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Assessment of the Efficacy of Pulsed Biphasic Defibrillation Shocks for Treatment of Out-of-hospital Cardiac Arrest

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Abstract: *This study evaluates the efficacy of a Pulsed Biphasic Waveform (PBW) for treatment of out-of-hospital cardiac arrest (OHCA) patients in ventricular fibrillation (VF). Large database (2001-2006), collected with automated external defibrillators (AED), (FRED®, Schiller Medical SAS, France), is processed.*

In Study1 we compared the defibrillation efficacy of two energy stacks (90—130—180 J) vs. (130—130—180 J) in 248 OHCA VF patients. The analysis of the first shock PBW efficacy proves that energies as low as 90 J are able to terminate VF in a large proportion of OHCA patients (77% at 5 s and 69% at 30 s). Although the results show a trend towards the benefit of higher energy PBW with 130 J (86% at 5 s, 73% at 30 s), the difference in shock efficacy does not reach statistical significance. Both PBW energy stacks (90—130—180 J) and (130—130—180 J) achieve equal success rates of defibrillation. Analysis of the post-shock rhythm after the first shock is also provided.

For Study2 of 21 patients with PBW shocks (130—130—180 J), we assessed some attending OHCA circumstances: call-to-shock delay (median 16min, range 11-41 min), phone advices of CPR (67%). About 50% of the patients were admitted alive to hospital, and 19% were discharged from hospital. After the first shock, patients admitted to hospital are more often presenting organized rhythm (OR) (27% to 55%) than patients not admitted (0% to 10%), with significant difference at 15 s and 30 s. Post-shock VFs appear significantly rare until 15s for patients admitted to hospital (0% to 9%) than for patients not admitted to hospital (40% to 50%). Return of OR (ROOR) and efficacy to defibrillate VF at 5 s and 15 s with first shock are important markers to predict patient admission to hospital.

Keywords: *Automated external defibrillator, Pulsed biphasic waveform, Low energy defibrillation, Outcome from defibrillation.*

Introduction

In the last decade, the Public Access Defibrillation is widespread as a program for early termination of ventricular fibrillation (VF) [10], leading to out-of-hospital cardiac arrest (OHCA) resuscitation rates of 14% to 46% [4, 6, 9, 12, 18-21]. The likelihood of survival depends on the response times, i.e. time to defibrillation and time to bystander cardio-pulmonary resuscitation massage (CPR). They are recommended within 6 to 10 minutes from time of collapse [7]. Such fast response could be supported by a wide field network of small, lightweight, and inexpensive automatic external defibrillators (AEDs) accessible for first responders (firefighters, police, and other individuals with responsibility for public safety). An important step in reducing the size, weight and cost of AEDs is improving the defibrillation pulse efficacy. The biphasic pulses for transthoracic defibrillation appeared to achieve the same defibrillation success rates as monophasic waveforms but at significantly lower energy levels [3, 7]. Moreover, low energy shocks for treatment of OHCA are advised by the ERC recommendations to decrease the possible shock related myocardial damage, thus improving the quality of life of OHCA survivors [17]. Therefore, it is important to achieve successful defibrillation with minimum amount of energy.

There is no uniform definition of shock success although transition of VF into any other rhythm has been advocated [22]. The AHA/ILCOR international guidelines propose as a definition of successful defibrillation, the absence of VF at 5 s after shock delivery [7], because this endpoint is not influenced by other subsequent interventions, such as chest compression and ventilation. Many researchers adopt this definition as an endpoint for estimation of the defibrillation efficacy [4, 6, 9, 12, 19, 21], however, there are also studies with different times and criteria accepted. In this respect, Bardy et al. [1] detected return of organized rhythm (ROOR) or asystole within 16 RR intervals after the shock; Van Alem at al. [21] defined as a primary endpoint the ROOR with at least two QRS complexes distanced at maximum 5 s within 1 min after the shock.

