Issues of daily ICU nursing care: safety, nutrition and sedation

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Chapter 8

The reliability and validity of a new and simple method to measure sedation levels in Intensive Care patients

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Abstract

Background
Since more sophisticated ventilation techniques have enabled patients to comply with the ventilator with little or no sedation, deep sedation levels can easily be avoided. However, successful ventilation techniques expanded also the treatment possibilities for the more severely ill patients who still need deeper sedation levels. We developed a new sedation score to improve the prevention of oversedation and to simplify scoring practice in the ICU.

Objective
To establish the validity and reliability of a new sedation score (Sedic score) for critically ill sedated adult patients.

Design
The prospective evaluation of reliability and validity of the Sedic score.

Setting
Thirty-bed Intensive Care Unit in a university teaching hospital.

Patients
Forty-six consecutive mechanically ventilated and sedated ICU-patients.

Measurements
The constructed scale consists of 5 levels of stimuli and 5 levels of responses. Sedation levels are defined by the sum of stimulus and response. Reliability of the Sedic score was assessed by simultaneous measurement by the research nurse and the attending nurse (n=70). Validity was expressed as: a) the hierarchical relation between stimulus and response (n=443); b) the prediction of wake up time by the Sedic score (n=46), and; c) the association between the Sedic score and the Ramsay scale (n= 88).

Main results
Excellent reliability. Validity: a) weighted kappa between stimulus and response was 0.82; b) multivariate analysis: (recover time as independent variable) regression line \( Y = -2.53 + 2.16 \times \beta; \ p < 0.001 \) (variance
explained = 42%); c) correlation between the Sedic scores and the Ramsay scores was \( r_s 0.74 \) (\( p = 0.01 \)). Sixty-seven percent of the patients with a maximum Ramsay score of 6 ranged between 6 and 10 on the Sedic scale, indicating that the Ramsay scale suffers from a serious ceiling effect.

**Conclusions**

The Sedic score demonstrated sufficient reliability and validity and correlates well with wake-up time. The Sedic score allows for frequent use by nurses in order to avoid oversedation.
Introduction

The principal aim of sedation in the critically ill is to relieve anxiety and agitation, to facilitate tolerance to procedures and to reduce awareness. Over the past decade, the sedation policy in the intensive care unit (ICU) has changed. Formerly, sedation aimed to completely detach the patient from the stressful ICU environment. Consequently, deep sedation levels were standard policy but this often led to prolonged mechanical ventilation and prolonged wake up time and ICU stay. Nowadays, deep sedation levels are avoided and sedation aims to achieve a sleepy but arousable patient. This approach has become feasible since more sophisticated ventilation techniques have enabled patients to comply with the ventilator with little or no sedation. On the other hand, more aggressive respiratory techniques are sometimes required. For instance in patients with an Acute Respiratory Distress Syndrome (ARDS) who are nursed in prone position with inverse ratio ventilation and/or permissive hypercapnia. These patients experience substantial distress necessitating deep levels of sedation.

If deep sedation is required, the prevention of overdosing becomes a major challenge especially in patients with altered pharmacodynamics and pharmacokinetics as a result of renal insufficiency or other organ dysfunction.

Symptoms of oversedation may co-exist with underlying disease (hypotension, bradycardia, ileus, venous stasis and immunosuppression). Hence, over-sedation is often only noticed when a patient requires a prolonged recovery period.

The Society of Critical Care Medicine (SCCM) have recommended the use of the Sedation Agitation Scale (SAS), the Motor Activity Assessment Scale (MAAS) and the Vancouver Interaction and Calmness Scale (VICS) for sedation assessment (a grade B level recommendation). The SAS scores a patient's level of consciousness and agitation from a seven-item list describing patient behaviour. The MAAS, adapted from the SAS, has seven categories to describe patient behaviours in response to stimulation. The VICS assesses patients for their capability to interact and communicate and for their level of restlessness. Although not recommended by the SCCM, the Ramsay scale is the oldest scale and has been used in many comparative sedation trials and is widely used clinically. It measures three levels of awake state and three levels of a sleep state.

The similarity in the methods used between these scales is the assessment of sedation depth by ordinally arranged statements that encompass mostly some stimuli and a variation of response characteristics defined in a narrative definition of sedation depth. The use of these sedation scores implies the availability of the description of the sedation levels at hand because they are difficult to memorize.

