Impact of a Nurse-Led Sedation Protocol on Selected Clinical Outcomes in Traumatic Brain Injury Patients in Intensive Care Units

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□ ABSTRACT □

Traumatic brain injury (TBI) is a major global cause of disability and death. Achieving appropriate sedation is vital to ensure both reliable neurological evaluation and patient comfort. This study aimed to evaluate the impact of nurse-led sedation protocol on selected clinical outcomes in TBI patients. A quasi-experimental design was used. A sample of 80 patients from intensive care units (ICUs) in Northwest Syria was enrolled between February and July 2025. The control group received routine care, while the intervention group followed a nursing sedation protocol. Baseline characteristics were comparable between groups. Patients in intervention group spent more time within optimal sedation range and experienced fewer episodes of over- or under-sedation. The mean ICU stay and mechanical ventilation duration were slightly lower in intervention group but differences were not statistically significant. Self-extubation (10% vs. 27.5%, $p = 0.045$) and reintubation (15% vs. 37.5%, $p = 0.022$) were significantly reduced in intervention group. Mortality did not differ significantly. In conclusion, Nursing sedation protocol improved sedation quality, lowered airway-related complications in TBI patients. This study recommends integrating nurse-led sedation protocol into ICU practice.

Keywords: Traumatic brain injury, nursing sedation protocol.

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تأثير بروتوكول تهدئة تمريضي على نتائج سريرية محددة لمرضى إصابات الدماغ الرضية في وحدات العناية المركزة

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□ ملخّص □

تشكل إصابات الدماغ الرضية أحد أبرز أسباب العجز والوفيات عالمياً، ويعتبر تحقيق التهدئة المثالية أمراً أساسياً لضمان التقييم الدقيق للحالة العصبية وراحة المريض. هدفت الدراسة إلى تقييم تأثير بروتوكول تهدئة تمريضي على نتائج سريرية محددة لمرضى إصابات الدماغ الرضية، استخدم المنهج شبه التجريبي لعينة من 80 مريضاً من وحدات العناية في شمال غرب سوريا بين شهري شباط وتموز من عام 2025. تلقت المجموعة الضابطة الرعاية الروتينية، بينما تم تطبيق بروتوكول التهدئة على مجموعة التداخل. كانت الخصائص الأساسية متشابهة بين المجموعتين، قضى مرضى مجموعة التداخل وقتاً أطول ضمن نطاق التهدئة المثالي وتعرضوا لعدد أقل من نوبات نقص أو فرط التهدئة. كانت مدة الإقامة في وحدة العناية ومدة التهوية أقل في مجموعة التداخل، لكن هذه الفروق لم تكن ذات دلالة إحصائية. انخفض معدل نزع الأنبوب الرغامي الذاتي (10%) مقابل (27.5%)، (p= 0.045) وإعادة التنبيب (15%) مقابل (37.5%)، (p=0.022) بشكل واضح في مجموعة التدخل. لم يكن هناك فرق ذو دلالة بالنسبة لمعدل الوفيات. بالنتيجة، أدى بروتوكول التهدئة إلى تحسين جودة التهدئة وتقليل المضاعفات لدى مرضى إصابات الدماغ الرضية. توصي هذه الدراسة بدمج بروتوكول التهدئة التمريضي في ممارسات وحدات العناية المركزة.

الكلمات المفتاحية: إصابات الدماغ الرضية، بروتوكول تهدئة تمريضي.

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1- Introduction:

Traumatic brain injury (TBI) is a devastating global health issue with profound consequences. Defined as an injury resulting from a violent blow to the scalp, skull, or brain, it can lead to impaired physical, cognitive, emotional, and behavioral functioning. The impact of TBI ranges from complete recovery to permanent disability or death [1], and is a significant contributor to morbidity and mortality, especially in cases of multisystem trauma [2].

TBI management critically involves sedation, a key element of care utilized for its direct and indirect neuroprotective effects, reducing further secondary brain injury. Sedation lowers cerebral metabolic demands, potentially reducing tissue hypoxia and ischemia. It decreases intracranial pressure (ICP) and mitigates ICP spikes caused by agitation, anxiety, or coughing, while also enabling tolerance of procedures such as tracheal intubation and mechanical ventilation. Furthermore, sedation can prevent seizures and facilitate targeted temperature management by preventing shivering and blunting excessive autonomic responses [3–5].

Globally, sedation practices in critically ill patients have evolved considerably. In the past, deep sedation and immobility were routine in the intensive care unit (ICU). However, evidence has shown that prolonged deep sedation can hinder weaning from mechanical ventilation, extend ICU stays, contribute to cognitive dysfunction, and increase mortality. It can also reduce opportunities for patient–family interaction, leading to psychological distress among relatives [6].

While invasive neuromonitoring such as ICP and EEG is ideal for sedated TBI patients, these modalities are rarely available in Low- and Middle-Income Countries such as Syria, making clinical assessment the mainstay of sedation monitoring [7]. Sedation scales have been developed as bedside tools to guide medication titration toward a preset sedation goal. These tools aim to reduce sedation-related complications [8].

