Resuscitation (2007) **73**, 86—95

ELSEVIER

RESUSCITATION

www.elsevier.com/locate/resuscitation

CLINICAL PAPER

Out-of-hospital cardiopulmonary resuscitation with the AutoPulse™ system: A prospective observational study with a new load-distributing band chest compression device☆

Henning Krep[b,*], Mathias Mamier[a], Martin Breil[a], Ulrich Heister[a], Matthias Fischer[c], Andreas Hoeft[a]

[a] *Department of Anaesthesiology and Intensive Care Medicine, University of Bonn, Bonn, Germany*
[b] *Department of Anaesthesiology and Intensive Care Medicine, University of Cologne, Kerpener Str. 62, D-50924 Köln, Germany*
[c] *Klinik am Eichert, Göppingen, Germany*

Received 30 January 2006; received in revised form 21 August 2006; accepted 31 August 2006

KEYWORDS
Cardiac arrest;
Cardiopulmonary resuscitation;
Automated CPR device;
Load-distributing band CPR device;
AutoPulse™

Summary
Objective: To evaluate the effectiveness, the safety, and the practicability of the new automated load-distributing band resuscitation device AutoPulse™ in out-of-hospital cardiac arrest in the midsized urban emergency service of Bonn city.
Study design: Prospective, observational study.
Methods: Measurements of effectiveness were the proportion of patients with a return of spontaneous circulation (ROSC) and end-tidal carbon-dioxide ($etCO_2$) values during cardiopulmonary resuscitation (CPR). The indications of safety was the proportion of injuries caused by the device, and practicability was assessed by the measurement of the time taken to setup the AutoPulse™.
Results: Forty-six patients were resuscitated with the device from September 2004 to May 2005. In 25 patients (54.3%) ROSC was achieved, 18 patients (39.1%) were admitted to intensive care unit (ICU), and 10 patients (21.8%) were discharged from ICU. End-tidal capnography showed significantly higher $etCO_2$ values in patients with ROSC than in patients without ROSC. The mean time to setup the AutoPulse™ was 4.7 ± 5.9 min, but activation of the device after arrival at the scene in 2 min or less was possible in 67.4%. No injuries were detected after use of the AutoPulse™-CPR.
Conclusion: The AutoPulse™ system is an effective and safe mechanical CPR device useful in out-of-hospital cardiac arrest CPR. Automated CPR devices may play an increasingly important role in CPR in the future because they assure continuous chest compressions of a constant quality.

☆ A Spanish translated version of the summary of this article appears as Appendix in the final online version at 10.1016/j.resuscitation.2006.08.027.

* Corresponding author. Tel.: +49 221 478 4845; fax: +49 221 478 6093.
E-mail address: henning.krep@uk-koeln.de (H. Krep).

0300-9572/$ — see front matter © 2006 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.resuscitation.2006.08.027

Introduction

During cardiopulmonary resuscitation (CPR), adequate perfusion of the heart and the brain is needed to reestablish spontaneous circulation and to achieve survival with a good neurological outcome. If manual chest compressions are performed during CPR, the blood flow to the ''vital organs'' is generally impaired. Even if trained health personnel provides manual CPR, the blood flow in the brain is reduced to approximately 30–40% of the normal blood supply and in the heart to 10–20%.[1] Vital organ blood flow may be even more reduced if the quality of the manual chest compressions is inadequate, because of incorrect compression rate or depth, or frequent interruptions. Suboptimal chest compressions correlate with a poor return of spontaneous circulation,[2,3] and interruptions to chest compression-generated blood flow are detrimental.[4,5] Improved survival of patients with out-of-hospital cardiac arrest was recently reported by Kellum et al. using a CPR protocol minimising the rate of interruptions of chest compressions.[6] A potential solution to overcome the difficulties of suboptimal chest compressions and CPR interruptions may be the use of automated mechanical CPR devices.

The first mechanical CPR device introduced to clinical and preclinical application, the ''Thumper'' (Michigan Instruments, USA), was a mechanical chest compressor using a piston driven by pressurised air and it has been used since the late 1970s.[7] Since then, various devices have been developed. In the present study, the AutoPulse™ system (Zoll Circulation, Chelmsford, MA, USA), a recently introduced device, has been assessed in a prospective observational trial in an urban emergency system. The AutoPulse™ is a fully automated CPR device that uses a load-distributing, broad compression band that is applied across the entire anterior chest. Previous animal and human studies demonstrated an improvement of haemodynamics and short term outcome using the AutoPulse™ technique compared to standard CPR performed by manual chest compressions or using the Thumper.[8–11] In the present observational study, resuscitation success rate was determined by achievement of the return of spontaneous circulation (ROSC), subsequent haemodynamics during AutoPulse™-CPR and long term outcome of the patients. Since invasive monitoring of patients with out-of-hospital cardiac arrest is not feasible, we used end-tidal carbon-dioxide ($etCO_2$) as an indirect measurement of cardiac output.[12] The patients admitted to an intensive care unit were visited daily for the first 3 days after admittance, and the hospital was regularly called until discharge or death. At discharge, the neurological state was evaluated by the attending physician using the Glasgow–Pittsburgh cerebral performance category (CPC), and 6 months after discharge, the patients or the relatives were called again for information about their further recovery.

