Evaluation of a Novel Defibrillation Unit with Dual-Vector, Quadriphasic Waveform Capabilities
-Towards a Miniaturized Defibrillator-

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Background

Automated external defibrillators (AEDs) can provide life-saving therapies to treat ventricular fibrillation. We developed a prototype unit (Figure 1, 2) that can deliver a unique quadriphasic shock produced by four independent capacitative sources that is delivered through two shock vectors, with the rationale of providing more robust shock pathways during emergent defibrillation. We describe the initial testing and feasibility of this unique defibrillation unit, features of which may enable downsizing of current defibrillator devices.

Methods

We tested our defibrillation unit in 2 canines (weight; 23.0kg and 37.2kg) and 2 swine (weight; 52.0kg and 51.6kg) under general anesthesia. Experimental defibrillation thresholds (DFT) were obtained by delivery of a quadriphasic waveform shock pulse via a dual-vector pathway with four defibrillation pads placed in the right lateral (vector 1) and left lateral (vector 2) positions (Figure 3). The prototype defibrillator unit has the ability to utilize up to 4 independent capacitative sources, each rated at 55 microfarads. The pulse widths of the quadriphasic waveform were set to 3ms, 2ms, 3ms and 2ms, respectively (Figure 4). The first two phases were passed through vector 1 and the second two phases were passed through vector 2. DFTs were measured and compared with those of a commercially available biphasic defibrillator (Zoll M series) tested in vector 1 and 2. Shocks were delivered after 10 seconds of stable ventricular fibrillation and the output characteristics and shock outcome recorded. Each defibrillation series used a step-down to failure protocol to define the defibrillation threshold.

Figure 1

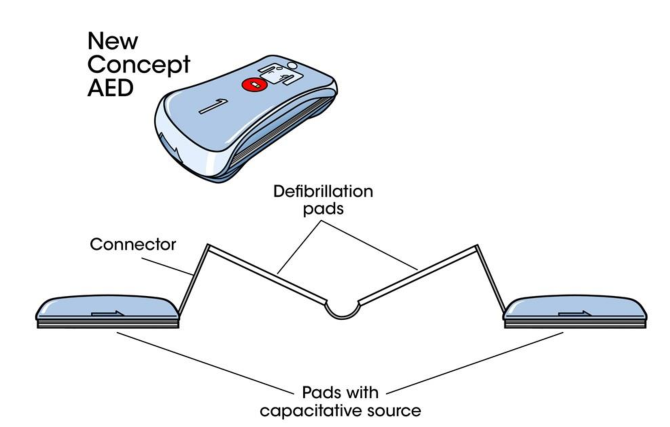


Image of the new concept AED. The two clamshells (with electronics), roughly the size of two smartphones, were connected by additional pads that accordianed out with intervening pads.

Figure 2

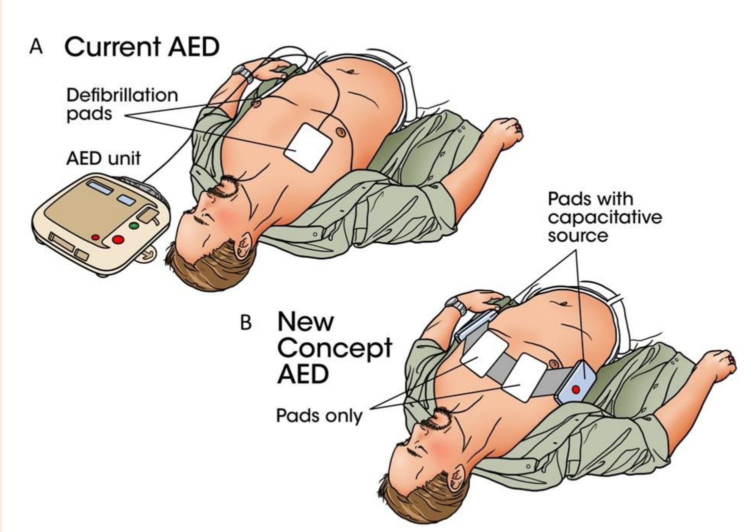
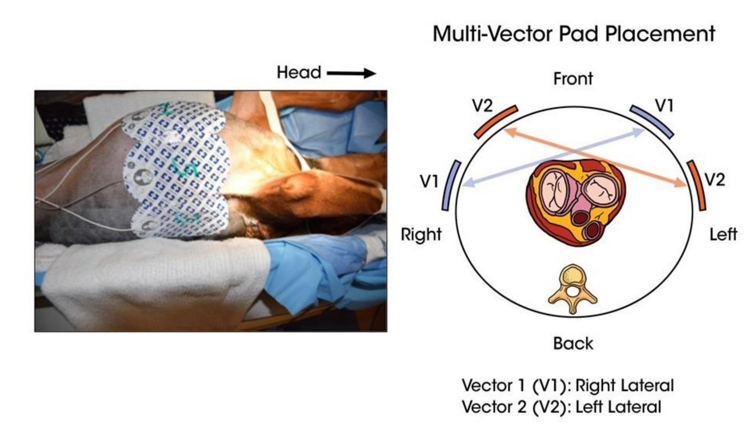


