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Review

Adverse events related to physical restraint use in intensive care units: A review of the literature

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ABSTRACT

Physical restraints are widely used and accepted as protective measures during treatment in intensive care unit (ICU). This review of the literature summarizes the adverse events and outcomes associated with physical restraint use, and the risk factors associated with their use during treatment in the ICU. The PubMed, Scopus, and Google Scholar databases were screened using predefined search terms to identify studies pertaining to adverse events and/or outcomes associated with physical restraint use, and the factors associated with their use in adult patients admitted to the ICU. A total of 24 articles (including 6126 patients) that were published between 2006 and 2022 were identified. The described adverse events associated with physical restraint use included skin injuries, subsequent delirium, neurofunctional impairment, and a higher rate of post-traumatic stress disorder. Subsequent delirium was the most frequent adverse event to be reported. No alternative measures to physical restraints were discussed, and only one study reported a standardized protocol for their use. Although physical restraint use has been reported to be associated with adverse events (including neurofunctional impairment) in the literature, the available evidence is limited. Although causality cannot be confirmed, a definite association appears to exist. Our findings suggest that it is essential to improve awareness regarding their adverse impact and optimize approaches for their detection, management, and prevention using protocols or checklists.

Introduction

Physical restraints are used and accepted as presumed protective measures for intensive care unit (ICU) patients worldwide.[1,2] They are used with the aim of enhancing patient safety and preventing the removal of devices, self-extubation, and potential falls.[2] However, there is considerable conflict among findings from different studies. Some studies that compared restrained and unrestrained critically ill patients suggested that they offer benefits by lowering mortality without increasing signs of physical harm.[1,3,4] Conversely, a number of studies (mainly, but not exclusively in the psychiatric setting), have shown that physical restraints may be associated with various complications and adverse outcomes.[5–8] In the intensive care setting, they may increase the risks of agitation, self-extubation, and device removal, and may lead to higher rates of nosocomial infection, deep venous thrombosis, prolonged hospital stay, and mortality.[9–11] They may also increase the prevalence of post-traumatic stress disorder (PTSD) in ICU survivors.[12–14] Certain patient-related factors including older age, administration of mechanical ventilation, nurse-to-patient ratios, and delirium are associated with an increased need for physical restraint use.[1,10,15] Conversely, early mobilization and prompt pharmacological management of delirium have been found to lower their use in the ICU setting.[16,17] Although the data pertaining to physical restraints are limited and conflicting, they are frequently used in the ICU. As few studies have evaluated their impact on patient outcomes, this literature review aimed to identify and describe specific adverse events and outcomes associated with physical restraint use. The review also aimed to

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determine and evaluate risk factors for their use during ICU management. In order to identify suitable studies, predefined search terms, namely, "physical restraint," "intensive care," "complications," "outcomes," and "risk" were used to screen the PubMed, Scopus, and Google Scholar digital databases for published articles; the process of study selection is shown in Supplementary document 1. Studies that involved the treatment of adult patients in the ICU were included. As outlined in Figure 1A, the level of evidence for the reported specific adverse events and outcomes (associated with physical restraint use) was quantified for each identified and included study; this was performed by two reviewers (Sebastian Berger and Raoul Sutter) according to the guidelines of the Oxford Centre for Evidence-Based Medicine Levels of Evidence Working Group.[18] The risk of bias was assessed (as appropriate) using the Risk Of Bias in Non-Randomized Studies – of Interventions (ROBINS-I) tool, which has been developed by the Cochrane Bias Methods and Cochrane Non-Randomized Studies for Interventions Methods groups.[19] The Risk of Bias (version 2) tool of the Cochrane group was used for randomized trials.[20] In this context, the ROBINS-I tool evaluates bias in non-randomized studies across seven domains. A full description of the methods can be found in Supplementary document 2.

