

Journal Watch (Sedation)

Efficacy and safety of palliative sedation therapy: A multicenter, prospective, observational study conducted on specialized palliative care units in Japan

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Abstract:

Although palliative sedation therapy is often required in terminally ill cancer patients, its efficacy and safety are not sufficiently understood. The primary aims of this multicenter observational study were to 1) explore the efficacy and safety of palliative sedation therapy, and 2) identify the factors contributing to inadequate symptom relief and complications, using a prospective study design, clearly defined measurements methods, and a consecutive sample from 21 specialized palliative care units in Japan. A sample of 102 consecutive adult cancer patients who received continuous deep sedation were enrolled. Physicians prospectively evaluated the intensity of patient symptoms, communication capacity, respiratory rate, and complications related to sedation. Symptoms were measured on the Agitation Distress Scale, the Memorial Delirium Assessment Scale, and the ad hoc symptom severity scale (0 = no symptoms, 1 = mild and tolerable symptoms, 2 = intolerable symptoms for less than 15 minutes in the previous one hour, and 3 = intolerable symptoms continuing for more than 15 minutes in the previous one hour). Inadequate symptom relief was defined as presence of hyperactive delirium (item 9 of the Memorial Delirium Assessment Scale ≥ 2) or grade 2 or 3 symptom intensity 4 hours after sedation. The degree of communication capacity was measured on the Communication Capacity Scale. Palliative Sedation therapy succeeded in symptom alleviation in 83% of the cases. Median time elapsed before patients initially had one continuous hour of deep sedation was 60 minutes, but 49% of the patients awakened once after falling into a deeply sedated state. The percentage of patients who were capable of explicit communication decreased from 40% before sedation to 7.1% 4 hours after sedation, and the mean Communication Capacity Score significantly decreased to the level of 15 points ($P < 0.001$). The respiratory rates did not significantly decrease after sedation (18 ± 9.0 to 16 ± 9.4 / min, $P = 0.62$), but respiratory and/or circulatory suppression (respiratory rate ≤ 8 /min, systolic blood pressure ≤ 60 mmHg, or 50% or more reduction) occurred in 20%, with fatal outcomes in 3.9%. There were no statistically significant differences in patient age, sex, performance status, target symptoms, or classes and initial dose of sedative medications between the patients with adequate and inadequate symptom relief. Respiratory and/or circulatory suppression was significantly more likely to occur in patients receiving sedation for delirium and those with higher levels on the Agitation Distress Scale. Higher dose of midazolam was significantly correlated with younger age, absence of icterus, pre-exposure to midazolam, and length of sedation.

Palliative sedation therapy is effective and safe in the majority of terminally ill cancer patients with refractory symptoms. However, a small number of patients experience fatal complications related to sedation. Comparison studies of different sedation regimens are needed to determine the most effective and safe sedation protocol.

Key Words: Palliative sedation therapy, refractory symptoms, palliative care, neoplasms

Comments:

Strengths/uniqueness:

This large multicentre study follows a novel approach to explore the efficacy and safety of palliative sedation.

Weakness:

The complexity of the study becomes somewhat problematic due to the inclusion of definitions and outcomes that appear weak, and as a result some of the results are of uncertain value. In addition there was no common approach or clinical practice guideline in place to ensure management used allowed meaningful comparison.

Relevance to Palliative Care:

The importance of developing Clinical Practice Guidelines in this area, followed by a clinical practice guideline based study similar to this study, would be an important step forward in this area.