FDA Circulatory System Devices Panel Classification of External Cardiac Compressor (ECC) Devices

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Public Citizen's Health Research Group

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We have no conflicts of interest

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FDA's Assessment

"[Available evidence] cannot provide reasonable assurance that the devices are safe and effective when used *in place of* standard manual CPR."

-FDA Executive Summary (emphasis in original)

Randomized Controlled Trials

mechanical v manual CPR

Title	N	Device	Number surviving to discharge	Assessed Neurological Function at Discharge?	Assessed Survival Beyond 30 days?
Taylor et al. (1978)	50	Thumper	5	No	No
Halperin et al. (1993)	34	Vest ECC Device	0	No	No
Ward et al. (1993)	15	Thumper	0	No	No
Dickinson et al. (1998)	20	Thumper	0	No	No
ASPIRE (2006)	767	AutoPulse	60	Yes	No

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The ASPIRE Trial: Results

N = 767
out-of-hospital cardiac arrest

Outcome	Manual CPR (n=373)	Mechanical CPR (n=394)
Survived ≥ 4 h after 911 call	92 (24.7%)	104 (26.4%)
Discharged alive	37 (9.9%)	23 (5.8%)
CPC Score of 1 or 2	28 (7.5%)	12 (3.1%)
CPC Score:		
1. Conscious and alert	25 (6.7%)	6 (1.5%)
2. Conscious	3 (0.8%)	6 (1.5%)
3. Dependent	5 (1.3%)	7 (1.8%)
4. Unconscious	2 (0.5%)	1 (0.3%)
5. Circulatory death	336 (90.6%)	371 (94.9%)

Hallstrom A, Rea TD, Sayre MR, et al. Manual chest compression vs use of an automated chest compression device during resuscitation following out-of-hospital cardiac arrest: a randomized trial. JAMA. 2006;295:2620-2628.

Conclusive evidence of harm?

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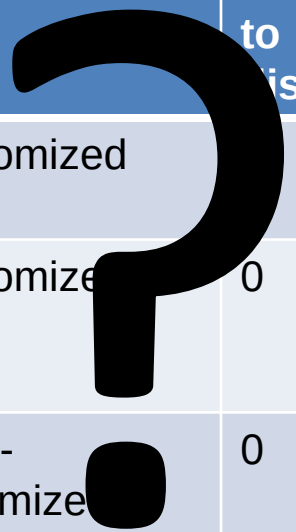
Randomized Controlled Trials

comparing EEC v manual CPR

Title	N	Device	Randomization Method	Number surviving to ischarge	Assessed Neurological Function at Discharge?	Assessed Survival Beyond 30 days?
Tayor et al. (1978)	50	Thumper	Randomized		No	No
Halperin et al. (1993)	34	Vest ECC Device	Randomize	0	No	No
Dickinson et al. (1998)	17	Thumper	Quasi-randomize	0	No	No
ASPIRE (2006)	767	AutoPulse	Cluster-randomized	60	Yes	No



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FDA Proposal: Limited Use

- During transport,
- Extended CPR when fatigue may prohibit delivery of effective/consistent CPR, or
- When insufficient EMS personnel are available to provide effective CPR

FDA Proposal: Limited Use

Manual

Mechanical

Manual

?

Mechanical

"The evidence from [the ASPIRE] trial is that the AutoPulse has no survival advantage and may be harmful. For now, the AutoPulse should be used only in the context of clinical research until evidence can sufficiently explain the ASPIRE results and provide assurance of survival advantage."

-Hallstrom A, Rea TD, Sayre MR, et al. 2010
ASPIRE study authors

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Recommendations

- Death and impairment are probable health risks
- Safety and effectiveness are not assured
- The probable benefits do not outweigh the risks

Retain in Class III