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Spinal Immobilization VS No-Immobilisation in Trauma Patients: A Systematic Review and Meta-Analysis

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Abstract

Background: Despite the common application of pre-clinical immobilisation in trauma patients for many years, the existing evidence for this intervention is still weak. The need for pre-clinical immobilisation and applying the right immobilisation procedures on the right trauma patients is still controversial in the scientific literature.

Objectives: This systematic review aims to compare different outcomes to answer whether the pre-clinical immobilisation of trauma patients is more effective than no pre-clinical Immobilisation and analyses it critically. Methods: A systematic literature search was conducted according to the PRISMA criteria in the PubMed and EMBASE databases with meta-analyses. We searched for randomized controlled trials (RCTs) and no randomized studies of intervention (NRSIs, both prospective and retrospective studies) comparing two different groups of trauma patients (pre-clinical immobilisation vs no pre-clinical immobilisation). We set no time or language limitations. Two reviewers screened the title/abstracts and the full-texts independently. We resolved any conflicts with discussion.

Results: We identified 2,726 studies from PubMed and EMBASE. After double stage screening, a total of 13 studies were included in the systematic review. Both spinal injuries (OR= 3.69, 95% CI from 1.82 to 7.49) and neurological deficits (OR= 2.67, 95% CI from 1.15 to 6.18) occurred in the pre-clinical immobilized patients significantly more often than non-immobilized. We found higher mortality (OR= 1.97, 95% CI from 1.12 to 3.46) and six times higher side effects (OR= 6.01, 95% CI from 2.880 to 12.91) in the group of pre-clinical immobilisation compared to the control.

Conclusion: Pre-clinical immobilisation seems unable to reduce the neurological deficits, mortality, or spine injuries in trauma patients than no-immobilisation. The side-effects of the intervention are higher than the control. The quality of evidence is low. Regarding this topic, there is a critical need for primary studies in general and randomized controlled trials in specific.

Keywords: Pre-Clinical; Spinal Immobilisation; Cervical Collar; Trauma

Abbreviations: ATLS: American's Advanced Trauma Life Support Policy: PHTLS: Prehospital Trauma Life Support Policy; OR: Odds Ratio; NAEMT: National Association of Emergency Medical Technicians; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Introduction

Immobilization of the spine generally and the cervical spine specifically has been an essential part of the pre-clinical management of trauma patients for decades [1,2]. This measure is based on the assumption that it minimizes the spine's mobility, reducing the assumed worsening of spinal cord injuries through the transport of the patients. Historically, spinal immobilisation using a spine board and a cervical brace in patients with suspected spinal injuries is since the 1960s a standard measure of the pre-clinical management of trauma patients [3]. Currently, both The American's Advanced Trauma Life Support Policy (ATLS) College of Surgeons as well as the Prehospital Trauma Life Support Policy (PHTLS) from the National Association of Emergency Medical Technicians (NAEMT) recommends the initial inline immobilisation in trauma patients until a cervical brace is in place. Upon closer inspection and interpretation of the guidelines, this measure (inline immobilisation) is considered partly equivalent to an airway safety device. According to the ABCDE scheme, cervical spine immobilisation in managing trauma patients is the same as assessing airways [4].

On the other hand, since the pre-clinical rescue team has no medically precise means to exclude spinal and spinal cord injuries, the team must judge the trauma mechanism and decide for or against the pre-clinical immobilisation. However, there is no unified guideline as a decision-making aid in this regard [5-7]. After all, the decision to perform the immobilisation cannot be alone based on these criteria, and there is still a huge controversy over how should be immobilized. In many situations, the pre-clinical emergency team takes the decision based on subjective judgment. And the supporting evidence of this practice is based only on weak studies or studies of healthy volunteers [8-11]. Some authors discussed that only a whole-body immobilisation has a meaningful therapeutic meaning for patients [8,9]. Still, whole-body immobilisation has several side effects, such as restricted lung function [12], difficult airway management [13], and increased intracerebral pressure [14,15]. So this systematic review aims to examine the evidence of spinal immobilisation and answer whether pre-clinical immobilisation is more effective than no immobilisation in trauma patients in reducing a worsening of the outcomes (neurological deficits, spine injuries, and mortality) that might result from a supposed spine injury. We assume that the pre-clinical spinal immobilisation of trauma patients brings no significant benefits but embodies unwanted side effects. The review question was set according to the PICO scheme and is shown in Table 1.

