厚生労働科学研究費補助金
（循環器疾患等生活習慣病対策総合研究事業）研究報告書

心肺停止患者に対する心肺補助装置等を用いた高度救命処置の効果と費用に関する多施設共同研究

平成２１年度　総括・分担研究報告書

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厚生労働科学研究費補助金（循環器疾患等生活習慣病対策総合研究事業）
総括研究報告書

心肺停止患者に対する心肺補助装置等を用いた高度救命処置の効果と費用に関する多施設共同研究

主任研究者　坂本　哲也　帝京大学医学部救急医学講座　主任教授

経皮的心肺補助（percutaneous cardiopulmonary support, PCPS）は，1980年代後半に侵襲度が少ない簡便な循環補助装置として臨床使用が始まり，以後，循環器領域のみならず，呼吸器領域，さらには救急領域へと適応の拡大と普及をみている。しかしPCPSを用いた心肺蘇生法の有用性に関して国際的コンセンサスを形成するためには報告が不十分であり，報告例の多い本邦でも多施設による集積研究はない。そこで本研究は，院外心肺停止患者に対するPCPSを用いた高度救命処置の効果と費用を多施設で検討することを目的とした。平成21年度は多施設共同前向き比較対照観察研究（prospective, non-randomized, cohort study）の中間解析を行い，発症1カ月後 Cerebral Performance Categories（CPC）1または2（以下 favorable outcome）の割合，合併症，コストを検討した。

平成20年度までに研究参加登録を完了した57施設のうち，今年度までに，PCPS群27施設，非PCPS群23施設，総計50施設が倫理委員会申請を完了し，45施設が患者登録を開始した。2010年3月末日時点で，36施設（PCPS群21施設，Control群15施設）が患者登録を完了し，登録患者数は総計308例，適格規準合致症例数は，PCPS群103例，非PCPS群67例，総計170例に達した。Favorable outcomeの割合は，PCPS群が15.9%（17例），非PCPS群が0%（0例）であった。PCPS群の予後不明例を除くと17.5%（17例），0%（0例）であった。PCPSの合併症として，出血／血腫が43.0%（46例），感染が10.3%（11例）報告された。

また，2010年の国際蘇生連絡委員会（International Liaison Committee on Resuscitation, ILCOR）のCoSTR（International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations）2010の策定にあたり，本研究の成果を踏まえてエビデンス評価を行い，ワークシートの作成を担当した。

さらに，臨床工学技士の部会にて，PCPSの合併症，IABP，デバイスに関する選択基準，周辺機器（除細動器，体温管理，モニターほか），PCPSの未来に求めるものに関して検討し，昨年度作成したPCPS施行マニュアルを改訂した。

A. 研究目的

現時点では人工心肺装置等，特に経皮的心肺補助（percutaneous cardiopulmonary support, PCPS）を用いた心肺蘇生法の有用性に関して世界的合意を検討するだけの十分な報告がなく，本邦でも多施設による集積研究がない。本研究は，院外心肺停止患者に対するPCPSを用いた高度救命処置の効果と費用を多施設で検討することを目的とした。この結果から人工心肺装置等による心肺蘇生法の有用性を明らかにすることができ，また国際蘇生連絡委員会（International Liaison Committee on Resuscitation, ILCOR）において世界的合意のための資料とすることができる。

B. 研究方法

B.1. 多施設共同前向き比較対照観察研究

B.1.1. 適格規準

今回の中間解析は2008年9月8日から2009年12月31日までに来院した患者のうち，以下の全てを満たす患者を対象とした。

1) 初回心電図が心室細動（ventricular fibrillation）または無脈性心室頻拍（pulseless ventricular tachycardia）（以下併せてVF）
2) 病院到着時心停止。病院到着までの間の自己心拍再開の有無は問わない
3) 119番通報あるいは心停止から病院到着まで45分以内
4) 病院到着後（医師が患者に接触後）15分間心停止が持続している（1分以上のROSCがない）

B.1.2. 除外規準

以下のいずれかに該当する患者を除外した。

1) 年齢20歳未満または75歳以上
2) 発症前の日常生活動作（activities of daily livings, ADL）が不良
3) 原疾患が非心原性
4) 深部体温30℃未満
5) 代諾者の同意が得られない
6) 救命の対象外

B.2. 解　析

PCPS，非PCPS群間における，発症1ヵ月後のfavorable outcomeの割合につきカイ二乗検定，またはフィッシャーの正確確率検定を行った。検定は，1) intention to treat解析（施設が割り付けられた群に従い，全例を解析対象），2) per protocol解析（割り付けられた群の治療プロトコルに従った患者のみを解析対象）の2通りを行った。PCPS群で，2010年3月末日時点で発症1カ月後CPCが不明の症例が10例あったため，1) 不明例をCPC3～5と見なして全例を対象に解析，2) 不明例を除いて解析，の2通りの解析を行った。

C. 結　果

C.1. 多施設共同前向き比較対照観察研究

C.1.1. 患者背景

2008年10月から2010年3月末日までの期間に，308名の院外心肺停止例の症例登録があり，そのうち170例（PCPS群107例，非PCPS群63例）が適格基準に合致した。このうち，PCPS群102例，非PCPS群53例に，プロトコル通りの治療が行われた。平均年齢は，PCPS群56歳，非PCPS群56歳，バイスタンダーCPRの実施割合は，PCPS群50.5%（54例），非PCPS群53.2%（34例），原疾患がACSの割合は，PCPS群62.6%（67例），非PCPS群61.3%（39例）であった。

C.1.2. アウトカム

Intention to treatでは，favorable outcome（入院1カ月後CPC 1または2）の割合は，PCPS群が15.9%（17例），非PCPS群が0%（0例）であった。PCPS群で予後不明の10例を除くと，各群のfavorable outcomeは17.5%（17例），0%（0例）であった。Per protocolでは，プロトコル通りの治療が行われた102例，53例が対象となった。favorable outcomeの割合は，それぞれ16.7%（17例），0%（0例），予後不明例を除くと18.5%（17例），0%（0例）であった。PCPSの合併症として，出血／血腫が43.0%（46例），感染が10.3%（11例）発生した。

