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Annual Cardiologist Meeting: TED - Time and lifesaving external defibrillator for home-use.

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Sudden cardiac death(SCD)-caused by ventricular fibrillation(VF) or stand still- occurs in about 350.000 persons every year in US alone(1000/day!) & in about 3 million worldwide & the majority of them occur in the low-risk group at relatively younger age, in their best years of life, usually witnessed -at home or office. Since survival drops by 10% for every minute delay-only few (5%) - survive: no ambulance in the world will be quick enough to save them or leave them without neurological damage that will put them in a nursing home, at a huge cost for family or society. Since Sudden cardiac death may occur in apparently healthy people, without any preceding symptoms-all people, especially above age 40 or at risk for myocardial infarction-are at risk. Therefore every home & office should have a defibrillator device, exactly like they have fire-extinguishers, but isn't our life more precious than our home? Of course the initial group in urgent need for such a device is the high risk group for sudden death-those with reduced heart function & heart failure after heart attacks- part of them will get automatic implantable defibrillators(AICDs)-at a cost of approximately 20.000$ each, but those uninsured or not eligible due to co morbidities or older age or during the first month after acute MI or CABG & the big rest of the world (developing countries)-no economy there can afford AICD implantation to all who need it-& it will be recommended by physicians to have at least a low-cost automatic external defibrillator(AED)- at home. AICDs-need surgical implantation & may deliver inappropriate shock thus are risky & related to grave psychological burden on the patients in whom they are implanted, with end-of life dilemmas. They need constant follow-up in dedicated centers & surgical battery replacement. The existing AEDs, that are now distributed in public places such as in airports, airplanes & schools - although approved by FDA for home use several years ago, since they are safe,- are not a good solution for home-use, due to their high cost (about1000-2000$ each)for battery & capacitor not needed in TED- & their big maintenance problem-such a device that lies for years in the office or home & not in use-may not work in the instance you urgently need it due to battery or capacitor failure. They do not have pacing capabilities due to their limited energy source. Since it receives its energy from the mains, it will always be operational, as long as it will be plugged in via a running cord to the mains outlet & its cost-affordable to every household-about 300$ only-& even less if mass production(as expected) will be used. In addition since there is no need to charge the capacitor it may deliver immediately repeated shocks in case of failed shocks, at a higher energy & to externally pace the heart in case bradycardia or stand still caused SCD or it occurred after the electric shock. It may also use rapid pacing to stop ventricular tachycardia instead of shock-all these features cannot be delivered by existing AEDs. New pulse sensor technology-like Apple watch, or Cardiac sense will allow detection of Sudden cardiac death even if it occurs during sleep or the person lives alone & will alert nearby people to enter the room & use TED to save him. Our device, which uses a new, breakthrough technology-protected by patents, will drastically reduce the huge number of sudden cardiac deaths-as well as may be reimbursed by insurance companies or HMOs. In order to prove the safety & feasibility of TED -we performed 2 animal experiments: in the first-we used a pig model; defibrillation thresholds were compared to that of a standard defibrillator using a step-down protocol & found to be identical. The paper describing this new technology was published in Europace journal 2010 & received the Neufeld prize from the Israel Heart Society.

In order to prove the safety & feasibility of TED, we performed 2 animal experiments; in the first, we used 5 small pigs (30–40 kg bodyweight) that were anesthetized with ketamine & isoflurane. A single quadripolar pacing catheter was inserted percutaneously through one of the femoral veins or jugular veins. VF was induced with rapid ventricular burst pacing or T wave shock & defibrillation of stable VF after 15s was applied by TED or by a standard AED. Defibrillation thresholds were compared using a step-down protocol & found to be similar. The second experiment used a rat model: six rats, with a mean weight of 492 g, underwent a mid-LAD coronary surgical closure at 3 months age & 3 months later VF was induced & TED defibrillation was successfully achieved in all, repeatedly. External pacing was successfully achieved using TED in all, at a heartrate above their sinus rate, for an unlimited time before & after defibrillation.

We conclude that modified alternating shock delivered by our device. TED- is feasible & as effective as that of the standard biphasic direct current defibrillator -thus will apply for 510k approval. Repeated higher energy shocks are quickly available; external pacing is feasible & durable due to unlimited energy. We suggest this type of defibrillation shock to be implemented in Automatic External Home Defibrillators. This low-cost modern technology should be used to treat sudden cardiac arrest occurring at home/office & implemented in AEDs to solve a huge unmet need, for an unlimited market.

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