Individualized titration of sedation depth is fundamental to achieving targeted sedation goals while avoiding both over- and under-sedation. Maintaining an appropriate level of sedation enhances patient comfort, minimizes sedative-related adverse effects, and supports timely weaning from mechanical ventilation. Achieving this balance requires continuous monitoring and real-time adjustment of sedation based on the patient's clinical status, pain assessment, and standardized sedation scoring to ensure that the sedation depth aligns with the patient's dynamic needs [9].

Critical care nurses play a vital role in ensuring patient safety during procedural sedation and analgesia. According to the American Nurses Association, nurses must have specific competencies to administer and monitor these medications effectively. This includes the ability to differentiate between various levels of sedation and to promptly recognize and manage any related complications [10]. Nurses are responsible for monitoring the depth of sedation, titrating the infused drugs and monitoring their effects, while maintaining the sedation at a retargeted level. Protocols or guidelines may assist ICU nurses in making effective clinical decisions [11].

Evaluating the agitation level using an appropriate protocol, helps nurses to identify the problems causing patients' agitation which have not been relieved by medicine, and to provide better pain relief and comfort for the patient [12]. Therefore, it is required for nurses to adopt an accurate monitoring method and decision- making framework for the safe administration of sedatives [13].

The Richmond Agitation-Sedation Scale (RASS) is widely recommended for assessing sedation levels in ICU patients, with validated reliability confirmed by Ely [14], and Sessler [15]. This study targeted a RASS range of –2 to +1, selected to accommodate the specific clinical requirements and neurological considerations of patients with traumatic brain injury and supported by previous studies in TBI patients by Jullette-Fantigrassi (2013) and Taran et al. (2019). These studies demonstrated that RASS can be effectively used to monitor sedation, guide titration of sedatives, and maintain target sedation ranges without compromising neurological assessment. In the present study, a RASS range of –2 to +1 was selected to accommodate the specific clinical requirements and neurological considerations of TBI patients [16,18]. This study evaluates the impact of a nurse-led sedation protocol guided by the RASS Scale on selected clinical outcomes in TBI patients admitted to general ICUs in Northwest Syria.

2- Significance and Aim of the Study:

This study holds particular significance for the care of TBI patients in Syrian intensive care units, where sedation management frequently depends on non-standardized practices that may heighten complications, prolong mechanical ventilation, and overburden limited ICU resources. By assessing a nurse-led, RASS-guided sedation protocol, this research offers context-specific evidence that structured, nurse-driven strategies can improve sedation quality, reduce airway complications, and optimize the utilization of ICU resources. In addition to enhancing patient outcomes, the study highlights the critical care role of nurses in delivering safe, evidence-based critical care. This study aimed to evaluate the impact of a nurse-led sedation protocol guided by the RASS Scale on selected clinically outcomes, including target sedation level, self-extubation, reintubation, duration of mechanical ventilation, ICU length of stay, and mortality in mechanically ventilated TBI patients admitted to general ICUs in Northwest Syria.

Study hypotheses:

1. Implementation of a nurse-led, RASS-guided sedation protocol significantly increases the proportion of time that TBI patients remain within the target sedation range compared with standard care.
2. The nurse-led, RASS-guided sedation protocol significantly reduces the incidence of self-extubation among TBI patients compared with standard care.
3. The nurse-led, RASS-guided sedation protocol significantly reduces the incidence of reintubation among TBI patients compared with standard care.
4. The nurse-led, RASS-guided sedation protocol significantly shortens the duration of mechanical ventilation compared with standard care.
5. The nurse-led, RASS-guided sedation protocol significantly reduces ICU length of stay among TBI patients compared with standard care.
6. The nurse-led, RASS-guided sedation protocol significantly reduces the mortality rate among TBI patients compared with standard care.

3- Material and methods

Research design:

Quesi experimental design was used to conduct the aim of this study.

Setting:

The study was carried out in three general intensive care unit (25 beds) in Northwest Syria: Idlib University Hospital, Al-Shifa Hospital, and the Specialized Surgical Hospital.

Sample:

A Purposive sample of 80 adult TBI patients were enrolled and randomly allocated into two equal groups (40 in each) control & study groups.

Sample size calculation:

The sample size was determined using an 80% power calculation to detect a moderate effect (d = 0.6) at a 5% significance level, requiring 34 patients per group (N = 68). Allowing for a 10% dropout rate, 80 patients were enrolled—40 in each group.

Randomization and allocation

- Block randomization using Microsoft Excel (size = 10), eight blocks of ten patients each.
- Sequence generated by independent researcher.
- Allocation was concealed using opaque sealed envelopes, which were opened only after confirming the participant's eligibility and collecting baseline data.
- Eligible patients who met the inclusion and exclusion criteria were purposively selected from the study population .Randomization was used only for group assignment, not for participant selection.