Material and methods

Study design

The study was approved by the ethical committee of the University of Bonn. We conducted a prospective observational study with the new chest compression device AutoPulse™ on out-of-hospital cardiac arrest patients in the EMS system of Bonn city. Inclusion criteria for the study were aged 18–85 years, and cardiac arrest of non-traumatic origin. Pregnant patients were excluded. The decision to apply the AutoPulse™ system was made individually by the emergency doctors at the scene. Patients admitted to an intensive care unit or their relatives were informed about the study and written informed assent was obtained. Patient data were collected and saved on a personal computer without personal identification.

AutoPulse™ system

The AutoPulse™ system is a portable chest compression device constructed around a back-board that contains a motor to retract a load-distributing band under microprocessor control (Figure 1). The band is connected to a shaft in the board. The band is tightened and loosened around the chest by a motor which alternates rotation of the shaft in both directions. The patient is positioned on the board, the two broad endings of the band are placed around the patients chest and connected to each other. The length of the band automatically adjusts to the size and the shape of the patient. The microprocessor is programmed to provide a constant 20% reduction in the anterior–posterior dimension of the individual patients chest during the compression phase. The compression rate is $80 \pm 5\,min^{-1}$ with equal periods of compression and unloading, and the device can be operated in a continuous compression mode or in a 15:2 mode. In the 15:2 mode, compressions stops for 3 s after 15 have been applied allowing two ventilations to be given to the patient. In the present observational study, all resuscitation attempts were performed in the continuous compression mode.

Figure 1 The AutoPulse™ portable board has a size of ~100 cm × 60 cm and contains a motor to retract the broad load-distributing band (lifeband) under microprocessor control.

Three months before the beginning of the observational study, the AutoPulse™ was introduced to all paramedics and emergency physicians serving in the EMS system of Bonn city. The introduction was followed by individual training on the device, conducted at initially in the presence of an instructor from Zoll Circulation, Germany. Before beginning of the study, an AutoPulse™ device had been available in the EMS department and further training was performed. Two weeks before the beginning of the study, intensive individual training on the device was repeated. During the study period, an instructor from Zoll Circulation, Germany, regularly visited the staff and provided refresher training, if required.

CPR algorithm, measurements, and evaluation of patients outcome

Cardiopulmonary resuscitation of patients with out-of-hospital cardiac arrest was performed using a specific algorithm following the ERC-guidelines 2000.[13] In the specific algorithm that has been used for more than a decade in the EMS system of Bonn, the dose of adrenaline (epinephrine) is given via the trachea. Adrenaline (2.5 mg) in 7.5 ml saline (total volume 10 ml) in prefilled syringes is injected into the bronchi with a small catheter (inner lumen diameter 0.2 mm, length 30 cm).

After connection of the patient to the ECG-monitor (Zoll M-series, Zoll Medical Germany, Düsseldorf), CPR started with basic life support. In case of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT) early defibrillation attempts were performed. If early defibrillation failed to produce ROSC or in non-VF/VT ECG rhythms tracheal intubation was performed immediately and 2.5 mg adrenaline was given endobronchially. Then, a venous line (2.1 mm i.d.) was inserted into an external jugular vein. Except for the first dose of adrenaline given via the tracheal route, other drugs, buffers, and infusions were given i.v. If the patients met the study inclusion criteria, the module of the Zoll monitor to measure end-tidal CO_2 (Novametrix Capnostat 3 Technology) was connected to the tracheal tube and the AutoPulse™ was taken from the emergency ambulance to the scene. After arrival of the AutoPulse™, the upper part of the patients body was briefly lifted to cut the clothes at the back, remove them and to slide the CPR device underneath the patient. Defibrillation patches (Stat Padz, Zoll Medical Germany) were attached to the thorax, the CPR-band was placed around the patients chest and the broad endings were connected to each other. After activation of the AutoPulse™ by pushing the start button, the device automatically tightened the compression band to determine the circumference and the anterior–posterior dimension of the thorax. Then, the device automatically switched over to the compression mode. During CPR with the AutoPulse™, the patient was ventilated manually with 100% O_2 via an Ambu breathing bag (Ambu Deutschland, Friedberg, Germany) connected to oxygen, and the effectiveness of the thoracic compression was verified by the palpation of the pulses in the carotid and femoral artery and by measurement of the end-tidal CO_2. Manual ventilation was performed initially to avoid thoracic pressure peaks caused by simultaneous ventilation and chest compression by the CPR device. After successful CPR with ROSC, the patients were ventilated (Medumat Standard, Weinmann, Hamburg, Germany) with 100% O_2 and tidal volumes of approximately 10 ml/kg and minute volumes of approximately 100 ml/kg bodyweight. The values of $etCO_2$ and oscillometric blood pressure, oxygen saturation, and the ECG recordings were saved on a PCMCIA-memory card in the Zoll monitor. Furthermore, the monitor works with a code marking technology allowing the

