The body electric: a review of literature on implantable cardioverter defibrillators

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The number of scientific research studies expounding the efficacy and effectiveness of the implantable cardioverter defibrillator (ICD) in the treatment of cardiac arrhythmias and the prevention of sudden cardiac death (SCD) is prolific. The results from clinical trials that have led to the acceptance of implanting the human heart with an ICD are not as convincing as medical science would have health-care consumers believe. There are many other scientific studies that deal with the hazards involved in heart implantation with an ICD. It is argued in this paper that the impact of heart implantation with an ICD is hazardous to a person's being in significant ways. Heart implantation with an ICD is hazardous to physiological wellbeing, to psychosocial wellbeing, and to quality-of-life wellbeing. It is also argued that although humanistic studies are beginning to filter through the maze of scientific studies, many gaps remain in ICD research. Scientific researchers agree that there remains much needed knowledge for cardiac patients, their family members, and for health professionals.

Keywords: Heart implantation, implantable cardioverter defibrillator, human hazards, health care, research

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Introduction

The implantable cardioverter defibrillator (ICD) has evolved from a bioelectronic treatment of last resort to the 'gold standard' therapy for people at risk of sudden cardiac death (SCD) and life-threatening arrhythmias (Glikson & Friedman 2001, Lee et al 2003). This bioelectronic strategy is highly regarded by science and medicine because of its innovative and effective ability, in most cases, to reliably revert cardiac arrhythmias by detecting and providing early defibrillation of the arrhythmic heart (Lee et al 2003).

In the Australian context, the first person received an ICD in 1988 (Mond & Whitlock 2001). In the last fifteen years the number of recipients of ICDs in Australia has grown significantly. In 1993 Australia and New Zealand joined a worldwide survey on cardiac pacing and ICD involvement that is collated every four years and submitted to the World Symposium on Cardiac Pacing and Electrophysiology (Mond & Whitlock 2001). Cardiologist Harry Mond (Mond 2003) reported that the last survey results collated for the year 2001 shows 72 ICDs implanted per million of population for Australia and New Zealand combined. This represents an increase of 125% in new ICD recipients by comparison to the previous survey for the year 1997 (Mond 2003). Furthermore, the number of institutions providing permanent ICD therapy for recipients has more than doubled in Australia. A continuance of this trend will account for predicted increases in ICD recipient numbers during the survey scheduled for the year 2005.

The USA is home base for the engineering and manufacturing companies, for example Medtronic and Guidant, of cardiac bio-electronic devices such as ICDs. The American Medicare program in June 2003 reportedly approved cover for double the number of patients who received ICDs in 2002 (Brown 2003). Moreover, this increase remains short of the anticipated number in excess of 300,000 people that cardiologists and bioelectronic companies believe will suffer SCD during 2003. Approved cover for increased heart implantation with ICDs was based on supposedly well-designed clinical trials that add to the body of research-based medicine (Brown 2003).

Looking from the known body of medical science-based research engages me, as a concerned cardiac nurse researcher, to argue that ICD research needs to be more closely examined. Much of

the research on ICDs draws attention to the risks associated with the function of the device within the human body. A critical evaluation of this research will encourage health care professionals working within cardiology to think outside the square of accepting the approval of the ICD as a life-saving technology. While this is true for some ICD recipients, there is a broader view of how the ICD impacts on the life of a recipient. Because of the prolific number of laboratory based studies and clinical trials on electronic pacing and defibrillation of the human heart, a review of recent and important ICD literature dealing with the impact of physiological hazards, the impact on psychosocial well being, and the impact on quality-of-life will hopefully disturb complacency amongst health professionals.

Heart implantation as body-hazard

The American Food and Drug Administration (FDA) defines complications in the use of ICDs as hazards (FDA 2000 p6):

> A hazard is a potential source of harm. Hazards arise in the use of medical devices due to the inherent risk of medical treatment, from device failure (or malfunctions), and from device use. Hazards resulting from medical devices impact patients, family members, and professional healthcare providers.

Heart implantation with an ICD has become the accepted therapy for patients with life-threatening arrhythmias, regardless of underlying morbidity. With the growing application of ICD therapy, concern about the long-term reliability of ICD leads is increasing (Gradaus Breithardt & Bocker 2003, Hauser et al 2003). Lead failures in ICDs as a body-hazard have prompted many researchers to study how to unravel the complexities of lead failures, an issue that continues to challenge modern bioelectronics (Bracke Meijer & Van Gelder 2003, Weretka et al 2003).

