ACLS DEFIBRILLATION PROTOCOLS WITH THE ZOLL RECTILINEAR BIPHASIC WAVEFORM

AHA/ERC GUIDELINES 2015

	Monophasic				ZOLL Biphasic			
Defibrillation	200J	300J	360J	360J	120J	150J	200J	200J
Synchronized Cardioversion	100J	200J	300J	360J	75J	120J	150J	200J
Pediatric Defibrillation	2J/kg				2J/kg			
Internal Defibrillation	Maximum of 50J				5J	10J	20J	30J	50J

J: joules

Introduction

The purpose of this document is to outline the equivalent biphasic protocols specific to the ZOLL® Rectilinear Biphasic™ waveform.

The recommendations for synchronized cardioversion and defibrillation protocols for ZOLL defibrillators are based on evidence cited for the ZOLL Rectilinear Biphasic waveform in two prospective randomized clinical trials[1,2] and the 2010 American Heart Association (AHA) Guidelines[3] (unchanged in the 2015 AHA Guidelines[4]).

Defibrillation

Over time, defibrillator shocks have evolved to a monophasic protocol of 200J–300J–360J to balance the need for increased "strength" to convert a rhythm from ventricular fibrillation with the potential of damaging cardiac tissue with too much current. ZOLL's Rectilinear Biphasic waveform was designed with internal resistors to control impedance so that low-impedance patients are not "overdosed" (more resistors are engaged to reduce the amount of current delivered to a low-impedance patient) and high-impedance patients get the maximum possible current. The biphasic protocol of 120J–150J–200J for the Rectilinear Biphasic waveform was chosen based on data from a prospective, randomized clinical trial, which showed 99% first shock efficacy at 120J, and 100% efficacy at 150J. Based on these data, the additional 200J shock level with ZOLL defibrillators clearly represents a safety margin.

Recommendations in the European Resuscitation Council (ERC) and AHA Guidelines suggest that rescue sequences with defibrillation move away from the concept of three stacked shocks to a sequence of single shocks, with CPR between each shock. The logic behind this recommendation is that stacked shocks result in too much "hands-off" time, during which chest compressions are not performed. Recent experimental data suggest that maximizing the amount of time compressions are performed, along with the quality of compressions, will have the most significant impact on survival.

Neither the 2010 nor the 2015 Guidelines altered the recommended defibrillation protocol for the ZOLL Rectilinear Biphasic waveform. In fact, the efficacy of the ZOLL Rectilinear Biphasic waveform is specifically incorporated through citations when energy levels are included in the discussion. Regarding monophasic versus biphasic, the 2015 Guidelines recommend: "Based on their greater success in arrhythmia termination, defibrillators using biphasic waveforms (BTE [biphasic truncated exponential] or RLB [rectilinear biphasic]) are preferred to monophasic defibrillators for treatment of both atrial and ventricular arrhythmias (Class IIa, LOE B-R)."[5]

Synchronized Cardioversion

In a randomized multicenter trial, the data demonstrated superior results using the ZOLL Rectilinear Biphasic waveform, compared with the monophasic waveform for both first shock and cumulative efficacy.[2] There was a significant difference between the first shock efficacy of biphasic shocks at 70J, compared with monophasic shocks at 100J, 68% versus 21%, respectively, (p=0.0001, 95% confidence interval of the difference of 34.1% to 60.7%). The results from this clinical trial therefore provide evidence to use 75J–120J–150J–200J (70J for the first shock when using the E Series®) as the recommended biphasic equivalent for any synchronized cardioversion procedure using the ZOLL Rectilinear Biphasic waveform. Following the publication of this paper, additional abstracts have also been presented showing statistically significant improvement over monophasic with energy settings as low as 5J with the ZOLL Rectilinear Biphasic waveform.[6,7,8]

Pediatric Defibrillation

The ZOLL Rectilinear Biphasic waveform has also been approved by the FDA for use in pediatric patients and for internal defibrillation. Defibrillation protocols for these uses are based on observational studies and animal testing. FDA approval for the use of ZOLL's Rectilinear Biphasic waveform on pediatrics was based on the results from a study entitled A Comparative Biphasic Defibrillation Study for Pediatric Dosing Levels Using a Porcine Model.[9] This study demonstrates the safety and efficacy of this waveform on pediatric patients and supports ZOLL's recommendation of using a defibrillation protocol of 2J/kg. Although this is the same protocol as used with monophasic waveforms, pediatric patients will benefit from a reduced possibility of myocardial dysfunction associated with the use of biphasic waveforms, which deliver less peak current than monophasic waveforms. The AHA Guidelines now allow 2 to 4J/Kg.[10]

Internal Defibrillation

The use of ZOLL's Rectilinear Biphasic waveform for internal defibrillation has also been cleared by the FDA. A shock sequence of 5J, 10J, 20J, 30J and 50J was used in an observational study. First shock success rate was 90% for 5J. In addition to the clinical data, anecdotal stories suggest that internal shocks delivered with the ZOLL Rectilinear Biphasic waveform do not cause as much myocardial movement as when the shock is delivered with a monophasic waveform. This should not be confused with failure to deliver the shock. If the heart does not defibrillate after the initial shock, additional shocks with incremental energy levels should be delivered until defibrillation is achieved.