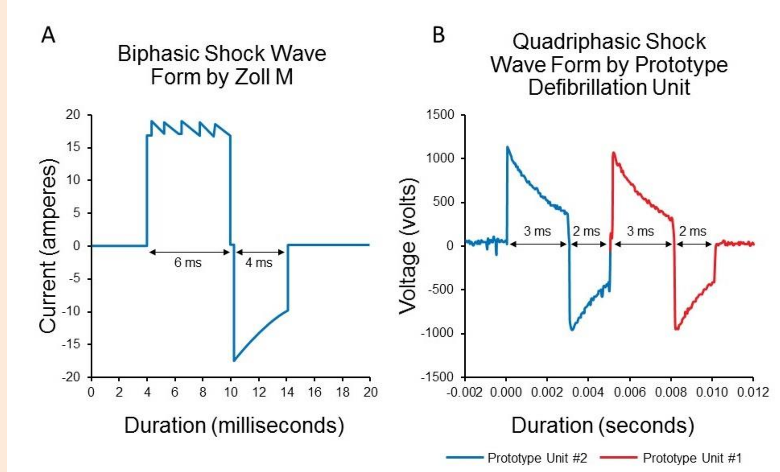
Image of the new concept AED. Unlike the current AED system which delivers a shock using two electrode pads (Figure 1A), the use of two small individual capacitative sources that can be physically distributed in a system with four pads placed across the chest wall permits delivery of a dual-vector shock via a potentially smaller, more compact unit (Figure 2B).

Figure 3



Defibrillation pads placement. Two sets of pads were placed; vector 1 (right lateral) and vector 2 (left lateral). V1: vector 1, V2: vector 2.

Figure 4



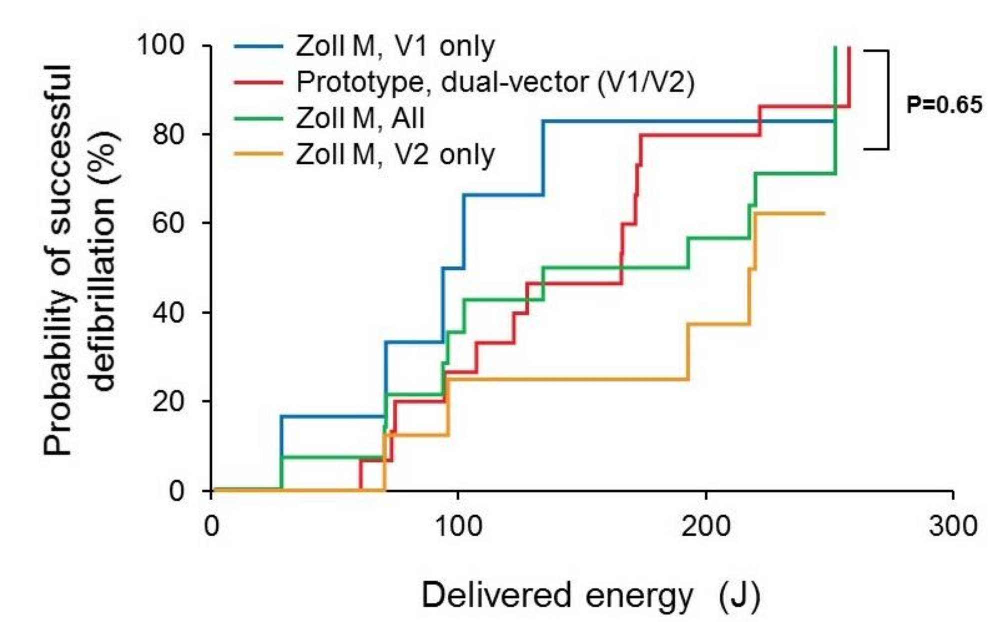
Shock wave form of Zoll M unit (Figure 4A) and prototype unit (Figure 4B). Figure 4A is a note from a technical manual of Zoll M series. The ZOLL M series produces a biphasic rectilinear waveform which consists of a 6 millisecond (ms) first phase followed by a 4 ms second phase. Our prototype unit produces a quadriphasic pulse consisting of 3 ms, 2 ms, 3 ms and 2 ms width pulses; each pulse begins with same voltage level as the previous pulse (Figure 4B).

