

BMJ Open Effects of advanced life support versus basic life support on the mortality rates of patients with trauma in prehospital settings: a study protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Advanced life support (ALS) is thought to be associated with improved survival in prehospital trauma care when compared with basic life support (BLS). However, evidence on the benefits of prehospital ALS for patients with trauma is controversial. Therefore, we aim to clarify if ALS improves mortality in patients with trauma when compared with BLS by conducting a systematic review and meta-analysis of the recent literature.

Methods and analysis We will perform searches in PubMed, Embase and the Cochrane Central Register of Controlled Trials for published observational studies, controlled before-and-after studies, randomised controlled trials and other controlled trials conducted in humans and published until March 2017. We will screen search results, assess study selection, extract data and assess the risk of bias in duplicate; disagreements will be resolved through discussions. Data from clinically homogeneous studies will be pooled using a random-effects meta-analysis, heterogeneity of effects will be assessed using the χ^2 test of homogeneity, and any observed heterogeneity will be quantified using the I^2 statistic. Last, the Grading of Recommendations Assessment, Development and Evaluation approach will be used to rate the quality of the evidence.

Ethics and dissemination Our study does not require ethical approval as it is based on findings of previously published articles. Results will be disseminated through publication in a peer-reviewed journal, presentations at relevant conferences and publications for patient information.

Trial registration number PROSPERO (International Prospective Register of Systematic Reviews) registration number CRD42017054389.

INTRODUCTION

Advanced life support (ALS) is widely accepted as the gold standard of prehospital care in patients with cardiopulmonary arrest (CPA) caused by intrinsic diseases.^{1–3} It has also been suggested that ALS in patients with trauma contributes to improved survival. However, it is not known if prehospital ALS

Strengths and limitations of this study

- We will conduct a systematic review and meta-analysis of the effects of advanced life support (ALS) and basic life support (BLS) on survival in patients with trauma in prehospital settings using appropriate methodologies and quality assessment tools.
- We will also perform subgroup analysis by trauma type to evaluate the efficacies of ALS versus BLS; this will provide further clinical evidence for clinicians and patients.
- The results of this systematic review and meta-analysis will be highly dependent on the quality of the included primary research studies; many observational studies might be included.

is more beneficial for patients with trauma than basic life support (BLS). In previous studies, prehospital ALS increased the time that was spent on the scene and thus delayed definitive in-hospital care.^{4 5} In contrast, prehospital BLS consists of non-invasive interventions that are easy to perform, require little added on-scene time and can often be performed en route by minimally trained emergency medical staff. The treatment of trauma is time-sensitive; thus, rapid transportation to the hospital is required as in-hospital surgery is typically needed to improve the prognosis of patients with trauma. ALS might put patients with trauma at risk as it increases the time spent on-scene; however, providing ALS can also be used to resuscitate patients with trauma on-scene. In 2017, von Vopelius-Feldt and colleagues⁶ reported in their systematic review that prehospital critical care had a limited effect; none of the included studies showed obvious benefits for non-trauma CPA patients. This implies that it is important to treat patients, and particularly patients with trauma, at the hospital rather

than in prehospital settings. Resources are very limited in prehospital settings.

In 2016, Evans *et al*⁷ reported that prehospital ALS procedures in patients with traumatic cardiac arrest were not associated with increased odds of survival using two large registry data sets (Resuscitation Outcomes Consortium Epistry-Trauma and the Prospective Observational Prehospital and Hospital Registry for Trauma registries). Endotracheal intubation in prehospital settings has not been shown to reduce mortality and morbidity in patients with severe trauma; moreover, there are concerns that performing this difficult task under trying conditions might cause harm.^{8–11} Endotracheal intubation by unskilled practitioners could result in adverse events and result in ineffective chest compressions with significant interruptions.⁸ The value of prehospital intravenous fluid resuscitation has also been questioned.^{12–14} Intravenous fluids given before surgical control of bleeding lead to either accentuation of ongoing haemorrhage or hydraulic disruption of an effective thrombus, followed by a fatal secondary haemorrhage. In addition, intravenous infusions of crystalloid may promote haemorrhage by diluting coagulation factors and by lowering blood viscosity.¹² In summary, suitable interventions for trauma care in prehospital settings are still controversial.

