MEDICAL UNIVERSITY OF SOUTH CAROLINA
VALUE INSTITUTE
Evidence-Based Practice Brief
Effectiveness of Earplugs in Patients in the ICU

Author(s): Amanda Davis, MPH, RD, CHES; Emily Brennan, MLIS

ASK THE QUESTION

Question(s):
Q1. In hospitalized patients admitted to the ICU, does the use of earplugs decrease the incidence of delirium or the incidence of hyperactive delirium?

Q2. In hospitalized patients admitted to the ICU, does the use of earplugs improve patient satisfaction scores with regard to quietness?

SEARCH FOR EVIDENCE

Databases: PubMed, CINAHL, PsychInfo

PubMed search strategies:
Q1. ("Ear Protective Devices"[Mesh] OR earplugs) AND delirium

Q2. ("Ear Protective Devices"[Mesh] OR earplugs) AND ("Patient Satisfaction"[Mesh] OR satisfaction OR experience OR quiet* OR noise) AND (hospital OR hospitalized OR patient OR patients OR ICU OR "intensive care")

Filters: English, Published last 10 years

CRITICALLY ANALYZE THE EVIDENCE

There were five primary research studies found addressing the use of earplugs in hospitalized patients admitted to the ICU. Two systematic reviews with meta-analyses (Hu et al., 2015; Litton et al., 2016) directly addressed the use of earplugs to decrease the incidence of delirium. Four studies (Hu et al., 2015; Hu et al., 2015; Richardson et al., 2007; Yazdannik et al., 2014), including one systematic review with meta-analysis (Hu et al., 2015) indirectly addressed the impact of earplugs on patient satisfaction scores for quietness.
**Delirium:**
Hu et al. (2015) systematically reviewed clinical studies (29 RCTs, 1 quasi-experimental; n=1569) to assess the efficacy of non-pharmacological interventions for sleep promotion in critically ill adults in the ICU. Of the 8 studies regarding earplugs, eye masks or both included in the review, only two studies examined the effects on delirium. A meta-analysis of these two studies found that earplugs, eye masks or both significantly decreased the risk of delirium or confusion (pooled risk ratio 0.55, 95% CI 0.38-0.80; I²=0%, p= 0.002). Litton et al. (2016) systematically reviewed clinical studies (9 studies; n= 1455 patients) to assess the efficacy of earplugs as an ICU strategy for reducing delirium. A meta-analysis of the five studies (832 patients) that reported incident delirium found that earplug placement was associated with a relative risk of 0.59 (95% CI, 0.44–0.78; I²=39%) for delirium compared with standard care.

**Patient Satisfaction:**
The systematic review above by Hu et al. (2015) also performed a meta-analysis of two studies that assessed nurse-measured subjective sleep quality in ICU patients using earplugs, eye masks or both versus usual care. The pooled mean difference in total sleep quantity when using earplugs, eye masks or both was 2.19 hours (95% CI 0.41-3.96; I² = 79%).

Hu et al. (2015) was a randomized controlled trial to determine the effect of earplugs, eye masks and relaxing music on the sleep quality of 50 adult patients admitted to the ICU for at least 2 nights following scheduled cardiac surgery (standard care n=25; intervention n=25). Multiple assessments were completed during this study, including: sleep quality using a validated questionnaire, nocturnal urine melatonin and cortisol levels, nocturnal noise (via digital sound level meter) and nocturnal light levels (via light detector every 2 hours). Even though the earplugs and eye masks were provided 2-3 days pre-operatively in order to get patients used to them, 5 patients in the intervention group withdrew from the study. Patients’ perceptions of nighttime noise, perceived depth of sleep, time to fall asleep, number of awakenings and sleep efficiency (all p<0.04) were significantly impacted by the intervention. There were, however, no significant differences in the recorded ICU nocturnal noise levels (69.8±2dB vs 69.6±2.2dB, p=0.6) or in urine melatonin and cortisol levels between the two groups.

Richardson et al. (2007) was a quasi-experimental study of the effect of eye masks and earplugs on noise and light exposure in 64 adult ICU patients (standard care n=28; intervention n=34). Patients were then asked about their sleep quantity and factors that disturbed or promoted sleep. The majority of patients in the study (82%) reported sleeping for 6h or less, with a greater percentage of patients reporting 0–2h and 2–4h in the control group (65% vs 56%) and 71% patients reported sleeping “less” or “much less” than their normal average with a greater percentage of patients in the intervention group (18% vs 7%) rating their sleep in the “more than average” or “much more than average” range. However, 41.4% of patients in the intervention group rated the earplugs as “uncomfortable” or “very uncomfortable” and 38.7% rated the eye masks as “uncomfortable” or “very uncomfortable”.

