International Journal of Cardiology 287 (2019) 81–85

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Load distributing band device for mechanical chest compressions: An Utstein-categories based analysis of survival to hospital discharge

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ARTICLE INFO

Article history:
Received 21 January 2019
Received in revised form 7 March 2019
Accepted 18 March 2019
Available online 20 March 2019

ABSTRACT

Purpose: The role of load distributing band device (LDB, AutoPulse®, Zoll Medical Corporation, Chelmsford, MA, USA) in out-of-hospital cardiac arrest is still a matter of debate, with few studies reaching conflicting results available in literature. We sought to assess whether the use of the LBD device could affect survival to hospital discharge in the different Utstein categories.

Materials and methods: All consecutive patients enrolled in our provincial cardiac arrest registry (Pavia CARe) from January 2015 to December 2017 were included and pre-hospital data were computed as well as survival to hospital discharge.

Results: Among 1401 resuscitation attempts, the LDB device was used in 235 (17%) patients. The LDB device was significantly more used for shockable cardiac arrest (42.6% vs 13.7%, $p < 0.001$). The rate of ROSC and of survival to hospital discharge in the LDB group compared to the manual group was 40% vs 17% ($p < 0.001$) and 10% vs 7% ($p = 0.2$), respectively. However, after correction for independent predictors of LDB use, LDB device was a strong independent predictor of survival to hospital discharge only for non-shockable witnessed OHCA [$n = 624/1401$, OR 11.9 (95% CI 1.5–95.2), $p = 0.02$]. In this categories of patients LDB group showed longer resuscitation time [49.3 min (IQR 37–71) vs 23.6 (IQR 15–35), $p < 0.001$] and a higher rate of conversion to a shockable rhythm ($33/83 = 40\%$ vs $29/541 = 5\%$, $p < 0.001$).

Conclusion: Utstein categories-based analysis showed that the LDB device positively affect survival to hospital discharge for non-shockable witnessed cardiac arrests with a neutral effect for shockable rhythms.

1. Introduction

Survival after out-of-hospital cardiac arrest (OHCA) represents a major challenge. Cardiopulmonary resuscitation (CPR) is essential for victims' survival based on its positive hemodynamic effects on cerebral and coronary circulation. Due to possible limitations of manual CPR, many devices for mechanical CPR have been tested from the sixties [1,2]. A load distributing band (LDB) device has been commercialized (AutoPulse®, Zoll Medical Corporation, Chelmsford, MA, USA) from early 2000 (Fig. 1). The LDB device generates blood flow according to the "thoracic pump" when a band surrounds the chest and compress it along its entire circumference cyclically 80 times a minute. When applied on animal models it showed good hemodynamics effects [3–6], but human use has shown conflicting results [7–15] both from randomized and observational studies or meta-analysis [16–19].

The aim of the present study was to assess the role of LDB device versus manual CPR in term of return of spontaneous circulation (ROSC) and survival to hospital discharge in the different Utstein categories of consecutive cases of OHCA.

2. Materials and methods

2.1. Setting and EMS description

The province of Pavia has an extension of 2965 km^2 with several rural and few urban areas with a total population of 548.722 inhabitants (as of December 31st, 2014). In our province, three hospitals are present (one hub center, with a Cath-lab available 24/7,

