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Cardioversion of Atrial Fibrillation and Flutter: Comparative Study of Pulsed vs. Low Energy Biphasic Truncated Exponential Waveforms

Delphine Lavignasse[1,*], Elina Trendafilova[1,*], Elena Dimitrova[2], Vessela Krasteva[3]

The First Two Authors are Co-Authors.

[1]*Paris University, Paris, France and INSERM, UMR-S970, Paris Cardiovascular Research Center, Paris, France.*

[2]*Intensive Cardiology Care Unit, Cardiology Clinic, National Heart Hospital, Konovitsa 65 str, 1309, Sofia, Bulgaria.*

[3]*Institute of Biophysics and Biomedical Engineering, Bulgarian Academy of Sciences, Acad. G. Bonchev Str, Bl. 105, 1113 Sofia, Bulgaria.*

Abstract

Background: Despite the widespread use of biphasic waveforms for cardioversion and defibrillation, the efficacy and safety of shocks has only been compared in a few studies.

Methods: This retrospective study aims at comparing the efficacy and safety of biphasic truncated exponential (BTE) pulsed energy (PE) waveform with a BTE low energy (LE) waveform for cardioversion of atrial fibrillation (AF) and atrial flutter (AFL). The treatment energies were following an escalating protocol for PE waveform (120-200-200J in AF and 30-120-200J in AFL) and LE waveform (100-200-200J in AF and 30-100-200J in AFL). The protocol was stopped at successful cardioversion (sinus rhythm at 1 minute post-shock), otherwise after the 3rd shock. If the 3rd BTE shock failed, a monophasic shock of 360J was delivered.

Results: From May 2008 to November 2017, 193 patients (153 PE, 40 LE) were included in the study. Both groups significantly differed in a few characteristics, including chest circumference ($p<0.05$). After adjustment, the success rate was not significantly different for the two waveforms (94.5% PE vs 92.5% LE, Odds Ratio [95% Confidence Interval] = 0.25 [0.03–2.2]).There was no difference in safety: post-shock changes in Hsc-TnI levels were similar ($p=0.25$). The efficient cumulative energy was particularly related with BSA ($\beta = 131.5$, $p=0.05$), AF/AFL duration ($\beta = 0.24$, $p=0.01$) and gender ($\beta = 61.8$, $p=0.05$).

Conclusions: The major clinical implications of this study concern the high success rate of cardioversion with both biphasic pulses and no superiority of LE over PE waveform with an excellent safety profile without post-shock myocardial injuries.

Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia (Chugh, 2010) and is the major risk factor for death, stroke, heart failure and coronary artery disease (Lip, 2016). It affects about 2-3% of the population in Europe (Zoni-Berisso, 2014).

According to the ESC Guidelines (Kirchhof, 2016), electrical cardioversion (ECV) is administered as a standard intervention for restoration of sinus rhythm in AF. In the short-term, ECV restores sinus rhythm quicker and more effectively than pharmacological cardioversion. AF is also associated with shorter hospitalization duration, although it includes risks from patient sedation.

Until the 90's, direct transthoracic current was delivered using external defibrillators with monophasic waveforms. During the last decades, new biphasic waveforms were designed and their superiority in efficacy and safety was explicitly demonstrated (Gurevitz, 2005; Inácio, 2016; Koster, 2004; Krasteva, 2001; Mittal, 2000; Page, 2002). Various biphasic waveforms became an industry standard: rectilinear biphasic (RB), biphasic truncated exponential (BTE) with high energy (HE), low energy (LE) and pulsed energy (PE).

The BTE technologies can differ in various design characteristics, such as capacitors, tilts, pulse durations or charge voltages and energies. The PE is the most recent designed waveform. Advanced PE defibrillators deliver a BTE waveform with an alternately turned on and off current. Although the initial peak currents are high, PE achieves therapeutic effect with low average current and almost complete utilization of the charged energy (Krasteva, 2001).

This original study is carried out to compare the efficacy and safety of PE and LE waveforms in elective ECV.