timepoints of drug administration, defibrillation, or other therapeutic interventions to be recorded in real time. All data were saved and analysed on a personal computer using the Zoll data control software. Vasopressors, anti-arrhythmics, buffers and DC-countershocks during CPR were given according to the ERC-guidelines 2000. CPR was continued until ROSC, or until the emergency doctor at the scene decided that CPR should be stopped. Patients with ROSC were taken by the emergency ambulance to the hospital closest to the scene capable of admitting the patient to the intensive care unit (ICU).

For the first 3 days after admission, the patients were visited daily and the results from haemodynamic measurements or blood analyses, drug therapy, and neurologic performance were saved on a worksheet. Neurological recovery was evaluated by the attending physicians, who were not informed about the use of the AutoPulse™, using the Glasgow—Pittsburgh cerebral performance category (CPC).[14] If the patients survived >72 h, the attending physicians on the ICU were regularly and briefly interviewed by telephone about the patients state during the ensueing weeks. After discharge from ICU, the attending physicians were asked to give a final classification of the neurological recovery of the patient using the CPC. Six months after discharge from the ICU, the patients or the relatives were interviewed by telephone about their further recovery.

Statistical analysis

All data assessed during CPR or during the hospital stay are given in mean ± standard deviation (S.D.). Differences in the $etCO_2$ between patients with ROSC or without ROSC were analysed using a one-way analysis of variance (ANOVA). Statistical significance was assumed for $p < 0.05$.

Results

Patients, cardiac arrest, and CPR characteristics

The study was performed in the EMS system of Bonn from September 2004 until May 2005. During this period, the AutoPulse™ was applied in 46 patients during CPR. The patients demographic data such as mean age, sex, and mean weight are given in Table 1. In patients resuscitated with the AutoPulse™, 63.0% of the cases cardiac arrest was witnessed, and in 30.4% bystander CPR was performed (Table 1). The initial ECG-rhythm was asystole in 52.2%, ventricular fibrillation or ventricular tachycardia in 17.4%, pulseless electrical activity (PEA) in 21.7%, and in 8.7% other ECG-rhythms such as brady-arrhythmias were recorded. The mean period from the arrival of the AutoPulse™ on the scene until the device was setup was 4.7 ± 5.9 min (median 2; range 1—25 min). In

Table 1 Demographic data and CA/CPR characteristics ($n = 46$) of patients with AutoPulse-CPR

	Mean (±S.D.)	Median
Age (years)	66.3 (±15.4)	
Gender (%male)	71	
Weight (kg)	78.7 (±13.2)	
Witnessed CA (%)	63.0	
Bystander CPR (%)	30.4	
ECG-rhythm (%)		
Asystole	52.2	
VF/VT	17.4	
PEA	21.7	
Others	8.7	
Duration until AutoPulse setup (min)	4.7 (±5.9)	2
AutoPulse-CPR (min)	18.4 (±12.3)	17
Sufficient (%)	91.3	
Palpable pulse* (%)	77.8	
Conversion asystole/PEA into shockable ECG-rhythm (%)	41.3	
Duration of CPR (manual CPR + AutoPulse) (min)	29.0 (±14.6)	26
DC-countershocks (n)	3.8 (±5.9)	1
ROSC (%)	54.3	

* Carotid or femoral artery.

Table 2 CPR characteristics of patients with AutoPulse-CPR

	Mean (±S.D.)	Median
Patients with ROSC ($n = 25$)		
Duration until AutoPulse setup (min)	4.5 (±5.7)	2
AutoPulse-CPR (min)	13.5 (±9.6)	10
Sufficient (%)	92.0	
Palpable pulse* (%)	83.3	
Conversion asystole/PEA into shockable ECG-rhythm (%)	56.0	
DC-countershocks (n)	5.2 (±6.7)	3
Patients without ROSC ($n = 21$)		
Duration until AutoPulse setup (min)	5.0 (±6.2)	3
AutoPulse-CPR (min)	25.0 (±12.8)	26
Sufficient (%)	90.5	
Palpable pulse* (%)	71.4	
Conversion asystole/PEA into shockable ECG-rhythm (%)	23.8	
DC-countershocks (n)	2.1 (±4.0)	0

* Carotid or femoral artery.

