Clinical evaluation of the AutoPulse automated chest compression device for out-of-hospital cardiac arrest in the northern district of Shanghai, China

Chengjin Gao[1], Yuanzhuo Chen[2], Hu Peng[2], Yanqing Chen[2], Yugang Zhuang[2], Shuqin Zhou[2]

[1]Emergency Department, Xinhua Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai, China
[2]Emergency Department, Tenth People's Hospital of Tongji University School of Medicine, Shanghai, China

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Corresponding author:
Chengjin Gao
Emergency Department
Xinhua Hospital
Affiliated to Shanghai Jiao
Tong University
School of Medicine
Kongjiang Road 1665
200092 Shanghai, China
Phone: +8615801985172
E-mail:
chengjingao2003@126.com

Abstract

Introduction: Whether the AutoPulse automated chest compression device is worthy of clinical use for out-of-hospital cardiac arrest (OHCA) remains controversial. A prospective controlled study was conducted to evaluate the effect of AutoPulse versus manual chest compression for cardiopulmonary resuscitation (CPR) of OHCA patients in the northern district of Shanghai, China.
Material and methods: A total of 133 patients with OHCA who were treated at the Emergency Medical Center of the Tenth People's Hospital Affiliated with Tongji University between March 2011 and March 2012 were included. The patients were randomly assigned to the Manual CPR (n = 64) and AutoPulse CPR groups (n = 69) in accordance with the approach of chest compression received. The primary outcome measure was return of spontaneous circulation (ROSC), and the secondary outcome measures included 24-h survival rate, hospital discharge rate, and neurological prognosis at hospital discharge.
Results: The ROSC rate of patients with OHCA was significantly higher in the AutoPulse CPR group than in the Manual CPR group (44.9% vs. 23.4%; p = 0.009). The 24-h survival rate of OHCA patients was significantly higher in the AutoPulse CPR group than in the Manual CPR group (39.1% vs. 21.9%; p = 0.03). The hospital discharge rate of the patients with OHCA was significantly higher in the AutoPulse CPR group than in the Manual CPR group (18.8% vs. 6.3%; p = 0.03). The proportion of patients with OHCA and a cerebral performance category score of 1 or 2 points at hospital discharge was higher in the AutoPulse CPR group than in the Manual CPR group, but the difference was not statistically significant (16.2% vs. 13.4%, p = 1.00).
Conclusions: Use of the AutoPulse increases CPR success and survival rates in patients with OHCA, but its ability to improve cerebral performance requires further evaluation.

Key words: out-of-hospital cardiac arrest, cardiopulmonary resuscitation, return of spontaneous circulation, cerebral resuscitation.

Introduction

High-quality cardiopulmonary resuscitation (CPR) is of great importance to cardiac and cerebral resuscitation [1–3]. However, chest compression often fails to meet relevant guidelines in terms of depth, fre-

quency, and compression/relaxation time [4, 5]. Manual chest compression is not ideal for blood perfusion in most patients. Even when chest compression is performed by a highly trained individual, the generated cerebral blood flow is only 30–40% of the normal level and the cardiac blood supply is only 10–20% of the normal level [6]. Thus, finding a proper automated chest compression device to replace manual chest compression is necessary.

The AutoPulse (ZOLL Circulation, Sunnyvale, CA, USA) is a chest compression device that was approved by the U.S. Food and Drug Administration for CPR in patients who suffer from cardiac arrest (CA) in 2001, and was approved in China by the China Food and Drug Administration in 2007. The AutoPulse is an electrical chest compression device that functions through the compression and relaxation of a load-distributing band connected to a hard board using an electric motor. The operation procedure of the AutoPulse was as follows: first, all clothing was removed from the patient, who was then placed on the hard board following the indicating line; next, both ends of the load-distributing band were fixed with a buckle to the front chest of the patient through the armpit; and finally, the device was started and the load-distributing band was automatically tightened to fit patients of different sizes. The default setting was as follows: compression strength, to reduce the patient's chest volume by 20%; and compression frequency, 80 times/min. The device was designed with continuous and 15:2 compression modes; in the latter case, compressions were performed 15 times and then paused for 3 s in each run, allowing for ventilation of the patient twice. In this research, the 15:2 compression mode was used. However, the compression frequency and two compression modes were fixed and could not be adjusted.

