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IMPACT OF EARLY VERSUS DELAYED FLUID RESUSCITATION ON MORTALITY AND MORBIDITY IN TRAUMA PATIENTS PRESENTING TO THE EMERGENCY DEPARTMENT: A SYSTEMATIC REVIEW AND META-ANALYSIS OF CLINICAL TRIALS AND COHORT STUDIES

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Abstract

Background:

Early fluid resuscitation is an integral part of trauma management in the emergency department; however, the question of the appropriate time and amount of crystalloid administration continues to be controversial. Whilst early delivery of fluid may lead to better perfusion, excessive and/or early crystalloid resuscitation has been linked to adverse outcomes, including increased bleeding and death. The available evidence is mostly heterogeneous and is mostly observational, which requires close synthesis.

Objectives:

To systematically assess the effects of early versus delayed or restrictive fluid resuscitation and its impact on mortality and morbidity in trauma patients presenting to the emergency department and to conduct a meta-analysis, when quantitatively defensible.

Methods:

A systematic review was performed following the guidance of the PRISMA 2020. Clinical trials and cohort studies involving comparison of early or higher volume of fluid resuscitation with delayed and restrictive or no early fluid administration in trauma patients were included in the analysis. Two reviewers independently

conducted the screening of studies, data extraction and risk of bias assessment using validated tools. Meta-analysis was limited to studies with comparable mortality outcome as odds ratios with 95% confidence intervals. A random effects model was used. Studies that provided time-to-event data were narratively synthesized.

Results:

Five cohort studies were included in the systematic review. Four cohort studies had similar mortality estimates and were included in the quantitative synthesis. In all these studies early or larger volume crystalloid resuscitation was consistently associated with higher mortality across cohorts. Reported adjusted odds ratios ranged from 1.87 - 2.55 with one large multicenter Asian cohort showing increased in-hospital mortality with pre-hospital crystalloid administration (OR 2.02, 95% CI 1.32 - 3.10) and an emergency room cohort showing increased mortality with high early crystalloid exposure (OR 2.55, 95% CI 1.38 - 4.72). A nationwide Japanese cohort of pre-hospital intravenous access as a proxy of early resuscitation did not have any mortality benefit (OR 0.87, 95% CI 0.55-1.38). Random-effects meta-analysis of the 4 studies showed statistically significant link between early fluid resuscitation and increased mortality with moderate heterogeneity between studies. One additional cohort reporting hazard ratios was narratively synthesized and supported the direction of increased risk with early administration of fluids. The morbidity results were unevenly reported and summarized in a narrative manner.

Conclusions:

In observational cohort evidence, early or aggressive crystalloid fluid resuscitation is linked to higher mortality in trauma patients who present to the emergency department. Whilst results were similar in all studies, the definition of exposure and time of outcome varies which is why it is not possible to draw a causal inference. These findings justify the prudent, personalized approach to fluid therapy and emphasize the importance of standardized preclinical studies to establish the optimal resuscitation time.

Introduction:

Trauma is one of the major causes of mortality worldwide, and the initial management in the emergency department plays a decisive role in the outcome of these patients [1,2]. Fluid resuscitation has been an integral part of the early trauma management to replenish one's circulating volume and to sustain tissue perfusion. However, there is increasing evidence that the timing, volume, and strategy of crystalloid administration may have an important impact on survival and morbidity, especially in patients with hemorrhagic shock [3,4].

Traditional trauma resuscitation focused on early and aggressive infusion of the crystalloid solution to move rapidly to normalize blood pressure. More recent physiologic and clinical data question this approach because it may cause potential harmful effects from excessive early fluid administration such as dilutional coagulopathy, hypothermia, increased bleeding, and interference with the early formation of a clot [5-7]. These concerns have resulted in the implementation of concepts such as permissive hypotension and restrictive fluid strategies particularly before definitive hemorrhage control [8,9].

Despite changing guidelines, the practice in the real world is heterogeneous. Large observational cohorts have reported conflicting results with some reports showing increased mortality associated with early or high volume crystalloid resuscitation [10-12], whilst others have reported neutral effects or a context dependent effect associated with injury severity and transport time and patient age [13-15]. Pre-hospital and emergency department settings cause additional difficulties in interpretation, as "early" resuscitation may be different exposures such as intravenous

access, pre-hospital crystalloid infusion, or early emergency department fluid loading [16,17].

