CLINICAL PREDICTORS FOR DEFIBRILLATION THRESHOLDS MEASURED INTRAOPERATIVELY DURING IMPLANTATION OF IMPLANTABLE-CARDIOVERTER DEFIBRILLATORS

A Thesis Submitted for Fulfillment of Medical Doctorate Requirements

By

Dr Ahmed Abdellatif Hussein, MD

Under the Supervision

Internal Supervisors from Cardiology Department

Cairo University School of Medicine

Prof Dr Medhat Elrefai, MD

Prof Dr Yasser Baghdaday, MD

Main External Supervisor from Cardiology Department

University of London School of Medicine

Prof. Dr John Camm, MD

Cairo university School of Medicine

University of London

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بسم الله الرحمن الرحيم

" ومَنْ أَحْيَاهَا فَكَأَنَّمَا أَحْيَا النَّاسَ جَمِيعًا "

سورة المائدة – آية ٣٢

"And if anyone saved a life, it would be as if he saved the life of all mankind "

Surat Al-Ma'idah- Verse 32

Other Supervisors and Contributors

Dr Jaswinder Gill, MD, FRCP

Consultant of Cardiology and Cardiac Electrophysiology, St George's Hospital London, UK

Prof Dr Ulrika M. Birgersdotter-Green, MD

Cardiology Division University of California San Diego

Dr Imran Arif, MD

Assistant Professor, University of Cincinnati, Ohio, US

Dr Esam Baryun, MD

Cardiac Electrophysiolgist St Mary's Hospital, Huntington, WV, US

Dr John Van Deren, MD, FACC

Cardiac Electrophysiolgist St Mary's Hospital, Huntington, WV, US

Dr Thomas Bartlett, MD, FACC

Cardiac Electrophysiolgist St Vincent Mercy Medical Center, Toledo, OH, US

Prof Dr Stephen Shorofsky, MD, PhD

Cardiac Electrophysiology Department, University of Maryland Medical Center, Baltimore, MD, US

Dr Magdi Saba, MD

Cardiac Electrophysiology Department, University of Maryland Medical Center, Baltimore, MD, US

Dr Timm Dickfeld, MD, PhD

Cardiac Electrophysiology Department, University of Maryland Medical Center, Baltimore, MD, US

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Dedication

This thesis is dedicated to Allah, the most gracious and the most merciful, to prophet Mohamed, peace be upon him, to my parents and my family.

Dr Ahmed Abdellatif Hussein

Abstract

Title: Clinical Predictors of Defibrillation Thresholds Measured Intraoperatively During Implantation of Implantable Cardioverter Defibrillators

Introduction Defibrillation Threshold Testing (DFT) testing is a lengthy, potentially painful, and a hazardous process. Little information is available concerning the identification of patients with high DFT who undergo ICD implantation with transvenous leads. Patients with predicted low DFTs may be eligible for abbreviated ICD testing but high-risk patients who require multiple shocks may require general anesthesia for patient comfort. Some suggested clinical characteristics that identify high DFT other than prior amiodarone use preoperatively. These include NYHA Class III, IV, low ejection fraction, no previous history of bypass surgery, and presenting with ventricular fibrillation. However, no specific recommendations have ever been suggested for DFT testing in patients having one or more high DFT predictors.

Aim of the Study: The aim of our study is to search for clinical predictors for defibrillation thresholds (DFTs) of implantable-cardioverter defibrillators (ICDs) in order to suggest the most suitable protocol for intraopertaive testing for DFTs to reduce episodes of VF induction and subsequently reducing the number of shocks in the procedure, if possible.