Patient	Patients of any age with penetrating or blunt trauma
Intervention	Pre-clinical application of cervical or spinal immobilisation through the emergency team
Control	No pre-clinical immobilisation of any type
Outcomes	Primary: neurological deficits determined through clinical examination at presentation in the treating hospital, Secondary: spine injuries determined through the complete clinical assessment in the treating hospital, mortality at the admission in the treating hospital, and the side-effects including any of the following: increased intracranial pressure, difficult intubation, unnecessary radiation, and pressure bruises.
Time	At the presentation and admission to the treating hospital
Setting	Pre-clinical emergency care
Study design	Randomized controlled trials (RCTs), and no randomized studies of interventions (NRSIs)

Table 1: Details of the review question per PICO.

Methods

We conducted a systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA statement 2020) [16]. The study protocol was prospectively published in the PROSPERO database under registration number CRD42021233704.

Inclusion and Exclusion Criteria

We included studies relevant to the research question, reported on spinal or cervical immobilisation in trauma patients of different age groups, exclusively in the pre-clinical setting, and compared two patient groups (immobilisation vs no immobilisation). There were neither time nor language limitations. Another inclusion criterion is the species of the study design. Since RCTs in evidence-based health care are the gold standard to explore an intervention research question [17], these were preferred. However, a lack of RCTs was anticipated by a primary search, so NRSIs were also included. Other study designs such as systematic reviews, case reports, and case series were excluded. Table 2 provides detailed in/exclusion criteria.

Inclusion criteria	Exclusion criteria
Human studies	Animal studies
Pre-clinical setting	Clinical, in-hospital setting
Trauma patients	Healthy volunteers
RCTs, NRSIs	Systematic reviews, case reports, case series

Table 2: Inclusion and exclusion criteria of the review.

Literature Search

We searched PubMed on 20 April 2021 and EMBASE on 08 May 2021. The search strategy was based on various keywords and MeShTerms (Medical Subject headings) directly related to the question. We used search terms such as ("Prehospital"), ("spinal trauma"), ("traumatic injury") AND ("Prehospital collar" OR" spinal immobili * "OR "No immobili *" OR "preclinical spine immobili *"). A medical librarian at the University of Jena checked the search strategy per the PRESS Guideline Statement [18].

Screening

We imported the citations of the search into the Covidence program. After removing the duplicates, two reviewers (SS and AM) screened the studies independently in two stages, first at the title/abstracts level and then as full texts per inclusion and exclusion criteria. If the reviewers came to a disagreement, an internal discussion followed, which was decided by consensus.

Data Extraction

One reviewer (SS) extracted data items into an excel spreadsheet, and another reviewer (AM) checked them in a second stage. Extracted data items were: study ID (name of the first author and year of publication), study design, patient group, type of trauma, type of immobilisation, sample size, number of patients in intervention and control arms, number of drop-outs, and outcome items.

Meta-Analysis

All statistical calculations for this work were done using StataCorp.2020.Stata Statistical Software: Release 17th College Station, TX: StataCorp LLC. We assumed that the treatment effect is due to real differences in treatment approaches in included studies and whose populations varied. Thus, a random-effects model was chosen to answer the research question in the context of a meta-analysis in systematic literature research [19]. As a random-effects model, we used for the primary and secondary outcomes the Sidik-Jonckman method [20]. We calculated the odds ratio (OR) for each outcome and its 95% confidence interval (95% CI). A value of OR equal to 1 means no differences in the outcome between the intervention and the control groups. Values greater than 1 indicate increasing Chances of outcomes in the immobilisation group, and values less than 1 mean that the chances of outcomes are greater in the no immobilisation group.

We also calculated the heterogeneity of the effect estimate (OR) among included studies and presented it as I^2 statistics (from 0% to 100%) [21]. This percentage indicates how much heterogeneity is due to true variability in the effect estimate between studies rather than chance. The results were shown as forest plots for each outcome, with each study represented a small box. The size of the box represents the statistical significance of the associated study. The boxes are shown around a vertical line, "no-effect line". The overall result of the meta-analysis is presented as a diamond (marked green). The width of the diamond represents the confidence interval of the final result [22].

