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Constant flow insufflation of oxygen as the sole mode of ventilation during out-of-hospital cardiac arrest

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Abstract *Background:* Constant flow insufflation of oxygen (CFIO) through a Boussignac multichannel endotracheal tube has been reported to be an efficient ventilatory method during chest massage for cardiac arrest. *Methods:* Patients resuscitated for out-of-hospital cardiac arrest were randomly assigned to standard endotracheal intubation and mechanical ventilation (MV; $n = 457$) or use of CFIO at a flow rate of 15 l/min ($n = 487$). Continuous chest compressions were similar in the two groups. Pulse oximetry level was recorded every 5 min. Outcome of initial resuscitation, hospital admission, complications, and discharge from the intensive care unit (ICU) were analyzed. The randomization scheme was changed during the study, but the

in-depth analysis was performed only on the first cohort of 341 patients with CFIO and 355 with MV, because of randomization problems in the second part. *Results:* No difference in outcome was noted regarding return to spontaneous circulation (CFIO 21%, MV 20%), hospital admission (CFIO 17%, MV 16%), or ICU discharge (CFIO 2.4%, MV 2.3%). The level of detectable pulse saturation and the proportion of patients with saturation above 70% were higher with CFIO. Ten patients with MV but only one with CFIO had rib fractures. *Conclusions:* CFIO is a simplified alternative to MV, with favorable effects regarding oxygenation and fewer complications, as observed in this group of patients with desperate prognosis.

Keywords Cardiopulmonary resuscitation · Ventilation · Orotracheal intubation · Continuous positive airway pressure · Emergency medicine

Introduction

Administration of adequate ventilation is essential to successful resuscitation after cardiac arrest but the management of ventilation remains largely empirical [1]. In a previous study in patients Saissy et al. [2] found that constant flow insufflation of oxygen (CFIO) at 15 l/min via small capillaries inserted into the wall of a standard-size endotracheal Boussignac tube maintained adequate ventilation and oxygenation compared to standard manual ventilation in out-of-hospital cardiac arrest. When delivered by means of this special tube, CFIO generates a constant positive alveolar pressure, and chest compression generates sufficient ventilation to achieve adequate gas exchange [3]. CFIO has been used to assist ventilation in intubated patients or to maintain lung volume and oxygenation during endotracheal suctioning [4, 5]. It has been reported that in animals cardiopulmonary resuscitation (CPR) can be performed with beneficial hemodynamic effects using the Boussignac tube for CFIO [6]. Stable arterial blood gas levels after 55 min of CFIO have also been reported in one case of in-hospital cardiac arrest before coronary bypass surgery [7]. Because of the simplicity of the technique it could be envisaged as an alternative to standard mechanical ventilation (MV) in specific circumstances. Experimental studies and one human study have shown that ventilation is at least as efficient as standard MV, together with improved gas exchange probably due to protection from massage-induced lung contusion thanks to a constant positive airway pressure [2, 6, 8]. Moreover, circulation is improved by CFIO during continuous chest compression, as demonstrated in two experimental studies in large animals [6, 8]. Steen et al. [8] also demonstrated better survival with CFIO. Lastly, this technique allows performing a continuous cardiac massage during CPR.

We tested the hypothesis that this technique is superior to standard MV and compared it to a standard approach in out-of-hospital cardiac arrest. We performed a multicenter, prospective, randomized, controlled trial to compare CFIO as the sole mode of ventilation during continuous chest compression vs. standard MV. By selecting a population not responding to initial defibrillation we studied a group with an extremely poor prognosis.

Material and methods

The French Emergency Medical System

Cardiac arrest occurring outside the hospital in France is managed by the Service d'Aide Medicale Urgente. By dialing the number 15 telephone callers are connected to the closest regional dispatch center, where a physician is available 24 h a day. The physician sends a team from the fire department rescue service and a medical unit from the nearest hospital. The fire department team begins basic life support (BLS), as they normally arrive prior to the medical team. As soon as the medical team arrives, it performs advanced cardiac life support (ACLS) according to the recommendations of the European Resuscitation Council [9].

Study design

The study was conducted between September 2000 and November 2003. A total of 1,042 patients were included during the study period. Patients' characteristics and clinical data were collected from a standardized form completed by the medical team as recommended by the Utstein Consensus Conference [10]. Recorded variables were: baseline characteristics, location of cardiac arrest, suspected cause of arrest, whether the arrest was witnessed, initial electrical rhythm, use of the cardiopump, medical history, principal event-to-event periods, total quantity of epinephrine, countershocks, and complications.

