poorer than in the invitation-based POTTER-AF study.
3. The locations of the events were significantly different, suggesting a low overlap of cases.
4. The mortality of esophageal fistula complicating AF catheter ablations was excessively high in both groups.

Between August 2009, and August 2019, the MAUDE database reported 47 cases of esophageal fistulas, whereas the POTTER-AF study identified 81 cases. The extremely low number of reports in the MAUDE database suggests that only a very small fraction of these highly lethal complications is being reported. The estimated worldwide incidence of esophageal fistulas between 2010 and 2019 using the MAUDE database was .00155%, which is considerably lower compared with that reported in the POTTER-AF study (.025%), but also in other publications.[13,14,17] This discrepancy raises concerns about the adequacy of postmarket surveillance in interventional cardiology.

As outlined on the FDA website regarding the reporting of MDRs, the MAUDE database operates as a passive surveillance system with notable limitations. These include the reporting of incomplete, inaccurate, untimely, unverified, or potentially biased data. In contrast, our results from the voluntary, invitation-based POTTER-AF registry suggest that health care professionals may be more willing to report specific complications when approached by their peers.

In addition, the quality of data regarding the examination, diagnosis, and treatment of events was superior in the invitation-based registry. However, the limitations of underreporting, as well as the risks of bias and inaccurate data, persist. Therefore, ongoing education and the creation of awareness of this potentially lethal complication in thermal based energy sources to treat AF are of crucial importance. Looking ahead, whether pulsed field ablation (PFA), a novel energy source to treat AF by catheter-based ablation will eliminate the risk esophageal fistula and esophageal injury remains to be seen.

As previously noted, the countries where events were reported differed between the 2 databases, indicating a low degree of overlap between the populations. This represents another argument in favor of underreporting of esophageal fistula complicating AF ablation, especially when considering that the MAUDE database is an international postmarket surveillance mechanism. Although most events in the FDA data were reported from the United States, France, and Australia, the majority of reports in the POTTER-AF study came from France, Germany, and the United States. This finding also suggests a higher FDA reporting behavior in the United States compared with other countries. Furthermore, the POTTER-AF study is a retrospective analysis, which inherently carries the risk of underreporting. The observation that the number of complications reported in the MAUDE database—and consequently the estimated incidence—was lower than that in a study that may also be affected by underreporting reinforces the argument for underreporting within the FDA database. It is important to note that, aside from Japan, no other Asian country reported esophageal fistula cases in either database. As in the POTTER-AF study, this may reflect the limitations of the invitation-based approach; for the MAUDE database, it clearly indicates underreporting. Furthermore, neither database included data from Latin American centers, despite these regions performing a significant number of AF ablations and having previously published independent findings on esophageal fistulas following AF ablation.[20,21] This absence represents a critical gap in the global understanding of this complication.

In both populations, the mortality rate associated with esophageal fistula complications following catheter-based AF ablation was exceptionally high. These results are consistent with other publications on this topic.[14,20,22] In contrast to the POTTER-AF 1 group, no significant difference in mortality could be observed among different treatment strategies in the MAUDE group. This discrepancy may be attributed to the small number of patients in the MAUDE group who received conservative treatment (n = 2). The lower number of patients undergoing conservative treatments in the FDA database, along with the slightly higher mortality compared with the POTTER-AF 1 group, may also suggest a specific reporting behavior. There appears to be a tendency to report cases involving invasive treatments or fatal outcomes rather than those involving conservative treatments in which the patient survived the complication.

We questioned whether it was necessary to investigate and publish data on a topic already well known among health care professionals, simply because it had not been studied before. Ultimately, we concluded that it was, for 2 key reasons. First, numerous publications in prestigious journals have used the MAUDE database to report on various device-related complications.[4–7] This underscores the importance of assessing the quality and integrity of these reports for further research. Second, the study's findings revealed significant underreporting of complications to the FDA, despite the mandatory nature of the reporting system.

Taking everything together, our findings are a call for the creation of a more unified, detailed, and homogeneous reporting system to improve data quality. National and international AF ablation registries collecting specific data related to clinical outcome, including complications, are needed.

Limitations

The current study represents a comparison between a nonstandardized, worldwide FDA database and a retrospective, invitation-based scientific registry. As previously mentioned, the data reported to the FDA do not follow a standardized protocol and are sometimes reported by non-health care professionals. Moreover, the patient cohort participating in POTTER-AF study is different from the cohort of patients worldwide, which is the source of the MAUDE database.

