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Adverse events related to Atricure EPi-Sense Coagulation Device - Analysis of the FDA MAUDE database

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Keywords

Hybrid Convergent Procedure; Atricure EPi-Sense Device; Adverse Events; Atrio-Esophageal Fistula; CONVERGE Trial

The Atricure EPi-Sense (EPi-sense) is a recently FDA approved device, used for the hybrid convergent procedure, an emerging treatment for persistent atrial fibrillation (AF) and long standing persistent atrial fibrillation (LSPAF). With the exception of adverse events (AE) published in the recent CONVERGE trial, there is a paucity of evidence regarding the AE related to the use of this device. Therefore, the primary objective of this analysis is to interrogate the post-marketing surveillance data from the U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database to evaluate the complications associated with EPi-sense [1].

We searched for keyword “EPi-SENSE” on the MAUDE database on 01/18/2021. There were 80 reports from 2016–2020. With more than 12,000 convergent procedures performed till date, using the EPi-sense device (based on personal communication with the device representatives) this represents an AE rate of less than 1%. The device was returned for evaluation in 79 reports which were then included in the final analysis. Although the indications for the EPi-sense were not specified on the MAUDE database, the manufacturer recommends its use solely for the hybrid convergent procedure. There was no mention of the type of atrial fibrillation treated on any device reports.

The AE were broadly classified into 11 categories as seen in table 1. The three most common categories of AE were: Cardiac and pericardial injury or inflammation: 27 (34%) events, Embolic: 20 (25%) events, and esophageal injury: 9 (11%) events. Many of the serious AE such as atrio-esophageal fistulas (AE-Fistulas), strokes, pericardial effusions, cardiac perforations and several others preceded the unfortunate event of death. Therefore, they were included in both categories. The most common AE was pericardial effusion,

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reported in 20 (25.3%) reports, followed by stroke in 14 (17.7%) cases. In contrast to CONVERGE trial which reported no deaths or AE-fistulas, 19% (15 patients) of cases reported to MAUDE died and 8.9% (7 patients) developed AE-fistulas. Pleural effusion was reported in 6 (7.6%) device related AE. 2 events (2.5%) each of acute renal failure, new onset heart failure, atrial fibrillation with rapid ventricular response and ventricular fibrillation were reported. Device malfunction was reported in 5 (6.4%) of cases, out of which 4 cases were of malfunction of saline perfusion. One event was reported as system malfunction with no further details. Transient ischemic attack (TIA) and pulmonary embolism (PE) were reported in 3 cases each, but no further information on their anticoagulation status was provided. 4 events of diaphragmatic, 1 report of incisional and 1 report of pericardial window hernias were reported.

MAUDE database houses reports submitted by mandatory and volunteer reporters to the FDA. Although, AE reported to MAUDE cannot be used as a true incidence rate, our data extracted from MAUDE shows low adverse events related to EPi-sense catheter and convergent procedures, considering the number of real-world convergent procedures that have been carried out. Pericardial effusion is a common AE reported in patients with convergence procedure and is well documented in the CONVERGE trial, a randomized controlled trial comparing the efficacy of hybrid convergent procedure to conventional catheter ablation in patients with persistent atrial fibrillation [2]. The CONVERGE trial protocol was therefore amended to recommend administration of a prophylactic regimen of steroids or NSAIDS to prevent it. Esophageal injuries are common in atrial fibrillation procedures involving posterior wall ablation techniques [3], where the radiofrequency energy is usually directed towards the esophagus. Convergent procedure is unique in that the epicardial ablations are performed on the posterior wall with the radiofrequency probe directed towards the heart and away from the esophagus. This should, in theory, reduce the AE-Fistulas and other esophageal injuries by reducing the number of posteriorly directed endocardial burns. However, there were reports of saline perfusion malfunction. As noted by Wats. K et. al. [4], the saline infusion system in the EPi-Sense device is meant to cool the device, improve energy penetration and prevent char. The malfunction of this system could lead to absence of saline infusion to cool the device in certain cases causing higher chances of injuries due to overheating. The occurrence of embolic phenomenon reflect interruption of periprocedural anticoagulation regimen. In-fact, several reports on the MAUDE database actually mention failure of compliance of anticoagulation regimen.

