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ELECTROMAGNETIC INTERFERENCE ON MEDICAL DEVICES: A CASE STUDY OF IMPROPER IMPLANTABLE CARDIOVETER DEFIBRILLATOR (ICD)

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Abstract —*Electromagnetic Interference (EMI) is one of the major issues that affect the proper functioning of various electronic devices. In this research, a case where EMI in the form of leakage current from an unearthed refrigerator resulted in the inappropriate delivery of an electric shock from an Implantable Cardioverter-Defibrillator (ICD) to the heart because it mistook it to be a sensed cardiac signal (in this case ventricular fibrillation) was considered. A description of the EMI coupling mechanism, estimation of the associated EMI and possible ways preventing EMI entry into ICDs was also included in this research.*

Keywords-*Electromagnetic Interference; Implantable Cardioverter Defibrillator; Unipolar sensing; Bipolar sensing*

I. INTRODUCTION

The recent advancements in medicine have resulted in the use of electronic devices for the treatment and prevention of diseases that usually lead to untimely death. One of such electronic devices is the Implantable Cardioverter Defibrillator (ICD). ICDs are used to treat patients prone to sudden cardiac arrest, which could lead to sudden death. The device is implanted in the chest cavity region of the body. The device communicates with the heart's veins via one or more leads (electrodes). This new device technology in medicine is designed to monitor the rhythm of the heat beat and to detect the rate with which the heart beats. The heart beat rate could be too fast (tachycardia), too slow (bradycardia) or both irregular and too fast (ventricular fibrillation). The ICD detects abnormal heartbeat and sends the required amount of electric signal or shock to the heart to restore it back to its normal rhythm [1].

However there are certain environmental conditions that could affect the normal operation and optimum performance of the ICD. The ICD begins to malfunctions when it starts sending undesired pulses or shocks to the heart. This could be due to interference either from within or outside the patient's body. There are a number of situations that could trigger the ICD to send false signals [2]. Such situations may be electromagnetic interference, mechanical faults, muscle related diseases etc.

The rest of the research is structured as follows, a brief description of an ICD is carried first carried out, after which a case study of a man whose ICD was affected by electromagnetic interference was considered. Then the coupling mechanism of the interference is investigated and the EMI estimate (noise voltage) obtained. The research is concluded by looking various ways in which electromagnetic interference on ICDs can be prevented.

II. BRIEF DESCRIPTION OF ICD

The ICD is made up of a pulse generator which houses the sensing, pacing and shock delivery circuits and a battery that powers the circuits. There are also leads which are connected to the pulse generator at one end and to the hearts through the veins at the other end. The lead comprises a tip (and in some cases tip and ring) electrode for pacing the heart and one or two integrated defibrillator coils that are placed in the right, left ventricle or superior vena cava for shock delivery. The ICD is programmed to detect the heart rate and depending the rate it senses pace the heart or deliver a high energy shock in the case of ventricular fibrillation detection [4]. The sensing can be unipolar sensing where the heart rate is sensed between a tip electrode acting as the cathode and the casing of the pulse generator acting as the anode or a bipolar sensing where the sensing and pacing electrode is made up of a tip electrode and a ring electrode which are separated by a distance of about 2.4cm [5].

III. EMI CASE REPORT

The victim is a 77 years old man who had previously been diagnosed with cardiac related diseases (coronary disease, myocardial infarction, depressed left ventricular function, symptomatic ventricular tachycardia (VT)). As a result, a single chamber ICD (i.e. ICD with a single lead that is connected to only one chamber of the heart) with bipolar sensing lead was implanted. His ICD was programmed to detect and treat ventricular fibrillation (at 290ms) and ventricular tachycardia (at 400ms). The lead was inserted into the left ventricle of the heart and it has a sensitivity of

0.3mV. The impedance of the ventricular lead was 361 ohm and the impedance of the defibrillator coil was 59 ohm. The patient on this particular occasion came and reported to his cardiologist that he was shocked once by his device without any prior warning. Usually before the ICD delivers a shock, the patient will have some feelings such as drowsiness, palpitation, headache that will give him an indication that a shock is about to be delivered but in this case there was no prior warning.

He further stated that he received the shock while he was bringing out some fruits from the refrigerator. The shock from his ICD was received immediately he touched the inside of the refrigerator after which he fell to the ground. After that no additional shock was received. A careful examination of his ICD revealed an incidence of Ventricular fibrillation detection resulting in the delivery of a single shock.

The ICD has memory chip called the electrocardiogram that stores all previous operations it performs. The output from the electrocardiogram revealed that a noise signal of frequency similar to the frequency of 60 Hz alternating current was the cause. Due to the fact the ICD was designed to send certain amount of shocks to heart when it detects tachycardia, bradycardia or ventricular fibrillation, the ICD misunderstood it to be a case of ventricular fibrillation detection and therefore fired a shock. It was later discovered that the refrigerator was not earthed and that led to the flow of leakage current into the victim which appeared as EMI on the cardiac electrocardiogram [3].