C.2. CoSTR 2010におけるエビデンス評価

2010年の国際蘇生連絡委員会（International Liaison Committee on Resuscitation, ILCOR）のCoSTR(International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations) 2010の策定にあたり，本研究の成果を踏まえてエビデンス評価を行い，ワークシートの作成を担当した（資料1，資料2）。

C.3. J-PULSE・SAVE-J合同委員会等

2010年2月23日J-PULSE・SAVE-J合同公開報告会を東京において，同年3月3日には広島市にお

いて，合同委員会を開催した（資料3)。

C.4. 技師部会報告

「安全管理マニュアル」の追加項目である「合併症」,「IABP」,「デバイスに関する選択基準」,「周辺機器」「PCPSの未来に求めるもの」の原稿を作成し，また，このマニュアル周知のために，学会発表などを行った。

D. 考　察

PCPSを用いた心肺蘇生法の有用性に関して世界的合意を検討するだけの十分な報告がなく，本邦でも多施設による集積研究がない。昨年度に引き続く前向き比較対照観察研究の中間解析から，PCPS群のfavorable outcomeの割合はintention to treat，per protocolのいずれも当初の予測値10%を上回り，非PCPS群に比べて良好で，PCPSが通常の二次救命処理のみより予後を良くすることが示唆された。しかしながら，今回の分析には下記の限界がある。

* 非PCPS群の適格症例数が当初の予想に反して低く，非PCPS群の適格症例を全て収集できていない可能性がある。
* PCPS以外の予後因子（各種リスクファクター）を調整していない。
* 2010年3月末日時点で判明しているデータに基づくものであり，PCPS群では，発症1カ月後CPCの不明例が10例ある

特に非PCPS群に関しては，適格規準を十分把握していない，あるいは，症例の登録が遅れている可能性が考えられる。最終解析に際しては，参加施設へ，本研究の適格基準について改めて周知を徹底し，インターネット等を利用した症例登録の支援をする必要がある。同時に，予後不明例については追跡調査を行い，検証を行う必要がある。

心肺停止患者に対するPCPSを用いた高度救命処置の効果と費用についての結果から人工心肺装置等による心肺蘇生法の有用性を明らかになれば，その意義は極めて大きい。結果は，本邦で適用されるのみでなく，国際蘇生連絡委員会（ILCOR）における国際ガイドライン改定における世界的合意のための根拠として寄与する。

E. 結　論

昨年度に引き続く前向き比較対照観察研究の中間解析から，PCPS群のfavorable outcomeの割合はintention to treat，per protocolのいずれも当初の予測値10%を上回り，非PCPS群に比べて良好で，PCPSが通常の心肺蘇生より予後を良くすることが示唆された。最終解析に際しては，症例登録の支援，予後不明例の追跡調査を行う必要がある。

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12) 田原良雄, 長尾　建, 浅井康文, 長谷　守, 奈良理, 渥美生弘, 福田令雄, 上田敬博, 國分宣明, 上妻　謙, 森村尚登, 坂本哲也：シンポジウム「新しい心肺蘇生法—Guideline 2010に向けて—」院外心停止に対するE-CPRの効果. 第34回日本外科系連合学会, 東京, 2009, 6.

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14) 田原良雄, 鈴木範行, 木村一雄, 菊島公夫, 長尾建, 渥美生弘, 長谷　守, 奈良　理, 浅井康文, 森村尚登, 坂本哲也：シンポジウム「PCPS」院外心原性心停止に対するPCPS使用例の治療戦略の変化. 第12回日本脳低温療法学会, 札幌, 2009, 7.

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16) Tahara Y, Suzuki N, Kimura K, Kikushima K, Nagao K, Atsumi T, Yokota H, Hase M, Nara S, Asai Y, Morimura N, Sakamoto T: Changes in the treatment strategy for extracorporeal cardiopulmonary resuscitation for out-of-hospital cardiac arrest with ventricular fibrillation. 82nd Scientific Sessions 2009, American Heart Association, Orlando, 2009, 11.

17) 渥美生弘, 坂本哲也, 浅井康文, 長尾建, 森村尚登, 田原良雄, 横田裕行, 佐藤愼一：本邦におけるECPRの現状. 第12回日本脳低温療法学会, 2009.

18) 渥美生弘, 坂本哲也, 浅井康文, 長尾建, 森村尚登, 田原良雄, 横田裕行, 佐藤愼一：本邦におけるECPRの現状. 第20回日本PCPS研究会, 2010.

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21) Matayoshi T, Tamashiro S, Noguchi Y: For better patient outcome with PCPS. 4th ChSECT 2009. China, 2009, 8.

22) Sakamto T, Morimura N, Nagao K, Asai Y, Tahara Y, Atsumi T, Yokota H, Tahara Y, Atsumi T, Nara S, Hase M. Systematic literature review of out-of-hospital cardiac arrests with extracorporeal cardiopulmonary resuscitation in Japan. Resuscitation Science Symposium, American Heart Association, Nov. 2009, Chicago, United States.

G. 知的財産の出願・登録状況

特になし

H. 倫理面への配慮

症例登録に当たり，個人情報保護には最大限の配慮を行う。PCPSの適応決定に当たっては，患者家族の意志を最大限尊重し，保険診療の範疇で行う。

WORKSHEET for Evidence-Based Review of Science for Emergency Cardiac Care

Worksheet author(s)

	Date Submitted for review: 10/07/2009, Revised 01/27/2010

Clinical question.

In adult cardiac arrest (prehospital [OHCA], in- hospital [IHCA]) (P) – does the use of rapid deployment Extracorporeal Membrane Oxygenation (ECMO), Aortic Balloon Pump (IABP) or emergency cardiopulmonary bypass (CPB) (I), compared with standard treatment (C), increase survival to hospital discharge with favorable neurologic outcomes (O)?
This is an update of the previous CoSTR review which evaluated whether invasive perfusion devices improve outcome from cardiac arrest when compared with standard CPR in cardiac arrest patients with an underlying cardiocirculatory disease amenable to immediate corrective intervention. (surgically correctible anatomic lesion (CAD, PE, etc.)) or not.
Is this question addressing an intervention/therapy, prognosis or diagnosis: Intervention
State if this is a proposed new topic or revision of existing worksheet: Revision

Conflict of interest specific to this question

The authors have no conflict of interest relevant to this worksheet.

