NICE advice

The AutoPulse non-invasive cardiac support pump for cardiopulmonary resuscitation

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Summary

The AutoPulse is a mechanical cardiopulmonary resuscitation device. It is designed to be used after manual chest compression has been started to reduce rescuer fatigue (and its effect on resuscitation). Two randomised controlled trials and several non-randomised studies show that outcomes are at least non-inferior compared with manual compression. The complete AutoPulse system costs £9400 if bought or £475 per month if rented.

Product summary and likely place in therapy	Effectiveness and safety
• The AutoPulse is a mechanical cardiopulmonary resuscitation (CPR) device in which a battery-powered load-distributing chest band provides automated compression. • The AutoPulse is designed to provide consistent CPR over long periods of time and is intended to reduce the impact of rescuer fatigue and to allow the rescuer to attend to other patient needs. • The device is designed to be used after manual chest compression has been started and can be used both in and out of hospital by trained personnel.	• Two randomised controlled trials have compared AutoPulse CPR with manual CPR (n=767 and n=4231 respectively). The Hallstrom et al. (2006) trial found no statistically significant differences in survival for up to 4 hours after the emergency call. The Wik et al. (2014) trial concluded that compared to high quality manual CPR, AutoPulse CPR resulted in a statistically equivalent survival to hospital discharge. • Two case-controlled studies (n=286 and n=162), 2 historical control studies (n=1011 and n=783), 5-non-controlled observational studies, 2-case report studies and 1-conference proceeding abstract were also identified. • Comparative and non-comparative studies suggest using the AutoPulse CPR is at least as good as manual CPR.

Technical factors	Cost and resource use
• The device can be used to maintain CPR when a patient needs to be moved. • The AutoPulse is powered by a rechargeable battery. • Its use is restricted to adults aged 18 years or over with a chest circumference of 76–130 cm, and a chest width of 25–38 cm.	• The AutoPulse would be added to an existing intervention. • The total purchase cost for the AutoPulse device is around £9,400. The rental cost is £475 per month.

Introduction

Non-traumatic cardiac arrest, or sudden cardiac arrest, is caused by a loss of heart function. The heart stops pumping blood around the body, reducing the blood flow to the brain which may lead to unconsciousness. If blood flow and oxygen are not restored, brain damage and eventually death will occur.

In the UK, the overall incidence of adult in-hospital cardiac arrest has been estimated at 1.6 per 1000 hospital admissions with an overall unadjusted survival to hospital discharge of 18.4% (Nolan et al. 2014). Out-of-hospital cardiac arrest affects approximately 60,000 people in the UK each year (Malhotra and Rakhit 2013), with an estimated survival to discharge rate of 2.2 to12% (Perkins and Cooke 2012). Non-modifiable risk factors for sudden cardiac arrest include coronary heart disease, a family history of coronary heart disease, age (incidence increases with age) and sex (men are at higher risk of sudden cardiac arrest). Modifiable risk factors include smoking, obesity, diabetes, a sedentary lifestyle, increased low-density lipoprotein cholesterol levels and hypertension (Zipes et al. 2006). Heart conditions such as coronary heart disease, heart attack, cardiomyopathy, valvular heart disease, congenital heart disease and electrical problems in the heart (such as Brugada syndrome and long QT syndrome) can lead to sudden cardiac arrest. Common non-cardiac causes of cardiac arrest include trauma, non-traumatic bleeding, intoxication, near drowning and pulmonary embolism (Kuisma and Alaspää 1997).

Cardiopulmonary resuscitation (CPR) is carried out when a person has a cardiac arrest. In manual CPR, 1 or more rescuers manually compress the person's chest and give rescue breaths. The purpose of CPR is to help the blood and oxygen to keep circulating in the body after the heart has stopped pumping. Rescuer fatigue can reduce the effectiveness of manual chest compressions. Although fatigue may not directly affect chest compression rate or rescue breath volume, the proportion of correctly delivered chest compressions has been shown to decrease from 52% in minute 1 to 39% in minute 5 (McDonald et al. 2013). There should be as little delay as possible during the changeover of rescuers, and chest compressions should not be interrupted; even short interruptions can result in a poorer neurological outcome or reduced chance of survival (Resuscitation Council UK 2010).

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of health care professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The AutoPulse is a class IIb medical device for which the manufacturer, ZOLL Circulation, received a CE mark in November 2003. The CE mark was renewed in January 2014.

Description

The AutoPulse device is an automated, portable, battery-powered chest compressor, which provides chest compressions as an adjunct to performing manual CPR. The AutoPulse administers standardised whole chest compressions at a consistent rate of 80±5 compressions per minute. The depth of compression causes a chest displacement equal to a 20% reduction in anterior-posterior chest depth, calculated for each patient according to their chest size. The combination of these factors leads to a constant blood flow to the vital organs (including brain, heart and lungs) and the periphery. The user can select the pattern of compression by choosing between 3 different modes: 30:2 mode gives 30 compressions followed by 2 ventilation pauses of 1.5 seconds, and 15:2 mode gives 15 compressions followed by 2 ventilation pauses of 1.5 seconds. Alternatively, continuous compressions can be given. The patient should be lying on his or her back during treatment.

The device consists of a LifeBand, a platform, and a power system. The latex-free LifeBand is a load-distributing band consisting of a cover plate and 2 Tyvek (polyethylene fabric) bands with a Velcro fastener integrated into a compression pad. The LifeBand is fitted across the patient's bare chest, allowing access to skin of the chest for defibrillation electrodes to be applied. The AutoPulse analyses the patient's size and based on this information the LifeBand automatically adjusts in length to fit the patient's chest and provide compressions to the thoracic area (heart region) of the patient. The AutoPulse can be used in people with a chest circumference measuring 76–130 cm, and a chest width of 25–38 cm.

Compressions are applied uniformly around the circumference of the chest, so that the load is distributed equally and no single area (such as the sternum) receives most of the force. The AutoPulse minimises the potential for patient injury by halting compressions and alerting the rescuer (with a single beep signal, a red light, and a message reading 'realign patient') if the LifeBand is improperly placed or it shifts as a result of an unsecured patient moving during transport.

The platform comprises a back-stabilising board, the mechanical drive mechanism, control system, the electronics and a user control panel.

The power system comprises either a lithium-ion (Li-Ion) or nickel-metal hydride (NiMH) battery, and the battery charger. The minimum battery run-time for both of these batteries is 30 minutes. Run-times greater than this are usually needed, depending on patient size and chest compliance. A low battery audio warning indicates when 5 minutes of active operation remain on a battery. This consists of 4 rapid beeps, followed by 2 beeps every 30 seconds. A low battery sign will also be visible in the user control panel. The battery can be changed during operation but the device must be switched off. The maximum charge time is less than 4.25 hours for the Li-Ion battery and less than 6.25 hours for the NiMH battery.

According to Resuscitation Council UK (2010) Guidelines, healthcare professionals in the Advanced Life Support algorithm must stop CPR every 2 minutes to check for the heart rhythm and pulsations. For this reason a 10 second pause is needed. The AutoPulse battery can be changed in this 10-second time slot so that there is a decrease in the hands-off fraction. If the battery must be changed during compressions, mechanical CPR must be stopped for a short period (less than 10 seconds). It is possible to continue or start manual CPR to further decrease the hands-off fraction.

A carry sheet is provided for out-of-hospital or pre-hospital use. The carry sheet allows the patient to be moved without the need for additional equipment such as a spine board or a scoop stretcher.

The carry sheet is CE-certified and can be used to carry people weighing up to 250 kg.

A transporter is provided for moving patients inside the hospital. The AutoPulse transporter is a cart that carries the AutoPulse vertically for in-hospital use. The transporter can be used to carry people weighing up to 136 kg, the maximum weight that the AutoPulse backboard will support.

The AutoPulse platform measures 82.6 cm long by 44.7 cm wide by 7.6 cm in height, with a weight (excluding the battery) of 9.3 kg. The rechargeable Li-Ion battery weighs 1.3 kg, and the rechargeable NiMH battery weighs 2.3 kg. According to the manufacturer, it should take 20 to 30 seconds to apply the AutoPulse, including the removal of the patient's clothes and the application of defibrillation electrodes.

Intended use

The device is intended to be used as an adjunct to, and not a replacement for manual CPR for adults aged 18 years or older, in cases of clinical death as defined by a lack of spontaneous breathing and pulse. In every non-traumatic cardiac arrest event, manual CPR should be started immediately according to current guidelines and continued until the AutoPulse is in use. The AutoPulse should not be used in people with traumatic injuries (wounds resulting from sudden physical injury or violence).

The use of the AutoPulse is intended to reduce the impact of rescuer fatigue. It is designed to allow the rescuer to attend to the patient's other needs, such as getting air into the lungs or administering defibrillation and medications to restart the heart, while mechanical chest compressions are ongoing. The AutoPulse can also be used while a patient has treatment for hypothermia.

The AutoPulse is expected to improve the safety of paramedics during transport in an ambulance, because they can remain seated and wearing a safety belt while the AutoPulse delivers compressions. Also, in a catheterisation laboratory, staff radiation exposure is minimised while AutoPulse CPR is ongoing.

