Quality assessment of sedation in intensive care

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Background: In the intensive care unit (ICU), analgesics and sedatives are used not only to facilitate procedures related to intensive care but also to maintain the safety and comfort of critically ill patients requiring mechanical ventilation (1–3). On the other hand, continuous infusion of sedatives prolongs the time on mechanical ventilation and ICU stay (4) thus increasing the risk of iatrogenic complications. Sedatives may have adverse effects on circulation, and their amnestic effects may augment disorientation and delirium. When using sedatives the benefits need to be balanced with the disadvantages.

Numerous studies have shown that the outcome of medical care can be improved by defining the goals and methods of treatment in the form of guidelines (5–7). The role of guidelines is emphasized in teaching hospitals with frequent changes in staff. The recent clinical practice guideline on ICU sedation recommends guideline-concordant care (1). Titration of sedatives to a defined endpoint with systematic tapering or daily interruption of sedative medication is recommended (1). A clear sedation goal combined with a protocol-driven sedation plan has been shown to reduce the duration of mechanical ventilation and ICU stay (8). Similar results have been achieved by daily interruption of sedative drug infusions (7). In monitoring sedation, the use of a validated assessment scale is recommended (1). Many scales are available, but a gold standard has not been established (9). The Ramsay scale (10) is the oldest, and most widely used (11). Once guidelines are introduced, it is essential to monitor whether they are being followed in clinical practice (12,13). Quality of care can be further improved by reinforcement of existing guidelines and education (14).

The mixed adult ICU in Meilahti Hospital has since 1996 had its own internal practice guidelines, the SOP (standard operating procedures). The objective of this cohort study was to find out to which degree the existing sedation guideline is being followed, and if adherence to the guideline can be improved by a simple intervention: reinforcement of the guideline. The primary endpoints of the intervention were the occurrence of daily interruption or tapering of sedation and achievement of the Ramsay scale target level.

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Methods

Setting
This prospective study was performed in an eight-bed medical/surgical ICU in Helsinki University Hospital. The internal practice guidelines of the ICU, the SOP, include evidence-based instructions on sedation with two references (1,7). The staff consists of two anaesthesiologists, one of whom works outside the ICU part-time, and three residents undergoing their 4-month-long ICU training. Between 15.00 and 08.00 hours, one of the physicians stays on duty in the unit. The nurse-to-patient ratio is 1 : 1. Due to a shortage of nurses, the number of beds available usually ranges from 5 to 7.

Intervention
In this study, the instructions on sedation included in the SOP were reinforced by creating a separate, more detailed guideline (one A4 page). Inappropriately deep sedation was to be avoided, and monitoring of sedation was emphasized. Sedatives were to be interrupted or the dose decreased every morning to define the minimal required doses. If continuous infusions of sedatives and analgesics were used, propofol (up to 5 mg/kg/h) and fentanyl (0.05–0.40 mg/h) were the standard drugs. If deep enough sedation could not be achieved with propofol, it could be supplemented with intravenous (i.v.) boluses of lorazepam (0.5–2.0 mg), or with an infusion of midazolam (2–15 mg/h) for a maximum period of 48 h. (Lorazepam was the standard sedative administered as intermittent boluses [0.5–2.0 mg i.v.]). To monitor sedation, the Ramsay scale has been in routine use in our ICU since 1998. The Ramsay scale target was set at 2–3 during the day and 3–4 in the night (Ramsay scale 2: patient cooperative, oriented and tranquil, 3: patient responds to commands only, 4: a brisk response to a light glabellar tap or loud auditory stimulus) (10). In the ICU clinical data management system, the scale is easily accessible from the main monitoring page. The contents of this guideline were consistent with the existing SOP, and the references listed were the same as in the SOP (1,7). The guideline was presented to both ICU physicians and nurses in their weekly meetings, where special emphasis was put on discussing the drawbacks of inappropriately deep sedation, and the use of the Ramsay scale as a monitoring instrument with the staff. The guideline was also distributed in writing, and it was available in the ICU constantly. Anyone interested in the detailed contents of the SOP and the sedation guideline is welcome to contact the authors (minna.tallgren@hus.fi).

Measurements and data collection
The first observation period took place before the intervention, in October to November 2003. After the intervention and a 2-week-long stabilization period, the second observation period took place in March to April 2004. Data from all consecutive patients admitted and discharged within the 6-week-long observation periods were included. During these periods, the researchers were not directly involved in patient care in the ICU.

