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Protocol paper

Long-term follow-up of cardiac arrest survivors: Protocol of the DESAC (Devenir des survivants d'Arrets Cardiaques) study, a French multicentric prospective cohort



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Abstract

Background: While the short-term prognosis of cardiac arrest patients - nearly 250,000 new cases per year in Europe - has been extensively studied, less is known regarding the mid and long-term outcome of survivors.

Objective: The aim of the DESAC study is to describe mid- and long-term survival rate and functional status of cardiac arrest survivors, and to assess the influence of pre and intra hospital therapeutic strategies on these two outcomes.

Methods: Between Jul 2015 and Oct 2018, adult patients over 18 years who were discharged alive from any intensive care units (public and private hospitals) in the Ile-de-France area (Paris and suburbs, France) after a non-traumatic cardiac arrest were screened for participation in this multicentric study. Survivors were included after they signed (or the proxies) an informed consent before discharge during initial hospitalisation. We calculated that including 600 patients in total would allow an 80% power to demonstrate a 2 years survival rate difference of 10% between patients who did and those who did not receive therapeutic hypothermia after resuscitation. Pre- and in-hospital data related to the circumstances surrounding the event and to the therapeutic interventions (such as cardio-pulmonary resuscitation, defibrillation, emergent coronary revascularization, neuroprotective therapeutics) were collected. After discharge, patients were interviewed at 3 months, 6 months and every year thereafter for a minimum follow-up of 26 months and a maximum follow-up of 48 months. Information on vital status, occurrence of cardiovascular events, medications and a comprehensive assessment of the functional status (qualitative of life as assessed by the Short-Form General Health Survey (SF36) scale, activities of daily living (ADL) scale, neurological Cerebral Performance Categories (CPC) and Overall Performance Categories (OPC) scales, socio-professional activities) were collected at follow-up interviews.

Discussion: The DESAC study should provide important information regarding several dimensions of the mid and long-term prognosis of cardiac arrest survivors and on the benefit (and potentially harm) of early therapeutic strategies.

Keywords: Cardiac arrest, Long-term outcome, Coronary angiogram, Targeted temperature management

Introduction

Out-of-hospital cardiac arrest (OHCA) is one of leading causes of death worldwide.¹ Every year, between 47.8 and 57.9 people per 100 000 inhabitants, corresponding to more than 300 000 patients,

experience cardiac arrest in Europe.² The overall survival rate remains extremely poor since less than 10% of patients with attempted resuscitation are discharged alive after cardiac arrest. Among survivors, some experience long-term severe neurological sequelae. The acute postcardiac arrest syndrome is mainly responsible for the morbidity and mortality of cardiac arrest survivors.

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Exposure to hypoxia during cardiac arrest and ischemia–reperfusion phenomenon that occurs after restoration of spontaneous circulation (ROSC) may worsen brain damages, which is the main cause of disability in cardiac arrest survivors.³

While predictive factors for short-term mortality after OHCA have been extensively investigated, less is known regarding the mid and long-term functional, cardiovascular and neurological outcome of these patients. Some studies focused on endpoints over 6 months and showed high survival rates reaching 90%,^{4–6} with similar pattern regarding neurological outcomes.^{7,8} However, patients'centered outcomes such as health-related quality of life (HRQoL) instead of vital status,⁹ are now recommended, because these endpoints better correspond to the expectations of patients and their relatives.

While several studies reported long-term qualitative functions very similar to that of the general population in particular in patients discharged without apparent disability, severe impairments are also reported in some cardiac arrest survivors.^{10,11} Furthermore, functional and neurological recovery could continue to evolve months after the event, as a dynamic course.^{12–14} However, most of the studies that focussed on long-term outcome were limited in sample size, design, population selection or completion of follow-up.

We therefore scheduled a prospective multicentric population-based registry of OHCA survivors to assess mid- and long-term neurological and functional and HRQoL status. The collection of pre and intra hospital data surrounding the OHCA together with a regular follow-up after hospital discharge may provide important benchmark on the evolution of these patients and the impact of acute interventions (such as cardio-pulmonary resuscitation, defibrillation, emergent coronary revascularization, neuroprotective treatments). This multicentric study should improve the knowledge regarding what factors and how they may influence mid- and long-term prognosis of these patients. The pre and intra hospital information together with the follow-up collected are critical to assess public health strategies in cardiac arrest management and ultimately to allocate adequate resources.