Animal studies have shown that compared to ordinary CPR, AutoPulse-assisted CPR improved cardiac and cerebral hemodynamics as well as neurological prognosis [7, 8]. A human study showed that compared to manual chest compression, the AutoPulse significantly increased the coronary blood flow [9]. In a retrospective study, the return of the spontaneous circulation (ROSC) rate was significantly improved in patients in the AutoPulse CPR group compared to those in the Manual CPR group [10]. A large-scale multi-center prospective study found that compared with patients in the Manual CPR group, those of the AutoPulse CPR group had significantly higher rates of ROSC, hospital admission, and hospital discharge [11].

Earlier research indicated that the AutoPulse was a good choice for clinical use in patients after CA. However, a large-scale multi-center prospective controlled study found that compared with patients of the Manual CPR group, those of the AutoPulse CPR group had a decreased 4-h survival rate (28.5% vs. 29.5%; $p = 0.74$) and hospital discharge rate (5.8% vs. 9.9%; $p = 0.6$) with significantly poor neurological prognosis [12]. Because of the contradictory results from similar studies, whether the AutoPulse is worthy of clinical use in CPR for patients after CA requires more comprehensive evaluation.

On the basis of the above-mentioned studies and Lerner's experience [13], we enhanced the control over the emergency treatment procedure and the professional level of emergency care personnel to minimize various interferences during the research. A prospective controlled study was designed to comprehensively evaluate the effect of the AutoPulse versus manual CPR for OHCA in the northern district of Shanghai, China. The results will provide valuable clinical evidence for the use of the AutoPulse to provide CPR for patients after OHCA.

Material and methods

Study design

The study was designed as a single-center, prospective, randomized, controlled clinical trial. This clinical trial was reviewed and approved by the ethics committee of the Tenth People's Hospital in Shanghai. The inclusion criterion was: patients with OHCA who were admitted to the Emergency Medical Center of our hospital between March 2011 and March 2012. The exclusion criteria were: pregnant females, trauma patients, patients with advanced cancer, or patients aged < 14 years or > 90 years old (Figure 1).

There are 10 ambulances in our Emergency Medical Center, which were encoded from number one to number ten optionally, then five numbers were randomly produced by a computer. The ambulances with the five numbers were equipped with an AutoPulse. The ambulances with or without the device were used in turn to visit the patients. After pre-hospital emergency treatment, all patients were sent to the Emergency Department of the Tenth People's Hospital Affiliated with Tongji University, which has an intensive care unit (ICU) and the corresponding advanced life support technologies. The patients or their families were informed of this research and signed informed consent prior to emergency treatment or after admission to the emergency room. The follow-up was terminated for patients who refused to participate in this research. All emergency personnel were familiar with this device as well as the 2010 American Heart Association (AHA) CPR guidelines. The personnel were familiar with our study design and research procedure.

