Review Protocol

ADMINISTRATIVE INFORMATION

Title
Formalized triage systems' outcomes on adult trauma patients: protocol for systematic review

Registration
According with current guidelines, our systematic review protocol is going to be registered with the International Prospective Register of Systematic Reviews (PROSPERO) on… (registration number…)

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Contributions
AA and AE are the principle reviewers under supervision by BM and MG. AA will draft the manuscript. AE, BM and MG will review and critically revise for important intellectual content.

Amendments
In case the protocol would need any amendments, the date, description and rationale behind the changes will be stated in this section.

INTRODUCTION

Introduction

Trauma is one of the most common causes of death worldwide and accounts for a considerable amount of the global burden of disease [1]. From 1990 to 2013 the total number of traumatic deaths per year increased from 4.3 million to 4.8 million (an increase of 10.4%), mainly because of a rapid increase in motorization in low- and middle-income countries [1]. Effective systems of trauma care are essential to ensure the best outcomes for these patients [2-4]. An integral part of these systems is the process to ensure that each patient gets to the appropriate hospital and receives the appropriate level of care based on the needs and resources available.

Such processes are called systems of trauma triage and are widely used in many different contexts: pre-hospital and hospital, civilian and military, single- and mass-casualty. The origins of these processes trace back to the 19th century [5]. These are meant to be easily implemented by any health care personnel to ensure rapid and accurate management of the patient. However, while trauma systems as a whole (i.e. triage, on-scene interventions, method of transport etc.) have been proven to lower trauma mortality to a significant degree [2-4], there are still doubts about the true efficacy of the triage systems themselves [6].

Triage systems come in many different forms and can be based on prognostic modelling [7], or guidelines created by experts [8], to name a few. Most research conducted on these trauma triage systems has been focused on the aspects of under- and over-triage, as well as ways of mitigating it [9-13]. However, evidence to support the actual impact of triage systems on patient outcomes is lacking. Since improving mortality and morbidity rates should be the main goal in implementing systems of trauma triage, it is paramount that research investigating patient outcomes in real world settings is performed.

Objectives

The aim of this study is to investigate if formalized systems of trauma triage have any effect on adult trauma patients in terms of morbidity and mortality. To complete this objective, this systematic review will answer the following question:

1. In adult trauma patients, do formalized triage systems, compared to no formalized triage system, reduce morbidity and mortality?
2. In adult trauma patients, how do different formalized triage systems compare with each other in terms of morbidity and mortality reduction?

METHODS

Eligibility criteria
Study designs

We will include randomized controlled trials, controlled clinical trials, controlled before-and-after studies, and interrupted time series studies that compare the implementation of

formalized triage systems to no formalized triage system or another formalized triage system already in place.

Participants

All trauma patients, as defined by the study authors, will be included in this review with the exception of studies that describe triage for patients with specific injuries (such as thoracic injuries or major bleeding) or specific trauma mechanisms only (such as road traffic injury). All studies with an adult population, here defined as > 15 years, will be included. Our rationale for only studying adults is that different triage protocols are often implemented for adults and children, potentially because of the differences in physiology.

Interventions

The intervention of interest is a formalized triage system intended for trauma care in both the prehospital and hospital setting. Trauma triage will be defined as the process used by medical professionals in routine decision-making on the level of care for trauma patients, including prioritizing patients for treatment and transport and decisions on what resources to activate. We define a formalized triage system as any system aimed to triage adult trauma patients according to a set of à priori defined criteria by any health care provider (for example a set of vital signs along with specific mechanisms of injury), or where a specific health care provider is assigned to triage patients (for example physician led triage).

Comparators

We will compare the outcomes of using a formalized triage system vs. no formalized triage system. We will also compare the outcomes of different formalized triage systems between each other.

Outcomes

We will include studies that investigate pre- and in-hospital morbidity and mortality outcomes as defined by the individual study authors (e.g. mortality within 24 hours, mortality within 30 days, various quality of life indices).

Timing

There will be no restrictions in regards to the timing of the studies.

Setting

There will be no restrictions in regards to the setting of the studies.

Language

All studies not published in English will be excluded from this review.

Publication status

Unpublished literature, commentaries, editorials and letters, as well as studies without abstracts, will all be excluded.

Information sources and search strategy

We will search for all original studies on formalized systems of trauma triage. The specific search strategy will be developed by the university library search consultation group at Karolinska Institutet in dialogue with us. We will search Medline, Web of Science, Embase and Cochrane library using the appropriate search terms (i.e. triage, wound, trauma, injury, etc.). Grey literature will not be searched. References of included studies will be checked for additional studies not presented in the original search. The full search strategy can be viewed in appendix 1.

Study records

Data management

Literature search results will be uploaded to Mendeley. The data will be extracted using an a priori designed Qualtrics survey, and the extracted data will later be analyzed using the R statistical environment.

Selection process

The review authors AA and AE will independently and in a three-step manner: screen titles, screen abstracts, and screen full texts of all studies identified by the search against the inclusion and exclusion criteria. Any disagreements in the title and abstract screening stages will be resolved by including the study in the following stage. Disagreements while reviewing the full text will be resolved firstly by discussion and secondly by the involvement of a third reviewer. All reasons for excluding studies will be recorded. References of all included studies will also be screened.