Inclusion criteria

- Adults aged (18-60) years with traumatic brain injury.
- requiring endotracheal intubation within 24 hours of ICU admission.
- GCS 7–12
- RASS > −4.
- APACHE II score (10–19).

Exclusion criteria

- Pre-existing neurological disorders or substance use
- Planned early extubation
- Surgery during enrollment.
- Requirement for continuous sedative infusion.

Tools

Four tools were used by the researcher in the study after reviewing of the related literature.

First tool: Patient demographic, health and clinical data tool

This tool developed by the researcher after a comprehensive review of related literature [18, 19], which includes two parts.

- *Part I:* demographic and health data which includes patient code, sex, age, medical diagnosis, and date of admission, date of discharge and health relevant data that include patient diagnosis on admission, chronic diseases history, causes of injury and sedation indication, baseline (APACH II, RASS, BPS)
- *Part II:* Clinical outcomes data including information about self-extubation, reintubation, duration of mechanical ventilation, ICU length of stay and mortality rates.

The second tool: Multi-Clinical Scales Tool

This tool includes 4 parts:

- *Part I:* Richmond agitation sedation scale (RASS), developed by Sessler et al. (2002), is a validated 10-point tool assessing sedation depth in critically ill patients. (From +4 to -5 point) the RASS has the unique feature of measuring length of eye contact by the patient following verbal command. The tool demonstrated excellent interrater reliability ($r = 0.956$; $\kappa = 0.73$), confirming its high consistency and validity in adult ICU patients.

- Patient is alert, restless, or agitated. **(**Score 0 to **+4)**
- Patient awakens with sustained eye opening and eye contact (Score –1)**.**
- Patient awakens with eye opening and eye contact, but not sustained. (Score –2)
- Patient has any movement in response to voice but no eye contact. (Score –3)
- Patient has any movement to physical stimulation. (Score –4)
- Patient has no response to any stimulation. (Score – 5) [14, 15]

Part II: The Behavioral Pain Scale (BPS), developed by Payen et al. (2001)**,** assesses three items (facial expressions, movements of the upper limbs, and ventilator compliance), with scores ranging from 3 (indicating no pain) to 12 (indicating severe pain). The tool demonstrated good interrater reliability, with correlation coefficients of $r^2 = 0.71$ at rest and $r^2 = 0.50$ during procedures, confirming its reliability and validity in sedated, mechanically ventilated ICU patients [20].

Part III: The GCS scores, originally developed by Teasdale and Jennett (1974) and later revised by Jennett (2005). Range between 3 (signifying deep coma) and 15 (indicating a fully awake and alert state), The tool demonstrated high interrater reliability, with reported kappa coefficients ranging from 0.80 to 0.90, confirming its excellent consistency and reliability in assessing consciousness levels in critically ill and trauma patients [21].

Part IV: The APACHE II score, developed by Knaus et al. (1985), is widely validated for its predictive accuracy regarding ICU patient mortality across diverse settings. Its interrater reliability has been confirmed by Kho et al. (2007), who reported an intraclass correlation coefficient ICC of 0.90 (95% CI: 0.84–0.94) [22].

The third tool: Pharmacological and non-pharmacological interventions Checklist, includes two parts:

- *Part I:* Non-pharmacological interventions covered psychological support, family communication, physiotherapy, patient positioning, noise and light reduction, adequate sleep, temperature regulation, airway suctioning, Reduce pressure connections, and the use or removal of physical restraints.
- *Part II:* The pharmacological medications including sedatives such as midazolam, propofol, thiopental, fentanyl, morphine and propofol along with their frequency and dosages.

The fourth tool: TBI Nurse-led sedation protocol

The nurse-led, RASS-guided sedation protocol was specifically developed and tailored for this study based on an extensive review of international sedation guidelines [18,19,23,26], adaptation to local ICU resources, and validation by a panel of critical care experts to ensure clinical feasibility and applicability.

Intervention

The intervention in this study consisted of implementing a nurse-led, RASS-guided sedation protocol specifically developed for TBI patients. It aimed to maintain patients within the target sedation range (RASS −2 to +1) by combining regular assessment, pharmacological titration, and prioritized non-pharmacological measures. When the RASS score was within the target range, no action was required except during invasive

procedures or specific safety indications. For RASS scores below −2, sedation reduction was considered in consultation with the ICU physician, provided that no elevated intracranial pressure or seizures were present. For RASS scores above +1 or in cases of agitation, reversible causes were corrected, pain was assessed using the Behavioral Pain Scale (BPS), and both non-pharmacological and pharmacological strategies were applied as indicated. A schematic representation of the protocol steps is shown in Figure 1.

Validity and Reliability

The tool was tested for content related validity by 7 experts (five academic staff members at the faculty of nursing from Syria and Egypt, and two from critical care medicines) for tested the content validity. According to their opinion, modification was carried out. The reliability was done on tool one using Cronach's Alpha and reliability level was 0.86 which was acceptable.