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https://doi.org/10.1016/j.ijcard.2019.03.037
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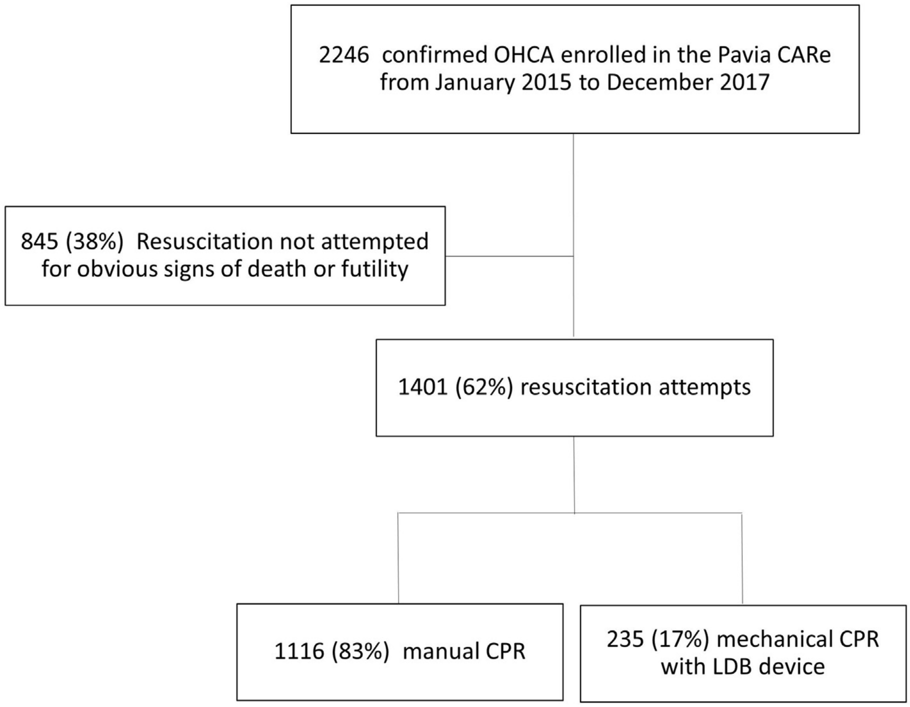

Fig. 1. This figure depicts the flow of data collection.

and two spoke centers). The dispatch center is connected to the European universal number for emergencies (112). As described in previous study, the local EMS dispatcher coordinates 20 ambulances staffed with BLS-D trained personnel, and 4 ALS-trained staffed cars. All the personnel are trained and periodically retrained according to the latest BLS-D and ALS guidelines. The ambulances are equipped with FR2, FR2 and FRX AEDs (Philips, Eindhoven, Netherlands) and ALS cars are equipped with manual monitor defibrillator Corpuls (by GS Elektromedizinische Geräte G. Stemple GmbH, Germany).

In case of a suspected OHCA, one ambulance and the ALS car are activated by the dispatcher. Before rescuers' arrival, the dispatcher assists the calling bystander during chest compression. By December 31st 2017, 503 PADs were available in Pavia's province (updated map available on https://www.areu.lombardia.it/web/home/mappa-dae-lombardia).

2.2. Cardiac arrest registry

The Pavia Cardiac Arrest registry named Pavia CARe [20] is an observational, multicentric, prospective registry of OHCA designed according Utstein style 2015 criteria [21]. It has been approved by our ethical committee in October 2014 (Ethical Committee approval n. 20140028219) and registered on ClinicalTrial.gov (Identifier: NCT03197142). We enroll in the registry all the OHCA for whom the EMS is activated. The variable collected and the definitions follow the Utstein style recommendations.

2.3. Study design and objectives

The present study is a retrospective analysis of prospectively collected data from the Pavia CARe registry.

The main objective of the study was to assess whether the use of a LDB device could increase the rate of ROSC, of survived event and of survival to hospital discharge both in the overall population and in the different Utstein categories.

According to our main objective, the OHCA subjects enrolled in the registry were divided into two groups according on whether a LDB device was used or not. The decision of using a LDB device was taken by the medical doctors on the field according their usual clinical practice. At the light of this, we looked for independent predictors of LDB device use.

2.4. Definitions

According to the Utstein recommendations:

- ROSC is defined as the return to spontaneous circulation with a palpable pulse for at least 30 s.
- "Survived event" indicates ROSC sustained until arrival at the emergency department and transfer of care to medical staff at the receiving hospital.
- Survival at hospital discharge indicates that the patient is alive at the moment of discharge. For those patients whose hospital stay was longer than 30 days, we considered survival at thirty days.
- Utstein categories were: 1) All EMS treated cardiac arrests; 2) EMS witnessed excluded cardiac arrests; 3) Shockable bystander witnessed cardiac arrest (the Utstein comparator group); 4) Shockable bystander CPR cardiac arrest and 5) Non-shockable bystander witnessed cardiac arrest.

