Modulated AC Current Defibrillation—A New, Equally Effective Method to DC Defibrillation

Shimon Rosenheck¹, Shraga Gorni⁴, Iony Katz¹, Asaf Rabin², Mendel Mandelbaum³, A. Teddy Weiss²

¹ Heart Institute, Arrhythmia Therapy Center, ² Internal Medicine, Cardiology Unit, Hadassah Hebrew University Medical Center, ³ Computer Authority, ⁴ Physics, Hebrew University, Jerusalem, Israel

Background. Defibrillation is the only clinically effective treatment of ventricular fibrillation. Early defibrillation improves the outcome and increases the chance of survival with full recovery. Immediate availability of a home-based defibrillator using mains-derived AC current will drastically improve outcome.

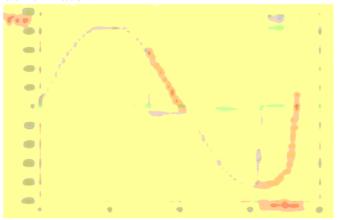
Aim. To develop a defibrillator based on modulated AC current, resembling biphasic configuration and compare its efficacy, in a pig model to a standard DC defibrillator.

Methods: A Computer controlled, modulated AC defibrillation system was developed using a High Voltage Switch and a High Voltage Transformer. The efficacy and safety was evaluated in 5 pigs (30-40 Kg), under general anesthesia with ketamin and isoflouran. A single quadripolar-pacing catheter was inserted percutaneously, VF was induced with rapid ventricular burst pacing and stable VF was defibrillated after 15 seconds.

DFT was determined in each animal with AC and standard DC shock using step-down protocol.

Results: The DFT with AC was 70.83±24.81 Joules and with DC was 65.83±12.41 Joules (p=0.49, Fisher Exact Test). The shock configuration is shown in the figure. No damage was observed after AC or DC defibrillation.

Conclusions: Modulated AC defibrillation is safe and effective as the commercially available DC defibrillation. The defibrillator is built from inexpensive High Voltage Transformer, without need for capacitor, batteries or routine maintenance, delivers repeated shock without any delay and provide pacing as well. It may be an ideal platform for automatic home defibrillator.



Excellent Long-Term Reproducibility of the Electrophysiologic Efficacy of Quinidine in Patients with Idiopathic Ventricular Fibrillation or Brugada Syndrome.

Bernard Belhassen, Aharon Glick, Sami Viskin

Cardiology, Electrophysiology, Tel-Aviv Sourasky Medical Center, Tel Aviv, Israel

Background. For almost 3 decades, our group has shown the extraordinary efficacy of quinidine in preventing the re-induction of sustained ventricular tachyarrhythmias during electrophysiologic study (EPS) in patients with idiopathic VF or Brugada syndrome. However, there are no data on the long-term reproducibility of this efficacy.

Methods. From 1979 to 2007, 76 patients with no obvious heart disease and inducible sustained VF at baseline underwent EPS on quinidine sulfate (Quiniduran*). In 71 (93.4%) of these patients, quinidine prevented re-induction of sustained ventricular tachyarrhythmias. Nine of these 71 patients underwent another EPS after 1.7 to 23.6 (9.8+6.8) years of quinidine therapy (> 5 years in 8/9 patients). In 1 of 9 patients, this EPS was performed on hydrochloride quinidine (Serecor*). In 7 of the 8 patients who underwent initial and repeat EPS on the same quinidine salt, identical drug dosages were tested. Two patients underwent two late EPS on quinidine; one pt 5 years and 8 years and the other 5 years and 8 years after the initial drug study. The goal of repeat EPS on quinidine was to ensure persistent long-term drug efficacy (n=6 patients) or to elucidate the reason of syncopal episodes during therapy (n=3 patients). The protocol of programmed ventricular stimulation significantly evolved over the years as it became more aggressive (more pacing sites and/or more ventricular extrastimuli).

Results. There were 7 males and 2 females, aged 21-72 (40+16.5) years at initial EPS. Eight patients had cardiac arrest with documented VF and 1 had recurrent syncope of unknown cause. Five patients had idiopathic VF and 4 had Brugada syndrome. All 9 patients well tolerated the medication during long-term therapy and had no recurrent documented arrhythmic events during follow-up. No sustained ventricular tachyarrhythmias could be induced in any patient during repeat late EPS. In 3 patients, more aggressive extrastimulation (triple) could be tested at repeat EPS while only double extrastimulation was applied at the initial EPS.

Conclusion. Our results showed an excellent long-term reproducibility of the EP efficacy of quinidine in patients with idiopathic VF or Brugada syndrome and inducible VF. This suggests that EP-guided quinidine therapy represents a valuable long-term alternative to ICD therapy for these unique types of malignant idiopathic ventricular tachyarrhythmias.