Setting and intended user

The AutoPulse can be used both in and out of hospital for non-traumatic cardiac arrest, by personnel trained in basic or advanced life support techniques. This would include emergency medical technicians, paramedics, nurses, physicians and other people certified to administer CPR.

The AutoPulse allows CPR to be continued while moving a patient (for example to an ambulance or

air-ambulance, and from these into the hospital). It can be used in the catheterisation laboratory during angiography and percutaneous coronary intervention, using slightly modified viewing angles. It can also be used during computed tomography (CT) imaging, trans-thoracic echography and trans-oesophageal echography. Although an X-ray of the thorax is possible while the AutoPulse is in place, imaging would be blurred by the electronic and mechanical components within the AutoPulse platform. Additionally, it is not recommended to perform an X-ray during the resuscitation of a patient without return of spontaneous circulation.

Current NHS options

NICE is aware of the following CE-marked device that appears to fulfil a similar function to the AutoPulse:

- LUCAS: Lund University Cardiopulmonary Assist System (Jolife AB/Physio-Control Lund, Sweden).

Current guidelines recommend manual CPR which involves applying 100–120 compressions per minute to the sternum to a depth of 5–6 cm. Rescue breaths, in combination with chest compressions, should be done in a 30:2 ratio (30 compressions followed by 2 breaths of no more than 5 seconds). If there is more than 1 rescuer present, 1 should take over CPR from the other every 1–2 minutes to prevent rescuer fatigue (Resuscitation Council UK 2010).

One specialist commentator stated that the European Resuscitation Council and the Resuscitation Council (UK) will publish evidence-based treatment recommendations on mechanical CPR devices in October 2015. This will be based on a systematic review of published evidence as part of the International Consensus on CPR Science.

Costs and use of the technology

The essential components needed include:

- the AutoPulse platform (£6289)
- 3 NiMH batteries, £1266 (£422 each) or 3 Li-Ion batteries, £1476 (£492 each)
- multi-chemistry charger (£1107) which can be used for either type of battery
- carry sheet for out-of-hospital use (£380) or a transporter for in-hospital use (£226)
- non-reusable LifeBands (£239 for a pack of 3).

The total cost for an out-of-hospital system with NiMH batteries is £9281 and with Li-Ion batteries is £9491. For an in-hospital system the total cost with NiMH batteries is £9127 and with Li-Ion batteries is £9337.

Alternatively, the rental cost of an AutoPulse device to the NHS is £475 per month (excluding VAT). The rental agreement in the UK is with ZOLL UK Ltd.

The AutoPulse Plus platform is an alternative to the standard AutoPulse platform with the same mechanism, but allowing connection to the defibrillator and synchronisation of electrical shocks (£6375). Additional items are the same and have the same cost for both platforms.

The AutoPulse has no user-serviceable parts, and does not need regular maintenance. There are no components that need calibration, although users should periodically inspect the AutoPulse to ensure the device's functionality. The Li-Ion battery should be replaced 3 years after date of manufacture and will not operate after 5 years from that date. The NiMH battery will not operate after 100 full charge/discharge cycles and will need to be replaced.

The AutoPulse has an anticipated lifespan of 7 to 10 years.

Likely place in therapy

The purpose of the AutoPulse is not to replace manual CPR, but to be used as a support to manual CPR. It can provide consistent CPR over long periods of time and would be used to reduce the impact of rescuer fatigue while also allowing the rescuer to attend to other patient needs. The AutoPulse can also be used to maintain CPR when there is a need to move a patient, either to conduct further examinations or to seek more specialist care. The AutoPulse is promoted by the manufacturer only for use in cases where manual CPR would normally be initiated (e.g. non-traumatic cardiac arrest).

Specialist commentator comments

One specialist commentator noted that for out-of-hospital cardiac arrests caused by myocardial infarction, using the AutoPulse could allow lifesaving interventions such as primary angioplasty (percutaneous coronary intervention) to be performed while compressions are maintained.

Another specialist commentator suggested that the ideal situations for prolonged use of the AutoPulse are during thrombolysis of patients with a pulmonary embolism or in cases of profound hypothermia. The commentator remarked that whereas the available literature does not show a

significant difference in the effectiveness of the AutoPulse compared with that of manual CPR, mechanical CPR devices (such as the AutoPulse) can provide more consistent chest compressions than manual CPR, and that this could have benefits in pre-hospital care.

The instructions for use of the AutoPulse device say that it should only be used in adults over 18 years of age. One specialist commentator suggested that the device could be used in people of an 'adult size' who are less than 18 years old, and that body size was a more relevant issue than age. This specialist commentator also disagreed with the manufacturer's recommendation that the AutoPulse should only be used in non-traumatic cardiac arrest. They suggested that some people who experienced traumatic cardiac arrest may benefit from automated chest compressions, for example people who have a hypoxic aetiology such as hanging, asphyxia and drowning.

One specialist commentator mentioned that trials such as the CIRC trial (Wik et al. 2014) may not be an accurate representation of real-life pre-hospital CPR scenarios. During such trials it is common for the people in the control group to have 'excellent manual CPR'. This means that clinicians in the control arm would have additional training in CPR and would be checked for compliance with current CPR protocols. People in control groups therefore often have CPR of a very high standard, whereas in reality there are frequently long 'hands-off times' and poor chest compression fractions, particularly when there is only a single rescuer.

One commentator remarked that the success of automated devices is dependent on other factors known to be associated with a good outcome, for example early CPR from bystanders at the time of the cardiac arrest. It was their view that CPR fractions in the hospital and pre-hospital phase are often inadequate, and although the trials quoted had chest compression fractions of over 80%, many observational studies have demonstrated fractions as low as 48%.

A specialist commentator mentioned that there are currently 2 high-quality randomised controlled trials evaluating the use of the AutoPulse (Hallstrom et al. 2006; Wik et al. 2014), and that these trials are less susceptible to bias than case series and case reports.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women, and

- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief, in the way we produce our guidance (these are protected characteristics under the Equality Act 2010).

Risk factors for cardiac arrest include age (incidence increases with advancing age) and sex (men are at higher risk of experiencing sudden cardiac arrest). Age and sex are protected characteristics under the Equality Act (2010).

Patient and carer perspective

The NICE Public Involvement Programme highlighted that particular benefits for people from the AutoPulse device relate to preventing neurological harm and re-establishing circulation.

Evidence review

Clinical and technical evidence

Regulatory bodies

Three events with the AutoPulse device were identified from searches of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE). One of the events described 3 fully charged nickel-metal hydride batteries indicating 'battery failure' during use on a cardiac arrest patient (August 2013). Another event (February 2013) concerning a nickel-metal hydride battery occurred because the battery did not have daily operational checks or battery swaps, and the battery was not fully charged. The third event (August 2012) is ongoing and only limited information is available, but it relates to an unexpected stop in AutoPulse compressions.

Clinical evidence

A literature search identified 2 randomised controlled trials (Wik et al. 2014; Hallstrom et al. 2006; tables 1–4), 2 case-control studies (Jennings et al. 2012; Casner et al. 2005; tables 5–8) and 2 historical control studies (Ong et al. 2006, 2012; tables 9–12). All of these studies compared AutoPulse CPR with manual CPR in people with out-of-hospital cardiac arrest. None of the studies was conducted in the UK.

A study by Paradis et al. (2010) re-analysed the data from the trial by Hallstrom et al. (2006).

Another study by Pinto et al. (2013) was a retrospective cohort study (table 13) comparing trauma associated with AutoPulse CPR and manual CPR using autopsy records.

Five non-controlled observational studies (summarised in table 14), 2 case report studies and 1 conference abstract are also presented in this briefing.

Randomised controlled trials

In the Wik et al. (2014) trial (presented in tables 1 and 2), 4753 adults (aged 18 years or over) experiencing out-of-hospital cardiac arrests of presumed cardiac origin were randomised to have either AutoPulse CPR (n=2359) or manual CPR (n=2394). Inclusion and exclusion were determined after patient enrolment to avoid treatment delay. Of those randomised, 522 met post-enrolment exclusion criteria and for 12 people there was no survival to hospital discharge data available. As such, 2099 of those who had AutoPulse CPR and 2132 of those who had manual CPR were included in the final analysis. The primary outcome was survival to hospital discharge.

Compared with the manual CPR group, the AutoPulse CPR group had slightly lower rates of 24-hour survival (21.8% compared with 25.0%) and survival to hospital discharge (9.4% compared with 11.0%; unknown for 12 cases). The adjusted odds ratio of survival to hospital discharge met the criteria for equivalence for comparison between the AutoPulse CPR group and the manual CPR group. No statistically significant differences in people with injuries were found between the 2 groups, although some injuries were more prevalent in 1 group than the other.