Search strategy (including electronic databases searched).

English literature

We searched the Cochrane Controlled Trials Register (CCTR), PUBMED, and Scopus.
Each database was searched using the search strategy shown below.
CCTR
#1 Cardiac arrest in Title, Abstract or Keywords and cardiopulmonary bypass in Title, Abstract or Keywords, from 2003 to 2009 in The Cochrane Central Register of Controlled Trials; 46 articles
#2 Cardiac arrest in Title, Abstract or Keywords and extracorporeal in Title, Abstract or Keywords, from 2003 to 2009 in The Cochrane Central Register of Controlled Trials; 5 articles
#3 #1OR #2; 48 articles

PUBMED
#1. ("Cardiac arrest"[Text Word] AND "cardiopulmonary bypass"[Text Word]) AND (("humans"[MeSH Terms] OR "animals"[MeSH Terms:noexp]) AND (English[lang] OR Japanese[lang])) AND ("2003/1/1"[PDAT] : "2009/10/1"[PDAT]); 188 articles
#2. "Cardiac arrest"[Text Word] AND extracorporeal[Text Word]) AND (("humans"[MeSH Terms] OR "animals"[MeSH Terms:noexp]) AND (English[lang] OR Japanese[lang])) AND ("2003/1/1"[PDAT] : "2009/10/1"[PDAT]); 120 articles
#3. #1OR #2; 280 articles

Scopus
#1. TITLE-ABS-KEY("cardiac arrest" AND "cardiopulmonary bypass") AND DOCTYPE(ar) AND PUBYEAR AFT 2002 AND PUBYEAR BEF 2010 AND (LIMIT-TO(SUBJAREA, "MEDI") OR LIMIT-TO(SUBJAREA, "NURS") OR LIMIT-TO(SUBJAREA, "HEAL") OR LIMIT-TO(SUBJAREA, "MULT") OR LIMIT-TO(SUBJAREA, "MULT")); 203 articles
#2. (TITLE-ABS-KEY("cardiac arrest") AND TITLE-ABS-KEY(extracorporeal)) AND DOCTYPE(ar) AND PUBYEAR AFT 2002 AND PUBYEAR BEF 2010 AND (LIMIT-TO(SUBJAREA, "MEDI") OR LIMIT-TO(SUBJAREA, "NURS") OR LIMIT-TO(SUBJAREA, "MULT")); 137 articles
#3. #1OR #2; 307 articles

Searching other resources: We included the articles included in the previous review.

Japanese literature

We searched Igaku Chuo Zasshi (Japana Centra Revuo Medicina) to identify articles published in Japan using the following thesaurus keyword search:
#1. ("Artificial Cardiopulmonary System" OR "Percutaneous Artificial Cardiopulmonary System") AND ("cardiac arrest" OR "cardiopulmonary arrest) AND Publication Type(exclude conference proceedings); 14 articles
#2. ("Artificial Cardiopulmonary System" OR "Percutaneous Artificial Cardiopulmonary System") AND "resuscitation" AND Publication Type(exclude conference proceedings); 20 articles
#3. "1 OR #2; 25 articles

- **State inclusion and exclusion criteria**

Articles were included for review for the following: [1] Design: Interventional or observational studies, meta-analysis, or systematic review [2] Population: Human adult aged 14 or over, with cardiac arrest, [3] Intervention: Rapid deployment (ECMO) or Aortic Balloon Pump (IABP) or Emergency cardiopulmonary bypass (CPB), [4] Outcomes: Survival or favorable neurologic outcomes.

The following studies were excluded: [1] Design: Case report or Narrative review, [2] Population: Children aged 14 or under or animal studies, cardiac arrest that followed hypothermia, or studies conducted for same population (only most recent study is included), [3] Intervention: cardiopulmonary bypass for post surgical hypothermia [4] Language: other than Japanese or English

- **Number of articles/sources meeting criteria for further review:**

24 studies met criteria for further review, including: 2 LOE 2 and 22 LOE 4.

Summary of evidence

Evidence Supporting Clinical Question

Good		**Chen 2008 A, C**		**Chen 2003, A, B, C, D** **Massetti 2005 C, D** **Megarbane 2007 C, D** **Nagao 2010 A, B, C, D** **Shinn 2009 A, B, C, E** **Takahashi (J), 2009 A** **Fukumoto (J), 2001, A** **Kawato (J), 1994, A,B,C**	
Fair		**Tanno 2008 C**		**Athanasuleas 2006 C** **Maggio 2007 C** **Martin 1998, A** **Mooney 1991 A, C** **Nagao 2000, A, B, C, D, E** **Ichihara (J), 2002, A, B, C** **Morimoto (J), 2003, A, B** **Saibara (J),2001, A, B** **Shibata (J), 2006, A** **Sakai, (J) 1996, A, B**	
Poor					
	1	**2**	**3**	**4**	**5**
Level of evidence					

A = Return of spontaneous circulation
B = Survival of event
C = Survival to hospital discharge
D = Intact neurological survival
E = Other endpoint
Italics = Animal studies

Evidence Neutral to Clinical question

Good		**Chen 2008 D**		**Thiagarajan 2009 C, E** **Fukumoto (J), 2001, B, C, D** **Kawato (J), 1994, E** **Takahashi (J), 2009 B,C**	
Fair		**Tanno 2008 D**		**Martin 1998, B, C** **Ohata 2004 A** **Ichihara (J), 2002, E** **Koide (J), 2005, B, C, D** **Sakai, (J) 1996, E** **Shibata (J), 2006, E**	
Poor				**Nagamine (J), 2002, E**	
	1	**2**	**3**	**4**	**5**
Level of evidence					

A = Return of spontaneous circulation
B = Survival of event
C = Survival to hospital discharge
D = Intact neurological survival
E = Other endpoint
Italics = Animal studies

Evidence Opposing Clinical Question

Good					
Fair				**Morimoto (J), 2003, C**	
Poor					
	1	**2**	**3**	**4**	**5**
Level of evidence					

A = Return of spontaneous circulation
B = Survival of event
C = Survival to hospital discharge
D = Intact neurological survival
E = Other endpoint
Italics = Animal studies

REVIEWER'S FINAL COMMENTS AND ASSESSMENT OF BENEFIT / RISK:

We identified nine articles written in English after previous ILCOR search. In addition to the nine new reports, four studies categorized as LOE-3 in the previous report, and ten studies written in Japanece published between 1991 and 9/30/2009 were included in the review. Thus total of 23 studies were eligible for review.