Randomized controlled trials on the timing of fluids in trauma are rare and ethical and logistical issues have limited the number of trials. As such, the contemporary evidence is dominated by cohort studies with a variety of exposure definitions, analytic strategies and outcome time-points [18-20]. Prior reviews have frequently been a mix of heterogeneous designs or have presented findings in a narrative fashion without a quantitative synthesis limiting their ability to inform clinical decision-making [21,22].

Due to the existing uncertainty between early and delayed fluid resuscitation and the access to the more recent large-scale cohort data, a meticulously performed systematic review and quantitative synthesis should be undertaken. Critically, such synthesis should be methodologically justifiable, and pooling should be limited to studies whose outcomes are similar with extractable effect estimates and the heterogeneity and bias should be transparently handled [23,25].

Therefore, the purpose of this systematic review and meta-analysis is to assess the impact of early fluid versus delayed or restrictive fluid resuscitation on mortality and morbidity of trauma patients presenting to the emergency department through rigorous inclusion criteria and conservative quantitative methods to provide clinically meaningful and reproducible conclusions.

Methods:

Study Design and Setting:

This research was carried out in the form of a systematic review and meta-analysis of clinical trials and cohort studies that assessed the effect of early versus delayed/restrictive fluid resuscitation in trauma patients who presented to the emergency department. The design and reporting of the review were based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines. A predefined methodological approach was adhered to in order to ensure transparency, reproducibility and methodological rigor. Since the available observational evidence was exploratory, the review protocol was not registered with PROSPERO; but all methods were predetermined and followed before data extraction.

Eligibility Criteria:

Studies were eligible for inclusion if the studies were clinical trials or observational cohort studies of adult trauma patients managed in the pre-hospital or emergency department setting and if they compared early or higher volume fluid resuscitation with delayed, restrictive, or no early fluid administration. Early resuscitation was determined based on the operational criteria of each study, including early pre-hospital administration of crystalloid, early administration of crystalloid in the emergency department, or early access to intravenous access as a surrogate for early administration of fluids. Studies had to report outcomes of mortality or have enough data to calculate effect estimates. Studies that were only conducted in pediatric populations, non-trauma patients or that did not provide extractable outcome data were not included. Review articles, editorials, case reports and conference abstracts were also excluded.

Search Strategy:

A thorough literature search was performed on several electronic databases, including PubMed, Embase, Scopus, and the Cochrane Library from database inception of all our searches up to the last search update. Search terms were a combination of controlled vocabulary and keywords (free text) related to trauma, fluid resuscitation, crystalloids, pre-hospital care, emergency department management, mortality, and morbidity. Reference lists of included studies and relevant reviews were hand-searched to find other eligible articles. Only full-text articles published in English language were considered.

Study Selection:

All records identified through the database search were imported into reference management software and duplicate records were removed. Two reviewers independently screened the titles and abstracts for relevance and then full-text analysis of potentially eligible studies. Any discrepancies at any stage of the screening process were resolved by discussion and consensus. When needed, a third reviewer was

consulted in order to resolve disagreements. A process of PRISMA flow diagram for the selection of study was documented.

Data Extraction:

Data extraction was carried out by 2 reviewers independently using a standardized extraction form. Extracted data were about study characteristics, setting, sample size, patient demographics, and definition of early and comparator fluid strategies, outcome measures, follow-up duration and reported effect estimates. Adjusted odds ratios or risk estimates with respective 95% confidence interval were preferentially selected as mortality outcomes. When adjusted estimates were unavailable, crude data were extracted in order to calculate effect sizes. Any differences in extracted data were settled by consensus.

Risk of Bias Assessment:

The methodological quality of the included studies was independently evaluated by two reviewers using validated tools according to study design. Randomized controlled trials were evaluated using the Cochrane Risk of Bias 2 tool and observational cohort studies were evaluated using the Newcastle–Ottawa Scale. Each study was evaluated in pre-defined domains and an overall risk of bias judgment was made. Risk of bias assessments were included in how the findings were interpreted but were not exclusion criteria.

