Prehospital randomised assessment of a mechanical compression device in out-of-hospital cardiac arrest (PARAMEDIC): a pragmatic, cluster randomised trial and economic evaluation

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Scientific summary

Mechanical chest compression for out-of-hospital cardiac arrest

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Scientific summary

Background

Chest compression is one of the crucial components of cardiopulmonary resuscitation (CPR). However, it is known that it is difficult to maintain adequate depth and frequency of compressions, reducing the patient's chances of survival. Mechanical chest compression devices have been proposed as a potential solution, as they can provide compressions of standard depth and frequency indefinitely, do not tire and can be used in situations in which manual chest compression is difficult. In this trial we evaluated use of the LUCAS-2 device (Lund University Cardiopulmonary Assistance System-2; Jolife AB, Lund, Sweden), which was introduced into UK ambulance services several years ago without any evidence of effectiveness.

Objectives

1. To conduct a pragmatic, cluster randomised trial of the LUCAS-2 device compared with standard manual chest compression for patients experiencing an out-of-hospital cardiac arrest.
2. To conduct an economic evaluation to estimate the cost-effectiveness of the LUCAS-2 device.
3. To perform a systematic review to combine the results of the current trial with those of other recent trials of mechanical chest compression.

Methods

Study design

The design was a cluster randomised controlled trial (RCT), with ambulance service vehicles [ambulances and rapid response vehicles (RRVs)] as the units of randomisation. Four UK ambulance services took part. An economic evaluation was also conducted and we performed a systematic review to synthesise the results of this and other recent randomised trials of mechanical chest compression.

Outcomes

Primary

1. Survival to 30 days post cardiac arrest.

Secondary

1. Survived event (survival to hospital).
2. Survival to hospital discharge.
3. Survival to 3 and 12 months.
4. Health-related quality of life at 3 and 12 months [Short Form questionnaire-12 items (SF-12)].
5. Neurological outcome at discharge from hospital [as measured via the Cerebral Performance Category (CPC) scale with a score of 1 or 2 vs. 3–5].
6. Neurological outcome at 12 months (as measured via the Mini Mental State Examination).
7. Anxiety and depression at 12 months (as measured via the Hospital Anxiety and Depression Scale).
8. Post-traumatic stress at 12 months (as measured via the Post-Traumatic Stress Disorder Civilian Checklist).
9. Hospital length of stay.
10. Intensive care length of stay.

Inclusion criteria

Patients were included if they were in cardiac arrest, if they were out of hospital, if resuscitation was attempted and if they were attended by a trial vehicle. Exclusions were cardiac arrest due to trauma, patients with a known or clinically apparent pregnancy and patients known to be or apparently aged < 18 years.

Randomisation and treatment

Cardiac arrests were identified from routine ambulance service records. Patients were automatically included in the trial if they met the inclusion criteria.

Data collection

Data were collected by research paramedics from ambulance service records. Deaths were identified from ambulance services and routine UK NHS data via the Health and Social Care Information Centre. Surviving patients were contacted for consent for follow-up and, if consent was given, they were visited at 3 and 12 months post cardiac arrest.

Analysis

We performed an intention-to-treat (ITT) analysis and, because of lower-than-expected compliance in the LUCAS-2 arm, complier average causal effect (CACE) analyses. For the CACE analyses, we classified cases of non-compliance into those that would happen in normal clinical practice (e.g. device malfunction, location too restricted to use the LUCAS-2 device) and those that were specific to the context of the trial.

Economic evaluation

The economic evaluation assessed the cost-effectiveness of use of the LUCAS-2 device. It consisted of two complementary sets of analyses: a within-trial analysis over the 12-month trial period and a decision-analytic model that was constructed to extrapolate the results over the expected lifetime of the trial participants. The cost-effectiveness analyses were conducted from the NHS and Personal Social Services perspective. The analyses report cost per incremental quality-adjusted life-year of LUCAS-2 compared with usual care (manual chest compression). Data from various sources were combined to estimate costs and treatment benefits, including trial case report forms, large data sets (i.e. Hospital Episode Statistics, Intensive Care National Audit and Research Centre data), self-completed patient questionnaires and data extracted from the literature.

Systematic review

We searched for randomised trials evaluating mechanical chest compression (using any device) published since 1990 (search date February 2015). Data were extracted by two authors and meta-analyses conducted using Review Manager software version 5.3 (RevMan, The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark). Outcomes were return of spontaneous circulation, survival of event, survival to discharge from hospital or 30 days and survival with good neurological outcome (measured by CPC or modified Rankin Scale).

Results

We enrolled 4471 eligible patients (1652 assigned to the LUCAS-2 group and 2819 assigned to the control group) between 15 April 2010 and 10 June 2013. Nine hundred and eighty-five (60%) patients in the LUCAS-2 group received mechanical chest compression and 11 (< 1%) patients in the control group received LUCAS-2 treatment. In the ITT analysis, 30-day survival was similar in the LUCAS-2 [104 (6.3%) of 1652 patients] and manual CPR groups [193 (6.8%) of 2819 patients; adjusted odds ratio (OR) 0.86, 95% confidence interval (CI) 0.64 to 1.15]. Survival with a CPC score of 1 or 2 was worse in the LUCAS-2 group (adjusted OR 0.72, 95% CI 0.52 to 0.99). No serious adverse events were noted. The systematic review found no evidence that mechanical chest compression was superior to manual. The economic analysis consistently showed that treatment with the LUCAS-2 device was more costly and less effective than manual CPR, although differences in mean costs and outcomes between both treatment arms were fairly small.

These results were obtained both in the within-trial analysis and in the analysis that modelled lifetime costs and outcomes. When missing data were handled by multiple imputation, estimated costs were higher in both arms, but the incremental cost-effectiveness ratios also indicated that manual CPR dominates LUCAS-2.

Conclusions

The trial, systematic review and economic evaluation all found that there was no evidence that mechanical chest compression using LUCAS-2 was superior to standard manual chest compression.

Trial registration

This trial is registered as ISRCTN08233942.

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