The primary outcome parameters were the occurrence of daily tapering or interruption of sedative medication and the achievement of the Ramsay scale target level. The clinical data were recorded routinely in the ICU data management system (CareVue, HP, Palo Alto, CA). As each patient was discharged from the ICU, the data for the study were collected from the system in a standardized fashion by one of the authors: medication, Ramsay and GCS scores, need for respiratory support, nurses’ shift reports, and patient characteristics, including the main diagnosis, APACHE II score, daily sequential organ dysfunction assessment (SOFA) score, age, height, weight, and ICU length of stay. Also indications for general anaesthesia instead of mere sedation (therapeutic hypothermia, prone position, use of muscle relaxants) were recorded. ICU days were analysed as 24-h periods starting from the moment of arrival in the ICU. ICU days were defined as sedation days and ventilator days, if sedatives or mechanical ventilation, respectively, were used.

Statistics
The sample size of 130 sedation days was calculated to give a > 90% power of detecting a 15% increase (from 75% to 90%) in the prevalence of daily interruption or tapering of sedatives with a level of significance at 5%. Thus observation periods of 6 weeks, in an ICU with median monthly intake of 25 patients and length of stay of 5 days, were estimated to be sufficient to detect a clinically significant change.

All data are presented as median (interquartile range) or number (percentage). Ordinal variables were compared using the Mann–Whitney U-test and categorical variables with the χ² test. Absolute change in the primary outcome parameter and its 95% confidence interval was calculated (15). SPSS for Windows 12.0.1 software (SPSS Inc., Chicago, IL) was used for the analyses. A P-value less than 0.05 was considered significant.
Results

The first observation period comprised 166 ICU days and the second 170 ICU days. Characteristics of the ICU days and patients are presented in Table 1. No significant differences were found between the two periods.

The sedation practices, before and after intervention, are presented in Table 2. The daily interruption or tapering of sedatives occurred, or sedatives were administered intermittently, during 94 out of 129 (73%) sedation days before and 109 out of 139 (78%) days after the intervention (NS) (absolute change 6%, 95% confidence interval from –5% to 16%).

The Ramsay scale recordings are shown in Table 3. After the intervention, the Ramsay scale level was recorded more frequently than before ($P < 0.01$). Other than that, no significant differences were observed between the two periods. In case general anaesthesia was indicated instead of mere sedation (13 days during the first and 20 days during the second observation period), Ramsay scale levels of 5 (5,6) and 6 (5,6) were recorded, respectively. The patients’ level of consciousness was described more often in the nurses written shift reports (free text) than by recording the Ramsay scale level, both before and after the intervention ($P < 0.01$). Such descriptions were found in 381 out of 470 (81%) shift reports before and 365 out of 471 (77%) after the intervention (NS).

Discussion

This study revealed low adherence to the local sedation guideline. Interruption or tapering of the dose of sedative medication only took place on three out of four sedation days, and most of the Ramsay scale recordings indicated inappropriately deep sedation. The attempt to improve the practice by reinforcing the local guideline had no significant effect.

The Ramsay scale recordings indicated a deeper level of sedation than the targets set in the guideline. As attempts to lessen the level of sedation did not take place more often, our results may suggest that the ICU personnel’s view of the best level of sedation differed from that in the guideline. Keeping the patient comfortable is a high priority goal for ICU nurses focusing on the care of one patient at a time. This goal may be in contradiction with the objective of avoiding inappropriately deep sedation (16). Within the perspective of one shift, it may be easier to maintain the level of analgesia and sedation close to the level needed for procedures, than to plan and implement timely and adequate changes for procedures such as suctioning, turning the patient, and wound care (17). One of the topics that came up when this guideline was discussed in staff meetings was that the current orientation programme for ICU nurses focuses more on keeping the patient comfortable than on harmful effects of continuous sedation. More thorough, interactive educational meetings on the positive and negative effects of sedation might have made the intervention more effective (18). Also, anaesthesiologists may be more used to keeping their patients asleep than physicians of other specialities. Although our residents are expected to study two publications on ICU sedation during their training (1,7), this topic may have low priority on their long reading list. It is difficult to adopt a number of guidelines on various aspects of critical care within a short rotation period (19).

The rate of recording the Ramsay scale was not high, although an increase was observed after the intervention. It is possible that changes in patient condition were missed, as scoring was not performed