Other crucial points for defibrillation efficacy are the energy of the first shock and the energy protocol for a sequence of shocks in case of defibrillation failure. Commercial AEDs operate with various biphasic waveforms, since they have been shown to be efficient in clinical practice [4, 14, 16]. The particular application of AEDs in OHCA should be considered as difficult circumstances for defibrillation, since the first shock arrives several minutes after the onset of the VF, being more severe for termination than VF of short duration [23]. It is recognised that survival rates decrease approximately 7% to 10% with every minute that defibrillation is delayed, reducing to approximately 50% at 5 minute down to 2-5% beyond 12 minutes [5, 13]. The OHCA defibrillation efficacy of the commonly used biphasic truncated exponential (BTE) waveforms is extensively investigated providing results for 150 J [6, 9, 19] and 200 J [12, 21]. Comparative studies of alternative waveforms for defibrillation are usually conducted to give a proof for their efficacy. Such work is provided for the novel Pulsed Biphasic Waveform (PBW) [4], confirming that the efficacy at five seconds after the first lower energy PBW shock (130 J) is not statistically different from the reported results for the BTE waveforms at 150 J-200 J. The same PBW has also been proved to be efficient in terminating atrial fibrillation during cardioversion with energies as low as 90 J [11].

The objective of this study is to provide more evidences for the efficacy of low energy PBW based on statistical evaluation of extensive data collected by AEDs from OHCA patients with VF requiring defibrillation.

Materials

This study considers large databases, collected with AEDs (FRED®, Schiller Medical SAS, France) during OHCA interventions between 2001 and 2006. The AEDs have been applied in the field by fire brigades and emergency service in the region of Nancy (SDIS 54), France, 714 000 inhabitants. The district comprises urban, suburban and rural portions. Standard self-adhesive PAD electrodes for defibrillation have been used, placed in sub-clavicular/sub-axillar position on the chest.

The AEDs under investigation embed a Pulsed Biphasic Defibrillation Waveform, US patented [2]. This technology allows construction of light devices with small capacitors, generating two defibrillation phases with chopped series of alternated active and inactive pulses. The particular FRED® AED model uses two 30 μF capacitors, supplying balanced energy discharge independently for each phase with chopping active and inactive pulses of 100 μs. The resultant pulsed defibrillation pulse is of relatively short duration (4+4 ms), illustrated in Fig. 1 for a common case of 130 J on 80 Ω. Although PBW has high peak voltage and current values, they are delivered for a very short interval (100 μs), applying lower mean currents (twice lower for the presented pulse).

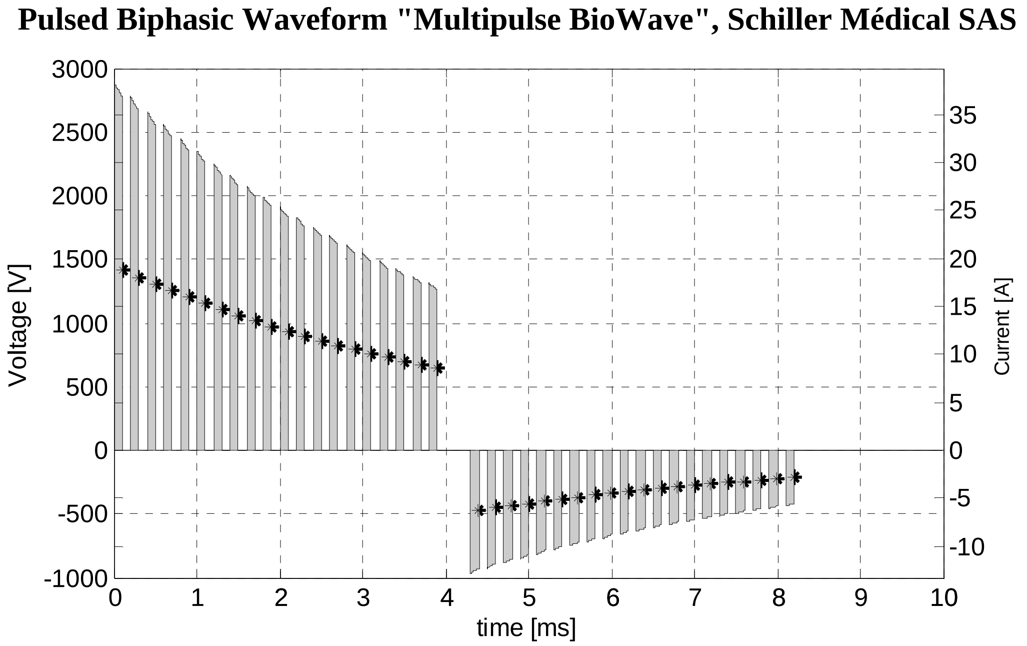


Fig. 1 Example of PBW with energy setting of 130 J applied on 80 Ω
(a load corresponding to the typical human transthoracic resistance in defibrillation).
The trace with "*" marks show the mean current/voltage of the chopped series of pulses

The data of two not overlapping intervention periods are independently studied, including two different populations of patients.

