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TREATMENT OF OUT-OF-HOSPITAL CARDIAC ARREST WITH LUCAS, A NEW DEVICE FOR AUTOMATIC MECHANICAL COMPRESSION AND ACTIVE DECOMPRESSION RESUSCITATION

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SWEDEN

ABSTRACT

LUCAS is a new gas-driven CPR device providing automatic chest compression and active decompression. This is a report of the first 100 consecutive cases treated with LUCAS due to out-of-hospital cardiac arrest (58 % asystole, 42 % VF). Safety aspects were also investigated and it was found that LUCAS can be safely used regarding noise levels and oxygen concentrations within the ambulance. A crash test (10 G) showed no displacement of the device from the mannequin. Of the 71 patients with witnessed cardiac arrest, 39% got bystander CPR. In those 28 patients where LUCAS-CPR was initiated more than 15 minutes from the ambulance alarm and in the 29 unwitnessed cases, there was none surviving 30 days. Of the 43 witnessed cases treated with LUCAS within 15 min, 24 had VF and 15 (63 %) of these cases got a stable ROSC and 6 (25%) of them lived with a good neurology after 30 days; five (26%) of the 19 patients with asystole got ROSC and 1 (5%) lived after 30 days. One patient where ROSC could not be obtained was transported with on-going LUCAS-CPR to the cath-lab and after performance of PCI against an occluded LAD a stable ROSC was obtained, but the patient never woke up and died 15 days later.

To conclude, establishment of an adequate cerebral circulation as quick as possible after cardiac arrest is mandatory for a good outcome. In this report patients with a witnessed cardiac arrest receiving LUCAS-CPR within 15 min from the ambulance alarm had a 30-day survival of 25 % in cases of VF and 5 % in case of asystole, but if more than 15 min passed, there were no 30-day survivors.

<u>Key words:</u> Active compression-decompression, Cardiac arrest, LUCAS-CPR, Out-of-hospital CPR, Return of spontaneous circulation.

INTRODUCTION

It has been estimated that 375,000 people in Europe (1) and 275,000 in the USA (2) are victims of sudden cardiac arrest each year. The great majority of these cases occur out of hospital and the 1-year survival rate remains extremely poor, less than 5% (1-3) (3). [Could add figures for survival rates that the reader can later use as reference for survival with LUCAS]. Recent insights into the physiology of cardiac arrest indicate that the role of adequate chest compressions needs to be upgraded in the guidelines for treatment of out-of-hospital cardiac arrest if better results are to be hoped for (4-7).

[Lancet is read by wide audience – is more background information needed on why adequate chest compressions need emphasising? – is there no emphasis on this? - what is emphasised today? Is more introduction needed to the concept of CPR devices? – must be a fairly new concept to many. Why not in common use already? (previous devices big, heavy, difficult to transport?)]

LUCAS (Lund University Cardiopulmonary Assist System) is a new gas-driven CPR device providing automatic chest compression and active decompression. In an experimental model on pigs, LUCAS-CPR gave significantly better circulation during ventricular fibrillation (VF) than manual CPR (8). When used on 20 patients with intra-hospital cardiac arrest, LUCAS was easy to handle, light (6.5 kg) and quick to apply (10-20 s). In one patient with a witnessed asystole where manual CPR failed, LUCAS-CPR achieved return of spontaneous circulation (ROSC) and one year later the patient was living at home, fully intact (8). In March 2002, 3 emergency cars were equipped with LUCAS in 2 cities in southern Sweden. The first cardiac arrest patient was treated with LUCAS on March 20, 2002, and this and the next 99 consecutive patients treated with LUCAS are followed here for up to 1 month after (ROSC).

Added information are given for recent LUCAS-treated patients illustrating important possibilities for a dramatic improvement in the treatment of cardiac arrest.

During 2002 and 2003, 100 patients with out-of-hospital cardiac arrest were treated with this new device. This is the first clinical report on treatment of out-of-hospital cardiac arrest with LUCAS.

MATERIAL AND METHODS

LUCAS was introduced in pre-hospital care in Lund and Malmö in southern Sweden during the spring of 2002, with permission from the Ethics Committee of the Medical Faculty of Lund University. Together the pre-hospital ambulance services in the two cities have an admission area of 921 square km with 440,000 inhabitants. The first cardiac arrest patient was treated with LUCAS on March 20, 2002, and this and the next 99 consecutive patients treated with LUCAS are followed here for up to 1 month after return of spontaneous circulation (ROSC). Added details are given for 3 patients illustrating important possibilities for a dramatic improvement in the treatment of out-of-hospital cardiac arrest.

