A Proposal For ICD Infection Symptom Prevention Using Automated Impedance Testing Devices (AITDs)

Nicolas Xu[1]
[1]Damien High School

Abstract:

Despite research and development to prevent infections and malfunctions in implantable cardioverter defibrillators (ICDs), infection rates of ICD implantations are still impactful. According to a study published on 4 Nov. 2022 by Michele Malagù et al., 1%-2% of patients who suffer from arrhythmia and resort to using ICDs (including the newest model ICD-11) have ICD infections [1]. This leads to complications, including signs of pain, erythema, swelling, or discharge on the ICD pocket site as well as fever, systematic infection, and even death if left untreated [2].

Introduction:

Current projects primarily focus on developing biocompatible materials, such as antibiotic-impregnated mesh to reduce the risk of infections [3]. Other studies focus on curing infections should they arise, including removal of the infected ICD [4] and antibiotics treatments that last up to 14-16 weeks [5]. However, neither cases consider the lasting effects of ICD infections on patients.

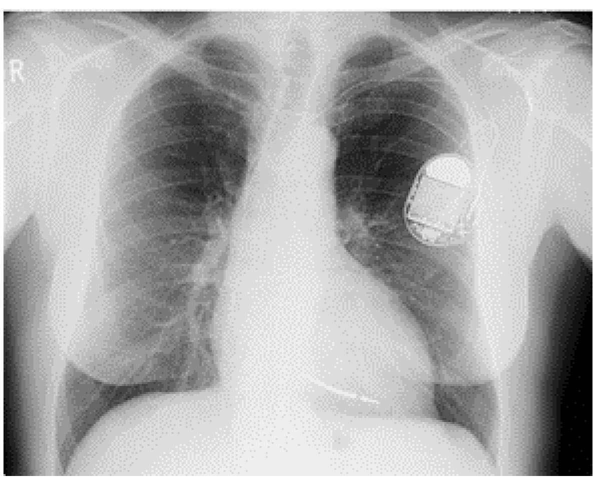

Figure 1 shows the location of a typical ICD (pacemaker) for the heart. The “egg” shape is the pacemaker, and the black area is where the heart and lungs are situated [8].

The concern is that ICD infections tend to be unidentifiable until symptoms emerge or until patients visit doctors for check-ups [6] (which occur every 3-6 months, usually done via impedance tests [7]). By the time ICD infections are identified, they may have already harmed the patient, leaving lasting effects including heart scarring (which decreases the heart's efficiency), psychological damage to the patient (fear and distrust in ICDs), and even death if not treated properly.

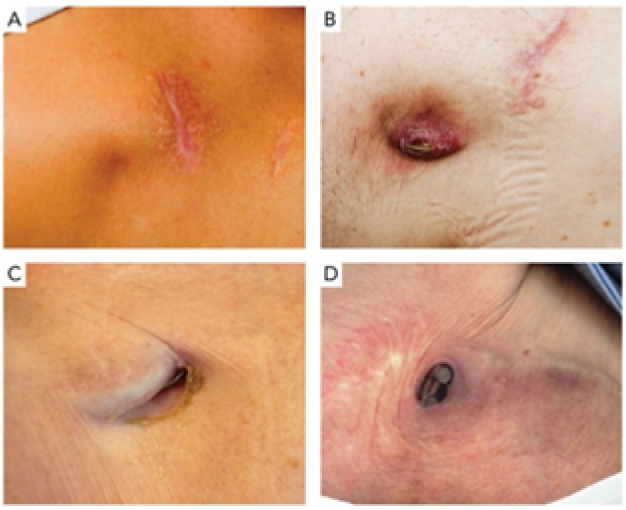

Figure 2: Pocket infection of ICD on four separate patients. Shows that treatment can be complex and the potential psychological damage to patients [9].

This raises the question; can a change to current approaches from prevention and after-symptom treatment of infection into the detection of infections before symptoms appear decrease the severity of harm and mortality rate of ICD infections?

This proposal posits the use of Automated Impedance Testing Devices (AITDs) to conduct monthly tests on patients to detect infections, thereby preventing the appearance of ICD infection symptoms and any lasting harm to said patients.

AITD is a miniature device containing a battery, impedance tester, transmitter, electrodes, pacemaker programmer, lead adapters, and lead extenders fitted into a titanium shell (due to its non-erosive, strong, and lightweight properties). It will be attached to the patient next to the ICD during surgery, and the lead wire will be attached to where the original impedance test program was in past designs. AITDs will work by applying a small, unnoticeable electric current through the lead (built into the pacemaker) to measure the resistance of current in order to check if there is a potential infection, inflammation, or immune rejection occurring. More specifically, an electric current will flow from the battery into the lead conductor. Then, the electric current would leave the AITD via electrodes to flow through the ICD and return to the lead adapters, eventually returning to the battery.

