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Mechanical versus manual chest compression for out-of-hospital cardiac arrest (PARAMEDIC): a pragmatic, cluster randomised control trial

There is no evidence of improvement of 30 day survival with the LUCAS-2 mechanical CPR device compared with manual chest compressions.
Level of Evidence: 1b (individual RCT with narrow confidence intervals).

Appraised by: A Greer and RP Tully

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Three-part clinical question: *Patients*: Adult patients (18 years or older) in cardiac arrest outside of a hospital.

Intervention: Mechanical Cardiopulomary resuscitation (CPR) using the LUCAS-2 device vs. traditional manual CPR.

Outcome: Primary outcome – survival to 30 days after the cardiac arrest. Secondary outcomes – survived event (return of spontaneous circulation sustained until admission), survival to three months, survival to 12 months, and survival with favourable neurological outcome (Cerebral Performance Category score of 1 or 2) at three months.

The study: Pragmatic, clustered, single blinded, randomised control trial with Intention-To-Treat and Complier Average Causal Effect (CACE) analyses.

The study patients: *Eligible*: Adult patients in cardiac arrest out of a hospital with a trial vehicle being the first ambulance service vehicle on scene.

Included: Patients were recruited between 15 April 2010 and 10 June 2013. Total: 4471 patients (418 clusters); 1652 patients (147 clusters) were assigned to the LUCAS-2 group and 2819 patients (271 clusters) assigned to the control group. Clusters were ambulance service vehicles. The number of LUCAS-2 devices available to the trial was 143; therefore, a ratio of approximately 1 experimental (LUCAS-2) to 2 control (manual) was used to optimise the power of the study.

Both groups had similar baseline characteristics. This included age (71 vs. 71.6 years in LUCAS-2 vs. control, respectively), cardiac aetiology of cardiac arrest (86% vs. 87%), bystander CPR (43% vs. 43%), and whether patients were intubated (45% vs. 46%). The initial rhythms in each group were also comparable (22% vs. 21% for VF, 1% vs. 1% for VT, 24% vs. 25% for PEA, and 50% vs. 49% for asystole).

Excluded: Two-hundred-eighteen patients* were excluded: 2 pregnant, 107 cardiac arrest caused by trauma, 107 aged younger than 18 years, and 9 not out of hospital. Further 1 patient in the control arm excluded due to unknown survival status.

*Seven patients met more than one exclusion criteria

LUCAS-2 group (intervention): Training for those using the mechanical device was designed by ambulance staff on guidance from the manufacturer of the LUCAS-2. Preparation included online training resources, face to face training with hands on deployment practice, and a competency checklist before staff were authorised to deploy the machine.

LUCAS-2 provided chest compressions between 40 and 53 mm in depth and at a rate of 102 min^{-1}. On arrival at the scene of a cardiac arrest, staff were instructed to commence manual CPR and switch the device on. Once powered up manual compressions were paused briefly, whilst the back plate was inserted. CPR was re-started, whilst the remainder of the device was assembled. (This included positioning the central arms, deploying the suction cup and activating the device.) Defibrillation was performed where indicated.

Manual CPR group (control): As per the Resuscitation Council's guidelines, patients in the control group received manual CPR at a target depth and rate of 50–60 mm and 100–120 min^{-1}, respectively. CPR was started on arrival and ECG monitoring attached. Chest compressions were paused briefly to allow rhythm analysis plus defibrillation if appropriate.

Both groups received compression to ventilation ratio of 30:2 before intubation and continuous compressions with asynchronous ventilation after intubation.

Results:

Outcome	Time to outcome	CER	EER	RRR	ARR	NNT
Death	**30 days**	0.932	0.938	−1%	−0.006	**ns**
	95% Confidence intervals:			−2% to 1%	−0.021 to 0.009	
Death	**3 months**	0.935	0.942	−1%	−0.007	**ns**
	95% Confidence intervals:			−2% to 1%	−0.021 to 0.007	
Favourable neurological outcome (CPC 1–2)	**3 months**	0.060	0.047	22%	0.013	**ns**
	95% Confidence intervals:			−1% to 44%	0.000 to 0.026	

CER: control event rate; EER: experimental event rate; RRR: relative risk reduction; ARR: absolute risk reduction; NNT: number needed to treat; CPC: cerebral performance category; ns: not significant.