2.5. Statistical analysis

Study data were collected and managed using REDCap electronic data capture tools hosted at Fondazione IRCCS Policlinico San Matteo [22]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

Categorical variables were compared with Chi-square test and presented as number and percentage.

Continuous variables were tested for normal distribution with the D'Agostino-Pearson test. If normally distributed, they were compared with t-test and presented as mean ± standard deviation, otherwise they were compared with Mann-Whitney test and presented as median and interquartile range (IQR).

To look for independent predictors of LDB device use, we entered in a multivariable logistic regression model all the variables, which were statistically significant at univariable analysis.

Concerning outcomes (ROSC, survived event and survival to hospital discharge), we tested for each one of the different Utstein categories the use of LDB device in a multivariable logistic regression model with all the statistically significant predictors at univariable analysis and the independent predictors of LDB use.

Statistical analysis was performed via MedCal software (Version 12.5.0.0 by MedCal software bvba). A p value < 0.05 was considered as statistically significant.

3. Results

During the study period, 2246 OHCAs have been enrolled in Pavia CARe registry and resuscitation was attempted in 1401 of them. A LDB device was used in 235 (17%) patients and only manual CPR was used in the remaining 1166 patients (Fig. 1). In OHCA and resuscitation attempts, the mean three years incidence/1000 inhabitants per year was 1.36 and 0.85 respectively. Table 1 shows the baseline characteristics of the study population.

Patients in the LDB group were mainly males, younger, with a higher rate of both witnessed event, bystander CPR and shockable rhythm and showed a significantly longer resuscitation time. Indeed, male gender, age, the presence of a shockable rhythm and of bystander CPR and the

Table 1
Baseline characteristics of the population.

Baseline characteristics				
Variable	Overall $n = 1401$	LDB device $n = 235$	No LDB device $n = 1166$	p
Male gender (%)	844 (60)	197 (83)	647 (55)	<0.001
Age, median (IQR) (years)	77 (65–85)	63 (52.3–71)	80 (68–86)	<0.001
Medical etiology (%)	1304 (93)	223 (95)	1081 (93)	0.29
Home location (%)	1111 (79)	177 (75)	934 (80)	0.12
EMS witnessed event (%)	236 (17)	43 (18)	193 (16)	0.76
Witnessed event (%)	1022 (73)	203 (86)	819 (70)	<0.001
Any bystander CPR (%)	472 (33.7)	121 (51.4)	351 (30)	<0.001
Shockable rhythm (%)	260 (18.6)	100 (42.6)	160 (13.7)	<0.001
EMS response time, median (IQR) (min)	10.7 (8–14)	10.4 (7.6–14)	10.8 (8–14)	0.53
Resuscitation time, median (IQR) (min)	27 (16–42)	51 (36–71)	23.9 (15.2–35.6)	<0.001
ROSC (%)	298 (21)	95 (40)	203 (17)	<0.001
Survived event (%)	240 (17)	71 (30)	169 (14)	<0.001
Survival to hospital discharge (%)	106 (7)	23 (10)	83 (7)	0.203

Medical etiology according to Utstein recommendations 2014; EMS response time: from the emergency call to the arrival of the first emergency team; Resuscitation time: from the arrival of the first emergency team to the end of ACLS.

resuscitation time were independent predictors of LDB device use (Table 2).

As far as the different Utstein categories are concerned, the "EMS witnessed excluded" category counted 1170 (83%) patients (195 in the LDB device group and 975 in the manual group); the "shockable bystander witnessed" counted 174 (12.4%) patients (80 in the LDB device group and 94 in the manual group); the "shockable bystander CPR" counted 150 (11%) patients (68 in the LDB device group and 82 in the manual group) and finally the "non-shockable bystander witnessed" counted 624 (45%) patients (83 in the LDB device group and 541 in the manual group) (Fig. 2D).

At a rough analysis, both the rate of ROSC and of survived event were significantly higher in the LDB group (40% vs 17%, $p < 0.001$ and 30% vs 14%, $p < 0.001$ respectively), while the survival to hospital discharge was similar in the two groups (10% vs 7%, $p = 0.203$).