Objectives

The objectives of the DESAC (Devenir des survivants d'arrêt cardiaque) study are two-folds. Firstly, we aim to describe the mid and long-term survival rate, the functional, neurological and cardiovascular status of OHCA survivors, particularly enumerating patients with heavy sequels. Secondly, we aim to identify pre- and in-hospital factors that may influence mid and long-term prognosis to pinpoint health care strategies that may improve outcome.

Methods

Overall study design

This is a multicentric, prospective, population-based dataset in which 600 patients who survived an OHCA and were discharged alive from hospital, are subsequently followed-up using regular phone interviews. Time of study entry corresponds to the day of ICU discharge. After enrollment, we perform a phone interview (visit) at the 3rd month, at the 6th month and every 6 months thereafter. Depending on the date of inclusion, the duration of follow-up is up to 48 months (for the first patients included) and at least 26 months (for the last patients included). (Figs. 1 and 2).

Outcomes

Primary endpoint

The primary endpoint combines survival rate and neurological status, assessed by the Pittsburgh Cerebral Performance Categories scale.¹⁶ The Pittsburgh CPC scale is one of the most employed tools for scoring neurological recovery after cardiac arrest. Briefly, this scale allows to classify patients according to 5 levels, from level 1 for normal or minimal disability (patient able to care for himself, discharged directly to home) to level 4 for severe disability (unconscious, discharged to a long-term nursing facility) or even 5 for death or brain-death (Table 1).

Secondary endpoints

Secondary endpoints include cardiovascular events, New York Health Association (NYHA) status, health-related quality of life (HR-QOL) using Short-Form General Health Related Survey-36 (SF-36),¹⁷ overall functional status using Overall Performance Categories (OPC) (Table 2) and autonomy level using the Activity Daily Life (ADL) (Table 3).¹ Information on socio-economic status, professional activity, and eventual rehospitalization are collected as well.

Participant eligibility

Patients' eligibility was assessed as summarized in Table 4.

Study procedure

When a patient was screened eligible, his/her written informed consent was sought. The principal investigator and sub-investigator observed and assessed each participant from the time of informed consent through the completion of observation. Enrolled survivors or their kin provided all information regarding their correspondence in order to implement a tracking system of follow-up after their discharge from ICU and further from hospital.

Follow-up interviews

The first interview took place at the third month after the event and then at the 6th month. Following interviews were performed each semester (Fig. 2). A researcher assistant, trained for phone interviews, called patients to submit the different questionnaires. The main investigators from the Sudden Death Expertise Center supervised both training and quality completion of the data using regular monitoring. In severely disabled patients, telephone interviews were carried out with their representatives. To minimize the risk of cohort attrition, up to 6 attempts to reach each patient were provided at different days and hours. For patients lost to sight and impossible to contact, their vital status was assessed at each interview by checking the death registry of the native commune. Participation of a participant discontinued in case of lost to follow up, voluntary withdrawal or study termination.

Data collection

At inclusion, the following data were assessed:

- the characteristics of the event: location of the arrest, presence of a witness, initial cardiac rhythm, use of a defibrillator, resuscitation interval times, initial treatments (defibrillations, epinephrine or anti-arrhythmic treatments...), pattern of the ECG obtained ROSC, and presumed cause of arrest.

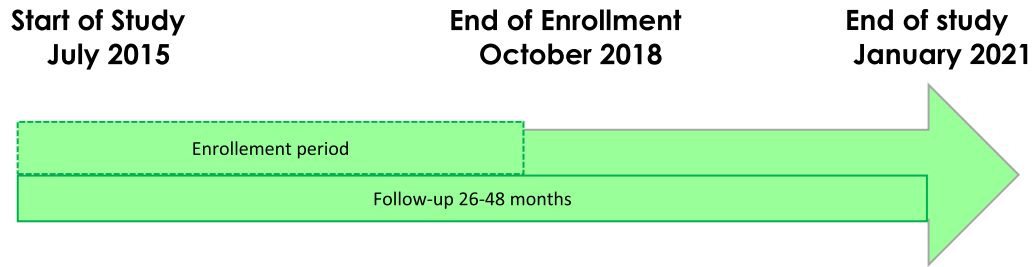


Fig. 1 – Study design.