Key Words

Cardioversion, Atrial fibrillation, Biphasic waveforms, Pulsed energy, Low energy.

Corresponding Author
Delphine Lavignasse,
Paris University, Paris, France" and "INSERM, UMR-S970, Paris Cardiovascular Research Center, Paris, France.

Material and Methods

Study population

This is a retrospective and monocentric trial, evaluating the results

of external transthoracic cardioversion using PE and LE waveforms. The clinical study takes place in the Intensive Cardiology Care Unit (ICCU), Cardiology Clinic of the National Heart Hospital (NHH), Sofia, Bulgaria, following the standard hospital procedures during ECV accepted in the NHH, and approved by the NHH local ethical committee.

Between May 2008 and November 2017, a total number of 820 patients undergo ECV in the ICCU-NHH, among them 729 are subjected to elective ECV of persistent AF or atrial flutter (AFL) with BTE defibrillators. The patient allocation is summarized in the CONSORT flow diagram [Figure 1].

Patients <18 years, pregnant, presenting other arrhythmias than AF or AFL, with a spontaneous heart rate (HR) <60 bpm, presenting a digitalis intoxication, conduction disturbances (patients without pacemaker) or an impossibility to sustained sinus rhythm irrespective to anti-arrhythmic therapy and frequent ECV are excluded. Asymptomatic patients with long duration of AF or AFL (>1 year); thyroid dysfunction; thrombosis in cardiac cavities; spontaneous echo contrast >2 degree; large atrial size >50 mm (parasternal long axis view) and small chance for sustained sinus rhythm; patients with planned cardiac operation in the next 3 months; patients with embolic event in the last 3 months are not eligible.

The inclusion criteria for elective ECV consider: symptomatic AF/AFL with duration <12 months; symptomatic first detected AF/AFL; persistent AF/AFL after successful causal therapy; rare recurrences of AF/AFL with long periods of sinus rhythm; impossibility to reach a sustained normal ventricular rate in AF/AFL; embolic events irrespective of proper anticoagulant therapy.

Patient preparation and ECV procedure

Standardized indications and procedures are applied as established in the ICCU-NHH. On the day of the cardioversion before the procedure, each patient signs a written informed consent form. In addition, patients have a transesophageal echocardiogram to evaluate the dimensions of the left atrium and ventricle, the ejection fraction of the left ventricle, the echo contrast and thrombosis. All therapy, including antiarrhythmic and anticoagulation drugs up to five days before ECV has been collected in medical records and reported in the study.

The patients are shaved before placement of the standard self-adhesive defibrillation pads in antero-lateral position. Afterwards, the patients are premedicated with 0.5 mg Atropine sc 15-30 min before ECV at the discretion of the attending physician with prophylactic considerations against post ECV bradycardia. The use of atropine is influenced mainly by the heart rate before ECV, treatment with combination of antiarrhythmic drugs and history of bradycardia in the particular patient without documented conductive disorders (the latter is excluding criteria if unprotected by pacemaker). The anesthesia is conducted by an anesthesiologist with slow intravenous injection of Propofol, adjusted individually to reach deep sedation (Cook's scale points < 7).

During the ECV intervention, the patient is shocked following the energy protocols described in [Figure 2]. The time-interval between consecutive shocks is respected to be at least 1 min. During the follow-up period of 24 hours in the Cardiology Clinic, vital signs and ECG are measured, as well as potential complications are recorded. Furthermore, 8 to 12 hours after the ECV intervention, blood samples are collected to analyze the high sensitive cardiac Troponin I (Hsc-TnI).

Protocol and study designs

Devices

PE shocks are delivered with an external semi-automatic defibrillator (Multipulse Biowave®, Defigard DG4000, Schiller Médical, Wissembourg, France). Otherwise, LE waveform is generated using another external defibrillator (HeartStart XL, Philips Medical Systems, 3000 Minuteman Road, Andover, MA USA). Both devices are embedding an impedance compensation technology, which adapts the pulse duration for proper delivery of the selected energy. The waveforms generated by both defibrillators are illustrated in [Figure 2].

