

Effectiveness of the use of bedrails in preventing falls among hospitalized older adults: a systematic review protocol

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Review question/objective

The objective of this review is to identify the effectiveness of the use of bedrails in preventing falls among hospitalized older adults when compared with no use of bedrails or any type of physical restraints.

More specifically, the review will focus on the following questions:

- What is the effectiveness of the use of bedrails in preventing falls among hospitalized older adults when compared with no use of bedrails?
- What is the effectiveness of the use of bedrails in preventing falls among hospitalized older adults when compared with no use of physical restraints?

Background

Falls are a major problem today affecting people of any age, but they have an increased importance in the elderly. They are the leading cause of injury or death among older adults.¹ A fall can be defined as an event whereby an individual comes to rest on the ground or another lower level with or without loss of consciousness.²

Direct consequences of a fall can vary from bruises and minor injuries (28%) to severe wounds of the soft tissues (11,4%) and bone fractures (5%).³ Moreover, falls can induce a fear of future falls, leading

to a decrease in function and an increased dependency on care,⁴ increased length of stay in hospital⁵ and higher risk of institutionalization. Falls have a significant impact not only on the quality of life of the older person, but also on their families and society as a whole, resulting in an increase in healthcare costs.⁶

The causes of falls are complex and multifactorial. They are associated with an individual patient's health issues, treatment, disabilities, mental state, behavior and environment.⁷ Hospitalized older people are particularly vulnerable to falls. In hospital, approximately 2% to 12% of patients experience at least one fall during their hospital stay.⁸⁻⁹ The incidence of falls in hospitals shows great variability (2.2-17.1% falls per 1000 patients days), depending on ward type and hospital population.¹⁰⁻¹¹ A significant proportion of falls (up 22%) in acute hospitals occur from beds.¹² There were around 44,000 reports to the *National Reporting and Learning System* (UK), between 1 September 2005 and 31 August 2006, of patients who appeared to have fallen from the bed in acute and community hospitals, mental health and learning disability units.⁷ Of this number around 90 patients fractured their neck of femur, and 11 patients died as a result of their falls.

The prevention of falls is commonly considered an indicator of quality of care. Therefore, health institutions and professionals treat the identification and implementation of strategies to prevent or minimize their effects as a high priority.

Fall prevention interventions involving physical restraints are still common and considered a primary preventative measure, despite controversy in their use, and the increase in technological alternatives.¹³ Restraint is defined as "a mechanism used to control or modify a person's behavior".^{14(p.100)} On the one hand, the restriction of movement firstly can lead to aggression, with more serious consequences than the fall itself. Second, restricting people's actions may infringe upon their basic rights and dignity. Protection and promotion of a respect for autonomy, integrity and dignity among older adults must be considered in the decision-making process regarding when to use restraints,¹⁵ and nurses from clinical practice should consider a solid rationale before authorizing their use.

One of the most frequently used restraint interventions are bedrails,^{14,16} (also called side rails, cotsides or safety rail⁷) and as a restraint is defined as the use of two full rails or four half-rails. Prevalence in use of bedrails in hospitals ranges from 8 to 64%.^{7,17-19} However, bedrails can be also classified as non-restrictive.²⁰ The argument for the effectiveness of bedrails is contradictory. In some cases bedrails are justified both ethically and legally, and therefore not considered a restraint restriction,²¹ for example, in situations where the bedrails are implemented at the request of the person, in order to feel safe or to support their movement.²¹ However, if the bedrails purposefully stop a patient from leaving their bed, this may be classed as a form of restraint.²²

In spite of the extensive use of bedrails to prevent falls in care, there have been serious incidents reported to the MHRA (Medicines and Healthcare Products Regulatory Agency)¹⁶ directly related to the use of bedrails where reports have suggested that the use of bedrails could result in serious injuries and even death.²⁵⁻²⁶ Of the reports of falls from beds made to the National Reporting and Learning System, 61% did not include information on whether bedrails were in use or not, 8% stated that the falls occurred when bedrails were being used, and 31% stated that bedrails were not in use when the falls occurred.⁷

The question of the effectiveness of bedrails to prevent falls cuts across all societies and cultures with a significant meaning to the clinical practice of nurses. These are professionals who implement the

intervention with this goal, often with mixed feelings.²⁸ Nursing staff and patients' families are often confronted with feelings of guilt and anxiety.²⁸

Reviews previously conducted on the subject of restraint did not focus specifically on bedrails or their use on the older population. They pointed out limitations such as the poor quality of studies and found little evidence to answer the question of the effectiveness of bedrails in preventing falls/injury. For example, a Joanna Briggs Institute (JBI) review of the effectiveness of physical restraint in reducing falls did not address bedrails as a specific intervention.¹³ Another example is a Cochrane review titled "Interventions designed to prevent healthcare bed-related injuries in patients".²⁹ The evidence base at last review could not conclude with any definitive evidence on the effectiveness due to limitations and poor predictive power. Even though research on restraint use in general has been given considerable attention since the mid-1980s,³⁰ research which specifically addresses the use of bedrails has been limited.³¹ This review will attempt to review the literature base beginning from 1980 and see if the evidence has become more definitive.