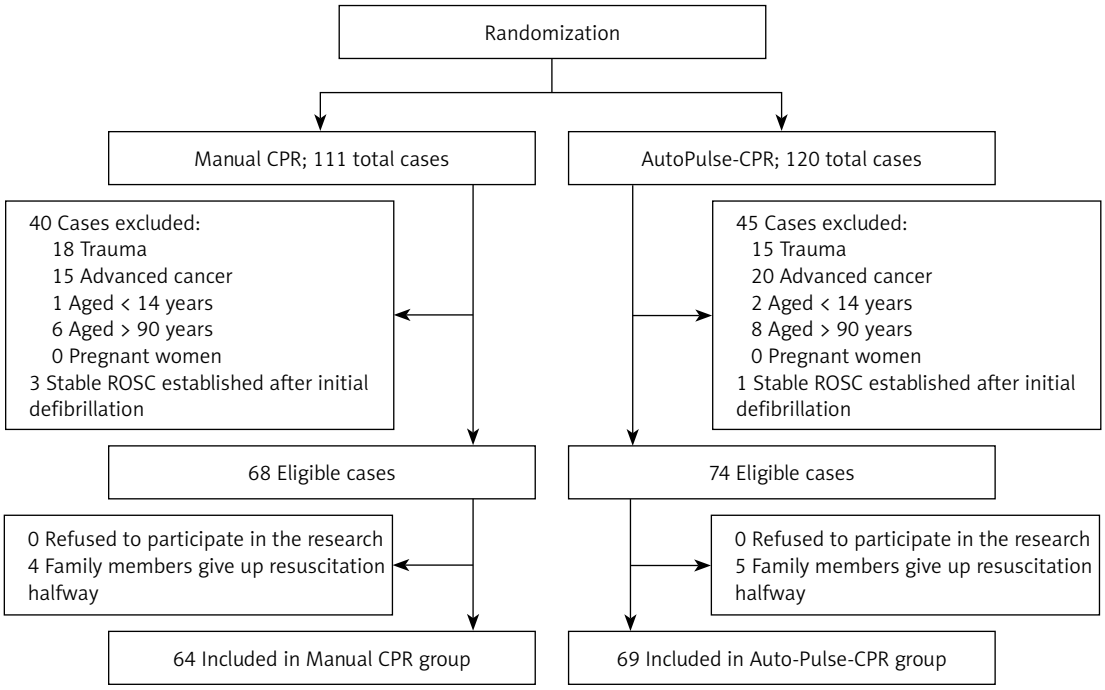

Figure 1. Flow of participants in trial

Research procedure

The unified regimen was as follows: the emergency personnel arrived at the scene and connected the monitor to determine the cardiac rhythm. In the case of ventricular fibrillation or pulseless ventricular tachycardia, defibrillation was performed immediately. If stable ROSC was achieved after defibrillation, then the patient was excluded from the research. If the patient failed to establish stable ROSC or the initial cardiac rhythm was not ventricular fibrillation or pulseless ventricular tachycardia, then the use of the AutoPulse was determined by the presence of this device in the ambulance. In the absence of an AutoPulse, manual chest compression was performed immediately; in the presence of an AutoPulse, 1 person performed manual chest compression while another two persons prepared the device. Endotracheal intubation was conducted simultaneously with balloon-assisted ventilation consisting of 100% oxygen. When the AutoPulse was in place, the patient was placed on the hard board in a supine position. The load-distributing band was connected and fixed as described above. The device was then started to deliver 15 compressions followed by two balloon-assisted ventilations in each run.

Patients who met the inclusion criterion were included in the study. For these patients, an end-tidal carbon-dioxide ($etCO_2$) module was connected to the intubation. Changes in the $etCO_2$ level were monitored and recorded. Chest compression was performed on the patient continuously until ROSC was achieved or death was announced by the emergency personnel. Surviving patients were sent to the emergency room for further treatment, where chest compression was performed in the same way. Patients who demonstrated ROSC before or after admission to the emergency room were changed to a ventilator for ventilation assistance. The ventilator was operated in a mode of volume control ventilation (tidal volume, 8 ml/kg; inspired oxygen concentration, 100%). Vasoactive drugs, antiarrhythmic drugs, a defibrillator [14], and the chest compression rate of the Manual CPR group were used or performed strictly following the 2010 AHA CPR guidelines.

The ROSC status of patients admitted to the emergency room was recorded. Patients who achieved ROSC were admitted to the ICU, where physicians and nurses were not allowed to know whether the patient had been treated with an AutoPulse. The following changes in patient condition were continuously recorded: 24-h survival rate, hospital discharge rate, and neurological prognosis at hospital discharge. Neurological prognosis was assessed in all patients achieving ROSC using Cerebral Performance Category (CPC) scores, which was repeated in those who survived at 24 h and once again in patients at the time of hospital discharge. Patients with multiple CPC scores were analyzed with data from the last scoring.

Statistical analysis

Statistical analysis was performed using SPSS 13.0 statistical software (SPSS Inc, Chicago, IL, USA). Measurement data are expressed as mean ± stan-

dard deviation, while enumeration data are described using the number of cases (percentage). Basic and CPR data of the patients were compared as follows: measurement data using the *t* test and enumeration data using the χ^2 or Fisher's exact probability test. Associations between treatment groups and all end points were analyzed using the χ^2 test. Values of $p < 0.05$ were considered statistically significant.

Results

A total of 133 patients were included in this clinical trial. During the treatment, no patients were changed from the AutoPulse to manual CPR and vice versa. Patients' gender, age, and weight in the Manual CPR and AutoPulse CPR groups are listed in Table I. Weight was provided by the family of the patient or estimated by the researcher. There were no significant differences in the above indicators between the two groups ($p > 0.05$), nor were there significant differences detected in the witness (59.4% vs. 66.7%, $p = 0.38$) or composition of the cardiac rhythm types ($p = 0.32$).