For each patient, the choice of the device used is left to the appreciation of the physician.

Escalating energy protocols

The protocol for selection of the treatment energies is part of the standard hospital procedure for elective cardioversion of AFL and AF. A protocol with escalating energies has been primary established in order to limit the energy of the shocks delivered to the «good» responders of the treatment. Because AFL is known to be easier to convert than AF (Gallagher, 2001), two different escalating energy protocols are used for AF and AFL patients, as indicated in [Figure 2]. In both protocols, a stack of three shocks are preset. If the third shock is inefficient, a fourth shock is administered using a monophasic waveform at 360J.

The choice of escalating protocols with different energy levels for PE (DG4000) and LE (HeartStart XL) is due to the different manually selectable energy settings available in both devices:

- DG4000 offers 11 energy settings: 2J, 4J, 8J, 15J, 30J, 50J, 70J, 90J, 120J, 150J, 200J
- HeartStart XL offers 12 energy settings: 2J, 3J, 5J, 7J, 10J, 20J, 30J, 50J, 70J, 100J, 150J and 200J.

The choice of minimal energy (30J) and maximal energy (200J) is corresponding in both devices, however, the energy level just in the middle range (115J) is provided by the closet selectable energy setting in DG4000 (120J) and HeartStart XL (100J).

End points

The primary efficacy endpoint corresponds to the success at the end of the ECV intervention, further denoted as cumulative success rate. Success is defined as the restoration of sinus rhythm for at least 1 minute after the shock.

The secondary efficacy endpoints are considered to be : the cumulative energy (the accumulated energy by the stacked shocks,

estimated as the cumulative energy setting, as well as the true delivered cumulative energy) and the number of delivered shocks.

The safety is evaluated by the troponin level change after ECV. The absolute Hsc-TnI values before and 8-12 hours after the ECV, as well as their normalized difference are compared.

Statistical analysis

Standardized Statistical analysis is performed with RStudio, version 3.5 (RStudio, Inc., Boston, USA).

According to the sample size of LE group (N=40), for a power of 80% to detect a difference of at least 15% in cumulative success rate with a risk alpha of 0.05 and bilateral test, the sample size of the PE group should be over 143 patients. Continuous data are expressed as mean value ± standard deviation (SD) and categorical data are expressed in percentages. Baseline characteristics are compared using χ^2 test or a Fisher's exact test for discrete variables and Mann-Whitney U test for continuous variables. All efficacy endpoints are compared adjusting both groups on baseline characteristics. Multivariate analysis of patients' baseline characteristics is performed with multivariate linear and logistic regressions. A first model (Model 1) is built using classical risk factors according to the literature (Kirchhof, 2016; Lip, 2016): age, gender, BMI, diabetes, renal failure and AF/AFL duration. A second model (Model 2) is designed using the same risk factors in combination with the baseline characteristics, which appear statistically different between PE and LE groups ($p < 0.05$). The significance of both models is estimated with the odds ratio (OR) and its 95% confidence interval (CI). Linear regression is evaluated with the β coefficient, giving the direction of the factor (X) effect on the variable to be explained (Y) : $Y=a+bX$. Safety is evaluated using the Student's paired t-test. All tests of statistical significance are 2 tailed and a p-value < 0.05 is considered significant.

Results

Patient characteristics

Among the 820 patients initially enrolled, 193 are allocated and treated with an escalating energy protocol [Figure 1]. Among those, 153 (79.3%) are treated with PE waveform and 40 (20.7%) with LE waveform. The major proportion of patients in PE group is mainly due to the more frequent use of the PE defibrillator in ICCU-NHH. [Table 1] summarizes the major baseline characteristics of both groups, which are properly matched for 68 variables, including age, gender, weight, height, BMI, BSA, etc. A few differences between both groups are found seen in 7 variables, including chest circumference, left ventricular tele diastolic dimension (LV tdd), valvular heart disease, ASA classes, the calcium channel blocker (CCB) administration and the diastolic blood pressure.