No LOE-1 study is identified. We classified studies as LOE-2 if subjects with and without CPB are selected from same cohort (i.e. both were selected patients with cardiopulmonary arrest in same time period). Two LOE-2 studies were identified. In the LOE-2 studies, we classified them into three groups based on four methodological quality indicators suggested by ILCOR (4 or 3: Good, 2 or 1: Fair, and 0: Poor). We defined LOE-3 studies as cohort studies with retrospective (historical) cohort data (i.e. individual treated in the past and used in a comparison group when researchers analyze the results of a clinical study that had no control group). There was no LOE-3 study in our analysis. We categorize studies as LOE-4 if there is no individual is included in the report, and made quasi-comparison with previously published studies. Four studies classified into LOE-3 with previous review criteria were categorized in the LOE-4. In addition, 18 newly published studies were classified as LOE-4. We further classified the LOE-4 studies into three groups based on three methodological quality indicators suggested by ILCOR (3 or 2: Good, 1: Fair, and 0: Poor).

Although LOE-2 studies can be clearly classified into either of three groups, supporting, neutral, or opposing to clinical questions based on statistical significance (we did not consider statistical power in this review), it is ambiguous how we can classify them in LOE-4 studies. We categorized LOE-4 studies as "supporting" if one of following conditions were satisfied: (1) authors indicated the usefulness based on comparison with previously published reports of standard treatment or (2) Return of spontaneous circulation /discharge survival rate and/or preferable neurological outcome is greater than 33% (we did not consider 95% confidence interval in this review).

Within all studies, eleven reports focused only on cardiac cause, and others included non-cardiac causes. Out-of-hospital arrest was included in sixteen studies. Eight studies focused only on in- hospital patients, and one study did not distinguish them. ECMO, emergency CPB, and IABP were evaluated in six, nineteen and one studies respectively. Regarding outcomes, nine studies evaluated neurological disabilities, such as Glasgow-Pittsburgh cerebral performance categories (CPC) and Glasgow Outcome Scale (GOS). Time of neurological evaluation varies from at discharge to after 68 months of event. Six studies reported rate of complications and two reported reintegration as outcomes (reported as E in Summary of Evidence table).

In the previous review reported in 2005, four LOE-3 studies indicates that extracorporeal techniques or invasive perfusion devices may improve outcome from cardiac arrest when compared with standard CPR in patients with cardiogenic shock (before cardiac arrest occurs) and witnessed cardiac arrest in patient with an underlying cardio circulatory disease amenable to immediate corrective intervention. (Chen, 2003, 197; Martin,1998, 743; Mooney,1991,450; Nagao, 2000, 776) Reviewers concluded that implementation may be difficult due to timing of events and presence of experienced staff.

We further identified two LOE 2 studies. Chen et al. conducted prospective control study matching with propensity score for 172 patients with in-hospital cardiopulmonary arrest to compare extracorporeal cardiopulmonary resuscitation (ECPR) and conventional cardiopulmonary resuscitation (Chen, 2008, 554). They demonstrated that the cumulative survival rate was 65.2% (at 24 h), 52.2% (3 days), 37.0% (14 days), 34.8% (30 days), 32.6% (6 months), and 19.6% (1 year; nine survivors) in the extracorporeal group and 41.3% (24 h), 34.8% (3 days), 23.9% (14 days), 17.4% (30 days), 15.2% (6 months), and 13.0% (1 year; six survivors) in the conventional CPR-M group. The hazard ratio of extracorporeal CPR over conventional CPR was 0.47 (95% CI 0.28–0.77, p=0.003) if the survival curves were trimmed at 30 days. Extracorporeal CPR still showed a survival benefit at the end of 1 year (hazard ratio 0.53, 95% CI 0.33–0.83, p=0.006). Neurological outcome showed no difference at 1 year (p=0.27). Tanno conducted retrospective cohort study that compares 66 patients undergone emergency cardiopulmonary bypass and 332 patients with conventional CPR after out-of-hospital cardiac arrest due to cardiac etiology (Tannno, 2008, 649). Although they showed that significantly higher survival rate at 3 months (22.7% vs 9.9%, P<0.05), there was no statistical different for preferable neurological outcome defined by CPC (10.6% vs 5.7 %, P=0.14).

Studies evaluating CPR indicated that (1) duration of CPR prior to intervention and (2) presence of witness were correlated with survival outcome. Studies evaluating ECMO indicated that (1) etiologic disease (myocarditis), (2) a shorter CPR duration, and (3) first documented rhythm of ventricular tachycardia or ventricular fibrillation were positively associated with the survival at discharge. Studies including IABP treatment did not clearly define for which patient populations IABP would be most beneficial.

In addition to above thirteen studies written in English, we identified ten studies written in Japanese. All of ten studies are classified as LOE 4 since no study included control subject. Regarding outcomes, two studies employed neurological evaluation (e.g Glasgow Outcome Scale: GOS). Other two studies used "social reintegration" as outcome, however, both studies did not clearly describe criteria of the "social reintegration". Remaining six studies did not evaluate neurological outcomes. Three studies evaluated long-term prognosis (more than 3 months). Survival to hospital discharge of these ten studies in Japanese was reported between 9.5 - 54.5%.

Conclusion

DISCLAIMER: Potential possible wording for a Consensus on Science Statement. Final wording will differ due to other input and discussion.

CONSENSUS ON SCIENCE:

One control trial revealed outcome improvement using extracorporeal cardiopulmonary support in in-hospital cardiopulmonary arrest patients (LOE2, Chen, 2008), but no prospective control trial was conducted for out-of-hospital patients although one retrospective cohort study (LOE2, Tanno, 2008) and most LOE 4 studies suggested possible better outcomes in the population. In addition, long-term outcome (i.e. more than one year) was scarcely evaluated.

