

TITLE: The Use of Restraints and Excited Delirium or Positional Asphyxia: A Review of the Safety and Guidelines

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CONTEXT AND POLICY ISSUES

In-custody death is a rare but devastating occurrence within correctional settings.¹ The use of physical restraints, development of excited delirium (ExD), and positional asphyxia have all been implicated in in-custody death.² Restraint related in-custody death is even more rare, occurring less than six times annually depending on the jurisdiction.^{3,4} However, it often occurs suddenly and without warning. Often, autopsy results fail to identify a specific cause of death.² Restraint related death in the health care system is also rare and limited to case reports.^{5,6}

Physical restraint is defined as the use of manual, device, or material intervention to restrict the movement of an individual. Restraints are utilized in both the health care and correctional systems.⁷⁻⁹ In both settings, restraints are often used in situations where individual are violent, aggressive, or at risk of harming themselves or others.^{10,11} Certain types of restraints may also be used as a method to prevent falls in a geriatric population or in those with movement disorders.⁶ Numerous types of physical restraints exist, such as straps or ties, bandages, protective blankets, mittens, handcuffs, thoracoabdominal compression, hog-ties, and restraining trays or chairs.^{6,8,9} Use of specific restraining methods depends on the setting for their use. Controversy exists surrounding the relative safety of both restraining methods and position of the restrained individual. Numerous complications have been reported with the use of physical restraints and resulting immobility. Risks of immobility secondary to restraints include deconditioning, venous thromboembolism, development of ulcers, pneumonia, and, rarely, rhabdomyolysis in cases where patients continue to struggle once restrained.^{6,12} Physical or psychological injury may also occur as a result of physical restraints. Deaths have also been reported in individuals who are physically restrained.⁶ Positional asphyxia through chest compression and strangulation, ExD, aspiration, and substance use have all been implicated in restraint related deaths in case series.^{4,6,9,12} Incorrect application of restraints is also a risk factor for death.⁶ Prone positioning has been implicated in restraint related deaths secondary to respiratory compromise, however, this risk has not been consistently demonstrated.^{7,9,13,14}

ExD is most commonly caused by psychiatric illness or drug induced psychosis.³ ExD is a syndrome that is poorly understood and has been defined as a state of extreme mental and

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physiological excitement. ExD has not yet been recognized as a unique disease state and diagnostic criteria do not currently exist.^{2,15} Many experts define the ExD syndrome as a constellation of symptoms of autonomic arousal including agitation, violent behavior, constant physical activity, high pain tolerance, tachypnea, sweating, tactile hyperthermia, lack of responsiveness to police presence, absence of fatigue, superhuman strength, wearing inappropriate or no clothing, and an abnormal attraction to glass or mirrors.^{2,15-17} Identifying, preventing and managing ExD is challenging. ExD can both necessitate or be a consequence of physical restraints and has been implicated as a cause of sudden death through hypoxia, asphyxia, or cardiopulmonary collapse in individuals in police custody.^{15,16} Restraining patients in a prone position, intoxication with alcohol or drugs, especially sympathomimetics such as cocaine, and violent struggles have been implicated in increasing the risk of sudden death secondary to ExD.^{2,3,7,16}

Positional asphyxia results from restraining an individual in a position that restricts the physiological functions of ventilation and has also been implicated in restraint related death of individuals in police custody.⁴

The objective of this report is to review the evidence regarding the safety of physical restraints in people in custody or in a healthcare facility and review evidence-based guidelines for prevention and management of ExD or positional asphyxia.

RESEARCH QUESTIONS

1. What is the safety of restraints or restraining methods for people in custody or in healthcare facilities?
2. What are the evidence-based guidelines for the prevention or management of excited delirium?
3. What are the evidence-based guidelines for the prevention or management of positional asphyxia?

KEY FINDINGS

One low quality systematic review, one fair quality randomized controlled trial and four cohort studies of varying quality address the safety of use of physical restraints on individuals in custody or in the health care system. Evidence from these studies demonstrate that adverse effects such as patient injury and psychological trauma are risks of physical restraint. The incidence of these adverse outcomes varies depending on the setting and was reported to be as high as 35%. One cohort study demonstrated that a prolonged period of restraint (72 hours) is associated with the development of deep vein thrombosis. Restraint related death was low in the included studies and was not significantly different based on position of the patient (prone vs. non-prone).

One poor quality consensus guideline was included that addressed the management of excited delirium in the emergency department. Goals of management include de-escalation techniques and supportive care directed at treating symptoms and addressing physiological derangements.

There was no evidence that met the inclusion criteria for this review that addressed prevention or management of positional asphyxia.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, and guidelines. The search was also limited to English language documents published between January 1, 2006 and July 10, 2016.