In the Hallstrom et al. (2006) trial (presented in tables 3 and 4), 1377 adults with out-of-hospital cardiac arrest were randomised to have either AutoPulse CPR (n=704) or manual CPR (n=673). Inclusion and exclusion were determined after patient enrolment. Of those randomised, 554 from the AutoPulse CPR group and 517 from the manual CPR group met the inclusion criteria and were eligible for analysis. Subgroup analysis was conducted based on the primary comparison population (cardiac arrests of cardiac aetiology at the time of emergency medical service arrival) and the non-primary population (cardiac arrests after emergency medical services arrival, non-cardiac aetiology, or advanced life support >90 seconds before study).

No significant difference in survival to 4 hours was found between the AutoPulse CPR group and the manual CPR group, either based on the randomised population (28.5% compared with 29.5%; p=0.74), or subgroup of a priori primary population (26.4% compared with 24.7%; p=0.62).

Among the primary population, survival to hospital discharge was lower in the AutoPulse CPR group than in the manual CPR group (5.8% compared with 9.9%, p=0.04; adjusted for covariates and clustering, p=0.06). Compared with the manual CPR group, the AutoPulse group had a

significantly lower percentage of people with cerebral performance category of 1 or 2 at hospital discharge indicative of being able to lead a normal life or being independent (3.1% compared with 7.5%, p=0.006).

The trial protocol allowed each emergency medical service site to choose from 3 options for resuscitation intervention. All sites initially chose option 1. One site (site C) changed its resuscitation intervention from option 1 to option 2 half way through the study. In option 2 there was a delay in the application of AutoPulse CPR. Logistic regression found site C to be statistically significantly associated with worsening of survival to hospital discharge. Following the first planned interim monitoring, the study enrolment was terminated for safety in every site.

Paradis et al. (2010) conducted a post hoc re-analysis of the primary data of the Hallstrom et al. trial, using the eligible patient dataset of all cardiac arrests (n=1071) regardless of cardiac and non-cardiac aetiology, to evaluate for possible secular factors (that is, changes over long periods of time), time factors, and trial design factors that may have affected the trial's outcome. The re-analysis found that survival to hospital discharge decreased significantly after the protocol change at site C (19.6% compared with 4%, p=0.024). Logistic regression analysis showed that site C was significantly different (p=0.008) from the remaining sites with respect to survival. Four-hour survival at site C decreased over time during the study period but increased at the other sites favourable to the AutoPulse (p=0.008). The authors concluded that the difference in survival appears to have been limited to 1 site after its protocol change.

However, the re-analysis was contested by the authors of the Hallstrom et al. (2006) trial on the grounds that it was a retrospective assessment with a different population and analysis from what was defined in the original study protocol (Hallstrom et al. 2010). Paradis and colleagues responded, arguing that their analysis was merely hypothesis-generating. They also stated that although they did not dismiss the results from the original trial, they considered that it lacked homogeneity between the trial sites. Also, because the protocol allowed sites to change the execution during the trial, the potential harm from using the device seemed to be associated with site C following a change in the protocol at that site.

Case-control studies

In the Jennings et al. (2012) study (presented in tables 5 and 6), 66 adults with out-of-hospital cardiac arrest having AutoPulse CPR were matched to 220 controls having manual CPR only, using registry data. Compared with manual CPR, AutoPulse CPR resulted in a higher rate of survival to hospital admission, but a tendency for a lower rate of survival to hospital discharge. However, these associations did not reach statistical significance.

In the Casner et al. (2005) study (presented in tables 7 and 8), 69 people who experienced out-of-hospital cardiac arrest had AutoPulse CPR after initial attempts at manual resuscitation had failed. These people were matched to 93 controls who had manual CPR (without the AutoPulse) of a similar duration. It was not stated whether the study included only non-traumatic cardiac arrests. There were significantly more people who had AutoPulse CPR following failed manual CPR with sustained return of spontaneous circulation, compared with those who had manual CPR only (39% compared with 29% respectively, p=0.003). A subgroup analysis of people in asystole or agonal rhythms also showed similar results (37% compared with 22%, p=0.008), and in an analysis based on the subgroup of people presenting with pulseless electrical activity the difference was not statistically significant.

Historical control studies

The study by Ong et al. (2012; presented in tables 9 and 10) compared resuscitation outcomes for two phases, before and after switching from manual CPR to AutoPulse CPR in a multicentre trial in emergency departments. The study population comprised adults who had non-traumatic cardiac arrest and were admitted to the emergency department, or whose cardiac arrest happened in the emergency department. There were 459 people in the manual CPR phase, and 552 in the AutoPulse CPR phase. There were no statistically significant differences in survival to hospital discharge for the AutoPulse CPR phase compared with the manual CPR phase (3.3% compared with 1.3%). The AutoPulse CPR phase had more survivors whose cerebral performance was category 1 to 2 (good) than in the manual CPR group (13 compared with 2; odds ratio [OR] for good cerebral performance 8.7, 95% confidence interval [CI] 1.1 to 71.6). Overall performance (reflecting cerebral and non-cerebral status) was measured as category 1 to 2 (good) in 12 people in the AutoPulse CPR group and 2 in the manual CPR group (OR 6.0, 95% CI 0.8 to 46.1). Neurological (functional) status was assessed using the Glasgow-Pittsburgh outcome categories.

The Ong et al. (2006) study (presented in tables 11 and 12) compared resuscitation survival outcomes in adults with out-of-hospital cardiac arrest of cardiac aetiology treated before and after the switching from manual CPR to AutoPulse CPR. There were 284 eligible people from the AutoPulse CPR phase and 499 from the manual CPR phase. Compared with manual CPR, AutoPulse CPR significantly increased the rate of return of spontaneous circulation (34.5% compared with 20.2%; adjusted OR 1.94; 95% CI 1.38 to 2.72), survival to hospital admission (20.9% compared with 11.1%; adjusted OR 1.88; 95% CI 1.23 to 2.86), and survival to hospital discharge (9.7% compared with 2.9%; adjusted OR 2.27; 95% CI 1.11 to 4.77).

Retrospective cohort study

Pinto et al. (2013) investigated the frequency of injuries following manual CPR or AutoPulse CPR

based on a retrospective analysis of 175 autopsy reports between 2005 and 2009 (presented in table 13). The cause of death for the people of this study was not restricted to cardiac arrest of known cause. It is presumed that the risk of trauma associated with CPR would be similar in people having CPR regardless of the cause of cardiac arrest. The Pinto et al. (2006) study is therefore included in this briefing (table 13).

Causes of death included natural (67%), accidental (24%, primarily deaths due to drug toxicity), suicide (5%), homicide (3%) and undetermined (1%). There was a significantly higher frequency of sternal fractures ($p<0.05$), overall rib fractures ($p=0.0038$) and anterior rib fractures ($p<0.0001$) in people having manual CPR. There was a higher frequency of posterior rib fractures ($p<0.0001$) in the AutoPulse group. No statistically significant differences were seen between the groups in fractures of the anterolateral, lateral, or posterolateral regions of the ribcage. Skin abrasions were present in 24% of people in the manual-only CPR group and in 96% of cases in the AutoPulse group ($p<0.0001$). The authors suggested that the combined rib fracture and abrasion pattern seen in people in the AutoPulse group was the result of the person's body being secured to a back-stabilising board (AutoPulse platform) during treatment, with the LifeBand guards being on the sides of the board that come into contact with the person's lateral torso or inner arm. The authors also noted that the resuscitation protocol using the AutoPulse required manual CPR to be used while the equipment is being prepared. Therefore it cannot be ruled out that some of these fractures may have been caused by manual CPR rather than the AutoPulse device.

Non-controlled studies

Table 14 summarises 5 non-controlled studies that were identified for this briefing. Four of the studies were prospective and 1 was retrospective.

Duchateau et al. (2010) compared blood pressure (systolic, diastolic, mean) and end-tidal CO_2 produced by manual CPR with those produced by mechanical CPR using the AutoPulse. All the people had manual CPR followed by AutoPulse CPR. Statistically significant increases were observed for systolic, diastolic and mean blood pressure but not in end-tidal CO_2 after using the AutoPulse.

Krep et al. (2007) reported 46 observations using the AutoPulse in an out-of-hospital setting. The authors also presented additional data from 46 people who were under the care of the same staff using manual CPR. The mean duration of CPR performed on people in the AutoPulse group was 19.3±16.7 minutes (median 13.0) and return of spontaneous circulation was achieved in 52% of the 46 people. Despite similar return of spontaneous circulation results, the authors explained that 39.6% of people in the manual CPR group had ventricular fibrillation or ventricular tachycardia as initial ECG-rhythm, compared with 17.4% in the AutoPulse group. The duration of CPR was lower

in the manual CPR group. Survival rates were not presented for the manual CPR group. The authors stated that no comparisons were made because this was not the aim of the study.

Omori et al. (2013) carried out a retrospective comparison between manual CPR (n=43) and AutoPulse CPR (n=49) performed before and during helicopter transport. Although the AutoPulse is meant for use in adults aged 18 years or over with non-traumatic cardiac arrest, in this study the AutoPulse was used for people aged 15 years. Also, for 20 people, the cardiac arrest was caused by trauma, including chest (n=1), abdominal (n=2) or thoracic injuries (n=5). Univariate analysis indicated that a shorter duration of manual CPR application (p=0.016) and additional use of the AutoPulse (p=0.009) were factors associated with increased rates for return of spontaneous circulation. Multivariate analysis suggests that younger age (p=0.042) and additional use of the AutoPulse (p=0.005) were factors associated with these increased rates.