Over the last years, our department has been confronted with an increasing number of patients ventilated in prone position requiring deep levels of sedation, often resulting in a prolonged recovery period. As a
result, we felt the need to develop an accurate method to detect oversedation that is simple to use, does not require too much effort and can be memorized easily. This article presents a novel and simple scale to detect sedation depth of ICU patients and in particular to detect and prevent oversedation (the Sedation Intensive Care score or Sedic score). The objective of this study was to depict the validity of the Sedic score by an external objective criterion and to evaluate its reliability.

Materials and Methods

Setting
The study was conducted in the thirty-bed Intensive Care Unit of the Academic Medical Center in Amsterdam, a tertiary care university teaching hospital with 1000 beds serving all specialties.

Sample
A consecutive sample of 46 mechanically ventilated and sedated ICU-patients was collected to investigate validity. Also bedside observations were made (without collecting patient data) to depict interobserver variability of the Sedic (n=70) and to investigate the association between Ramsay and Sedic scores (n=88). Measurement properties of the Sedic were retrospectively evaluated by collecting registration forms (n=443).

Scale construction
In general, “sedation depth” is expressed by the level of arousal (response) triggered by an applied stimulus (verbal or physical), which can vary in intensity. Although stimulus and response are separate qualities, both are required to describe the clinical condition of sedation depth.

Items for our new scale (in terms of both stimulus and response) were taken from other published sedation scales if reported valid and reliable. The items with the highest concordance between scales were selected. The stimuli were then arranged from the weakest to the strongest while redundant and overlapping stimuli were removed. Responses were related to the stimuli levels and arranged according to the level of consciousness they describe. Five levels of stimuli and five levels of responses were identified; items in both categories were valued from 1 to 5 points (see appendix 1). To measure sedation depth the stimuli were applied in a denoted order (starting with the weakest) until the patient showed a reaction, i.e. a minimal but defined response. The sum of the stimulus used and the response that was noted expressed the level of sedation (the total summated scale score ranges from 2-10).

Reliability and validity
The clinimetric properties of the Sedic scale were evaluated in terms of reliability and validity. Interobserver reliability refers to the score agreement between different observers measuring a clinical phenomenon using an identical instrument at the same time.
The reliability of the Sedic was assessed after a training period among nurses of three months. A research nurse (JMB) scored patients simultaneously (time difference less than 5 minutes) but independent from the nurse who was attending the patient and who performed the Sedic score [data set 1].

The validity reflects the degree to which a scale measures what it is intended to measure. In this study validity was based on three hypotheses: a) there is a hierarchical structure in the relation between stimulus and response. For example, an overall absence of response (response level 5) can only be concluded if the patient has not responded on the stimuli that are weaker than “pressure on the nail bed”, a level 5 stimulus [data set 2]. In other words, we assumed a high concordance between a stimulus score and its response score; b) the Sedic score predicts the time needed to wake up after terminating the sedative [data set 3], and; c) there is a significant association between the Sedic score and the Ramsay scale (see appendix 2) [data set 4].

Data collection
We used four data sets: 1) The Sedic scale scored by the nurses attending the patient and a simultaneously but independently scored Sedic scale by the research nurse (n=70); 2) randomly collected Sedic scores measured by the attending nurses to evaluate the hierarchical relation between stimulus and response (n=443); 3) Sedic scores and the Ramsay scale of patients taken just before terminating the administration of sedative drugs and the subsequent wake-up period as recorded by the research nurse (n=46), and; 4) the Sedic scale scored by the nurses attending the patient and a simultaneously scored Ramsay score by the research nurse (n=88).

Sedation policy
Patients were sedated by a continuous infusion of a combination of midazolam and morphine in a one-mg-to-one-mg relation. Sedation was titrated to achieve the desired level of sedation as assessed by the Sedic score. The sedation policy did not include the use of a neuromuscular blocking agent.

Inclusion of patients
Patients with diminished consciousness due to reasons other than the administration of sedative medication and patients who need a form of renal replacement therapy (dialysis or hemofiltration) were not included in this study.

Statistics
Descriptive statistics were used to describe patient sex, age, SAPS II and sedation (dose, duration) characteristics from data set 1. All patient and sedation characteristics that were univariate associated with wake-up time (p<0.20) were entered into a multiple linear regression model (with a forward selection strategy, using the F statistic with p<0.05 on the criterion level of inclusion) to identify those variables that were independently associated with the dependent variable.
The association between the Ramsay scale and the Sedic score was summarized using a Spearman’s rank-order correlation coefficient ($r_s$).