LUCAS can be driven with oxygen or air. It produces 100 compressions/decompressions per min. The maximal depth of each compression is 5 cm and the maximal compression and decompression force are 500 N and 41 00 N, respectively. With a 6.5 L gas bottle (300kPa) LUCAS can be run for about 30 minutes. A detailed description of the device and how it may be used have been given elsewhere (4,8,9).

Special tests were done to study the oxygen concentration and the noise created by LUCAS in two different types of ambulances (Volvo 90 and Mercedes). [*Background? Are these considered potential problems due to past experience?*] During these measurements we also simulated treatment with a Boussignac endotracheal tube (9) or a CPAP-mask consuming 20 l/min of oxygen. As LUCAS releases 60 l/min, totally 80 l/min oxygen was released within the ambulance during the measurements. Oxygen concentrations were measured in the middle of the ambulance by means of an Oxygen Monitor No. 5590 (Hudson Respiratory Care

Incorporated, Temecula, CA, USA). Before each measurement, the sensor was calibrated to air and mixtures of oxygen up to 100% oxygen, and good linearity of the sensors was shown. The frequency and level of noise were measured in the middle of the ambulance by means of CEL 383 equipment with an octave band filter (Casella CEL Ltd, Kempston, Bedford, UK). The inbuilt calibrating function was checked, measurements were performed in both dB(A) and dB(L) modes, and an octave band analysis was performed.

A crash test was performed at a company with the appropriate authorization. LUCAS was applied to a mannequin fixed to a stretcher with a 4two-point fixation belt on an ambulance model run against a wall at a speed of 30 km/hour which should be comparable to a force of 10 G.

When LUCAS was introduced in the ambulances, a report form was constructed and ambulance staff required to fill it in after each use of LUCAS. The results of this study are based on data from these forms, pre-hospital data records, and hospital records for the first month of follow-up of patients with ROSC.

The guidelines for treatment of cardiac arrest of the Swedish Association for Cardiology were followed. When the ambulance personnel arrived at the scene, an ECG was taken, and if VF was diagnosed, 3 defibrillations were given before manual CPR was started. LUCAS-CPR could not be started before the second tier arrived with the device. [Is more background needed about first and second tier for a general reader audience?]. LUCAS was introduced as an aid for the staff to do chest compressions within the existing guidelines. Eighty-eight of the patients were intubated at the scene of the cardiac arrest, and twelve were ventilated with a face mask over a pharynx tube. Ventilation was given with a Rubens' bag and 15 l/min of

oxygen was given into the reservoir attached to the Rubens' bag. Adrenalin was given (1 to 7 mg totally) to 93 of the patients and atropine to 7. Of the patients with ROSC (31 patients), 9 were cooled to 33°C on arrival at the hospital. Cooling was initiated with cold Ringer solution (30 mgl/kg) and a cooling mattress was used to maintain the cooling (332°C) for 24 hours, after which the body temperature was gradually increased to normothermia over the next 8 hours.

RESULTS

LUCAS was used on all types and causes of cardiac arrest. Male victims had an age (in years) of 64±17; 67(22-94); 75, and female of 70±15; 74(25-89); 25, given as mean±SEM; median(range); number of patients. [Is the presentation and level of detail appropriate for Lancet? Enough to say: "There were 75 men with a mean age of 64 (range 22 to 94) years and 25 women with a mean age of 70 (25 to 89) years.". The first ECG showed VF in 42 % of the patients and asystole/PEA in 58 %.? Would readers perhaps like some details on types and causes of arrest?] Fifty-seven of the cardiac arrests took place in the home and 43 in other places. The ROSC-rate and 30-day survival are reported in fig 1, and logistics are summarised in fig 2.

Return of spontaneous circulation (ROSC)

Thirty-one per cent of the patients achieved stable ROSC and were admitted to the intensive care unit. Of the 43 patients with a witnessed cardiac arrest that were treated with LUCAS within 15 minutes of the ambulance staff being alarmed, 20 (47%) achieved stable ROSC.

