

Automatic External Defibrillator and Pacemaker-for Home/office-to Prevent Sudden Cardiac Death

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Sudden cardiac death (SCD)-caused by ventricular fibrillation (VF) or standstill- occurs in about 350.000 persons every year in US, and in Europe alone (1000/day!) and in Israel-30/day and 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 and society. Since SCD may occur in apparently healthy people, without any preceding symptoms-it cannot be predicted. Thus-all people, especially above age 40, or with CHF, or with DM or at risk for myocardial infarction-are at risk.

Therefore-ideally every home or office should have a defibrillator device, exactly like they have fire-extinguishers. Of course, the first group in urgent need for such a device is the high risk group for sudden death-those with reduced heart function and heart failure after heart attacks or cardiomyopathy- 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 and the big rest of the world (developing countries)-no economy there can afford AICD implantation to all who need it. AICDs-need surgical implantation and may deliver inappropriate shock-thus are risky and related to psychological burden implanted, with end-of-life dilemmas. Most of them-are not even used and primary prevention may not be needed! They need constant follow-up in dedicated centers and surgical battery replacement. TED will not reduce AICDS implantation: all those saved by it-will get them appropriately as secondary prevention.

TED will not reduce existing AEDs, that are now distributed in public places -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 (about 1000\$) for battery and capacitor not needed in TED- and their big maintenance problem-such a device that lies there-may not work due to battery or capacitor failure. They do not have pacing capabilities due to their limited energy source.

Our TED device, modifies by computer the sinusoidal alternating electrical current from the mains to a biphasic defibrillatory wave, similar to that of a standard AED. Since it derives 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 and it will cost-about 300\$ only-and 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-(see the success of double defibrillatory shock), and to externally pace the heart in case bradycardia or standstill caused SCD or it occurred after the electric shock. New pulse sensor technology-like Apple watch-will allow detection of SCD even if it occurs during sleep or the person lives alone and will alert nearby people to enter the room and use TED to save him in time. Our device, which uses a new, breakthrough technology(1)-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 and 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 and found to be identical. The paper describing this new technology was published by us in Europace journal 2009; 11:239-234 and received the Neufeld prize from the Israel Heart Society. The second experiment-done recently, used a rat model: six rats, underwent a mid-LAD coronary surgical closure at 3 months age and 3 months later VF was induced and TED defibrillation was successfully achieved in all, repeatedly similarly to AED use. External pacing was successfully achieved using TED in all, at a heart rate above their sinus rate, for an unlimited time before and after defibrillation. A new patent -based on defibrillation and pacing was granted a few years ago.

We conclude that modified alternating shock delivered by our device-TED-is similar and as effective as that of the standard biphasic direct current defibrillator (AED)-thus will apply for 510k approval. This low-cost new technology should be used to prevent SCD occurring at home/office and is the only strategy to save thousands every day! We still need a few million \$ for clinical trials-(no reason to fail), get regulatory approval and then mass production to an unlimited market... see www.aedinhome



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