EBM questions:

1. Do the methods accurately allow testing of the hypothesis? Yes.

Individual ambulance vehicles (clusters) were assigned with a computer-generated randomisation sequence, which stratified by station and vehicle type. Individual patients were then allocated to the LUCAS-2 or control group according to the first trial vehicle on scene. Ambulance dispatch staff were unaware of the randomised allocations. Masking of ambulance clinicians was not possible since they gave the intervention.

The study had 80% power to find a significant result (with threshold two-sided p value of 0.05) if the incidence of survival to 30 days was 5% in the manual CPR group and 7.5% in the LUCAS-2 group. Using a correlation co-efficient of 0.01 to allow clustering in groups of 15, the study recruited 245 clusters (3675 patients) into the trial.

The primary analysis was by intention to treat, whereby fixed effect logistic regression models were used to obtain unadjusted and adjusted odds ratios. Complier average causal effect (CACE) was also implemented. The aim of CACE was to estimate the treatment effect in people randomly assigned to the intervention who actually received it. CACE1 treated as non-compliant those cases in which LUCAS-2 was not used for unknown or trial related reasons that would not occur in real life clinical practice. CACE2 only treated as compliant those cases in which LUCAS-2 was actually used.

Pre-specified subgroup analyses were performed and defined as: initial rhythm (shockable vs. non-shockable), cardiac arrest witnessed vs. not witnessed, type of vehicle (RRV vs. ambulance), bystander CPR vs. no bystander CPR, region, aetiology, age and response time.

2. Do the statistical tests correctly test the results to allow differentiation of statistically significant results? Yes.
3. Are the conclusions valid in light of the results? Yes.

The introduction of LUCAS-2 did not improve the primary outcome of survival to 30 days. This result was valid in the Intention-to-Treat and CACE groups. Furthermore, secondary outcomes were also equivocal in each group, i.e. there was no statistically significant difference in outcome in survival to 3 months, survival to 12 months and survival with favourable neurological outcome (Cerebral Performance Category score of 1 or 2) at 3 months.

The study found that patients presenting in a shockable rhythm had marginally worse neurological outcomes and lower survival rates. The author acknowledged that this was not the primary objective of the trial and that the results should be interpreted with caution.

4. Did results get omitted, and why?

In the control group, one patient was omitted due to unknown survival status. No patient or personal consultee requested to withdraw from the study. The remaining patients initially recruited were accounted for in the final results.

5. Did they suggest areas for further research?

The implementation process was tailored to reflect how the LUCAS-2 device would be introduced in the National Health Service (NHS). Large capital investment would be required to purchase a sufficient number of devices and fully implement them. The PARAMEDIC study suggests that future research should look to define the optimum method and frequency of training of staff using the device.

The study creates scope for further research and also leaves some outstanding questions. Examples of unanswered questions include:

- Are there any disadvantages or limitations to using the LUCAS-2 device that are not explored in the study?

- Can we explore other benefits of using mechanical CPR devices (e.g. LUCAS-2) in the pre-hospital setting, i.e. to free up additional ambulance staff once the device is deployed?
  - Are there ways to overcome the device-related factors that limited the use of the LUCAS-2? For example, what were the issues surrounding implementation of the equipment and the training and quality issues associated with it?
  - As the authors hypothesized, is the interruption in CPR whilst applying the mechanical device sufficient to affect cerebral perfusion and subsequent Cerebral Performance Score?

6. Did they make any recommendations based on the results and were they appropriate?

The authors highlighted the difficulties of training and implementing mechanical CPR devices (e.g. LUCAS-2) into routine practice. The recommendation was that deployment of the device across services would require substantial investment and should be commenced with caution. The authors advised that the investment should be balanced against the accepted role that the devices would have, such as prolonged CPR or during transportation. It should be noted that currently there is no evidence that the LUCAS-2 device provides a beneficial effect in the pre-hospital environment.

7. Is the study relevant to my clinical practice? Yes.
8. What level of evidence does this study represent? 1b
9. What grade of recommendation can I make on this result alone? A.
10. What grade of recommendation can I make when this study is considered along with other available evidence? A.
11. Should I change my practice because of these results?

This study does not provide sufficient evidence that mechanical CPR with the LUCAS-2 has an improved outcome for pre-hospital cardiac arrests compared to manual CPR. As a consequence, current practice should not be changed on the basis of this study alone. However, there may be a role for mechanical CPR devices if prolonged CPR is required and during cardiac catheterization. Further research is therefore required.

12. Should I audit my current practice because of these results?

No. The study failed to show any benefit from using the device compared with manual CPR.

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