Table II compares the CPR data of patients between the Manual CPR and AutoPulse CPR groups. There were no statistically significant differences in the number of patients receiving CPR before the arrival of professional emergency personnel between groups (25.0% vs. 27.5%, $p = 0.70$), the duration from the emergency call to the arrival of emergency care personnel (11.5 vs. 11.7 min, $p = 0.70$), or the total duration of CPR (33.4 vs. 19.6 min, $p = 0.21$) between groups. In the AutoPulse CPR group, the average device preparation time was 3.4 ±1.0 min. The rates of epinephrine and defibrillation utilization during CPR did not differ statistically significantly between the two groups (87.5% vs. 76.8%, $p = 0.10$ and 20.3% vs. 15.9%, $p = 0.51$, respectively). However, patients in the AutoPulse CPR group had significantly higher $etCO_2$ than those of the Manual CPR group (22.3 vs. 16.1 mm Hg, $p < 0.05$). Also, the 1-h re-

Table I. Comparison of basic patient characteristics between the Manual CPR and AutoPulse CPR groups

Parameter	Manual CPR ($n = 64$)	AutoPulse CPR ($n = 69$)	*P*-value
Male	44 (68.8)	50 (72.5)	0.64
Age, mean ± SD [years]	64.2 ±12.6	62.6 ±14.9	0.53
Weight, mean ± SD [kg]	68.4 ±8.9	67.3 ±8.1	0.47
Witness	38 (59.4)	46 (66.7)	0.38
Cardiac rhythm:			0.32
Ventricular fibrillation/pulseless ventricular tachycardia	8 (12.5)	9 (13)	
Pulseless electrical activity	20 (31.3)	31 (44.9)	
Asystole	32 (50.0)	24 (34.8)	
Others	4 (6.3)	5 (7.2)	

Data are presented as number (percentage) unless otherwise specified; mean values were compared using the t test, while percentages were compared using the χ^2 or Fisher test.

Table II. Comparison of patient resuscitation characteristics between the Manual CPR and AutoPulse CPR groups

Variable	Manual CPR ($n = 64$)	AutoPulse CPR ($n = 69$)	*P*-value
CPR before arrival of emergency care personnel	16 (25.0)	19 (27.5)	0.74
Duration from call to arrival of emergency care personnel, mean ± SD [min]	11.5 ±3.1	11.7 ±2.8	0.70
Total CPR time [min]	33.4 (15.1)	19.6 (19.3)	0.21
AutoPulse preparation time, mean ± SD [s]*	NA	52 ±23	
Epinephrine	56 (87.5)	53 (76.8)	0.1
Defibrillation	13 (20.3)	11 (15.9)	0.51
$EtCO_2$ [mm Hg]	16.1 (5.4)	22.3 (6.1)	< 0.001
1-h return of spontaneous ventilation	7 (10.9)	17 (24.6)	0.04

*Data are presented as number (percentage) unless otherwise specified; mean values were compared using the t test, while percentages were compared using the χ^2 or Fisher test. *Time to apply the AutoPulse and thus terminate manual chest compressions, which was exactly the time to place the patient on the hard board, connect and fix the load-distributing belt, and start the AutoPulse device.*

Table III. Comparison of patient clinical prognosis between the Manual CPR and AutoPulse CPR groups

Parameter	Manual CPR	AutoPulse CPR	*P*-value
ROSC	15 (23.4)	31 (44.9)	0.009
24-h survival	14 (21.9)	27 (39.1)	0.03
Hospital discharge	4 (6.3)	13 (18.8)	0.03

Table IV. Comparison of CPC scores of patients between Manual CPR and AutoPulse CPR groups

CPC score*	Manual CPR (n = 15)	AutoPulse CPR (n = 31)	*P*-value
1	1 (6.7)	2 (6.5)	1.00#
2	1 (6.7)	3 (9.7)	
3	4 (26.7)	5 (16.1)	
4	0 (0)	1 (3.2)	
5	9 (60.0)	20 (64.5)	

*Data are presented as number (percentage) unless otherwise specified; mean values were compared using the t test, while percentages were compared using the χ^2 or Fisher test. *CPC scoring of all ROSC patients; #comparison of the ratio of patients scored as CPC 1 or CPC 2 in ROSC patients at hospital discharge between AutoPulse CPR and Manual CPR groups.*

turn of spontaneous breathing (ROSB) rate was significantly higher in patients in the AutoPulse CPR group than in the Manual CPR group (24.6% vs. 10.9%, p = 0.04).

The patients' clinical prognostic features are shown in Table III. In terms of the primary endpoint, the ROSC rate was significantly higher in the AutoPulse CPR group than in the Manual CPR group (44.9% vs. 23.4%; p = 0.009). In terms of the secondary endpoint events, the 24-h patient survival rate was significantly higher in the AutoPulse CPR group than in the Manual CPR group (39.1% vs. 21.9%; p = 0.03). Similarly, the hospital discharge rate was significantly higher in the AutoPulse CPR group than in the Manual CPR group (18.8% vs. 6.3%; p = 0.03). The neurological prognosis results are shown in Table IV. In the Manual CPR group, 13.4% of the ROSC patients were scored as CPC 1 or CPC 2 vs. 16.2% in the AutoPulse CPR group. Despite a relative increase in the latter group, there was no statistically significant difference (p = 1.00).