47.8% (22/46) patients, the AutoPulse™ setup was accomplished within 2 min, and in 67.4% (31/46) within 3 min. The mean duration of CPR with the device was 18.4 ± 12.3 min, and the mean duration of complete CPR including manual chest compression and AutoPulse™-CPR was 29.0 ± 14.6 min (median 26 min). In 91.3% (42/46) patients, the AutoPulse™-CPR was considered to be sufficient by the emergency physician, and in 77.8% (36/46) a pulse was palpable in the carotid or femoral artery during CPR. In three cases, CPR with the device was considered insufficient and stopped, and the CPR was continued using a cardiopump (Ambu Deutschland) giving active compression—decompression (ACD) CPR. In two patients, CPR was not improved with the use of the ACD-technique, but one patient was successfully resuscitated. The weight of this female patient was 120 kg. Conversion of asystole or PEA into a shockable ECG rhythm occurred in 41.3% (19/46) of the patients, and the mean number of DC-countershocks delivered to each patients over all of the cases 3.8 ± 5.9 (median 1). In 25/46 (54.3%) patients, return of spontaneous circulation after AutoPulse™-CPR was achieved. Patients with or without ROSC had a similar period to setup of the CPR device (4.5 min versus 5.0 min; Table 2). In patients with ROSC, the mean operating time of the AutoPulse™ was 13.5 ± 9.6 min, in patients without ROSC the device was operated for almost twice as long. However, despite the different outcome of the two groups, the AutoPulse™-CPR was considered in both groups to be sufficient in 90% of cases by the emergency doctors on the scene. In patients with ROSC conversion of asystole or PEA into a shockable ECG-rhythm was possible in 56% (14/25), whereas electrical conversion was achieved only in 23.8% (5/21) of patients without ROSC. This explains the different number of DC-countershocks applied in the two groups (Table 2). Another explanation for the latter finding was a slight difference in the rate of patients with VF as the initial ECG rhythm between the two groups, 20% (5/25) in patients with ROSC versus 14.3% (3/21) in the group of patients without ROSC (data not shown).

During the study period, an additional 48 CPR attempts were performed by the same EMS personnel without using the AutoPulse™. Table 3 provides demographic data, CA and CPR characteristics of the patients resuscitated via ACD-CPR using a cardiopump (Ambu Deutschland). The demographic data of age, weight, and sex, and the

Table 3 Demographic data and CA/CPR characteristics ($n = 48$) of patients with ACD-CPR

	Mean (±S.D.)	Median
Age (years)	67.4 (±14.4)	
Gender (%male)	58	
Weight (kg)	75.7 (±14.1)	
Witnessed CA (%)	50	
Bystander CPR (%)	33.8	
ECG-rhythm (%)		
Asystole	43.8	
VF/VT	39.6	
PEA	8.3	
Others	8.3	
Duration of CPR (min)	19.3 (±16.7)	13
DC-countershocks (n)	2.9 (±6.1)	2
ROSC (%)	52.0	

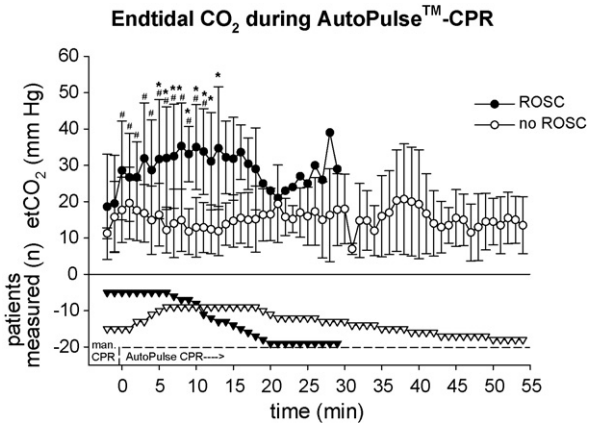

Figure 2 End-tidal CO_2 ($etCO_2$) partial pressure (mmHg) measured during CPR in patients resuscitated successfully (black circles; $n = 15$) and patients without ROSC (open circles; $n = 11$). The first two data points of each time course depict the $etCO_2$ during the last 2 min of manual chest compression, and the time point zero marks the onset of the AutoPulse™-CPR. Statistical comparison of $etCO_2$ values was only performed between patients with ROSC vs. patients without ROSC (ANOVA); $^{*}p < 0.05$.

rate of successful CPR attempts with ROSC (52.0%; Table 3) were similar to the group of patients resuscitated with the AutoPulse™ (Table 1). But more than twice as many of the patients in the ACD group had VF/VT as initial ECG-rhythm (39.6%; Table 3) compared to the AutoPulse group (17.4%; Table 1), and the mean duration of the CPR in the ACD group was only 19.3 ± 14.6 min (median 13 min) versus 29.0 ± 14.6 min (median 26 min) in the AutoPulse™ group. However, it was not the aim of the present study to compare resuscitation success rates with different chest compression techniques, automated CPR versus ACD-CPR, therefore no statistical comparison of the data of the two groups was performed.