One of the unwitnessed cases was a 71 years old man found collapsed in an office. After call to the emergency number, bystander CPR was started. The first tier arrives after 7 min and the staff found an unconscious and cyanotic man without pulses. Manual chest compressions were started and the airway was secured by intubation. The first ECG shows VF and several defibrillations are done without success. Seven min after the arrival of the first tier, the second tier arrives with LUCAS, which was applied to the patient immediately. Defibrillation was done during ongoing LUCAS-CPR and the patient regained sinus rhythm and a measurable blood pressure within the normal range. The patient was then loaded in the ambulance.

During the transportation to the hospital the patient got pulseless electrical activity (PEA) and LUCAS-CPR was restarted. The patient was taken to the cath-lab with ongoing LUCAS-CPR. Coronary angiography shows 3-vessel disease with occlusion of the left coronary artery (LAD). After PCI, ROSC was obtained and the patient was transferred to the intensive care unit. The patient had a stable circulation but never regained consciousness and died after 15 days because of a severe brain damage. [How many ROSC in patients treated with LUCAS after 15 min, and how many in non-witnessed arrests? – missing from diagram.]

30-day survival

Only patients with a witnessed cardiac arrest that were treated with LUCAS within 15 minutes of the ambulance alarm survived for 30 days, in all 7 of the 43 patients (16%) (Fig 1). Six of these patients had ventricular fibrillation and one had pulseless electrical activity according to the first obtained ECG. All 7 had good cerebral performance at 30 days. Of these 7 patients, 5 had been cooled to 33°C for 24 hours after their admittance to the hospital.

One of these patients illustrates that LUCAS-treatment should not be interrupted too soon. This was an 81-year-old woman who had undergone coronary bypass surgery in 1996. She collapsed during a Christmasin a concert hall in 2002. The ambulance staff arrived afterwithin 7 minutes and ECG showed ventricular fibrillation was confirmed. One defibrillation caused asystole. LUCAS-CPR was started and an orotracheal tube inserted. No ROSC was obtained at the scene, but the patient was transported to the hospital with ongoing LUCAS-CPR. On arrival at the hospital, the LUCAS-CPR was briefly interrupted, but this resulted in unacceptably low blood pressure. After a further 10-min period with LUCAS-CPR and pharmacotherapy, ROSC was achieved. The patient was able to leave the hospital in good

condition 2 weeks later, and at a neurological investigation 6 months after her cardiac arrest she was in a very positive state of mind, and without any handicap.

The chain of survival logistics

As seen in fig 2, the alarm system did not function optimally. In one case it took 12 minutes between the SOS-alarm being given and the time it reached the ambulance staff, and in another case 35 minutes before the second tier (with LUCAS) was alerted. Since many of the ambulance staff had very little experience with the LUCAS device in the beginning, they hesitated before using it. As seen in fig 2, it took a mean of 8 6 minutes before LUCAS-CPR was started, and in one case 35 25 minutes. [NB Title indicates that logistics will be coupled to survival, but this is not done.]

Oxygen concentration within the ambulance during LUCAS-CPR

The oxygen concentration in the ambulance during LUCAS-CPR (60 l oxygen/minute) plus CPAP treatment (20 l oxygen/min) was dependent on the speed of the ambulance and the ventilation settings. When the vehicle was standing still with all ventilation openings closed, the oxygen concentration increased to about 35% after 15 min, but when the vehicle was moving and the ventilation fan working at the highest speed, the oxygen concentration never exceeded 22%.

Noise levels within the ambulance during LUCAS-CPR

The noise measurements showed that when the vehicle engine was running but the vehicle standing still, LUCAS produced a noise level of 83-88 dB(A), the same level of dB(L), and a peak value of 111 dB. The highest frequencies were in the octave band at 1000 Hz. When the

ambulance was moving in the city the level of noise was $67 \, dB(A)$ and $88 \, dB(L)$, on the highway it was $70-71 \, dB(A)$ and $88 \, dB(L)$, and when the siren was on it was $89 \, dB(L)$.

Crash test

When the ambulance crashed against a wall at a speed of 30 km/hour, the mannequin moved up to 40 cm forward despite being fastened to the stretcher with a 24-point safety belt. The LUCAS device moved with the mannequin and did not detach from the back plate.