<table>
<thead>
<tr>
<th>Table 1</th>
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<td>Characteristics of the intensive care unit (ICU) days and the patients.</td>
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<tr>
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<th>First observation period</th>
<th>Second observation period</th>
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<tbody>
<tr>
<td>ICU days</td>
<td>166</td>
<td>170</td>
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<tr>
<td>Sedation days</td>
<td>129/166 (78%)</td>
<td>139/170 (82%)</td>
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<tr>
<td>General anaesthesia</td>
<td>13/166 (8%)</td>
<td>20/170 (12%)</td>
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<tr>
<td>Ventilator days</td>
<td>117/166 (70%)</td>
<td>137/170 (81%)</td>
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<tr>
<td>ICU patients</td>
<td>24</td>
<td>29</td>
</tr>
<tr>
<td>Medical/surgical</td>
<td>11 (46%)/13 (54%)</td>
<td>13 (45%)/16 (55%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>58 (45–66)</td>
<td>59 (50–62)</td>
</tr>
<tr>
<td>APACHE II score</td>
<td>17 (14–20)</td>
<td>23 (16–26)</td>
</tr>
<tr>
<td>Maximal SOFA score</td>
<td>9 (8–10)</td>
<td>10 (7–12)</td>
</tr>
<tr>
<td>ICU length of stay (days)</td>
<td>5 (3–10)</td>
<td>4 (3–7)</td>
</tr>
<tr>
<td>ICU discharge to HDU or another ICU</td>
<td>12/24 (50%)</td>
<td>19/29 (68%)</td>
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The data are presented as number (percentage) or median (interquartile range). No significant differences between the two observation periods. ICU, intensive care unit; HDU, high-dependency unit; SOFA, sequential organ dysfunction assessment.
often enough. The fact that the level of consciousness was described more often in the free text of the nurses’ shift reports than by using the scale, suggests the Ramsay scale may have been perceived difficult to use. Indeed, the Ramsay scale has been criticised for its inability to distinguish between conditions that may take place simultaneously (9). Although the scale recognizes three aspects of sedation (consciousness, agitation and anxiety), it is a one-dimensional instrument with categorical grading. For instance, it is possible for a patient to be both restless (Ramsay scale 1) and unconscious, responding to glabellar tap (Ramsay scale 4–5). Another explanation might be that ICU nurses were not motivated enough to find time for Ramsay scale recording among their many tasks. Recording events in a patient information system is more time-consuming than documentation on paper.

Were there barriers for guideline-concordant care? Emphasizing the routine of interrupting or tapering sedation once daily, we may have overlooked the need of continuous re-evaluation. Tapering of the sedative dose might have been considered more like everyone’s task, if the instructions had been to perform it at least once every shift, as recommended by Tonner and co-workers (2). Also the timing in the morning may have been unfavourable, as many procedures in the ICU are scheduled at this particular time. Instead of providing the alternatives to either interrupt or to decrease sedation (1), the strategy of daily interruption of sedatives as described by Kress and co-workers (7) could have been a more effective way to reach the targets. We did not choose the Kress strategy, as the quality of analgesia and anxiolysis was not reported in their study.

Adherence to the sedation guideline remained unsatisfactory, although the intervention possessed several features that have been associated with high compliance in other studies: the guideline was simple, evidence-based, compatible with the earlier instructions in the clinical protocol (SOP), and new skills were not required (6,20). Usually interventions developed and marketed by current multidisciplinary local consensus processes are effective (18). The sedation protocol in our SOP had been planned by a multidisciplinary team several years earlier, and no changes were made when this reminder was launched. This intervention did not include regular feedback or control, which have been effective in some studies (18). The use of positive feedback was considered one of the keys to success in the study by Brattebo and co-workers, who documented achievement as the project went on (6). Automated surveillance by audit software or video-camera have also been successful (21,22). Other potential control measures include reminder-check lists attached to the patient chart and peer review feedback (23). Significant quality improvement can be achieved by large-scale projects involving multidisciplinary planning, interactive education, discussion, and feedback (6,14,18,24,25). However, for the process to continue, regular training and reassessment are essential (12–14). This study provides further evidence, that the quality of clinical work may be poorer than expected if a quality assurance programme is lacking. For a small unit, it is not easy to provide regular all-embracing training for the whole staff. At the time of this study, a more comprehensive project on sedation was not feasible.

Our study has limitations. First, it was performed in real life, in a university hospital teaching ICU with residents as part of the patient care team. The results of this type of intervention could be different in a non-teaching ICU staffed by consultants. Second, the sample size may have been too small to reveal a change in practice. However, the upper 95%
confidence limit for the change in the daily interruption or tapering of sedation (16%) shows that significant change was unlikely. Third, although the Ramsay scale has been used for a long time, the correctness of its use has not been evaluated in our ICU. Fourth, our ICU is one of four units in the same house. Specialization to certain therapies and shortage of beds has led to frequent traffic of patients between ICUs in this and other hospitals. Although no differences in patient characteristics were found between the two periods, based on the APACHE II and SOFA score levels, number of ventilator days, and median length of stay, the patients during the second period may have been more severely ill and transferred to other units earlier. However, we do not believe the results of this study would have been affected if it were so.

In conclusion, the compliance rate to the local sedation guideline was not high, and it did not increase after the intervention. The only improvement found was an increase in Ramsay scale recordings. More thorough education on the desirable and undesirable effects of sedation, followed by multidisciplinary re-evaluation of the local guideline, is indicated in our unit.

References


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