End-tidal CO_2-measurements during AutoPulse™-CPR

During CPR end-tidal CO_2-measurements were performed as an indirect measurement of cardiac output. In the upper part of Figure 2, the $etCO_2$ measurements during CPR in successfully resuscitated patients (black circles; $n = 15$) and patients without ROSC (open circles; $n = 11$) are depicted. The black and open triangles in the bottom part of Figure 2 show the absolute number of patients at the different time points with reliable $etCO_2$ measurements during CPR. The curve showing black triangles started with 15 and decreased over time because patients developed ROSC. The curve showing open triangles started with five, transiently increased to the maximum of 11 patients, but secondarily decreased because CPR-attempts were discontinued. In the other patients, the $etCO_2$ was not measurable at the beginning of CPR. In 20 patients, the $etCO_2$ measurements were not reliable and not included into the averaging. The first two data points in each time course depict the $etCO_2$ during the last 2 min of manual chest compression, and the time point zero marks the onset of AutoPulse™-CPR. In patients developing ROSC, the $etCO_2$ increased sharply after the onset of AutoPulse™-CPR from 18 to 29 mmHg. In this group, the $etCO_2$ was sustained above 30 mmHg for the following 15 min. During this period, $etCO_2$ values from patients with ROSC were significantly higher than from patients without ROSC ($p < 0.05$; ANOVA). From minute 7 until 19, 14 patients developed ROSC, only in one case did CPR last longer than 20 min. Even during this prolonged CPR attempt, the $etCO_2$ remained above 25 mmHg. In contrast, $etCO_2$ values in patients who were not successfully resuscitated only slowly increased during AutoPulse™-CPR and only to a level of 15—20 mmHg. The mean $etCO_2$ during manual chest compression (the last 2 min before onset of the AutoPulse™) in patients without ROSC was 13.8 ± 7.4 mmHg and was not increased by the CPR device (15.2 ± 8.0 mmHg).

Survival rate and neurological recovery

Eighteen (18/46 = 39.1%) of the 25 patients with ROSC were admitted to the ICU (Table 4), 7 patients died during transport, 14 patients (14/46 = 30.4%) survived longer than 72 h, and 10 patients (10/46 = 21.8%) were discharged from ICU after a mean stay of 13.6 ± 10.7 days. Two of the discharged patients showed complete neurological

Table 4 Survival rate and neurologic outcome of patients with AutoPulse-CPR

ICU admission	39.1% (18/46)
Survival 0—72 h	8.7% (4/46)
Survival >72 h	30.4% (14/46)
Hospital discharge	21.8% (10/46)
Mean ICU stay (days)	13.6 ± 10.7
Neurologic state at ICU discharge	
CPC 1	$n = 2$
CPC 2	$n = 1$
CPC 3	$n = 7$
CPC 4	$n = 0$
6-Months survival rate	10.9% (5/46)

CPC, Glasgow—Pittsburgh cerebral performance category.

recovery (CPC 1; Table 4), one patient suffered from mild to moderate neurological disability (CPC 2) and seven patients from severe disability (CPC 3). No patient was discharged in a comatose state. Six months after discharge from the ICU, five patients were still alive and in an unchanged neurological state, three patients had died, and no information was available for the remaining two patients. The three patients who had died were discharged from ICU with a CPC of 3.

Discussion

We performed a prospective observational preclinical study with the new load-distributing band chest compression device AutoPulse™ (Revivant Corporation, Sunnyvale, CA, USA) in the EMS system of Bonn city. Primary goals of the study were to verify the effectiveness, safety, and practicability of the automated mechanical resuscitation device in out-of-hospital cardiac arrest. The effectiveness was shown by the number of patients with ROSC and by the measurement of end-tidal CO_2 during CPR. The safety was determined by the rate of injuries caused by the device, and the practicability was assessed by the measurement of the period to setup the AutoPulse™ and the individual evaluation of the emergency doctors at the scene.

