

Insufficient quality of research on prehospital medical emergency care – where are the major problems and solutions?¹

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Summary

It is still unclear today whether a few minutes more or less spent in prehospital medical emergency care have a positive effect on a range of outcome variables. Modern emergency medical services (EMS) systems are expensive and have been introduced all over the industrialized world. Yet their effectiveness and efficiency are supported by scant scientific evidence. This is why research into EMS systems is urgently needed.

There are significant differences between the approach to EMS research and traditional clinical research. New methodological approaches, such as system-orientated research and risk-adjustment measurements, must be further developed.

The implementation of randomized controlled trials (RCTs) in the prehospital setting is often very difficult and not always possible or suitable. Valid alternatives to RCTs exist and should be further developed. Epidemiologists would be of assistance here.

Agreement on clear definitions, standard data elements and validated severity scoring for trauma

and non-trauma conditions, as well as their validation and routine use throughout the world are urgently needed.

Clarifying many questions with regard to EMS systems cannot be left to chance. An internationally recognized research agenda with prioritisation and adaptation to regional requirements would be of great assistance here.

Finally, reliable research in Switzerland into EMS enabling relevant decisions will hardly be possible without financial support from the Swiss National Fund and other institutions. Furthermore, it would be inappropriate to decrease the current standard of prehospital care we offer in the short term in order to save money as long as we have no reliable results that indicate that we should. This would also render impossible the very research into this sector that is urgently needed.

Key words: emergency care; randomized controlled trials; cohort studies; research

Introduction

The origins of modern emergency medical services (abbreviated to EMS in the following) go back to the creation of mobile coronary care units to improve the survival of myocardial infarction patients in the out of hospital setting in 1966 in Belfast, Northern Ireland [1]. Within a very short space of time, the concept of bringing the hospital to the patient had been extended to include out of hospital cardiac arrest victims (OHCAVs) and trauma patients. The first real EMS as we know them today were introduced at the beginning of the 1970s in the USA [2]. The objective of these was to reduce the mortality of OHCAVs and trauma patients [2, 3]. Numerous studies into EMS systems subsequently demonstrated a more or less across the board statistically significant reduction in the mortality of OHCAVs [4] and patients with severe trauma who were directly transferred to the

nearest trauma centre in North America [5]. Only few of these findings, however, were derived from the generally required prospectively randomised, controlled trials (RCTs).

Despite the introduction of modern EMS, the survival rates of OHCAVs in many communities in the USA have hardly risen and, in general, the survival rates have remained low [2]. Although there was largely no scientific basis [6, 7], within a few years, the indications for the use of EMS were extended to non-life threatening and less acute situations [3]. EMS with different levels of care have now been introduced in all industrialized countries and are well established.

In view of the high costs of running and maintaining such systems, especially medical systems or systems which provide advanced life support (ALS), their effectiveness and efficiency are now,

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however, increasingly being questioned, i.e. “whether preclinical ALS really works and, if it works, whether it is worthwhile?” Such questions are not only threatening the further development of EMS, but in some cases also their very existence. It is high time that the methods and role of the management of patients in the prehospital situation were scientifically examined in order to create a basis for any corrective action needed.

Successful research into EMS, however, will

only be possible if we learn from problems in the past. First of all, we should look at the reasons why so few studies have been conducted and why the quality of most of these studies leaves much to be desired. In this paper I will focus on the question of poor quality, i.e. on the principal methodological problems and the fundamental differences to traditional clinical research [8] and present a range of possible solutions.

Current methodological approaches and their main problems

The fundamental question in medical research is: “Why do we believe what we do and not something else [9]?” Although the quality of good medical research depends largely on the selection of a suitable method of investigation, our fundamental question has to be viewed in a wider context and with special attention to the idea of truth. The link between “what we believe” and the truth we are looking for is elastic, because the evidence to support what we believe is largely coloured by subjective factors. This means that even the best methodology cannot alter the fact that the results of research, i.e. the measurements and numbers, must be interpreted and translated into practical conclusions by the researcher. Interpretations and conclusions are, however, markedly prone to subjective influence. Poets and philosophers have often drawn attention to the interference of subjectivity that affects not only scientific conclusions. André Gide, for example, wrote, “Believe those who are seeking the truth. Doubt those who find it”. Somewhat more profane, but pointing in the same direction, are the words of the *enfant terrible* of American philosophy, Richard Rorty, who said, “Knowledge (truth) is the justification for believing something on the strength of the present standards”. In the knowledge that we are unable to explain and demonstrate everything using calculations and our mind and that many things remain a matter of interpretation and belief, I would now like to present an overview of the methods used for EMS research and the most frequently associated problems.

