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Study protocol

Title of the study: The International Avalanche Registry

Study type: perspective, observational study

Non-disclosure policy

The content of this document is highly confidential. The publication of this document is strongly prohibited without a written permission of the project coordinators. The code of behaviour described inside has to be respected by all study participants.

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3. Introduction

3.1 Background

The emergency medical treatment of people involved in avalanche accidents is still a controversial topic, because of the lack of comprehensive perspective and observational studies in this regard. This is due to the fact that avalanche accident scenarios are not only a challenge for the emergency medical practioner(s) on scene, but also because highly technical factors associated with rescue under these conditions usually come into play. The safety of the rescuer has the main priority - nevertheless, the medical care of avalanche victims in a pre-hospital, harsh environmental setting is a particularly high risk mission. Therefore, for the safety of the rescue teams, it is necessary to set clear criteria according to which a rescue mission can be abandoned or cancelled. Asphyxial avalanche victims must be distinguished from hypothermic ones and treated accordingly. As a consequence, also the rescue chain has to be organised differently, plus the choice of the hospital where the victims should be transported carefully considered. The hospitalisation of severely hypothermic patients in hospitals where the extracorporeal blood circulation (ECMO) can be provided is crucial in these circumstances. Asphyxial and traumatised avalanche victims should be treated with an advanced trauma life support (ATLS) on the spot, and then transported as soon as possible to the nearest hospital. Avalanche accidents are usually major events where many victims and rescuers are involved. Evidently, this is the reason why triage criteria and optimised rescue strategies are determinant for a positive outcome of the patients involved in avalanche accidents.

International mountain medicine societies, such as the International Commission for Alpine Rescue (ICAR MEDCOM), the International Liaison Committee of Resuscitation (ILCOR) and the European Resuscitation Council (ERC), have previously suggested many approaches for the emergency medical treatment of avalanche victims. These suggestions are mainly in the format of consensus papers. These papers are based on expert discussion of specific case reports or case series with low sample sizes, and therefore unfortunately in the main are of alow level of evidence base.

3.2 Purpose of the registry

This registry aims to keep record of pre-hospital and in-hospital data of avalanche accidents and of their victims. These data will be collected according to standardised criteria and they will be stastically analysed. The registry should collect data from as many countries as possible where avalanche accidents occur, plus ensure thatdata collection is enabled for a significantly long

duration. In this way, an international database for the scientific analysis of avalanche accidents, treatment protocols employed, rescue technicalities and patient mortalitywill be created. The main aim being to improve the treatment and the outcome of avalanche victims both now and in future.

Another long-term aim is to provide to the international societies ICAR MEDCOM, ILCOR and ERC, a tool to better evaluate the evidence level for particular treatment protocol, and to the national health services a basis to better organise and optimise their rescue services. The incidence, mortality and morbidity of avalanche accidents and their medical and logistical challenges can be documented, statistically analysed and compared to the results of the existing benchmarks. The ultimate scope of this project is to lower the mortality and morbidity rate of avalanche victims and to improve their outcome.

4. Methods / Study protocol

In order to ensure a significante sample size, all avalanche victims of a specific geographic area and of a delimited timespan should be included. To ensure the completeness of all in- and out-of-hospital data, the data collection should be made by the rescue teams and the regional hospitals working together in a collaborative effort.

4.1 Study type

Perspective, observational study.

4.2 Place and coordination of the study

A multi-center study, with data coming from many countries of Europe and North America, where avalanche accidents happen. All coordination will be made by the EURAC Institute of Mountain Emergency Medicine in Bolzano.

4.2.1 Regional group registries

The data from each region involved in the study is collected initially by small group registries. A group registry usually includes 2-3 people, inclusive of: members of mountain or helicopter rescue teams, and emergency doctors who work directly with the team reponsible to repond to an avalanche accident scenario. The group registry of a region is responsible for the correct data collection and data entry into the online repository.

4.3 Inclusion criteria

All victims of avalanche accidents are recorded in the registry.

4.4 Exclusion criteria

None.

4.5 Data collection and analysis

From the joint reports of both the rescue teams and hospital departments involved in each avalanche case the following data for each patient will be extracted and recorded in the registry: 24 data concerning technical and mountain rescue details, 13 data concerning the avalanche, 29 data concerning medical information. All data will be collected in an anonymized form (see also the attached Case Report Form – CRF).

The data will be inserted in an online platform, developed by the Information & Communication Technologies (ICT) of EURAC. The data are saved on the server of EURAC, located in 1 Drusos street,Bolzano/Bozen (Italy). The access to this platform is only possible for registered users through a personal username and password entry procedure, via a Secure Socket Layer (SSL). Each group registry only has access to the data of their country of activity. Authorised EURAC employees may view the entire database.

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It is also planned to record a follow-up of all the patients, up to one year after the accident. Data related to the wellbeing of the patient, his/her ability to work again, plus presence of any post-traumatic symptoms or disabilities will be recorded. For this purpose, the persons will be contacted via email or phone directly.

5. Privacy policy

The treatment of personal data corresponds to the Italian legislation, stating in accordance with the legislative decree n. 196/03 with regard to data privacy. The legal responsible for the storage and treatment of personal data is EURAC Research, located in Bolzano/Bozen: represented by the Director and Legal representative Dr. Stephan Ortner.

All data will be collected in an anonymised form. The analysis and transfer of the data of the registry will be done for medical and scientific purposes exclusively.

The names of the patients stored in the archives will only be used for their clinical follow-up. The patients will be asked to sign a written consent to allow authorised registry adminstartion to contact them to enable their clinical follow-up. For this purpose, the patients will be informed verbally and in a written form about the scope of the registry and they will keep one copy of their signed written consent.

The documents related to the record of the avalanche accidents will be stored – after the collection of the anonymised data – in the archives of the rescue organisations and of the hospitals. In the case that results of the study are published in scientific journals or presented at congresses, all information related to the identity of the patients will be made unidentifiable.

6. Ethical principles

Only previously stored data for patients will be recorded in the registry, to avoid unnecessarily contacting the patients with further questions at a later stage. At any time, the patient can revoke his/her consent to participate in the study without stating any reason(s). He/she will have no negative consequences due to termination of consent.

Each regional group registry outside South Tyrol must collect the approval of their local ethics committee to participate in this study.

7. Originality

There is no comparable study at this time having the same emergency medicine approach.

8. Financing

The financing for the collection, record and analysis of the data for this study is in South Tyrol is provided by the province of Bolzano, whereas expenses incurred by other centres in the record and analysis of the same data from other pertinent geographical locations, will be financed by the Institute of Mountain Emergency Medicine directly or via the acquisition of specific grants. The collection of data in the other centres will be financed by themselves.

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9. Time plan

Previously, after the initial approval by the Ethics Committee of Bolzano in 2016, a pilot phase of this project began in the province of South Tyrol, in close collaboration with the local hospital and the emergency services.

After the completion of this pilot phase, followed a first analysis and critical evaluation of the quality of the collected data. In the winter season 2016/2017 the registry was implemented and opened to other potential participants of other countries. These would have to comply to the ethical and privacy rules listed above.

10. Publications

All publications that include data taken during this study must report the name of the local members of the regional group registries. If these members made a substantial contribution, they have rights to potential authorship, based on the guidelines for the elaboration of scientific material of the International Committee of Medical Journal Editors (ICMJE).

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11. Literature

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