Study 1

- The data is collected between April 2001 and January 2004.
- Up to 77 AEDs were used during the study period, following the AHA/ERC 2000 guidelines for resuscitation [8].
- The data include more than 1200 OHCA patients among whom all 248 patients with shocks are reported in this study.

Study 2

- The data is collected between July 2006 and December 2006.
- 19 AEDs were used during the study period, following the AHA/ERC 2005 guidelines for resuscitation [15].
- The data includes 84 patients among whom only 21 with shocks are considered.

Method

ECG Rhythms

The electrocardiogram (ECG) is acquired via the defibrillation PAD electrodes in a lead equivalent to limb Lead II. The ECG is examined before and after delivery of each transthoracic shock. The expert decision for the rhythm annotation has been taken by biomedical engineer and reviewed by cardiologist.

Three ECG rhythms are recognized as the outcome of defibrillation:

- **Ventricular fibrillation**: pulseless disorganized rhythm with peak-to-peak amplitude of at least 130 μV;
- **Organized rhythm** (OR): at least 2 QRS distanced by less than 5 s;
- **Asystole** (ASYS): ECG amplitude below 130 μV from peak-to-peak.

Successful defibrillation is defined as termination of VF, i.e. post-shock OR or ASYS are considered as successful defibrillation and recurrent or persistent VF is classified as unsuccessful defibrillation.

Measurements for Study 1

- **Shock sequence efficacy:** The AEDs have been configured with selected energy stack of three consecutive shocks (90—130—180 J) or (130—130—180 J), according to the ERC/AHA 2000 recommendations for stacking shocks [7]. The two energy stacks are evaluated independently. The endpoint of the study is the percentage of successful defibrillations counted at post-shock delay of 5, 15, 30 s after the final shock of each energy stack. The final shock could be the first, the second or the third one in the sequence until either successful defibrillation is reached or third shock (energy of 180 J) is delivered.
- **First shock efficacy:** We focus on the efficacy of the first shock for each energy stack defined above, i.e. 90 J or 130 J. The shock success is counted at post-shock delay of 5, 15, 30 s after the very first defibrillation attempt.
- **Rhythm analysis after the first shock:** We studied the rhythm (VF, ASYS or OR) at post-shock delay of 5, 15, 30, 60 s, comparing shocks with 90 J vs. 130 J.

Measurements for Study 2

- **Statistical information:** The AEDs have been configured with selected energy stack of three consecutive shocks (130—130—180 J). We studied some attending OHCA circumstances and outcomes from defibrillation for which we have documented information. We make statistical analysis of the following factors: rate of OHCA bystander witness, proportion of defibrillated patients, call-to-shock delay, admission to hospital, proportion of patients who obtained basic life support from bystander (bystander CPR), place of OHCA, and rate of hospital discharge.
- **First shock efficacy:** The endpoint of this study is the efficacy of the first shock (130 J), measured by two different criteria:

  - Termination of VF at post-shock delay of 5, 15, 30, 60 s;
  - ROOR: measured according to the definition in [21] – detection of at least 2 QRS separated by less than 5 s within 60 s after the first shock.
- **Rhythm analysis after the first shock:** We studied the rhythm (VF, ASYS or OR) at post-shock delay of 5, 15, 30, 60 s, comparing patients admitted vs. not admitted to hospital.

The analysis of the first shock efficacy and the post-shock rhythm aims to find markers to predict patient admission to hospital.

Results

Study 1

From the total number of 248 OHCA patients experienced shocks:

- 48% (119/248) are defibrillated with energy stack (90-130-180 J);
- 52% (129/248) are defibrillated with energy stack (130-130-180 J).