Selection Criteria and Methods

One reviewer screened the titles and abstracts of the retrieved publications. A different reviewer evaluated the full-text publications for the final article selection, according to the selection criteria in table 1.

Population	Adults in custody or in health care facilities
Intervention	Physical restraints or restraining methods
Comparator	Any
Outcomes	Safety (e.g. risk of excited delirium or positional asphyxia, mortality), guidelines for the prevention or management of excited delirium or positional asphyxia (including proper restraining techniques)
Study Designs	Health Technology Assessments, Systematic Reviews, Meta-analysis Randomized Controlled Trials Non-Randomized Studies Evidence-based Guidelines

Exclusion Criteria

Studies were excluded if they did not meet the selection criteria, were duplicate publications, or were published prior to 2006. Articles were also excluded if they were reported as part of an included HTA or systematic review.

Critical Appraisal of Individual Studies

Critical appraisal of a study was conducted based on an assessment tool appropriate for the particular study design. The AMSTAR checklist was used to critically appraise the systematic reviews.¹⁸ The Cochrane Collaboration's tool for assessing risk of bias was used to critically appraise the randomized controlled trials.¹⁹ The Newcastle-Ottawa Quality Assessment Scale^{20,21} was used for cohort studies and the AGREE II instrument for appraisal of guidelines.²²

For critical appraisal, a numeric score was not calculated. Instead, the strengths and limitations of the study were described narratively.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 443 articles were identified from the electronic literature search and eight potentially relevant articles from the grey literature search; 33 were selected for full-text screening. Seven of the full-text references screened met the inclusion criteria.

There was one systematic review,²³ one RCT²⁴ and four cohort studies²⁵⁻²⁸ that reported on safety outcomes of restrained individuals in custody or health care settings. One evidence based guideline on the management of excited delirium was included.²⁹ There were no studies identified that met the inclusion criteria that addressed the prevention or management of positional asphyxia.

Appendix 1 describes the PRISMA flowchart of the results of the literature review for this report.

Summary of Study Characteristics

Characteristics of the included systematic review, RCT, cohort studies and guidelines are summarized below. Additional details on the systematic review, RCT and cohort studies are detailed in Appendix 2.

Systematic Review

Rakhmatullina²³ and colleagues published a systematic review in 2013 in the USA. The objective of their review was to summarize the literature on use of restraints that was published between 2002 and 2012, with a focus on adverse outcomes. A total of 48 studies were included; 10 review papers and 38 clinical trials. Of the 38 included clinical trials, most were retrospective cohort studies, structured questionnaires, or case-reports. The setting of the included studies was mainly inpatients, most commonly nursing homes, psychiatric wards or intensive care units. Authors reported on adverse events associated with the use of physical restraints including psychological trauma and death. No meta-analysis was performed and all outcomes were reported in a narrative descriptive format.

Randomized Controlled Trial

In 2006, Nawaz and colleagues published a single centre RCT that was conducted in the USA.²⁴ They compared the use of standard restraints with a safe enclosure in general internal medicine inpatients admitted to a community hospital. The safe enclosure consisted of a nylon canopy that covered the patient's entire bed and was secured to a metal frame on the floor. Standard restraints consisted of a Posey vest, 2 or 4 point hard or soft restraints. A total of 49 patients were randomized between April 2003 and February 2005; twenty patients were restrained using the safe enclosure and 29 with traditional restraints. The primary outcomes were family member, physician, and nurse perception survey scores and patient agitation scores. Patient agitation scores were recorded using both the alcohol withdrawal assessment form and agitated behavior scale (ABS). The ABS is a 14 item scale that measures behaviors of agitation on a four point Likert scale with final scores ranging from 0 to 42. Additionally, the

authors reported on the use of medication use to treat delirium and injuries sustained by the patient while restrained.

Cohort Studies

In 2015, Hall et al. published a cohort study reporting on the results of 4828 police use of force events that took place between August 2006 and March 2013 in seven police agencies across Canada.²⁵ Use of force events were defined as any of the following: physical strikes, use of pepper spray, handheld baton, vascular neck restraint, conducted energy weapon, or use of fire arm. Specifically, the authors were interested in the final resting position of the patient (prone vs. not-prone) and the incidence of in custody death. Of the 4828 use of force events, the final position was known for 4373 (90%). Of these, 4056 (93%) were restrained using handcuffs. The final position was prone in 2015 (46.1%) individuals and not prone in 2358 (53.9%). Overall, the majority of the individuals were male (87.5%) and the median age was 32 years. In addition to in-custody death, the authors also reported on the number of features of excited delirium that were present at the time of police use of force. Features of ExD that were recorded included inappropriate clothing, attraction to glass, failure to respond to police presence, constant physical activity, unusual strength, lack of fatigue, lack of response to pain, rapid breathing, hyperthermia, and excess sweating.