The patients from the PE group have a better ASA class and higher values of chest circumference and LV tdd compared to the LE group. Conversely, the patients from the LE group have a higher rate of valvular disease and CCB. These differences are taken into account when both groups were compared in respect of efficacy and safety.

Table 1: Baseline characteristics of patients included in the study. Continuous data are expressed as mean value ± SD and categorical data are expressed as % (number n)

BASELINE CHARACTERISTICS	PE N = 153	LE N = 40	p-value
AGE (years)	59.7 ± 11.0	59.4 ± 11.8	0.93
MEN (%)	70.6 (108)	62.5 (25)	0.43
WEIGHT (kg)	89.3 ± 15.9	85.5 ± 16.3	0.12
HEIGHT (cm)	174.3 ± 9.05	172.9 ± 8.61	0.49
BMI (kg/m2)	29.3 ± 4.40	28.5 ± 4.68	0.20
BMI > 25 (%)	83.7 (128)	72.5 (29)	0.07
BSA (m^2)	2.05 ± 0.22	1.98 ± 0.20	0.06
LEAN BW (kg)	62.2 ± 11.0	59.4 ± 9.86	0.17
FAT BW (kg)	27.1 ± 10.3	26.0 ± 10.0	0.41
CIRCUMFERENCE (cm)	105.4 ± 11.1	100.6 ± 9.00	0.01*
FIRST ECV (%)	78.4 (120)	75.0 (30)	0.80
STRUCT HEART DISEASE (%)	90.2 (138)	95.0 (38)	0.53
HEART FAILURE (%)	35.3 (54)	47.5 (19)	0.09
DIABETES (%)	14.4 (22)	10.0 (4)	0.68
THYROID NORMAL (%)	37.9 (58)	35.0 (14)	0.66
TSH	1.79 ± 1.22	2.37 ± 0.99	0.06
TSH NORMAL (%)	41.8 (64)	35.0 (14)	0.79
COPD (%)	1.31 (2)	2.50 (1)	0.43
RENAL FAILURE (%)	24.2 (37)	22.5 (9)	0.53
GFR (ml/min)	217.5 ± 111.0	234.6 ± 123.6	0.43
AF/AFL DURATION (days)	120.6 ± 119.8	165.6 ± 277.0	0.99
PREVIOUS HF (%)	13.1 (20)	20.0 (8)	0.39
NOW HF (%)	3.27 (5)	0.00 (0)	-
HB (G/L)	141.9 ± 13.5	139.8 ± 15.1	0.31
HT (%)	42.1 ± 4.08	42.4 ± 4.80	0.64
WBC (109/L)	7.49 ± 1.86	7.17 ± 1.74	0.26
GLU (mmol/L)	6.23 ± 1.90	6.45± 2.90	0.61
UREA (mmol/L)	6.64 ± 2.24	6.65 ± 2.23	0.91
CREAT (mmol/L)	98.8 ± 18.4	92.0 ± 15.4	0.05
K (MMOL/L)	4.31 ± 0.41	4.31 ± 0.37	0.77
NA (MMOL/L)	139.0 ± 2.97	139.3 ± 2.56	0.93
AST (U/L)	26.9 ± 18.0	20.3 ± 4.24	0.22
ALT (U/L)	30.5 ± 20.9	23.1 ± 9.76	0.15
CK (U/L) MB (U/L)	123.3 ± 171.6 13.4 ± 7.99	90.6 ± 48.9 13.1 ± 6.66	0.08 0.74
TN (U/L)	0.03 ± 0.08	0.03 ± 0.02	0.95
TEE (%)	97.4 (149)	100.0 (40)	0.58
ECHOCONTRAST (%)	20.3 (31)	25.0 (10)	0.77
LA (MM)	50.8 ± 8.17	50.3 ± 6.95	0.90
NORMAL LA <50MM (%)	70 (45.8)	17 (42.5)	0.86
LV TSD (mm)	34.0 ± 7.14	32.6 ± 6.67	0.31
NORMAL LV TSD <36mm (%)	51.6 (79)	57.5 (23)	0.59
LV TDD (MM)	51.1 ± 6.32	48.6 ± 5.47	0.04*
NORMAL LV TDD <57mm (%)	71.9 (110)	85.0 (34)	0.18
LV TSV (ML)	47.4 ± 22.6	44.5 ± 16.0	0.95