After correction for all independent predictors of LDB use (Table 2) for each Utstein category, mechanical CPR significantly increased the odds of ROSC and of survived event in all but in the shockable Utstein categories (Fig. 2A and B). As far as the survival to hospital discharge is concerned, the use of the LDB device showed a strong statistically significant favorable effects only for non-shockable bystander-witnessed OHCAs [OR 11.9 (95% CI 1.5–95.2), $p = 0.02$] (Fig. 2C). Moreover, in this category, patients treated with the LDB device showed longer resuscitation time [49.3 min (IQR 37–71) vs 23.6 (IQR 15–35), $p < 0.001$] and a higher rate of conversion to a shockable rhythm (33/83 = 40% vs 29/541 = 5%, $p < 0.001$) with respect to patients treated only with manual CPR.

The use of a LDB device in non-shockable bystander witnessed cardiac arrest was also shown to be an independent predictor of conversion from non-shockable to a shockable rhythm [OR 4.1 (95% CI 2.2–7.6), $p < 0.001$] after correction for resuscitation duration, bystander CPR, epinephrine administered, age and call to arrival time.

Table 2
Multivariable analysis for LDB use.

Multivariable logistic regression model for use of LDB device			
Variable	OR	95% CI	p
Age	0.97	0.96–0.98	<0.001
Shockable rhythm	2.7	1.8–4	<0.001
Male gender	2.3	1.5–3.6	<0.001
Witnessed event	1.9	1.2–3	0.007
Resuscitation time	1.04	1.03–1.05	<0.001
Bystander CPR	1.7	1.2–2.5	0.003

4. Discussion

In the last sixty years, CPR have reached a pivotal role in the treatment of cardiac arrest and its positive role on survival is now undiscussed. On the contrary, mechanical CPR did not manage to confirm its positive role in the treatment of cardiac arrest at least on the general population of cardiac arrest victims. As a result, both the last European and the American guidelines for resuscitation [23,24] recommend their use only for some special situations when maintaining high quality CPR may be difficult such as during transport and they do not refer to a specific device. Actually, the studies are quite inhomogeneous in terms of end-point and design. There are two randomized trials [7,11] with two different end-points: 4 h survival in the paper by Hallstrom et al. (ASPIRE trial) [7] and survival to hospital discharge in Wik et al. (CIRC trial) [11]. The first demonstrated a non-significant trend towards negative results while the second reached similar hospital discharge between LDB and high-quality manual CPR. In addition, there are four observational studies [8–10,12] with different end-points (ROSC for the first one and survival to discharge for the others) and different methodology: comparison with an historical control group [9], comparison with case-matched control group [8,12] or without a control group [10]. Concerning meta-analysis [16–19], only two [18,19] assessed separately the role of piston driven device and of LDB device in term of ROSC and survival to hospital discharge showing conflicting results: a neutral effect in the former and a negative result for LDB in the latter in term of survival with good neurological outcome. All these amount of literature was mainly focused on the entire population of cardiac arrest victims, but we all know that the overall population of OHCA is quite inhomogeneous. Therefore, it appears optimistic to assume that a treatment could be the best choice for all the treated patients. From our perspective, it is more logical to postulate that the treatment could be beneficial only for some categories of patients. That's why we analyzed different categories of patients via an Utstein-categories based analysis looking for differences in benefit. The only study providing data about shockable and non-shockable rhythms which, moreover, has reached similar results to ours, was those by Casner et al. [8]. In that study, even if the average +/−SD response time was 15 +/− 5 min, which is 5 min longer than in the present paper, mechanical CPR (in that paper A-CPR) showed an improvement in the primary outcome when compared with manual CPR with any presenting rhythm (A-CPR 39%, manual 29%, $p = 0.003$). When patients were classified by first presenting rhythm, shockable rhythms showed no difference in outcome (A-CPR 44%, manual 50%, $p = 0.340$). Outcome was improved with mechanical CPR in initial presenting asystole and approached significance with pulseless electrical activity (PEA) (asystole: A-CPR 37%, manual 22%, $p = 0.008$; PEA: A-CPR 38%, manual 23%, $p = 0.079$). In the present study, we not only confirmed the increased survival for non-shockable rhythms at hospital admission like Casner did, but also we demonstrated an increased survival to hospital discharge which is an harder endpoint. Like Casner, we confirmed a neutral effect of LDB device for shockable bystanders-witnessed OHCA patients both in terms of ROSC, of survived event and of survival to hospital discharge. The reason for this probably lies on a priori better prognosis of these patients [25] and on some evidences suggesting that LDB device use could increase the hands off time mostly in the first minutes of resuscitation or delay first defibrillation [7,26,27]. Unfortunately, we don't have data supporting these hypothesis. Among the non-shockable rhythms, notably the LDB device increased the odds of survival to hospital discharge only for those patients with non-shockable bystander-witnessed OHCA meaning that probably those patients with a non-shockable unwitnessed OHCA have such a poor prognosis that even the use of a prolonged mechanical CPR is not able to increase survival. In our experience, the use of a LDB device allowed longer high-quality resuscitation time resulting in a higher rate of conversion to a shockable rhythm, which has been shown to be a