A total of 24 articles that included 6126 patients and were published between 2006 and 2022 were included in this review. Most studies originated from North America, Europe, and Asia;

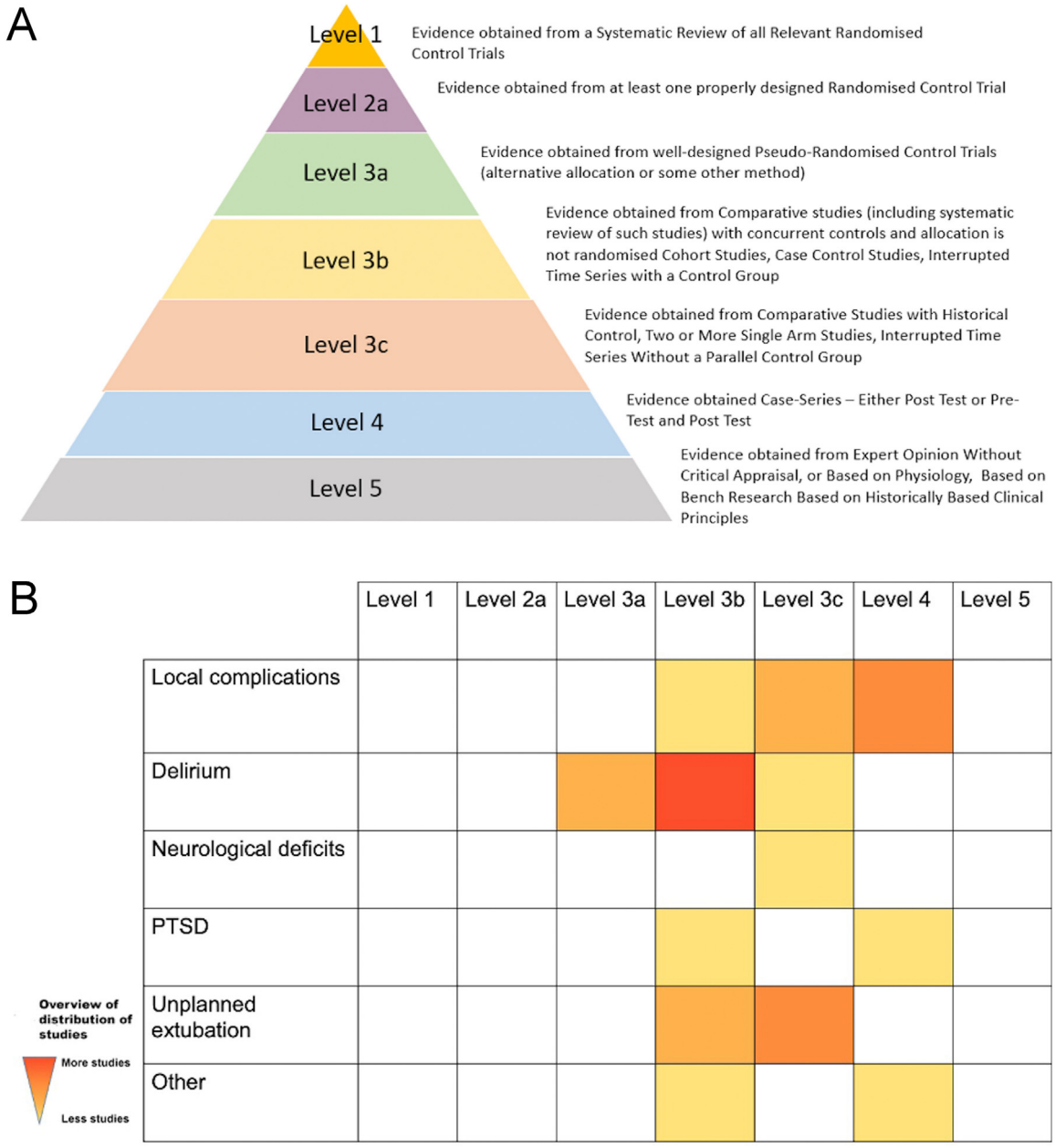

Figure 1. Level of evidence of included studies. A: Quantification of levels of evidence of included studies according to the guidelines of the Oxford Centre for Evidence-Based Medicine Levels of Evidence Working Group.[18] B: Heatmap of the levels of evidence regarding specific adverse events associated with physical restraint use in the ICU.
ICU: Intensive care unit; PTSD: Post-traumatic stress disorder.

