A Study on Performance and Safety Tests of Defibrillator Equipment

Tavakoli Golpaygani A.[1], Movahedi M. M.[2, 3]*, Reza M.[4]

ABSTRACT

Introduction: Nowadays, more than 10,000 different types of medical devices can be found in hospitals. This way, medical electrical equipment is being employed in a wide variety of fields in medical sciences with different physiological effects and measurements. Hospitals and medical centers must ensure that their critical medical devices are safe, accurate, reliable and operational at the required level of performance. Defibrillators are critical resuscitation devices. The use of reliable defibirillators has led to more effective treatments and improved patient safety through better control and management of complications during Cardiopulmonary Resuscitation (CPR).

Materials and Methods: The metrological reliability of twenty frequent use, manual defibrillators in use ten hospitals (4 private and 6 public) in one of the provinces of Iran according to international and national standards was evaluated.

Results: Quantitative analysis of control and instrument accuracy showed the amount of the obtained results in many units are critical which had less value over the standard limitations especially in devices with poor battery. For the accuracy of delivered energy analysis, only twelve units delivered acceptable output values and the precision in the output energy measurements especialy in weak battry condition, after activation of discharge alarm, were low.

Conclusion: Obtained results indicate a need for new and severe regulations on periodic performance verifications and medical equipment quality control program especially for high risk instruments. It is also necessary to provide training courses on the fundumentals of operation and performane parameters for medical staff in the field of meterology in medicine and how one can get good accuracy results especially in high risk medical devices.

Keywords

Meterology, Reliability, Defebrillator, Electroshock, Patient Safety, Medical Electrical Equipment

[1]Department of Biomedical Engineering, Standard Research Instituite, Karaj, Iran
[2]Department of Medical Physics, School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran
[3]Ionizing and Non-Ionizing Radiation Protection Research Center, Paramedical Sciences School, Shiraz University of Medical Sciences, Shiraz, Iran
[4]Department of Electrical Engineering, Iranian Research Organization for Science and Technology (IROST), Tehran, Iran

*Corresponding author:
M. M. Movahedi
Department of Medical Physics, School of Medicine; Ionizing and Non-Ionizing Radiation Protection Research Center, Paramedical Sciences School, Shiraz University of Medical Sciences, Shiraz, Iran
E-mail: mehdi_movahedi@yahoo.com

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Introduction

Medical research and statistical analysis all over the world show generally over 135,000 people die annually following acute myocardial infarction as ventricular fibrillation (VF) or ventricular tachycardia (VT) and the only effective treatment for which is early defibrillation. Defibrillation consists of delivering a therapeutic dose of electrical energy with a device called defibrillator to the affected heart. Defibrillation is the application of a predefined electrical current across the myocardium to cause synchronous depolarization of the cardiac muscle; this action terminates the arrhythmia and allows normal sinus rhythm to be reestablished. In 1899, Prevost and Batelli, two physiologists from University of Geneva, demonstrated small electric shocks

could induce ventricular fibrillation in dogs and larger charges would reverse the condition. The defibrillator was invented in 1932 by Dr. William Bennett Kouwenhoven and the first use on a human was in 1947 by Claude Beck. In 1959, Bernard Lown commenced research into an alternative technique which involved charging of a bank of capacitors and then delivering the charge through an inductance to the heart by way of 'paddle' electrodes. The work of Lown was taken to clinical application by engineer Barouh Berkovits with his "cardioverter". The Lown waveform was the standard for defibrillation until late 1980s when numerous studies showed that a biphasic truncated waveform (BTE) was equally efficacious while requiring the delivery of lower levels of energy to produce defibrillation with less hazards and side effect [1, 2].

Early defibrillation is critical for survival from cardiac arrest for several reasons: (1) the most frequent initial rhythm in witnessed sudden cardiac arrest is VF; (2) the most effective treatment for VF is electrical defibrillation; (3) the probability of successful defibrillation diminishes rapidly over time; and (4) VF tends to convert to asystole within a few minutes. The chance of a successful treatment decline at a rate of about 10% for each minute cardiac defibrillation is delayed.

So, a complete understanding of defibrillator classification, mechanism of action, preparation and techniques for defibrillation is critical in reducing potential complications and hazards. Moreover, it must be regularly the performance and safety of these devices verified at least annually by using adequate analyzer by experts. Particularly, for defibrillator equipment type, approval involves compliance with these standards; a) IEC 60601-1 (Medical Electrical Equipment – Part1: General requirements for safety), b) The particular standard IEC 60601-2-4 (Medical Electrical Equipment – Part2: Particular requirements for the basic safety and essential performance of cardiac defibrillators) and/or c) national standards [2,3].