Results

Results of Search

We found thirteen studies that met the inclusion and exclusion criteria. Figure 1 shows the PRISMA flow chart of the literature search. There were two separate studies published in 2009 using the same population. In the first report, the authors aimed to determine whether there was a link between the pre-clinical cervical spine immobilisation and mortality in patients with penetrated neck trauma. The authors examined a total of 153 trauma patients from the New Orleans Charity Hospital [23]. The authors explored the relationship between cervical immobilisation and the resulting neurological sequelae in trauma patients in the second report. However, they used the same population as the first study plus a small group of patients (43 Patients) from Hurley Hospital [24]. Using the same patient group for several studies is inherently legitimate, but using them in the systematic review and meta-analysis is statistically incorrect. Thus, we included the two reports as one study with the two outcomes (mortality and neurological deficits).

We divided another report into two sub-studies and included them in the meta-analysis [25]. This study compared two patient groups using a pre-clinical protocol for selective spinal immobilisation. According to this protocol, a group of patients was classified as positive for pre-clinical immobilisation, and the second one was judged negatively. Positive and negative assessment groups were divided into two subgroups (pre-clinical immobilisation vs no pre-clinical immobilisation). Because of this subdivision, we divided it into two sub-studies to reduce the risk of bias.

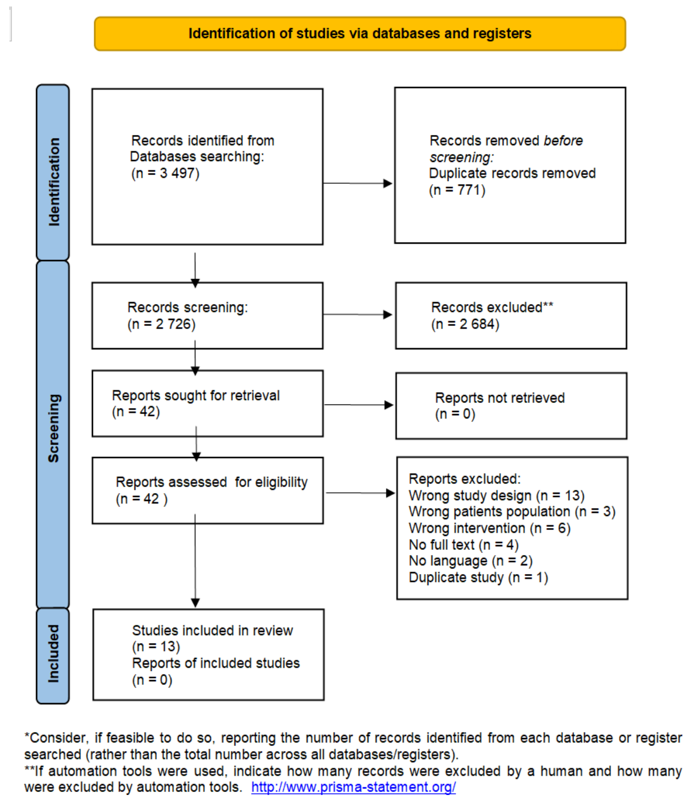

Figure 1: PRISMA flow chart.

Characteristics of Included Studies

Table 3 provides an overview of the included studies and their most important properties. As expected by our primary search, there was a lack of randomized controlled trials. Thus, we included eleven retrospective and two prospective studies. Most studies reported on pre-clinical immobilisation in adults. Only four studies included two age groups (adults and children), and one study reported exclusively on pre-clinical immobilisation in children [26]. Another study did not give any age specification [27].