As authorized by law, the Consultative Committee for the Protection of Persons Volunteering for Biomedical Research (Ethics Committee, or CCPPRB) of Henri Mondor Hospital, Creteil, approved the study for all participating study centers. Deferred informed consent was obtained in all cases, either on site or after hospital admission from a relative or next of kin. The trial involved 15 centers. These centers cover a population of approx. 11.5 million (11 million urban, 0.5 million rural).

Patients 18 years or older who had nontraumatic cardiac arrest outside the hospital were eligible for inclusion if they remained in ventricular fibrillation despite three suc-

cessive countershocks delivered during BLS or in asystole or with pulseless electrical activity. Cardiac arrest was defined as the absence of both spontaneous respiration and palpable carotid pulse. Patients were not eligible if intubation was not technically possible, or if they had obvious signs of irreversible cardiac arrest such as cadaver rigidity or livid spots.

BLS consisted of cardiac massage and manual insufflation of oxygen with a facial mask and an autofilling bag allowing a fraction of oxygen close to 1. The active compression-decompression device (ACD) was used for both groups in centers in which it was currently available. Automated external defibrillator was not always part of the equipment.

Patients in the control group were intubated using a standard cuffed tube with an internal diameter (ID) of 7.5 mm. MV was started with the following parameters: tidal volume 12 ml/kg, respiratory frequency 12 cycles/min and $FIO_2 = 1$, upper alarm set at 40 cmH_2O. Patients in the CFIO group were intubated using a multichannel, cuffed endotracheal tube with an ID of 7.5 mm (Boussignac-type tube; Vygon, Ecouen, France). CFIO was performed using the capillaries from the common proximal end at a flow rate of 15 l/min, which is known to generate a constant endotracheal pressure of approx. 10 cmH_2O. The proximal end of the tube was left open to atmosphere. In the wall of this tube five small capillaries were molded by extrusion, allowing the delivery of high-velocity microjets near the distal tracheal end of the tube. Compression of the thorax generated active expiration through the open endotracheal tube, while passive decompression resulted in inspiratory flow entering the lungs up to the level of positive pressure generated by the CFIO.

Epinephrine was injected intravenously via a peripheral route at the rate of 1 mg every 3 min. Epinephrine was the only vasoconstricting drug allowed. MV was performed during ACLS without interruption of chest compressions, according to French practice [9, 11, 12]. Continuous chest compressions were provided after intubation in both groups at a rate of 100 compressions/min. ACD was continued only if started during BLS in both groups. After intubation pulse oximetry was started, and oxygen saturation (SpO_2) was recorded every 5 min for at least 30 min.

As soon as a spontaneous palpable carotid pulse was restored for a period of 1 min, standard MV using the transport ventilator was the sole mode of ventilation in both groups. Patients were admitted to the intensive care unit (ICU) or transferred to the coronarography center. To facilitate teaching for all teams, a 10-min video describing the correct procedures was delivered to all centers prior starting the study. In March 2002 the study design was modified due to slow enrollment rate combined with uncertainties in financial support and maintenance of adequate clinical monitoring. Approval was subsequently given by the CCP-PRB to simplify the procedure in order to facilitate inclusions. In July 2002 the study restarted using a simplified method of odd and even days for randomization. ACLS could also be performed by two persons instead of three.

Patient groups

Patients were randomly selected by the medical team at the scene, according to predetermined sealed envelopes placed in the medical ambulances of the 15 centers until March 2002. Randomization was computed by block sizes of 4. Unfortunately, major discrepancies in randomization between odd and even days were observed during the second period of the study starting in July 2002 (higher than 30%), casting doubts on the quality of the data in this period and suggesting patients may have been selected in the absence of the sealed envelopes. Consequently, we provide the results for hospital admission on an intention-to-treat analysis as well as the main characteristics of the overall group and the results of SpO_2 (with details in the Electronic Supplementary Material, including Figures S1, S2, and S3) as an intention-to-treat analysis. However, only the first part of the study was used for a detailed analysis. In the first period, 45 patients were excluded because of missing data. The analysis established that randomization worked properly during the first period. All patients in the first period of study were followed throughout (Fig. 1).