In order to access the requirement of periodic verifications, the metrological reliability of defibrillators which are in use at healthcare centers should be evaluated. For this purpose, in this research, twenty defibrillators were used at ten hospitals and clinics, six public and four private, in one of Iran's provinces to evaluate and teste under some of the relevant safety and performance parameters.

Technical Background

Principles of Defibrillator

A typical defibrillator includes a power supply, capacitor, induc¬tor, variable transformer and rectifier. Figure 1 shows a simple circuit of a defibril¬lator. The power source can come from a battery or the main supply.

Capacitor is the most important component of a defibrillator that stores a large amount of electrical charge, then releases it over a short period of time in a patient's heart. Effective defibrillation depends on released energy at the heart. The current and charge delivered by a discharging capacitor decay rapidly in exponential function. The current delivered must be maintained in several milliseconds for a successful defibrillation. The inductor minimizes the rapid decay of current flow (delivered energy), it prolongs the duration of current flow to allow for optimum time.

An adjustable transformer is used to convert the mains voltage of 240 V AC to 5000 V AC. By a rectifier, this is then converted to 5000 V DC. In practice, a variable voltage step-up transformer for selecting different amounts of

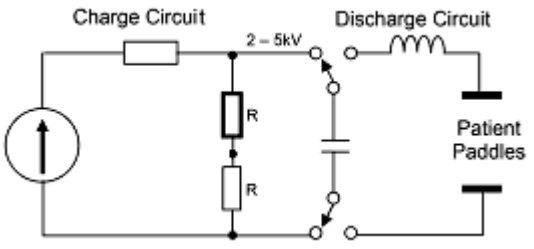

Figure 1: A simple circuit of a defibrillator

adequate charge is used by the physician [4, 5].

Types of Defibrillators

There are three types of defibrillators:

Energy-based Defibrillators

Most defibrillators are energy-based. In this type, the device charges a capacitor to a defined voltage and then delivers a specified amount of energy in Joules to body. The amount of energy is dependent on the selected voltage and the transthoracic impedance, which varies from patient to patient.

Impedance-based Defibrillators

This type of defibrillator allows selection of the current applied based upon the transthoracic impedance (TTI). The capacitor charges to the appropriate voltage after the impedance of transthoracic is assessed initially with a test pulse.

Current-based Defibrillators

This type of defibrillator delivers a fixed dose of current which results in defibrillation thresholds that are independent of the impedance of transthoracic. The optimal current for ventricular defibrillation appears to be 30 to 40 amperes independently of both body weight and the transthoracic impedance thus achieving defibrillation with considerably less energy than the conventional energy-based method [4,5].

Defibrillator Waveforms

Energy-based defibrillators can deliver energy in a variety of waveforms, characterized as monophasic, biphasic or triphasic. These three types of energy waveforms are shown in Figure 2, [4,5].

Monophasic

In a defibrillator with this type of waveform, current flows in one direction between the two paddles during discharge of the defibrilla¬tor. They can be further categorized by the rate at which the current pulse decreases to zero. If the waveform falls to zero gradually, the term "damped sinusoidal" is used. If the waveform falls instantaneously, the term "truncated exponential" is used. Damped sinusoidal monophasic waveforms have been the mainstay of external defibrillation for three last decades.

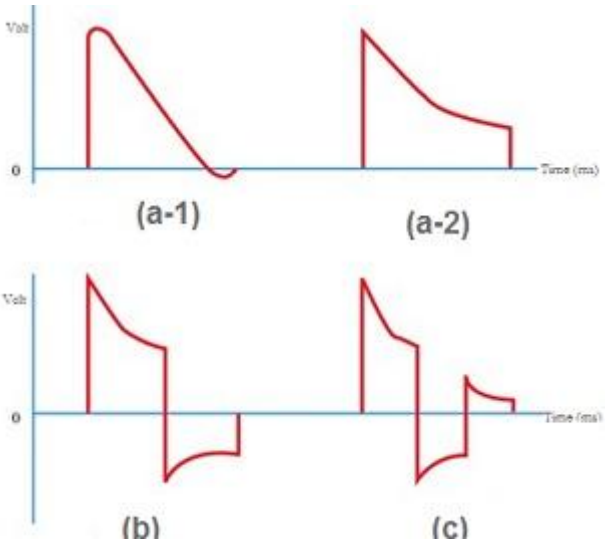

Figure 2: Different types of Waveforms
a-1) Monophasic sine wave,
a-2) Monophasic truncated exponential waveform,
b) Biphasic truncated exponential waveform,
c) Triphasic truncated exponential waveform

Biphasic

This type of waveform was developed later. In a defibrillator with this type of waveforms, the current flows in one direction for a specified time before reversing to another direction for the remainder of the electrical discharge time. With this type of waveform, there is a need for a lower defibrillation threshold (DFT), and it reduces the effective energy required for defibrillation. The use of biphasic waveforms permits a reduction in the weight and size of device.