Steinmetz et al. (2008) compared survival rates and return of spontaneous circulation with out-of-hospital cardiac arrest before and after the implementation of 2005 European Resuscitation Council guidelines. The new guidelines gave chest compressions a higher priority and stated that ventricular fibrillation should be treated with only 1 direct current shock, followed by chest compressions and ventilation without checking the rhythm or the pulse. After implementation of the 2005 guidelines, the authors also compared patients receiving manual CPR according to the new guidelines with those receiving AutoPulse CPR in this time period. Although a statistically significantly higher proportion of people obtained spontaneous circulation at admission, the 30-day survival was not significantly different between the 2 groups of people. Survival at discharge was not reported for people who had CPR with the AutoPulse. Logistic regression analysis suggested that using the AutoPulse was associated with worse 30-day survival. However, the authors acknowledged that the use of the AutoPulse was not fully implemented in their unit: it was only used in 77 of 419 cardiac arrests (18%) after implementation of the guidelines.

Timerman et al. (2004) compared pressure forces between manual CPR and AutoPulse CPR. Alternating periods of manual CPR and AutoPulse CPR for 90 seconds each were carried out after a 10-minute period of manual CPR failed. All people in this study were terminally ill from heart disease and had additional co-morbidities. The mean time between cardiac arrest and start of protocol was 30±18 minutes (range 8–69). The AutoPulse produced statistically significantly higher forces and coronary perfusion pressure than manual CPR with the exception of aortic diastolic pressure, right atrial diastolic pressure and calculated chest applied pressure. Pressure applied to the chest was higher with manual CPR (1381±432 mmHg) than with AutoPulse CPR (203±20 mmHg). The authors suggest that the increased pressure with manual CPR is due to the smaller area of application of force when compared with AutoPulse CPR.

Comparative and non-comparative studies suggest that use of the AutoPulse is not associated with worse outcomes. No statistically significant differences for survival were observed in 4 different studies (Jennings et al. 2012; Ong et al. 2012; Omori et al. 2013; Steinmetz et al. 2008). One study observed superiority of the AutoPulse in terms of survival to admission and discharge (Ong et al. 2006), another reported a higher proportion of survivors with good neurological outcomes (Ong et al., 2012), 4 studies identified a higher proportion of people achieving return of spontaneous circulation (Casner et al. 2005; Ong et al. 2006; Omori et al. 2013; Steinmetz et al. 2008).

Table 1 Overview of the Wik et al. (2014) trial

Study component	Description
Objectives/ hypotheses	To compare the AutoPulse with high-quality manual CPR to determine equivalence, superiority or inferiority in survival to hospital discharge.
Study design	Randomised, unblinded, controlled trial. People were allocated to the 2 comparison arms in a 1:1 ratio using randomised permuted blocks of 24 stratified by study site.
Setting	The study was conducted in 3 US sites and 2 European sites (Austria and the Netherlands) which represented a variety of emergency medical service system types. Follow-up duration was to hospital discharge.
Inclusion/ exclusion criteria	Inclusion criteria: age ≥18 years of out-of-hospital cardiac arrests of presumed cardiac origin. Exclusion criteria: presumed to be pregnant, had a 'do not resuscitate' order, were presumed too large for the CPR device (estimated weight greater than 300 pounds or chest circumference greater than 1.3 metres), were a prisoner or ward of the state, had had mechanical chest compressions prior to randomisation, or if the randomising emergency medical service unit arrived more than 16 minutes after emergency call. In some cases, inclusion and exclusion criteria were determined after the person was enrolled to avoid treatment delay. Exclusion for size of the patient was not permitted after enrolment.
Primary outcomes	Survival to hospital discharge.

Statistical methods	Sample size was calculated. The analyses excluded people who were retrospectively found to meet exclusion criteria and people without survival to hospital discharge data. Two-sided significance level of 5% and a power of 97.5% to detect a log-OR of 0.37 (i.e. an OR of 1.44) were used; equivalence would be declared if the 95% CI of the log-OR lay fully between −0.37 and 0.37 (i.e. OR between 0.69 and 1.44). Variables associated with survival to hospital discharge were selected as covariates, including the age category of the person, witnessed arrest, initial cardiac rhythm, and enrolment site. Interim (first after 748 people were enrolled and then every two month until a stopping boundary was crossed) and final analyses were based on score statistics for the log-OR adjusting for the pre-identified covariates and multiple interim analyses. One sided p-values for testing non-inferiority of each intervention arm were calculated.
Participants	Adults (age ≥18 years) of out-of-hospital cardiac arrests of presumed cardiac origin. Of 4753 randomised people (2359 to the AutoPulse and 2394 to the manual group), 522 met post enrolment exclusion criteria. Therefore, 2099 people who had AutoPulse and 2132 who had manual CPR were included in the final analysis.
Results	Compared with the manual CPR group, the AutoPulse CPR group had slightly lower rates in terms of hospital discharge (9.4% vs 11.0%; unknown for 12 cases), 24-hour survival (21.8% vs 25.0%), and sustained ROSC (emergency department admittance; 28.6% vs 32.3%). The adjusted odds ratio of survival to hospital discharge for the AutoPulse CPR compared to manual CPR was 1.06 (95% CI 0.83 to 1.37), meeting the criteria for equivalence. There was no significant difference in people with injuries between the AutoPulse group and the manual group (12% vs 11%; OR=1.10, 95% CI 0.91 to1.34, p=0.31).
Conclusions	The authors concluded that, compared to high-quality manual CPR, AutoPulse CPR resulted in statistically equivalent survival to hospital discharge.
Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; n, number of people; OR, odds ratio; vs, versus.	

Table 2 Summary of the Wik et al. (2014) trial

	AutoPulse CPR	Manual CPR	Analysis
Randomised	n=2359	n=2394	
Efficacy	n=2099	n=2132	
Primary outcome:			
Survival to hospital discharge[a] (n)	9.4% (196/ 2099)	11.0% (233/ 2132)	• OR 0.84; 95% CI 0.69 to 1.02 • OR adjusted for covariates 0.89; 95% CI 0.72 to 1.10 • OR adjusted for covariates and multiple interim analyses 1.06; 95% CI 0.83 to 1.37
Survival to hospital discharge - sensitivity analysis of all randomised people (n=4753)	n=2359 Survival not reported	n=2394 Survival not reported	• OR 0.83; 95% CI 0.68 to 1.01 • OR adjusted for covariates 0.88; 95% CI 0.72 to 1.08 • OR adjusted for covariates and interim analyses1.06; 95% CI 0.83 to 1.36
Survival to 24 hours[b] (n)	21.8% (456/ 2099)	25.0% (532/ 2132)	OR adjusted for covariates: 0.86; 95% CI 0.74 to 0.998
Sustained ROSC[c] (n)	28.6% (600/ 2099)	32.3% (689/ 2132)	OR adjusted for covariates 0.84; 9% CI 0.73 to 0.96
People with a reported injury[d] (n)	12% (242/ 2099)	11% (225/ 2132)	OR1.10; 95% CI 0.91 to 1.34, p=0.31
Flail chest (n)[e]	0	1	

Haemothorax (n)	1	1	
Large vessel injury(n)[e]	0	0	
Liver injury (n)	1	0	
Mediastinal injuries (n)	1	1	
Myocardial laceration(n)[e]	0	1	
Pneumothorax (n)	33	20	
Pulmonary oedema (n)	159	176	
Rib fractures (n)	69	31	
Spine fracture (n)	4	2	
Spleen injury (n)	0	0	
Sternum fracture (n)	1	4	
Subcutaneous emphysema (n)	21	6	
Tympanic membrane rupture (n)	0	0	

Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; n, number of people; OR, odds ratio; p, p value; ROSC, return of spontaneous circulation.

[a] Not included 12 people (5 in the AutoPulse and 7 in the manual group) with unknown outcome.

[b] There were 10 unknown cases in the AutoPulse group. Unclear whether the 10 cases were included in the analysis.

[c] Defined as being admitted to the hospital with perfusing blood pressure.

[d] Listed injuries are not mutually exclusive (one person can have multiple injuries) and neither diagnostic exams nor autopsy were needed as part of the protocol. Injuries were identified using clinical record review.

[e] Required to be submitted to the medical monitor for review.

