Mechanical Chest Compressions and Simultaneous Defibrillation vs Conventional CPR in OHCA

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背景

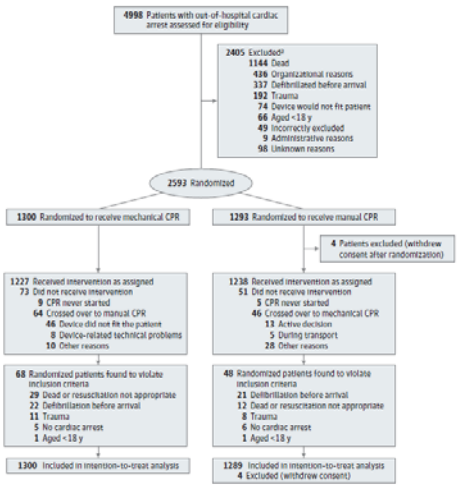
- 許多因素會影響心跳停止後的存活率
- 其中一項是施行**高品質的壓胸**來幫助恢復心跳
- 徒手壓胸受限於施術者的體力、技巧
- 至多只能提供 **30%** 的心輸出
- 電擊時必須中斷，輸送病患時也很難做好
- 為了克服上述缺點，發明了心肺復甦機
- 先前的使用經驗發現能提供較好的循環功能
- 甚至能提供心導管所需的血流
- 兩次前導實驗未能證實心肺復甦機能否改善存活率

研究目的

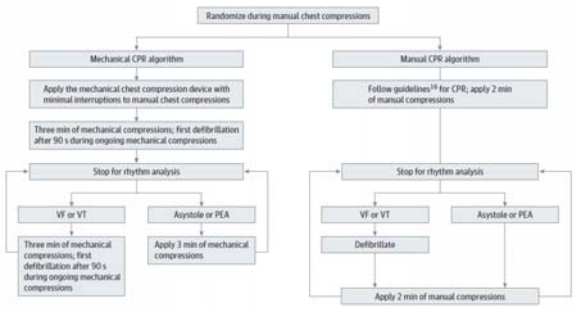
- 判斷使用心肺復甦機施行「電擊時不間斷」的壓胸，與遵守臨床指引的徒手壓胸相比，是否能改善四小時內的存活率

方法

- 多中心的隨機分派臨床試驗
- 收案期間：2008/01~2013/02
- 六個急救服務及其轉送醫院
  - 4個瑞典、1個英國、1個荷蘭
- 共 2589 位到院前心跳停止患者列入試驗
  - 隨機分派為心肺復甦機組(n=1300)與徒手壓胸組(n=1289)
- 主要比較四小時的存活率
- 另調查六個月神經學功能 (以 CPC 分數比較)



急救流程



Cerebral Performance Categories Scale

CPC Scale

Note: If patient is anesthetized, paralyzed, or intubated, use "as is" clinical condition to calculate scores.
CPC 1. Good cerebral performance: conscious, alert, able to work, might have mild neurologic or psychologic deficit.
CPC 2. Moderate cerebral disability: conscious, sufficient cerebral function for independent activities of daily life. Able to work in sheltered environment.
CPC 3. Severe cerebral disability: conscious, dependent on others for daily support because of impaired brain function. Ranges from ambulatory state to severe dementia or paralysis.
CPC 4. Coma or vegetative state: any degree of coma without the presence of all brain death criteria. Unawareness, even if appears awake (vegetative state) without interaction with environment; may have spontaneous eye opening and sleep/awake cycles. Cerebral unresponsiveness.
CPC 5. Brain death: apnea, areflexia, EEG silence, etc.

Safar P. Resuscitation after Brain Ischemia, in Grenvik A and Safar P Eds: Brain Failure and Resuscitation, Churchill Livingstone, New York, 1981; 155-184.