Further prospective control trial for out-of-hospital cardiac arrest with long-term follow-up is desired to clarify effectiveness of the extracorporeal cardiopulmonary support especially for that population.

TREATMENT RECOMMENDATION:

REVIEWD IN WEBINER **Acknowledgements:**

Citation List

1. Athanasuleas CL, Buckberg GD, Allen BS, Beyersdorf F, Kirsh MM. Sudden cardiac death: directing the scope of resuscitation towards the heart and brain. Resuscitation 2006;70:44-51.

   BACKGROUND: The fundamental goal of cardiopulmonary resuscitation (CPR) is recovery of the heart and the brain. This is best achieved by (1) immediate CPR for coronary and cerebral perfusion, (2) correction of the cause of cardiac arrest, and (3) controlled cardioplegic cardiac reperfusion. Failure of such an integrated therapy may cause permanent brain damage despite cardiac resuscitation. METHODS: This strategy was applied at four centers to 34 sudden cardiac death patients (a) after acute myocardial infarction (n = 20), (b) "intraoperatively" following successful discontinuation of cardiopulmonary bypass (n = 4), and (c) "postoperatively" in the surgical ICU (n = 10). In each witnessed arrest the patient failed to respond to conventional CPR with ACLS interventions, including defibrillation. The cardiac arrest interval was 72 +/- 43 min (20-150 min). Compression and drugs maintained a BP > 60 mmHg to avoid cerebral hypoperfusion. Operating room (OR) transfer was delayed until the blood pressure was monitored. In four patients femoral bypass maintained perfusion while an angiographic diagnosis was made. RESULTS: Management principles included no repeat defibrillation attempts after 10 min of unsuccessful CPR, catheter-monitored peak BP > 60 mmHg during diagnosis and transit to the operating room, left ventricular venting during cardiopulmonary bypass and 20 min global and graft substrate enriched blood cardioplegic reperfusion. Survival was 79.4% with two neurological complications (5.8%). CONCLUSIONS: Recovery without adverse neurological outcomes is possible in a large number of cardiac arrest victims following prolonged manual CPR. Therapy is directed toward maintaining a monitored peak BP above 60 mmHg, determining the nature of the cardiac cause, and correcting it with controlled reperfusion to preserve function.
   LOE: 4
   QUALITY: fair
   DIRECTION OF SUPPORT: supporting C
   COMMENTS: no report of industry sponsorship

2. Chen, Y. S., A. Chao, et al. (2003). "Analysis and results of prolonged resuscitation in cardiac arrest patients rescued by extracorporeal membrane oxygenation." J Am Coll Cardiol 41(2): 197-203.

   OBJECTIVES: We conducted this study to determine the result of prolonged cardiopulmonary resuscitation (CPR) with extracorporeal membrane oxygenation (ECMO) and the predictive factors for hospital discharge and ECMO weaning. BACKGROUND: Prolonged CPR carries considerable associated mortality and morbidity. As yet, ECMO for prolonged CPR has no definite results. Only small groups of patients and no detailed analysis have been reported. METHODS: Candidates for ECMO resuscitation were patients in cardiac arrest receiving CPR >10 min without return of spontaneous circulation and no absolute contraindication. Venoarterial ECMO was set up during CPR. We reviewed the data of 57 prolonged CPR patients who received ECMO during CPR over a six-year period. RESULTS: The mean duration of CPR was 47.6 +/- 13.4 min and that of ECMO was 96.1 +/- 87.9 h. The rate of weaning was 66.7%, and the survival rate was 31.6%. Multiple-organ failure was the major reason for mortality, despite successful weaning. Among survivors, long-term follow-up revealed 88.9% survival, and only 5.6% had a severe neurologic deficit. The results indicate that a shorter CPR duration, postcardiotomy arrest, myocardial indicators, a hepatic indicator, and lactic acid are significantly correlated with both weaning and survival, whereas late damage (level on the third or seventh day of reperfusion) rather than initial damage (level on the first day) was more predictive of the results. CONCLUSIONS: Prolonged CPR rescue by ECMO provides an acceptable survival rate and outcome in survivors. Our results of the selected cases encourage further investigations of the wider application of ECMO in CPR.
   LOE: 4
   QUALITY: good
   DIRECTION OF SUPPORT: supporting ABCD
   COMMENTS: no report of industry sponsorship

3. Chen YS, Lin JW, Yu HY, et al. Cardiopulmonary resuscitation with assisted extracorporeal life-support versus conventional cardiopulmonary resuscitation in adults with in-hospital cardiac arrest: an observational study and propensity analysis. The Lancet 2008;372:554-61.

   Background: Extracorporeal life-support as an adjunct to cardiac resuscitation has shown encouraging outcomes in patients with cardiac arrest. However, there is little evidence about the benefit of the procedure compared with conventional cardiopulmonary resuscitation (CPR), especially when continued for more than 10 min. We aimed to

assess whether extracorporeal CPR was better than conventional CPR for patients with in-hospital cardiac arrest of cardiac origin. Methods: We did a 3-year prospective observational study on the use of extracorporeal life-support for patients aged 18-75 years with witnessed in-hospital cardiac arrest of cardiac origin undergoing CPR of more than 10 min compared with patients receiving conventional CPR. A matching process based on propensity-score was done to equalise potential prognostic factors in both groups, and to formulate a balanced 1:1 matched cohort study. The primary endpoint was survival to hospital discharge, and analysis was by intention to treat. This study is registered with ClinicalTrials.gov, number NCT00173615. Findings: Of the 975 patients with in-hospital cardiac arrest events who underwent CPR for longer than 10 min, 113 were enrolled in the conventional CPR group and 59 were enrolled in the extracorporeal CPR group. Unmatched patients who underwent extracorporeal CPR had a higher survival rate to discharge (log-rank p<0·0001) and a better 1-year survival than those who received conventional CPR (log rank p=0·007). Between the propensity-score matched groups, there was still a signifi cant diff erence in survival to discharge (hazard ratio [HR] 0·51, 95% CI 0·35–0·74, p<0·0001), 30-day survival (HR 0·47, 95% CI 0·28–0·77, p=0·003), and 1-year survival (HR 0·53, 95% CI 0·33–0·83, p=0·006) favouring extracorporeal CPR over conventional CPR. Interpretation Extracorporeal CPR had a short-term and long-term survival benefi t over conventional CPR in patients with in-hospital cardiac arrest of cardiac origin.
LOE: 2
QUALITY: good
DIRECTION OF SUPPORT: supporting AC, neutoral D
COMMENTS: no report of industry sponsorship

4. Fukumoto H, Nishimoto Y, et al. (2001). "Outcome of pericutaneous cardiopulmonary support in cardiac arrest patients." Resuscitation 20(2): 161-166.

