The following is an excerpt from Defibrillation – What you need to know – Published by the National Center for Early Defibrillation. For a copy of this book, contact the National Center for Early Defibrillation (www.early-defib.org) or the American Heart Association National Center (www.americanheart.org) directly.

ENERGY LEVELS

Much research has been done to determine the energy required for successful defibrillation. Prospective studies of low (175 to 200 joules) versus high (300 to 400 joules) energy for first shocks showed no benefit from initial shocks above 200 joules.[6] The AHA recommends the following energy settings for adults: 200 joules for the initial shock; if the first shock is unsuccessful, the second shock should deliver 200 to 300 joules. The third and subsequent shocks should be at 360 joules. If ventricular fibrillation recurs after successful defibrillation, the energy, which initially converted the patient, should be used.[6]

Guidelines from the ERC are: 200 joules for the first and second shocks, and 360 joules for subsequent shocks.[1,4,6] While body weight does not appear to be a major factor in determining adult defibrillation energy requirements, children require less energy than adults. Ventricular fibrillation is uncommon in children and has been documented in less than 10% of the pediatric cases of terminal arrhythmias.[5,6,7] ***If ventricular fibrillation occurs, however, the AHA and ERC recommend a weight dependent energy dose of 1 joule per pound (2 joules per kg) for the initial shock.*** [3,4,5,8] ***If the first shock is unsuccessful, the energy should be doubled for subsequent shocks.*** [2,4]

1. Prevost JL, Batelli F: Sur quelques effets des descharges electriques sur le coeur des mammiferes. Acad. Sci. Paris, FR.: 1899; 129:1267–1268.

2. American Heart Association. Textbook of Pediatric Advanced Life Support 1994; Chap. 7.

3. Zideman D, Bingham R, Beattle T, et al. Guidelines for peadiatric life support. Resuscitation. 1994; 27: 91–105.

4. American Heart Association. Currents in Emergency Cardiac Care. 1990; 1:1:1.

5. Beck CS, Pritchard WH, Feil HS. Ventricular fibrillation of long duration abolished by electrical shock. JAMA.1947; 135:985–986.

6. American Heart Association. Textbook of advanced cardiac life support. 1994; Chapter 4.

7. Bossart L, Koster R. Defibrillation: methods and strategies. Resuscitation. 1992; 24:211–223.

8. Gutgesell HP, Tacker WA, Geddes LA, et al. Energy dose for ventricular defibrillation of children. Pediatrics. 1976; 58:898–901.

WelchAllyn

Summary Of Studies Of Waveform Safety & Effectiveness- MRL Biphasic

Introduction

Over 30 years ago, MRL – A Welch Allyn Company, patented a unique monophasic truncated exponential waveform, which utilized a low peak current, impedance compensated defibrillation waveform. The Welch Allyn (MRL) monophasic waveform was developed as an alternative to the monophasic damped sine (MDS) waveform (often referred to as the Edmark waveform) defibrillator, which was associated with higher peak currents and did not actively compensate for varying patient impedances. In fact, the Welch Allyn (MRL) monophasic waveform defibrillator delivers less than half of the peak current of an MDS waveform defibrillator at equal delivered energies. A new Welch Allyn (MRL) defibrillator (the MRL AEDefibrillator 2) has been introduced, which offers a biphasic truncated exponential waveform that incorporates Welch Allyn's (MRL) original low peak current, impedance compensation design. The Welch Allyn (MRL) biphasic truncated exponential waveform has been extensively tested in multiple scientific safety and effectiveness studies. Over 524 fibrillation/defibrillation shock episodes have been conducted using the Welch Allyn (MRL) Biphasic waveform comparing it to MDS, MTS and another commercially available 2kV biphasic (360 J capable) defibrillators. Results of three of the scientific safety and effectiveness studies are summarized below.

STUDY 1

Objective - To evaluate the Welch Allyn (MRL) Biphasic waveform defibrillator against a monophasic damped sinusoidal waveform defibrillator.

Methods - A canine model (n=5, 71±7 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with 20 mpk sodium pentothal i.v., and maintained as required through an intravenous catheter in the foreleg. The external jugular vein was cannulated and a bipolar pacing catheter was introduced under fluoroscopic control and advanced into the right ventricle. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure. The chest was shaved and defibrillating patch electrodes (R2 part number 3200-1715) were placed on the left and right chest walls.

Fibrillation was induced by delivering 60 Hz current to the right ventricular electrode. The energy required to defibrillate was determined by a protocol that has been used in several other biphasic comparison studies. An initial shock strength of 50 to 70 joules was used. If successful, VF is reinduced after a 4 minute rest period, and the shock strength is reduced by approximately 20% for the next defibrillation attempt. If the initial shock fails, a rescue shock is delivered, and after a rest period, VF is again induced. The energy is now increased about 20% for the next defibrillation attempt. This procedure was continued until at least 3 reversals in result were observed with each waveform. Two ED50 estimation procedures were run in parallel, with the device being used alternated on each shock. In practice, actual clinical units were used, so the energy steps were limited to those selectable on the devices tested.

Results - The study consisted of 82 total fibrillation/defibrillation episodes. ID50 peak currents and ED50 delivered energies are shown below for each group. The mean impedance for these animals was 62 ohms. The mean ED50 energies were compared and were found to be significantly different. The significance of difference (p-value) was calculated by the Wald test in each case, and are shown below. The mean ED50 peak current for the biphasic waveform was 39 percent of that required with the MDS waveform.

Summary Table - ED50 & ID50

Mean	Welch Allyn (MRL) AEDefibrillator 2 Biphasic	Monophasic Damped Sine
ID50 Peak Current (Amps)	6.4	16.6
Significance of difference (p-value)	<0.001	
ED50 Delivered Energy (Joules)	26.3	35.3
Significance of difference (p-value)	0.014	

Study 1 Conclusion - The Welch Allyn (MRL) Biphasic waveform is capable of converting fibrillation episodes using less energy than the MDS waveform, and requires lower peak currents than MDS waveform defibrillators.

Study 2

Objective - Comparison of the defibrillation effectiveness of the Welch Allyn (MRL) Biphasic waveform defibrillator, with a commercially available Biphasic 2KV defibrillator capable of 360 J and a monophasic truncated exponential defibrillator.