Study ID	Study design	Age group (year)	Type of trauma	Type of immobilisation
Hauswald M [5]	R	adult	Blunt	Spinal
Kapus KR, et al. [28]	R	adult	Penetrating	cervical
Burton JH, et al. [29]	R	(0 -109)	Blunt	cervical or spinal
Domeier RM, et al. [25]	P	(0 – 104)	Blunt	Spinal
Vanderlan WB, et al. [24]	R	(> 17)	Penetrating	spinal
Haut ER, et al. [30]	R	(>= 0)	Penetrating	cervical
Lin HL, et al. [31]	R	(10 -96)	Blunt	cervical
Leonard JC, et al. [26]	P	(< 18)	Blunt	cervical or spinal
Postma ILE, et al. [27]	R	NA	Blunt or penetrating	cervical or spinal
Schubl SD, et al. [32]	R	adult	Penetrating	spinal
Tatum JM, et al. [33]	R	(>= 18)	Blunt	cervical
Drain J, et al. [34]	R	adult	Blunt or penetrating	cervical
Asha ES, et al. [35]	R	adult	Blunt	cervical

R= Retrospective Design, P= Prospective Design.
Table 3: Characteristics of included studies.

Primary Outcome

Of the thirteen included studies, only four provided information on neurological deficits (indicating any failure of neurological function such as impaired consciousness, paraplegia, complete quadriplegia or sensibility disturbance). The overall pooled effect estimate indicates that pre-clinical immobilisation is associated with neurological deficits almost three times more in patients with trauma than no immobilisation. Although the I^2 statistics are 72%, the amount of true heterogeneity could be attributed to the fact that only one study differs significantly from the others [32], as shown in Figure 2.

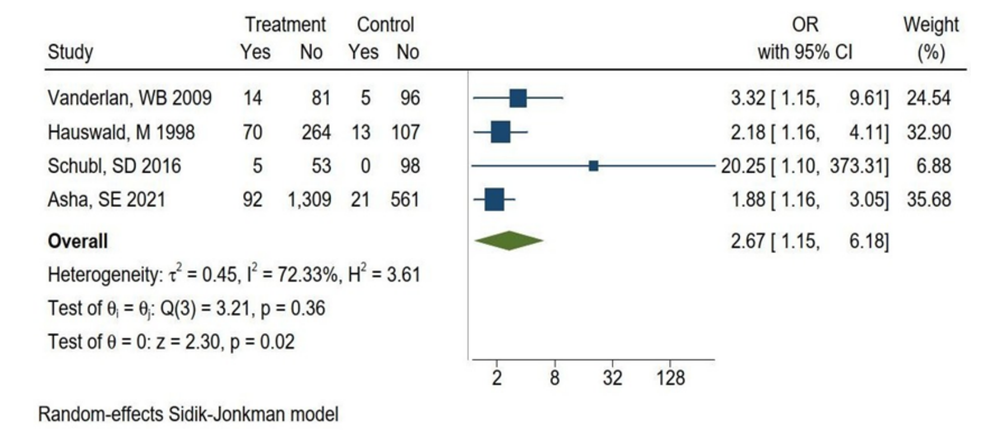

Figure 2: Forest plot of the primary outcome (neurological deficits).

Secondary Outcomes

Spine injuries were also more common in the intervention group (OR= 3.69 and 95%CI from 1.82 to 7.49), as shown in Figure 3. The mortality was also almost twice higher in the intervention group (OR= 1.97 and 95% CI from 1.12 to 3.46). The heterogeneity was less than observed in the primary outcome with I^2 statistics of 45%, as shown in Figure 4. On the other hand, the side-effects were significantly higher in the immobilisation group (OR= 6.01 and 95% CI from 2.80 to 12.91). These side-effects included unnecessary radiation through computer tomography, difficult or false intubation (Figure 5).