Typically, non-automatic impedance tests occur every 3-6 months during doctor appointments, where an electric current is applied to conduct the test, and the data is shown on a graph to the doctor. AITDs work similarly to the current approach, with the critical difference of conducting an automated monthly impedance test. The result from the AITD will be sent to and analyzed by a program called Automated Impedance Analyzer Program (AIAP), which utilizes a database of ICD infection patterns and compares them to determine if the ICD patient truly has an infection even if the patient is asymptomatic (Results of resistance returning from the impedance test conducted on a healthy patient is between 25 to 50 Ω. However, if the resistance is ≥ 51 Ω, there may be a potential infection or inflammation on the ICD site. [10]). Should the analysis determine that the patient displays evidence of an infection, a message would be sent to the patient as well as their doctor so appointments or treatments could be offered.

Testing of AITDs and AIAPs will first be done on mice to ensure the safety together with efficiency of the devices. As more tests are conducted, data of healthy mice with ICDs and mice with infected ICDs will be fed to a model AIAP database for mice specifically (So not to cause error in the case of human trials, since mice and humans are not the same organism, despite sharing similar genetics). After adequate testing is done, human trials may begin, and a new AIAP database for humans will be used. It is anticipated that AITD, as well as AIAP, would function flawlessly to ensure that patients whose infections would otherwise go unnoticed are warned of threats. In so doing, they are able to be prescribed antibiotic treatments or the replacement of the infected ICD.

Conclusion:

AITDs could ensure the safety of patients who currently employ ICDs. In addition, AITDs can safeguard that errors in current designs are resolved, possibly saving the 1%-2% of patients who would otherwise fight infection, posing a risk to their lives. This is especially important in the medical field, where small risks may pose considerable threats to the future of these patients.

References:

[1]. Malagù, Michele, et al. “Risk Scores for Cardiac Implantable Electronic Device Infection: Which One to Believe In?” Journal of Clinical Medicine, vol. 11, no. 21, Multidisciplinary Digital Publishing Institute, Nov. 2022, p. 6556. https://doi.org/10.3390/jcm11216556.

[2]. MY APPROACH to the Patient With an Infected Implantable Cardioverter Defibrillator (ICD).” PracticeUpdate, www.practiceupdate.com/content/my-approach-to-the-patient-with-an-infected-implantable-cardioverter-defibrillator-icd/52868.

[3]. Barbar, Tarek, et al. “Strategies to Prevent Cardiac Implantable Electronic Device Infection.” National Library of Medicine, vol. 11, no. 1, Jan. 2020, pp. 3949–56. https://doi.org/10.19102/icrm.2020.110102.

[4]. Povsic TJ, Najjar SS, Prather K, et al. Design and rationale of the PREDICTS study: a randomized, multicenter, clinical trial assessing superiority of preventive antibiotics versus standard of care in patients at high risk for implantable cardioverter-defibrillator infections. Am Heart J. 2016;173:95-102. doi:10.1016/j.ahj.2015.10.018

[5]. European Consensus Document on Cardiac Implantable Electronic Device Infections - American College of Cardiology.” American College of Cardiology, 2 Mar. 2020, www.acc.org/Latest-in-Cardiology/ten-points-to-remember/2020/03/02/13/54/European-Heart-Rhythm-Association-EHRA.

[6]. Team, Heart and Vascular. “Is a Hidden Pacemaker Infection Making You Sick?” Cleveland Clinic, 20 Mar. 2023, health.clevelandclinic.org/is-a-hidden-pacemaker-infection-making-you-sick.

[7]. Implantable Cardioverter-defibrillators (ICDs) - Mayo Clinic. 2 Dec. 2021, www.mayoclinic.org/tests-procedures/implantable-cardioverter-defibrillators/about/pac-20384692.

[8]. Coxworth, Ben. “New Type of Electrotherapy Makes Implantable Defibrillators Less Shocking.” New Atlas, 2 May 2015, newatlas.com/less-shocking-implantable-defibrillators/25126.

[9]. Kirkfeldt, Rikke Esberg. “Management of Cardiac Electronic Device Infections: Challenges and Outcomes.” Radcliffe Cardiology, Dec. 2020, www.aerjournal.com/articles/management-cardiac-electronic-device-infections-challenges-and-outcomes.

[10]. Swerdlow, Charles D., et al. “Impedance in the Diagnosis of Lead Malfunction.” Circulation-arrhythmia and Electrophysiology, vol. 13, no. 2, Lippincott Williams and Wilkins, Feb. 2020, https://doi.org/10.1161/circep.119.008092.