結果

- 四小時存活率：
  - 復甦機 307/1300 (23.6%)、徒手 305/1289 (23.7%)
  - 風險差異 −0.05%; 95%CI, −3.3% to 3.2%; P > .99
- 神經學損傷不構成日常生活功能障礙人數：
  - 於轉出 ICU 時：
    98 (7.5%) vs 82 (6.4%)(RD 1.18%; 95%CI, −0.78% ~ 3.1%)
  - 一個月後：
    105 (8.1%) vs 94 (7.3%)(RD, 0.78%; 95%CI, −1.3% ~ 2.8%)
  - 六個月後：
    110 (8.5%) vs 98 (7.6%)(RD, 0.86%; 95%CI, −1.2% ~ 3.0%)
- 活過六個月的患者中日常無礙的人數：99% vs 94%

結論

- 對於成人到院前死亡患者而言，使用心肺復甦機和徒手壓胸急救對於四小時存活率並無統計上顯著影響。
- 大多數存活六個月的患者在兩組保有良好神經學功能
- 以前述流程圖配合心肺復甦機急救，與徒手壓胸急救相比，無法提升急救效果

討論

- 與裝置相關的嚴重副作用和不良反應發生率不高
- 選擇比對四小時存活率，是擔心復甦後的照護會有差異，不過在實驗中其實兩組復甦後的照護很相似，六個月存活率也支持這項發現。
- 雖無明確差異，但無法排除略為有利或有害的可能
- 心肺復甦機流程圖設計了無論如何先電擊，以及三分鐘確認一次心律的特性，理論上來說應該有點優勢
- 未能體現這個優勢，可能是裝上裝置後 90 秒才電擊造成的拖延，但多 90 秒壓胸也可能是有利的

討論

- 急救人員到達前就接受過電擊的患者，被醫療人員目睹倒下並接受電擊後恢復自主循環的患者均被排除，因此實際的存活率可能比實驗中測出的更高一些。
- 機械故障率 <1%
- 5% 的人因為太大或太小無法使用心肺復甦機
- 本實驗的限制之一是未能評估急救流程圖的順從率
- 心肺復甦機配合徒手壓胸流程是否有好處須另行實驗

評讀

使用 Critical Appraisal Skills Programme (CASP)
Randomised Controlled Trials Checklist

1. Did the trial address a clearly focused issue? ☑ Yes ☐ Can't tell ☐ No

HINT: An issue can be 'focused' in terms of
- The population studied
- The intervention given
- The comparator given
- The outcomes considered

•研究對象：歐洲六個急救服務經手的
成人到院前心跳停止患者 (排除死亡、外傷、裝不下)
•介入：使用 LUCAS心肺復甦機配合新流程急救
•對照：使用遵照現行臨床指引的方式徒手壓胸
•結果：比較四小時存活率、六個月神經學功能

2. Was the assignment of patients to treatments randomised? ☑ Yes ☐ Can't tell ☐ No

HINT: Consider
- How was this carried out?
- Was the allocation sequence concealed from researchers and patients?

•隨機分派方式：於參與研究的急救車上放置心肺復甦機
以及一個不透明信封，裡面隨機寫著是否使用機器壓胸
•無論研究者還是患者都不可能預先知道信封內容

3. Were all of the patients who entered the trial properly accounted for at its conclusion? ☑ Yes ☐ Can't tell ☐ No

HINT: Consider
- Was the trial stopped early?
- Were patients analysed in the groups to which they were randomised?

•研究並未提早叫停
•使用立意治療分析

4. Were patients, health workers and study personnel 'blind' to treatment? ☐ Yes ☑ Can't tell ☐ No

HINT: Think about
- Patients?
- Health workers?
- Study personnel?

•患者當下無法得知自己被以何種方式急救
•論文中未說明事後同意時是否告知分組
•施救者可明確知道以何種方式急救
•論文中未說明研究者是否得知患者的組別

5. Were the groups similar at the start of the trial? ☑ Yes ☐ Can't tell ☐ No

HINT: Look at
- Other factors that might affect the outcome such as age, sex, social class

•患者的年齡、性別、underlying disease 分布均相似
•此研究並未調查患者的社經地位

6. Aside from the experimental intervention, were the groups treated equally? ☑ Yes ☐ Can't tell ☐ No

•所有恢復自發性循環的患者，只要沒有禁忌症，都以
輕度低體溫療法 (32˚C-34˚C)治療 24 小時
•所有患者在頭 48 小時都會被評估是否需要 1˚ PCI

7. How large was the treatment effect?

HINT: Consider
- What outcomes were measured?
- Is the primary outcome clearly specified?
- What results were found for each outcome?