Keywords

Bedrails; Hospital; Hospitalized; Aged; Elderly; Falls; Side rails; Cot sides; Safety rail

Inclusion criteria

Types of participants

The quantitative component of this review will consider studies that include hospitalized adults (female and male), 65 years and over with any clinical condition in a non-intensive care unit (ICU).

Types of intervention(s)/phenomena of interest

The quantitative component of the review will consider studies that evaluate the use of bedrails as a restraint to prevent falls among older adults in non-ICUs compared to no use of bedrails or any type of physical restraints, for example: bedrails versus no bedrails, and bedrails versus no wrist or ankle ties.

Types of outcomes

This review will consider studies that include the following outcome measures:

Primary outcomes – Number of patients who fall or the number of falls per patient.

Secondary outcomes – Number of head trauma, bone fractures or soft tissue injuries.

Types of studies

The quantitative component of the review will consider any randomized controlled trials (RCTs) that examine the effectiveness of the use of bedrails in preventing falls among hospitalized older adults when compared with no use of bedrails or any type of physical restraints.

In the absence of RCTs, other research designs of a quantitative nature, such as non-randomized controlled trials, before and after studies, cohort studies, case control studies, descriptive studies, case series/reports and expert-opinion, will be considered for inclusion to enable the identification of current best evidence regarding the effectiveness of the use of bedrails in preventing falls among hospitalized older adults when compared with no use of physical restraints.

Search strategy

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in Portuguese, English and Spanish will be considered for inclusion in this review. Studies published between 1980 and 2014 will be considered for inclusion in this review.

The databases to be searched include:

CINAHL

PsycINFO

Web of Science™ Core Collection

Cochrane Central Register of Controlled Trials

MEDLINE

Scielo

MedicLatina,

Academic Search Complete

Nursing & Allied Health Collection: Comprehensive

The search for unpublished studies will include:

RCAAP - Repositório Científico de Acesso Aberto de Portugal

Banco de teses da CAPES (www.capes.gov.br)

ProQuest – Nursing and Allied Health Source Dissertations

“Grey Literature Report” from New York Academy of Medicine

Initial keywords to be used will be:

Bedrails

Hospital

Hospitalized

Aged

Elderly

Falls

Side rails

Cot sides

Safety rail

During the process of conducting the search, various terminology and spelling of keywords will be taken into consideration as they might affect the identification of relevant studies.

Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data extraction

Quantitative data will be extracted from papers included in the review independently by two reviewers using the standardized data extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. For missing information or data that needs clarification, the authors of primary studies will be contacted. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data synthesis

Quantitative papers will, where possible, be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square and also explored using subgroup analyses based on the different study designs, comparator or patient clinical condition. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Conflicts of interest

The authors declare that there are no conflicts of interest.

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Appendix I: Appraisal instruments

MAStARI appraisal instrument

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer Date

Author Year Record Number

| | Yes | No | Unclear | Not Applicable |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. Was the assignment to treatment groups truly random? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Were participants blinded to treatment allocation? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Was allocation to treatment groups concealed from the allocator? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Were the outcomes of people who withdrew described and included in the analysis? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Were those assessing outcomes blind to the treatment allocation? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Were the control and treatment groups comparable at entry? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Were groups treated identically other than for the named interventions | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Were outcomes measured in the same way for all groups? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Were outcomes measured in a reliable way? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Was appropriate statistical analysis used? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Overall appraisal: Include Exclude Seek further info.

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer Date

Author Year Record Number

| | Yes | No | Unclear | Not Applicable |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. Was study based on a random or pseudo-random sample? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Were the criteria for inclusion in the sample clearly defined? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Were confounding factors identified and strategies to deal with them stated? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Were outcomes assessed using objective criteria? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. If comparisons are being made, was there sufficient descriptions of the groups? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Was follow up carried out over a sufficient time period? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Were the outcomes of people who withdrew described and included in the analysis? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Were outcomes measured in a reliable way? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Was appropriate statistical analysis used? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

Reviewer Date

Author Year Record Number

| | Yes | No | Unclear | Not Applicable |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. Is sample representative of patients in the population as a whole? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Are the patients at a similar point in the course of their condition/illness? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Has bias been minimised in relation to selection of cases and of controls? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Are confounding factors identified and strategies to deal with them stated? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Are outcomes assessed using objective criteria? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Was follow up carried out over a sufficient time period? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Were the outcomes of people who withdrew described and included in the analysis? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Were outcomes measured in a reliable way? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Was appropriate statistical analysis used? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Overall appraisal: Include Exclude Seek further info.

Comments (Including reason for exclusion)

Appendix II: Data extraction instruments

MAStARI data extraction instrument

**JBI Data Extraction Form for
Experimental / Observational Studies**

Reviewer Date

Author Year

Journal Record Number

Study Method

RCT Quasi-RCT Longitudinal
 Retrospective Observational Other

Participants

Setting _____

Population _____

Sample size

Group A _____ Group B _____

Interventions

Intervention A _____

Intervention B _____

Authors Conclusions:

Reviewers Conclusions:

Study results

Dichotomous data

| Outcome | Intervention () number / total number | Intervention () number / total number |
|---------|---|---|
| | | |
| | | |
| | | |
| | | |

Continuous data

| Outcome | Intervention () number / total number | Intervention () number / total number |
|---------|---|---|
| | | |
| | | |
| | | |
| | | |