The results of this study demonstrate that the AutoPulse™ system is an effective and safe mechanical CPR device suitable for use in out-of-hospital cardiac arrest CPR. The rate of initially successful resuscitation attempts was 54.3% (25/46 patients) despite the high proportion of patients with asystole or PEA as the initial ECG rhythm (73.9%; 34/46 patients). End-tidal CO_2-measurements, even during prolonged CPR, ranged from 15 to 45 mmHg. However, end-tidal CO_2 values were neither adjusted to blood gases nor correlated with minute ventilation because manual ventilation was performed during CPR. Capnography has been shown to be a valuable measurement during CPR, since $etCO_2$ correlates well with cardiac output[15,16] and ROSC.[17,18] The latter finding has been confirmed recently by ILCOR during the 2005 International Consensus Conference on cardiopulmonary resuscitation.[19] However, $etCO_2$ values during AutoPulse™-CPR were not compared with results from other chest compression techniques in a randomised study design, therefore, we were only able to demonstrate that $etCO_2$ values in patients with ROSC were significantly higher than in patients without ROSC. Since we were the first to measure $etCO_2$ during AutoPulse™-CPR in humans, our observations cannot be compared with results from other publications. In previous human investigations, Timerman et al.[8] demonstrated increased coronary perfusion pressure in terminally ill patients by the AutoPulse™ system compared to manual chest compressions, and Casner et al.[10] reported a significant improvement in the ROSC rate after out-of-hospital cardiac arrest (ROSC 39% versus 29% with manual CPR; $p = 0.003$, χ^2-test). Only recently, two larger preclinical studies with contradictory outcomes were published in *JAMA*.[20,21] In a phased, observational cohort evaluation with intention-to-treat analysis of 783 adults with out-of-hospital CA in an urban EMS system, Ong et al. found increased rates for ROSC and survival after CPR during the period in which the load-distributing band chest compression device AutoPulse™ was used in comparison to the period in which manual chest compressions were performed (34.5% versus 22.5% for ROSC; 20.9% versus 11.1% for survival to hospital admission; 9.7% versus 2.9% for survival to hospital discharge).[20] In the secondary analysis of the 210 patients, in whom the device was applied, 18.1% survived to hospital admission, and 5.7% to hospital discharge. Survivors of both groups, manual versus AutoPulse™-CPR, showed no significant difference in cerebral or overall outcome. However, the authors concluded that a resuscitation strategy using a load-distributing band chest compression device on EMS ambulances is associated with improved survival to hospital discharge in adults with out-of-hospital non-traumatic CA. In contrast, Hallstrom et al.[21] found in a multicenter, cluster-randomised trial on 767 patients (AutoPulse Assisted Prehospital International Resuscitation trial: ASPIRE), performed in 5 centres in the US and Canada, no difference in the primary endpoint of the study, survival to 4 h after the 911 call (24.7% manual CPR group versus 26.7% AutoPulse™ group), and even a worse survival to hospital discharge (9.9% manual CPR group versus 5.8% AutoPulse™ group) associated with a worse neurological outcome. The trend towards worse survival and neurological outcome with the CPR device in the first planned interim monitoring, conducted by an independent data and safety monitoring board after a study period of 6—9 months, resulted in a halt of enrollment in all sites. Although the design of the study, a randomised multicenter trial, should have augmented the external validity, the interpretation of the negative result was complicated by the inclusion of one study site that modified the intervention part way through the study period and yielded different outcomes to the other four study sites. Moreover, the evidence of harm from the AutoPulse™-CPR existed only for patients resuscitated at this particular study site.

Hallstrom et al. provided various potential explanations for the negative study results, i.e. that patients in the manual CPR group could have benefitted from a Hawthorne effect such that manual CPR quality exceeded standard practice,[22] that the deployment time for the device may have been prolonged, that enthusiasm for the automated CPR device could have caused an enrollment bias, and finally that the device could have caused direct physical damage. The last explanation was ruled out after review of the hospital records that did not reveal chest compression injuries. In an editorial in *JAMA*, Lewis and Niemann debated whether the differing conclusions of the two studies may be reconciled.[23] They decided that a definitive conclusion was not possible until additional data would be available. They postulate that future comparative studies will need to pay particular attention to the definition and consistency of the method of use of the device, to measuring the important time intervals with precision, and to ensuring the quality of the manual CPR administered in both trial groups. To our knowledge, Zoll Circulation is planning a new multicentre trial involving leading experts in the US and Europe and in which the difficulties of the study design of the ASPIRE trial will presumably be noted. The trial will presumably be performed in Europe and will be led by Dr. Lars Wik from Norway.

During our observational study, no severe chest compression injuries like rupture of the liver or rib fractures were observed, indicating the safety of the AutoPulse™ technique. This observation stands in line with the ASPIRE trial[22] and two other human studies of the AutoPulse™.[8,10] The only injury that was noticed in some patients were mild abrasions of the skin over the lateral chest as already described.[24] However, broken ribs could have been excluded only in patients admitted to an ICU after chest X-ray. Since autopsies were not regularly performed in patients without ROSC we cannot be entirely certain that rib fractures did not occur in some patients in which the AutoPulse™ was used for almost 1 h.