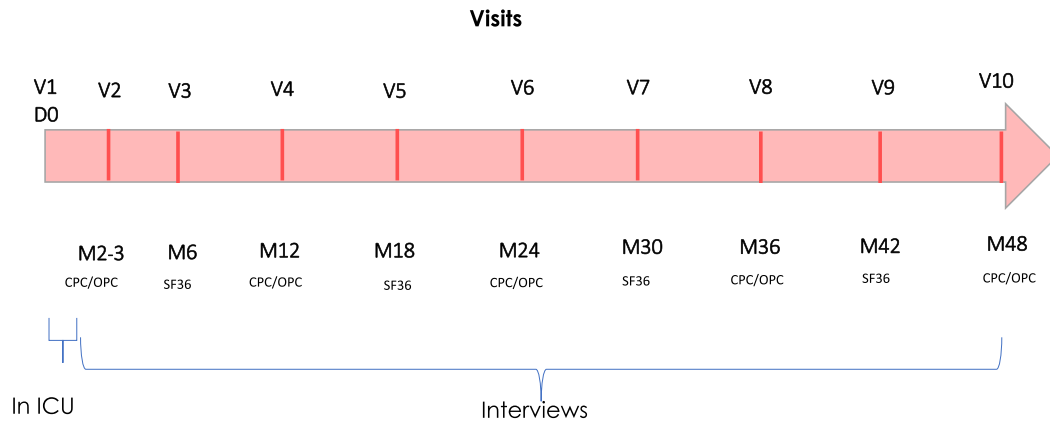


Fig. 2 – Follow-up interviews.

Table 1 – Cerebral category performance scale.

CPC 1	Good cerebral performance (normal life).	Conscious, alert, able to work and lead a normal life. May have minor psychological or neurologic deficits (mild dysphasia, nonincapacitating hemiparesis, or minor cranial nerve abnormalities).
CPC 2	Moderate cerebral disability (disabled but independent).	Conscious. Sufficient cerebral function for part-time work in sheltered environment or independent activities of daily life (dress, travel by public transportation, food preparation). May have hemiplegia, seizures, ataxia, dysarthria, dysphasia, or permanent memory or mental changes.
CPC 3	Severe cerebral disability (conscious but disabled and dependent).	Conscious; dependent on others for daily support (in an institution or at home with exceptional family effort). Has at least limited cognition. This category includes a wide range of cerebral abnormalities, from patients who are ambulatory but have severe memory disturbances or dementia precluding independent existence to those who are paralyzed and can communicate only with their eyes, as in the locked-in syndrome.
CPC 4	Coma or vegetative state (unconscious).	Unconscious, unaware of surroundings, no cognition. No verbal or psychological interaction with environment.
CPC 5	Brain death	Certified brain dead or dead by traditional criteria.

- the hospital clinical and biological data at admission: repeated measures of temperature, blood tests results at admission (lactate, potassium, creatinine, troponin), coronary angiogram findings (presence of acute or chronic coronary occlusion, location of lesions and performance of percutaneous intervention), temperature management (intentional cooling, interval times, length of treatment).
- the outcome during initial hospitalization: occurrence and cause of death, complications (infection, post-resuscitation shock, neurological complications), other treatments (such as coronary artery bypass graft or insertion of automatic internal cardiac defibrillator).
- at hospital discharge: destination (home, specialized center, or nursing home), CPC level.

During each follow-up interview, the following data have been collected:

- if applicable, date and cause of death (interview with the next of kin);
- neurological status using the CPC scale, functional status as measured by OPC and autonomy using the ADL scale;
- during interviews performed at the 6th month and then every 12 months, HR-QOL assessed by the SF-36 questionnaire that evaluates different aspects (functional, emotional and physical) of QOL;
- List of current medications;

Table 2 – Overall performance category.

OPC 1	Good overall performance. In good health. Alert, able to lead a normal life. Good brain performance (CPC 1) and no deficits or minor functional deficits of any organ other than the brain.
OPC 2	Moderate overall deficit. Aware. Moderate cerebral deficit (CPC 2) and/or minor functional deficit of an organ other than the brain. Independent for activities of daily living (dressing, travelling, preparing food). Can work part-time in a sheltered environment but cannot work competitively.
OPC 3	Severe overall deficit. Aware. Severe cerebral deficit (CPC 3) and/or severe functional deficit of an organ other than the brain. Dependent on others for daily life activities.
OPC 4	Coma. vegetative state. Unconscious. Without perception of the environment. No cognitive activity. No verbal or psychological interaction with the entourage.
OPC 5	Deceased or brain dead.

Table 3 – Katz scale.

