Journal of Critical Care 31 (2016) 31–35

Contents lists available at ScienceDirect

Journal of Critical Care

journal homepage: www.jccjournal.org

Prevalence, risk factors, and outcomes associated with physical restraint use in mechanically ventilated adults☆,☆☆,★

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ARTICLE INFO

Keywords:
Physical restraint
Chemical restraint
Sedation protocol
Daily sedation interruption
Intensive care

ABSTRACT

Purpose: The purpose was to describe characteristics and outcomes of restrained and nonrestrained patients enrolled in a randomized trial of protocolized sedation compared with protocolized sedation plus daily sedation interruption and to identify patient and treatment factors associated with physical restraint.
Methods: This was a post hoc secondary analysis using Cox proportional hazards modeling adjusted for center- and time-varying covariates to evaluate predictors of restraint use.
Results: A total of 328 (76%) of 430 patients were restrained for a median of 4 days. Restrained patients received higher daily doses of benzodiazepines (105 vs 41 mg midazolam equivalent, $P < .0001$) and opioids (1524 vs

☆ Conflict of interest: The authors have no conflicts of interest to declare.
☆☆ ClinicalTrials.gov NCT 00675363.
★ Funding: The SLEAP trial was funded by the Canadian Institutes of Health Research. The secondary analysis of restraint use was funded by the Canadian Association of Critical Care Nurses and a Sigma Theta Tau International Lambda Pi-At-Large Research Seed Grant and the Mount Sinai Hospital Department of Medicine.
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http://dx.doi.org/10.1016/j.jcrc.2015.09.011
0883-9441/

919 μg fentanyl equivalents, $P < .0001$), more days of infusions (benzodiazepines 6 vs 4, $P < .0001$; opioids 7 vs 5, $P = .02$), and more daily benzodiazepine boluses (0.2 vs 0.1, $P < .0001$). More restrained patients received haloperidol (23% vs 12%, $P = .02$) and atypical antipsychotics (17% vs 4%, $P = .003$). More restrained patients experienced unintentional device removal (26% vs 3%, $P < .001$) and required reintubation (8% vs 1%, $P = .01$). In the multivariable analysis, alcohol use was associated with decreased risk of restraint (hazard ratio, 0.22; 95% confidence interval, 0.08-0.58).

Conclusions: Physical restraint was common in mechanically ventilated adults managed with a sedation protocol. Restrained patients received more opioids and benzodiazepines. Except for alcohol use, patient characteristics and treatment factors did not predict restraint use.

1. Introduction

Physical restraints are used to promote the safety of critically ill patients; however, their use has been associated with adverse outcomes including injury to restrained limbs [1], delirium [2–4], unplanned extubation [5,6], and an increased prevalence of posttraumatic stress symptoms in intensive care unit (ICU) survivors [7,8]. Although physical restraints are often applied to prevent patient-initiated device removal, several studies indicate high failure rates [9]. One large multicenter prevalence study conducted in the United States found that 44% of patients were physically restrained at the time of device removal [10]. Given the recognized adverse physical and psychological patient consequences of physical restraints and their lack of efficacy in preventing device removal, professional society guidelines, government legislation, and hospital accreditation standards advocate that physical restraint use be minimized across all health care settings [11–13].

Physical restraint use varies substantially across countries from 0% to 100% [14] and even among hospitals in the same country [15]. In a 2013 survey of 121 French ICUs, restraints were used at least once during mechanical ventilation in more than 50% of patients; and in 65% of these ICUs, restraints were applied for more than 50% of mechanical ventilation days [16]. A prospective observational study (I-CAN-SLEAP) conducted in 2008/2009 in 51 Canadian ICUs found that 53% of 711 mechanically ventilated patients were physically restrained for an average of 4 days [17]. More recently, the SLEAP trial, a prospective randomized trial conducted in 16 tertiary ICUs in Canada and the United States comparing protocolized sedation (control group) with protocolized sedation plus daily interruption (DI) (interruption group), found that most (328/430, 76%) patients had physical restraints applied at least once during their ICU admission [18]. In this study cohort, overall mean Sedation-Agitation Scale (SAS) scores were 3.3 vs 3.2 in the interruption and control groups, respectively, reflecting appropriate sedation.