Table 1
Main findings of included studies.

Complications	Numbers of patients included	Reported frequencies, odds, hazards, and IRRs for physical restraint use
Local complications 2005–2022[23–28]	1102 patients from 30 ICUs	Increased OR for pressure injuries (OR=6.03, 95% CI: 1.52 to 23.96)[23] AND Increased frequency of redness, edema, bruising, and skin necrosis[24–28]
Subsequent delirium 2009–2021[10,21,30-34,51]	2093 patients from 25 ICUs	Increased OR for development of delirium (OR=2.9, 95% CI: 1.3 to 6.5 to OR=45.02, 95% CI: 1.4 to 1411.5)[31,33] AND Increased HR for delirium (HR=1.87, 95% CI: 1.33 to 2.63)[21] AND Increased frequency of delirium[10,30,32,34,51]
Neurofunctional decline 2021[35]	101 patients from 1 ICU	Increased odds of higher modified Rankin scale at discharge (OR=3.54, 95% CI: 1.05 to 13.06)[35]
PTSD 2007–2010[12,13]	336 patients from 6 ICUs	Increased frequency of PTSD[12,13]
Unplanned extubation or device removal 2008–2019[9,22,36-38]	1430 patients from 55 ICUs	Increased IRR for any device removal or extubation (IRR=8.27, 95% CI: 2.07 to 33.08)[22] AND Increased frequency of device removal and unplanned extubation[9,36-38]
Other 2004–2020[9,11,22,39]	1171 patients from 53 ICUs	Increased odds of benzodiazepine and opioid use (OR=2.33, 95% CI: 1.58 to 3.44)[11] AND Increased IRR for benzodiazepine use (IRR=1.07, 95% CI: 1.01 to 1.13)[22]

CI: Confidence interval; HR: Hazard ratio; ICU: Intensive care unit; IRR: Incident rate ratio; OR: Odds ratio; PTSD: Post-traumatic stress disorder.

no studies could be identified from Australia or South America. The number of patients varied markedly across different countries (Figure 2).

Only one study was a randomized controlled trial[21]; 10 studies had a prospective cohort, 5 studies had a retrospective cohort, and 6 studies had a case-control study design, respectively. Two studies were post hoc analyses of data from randomized controlled trials.[10,22] A heatmap of the available evidence regarding specific adverse events associated with physical restraint use is shown in Figure 1B.

Local Complications

Local skin and/or subcutaneous injuries related to restraint use were described in five retrospective (or cross-sectional)[23–27] and one prospective study[28] that included a total of 1102 patients from 30 ICUs (Table 1).

The highest level of evidence (although limited) was available from a retrospective cohort study in which patients received therapeutic temperature management after cardiac arrest (Figure 1A: evidence level 3b); the findings suggested that the use of physical restraints led to a 6-fold increase in the likelihood of pressure injuries.[23] These results need to be interpreted with caution due to potential confounding by the use of a cooling device, lack of protocols for restraint usage, and the retrospective single-center design.[23] A total of three cross-sectional studies offered further evidence (Figure 1A: level 4); they reported the development of skin and/or subcutaneous lesions such as bruising, redness, ulcers, skin necrosis, and limb edema in up to 30% of patients.[24,26,27] However, causality based on the Bradford Hill criteria[29] could not be inferred, as the studies did not report on control groups and could not establish a clear temporal association.[24,26,27] In contrast to the findings from these studies, there was one study reporting no differences between restrained and non-restrained patients in terms of skin injuries.[25] However, the scope of the study was limited by the observational single-center design. A detailed summary of all included studies can be found in Supplementary Table S1.