In 2014, Ishida and colleagues published a cohort study of restrained psychiatric inpatients in Japan.²⁶ The study was conducted between December 2008 and September 2010. The objective of the study was to determine the incidence of deep vein thrombosis (DVT) in restrained patients who were receiving routine DVT prophylaxis. A total of 181 patients were included, of which 98 were male and the mean age was 48 years. None of the patients had a positive history of DVT or pulmonary embolism, and there were no pregnant patients. One patient had a history of malignancy and two had undergone recent surgery. On average, patients were restrained for 74 hours (standard deviation 94 hours). Authors reported that during the period of restraint, all patients were to receive DVT prophylaxis including graduated compression stockings and twice daily subcutaneous injections of 5000 units of unfractionated heparin, unless it was contraindicated. Of the 181 included patients, 63.5% received the recommended prophylactic unfractionated heparin. To determine the incidence of DVT, all patients had d-dimer levels measured at the time of restraint removal, and those with levels $\geq 0.5\mu\text{g/dL}$ underwent a Doppler ultrasound of the lower extremities.

In 2007, Howard et al. published a cohort study of patients admitted to a psychiatric intensive care unit over a three-year period beginning in November 2002.²⁷ The hospital staff were required to complete a form detailing the events of either an episode of physical violence directed at a staff member or the use of manual restraints. A total of 55 documented incidents of patient restraint were included. Twelve forms had incomplete data, and 43 forms were included in the study analysis. The authors reported on the injuries sustained by either staff or patients during the use of restraints.

In 2006, Riley and colleagues published the results of a cross-sectional survey that was conducted over a 2-year period from 1999 to 2001.²⁸ The survey was a 122-item form completed by hospital staff within 72 hours of an incident of patient aggression. A total of 266 forms were completed on first episode physical restraint of psychiatric inpatients within the Mercy Care NHS Trust in the United Kingdom. Authors reported on the frequency of injury during an episode of physical restraint.

Guidelines

In 2009, the Excited Delirium Task Force of the American College of Emergency Physicians (ACEP) endeavored to develop recommendations regarding the identification and treatment of excited delirium based on available evidence.²⁹ Clinical trial evidence regarding the management of excited delirium was found to be sparse. As such, the task force based their management guidelines on consensus.

Summary of Critical Appraisal

Strengths and limitations of the systematic review, RCT, cohort studies and guideline are provided in Appendix 3.

Systematic Review

Overall, the systematic review was of poor quality.²³ Strengths of this publication were the use of an a priori study design with a clear clinical question and reporting of the characteristics of the included studies. Authors did report that major databases were searched and key words that were used in the search. However, many specific details on the process of the literature search, study selection or data abstraction were not reported. Quality of the included trials was not assessed or incorporated into the development of study conclusions. Publication bias was not evaluated. While the authors of the systematic review did not have any conflicts of interest to declare, they did not report on the potential conflicts of interest in the included studies.

Randomized Controlled Trial

The quality of the RCT was fair.²⁴ Nawaz and colleagues used an appropriate method of randomization (permuted block) and maintained allocation concealment with opaque white envelopes. Because of the nature of the study, blinding was not possible. The quality of the study was limited by the lack of reporting of the attritions or exclusions from the outcome analysis. When interpreting the study findings, it should be noted that the study was terminated early secondary to slow recruitment and lack of available funds. Slow recruitment may limit the external validity and application of the study findings to a clinical population.

Cohort Studies

One of the included cohort studies was good quality,²⁵ two were fair,^{26,28} and one was poor.²⁷

Hall and colleagues²⁵ used a representative cohort, ensured that the outcome of interest was not present at the start of the study and ascertained exposure based on a structured report. Outcome assessment was blinded and the follow-up rate was high (90%). One limitation of their study was that no confounding variables were considered in the analysis.

Ishida and colleagues²⁶ also used a representative cohort and ascertained exposure by secured record. A multiple logistic regression model was used to determine the impact of confounding variables. The follow-up rate was high with 95% of the study population included in the outcome analysis. The authors failed to demonstrate that the outcome, specifically DVT, was absent at the outset of the study. Two-thirds of the patients received the recommended DVT prophylaxis, which may have had implications on the incidence of DVT development in at risk patients. No details regarding the method of restraint were provided and patients were restrained for long

periods of time (mean 74 hours). Both of these characteristics of the study limit the application of study findings. Authors did not report on blinding of the outcome assessment and it was unclear whether the length of follow-up was adequate. It is also unclear whether the diagnosed DVT were proximal or distal, which has implications for both treatment and risk of pulmonary embolism.

Riley and colleagues²⁸ also used a representative cohort, ascertained exposure by secured record, and considered the impact of confounders in their outcome analysis. The authors failed to demonstrate that the outcome variable was absent at the start of the study. Assessment of the outcome relied on staff completion of an audit form and only included the first episode of restraint. This may result in lack of reporting restraint related adverse outcomes in individuals who are restrained more than once.