Besides the efficacy and the safety of a new automated CPR technique, practicability plays a significant role whether it is valuable in out-of-hospital cardiac arrest. For example, the pneumatic vest, to date the only mechanical CPR-technique with a IIa-recommendation by the ILCOR,[13] is not suitable for use in out-of-hospital cardiac arrest due to the large volume and weight of the compressor that is required to inflate and deflate the vest. In contrast, due to relatively small size ($\sim$100 cm $\times$ 60 cm) and weight ($\sim$14 kg), the AutoPulse™ can be carried easily to the scene and be activated very quickly. In approximately two-thirds of our patients, activation of the device was accomplished within 2 min after arrival at the scene. The new ILCOR-guidelines 2005 emphasise the avoidance of no-flow or low-flow periods due to interruptions of chest compressions or inadequate and erratic chest compressions.[19] Continuous chest compression of constant quality may represent the main benefit of automated CPR devices in general. Therefore, recently developed mechanical CPR devices like the AutoPulse™ or the LUCAS™ (Jolife, Lund, Sweden[25]), that are quick to apply and easy to handle, may play an increasingly important role in CPR in the near future. An additional benefit of these two devices is the possibility to transport patients on stretchers and in ambulances without an impairment of the CPR quality. With a board sized $\sim$1 m $\times$ 0.6 m, the AutoPulse™ even allows lifting and transportation of the patient over short distances without the use of a stretcher. In one case of the present observational study, a patient with cardiac arrest due to acute myocardial infarction was transported under continuous chest compression with the AutoPulse™ to hospital for coronary angioplasty. PTCA was performed successfully and the patient was discharged from ICU after 9 days, unfortunately with a severe neurological deficit (CPC 3). The severe neurological disability was presumably caused by the fact that no bystander CPR was performed in this patient, because capnography during AutoPulse™-CPR for 17 min showed continuous $etCO_2$-values > 35 mmHg indicating the efficacy of the CPR. Furthermore, neurological recovery was not supported by therapeutic hypothermia in this patient, nor in the other patients. Ten patients (10.9%) of the study population were discharged from ICU after a mean stay of 13.6 ± 10.7 days. Three patients had only a mild to moderate neurological deficit at ICU discharge (CPR 1 or 2), but seven patients suffered from severe neurological disability. A possible explanation for the high rate of severely disabled patients may be the age of these patients, 70.6 ± 9.7 years. In contrast, patients with a CPC of 1 or 2 at ICU discharge had a mean age of 48.0 ± 7.9 years. However, a great variety of haemodynamic and metabolic factors may compromise neurological recovery after cardiac arrest and cardiopulmonary resuscitation and the discussion of the possible role of these factors in the individual patients is not the issue of this manuscript.

During the earlier part of the study period, an additional 48 patients were resuscitated by the same EMS personnel without the AutoPulse™, mostly because the device was not taken to the scene. Various reasons were responsible for the rare application of the device in the beginning

of the study, but the most frequently provided explanation by the EMS-personnel was that they simply ''forgot'' to take the device to the scene. However, with increasing experience of success, the rate of use rose. In considering the ROSC rate in patients resuscitated via ACD-CPR, no difference is detectable compared to the patients resuscitated with the AutoPulse™. In both groups, the ROSC rate was approximately 50%. This result could be misinterpreted that there was no benefit using the automated device. But the higher fraction of patients with shockable ECG-rhythms (39.6% versus 17.4%) and the shorter duration of CPR (19.3 ± 16.7 min versus 29.0 ± 14.6 min) in the ACD-CPR group provide a plausible explanation for the identical ROSC rates in the two groups. However, the present observational study was not designed to compare resuscitation success rates or survival with different chest compression techniques.

Conclusions

In conclusion, we presented operating experience and resuscitation success and survival rates after out-of-hospital cardiac arrest cardiopulmonary resuscitation with the new load-distributing band chest compression device AutoPulse™. In our observational preclinical study, the AutoPulse™ system proved to be an effective and safe mechanical CPR device for use in out-of-hospital cardiac arrest CPR. Automated CPR devices may play an increasingly important role in CPR in the future because they assure continuous chest compressions of a constant quality. However, the question whether the application of automated CPR devices will be able to increase ROSC and survival rates, or even improve the neurological recovery of resuscitated patients, is controversial as demonstrated by the contradictory results of two recently published larger trials.

Conflict of interest

The authors confirm that they have no financial interest in Zoll Circulation or other conflict of interest in performing the presented study.

Acknowledgements

We would like to thank the emergency doctors of the University Clinics of Bonn and the staff of the emergency medical system of Bonn for cooperation in our study.