In the intention-to-treat analysis, 457 patients were included in the MV group and 487 in the CFIO group. Characteristics of the patients were similar in the two groups (ESM, Table S1), and no difference was observed in the course of resuscitation (ESM, Table S2). The number of patients admitted to the hospital was similar in the two groups (MV 84, 19%; CFIO 71, 15%).

The number of patients from the first period kept for the final analysis was 696, with 341 (49%) randomized to the CFIO group and 355 (51%) to the MV group. The characteristics of the patients in the two groups were similar. No major difference in demographic data or characteristics of the two groups was noted. The two groups were also comparable in terms of initial rhythm. Only 65 patients with ventricular fibrillation were included in the study. These results are shown in Table 1. Times of intervention, as reported according to the Utstein style of description for cardiac arrest, were also comparable (Table 2). The study was stopped because of demonstrated futility after interim analysis. The total number of CFIO was 48% vs. 52% in the overall population.

Primary end points

The primary outcome measure was survival to ICU discharge, defined as the patient's leaving the unit alive. The effectiveness of resuscitation was assessed by the rate of

Fig. 1 CONSORT diagram

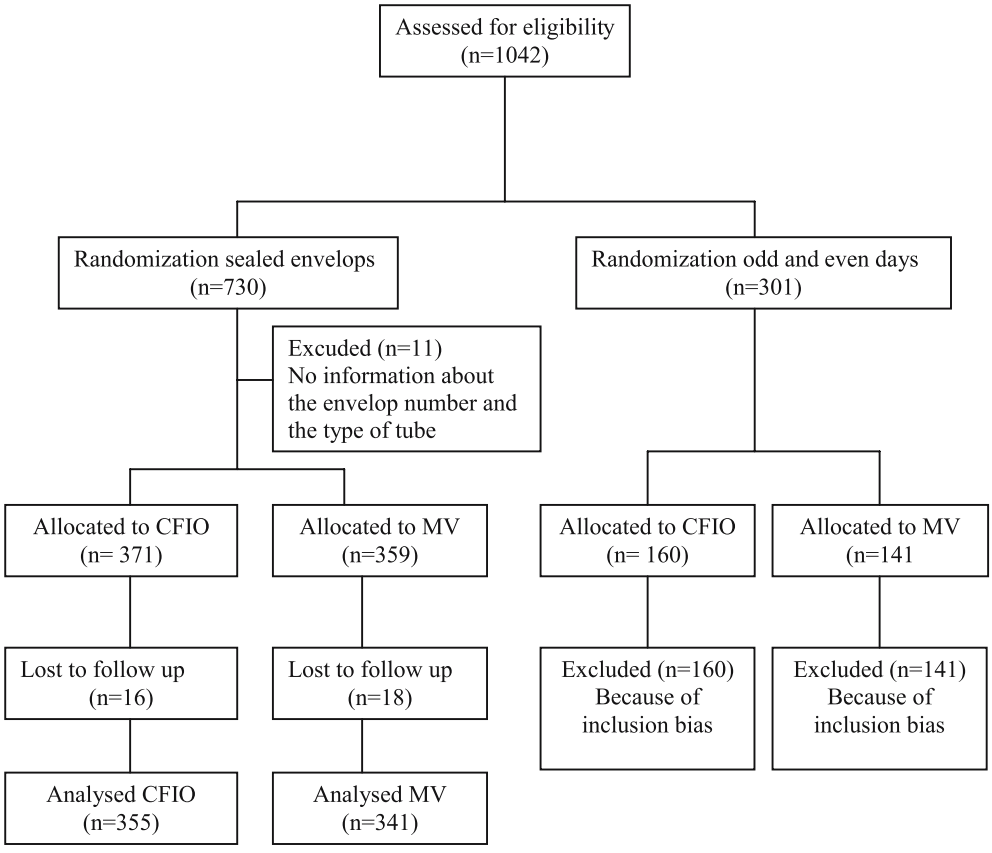

Table 1 Characteristics of the 696 patients with out-of-hospital cardiac arrest (*MV* mechanical ventilation, *CFIO* constant flow insufflation of oxygen)