NORMAL LV TSV <50ml (%)	61.4 (94)	57.5 (23)	0.48
LV TDV	101.7 ± 33.1	102.1 ± 26.3	0.62
NORMAL LV TDV <140ml (%)	81.1 (124)	82.5 (33)	0.55
EF (%)	55.7 ± 8.55	56.4 ± 8.17	0.34
NORMAL EF > 50% (%)	69.9 (107)	70.0 (28)	1.00
ASA CLASS			0.02*
CLASS 1	1.96 (3)	7.50 (3)	
CLASS 2	64.7 (99)	35.0 (14)	
CLASS 3	30.7 (47)	50.0 (20)	
CLASS 4	2.60 (4)	7.50 (3)	
FIRST DIAGNOSIS			
AH (%)	55.6 (85)	47.5 (19)	0.46
CAD (%)	7.84 (12)	2.50 (1)	0.31
CMP (%)	6.54 (10)	7.50 (3)	0.73
VALVE (%)	18.3 (28)	40.0 (16)	0.01*
NONE (%)	11.8 (18)	2.50 (1)	0.13
ANESTHETIC			
PROPOFOL DOSIS (mg)	117.4 ± 32.0	122.5 ± 40.8	0.64
ANTICOAGULATION			
SINTROM (%)	89.5 (137)	90.0 (36)	1.00
HEPARIN (%)	7.19 (11)	10.0 (4)	0.52
NOAC (%)	3.27 (5)	0.00 (0)	0.59
ANTIARRHYTMIC DRUGS			
AMIODARONE (%)	69.9 (107)	67.5 (27)	0.92
BETA BLOCKER (%)	45.1 (69)	45.0 (18)	1.00
CCB (%)	6 (3.92)	7 (17.5)	0.01*
DIGITALIS (%)	3.27 (5)	5.00 (2)	0.64
PROPAFENONE (%)	11.8 (18)	2.50 (1)	0.13
NUMBER DRUGS	1.34 ± 0.49	1.38 ± 0.54	0.85
ACE INHIBITOR/ARB (%)	64.7 (99)	60.0 (24)	0.74
ATROPIN BEFORE (%)	34.6 (53)	37.5 (15)	0.83
HR BEFORE (bpm)	93.6 ± 20.0	96.5 ± 19.7	0.32
SYSTOLIC BP (mmHg)	133.7 ± 16.5	132.4 ± 13.3	0.55
DIASTOLIC BP (mmHg)	85.1 ± 12.3	81.5 ± 11.1	0.04*

Note: *: p<0.05 marks significant differences.
BMI: body mass index, BSA: body surface area, BW: body weight, HF: heart failure, TSH: thyroid stimulating hormone, COPD: Chronic obstructive pulmonary disease, GFR: glomerular filtration rate, TEE: transesophageal echocardiogram, LA: left atrium, LV: left ventricle, TSD: telesystolic diameter,TDD: telediastolic diameter,TSV: telesystolic volume,TDD: telediastolic volume, EF: ejection fraction, ASA: the American Society of Anesthesiologists physical status classification system, AH: arterial hypertension, CAD: coronary artery disease, CMP: cardiomyopathy, Valve: valvular heart disease, CCB: calcium channel blocker, HR: heart rate, BP: blood pressure.