Triphasic

There are no serious human studies to support the use of multiphasic waveforms over biphasic. The efficacy of triphasic waveforms depends on phase durations and electrode polarity. Investigation in animals suggests that the benefits of biphasic waveform could be harnessed through the use of a triphasic waveform in which the second phase has the larger strength to lower DFT and the third phase the lower strength, to minimize damage. Some

investigations show triphasic transthoracic shocks composed of equal duration pulses were superior to biphasic shocks for VF termination at low energies causing less VT and asystole.

Types of Defibrillators

Several types of defibrillators are used to correct abnormal and life threatening heart rhythms. Defibrillators are categorized into external, transvenous or implanted depending on the type of device used or needed [4,5].

Some of these types are mentioned below:

a) Manual external defibrillator,
b) Manual internal defibrillator,
c) Automated external defibrillator (AED),
d) Implantable cardioverter-defibrillator (ICD),
e) Wearable cardiac defibrillator.

Influencing Factors on Defibrillation

Successful defibrillations depend on the delivery of the shock to a critical mass of myocardium depending on some parameters such as; transthoracic impedance, cellular response, defibrillation threshold, electrode size, quality of electrode surface, electrode paddles-skin interface, electrode paddle force, electrode position, phase of ventilation, etc. Three important characteristics are impedance, defibrillation threshold and cellular response [4,5].

Impedance

Impedance is defined as the resistance to the flow of electrical current. The number one difficulty in delivering current (or energy) through the heart in external defibrillation is the patient's impedance. Body tissues such as skin, fat under the skin, muscles and lungs surrounding the heart all "impede" the flow of electrical current to the heart. The higher amount of patient's impedance, the greater the resistance to defibrillation energy. Impedance varies from patient to patient based on many factors such as: skin condition, electrode size, quality of electrode surface, electrode paddles-skin interface, electrode paddle force, electrode position, shaving the chest and the number and timing of previous shocks. For optimize energy delivery, adjustments must be considered according to the patient's impedance.

Defibrillation Threshold

The minimum current required to defibrillate the heart is defined as defibrillation threshold. DFT varies from body to body based primarily on the patient's anatomy, metabolic state of the heart and disease condition. Not achieving to exceed a patient's DFT means failure in defibrillation. As a result, standard practice is increasing energy in order to exceed the patient's DFT, if the first shock is unsuccessful. The goal is to exceed the patient's DFT as quickly as possible, because the longer the heart fibrillates, the lower

the chance of patient's survival.

Cellular Response

Heart is made up of individual cells that respond to defibrillation. When a patient has been defibrillated, his heart can retain excessive charge from the shock. If not addressed, this can lead to immediate heart returning to ventricular fibrillation. The most appropriate level of energy is delivered initially, by a proper estimation and adjustment of patient's impedance level, reducing the likelihood of the heart retaining excess charge and returning to an abnormal rhythm.

Material and Methods

In this study twenty defibrillators, five different brands were used at ten hospitals, six public and four private, were tested. The technical history of each unit was not informed or not completed by the hospital; however, they announced that none of the unit analyzed had been acquired recently.

The setup which was used for the accuracy of controls and instrument measurements was designed in accordance with the particular safety standard IEC 60601-2-4. Delivered energies were measured with a Neteck Bio-

medical Analyzer (DELTA 3000) and a Fluke Electrical Safety Analyzer (ESA 620) used for general electrical safety evaluations for measuring the patient's leakage current and patient's auxiliary leakage current [5,7].

Performance Parameters

There are several parameters that impact the performance of medical devices [6]. Some of these parameters for defibrillator devices are demonstrated in Table 1, [7,8].

Ideally, all safety and performance parameters have to be evaluated, but as emergency situation of these devices in medical centers, the number of performed tests are limited and only the critical parameters are considered.

According to the particular safety standard IEC 60601-2-4, accuracy of delivered energy should be performed in different simulated impedances (25 Ω, 50 Ω,75 Ω, 100 Ω, 125 Ω, 150 Ω and 175 Ω). So, the test was performed for maximum output delivered energy in three different loads 25, 50 and 100 Ω and the other selected energy in 50 Ω. In order to prevent unintended interruption in actual emergency situation, it is necessary for all evaluation processes to be carried out based on battery mode.