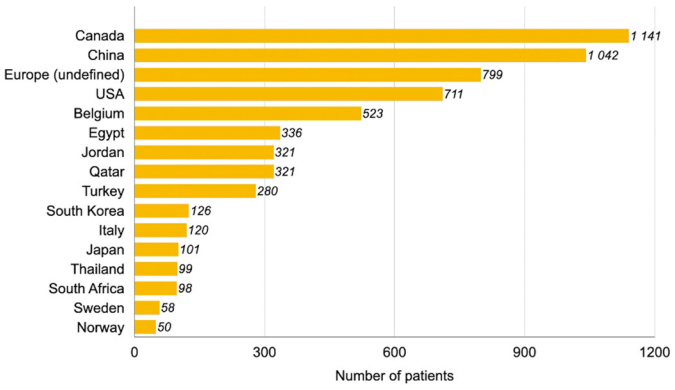

Figure 2. Number of patients per country.

Subsequent Delirium

Delirium was the most frequently reported complication among eight studies that included 2093 patients from 25 ICUs (Table 1). Four prospective studies clearly stated that the restraints were used before the emergence of delirium.[30–33] However, patients in most studies were screened for delirium only once a day during the duration of ICU stay. In addition, a considerable number of patients had neurological deficits, which may have further impeded the detection of delirium.

The strongest evidence (Figure 1A: level 3a) was offered by one randomized controlled trial that included a general ICU population. The study compared patients who received sedation as per protocol, with or without daily interruption; the restrained patients demonstrated a higher risk of delirium.[21] The study appears to provide a high level of evidence, as patients were screened daily using three clinical neurologic scoring systems, namely, the Richmond Agitation Sedation Scale, the Sedation Agitation Scale, and the Intensive Care Delirium Screening Checklist. However, patients who developed delirium prior to the use of restraints were not categorically excluded from this study.[21] This may have influenced risk analysis in terms of the impact of physical restraints on delirium (Figure 1A: evidence level 3a). In addition to this study, five prospective studies that included patients from the general ICU,[30,34] cardiology

and cardiac surgery ICU,[31] and neurological ICU,[32] and those with acute stroke,[33] demonstrated physical restraint use to be associated with a higher likelihood of delirium (Table 1). The notable limitations of these studies include their small sample size, single-center design, and the lack of definitive protocols for sedation and physical restraint use. The details pertaining to all included studies have been summarized in Supplementary Table S2.

Subsequent Neurofunctional Decline

A retrospective study (Figure 1A: evidence level 3c) that included 101 patients with subarachnoid hemorrhage (Table 1) reported a neurofunctional decline to be another potential complication associated with physical restraint use. The decline was defined by a higher modified Rankin score at discharge.[35] The findings suggested that the repeated and prolonged use of restraints increased the likelihood of neurofunctional decline, as quantified by a higher Rankin score at hospital discharge.[35] No information was available regarding the use of sedation or protocols for the use of restraints; this potentially led to unmeasured residual confounding. A detailed summary of all included studies can be found in Supplementary Table S3.

PTSD

Two studies (one each with prospective and retrospective cohort designs) that included a total of 336 patients treated across six different ICUs (Table 1) described PTSD as another potential complication of restraint use.[12,13] PTSD had developed in patients who received physical restraints, and this was particularly evident in cases where appropriate sedation was not administered and the patients were able to recall being restrained (Figure 1A: evidence levels 3b and 4). However, a close temporal association was not reported and the authors mentioned the possibility of selection bias, as many patients who experienced PTSD may not have reported any symptoms or were lost to follow-up. A detailed summary of all included studies can be found in Supplementary Table S3.