Shock sequence efficacy:

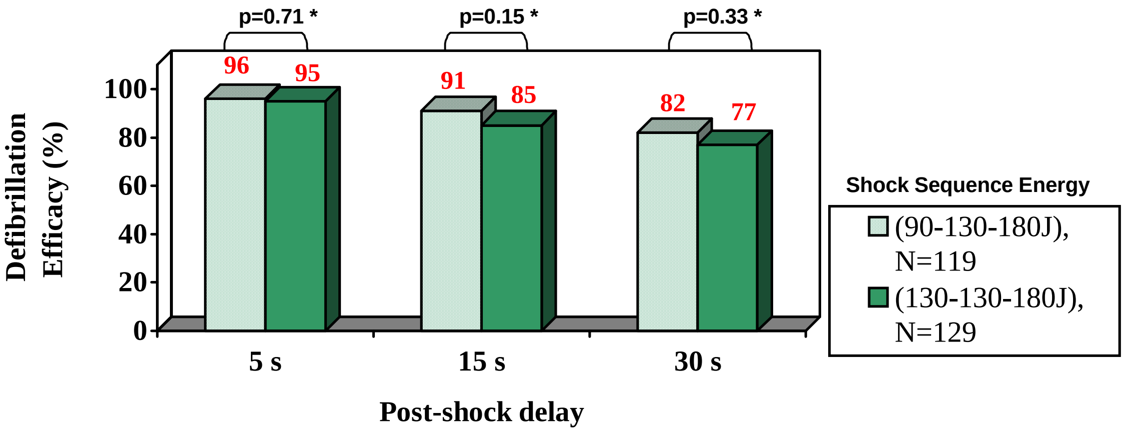


Fig. 2 Comparison between the defibrillation efficacies of the final shock of the **two shock sequences**: (90-130-180 J) vs. (130-130-180 J).
* - p > 0.05 is considered as statistically not significant difference

First shock efficacy:

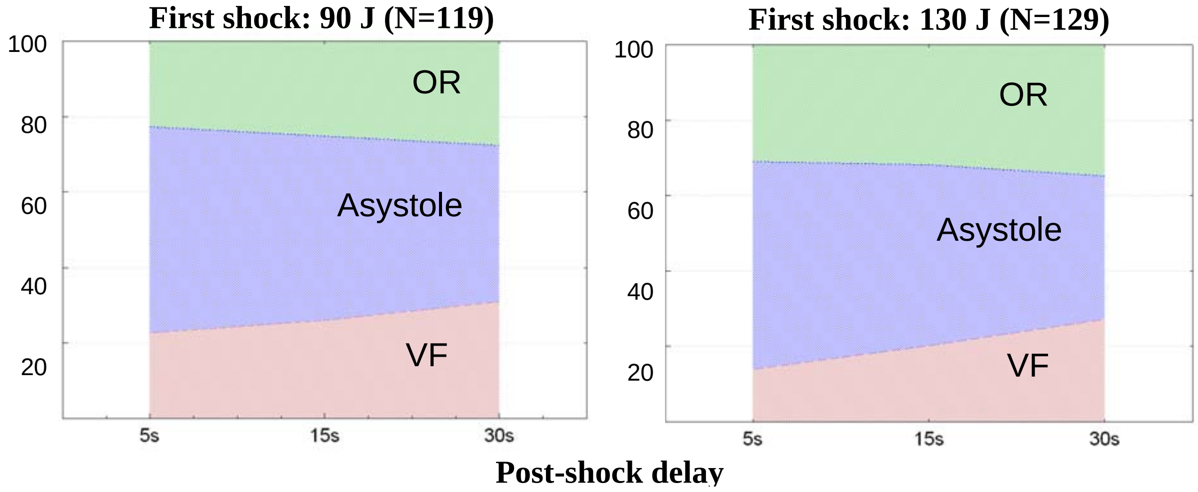


Fig. 3 Time distribution of the post-shock rhythm in dependence of the **first shock** energy: 90 J vs. 130 J

Table 1. The data in Fig. 3 for the distribution
of the post-shock rhythm after the first shocks with 90 J and 130 J

Post-shock delay	**OR**			**ASYS**			**VF**		
	90 J	**130 J**	**p-val.**	**90 J**	**130 J**	**p-val.**	**90 J**	**130 J**	**p-val.**
5 s	22.7%	31%	0.16*	54.6%	55%	1*	22.7%	14%	0.07*
15 s	25.2%	31.8%	0.22*	48.7%	48.1%	0.89*	26.1%	20.2%	0.26*
30 s	27.7%	34.9%	0.24*	41.2%	38%	0.63*	31.1%	27.1%	0.49*