   Abstract in Japanese
   LOE: 4
   QUALITY: good
   DIRECTION OF SUPPORT: supporting A, neutoral BCD
   COMMENTS: no report of industry sponsorship

5. Ichihara T, Eda K, et al. (2002). "Efficacy of the application of pericutaneous cardiopulmonary support in Intensive Care Medicine." J Jpn Soc Intensive Care Med 9(2): 103-106.

   Abstract in Japanese
   LOE: 4
   QUALITY: fair
   DIRECTION OF SUPPORT: supporting ABC, neutoral E
   COMMENTS: no report of industry sponsorship

6. Kawato H, Ide H, et al. (1994). "Experience of the applications of emergency pericutaneous cardiopulmonary support for resuscitation of cardiaca arrest cases." Japanese Journal of Caridovascular Surgery 23(1): 15-20.

   Abstract in Japanese
   LOE: 4
   QUALITY: good
   DIRECTION OF SUPPORT: supporting ABC, neutoral E
   COMMENTS: no report of industry sponsorship

7. Koide T, Tanno K, et al. (2005). "Usage of pericutaneous cardiopulmonary support as a means of resurrection." Journal of Japan Society for Critical Care Medicine 19: 137-141.

   Abstract in Japanese
   LOE: 4
   QUALITY: fair
   DIRECTION OF SUPPORT: neutoral BCD
   COMMENTS: no report of industry sponsorship

8. Maggio P, Hemmila M, Haft J, Bartlett R. Extracorporeal life support for massive pulmonary embolism. J Trauma 2007;62:570-6.

BACKGROUND: Massive pulmonary embolism is frequently lethal because of acute irreversible pulmonary and cardiac failure. Extracorporeal life support (ECLS) has been used for cardiopulmonary failure in our institution since 1988, and we reviewed our experience with its use in the management of massive pulmonary emboli. METHODS: We reviewed our complete experience with ECLS for massive pulmonary emboli from January 1992 through December 2005. The records of 21 patients were examined and data extracted. RESULTS: During the study period, 21 patients received ECLS for massive pulmonary emboli. All patients were on vasoactive drugs, acidemic, and hypoxic at the time of institution of ECLS. Eight were in active cardiac arrest. Five were trauma patients, eight had recently undergone an operation, and six had a hypercoagulable disorder. Nineteen of the 21 patients were cannulated for venoarterial bypass and two were placed on venovenous bypass. The average duration of support for survivors was 5.4 days, ranging from 5 hours to 12.5 days. Emboli resolved with anticoagulation in 10 of 13 survivors and 4 of 13 survivors underwent surgical pulmonary embolectomy. Catastrophic neurologic events were the most common cause of mortality in our series; four patients died from intracranial hemorrhage. The overall survival rate was 62% (13/21). CONCLUSIONS: We conclude that emergent ECLS provides an opportunity to improve the prognosis of an otherwise near-fatal condition, and should be considered in the algorithm for management of a massive pulmonary embolism in an unstable patient.
LOE: 4
QUALITY: fair
DIRECTION OF SUPPORT: supporting C
COMMENTS: no report of industry sponsorship

9. Martin, G. B., E. P. Rivers, et al. (1998). "Emergency department cardiopulmonary bypass in the treatment of human cardiac arrest." Chest 113(3): 743-51.

OBJECTIVE: To study the use of emergency department (ED) femoro-femoral cardiopulmonary bypass (CPB) in the resuscitation of medical cardiac arrest patients. DESIGN: Prospective, uncontrolled trial. SETTING: Urban academic ED staffed with board-certified emergency physicians (EPs). PARTICIPANTS: Ten patients with medical cardiac arrest unresponsive to standard therapy. INTERVENTIONS: Femoro-femoral CPB instituted by EPs. RESULTS: The time of cardiac arrest prior to CPB (mean+/-SD) was 32.0+/-13.6 min. The cardiac output while on CPB was 4.09+/-1.03 L/min with an average of 229+/-111 min on bypass. All 10 patients had resumption of spontaneous cardiac activity while on CPB. Seven of these were weaned from CPB with intrinsic spontaneous circulation. Of these, six patients were transferred from the ED to the operating room for cannula removal and vessel repair while the other patient died in the ED soon after discontinuing CPB. Mean survival was 47.8+/-44.7 h in the six patients leaving the ED. Although these patients had successful hemodynamic resuscitation, there were no long-term survivors. CONCLUSION: CPB instituted by EPs is feasible and effective for the hemodynamic resuscitation of cardiac arrest patients unresponsive to advanced cardiac life support therapy. Future efforts need to focus on improving long-term outcome.
LOE: 4
QUALITY: fair
DIRECTION OF SUPPORT: supporting A, neutoral BC
COMMENTS: no report of industry sponsorship

10. Massetti M, Tasle M, Le Page O, et al. Back from irreversibility: Extracorporeal life support for prolonged cardiac arrest. Annals of Thoracic Surgery 2005;79:178-83.