Survival of Defibrillators the "Real World"

Michael Geist, Daniel Tarchitzky, Zaev Halfin, Michael Kriwisky, Larisa Rosenshtein, Tal Sela, Leonid Rosenthal, Yoseph Rozenman

Heart Institute, Wolfson Medical Center, Holon, Israel

Background: Defibrillator (ICD) usage is expanding rapidly, especially the use of ICD's for primary prevention. The use of this advanced and costly technology is based on assumptions of cost versus survival benefit. Most of the analysis estimate 5-7 year battery life as a base for calculations of cost benefit. The purpose of this study was to evaluate the actual survival of implanted ICD's.

Methods: The study group included 298 patients who underwent ICD implantation between 1993 and November 2007 at our hospital. We evaluated all devices replaced and also looked at patients surviving for 5 years (60 month) after implant.

Results: There were 256 men (86 %) and 42 women, mean follow up 41±26 month (6 were excluded). 203 were implanted for secondary indications (68%). 69 Devices were replaced in 61 patients 1-3 devices replaced per patient. In patients who underwent replacement the average time to replacement was 53±13 month (13-97 month). Most of the devices were replaced due to battery depletion, need for upgrade or replacement at time of procedure due to lead failure. No device was replaced due to company alert (as the only indication). Altogether 81 patients had a follow-up of more than 60 months, 31 (38%) of them without replacement.

Conclusions: The longevity of ICD's may not be as expected. The rate of ICD replacement within 5 years is higher than assumed (in the cost-effective calculations) even with a very conservative policy regarding replacement due to company alerts. Cost benefit estimations should probably be based on actual clinical data. Evaluations relying mainly on expected device longevity estimations may be inaccurate.

Is There Really No Role for EPS Testing in Risk-Stratification of the ICD-Eligible Patient Population?

<u>Avraham Wagshal</u>¹, Guy Amit¹, Amos Katz^{1,2}, Reuven Ilia¹, Raphael Rosso³, Sami Viskin³, Bernard Belhassen³, Otto Costantini⁴, David Rosenbaum⁴

The role of EPS testing in risk-stratification of CAD patients with decreased LVEF has been questioned based on poor predictability of a negative EPS in MUSTT and MADIT-II sub-However "positive EPS" in these studies excluded ventricular flutter (Vfl) or polymorphic VT (PMVT) with 3 extra-stimuli, which may be inappropriate. The recently completed Alternans (MTWA) Before Cardioverter-Defibrillator (ABCD) study included mandatory EPS -- thus providing a unique opportunity to re-assess the appropriate definition of a "positive EPS" not only based on events but also as a marker of a MTWA+ (and thus high-risk) patient. We compared on a patient-to-patient basis EPS and MTWA in the 46 patients enrolled in the 2 Israeli centers of the ABCD study. Of the 17 MTWA+ patients, 7 patients had "only" inducible Vfl or PMVT with 3 extra-stimuli ("pseudo-negative" EPS); 9 had a traditionally-defined positive EPS; and only 1 EPS was completely negative; whereas 8 of the 25 MTWA- patients had completely negative EPS. All 10 EPS- patients were free of arrhythmic events during follow-up, whereas 4 of the 7 patients with "pseudo-negative" EPS and MTWA+ had arrhythmic events. In conclusion, the definition of a +EPS test for riskstratification needs to be broadened to include inducible PMVT or Vfl with 3 extra-stimuli, the negative predictive value of a completely negative EPS warrants a second look as a marker of a low risk patient, and most importantly no patient should be denied an ICD based on a "pseudo-negative" EPS of Vfl or PMVT with 3 extra-stimuli!

¹ Cardiovascular Disease, Soroka Medical Center, Beer Sheva, ² Cardiovascular Disease, Barzilai Medical Center, Ashkelon, ³ Cardiovascular Disease, Tel Aviv Medical Center, Tel Aviv, Israel, ⁴ Cardiovascular Disease, Metro Health Medical Center, Cleveland, USA

Outcome after Implantation of ICD in Patients with Brugada Syndrome: a Multicenter Israeli Study (ISRABRU)

Rafael Rosso¹, Aharon Glick¹, Michael Glikson², Abraham Wagshal³, Moshe Swissa⁴, Shimon Rosenhek⁵, Israel Shetboun⁶, Amos Katz⁷, Therese Fucks⁸, Munther Boulos⁹, Michael Geist¹⁰, Boris Strasberg¹¹, Bernard Belhassen¹

¹ Tel-Aviv Sourasky Medical Center, Tel-Aviv, ² Sheba Medical Center, Tel-Hashomer, ³ Soroka Medical Center, Beer-Sheva, ⁴ Kaplan Hospital, Rehovot, ⁵ Hadassa Hospital, Jerusalem, ⁶ Meir Hospital, Kfar Saba, ⁷ Barzilai Hospital, Ashkelon, ⁸ Assaf Harofe, Zrifin, ⁹ Rambam Medical Center, Petah Tikva, ¹⁰ Wolfson Hospital, Haifa, ¹¹ Rabin Medical Center, Holon, Israel

Background: Many electrophysiologists recommend the implantation of a cardioverter-defibrillator (ICD) in patients with Brugada syndrome who are cardiac arrest survivors or presumed to be at high-risk of sudden death (patients with syncope, familial history of sudden cardiac death or inducible VF at EPS). This multicenter study analyzes the outcome of the patients implanted in Israel.