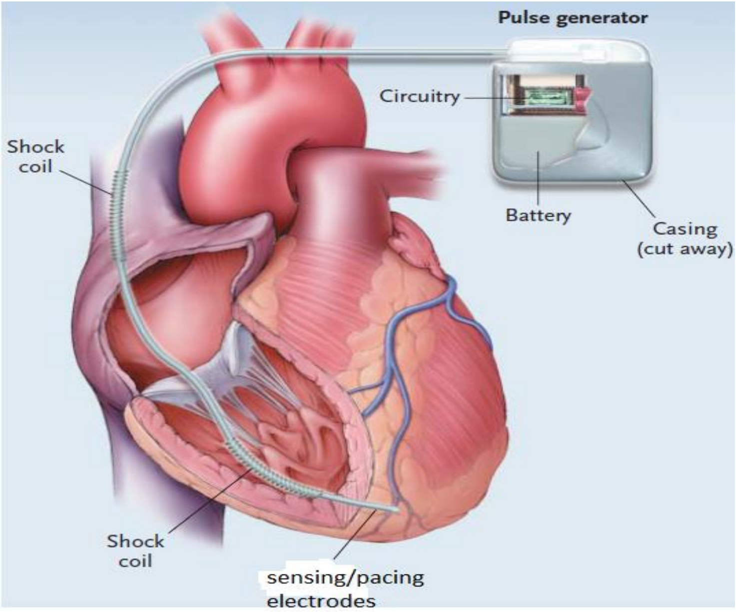

Figure 1. A Single Chamber Implantable Cardioverter-Defibrillator [4]

IV. EMI COUPLING MECHANISM

For Electromagnetic Interference to occur, certain essential elements that must be present and for this case study it includes:

EMI Source: Refrigerator

Coupling path: Leakage current from the refrigerator enters the victim's body through his hands and then into the cardiac region. It then enters the ICD pulse generator through the lead which causes it send an inappropriate shock to the heart

Victim: The Implantable Cardioverter-Defibrillator (ICD)

Interference coupling mode: Differential mode coupling (i.e. EMI signal enters ICD through the same route as intended (cardiac) signal [10])

Type of signal causing EMI: Analog low frequency signal (60Hz)

ICD frequency susceptibility range: 10-300Hz

EMI can interfere with ICD via conducted or radiated emissions from metal detectors, muscle stimulators, slot machines, radio frequency remote controls, electronic article surveillance systems, currents leaks from swimming pool, drilling machine, washing machines, showers and welding equipment, magnetic field from magnetic resonance image scanners, radio frequency interference from mobile phones, radio transmitter antennas, radar [6] etc.

When the ICD is exposed to very large EMI particularly from a nearby source and for a long period of time it could lead to serious damage to the ICD pulse generator, burns may occur at the point of contact between lead electrode and heart tissues, there could also be reprogramming of the pacing threshold [2][6].

An illustration of the electromagnetic interference coupling mechanism is depicted in figure 2(a&b) respectively.

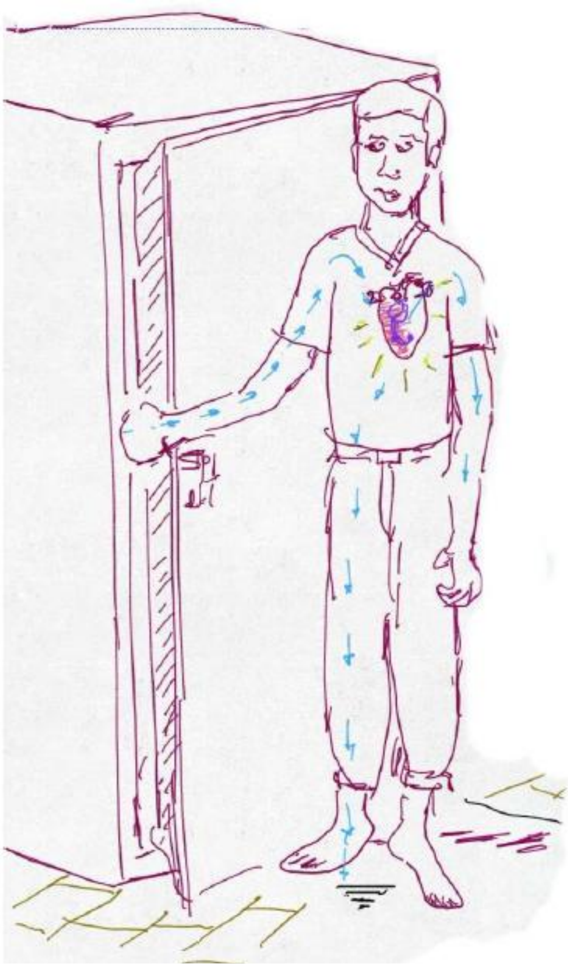

Figure 2(a)