Howard et al.²⁷ used a structured report to assess the outcomes of interest. This study had several limitations that affected the quality. It was unclear whether the cohort was truly representative of the population of interest. The authors did not demonstrate that the outcome was absent at the start of the study, confounding variables were not considered in the outcome analysis and it was unclear whether the outcome assessment was blinded. This study also had inadequate follow-up with <80% of participants included in the outcome analysis.

Evidence Based Guidelines

Overall the ACEP guidelines on Excited Delirium were of poor quality.²⁹ Strengths of the guidelines were clarity in their objectives and target population. The limitations of the current body of evidence were outlined by the authors and barriers to guideline development and application are also clearly described. The main strength of these guidelines was the clarity in which the options for managing excited delirium are discussed. The guidelines did not address the prevention of excited delirium. The main limitations of the ACEP Guidelines was the lack of stakeholder involvement, poor reporting on the evidence search methods and selection, lack of linkage between the evidence and recommendations are ambiguity around key messages. It is also unclear how consensus was achieved and whether the guidelines were subject to peer review. Conflicts of interest were not provided.

Summary of Findings

The overall findings are summarized below and details are available in Appendix 4.

Safety of restraints or restraining methods for people in custody or in health care facilities

Systematic Review

Rakhmatullina and colleagues²³ included a total of 48 publications in their systematic review; 10 were review papers and 38 were clinical studies. In reporting results, they did not undertake a meta-analysis of the data, but rather a descriptive summary of individual study results. One included retrospective study reported that when physically restrained, 35% of patients with a traumatic brain injury living in a nursing home experienced an upper limb injury. Another retrospective cross-sectional study of 152 psychiatric inpatients reported that 34% of patients who were physically restrained experienced significant distress as a result. Narrative descriptions of the findings of six included studies highlighted that the use of physical restraints leads to negative feelings on the part of patients and care providers. Examples of negative emotional impact on patients include feeling of traumatization, humiliation, neglect, and

isolation. Restraint-related deaths were reported in nine inpatients in a Turkish hospital. In all cases patients were wearing chest restraints. Finally, a German study analyzed the autopsy results of all deaths which had occurred with use of restraints between 1997 and 2001. Of the 26 cases, deaths were most commonly a result of chest compression or strangulation. The authors also commented that in several cases the restraints had been applied incorrectly.

Randomized Controlled Trials

Nawaz and colleagues²⁴ found that compared to standard restraints, there was no difference in the use of medications for delirium compared to patients who were restrained in the safe enclosure ($P=0.59$). There was one injury that occurred during the study; one patient in the standard restraint group experienced a minor abrasion. Agitated behavior score was not statistically different between the safe enclosure and standard restraints at 24, 48 or 72 hours ($P>0.05$ for all time points).

Cohort Studies

Hall et al.²⁵ reported that significantly more patients with non-prone final resting position had three or more features of excited delirium at the time of police use of force compared to those individuals who were restrained in the prone position (12.4% vs. 10.2%; difference 2.2%, 95% confidence interval [CI] 0.3% to 4.1%). There was no significant difference in the final resting position (prone vs. non-prone) of individuals with six or more features of excited delirium (1.6% vs. 2.3%; difference 0.7%, 95%CI -0.2% to 1.4%). There was one death in the study. The deceased was restrained in a non-prone position (side lying) at the time of his cardiopulmonary arrest. At the time of death, he was displaying all 10 features of excited delirium. Ishida et al.²⁶ reported the risk of DVT in 180 restrained psychiatric inpatients. D-dimer levels were found to be $\geq 0.50\mu\text{g/dL}$ in 72 patients. Of these patients with elevated d-dimer levels, Doppler ultrasound demonstrated a DVT in 21 patients (11.6%). Howard et al.²⁷ reported that the number of injuries that occurred with 43 incidents of restraint in a psychiatric intensive care unit were low. Minor injuries were reported in seven restraint reports; two of these were injuries to the patient and five injuries were inflicted on the staff member by the patient being restrained. Riley et al.²⁸ also reported on patient injury with the use of restraints based on the results of a cross-sectional survey over a 3-year period. Patient injuries after 266 first episode restraint instances occurred in 6% of patients in both the prone and supine position. There was no significant difference in the incidence of injury based on restraint position (difference -0.5%, 95% CI -8% to 8.4%).

