GROUPE HOSPITALIER
DE LA ROCHELLE - RÉ - AUNIS

Unexpected Cardiac Arrest in Intensive Care Unit

Prospective multi-centre observational study on the epidemiology, risk factors and consequences of unexpected cardiac arrest in intensive care units.

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1. Abstract

1.1. Justification and objectives

Unexpected cardiac arrest (UCA) occurs in 0.5 to 5 % of intensive care unit (ICU) admissions. Despite continuous monitoring and immediate advanced life support in situation of cardiac arrest administered in ICU, patients that often suffer from chronic or multisystem diseases have poor outcome after cardiopulmonary resuscitation. The etiologies of UCA occurring in ICU are rarely reported in the literature (never in France).The study aims at prospectively describing the epidemiology of unexpected cardiac arrest occurring in ICU.

1.2. Studypatient characteristic

Patients who suffer unexpected cardiac arrest during ICU stay and who undergo cardiopulmonary resuscitation (chest compression and/or external electrical shock).

1.3. Study design

This is a prospective multicenter cohort study covering one calendar year. For patients who suffer unexpected cardiac arrest, collecting epidemiological data, circumstances surrounding unexpected cardiac arrest, unexpected cardiac arrest characteristics, consequences of the unexpected cardiac arrest and patient outcome (patients alive at ICU and hospital discharge).

1.4. Number of patients screened

The results of a previous prospective study carried out by 43 French ICU, suggest that around 30 000 patients are expected to be screened in one calendar year in the participating ICU. Thanks to the incidence rate of unexpected cardiac arrest occurring in ICU reported in the literature, from 150 to 1500 may undergo an unexpected cardiac arrest.

1.5. Main outcome mesure

Incidence rate of unexpected cardiac arrest in participating ICU

1.6. Results and expected contributions of the study

The ACIR registry will allow identifying the warning signs preceding cardiac arrest and find measures to prevent their occurrence and/or limit their consequences.

Based on the obtained results, recommendation proposals will be provided about development of safety culture, staff training, improvement of cardiopulmonary resuscitation quality and postresuscitation care, and effective use of a donotresuscitate policy.

2. Investigators

3.1 Coordinator

Dr. Maxime LELOUP, Service de Réanimation, Groupe Hospitalier de La Rochelle Ré Aunis.

3.2 Coinvestigators

Name	Town of Institution
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VAN DER LINDEN Thierry	Lille GHICL
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PLOUVIER Fabienne	Agen
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CHELLY Jonathan	Melun

3. Context

Unexpected Cardiac Arrest in Resuscitation (ACIR) is a cardiocirculatory arrest that has led to at least one cardiopulmonary resuscitation technique (external cardiac massage, adrenaline and/or electric shock). They concern approximately 0.5 to 5% of the admissions in Resuscitation(1–14). Although they benefit from a technical environment conducive to prompt diagnosis and management, resuscitation patients suffer from chronic diseases and organ failure(s) that worsen the prognosis for CARI. The etiologies of ACIR are rarely described in the literature. (4,5,14). Their specificity lies in the fact that they can be linked to the medical characteristics of the patient, but also to the deleterious effects of the substitution techniques in place at the time of circulatory arrest (respiratory assistance, vasopressor drugs, extracorporeal circulation, etc.) (6,9,11,12,14). These same techniques can also reduce the effectiveness of cardiopulmonary resuscitation (cardiorespiratory interactions of respiratory assistance, proarrhythmogenic effect of vasopressor drugs, hemodynamic repercussions of extracorporeal circulation). Although there are many publications on extra or intrahospital cardiac arrest, few studies specifically concern ACIR (none in France). However, the prognosis is different: after an ACIR, 50% of patients recover spontaneous cardiac activity but only 15% leave hospital alive (3 to 4% with good functional autonomy) (14). A prospective description of risk factors, circumstances and mediumterm consequences would help identify (and prevent) risk situations and distinguish among patients at risk for CAIR those for whom PCR is warranted.

4. Objectives

4.1. Main objective

Describe the epidemiology of unexpected cardiac arrest in Resuscitation (ACIR).