Yazdannik et al. (2014) was a randomized cross-over trial to assess the effect of earplugs and eye masks on sleep quality in 50 adult ICU patients. Patients received earplugs and eye masks for use during either Night 1 or Night 2 of their ICU stay, with a cross-over standard sleep regimen as a control. Sleep was assessed using a validated questionnaire regarding sleep disturbance, sleep effectiveness, and supplemental sleep (i.e., naps). The mean score changes (pooling both groups) showed significant differences in sleep effectiveness (14.54±11.46, p<0.001) and sleep disturbance (25.82±16.87, p<0.001) between the control and intervention nights. Additionally, there was a significant difference is sleep supplementation between the two nights (mean score: intervention 27.1 and control 16; p<0.001), indicating that the intervention decreased patients’ need for daily naps.
**PICO Question:** In hospitalized patients admitted to the ICU, does the use of earplugs decrease the incidence of delirium or the incidence of hyperactive delirium?

<table>
<thead>
<tr>
<th>Author/Date/Journal</th>
<th>Purpose of Study</th>
<th>Study Design</th>
<th>Sample&amp; Setting</th>
<th>Outcomes</th>
<th>Design Limitations</th>
</tr>
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<tbody>
<tr>
<td>Hu et al., 2015, Cochrane Database of Systematic Reviews</td>
<td>To assess the efficacy of non-pharmacological interventions for sleep promotion in critically ill adults in the ICU</td>
<td>Systematic review &amp; meta-analysis</td>
<td>30 studies (1569 participants) -29 RCTs, 1 quasi-experimental -8 studies regarding earplugs, eye masks or both (2 studies examined effect on delirium)</td>
<td>Earplugs, eye masks or both significantly decreased the risk of delirium or confusion (pooled risk ratio 0.55, 95% CI 0.38-0.80; I²=0%, p= 0.002)</td>
<td>Study Limitations = None</td>
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<td>Litton et al., 2016, Critical Care Medicine</td>
<td>To assess the efficacy of earplugs as an ICU strategy for reducing delirium</td>
<td>Systematic review &amp; meta-analysis</td>
<td>9 studies (1455 patients) -earplugs only: 3 studies -earplugs + eye masks: 2 studies -earplugs + eye masks + additional noise strategies: 4 studies 5 studies (832 patients) reported incident delirium</td>
<td>6 studies reported compliance with ear plugs, as assigned with a mean, per-patient, noncompliance of 13.1% (95% CI, 7.8–25.4) <strong>Earplug placement was associated with a relative risk of 0.59 (95% CI, 0.44–0.78; I²=39%; 5 studies) for delirium compared with standard care</strong> Results were not substantially different when comparing earplugs alone (1 study) to earplugs as part of a bundle of sleep hygiene (4 studies) (RR 0.58, 95% CI 0.40–0.85; and</td>
<td>Study Limitations = None</td>
</tr>
</tbody>
</table>

**GRADE CRITERIA**
(See Appendix A)

- **Lower Quality Rating if:**
  - High risk of bias (When design limitations for one or more criteria impact the quality of studies sufficiently enough to lower confidence in the estimate of effect)
  - Studies inconsistent (When there are differences in the direction of the effect, populations, interventions or outcomes between studies)
  - Studies are indirect (Your PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)

- **Increase Quality Rating if:**
  - Large effect (When the relative risk of association between two
Results were not substantially different when comparing randomized (3 studies) to non-randomized studies (2 studies) (RR 0.58, 95% CI 0.40-0.84; and RR 0.57, 95% CI 0.33-0.97, respectively).

Factors is large or very large:

- [ ] Dose response (When the dose-response relationship increases the confidence than an effect is real and substantial)
- [ ] Plausible confounders (When plausible residual confounding is directly impacting the magnitude of effect)

Level of evidence for studies as a whole:

- [ ] High
- [x] Moderate
- [ ] Low
- [ ] Very Low

PICO Question: In hospitalized patients admitted to the ICU, does the use of earplugs improve patient satisfaction scores with regard to quietness?