Methods - A canine model (n=6, 61.6 ± 5.5 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with an intravenous injection of 20 mg/kg sodium pentothal. They were then intubated with a cuffed endotracheal tube, and maintained on isoflurane gaseous anesthetic. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure, and for acquiring samples for arterial blood gas and electrolyte monitoring. The chest was shaved and adhesive defibrillating electrode pads were placed on the left and right chest walls.

Fibrillation was induced by delivering 60 Hz current to the external electrodes. The ED50 energy (that required to defibrillate with 50% probability) was determined by a protocol modeled after that of Dixon. An initial shock strength of 30 joules was used, which was applied after 15 seconds of ventricular fibrillation (VF). If successful, VF was re-induced after a 4 minute rest period, and the shock strength was reduced by one energy step for the next defibrillation attempt. If the initial shock failed, a rescue shock was delivered, and after a rest period, VF was again induced. The energy was now increased one energy step for the next defibrillation attempt. This procedure was continued until a nominal sample size of six episodes was achieved (both sides of the first reversal in result, plus 4 episodes). Three ED50 estimation procedures were run in parallel, with the device being used alternated on each shock. After each of the three independent ED50 estimation procedures had been completed, the entire protocol was repeated twice more, each time starting all devices at an energy of 30 joules. The ED50 peak current and energy was then estimated for each animal by logistic regression analysis. Individual phase durations and overall pulse durations were measured and recorded on each shock.

Results - The study consisted of 344 total fibrillation/defibrillation episodes. The mean ED50 and ID50 estimates (to one decimal place) are shown below. The significance of difference (p-value) was calculated by the Wald test in each case, and are shown below. Also shown are the mean total durations measured for each device.

Summary Table -ED50, ID50, & Duration

Mean	Monophasic Waveform	Welch Allyn (MRL) AEDefibrillator 2 Biphasic	2kV Biphasic Waveform
ID50 Peak Current (Amps)	9.0	6.4	8.3
Significance of difference (p-value)	<0.001 (AEDefibrillator 2 vs. Monophasic)		<0.001 (AEDefibrillator 2 vs. 2kV Biphasic)
ED50 Delivered Energy (Joules)	40.2	21.4	22.7
Significance of difference (p-value)	<0.001 (AEDefibrillator 2 vs. Monophasic)		0.4937 (AEDefibrillator 2 vs. 2kV Biphasic)
Total Duration (msec)	11.9	12.3	13.1

Study 2 Conclusion - The Welch Allyn (MRL) Biphasic waveform was as effective as the Biphasic 2KV waveform, and more effective than the monophasic waveform. While both biphasic waveforms required less peak current than the monophasic waveform, the Welch Allyn (MRL) Biphasic waveform required statistically less peak current than the 2 KV biphasic waveform defibrillator.

Study 3

Objective - Comparison of the defibrillation effectiveness of the Welch Allyn (MRL) Biphasic waveform defibrillator, with a commercially available Biphasic 2KV defibrillator capable of 360 J in a simulated higher impedance model.

Methods - A canine model (n=6, 53.7 ± 6.1 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with 20 mpk sodium pentothal i.v., and maintained as required through an intravenous catheter in the foreleg. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure. The chest was shaved and defibrillating patch electrodes were placed on the left and right chest walls.

Fibrillation was induced by delivering 60 Hz current to the chest electrodes. The energy required to defibrillate was determined by a protocol that has been used in several other biphasic comparison studies. An initial shock strength of 70 to 100 joules was used. If successful, VF was re-induced after a 5 minute rest period, and the shock strength was reduced by approximately 20% for the next defibrillation attempt. If the initial shock failed, a rescue shock was delivered, and after a rest period, VF was again induced. The energy was now increased about 20% for the next defibrillation attempt. This procedure was continued until approximately 4 reversals in result were observed with each waveform. Two ED50 estimation procedures were run in parallel, with the device being used alternated on each shock. In practice, actual clinical units were used, so the energy steps were limited to those selectable on the devices tested. The ED50 peak current and energy was then estimated for each animal by logistic regression analysis.

This study simulated a higher impedance patient by having a 32 ohm resistor placed in series with each subject.

Results - The study consisted of 98 total fibrillation/defibrillation episodes. The mean ED50 and ID 50 estimates for peak current and energy for each animal (to one decimal place) are shown below. The significance of difference (p-value) was calculated by the Wald test in each case, and is shown below. Also shown are the mean total durations measured for each device.

Summary Table - ED50 & ID50

Mean	Welch Allyn (MRL) AEDefibrillator 2 Biphasic	2kV Biphasic Waveform
ID50 Peak Current (Amps)	5.8	7.4
Significance of difference (p-value)	<0.001	
ED50 Delivered Energy (Joules)	34.3	32.0
Significance of difference (p-value)	0.885	
Total Duration (msec)	21.3	15.6

Study 3 Conclusion - The Welch Allyn (MRL) Biphasic waveform was as effective as the 2KV Biphasic waveform in this model of a higher impedance patient. When these devices are compared on the basis of peak current, the Welch Allyn (MRL) Biphasic required less peak current than the 2KV Biphasic waveform.

Rationale for Animal Studies

Electrical waveforms for transthoracic ventricular defibrillation have been well studied for nearly 50 years. These studies led to the development of monophasic waveforms such as the Edmark, Lown, and truncated exponential waveforms which have now been used in humans for over 30 years. Starting in the early 1980s, biphasic waveforms have been extensively studied in animal models of transthoracic ventricular defibrillation. These studies have shown that a wide variety of biphasic waveforms exhibited superior defibrillation effectiveness to these conventional monophasic waveforms. In many cases, the waveform comparisons performed in animals were repeated in clinical trials involving humans. These studies have conclusively demonstrated that well-designed animal studies can and do predict the results that will be observed in humans.

The reasons for conducting animal trials (as opposed to additional human clinical studies) are:

1. Animal studies can use a much larger sample size (more shocks per subject), and thus, result in far more accurate comparisons.