DISCUSSION

To establish adequate circulation to the brain as quickly as possible after cardiac arrest is of primecritical importance for survival with good neurological outcome. Of the cases reported here, only patients with a witnessed cardiac arrest that were treated with LUCAS-CPR within 15 min of the ambulance staff being alarmed survived for 30 days. Stable ROSC was obtained in 31% of the patients, but only 7% survived 30 days; the other patients never regained consciousness and all died within 18 days. The patients with a witnessed cardiac arrest that was caused by ventricular fibrillation and that was treated with LUCAS-CPR within 15 minutes had a 25% 30-day survival rate with good neurological outcome. [Compare with survival rates without LUCAS?]

Among the 29% of the patients with a non-witnessed cardiac arrest, none survived 30 days.

[How many achieved ROSC?] In many of the witnessed cases, the time that passed from the collapse of the patient to the time the alarm reached the SOS centre is unknown, but in other studies done in Sweden this interval has been estimated to range from 2 to 5 minutes (3). The time needed for the SOS centre to alert the ambulance staff can and should be less than 1 minute. Thus, if more than 20 minutes elapse after a collapse due to cardiac arrest in normothermia, and if no bystander CPR is given, the chance of survival seems to be very poor and this is in accordance with other studies done in Sweden (3). [In accordance with

Recently we had a patient with a witnessed cardiac arrest on a golf courseout-of-hospital. Bystander CPR was started immediately and continued for 22 minutes before thean second tierambulance equipped with LUCAS arrived at the scene and LUCAS-CPR was started,. Tthe patient was intubated and defibrillation was done during on-going LUCAS-CPRcompressions (4). The patient did not achieved ROSC after a few minutes of LUCAS-CPR and was transported to the hospital with on-going the LUCAS-CPR device in position but switched off.. Just before the ambulance arrived at the hospital, the patient awoke and extubated himself. Emergency coronary angiography showed 3-vessel disease. The patient had an acute bypass operation with a normal postoperative course. This case illustrates the critical importance of good bystander CPR. The alarm operator should give instructions to start forceful chest compressions immediately, and of giving the general public the necessary instructions, if not before, then by the alarm operator when they are urgently needed. New insights into the physiology of cardiac arrest with an underlying cardiac cause (4,5) indicate that chest compressions should be considered the prime and most essential element of the early treatment during the early phase of cardiac arrest out-of-hospital, and the defibrillation should be done with a minimal delay between chest compressions and subsequent defibrillation. In one of the cases referred to in the result section, successful defibrillation was not obtained during manual CPR, but first during on-going LUCAS-CPR. The reason for this is that the coronary perfusion pressure is lost within seconds of interrupting the chest compressions and to defibrillate a fibrillating heart without blood circulation is less effective (4)., and this makes telephone instructions much easier to give.

Another recent case illustrates what can be done when mechanical circulation keeps the brain alive until the heart may be adequately treated and its function restored.indicates a paradigm shift [needs more explanation – from what to what? Is "indicate" the right word, or should it

be something like "justifies", or "justifies consideration of"?] in the treatment of cardiac arrest out-of-hospital (10) A 61-year old man had a cardiac arrest in his home witnessed by his wife. He received no bystander CPR, but the wife immediately alerted the SOS centre and LUCAS-CPR could be started within 10 minutes of the time of the alert being received. No ROSC was obtained at the scene. The patient was transported to the hospital with on-going LUCAS-CPR. Still no stable ROSC was achieved, and cold lactated Ringer solution (30 ml/kg) was given intravenously and a decision to do coronary angiography was taken. The patient arrived at the cath-lab 1 hour after the cardiac arrest. Angiography showed occlusion of the left main coronary artery and no movement of the left ventricle was seen. PCI [define] Percutaneous coronary intervention (PCI) was successfully done between manual chest compressions and the patient recovered fully (10). Three months later he underwent a coronary bypass operation due to stenosis of the left main coronary artery and the postoperative course was normal. He showed no signs of rib fractures despite the prolonged period of chest compressions. This case illustrates a new chain of survival for cardiac arrest patients. This case illustrates that aA patient with a witnessed cardiac arrest out-ofhospitalwhere a stable ROSC cannot be obtained should, ideally, receive adequate mechanical chest compressions as soon as possible and be transported to a hospital with PCI service while being giving continuous adequate mechanical circulation to keep the brain alive until ROSC may be obtained.