Cardioversion results

Efficacy

The results of the cumulative success rates achieved after each shock are summarized in [Table 2]. They indicate that after the final 3rd shock of the BTE stack, the cumulative success rates are very high and insignificantly different for both groups (PE and LE): 146 (95.4%) patients from PE group are converted against 37 (92.5%) from LE group (p = 0.90), considering AF and AFL patients together. The same insignificant differences of the cumulative success rates are observed for the treatment of AF and AFL patients separately with both PE and LE stacks. Moreover, the total number of delivered shocks with both devices do not differ: 1.63±0.83 (PE) vs. 1.70±0.88 (LE), p = 0.67. Finally, the cumulative success rate is not found to be

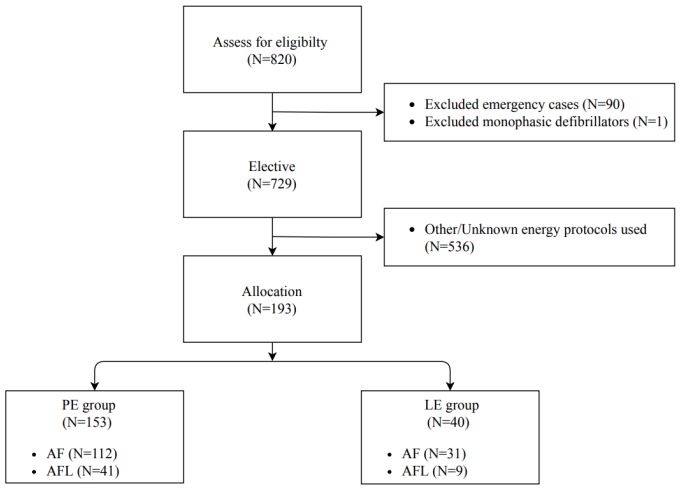
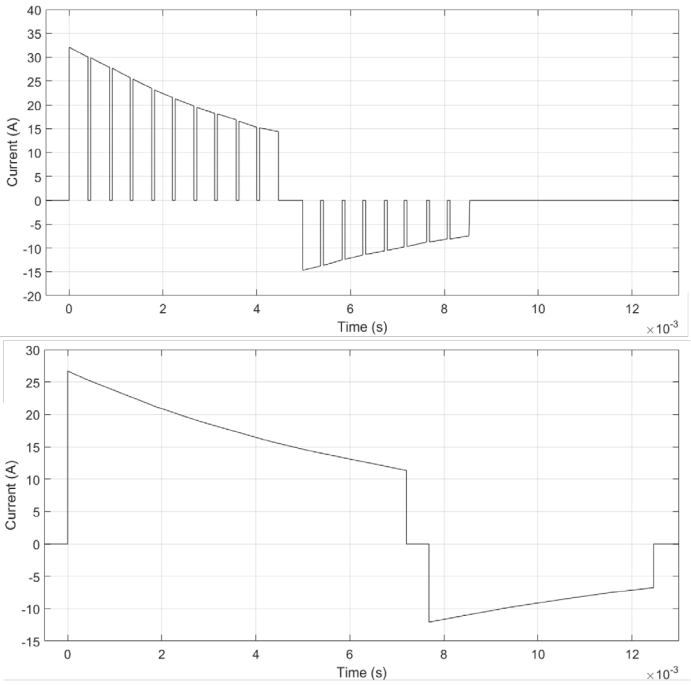


Figure 1: CONSORT flow diagram showing the patient allocation groups.



Rhythm	Group 1 DG4000 (PE)	Group 2 HeartStart XL (LE)
AF	120J-200J-200J	100J-200J-200J
AFL	30J-120J-200J	30J-100J-200J

Figure 2: Waveforms of PE (top trace) and LE (bottom trace) recorded during ECV interventions with energy setting of 200J and a patient impedance of 75Ω. Below, the escalating energy protocol applied at 1st-2nd-3rd shocks for both waveforms.

Table 2: Number of patients shocked (PS) and cumulative success rate (CSR) at each ECV shock for patients (AF+AFL) grouped to BTE waveforms (PE and LE). The values are reported as % (number of patients N). The last shock delivered is a monophasic shock (MS). Both groups (PE and LE) are compared with Model 1 and Model 2, reporting their respective OR [95% CI].