2. Animal studies do not place human subjects at risk from additional (and clinically unneeded) shocks.

3. The animal hearts can be inspected for damage after the defibrillation studies.

Waveform Safety & Effectiveness Conclusions:

These scientific studies have demonstrated that:

1. The data suggests that the Welch Allyn (MRL) Biphasic waveform in the AEDefibrillator 2 is at least as effective as, and may be more effective than either of the two tested monophasic waveforms, appearing to allow termination of fibrillation episodes using lower energies.

2. The Welch Allyn (MRL) Biphasic waveform in the AEDefibrillator 2 is as effective as the 2KV biphasic truncated exponential waveform in another commercially available defibrillator.

3. The Welch Allyn (MRL) Biphasic waveform in the AEDefibrillator 2 requires less peak current to achieve defibrillation effectiveness than either of the two monophasic waveforms or the 2KV biphasic truncated exponential waveform that is used in another commercially available defibrillator.

WelchAllyn

AHA Statement
07/01/2003

American Heart Association says AEDs safe to use on children ages 1 to 8

DALLAS, July 1 – Automated external defibrillators (AEDs) – devices that shock the heart to restore a normal heartbeat after a life-threatening irregular rhythm – are safe for children as young as age 1, according to an American Heart Association scientific statement published today in *Circulation: Journal of the American Heart Association.*

“AEDs are the first line of treatment for cardiac arrests in adults. Until recently, they were only approved for people age 8 and older,” says Ricardo Samson, M.D., associate professor of pediatrics, University of Arizona, Tucson, and lead author of the statement. Prior to this statement, children under age 8 could receive manual defibrillation at a hospital but were excluded from the automated machines designed for use by emergency personnel, or even lay responders outside of a hospital.

“Typically, a child in cardiac arrest would have to wait for experienced medical personnel to evaluate if the rhythm required a shock,” he says. “What has been shown in adults is that the earlier they receive a shock, the greater the chances of survival. For every minute that defibrillation is delayed, survival decreases by 7 percent to 10 percent. If it’s delayed by more than 12 minutes, the chance of survival in adults is less than 5 percent.”

There is no specific data, but pediatric cardiac arrests occur much less often than adult cardiac arrests, Samson says. “But in those cases where it’s necessary, AEDs can save a young person’s life. Extending their use to younger children may mean more children’s lives may be saved.”

Ventricular fibrillation is an extremely fast and chaotic heart rhythm during which the heart’s lower chambers (ventricles) quiver and don’t pump any blood. AEDs diagnose heart rhythms, differentiating those that need a defibrillating shock from those that don’t. The devices can be operated by bystanders or emergency responders such as paramedics or police officers.

AEDs were originally designed for adults, but they now have been shown to also accurately diagnose a child’s heart rhythm. Some AED manufacturers now offer pediatric-sized electrode pads with cables that reduce the adult-size shock to a level more suitable to children 1 to 8.

“With that information, we are issuing the statement that AEDs can now be used on children with no signs of circulation as young as 1 year of age,” Samson says.

However, even an AED without pediatric electrode pads can be used on children 1 and older.

Authors of the statement include pediatric specialists in intensive care, cardiology and anesthesia. Their review of the literature on AED use in children also reaffirms previous recommendations that:

- there is insufficient evidence to suggest that AEDs be used in children younger than age 1
- rescuers working alone should first try a minute of cardiopulmonary resuscitation (CPR) before any other action on children, because some unconscious children may be revived by rescue breaths alone if they are not suffering a cardiac problem
- defibrillation is recommended for documented ventricular fibrillation.

There is a widespread misconception that smaller children should get proportionately lower shock doses. But the research suggests that children might need higher doses than what was previously thought for effective defibrillation, Samson says. More research is needed to determine the optimum dose in children, he says.
“We encourage manufacturers to test their rhythm detection software in their AEDs against ‘libraries’ of previously recorded pediatric rhythms. That provides information on the device’s accuracy for determining if a shock should be delivered to a child or not,” he says.
AEDs are often available in public places where large numbers of people might gather such as airports, theaters, casinos and sports stadiums. People trained to use them can include non-medical personnel who have been designated to respond with the devices should someone collapse.
“It’s important that more people are trained in CPR and AED use. Site-specific response plans must also be in place to ensure that an AED gets to the victim,” Samson says. “There have been situations reported where an AED was available but a child died because there was no one trained to retrieve and use the device.”

Statement co-authors are: Robert A. Berg, M.D.; Dominique Biarent, M.D.; Bob Bingham, MBBS; Ashraf Coovadia, M.D., Mary Fran Hazinski, R.N.; Robert W. Hickey, M.D.; Vinay Nadkarni, M.D.; Graham Nichol, M.D. M.P.H.; Amelia Reis, M.D.; Jim Tibballs, MBBS; Sandy Tse, M.D.; David Zideman, MBBS ; Jerry Potts, Ph.D.; Karen Uzark, Ph.D. and Diane Atkins, M.D.

The statement will also published in *Pediatrics* and *Resuscitation*.
NR03-1098 (Circ/Samson)
####

COMPARED IN TWO MODELS

Wayne McDaniel, Ph.D., Brian Skelton, Michael Garrett, John Schuder, Ph.D.

University of Missouri, Columbia, MO, Welch Allyn, Buffalo Grove, IL

ABSTRACT

Biphasic truncated exponential (BTE) waveforms are now being implemented in all new transthoracic defibrillators. Not all BTE waveforms are the same, but the direct comparison of BTE defibrillators is rare. Here we compared the efficacy of Zoll, Agilent, and Welch Allyn defibrillators in a model that simulates normal and higher impedance patients

Methods - Canines (n=6, 23.9 +/- 2.4 kg) were anesthetized and adhesive defibrillating patches attached. ED50 peak current and energy required to reverse VF (15 sec duration) were then estimated for each animal at normal and higher impedance (+ 32 Ω) by logistic regression.

Results - Shown in table. Significance between devices at p<0.01 level indicated by (*). All devices required significantly higher energy with higher impedance.

Conclusion – All 3 defibrillators required higher energy for higher impedance animals, but ED50s did not differ between defibrillators. Peak currents required were lower with Zoll and Welch Allyn for normal impedance, and were lower with Welch Allyn for simulated higher impedance patients.