Ethical considerations

- The study protocol was reviewed and approved by the Institutional Ethics Committee at Idlib University (Approval No. REC-0100).
- Official permissions for data collection were obtained from three hospitals at northwest Syria.
- Written informed consent obtained from patients' guardians after explaining purpose of the study.
- The study was following common ethical principles in clinical research.
- Confidentiality and anonymity were assured.
- Study subject has the right to refuse to participate and or withdraw from the study at any time.
- Study subjects' privacy was considered during collection of data.
- Patient safety was prioritized through continuous monitoring, daily clinical assessments.

Pilot study

It was conducted on (9 patients) to assess the tools' clarity, applicability, feasibility and proverbial to estimate the time bearable to consummates the tools. Consequently, necessary modifications were done. The study didn't include these patients.

Methods:

The study was conducted through three phases, preparatory, assessment and implementation phases.

Preparatory phase

1. Data collection was carried out over six months, from February to July 2025.
2. Permission to conduct the study was obtained from the hospital's responsible authorities after explanation of the aim and natural of the study.
3. The researcher provided training to research assistants across all shifts to ensure consistency in data collection. Research assistants (26–38 years, ≥3 years ICU experience) received 4-hour training on TBI sedation and RASS application, then applied the protocol to five patients independently. Substantial inter-rater reliability with the researcher was observed (weighted Cohen's kappa = 0.77, 95% CI: 0.62–0.92) indicating substantial agreement between raters.

Assessment phase

1. During this phase the patient assessed from the first day of admission and record patient demographic and clinical data by taking this information from his or her sheet using tool 1(part I).

2. The researcher assesses the patients using tool 2 to determine the level of sedation (RASS), pain (BPS), consciousness (GCS) and APACH II score at admission.
3. For the control group: the researcher assessed patients who were receiving the routine ICU care for sedated patients without a protocolized RASS-driven titration.
4. For study group: the researcher assesses the patient then applying nursing sedation protocol.
5. Pharmacological and non-pharmacological interventions were recorded.
6. The ICU physician supervised the entire process.
7. Medications were administered equally according to ICU protocols.
8. Sedation and pain levels measured every two hours across all shifts in the two groups.

Implementation phase

The researcher applied the nursing sedation protocol as follow, Figure (1):

- If RASS was in target level between −2 to +1, no intervention, except for invasive procedures or elevated intracranial pressure or seizures, and review target score once per shift.
- For RASS<-2 in absence of elevated ICP or seizures, consult ICU physician for sedation reduction if possible and continuous reassess ever two hours.
- If RASS> +1, correct reversable causes and assess pain using BPS and treat pain first
- If undersedation persisted, non-pharmacological interventions (e.g., psychological support, family contact, physiotherapy, reduce pressure of connections) were applied.

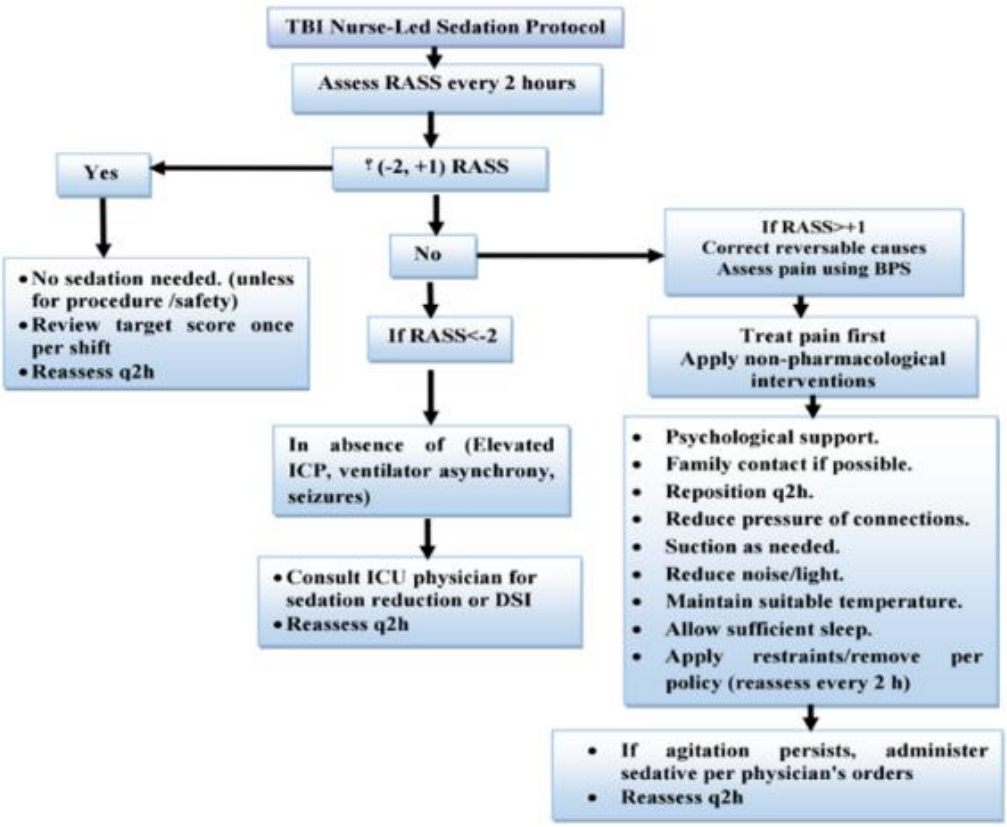

Figure 1. Nurse-led sedation protocol for TBI patients guided by RASS.