Other minimally invasive surgical ablation (SA) techniques have been compared to catheter ablation in the FAST trial (n=162) [5] in 2012 and the Randomized Controlled Trial of Surgical Versus Catheter Ablation for Paroxysmal and Early Persistent Atrial Fibrillation, 2018 (n=52) [6]. However, both the studies reported significantly higher number of major adverse events in the SA arm compared to the catheter ablation arm. Serious adverse events included pneumothorax, requirement for pacemaker, lung herniation requiring surgical correction and laryngeal nerve palsy. Nevertheless, it is to be noted that the SA techniques involved in these studies are more invasive compared to the convergent procedure. Both studies performed thoracoscopic surgical epicardial ablation (bipolar radiofrequency isolation of pulmonary veins and ablation of the ganglionated plexi) as opposed to a sub-xiphoid endoscopic approach used in most convergent procedures. In addition, these

studies performed concomitant surgical removal of LAA, which is not a routine practice in convergent AF ablation. In comparison to these procedures, convergent procedure is extremely safe, as evident from the CONVERGE trial (n=149) where no significant differences in adverse events were reported compared to the CA arm (7.8% vs 0%, p = 0.0525).

There are major limitations of using the MAUDE database. One of them is the underreporting of AE, especially those occurring because of clinician's error. This is important in a relatively novel procedure like the convergent procedure which involves a steep learning curve and high chances of operator error. In addition, the type of atrial fibrillation and history of prior ablation procedures in these cases, which might affect the proportion of AE were unknown. Lastly, there is no way to determine if these adverse events were related specifically to the endocardial or the epicardial part of the procedure, a limitation which also applies to the findings reported in the CONVERGE trial since no clarification was provided. Nevertheless, our report highlights the most important adverse events associated with the use of Atricure EPI-sense device and the need for continued surveillance of safety profiles, patient outcomes and device failures.

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Data availability statement

The post-marketing surveillance data related to the adverse events associated with the Atricure EPi-Sense Device that support the findings of this study are openly available in U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm reference number 7.

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Table 1:

Adverse events related to the Atricure EPi-Sense Coagulation Device. The table shows various different complications associated with the use of the Atricure EPi-Sense coagulation device. The complications are grouped into 11 categories. Percentages reflect proportion of the total AEs reported.

Complication	N (%)	Complication	N (%)
Embolic		**Pulmonary**	
Transient Ischemic Attack	3 (3.8%)	Pleural effusion	6 (7.6%)
Stroke	14 (17.7%)	Pneumothorax	1 (1.3%)
Pulmonary Embolism	3 (3.8%)		
		Esophageal	
Rhythm		Esophageal burn - non perforation	1 (1.3%)
Bradycardia	1 (1.3%)	Esophageal perf	1 (1.3%)
Atrial Fibrillation	2 (2.5%)	Atrio-esophageal perforation	7 (8.9%)
Ventricular Fibrillation	2 (2.5%)		
Ischemic		**New onset Heart Failure**	2 (2.5%)
Acute Myocardial Infarction	1 (1.3%)		
		Acute Renal Failure	2 (2.5%)
Device			
System malfunction	1 (1.3%)	**Hernia**	
Malfunction of saline perfusion	4 (5.1%)	Incisional hernia	1 (1.3%)
		Diaphragmatic hernia	4 (5.1%)
Cardiac and Pericardial injury or inflammation		Pericardial window hernia	1 (1.3%)
Pericardial effusion	20 (25.3%)		
Cardiac tamponade	4 (5.1%)	**Miscellaneous**	
Dressler syndrome	1 (1.3%)	Hemidiaphragmatic paralysis	1 (1.3%)
Cardiac perforation	2 (2.5%)	Excessive bleeding	1 (1.3%)
		Death	15 (19.0%)