

Clinical summary

Mechanical chest compressions and simultaneous defibrillation vs conventional cardiopulmonary resuscitation in out-of-hospital cardiac arrest. The LINC randomized trial.¹

Objective:

To determine whether administering mechanical chest compressions with defibrillation during ongoing compressions (LUCAS-CPR), compared with manual cardiopulmonary resuscitation (Manual-CPR), according to the guidelines, would improve 4-hour survival.

Intervention:

Start manual CPR. Randomize to:

- LUCAS-CPR:
 - Apply and start the LUCAS device
 - 3 minute compression cycles (90 s + defibrillation + 90 s), then stop for rhythm checks
- Manual-CPR:
 - Continue manual chest compressions according to 2005 European Resuscitation Council (ERC) guidelines
 - 2 minute compression cycles with stops for rhythm checks and defibrillation

Both groups received medications according to ERC guidelines.

Primary endpoint

- Four-hour survival after successful return of spontaneous circulation (ROSC)

Secondary endpoints

- ROSC defined as a spontaneous palpable pulse
- Arrival to the emergency room with spontaneous palpable pulse
- Survival to discharge from ICU without severe neurological impairment with a Cerebral Performance Category² (CPC) scale of 1 or 2
- Survival to hospital discharge with good neurological outcome (CPC 1 or 2)
- Survival 1 and 6 months after cardiac arrest with good neurological outcome (CPC 1 or 2)

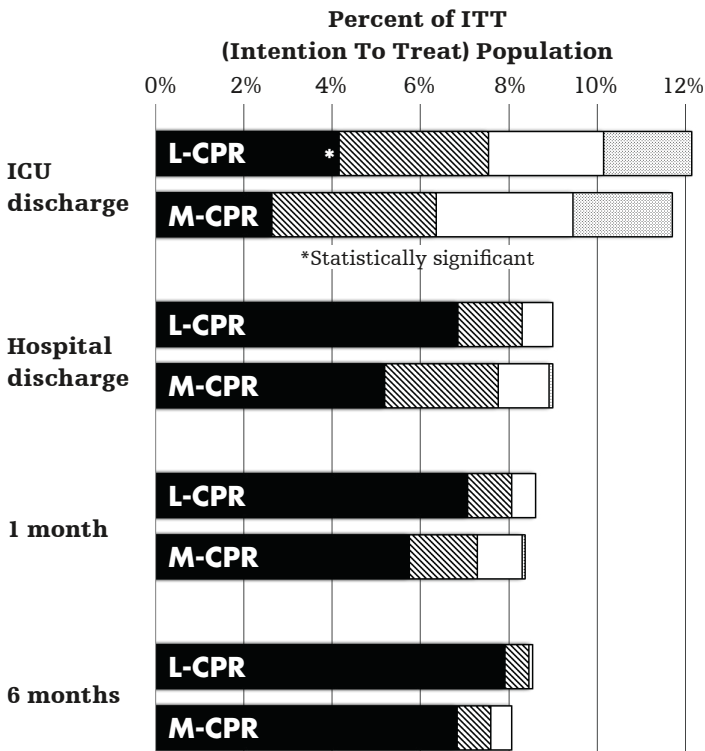
Method:

- Study was conducted from January 2008 to August 2012 in 6 European sites.
- 2,589 out-of-hospital cardiac arrest patients were randomized to treatment with LUCAS-CPR (n=1,300) or with Manual-CPR (n=1,289).
- Surviving patients were followed for 6 months and evaluated for neurological outcome using the CPC Scale. Good neurological outcome was a CPC score of 1-2.
- Patients treated with defibrillation prior to arrival of the ambulance crew or crew witnessed cardiac arrest successfully treated with the first defibrillation were excluded.

Results:

- Four-hour survival rate was 23.6% (n=307) with LUCAS-CPR and 23.7% (n=305) with Manual-CPR (risk difference -0.05%, 95% C.I. -3.3 to 3.2, p=1.00).
- ROSC defined as a spontaneous palpable pulse:
 - 35.4% vs. 34.6% (95% C.I. -2.9 to 4.5, p=.68)
- Arrival to emergency room with spontaneously palpable pulse:
 - 28.2% vs 27.7% (95% C.I. -3.0 to 3.9, p=.83)
- Survival with good neurological outcome (CPC 1-2) in the LUCAS-CPR and Manual-CPR was:
 - 8.3% (n=108) vs. 7.8% (n=100) (p=0.61) at hospital discharge
 - 8.1% (n=105) vs. 7.3% (n=94) (p=0.46) at one month
 - 8.5% (n=110) vs. 7.6% (n=98) (p=0.43) at 6 months
- The percent of surviving patients with good neurological outcome (CPC 1-2) in relation to the overall number of survivors in the LUCAS-CPR and Manual-CPR group respectively were:
 - 62% vs. 54% at intensive care unit (ICU) discharge
 - 92% vs. 86% at hospital discharge
 - 94% vs. 88% at one month
 - 99% vs. 94% at 6 months after cardiac arrest

Neurological outcomes



n (%)				p
CPC 1 ■	CPC 2 ▨	CPC 3 □	CPC 4 ■	
54 (4.2%)	44 (3.4%)	34 (2.6%)	26 (2.0%)	0.04
34 (2.6%)	48 (3.7%)	40 (3.1%)	29 (2.2%)	
89 (6.8%)	19 (1.5%)	9 (0.7%)	0 (0%)	0.08
67 (5.2%)	33 (2.6%)	15 (1.2%)	1 (0.1%)	
92 (7.1%)	13 (1.0%)	7 (0.5%)	0 (0%)	0.17
74 (5.7%)	20 (1.6%)	13 (1.0%)	1 (0.1%)	
103 (7.9%)	7 (0.5%)	1 (0.1%)	0 (0%)	0.29
88 (6.8%)	10 (0.8%)	6 (0.5%)	0 (0%)	

Conclusions:

There was no significant difference in 4-hour survival between patients treated with the LUCAS-CPR algorithm or those treated with Manual-CPR. The vast majority of survivors in both groups had good neurological outcome by 6 months.