Evidence-based guidelines for the prevention or management of excited delirium

The ACEP excited delirium task force recommends that the management of excited delirium in the emergency department setting be targeted at supportive measures and reversing underlying metabolic abnormalities and organ dysfunction. Recommended first-line measures in the management of a patient with ExD are de-escalation techniques such as verbal calming. If those are unsuccessful, the task force recommends obtaining physical control of the patient while optimizing the use of hospital personnel to limit the duration of physical struggle. The task force recommends that agitation be treated with parenteral sedation with a benzodiazepine, antipsychotic or ketamine in a setting with continuous cardiorespiratory monitoring. The task force recommends specific interventions based on underlying physiologic derangements. Hyperthermia should be managed with external cooling, such as water mist or icepacks placed in the axilla or groin, as well as removal of clothing. Infusion of cool saline is also a potential treatment option. Acidosis may be a result of hypovolemia and can be managed with volume

resuscitation. Bicarbonate infusions may be considered but are reported to be controversial by the task force. The task force did not address prevention of ExD in these guidelines.

Evidence-based guidelines for the prevention or management of positional asphyxia

There were no studies identified that met the inclusion criteria to address this question.

Limitations

Studies addressing the safety of restraints in people in custody or in health care facilities included one systematic review,²³ one RCT,²⁴ and four cohort studies.²⁵⁻²⁸ There was one evidence-based guideline that addressed the prevention or management of ExD.²⁹ There were no evidence-based guidelines on the prevention or management of positional asphyxia. The range of quality of the included studies was wide. One of the cohort studies was of good quality,²⁵ and the remaining evidence was fair^{24,26,28} or poor.^{23,27,29} The sample sizes of the cohort studies were small and therefore likely underpowered to detect rare events such as restraint related death.

Safety of restraints is poorly studied. There are many factors to consider when determining the safety of any intervention, such as circumstances surrounding its use, underlying medical conditions, and concomitant substance use. The risks of restraints may be different across the health care and correctional systems and the restraint technique employed. None of the studies included in this report adequately clarified these issues and few reported on the exact nature of the restraining technique used. The risks of restraints may also be confounded by the duration of their use. Risks early in the process of restraining an individual may be different than after several hours in restraints. None of the included evidence addressed the appropriate duration of physical restraint.

ExD is a poorly understood physical state. Without clear diagnostic criteria, recognizing the syndrome is challenging for correctional officers and health care providers. Without a clear definition of ExD, studying the risks and consequences of this syndrome is also challenging. Based on the available evidence, ExD may be a cause or consequence of physical restraint. Because of this, determining the risk of ExD as an outcome of physical restraint is difficult. Evidence that ExD increases the risk of sudden death in physical restraints is presently limited to case reports or case series.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

The evidence addressing the safety of the use of restraints in individuals in custody or in health care settings indicates that the use of restraints is associated with risks to the restrained individual. One cohort study²⁵ demonstrated that individuals who are physically restrained often exhibit symptoms of ExD prior to being restrained. This study also found that the incidence of in-custody death of restrained individuals was low. One death occurred in the study, limiting any conclusions regarding the relative risk of death based on position of the restrained individual (prone vs. non-prone). An RCT of general medicine inpatients found that alternative methods of physical restraints, such as a safe enclosure, are associated with fewer episodes of patient injury but no difference in patient agitation scores.²⁴ One cohort study in physically restrained psychiatric inpatients found that there is a risk of developing DVT after a prolonged period of physical restraint and this risk appears to be increased compared to the general population.²⁶ Two other cohort studies found that physical restraint resulted in few episodes of patient or staff

injury and the risk of injury was not different based on the position of the restrained patient.^{27,28}

Overall, the safety of restraining an individual, regardless of the setting, is poorly defined in the literature. The results of the systematic review²³ suggest that in addition to the risk of physical injury, patients experience adverse psychological impact as a result of being restrained. Based on the evidence from the included studies, the risk of restraint-related injury is widely variable. The included evidence suggests that the risk of restraint-related death is low. The risk of adverse outcome did not appear to differ based the position of the individual in restraints (i.e. prone compared to non-prone), however, the use of chest restraints appears to be associated with restraint-related death. These results should be interpreted with caution as they are based on few incidents of restraint-related adverse outcomes.

The main limitation to the development of guidelines for managing ExD is the lack of diagnostic criteria. Current guidelines, while based on consensus and of poor quality, suggest that the management of ExD should mainly be supportive and directed at underlying physiological abnormalities and patient symptoms. Further research should be directed at better defining ExD and establishing diagnostic criteria. No conclusions can be made regarding the prevention or management of positional asphyxia as there were no trials that met the inclusion criteria for this report.