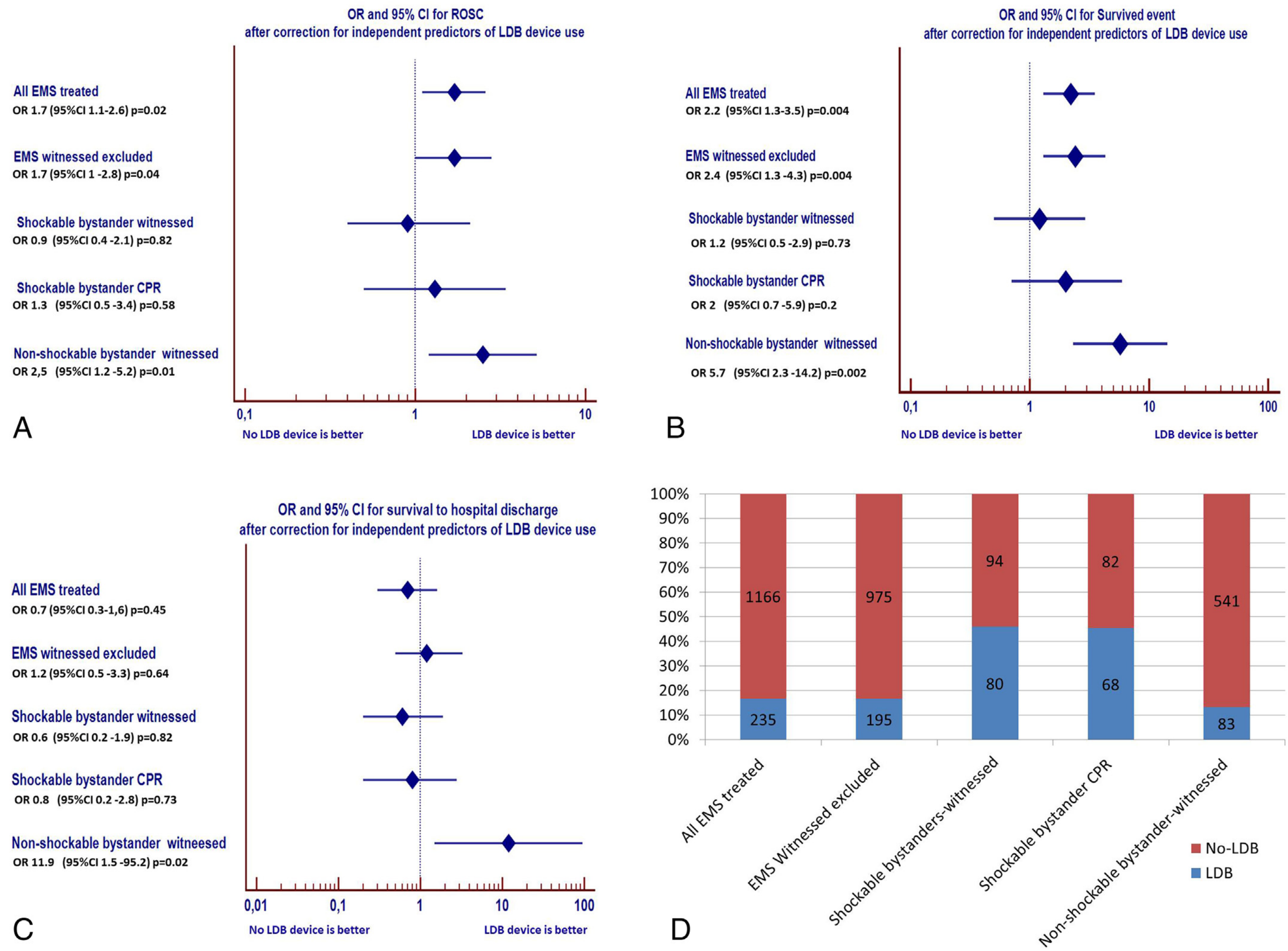

Fig. 2. This figure shows the OR and 95% CI for ROSC (panel A), for Survived event (panel B) and for survival to hospital discharge (panel C) in case of use of a LDB device after correction for independent predictors of LDB use in the different Utstein categories. Panel D shows the distribution of patients in the different Utstein categories.

favorable indicator [28,29] and this could represent the explanation of their better survival.

The last comparison we would like to discuss about is those with a very recent retrospective study published by Seewald et al. [30] from the German cardiac arrest registry. They found that mechanical-CPR was an independent predictor of ROSC in the general population with an OR (1.77) very close to ours. However, exception made for ROSC rate, this study is not easily comparable with ours, first of all because they used both the LDB device and the piston driven device and they analyzed the two devices together under the name of mechanical-CPR. Secondly, even if the predictors of mechanical CPR using were the same as ours, the rate of use of mechanical CPR was only 4.7% (about 2% of LDB device) vs 17% in the present paper. Finally, they did not perform an Utstein categories-based analysis, but they compared the rate of ROSC in the manual and in the mechanical CPR group with the expected rate of ROSC basing on RACA score. No survival analysis has been provided. Therefore, as a matter of fact, the current study is the first providing an Utstein-categories based analysis.

It must finally be underlined that we enrolled in the present study all the treated OHCAs regardless of the etiology, which is different from the previous studies [7–17] where OHCAs of presumed cardiac origin were considered. This could be of interest if you consider that in the present study 5% (12/235 pts) of the patients treated with the LDB device had a non-medical cause with a 50% of ROSC (data not shown in the Results section). Our data reflects a real life use of the LDB device typical of a registry but, above all, they could suggest other potential applications of LDB device and open the way for research in this field.