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<td>To assess the efficacy of non-pharmacological interventions for sleep promotion in critically ill adults in the ICU</td>
<td>Systematic review</td>
<td>30 studies (1569 participants) -29 RCTs, 1 quasi-experimental -8 studies regarding earplugs, eye masks or both (2 assessed nurse-measured subjective sleep quality)</td>
<td>The mean difference in total sleep quantity when using earplugs, eye masks or both versus usual care was 2.19 hours (95% CI 0.41-3.96; I² = 79%)</td>
<td>Study Limitations = None Systematic Review Review did not address focused clinical question Search was not detailed or exhaustive Quality of the studies was not appraised or studies were of low quality Methods and/or results were inconsistent across studies</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Patients</td>
<td>Key Findings</td>
<td>Study Limitations</td>
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<td>Hu et al., 2015, <em>Critical Care Medicine</em></td>
<td>RCT</td>
<td>50 adult patients who underwent scheduled cardiac surgery (data on only 45 patients) admitted to the ICU postoperatively for at least 2 nights&lt;br&gt;-20 intervention (earplugs, eye mask and 30-min relaxing music BID); 5 withdrawals&lt;br&gt;-25 control</td>
<td>Patients’ perceptions of nighttime noise were significantly lower in the experimental group than in the control group (25.0±24.0 vs 40.2±28.8, p=0.047), however there were no significant differences between actual nighttime noise between the groups (69.8±2dB vs 69.6±2.2dB, p=0.6)&lt;br&gt;&lt;br&gt;Patients’ perceptions of perceived depth of sleep (p=0.00), time to fall asleep (p=0.00), number of awakenings (p=0.00) and sleep efficiency (p=0.00) were also significantly impacted by the intervention&lt;br&gt;&lt;br&gt;There was no significant influence on nocturnal melatonin or cortisol levels due to the intervention</td>
<td>None&lt;br&gt;&lt;br&gt;RCT &amp; Quasi-Experimental Studies&lt;br&gt;&lt;br&gt;Insufficient sample size&lt;br&gt;Lack of randomization&lt;br&gt;Lack of blinding&lt;br&gt;Stopped early for benefit&lt;br&gt;Lack of allocation concealment&lt;br&gt;Selective reporting of measures&lt;br&gt;Large losses to F/U</td>
<td></td>
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<td>Richardson et al., 2007, <em>Nursing in Critical Care</em></td>
<td>Quasi-experimental</td>
<td>64 adult patients (convenience sample) in a cardiothoracic ICU with a length of stay of &gt;1 day able to apply and remove eye masks and earplugs themselves&lt;br&gt;-34 intervention group (eye mask, earplugs)&lt;br&gt;-28 control</td>
<td>A majority of patients, 51 (82%) reported sleeping for 6 h or less and 44 (71%) patients reported sleeping “less” or “much less” than their normal average&lt;br&gt;-In the two low ranges of sleep (0–2 h and 2–4 h) a greater percentage of patients were in the control group (65% vs 56%)&lt;br&gt;-More patients in the intervention group (18% vs 7%) rated their sleep in the “more than average” or</td>
<td>None&lt;br&gt;&lt;br&gt;RCT &amp; Quasi-Experimental Studies&lt;br&gt;&lt;br&gt;Insufficient sample size&lt;br&gt;Lack of randomization&lt;br&gt;Lack of blinding&lt;br&gt;Stopped early for benefit&lt;br&gt;Lack of allocation concealment&lt;br&gt;Selective reporting of measures&lt;br&gt;Large losses to F/U</td>
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| Yazdannik et al., 2014, Iranian Journal of Nursing and Midwifery Research | To determine the effect of earplugs and eye mask on patients' sleep quality in ICU | RCT cross-over study | 50 adult ICU patients (convenience sample) randomly assigned to two groups
-Group A: patients wore earplugs and eye mask the first night, standard care second night (n=25)
-Group B: patients treated with standard care first night, wore earplugs and eye mask the second night (n=25)
Excluded if: injuries to eyes and ears, allergy to intervention, head injury, chronic sleep disorders or mental illness
Assessment: Verran and Snyder-Halpern Sleep Scale (disturbance, effectiveness, supplemental sleep)
-higher = better sleep | Sleep effectiveness (p<0.001) and sleep disturbance (p<0.001) scores were significantly different between the intervention and standard care night for both Groups
-Group A scores for both effectiveness and disturbance were better following standard care (night 2)
-Group B scores for both effectiveness and disturbance were better following the intervention (night 2)
-Mean score changes (pooling both Groups) showed significant differences in effectiveness (14.54±11.46, p<0.001) and disturbance (25.82±16.87, p<0.001) between the control and intervention nights
There was a significant difference in sleep supplementation between the two nights (mean: treatment 27.1 and control 16; p<0.001), which shows that the intervention decreased patients' need for daily naps |

**REFERENCES**


## Appendix A: GRADE criteria for rating a body of evidence on an intervention

Developed by the GRADE Working Group

### Grades and interpretations:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Further research is very unlikely to change our confidence in the estimate of effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.</td>
</tr>
<tr>
<td>Low</td>
<td>Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.</td>
</tr>
<tr>
<td>Very low</td>
<td>Any estimate of effect is very uncertain.</td>
</tr>
</tbody>
</table>

### Type of evidence and starting level

<table>
<thead>
<tr>
<th>Evidence Type</th>
<th>Starting Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized trial</td>
<td>High</td>
</tr>
<tr>
<td>Observational study</td>
<td>Low</td>
</tr>
<tr>
<td>Any other evidence</td>
<td>Very low</td>
</tr>
</tbody>
</table>

### Criteria for increasing or decreasing level

#### Reductions
- Study quality has serious (−1) or very serious (−2) problems
- Important inconsistency in evidence (−1)
- Directness is somewhat (−1) or seriously (−2) uncertain
- Sparse or imprecise data (−1)
- Reporting bias highly probable (−1)

#### Increases
- Evidence of association† strong (+1) or very strong (+2)
- Dose-response gradient evident (+1)
- All plausible confounders would reduce the effect (+1)

†Strong association defined as significant relative risk (RR 2-5 or 0.5-0.2) based on consistent evidence from two or more studies with no plausible confounders; Very strong association defined as significant relative risk (RR >5 or <0.2) based on direct evidence with no threats to validity