Many patients could have been treated with LUCAS-CPR within 15 min from the alarm if all the ambulances had been equipped with the device. During 2005, all 54 ambulances in Skåne (southern Sweden) will be equipped with a LUCAS device and the guidelines will be adjusted to take full advantage of the device. When the ambulance personnel arrive at the scene, LUCAS-CPR shouldwill be started as soon as possible immediately, followed by ventilation

and if indicated, defibrillation during on-going LUCAS-CPR. A most simple ("handsfree") and efficient way to oxygenate a LUCAS-treated patient and at the same time get rid of the CO₂, is to give continuous insufflation of oxygen (CIO) into the trachea via a Boussignac endotracheal tube (9). If ROSC is not obtained within minutes, the patient should be transported to a hospital that can do PCI, and ideally also coronary surgery, if PCI is not sufficient to obtain ROSC.

LucasUCAS can be driven by oxygen or air. If oxygen is used in a small ambulance there is a possibility that the oxygen concentration will increase. Our measurements showed that the oxygen concentration can easily be held low (22%) if the ventilation fan is on and ventilation openings are fully open.

The noise level limits for workers, set up by The Swedish Work Environment Authority, noise level limits for workers are 85 dB(A) for 8 hours of work, or peak levels of 115 dB(A); noise levels higher than this are considered harmful. LucasUCAS produced noise below these levels, but obviously if the noise is felt to be disturbing, ear plugs can be used.

The crash test showed that in spite of 42-point fixation of the mannequin, it moved forward up to 40 cm when the ambulance crashed against a wall at a speed of 30 km/hour. Despite a force of 10 G, LUCAS did not loosen from its back plate. The ambulance staff responsible for the treatment of the a patient should sit belted beside the patient and no hard material should be within a distance of 40 cm from the head of the patient. The patient should be fastened carefully to the stretcher before the start of the ambulance trip.

It is impossible to do adequate manual chest compressions for more than a few minutes (11). iIn a running ambulance (11-12)it is impossible to ensure adequate circulation by manual chest compressions and furthermore, any attempt to do so entails a risk to the life of the ambulance staff (12). Thus during transport of a patient with cardiac arrest, mechanical chest compressions should be usedmandatory foremost, for safety reasons. Besides giving adequate circulation to the brain until PCI/coronary surgery eventually has to be done to obtain ROSC, a further advantage of mechanical CPR is that defibrillation can be given during ongoing CPR (4); thiswhich can not be done, for safety reasons, during manual CPR (8,12).

To conclude, establishment of an adequate brain circulation as quick as possible after cardiac arrest is mandatory for a good outcome. In this report patients with a witnessed cardiac arrest receiving LUCAS-CPR within 15 min had a 30-day survival of 25 % in cases of VF and 5 % in case of asystole, but if more than 15 min passed, and in all unwitnessed cases, none survived 30 days.

LUCAS-CPR gives superior circulation compared to manual CPR (8,12), and it leaves the ambulance personnel free to consider other therapeutic procedures, such as cooling (1-2). Post-cardiac arrest heart failure is common and LUCAS-CPR is a most efficient therapy for that condition, until time or more radical therapy such as PCI or urgent surgery can be done to ensure a stable ROSC.

[Förstår inte riktigt sista mening. Slutar dessutom något tvärt – inget mer sammanfattande stycke som avslutning?]