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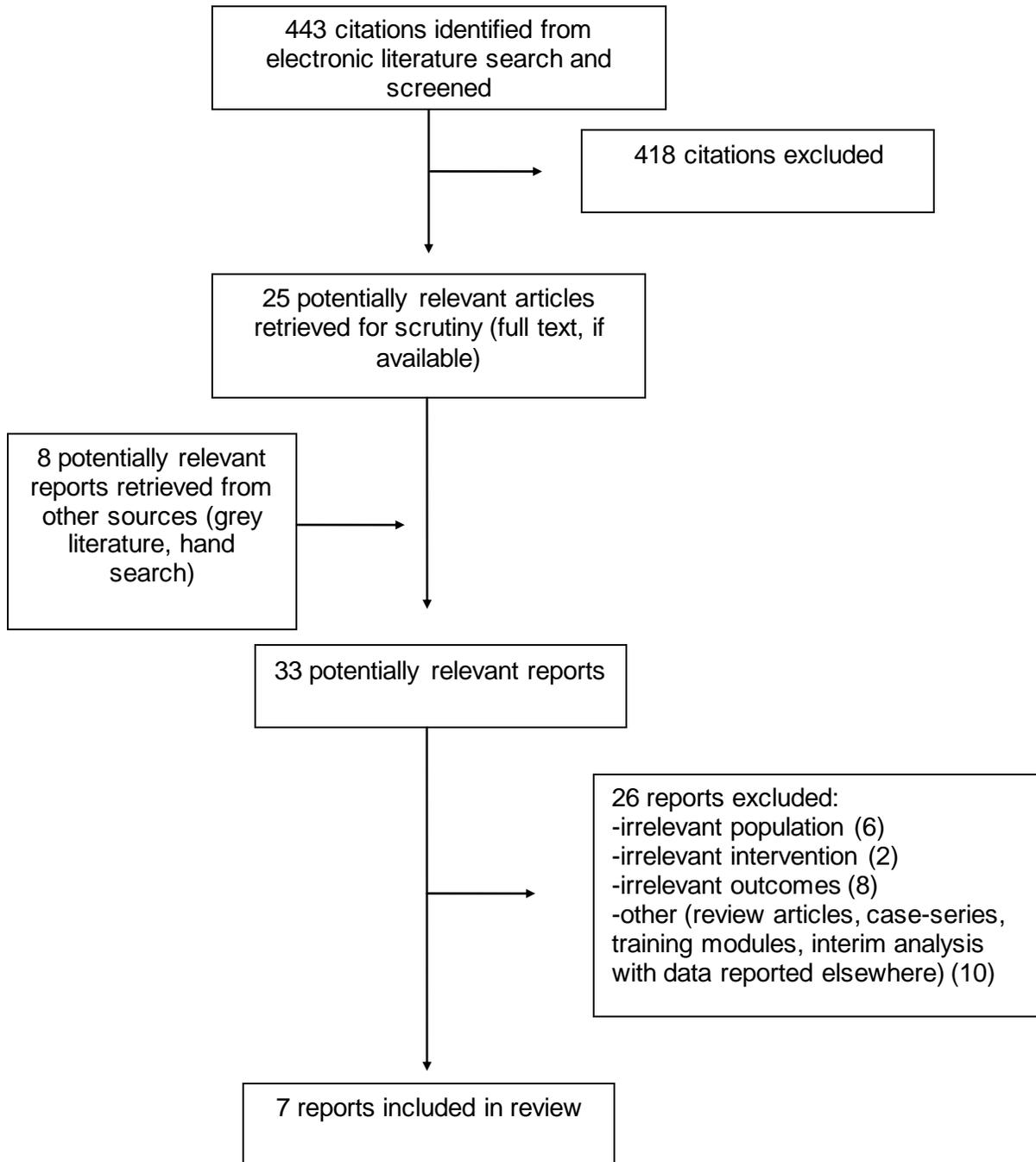
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ABBREVIATIONS

ABS	Agitated Behavior Scale
ACEP	American College of Emergency Physicians
AGREE	Appraisal of Guidelines Research and Evaluation
AMSTAR	A Measurement Tool to Assess Systematic Reviews
CI	Confidence Interval
DVT	Deep Vein Thrombosis
ExD	Excited Delirium
HTA	Health Technology Assessment
RCT	Randomized Controlled Trial

APPENDIX 1: Selection of Included Studies



APPENDIX 2: Characteristics of Included Clinical Studies

Table A2: Characteristics of Included studies					
First Author, Publication Year, Country	Study Design, Study Duration	Patient Characteristics, Sample Size (n)	Intervention	Comparator(s)	Clinical Outcomes
Systematic Review					
Rakhmatullina, 2013, ²³ USA	Systematic Review, 10 years	n=48 included studies (n=10 review papers, n=38 clinical studies) Health Care facilities	Physical restraints	None	Psychological trauma Death
Randomized Controlled Trial					
Nawaz, ²⁴ 2006, USA	RCT, 22 months	Community general medicine inpatients, n=49 Age: 81.3 years Male: 53.1% (n=26)	Safe enclosure (bed net) n=20	Standard restraints n=29	Injury
Cohort Studies					
Hall, ²⁵ 2015, Canada	Prospective cohort study, 6.6 years	Police-public interaction requiring use of force n=4828 Mean Age: 32 years Male: 87.5% Handcuffed: 4056/4373 (93%)	Prone position n=2015 ≥3 ExD features n=206 (10.2%) ≥6 ExD features n=33 (1.6%)	Not prone position n=2358 ≥3 ExD features n=293 (12.4%) ≥6 ExD features n=53 (2.3%)	Excited delirium features Mortality
Ishida, ²⁶ 2014, Japan	Cohort study, 22 months	Psychiatric inpatients, n=181 Mean Age (SD): 47.8±17 years Male: 54.1% (n=98) Duration of restraint, mean (SD): 74.1±93.6 hours	Restraint	No comparator	DVT
Howard, ²⁷ 2007, United	Cohort Study, 3	Psychiatric intensive care,	Restraint	No comparator	Injury