Therefore, we aim to clarify if ALS improves mortality in patients with trauma when compared with BLS by conducting a systematic review and meta-analysis of the recent literature.

METHODS AND ANALYSIS

This systematic review and meta-analysis protocol has been registered in PROSPERO, an International Prospective Register of Systematic Reviews at the National Institute for Health Research and Centre for Reviews and Dissemination at the University of York (<http://www.crd.york.ac.uk/PROSPERO/>; registration no CRD42017054389).¹⁵ The protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statements (online supplementary file 1),^{16 17} and the systematic review and meta-analysis will be reported in accordance with PRISMA guidelines.^{16 18 19}

Types of studies

Observational studies, controlled before-and-after studies (CBAs; studies with contemporaneous data collection before and after an intervention), randomised controlled trials (RCTs) and other controlled trials (CTs; studies that are not truly randomised but have treatment allocations) will be included. Conference abstracts, studies in animals and those that only include patients with trauma transported by helicopter will be excluded.

Study population

Our study population of interest is adult (>18 years old) patients with trauma who were transported by ground transportation and required resuscitation in prehospital

settings. We will not restrict our analysis by country and will include all severities and types of trauma. Data on patients without signs of life and studies with participants aged ≤ 18 years will be excluded.

Intervention types

The interventions of interest are ALS and BLS. ALS will be defined as one or more of the following intervention components: (1) tracheal intubation, (2) needle tracheostomy, and administration of (3) intravenous fluids, (4) epinephrine or (5) other intravenous drugs (eg, amiodarone, lidocaine or magnesium). BLS will be defined as BLS procedures only.

Outcomes

Our primary outcomes of interest are survival to hospital admission and survival to hospital discharge. Secondary outcomes include neurological outcomes and adverse events/complications (including failure rates of ALS and time spent on scene).

Database searches

Database searches will be conducted in Medline (via PubMed), Embase and the Cochrane Central Register of Controlled Trials to retrieve relevant articles for the literature review. We will search for full-text observational studies, CBAs, RCTs and other CTs in humans that were published until March 2017 in all languages. We will attempt to translate non-English-language articles by using professional translators, if possible. We will consult a librarian for conducting the database searches. Search terms will include 'Trauma', 'Advanced Cardiac Life Support', 'Basic Life Support', 'Life Support Care', 'Emergency Medical Services', 'First Aid' and 'Resuscitation'. We will use a combination of these key terms and establish a full search strategy (online supplementary file 2).

Data extraction and management

The following data will be extracted: author(s), title, journal name, year of publication, website (URL) and abstract. The authors (YK, TF and RU) will perform a first-line comprehensive literature search independently and blindly followed by filtering for duplicates. After removal of duplicates by two of the three authors, titles and abstracts will be screened independently and blindly for potential relevance using a pretested electronic screening form (Covidence web platform: <http://www.COVIDENCE.org>). In cases of disagreements among the reviewers, the full text of the paper will be retrieved; disagreements will be reconsidered and discussed until a consensus is reached. If disagreements cannot be reconciled, a third reviewer will be consulted. Inter-reviewer agreement will be assessed through the Cohen's κ coefficient.^{20 21} For this statistic, values <0.4 indicate poor, 0.4–0.59 fair, 0.60–0.74 good and >0.75 excellent agreement.²²

The full text of the articles included in the final selection will be independently reviewed by two authors, who