Data items

The two reviewers AA and AE will independently extract data from each of the included studies. Data will be collected using the Qualtrics survey software. Disagreements in data extraction will be resolved firstly by discussion and secondly by the involvement of a third reviewer. The following items will be recorded:

Source:

- Study ID
- Report ID
- Reviewing author ID
- Citation
- Contact details.

Eligibility:

- Confirm eligibility for review, reason for exclusion.

Methods:

- Study design
- Total study duration
- Blinding
- Unit of analysis
- Power calculation
- Follow-up time.

Participants:

- Intervention and control triage system
  - Centre description
  - Centre location
  - Patients
    - Total number
    - Definition of trauma
    - Age
    - Gender
    - Severity of injury
    - Mechanism of injury

Interventions:

- Number of intervention groups
- Type of triage system (if applicable)
  - Physician led triage according to predefined criteria
  - Physician judgement only
  - EMT technician/paramedic led triage according to predefined criteria
  - EMT technician/paramedic judgement only
  - Nurse led triage according to predefined criteria
  - Nurse judgement only

Outcomes:

- Mortality as defined by the author
  - Value
  - Units
- Morbidity as defined by the author
- Units of measurement

Results:

- For each outcome of interest
  - Sample size
  - Missing participants
  - Outcomes in natural units
  - Effect estimate with confidence interval and P-value

        o Subgroup analyses undertaken

Miscellaneous:

- Funding source
- Key conclusions of the study authors
- References to other relevant studies
- Correspondence required
- Comments by the review team

Risk of bias in individual studies

Randomized controlled trials and controlled clinical trials

We will use the Cochrane Collaboration's 'Risk of bias' assessment tool [14]. This will include screening for the following sources of bias: sequence generation, allocation concealment, blinding of participation, personnel and outcome assessors, incomplete outcome data, selective outcome reporting, and 'other' identified concerns about sources of bias. We will judge the bias according to the recommendation of the tool, meaning either "yes" (low risk of bias), "no" (high risk of bias), or "unclear" (insufficient amount of information to determine). If there are any cluster-randomized trials included, we will assess additional sources of bias including recruitment bias, baseline imbalance in either clusters or individuals, loss of clusters, incorrect analysis, comparability with individually-randomized trials.

Controlled before-and-after studies

We will assess these studies according to six modified EPOC guideline criteria [15] and make judgments according to the "yes", "no", or "unclear" system as defined above.

- Baseline measurement of triage system or no system performance;
- Similarity of comparator control triage systems or no system to intervention systems;
- Blinded assessment of primary outcomes;
- Protection against contamination;
- Reliable primary outcome measures;
- Follow up of patients > 80%.

Interrupted time series studies

We will assess these studies according to eight modified EPOC guideline criteria [16] and make judgments according to the "yes", "no", or "unclear" system as defined above.

- Protection against secular changes;
- Data were analyzed appropriately (ARIMA models or time series regression with serial correlation testing);
- Reason for the number of points pre- and post-intervention are given;
- Shape of the intervention effect was specified;
- Protection against detection bias;

- Blinded assessment of primary outcome;
- Completeness of data set (> 80% of participants or episodes of care are included);
- Reliable primary outcome measure.

Data synthesis

Randomized controlled trials and controlled clinical trials

For each outcome in every study group we will record outcomes in natural units, and report the baseline and post-intervention differences between each study group. Where applicable, we will document measurements of effect size, as well as 95% confidence intervals with corresponding P-values.

Controlled before-and-after studies

For each outcome in every study group we will record outcomes in natural units. According to current guidelines [15] we will present pre- and post-intervention means, together with the absolute change and relative percentage change to post-intervention, as well as the absolute change and difference in absolute change from baseline.

Interrupted time series studies

For each outcome in every study group we will record outcomes in natural units. We will present the data in accordance with current guidelines which include the number of time points pre- and post-intervention, the number of patients in the whole series, the time interval between points, pre- and post-intervention means, absolute changes in outcomes reported in natural units, relative percentage change, and the model used and statistical significance of any findings [16].

Statistical Analysis

All outcomes will be combined and synthesized using the R statistical environment. Missing data will be well documented and recorded together with all extracted data. If there is not enough data to synthesize, we will provide a systematic narrative synthesis of the studies included.

Heterogeneity

If there is a need to assess heterogeneity, we will use Chi^2 test (P value < 0.1) and then quantify using the I^2 statistic (with an I^2 value > 50% which represents substantial heterogeneity) [14].

Meta- and subgroup analyses

If at all possible, in terms of study homogeneity, we will conduct a meta-analysis using random-effects models. If there is substantial heterogeneity we will investigate the possible sources of this by conducting a subgroup analysis using a meta-regression approach.

Meta-bias(es)

We will determine if there are any reporting bias by comparing study protocols with their respective reports, as well as comparing the methods section to the results. If we fail to identify any published protocol we will attempt to contact the study authors by email. If a sufficient number of studies are included, we will generate a funnel plot. We have no plans to investigate any unpublished or "grey" literature at this time. Since we will only include studies published in English there is a risk for language bias.

Confidence in cumulative evidence

We will judge the quality of evidence for all outcomes and the strength of the whole body of evidence using the Grading of Recommendations Assessment, Development and Evaluation working group methodology. We will rate the quality from high (meaning that we are very confident that the true effect lies close to that of the estimate of effect) to very low (meaning that we have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect). If at all possible, we will conduct a meta-analysis.

Appendix 1

Full search strategy report

References

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