Table A2: Characteristics of Included studies

First Author, Publication Year, Country	Study Design, Study Duration	Patient Characteristics, Sample Size (n)	Intervention	Comparator(s)	Clinical Outcomes
Kingdom	years	n=55			
Riley, ²⁸ 2006, United Kingdom	Cross-sectional survey, 2 years	Psychiatric Inpatient, n=266	Supine restraint	Prone restraint	Patient injury

USA=United States of America; RCT=Randomized Controlled Trial; ExD=Excited Delirium

APPENDIX 3: Critical Appraisal of Included Studies

Table A3: Strengths and Limitations of Included Studies		
First Author, Publication Year	Strengths	Limitations
Systematic Reviews		
Rakhmatullina, 2013 ²³	<ul style="list-style-type: none"> • A priori study design was provided • Characteristics of included studies were provided 	<ul style="list-style-type: none"> • Authors did not report whether study selection and data abstraction was completed in duplicate • Authors provided few details on the literature search. That data bases searched were not reported • No grey literature was searched • List of excluded studies was not provided • Quality of included studies was not appraised and not taken into consideration when formulating conclusions • Likelihood of publication bias was not assessed • Conflict of interest was stated only for the systematic review but not the included studies
Randomized Controlled Trials		
Nawaz, 2006 ²⁴	<ul style="list-style-type: none"> • Method of randomization (permuted block) likely to decrease selection bias and result in comparable groups at baseline • Allocation concealment was maintained with opaque white envelopes 	<ul style="list-style-type: none"> • Study participants and investigators were unblinded • Authors did not report whether outcome assessors were blinded to treatment allocation • Study was terminated early secondary to slow recruitment and limited funds • Attrition or exclusion were not reported
Cohort Studies		
Hall, 2015 ²⁵	<ul style="list-style-type: none"> • Cohort was representative of population of interest • Exposure was ascertained by structured report • Outcome of interest was not present at beginning of study • Outcome assessment was blinded • High frequency of follow-up (90%) and length of follow-up adequate 	<ul style="list-style-type: none"> • Authors did not control for any potentially confounding variables
Ishida, 2014 ²⁶	<ul style="list-style-type: none"> • Cohort was representative of population of interest • Exposure was ascertained by secured record • Multiple logistic regression model was used to determine significant confounding variables • High frequency of follow-up (95%) 	<ul style="list-style-type: none"> • Authors did not demonstrate the outcome of interest was absent at the outset of the study • Authors did not report whether the outcome assessment was blinded • Unclear whether the length of follow-up was adequate in all cases

Table A3: Strengths and Limitations of Included Studies

First Author, Publication Year	Strengths	Limitations
Howard, 2007 ²⁷	<ul style="list-style-type: none"> Exposure was ascertained by a structured report 	<ul style="list-style-type: none"> It is unclear whether the cohort is representative of the population of interest Authors did not demonstrate the outcome of interest was absent at the outset of the study Authors did not control for any potentially confounding variables Authors did not report whether the outcome assessment was blinded There was inadequate follow-up (<80%) and it is unclear whether the length of follow-up was adequate to determine the presence of the in all cases
Riley, 2006 ²⁸	<ul style="list-style-type: none"> Cohort was representative of population of interest Exposure was ascertained by secured record Authors considered the impact of 10 clinically relevant variables 	<ul style="list-style-type: none"> Authors did not demonstrate the outcome of interest was absent at the outset of the study Outcome ascertainment was based on staff completion of an audit form Only first episode of physical restraint was considered in outcome assessment
Guidelines		
ACEP, 2009 ²⁹	<ul style="list-style-type: none"> Guideline objectives, target population are specifically described Target users of the guideline were clearly defined Authors clearly describe the limitations of the current body of literature Management options for excited delirium are clearly outlined Barriers to guideline development and application are clearly described, but does not address any specific methods to overcome these barriers 	<ul style="list-style-type: none"> Guideline task force includes only a narrow spectrum of potential stakeholders, specifically emergency physicians Opinions of patients and the public were not incorporated into guideline development Authors did not report on the methods used to search for or select evidence for inclusion in the guidelines Methods used to develop guideline recommendations were not clearly described Link between evidence and recommendations for management of excited delirium is unclear It is unclear whether the guidelines underwent a peer review process Key recommendations are ambiguous and resource implications have not been considered Authors do not provide details of future plans to update the guidelines and do not report their conflict of interest