The data used to calculate the incidence of esophageal fistula are incomplete and the calculation of the total number of AF ablations performed is based on estimations. Because of the lack of available data, we were unable to determine the exact incidence of esophageal fistula for each energy modality or catheter type.

The time of event reporting in the MAUDE database was compared with the time of event occurrence in the POTTER-AF study. However, in the FDA reports, there was a delay between occurrence and reporting of the event. Thus, the 2 times do not perfectly match.

The MAUDE database was searched using predefined terms and then manually reviewed. There exists, however, the possibility that reports of esophageal fistula were omitted. A clear differentiation between time to symptoms onset and time to hospital presentation was not possible in the MAUDE group.

Conclusion

Significantly fewer cases of esophageal fistula were reported in the mandatory/voluntary FDA MAUDE database compared with the voluntary, invitation-based POTTER-AF worldwide scientific registry. The data quality in the MAUDE database was substantially poorer, as only a limited number of patients had complete reports. The current postmarket surveillance system for reporting of complications following AF ablation appears to have major limitations, such as underreporting and poor data quality, and the observed differences call for further study to identify their causes and enhance reporting on lethal complications linked to medical products.

Our findings are a call for the creation of a more unified, detailed and homogeneous reporting system to improve data quality. National and international AF ablation registries collecting specific data related to clinical outcome including complications are needed.

Acknowledgements

The authors used the data from the POTTER-AF study in the present analysis, and would like to acknowledge the authors of the original paper in this publication. Please see the full list of POTTER-AF study authors in the Supplementary Material.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2024.09.060.

Funding Sources: This research did not receive ay specific grant from funding agencies in the public, commercial, or not-for-profit sectors,

Disclosures: Dr Tilz is a consultant for Boston Scientific, Philips, Medtronic Biosense Webster, and Abbott Medical; he has received speaker`s honoraria from Boston Scientific, Biotronik, Biosense Webster, Abbott Medical, Lifetech, and Pfizer and research grants from Abbott, Biotronik, Medtronic, Biosense Webster, and Lifetech. He has received travel grants from Abbott, Biosense Webster, Boston Scientific, Medtronic, and Philips. Dr Heeger has received travel grants and research grants from Abbott, Boston Scientific, Lifetech, Biosense Webster, and Haemonetics and speaker honoraria from Abbott, Boston Scientific, Lifetech, Biosense Webster, CTI GmbH, Doctrina Med, Wikonnekt, Haemonetics, and Pfizer. Dr Popescu has received travel grants and congress grants from Lifetech and an educational grant and speaker grant from Abbott Medical. Dr Pürerfellner servers as a consultant for Boston Scientific, Biosense Webster, Abbott Medical, and Medtronic; he has received speaker`s honoraria from Boston Scientific, Biotronik, Biosense Webster, Abbott, and Medtronic. Dr Catanzaro has received royalties from the University of Florida Research Foundation and research funding from Circa Scientific. Dr Kuck has received grants and personal fees from Abbott Vascular, Medtronic, and Biosense Webster outside the submitted work. Dr Vogler has received speaker honoraria from Abbott, Boston Scientific, Impulse Dynamics, Pfizer, and Doctrina Med. Dr Steven has received speaker honoraria from Abbott and Biosense Webster and is a consultant for Abbott and Boston Scientific. Dr Veltmann is a consultant for Biotronik and Medtronic; he has received speaker`s honoraria from Boston Scientific, Biotronik, Abbott Medical, BMS, Medtronic, and Zoll. Dr Merino has received fees and honoraria for lectures, education, and scientific advice from Biotronik, Microport, and Zoll. The other authors have no conflicts of interest to disclose.

Ethics Approval: As this retrospective analysis involves publicly available FDA reports, ethics approval was not required. The ethics approval was obtained for the previously published POTTER-AF study

Data Availability: Data of the MAUDE database are public and can be found on the FDA website (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm). Data supporting the POTTER-AF study are curated at the Study Centre of the Department of Rhythmology, University Hospital Schleswig-Holstein, Germany. These data are not shared openly but are available on reasonable request from the corresponding authors.

Declaration of Generative AI and AI-Assisted Technologies in the Writing Process: During the preparation of this work the author(s) used ChatGPT–OpenAI to improve the language and readability of the manuscript. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

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