Unplanned Extubation and Device Removal

In most studies, restraint use was primarily indicated to prevent unplanned extubation or device removal. Five studies that included 1430 patients from 55 ICUs found a higher rate of self-extubation and device removal in restrained patients (Table 1).[9,22,36-38] One of these studies[22] involved a secondary analysis of data from a prospective cohort study[11] that included 711 mechanically ventilated patients from 51 ICUs across Canada. The findings demonstrated a higher incident-risk ratio for device removal in restrained as compared to unrestrained patients. Four further studies reported a higher frequency of device removal in restrained patients.[9,36–38] However, a causal relationship between physical restraint use and device removal or self-extubation could not be established (Figure 1A: evidence levels 3b to 3c). A detailed summary of all the included studies can be found in Supplementary Table S4.

Other Potential Adverse Events

Other potential adverse events reported from three previously mentioned studies included more frequent use and higher dosing of sedatives in restrained patients (Table 1).[10,11,22] In a post hoc analysis of data from a randomized trial,[21] restraint use increased the likelihood of administration of benzodiazepines, opioids, atypical antipsychotics, and haloperidol.[10] A prospective study that included 712 patients from 51 ICUs across Canada also reported higher incident-risk ratios for opioid, antipsychotic drugs, and benzodiazepine administration in restrained patients.[11] However, a causal relationship between restraint use and increased administration of specific drugs could not be established based on the findings from these studies. This may be attributed to the fact that several Bradford Hill criteria[29] were not fulfilled, including the lack of a clear temporal association and correction for potential confounders (as agitated/delirious patients may be restrained and sedated as a consequence of delirium). A detailed summary of all included studies can be found in Supplementary Table S4.

Physical Restraint Use and Associated Outcomes

Our review identified one study that reported specific outcomes associated with physical restraint use. The study cohort included 430 patients from a general ICU who received mechanical ventilation; restrained patients demonstrated a higher mortality rate. However, a causal relationship could not be established as the study was a post hoc analysis.[10]

Standardized and Protocol-Based Use of Physical Restraints

A standardized and protocol-based procedure for physical restraint use was identified in one case-control study.[9] The limited evidence (Figure 1A: level 3c) reflects the lack of standardized protocols (for restraint use in ICUs) in routine clinical practice. This limitation is evident from another cross-sectional study, in which minimal documentation is available regarding the indications for physical restraint use or alternative methods.[39] None of the identified reports had adequately discussed the available alternatives to physical restraints.

Reported Risk Factors for the Use of Physical Restraints

Seven studies reported numerous potential risk factors for the use of physical restraints (Supplementary Tables S1-S4).[9,10,22,24,26,27,39] One cross-sectional study, which included 321 patients who received mechanical ventilation, reported young age, duration of ICU stay, larger ICU capacity, high patient-to-nurse ratios, night shift periods, and the conscious state to be associated with restraint use.[24] Conversely, another cross-sectional study revealed a correlation between increased age and physical restraint use.[26] In yet another cross-sectional study, younger nurses were found to use restraints more frequently.[27]

Notably, a post hoc analysis of data from a randomized trial (that included 430 mechanically ventilated patients from a general ICU) found alcohol abuse to be associated with a lower like-

lihood of restraint use.[10] However, no further identified studies confirmed these findings.

A secondary analysis of data from a prospective cohort study (that included 711 patients treated in 51 ICUs across Canada) found no association between age or dementia and the use of restraints.[22] A cross-sectional study that included 58 neurosurgical patients found that a higher proportion of patients were restrained in the ICU than in intermediate care units or general wards.[39] Although the findings are of particular interest, the levels of evidence for these potential risk factors were low (Figure 1A: 3a to 4); this may be attributed to the lack of reliable statistical analysis and potentially severe confounding by different patient and environmental factors.

Discussion

In this review, we assessed the potential risk of adverse events among patients in whom physical restraints were used during ICU stay. The identified evidence (including that pertaining to various adverse events and risk factors) was of variable quality, and mostly of a low level. Delirium was found to be the most frequent adverse event associated with physical restraint use. However, the study designs precluded the evaluation of any temporal association between delirium and physical restraint use. Other important adverse events described in association with physical restraint use included skin injuries, neurofunctional impairment leading to a decline in activities of daily living, and a higher rate of PTSD. The overall level of evidence was unfortunately low, with a moderate to serious risk of bias in all studies. The findings from these studies are concerning, and they indicate a possible causal relationship between physical restraint use and adverse events and outcomes. However, a causal relationship could not be established owing to a lack of randomized controlled trials in this field. Notably, none of the identified studies either described or evaluated the use of alternative measures. Only one study reported the use of standardized protocols for physical restraint use during ICU stay.