Statistical analysis

The data were reviewed and prepared for computer entry, coded, analyzed and tabulated using computer program (SPSS \version 26). Descriptive analyses, including frequencies, percentages, means, and standard deviations, were performed. Chi-square test (or Fisher's exact when appropriate), independent t-test were applied in the relationship between study and control groups. Cox proportional hazards regression was used to assess the effect of the intervention and covariates on mechanical ventilation duration and ICU length of stay. The critical value of the tests P was considered statistically significant when P less than 0.05. Cronbachs alpha was done to test reliability of the tool. Missing values were addressed using listwise deletion, with analyses performed on a complete-case basis to avoid bias introduced by incomplete data.

4- Results and Discussion:

Results:

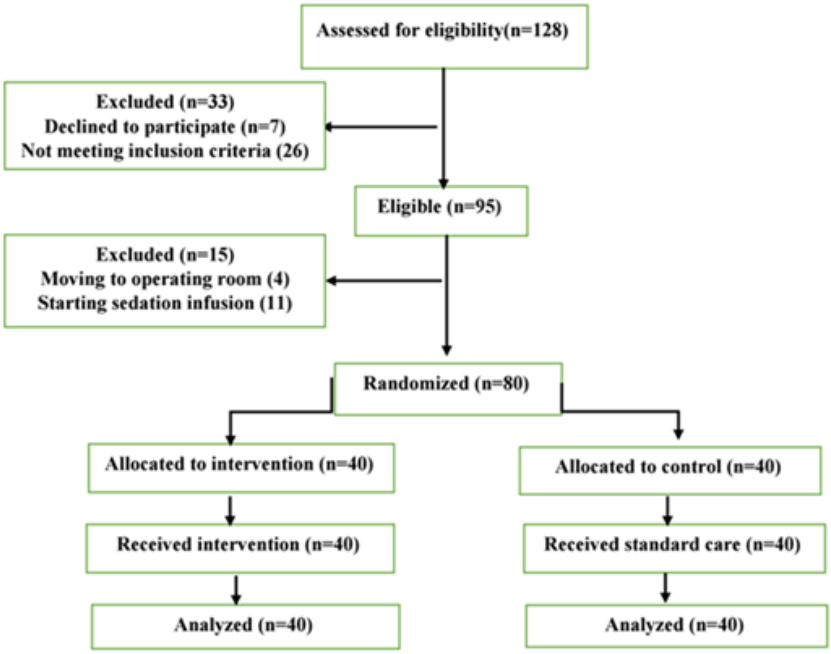

Figure 2. CONSORT flow diagram illustrating participant progression through the study

Figure 2. Shows that of 128 patients screened, 33 were excluded (7 refused, 26 ineligible). Of 95 eligible, 15 were excluded before intervention (4 surgery, 11 already sedated). The final 80 patients were randomized equally into intervention and control groups, with all completing the study. The intervention group received standard ICU routine care in addition to the nurse-led, RASS-guided sedation protocol. The control group received standard routine care only.

Table 1. Demographic and baseline clinical characteristics of participants.

Variable	Control (n = 40)	Intervention (n = 40)	*p*-value
Age, years, mean ± SD	33.10 ± 13.09	37.40 ± 12.13	0.132
Male sex, n (%)	29 (72.5)	33 (82.5)	0.284
Admission GCS, mean ± SD	7.88 ± 1.11	8.25 ± 1.10	0.134
APACHE II score, mean ± SD	15.23 ± 1.96	15.48 ± 2.36	0.609
Baseline RASS, mean ± SD	−3.00 ± 0.96	−3.00 ± 0.88	0.335
Cause of injury, n (%)			0.110
Road traffic accident	23 (57.5)	25 (62.5)	
Fall from height	8 (20.0)	2 (5.0)	
War-related injury	9 (22.5)	13 (32.5)	
Indications for sedation, n (%)			
Decrease intracranial pressure (ICP)	20 (50.0)	27 (67.5)	0.112
Reduce agitation	33 (82.5)	28 (70.0)	0.189
Pain control	17 (42.5)	15 (37.5)	0.310
Facilitate mechanical ventilation	40 (100.0)	38 (95.0)	0.152
Procedural sedation	22 (55.0)	20 (50.0)	0.654
Promote sleep	17 (42.5)	14 (35.0)	0.314
Seizure management	5 (12.5)	7 (17.5)	0.531

Abbreviations: GCS = Glasgow Coma Scale; APACHE II = Acute Physiology and Chronic Health Evaluation II; RASS = Richmond Agitation–Sedation Scale; ICP = intracranial pressure.