Activities points (0 or 1)	Independence (1 point) No supervision, direction or personal assistance)	Dependence (0 point) With supervision, direction, personal assistance or total of care)
Bathing	Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity	Needs help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing
Dressing	Gets clothes from closets and drawers and puts on clothes and outer garments complete fasteners. May have help tying shoes	Needs help with dressing self or needs to be completely dressed
Toileting	Goes to toilet, gets on and off, arranges clothes, cleans genital area without help	Needs help transferring to the toilet, cleaning self or uses bedpan or commode
Transferring	Moves in and out of bed or chair unassisted. Mechanical transferring aides are acceptable	Needs help in moving from bed to chair or requires a complete transfer
Continence	Exercises complete self control over urination and defecation	Is partially or totally incontinent of bowel or bladder
Feeding	Gets food from plate into mouth without help. Preparation of food may be done by another person	Needs partial or total help with feeding or requires parenteral feeding
Total	from 6 (high) to 0 (low)	

Table 4 – Inclusion and exclusion criteria.**Inclusion Criteria:**

- Patients alive after resuscitation from a cardiac arrest
- All causes for cardiac arrest
- Age above 18
- Informed consent from the patient or next of kin
- Social security affiliation

Exclusion Criteria:

- Impossibility for communication after hospital discharge (language, residence. . .)
- Follow-up refusal from the patient or next of kin
- Usual place of residence outside Ile de France

- Cardiovascular events that occurred between interviews: acute coronary syndromes, arrhythmias, stroke or other cerebrovascular events.

alpha risk and a two-sided test, we calculated that 292 subjects per group (with and without induced hypothermia, $n = 594$) would be needed to observe a 10% difference in favor of hypothermia at 2 years. With $n = 600$ patients, the study was sized to answer the research question.

Sample size calculation and study duration**Sample size**

According to previous publications,¹⁵ 85% of OHCA survivors who were treated with induced therapeutic hypothermia were reported to be alive with a good neurological recovery (CPC 1 or 2) at 2 years versus 75% in those who did not receive such a treatment. Based on these previous data, and assuming a statistical power of 80%, a 5%

Study duration

Based on usual recruitment of OHCA patients in participating centers and considering a survival rate at hospital discharge comprised between 20 and 30%, we initially anticipated that these 600 survivors would be enrolled in 24 months. Due to a slower-than-expected rate of inclusion, this inclusion period was eventually extended by additional 15 months to allow full completion of recruitment.

Statistical and analytic plans

Descriptive analysis

The distribution of pre- and in-hospital clinical and biological characteristics, as well as the distribution of socio-demographic characteristics, will be described according to the categories of the CPC scale at 3 months, and then every 12 months. Qualitative variables will be described by their frequency; quantitative variables, depending on their distribution, by their mean and standard deviation, or by the median and interquartile range. The chi-square test (Fisher exact if necessary) and tests of comparison of means or comparison of ranks will be used to compare the distribution of qualitative and quantitative variables respectively.

Prognostic analysis of the CPC score at 24 months

An analysis of the prognostic factors of the CPC scale at 24 months will be performed. In the main analysis, two groups of patients will be a priori considered: grouping of CPC 1–2 patients (favorable evolution) vs grouping of CPC 3–4–5 patients (unfavorable evolution).

Pre- and intra-hospital sociodemographic, clinical and biological characteristics likely associated with CPC will be studied with univariate logistic regression. At this stage, a p value $\leq 15\%$ will be used as a threshold for being selected in the multivariable analysis. We will consider the selected variables in a multivariate model to identify independent prognostic factors, using a backward procedure and a significance level of 5%. In the final model, interaction terms with gender, age or any other variable of interest will be tested using the Wald test ($p < 0.10$).

In a second step, analysis will consider the CPC scale in three categories, CPC1, 2 and 3+ using multinomial logistic regression. The objective of this second analysis will be to test the existence of heterogeneity of prognostic factors according to the level of the CPC scale, in particular between CPC 1 and 2 scale.

Repeated measures of the CPC score

The repeated evaluations over a minimum of 26 months of follow-up will allow to quantify and describe the evolution of the CPC score and to study the prognostic factors of this evolution. To take into account the correlation between the measures, we will alternatively use linear mixed models (when the CPC score will be considered as discrete variable) and logistic regressions with repeated measures (GEE: generalized estimating equation) (when the CPC score will be binary (CPC 1 + 2 vs. 3 +)).

Longitudinal analyses of quality-of-life (SF 36), activity daily life scale (ADL), recurrence of cardiovascular events and death at 24 months will be also performed.

Sensitivity analysis

The pattern of missing covariates will be described and two methods of imputations will be considered. First, simple imputation by the mean (continuous variable) or by the addition of one category of missing variable (categorical variable) will be used. Second, multiple imputations will be considered (10 datasets).