4.2. Secondary Objectives

- Investigate the predictive and prognostic factors of unexpected cardiac arrest;
- Describe the etiologies of unexpected cardiac arrest;
- Observe the fate of patients suffering from unexpected cardiac arrest at 24 hours, at the end of resuscitation, at hospital discharge and 6 months after ACIR ;
- Describe the proportion of patients with unexpected cardiac arrest who have not been resuscitated without a previous DNR order;
- Describe the proportion of patients with unexpected cardiac arrest who were resuscitated despite a previous DNR order.

5. Methodology

This is a 12month prospective multicentre observational study.

It will be carried out by the "EPILAT" group, which has already worked and published on the epidemiology of therapeutic limitation measurements in intensive care units in France. (15,16).

The data will be collected on a computerized register, carried out according to the recommendations of the UtsteinStyle (17).

5.1. Inclusion criteria

- Age over 18
- Patient with unexpected cardiac arrest during his / her hospitalization in the ICU
- Patients who have benefited from at least one basic cardiopulmonary resuscitation technique by the ICU team to treat this circulatory arrest (external electric shock, external cardiac massage, adrenaline injection ...)
- Patients with multiple unexpected cardiac arrest during hospitalization will be included only for the first circulatory arrest.

5.2. Non inclusion criteria

- Patients with unexpected cardiac that have not been resuscitated.
- Patients in cardiac arrest at admission to ICU

5.3. Study population

The study period is 12 months. Included are patients admitted to Resuscitation during the study period with ACIR.

Patients included will be followed until discharge from Resuscitation/Hospital or until death. For patients alive at discharge, a neurological assessment will be performed according to the cerebral performance categories (CPC) scale before discharge and at 6 months (18).

5.4. Sample size

A recent prospective multicenter study conducted in 43 ICU departments over a period of 60 to 90 days included 5,589 patients. (15,16). The prevalence of ACIR in resuscitation patients being between 0.5 and 5% in the literature (1–14), a 2month observation period over the same number of centres would allow the analysis of between 150 and 1500 ACIRs. It should be noted that in the study by the EPILAT group (15,16), 8% of the patients admitted were reported to have died of ACIR, resuscitated or not. To explain this difference, our hypothesis is that a large number of circulatory arrests, described as unexpected but highly predictable given the seriousness of the patient, occur outside any context of therapeutic limitation, without any resuscitation measures being taken. The ACIR for which no resuscitation measures are undertaken given the severity of the patient will therefore not be included in the study.

6. Description of data collected

Data for the participating centres in the study will be collected on an "ACIR Centre" form:

- The name of the centre
- The academic or nonacademic character of the institution (CHU, CHR, CHG, PSPH)
- The type of resuscitation (multipurpose, surgical, medical, neurosurgical)
- The number of resuscitation beds
- FDI/patient ratio
- Whether or not to organise CPR training for all staff
- The frequency of these training courses if they are offered
- The practice of simulation workshops by physicians and/or staff.

A count of all inpatients in the ICU during the study period will be conducted in each centre. This census will include :

- Initials of patient's first and last name
- Date of Birth
- Patient's gender
- IGS II
- Main diagnosis (medical, scheduled surgery, emergency surgery)
- Length of stay
- Lively exit from the service
- For patients who died in resuscitation: death by brain death, ACIR or predictable cardiac arrest

A screening will be completed for all patients with circulatory failure in the department during the study period. The study will collect the following information:

- Initials of the patient's first and last name
- Month and year of birth
- Date of circulatory stop
- Date of admission to Resuscitation
- Reason for admission to Intensive Care Unit (Medical, Scheduled Surgical, Urgent Surgical)
- Score IGS 2
- Carrying out resuscitation or non resuscitation maneuvers
- If not, reason for nonresurrection:
    - prior decision of limitation or therapeutic discontinuation
    - Nonresponse to maximum treatment
    - Other reason to be specified

When the patient will benefit from resuscitation maneuvers (external cardiac massage, external electric shock, adrenaline...), he will be included in the study and the data will be collected in the observation notebook "Data on ACIR":