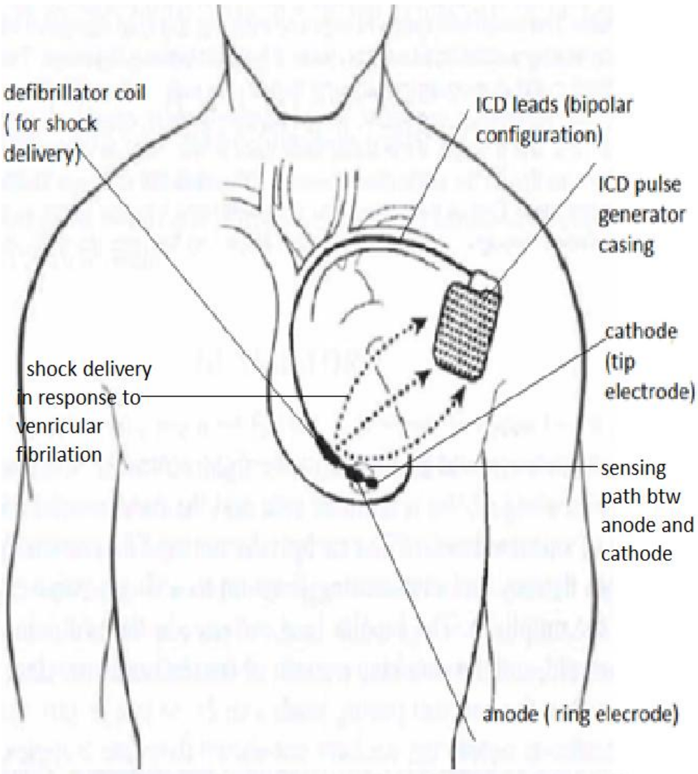

Figure 2(b) adapted from [7] modified

Figure 2(a) shows leakage current flowing through the body of a patient who has an ICD implanted in him from an unearthed refrigerator leading to improper shock delivery from his ICD. Figure 2(b) tells us what happens when the leakage current reached the cardiac region. The ICD lead electrodes sensed the interfering leakage current between its anode and the cathode, misinterprets it to be ventricular fibrillation (irregularly fast heat rhythm) and the defibrillation coil is seen sending a shock therapy to restore the heart back to its cardiac rhythm.

For EMI to occur in ICDs, it requires the following conditions [8]:

- The signal entering into the ICD sensing circuit must have a resemblance to that of the cardiac signals from the heart.
- The magnitude of the incoming signal (EMI) must be greater than the minimum sensing level (threshold) of the ICD sensing circuit.

The above mentioned conditions could arise as a result of the following:

1. Direct conduction currents
2. Alternating magnetic fields
3. High voltage electric fields.

The focus here is on how direct current (leakage current) conduction from an unearthed refrigerator entered into the patient's cardiac cavity and triggered a defibrillation shock therapy from his ICD. Usually electrical appliances are earthed in order to prevent current leakage to other parts of the appliance like the outer casing which could result in electric shock. The leakage could be as a result of using a two wire plug with the earth (ground) conductor absent to connect a device to the power supply and since current flows from live conductor and returns to supply through the neutral conductor, any imperfection in the return process (which always exists) will cause current to leak to its surrounding and energize other conductive parts. It might also be due to insulation breakdown in the live conductor which when it comes in contact with any metallic material (in our case the casing of the refrigerator) could result in current leakage to the metal casing. However in this case the cable connecting the refrigerator to power supply did not comprise of an earth conductor, hence the leakage current (which usually exists in unearthed appliances even though it might not be perceptible to human body since it is usually below 0.5mA can be captured by ICD because of its low sensitivity setting, 0.3mV) flowed through the body of the patient with the ICD implanted when he made contact with the casing of the refrigerator and easily found a route to the ground because his body simply served as a passage way for this leaked current to the earth. It is this current that flowed through the patient's body that went to his heart region and interfered with the ICD lead (electrode), mimicking the heart rhythm (because it is similarity in frequency to the heart cardiac signals) that the ICD sensed as rapid heartbeat (which corresponds to ventricular fibrillation) and triggered it to deliver a shock [9].