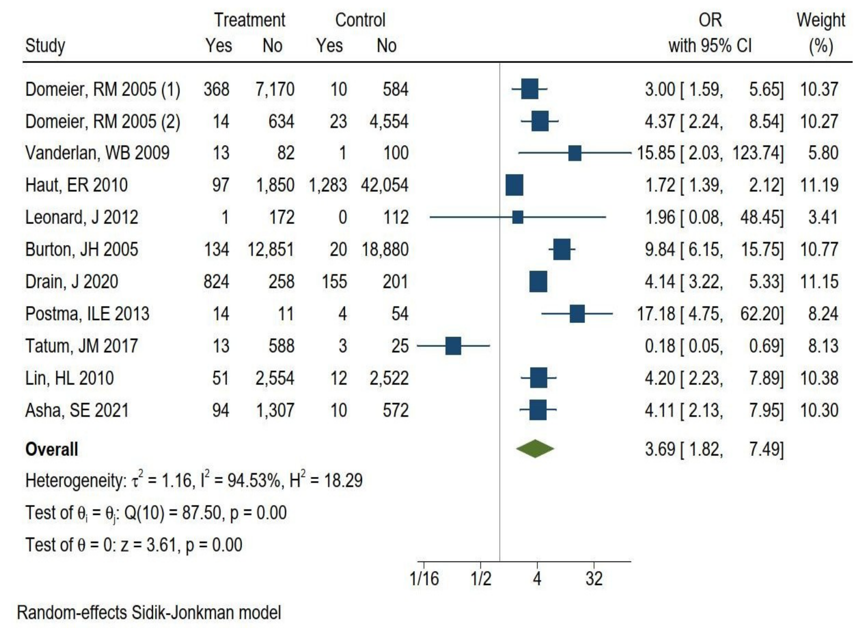

Figure 3: Forest plot of the secondary outcome (spine injuries).

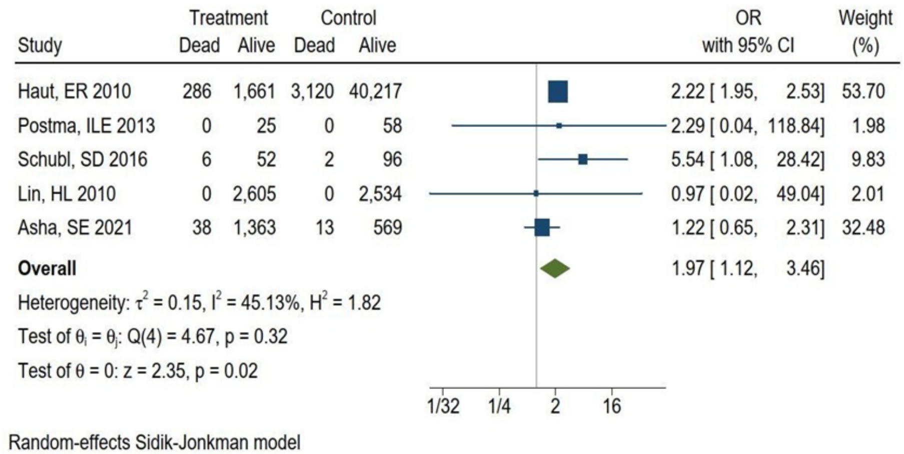

Figure 4: Forest plot of the secondary outcome (mortality).

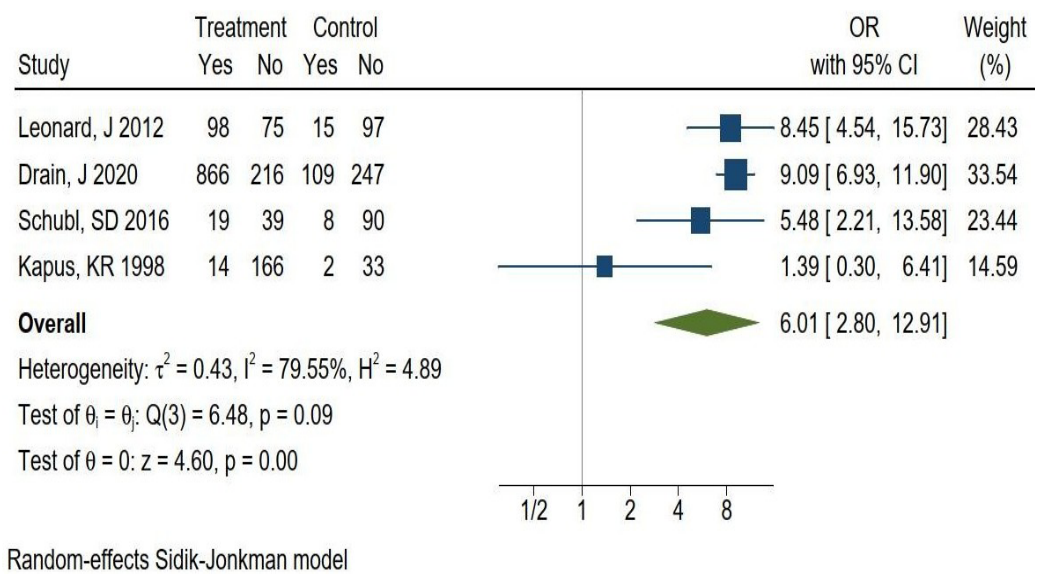

Figure 5: Forest plot of the secondary outcome (side-effects).