5. Limitations

This study has some potential limitations. As first, it is not a randomized trial, but it is an observational prospective study. However, even if data from randomized trials are statistically stronger, real life data are closer to what really happens in the daily practice.

Secondly, the study population is not the biggest present in literature, however, it is by far bigger than some previous studies.

The two groups (LDB device and no-LDB) are inhomogeneous. This reflects once again the real life use of the device. We tried to overcome this possible limitation with a correction in the multivariable model for all the independent predictors of LDB use (Table 2).

Finally, we considered all the causes of cardiac arrest and not only those with a presumed cardiac origin. As argued in the Discussion section, this could be a limitation, but it could also be a food for thought.

6. Conclusions

The present Utstein-categories based analysis of survival to hospital discharge showed that the use of a load-distributing band device can increase survival to hospital discharge for non-shockable bystanders witnessed out-of-hospital cardiac arrests with a neutral effect for patients with a shockable presenting rhythm.

Conflict of interest

None of the authors have any conflict of interest to disclose.

Acknowledgment

Special thanks to Maurizio Migliori, MD, Guido Villa, MD, Paolo Galimberti MD and Claudio Mare, MD from AREU Lombardia for the support they give us in carrying out our out-of-hospital cardiac arrest registry Pavia CARe.

Thanks to all the Pavia CARe researchers: From the AAT of Pavia: Vito Sgromo, MD and Enrico Contri, MD; from the intensive care unit Michele Pagani, MD, Francesco Mojoli, MD and Bruno Lusona, MD; from the Cardiac Intensive Care: Rita Camporotondo, MD, from the Cardiology of the Azienda Ospedaliera della Provincia di Pavia: Riccardo Osti, MD and Roberta Bertona, MD.

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