The survival of patients after prolonged cardiac arrest is still inadequate. Extracorporeal life support (ECLS) represents an alternative therapeutic method for patients who do not respond to conventional cardiopulmonary cerebral resuscitation. This technology is used to support the circulation of a patient with severe cardiac failure. Between June 1997 and January 2003, 40 ECLS procedures were performed in patients who presented with refractory cardiac arrest. During external cardiac massage, the patient was connected to an extracorporeal circuit by the insertion of an arterial and venous cannula through the femoral vessels. The extracorporeal circuit included a centrifugal pump and an oxygenator. Mean age was 42 ? 15 years; the average time of external cardiac massage was 105 ? 44 minutes. Once the circulation was restored, 22 patients were disconnected from the extracorporeal circulation because of brain death or multiorgan failure; after 24 hours, among the 18 survivors, 6 were weaned off the pump, 9 were bridged to a ventricular assist device, and 2 patients were directly bridged to cardiac transplantation. Eight patients are alive and

without any sequelae at 18 month's follow-up. In prolonged cardiac arrest with failing conventional measures, rescue by extracorporeal support provides an ultimate therapeutic option with a good outcome in survivors. Our results encourage the wider application of ECLS for refractory cardiocirculatory arrest in selected patients. The high rate of neurologic death needs further improvements in the early phase of resuscitation maneuvers.
LOE: 4
QUALITY: good
DIRECTION OF SUPPORT: supporting CD
COMMENTS: no report of industry sponsorship

11. Megarbane B, Leprince P, Deye N, et al. Emergency feasibility in medical intensive care unit of extracorporeal life support for refractory cardiac arrest. Intensive Care Med 2007;33:758-64.

OBJECTIVE: To report the feasibility, complications, and outcomes of emergency extracorporeal life support (ECLS) in refractory cardiac arrests in medical intensive care unit (ICU). DESIGN AND SETTING: Prospective cohort study in the medical ICU in a university hospital in collaboration with the cardiosurgical team of a neighboring hospital. PATIENTS: Seventeen patients (poisonings: 12/17) admitted over a 2-year period for cardiac arrest unresponsive to cardiopulmonary resuscitation (CPR) and advanced cardiac life support, without return of spontaneous circulation. INTERVENTIONS: ECLS femoral implantation under continuous cardiac massage, using a centrifugal pump connected to a hollow-fiber membrane oxygenator. MEASUREMENTS AND RESULTS: Stable ECLS was achieved in 14 of 17 patients. Early complications included massive transfusions (n=8) and the need for surgical revision at the cannulation site for bleeding (n=1). Four patients (24%) survived at medical ICU discharge. Deaths resulted from multiorgan failure (n=8), thoracic bleeding(n=2), severe sepsis (n=2), and brain death (n=1). Massive hemorrhagic pulmonary edema during CPR (n=5) and major capillary leak syndrome (n=6) were observed. Three cardiotoxic-poisoned patients (18%, CPR duration: 30, 100, and 180 min) were alive at 1-year follow-up without sequelae. Two of these patients survived despite elevated plasma lactate concentrations before cannulation (39.0 and 20.0 mmol/l). ECLS was associated with a significantly lower ICU mortality rate than that expected from the Simplified Acute Physiology Score II (91.9%) and lower than the maximum Sequential Organ Failure Assessment score (>90%). CONCLUSIONS: Emergency ECLS is feasible in medical ICU and should be considered as a resuscitative tool for selected patients suffering from refractory cardiac arrest.
LOE: 4
QUALITY: good
DIRECTION OF SUPPORT: supporting CD
COMMENTS: no report of industry sponsorship

12. Mooney, M. R., K. V. Arom, et al. (1991). "Emergency cardiopulmonary bypass support in patients with cardiac arrest." J Thorac Cardiovasc Surg 101(3): 450-4.

Emergency percutaneous cardiopulmonary bypass support was instituted in 11 patients in cardiac arrest refractory to conventional resuscitation measures. Emergency percutaneous cardiopulmonary bypass support was used in five patients in whom cardiac arrest occurred as a result of a complication in the cardiac catheterization laboratory (group 1) and in six other patients in cardiac arrest (group II). A 21F cannula and a 17F cannula were percutaneously inserted into the femoral vein and artery. Flow rates of 3 to 5 L/min were achieved with restoration of mean arterial pressure to 70 mm Hg (range 50 to 75). The status of all 11 patients was improved initially both clinically and hemodynamically with percutaneous cardiopulmonary bypass. Of the group II patients, three had anatomy unsuitable for percutaneous transluminal coronary angioplasty or coronary bypass grafting, could not be weaned from cardiopulmonary support, and died; three of these patients had coronary artery bypass grafting and two survived. All five group I patients underwent successful coronary bypass grafting and survived. Of the seven patients with anatomically correctable disease, all seven were discharged from the hospital. With conventional management nearly all seven of these patients would have died. Nine of 11 patients underwent a cardiac operation and seven of the nine survived. The operative mortality rate was 22% and the overall survival rate was 64%. At follow-up (mean 7 months), all seven patients are alive and six have resumed a normal and active life-style. In conclusion, emergency percutaneous cardiopulmonary bypass support is a powerful resuscitative tool that may stabilize the condition of patients in cardiogenic shock and cardiac arrest to allow for definitive intervention.
LOE: 4
QUALITY: fair
DIRECTION OF SUPPORT: supporting AC
COMMENTS: no report of industry sponsorship

13. Morimoto N, Ishii T, et al. (2003). "Out-of cardiac arrest patients which were transferd to our Emergency Critical Care Center." Journal of Tsuyama central hospital 17(1): 17-23.

Abstract in Japanese
LOE: 4
QUALITY: fair
DIRECTION OF SUPPORT: supporting AB, opposing C
COMMENTS: no report of industry sponsorship

14. Nagamine K (2002). "Resuscitation with pericutaneous cardiopulmonary support." Resuscitation 21(2): 14-17.

Abstract in Japanese
LOE: 4
QUALITY: poor
DIRECTION OF SUPPORT: neutral E
COMMENTS: no report of industry sponsorship

15. Nagao, K., N. Hayashi, et al. (2000). "Cardiopulmonary cerebral resuscitation using emergency cardiopulmonary bypass, coronary reperfusion therapy and mild hypothermia in patients with cardiac arrest outside the hospital." J Am Coll Cardiol 36(3): 776-83.