Methods: Our study group comprised 50 consecutive patients who received ICDs for primary or secondary prevention of sudden cardiac arrest who were recruited in the period between January 2006 and December 2008 in St Thomas Hospital, University of London, London, UK, University of Maryland Medical Center, University of California San Diego Hospital, and St Vincent Mercy Medical Center, Toledo, Ohio. The study group mean age was 59 ± 13 year. The 50 patients included 31male and 19 female. Thirty patients (60%) had hypertension, and 13 (26%) had diabetes Mellitus

Results: According to the measured DFT, the study group was subdivided into two groups; group I (n=42, 84%) with normal DFT defined as DFT <20J and group II (n=8, 16%) with high DFT defined as DFT ≥ 20J. The continuous clinical variables which were used for comparison between groups I

and II included: age, body Surface Area (BSA), Body Mass Index (BMI), QRS complex duration, Left Ventricular Ejection Fraction (LVEF), R wave amplitude, RV Pacing threshold and Pace/sense lead impedance. Despite the trend of increase in DFT with the increase of age, there was no significant correlation between the two variables. Comparison between the two groups in terms of sex with more males in the high DFT group compared to lower DFT group. Also, patients in group II, with higher DFT, were more likely to have the diagnosis of dilated cardiomyopathy, have lower LVEF and were likely to receive 3 or more shocks during DFT testing. Multivariate regression analysis was conducted for the study group utilizing DFT as the dependent variable. Both pacing threshold and LVEF were found to correlate with DFT. It was found that pacing threshold had a negative correlation with DFT.

Conclusion: Our study demonstrated that the clinical variables of male sex, presence of non-ischemic cardiomyopathy, and higher degree of myocardial dysfunction reflected by lower LVEF and higher pacing thresholds may predict the group of patients who have higher DFT.

Key Words: Defibrillation Threshold, Implantable Cardioverter Defibrillators, Non-ischemic Dilated cardiomyopathy, Left Ventricular Ejection Fraction (LVEF).

PART I: REVIEW OF LITERATURE

CHAPTER I

INTRODUCTION

A HISTORICAL PERSPECTIVE

Despite advances in emergency medical systems and in techniques of resuscitation, sudden death from cardiac arrest remains a major public health problem. Most persons who have an out-of-hospital cardiac arrest do not survive ***(Zipes and Wellens, 1998)***. Those who are resuscitated may have severe, long-term cognitive impairment and motor impairment due to delays before a stable rhythm could be restored. In the 1970s, motivated by the death of a colleague, Drs. Michel Mirowski and Morton Mower, and their colleagues, developed the concept of an implantable device that could automatically monitor and analyze cardiac rhythm and deliver defibrillating shocks when it detected ventricular fibrillation ***(Mirowski M et al, 1978)***. The ICD was inspired by the success of prompt external defibrillation in terminating VF complicating acute myocardial infarction in the coronary care unit and by the high recurrence rate in patients resuscitated from out-of-hospital cardiac arrest. After Mirowski and Mower developed the first implantable prototype and they began testing in the animal lab, specifically with dogs. The system performed well in the canine tests, and could even recycle and deliver a second shock if the initial shock failed. In 1975 Mirowski and Mower made a film in which the implanted device resuscitated a dog from an induced VF ***(Kenny T, 2006).***

After years of testing, in 1980 the first clinical implantation was performed in a young woman with recurrent ventricular fibrillation ***(Mirowski M et al,***

1980). Early ICDs were primitive by current standards. The generators were bulky, nonprogrammable, and lacked shock synchronization capability. A thoracotomy was required to position at least one defibrillation patch epicardially ***(vide infra)***. The next generation of devices allowed programming of the rate and duration for arrhythmia detection, as well as of the initial shock energy. Several different manufacturers joined the first in researching, developing, and marketing ICD systems, accelerating the technological progress ***(Pinski S and Chen P, 2002)***.In the early 1990s; the advent of transvenous-subcutaneous defibrillation leads obviated the need for thoracotomy ***(Saksena S and Parsonnet V, 1988)***. The adoption of biphasic shock waveforms improved defibrillation efficiency, and the addition of extensive telemetric and diagnostic capabilities refined patient follow-up. Current ICDs deliver not only high-energy defibrillation shocks, but also low-energy shocks, antitachycardia pacing for VT, and pacing for bradyarrhythmias. They are less than 40 mL in size and are implanted transvenously with techniques similar to those used for implantation of standard pacemakers ***(Pinski S and Chen P, 2002)***.

More recently, randomized controlled trials have clarified the indications for ICD therapy. Subsequently, the implantable cardioverter-defibrillator evolved from a therapy of last resort for patients with recurrent cardiac arrest to a management standard for use in primary prevention and secondary prevention in patients with coronary heart disease ***(DiMarco J, 2006)***.