Quality Sleep Using ear plugs in the Intensive Care Unit: The QUIET Study

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‘A multi-centre, cluster-randomised, crossover, registry trial to determine whether the overnight placement of ear plugs in addition to standard care, compared with standard care alone decreases duration of admission and utilisation of medication to treat delirium in patients admitted to the ICU’

Steve Webb, Rinaldo Bellomo, Andrew Forbes, Paul Young, Ed Litton
Overview

• **Design**: Registry-Based Cluster Crossover
• **Participants**: All patients admitted to the ICU
• **Intervention**: Nocturnal placement of ear plugs between 2200-0600 whilst in ICU
• **Comparator**: No ear plugs
• **Primary outcome**: ICU Length of stay
Role of Sleep

- Defined physiologically or behaviorally

- Physiologically:
  - REM non-REM
  - Controlled by circadian rhythm and neurochemical pathways
Sleep – In Health

- Absolute short term and partial persistent sleep loss detrimental
- Consequences:
  - Cognitive function
Sleep – In Health

• Absolute short term and partial persistent sleep loss detrimental

• Consequences:
  – Cognitive function
  – Physical impairment

Chen et al. Sleep loss impairs inspiratory muscle endurance. The American Review of Respiratory Disease. 1989 140(4); 907-9
Sleep – In Health

- Absolute short term and partial persistent sleep loss detrimental
- Consequences:
  - Cognitive function
  - Physical impairment
  - Metabolic derangement

Broussard et al Impaired insulin signaling in human adipocytes after experimental sleep restriction Annals of internal Medicine 2012; 157(8)549-57
Sleep – In Health

- Absolute short term and partial persistent sleep loss detrimental
- Consequences:
  - Cognitive function
  - Physical impairment
  - Metabolic derangement
  - Immunological impairment

Kruger et al. The role of cytokines in physiological sleep regulation. Annals of the NY Academy of Sciences 2001; 933:211-21
Sleep – In Critical Illness

- Severely disrupted and with a typical pattern
- Small amount of sleep research in MV patients

# Sleep Disruption – ICU Outcomes

## Short Term
- Delirium
- Others:
  - Immune suppression
  - Metabolic derangement
  - Physical performance

## Long Term
- Persistence of sleep disturbance
  - Frequently cited stressor
  - Associated with long term reduced QoL
- Others:
  - Immune suppression
  - Metabolic derangement
  - Physical performance

*Weinhouse et al Delirium in ICU patients – Importance of sleep deprivation Critical Care 2009; 13(6);234
McKinley et al Sleep and other factors associated with mental health and psychological distress after intensive care for critical illness ICM 2012;38(4)627-33*
Noise Levels in ICU

- Sleep disturbance multifactorial
- WHO recommendation:
  - 35dB day and 30dB night
- Mean and maximum daily noise levels:
  - 55dB
  - 65dB
  - Peaks over 80dB
Ear Plugs in ICU

• Three possible mechanisms:
  – 1. Reduction in sedation requirement during mechanical ventilation
  – 2. Improvement in sleep quantity, quality and timing
  – 3. Trigger for other related changes that may improve outcome
Ear Plugs – Reduces Sedation

• Neonatal RCT improved weight gain with ear plugs
• Paediatric RCT reduced sedation requirement under GA for MRI
• Adult RCT reduced awareness under propofol sedation
• Three arm adult RCT reduced sedation intensity

Abou Turk et al A RCT evaluating silicone earplugs for very low newborns in ICU Journal of Perinatology 2009;29(5)358-63
Ear Plugs – Improved Sleep

- Healthy volunteers
- ICU before and after studies
- 3 ICU RCTs reporting delirium:
  - 136 patients single Dutch ICU
  - Hazard ratio for confusion 0.47 (95% CI 0.27-0.82)
Cluster Cross Over Registry Design

• Benefits of CXO:
  – Sleep disturbance is common problem in substantial proportion of patients admitted to ICU
  – Ear plugs are cheap, safe and applicable as a ‘ubiquitous intervention’
  – Plausible benefit but not currently applied in a broad, routine fashion
  – Existing data sources can be used to collect all trial data
Eligibility Criteria

Study Centre

• Inclusion criteria
  – Any ICU where routine nocturnal placement of ear plugs is not currently standard care

• Exclusion criteria
  – ICUs unable or unwilling to follow the trial protocol
  – ICUs that do not submit data to the ANZIC CORE registry

Individual Patient

• Inclusion criteria
  – All patients admitted to the ICU who have an admission that includes any time between 2200 and 0600

• Exclusion criteria
  – Previous confirmed diagnosis of deafness
  – Treating clinician believes the placement of ear plugs may be harmful
  – Confirmed or suspected brain death
  – Confirmed or suspected ruptured tympanic membrane
  – Patient declines offer to wear ear plugs
Study Process

• Half participating ICUs randomised to 305 days of no ear plugs followed by 60 day washout, then 305 days of ear plugs
• Other half of participating ICUs randomised to 305 days of ear plugs followed by a 60 day washout, then 305 days of no ear plugs
• No CRF
• Nocturnal audit of ear plug prevalence
• Substudy potential +++
Outcome Measures

• Primary Outcome:
  – ICU Length of stay (censored at 60 days)

• Secondary Outcomes:
  – ICU mortality
  – Hospital mortality
  – 1-year mortality (linked data)
  – ICU costs (imputed from length of stay)
  – Total dispensed dose of:
    • Anti-delirium drugs
    • Others
  – Coding of delirium
Refinement...

• Statistical analysis
• Understanding delivery of the intervention:
  – Before/after pilot study
• Ethics
• How this might fit in with:
  – Current sedation and delirium studies
  – Planned, funded cluster cross over studies
Summary

• Sleep disturbance ubiquitous in ICU
• Associated with short term impaired cognitive, physical, metabolic and immunological problems
• Associated with long term impaired quality of life
• Plausible that ear plugs reduce delirium, and consequently improve long term health outcomes
• Multicentre registry-based cluster crossover trial may be optimal strategy to test this safe and low cost intervention
Questions?

• Plausible?
• Implementable?
• Optimal intervention?
• Optimal study design?
Thank You