*p > 0.05 is considered as statistically not significant difference

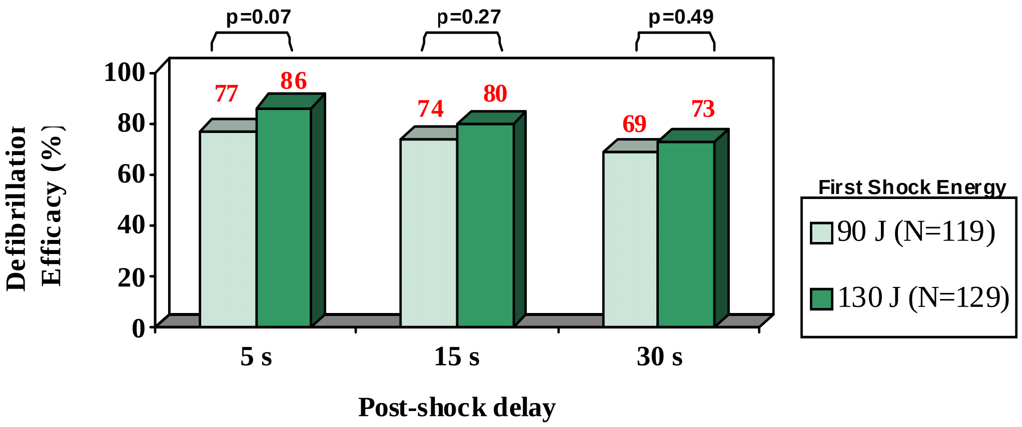


Fig. 4 Comparison between the defibrillation efficiencies of **first shocks**: 90 J vs. 130 J
*p > 0.05 is considered as statistically not significant difference

Study 2

Statistical information

The base line information collected for all **84** patients experienced OHCA is:

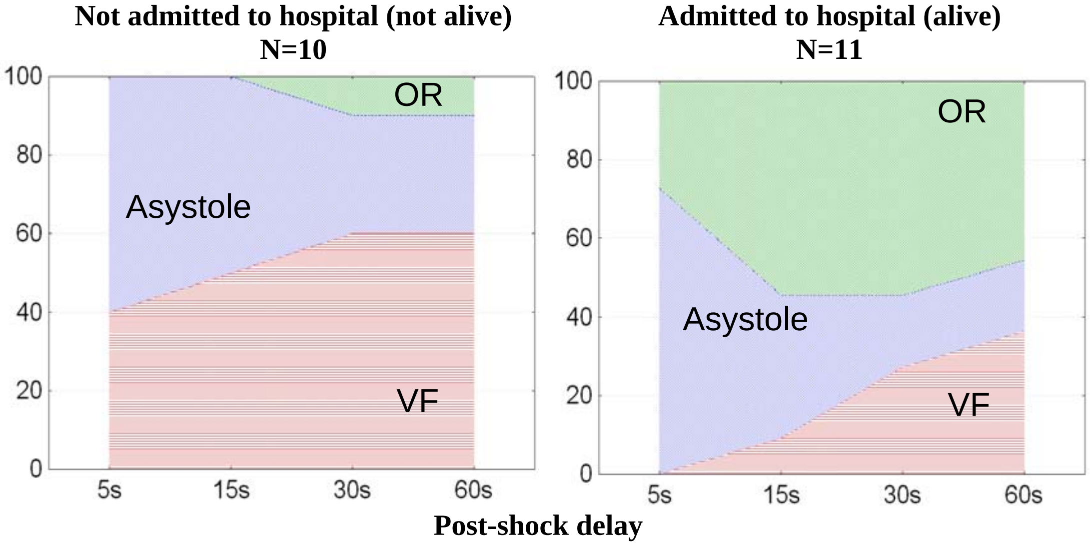
- 64% (54/84) are witnessed among whom:
  - 33% (18/54) are witnessed by rescuers;
  - 67% (36/54) are witnessed by non rescuers.
- 25% (21/84) have documented witnessed VF and are defibrillated.