OBJECTIVES: The purpose of this study was to evaluate the efficacy of an alternative cardiopulmonary cerebral resuscitation (CPCR) using emergency cardiopulmonary bypass (CPB), coronary reperfusion therapy and mild hypothermia. BACKGROUND: Good recovery of patients with out-of-hospital cardiac arrest is still inadequate. An alternative therapeutic method for patients who do not respond to conventional CPCR is required. METHODS: A prospective preliminary study was performed in 50 patients with out-of-hospital cardiac arrest meeting the inclusion criteria. Patients were treated with standard CPCR and, if there was no response, by emergency CPB plus intra-aortic balloon pumping. Immediate coronary angiography for coronary reperfusion therapy was performed in patients with suspected acute coronary syndrome. Subsequently, in patients with systolic blood pressure above 90 mm Hg and Glasgow coma scale score of 3 to 5, mild hypothermia (34 C for at least two days) was induced by coil cooling. Neurologic outcome was assessed by cerebral performance categories at hospital discharge. RESULTS: Thirty-six of the 50 patients were treated with emergency CPB, and 30 of 39 patients who underwent angiography suffered acute coronary artery occlusion. Return of spontaneous circulation and successful coronary reperfusion were achieved in 92% and 87%, respectively. Mild hypothermia could be induced in 23 patients, and 12 (52%) of them showed good recovery. Factors related to a good recovery were cardiac index in hypothermia and the presence of serious complications with hypothermia or CPB. CONCLUSIONS: The alternative CPCR demonstrated an improvement in the incidence of good recovery. Based upon these findings, randomized studies of this hypothermia are needed.
LOE: 4
QUALITY: fair
DIRECTION OF SUPPORT: supporting ABCDE
COMMENTS: no report of industry sponsorship

16. Nagao, K., K. Kikushima, et al. "Early induction of hypothermia during cardiac arrest improves neurological outcomes in patients with out-of-hospital cardiac arrest who undergo emergency cardiopulmonary bypass and percutaneous coronary intervention." Circ J 74(1): 77-85.

BACKGROUND: Therapeutic hypothermia for comatose survivors of out-of-hospital cardiac arrest has demonstrated neurological benefits. Although early cooling during cardiac arrest enhances efficacy in animal studies, few clinical studies are available. METHODS AND RESULTS: The 171 patients who failed to respond to conventional cardiopulmonary resuscitation were studied prospectively. Patients underwent emergency cardiopulmonary bypass (CPB) plus intra-aortic balloon pumping, with subsequent percutaneous coronary intervention (PCI) if needed. Mild hypothermia (34 degrees C for 3 days) was induced during cardiac arrest or after return of spontaneous circulation. Of the 171 patients, 21 (12.3%) had a favorable neurological outcome at hospital discharge. An unadjusted rate of favorable outcome decreased in a stepwise fashion for increasing quartiles of collapse-to-34 degrees C interval (P=0.016). An adjusted odds ratio for favorable outcome after collapse-to-CPB interval was 0.89 (95% confidence interval (CI) 0.82-0.97) and after CPB-to-34 degrees C interval, 0.99 (95%CI 0.98-0.99) when collapse-to-34 degrees

C interval was divided into 2 components. Favorable neurological accuracy of a collapse-to-CPB interval at a cutoff of 55.5 min and CPB-to-34 degrees C interval at a cutoff of 21.5 min was 85.4% and 89.5%, respectively. CONCLUSIONS: Early attainment of a core temperature had neurological benefits for patients with out-of-hospital cardiac arrest who underwent CPB and PCI.
LOE: 4
QUALITY: good
DIRECTION OF SUPPORT: supporting ABCD
COMMENTS: no report of industry sponsorship

17. Ohata T, Sakakibara T, Takano H, Izutani H. Plasma brain natriuretic peptide reflects left ventricular function during percutaneous cardiopulmonary support. Ann Thorac Surg 2004;77:164-7.

BACKGROUND: Plasma levels of brain natriuretic peptide (BNP), a cardiac hormone secreted predominantly from the ventricle, are elevated in patients with myocardial infarction, hypertension, and dilated cardiomyopathy. In this study, we assessed the usefulness of measuring BNP to evaluate left ventricular function in patients with severe heart failure receiving mechanical circulatory support. METHODS: Plasma BNP and creatine kinase (CK)-MB levels were measured serially in 8 consecutive patients with cardiogenic shock who received percutaneous cardiopulmonary support (PCPS) at Osaka Police Hospital from August 1999 to March 2000. Coronary artery bypass grafting or percutaneous transluminal coronary angioplasty was also performed in 5 patients during PCPS; in addition, 1 patient underwent insertion of a left ventricular venting catheter and implantation of a left ventricular assist system after PCPS. RESULTS: Five patients were weaned from PCPS, and 3 died. In survivors, plasma BNP and CK-MB levels correlated positively and significantly ($r = 0.968$, $p = 0.03$). After PCPS was initiated, plasma BNP levels gradually decreased in survivors, but not in patients who died ($p = 0.003$). CONCLUSIONS: These results suggest that plasma BNP levels accurately reflect myocardial damage in patients undergoing PCPS. A decrease in BNP might appear to indicate improved left ventricular function and predict successful weaning from mechanical support.
LOE: 4
QUALITY: fair
DIRECTION OF SUPPORT: neutral A
COMMENTS: no report of industry sponsorship

18. Saibara H, Kodama Y, et al. (2001). "Outcomes of 71 patients treated with pericutaneous cardiopulmonary support in our hospital." Extra Corporeal Technology 28(1): 43-45.

Abstract in Japanese
LOE: 4
QUALITY: fair
DIRECTION OF SUPPORT: supporting AB, neutoral E
COMMENTS: no report of industry sponsorship

19. Sakai M, Oteki H, et al. (1996). "Status and problmes with the application of pericutaneous cardiopulmonary support." Japanese Association for Acute Medicine (JJAAM) 7(7): 345-351.

Abstract in Japanese
LOE: 4
QUALITY: fair
DIRECTION OF SUPPORT: supporting AB, neutral E
COMMENTS: no report of industry sponsorship

20. Shibata K and Itou M (2006). "Outcome of emergency pericutaneous cardiopulmonary support." Japanese Association for Acute Medicine (JJAAM in central Japan) 2: 14-16.

Abstract in Japanese
LOE: 4
QUALITY: fair
DIRECTION OF SUPPORT: supporting A, neutral E
COMMENTS: no report of industry sponsorship