Impedance	Normal (62 Ω)		High (94 Ω)	
Device	Current	Energy	Current	Energy
Zoll	6.7 A*	21.2 J	7.2 A	26.6 J
Agilent	9.9 A	23.4 J	8.9 A	28.9 J
Welch Allyn	6.0 A*	24.6 J	5.3 A*	29.4 J

BACKGROUND

- Biphasic waveforms are now generated by all implantable cardioverter defibrillators (ICDs), and are now being implemented in most transthoracic defibrillators.
- Not all biphasic waveforms are the same, as is shown graphically in Figs. 1, 2, and 3.
- Comparison of the efficacy of biphasic waveform defibrillators is rare, and is difficult to perform in humans.
- Human transthoracic impedance has been shown to vary from 40 to more than 170 ohms.
- Different defibrillators compensate for variations in impedance in different ways as is shown graphically in Figs. 1, 2, and 3.
- Comparison of the impedance compensation strategies of commercial defibrillators is rare, and is difficult to perform in experimental models.

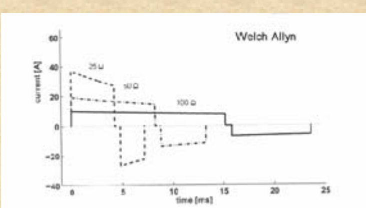


Figure 1. These graphs demonstrate the output of a Welch Allyn AED20 defibrillator at an energy setting of 150 joules, into patient impedances of 25, 50, and 100 ohms from Rheinberger et al, 2003.

OBJECTIVE

To compare the defibrillation efficacy of three commercial biphasic waveform transthoracic defibrillators. A Welch Allyn AED 20 was compared to a Zoll M Series and a Philips-Agilent Heartstart XL in two studies that simulated both normal and high impedance patients.

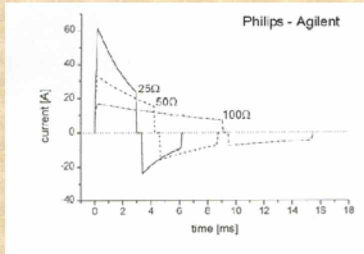


Figure 2. These graphs demonstrate the output of a Philips – Agilent Heartstart XL defibrillator at an energy setting of 150 joules into patient impedances of 25, 50, and 100 ohms. From Achleitner, 2001.

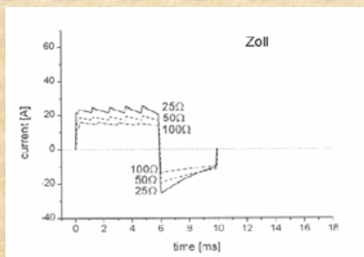


Figure 3. These graphs demonstrate the output of a Zoll M Series defibrillator at an energy setting of 150 joules into patient impedances of 25, 50, and 100 ohms. From Achleitner, 2001.

METHODS

- Canines (n=6, 23.9 ± 2.4 kg) were anesthetized with IV injection of sodium pentothal and maintained under isoflurane gaseous anesthetic.
- Self-adhesive external defibrillation electrodes (Welch Allyn) were attached to the shaved chest.
- Fibrillation was induced with 1 sec 60 Hz alternating current waveform and the test shock was delivered after 10 sec VF.
- Three defibrillators were compared at the normal impedance observed in this model (62 ohms).
- Defibrillators were also compared at a higher impedance by adding a 32 ohm resistor in series with the animals.
- An up-down protocol was used to select the energy levels for each defibrillator, and the defibrillator used was alternated on each episode.
- Logistic regression analysis was used to estimate the ED50 peak current and energy.

RESULTS

- Data from both studies are shown in Table 1.
- Mean impedance for normal animals was 62 ohms and for higher impedance animals was 94 ohms (including 32 ohm added resistor).
- All three defibrillators required significantly higher energy with the simulated higher impedance animals, but there were no significant differences among defibrillators.
- Mean ED50 peak currents required to defibrillate the normal impedance animals were lower with Welch Allyn and Zoll defibrillators.
- Mean ED50 peak currents required to defibrillate the higher impedance animals were lower with the Welch Allyn defibrillator.
- Total pulse durations for each shock are shown in Fig. 4 plotted against total circuit resistance.

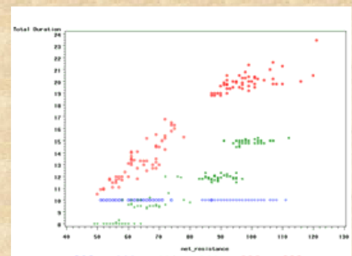


Figure 4. Shown are the observed total durations (in msec) for each shock as a function of net resistance. Welch Allyn is shown in Red, Agilent in Green and Zoll in Blue.

CONCLUSIONS

- The three biphasic waveform defibrillators were equally effective on the basis of delivered energy.
- All three biphasic waveform defibrillators required higher delivered energy to defibrillate higher impedance animals.
- In normal impedance animals, Welch Allyn and Zoll required less peak current to defibrillate than Philips-Agilent.
- In higher impedance animals, Welch Allyn required less peak current to defibrillate than Zoll or Philips-Agilent.
- Adding a series resistance allowed the defibrillators to be tested at an impedance higher than average human impedance.

TABLE 1

Normal Impedance (62 ohms)	Welch Allyn	Zoll	Philips-Agilent	p Value
Mean ED50 peak current	6.0 A *	6.7 A *	9.9 A	p < 0.001
Mean ED50 Energy	24.6 J	21.2 J	23.4 J	n.s.
Total Duration	13.3 ms *	10.0 ms *	8.9 ms *	p < 0.001
Higher Impedance (94 ohms)				
Mean ED50 peak current	5.3 A *	7.2 A	8.9 A	p < 0.001
Mean ED50 Energy	29.4 J	26.6 J	28.9 J	n.s.

ACKNOWLEDGMENT

This study was supported by a research grant from Welch Allyn, Buffalo Grove, IL, USA.

E-mail: mcdanielwc@missouri.edu

Comparison of the Efficacy of Three Commercial Transthoracic Defibrillators in Canines

Wayne McDaniel, Ph.D., Michael Garrett, Timothy Turpin, B.S., John Schuder, Ph.D

University of Missouri, Columbia, MO, and Medical Research Laboratories Inc., Buffalo Grove, IL

ABSTRACT

runcated exponential (BTE) waveforms are generated by all modern le cardioverter defibrillators (ICDs), and are now being implemented racic defibrillators. However, not all biphasic waveforms are the e the efficacy of 3 commercial transthoracic defibrillators was a Physio-Control (PC) BTE, a Medical Research Labs (MRL) BTE, L monophasic (Mono) defibrillator.