Table 1

Measured Defibrillation Threshold by Zoll M Series and Prototype Units

	Canine #1		Canine #2		Swine #1		Swine #2	
	Vector	DFT (Joules)	Vector	DFT (Joules)	Vector	DFT (Joules)	Vector	DFT (Joules)
Zoll M Series	1	101.1	1	69.4	1	133.2	1	251.8
(6/4ms, biphsic)	1	92.5	1	27.0				
Average: vector 1		**96.8**		**48.2**		**133.2**		**251.8**
	2	94.7	2	192.1	2	Fail at Max	2	219.0
	2	68.7	2	Fail at Max	2	216.8		
			2	Fail at Max				
Average: vector 2		**81.7**		**192.1<**		**216.8<**		**219.0**
Experimental Units	1 & 2	72.0	1 & 2	121.4	1 & 2	221.3	1 & 2	Fail at Max
(3/2/3/2ms, quadriphasic)	1 & 2	59.2	1 & 2	126.7	1 & 2	173.0	1 & 2	257.5
	1 & 2	93.3	1 & 2	106.0	1 & 2	165.2	1 & 2	171.3
	1 & 2	73.3	1 & 2	165.5			1 & 2	170.7
Average: vector 1 & 2		**74.5**		**129.9**		**186.5**		**199.8<**

Figure 5



Relationship of delivered energy and likelihood of successful defibrillation sorted by the Zoll M series (blue line: through vector 1, orange line: through vector 2, green line: average) and prototype unit using the dual-vector (red line). In comparison to the averaged DFT value of the Zoll, the hazard ratio of success for the novel dual-vector quadriphasic shock was 1.21, P=0.65 (blue vs. red line). V1: vector 1, V2: vector 2.

Results

A total of 96 shocks through 29 sets of DFT testing were delivered during VF in four animals. The measured DFTs by Zoll M series and the prototype units in each animal model are shown in Table 1. The maximum delivered energy by Zoll M series and the prototype unit were 251 Joules and 257 Joules, respectively. In several of the animal models, high DFTs were observed through vector 2. Figure 5 plots the probability of successful defibrillation vs. energy. In comparison to the averaged DFT value of the Zoll M series (green line), the hazard ratio of success for the novel dual-vector quadriphasic shock (red line) was 1.21, P=0.65.

Discussion

The higher than expected Zoll failure rate likely reflects the ineffective position of the pads for vector 2. Since the quadriphasic waveform uses two biphasic vectors for each shock, it may be less susceptible to failure if one of the vectors is suboptimal. In comparison to the Zoll M series, the energy required for successful defibrillation by our prototype unit did not differ significantly despite the high defibrillation threshold in the left lateral vector. This suggests that it may be possible to significantly downsize a device while maintaining equivalent efficacy for defibrillation.

Conclusions

Our early findings support the feasibility of a unique external defibrillation unit using a dual-vector, quadriphasic waveform approach. This warrants further study to leverage this unique concept and work towards a miniaturized, portable shock delivery system.

Disclosures

Hideo Okamura is a recipient of the Medtronic Japan Fellowship for Young Japanese Investigator conducted by Japanese Heart Rhythm Society. Peter D. Gray and Walter T. Savage are employees and equity owners in CardioThrive, which is developing this novel defibrillation unit.