References

1. Kern KB. Coronary perfusion pressure during cardiopulmonary resuscitation. Baillieres Clin Anesth 2000;14:591—609.
2. Abella BS, Sandbo N, Vassilatos P, et al. Chest compression rates during cardiopulmonary resuscitation are suboptimal. A prospective study during in-hospital cardiac arrest. Circulation 2005;111:428—34.
3. Abella BS, Alvarado JP, Myklebust H, et al. Quality of cardiopulmonary resuscitation during in-hospital cardiac arrest. JAMA 2005;293:305—10.
4. Valenzuela TD, Kern KB, Clark LL, et al. Interruptions of chest compressions during emergency medical system resuscitation. Circulation 2005;112:1259—65.
5. Kern KB, Hilwig RW, Berg RA, Sanders AB, Ewy GA. Importance of continuous chest compressions during cardiopulmonary resuscitation. Improved outcome during a simulated single lay-rescuer scenario. Circulation 2002;105:645—9.
6. Kellum MJ, Kennedy KW, Ewy GA. Cardiocerebral resuscitation improves survival of patients with out-of-hospital cardiac arrest. Am J Med 2006;119:335—40.
7. Lilja JP, Hill M, Ruiz E, Clinton J. Clinical assessment of patients undergoing CPR in the emergency department. JACEP 1979;8:81—3.
8. Timerman S, Cardoso LF, Ramires JA, Halperin H. Improved hemodynamic performance with a novel chest compression device during treatment of in-hospital cardiac arrest. Resuscitation 2004;61:273—80.
9. Halperin HR, Paradis N, Ornato JP, et al. Cardiopulmonary resuscitation with a novel chest compression in a porcine model of cardiac arrest: improved hemodynamics and mechanisms. J Am Coll Cardiol 2004;44:2214—20.
10. Casner M, Andersen D, Isaacs SM. The impact of a new CPR assist device on rate of return of spontaneous circulation in out-of-hospital cardiac arrest. Prehosp Emerg Care 2005;9:61—7.
11. Ikeno F, Kaneda H, Hongo Y, et al. Augmentation of tissue perfusion by a novel compression device increases neurologically intact survival in a porcine model of prolonged cardiac arrest. Resuscitation 2006;68:109—18.
12. Blumenthal SR, Vorhees WD. The relationship between airway carbon dioxide excretion and cardia output during cardiopulmonary resuscitation. Resuscitation 1997;34:263—70.
13. The European Resuscitation Council. International guidelines 2000 for CPR and ECC—a consensus on science. Resuscitation 2000;46:1—448.
14. Gottschalk A, Burmeister MA, Freitag M, Cavus E, Standl T. Influence of early defibrillation on the survival rate and the quality of life after CPR in prehospital emergency medical service in a German metropolitan area. Resuscitation 2002;53:15—20.
15. Weil MH, Bisera J, Trevino RP, Rackow EC. Cardiac output and end-tidal carbon dioxide. Crit Care Med 1985;13:907—9.
16. Callaham M, Barton C. Prediction of outcome of cardiopulmonary resuscitation from end-tidal carbon dioxide concentration. Crit Care Med 1990;18:358—62.
17. Grmec S, Klemen P. Does the end-tidal carbon dioxide ($EtCO_2$) concentration have prognostic value during out-of-hospital cardiac arrest? Eur J Emerg Med 2001;8:263—9.
18. Sanders AB, Kern KB, Otto CW, Milander MM, Ewy GA. Endtidal carbon dioxide monitoring during cardiopulmonary resuscitation: a prognostic indicator for survival. JAMA 1989;262:1347—51.
19. International Liaison Committee on Resuscitation. 2005 international consensus conference. Part 4: Advanced life support. Resuscitation 2005;67:213—47.

20. Ong MEH, Ornato JP, Edwards DP, et al. Use of an automated, load-distributing band chest compression device for out-of-hospital cardiac arrest resuscitation. JAMA 2006;295(22):2629—37.
21. Hallstrom A, Rea TD, Sayre MR, et al. Manual chest compression vs. use of an automated chest compression device during resuscitation following out-of-hospital cardiac arrest. JAMA 2006;295(22):2620—8.
22. Campell JP, Maxey VA, Watson WA. Hawthorne effect: implications for prehospital research. Ann Emerg Med 1995;26: 590—4.
23. Lewis RJ, Niemann JT. Manual vs. device-assisted CPR. Reconciling apparently contradictory results. JAMA 2006; 295(22):2661—4.
24. Hart AP, Azar VJ, Hart KR, Stephens BG. Autopsy artifact created by the Revivant AutoPulse resuscitation device. J Forensic Sci 2005;50:164—8.
25. Steen S, Liao Q, Pierre L, Paskevicius A, Sjoberg T. Evaluation of LUCAS, a new device for automatic mechanical compression and active decompression resuscitation. Resuscitation 2002;55:285—99.