1- Hospitalization in intensive care
   a. Reason for admission
   b. Mc Cabe score (20)
   c. Knaus score (21)

2- Patient history and co-morbidities
   a. Diabetes
   b. High blood pressure
   c. Smoking
   d. Chronic Ethylism
   e. Dyslipidemia
   f. Coronary artery disease
   g. Chronic Respiratory Failure
   h. Chronic heart failure
   i. Chronic renal failure
   j. Chronic Liver Failure
   k. Chronic neurological pathology
   l. Cancer, haematological malignancies
   m. Cardiac arrest successfully resuscitated prior to this hospitalization

3- Patient organ failures at the time of cardiac arrest
   SOFA score (22)
   Patients will be considered deficient when the SOFA score is greater than or equal to 3 on the organ concerned.

4- Had the patient already been the subject of a decision to limit or stop therapy prior to unexpected cardiac arrest?

5- Treatments in place at the time of occurrence the unexpected cardiac arrest

   a. Non-ventilated patient without tracheal approach
   b. Non-ventilated tracheostomy patient
   c. High-flow oxygenation device
   d. Intermittent or continuous non-invasive ventilation
   e. Invasive intubation catheter ventilation
   f. Invasive tracheostomy ventilation
   g. Sedation
   h. Catecholamines
   i. Extra-renal purification
   j. Other

6- The last constants noted on the monitoring before the unexpected cardiac arrest
   a. Time of recording
   b. Level of awareness
   c. Blood pressure monitoring
   d. Blood pressure
   e. Heart rate
   f. Oxygen saturation
   g. Temperature

7- Date and time of occurrence of the unexpected cardiac arrest

8- The activity of the service on the day of the occurrence of the unexpected cardiac arrest according to the resuscitator

9- The bed occupancy rate at the time of the unexpected cardiac arrest

10- The Special Circumstances at the Occurrence of the unexpected cardiac arrest
   a. Patient in bed with no special circumstances
   b. Patient in prone position
   c. Chair Patient
   d. During an intra-hospital transfer
   e. During an extra renal cleansing session
   f. During a disconnection session (T-piece)
   g. During a non-invasive ventilation (NIV) session
   h. During an intubation
   i. During central venous line placement
   j. During a bronchial fibroscopy
   k. During a transfusion of labile blood products
   l. During a diaper change, nursing care
   m. Subsequent to the administration of a medicament
   n. During another risky procedure

11- Data specific to Cardiopulmonary Resuscitation
   a. CPR start time
   b. Initial heart rate (FV/TV, Pulseless electrical activity, asystole)
   c. External electric shock (time of first, number of shocks)
   d. External cardiac massage (start time, total duration of massage)
   e. Intubation (time of intubation)
   f. Injections :
      i. Adrénaline (heure de première injection, dose totale)
      ii. Other (Amiodarone, fibrinolysis, atropine, isoprenaline, others)
   g. Volumetric expansion (total volume)
   h. Transfusion (number of red blood cells)
   i. Other (depending on the circumstances of occurrence)

12- Monitoring during CPR
    a. Bloody pressure
    b. Capnometry
    c. Pulse oximetry
    d. Electrocardioscope
    e. Transthoracic ultrasound
    f. Other

13- The identified etiologies of the unexpected cardiac arrest
    a. Related to means of substitution
        i. Respiratory
            1. Respirator abnormality
            2. Pipe anomaly
            3. Accidental Extubation
            4. Intubation tube obstruction
            5. Other
        ii. Circulatory
            1. Failure to infuse catecholamines
            2. Accident during an extrarenal purification or extracorporeal circulation (if yes continuation of extrarenal purification?)
            3. Error in drug, ion or toxin administration
            4. Drug overdose
            5. Other
    b. Patient-related
        i. Hypothermia
        ii. Hypoxia
        iii. Hypovolemia
        iv. Hemorrhage
        v. Metabolic (dyskalemia, dyscalcemia...)
        vi. Acute coronary syndrome
        vii. Pulmonary embolism
        viii. Pneumothorax
        ix. Tamponnade
        x. Other