Canines (n=6, 61.6 ± 5.5 lbs) were anesthetized with sodium and maintained on isoflurane. Adhesive defibrillating electrode pads -1715) were placed on the shaved left and right chest walls. r fibrillation (VF) was induced with 60 Hz current, and allowed to 10 seconds. The ED50 energy data were acquired by an up-down nodified after that of Dixon, starting with a delivered energy of 30 ree ED50 procedures were run in parallel, with the device being used on each shock. After the three independent ED50 estimation s had been completed, the entire protocol was repeated twice more, starting all devices at an energy level of 30 joules. The ED50 peak d energy was then estimated for each animal by logistic regression

Mean ED50 peak current and energy estimates are shown in the table RL BTE mean peak current was lower than MRL Mono and PC BTE), while PC BTE was lower than MRL Mono ($p < 0.001$). The mean vered energy for both the MRL BTE and PC BTE were less than no ($p < 0.001$).

on: The MRL BTE waveform was as effective as the PC BTE at equal energies, while requiring significantly less peak current. waveforms were superior to the MRL Mono waveform.

	MRL Mono	MRL BTE	PC BTE
50 Peak Current	9.0 A	6.4 A	8.3 A
50 Delivered Energy	40.2 J	21.4 J	22.7 J

OBJECTIVE

npare the efficacy of three commercially le defibrillators in a canine model:

MRL Life Quest – Monophasic

MRL Life Quest – Biphasic

PhysioControl Lifepak 12 - Biphasic

BACKGROUND

Biphasic waveforms have become the waveform of choice for implantable cardioverter defibrillators (ICDs), and are now being implemented in transthoracic defibrillators. A monophasic truncated exponential waveform defibrillator has been manufactured by Medical Research Laboratories (MRL) for 30 years, as a low current alternative to the Edmark waveform defibrillators, which have dominated the market. The MRL monophasic waveform defibrillator delivers less than half of the peak current of an Edmark waveform defibrillator at equal delivered energies.

A new MRL defibrillator has been developed, which extends this low peak current concept to biphasic waveforms. The MRL defibrillators utilize a larger capacitance (500 microfarads) than other available models, such as the PhysioControl Lifepak defibrillators (200 microfarads), or the Agilent Forerunner (100 microfarads), and therefore deliver a lower maximum voltage at any given energy level, with lower tilt and higher terminating current.

A recent study compared the defibrillation efficacy of the MRL biphasic waveform to the Edmark waveform in transthoracic defibrillation of canines (ACC, 2002). This study found that the MRL biphasic waveform mean ED50 delivered energy was 25 percent less than that required with the Edmark waveform ($p = 0.014$). In addition, the mean ED50 peak current required for the MRL biphasic waveform was 61% lower than that required by the Edmark waveform ($p<0.001$).

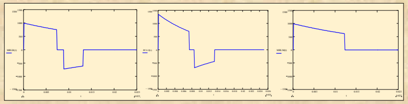
Studies directly comparing the efficacy of commercial biphasic waveform defibrillators are rare, but are necessary to compare the different biphasic waveforms. Here the defibrillation efficacy of commercial units generating the MRL biphasic waveform, the MRL monophasic waveform, and the PhysioControl biphasic waveform are compared in transthoracic defibrillation of canines.

METHODS

- This study was approved by the Institutional Animal Care and Use Committee of the University of Missouri - Columbia, MO.
- Canines (n=6, 61.6 ± 5.5 lbs) were anesthetized with IV injection of 20 mg/kg sodium pentothal and maintained on isoflurane gaseous anesthetic.
- The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure, and for acquiring samples for arterial blood gas and electrolyte monitoring.
- The chest was shaved and adhesive defibrillating electrode pads (R2, 320-1715) were secured on the left and right chest walls.
- Fibrillation was induced with 60 Hz current and maintained for 10 seconds.
- The ED50 energy was estimated for each device in parallel three times, with a protocol modified after that of Dixon, starting at an energy level of 30 J each time.
- The ED50 peak current and energy was then estimated for each animal by logistic regression analysis.
- Individual phase durations and overall pulse durations were measured and recorded on each shock.

FIGURE 1

Representative waveforms for MRL biphasic, PC biphasic and MRL monophasic units (left to right) with 50 ohm load at 150 J.



RESULTS

Summary Table - ED50 Estimates, Durations, and Impedance				P Values for Comparing Data at Left		
	MRL Mono (1)	MRL Biphasic (2)	PC Biphasic (3)	1 vs 2	1 vs 3	2 vs
Peak Current	9.0 Amps	6.4 Amps	8.3 Amps	< 0.0001	0.0081	< 0.00
Delivered Energy	40.2 Joules	21.4 Joules	22.7 Joules	< 0.0001	< 0.0001	0.49
Total Duration	11.9 msec.	12.3 msec.	13.1 msec.	< 0.0001	< 0.0001	< 0.00
Impedance	54.2 ohms	55.9 ohms	54.7 ohms	n.s	n.s.	n.s.

CONCLUSIONS

- When compared in terms of delivered energy, the MRL biphasic waveform was as effective as the Physio-Control biphasic waveform, and both were more effective than the MRL monophasic waveform.
- When compared in terms of peak current, both biphasic waveforms required less peak current than the monophasic waveform, but the MRL biphasic also required less peak current than the Physio-Control biphasic waveform.
- Therefore in this model, the MRL biphasic waveform was as effective as the Physio-Control biphasic waveform, while requiring less peak current.