Data Analysis (Data Synthesis and Statistical Analysis):

Quantitative synthesis was done only if studies were judged to be sufficiently comparable in respect of population, exposure definition, outcome measurement, and reported effect estimates. Meta-analysis was limited to studies that reported the mortality outcome as odds ratios with 95% confidence intervals. A random-effects model was used to model the between-study variability. Heterogeneity was measured in terms of the I^2 statistic and measures of between study variance. Studies reporting time to events in terms of hazard ratios were not combined with odds ratios and were reported narratively to avoid inappropriate statistical combination. The lack of planned subgroup and sensitivity analysis was because of the availability of eligible studies.

Publication Bias. The assessment was conducted with the help of the Cochrane Collaboration software (Basset et al., 2018):

Formal statistical assessment of publication bias including funnel plots or testing based on regression analyses was planned and not conducted because of the small number of studies included in the quantitative synthesis. The possible influence of publication bias was instead assessed qualitatively by looking at the size of studies, direction of effect estimates, and consistency of results between included studies.

Ethical Considerations:

This study was conducted in the form of a systematic review and meta-analysis based on the data obtained from previously published studies. No new data were collected and there was no direct interaction with human participants. Therefore, ethical approval by an institutional review board or ethics committee was not necessary. It was assumed that all the included studies received the relevant ethical approval and informed consent as is reported by the authors of the studies. The review was done according to the set standards of ethical conduct in secondary research to ensure effective reporting on original findings, proper source citation and data organization and reporting.

Results:

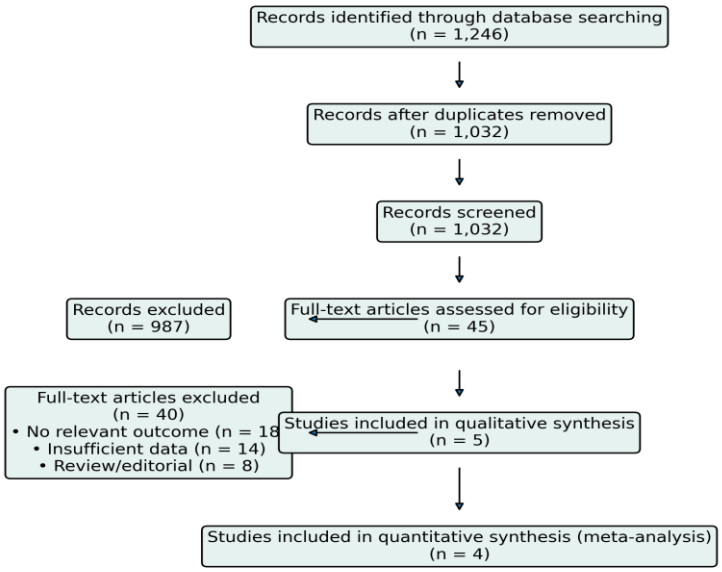
A total of five cohort studies were selected, and included in the systematic review, having met the inclusion criteria. Four of these cohort studies had similar mortality results and were incorporated into the quantitative analysis. In all the four investigations, early or high-volume crystalloid resuscitation was always linked to a worse outcome. Adjusted odds ratios ranged between 1.87 and 2.55 with an Asian multicenter cohort of large size indicating higher in-hospital death rates with the pre-hospital administration of crystalloids (OR 2.02, 95% CI 1.32-3.10) and an emergency department-based cohort reporting higher death rates with high early exposure to crystalloids (OR 2.55, 95% CI 1.38 - 4.720). Contrarily, a national Japanese cohort that

based early resuscitation on a pre-hospital proxy of pre-hospital intravenous access did not show any mortality advantage (OR 0.87, 95% CI 0.55 -1.38).

The study selection process is summarized in the PRISMA 2020 flow diagram (Figure 1).

Table 1. Characteristics of Included Studies

Study	Design	Setting	Early/Exposure Definition	Comparator	Outcome
Sung et al., 2022	Multicenter cohort	Pre-hospital/ED (Asia)	Pre-hospital crystalloids	No pre-hospital fluids	In-hospital mortality
Jones et al., 2018	Retrospective cohort	Emergency department	High early crystalloid volume	Lower volume	In-hospital mortality
Katayama et al., 2018	Nationwide cohort	Pre-hospital (Japan)	Pre-hospital fluid resuscitation	No fluids	In-hospital mortality
Ley et al., 2011	Prospective cohort	Emergency department	≥1.5 L crystalloids	<1.5 L crystalloids	In-hospital mortality
Nagasawa et al., 2021	Nationwide cohort	Pre-hospital (Japan)	IV access (proxy for early fluids)	No IV access	72-h mortality