LINC discussion points

- The large, randomized LINC trial provides the highest level of evidence that the LUCAS device can be routinely used to treat prehospital cardiac arrest patients with good survival rates and neurological outcomes. Ninety-nine percent (99%) of the survivors treated with LUCAS had a good neurological outcome at 6 months follow up. Both the absolute and relative number of patients with good neurological outcome was consistently higher in the LUCAS-CPR group, however, not reaching statistical significance difference to Manual-CPR. This data supports implementation of the LUCAS® chest compression system.
- Throughout the LINC trial activities were made to ensure the LUCAS device was compared to high quality Manual-CPR³:
 - Rescuers were trained twice as often as typically done; every 6 months, in both CPR methods and algorithms
 - Over 800 tests were made with rescuers at the sites to evaluate CPR performance and as well as adherence to study algorithms in a manikin setting, with immediate feedback

- Many rescuers participating in the LINC trial stated they were motivated to provide high-quality manual CPR and “competed” with LUCAS to help save patients randomized to the Manual-CPR group. Being part of a study itself might have improved CPR skills and behavior.
- The LINC trial excluded the most viable prehospital cardiac arrest patients; the ones that had been defibrillated before the arrival of the ambulance (e.g. with an AED) as well as the ones who had a crew-witnessed cardiac arrest and were successfully defibrillated with the first shock. The overall survival rate is likely to be considerably higher when these patients are included.
- The investigator and steering committee designed an algorithm for the LUCAS-CPR group designed to minimize pre- and post-shock pauses. Thus the defibrillation was provided during ongoing CPR in the midst of each 3 minute cycle of chest compressions, e.g. each defibrillation was preceded and followed by 90 seconds of chest compressions without any interruption.
- The LINC trial also provides valuable data on the usability and reliability of the LUCAS device:
 - The LUCAS device showed a high reliability of 99.4% during the four years the study was conducted
 - 95% of patients fit the device

Putting the LINC trial into perspective

- Using randomization envelopes at the patient's side, as in the LINC trial, effectively reduces patient selection bias and other confounding factors. This gives the LINC trial a higher scientific value than cluster, retrospective or historically controlled studies.
 - Cluster-randomized studies run a higher risk of patient selection biases and geographical or temporal inconsistencies.
 - Retrospective analyses of contemporary use of manual and mechanical CPR run a risk of skewed survival results as it is typically more of the difficult/prolonged resuscitations that receive mechanical CPR.
 - Historically controlled studies may more truly reflect the actual effect of implementing mechanical CPR and its synergistic effects on the chain of survival, but may also include effects caused by other factors.
- The largest site participating in the LINC trial purchased their LUCAS study devices before the LINC trial results were available. They appreciated not only the effectiveness of the device, but also the many operational efficiencies and safety aspects provided to the team.
- With a mechanical compression device, there is an increased emphasis on clinical judgment, rather than rescuer fatigue and practical considerations, when deciding whether to continue or stop resuscitation efforts. Recently, positive outcomes after prolonged CPR have received attention.^{4,5}
- The LINC trial is part of over 100 LUCAS publications⁴ showing the LUCAS device can safely and effectively be implemented as a tool to:
 - secure consistent, continuous and high quality of chest compressions to sustain vital circulation to the heart and brain
 - facilitate safe and effective CPR during patient movement and transportation
 - facilitate prolonged CPR bridging to other lifesaving therapies or ROSC
 - facilitate emergency PCI during ongoing CPR in the cath lab to treat the cause of cardiac arrest (Class IIa AHA)
- The results from the LINC trial apply only to the LUCAS device and no other mechanical chest compression device.

References

1. Rubertsson S, Lindgren E, Smekal D, et al. Mechanical chest compressions and simultaneous defibrillation vs conventional cardiopulmonary resuscitation in out-of-hospital cardiac arrest: The LINC Randomized Trial. *JAMA*. 2014;311:53-6.
2. Cerebral Performance Category:
CPC 1: Return to normal cerebral function and normal living
CPC 2: Cerebral disability but sufficient function for independent activities of daily living
CPC 3: Severe disability, limited cognition, inability to carry out independent existence
CPC 4: Coma
CPC 5: Death
3. Rubertsson S, Silfverstolpe J, Rehn L, et al. The Study Protocol for the LINC (LUCAS in Cardiac Arrest) Study: a study comparing conventional adult out-of-hospital cardiopulmonary resuscitation with a concept with mechanical chest compressions and simultaneous defibrillation. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine*. 2013;21:5.
4. LUCAS Selected and Summarized Bibliography available from your sales representative or at www.physio-control.com/clinicalinfo.asp
5. Goldberger Z, Chan F, Berg R, et al. Duration of resuscitation efforts and survival after in-hospital cardiac arrest: an observational study. *Lancet*. 2012;380(9852):1473-81.

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