ACKNOWLEDGMENT

This study was supported by a research grant f Medical Research Laboratories Inc., Buffalo Grove, IL

E-mail: mcdanielwc@missouri.edu

Biphasic Defibrillation: Increasing Efficacy While Decreasing Risk

Clinical Considerations

Michael R. Gold, M.D., PhD.
Chief, Division of Cardiology
Medical Director Heart and Vascular Center
Medical University of South Carolina
Charleston, SC

The Issue

New technologies expand therapeutic options but often add confusion until experience and research provide clear guidelines. This phenomenon has been observed with the introduction of biphasic current in external defibrillation. A case in point is the misconception that biphasic shocks >200J are damaging. Risk of damage depends on peak current of the waveform, not the joules of energy used. Cardiac damage has not been a major concern with monophasic defibrillation, and most biphasic defibrillators provide the advantage of delivering shocks with much lower peak current than monophasic shocks at the same energy (joule setting). Biphasic technology offers improved shock efficacy with decreased risk of shock-induced cardiac damage when compared with traditional monophasic. Although all manufacturers must receive approval from national and international regulatory agencies, the underlying technology differs among biphasic defibrillators on the market and the peak current varies among biphasic defibrillators at the same energy level. An understanding of the components of a defibrillation shock and their effects on the myocardium, the differences among waveforms and research on myocardial damage can lead to increased confidence in the technology and improvement in defibrillation therapy outcomes.

The Challenge

Successful defibrillation requires a brief pulse of electricity quickly sent through the thorax with adequate current to terminate the dysrhythmia. The challenge is delivering enough current to halt fibrillation while limiting risk of shock-induced cardiac damage. In a cardiac arrest, shocks of adequate strength must be delivered as soon as possible as survival rates decline 7 to 10 percent for every minute that defibrillation is delayed.[1] In addition, patients undergoing electrical cardioversion often have underlying cardiac pathology and comorbidities that necessitate limiting a procedure, both in duration of sedation and number of shocks. External defibrillation with a monophasic waveform has been effective for over 40 years, now biphasic waveform technology offers improved shock efficacy at the same energy level with less risk of shock-induced cardiac damage.[2, 3]

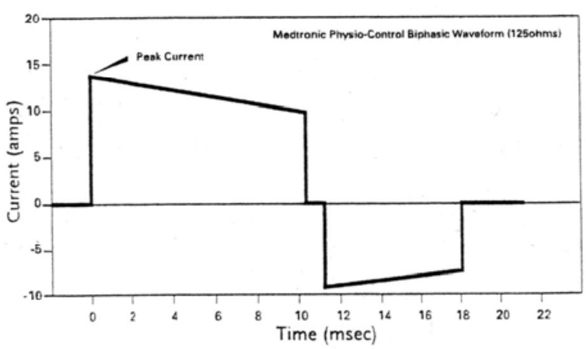
Defibrillation Shocks

Traditionally, defibrillation is discussed in terms of "joules", the amount of electrical energy used in the procedure. This is limiting and misleading as there are several components of energy, each playing a specific role in defibrillation. A joule includes the amount of current delivered, the duration the current flows and the voltage that drives current through thoracic tissue. Electrical current, the flow of electrons, actually terminates the arrhythmia. The number of joules describes how much work must be done by the defibrillator to generate the pulse of current and, in some defibrillators, the energy setting is not indicative of the actual amount of energy delivered.[4] Relating either ventricular defibrillation or atrial cardioversion to the number of joules programmed does not measure the amount of current applied to the myocardium. More importantly, this joule quantity does not provide sufficient data about the potential risk of shock-induced cardiac injury. This risk directly correlates with the amount of current flow. The American Heart Association (AHA) and European Resuscitation Council (ERC) have suggested "current-based defibrillation" as a better approach to delivering appropriate shocks for the spectrum of patients. The optimal current dosing for monophasic defibrillation appears to be 30 to 40 amperes (amps); research on dosing for biphasic defibrillation is ongoing.[1]

Since the current level changes over the duration of the shock, one must look at the maximum level of current flow to gauge the risk of damage accurately. This current flow is commonly illustrated as a waveform graph as shown in Figure 1. The vertical axis depicts current, measured in amperes (amps). The duration, measured in milliseconds (msec), is plotted on the horizontal axis. Peak current is the point at which the current level is highest and, consequently, the point of greatest chance of risk of myocardial damage.

Figure 1

BIPHASIC SHOCK WAVEFORM

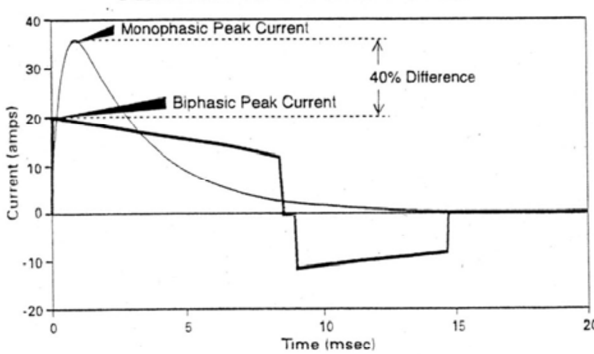


Waveform Differences

Compared to a monophasic defibrillator, most biphasic defibrillators deliver less current at the same energy setting (Figure 2). Note the 40 percent difference between the peak current of the monophasic waveform compared to the biphasic waveform. Although the current is less, the biphasic delivery provides a higher efficacy at the same energy settings.[2]

Figure 2

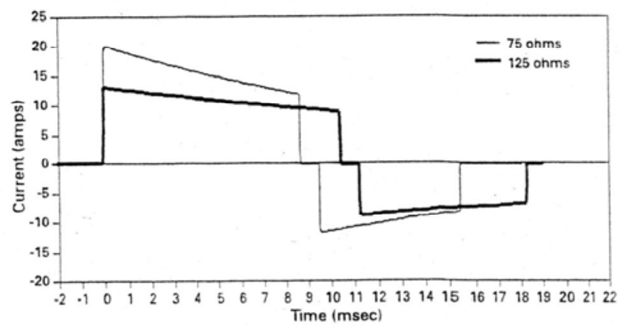
TEST DEFIBRILLATION SHOCK WAVEFORMS DELIVERED TO A 75-OHM TEST LOAD



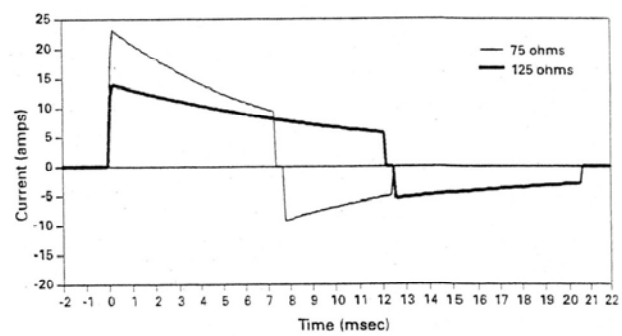
A misconception exists that low energy biphasic defibrillation with fixed, limited-joule protocols provide effective shocks with less risk. However, lower joule settings do not equate to lower current in all biphasic defibrillators, and limiting energy does not equate to limiting shock-induced damage (Figure 3).[4] Comparing different defibrillator shocks in terms of their maximum level of current flow, i.e. peak current, provides much more relevant information. A range of 10.2 to 49.5 amps peak current has been reported in 150J shocks to victims of cardiac arrest.[5]