Several safety tests according to general standard for medical electrical equipment (IEC 60601-1), especially patient's leakage current and patient's auxiliary leakage current, were performed in all defibrillator devices [7,8].

Table 1: Performance parameters of defibrillators equipment

Qualitative Tasks	Quantitative Tasks
Chassis/Housing	Accuracy of controls and instruments
Strain Reliefs	Charging time
Paddles/Electrodes	Internal electrical power source
Fitting/Connectors	SYNCHRONIZER
Controls/Switches	Device operation after battery Alarm
Indicators/Displays	Batteries
Alarm/Audible Signals	Energy waveform
Battery/Charger	Electrical Safety Tests

Results and Discussion

The performance and safety testing of frequent use, manual defibrillators equipment in use at ten hospitals was evaluated. Table 2 shows a brief history of obtained results at maximum setting level.

Quantitative analysis of accuracy of delivered energy measurements showed the amount of obtained results in many units are critical and have less value over standard limitations, especially in devices with poor battery. The delivered energy of defibrillators especialy in frequent discharge depends seriously on the power battery condition.

For the accuracy of delivered energy analysis (Table 2), only twelve units delivered acceptable output values and the precision in the output energy measurements especialy in poor battry condition, after activation of discharge alarm was low.

General electrical safety evaluations for measuring the patient's leakage current and patient's auxiliary leakage current were carried out for all of the devices. In some cases, the amounts of leakage currents were over the standard limitations. As a technical investigation, it is shown that the earth system quality of hospital has a key role in electrical safety test, and it is necessary to evaluate the quality of hospital earth system.

Conclusion

Defibrillators are critical resuscitation devices. Their failure to perform effectively may result in the death of a patient undergoing resuscitation or cause further cardiac damage or even death in a patient undergoing cardioversion of a life-threatening arrhythmia. The use of defibirillators has led to more effective treatments and improved patient safety through better control and management of complications during Cardiopulmonary Resuscitation (CPR).

Obtained results indicate an urgent need for

Table 2: A brief summary of evaluated technical result for each unit (units are frequent use, manual defibrillators)

Items	U1	U2	U3	U4	U5	U6	U7	U8	U9	U10	U11	U12	U13	U14	U15	U16	U17	U18	U19	U20
Energy Wave-form	√	√	√	*	√	*	√	*	√	×	√	√	√	×	√	×	√	×	√	×
CT	√	√	√	×	√	×	√	×	√	×	√	√	√	×	√	×	√	×	√	×
SYNC.	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
Battery	√	√	√	×	√	×	√	×	√	×	√	√	√	×	√	×	√	×	√	×
DE	**	*	*	**	*	**	*	**	*	**	*	*	*	**	*	***	**	***	*	***
ENRGY E(A)	*	*	*	**	*	**	*	**	*	**	*	*	*	**	*	**	*	**	*	***
ENRGY E(B)	*	*	*	**	*	**	*	**	*	**	*	*	*	**	*	**	*	***	*	***
Patient Leak-age Current	√	√	√	×	√	√	√	×	√	√	√	√	√	×	√	×	√	×	√	×
Patient Auxil-lary Leakage Current	√	√	√	×	√	√	√	×	√	×	√	√	√	×	√	×	√	×	√	×

E(A): Accuracy of Delivered Energy in 50Ω load

E(B): Accuracy of Delivered Energy in different loads

* 5-15%

** 15-30%

*** Above 30%

CT:for Frequent Use, Manual Defibillators,Time Charging after 15 Sequential Discharge ≤ 15 s

Patient Auxillary Leakage Current
Normal Condition
CF Type: 10 µA
BF Type: 100 µA

Patient Auxillary Leakage Current
Fault Condition
CF Type: 50 µA
BF Type: 500 µA

DE: Delivered Energy after Discharge Alarm

SYNC: Syncronization Operation

Patient Leakage Current
Normal Condition
CF Type: 10 µA
Bf Type: 100 µA

Patient Leakage Current
Fault Condition
CF Type: 50 µA
BF Type: 500 µA

√ - In Standard Limitation

NA: Not Applicable

NP: Not Performed

× - Out of Standard Limitation

new and severe regulations on periodic performance verifications and medical equipment quality control programs especially for high risk instruments. It is also necessary to provide training courses on the fundumentals of operation and performane parameters for medical staff in the field of meterology in medicine and how one can get good accuracy results especially in high risk medical devices.

Conflict of Interest

None

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