The main path through which EMI enters or couples into an ICD is by the induction of voltage between the anode and the cathode of the leads used in sensing cardiac rhythm. This is a result of the way in which the lead (bipolar configuration) is being designed. On the side of the lead that connects to the heart tissues the cathode extends a little further by about 2.4 cm than the anode also instead of using a true coaxial design for the lead a wound coaxial configuration was utilized such that the outer electrode (anode) was wound on the inner electrode (the cathode) with an insulating material separating both of them. The combination of this lead configuration and anode and cathode length difference makes it possible for voltage to be induced in between both terminals of the sensing lead by interfering signals. The bipolar lead design figure is shown below [5]:

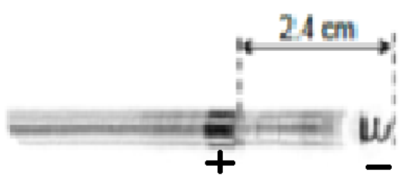

Figure 3 Bipolar ICD lead configuration [5] modified

V. EMI ESTIMATION CALCULATIONS

There are basically two principal ways in which electromagnetic interference via direct current conduction can occur. It can either be common mode interference or differential mode interference. However the mode of interference that took place in this case it is that of differential mode interference. In differential mode interference, the disturbing signals usually shows up at the input terminals, in-between the anode and the cathode and follows the same path through the circuit just like the intended signal would [10][11].

Hence to estimate the EMI (noise voltage) induced into the ICD pulse generator through the lead electrodes the ICD is represented with the equivalent circuit diagram as shown below:

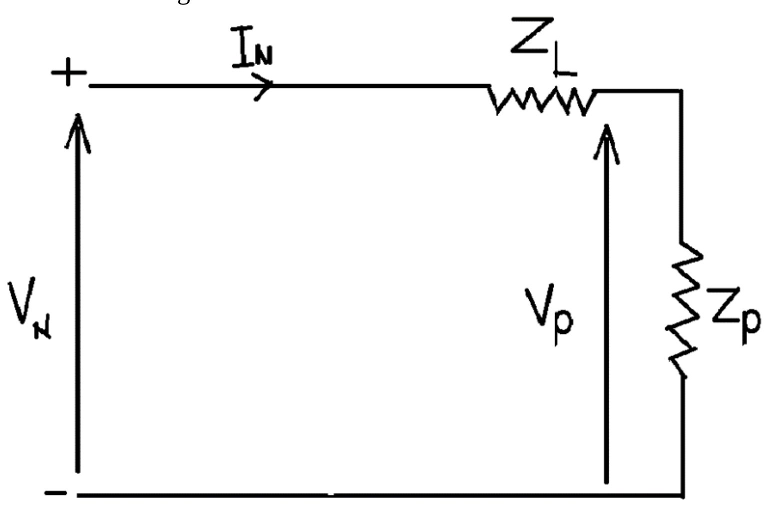

Figure 4 Equivalent Circuit diagram for ICD

Where:

Z_L is the lead impedance, Z_P is the equivalent resistance of the pulse generator circuit viewed from lead connector input, I_N is the interfering noise current and V_N is the induced noise voltage at the lead input.

$$V_N = I_N(Z_L + Z_N) \ldots\ldots\ldots\ldots\ldots\ldots\ldots (1)$$

The refrigerator operates at 220V, 60Hz and the maximum allowable leakage current for such appliance according to [9] is 0.25mA. The ICD is single chamber type affixed to the right ventricle and has a lead impedance of 361Ω, sensitivity threshold is 0.3mV, ventricular sensing range is 5.0mV – 1.0V, and ICD sensing circuit impedance range is 500 – 2000Ω, since it is a single chamber ICD, sensing circuit impedance should not exceed 1000Ω [12].

Substituting the relevant values into the formula above, we obtain the noise voltage induced at the input of the leads:

$I_N = 0.25mA, \qquad Z_L = 361\Omega, \qquad Z_P = 1000\Omega$

$V_N = I_N(Z_L + Z_P) = 0.25 \times 10^{-3}(361 + 1000) = 0.34V$

Hence, the magnitude of the voltage induced on the sensing circuit is from voltage divider rule:

$$V_P = \frac{Z_P}{(Z_L + Z_P)} V_N \dots\dots\dots\dots\dots\dots\dots(2)$$

$$V_P = \frac{1000}{1361} \times 0.34 = 0.25V$$

VI. CONCLUSION

The normal sensing range of the ICD is usually in the millivolts range hence a voltage of about 0.25V induced on the ICD sensing circuit will definitely be considered by the sensing circuit to mean a fast heart rhythm and hence trigger a delivery of an electric shock.

In order to prevent or reduce EMI entry into ICD circuits, [2] [6] proper shielding of the ICD pulse generator, use of filters differentiate cardiac signals from external or interfering signals and ensuring that patients that have ICD implant stay away from areas that may expose them to electromagnetic radiations are some of the recommended solutions to reduce the incidence of EMI interference on ICD.

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