Figure 3

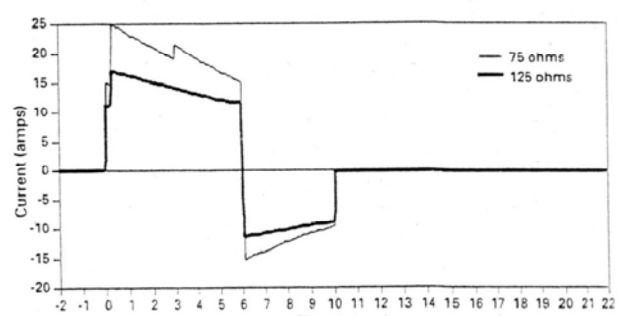
COMPARISON OF PEAK CURRENT IN THREE DIFFERENT DEFIBRILLATORS



Biphasic current waveforms delivered by Medtronic Physio-Control LIFEPAK® 12 defibrillator. Shocks at 200J setting delivered from commercial device into resistors Source: Medtronic Physio-Control



Biphasic current waveforms delivered by Philips® FORERUNNER defibrillator. Shocks at 150J setting delivered from commercial device into resistors. Source: Medtronic Physio-Control

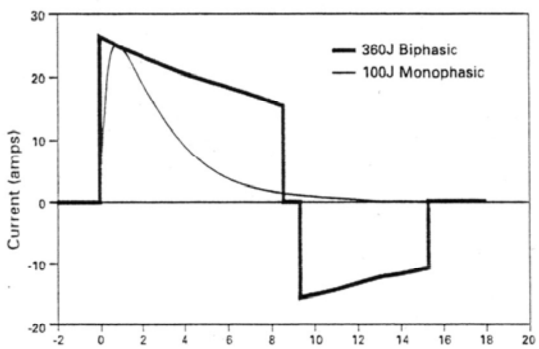


Biphasic current waveforms delivered by Zoll® M Series defibrillator. Shocks at 200J setting delivered from commercial device into resistors. Source: Medtronic Physio-Control

Research on one type of defibrillator with biphasic technology shows a typical patient with an average transthoracic impedance of 75 ohms receives about the same peak current from a 360J biphasic shock as from a 100J monophasic shock (Figure 4). This is not true of all biphasic defibrillators. A shock of 150J with one biphasic device can actually deliver more peak current than a 200J shock from another biphasic defibrillator (Figure 5). The differences in peak current between monophasic and biphasic defibrillation and between different defibrillators must be considered in selecting devices and protocols.

Figure 4

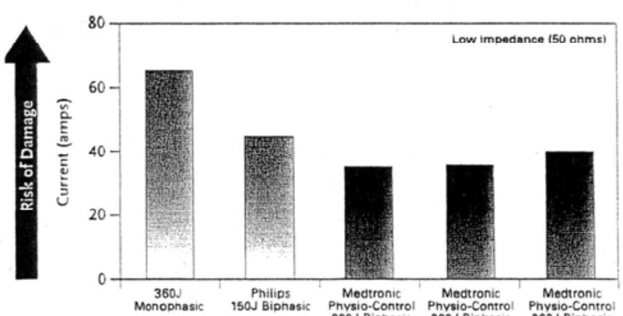
EDMARK MONOPHASIC DAMPED SINE WAVEFORM AND ADAPTIV™ BIPHASIC WAVEFORM



Current waveforms delivered by Medtronic Physio-Control LIFEPAK* 12 defibrillator delivered into a 75ohm resistive load.

Figure 5

PEAK CURRENT VARIES AMONG DEFIBRILLATORS



Risk of Cardiac Damage

Extremely high current levels can damage heart cells.[6] Studies using monophasic waveforms reported evidence of damage in dogs with energy levels of greater than 400J.[7] Animal studies that have demonstrated shock-induced damage have generally used shocks with current levels that are significantly greater than the therapeutic range of any clinically available monophasic or biphasic defibrillator.[6] Conclusions about injury drawn from studies using monophasic shocks delivered to small animals with lower transthoracic impedances are not clinically representative for biphasic defibrillation in the human population. The reduced resistance to the current flow results in a relative overdose in small animals. This high current dose will exaggerate any damage effect to body size and impedance range in humans. Unfortunately, this is not always recognized as most researchers have reported their results in terms of the energy (joules) setting on the defibrillator, not the amount of current actually delivered to the animals. Biomarkers (Troponin T and Troponin I) and ECG changes have been used to detect evidence of damage from defibrillating current in elective cardioversion of atrial fibrillation (AF). This controlled environment eliminates compounding factors encountered in cardiac arrest such as possible damage from CPR compression, acute ischemia and myocardial infarction.

Myocardial damage has not been seen in studies of patients undergoing elective direct current cardioversion of atrial fibrillation/flutter using monophasic shocks with higher peak currents than corresponding biphasic shocks of escalating strengths (100J, 200J, 300J and 360J).[8] In a monophasic AF cardioversion study of 38 patients, only three had minimally raised cardiac Troponin I levels and none presented clinical events or electrocardiographic evidence to suggest myocardial infarction.[9] Prior to the availability of biphasic external defibrillation, electrophysiology laboratories challenged with refractory AF patients, occasionally applied two monophasic defibrillators delivering 720J shocks.[10, 11] Although biphasic shocks are more efficacious, shocks >200 can be needed to terminate atrial and ventricular arrhythmias in some patient populations.[12, 13]

Repeated ineffective shocks not only delay successful defibrillation, but also may carry the risk of more damage than a single effective shock.[14] Elevated Troponin I levels have been seen in repeated shocks with biphasic implantable cardioverter-defibrillators.[15] Although the present AHA and ERC guidelines do not provide definite settings for external defibrillation or cardioversion, they note "Selection of appropriate current also reduces the number of repetitive shocks and limits myocardial damage."[1] This suggests the need for protocols of escalating energies >200J that can result in fewer shocks and more rapid termination of the dysrhythmia.