•此研究統計了四小時存活率、六個月的神經學功能
其他還有恢復自發性循環、到院時是否有脈搏等等
•主要結果有明確定義，即成功恢復自發性循環後，
於四小時仍存活的比率
•本研究發現兩組四小時存活率並無顯著差別
•所有調查的結果中，只有「轉出 ICU 的存活者中，
神經學功能不受影響」這個項目有顯著優勢。

Outcomes	No. (%) of Participants		*P* Value	Treatment Difference, % (95% CI)
	Mechanical CPR (n = 1300)	Manual CPR (n = 1289)		
4-Hour survival[a]	307 (23.6)	305 (23.7)	>.99	−0.05 (−3.3 to 3.2)
ROSC[b]	460 (35.4)	446 (34.6)	.68	0.78 (−2.9 to 4.5)
Arrival at emergency department with palpable pulse	366 (28.2)	357 (27.7)	.83	0.46 (−3.0 to 3.9)
Survival to discharge from ICU with CPC 1-2[c]	98 (7.5)	82 (6.4)	.25	1.18 (−0.8 to 3.1)
Survival to hospital discharge with CPC 1-2[c]	108 (8.3)	100 (7.8)	.61	0.55 (−1.5 to 2.6)
1-Month survival with CPC 1-2[d]	105 (8.1)	94 (7.3)	.46	0.78 (−1.3 to 2.8)
6-Month survival with CPC 1-2[d]	110 (8.5)	98 (7.6)	.43	0.86 (−1.2 to 3.0)
Survival to discharge from ICU[e]	158 (12.2)	153 (11.9)	.86	0.28 (−2.2 to 2.8)
With CPC 1	54(4.2)	34(2.6)	.04	1.52 (0.1 to 2.9)
With CPC 2	44 (3.4)	48 (3.7)		
With CPC 3	34 (2.6)	40 (3.1)		
With CPC 4	26 (2.0)	29 (2.2)		
Survival to discharge from hospital[e]	117 (9.0)	118 (9.2)	.89	−0.15 (−2.4 to 2.1)
With CPC 1	89 (6.8)	67 (5.2)	.08	1.65 (−0.2 to 3.5)
With CPC 2	19 (1.5)	33 (2.6)		
With CPC 3	9 (0.7)	15 (1.2)		
With CPC 4	0	1 (0.1)		
1-Month survival[f]	112 (8.6)	109 (8.5)	.89	0.16 (−2.0 to 2.3)
With CPC 1	92 (7.1)	74 (5.7)	.17	1.34 (−0.6 to 3.2)
With CPC 2	13 (1.0)	20 (1.6)		
With CPC 3	7 (0.5)	13 (1.0)		
With CPC 4	0	1 (0.1)		
6-Month survival[f]	111 (8.5)	104 8.1)	.67	0.47 (−1.7 to 2.6)
With CPC 1	103 (7.9)	88 (6.8)	.29	1.10 (−0.9 to 3.1)
With CPC 2	7 (0.5)	10 (0.8)		
With CPC 3	1 (0.1)	6 (0.5)		
With CPC 4	0	0		

8. How precise was the estimate of the treatment effect?

HINT: Consider

- What are the confidence limits?

•本研究的各項結果信賴界限幾乎都跨過零
•四小時存活率的信賴界限是 -3.3% ~ 3.2%

9. Can the results be applied in your context? (or to the local population?) ☐Yes ☑Can't tell ☐No

HINT: Consider whether

- Do you think that the patients covered by the trial are similar enough to the patients to whom you will apply this?, if not how to they differ?

•LUCAS 心肺復甦機的價值在於到院前提供持續不中斷的高品質壓胸，故需考慮裝置何時能裝上裝上後將使用多久，幅員、交通狀況、體型均須考慮

10. Were all clinically important outcomes considered? ☑Yes ☐Can't tell ☐No

HINT: Consider

- Is there other information you would like to have seen?
- If not, does this affect the decision?

•研究已統計了四小時存活率、ROSC與否以及轉出ICU、出院、一個月及六個月時的神經學功能
•機械故障 (8例) 及嚴重副作用 (7例) 均相當稀少