Other Arrhythmias

The use of the ZOLL Rectilinear Biphasic waveform has not been studied in randomized prospective clinical trials for all types of arrhythmias covered by ACLS algorithms. Nonetheless, the following factors support using the biphasic energy equivalents for either synchronized cardioversion or defibrillation as required:

1. All ACLS algorithms that refer to electrical conversion specify either synchronized cardioversion or defibrillation, depending on the specific rhythm. Evidence for the ZOLL Rectilinear Biphasic waveform exists for both synchronized cardioversion and defibrillation.

2. The ZOLL Rectilinear Biphasic waveform has been documented as clinically equivalent or superior (in accordance with the AHA recommendation that the upper boundary of the 90% confidence interval of the difference between standard and alternative waveforms must be <0%[11]) to reports of monophasic shock success in two separate prospective randomized clinical trials.[1,2]

Defibrillation During Open Heart Surgery

An observational study was performed to demonstrate the safety and efficacy of the ZOLL Rectilinear Biphasic waveform when the waveform was applied directly to the heart in ventricular fibrillation (VF) during open heart surgery.[12] There were 20 patients enrolled in the study. All patients were classified as NYHA class III, had significant coronary artery disease, and underwent coronary artery bypass graft surgery as the method of treatment. One or more ZOLL Rectilinear Biphasic waveform shocks were applied directly to the heart if VF occurred. The shock sequence was 5J, 10J, 20J, 30J, and 50J. Shock energies were applied in sequence until defibrillation occurred.

All patients were successfully defibrillated with a selected shock energy less than or equal to 20J. The first shock defibrillation success rate at the initial energy selection of 5J was 90% (18/20), compared with the reported cumulative success rate for the BTE waveform of 50% (25/50) at 5J. The threshold energy was 6.0 ± 3.5J, the cumulative energy was 7.0 ± 7.0J, and the average number of shocks was 1.2 ± 0.5 shocks. No patient experienced abnormal left ventricular wall motion at any time and all patients were defibrillated to normal sinus rhythm.

Note: The clinical results for the ZOLL Rectilinear Biphasic waveform are based upon the use of ZOLL multifunction electrodes. The combination of the Rectilinear Biphasic waveform, with ZOLL electrode properties and gel characteristics, achieves efficacy results as described above. There are no data to support equivalent claims with non-ZOLL electrodes.

[1]Mittal S, et al. Comparison of a novel rectilinear biphasic waveform with a damped sine wave monophasic waveform for transthoracic ventricular defibrillation. *Journal of American College of Cardiology.* 1999;24:1595-1601.

[2]Mittal S, et al. Transthoracic cardioversion of atrial fibrillation. *Circulation.* 2000;101:1282-1287.

[3]Field JM, et al. Part 1. Executive Summary. 2010 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation.* 2010;122;S640-S656.

[4]Neumar RW, et al. Part 1: Executive Summary. 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation.* 2015;132[suppl 2]:S315–S367.

[5]Link MS, et al. Part 7: Adult Advanced Cardiovascular Life Support. 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation.* 2015;132[suppl 2]:S444-S464.

[6]Niebauer, et al. Cardioversion thresholds of atrial fibrillation and atrial flutter using an external biphasic waveform defibrillator. Presented at NASPE 2000 (abstract).

[7]Friedman, et al. Role of ibutilide and biphasic waveforms for cardioversion of atrial fibrillation in routine clinical practice. PACE. 2002;24:634 (abstract).

[8]Schutte D, et al. Rectilinear biphasic rather than monophasic waveforms for Transthoracic cardioversion of patients with rheumatic heart disease and longstanding atrial fibrillation after corrective mitral valve procedures. *Journal of American College of Cardiology.* 2002;39:429A (abstract).

[9]Study data submitted to the FDA.

[10]Atkins DL, et al. Part 11:Pediatric Basic Life Support and Cardiopulmonary Resuscitation Quality. 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation.* 2015;132[suppl 2]:S519-S525.

[11]Kerber RE, et al, AHA Scientific Statement. *Circulation.* 1997;95:1677-1682.

[12]Schwarz B, et al. Biphasic shocks compared with monophasic damped sine wave shocks for direct ventricular defibrillation during open heart surgery. *Anesthesiology.* 2003;98:1063.

ZOLL Medical Corporation • Chelmsford, MA, USA • 800-348-9011 • www.zoll.com

MCN HP 1601 0186