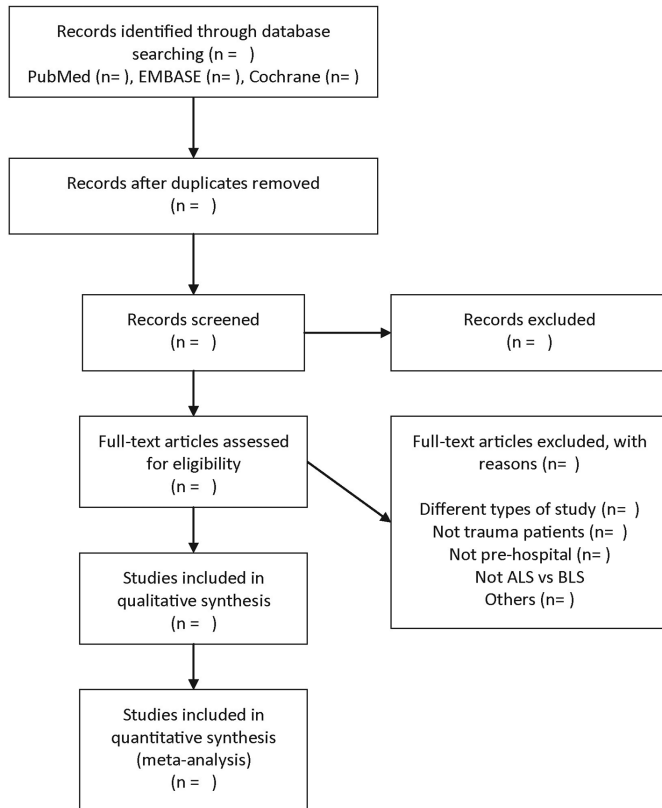


Figure 1 Flow chart of the study selection process. ALS, advanced life support; BLS, basic life support.

will be randomly chosen from five authors (YK, TF, RU, TH and KH). The flow diagram of our study, which has been adapted from the PRISMA statement (2009),¹⁹ is shown in [figure 1](#).

Assessment of risk of bias

To assess the quality of the included studies, we will adapt the Cochrane risk of bias tool.²³ Each study will be assessed for (1) random sequence generation (selection bias), (2) allocation concealment (selection bias), (3) blinding of participants and personnel (performance bias), (4) blinding of related outcomes assessment (detection bias), (5) incomplete outcome data (attrition bias), (6) selective reporting (reporting bias) and (7) other bias. Studies will be categorised as having a low, unclear or high risk of bias in each domain. The risk of bias for each element will be considered ‘high’ when bias is present and likely to affect outcomes, and ‘low’ when bias is not present or present but unlikely to affect outcomes.²⁴

Two independent reviewers, chosen from the five authors (YK, TF, RU, TH and KH), will perform the risk of bias assessment. Disagreements will be resolved through discussion; a third reviewer will provide his/her opinion, if necessary.

Summarising data

We plan to perform a meta-analysis when data are available in one or more trials according to the ‘Cochrane Handbook for Systematic Reviews of Interventions’ and

the PRISMA guidelines by using the Review Manager software (RevMan V.5.3, Copenhagen, Denmark: The Nordic Cochrane Centre, The Cochrane Collaboration 2014). Results will be summarised using the generic inverse variance method to facilitate pooling of estimates of the treatment effects.

OR and 95% CIs will be used for dichotomous outcomes, and mean differences or standardised mean differences and 95% CIs for continuous outcomes, when appropriate. If quantitative synthesis is not appropriate for a particular outcome, we will provide a qualitative summary for this outcome.²⁵

Assessment of heterogeneity

Heterogeneity between trials for each outcome will be evaluated using the I^2 statistic for quantifying inconsistency.²⁶ We will consider heterogeneity as being significant if the reason for heterogeneity cannot be explained, and if I^2 is 50% or greater. If significant heterogeneity is found, the median of the estimates rather than a weighted pooled estimate will be reported. Clinical heterogeneity will be explored by assessing differences in baseline data, types of trauma, ALS definitions and other outcome parameters. The presence of strong clinical heterogeneity will be considered in the decision to conduct a quantitative synthesis of data or to perform sensitivity analyses with a special focus.²⁷

Assessment of reporting bias

We will investigate the potential for publication bias using a funnel plot. To test for funnel plot asymmetry, we will apply the Egger and arcsine tests for continuous and dichotomous outcomes, respectively, using the STATA SE V.13 statistical software.^{28 29}

Data synthesis

Estimates will be pooled using a random-effects model. We will attempt to contact the primary authors of the publications for additional data, if possible. In detail, we will email the authors and wait for a response for 1 week. If we do not receive a response by then, we will send another email. We will not use data that include identifiable information. The meta-analysis will be performed based on all published data and data made available to us.²⁴ We do not plan to perform multiple imputation for missing data.