Assessment of the risk of bias using the Cochrane Risk of Bias (version 2) and ROBINS-I tools showed most studies to have a moderate to serious risk of bias; the details are shown in Supplementary Table S5.[19,20] Studies often had no clear protocols for initiating the use of physical restraints; in addition, the type and duration of restraint use or the use of alternative measures were not described. All studies were susceptible to potential confounding due to their non-interventional design and heterogeneous populations. None of the studies reported on protocols for sedation or de-escalation techniques before physical restraint use.

Some studies attempted to address potential confounding factors using multivariable regression models. However, the reported confidence intervals were mostly large, suggesting the potential of being underpowered; tests for model fit adequacy were also largely lacking. In addition, the lack of uniform sedation protocols and the inconsistent use of physical restraints may have further influenced the results. Despite these limitations, the findings indicate that the inappropriate use of physical restraints may promote or exacerbate agitation and lead to an increase in the use of sedative agents; this may in turn increase the risk of delirium and subsequent device removal.[40] In view of these limitations, it is essential that large and well-designed randomized controlled trials be performed. These trials need to employ more standardized approaches (such as the initiation of sedation based on predefined protocols and randomized use of physical restraints). In this context, an ongoing randomized controlled trial (ARBORéa) is studying the impact of a decision-making tool for physical restraint use. This study is enrolling patients from several ICUs across France and will provide urgently needed information in this regard.[41]

As delirium is a well-described and independent predictor of long-term neurological outcomes and mortality, the neurological deficits observed with restraint use may be related to the higher risk of delirium.[42] Nevertheless, restraints may hinder early rehabilitation and mobilization; this may be detrimental to the recovery of neurological function and activities of daily living. Well-designed trials are needed to better understand the factors that contribute to poorer neurological outcomes and their underlying mechanisms. Studies are also needed to evaluate the inconsistencies in the length of ICU or hospital stay and mortality. In this context, some studies showed an increased incidence of these events among physically restrained patients while others did not.[35]

As mentioned previously, studies have shown that restraints do not effectively prevent patients from removing medical devices.[9,10,38] Numerous studies have reported higher rates of device removal and self-extubation among physically restrained patients in the ICU.[9,22,36-38] These issues may prompt ICU staff to determine and implement alternative strategies.

Among the studies included in this review, only a few discussed the development of other presumably common complications (associated with physical restraint use) in the ICU; these include nosocomial infections and thromboembolic events. However, evidence from cohorts outside the ICU setting (including psychiatric and general wards) suggests the rates of such complications (including mortality) to be higher in restrained patients.[5–8]

Previous reviews have shown that although available evidence questions the benefits of physical restraint use, they are widely used in ICUs without adequate protocols.[43] Similarly, our review could not identify any studies focusing on the potential benefits of physical restraints; this indicates an urgent need for further investigations in this regard. In contrast to unmodifiable risk factors, such as age and length of ICU stay, potentially modifiable factors play a crucial role in determining scenarios where physical restraints should be avoided. These include factors related to the environment (such as the maintenance of a day-and-night rhythm for the reduction of nightly disturbances) and those related to the workplace (including a lower nurse-to-patient ratio and specific training and sensitization of nurses and physicians for the management and prevention of agitation in ICU patients). A previous review that investigated physical restraint use in ICUs found that a lower nurse-to-patient ratio usually limits their use.[44]