APPENDIX 4: Main Study Findings and Authors' Conclusions

Table A4: Summary of Findings of Included Studies																			
First Author, Publication Year	Main Study Findings	Authors' Conclusions																	
Systematic Review																			
Rakhmatullina, 2013 ²³	<p>Physical Trauma 1 study, n=NR TBI inpatients Upper limb injury=35%</p> <p>Psychological Trauma 1 study, n=152 psychiatric inpatients Distress=34%</p> <p>Death 1 study, n=NR 9 deaths (all patients in chest restraints)</p>	More research is required to delineate the mechanisms of injury during physical restraint																	
Randomized Controlled Trial																			
Nawaz, 2006 ²⁴	<p>Injury Safe enclosure n=0 Standard restraint n=1 (minor abrasion)</p> <table border="1"> <thead> <tr> <th>Agitated Behavior Scale Score</th> <th>Safe Enclosure (n=20)</th> <th>Standard restraint (n=29)</th> <th>P-value</th> </tr> </thead> <tbody> <tr> <td>24 hours</td> <td>11.93</td> <td>8.33</td> <td>0.23</td> </tr> <tr> <td>48 hours</td> <td>6</td> <td>8.75</td> <td>0.37</td> </tr> <tr> <td>72 hours</td> <td>7.83</td> <td>7.11</td> <td>0.78</td> </tr> </tbody> </table>	Agitated Behavior Scale Score	Safe Enclosure (n=20)	Standard restraint (n=29)	P-value	24 hours	11.93	8.33	0.23	48 hours	6	8.75	0.37	72 hours	7.83	7.11	0.78	For hospitalized patients the safe enclosure is more acceptable to both patients and their family	
Agitated Behavior Scale Score	Safe Enclosure (n=20)	Standard restraint (n=29)	P-value																
24 hours	11.93	8.33	0.23																
48 hours	6	8.75	0.37																
72 hours	7.83	7.11	0.78																
Cohort Studies																			
Hall, 2015 ²⁵	<p>Mortality: Prone position, n=0 Not prone position, n=1 (side-lying, all 10 features of ExD, cardiopulmonary arrest) % (95% CI): 0.04% (0.001%, 0.2%)</p> <p>Excited Delirium:</p> <table border="1"> <thead> <tr> <th>ExD Features</th> <th>Prone, n/N (%)</th> <th>Not prone, n/N (%)</th> <th>Difference (95% CI)</th> </tr> </thead> <tbody> <tr> <td>≥3</td> <td>206/2015 (10.2%)</td> <td>293/2358 (12.4%)</td> <td>2.2% (0.3%, 4.1%)</td> </tr> <tr> <td>≥6</td> <td>33/2015 (1.6%)</td> <td>53/2358 (2.3%)</td> <td>0.7% (-0.2%, 1.4%)</td> </tr> </tbody> </table>	ExD Features	Prone, n/N (%)	Not prone, n/N (%)	Difference (95% CI)	≥3	206/2015 (10.2%)	293/2358 (12.4%)	2.2% (0.3%, 4.1%)	≥6	33/2015 (1.6%)	53/2358 (2.3%)	0.7% (-0.2%, 1.4%)	Prone positioning after police use of force event is very common and not associated with an increased risk of death					
ExD Features	Prone, n/N (%)	Not prone, n/N (%)	Difference (95% CI)																
≥3	206/2015 (10.2%)	293/2358 (12.4%)	2.2% (0.3%, 4.1%)																
≥6	33/2015 (1.6%)	53/2358 (2.3%)	0.7% (-0.2%, 1.4%)																
Ishida, 2014 ²⁶	DVT: n=21 (11.6%)	Finding emphasize the need for routine screening for DVT and limiting the duration of restraint and use of sedation																	

Table A4: Summary of Findings of Included Studies

First Author, Publication Year	Main Study Findings	Authors' Conclusions
Howard, 2007 ²⁷	Injuries during restraint Minor injuries restraint: n=6 Number of minor injuries: patient n=2, staff n=5	Restraint procedures to control violent patients in the psychiatric intensive care are relatively safe
Riley, 2006 ²⁸	Patient Injury: Supine 6% vs. Prone 6% Difference (95% CI): -0.5% (-8%, 8.4%)	Patient injuries were similar regardless of the restraint position used
NR=not reported; TBI=traumatic brain injury; ExD=excited delirium; DVT=deep vein thrombosis; CI=confidence interval		