Table (1) shows that there were no statistically significant differences between the intervention and control groups regarding demographic and clinical baseline characteristics, including age, sex distribution, admission GCS score, APACHE II score, baseline RASS score, causes of injury, or indications for sedation (all $p > 0.05$).There were no statistically significant differences in age ($p = 0.132$), sex distribution ($p = 0.284$), admission Glasgow Coma Scale (GCS) score ($p = 0.134$), APACHE II score ($p = 0.609$), baseline RASS score ($p = 0.335$), or causes of injury ($p = 0.110$). Similarly, no significant differences were found in sedation indications, including control of ICP, agitation, pain, tolerance to mechanical ventilation, procedural sedation, seizure management, or sleep promotion.

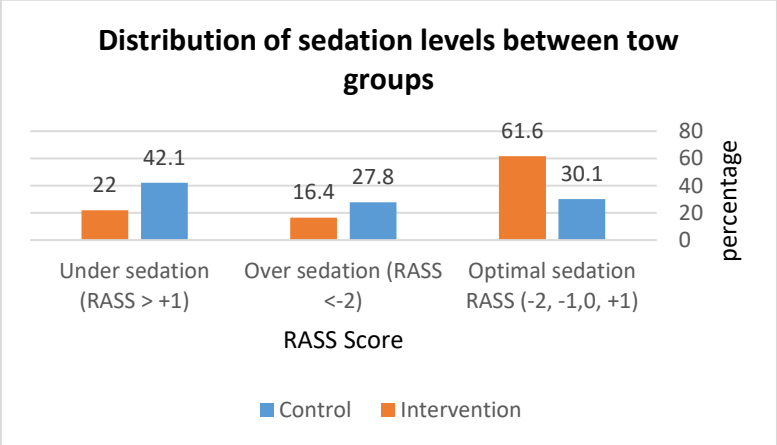

Figure 3. Distribution of RASS levels in control and intervention groups during total period

Figure (3) illustrates the distribution of sedation levels throughout the study period. The intervention group spent 61.6% of the time within the optimal sedation range (RASS −2 to +1), compared with 30.1% in the control group. In contrast, oversedation episodes (RASS < −2) were more frequent in the control group (27.8%) than in the intervention group (16.4%), and undersedation episodes (RASS > +1) occurred more often in the control group (42.1%) than in the intervention group (22.0%).

Table 2. ICU stay and mechanical ventilation duration

Outcome	Control Mean ± SD	Intervention Mean ± SD	*t*	*p*-value
ICU stay, days	8.03 ± 1.75	7.33 ± 1.80	1.46	0.15
Mechanical ventilation, days	5.95 ± 1.63	5.72 ± 2.10	0.82	0.41

Abbreviations: ICU = intensive care unit.

Table (2) the study results showed that the mean ICU stay was 8.03 ± 1.75 days in the control group and 7.33 ± 1.80 days in the intervention group. The mean duration of mechanical ventilation was 5.95 ± 1.63 days in the control group and 5.72 ± 2.10 days in the intervention group. Although the means suggest a trend toward shorter ICU stay and ventilation duration in the intervention group, the independent-samples t-test indicated that these differences were not statistically significant (p = 0.15 and p = 0.41, respectively).

Table 3. Ventilation-related outcomes

Outcome	Control (n = 40)	Intervention (n = 40)	Test statistic	*p*-value
Self-extubation, n (%)	11 (27.5)	4 (10.0)	$\chi^2 = 4.02$	0.045*
Reintubation, n (%)	15 (37.5)	6 (15.0)	$\chi^2 = 5.23$	0.022*
Successful weaning, n (%)	36 (90.0)	38 (95.0)	Fisher's exact	0.675
Failed weaning, n (%)	6 (15.0)	3 (7.5)	Fisher's exact	0.481

Fisher's exact = Fisher's exact test, χ^2 = Chi-square test, *(*) Statistically significant at p < .05*

Table (3) shows that the intervention group had significantly lower rates of self-extubation (10.0% vs. 27.5%; $\chi^2 = 4.02$, p = 0.045) and reintubation (15.0% vs. 37.5%; $\chi^2 = 5.23$, p = 0.022) compared with the control group, whereas rates of successful weaning from mechanical ventilation (95.0% vs. 90.0%; p = 0.675) and failed weaning attempts (7.5% vs. 15.0%; p = 0.481) did not differ significantly.

Table 4. Final patient outcomes.

Outcome	Intervention *n* (%)	Control *n* (%)	*p*-value
Discharge to ward	38 (95.0)	36 (90.0)	0.675
Death	2 (5.0)	4 (10.0)	0.334

Table (4): Demonstrate that most patients in both groups were discharged to the ward (intervention 95.0% vs. control: 90.0%; p = 0.675), and mortality rates were low with no significant difference between groups. Mortality rate was defined as the proportion of patients who died during ICU stay relative to the total number of patients in each group.