	MV ($n = 341$)	CFIO ($n = 355$)	p
Average age (years; range)	67 (39–85)	66 (40–88)	0.78
Male sex	202 (59%)	230 (65%)	0.20
Female sex	106 (31%)	97 (27%)	
Witnessed arrest	212 (63%)	222 (63%)	0.92
Bystander CPR	33 (10%)	31 (9%)	0.65
Asystole	240 (70%)	257 (72%)	0.82
Pulseless electrical activity	32 (9%)	30 (8%)	
Ventricular fibrillation	30 (9%)	35 (10%)	
Home	228 (67%)	248 (70%)	0.20
Public place	55 (16%)	53 (15%)	
Nursing home	8 (2%)	15 (4%)	
Other	16 (5%)	11 (3%)	
History of cardiac disease	78 (23%)	100 (28%)	0.11
Suspected cardiac cause of arrest	68 (20%)	76 (21%)	0.76
Diabetes	52 (15%)	44 (12%)	0.28
Obesity	77 (23%)	68 (19%)	0.23
Cancer and poor health status	66 (19%)	65 (18%)	0.72
Cyanosis	154 (45%)	160 (45%)	0.79
Vomiting	73 (21%)	64 (18%)	0.26
Difficult intubation	36 (11%)	54 (15%)	0.07
Mydriasis	228 (67%)	236 (66%)	0.27

return of spontaneous circulation (ROSC), and the rate of hospital admission. The effectiveness of oxygenation during chest compressions was assessed in both groups comparing the number of patients with a legible SpO_2 signal and with a value above 70%.

Statistical analysis

The number of patients was calculated from the previous French studies [13, 14] to observe a rate of ICU discharge increased from 2.4% to 4.8%. The initial calculation of

Table 2 Course of resuscitation (*MV* mechanical ventilation, *CFIO* constant flow insufflation of oxygen, *BLS* basic life support, *ACLS* advance cardiac life support, *ROSC* return of spontaneous circulation)

	MV	CFIO	*p*
Time to BLS			0.3
Mean ± SD	12 ± 9.2	11 ± 8.4	
Median (95% CI)	11 (0–25)	10 (0–23)	
Time to ACLS			0.6
Mean ± SD	24 ± 11.5	24 ± 17	
Median (95% CI)	23 (7–41)	24 (8–40)	
Time to tracheal intubation			0.56
Mean ± SD	26 ± 11.8	26 ± 11.2	
Median (95% CI)	25 (10–45)	25 (9–43)	
Time to ROSC			0.6
Mean ± SD	38 ± 13.3	37 ± 15.2	
Median (95% CI)	36 (20–61)	36 (19–67)	

the required number of patients was 1,884 with a power defined at 80% and a p value of 0.029 to protect the α risk due to the intermediate analysis. Intermediate analysis was initially planned at 942 patients. Survival rates and levels of oxygen were also assessed according to the use of the cardiopump. Continuous variables are presented with median values. The proportions in the groups and the absolute differences between percentages were calculated with 95% confidence intervals. Statistical tests included the χ^2 test, with Fisher's exact test when needed. Quantitative values were compared using the Mann-Whitney nonparametric test. To evaluate the effect of CFIO on SpO_2 during CPR we used a mixed model [15]. This allows analysis of repeated-measures data by modeling the variance and within-patient correlation of the repeated measures. The estimated covariance structure was used to obtain maximum likelihood estimates of treatment and time differences. The variables included in the model are type of tube, time, and the interaction between type of tube and time. All tests were conducted with a two-tailed α level set at 0.05. All calculations were performed with SAS software (version 9.13)

Results

No significant difference was observed in ICU survival between the groups (eight in each group). The survival groups had similar profiles, with a comparable proportion of ventricular fibrillations (MV 6/8, CFIO 4/8) witnessed arrests (MV 7/8, CFIO 6/8), and ACD (MV 1/8, CFIO 1/8). There also was no significant difference between groups in the rate of ROSC or admission to hospital. No difference was observed using this technique with CFIO or MV in terms of survival, admission or ROSC, with a similar use of ACD in both groups at every stage of the analysis (Table 3). The prognosis of the overall group was related to the time to defibrillation and time to ROSC, according to the Utstein description (see ESM Table S3).

A significant difference between the two groups was found in the analysis of SpO_2. Figs. 2 and 3 show the percentage of patients with measurable SpO_2 ($p = 0.005$) and with values above 70%, which were both significantly greater in the CFIO group ($p = 0.009$). Higher levels of SpO_2 were observed in the CFIO group at each 5-min interval during the 30-min resuscitation period. In the subgroups with ACD the analysis of pulse oximetry revealed that detection of SpO_2 was significantly more frequent in every 5-min time interval for CFIO than for MV ($p = 0.013$) The change in SpO_2 at 5-min intervals to 30 min is shown in Fig. 4. No significant interaction between the effect of the tube and the time was found ($p = 0.55$). Similar results were observed in the intention-to-treat analysis (see ESM).