Critique of the component-orientated approach

Traditional medical research is component orientated, that is to say, it is disease specific and dominated by the respective specialties [8]. Using this type of model, usually only one specific disease process, e.g. myocardial infarction, with the focus on one single interventional process, e.g. fibrinolysis, is investigated in a controlled environment. In out of hospital research, a prehospital intervention, e.g. intubation in the case of head trauma, is very often the initial intervention in a continuous treatment process. Additionally, it is difficult to standardize not only the prehospital but also the

emergency room situation and it is almost impossible to differentiate between the value of this role in the final outcome, e.g. discharge alive from hospital, of the contributions made by the individual protagonists. Each team of specialists involved – the prehospital emergency care team, the team in the emergency room, the surgical team in the operating room and the various teams in the intensive care unit, ward and rehabilitation centre – all make their own special contribution to the restoration of the patient’s health. In this context, the positive effects of outstanding prehospital care can be rendered useless if necessary surgical interventions are carried out too late or are inadequate.

Therefore it is not surprising that the complex questions thrown up by EMS can often not be adequately answered using traditional research models [8]. Even worse, the wrong questions are often asked. There are, for example, many instances in the literature of opinions and dogmas on the value of the on scene prehospital management of trauma patients. The aims of investigations with a component-oriented approach have often been no more ambitious than to determine the “on scene time”. However, in most cases the “on scene time” accounts for only a small part of the total prehospital period and a reduction of the reaction time, transport time or rescue period would probably have had a much greater influence on time management and therefore on outcome.

Difficulties in planning and performing randomized, controlled trials (RCTs)

RCTs at present occupy first place in the study method hierarchy. This contrasts starkly to the reality in the prehospital setting, where it is estimated that at present less than 1% of all EMS studies have been conducted using this approach [7]. The majority are observational studies, case series or cohort studies. There are many reasons for this discrepancy. These include a lack of emergency personnel trained in research methods, high costs and logistical problems. Furthermore, not all questions can be answered with the RCT-approach, for example, investigations into the influence of rescue times on outcome. Finally, RCTs also have clear disadvantages [10]. They are complex, time and labour intensive to conduct and are not robust

enough to investigate multiple outcomes simultaneously. Rigorous exclusion criteria often lead to limitations on the subsequent generalizability of the results to our patients and they therefore lose their relevance to daily practice. Additionally, the possibilities of informing the patients about the study are very limited and it is not always possible to obtain informed consent. Further considerations also come into play, in that we may be refusing to treat our patients with a therapeutic approach for which there is some positive evidence not derived from RCTs. On top of this, new ethical guidelines question the use of RCTs in prehospital research in general [11]. In summary, it can be said that the RCT is not always the most suitable type of investigation, that it is not able to answer certain types of question, that the new ethical requirements are hardly feasible in practice and that this approach is therefore often not suitable or possible for research into EMS.

Use of different data elements, definitions and classifications

Many questions in EMS research cannot be answered by one single study or one single database. A reliable answer can be obtained only by viewing the findings of several studies or analyzing the data in several databases together. To achieve this, however, reliable data elements (e.g. describing the trauma), consistent definitions (e.g. mortality is 30-day mortality) and classifications (e.g. severity of injuries and diseases) must be available [12, 13]. Internationally accepted and validated values for these are largely missing at present.

Confounding factors in cohort studies

The relationship between an intervention and its outcome can be biased by confounding factors. Confounding factors could be patient characteristics, treatment, system factors and random events. RCTs help to minimize confounding factors. In realistic terms, we are currently restricted to less rigorous study methods than the RCT design for the above reasons. The principle method at present is the prospective observational or interventional cohort study. Yet such studies are susceptible to confounding factors. What is not available here is a list of the most significant factors that again and again have a confounding influence and statistical methods that enable at least a certain post hoc control.

Absence of a national research program and prioritization

With a few exceptions, academic research into EMS in Switzerland is not only largely non-existent but we also have no objectives formulated on a higher level. Both elements are, however, necessary to enable us to solve the problems in hand in a sensible time frame. In the present situation too many questions are still open in EMS research for us to be able to leave the answers to them to chance. Health legislators and health economists will not tolerate this unresearched and unproved area for much longer and will require us to supply conclusive evidence that out of hospital care is worth the money it costs. It is therefore of the utmost importance to investigate the problems with adequate methods and to agree as quickly as possible on a properly prioritized research programme in the medium term.

