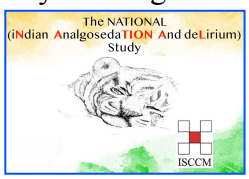
Study Summary

NATIONAL (i**N**dian **A**nalgoseda**TION A**nd de**L**irium): A Multi-center prospective study of analgosedation practices and delirium in Indian ICUs



[INSTINCT (**IN**haled **S**eda**T**ion **IN C**ri**T**ically ill patients) study Group, ISCCM]

Background

The current sedation practices and the incidence of delirium in the Indian ICUs (in 2019) are not known. We also do not know the incidence of delirium in our practice. Delirium has been shown to prolong mechanical ventilation, duration of ICU and hospital length of stay and in some studies even mortality. A questionnaire-based survey carried out by ISCCM in 2013; [1] found the following about analgesia and sedation practices in India. Midazolam was the commonest agent used, while propofol was the second. Few respondents had occasionally used dexmedetomidine. Fentanyl was the most common analgesic agent used, followed by Tramadol and Paracetamol. "Analgesia first" approach was used by a few while many used Analgo-sedation approach. Rarely "analgesia only" regimen was used. Most analgesics and sedatives were given as continuous IV infusion by a large number of respondents and as intermittent boluses by a few, and both methods were used by some respondents. About two-thirds of the responders felt that the incidence of delirium in mechanically ventilated patients was less than 10% in their practice. Majority reported not assessing delirium in the ICU.

The PADIS (Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption) guidelines of Society of Critical Care Medicine were first formulated in 2013 and later updated in 2018. [2] Dexmedetomidine is better and safer with advantages of quick onset and offset, but is costly. Importantly both agents do not lead to delirium unlike benzodiazepines.

The aim of the study is find out the incidence of delirium and the analgosedation practices in Indian ICUs.

Setting: Intensive Care Units in India, willing to share the data for this purpose.

Study design: Prospective observational study

Study duration: Data will be collected for all consecutive adults patients to the ICU who need sedation and analgesia, for a period of one month after obtaining the IEC approval.

Follow-up period: For each patient recruited in the study, 30-day follow-up. The duration of follow-up for each ICU will last till the 30-day (or discharge from the hospital or death, which ever occurs earlier) follow-up data is collected for the last patient enrolled from that ICU. This will include the data for the secondary outcomes.

Primary Endpoint

1. Incidence of delirium

Secondary End-points:

1. Proportion of time spent in target sedation range (RASS 0 to -2)
2. Mean (± SD) pain score each day in the ICU
3. Type and duration of delirium

duration of infusion, antipsychotic medications)
5. Duration of Mechanical ventilation a. invasive b. non-invasive
6. ICU Mortality (if within 30 days)
7. Hospital Mortality (if within 30 days)
8. ICU and Hospital LOS (if < 30 days)
9. 30 days outcomes (if above not present)

Inclusion Criteria:
1. Age > 18-80 years
2. Anticipated duration of ventilation > 48 hrs.

Exclusion Criteria:
1. Severe Brain Injury GCS < 9
2. Mechanical ventilation needed < 24 hrs.
3. Mechanical Ventilation initiated > 24 hrs. after ICU admission (NIV counts as Mechanical Ventilation)
4. Not expected to survive for > 24 hrs.
5. Admitted for end of life care

The following data will be collected:
1. Baseline characteristics
2. Admission source
3. Demographic characteristics
4. Initial neurological assessment
5. Substance abuse history
6. SAPS III score
7. SOFA score
8. Primary Diagnosis
9. Hemodynamic status
10. Sedation score (RASS)
11. Pain Score (VAS)

The data collection process will be as follows:
1. Patient will be assessed as in baseline characteristics
2. Pain score at initiation of analgesia will be recorded
3. Sedation score at initiation of sedation will be recorded
4. Both scores will be recorded thrice a day
5. Scores are also recorded at escalation or de-escalation of dosage, the reason for change of dosage, i.e., was there a change

Indications for de-escalation/escalation of doses of either sedatives or analgesics will be recorded under the following heads
1. No longer needed
2. Neurological assessment
3. Hemodynamic instability
4. Adverse effects
5. Others: Please specify:

Indications for escalation
1. Didn't meet sedation or analgesia score target
2. Ventilator asynchrony
3. Procedure to be undertaken
4. Others: Please specify:

Other data

1. Choice of sedatives will be recorded
2. Dose and route of administration of sedation will be recorded
3. Choice of analgesia will be recorded
4. Dose and route of administration of sedation will be recorded of analgesics will be recorded
5. Use of neuraxial analgesia will be recorded
6. Presence of delirium (CAM-ICU score, at each shift change, i.e. 3 times a day, if patient is awake (RASS> -3)
7. Weaning criteria will be recorded as per commonly used scores
8. Extubation criteria will be recorded
9. Duration of mechanical ventilation including post extubation NIV will be recorded
10. ICU LOS will be recorded
11. ICU Discharge status will be recorded
12. Hospital discharge status will be recorded

Statistics

For choice of agent tests of frequency will be used. For cumulative dosages Median value and IQR will be used. For comparative parameters like sedation score vs drug dose Chi Square test will be used. Descriptive statistics will be used to calculate the proportion of time spent by each patient in the adequate sedation range (along with Confidence Intervals). P-trend test will be used for to assess a proportional decrease or increase in need for the sedative agent. P value < 0.05 will be assumed to be significant. Uni-variate and multi-variate analysis for cause of delirium, ICU outcomes. Survival analysis will be done by Cox proportional regression analysis

Ethical issues

Each participating ICU will obtain approval to conduct the study with a waiver of informed consent (if possible). If not, then brief consent from LAR with deferred consent from patients will be obtained.

References

1. Chawla R, Myatra SN, Ramakrishnan N, Todi S, Kansal S, Dash SK. Current practices of mobilization, analgesia, relaxants and sedation in Indian ICUs: A survey conducted by the Indian Society of Critical Care Medicine. Indian J Crit Care Med. 2014; 18(9): 575-84.

2. Devlin JW, Skrobik Y, Gélinas C, Needham DM, Slooter AJC, Pandharipande PP, et al. Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU. Crit Care Med. 2018; 46(9): e825-e873.

The NATIONAL **(**i**N**d**ian** A**nalgoseda**TION A**nd de**L**irium)** STUDY

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