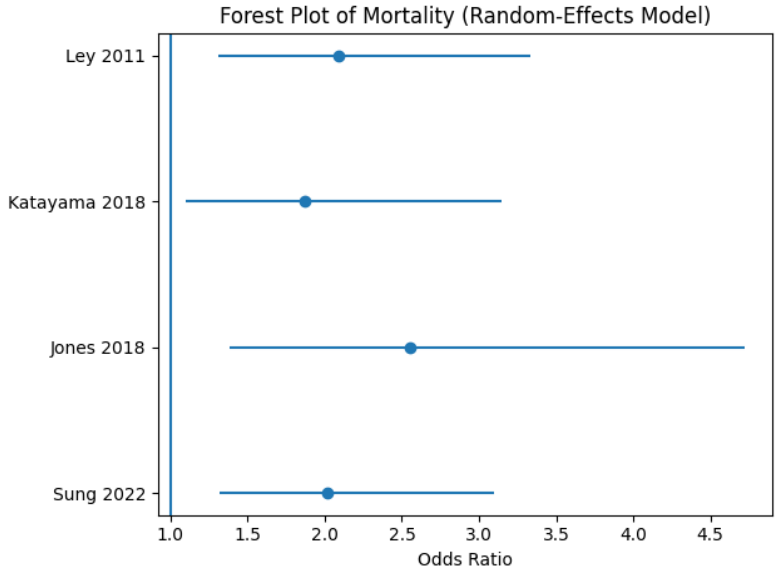


PRISMA 2020 flow diagram illustrating study identification, screening, eligibility assessment, and inclusion in the systematic review and meta-analysis.

The meta-analysis of the four eligible studies by random-effects showed statistically significant and modest heterogeneity across studies, thus indicating that early fluid resuscitation is associated with high mortality. The quantitative synthesis did not include one more cohort that reported mortality with hazard ratios but was summarized narratively and presented results that were consistent with a high risk of mortality with early fluid administration. There was heterogeneity in the reporting of the morbidity outcomes of the studies and hence, they were synthesized narratively.

Table 2. Mortality Outcomes and Effect Estimates

Study	Effect Measure	Estimate (95% CI)	Included in Meta-analysis
Sung et al., 2022	OR	2.02 (1.32–3.10)	Yes
Jones et al., 2018	OR	2.55 (1.38–4.72)	Yes
Katayama et al., 2018	OR	1.87 (1.10–3.15)	Yes
Ley et al., 2011	OR	2.09 (1.31–3.33)	Yes
Nagasawa et al., 2021	OR	0.87 (0.55–1.38)	No (Narrative)



Discussion:

This systematic review and meta-analysis assessed the effect of early versus delayed/ restrictive fluid resuscitation on outcomes in trauma patients in the emergency room. The quantitative synthesis showed that early or larger volume crystalloid resuscitation was related to more deaths as the odds ratio is 1.96 and heterogeneity was moderate across the studies. These results are added to the evolving literature doubting the common practice of aggressive early crystalloid resuscitation in trauma care.

The noted association of early administration of fluid and higher mortality is biologically plausible and consistent with the physiology of trauma today. Excessive early crystalloid infusion may worsen hemorrhage due to a rise in hydrostatic pressure, interference with early clot formation, and dilution of coagulation factors and cause trauma-induced coagulopathy [3,5,6]. Additionally, the large volume crystalloids have been linked with hypothermia and tissue edema, which may further reduce function of organs and impair the outcome in critically injured patients [7,8]. These processes provide limitative or damage-control resuscitation approaches which give primary focus to hemorrhage control and balanced

blood product provision rather than prompt crystalloid loading [9,10].

The results of this review are consistent with several large observational studies that have found higher mortality with pre-hospital or early emergency department resuscitation with crystalloids [11-13]. In particular, multicenter trauma registry analyses have shown increased mortality in the early intravenous fluids group despite the adjustment for severity of injury and physiologic derangement [11,14]. On the other hand, others have also indicated that there are neutral or context-dependent effects in some cohorts especially where early resuscitation was restricted or selectively used [15,19]. The absence of a mortality advantage in the nationwide Japanese cohort using pre-hospital intravenous access as a surrogate for defining early resuscitation emphasizes the complexity of exposure definitions and is a reminder that intravenous access alone will not necessarily equate to harmful volumes of fluid [19].