No specific problem related to the use of CFIO was reported by the medical teams. No difference in insertion of the tracheal tube or in time needed to ventilate the patient was observed. Adverse effects of CPR were analyzed

Table 3 Outcome (*MV* mechanical ventilation, *CFIO* constant flow insufflation of oxygen, *ACD* active compression decompression)

	MV ($n = 341$)	CFIO ($n = 355$)	*p*
Use of ACD	130 (38%)	150 (42%)	0.27
Return of spontaneous circulation			0.99
Overall	71 (21%)	67 (19%)	
ACD	30 (23%)	39 (26%)	
Survival at hospital admission			0.81
Overall	59 (17%)	57 (16%)	
ACD	17 (13%)	23 (15%)	
Survival to ICU discharge			0.96
Overall	8 (2.4%)	8 (2.3%)	
ACD	1 (0.8%)	1 (0.7%)	

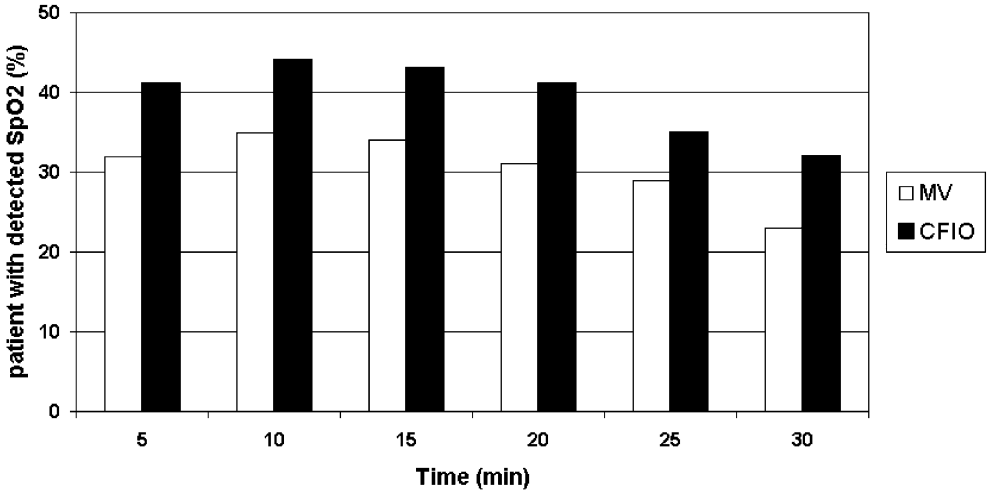

Fig. 2 Proportion of patients with measurable SpO_2. Groups differed significantly ($p = 0.005$)

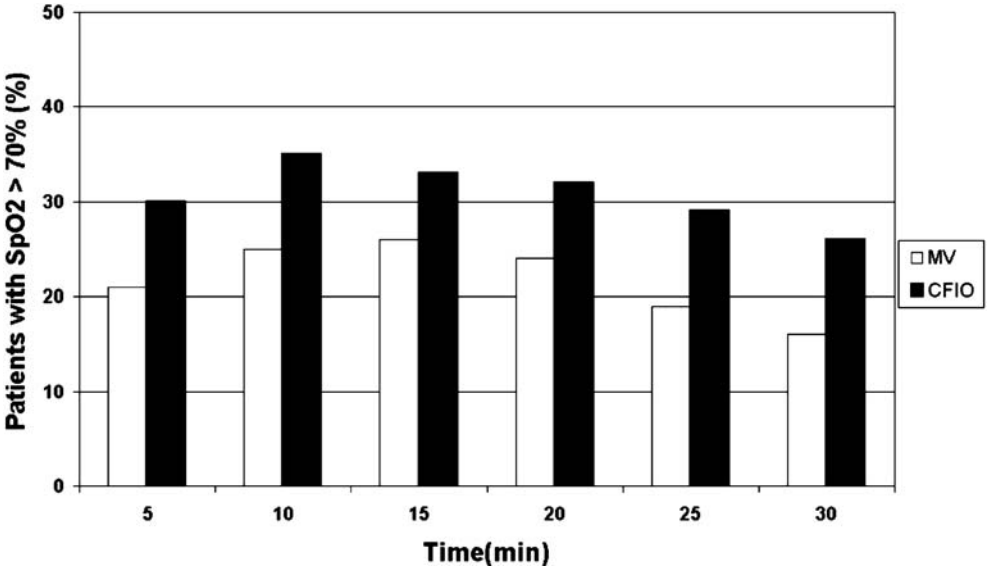

Fig. 3 Proportion of patients with SpO_2 values above 70%. Groups differed significantly ($p = 0.009$)

