HeartSine Technical Concept Paper

The use of Biphasic defibrillators to reduce the amount of energy delivered transthoracically to an upper limit of 200 Joules

This Technical Concept Paper will review the advantages of biphasic waveforms of 200 joules or less vs those operating at 360 joules. Considerations include shock efficacy and minimizing damage to the myocardium.

The current 2005 AHA guidelines have recommended the use of higher energies in defibrillators which use monophasic waveforms. However, most modern commercial Automated External Defibrillators (AEDs) use biphasic waveforms [1, 8, 11]. Although there is no consensus on how much energy is required to convert a patient to normal sinus rhythm on the current guidelines they do suggest much lower energy thresholds for both truncated and rectilinear biphasic waveforms i.e. between 150-200 Joules [1]. Most companies quote an optimum or average energy delivered in order to achieve around a 90% success rate of 200 Joules [7-11]. This figure is even quoted by those who manufacture AEDs which have the facility to deliver energies of up to 360 Joules biphasic [16].

It is the aim of both industry and academia to strike a balance between increasing shock success whilst minimizing damage to the myocardium post defibrillation and therefore myocardial dysfunction as reported by Jones et al in 1984 [2-3]. There is much literature to confirm the fact that 360 Joules causing significant damage to the myocardium due to the excessive voltages and currents applied to the patient [2, 4, 5-6]. The development of biphasic waveforms was driven by the internal defibrillation market as the components currently used in the original Lown waveform could not be easily applied to implant circuitry and also the requirement for lower energies to minimize post shock cardiac dysfunction and myocardial damage [5-6, 17]. The biphasic waveform at 200 joules is generally accepted to be comparable in terms of overall success rate to the previously used monophasic waveform which uses energies of up to 360 Joules [7-11, 15].

Prior to the development of the biphasic waveforms several studies were completed with the aim of reducing delivered energies. In fact in 1975 Pantridge and colleagues published a paper entitled Electrical Requirements for VF following the group's successful deployment of the first completely portable defibrillator. The study showed that the delivery of a single low energy monophasic shock succeeded in removing VF in 73 out of 82 episodes. The energy levels used in this study were between approximately 150 and 165 Joules [13-14]. The group then demonstrated in a later study that 200 Joule shocks were successful in 95% of cases following monophasic defibrillation [18].

The development of biphasic waveforms enabled the production of not only implantable defibrillators but also the development of smaller, lightweight Semi-automated and automated defibrillators which could deliver shocks at much lower energies when compared with their DC predecessors. The development of these systems facilitated the implementation of public access defibrillation programmes worldwide to tackle the issue of early access to the patient [17].

The HeartSine SCOPE® waveform was developed during a detailed study involving collaboration between the Northern Ireland Bioengineering Centre and the Regional Medical Cardiology Centre at the Royal Victoria Hospital in Belfast. The SCOPE was the next logical step in the development of a more efficacious and miniaturized defibrillation system building on the numerous ground breaking studies completed at the Royal Victoria Hospital over the last 40 years [13-15, 18].

The investigation involved a number of comparative phases. Each of the different biphasic waveforms and the commercially available Philips HeartStream® waveform were tested against the proposed SCOPE waveform which were all in turn compared to the Lown waveform (gold standard monophasic) for efficacy. The SCOPE used both a significantly lower peak voltage and current than the original Lown waveform to produce the same success rates. The SCOPE waveform also produced a significantly lower DFT (defibrillation threshold) than the

Codemaster® Defibrillator with an overall energy reduction factor of 41% and an average DFT of 65 Joules compared to 105 Joules using the Codemaster ®. A prospective clinical study then followed which again showed that the SCOPE was capable of achieving greater success rates at lower energies with an average required energy of 125 Joules compared to 150 Joules using the Codemaster ® with success rates of 66.7% compared to 39% for VF and 100% compared to 62.5% for VT with the HeartSine Samaritan® and Codemaster ® respectively [15].

The above results clearly illustrate the SCOPE® biphasic waveform is superior to the Philips Codemaster ® and the original Lown waveform devices. The study also emphasizes that the improved success rates can be achieved at much lower energy ranges than previously used in the monophasic and some biphasic defibrillators of up to 360 Joules [15]. Energies of 360 Joules are rarely used today as a result of the wealth of information available to confirm that energy ranges of between 120 and 200 Joules are more than adequate. Indeed as previously mentioned the AHA recommends the use of biphasic defibrillators at lower energies (less than or equal to 200 Joules) than their monophasic equivalent. Therefore it can be concluded that the current energy ranges used in the PAD are more than adequate due to the superior performance of the HeartSine SCOPE® waveform [1].

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