Potential alternatives to physical restraints, and clinical scenarios in which they may show promise with less risks, represent an area of particular interest. In this context, our data suggested that patients who were restrained without sufficient sedation were more likely to develop PTSD after ICU stay. As up to 10% of ICU patients develop PTSD, this finding is of particular importance and needs to be considered when using restraints.[45] Outside the ICU setting, physical restraint use has been demon-

strated to be a risk factor for medical complications and severe psychological sequelae in patients with psychiatric disorders.[46] In this context, other reviews have focused on decision-making regarding physical restraints and their effects on patient behavior.[44]

Proposed potential intervention targets and considerations

We propose several potential intervention targets and considerations for physical restraint use during the course of ICU stay and for further studies (including the implementation of a standardized procedure with documentation); these have been outlined in Figure 3. The empirical evidence presented in this literature review indicates the need for formulation, implementation, and systematic evaluation of protocols regarding the appropriate timing and methods for employing physical restraints.

Notably, adherence to a protocol appears to be difficult for alternative measures and warrants further investigation. In this context, previous studies have shown that alternative treatment options mostly fail due to deviation from protocols and switching to physical restraints without clear indications.[1,47] Established protocols therefore need to incorporate frequent evaluation for local complications and periodic re-assessment of the indications for continued restraint use. This will reduce the duration of physical restraint and thereby potentially minimize associated risks. Non-pharmacologic and pharmacologic strategies need to be used to prevent delirium, and efforts should be made to explore alternatives to physical restraints. These alternatives may include early ambulation, pain and anxiety management, early involvement of family and caregivers, frequent communication with the patient, and appropriate use of sedative medications.[47] Physically restrained patients should be monitored closely for the development of complications such as thrombosis, aspiration pneumonia, and other nosocomial infections. Finally, as shown in Figure 3, ICU survivors should be followed up after discharge to ensure they do not experience psychological sequelae from their ICU stay (and any physical restraint, if used).[48]

It is important to note that the studies included in this review did not offer high-quality evidence. Retrospective cohort studies and case-control series may overlook important confounders that contribute to higher physical restraint use, and subsequently lead to a higher incidence of delirium and poorer neurological outcomes. For instance, patients who are at a higher risk of developing delirium and complications may be restrained more frequently. In addition, the included studies offered no information regarding the different approaches used for managing agitated patients (such as deep sedation or verbal de-escalation techniques).

Notably, the feasibility of reducing physical restraint use is unclear, as even ICUs with less restrictive policies continue to restrain 50%–80% of patients.[47] These proportions may increase further owing to the under-prioritization of critical care and a global shortage in healthcare staff. This may further hinder the implementation of potential alternative measures (which may entail an increase in patient-to-nurse ratios).[49,50] In this context, considerable differences appear to exist between different nations, suggesting an impact of the prevailing cultural and moral perspective.[47]