With regard to complications, there was a lack of detailed data for comparison of injuries between groups. This is because an autopsy was refused by the families of all patients due to Chinese tradition. As required by patient condition, bedside X-ray examinations were performed upon admission to the emergency room; additionally, all deceased patients were subjected to bedside X-ray examination. The results showed that the incidence of rib fracture was 6.7% in the AutoPulse group (4/60), slightly higher than that in the Manual CPR group (4.8%, 3/63), but the difference was not statistically significant (p = 0.71). Due to the following condition of the illness, 6 patients (two in the Manual CPR group and four in the AutoPulse CPR group) underwent abdominal computed tomography (CT) examinations, in which no abdominal organ injuries were found.

Discussion

Studies have shown that the increased circulating blood flow in CPR is closely related to the success rate of resuscitation [2]. Animal studies in a porcine model of CA confirmed that the AutoPulse generated better blood circulation than manual chest compression [7, 8]. Similar conclusions were obtained in a number of human studies [9, 15, 16]. A retrospective study found that the ROSC rate of patients with CA was significantly higher in those treated with the AutoPulse than in those treated with manual CPR [10]. A recent multi-center prospective study compared the effects of the AutoPulse CPR versus manual CPR, which found that at one of the medical centers, the survival rate of patients in the AutoPulse group declined from 19.6% to 4% after the implementation of an updated experimental program with delayed use of the AutoPulse (p = 0.024); at the other medical centers, the 4-h survival rate at the primary endpoint was significantly higher in the AutoPulse CPR group than in the Manual CPR group (p = 0.008) [17]. The earlier studies confirm that the AutoPulse plays a positive role in CPR and that stable effective blood circulation is a key factor of CPR success.

Our study found that the 1-h ROSB rate was significantly higher in the AutoPulse CPR group than in the Manual CPR group. Basic research has shown that the respiratory center is located in the medulla oblongata and that even a few min-

utes of ischemia and hypoxia injury can cause irreversible brain damage. Thus, the higher ROSB rate indicates that patients treated with the AutoPulse achieved better cerebral blood supply and that the AutoPulse is superior to manual CPR for improving cerebral blood flow. Additionally, we found that the $etCO_2$ level was significantly higher in the AutoPulse CPR group compared to the Manual CPR group. Under normal physiological conditions, the $etCO_2$ level is determined by CO_2 production, pulmonary alveoli ventilation capability, and pulmonary blood flow. When CA occurs, CO_2 is continuously generated *in vivo*. The major influencing factors of CO_2 discharge into the lung are CO_2 transmission speed and volume from the peripheral tissues (CO_2-generating site) to the lung, which depend on the pulmonary blood flow. Thus, if the ventilation remains constant, then the $etCO_2$ level changes reflect cardiac output changes as well as the effect of CPR. In recent years, several studies have reported that $etCO_2$ can be used as a noninvasive monitoring indicator for CPR that is related to prognosis [18, 19]. The 2010 AHA CPR guidelines clarify that during CPR of patients with CA, $etCO_2$ can be used as a physiological parameter to indicate the cardiac output and myocardial perfusion, which helps to optimize the quality of chest compression. Together our results indicate that the AutoPulse is superior to manual CPR for improving cardiac blood flow. Thus, we consider that better cardiac and cerebral blood circulation achieved by mechanical chest compression compared to manual chest compression is the main reason for the high success rate of CPR with the use of AutoPulse.

Additionally, uninterrupted chest compression in a patient by an AutoPulse even during delivery may be another important factor contributing to the high ROSC rate [1–3]. The importance of continuous chest compression was emphasized by the 2010 AHA CPR guidelines. A recent study showed that in the helicopter emergency medical service, the ROSC rate was significantly higher in the AutoPulse CPR group than in the Manual CPR group, mainly because the former strategy achieved sustained chest compression during transportation [20]. A simulation study on a human body suggested that compared to manual chest compression, the AutoPulse achieves more sustained and stable chest compression during transportation [21]. From the occurrence of CA to emergency room admission, patients need to be carried for transportation at least twice. In this process, manual chest compression will inevitably be interrupted, whereas the AutoPulse can avoid this problem. Although AutoPulse preparation requires time (average 52 s in our study), it may bring more benefit by continuous chest compression during transportation than the potential risks that arise from CPR interruption during device preparation.