The frequent use of physical restraints identified in the SLEAP trial was unexpected. Therefore, we conducted a secondary analysis to describe characteristics and outcomes of restrained and nonrestrained patients and to identify associations between patient and treatment factors and restraint application.

2. Methods

We performed a post hoc secondary analysis of SLEAP trial data to identify factors associated with restraint use. The SLEAP trial methods have been published previously [18]. The trial was conducted in 16 tertiary ICUs in Canada and the United States from January 2008 until July 2011 following local institutional review board approvals.

2.1. Participants and procedures

The SLEAP trial enrolled patients expected to require mechanical ventilation for at least 48 hours and who were receiving continuous intravenous opioid and/or benzodiazepine infusions. In the interruption and control groups, infusions of opioid (morphine, fentanyl, or hydromorphone) and benzodiazepine (midazolam or lorazepam) were titrated hourly by the bedside nurse according to a protocol that prioritized pain management and targeted a comfortable and rousable state, with a SAS [19] (8 sites) of 3 or 4 or Richmond Agitation-Sedation Scale (RASS) [20] (8 sites) of −3 to 0. In the interruption group, continuous infusions were interrupted daily, and patients were assessed hourly for wakefulness and the ability to perform at least 3 of the following tasks on request: eye opening, tracking, hand squeezing, and toe moving. Infusions were not restarted if the patient's SAS was 3 to 4 without them, and patients subsequently received intravenous bolus or oral sedative therapy at the discretion of the clinical team. Infusions were resumed at 50% of the previous dose and adjusted to achieve the sedation target if ongoing continuous intravenous therapy was required.

Initial application and continued use of physical restraints were at the discretion of the ICU team, in accordance with restraint policies of the participating hospitals which advocated for use of restraints as a last resort to ensure patient safety. In the all sites, application of physical restraints required a physician order every 24 hours. This process was generally initiated by the bedside nurse in response to actual or anticipated threats to patient safety.

2.2. Data collection and outcome measurements

We recorded patient demographic data at the time of enrolment, including presence of psychiatric disease, dementia, stroke, cardiac disease, tobacco and alcohol consumption, and Acute Physiology and Chronic Health Evaluation (APACHE) II score. We collected daily psychoactive drug exposure (opioids, benzodiazepines, antipsychotics, adjunctive oral analgesics and sedatives, and anticholinergic agents), SAS (alternatively, RASS) scores, physical restraint use, and accidental device removal (endotracheal tube, vascular catheters, gastric tube) during mechanical ventilation. Patients were screened daily for delirium by the bedside nurse using the Intensive Care Delirium Screening Checklist (ICDSC) [21]; a score of 4 or greater at any time during the study indicated delirium. *Coma* was defined as a SAS score of 1 or 2, or RASS score of −5 or −4, for 4 or more contiguous hours during 24 hours. Using a 10-point visual analogue scale (1 = very easy; 10 = difficult), registered nurses and respiratory therapists recorded their perception of workload related to study procedures twice daily. Requirement for tracheostomy, duration of mechanical ventilation, lengths of ICU and hospital stay, discharge destination, and mortality were recorded.

2.3. Statistical analysis

We summarized demographic and clinical variables using descriptive statistics. For continuous variables, we report means and standard deviations (SDs) or medians and interquartile ranges (IQRs) dependent on data distribution. For dichotomous variables, we report proportions and their 95% confidence intervals (CIs). We compared continuous variables between restrained and nonrestrained patients using either Student *t* tests or the Wilcoxon rank sum test as appropriate and categorical variables using the χ^2 test or Fisher exact test. We converted opioids to fentanyl equivalents (10 mg morphine = 2 mg hydromorphone = 100 μg