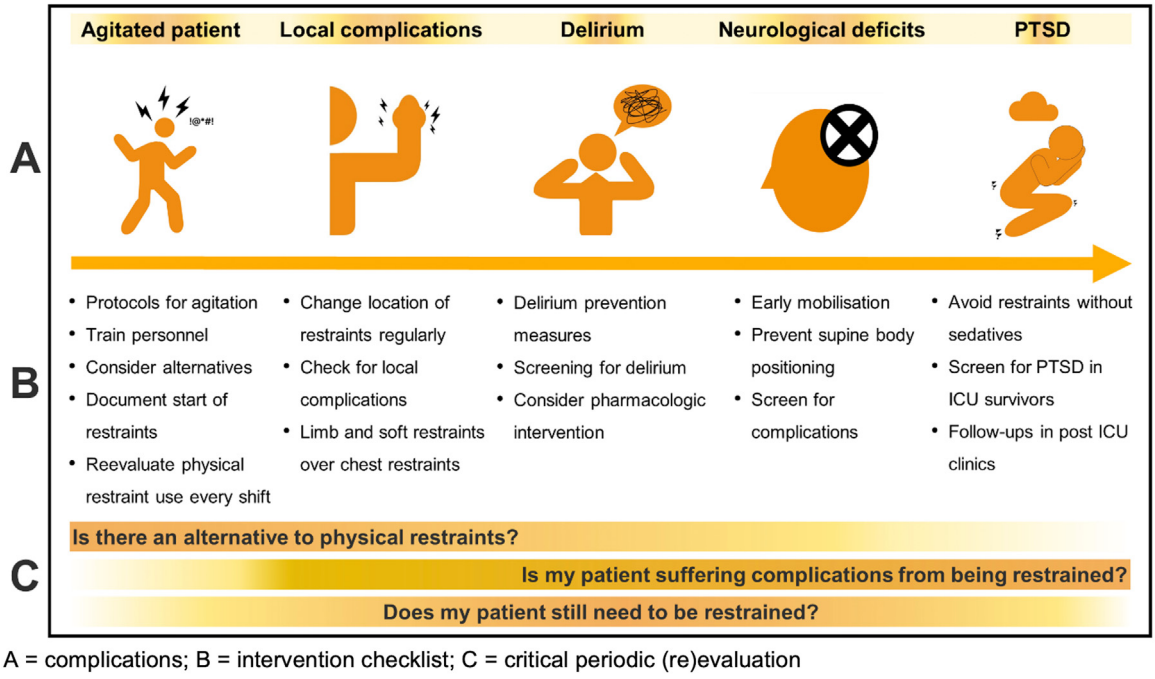

Figure 3. Potential intervention targets and considerations for physical restraint use during the course of ICU stay. A: Complications; B: Intervention checklist; C: Critical periodic (re)evaluation.
ICU: Intensive care unit; PTSD: Post-traumatic stress disorder.

Conclusions

In this review, we identified a limited number of heterogeneous studies that were conducted worldwide to evaluate potential associations between physical restraint use in critically ill patients and various adverse events during ICU stay. The complications included local skin and subcutaneous injuries (such as edema, skin bruising, and pressure ulcers), delirium, PTSD, neurological deficits, and other unfavorable short-term outcomes. Notably, the current data do not permit the establishment of a causal relationship between physical restraint use and adverse events in the ICU due to inherent limitations (including substantial bias and potential confounding). However, a causal association seems plausible and more than likely. It is therefore essential that awareness of the potential harmful effects of physical restraints is increased among physicians and nurses. Protocols and/or checklists (such as the one proposed) also need to be established and used for identifying, managing, and preventing adverse events. Further prospective randomized trials are needed to investigate the complications and adverse events associated with physical restraint use in the ICU, gain a better understanding of the consequences of their use, and explore the efficacy of specific interventions or alternative measures.

Author Contribution

Sebastian Berger: Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Pascale Grzonka**: Writing – review & editing, Formal analysis, Data curation. **Simon A. Amacher**: Writing – review & editing, Formal analysis. **Sabina Hunziker**: Writing – review & editing, Formal analysis. **Anja I. Frei**: Writing – review & editing, Formal analysis. **Raoul Sutter**: Writing – review & editing, Writing – original draft, Supervision, Formal analysis, Data curation.

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Ethics Statement

Not applicable.

Conflict of Interest

Sabina Hunziker is supported by the Swiss National Foundation (SNF) (Ref 10001C_192850/1 and 10531C_182422), the Gottfried Julia Bangerter-Rhyner Foundation (8472/HEG-DSV), and the Swiss Society of General Internal Medicine (SSGIM). Anja Frei reports no disclosures. Raoul Sutter received research grants from the Swiss National Foundation (No 320030_169379), the Research Fund of the University Basel, the Scientific Society Basel, and the Gottfried Julia Bangerter-Rhyner Foundation. He received personal grants from UCB-pharma and holds stocks from Novartis, Roche, Alcon, and Johnson & Johnson. The other authors declare that they have no competing interests.

Data Availability

All data generated or analyzed during this study are included in this published article and its supplementary information files. The data sets generated during and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Supplementary Materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jointm.2023.11.005.

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