14- Complementary examinations carried out at the immediate disbursement of the unexpected cardiac arrest
    a. Standard Life Cycle Assessment
    b. Chest X-ray
    c. Transthoracic echocardiography
    d. eFast echo
    e. Coronary angiography
    f. Brain scan
    g. Other

15- Cessation of CPR
    a. Recovery of spontaneous cardiac activity (RACS) and time of RACS
    b. CPR failure and patient death (time of death)

16- For patients who have resumed spontaneous cardiac activity (RACS)
    a. Therapeutic measures carried out during the course of the unexpected cardiac arrest
        i. Thermal control (32 - 36°C)
        ii. AOHC Prevention
        iii. Emergency surgery
        iv. Thoracic drainage
        v. Pericardial drainage
        vi. Angioplasty
        vii. Transfusion
        viii. Vascular filling
        ix. Extra renal purification
        x. Reintubation
        xi. Bronchial fibroscopy
        xii. Electrosystolic drive
        xiii. Other

    b. Tests performed to assess post-unexpected cardiac arrest neurological prognosis
        i. Clinical Examination: Glasgow score, encephalopathy (convulsions, abnormal movements), trunk reflexes
        ii. Electroencephalogram (Burst suppression, epileptiform discharges, poor EEG activity)
        iii. Determination of the NSE (with the day of sampling and its value)
        iv. Somatosensory evoked potentials (presence of an N20 wave)
        v. Brain MRI (Normal or abnormal)
        vi. Other

    c. Patient outcome
        i. For patients who died in intensive care
            1. The date of death
            2. The method of death certification (brain, circulatory)
            3. Has it been the subject of a multi-organ harvesting procedure?
            4. Has it been the subject of Limitation or discontinuation of therapy after the onset of unexpected cardiac arrest?

        ii. For patients discharged alive from resuscitation
            1. The date of resuscitation release
            2. The Cerebral performance category scale (CPC) score at the exit of resuscitation.
            3. Date of discharge from hospital
            4. Did the patient leave the hospital alive or dead?

5. Is the patient alive or dead 6 months after the onset of CARI? If alive, what is the Cerebral performance category scale (CPC) score at 6 months?

17- Risk prevention policy: has the unexpected cardiac arrest resulted in
   a. A serious adverse event report?
   b. A morbidity and mortality review?
   c. A material vigilance report?
   d. A pharmacovigilance declaration?
   e. A haemovigilance declaration?
   f. A drug dosage?
   g. Allergic explorations?
   h. A change in service practices (if yes, which ones?)?

The computerized data will be recorded on the eCRF managed by the Medsharing company. They will then be used on Dr LELOUP's computer thanks to EPIINFO and R software. They will be consulted exclusively by Dr LELOUP and Mrs Alice LANGLOIS, Clinical Research Associate.

6. Statistical analysis

Statistical analyses will be carried out using EPIINFO and R software.

Quantitative variables will be expressed as means (+/ standard deviation) or medians and quartiles depending on the size and distribution of the workforce. These variables will be compared using Student's tests or Mann Witney Wilcoxon tests.

Qualitative variables will be expressed as absolute values and percentages. They will be compared by Chisquare tests or exact FISCHER tests.

Differences will be estimated to be significant when the p is less than 0.05.

If possible, multivariate analyses will be carried out using a stepwise logistic regression. The variables included will be those whose comparison obtained a p of less than 0.2 in univariate analysis.

Missing or lost data will not be included in the statistical analysis.

7. Ethics

This work received a favourable opinion from the Advisory Committee on Information Processing in Health Research on 9 July 2015 (Dossier n°15.487).

It received a favourable opinion from the Commission Nationale de l'Informatique et des Libertés on 25 February 2016.

It received a favourable opinion from the Comité de Protection des Personnes Ile de France II on 11 January 2016 (IRB registration: 00001072).

In view of the epidemiological nature of the collection, an information letter will be given to the patient's relatives, who are free to accept or refuse the patient's inclusion in the register (Annexe 1).

The patient, once again competent and able to receive the information, will be able to accept or refuse his or her own entry in the register (Annexe 2).