Table 5. Cox proportional hazards for mechanical ventilation duration.

Variable	B	HR (Exp B)	SE	*p*-value
Intervention vs. control	−0.980	0.375	0.426	0.021*
APACHE II score	−0.190	0.720	0.030	0.002*
Sex (male)	−0.758	0.469	0.507	0.135
Age	−0.230	0.750	0.020	0.540

Abbreviations: HR = hazard ratio; SE = standard error; APACHE II = Acute Physiology and Chronic Health Evaluation II. *(*) Statistically significant at p < .05*

Table (5): Illustrate that patients in the intervention group were significantly more likely to be weaned earlier from mechanical ventilation than controls (hazard ratio [HR] = 0.38, p = 0.021), reflecting a 62% greater likelihood of earlier liberation. Higher APACHE II scores predicted prolonged ventilation (HR = 0.72, p = 0.002), whereas sex and age were not significant predictors.

Table 6. Cox proportional hazards for ICU length of stay.

Variable	B	HR (Exp B)	SE	*p*-value
Intervention vs. control	−1.091	2.976	0.412	0.008*
Sex (male)	−1.053	2.865	0.459	0.022*
Age	−0.220	0.802	0.250	0.371
APACHE II score	−0.110	0.896	0.130	0.924

Abbreviations: HR = hazard ratio; SE = standard error; APACHE II = Acute Physiology and Chronic Health Evaluation II; ICU = intensive care unit. *(*) Statistically significant at p < .05*

Table (6): Shows that the intervention group had nearly three times the likelihood of earlier ICU discharge compared with controls (HR = 2.98, p = 0.008). Male sex was also associated with earlier discharge (HR = 2.87, p = 0.022), whereas age and APACHE II score were not significant predictors."

Discussion:

The intervention and control groups were comparable at baseline in terms of age, sex, GCS, APACHE II scores, RASS scores, causes of injury, and indications for sedation. Baseline equivalence is crucial to isolate the effects of the intervention; this balance minimizes confounding and supports the validity of the observed outcomes.

The mean age was in the third decade of life, which is consistent with the fact that TBI disproportionately affects young adults [24]. According to Rosyidi et al. (2019), Traumatic brain injury is a major cause of mortality and morbidity in patients in the age between 18 and 45 years [25]. The study also had a predominance of male patients, which aligns with global and regional data on TBI incidence [24,25]. Baseline GCS scores in both groups indicated moderate brain injury, while APACHE II scores reflected a moderate severity of illness. This similarity suggests that subsequent differences in sedation quality or outcomes were unlikely to be driven by pre-existing neurological or physiological disparities. Comparable baseline RASS scores further support that changes in sedation levels after randomization were attributable to the intervention.

Regarding causes of injury, both groups exhibited a mix of road traffic accidents, falls, and war-related injuries, with no significant differences in distribution. Similarly, sedation indications—including intracranial pressure control, agitation, pain, ventilator tolerance, procedural needs, seizure management, and sleep promotion—were balanced between groups. This minimizes the risk that disproportionate representation of patients with intensive sedation needs biased the outcomes.

Patients in the intervention group spent a significantly greater proportion of time within the target sedation range (RASS –2 to +1) and experienced fewer episodes of both over- and under-sedation compared with the control group. These results align with a study conducted by Jullette-Fantigrassi (2013) at the University of Arizona, which evaluated the use of the Richmond Agitation Sedation Scale (RASS) in ventilated traumatic brain injury (TBI) patients. The study aimed to assess how RASS guided sedation titration and to examine nurses' perspectives on sedation protocols. Findings showed that the prescribed RASS was largely maintained (mean actual RASS -2.04 ± 1.05), and nurses reported that the use of RASS did not impede accurate neurological assessments. [16] The reduction in sedation extremes is particularly important in TBI, where excessive sedation can mask neurological deterioration, while insufficient sedation may trigger agitation-related increases in intracranial pressure [3].

The study showed no statistically significant differences between groups in terms of ICU stay and mechanical ventilation duration, although numerical trends favored the intervention. Patients in the intervention group had a slightly shorter ICU stay and a marginally reduced duration of mechanical ventilation. While these differences did not reach statistical significance, they may still be clinically relevant, particularly in resource-limited settings where even small reductions in ICU occupancy can alleviate bed shortages and reduce costs. These results align with the findings of Bugedo et al. (2013) in a Brazilian ICU, who aimed to evaluate the safety and feasibility of an analgesia-based sedation protocol for mechanically ventilated patients. They reported reduced deep sedation, stable agitation levels, and overall feasibility and safety of the protocol.[29]. The lack of statistical significance may be attributable to an insufficient sample size rather than a true absence of effect.

On the other hand, a systematic review and meta-analysis by Qi et al. (2021) evaluated the effects of nurse-led sedation protocols on mechanically ventilated adult ICU patients across multiple countries. The review included multiple randomized controlled trials and pre–post intervention studies and found that nurse-led protocols significantly reduced the duration of mechanical ventilation, ICU length of stay, and sedation-related complications [27].