**Table 1** Patient characteristics (data set 3)

<table>
<thead>
<tr>
<th>Patients</th>
<th>46</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients % (n/N) male</td>
<td>76% (35/46)</td>
</tr>
<tr>
<td>AGE, mean (sd)</td>
<td>58 (20)</td>
</tr>
<tr>
<td>SAPS II score, mean (sd)</td>
<td>39 (13)</td>
</tr>
<tr>
<td>Referral specialty</td>
<td></td>
</tr>
<tr>
<td>- Medical</td>
<td>37% (17/46)</td>
</tr>
<tr>
<td>- Surgical</td>
<td>43% (20/46)</td>
</tr>
<tr>
<td>- Cardio-surgery</td>
<td>20% (9/46)</td>
</tr>
<tr>
<td>Sedatives</td>
<td></td>
</tr>
<tr>
<td>- Dose/hour, median (q25/q75)*</td>
<td>5 (4/6)</td>
</tr>
<tr>
<td>- Dose before termination, median (q25/q75)</td>
<td>3 (2/5)</td>
</tr>
<tr>
<td>- Total administered, median (q25/q75)</td>
<td>167 (93/393)</td>
</tr>
<tr>
<td>- Total hours sedated, median (q25/q75)</td>
<td>35 (22/84)</td>
</tr>
<tr>
<td>Periods in hours</td>
<td></td>
</tr>
<tr>
<td>- Length of ICU stay, median (q25/q75)</td>
<td>236 (139/471)</td>
</tr>
<tr>
<td>- Sedation stop to extubation, median (q25/q75)</td>
<td>100 (42/262)</td>
</tr>
<tr>
<td>- Wake-up time, mean (sd) [minimum-maximum]</td>
<td>12 (8) [0 – 32]</td>
</tr>
<tr>
<td>Sedic score at terminating sedation, mean (sd)</td>
<td>7 (3)</td>
</tr>
</tbody>
</table>

* median and interquartile range

The interobserver reliability of the Sedic total scale score was analysed using the Intra Class Correlation Coefficient (ICC, two-way random model). Statistical uncertainty was expressed in 95% confidence limits (CL). The assumed hierarchical relation between stimulus and response, hence the concordance between stimulus and response scores, was expressed in percentage observed agreement and the weighted Kappa ($K_w$) statistics.

**Results**

We predicted the wake-up time from the Sedic score taken just before terminating the administration of the sedative. Patient and sedation characteristics are described in Table 1. Variables included into the multivariate regression analysis that were
significant at \( p \leq 0.20 \) included: total number of hours sedated, total
number of sedatives administered, SAPS II score and the Sedic score at
termination of the sedation.

After the stepwise forward selection only the Sedic score remained in the
model (variance explained 42\%). The slope of the regression line \( (Y = -2.53 + 2.16 * \beta) \) was significantly \( (p < 0.001) \) greater than zero, indicating
that the wake-up time prolongs as the Sedic score increases. For example,
if the patient’s Sedic score turns out to be 10, the expected wake-up time
is \((-2.53 + 21.6) 19\) hours, whereas in case of a Sedic score of 4 the
expected wake-up time is 6 hours.

Reliability as shown by the ICC was 0.88 (95\% CL 0.81/0.92). Table 2
presents the hierarchical relation between stimulus and response scores.

| Table 2 | Percentage of responses in relation to the stimulus levels, i.e. the
| Response | response level is similar to the stimulus. |
| Stimulus | 1 | 2 | 3 | 4 | 5 |
| 1 | 80 | 20 (18/92) | - | - | - |
| (74/92)* | 2 | 10 (13/131) | 74 | 16 (21/131) | - | - |
| (97/131) | 3 | - | 13 (9/72) | 74 | 13 (9/72) | - |
| 4 | 6 (6/96) | 12 (11/96) | 48 (46/96) | 30 | 4 (4/96) |
| 5 | - | - | 10 (5/52) | 29 (15/52) | 61 | 32/52 |

Percentage *(response/total stimuli per level). Stimuli: 1) spoken request; 2) loud call; 3) tap on the forehead; 4) shake shoulder; 5) pain stimulus. Response: 1) eyes open, squeeze hand on request; 2) rousable; 3) difficult to arouse; 4) only facial or motor expression; 5) no response.