Shock number	Energy Setting PE (J)	Energy Setting LE (J)	Outcome	PE (N=153)	LE (N=40)	Model 1 OR [95% CI]	Model 2 OR [95% CI]
1	120	100	PS	100% (153)	100% (40)	-	-
			CSR	54.9% (84)	52.5% (21)	0.78 [0.37–1.6]	0.56 [0.21–1.5]
2	200	200	PS	45.1% (69)	47.5% (19)	0.98 [0.43–2.1]	1.11 [0.39–3.0]
			CSR	86.3% (132)	82.5% (33)	0.57 [0.22–1.6]	0.35 [0.09–1.5]
3	200	200	PS	13.7% (21)	17.5% (7)	1.83 [0.52–5.8]	2.30 [0.48–9.9]
			CSR	95.4% (146)	92.5% (37)	0.35 [0.07–1.9]	0.25 [0.03–2.2]
4(MS)	360	360	PS*	4.5% (7)	5.0% (2)	-	-
			CSR	97.8% (149)	92.5% (37)	0.23 [0.04–1.4]	0.13 [0.09–1.8]

*OR were not assessed for PS 4 due to the too small sample size.

associated with any confounding factors in both regression models (i.e. age, gender, BMI, diabetes, renal failure and AF/AFL duration, baseline characteristics, etc.).

[Figure 3] compares the cumulative success rates of PE and LE groups, depicted in function of the cumulative energy setting after each shock. Although there are disparities in the protocols of both PE and LE groups, we do not notice any significant differences in the distributions of both types of cumulative energies (reported as median values [interquartile range]): cumulative energy setting (120J [120-320J] for PE vs. 100J [100-300] J for LE, p = 0.93) and cumulative delivered energy (122J [119-320J] for PE vs. 134J [103-315J] for LE, p = 0.34).

Overall, only 9 (4.7%) patients are not converted with BTE shocks and received monophasic shocks [Table 2]. Among them, 7 (4.5%) are treated with PE waveform and 2 (5.0%) with LE waveform. Sinus rhythm has been restored only for 3 (2.0%) patients from the PE group using monophasic shocks. This difference between both groups conversion after 3 BTE shocks is not significant (OR [95% CI] = 0.25 [0.03–2.2]). In addition, there is no difference in baseline characteristics between successfully and unsuccessfully converted patients. However, all unsuccessful patients present a structural heart disease.

Cumulative energy setting differs with patient characteristics. Using a multivariate linear regression, six variables are found to be significantly associated with efficient cumulative energy setting: AF/AFL duration, gender, BSA, LVtdd, valvular disease and chronic respiratory disease. The efficient cumulative energy is higher for men (β = 61.8, p =0.05), increases with the AF/AFL duration (β = 0.24, p=0.01), BSA (β = 131.5, p=0.05), LVtdd (β = 6.0, p=0.02) and the presence of chronic respiratory disease (β = 136.5, p = 0.01), while decreases with the presence of valvular disease (β = - 65.8, p=0.05).

The safety of each waveform is evaluated, comparing Hs-cTnI before and after ECV [Table 3]. No difference between both groups is found in Hs-cTnI levels before and after ECV, or in their normalized ratio (p>0.05).

Table 3: Hs-cTnI levels before and after ECV

Troponin levels	PE (N = 153)	LE (N=40)	p
Hs-cTnI before ECV (µmol/L)	0.026±0.077	0.027±0.019	0.87
Hs-cTnI after ECV (µmol/L)	0.034±0.087	0.029±0.019	0.49
(Hs-cTnI before - Hs-cTnI after)/(Hs-cTnI before)	0.539±1.582	0.304±0.922	0.25

Discussion

This is the first clinical trial, which compares PE and LE waveforms. Using the cumulative success rate as the primary endpoint; the superiority of the LE waveform could not be demonstrated in the present study.