Table 3 Overview of the Hallstrom et al. (2006) trial

Study component	Description

Objectives/ hypotheses	To compare resuscitation outcomes following out-of-hospital cardiac arrest when the AutoPulse was used in addition to standard emergency medical services care with manual CPR.
Study design	Randomised controlled trial.
Setting	The study was conducted in multiple centres in the US and Canada. Follow-up duration was 4 hours for the primary outcome and up to discharge for the secondary outcomes.
Inclusion/ exclusion criteria	Adults with out-of-hospital cardiac arrest who had attempted CPR by a participating emergency medical service agency were enrolled. Exclusion criteria: aged <18 years; prisoner or Ward of State; "do not resuscitate" order; dead on arrival with CPR only; trauma; recent surgery; no study vehicle or personnel at scene. People whose cardiac arrest was treated by emergency medical service and subsequently determined not to meet the inclusion criteria were excluded from the analysis.
Primary outcomes	Survival to 4 hours after the call to the emergency services.
Statistical methods	Sample size was calculated. Analyses were based on people eligible rather than randomised. Logistic regression using generalised linear mixed models was applied to compare the outcome of individual episodes between the 2 comparison groups. The model was adjusted for covariates previously demonstrated to predict survival as well as cluster (based on an emergency service station or group of stations). Unless stated, p values are unadjusted for covariates or clustering. For the primary and secondary end points, p values were generally adjusted. Subgroup analysis was conducted for a priori primary population and non-primary population respectively.

Participants	People randomised: adults with out-of-hospital non-traumatic cardiac arrest of presumed cardiac origin who had attempted CPR by a participating emergency medical services agency (n=1377, including 704 randomised to the AutoPulse CPR group and 673 to the manual CPR group). People eligible: randomised people, excluding those who met the exclusion criteria (n=1071, including 554 in the AutoPulse group and 517 in the manual group). Primary comparison population: of those eligible, people who were in cardiac arrest at the time of emergency medical service arrival and whose cardiac arrest was considered to be of cardiac origin (n=767, including 394 in the AutoPulse group and 373 in the manual group). Non-primary population: of those eligible, people with cardiac arrest after emergency medical services arrival, non-cardiac aetiology, or advanced life support > 90 seconds before study (n=304, including 160 in the AutoPulse and 144 the manual group).
Results	There was no significant difference in survival to 4 hours between the AutoPulse group and the manual resuscitation group, either based on the randomised population (28.5% vs 29.5%; p=0.74), or subgroup of a priori primary population (26.4% vs 24.7%; p=0.62). Among the primary population, survival to hospital discharge was 5.8% in the AutoPulse group and 9.9% in the manual CPR group (p=0.06, adjusted for covariates and clustering). A cerebral performance category of 1 or 2 at hospital discharge was found in 3.1% of the AutoPulse group and 7.5% of people in the manual CPR group (p=0.006).
Conclusions	The authors concluded that use of an automated AutoPulse device as implemented in the study was associated with worse neurological outcomes and a trend toward worse survival than manual CPR. Device design or implementation strategies need further evaluation.

Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; n, number of people; OR, odds ratio; vs, versus.

Cerebral performance category scores describe good (1–2) and poor (3–5) outcomes. Score of 1: conscious and alert with normal function or only slight disability; 2, conscious and alert with moderate disability; 3, conscious with severe disability; 4, comatose or persistent vegetative state; and 5, brain dead or death from other causes.

An overall performance category score of 1 indicates good overall performance; 2, moderate overall disability; 3, severe overall disability; 4, coma/vegetative state; and 5, brain death: certified brain dead or dead by traditional criteria.

Table 4 Summary of the Hallstrom et al. (2006) trial

	AutoPulse CPR	Manual CPR	Analysis
Randomised	n=554	n=517	
Primary outcome:			
• Survival to 4 hours (based on randomised)	28.5%	29.5%	p=0.74
• Survival to 4 hours – based on primary population of 767 people (n)	26.4% (104/394)	24.7% (92/373)	p=0.62
• Survival to hospital discharge (n)	5.8% (23/394)	9.9% (37/373)	p=0.04; p=0.06 adjusted for covariates and clustering
• Cerebral performance category of 1 or 2 at hospital discharge[a] (n)	3.1% (12/391)	7.5% (28/371)	p=0.006

Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; n, number of people; p, p value.

[a] Excluding 5 survivors with incomplete neurological data. Cerebral performance category score 1=conscious and alert; score 2=conscious.

Table 5 Overview of the Jennings et al. (2012) study

Study component	Description
Objectives/ hypotheses	To compare the rates of survival between conventional CPR and automated CPR using the AutoPulse in adults following out-of hospital cardiac arrest.
Study design	Case-control study using prospectively collected case data matched to an Australian emergency service data registry. Each case was matched to 2–4 controls using known predictors of survival including age (±5 years), gender, response time (defined as 'at patient' – 'call received' time, ±5 minutes), presenting cardiac rhythm and bystander CPR.
Setting	Three regional sites in mixed urban or rural settings of Ambulance Victoria, Australia; out-of hospital cardiac arrest cases using the AutoPulse from 1 October 2006 to 30 April 2010.
Inclusion/ exclusion criteria	Adult (>18 years of age) with out-of-hospital cardiac arrest using the AutoPulse CPR at the sites from 1 October 2006 to 30 April 2010.
Primary outcomes	Survival to hospital (defined as pulse on arrival to hospital in the absence of chest compressions).
Statistical methods	Continuous data was reported as medians (IQR). Adjusted ORs were calculated using conditional logistic regression with manual CPR cases as the reference group and controlling for confounders. Confidence limits were set at the 95% level and 2-sided p values were presented. For each analysis $p<0.05$ was considered significant. Deriving and adjusting for propensity score was attempted to reduce selection bias introduced via non-random assignment of treatment groups. Subgroup analysis was conducted for those of presumed cardiac aetiology.
Participants	Case: adult (>18 years of age) with out-of-hospital cardiac arrest cases using AutoPulse CPR at the study sites from 1 October 2006 to 30 April 2010 (n=66). Control: cases were matched to controls from an Australia emergency service data registry using age (±5 years), gender, response time (defined as 'at patient' – 'call received' time, ±5 minutes), presenting cardiac rhythm and bystander CPR. Out-of-hospital cardiac arrests having manual CPR only during the study period were eligible for matching. All controls were selected from regional settings similar to those of the AutoPulse trial sites (n=220).

Results	Survival to hospital arrival was achieved in 26% (17/66) of cases having AutoPulse CPR compared with 20% (43/220) of controls having manual CPR; the propensity score adjusted OR was 1.69 (95% CI 0.79 to 3.63). Results were similar using only bystander witnessed out-of-hospital cardiac arrest cases with presumed cardiac aetiology. Sub-group analysis of only bystander witnessed, of presumed cardiac aetiology, survival to hospital arrival was achieved for 29% (14/48) of cases having AutoPulse CPR compared with 18% (21/116) of those having manual CPR; propensity score adjusted OR 1.80 (95% CI 0.78 to 4.11). Survival to hospital discharge was 3% (2/66) for those patients having AutoPulse CPR and 7% (15/220) for those having manual CPR (p=0.38).
Conclusions	The authors concluded that, compared with manual CPR, AutoPulse CPR resulted in a higher rate of survival to hospital but a tendency for a lower rate of survival to hospital discharge. However, these associations did not reach statistical significance. Further research is warranted with prospective nature, randomisation and larger number of cases to investigate potential sub-group benefits of the AutoPulse including survival to hospital discharge.
Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; IQR, inter-quartile range; n, number of people; OR, odds ratio; SD, standard deviation.	

Table 6 Summary of the Jennings et al. (2012) study

	AutoPulse CPR	Manual CPR	Analysis
Number of people	n=66	n=220	
Primary outcome:			
• Survival to hospital admission[a] (n)	26% (17/66)	20% (43/220)	Adjusted[b] OR1.69; 95% CI 0.79 to 3.63; p=0.23
• Survival to hospital discharge (n)	3% (2/66)	7% (15/220)	p=0.38

• Survival to hospital discharge — subgroup based on bystander witnessed (presumed cardiac aetiology) (n)	29% (14/48)	18% (21/116)	Adjusted[b] OR1.80; 95% CI 0.78 to 4.11
Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; n, number of people; OR, odds ratio; p, p value. [a] Defined as presence of pulse on arrival to hospital in the absence of chest compressions. [b] Adjusted for propensity score.			

Table 7 Overview of the Casner et al. (2005) study

Study component	Description
Objectives/ hypotheses	To determine whether AutoPulse CPR had altered short-term survival in people with out-of-hospital cardiac arrest. Hypotheses: use of the AutoPulse after manual CPR would increase the probability that the patient has a ROSC, which is defined as arrival at a hospital emergency department with a sustained spontaneous pulse in the absence of any external compressions.
Study design	Case-control study.
Setting	San Francisco General Hospital Emergency Services, California, US. The study period was from February to December 2003.
Inclusion/ exclusion criteria	People with out-of-hospital cardiac arrest who had AutoPulse CPR after initial failed attempts at resuscitation were case-matched with controls who had manual CPR (and no CPR with the AutoPulse) of a similar situation. It was not stated whether the study included non-traumatic cardiac arrests only. All matched cases were from the study period or the preceding 12 months. Cases were matched using exact matches for all values with the following prospectively defined criteria: age (±3 years), gender, presenting cardiac rhythm, number of shocks delivered, and number of doses of medication administered. Matching was performed by an investigator blinded to the treatment group and patient outcome.
Primary outcomes	ROSC (determined by a measureable non-invasive blood pressure at arrival to the receiving hospital).