The intervention group experienced significantly lower rates of self-extubation (10% vs. 27.5%, $p = 0.045$) and reintubation (15% vs. 37.5%, $p = 0.022$). Notably, few contemporary studies have directly examined the effect of nurse-led sedation protocols on self-extubation, making this an important contribution to the literature. These results suggest that consistent sedation assessment and timely titration can improve patient safety by maintaining optimal sedation levels. However, findings across the literature remain mixed. For example, Hernandez et al. (2024) conducted a systematic review and meta-analysis across multiple international ICU settings to evaluate the effectiveness and safety of protocolized sedation in mechanically ventilated ICU patients. They reported no significant reduction in self-extubation compared with standard practice [24]. This

discrepancy underscores the likelihood that contextual factors—such as ICU resources, staffing, and baseline practice quality—may influence outcomes.

Regarding reintubation, the reduced rate observed in the present study aligns with Taran et al. (2019), who conducted a single-blind randomized clinical trial in an ICU in Iran to evaluate the effect of a RASS-based sedation protocol on clinical outcomes in mechanically ventilated traumatic patients. The study found that implementing the protocol reduced reintubation rate [18]. The lower reintubation rate observed here contrasts with Mingua (2022), who conducted a before/after comparative study in ICUs in the United States to evaluate the impact of a multifaceted intervention on nurse compliance with a sedation protocol and patient outcomes. The intervention did not lead to a significant reduction in reintubation rates [28], likely reflecting the more homogeneous cohort of TBI patients in the present trial.

The absence of significant differences in weaning success rates suggests that sedation alone does not determine liberation from mechanical ventilation, as neurological recovery and respiratory function remain key factors. These findings suggest that minimizing oversedation can reduce ventilator dependence and facilitate timely extubation. However, other investigations have failed to show a significant benefit. This inconsistency may stem from variations in study design, patient populations, and local practices. In units with already high staff-to-patient ratios and established sedation monitoring practices, additional protocols may yield only incremental improvements. Conversely, in settings where sedation management is less standardized, protocol implementation can produce a more pronounced effect.

No significant difference in short-term mortality was observed between groups. This is consistent with most prior studies, which generally report that sedation protocols improve process-related outcomes (e.g., sedation quality, ventilation duration, ICU stay) rather than survival [24,18]. Mortality in critically ill trauma populations is strongly influenced by non-modifiable factors such as initial injury severity, delayed presentation, or associated extracranial trauma. Nonetheless, some studies, such as Qi et al. (2021), have reported mortality reductions with nurse-led protocols, particularly when implementation meaningfully altered bedside practice. This variation likely reflects differences in case mix, baseline practices, and protocol adherence [27].

Cox regression analysis demonstrated that intervention patients were more likely to achieve earlier weaning from mechanical ventilation ($Exp = 0.375$, $p = 0.021$) and earlier ICU discharge ($Exp = 2.976$, $p = 0.008$) than controls. These findings align with Barr et al. (2013) in the United States, who developed clinical practice guidelines emphasizing protocolized sedation in adult ICU patients. Their recommendations highlighted that systematic, nurse-led, protocolized sedation reduces agitation-related adverse events and facilitate earlier weaning from mechanical ventilation [8]. Higher APACHE II scores independently predicted prolonged ventilation, consistent with prior research. These findings reinforce the potential value of structured sedation strategies in optimizing outcomes, even in resource-constrained environments.

Study Limitations

This study has several identified limitations. First, its findings might have limited generalizability because it focused exclusively on TBI patients in general ICUs in Idleb. This could restrict its applicability to other patient populations or different ICU settings. To address potential confounding factors, we implemented several strategies, including randomization, using standardized medication regimens based on physician orders, and

matching patient severity with APACHE II scores. The risk of bias was also partially reduced by blinding the research assistants who administered the intervention. The principal investigator, however, was responsible for collecting the outcome data.

5- Conclusion and Recommendations

Conclusion:

In mechanically ventilated TBI patients, a structured nurse-led sedation protocol significantly reduced ICU stay, mechanical ventilation duration, and adverse airway events, without affecting short-term mortality. These findings support the integration of nurse-driven sedation strategies into ICU practice, even under severe resource constraints, with potential to improve both patient outcomes and ICU efficiency.

Recommendations:

In light of the results of this study, the following recommendations are made.

- Further multi-center trials in similar low-resource settings are needed to confirm these findings
- Nurse-led, RASS-guided sedation protocols should be integrated into ICU practice to optimize sedation quality and patient safety.
- Assess cost-effectiveness, and evaluate longer-term patient outcomes.
- Equip intensive care units with simple illustrated book let about nursing sedation protocol.
- Ongoing training and support for ICU nurses are essential to sustain protocol adherence and improve outcomes for TBI patients.
- Reapply this research on a larger probability sample acquired from different geographical areas in Syria for generalization.
- Research should also examine strategies to optimize protocol adherence when staffing and monitoring resources are limited.

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