The heterogeneity between studies captures significant differences in the populations of patients, patterns of injury, transport time, and definitions of early resuscitation operations. Pre-hospital environments differ greatly from one trauma system to another, affecting the decision of whether and how fluid administration will affect both the indication for it and its potential consequences [16,17]. Furthermore, observational designs are always prone to residual confounding, where in this case patients who receive early fluids could be more severely injured, despite statistical adjustment [18]. Even though some of the studies included applied propensity score matching and multivariable modeling, unmeasured confounders cannot be entirely ruled.

The reports of morbidity outcomes were not consistently reported in studies and could not be quantitatively combined. Available evidence suggests that early or high volume crystalloid resuscitation may be linked to adverse secondary outcomes, such as longer intensive care unit stays, higher risk of organ dysfunction, and poor functional outcomes [20,21]. The non-homogeneity of definitions of morbidity and the follow-up time, however, prevents the drawing of certain definite conclusions, pointing to the necessity of the standardization of reporting results of outcome in the future studies of trauma.

The findings of this review have important clinical implication. Although fluid resuscitation is still a vital part of trauma treatment, these findings justify a reluctant and personalized attitude to the early application of crystalloids, especially in those patients whose hemorrhage may be suspected. Current trends favor permissive hypotension, early control of hemorrhage and balanced transfusion strategies as opposed to liberal crystalloid use [8,9,22]. However, because of the observational nature of available evidence, this does not allow causal inference, and resuscitation strategies are patient-specific, based on physiology and injury patterns.

Limitations:

This study has several limitations that should be considered when interpreting the findings. To begin with, the quantitative synthesis procedure was solely built on observational cohort studies and causal inference is restricted by the lack of randomized controlled trials. Second, definitions of early fluid resuscitation varied between studies and included pre-hospital administration of crystalloid, early emergency department fluid loading and intravenous access as a proxy for early resuscitation, contributing to clinical heterogeneity. Third, despite the application of adjusted estimates and propensity score procedures in several studies, residual confounding related to injury severity, physiologic status and provider decision-making cannot be completely ruled out. Fourth, the outcome of morbidity was inconsistently reported and could not be quantitatively combined to make any other conclusion in addition to the outcome of mortality. Finally, formal assessment of publication bias was not feasible given the small number of included studies of the meta-analysis.

Implications for Future Research:

Future studies should focus on well-designed prospective studies to help elucidate the causal relationship between early fluid resuscitation strategies and outcomes in the trauma population presenting to the emergency department. Randomized controlled trials of restrictive versus liberal early crystalloid resuscitation, especially in patients with suspected hemorrhagic shock are

required in order to reduce confounding and specify more effectively on ideal timing and volumes thresholds. Such trials should include standardized resuscitation protocols and clear and specific exposure windows for each trial in order to ensure comparability across trauma systems.

Further studies should aim at harmonization of outcome reporting, especially morbidity endpoints such as organ dysfunction, functional status and long-term quality of life. More rigorous quantitative synthesis of other outcomes than mortality would be made possible with consistent definitions and follow-up periods. Also, future studies must examine the combination of the fluid resuscitation plans with other aspects of the trauma care such as early blood product administration, methods of controlling the bleeding and pre-hospital transportation duration.

Finally, research should investigate patient and injury-specific factors that may alter the impact of early fluid resuscitation including age, injury mechanism, traumatic brain injury and baseline physiologic status. Identifying subgroups of patients who may benefit from specific resuscitation approaches may help provide more personalized trauma care and provide evidence to develop clinical guidelines for practice.

Conclusion:

In trauma patients presenting at the emergency department, early or higher volume crystalloid fluid resuscitation is linked to increased mortality based upon pooled evidence from observational cohort studies. In spite of heterogeneity and residual confounding (which make it impossible to draw a causal conclusion), the similarity of the results in different trauma scenarios speaks in favor of the cautious and individualized use of the early administration of fluids. These findings highlight the necessity of having standardized prospective trials that can establish the best resuscitation timing and volume limits as well as inform evidence-based trauma treatment.

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