The observed agreement between the score categories was 65\%, \( Kw = 0.82 \). The least concordance was found between stimulus category 4 (shake shoulder) versus response categories 3 (difficult to arouse) and 4 (only facial and motor expression). If stimulus scores were related to response scores plus/minus one point, the observed agreement was 92\%. Spearman’s rank-order correlation between the Sedic scores and the Ramsay scores was \( r_s 0.74 \) (\( p=0.01 \)).
Sixty-seven percent of the patients with a maximum Ramsay score of 6 ranged between 6 and 10 on the Sedic scale, indicating that the Ramsay scale suffers from a serious ceiling effect (Figure 1).

Figure 1

Figure 2 *Ramsay score (Y axis): [awake] 1) anxious and/or agitated; 2) cooperative, orientated and tranquil; 3) response to commands; [Asleep] 4) quiescent with brisk response to light glabellar tap or loud auditory stimulus; 5) sluggish response to light glabellar tap or loud auditory stimulus; 6) no response to light glabellar tap or loud sound.

'Sedic score (X axis): [interpretation of sum score]: 2) not sedated; 3-4) lightly sedated; 5-7) moderately sedated; 8-9) deeply sedated; 10) anaesthetised.

† Variation of Sedic scores within a Ramsay score of 6.

Discussion
The 5 level stimulus response grading is the result of a systematic arrangement of items from a large number of existing sedation scales. Only items with a high concordance between the sedation scales were selected. During the subsequent simplification of the set by deleting redundant items and separating stimulus and response items the Sedic was created.

Compared to the sedation scales used as a source to create the Sedic score, the Sedic score stands out for its simplicity. Moreover, it appears to be a reliable and valid instrument. Validity is shown by the predictability of the wake-up time, as demonstrated by the significant positive linear regression coefficient between Sedic score and wake-up time. The validity is also supported by the predictability of the response once a specific stimulus is applied.
according to the required sequence. And finally, validity is shown by the significant correlation between the Ramsay scale and the Sedic scores. One of the interesting features of the Sedic score is its complete separation of stimulus and response. If patients are lightly sedated, the stimulus required will remain little. If patients require more profound sedation, the strength of the stimulus will increase, but stops at the first minimal defined response. Moreover, if the patient is oversedated, the patient will fail to show any response. This sedation score has not yet been validated in other hospitals, and hence only applies for the locally used sedation regime. The Ramsay scale has been used for decades in both clinical practice and research. The Sedic scores varied consistently above the highest Ramsay score, i.e., broke through the ceiling effect of the Ramsay score, showing more nuances in the higher levels of sedation. Moreover, in daily practice the upper limit of the Sedic score, i.e., 10 points, is without exception a signal for the nurse to lower the sedative dosage. Numerous sedation scales have been developed over the years. Most of the reported scales combined stimulus and response in one expression that was organized in rank-ordered narrative statements along sedation depth. Stimuli in these scales are unclearly defined as 'tactile,' 'noxious,' 'pain,' 'physical' and 'auditory,' or as commands, giving little instruction on what to do. Most sedation scales report a good reliability. Validity was based on: auditory evoked potentials; related variation in blood pressure; heart frequency; bispectral index; visual analog scales; and other sedation scales such as Ramsay and the Sedation Agitation Scale. All scales demonstrated at least fair to good validity properties. However, none of the scales was related to an endpoint indicating the predictive value of the score for the time needed to wake up. An alternative approach, the daily interruption of sedative infusions, is reported to lower the risk of oversedation. As this procedure reduced the median duration of mechanical ventilation by 33%, the median length of ICU stay with 35% and the median length of hospital stay by 21%, seriousness of the problem of oversedation was confirmed. However, it is yet unclear how labour intensive and hazardous this procedure is as periodic awakings may lead to accidental removal of catheters or other adverse events. During this trial an investigator remained with the patient to prevent accidental removal of catheters during a possibly agitated awaking. This is not feasible in routine daily care. Because of its simplicity, the Sedic score can be used frequently and provides a good measure to monitor sedation depth. Although we have demonstrated a relation between the Sedic scale and the time to awaken in a selected group of patients, more work must be performed in order to determine the power to control sedation depth with the Sedic scale. This pilot study needs replication in other ICU's and sedation regimens. We believe that our results are promising enough to justify the effort of further study.
References


