STUDY PROTOCOL

A Prospective Study of Agitation in Post-craniotomy Patients:
   Incidence, Risk factors, and Outcomes

Department of Critical Care Medicine,
Beijing Tiantan Hospital, Capital Medical University
October, 2011
Background

Agitation has been investigated in patients admitted to medical intensive care unit (ICU), surgical ICU and post-anesthesia care unit (PACU) [1-4]. Results of these studies indicate that agitation is associated with worse outcome, such as unplanned catheter removal, nosocomial infections, prolonged ICU and hospital stay, and mortality. Clinical experience shows that agitation occurs in patients after craniotomy, and this might result in serious consequences, especially for post-operative hematoma [5,6]. But up to now, agitation in post-operative neurosurgical patients is poorly studied. In present study, we prospectively investigated acute post-operative agitation in the neuro-ICU after craniotomy. The objective of this study was to define the incidence, risk factors and outcome of acute agitation in post-operative neurosurgical patients.
Study protocol

I  Study design
Prospective cohort study. No attempt will be made to change or influence the standard practice of patient care.

II  Setting
12-bed Neurosurgical ICU in an University Affiliated Hospital.

III  Enrollment
All consecutive admitted patients after an elective craniotomy under general anesthesia will be included.

Exclusion criteria:
1. age under 18 years old;
2. emergency operation;
3. re-operation within 72 hours
4. unarousable during the first 24 hours after operation;
5. time interval between the end of operation to neurosurgical ICU admission longer than 24 hours.

IV  Judgment of agitation
The Riker sedation-agitated scale (SAS) [7] will be employed to assess each patient’s level of agitation (Table).

Two chief nurses, who will not involve the patient care, evaluated and
documented the SAS of enrolled patient hourly. Two investigators will review nursing records daily. The maximal SAS for each patient will be determined and confirmed by these four investigators in daily meeting.

According to the maximal SAS in the first 12 hours after operation, patients will be divided into 2 categories: non-agitated patients (Riker SAS levels 1-4) and agitated patients (Riker SAS levels 5-7).

Riker sedation-agitation scale

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Dangerous agitation</td>
</tr>
<tr>
<td>6</td>
<td>Very agitated</td>
</tr>
<tr>
<td>5</td>
<td>Agitated</td>
</tr>
<tr>
<td>4</td>
<td>Non-agitated</td>
</tr>
<tr>
<td>3</td>
<td>Sedated</td>
</tr>
<tr>
<td>2</td>
<td>Very sedated</td>
</tr>
<tr>
<td>1</td>
<td>Unarousable</td>
</tr>
</tbody>
</table>
V Risk factors

Collection of potential risk factors include:

1. Pre-operative data: demographic characteristics (gender, age and body weight); history of smoke and alcohol abuse, long-term (>1 month) use of anti-depressive drugs or benzodiazepines; length of stay (LOS) in hospital before operation; frontal location of the tumor.

2. Data during anesthesia and operation included: frontal approach of the operation, duration of anesthesia, amount of bleeding and anesthesia by total intravenous anesthesia (TIVA).

Post-operative data included: Glasgow coma scale (GCS) at neurosurgical ICU admission, presence of endotracheal intubation, need mechanical ventilation, presence of external ventricular drainage (EVD) tube, complaint of pain, episode of pulse oxygen saturation (SpO2) below 90%, respiratory rate (RR) below 8/minute, mean blood pressure (MAP) above 130 mmHg or below 70 mmHg, and concentration of blood glucose above 10 mmol/L.

VI Outcomes

Patients will be followed up to hospital discharge.

Primary outcomes include: self-extubation of endotracheal tube and accident removal central venous or bladder catheters.

Secondary outcomes include: length of stay in ICU and Glasgow outcome score (GOS) at hospital discharge.
Statistical analysis

Categorical variables are expressed as percentages. Continuous data are checked for normal distribution by Kolmogorov-Smirnov test, and are shown as mean and standard deviation (SD) or median with the 25th and 75th percentiles, when applicable.

Distribution of maximal SAS will be analyzed and incidence of agitation will be calculated to present the epidemiology knowledge. Univariate analyses between the agitation and non-agitation groups are carried out. Categorical variables are analyzed by $\chi^2$ test. Comparisons of continuous data are performed by using unpaired t-test for normally distributed variables, and the Mann-Whitney U test for non-normally distributed variables. Factors with a P-value < 0.20 will be included in multivariate analysis (stepwise backward logistic regression) to identify the independent factors of agitation. Odds ratios and their 95% confidence intervals (CIs) are used to assess the independent contribution of significant factors. The Hosmer and Lemeshow test will be used to determine appropriateness of the model.

A P-value of less than 0.05 is considered statistically significant.
Planing schedule and sample

Study will be carried out in July, 2012, and is anticipated to finish in December, 2012. We plan to enroll 120 patients.
References