Subgroup analyses

Subgroup analyses will be used to investigate the differences in pooled effect estimates related to different patient subgroups included in the studies. We will evaluate if a differential intervention effect among the various subgroups exists by using an interaction analysis, as this is preferred over separate subgroup group-specific analyses. Subgroup analyses will be performed for types of trauma (blunt vs penetrating), rural versus urban, and by prehospital procedures. Moreover, we will categorise the studies by time of publication (published in the last 10 years vs

published 10 years ago or longer) and analyse potential differences between the two groups.

Sensitivity analysis

To ensure the robustness of evidence, we will perform sensitivity analysis to assess the effect of studies with a high risk of bias. We will compare the results to decide whether lower quality studies should be excluded based on sample size, strength of evidence or effect on pooled effective size. Moreover, we might consider a leave-one-out sensitivity meta-analysis if a study shows big population and looked different types of study.³⁰

Rating the quality of evidence using the GRADE approach

Two authors (randomly chosen from YK, TF, RU, TH and KH) will independently use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool to rate the quality of the evidence on the effect of ALS and BLS on important outcomes in patients with trauma.^{31–34} Although the quality of evidence represents a continuum, it will be assessed for each outcome and categorised as high, moderate, low or very low using the GRADEpro Guideline Development Tool.

DISCUSSION

The benefits of ALS in patients with trauma in prehospital settings have not been clearly established yet.^{35–37} Thus, we aim to clarify if ALS increases survival when compared with BLS in prehospital trauma care by conducting a systematic review and meta-analysis of the recent literature. Importantly, we will exclude patients with trauma transported by helicopter from our analyses. Excluding these patients will likely result in more accurate data when compared with previously published meta-analyses, as helicopter transportation differs from a typical prehospital setting (eg, it is difficult to perform chest compressions in a flying helicopter).

To the best of our knowledge, only two meta-analyses reported data on ALS versus BLS in patients with trauma thus far. In 2000, Liberman *et al*³⁸ showed that ALS was associated with an increased mortality rate (2.5 times) when compared with BLS. Moreover, the time spent on scene was higher for ALS than for BLS providers (18.5 min vs 13.5 min, respectively; $p=0.005$)³⁸; this can affect mortality. In a study by Bakalos *et al*³⁹ in 2011, ALS care was not associated with increased survival. The authors retrieved data from nine trials including 16857 patients who met their inclusion criteria.^{11 40–47} ALS care in patients with trauma was shown to reduce the probability of survival to hospital discharge by almost 10% when compared with BLS care (pooled OR 0.892, 95% CI 0.775 to 1.026).³⁹ However, this study included only few CTs of sufficient quality and strength that examined the survival of patients with trauma that were published at the time.

Since then, more publications on ALS have become available, and transportation systems and care for patients have been improved. Our study will include all types of

trauma as ALS and BLS are performed independent of the type of trauma. We will also perform subgroup analysis by trauma type to evaluate the efficacies of ALS and BLS; this can be a more informative study because it has been argued a lot for several decades. As the effectiveness of prehospital care depends on the transportation method that is used,⁴⁸ studies with helicopter transportation will be excluded from our meta-analysis due to the potential risk of bias. In contrast to BLS, most patients with trauma receiving ALS are transported by helicopter. Moreover, the ALS group might include patients with more severe trauma who will also have a worse prognosis (as previous meta-analyses have reported). Our meta-analysis will be the first to exclude patients transported by helicopter transportation, which might result in novel findings. This systematic review and meta-analysis will provide current evidence for researchers in this field and be helpful for clinical staff in treating patients with trauma.

Contributors YK and TF conceived the idea for this systematic review. YK, TF, RU, TH and KH developed the methodology. The manuscript was drafted by YK, TF, RU, TH and KH supported in revising the manuscript. All authors critically reviewed and approved the final manuscript.

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