Cerebral resuscitation remains a major problem in medical science [22, 23]. A large-scale clinical trial showed that only 27% of adults achieved good recovery of neurological function after CPR [24]. Therefore, the ability of the AutoPulse in improving cerebral resuscitation and neurological function recovery should be of concern. Despite the above statement, patients seem to have better cerebral blood supply in the AutoPulse CPR group than in the Manual CPR group. Animal experiments also demonstrated that compared to manual CPR, AutoPulse-assisted CPR more significantly improved the neurological prognosis in a porcine model of CA. However, it is disappointing that we observed no statistically significant difference in neurological prognosis between the AutoPulse CPR and Manual CPR groups.

In terms of complications, there is evidence that compared to manual CPR [25], AutoPulse-assisted CPR increases the risk of organ damage [26–28]. In particular, Truhlar [29] proposed that caution should be taken in the use of AutoPulse in thrombolysis to avoid hemorrhage in the abdominal cavity. Because none of the patients' families consented to an autopsy, we have no detailed data for comparative analysis of relevant organ damage between the two groups. However, bedside X-ray films were taken in all patients upon admission to the emergency room, showing that the incidence of rib fractures was slightly lower in the AutoPulse CPR group than in the Manual CPR group. Thereafter, 6 patients were subjected to abdominal CT examination as required by their condition, and none had abdominal organ damage. Because not all patients underwent the above checks, we could not conclude that the AutoPulse is safer than manual CPR in terms of rib fracture and abdominal organ injury or that there is no difference between the risks of organ damage between the AutoPulse and manual CPR.

It is worth noting that a recent study using a porcine model of ventricular fibrillation indicated that manual chest compression is advantageous compared to the AutoPulse for improving hemodynamic parameters [30]. A retrospective comparative study by Jennings [31] found that compared to conventional CPR, AutoPulse-assisted CPR improves the hospital admission rate but reduces the hospital discharge rate of patients with OHCA. Whether the AutoPulse can improve the prognosis of patients with OHCA remains controversial.

Considering previous studies [12, 13] and the characteristics of the emergency medicine in the Shanghai area, we used a prospective, random-

ized, controlled method in this study. On the basis of the previous studies [11, 12] and the characteristics of emergency medicine, ROSC was chosen as the primary outcome measure, and 24-hour survival, discharge rate and discharge neurologic prognosis were chosen for secondary outcome measures. The parameters of $etCO_2$, defibrillation, use of epinephrine, etc, were also analyzed in the results. Due to the uncertain time and places of cardiac arrest onset, it was difficult to achieve complete randomization for the research. Hallstrom *et al.* [12] assigned the patients to two groups randomly according to the emergency medical services (EMS) station with or without the AutoPulse. However, it was impossible for us to follow because our study was performed in a single emergency medicine center. So we finally equipped half of the ambulances with an AutoPulse randomly by using a computer. It may be the most relevant method to achieve randomization as far as possible.

This prospective study has brought new findings at both the primary and secondary endpoints of clinical events. Data comparison showed that the ROSC, 24-h survival, and hospital discharge rates of patients with OHCA were significantly higher in the AutoPulse CPR group than in the Manual CPR group. However, in the final neurological prognosis, there was no statistically significant advantage in patients with OHCA within the AutoPulse CPR group. Our work represents the first prospective controlled study regarding the clinical use of the new chest compression device AutoPulse for CPR of patients with OHCA in China. The results are of guiding value for application of this device worldwide, especially in China's Emergency System.

The major limitations of our study are as follows: 1) the small sample size may lead to a biased conclusion; and 2) it is difficult to achieve complete randomization based on the grouping method for the ambulance visiting mode because of the particularity of pre-hospital emergency treatment. Due to our present finding that the AutoPulse can improve the ROSC and 24-h survival rates of patients with OHCA, a multi-center prospective study has been designed for in-depth research in China.

In conclusion, in Shanghai's Emergency Medical System in the northern district, AutoPulse CPR is superior to manual CPR for increasing resuscitation success and survival rates in patients with OHCA. This device also improves cardiac and cerebral blood circulation in patients but has no significant positive effect on their neurological prognosis. Thus, we conclude that the AutoPulse is worthy of clinical use but that its application prospects require further comprehensive evaluation.

Conflict of interest

The authors declare no conflict of interest.

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