The statistical information concerning the defibrillation attempts applied to all **21** patients with witnessed VF is as follows:

- Call-to-shock median delay = 16 min (min = 11 min, max = 41 min);
- Bystander CPR: 67% (14/21) patients probably received CPR before arrival of the AED (the person who witnessed the OHCA was advised to apply CPR via the phone):
  - 29% (6/21) received CPR by rescuer who witnessed the OHCA;
  - 38% (8/21) received CPR by non qualified person who witnessed the OHCA (efficiency of CPR is not reported);
  - 33% (7/21) did not receive bystander CPR.
- Place where the patient experienced OHCA due to VF:
  - 48% (10/21) OHCA took place at home;
  - 43% (9/21) OHCA occur in public places;
  - 9% (2/21) OHCA place is not registered.
- Admission to hospital:
  - 52% (11/21) are admitted to hospital (alive patients);
  - 48% (10/21) are not admitted to hospital (not alive patients).

- Patients with VF discharged from hospital alive without neurological alteration:
  - 19% (4/21) is the overall survival to discharge;
  - 36% (4/11) is the survival to discharge for patients admitted to hospital.

First shock efficacy:


Not admitted to hospital (not alive) N=10

Admitted to hospital (alive) N=11

Fig. 5 Time distribution of post-shock rhythm after the **first shock** with 130 J, regarding the admission to hospital

Table 2. The data in Fig. 5 for the distribution of the post-shock rhythm after the first shocks for patients admitted (AD) and not admitted (NAD) to hospital

Post-shock delay	**OR**			**ASYS**			**VF**		
	NAD	**AD**	**p-val.**	**NAD**	**AD**	**p-val.**	**NAD**	**AD**	**p-val.**
5 s	0%	27.3%	0.09*	60%	72.7%	0.54*	40%	0%	0.03
15 s	0%	54.6%	0.01	50%	36.4%	0.52*	50%	9.1%	0.05
30 s	10%	54.6%	0.04	30%	18.2%	0.53*	60%	27.3%	0.14*
60 s	10%	45.5%	0.08*	30%	18.2%	0.53*	60%	36.4%	0.29*

*p > 0.05 is considered as statistically not significant difference

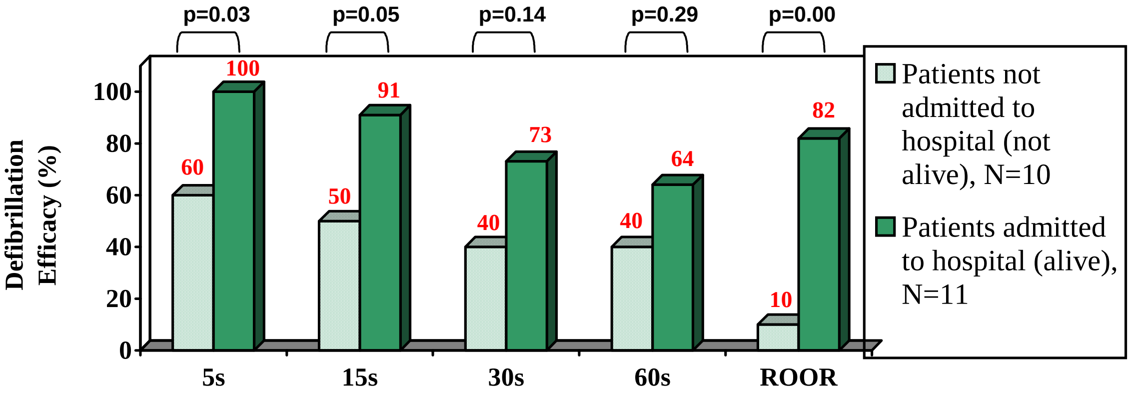


Fig. 6 The post-shock positive outcomes after **the first shock** with 130 J measured as termination of VF at 5 s, 15 s, 30 s, 60 s, and ROOR within 60 s after the defibrillation Two groups of patients (admitted and not admitted to hospital) are compared. *p > 0.05 is considered as statistically not significant difference

Discussion and conclusions

The data reported here support the efficacy of the low energy defibrillation with PBW.