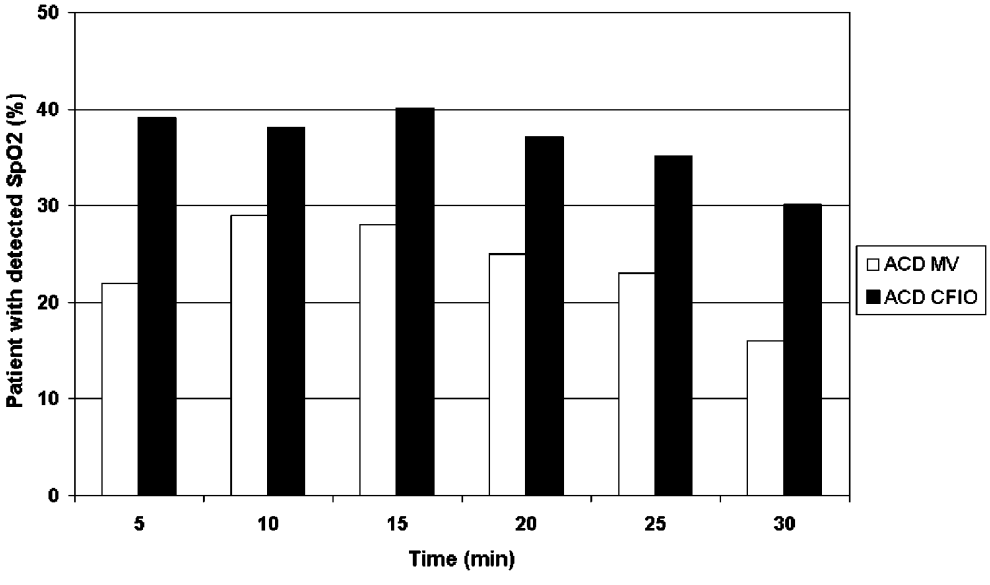

Fig. 4 Comparison of percentage of patients with measurable SpO_2 according to ACD use. Groups differed significantly ($p = 0.013$)

for patients admitted alive in the hospital. Rib cage fractures were more frequent in the MV group ($n = 10$) than in the CFIO group ($n = 1$, $p = 0.005$). In the CFIO group the rib cage fracture occurred in a patient treated with ACD. The quantity of epinephrine administrated in the CFIO and MV groups were, respectively, 16.5 ± 9.6 and 15.9 ± 9.6 ($p = 0.36$).

Discussion

Outcome

This is the first study comparing CFIO and MV in the prehospital setting in such a large cohort of patients. Previous studies were experimental or limited to small groups of patients [2, 6, 7, 8]. No difference and no trend was observed in the hospital admission and survival rates.

The population included had a very poor prognosis for two reasons. Because not all patients responding to defibrillation provided during BLS were included, the small proportion of patients with ventricular fibrillation, refractory to external shock (fewer than 10%), and the very long delay to perform BLS (more than 11 min) and ACLS (more than 20 min) explains the extremely low survival rate (16/696). This has been previously described in studies looking at out-of-hospital cardiac arrest in urban settings [16, 17]. Secondly, all causes of cardiac arrest were included, and only 21% were suspected to be cardiac causes. Cardiac causes of cardiac arrest have a much higher prognosis than noncardiac causes.

Reliability of saturation

The main finding of this study is the improved detection of SpO_2 in patients ventilated during chest massage by CFIO. The difference in SpO_2 detection between the two groups needs to be discussed. This variable is not commonly analyzed in cardiac arrest patients although measurement of SpO_2 is a standard of care in many prehospital care teams [18]. In clinical practice SpO_2 is commonly considered to be unreliable or not recordable in low flow state such as cardiac arrest, hypothermia, and extreme peripheral vasoconstriction. Differences have been observed according to the type of the probe used and its location [19, 20, 21]. Consequently the exact value of SpO_2 is probably of minor interest, but the possibility to detect SpO_2 may be a consequence of improved peripheral circulation and/or of peripheral oxygenation. The difference observed between the two groups of patients while SpO_2 was recorded by the same teams with the same devices in the same settings may therefore have a clinical value. This was not related to a difference in vasoconstriction because the same quantity of epinephrine was administered in the two groups. It was not related to chest compressions as they were carried out continuously in both groups at the same pace. Saissy et al. [2] did not observe a difference in SpO_2 detection above 70% when comparing artificial ventilation and CFIO. This is probably explained by their small number of patients.