Post-resuscitation Cardiac Dysfunction

It is recognized that resuscitated patients—even those who are not administered defibrillation shocks—show altered cardiac function.[16] Among the changes noted are: transitory ECG variations such as ST changes, elevations in serum levels of cardiac enzymes, altered ventricular contractions seen on echocardiogram, heart rate variations such as bradycardia, and/or systemic hypotension. Studies suggest that underlying ischemia myocardial injury, prolonged CPR, and vasoconstrictive drugs are factors in myocardial stunning and patient outcomes post-resuscitation.[8, 16, 17] A recent experimental study on 15 rats receiving biphasic shocks of 2 to 20J did show survival and dysfunction was inversely related to energy delivered. This evidence is often shown in warning of damage in biphasic shocks >200J, however the dosing of electrical current in the 450-550 gram rats equates to 2000-3200J in the average human adult.[18]

Pediatric Biphasic Defibrillation

The potential for cardiac damage has been of particular concern when treating pediatric patients. Guidelines for pediatric dosing with monophasic shocks have been 2-4 J/kg.[1] The restrictions of performing defibrillation trials in children require studies that utilize porcine models. Biphasic shocks of 50J have successfully resuscitated animals ranging from 3.5 kg (the average weight of human newborns) to 25 kg (average weight of 8-year-old children).[19] Although cardiac dysfunction was seen following multiple shocks at 14 J/kg, (or average cumulative doses of 46J/kg) the study concluded larger total shocks did not adversely affect myocardial function.[19] Pediatric-size piglets receiving shocks up to 360J (90J/kg) and total cumulative energy of 7455±531.75J have been reported to have small transient changes in myocardial function.[20]

Summary

Used in implantable defibrillators for over a decade, biphasic waveforms are relatively new in external defibrillation. Despite the improved efficacy of biphasic shocks, some patients continue to need more than 200J to terminate their atrial or ventricular arrhythmias. There is no clinical evidence that biphasic shocks at these higher energy settings cause cardiac damage. Although final guidelines and protocols are not yet established, this technology provides improved shock efficacy with decreased risk of shock-induced cardiac damage when compared with traditional monophasic defibrillation.

References:

1. Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Care. *Circulation* Supp.:102.8.
2. Higgins, S.L., *et al.* 2000. A Comparison of Biphasic and Monophasic Shocks for External Defibrillation. *Prehospital Emergency Care* 4(4):305-313.
3. Bardy, G.H., *et al.* 1996. Multicenter Comparison of Truncated Biphasic Shocks and Standard Damped Sine Wave Monophasic shocks for Transthoracic Ventricular Defibrillation. *Circulation* Nov 15; 94(10):2507-2514.
4. Achleitner, U., *et al.* 2001. Waveform analysis of biphasic external defibrillators. *Resuscitation* 50:61-70.
5. Poole, J.E., *et al.* 1997. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. *J Cardiovasc Electrophysiology*. 8:1373-85.
6. Babbs, C.F., *et al.* 1980. Therapeutic indices for transchest defibrillator shocks: effective, damaging, and lethal electrical doses. *Am Heart J*. 99(6):734-8.
7. Kerber, R.E., *et al.* 1988. Energy, current, and success in defibrillation and cardioversion: clinical studies using an automated impedance-based method of energy adjustment. *Circulation* 77(5):1038-1046.
8. Rao, A.C., *et al.* 1998. Direct current cardioversion does not cause cardiac damage; evidence from cardiac troponin T estimation. *Heart* 80:229-230.
9. Allan, J.J., *et al.* 1997. Cardiac Troponin I Levels Are Normal or Minimally Elevated After Transthoracic Cardioversion. *JACC* 30(4):1052-1056.
10. Bjerregaard, P., *et al.* 1999. Double external direct-current shocks for refractory atrial fibrillation. *Amer J Cardiol* 83(6): 972-4, A-10
11. Saliba, W., *et al.* 1999. Higher Energy Synchronized External Direct Current Cardioversion for Refractory Atrial Fibrillation. *JACC* 34(7):2031-2034.
12. Jain, V. C., *et al.* 2002. Successful Cardioversion of Atrial Fibrillation Using 360-Joules Biphasic Shock. *Amer J Cardiol* 90:331-332.
13. Koul, A., *et al.* 2002. Is 360 Joules Necessary for Biphasic Transthoracic Cardioversion of Atrial Fibrillation? (Abstract) *Pacing and Electrophysiology* 25(4).
14. Gazmuri, R.J. 2000. Effects of repetitive electrical shocks on postresuscitation myocardial function. *Critical Care Medicine* 28:N228-32.
15. Joglar, J.A., *et al.* 1999. Effects of repeated electrical defibrillation on cardiac troponin I levels. *Am J Cardiol*. 83:270-2.
16. Kern, K.B., 2002. Postresuscitation Myocardial Dysfunction. *Cardiology Clinics* 20(1):89-101.
17. Tacker, W.A. 1994. Fibrillation Causes and Criteria for Defibrillation. Chapter 1 in *Defibrillation of the Heart*, edited by W.A. Tacker, St. Louis, Missouri: Mosby Year Book.
18. Xie, J., *et al.* 1997. High-Energy Defibrillation Increases the Severity of Postresuscitation Myocardial Dysfunction. *Circulation* 96(2):683-693.
19. Wann, S.R., *et al.* 2000. Effects of Defibrillation on Post Resuscitation Myocardial Function in Pediatric and Neonatal Models of Cardiac Resuscitation. (Abstract) *Critical Care Medicine* 29(12).
20. Killingsworth, C.R., *et al.* 2002. Defibrillation threshold and cardiac responses using an external biphasic defibrillator with pediatric and adult adhesive patches in pediatric-sized piglets. *Resuscitation* 55(2):177-185.