Possible solutions and alternatives

The critical appraisal of the scientific methods of investigation used so far has shown clearly that these can hardly supply answers to the urgent questions that the field of medicine, society and the economy have about our EMS systems. We must seek new solutions and find new ways. Fortunately, we do have some alternatives that are relatively easy to put into practice. The following briefly describes these.

Away from the component orientated approach towards system orientated research [8]

So far, groups researching into EMS have mostly worked with the component model, and as was shown above, the objectives and investigative methods have therefore often been inadequate. A system-orientated approach would therefore seem to be more appropriate to address the complex questions involved in EMS. Phase specific variables should be documented and evaluated in order to demonstrate the benefit of EMS. In doing so, we must not limit ourselves to one single compo-

nent such as the "on scene time", but should take into account the entire period involved, i.e. all treatment phases. Phase specific variables mean also that possible confounding factors, e.g. primary or secondary transfer to the trauma centre, the treatment outcome, e.g. the improvement in O₂ saturation following intubation, and the patient outcome, e.g. survival, should ideally be documented in every phase of emergency treatment. With regard to the patient outcome, the effects on the short-term, intermediate and long-term outcome have to be taken into account. In doing so, we must divorce ourselves from mortality as the only target variable [3] and investigate other important variables such as morbidity, physical disturbances, pain, suffering, satisfaction and cost analysis aspects [14]. For the future, the data and findings of the previous rescue phase could be conceived of as the basis for the subsequent phase. Putting this idea sensibly into practice would, however, require the efforts of a committee of experienced experts.

The concept of dividing a course of treatment

up into different rescue phases is covered by the term “episode of care” [15] and, in terms of a system, is more suitable for investigating out of hospital questions than so-called component orientated investigation.

Alternatives to randomized controlled trials (RCTs)

In the light of the different and serious problems that often impair the planning and execution of RCTs in the prehospital setting and hamper appropriate research efforts, we urgently need alternatives that supply reliable results. One obvious option is prospective observational and interventional cohort studies. They are cheaper, simpler to conduct and the results are more easily generalizable to everyday practice. The basis for meaningful cohort studies would be the creation of supraregional, consistent and well organized databases and the use of available epidemiological databases.

The first step would be to agree on a uniform minimum set of data elements. This dataset should cover the most important variables and be able to be integrated into routinely used medical rescue protocols. Furthermore, suitable methods of evaluation need to be developed. With this, real life datasets of the trauma register type would be available for the evaluation of interventions, such as early intubation in cases of head trauma. This would enable us to avoid the usual effect of non-randomized controlled intervention studies on outcome, namely the high rate of false-positive results [7]. The probability of achieving a positive outcome is very much higher with non-randomized intervention studies than with a randomized approach. Many different questions would be able to be investigated routinely. A further advantage is that a core dataset of this type could be supplemented by any number of selected variables and new interventions. This would enable the study of a wide range of special questions.

We should also make greater use of existing databases. Ecological studies developed by epidemiologists for public health purposes would be suitable [16]. Ecological studies are studies that investigate groups and not individuals and often use geographical variables as inclusion criteria. These can be conducted relatively quickly and cheaply. For example, the aim of a study is to demonstrate that ALS reduces the mortality following road traf-

fic accidents (RTAs) in a particular region. In this hypothetical case, the proportion of the population receiving ALS is compared with the overall mortality from RTAs [16]. The relationship is found to be inverse. The mortality from RTAs is plotted over time and shows an abrupt and persistent reduction following the introduction of ALS. This would be an indication that ALS reduces mortality from RTAs.

We urgently require the assistance of epidemiologists in the creation of alternatives to RCTs. Only they can help us with the selection of the right questions and the planning and conducting of suitable studies.

Consensus on uniform data elements, definitions and classifications

In order to ensure that the results of studies and databases are comparable, we need clear definitions and defined uniform datasets, as are applied in the area of resuscitation (Utstein Style). In my opinion, for example, the recommendations of the International Trauma Anaesthesia and Critical Care Society (ITACCS) for the research of trauma should be implemented in a simplified and revised format as a standard [13]. Other standard datasets should follow for intoxications, acute coronary syndromes etc. Such datasets must differentiate between three types of variable: outcome, exposure and case-mix variables. Furthermore, the agreement on single severity definitions for trauma and non-trauma conditions is of great importance. At present, more than a dozen different scales are used in the literature on trauma. This situation makes it impossible to compare different studies or perform adequate meta-analyses. Table 1 summarizes the few prehospital datasets in international use at present and table 2 shows the traumatology severity scales and outcome variables relevant to the prehospital setting. Despite their popularity, the different severity and outcome classifications are controversial.