Statistical methods	Descriptive statistics are presented as mean ± standard deviation and differences were evaluated using Student's t-test. Differences between treatment groups in the primary outcome were determined with the Chi-square test. Differences were considered significant with $p<0.05$.
Participants	Sixty-nine cases of AutoPulse CPR following failed manual CPR were matched to 93 controls with manual CPR only.
Results	Among those who had AutoPulse CPR following failed manual CPR, the proportion of people with sustained ROSC was significantly higher than among those who had manual CPR only (39% vs 29%, p=0.003).
Conclusions	The authors concluded that the AutoPulse may improve the overall likelihood of ROSC and may particularly benefit people with non-shockable rhythms.
Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; n, number of people; OR, odds ratio; ROSC, return of sustained circulation; vs, versus.	

Table 8 Summary of the Casner et al. (2005) study

	AutoPulse CPR	Manual CPR	Analysis
Number of people	n=69	n=93	
• ROSC[a] (n)	39% (27/69)	29% (27/93)	p=0.003
• based on subgroup of people in asystole or agonal rhythms	37% (number not reported)	22% (number not reported)	p=0.008
• based on subgroup of people presenting with pulseless electrical activity (n)	38% (number not reported)	23% (number not reported)	p=0.079
• No sustained ROSC (n)	61% (42/69)	71% (66/93)	p=0.008
Abbreviations: CPR, cardiopulmonary resuscitation; n, number of people; p, p value; ROSC, return of sustained circulation. [a] Defined as spontaneous pulses at hospital arrival.			

Table 9 Overview of the Ong et al. (2012) study

Study component	Description
Objectives/ hypotheses	To compare resuscitation outcomes before and after switching from manual CPR to AutoPulse CPR in a multi-centre emergency department trial.
Study design	Historical controlled study.
Setting	Two urban emergency departments in Singapore. Follow-up duration was to survival to hospital discharge (defined as the patient surviving the primary event and to discharge from the hospital) or survival to hospital admission (defined as the admission to hospital without ongoing CPR or other artificial circulatory support).
Inclusion/ exclusion criteria	Not specified, but stated that the study population comprised adults with non-traumatic cardiac arrest occurring out of hospital or in the emergency department over the study period (i.e. the manual CPR phase from 1 January 2004 to 24 August 2007, and the AutoPulse CPR phase from 16 August 2007 to 31 September 2009).
Primary outcomes	Survival to hospital discharge, defined as the patient surviving the primary event and to discharge from the hospital.
Statistical methods	All statistical analyses were carried out on an ITT basis. Frequency tables and descriptive statistics with 95% CIs were calculated for all outcome variables. Associations between treatment groups and all endpoints were analysed using the Chi-square test with ORs presented where applicable. For each end point, logistic regression was used to compare the 2 comparison groups, adjusting for covariates that on univariate analysis were significantly different between treatment groups at $p<0.10$.
Participants	Adults with non-traumatic cardiac arrest (n=1011, with 459 in the manual CPR phase and 552 in the AutoPulse CPR phase).

Results	People in the manual CPR and AutoPulse phases were comparable for mean age, gender and ethnicity. In the AutoPulse phase, the AutoPulse device was applied in 454 people (82.3%). The mean duration from collapse to arrival at emergency department was 34:03 (SD16:59) minutes for manual CPR and 33:18 (SD14:57) minutes for AutoPulse CPR. Survival to hospital discharge showed no statistically significant difference in the AutoPulse phase than manual phase (3.3% vs 1.3%; adjusted OR 1.42; 95% CI 0.47 to 4.29). There were more survivors in AutoPulse group with CPC 1 to 2 (good) than in the manual group (13 vs 2, OR for good CPC 8.7, 95% CI 1.1 to 71.6). OPC 1 to 2 (good) was 12 with AutoPulse and 2 with manual CPR, OR 6.0, 95% CI 0.8 to 46.1 (not statistically significant).
Conclusions	The authors concluded that a resuscitation strategy using the AutoPulse in an emergency department environment was associated with improved neurologically intact survival on discharge in adults with prolonged, non-traumatic cardiac arrest.
Abbreviations: CI, confidence interval; CPC, cerebral performance category; CPR, cardiopulmonary resuscitation; ITT, intention to treat; n, number of people; OPC, overall performance category; OR, odds ratio; SD, standard deviation; vs, versus.	

Table 10 Summary of the Ong et al. (2012) study

	AutoPulse CPR	Manual CPR	Analysis
Number of people	n=552	n=459	
Primary outcome:			
• Survival to hospital discharge (n)	3.3% (18/552)	1.3% (6/459)	Adjusted OR[a] 1.42; 95% CI 0.47 to 4.29
• Survival to hospital admission[b] (n)	19.8% (109/552)	14.2% (65/459)	OR 1.49; 95% CI 1.07 to 2.09 Adjusted OR[a] 1.23; 95% CI 0.84 to 1.81
• Survival with good cerebral performance category 1–2 (n)	12	1	p=0.01

• Survival with good cerebral performance category 1–2 (n)	10	1	p=0.06
• ROSC[c] (n)	35.3% (195/552)	22.4% (103/459)	OR 1.89, 95% CI 1.43 to 2.50 Adjusted OR[a] 1.60; 95% CI 1.16 to 2.22
Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; n, number of people; OR, odds ratio; p, p value; ROSC, return of sustained circulation. [a] Adjusted for hospital, arrest location, bystander witnessed, Emergency Medical Service witnessed, initial rhythm, pre-hospital defibrillation, and bystander CPR. [b] Defined as the admission to hospital without ongoing CPR or other artificial circulatory support. [c] Defined as the presence of any palpable pulse, which is detected by manual palpation of a major artery.			

Table 11 Overview of the Ong et al. (2006) study

Study component	Description
Objectives/ hypotheses	To compare resuscitation survival outcomes in people with out-of-hospital cardiac arrest treated before and after an urban emergency medical services system switched from manual CPR to AutoPulse CPR.
Study design	Historical control study.
Setting	An urban emergency medical services system in Richmond, Virginia, US.
Inclusion/ exclusion criteria	AutoPulse CPR phase: between 20 December 2003 and 31 March 2005, individuals aged 18 years or older, with cardiac arrest of cardiac aetiology, and with CPR attempted, were eligible for the analysis of AutoPulse CPR regardless of whether the AutoPulse device was applied (n=284). Manual CPR phase: between 1 January 2001 and 31 March 2003, individuals aged 18 years or older, with cardiac arrest of cardiac aetiology, who had only manual CPR, were eligible for the analysis for the manual CPR (n=499).

Primary outcomes	Return of spontaneous circulation.
Statistical methods	Statistical analyses were performed on an intention-to-treat basis. The analyses included all people in the manual CPR phase with cardiac arrest and manual CPR, and all people in the AutoPulse phase with cardiac arrest, regardless of whether the AutoPulse device was used or not applied, but excluded those with missing data. Univariate comparisons using *t* tests, Chi-square tests, or Fisher tests were conducted to identify differences in distribution of covariates between phases. Those comparisons with $p<0.20$ were included for consideration in the final logistic regression models. Associations between treatment groups and all end points were analysed using the Chi-square test and presented with ORs where applicable. Logistic regression was used to adjust for relevant covariates and adjusted ORs and 95% CIs were given for all end points.
Participants	See inclusion/exclusion criteria above.
Results	Compared with manual CPR, AutoPulse CPR significantly increased the rate of ROSC (34.5% vs 20.2%; adjusted OR 1.94; 95% CI 1.38 to 2.72), survival to hospital admission (20.9% vs 11.1%; adjusted OR 1.88; 95% CI 1.23 to 2.86), and survival to hospital discharge (9.7% vs 2.9%; adjusted OR 2.27; 95% CI 1.11 to 4.77).
Conclusions	The authors concluded that, compared with resuscitation using manual CPR, a resuscitation strategy using the AutoPulse on emergency medical service ambulances was associated with improved survival to hospital discharge in adults with out-of-hospital non-traumatic cardiac arrest.
Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; IQR, inter-quartile range; n, number of people; OR, odds ratio; SD, standard deviation; ROSC, return of spontaneous circulation; vs, versus.	

