H134 Sudden Deaths in Patients With Cardiac Rhythm Devices Via Medical Examiner Surveillance and Systematic Autopsy

Zian Tseng, MD, Electrophysiology & Arrhythmia Service, 400 Parnassus Avenue, Fl B1, Rm 094, San Francisco, CA 94143; Christopher Mulvanny, BS, University of California, San Francsico, 400 Parnassus Avenue, San Francsico, CA 94143; Nina Clark, BS, University of California, San Francisco, Box 1354, Rm MUE 430, 500 Parnassus Avenue, San Francisco, CA 94143; Philip Ursell, MD, Medical Sciences, 513 Parnassus Avenue, Box 0102, Rm 546C, San Francisco, CA 94143; Jeffrey Olgin, MD, Moffitt Hospital, 505 Parnassus Avenue, Box 0124, Rm 1182, San Francisco, CA 94143; Amy P. Hart, MD, San Francisco OCME, 850 Bryant Street, N Terrace, San Francisco, CA 94103; Nikolas P. Lemos, PhD, OCME, Forensic Lab Division, Hall of Justice, N Terrace, 850 Bryant Street, San Francisco, CA 94103; and Ellen Moffatt, MD*, City & County of San Francisco, OME, 850 Bryant Street, San Francisco, CA 94103*

After attending this presentation, attendees will understand that cardiac devices such as pacemakers and defibrillators may contain useful information as to the heart rhythm at the time of death, as well as giving important clues as to why the patient died through interrogation of the device and inspection of the programming details and device settings, as well as uncovering possible malfunctions of the device.

This presentation will impact the forensic science community by reminding members of their role in public safety in finding malfunctions and defects in products placed into patients and their duty to help the living by giving feedback to cardiologists who program and implant these devices into patients.

Introduction: Data on device malfunctions are based on the Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database, participation in which is mandatory for manufacturers but voluntary for healthcare providers; however, because the vast majority of Sudden Cardiac Deaths (SCDs) occur out of hospital, interrogations and autopsies of SCDs with devices are rarely performed; thus, actual rates of device failure that lead to sudden death are unknown. This study was initiated to determine the Causes Of Death (COD) in SCDs with devices in a prospective autopsy study of all incidents of SCDs in San Francisco.

Methods: In the first 30 months of the San Francisco Postmortem Systematic Investigation of SCD (POST SCD) Study (02/1/2011-11/30/2013), autopsies were performed on 468 of 480 (97.5%) of all incident SCDs and demographically matched trauma death cases captured through active surveillance of all deaths reported to the Medical Examiner (ME). Evaluation for all cases included full autopsy, toxicology, histology, and detailed examination of the heart and cranial vault. Device interrogation was performed on all SCDs and selected trauma controls with a device. A multidisciplinary committee reviewed pre-hospital medical records and autopsy results to adjudicate a final COD by consensus.

Results: Twenty-one of 468 (4.5%) incident SCDs and three trauma controls had devices (SCDs: eight Implantable Cardioverter Defibrillators (ICDs), 13 Permanent Pacemakers (PPMs); Trauma: one ICD, two PPM.

Six of eight ICDs showed a terminal rhythm of Ventricular Fibrillation (VF) with undersensing and delayed shock in SCD cases. Acute COD (e.g., pulmonary embolism, lethal toxicology, acute myocardial infarct) was excluded in all six. Three of six ICDs had delay of shock due to Antitachycardia Pacing (ATP) programming in VF zone. Four of 13 PPM showed a terminal rhythm of VF in SCD cases. Three of 13 (23%) PPMs had evidence of malfunction, acute COD was excluded in all three. Two PPM-dependent patients had evidence of acute premortem lead fracture; one PPM-dependent patient had rapid battery depletion the day prior to death. Search of MAUDE showed no prior deaths reported for the two leads.

All three trauma control cases showed no evidence of device malfunction at or around the time of accidental death.

Conclusions: By prospective ME surveillance, arrhythmic sudden death despite ICD was common, often due to undersensing and/or delay of VF therapy. VF was the most common mechanism of death in PPM SCDs, followed by lead fracture. Without systematic interrogation and autopsy, these events would have been missed, thus current calculated rates of malfunctions are likely substantial underestimates.

Sudden Cardiac Death, Pacemaker, Defibrillator