Internationally recognized risk adjustment measurements (RAMs)

The evaluation and analysis of prospective observational and interventional cohort studies in EMS research must also incorporate the development of suitable instruments to control confounding factors. Risk adjustment, i.e. the documentation of factors that may confound results and their

Table 1
Datasets in international use.

Dataset	used for	reference
Utstein style	out-of-hospital cardiac arrest	Cummins RO et al. Recommended guidelines for uniform reporting of data from out-of-hospital cardiac arrest: the Utstein Style. <i>Circulation</i> 1991; 84:960-75.
Trauma registry	major trauma	American College of Surgeons “National Tracs®” www.facs.org/trauma/national-tracs/tracmenu.html
Utstein style* (ITACCS: International Trauma Anaesthesia and Critical Care Society)	major trauma	Dick WF, et al. Recommendations for uniform reporting of data following major trauma – the Utstein Style. <i>Europ J Emerg Med</i> 1999;6:369-87.

* not yet officially introduced

Table 2

Classifications in international use.

Classification	target	used for
GCS (Glasgow Coma Scale)	T, N-T*	level of consciousness in all kind of diseases and S of cranio-cerebral trauma
ISS (Injury Severity Score)	T	S of injuries (anatomical criteria)
TRISS (Trauma and Injury Severity Score)	T	S and P of injuries (physiological and anatomical criteria)
ASCOT (A Severity Characterization of Trauma)	T	S and P of injuries (physiological and anatomical criteria)
GOS (Glasgow Outcome Scale)	T, N-T	O following resuscitation, cranio-cerebral trauma and diseases
GOS-E (Glasgow Outcome Scale Extended)	T, N-T	O following resuscitation, cranio-cerebral trauma and diseases
NACA Index (National Advisory Committee for Aeronautics)	T, N-T	general assessment of the state of severity of emergency patients (restricted to Switzerland, Austria and Germany)

These and other classification systems for trauma patients can be found under www.medal.org/ch29.html where it is also possible to enter data directly and calculate scores

N-T Non-trauma
O Outcome
P Prognosis
S Assessment of severity
T Trauma
* Not validated for non-trauma

control with statistical methods, offers good solutions. The “Emergency Medical Services Outcomes Project” (EMSOP) in the United States proposed the development of risk adjustment measurements (RAMs) of this sort [17]. A suggestion for so-called core RAMs has already been made. These include age, sex, initial and final assessments and both pre- and post-intervention vital variables, time periods and subjective assessments made by the EMS provider. Further proposed RAMs are, for example, level of team training, team performance and knowledge management.

Setting up and implementation of a research program with priorities

To enable us to answer the most important questions with regard to prehospital medicine within a sensible time frame, we urgently need to agree upon a Swiss research programme that sets clear priorities. Such a programme would have to lay down the circumstances to be investigated, with which objectives and outcomes and with which priorities. An agenda of this sort would have to be internationally accessible and each research project should be listed in a central register. In the USA, within the framework of the EMSOP, an initial list of this sort has been prepared and published [15]. Continuation and further development of this work together with adaptation to special regional requirements is urgently needed.

Conclusions

The most important questions in prehospital medicine remain largely unanswered, not only in Switzerland but throughout the world. Methodological problems such as unsuitable or inappropriate research methods are one of the reasons for this. Fortunately, valid alternatives that are relatively easy to implement are available, such as the system-orientated approach and the prospective cohort design. These merely have to be adapted to the prehospital setting. Agreement on uniform datasets, definitions and classifications, the formulation of so-called risk adjustment measurements to check for the ever present confounding factors and, in the medium term, the setting up of a Swiss research programme that sets clear priorities are urgently needed. If research in Switzerland is to achieve results relevant to EMS that permit deci-

sions to be taken, it is clear that this will hardly be possible without financial support from the Swiss National Fund and other institutions. Furthermore, until we have reliable results, the level of prehospital care we already offer should not be lowered to save money, since this would render the very research necessary largely impossible.

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