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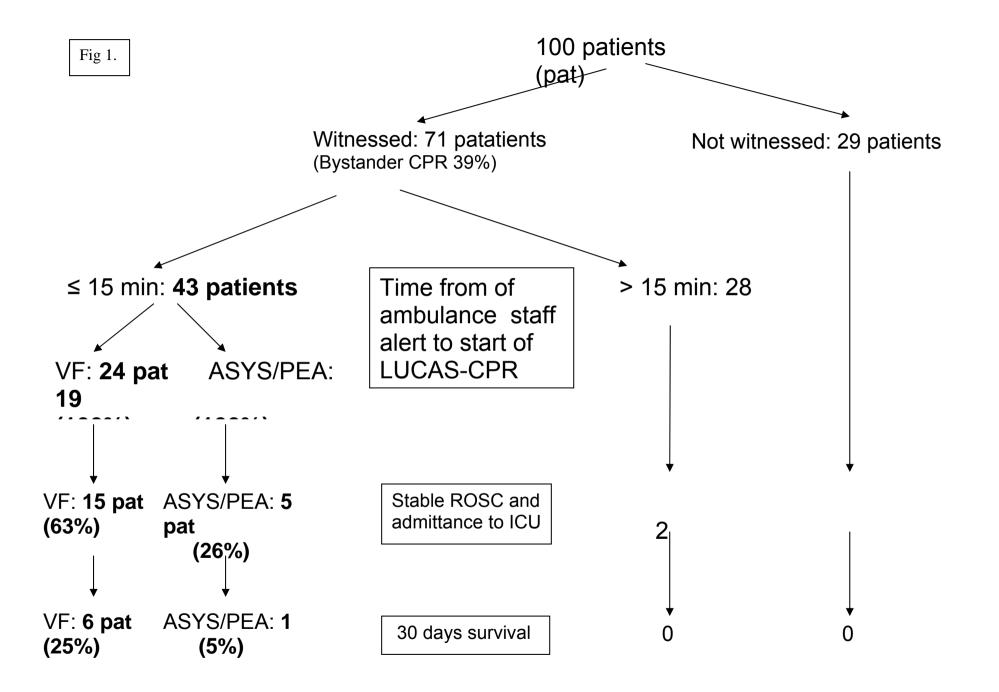
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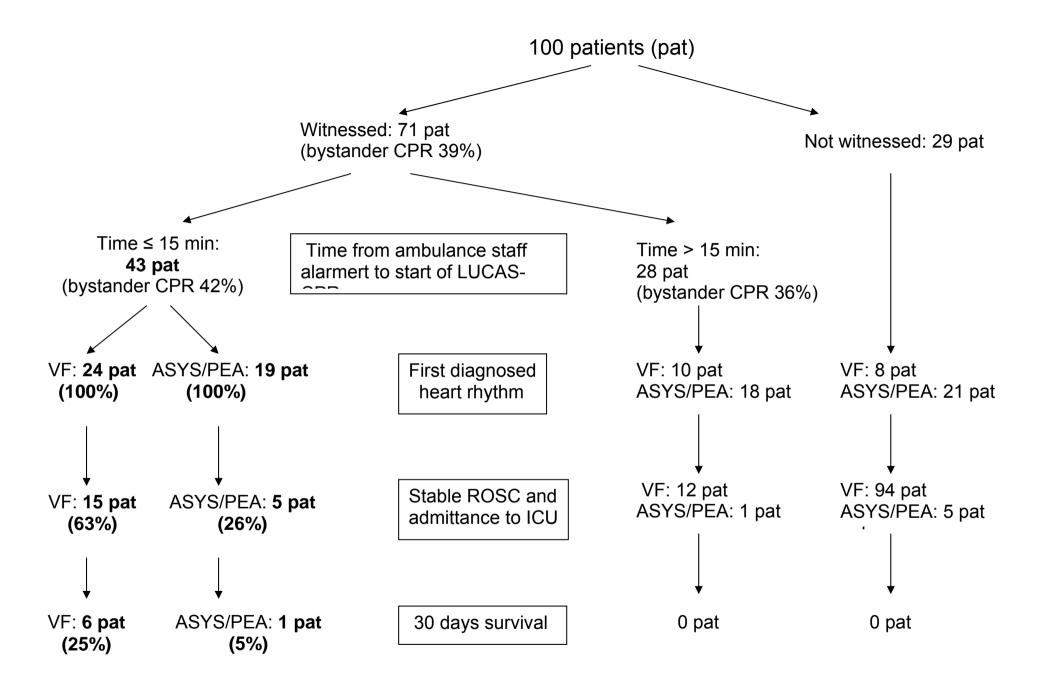
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LEGENDS TO FIGURES

Fig 1. Flow chart showing the results of the study. [NB ROSC figures not visible for >15 min and not witnessed (text boxes need adjusting)]

Fig 2. Times of interest given as mean±SEMD; median (range); number of casesobservations. [*Could the figure be made to scale?*]





Cardiac arrest	so		•	Arrival to patient			•	rrival to lospital
5±6;	3(0-28); 47							_
		1±2; 1(0-12); 49 3±7; 1(0-35); 44						
	1st tier 2nd tier	6±3; 6(1- 8±7; 6(1-	* *					
		•	14±9; 12(2-52)	; 52				
				ier 8±6; 6(1- ier 6±5; 5(1-				
			1st ti 2nd t		•	(1-38); 94 (3-38); 83		
						9±6; 9(0-24); 85		
						14±7; 15	(1-35); 92	
							6±3; 5(0-21);	94