The lack of difference in efficacy between both devices is in accordance with previous comparisons between biphasic waveforms. In fact, no difference in cardioversion efficacy was reported in other studies comparing RB vs. HE waveforms (Alatawi, 2005; Kim, 2004; Neal, 2005) or RB and LE waveforms (Deakin, 2013). Only one study (Schmidt, 2017) comparing the success rate of HE and PE waveforms showed a difference (89% vs. 67%). The lower success rate obtained with the PE waveform could be explained by the use of a defective device as mentioned by this research team (Schmidt, 2017).

The success rates of both BTE waveforms estimated in this work are in accordance with previously published results. A study comparing RB and LE shocks (Deakin, 2013) reported a cumulative success rate of 90.9% for LE waveform. This study also used an escalating protocol with a comparable final energy (200J) and the same definition of success (1 minute post-cardioversion). This success rate is not statistically different to our results (p = 0.76).

PE, LE and HE are BTE waveforms using the same impedance compensation method (varying the pulse duration). However, these waveforms differ in various design characteristics, including charging

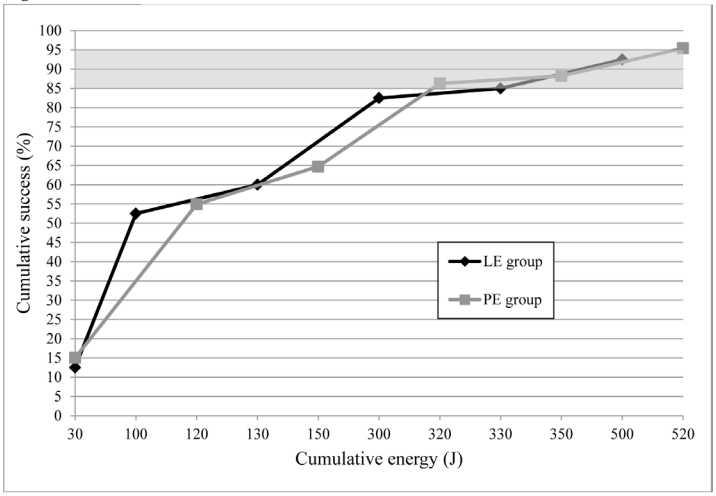


Figure 3: **Cumulative success rate versus cumulative selected energy for patients treated with PE waveform (N=153) and patients treated with LE waveform (N=40). Results for AF and AFL patients are combined.**

voltage (lowest for HE, highest for PE) and charging capacitor (lowest for PE, highest for HE). One study (Anantharaman, 2017) considered that HE and LE shocks differed only by the selected energy levels and by the pulse duration. To compare both groups, the same defibrillator was used. However, the type of the shock (HE, LE or PE) was defined by the waveform characteristics.

In this work, there was no difference in safety: Hs-cTnI levels were not different in both PE and LE groups. These results agree with previous studies, showing no difference in Hs-cTnI levels after ECV between both BTE waveforms (Neal, 2003; Schmidt, 2017). Furthermore, no elevation of Hs-cTnI after the procedure was found according to the literature (Neal, 2003; Schmidt, 2017; Glover, 2008; Vikenes, 2000; Allan, 1997; Bonnefoy, 1997).

In conclusion, we observed a high success rate with both biphasic pulses and no superiority of LE over PE with an excellent safety profile without myocardial injuries.

Limitations

To interpret the findings, limitations must be considered. Ideally, this study should have been randomized. Despite its retrospective nature, both groups are rather similar in baseline characteristics. Skin burns information has not been collected during the study.

In addition, with the small sample size only a power of 80% can be reached. But, the results [Table 2] show a similarity and it is unlikely that a better outcome with a higher power can be attained.

Finally, the energies used in the escalating energy protocol do no match due to slight differences in the energy settings available in both devices. Thus, the energy of the first shock (AF patients) or second shock (AFL patients) is different: 100J for LE waveform and 120J for PE waveform. However, cumulative delivered energies were similar.

Conclusion

This study aimed to compare PE (Pulsed Energy) and LE (Low Energy) waveforms in respect of efficacy and safety. The difference in observed efficacy of the PE vs. LE did not reach statistical significance. No difference in safety between both waveforms was also highlighted.

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