Hemodynamic effect and oxygenation

The difference in SpO_2 detection may be related to both an improvement in oxygenation, as suggested by previous work on CFIO [2], and an improvement in peripheral circulation related to an increase in cardiac output [6, 8]. The greater proportion of patients with measurable SpO_2 values in the CFIO group supports a better hemodynamic effect. The better level of SpO_2 in the CFIO group suggests better oxygenation. One wonders whether a higher detection rate could be the result of a higher SpO_2 in the experimental group. Although this cannot be excluded, the fact that SpO_2 had to be continuously measured and recorded in all patients to minimize this possibility. Previous animal studies have shown that continuous insufflation of oxygen in the trachea maintains arterial oxygenation in the absence of respiratory movement in animals [22]. External cardiac compressions combined with CFIO generate adequate ventilation while CFIO generates a positive pressure in the lungs [23]. During constant flow insufflation at a rate of 15 l/min chest pressure varies between 2 and 15 cmH_2O. CFIO may have a protective effect against pulmonary lesions such as atelectasis created by prolonged chest massage, or lung contusion and edema induced by massage or by the ACD [24]. The multichannel tube used in this study allows the expired gas to be replaced continuously by inspired fresh gas and may produce better mixing in the distal part of the airway [3].

A recent experimental study showed the advantage of CFIO over MV regarding oxygenation and coronary perfusion pressure [8]. The airway pressure induced by CFIO was positive during the entire cycle of CPR, including the decompression phase, increasing the functional residual capacity and decreasing the physiological deadspace during CPR.

The exact mechanism of SpO_2 improvement, however, remains to be clarified, and its relationship to survival has not yet been demonstrated. CFIO also allows the performance of continuous chest compressions during ventilation, which could improve cardiac output [25, 26]. If not turned into a survival benefit in this population, the improvement in oxygenation during CPR could potentially offer better salvage of organs for donation. It may also be interesting to use Boussignac CFIO during CPR in situations where intubation is required, and an MV device is not immediately available, such as in-hospital cardiac arrest and at disaster sites during catastrophes with a large number of patients in cardiac arrest.

Complications

The relatively low number of traumatic injuries (rib cage fracture) related to chest compression in the CFIO group is also of interest. Complications have been reported with ACD and may explain the only case observed with CFIO [27]. One hypothesis is that CFIO exerts a protective effect by maintaining a positive pressure inside the chest. CFIO increases pulmonary volume and intrathoracic pressure. This may have attenuated the thoracic chest wall injury induced by chest massage.

Although no difference in survival was demonstrated, the relative simplicity of CFIO use in the prehospital field was confirmed by this study. CFIO efficiently replaced MV. When artificial ventilation was performed via a self-inflating bag connected to the endotracheal tube, one member of the team had to be assigned to squeeze the bag. This was not needed with CFIO, thus freeing this member of the team for other ACLS procedures. The physical characteristics of the two tubes were identical: length, composition, and external diameter except for the first series of 50 Boussignac tubes that was not rigid enough and slightly more difficult to insert than a standard tube. No difference was found after this first series, and this probably explain a trend found with the first tubes for more difficult intubation.

Limitations of the study

Limitations may be related to a lack of power of the study caused by an extremely poor prognosis and a limitation of inclusions. We had to exclude 301 patients because bias was observed with odd and even randomization. We are unable to explain why health care workers used the wrong tube in 30% in cases of each group. We had no possibility in this study to examine the correlation with the higher levels of oxygen that occurred during cardiac massage with better levels of PO_2 and PCO_2 at the hospital's arrival as previously shown. This prevents us from making conclusions about the adequacy of ventilation with the Boussignac tube in this study, although this has previously been shown in similar circumstances.

Conclusion

Although there was no evidence of any survival advantage in this study performed in a group of patients with an extremely poor prognosis, the study illustrates that CFIO is a simple and safe method of providing ventilation during CPR. The improved detection of SpO_2 during cardiac massage may be related to an increase in peripheral oxygenation and circulation.

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