Methods and results: All patients with Brugada syndrome who underwent ICD implantation in 11 Israeli centers between 1994 and 2007 were analyzed. There were 58 patients (52 males, 89.6%) with a mean age of 43.4 years. The indications for ICD implantation were a history of sudden cardiac arrest (10 patients, 17.2%), syncope [30 patients (51.7%) including 19 of 21 (90.4%) with inducible VF], inducible VF in asymptomatic patients (12 patients, 20.6%), history of familial sudden cardiac death (3 patients, 0.5%) and various reasons in 3 patients (0.5%). VF was induced in 4 of 5 (80%) patients who presented with cardiac arrest (n=10) and in 35 of 38 (92.1%) patients without documented cardiac arrest (n=48). During a follow up of 1-156 months (mean 42 + 35) months no patient died, 4 patients (7%) had an appropriate device therapy that was limited to those patients with a previous history of cardiac arrest. Indeed, the appropriate device therapy rate in these patients was 40%. Conversely, none of the other "high-risk" patients implanted with an ICD had an appropriate device therapy during a mean 36 + 30 months follow up period. The overall complication rate was 31.5% during follow-up, including an inappropriate shock in 16 (27.1%) patients caused by lead failure/ dislodgment (5 patients), T wave oversensing (2 patients), device failure (1 patient), sinus tachycardia (4 patients) and supraventricular tachycardia (4 patients). One patient suffered a pneumothorax and another brachial plexus injury during the implant procedure. One patient suffered a late (2 months) perforation of the right ventricle by the implanted lead that manifested with chest pain and hypotension without signs of cardiac tamponade. Eleven (18.9%) patients required a re-intervention either for infection (1 patient) or lead problems (10 patients). Eight patients (13.7%) required psychiatric assistance during follow-up due to complications related to the ICD (mostly inappropriate shocks in 7 patients). Conclusions: In this Israeli patient population with the Brugada syndrome implanted with an ICD and followed during a mean 42-month period: 1) Appropriate device therapy was limited to cardiac arrest survivors while none of the other "high-risk" patients including those with a positive electrophysiologic study suffered an arrhythmic event; 2) The overall complication rate was particularly high, especially inappropriate device therapy, need for re-intervention and severe psychiatric disorders.

What Makes Patients with Implantable Cardioverter Defibrillator (ICD) Miserable? A Prospective Quality of Life Assessment

Nahum Freedberg, <u>Gennady Shafir</u>, Raya Tamaev, dante Antonelli, Alexander Feldman, Yardena Drori, Yoav Turgeman

Cardiology Department, HaEmek Medical Center, Afula, Israel

The quality of life (QOL) in patients (pts) with Implantable Cardioverter Defibrillator (ICD) may be compromised by many facets of their illness and therapy

Aim of the study: To assess impact of socio-economical and clinical characteristics of ICD pts on their QOL and on their attitude toward arrhythmia symptoms and ICD therapy.

Methods: A prospective study on ICD pts, hospitalized in the Ha'Emek Cardiology Department. Demographic and clinical data was collected. A structured questioner on educational, social-economic background, experience with ICD therapy, attitude toward arrhythmia recurrences, death, and disability was administered by ICCU nurses to the pts. QOL was assessed by the Minnesota living with heart failure questioner (A high score signifies a low QOL).

Results: Thirty five pts, (5 female), mean age 68+/-10 (53-89). Time from the first ICD implantation was 2-12 years. Six pts were Israeli-Arab, 29 Israeli-Jews (5 new immigrant). Only 7 pts (21%) were employed. Seventeen pts (48%) received symptomatic ICD shocks. Eight pts (23%) had syncopal ventricular arrhythmia documented by the ICD. There was no significant difference in clinical baseline characteristics between pts who had ICD therapy or syncope and those who did not. Twenty one pts (60%) expressed fear of receiving ICD shock in public place and 14 pts (40%) expressed fear of dying from cardiac arrest. Nevertheless, 26 pts (74%) would recommend ICD to others. The mean QOL score was 21.2+/-16.7. The QOL in man was 19+/-16 versus 34+/-14 in women (p=0.063). QOL in pts who had ICD shock was 26+/-18 versus 16+/-14 (p=0.069). In pts with syncopal arrhythmia QOL was 33+/-19 versus 17+/-14 (p<0.015). No other clinical or socio-economical factor predicted QOL score.

Conclusion: In pts with ICD, the QOL is significantly lower following syncopal arrhythmia. Patient who had ICD shock and women tend to have a lower QOL.