Table 12 Summary of the Ong et al. (2006) study[a]

	AutoPulse CPR	Manual CPR	Analysis
Number of people	n=284	n=499	
Primary outcome:			

• ROSC (n)	34.5% (96/278); 95% CI 29.2 to 40.3	20.2% (101/499); 95% CI16.9 to 24.0	OR 2.08; 95% CI1.49 to 2.89 Adjusted OR 1.94; 95% CI 1.38 to 2.72[b]
• Survival to hospital admission (n)	20.9% (58/277); 95% CI 16.6 to 26.1	11.1% (54/485); 95% CI 8.6 to 14.2	OR 2.11; 95% CI 1.41 to 3.17 Adjusted OR 1.88; 95% CI 1.23 to 2.86[b]
• Survival to hospital discharge (n)	9.7% (27/278); 95% CI 6.7 to 13.8	2.9% (14/486); 95% CI 1.7 to 4.8	OR 3.23; 95% CI 1.66 to 6.51 Adjusted OR 2.27; 95% CI 1.11 to 4.77[c]
• Cerebral performance category[d] (n)			For the overall categories p=0.36
• Score 1	15.1% (13/96)	5.6% (5/101)	
• Score 2	3.5% (3/96)	3.4% (3/101)	
• Score 3	2.3% (2/96)	2.3% (2/101)	
• Score 4	3.5% (3/96)	3.4% (3/101)	
• Score 5	75.6% (65/96)	85.4% (76/101)	
• Overall performance category[d] (n)			For the overall categories p=0.40
• Score 1	4.7% (4/96)	2.3% (2/101)	

• Score 2	11.6% (10/96)	4.5% (4/101)	
• Score 3	4.7% (4/96)	4.5% (4/101)	
• Score 4	3.5% (3/96)	3.4% (3/101)	
• Score 5	75.6% (65/96)	85.4% (76/101)	

Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; n, number of people; OR, odds ratio; p, p value; ROSC, return of sustained circulation.

[a] People with missing data were not included in the analysis.

[b] Adjusted for differences in response time intervals and percentage of emergency medical service witnessed.

[c] Adjusted for differences in response time intervals, percentage of emergency medical service witnessed, and whether post-resuscitation hypothermia was used. For the unadjusted and adjusted ORs and 95% CIs, a weighted logistic regression was performed.

[d] Percentages based on people with ROSC; numbers in performance categories do not sum to total number of patients in each phase due to missing data.

Table 13 Overview of the Pinto et al. (2013) study

Study	Study characteristics	
Pinto et al. (2013)	Study design	Retrospective cohort study.
	Setting	Harris County Institute of Forensic Sciences in Houston, Texas, US.
	Population	87 cadavers that had manual CPR and 88 cadavers that had a combination of manual and AutoPulse CPR.
	Intervention	Manual CPR versus a combination of manual and AutoPulse CPR.
	Outcome measures	Frequency of rib fractures, sternum fractures, skin abrasions, visceral injuries.

	Findings	• Higher overall occurrence of rib fractures in manual CPR (p=0.0038). • Higher frequency of anterior rib fractures in manual CPR (54%) vs the AutoPulse (29%), p<0.0001. • Higher frequency of posterior rib fractures in the AutoPulse group (33%) vs manual CPR (0.4%), p<0.0001[a]. • No difference in frequencies for anterolateral (p=0.1664), lateral (p=0.0678) and posterolateral (p=0.1585) rib fractures. • Higher frequency of sternum fractures in manual CPR (45%) vs AutoPulse CPR (14%), p<0.05. • Higher frequency of skin abrasions in AutoPulse CPR (96%) vs manual CPR (24%), p<0.0001[a]. • One case of visceral injury with manual CPR and 3 cases with AutoPulse CPR.
Abbreviations: CPR, cardiopulmonary resuscitation; versus, vs. [a] Authors reported as p < 0.0000 and p = 0.0000. We have changed to p < 0.0001 as a value of p < 0.0000 or p = 0.0000 would be reported inappropriately.		

Table 14 Summary of non-controlled studies

Study	Study characteristics	
Duchateau et al. (2010)	Study design	Prospective non-controlled.
	Setting	Emergency Medical Service Departments of 2 teaching hospitals in Paris, France.
	Population	32 adult people aged 62±16 years with refractory out-of-hospital cardiac arrest despite having had adequate CPR. Three people were not included because BP curves could not be digitalised as a result of inadequate scale setup.
	Intervention	Manual CPR followed by mechanical CPR using the AutoPulse.

	Outcome measures	Primary outcome: diastolic BP. Secondary outcomes: systolic BP, mean BP and $ETCO_2$.
	Findings	• With the AutoPulse diastolic BP increased from 17 (11–25) mmHg to 23 (18–28) mmHg (p<0.001). • Systolic BP increased from 72 (55–105) mmHg to 106 (78–135) mmHg (p=0.02). • Mean BP from 29 (25–38) mmHg to 36 (30–15) mmHg (p=0.002). • No significant increase for $ETCO_2$ – 21 (13–36) versus 22 (12–35) mmHg, p=0.80.
Krep et al. (2007)	Study design	Prospective non-controlled.
	Setting	Emergency Medical Service system in Bonn, Germany.
	Population	46 adult people with out-of-hospital, non-traumatic cardiac arrest and a mean age of 66.3±15.4 years.
	Intervention	Mechanical CPR using the AutoPulse device.
	Outcome measures	Time to the AutoPulse setup; duration of CPR with the AutoPulse; total duration of CPR; ROSC; survival to ICU admission, 0–72 hours, >72 hours, hospital discharge, 6 months; mean ICU stay; neurologic state at ICU discharge using the CPC.

	Findings	• Time to set up the AutoPulse 4.7±5.9 minutes (median 2; range 1-25). • Mean duration of CPR with the AutoPulse was 18.4±12.3 minutes (median 17), and mean total duration of CPR was 29.0±14.6 minutes (median 26). • ROSC was achieved in 25/46 (54.3%) people. • Survival ICU admission: 39.1% (18/46). • Survival 0-72 hours: 8.7% (4/46). • Survival >72 hours: 30.4% (14/46). • Survival to hospital discharge: 21.7% (10/46). • Survival to 6 months: 10.9% (5/46). • Mean ICU stay was 13.6±10. 7 days. • Neurologic state at ICU discharge: CPC 1 n=2; CPC 2 n=1; CPC 3 n=7; CPC 4 n=0.
Omori et al. (2013)	Study design	Retrospective non-controlled.
	Setting	Helicopter Emergency Medical Service in Shizuoka, Japan.
	Population	92 people who had an out-of-hospital cardiac arrest and were resuscitated with either manual or mechanical CPR during helicopter transport (manual CPR group, n=43; the AutoPulse group, n= 49); mean age (manual CPR group, 65 years (26–92); the AutoPulse group, 71 years (15–87).
	Intervention	Manual CPR or mechanical CPR with the AutoPulse.
	Outcome measures	Duration of CPR, ROSC, survival to hospital discharge, CPC at discharge.

	Findings	• Duration of CPR in manual CPR only group: 53 minutes (10–87)[a]. • Duration of CPR in AutoPulse group: manual CPR, 41 (0–71); AutoPulse CPR, 15 minutes (3–30)[a]. • ROSC: manual CPR, 7% (3/43; AutoPulse CPR, 30.6% (15/49); (p=0.007). • Survival to hospital discharge - manual CPR, 2.3% (1/43); AutoPulse CPR, 6.1% (3/49); (p=0.620). • CPC at discharge: manual CPR, CPC1 n=1; AutoPulse CPR, CPC1 n=2, CPC3 n=1. • Univariate analysis indicated that a shorter duration of manual CPR application (p=0.016) and additional use of the AutoPulse (p=0.009) were factors associated with increased rates for return of spontaneous circulation. • Multivariate analysis suggests that younger age (p=0.042) and additional use of the AutoPulse (p=0.005) were factors associated with these increased rates.
Steinmetz et al. (2008)	Study design	Prospective non-controlled
	Setting	Mobile Emergency Care Unit of Copenhagen, Denmark.
	Population	77 out-of-hospital adult people.
	Intervention	Mechanical CPR with the AutoPulse.
	Outcome measures	Primary outcome: 30-day survival. Secondary outcomes: ROSC at hospital admission, survival to discharge.

	Findings	• 30-day survival: 13% (10/77) vs 16.7% (57/342) of people who did not have AutoPulse CPR (p=0.43). • ROSC at hospital admission: 52% (40/77) vs 36.3% (124/342) of people who did not have AutoPulse CPR (p=0.01). • Survival to discharge: not reported for the AutoPulse. • Logistic regression indicated that AutoPulse was associated with worse 30-day survival: OR 0.4; 95% CI 0.2 to 1.0 (p=0.04).
Timerman et al. (2004)	Study design	Prospective non-controlled crossover study.
	Setting	The Heart Institute (InCor) in São Paulo, Brazil.
	Population	16 adult people (mean age 68±6 years) with in-hospital sudden cardiac arrest.
	Intervention	10 minutes of manual CPR followed by alternating periods of manual CPR and AutoPulse CPR for 90 seconds each.
	Outcome measures	Vascular pressure (n=16), force of compression (n=10).

