EDITORIAL

Are the results of hospital based studies generalisable to the pre-hospital setting? Article No. 990095

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The emergency care department of the Agency of Public Health of the Lazio Region (Central Italy) has launched a program to develop a series of evidence-based critical pathways for the management of patients with suspected stroke, ischaemic heart disease, eclampsia, and acute respiratory failure. All pathways start when a call to the emergency services is made and stop when the patient arrives in hospital.

To ensure that robust methodology would be used in the preparation of the pathways, the Agency enrolled the help of Tom Jefferson, who has co-authored numerous systematic reviews. A new project unit was also created, which is led by Marica Ferri, an experienced Cochrane methodologist.

As with the preparation of all clinical pathways, work involved systematically reviewing the available evidence to prepare draft pathways that were subsequently assessed by a panel of experts. The two mentioned investigators independently searched the major databases looking for relevant systematic reviews, trials and other relevant studies or evidence-based documents.

Results were lacking. We found few comparative studies on pre-hospital procedures, none of which were on emergency transport of patients. There appeared to be a complete lack of randomised controlled trials carried out in a pre-hospital setting (which could perhaps be justified by the ethical limits in randomising very critical patients), and only a few observational comparative and/or registry studies. However, several case-series studies have been published (mainly) in specialised journals. While, in the absence of comparative studies, case-series were used to inform pathway construction, we do not believe that such non-comparative designs are a reliable source of information. Routine data on the fate of patients between emergency services call-out and arrival to hospital is also lacking, making evaluation of care administered in these circumstances very difficult to assess.

We found a number of systematic reviews of the effects of emergency procedures. However, these reviews were predominantly based on 'in-hospital' patients and carried out in hospital settings. Studies addressing the out of hospital environment were lacking, and the generalisability of the results in the hospital-based studies to a pre-hospital setting, is unclear.

In the case of acute asthma for instance, the four Cochrane systematic reviews we found^{1,2,3,4}, explicated that inclusion criteria for trials was to consider patients presenting at the emergency department with a diagnosis of acute asthma and who were treated respectively with systemic corticosteroids, inhaled corticosteroids, intravenous beta2-agonists, and magnesium sulfate.

We suspect the presence of selection bias in all the experimental studies which were carried out on emergency patients as the patients were already admitted to hospital. If we assess interventions for acute conditions only on those patients who reach the hospital, receive an appropriate and confirmed diagnosis and who are treated under the care of full-time specialized and dedicated medical staff, what do we really know about the effectiveness of treatment? Can we generalise the results of randomised experiments carried out in hospital to a pre-hospital setting?

The suspicion of a systematic selection and exclusion of all severely ill patients who die during transportation, or those who experience their events too far from a specialised unit and who also die during transportation, is difficult to allay. Furthermore, we cannot assess the impact of using evidence which is based on well-lit, equipped and staffed departments to the management of roadside emergencies.

In our pre-hospital emergency stroke care pathway we discovered a solid body of evidence showing that getting suspected stroke patients to appropriate hospitals swiftly is important, but we found a lack of evidence to support a pre-hospital pathway. We identified evidence of effective hospital-based procedures and we prepared a pre-hospital pathway for emergency medical services to maximise timely access to thrombolysis for people who could benefit from it and to optimise appropriate care for other patients. However we are not sure that high grade hospital-based evidence is applicable or that the scientific community is not overlooking potentially effective treatments or interventions in its near-total focus on emergency hospital care.

It is for these reasons that we intend to evaluate our pathway in a cluster-randomised trial which is due to start in early 2005 and we strongly welcome the birth of the Cochrane Prehospital and Emergency Health Field. The Field should help clarify the need for studies in emergency care and facilitate development of this crucial (and sadly neglected) aspect of health care.

Bibliography

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