Lead malfunction as body-hazard

Ellenbogen et al (2003) systematically followed lead function in 74 patients with ICDs over a five year period. During the five year follow-up period 15 patients underwent lead extraction and replacement, two patients had ICD leads capped and new leads implanted, one patient required a new sensing lead, and one patient required a new ICD system. The body-hazards encountered by these patients included over-sensing of the ICD resulting in inappropriate and sustained shock therapy, under-sensing of arrhythmia, and infection. While identification of ICD lead malfunction is imperative for the continued well being of patients, Ellenbogen et al (2003) described the hazard as a scientific achilles heel. However, the authors neglect to extend this achilles heel metaphor to include the broader issue of patient wellbeing and the potential for loss of life as a result of the body-hazards identified with ICD lead malfunction.

The extraction of chronic indwelling ICD leads is a non-trivial event (Cooper et al 2003) because scar tissue forms after implantation and progresses over time, especially under high-energy shock therapy. Cooper reported retrospectively on 14 young and active ICD recipients who required extraction procedures to remove 21 malfunctioning leads. Lead adherence to vessels causing altered anatomy is a result of the large size of ICD leads. In these cases lead extraction is vital if accumulation of implanted hardware is to be avoided (Cooper et al 2003). The conclusions of Cooper's study indicate that these researchers are concerned about the accumulation of technological hardware retained within human anatomy. Yet the ultimate focus in Cooper's work redirects from the non-trivial issue of chronic indwelling ICD leads to the substantial cost to the bioelectronic industry. Thus, it is argued there is a conflict of interest in a study that interprets altered human anatomy in terms of industrial cost.

Lead malfunction has been presented as predominantly resulting from infection and twiddler's syndrome. Bayliss coined the term 'twiddler's syndrome' in relation to cardiac pacing leads in 1968 (Bayliss et al 1968 p1). Twiddler is a pejorative label that essentially blames the person for either consciously or unconsciously interfering with the implanted ICD (DeBuitleir & Canver 1996). Patient blaming could be used as a tool to decrease scientific responsibility in order to meet FDA guidelines on ICD hazards. More recently, Bracke Meijer & van Gelder (2002) included twiddler's syndrome in a literature review on ICD lead malfunction and extraction. These authors concluded that the follow-up period of two years, used in 11 studies, was inadequate due to lead malfunction increasing over time. Such a conclusion suggests that ICD leads within the human body may be a permanent body-hazard rather than interference by patients.

A contrasting attribution of hazard-cause was presented by Stephen Pavia, Director of Cardiac Pacing and Tachyarrhythmia Devices, The Cleveland Clinic Foundation, who chose to classify lead malfunction and other ICD hazards as complications arising from lack of meticulous implantation by physicians (Pavia & Wilkoff 2001). The authors of a meta-analysis of hazards associated with implantable cardiac arrhythmia devices described the risk of developing complications as "significant and enormous" (Pavia & Wilkoff 2001 p71). In addition, decisions on heart implantation needed to be based on sound guidelines which would evaluate the efficacy of implantation. This meta-analysis throws doubt on the efficacy of implantation with an ICD in the absence of re-evaluated reforms governing the enormous risks known to exist.

Infection as body-hazard

Over recent years the research on ICD hazards has inclined towards all-cause complications with heart implantation, even though post implantation infection contributes to significant mortality (Kuhlkamp et al 2003, Takahashi et al 2002, Wasson et al 2003). These authors contend that the lack of research into ICD infection post implantation is a limiting factor in prevention-research on nosocomial cardiac infections. Regardless of antibiotic treatment being part of standard protocol, Giamarellou (2002) ascertained that infection rates in ICDs would approximate pacemaker infection rates as high as 50%.

Authors of studies on implantation infection state that explantation of the ICD system is unavoidable if patient survival is to be achieved (Kron et al 2001, Mela et al 2001). In addition, risk of acute and chronic infection exists at multiple body sites from numerous hazards. The Kron (2001) study team treated 78% of 539 ICD recipients with preoperative antibiotics, with intraoperative antibiotics, and with postoperative antibiotics. Even