Discussion

This report is the first systematic review that includes a meta-analysis of different outcomes related to pre-clinical spinal or cervical immobilisation compared to no immobilisation to the best of our knowledge. All previous reviews were critical or included only a subgroup of patients. Our review showed that pre-clinical spinal immobilisation of trauma patients is accompanied by higher neurological deficits, mortality and spine injuries than no immobilisation. This observation could be attributed to the fact that most pre-clinical emergency teams tend to apply this intervention on patients who would have spine injuries, which predispose those patients to more neurological deficits and deaths. And since we could not be able to find RCTs, these observations are inherited with the risk of selection bias of NRSIs. However, this risk of bias was low in the pioneered study of Hauswald, who found that pre-clinical spinal immobilisation of blunt trauma patients brings no or only a minimal effect on the neurological outcomes. Although it was an observational study, the fact of choosing two places with different pre-clinical management approaches (one with and another without immobilisation) leaves little space for selection bias.

On the other hand, our results showed that the side-effects are more common in patients with immobilisation which the selection bias could not influence. More side-effects in the immobilisation group were also noted in a study by

Mobbs and a review by Nunez-Patino. They reported an association between cervical spine immobilisation and increased intracranial pressure after head injury [14,15]. Applying pre-clinical spinal immobilisation is still based on emergency teams' subjective judgment with no strong evidence. Although the sole application of the cervical brace has been obsolete for a long time [8], this systematic review included six studies where this measure was the only immobilisation technique. That means the difference between immobilisation and restriction of movement for the emergency personnel is still unclear, indicating that relying on emergency teams' subjective judgment is insufficient.

Our review showed a great amount of heterogeneity in reporting the outcomes among included studies. This attributed to including different subgroups per trauma type and age. Regarding the trauma subtype, all included studies in this review showed the negative effect of pre-clinical spinal immobilisation in penetration trauma patients, in line with the new Danish guidelines [36]. All other previous reviews about pre-clinical immobilisation found no RCTs investigating its effect on trauma patients and concluded the uncertainty of applying this intervention to improve the outcomes.

Our review has some limitations. The search strategy was not applied comprehensively. However, we searched the two Cochrane recommended databases (Medline and Embase). We think that extending the search databases would not change the overall conclusions of this review. Another limitation is not conducting a risk of bias evaluation or grading of the evidence [37,38]. However, finding no RCTs will automatically downgrade the certainty of the evidence of the efficiency of pre-clinical immobilisation.

Conclusion

Pre-clinical spinal immobilisation seems ineffective in reducing the neurological deficits, spine injuries or mortality in trauma patients than no-immobilisation. Still, the side-effects of this intervention are six times higher than no care [39]. Due to the low quality of the included studies (retrospective and prospective) and the inherited risk of selection bias, the quality of evidence for this research question is still low or very low. Further primary studies in medical research of high quality with randomization process are needed. Considering the ethical issues, randomized controlled trials in trauma patients who are conscious, cooperative and with no obvious signs of spinal injuries are justified. Moreover, because of the noticeable heterogeneity in the meta-analysis, exploring the effect of pre-clinical immobilisation should also take the subgroups of the study population (children vs adult), the type of trauma (blunt vs penetrating), and the severity and cause of the accident mechanism into consideration.

Declarations

Funding: no funding was obtained for this research
Conflicts of interest: The authors declare that they have no conflict of interest.
Availability of data and material: all data and material used in this study are available for sharing with researchers
Code availability: at request from corresponding author
Authors' contributions: SS is the principal author; she designed the protocol of the review, served as the first reviewer and drafted the main manuscript, AM is the corresponding author; he served as the second reviewer, conducted the meta-analysis, and contributed to editing the manuscript, JW is the senior author, he reviewed the final version of the manuscript.
Ethics approval: not applicable
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Consent for publication: not applicable
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