Informed consent and patient registration

The local investigator (or sub-investigator) provided all explanation regarding the study to each eligible participant. For every included patient, the investigator provided an information form and any participation, including the follow-up, required a signed consent applica-

tion. When the condition of the surviving patient did not allow him to understand and consent himself at time of inclusion, his/her relative could give consent. When consent had initially been obtained from a relative, that of the patient was then systematically sought during follow-up, depending on his neurological improvement.

Ethics

The study protocol was approved by the Comité de Protection des Personnes Paris Ile de France IV according to the article L.1123-6 from French Public Health code. The collection of individual data was simultaneously declared to the Commission Nationale de l'Informatique et Libertés (CNIL) according to the articles L1121-1 et al. from French Public Health code (#914505).

Discussion and dissemination

The DESAC study consists of the creation of a complete cohort of survivors of cardiac arrest, with regular follow-up of at least 26 months combining neurological status, functional status and quality of life. This study should make it possible to overcome the difficulties encountered in understanding the future of survivors of cardiac arrest. To date, information concerning the fate of survivors of cardiac arrest remains rather crude, and it is often limited to short-term survival. In addition, little is known about subsequent quality of life, although this parameter is now considered the best assessment for public health and intervention strategies in this specific area.^{9,19} Until now, previous studies that focused on this topic remained too few.^{20–22} Most of them looked at selected populations (most often coronary cardiac arrest) and were limited by the number of repeated assessments and the proportion of patients lost to follow-up.

It is therefore appropriate to extend the results of previous studies by examining a large sample size, using a longer follow-up (at least over 26 months). Moreover, the originality of the design is based on the repeated measurements (up to 6 repeated evaluations of CPC/OPC scores and up to 4 repeated evaluations of SF 36 scale) and on the variety of the domains explored during follow-up, which will make it possible to evaluate with precision the trajectories of several dimensions of the prognosis of these survivors including neurological, functional and quality of life dimensions.

The data collected during hospitalization will also permit to describe the patient characteristics and their initial clinical management. In addition, this registry will provide important characteristics to assess the influence of resuscitation interventions on long-term outcomes, such as early defibrillation or post-cardiac arrest interventions. The analyzes of these data should also make it possible to identify the needs for improving care and to determine the best course of survival in cardiac arrest survivors, including the rehabilitation strategy. Finally, the study findings should be useful for clinicians' awareness, clinical competencies and practice. They should also be crucial for the patients and the families awareness on prognosis, permitting to anticipate and organize the daily life in the future.

Trial status

This trial is registered at clinical trials as NCT02494414. The enrollment started on July 24, 2015, and the last patient was included on

October 2018. The last follow-up interview took place in January 2021 (Figs. 1 & 2). Regulatory issues and data management were finalized by 2022. Several analyses will be launched by the end of 2023 and will include the description of the prognosis over time in its various dimensions (neurological, functional and quality of life status), the identification of prognostic factors for CPC, functional and quality of life status. Publication of the findings are planned during 2024.

List of investigators

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CRedit authorship contribution statement

F. Dumas: Conceptualization, Formal analyses, Methodology, Project administration, Supervision, Validation, Visualization, Writing – original draft. **W. Bouguin:** Conceptualization, Investigation, Methodology, Validation, Visualization. **M.C. Perier:** Formal analyses, Software, Writing – review & editing. **N. Marin:** Investigation, Writing – review & editing. **C. Goulenok:** Investigation, Writing – review & editing. **A. Vieillard-Baron:** Investigation, Writing – review & editing. **J.L. Diehl:** Investigation, Writing – review & editing. **S. Legriël:** Investigation, Writing – review & editing. **N. Deye:** Investigation, Writing – review & editing. **P. Cronier:** Investigation, Writing – review & editing. **S. Ricôme:** Investigation, Writing – review & editing. **F. Chemouni:** Investigation, Writing – review & editing. **A. Mekontso Dessap:** Investigation, Writing – review & editing. **F. Beganton:** Resources, Writing – review & editing. **E. Marijon:** Resources. **X. Jouven:** Resources. **J.P. Empana:** Conceptualization, Funding acquisition, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing – original draft. **A. Cariou:** Conceptualization, Data curation, Funding acquisition, Investigation, Methodology, Supervision, Validation, Visualization, Writing – original draft.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: [Antoine Vieillard-Baron declares being member of a research advisory board for Air Liquide Company. Alain Cariou received fees from Bard for lectures and conferences].

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