	Findings	• Peak aortic pressure (the AutoPulse: 153±28 mmHg vs 115±42 mmHg, p<0.0001). • Mean aortic pressure (the AutoPulse: 70±16 mmHg vs 56±15 mmHg, p<0.0001). • Aortic diastolic pressure (the AutoPulse: 29±12 mmHg vs 27±10 mmHg, p=0.366). • Right atrial peak pressure (the AutoPulse: 129±32 mmHg vs 83±40 mmHg, p<0.0001). • Right atrial diastolic pressure (the AutoPulse: 11±7 mmHg vs 12±6 mmHg, p=0.6571). • Right atrial mean pressure (the AutoPulse: 50±12mmHg vs 36±13 mmHg, p<0.0001). • Coronary perfusion pressure (the AutoPulse: 20±12mmHg vs 15±11 mmHg, p=0.015). • Force of compression (the AutoPulse: 125±18 kg vs 51±20 kg, p<0.0001).
Abbreviations: BP, blood pressure; CA, cardiac arrest; CPC, Glasgow-Pittsburgh cerebral performance category; CPR, cardiopulmonary resuscitation; $ETCO_2$, end-tidal CO_2; ICU, intensive care unit; mmHg, millimetres of mercury; n, number of people; ROSC, return of spontaneous circulation; versus, vs. [a] The authors did not report if this was the mean or median.		

Case reports

Two publications with 3 relevant case reports were identified. Risom et al. (2010) presented the case of a 44-year-old man who collapsed with cardiac arrest in Copenhagen, Denmark. A bystander administered immediate manual CPR for 9 minutes, which was then performed by paramedics in the first ambulance for 4 minutes but with no ROSC. A Mobile Emergency Care Unit then arrived, the AutoPulse was fitted to the patient and endotracheal intubation was performed. Following arrival at the hospital, sinus rhythm with ROSC was obtained a total of 60 minutes after cardiac arrest and 48 minutes after CPR with the AutoPulse. The patient was discharged from the hospital on day 11 after cardiac arrest with no signs of neurological deficits. The other case reported by

Risom et al. (2010) refers to a 26-year-old woman who fell into a canal in very cold weather. Manual CPR was carried out after the woman was pulled from the water, followed by CPR with the AutoPulse. On arrival at the hospital, the person's core temperature was 28.5°C. Sinus rhythm was obtained after 120 minutes of CPR with the AutoPulse and the patient reached a core temperature of 34.5°C. The patient was discharged 12 days after the accident with no signs of neurological deficit.

Wind et al. (2009) presented a case of 49-year-old woman from Maastricht, the Netherlands with a suspected pulmonary embolism who had at least 45 minutes of manual CPR. After an intravenous tenecteplase (8000 IU) bolus was administered, CPR continued with the AutoPulse. After a total of 105 minutes, resuscitation was stopped and the patient died. Autopsy revealed that the patient had a ruptured liver and spleen with 1 litre of abdominal blood. No pulmonary embolus was found. Other injuries included bilateral dorsal rib fractures, a fractured manubrium of the sternum and lateral cutaneous lacerations. Although the authors suggest that the AutoPulse device may have caused the injuries, the possibility of injury related to manual CPR (which was performed for a minimum of 45 minutes) cannot be excluded.

Abstract from conference proceedings

One study published as an abstract was identified to be potentially relevant (Jalali et al. 2014). This study was a prospective observational study conducted in Poland, which compared the use of the AutoPulse CPR (n=117) with manual CPR (n=175) on people with in-hospital and out-of-hospital cardiac arrest. It was not clear if the study included only non-traumatic cardiac arrests. Effectiveness of the interventions was measured by return of spontaneous circulation, 6-hour survival, blood pressure and blood gas. Compared with manual CPR, the AutoPulse CPR resulted in a significantly higher rate of return of spontaneous circulation (46% compared with 20.8%) and 6-hour survival (21% compared with 8%).

Recent and ongoing studies

Two ongoing or in-development trials on the AutoPulse for cardiac arrest were identified in the preparation of this briefing (Clinicaltrials.gov identifiers: NCT00951704; NCT01186614). NCT00951704 is a prospective cohort study to determine the epidemiology of sudden cardiac arrest in a pre-hospital setting, the quality of the CPR, and also the associations between depth and frequency of chest compressions, invasive arterial pressure, end-tidal CO_2, cerebral oxygenation and iatrogenic injuries associated with chest compressions. Estimated enrolment is 500 patients.

NCT01186614 is a non-randomised, open-label, single-group study on the safety and efficacy of the AutoPulse in patients with sudden out-of-hospital cardiac arrest. Automated CPR,

extra-corporeal membrane oxygenation, coronary angiography, and therapeutic hypothermia will be used. Estimated enrolment is 24 patients

Costs and resource consequences

No published evidence on resource consequences was identified. In addition to the initial cost of the AutoPulse and essential components, there are ongoing costs associated with its use (such as LifeBands, replacement of batteries). Time would be needed to make sure that the batteries were fully charged prior to use of the device and for periodic inspection of the AutoPulse to ensure the device's functionality. Space in the ambulances must be allocated to the AutoPulse platform and essential items (e.g. disposable LifeBands). Staff would need training to ensure that they can deploy the device in the minimum amount of time. Efficiencies to the NHS could arise if use of the AutoPulse resulted in freeing the rescuers' time, which would otherwise be taken up with manual CPR. However, it should be noted that the AutoPulse is normally an addition to the treatment pathway.

Savings could be achieved if people who had the AutoPulse had improved neurological outcomes compared with manual CPR. Better neurological outcomes may lead to a decrease in subsequent treatment costs and a reduction in the duration of hospital stay following the cardiac arrest episode. If the level of patient injuries sustained during manual CPR was reduced by the AutoPulse, people could need shorter hospital stays.

Strengths and limitations of the evidence

Two randomised controlled trials with power calculations comparing AutoPulse CPR with manual CPR were identified. In both trials, exclusion criteria were applied after the patient had either manual CPR or AutoPulse CPR, in order to avoid treatment delay. Therefore, only those who met the inclusion criteria following treatment were included in the analysis. Due to the nature of the AutoPulse device it would be impossible to blind the patient, rescuer and outcome assessor to the intervention being delivered. However, allocation could have been concealed for data analysis to prevent a potential source of bias.

The AutoPulse device was implemented at various stages of resuscitation; a protocol specifying device implementation at a set point of care might have produced different results. In both randomised controlled trials people had manual CPR before the AutoPulse was used. It was not possible to measure the quality of manual CPR in the ASPIRE trial (Hallstrom et al. 2006). In the CIRC trial (Wik et al. 2014), the quality of CPR was measured in both the manual CPR and integrated AutoPulse CPR arms by recording CPR fraction. The quality of CPR was shown to be

high for both arms (20-minute CPR fraction was 80.4% for AutoPulse CPR and 80.2% for manual CPR). The training and experience of personnel using the device would potentially also impact on the effectiveness of the intervention. It was also impossible to standardise hospital-based post-resuscitation care at the study sites and centres.

Enrolment terminated early in the Hallstrom et al. (2006) trial. The conditional power to detect the hypothesised difference in the primary outcome was 0.55 at the time of study termination, therefore not allowing definitive conclusions as established a priori by the authors. When comparing manual CPR only with AutoPulse CPR, the ASPIRE trial results suggest no statistically significant differences in survival to 4 hours. The CIRC trial reported statistically equivalent survival to hospital discharge.

The results of the comparative and non-comparative studies are susceptible to the bias inherent to their study design.

Relevance to NICE guidance programmes

NICE has accredited the guidance development methods used by the Resuscitation Council (UK), which has developed the following guideline which is relevant to this briefing:

- Resuscitation Guidelines. Resuscitation Council (UK) (2010). Date for review: 2015.

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Search strategy and evidence selection

Search strategy

1. Databases were searched from inception to October 2014. The following keywords were used

for the searches: AutoPulse; load distributing band-CPR; LDB-CPR. The number of citations found is in brackets after each database:

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)1946 to Present (47); Embase (via OVID) (169); Cochrane Library (total 12 including: 1 Cochrane review, 9 Trials, and 2 Technology Assessments); CAB Abstracts (0); Web of Science Core Collection (44).

These citations were searched for relevant material, using the inclusion criteria below.

2. ClinicalTrials.gov, WHO ICTRP, and Current Controlled Trials were also searched for ongoing trials.

3. Information provided by the company to support this briefing was checked to identify any further information.

4. The company's website was thoroughly investigated.

Evidence selection

The inclusion criteria were as follows:

- Patients/settings: adult patients (≥18 years) suffering non-traumatic cardiac arrest in out-of-hospital and in-hospital settings.
- Intervention: the AutoPulse (load-distributing band CPR from Zoll) that provides circumferential thoracic compressions.
- Comparator: manual chest compression for cardiopulmonary resuscitation (CPR).

- Outcomes: any relevant efficacy and safety clinical outcomes, including but not limited to:
  - survival to hospital discharge with good neurological function (e.g. Rankin scale score ≤3)
  - survival to hospital discharge
  - survival to hospital admission
  - short-term survival (≤30 days)
  - long-term survival (>30 days)
  - sustained return of spontaneous circulation (ROSC)
  - neurological outcome (e.g. Rankin scale)
  - intervention-related adverse events/injuries
  - duration of CPR
  - intensity of compression.
- Study design: for effectiveness any controlled study will be included; for safety aspect of the device, any controlled study, non-controlled study and case report will be included. Systematic reviews and meta-analyses will be used for identifying relevant primary studies only.

Only studies fully published in English language were included.

Changes after publication

March 2015: Minor maintenance

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by the Birmingham and Brunel Consortium. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

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