Disclaimer

The FDA chose a specific outcome algorithm that met its need for a given medical product-outcome assessment. The use of a specific outcome algorithm in a Sentinel assessment should not be interpreted as an endorsement from FDA to use the algorithm for all safety assessments. Investigators should always consider the objective, study design, analytic approach, and data source of a given medical product safety assessment when choosing the outcome algorithm. The suitability of an outcome algorithm may change when applied to different scenarios. For additional information, please refer to the

Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data guidance document provided by the FDA.

Overview

Title	Atrioventricular (AV) Block Algorithm Defined in "Cardiovascular Outcomes following Percutaneous Transluminal Septal Myocardial Ablation (PTSMA) Procedures: A Descriptive Analysis"
Request ID	cder_mpl1r_wp228
Description	This report lists International Classification of Disease, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes and algorithms used to define atrioventricular (AV) block in this request. For additional information about the algorithm and how it was defined relative to the cohort and exposures of interest in the analysis, see the analysis page here: https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/cardiovascular-outcomes-following-percutaneous-transluminal
Outcome	Atrioventricular (AV) block
Algorithm to Define Outcome	Atrioventricular (AV) block outcomes were defined using ICD-9-CM and ICD-10-CM codes that occurred in any care setting within 30 days following and including the index PTSMA procedure date.
Query Period	January 1, 2014 - December 31, 2021
Request Send Date	August 5, 2022

Glossary

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or missing (U)

Outcome - outcome of interest (either primary or secondary)

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest

Request Send Date - date the request was sent to Sentinel Data Partners

List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Atrioventricular (AV) Block in this Request

Code	Description	Code Category	Code Type
Atrioventricular (AV) Block			
426.0	Atrioventricular block, complete	Diagnosis	ICD-9-CM
426.1	Atrioventricular block, other and unspecified	Diagnosis	ICD-9-CM
426.10	Unspecified atrioventricular block	Diagnosis	ICD-9-CM
426.11	First degree atrioventricular block	Diagnosis	ICD-9-CM
426.12	Mobitz (type) II atrioventricular block	Diagnosis	ICD-9-CM
426.13	Other second degree atrioventricular block	Diagnosis	ICD-9-CM
426.7	Anomalous atrioventricular excitation	Diagnosis	ICD-9-CM
I44.0	Atrioventricular block, first degree	Diagnosis	ICD-10-CM
I44.1	Atrioventricular block, second degree	Diagnosis	ICD-10-CM
I44.2	Atrioventricular block, complete	Diagnosis	ICD-10-CM
I44.30	Unspecified atrioventricular block	Diagnosis	ICD-10-CM