Study 1

The estimation of the first shock efficacy of PBW (Fig. 4) proves that energies as low as 90 J are able to terminate VF in a large proportion of OHCA patients (77% at 5 s, 69% at 30 s). Although the results show a trend towards the benefit of higher energy PBW with 130 J (86% at 5 s, 73% at 30 s), the difference in shock efficacy does not reach statistical significance. The general conclusion is that first shock efficacy with 90 J PBW is not different to 130 J PBW. The later can be used as a reference proved to have the same efficacy at 5 s as commonly used BTE waveforms with initial energy of 150-200 J [4]. In regard to the shock sequence efficacy, the results reported (Fig. 2) support that both PBW energy stacks (90—130—180 J) and (130—130—180 J) achieve equal success rates of defibrillation, estimated at 5, 15, 30 s.

The other aspect is the analysis of the post-shock rhythm after the first shock (Fig. 3, Table 1). It reveals that the most common rhythm is ASYS (55% at 5 s), followed by OR and VF with almost the same probability to occur. However, 130 J is slightly more beneficial than 90 J for restoration of OR (31% vs. 23% at 5 s, p = 0.16). For both 90 J and 130 J, we observe the same tendency of increase of the VF percentage over time due to refibrillation, as suggested in [6], as well as we follow the evolution of some transient ASYS to OR after 5 s.

Study 2

In *Study* 2 we have assessed data for which we have documented information, related to some attending OHCA circumstances influencing the outcome from defibrillation. In our study only 64% of the cardiac arrests were witnessed for which in-time intervention has been provided, increasing the chance for survival. The statistics show that more often OHCA is witnessed by non rescuers (67%), who are not experienced in first aid.

It is relevant to consider only the patients with documented witnessed VF, who are only 25% of the total OHCA incidents. We should underline the high dispersion of call to first shock times (11 min to 41 min, median 16 min); the low rate of bystander CPR before arrival of the AED from qualified rescuer (29%), and from non-qualified person (38%); and the place of VF incident, which is equally probable to occur at home (48%) and at public place (43%). The above factors affect the resuscitation rate, which for population in *Study* 2 is about 50% considering the patients admitted alive to hospital, and 19% considering the patients discharged from hospital without neurological alterations. Nearly 36% from all OHCA patients with VF, who have been admitted alive to hospital, survived to discharge.

In the population of *Study* 2, we assess the 130 J PBW first shock efficacy in respect to OHCA survival until admission to hospital. After the first shock, patients admitted alive to hospital did present OR more often (27% to 55%) than patients that were not admitted (0% to 10%). Significant difference is present at 15 s and 30 s (Fig. 5, Table 2). As expected, an opposite tendency is observed for post-shock VFs which appear significantly rare until 15 s for patients admitted to hospital (0% to 9%) than for patients not admitted to hospital (40% to 50%). Quantifying the PBW first shock efficacy allows to consider potential predictors to hospital admission (Fig. 6). ROOR is the best one, presenting difference of 72% (82% vs. 10%, p=0.004), followed by efficacy to defibrillate VF at 5 s (60% vs. 100%, p = 0.03) and 15 s (50% vs. 91%, p = 0.05). ROOR and Efficacy to defibrillate at first shock are important markers to predict patient admission to hospital.

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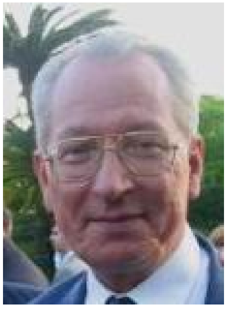

Guy Fontaine was born in 1936 in the city of Corbeil Essonnes in Ile de France a broad area including Paris. After the end of World War II he completed his secondary school in Paris. For the last 30 years he has expanded the frontiers of electrocardiography and clinical electrophysiology. His training in electrical engineering, together with his medical degree was an excellent background to enable him to contribute to this field when he first started his career in the 1960s. He is the author of 827 scientific articles of which 426 are written in English. Among these articles, there are 214 book chapters of which 150 have been published in English. He is the author of five books on different subjects of Electrocardiography or Electrophysiology.

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Manuel Contini, graduated from university of Nancy in 2005 and works as an emergency physician in the Service d'Aide Médicale d'Urgence (SAMU) of Nancy. He is currently managing a MD thesis about analysis of prehospital ECG signals. He is co-investigator in several studies (FINESSE, EVA-AMI, KETASED, MISTRAL) and participated to the development of the REGLOR registry of STEMI in France. His centers of interest concern out of hospital cardiac arrest and ECG analysis.