8. Bibliographie

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ANNEXE 1

Dear Madam, dear sir,

One of your family members hospitalized in Resuscitation at the hospital center of …….. has just suffered a cardiac arrest and was subjected to cardiopulmonary resuscitation.

Unexpected cardiac arrest is a rare but serious event that can occur in Resuscitation despite the monitoring and back-up techniques in place. As part of a research project involving many French hospitals, we are currently studying the incidence, circumstances and consequences of such an event. The final objective of this work is to propose practical measures to prevent the occurrence of unexpected cardiac arrest in intensive care or to reduce the consequences as much as possible.

In order to optimize the care of our patients, a certain amount of medical information is collected and recorded at the hospital on a computer server: history, previous hospitalizations, history of the disease, possible allergies, clinical examination, biological examinations, medical imaging, specialized opinions, report of additional examinations or interventions, discharge letter, etc. Thanks to a secure access system, this confidential information can only be consulted by the health professionals concerned. The computerization of the data collected is intended to facilitate the transmission of useful information and to ensure its traceability, including in the event of new hospitalization.

It is also possible to make this data anonymous, to group and analyse it collectively in order to assess the quality of our practices a posteriori. Indeed, it is by multiplying the number of observations that medical knowledge progresses. These so-called "epidemiological" or "non-interventional" studies also make it possible to determine the means necessary for the proper functioning of our services. French and European regulations stipulate that hospitalized patients may object to any present or future use of data concerning them, even if it does not allow them to be identified. If the patient is unable to express his or her choices, relatives are asked to testify to any opposition to this type of research.

Expressed directly or through relatives, individual preferences in terms of epidemiological research in no way influence the quality of care provided to the patient and the vigilance of caregivers in their hospital missions. Doctor…… (Telephone……..), more particularly in charge of the study on unexpected cardiac arrest, is at your disposal for any information concerning this research protocol.

ANNEXE 2

Dear Madam, dear sir,

You are (or have been) hospitalized in Resuscitation at the hospital center of ……..

To improve your care, a certain amount of personal information is collected and recorded on a computer server: history, previous hospitalizations, history of the disease, possible allergies, clinical examination, biological examinations, medical imaging, specialized opinions, reports of additional examinations or interventions, discharge letter, etc. Thanks to a secure access system, this confidential information can only be consulted by the health professionals directly involved in your care. The computerization of the data collected is intended to facilitate the transmission of useful information and to ensure its traceability, including in the event of new hospitalization.

It is also possible to anonymize this data, to aggregate and analyze it collectively in order to evaluate the quality of our practices a posteriori. It is indeed by multiplying the number of observations that medical knowledge progresses. These so-called "epidemiological" or "non-interventional" studies also make it possible to determine the means necessary for the proper functioning of our services.

Unexpected cardiac arrest is a rare but very serious event that can occur in Resuscitation despite the monitoring and replacement techniques in place. As part of a research project involving several hospitals, we are currently studying the incidence, circumstances of occurrence and consequences of such an event. The final objective of this work is to propose practical measures to prevent the occurrence of unexpected cardiac arrest in the ICU or to reduce its consequences as much as possible. You yourself have suffered a cardiac arrest during your stay in Resuscitation. Your relatives have not expressed any objection to the collection of information about you, until you yourself are able to give your opinion on this study.

French and European regulations stipulate that you may oppose any present or future use of data concerning you, even if they do not allow you to be identified. All you have to do is explicitly indicate this when you are hospitalized, or through a relative. You do not have to justify the reasons for this opposition, which may be expressed orally or in writing. Your decision obviously has no impact on the quality of the care you will receive. If you do not object to the use of your anonymous medical data, you are fully entitled to know the results of the study and the practical measures that will be taken as a result at a later date.

During your stay and on the way out, you may at any time specify, modify or cancel any directives concerning you. As guarantors of your freedom of choice, the carers around you have a duty to listen to your wishes and to testify to them if necessary. Do not hesitate to ask them for more information. In Resuscitation, Doctor …….. (Phone……..) is more particularly in charge of the study on unexpected cardiac arrest and is at your disposal for any further information.