DELIRIUM MANAGEMENT IN THE ICU

SUMMARY

Delirium has been previously described as a syndrome of organ dysfunction involving the central nervous system. The prevalence of delirium in the ICU varies from 20-80%. Delirium has been associated with increased hospital length of stay, duration of mechanical ventilation, and mortality. Sedative and narcotic use has been shown to increase the risk and severity of delirium. Haloperidol is the mainstay of delirium management as recommended by the Society of Critical Care Medicine (SCCM) due to extensive clinical experience with this medication. However, its usage is often limited by safety concerns. Atypical antipsychotics such as quetiapine have been shown to have equivalent success in the treatment of delirium while being associated with fewer side effects.

RECOMMENDATIONS

- **Level 1**
  - **None**

- **Level 2**
  - **First line treatment for delirium is haloperidol IV 2.5-10 mg Q 2 hours as needed**
  - **Consider adding quetiapine 50 mg po Q 12 hours (increase by 25 mg Q 12 hours every 24 hours as needed)**

- **Level 3**
  - **Benzodiazepine use should be limited in patients with delirium**
  - **The Intensive Care Delirium Screening Checklist (ICDSC) should be used as the screening tool for ICU delirium (performed once per shift)**
  - **Reassess the need for quetiapine daily (especially for therapy lasting >2 weeks)**

INTRODUCTION

Delirium is characterized by changes in mental status, inattention, disorganized thinking, and altered consciousness that may be accompanied by agitation. The prevalence of delirium in medical and surgical ICU cohorts has varied from 20-80% depending on the severity of illness. Despite its high prevalence, delirium is often under-recognized by clinicians due to the difficulty in diagnosis and lack of an easy to use screening tool. Several studies demonstrate that delirium is associated with increased mechanical ventilation days, hospital length of stay, and mortality, all of which lead to increased health care costs (1-3). Several risk factors have been identified to increase the risk of delirium including advanced age, prolonged ICU stay, and exposure to benzodiazepines.

Haloperidol is recommended as the drug of choice for the treatment of ICU delirium by the SCCM despite a lack of placebo-controlled clinical trials (4). Haloperidol is a typical antipsychotic that blocks D2 dopamine receptors resulting in amelioration of hallucinations, delusions, and unstructured thought patterns. In a retrospective study, the use of haloperidol was shown to reduce ICU mortality in ventilated patients with delirium (5). However, safety is a major concern associated with haloperidol use. Atypical antipsychotics appear to be as effective as haloperidol in treating delirium with a better safety profile. Thus, these agents have become an attractive alternative to haloperidol even in the face of lack of

EVIDENCE DEFINITIONS
- **Class I:** Prospective randomized controlled trial.
- **Class II:** Prospective clinical study or retrospective analysis of reliable data. Includes observational, cohort, prevalence, or case control studies.
- **Class III:** Retrospective study. Includes database or registry reviews, large series of case reports, expert opinion.
- **Technology assessment:** A technology study which does not lend itself to classification in the above-mentioned format. Devices are evaluated in terms of their accuracy, reliability, therapeutic potential, or cost effectiveness.

LEVEL OF RECOMMENDATION DEFINITIONS
- **Level 1:** Convincingly justifiable based on available scientific information alone. Usually based on Class I data or strong Class II evidence if randomized testing is inappropriate. Conversely, low quality or contradictory Class I data may be insufficient to support a Level I recommendation.
- **Level 2:** Reasonably justifiable based on available scientific evidence and strongly supported by expert opinion. Usually supported by Class II data or a preponderance of Class III evidence.
- **Level 3:** Supported by available data, but scientific evidence is lacking. Generally supported by Class III data. Useful for educational purposes and in guiding future clinical research.

definitive data. Dexmedetomidine, an alpha-2-receptor agonist, is another medication being studied for delirium management. However, clinical data is scarce to support its routine use.

LITERATURE REVIEW
Delirium Assessment
Due to severity of illness, frequent use of sedation and analgesia, and lack of verbal communication, it may be difficult to assess delirium in the critically ill population. Under-recognition may lead to lack of proper delirium treatment in ICU patients. The ideal delirium assessment scale would incorporate important delirium diagnostic criteria and be quickly and easily administered at the patient bedside. Assessment methods such as the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) and Intensive Care Delirium Screening Checklist (ICDSC) have been developed to help improve delirium recognition among the critically ill.

Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) (Appendix 1)
The CAM was developed in 1990 by Inouye et al. to aide in delirium assessment by non-psychiatric personnel (6). It was modified to the CAM-ICU by Ely et al. in 2001 for use in mechanically ventilated ICU patients not able to verbalize (7,8). The scale utilizes four key criteria to assess delirium including 1) acute mental status change, 2) inattention, 3) disorganized thinking and 4) altered level of consciousness. The CAM-ICU was prospectively tested in 96 mechanically ventilated patients with a sensitivity of 93% and a specificity of 98% for predicting the presence of delirium (7). Patients with a history of psychosis or neurologic disease and patients who were comatose throughout admission were excluded however. (Class II)

Intensive Care Delirium Screening Checklist (ICDSC) (Appendix 2)
The ICDSC was developed in 2001 by Bergeron et al. to assess critically ill ICU patients for delirium based on DSM criteria (5). The scale was validated by assessing 93 medical and surgical ICU patients daily during the first 5 days of ICU stay (5). A score of 4 or higher was considered positive for diagnosis of delirium with a sensitivity of 99% and a specificity of 64%. The incidence of delirium was 16% in this study as compared to 80% in previous CAM-ICU studies. Unlike the CAM-ICU studies, this study included patients with neurological injuries, dementia, or history of psychiatric disorders. (Class II)

Devlin et al. performed a validation study of ICDSC in a medical ICU for detection of delirium before and after implementation of the screening tool (9). Physicians and nurses had greater ability to detect delirium after implementation of the ICDSC. There was also greater correlation between physician and nurse assessment after screening tool implementation. (Class II)

CAM-ICU vs. ICDSC
In a prospective observational study, both assessment tools (CAM-ICU and ICDSC) were compared in a medical and surgical ICU population for up to 7 days after ICU admission (10). Delirium was found in 41% of patients as determined by a positive result from either test. Agreement between tests was high, with a kappa coefficient for agreement of 0.8. There was an 8% discrepancy rate in delirium-negative patients and 11% discrepancy in delirium-positive patients. The study concluded that results of either assessment method are comparable. (Class II)

While it may appear that the CAM-ICU had higher specificity than the ICDSC in clinical trials, the studies validating CAM-ICU excluded patients with neurological abnormalities whereas the ICDSC trials did not. The CAM-ICU questionnaire is more involved than that of ICDSC. Thus, based on available evidence, the scales have similar reliability, but the ICDSC may be a quicker and easier tool to use.

Clinical Trials: Haloperidol and Atypical Antipsychotics
Current data supporting the use of haloperidol for ICU delirium is largely based on one retrospective review of a mixed ICU population (11). Over 900 patients (83 received haloperidol; 906 no haloperidol) who remained mechanical ventilated for greater than 48 hours were evaluated for mortality, duration of mechanical ventilation, and ICU length of stay. The average dose and duration of haloperidol was 11.5 mg/day for 3.5 days. While there were no differences in the duration of mechanical ventilation and ICU

length of stay, haloperidol use was associated with a significant decrease in hospital mortality compared to the non-haloperidol group (adjusted relative risk 15.6%). (Class II) More recently, the MIND trial prospectively evaluated the efficacy of haloperidol for ICU delirium management in comparison to placebo (12). The use of haloperidol was not found to improve delirium days, ventilator-free days, or mortality. Authors concluded that the small sample size may contribute to the negative findings and a large multi-center placebo trial is warranted.

Several studies have examined the role of atypical antipsychotics for delirium management in various populations (Table I) (13-17). One study prospectively evaluated the use of olanzapine vs. haloperidol in medical-surgical ICU patients (16). The duration of the study was 5 days and the ICDSC screening tool was used for delirium assessment. Both olanzapine and haloperidol were found to reduce delirium symptoms. (Class II) Patients who received haloperidol experienced more extrapyramidal side effects, and no adverse events were reported in olanzapine group. Devlin et al. conducted a prospective, randomized, placebo-controlled trial evaluating the efficacy and safety of quetiapine (17). More than 70% of the study population were medical ICU patients. Quetiapine resulted in a faster resolution of delirium compared to placebo, but no significant differences in duration of mechanical ventilation, ICU and hospital length of stay, or mortality. (Class II) The incidence of adverse drug events was similar between the two groups. Results from this study suggest that quetiapine is a safe choice for delirium management and can be considered as an add-on therapy to haloperidol.

TABLE I

Study	Design	Methods	Conclusions
Haloperidol Study			
Milbrandt EB 2005	• Retrospective cohort • >48 hr MV • Mixed MICU, SICU, CVICU, TICU	• N=989 pt: Haloperidol 83; Nonhaloperidol 906 • Mean daily dose 11.5 ± 11.6 mg x 3.5 days	• Haloperidol use was associated with decreased hospital mortality and increased survival compared to non-haloperidol group • No difference in the duration of MV or ICU LOS between 2 groups
Girard T 2010	• Prospective, R,D,P (MIND Trial) • Mechanical ventilated Medical and surgical ICU patients	• N=101: Haloperidol N=35; Ziprasidone N=30; Placebo N=36 • Dose: H 15 mg/day; Ziprasidone 113.3 mg/day; all given orally • CAM-ICU used for screening	• No difference in the duration of delirium or coma among study groups • No significant adverse events were reported
Atypical Antipsychotic Study			

Sipahimalani A 1998	• Prospective nonrandomized
	• Patients with primary psychiatric disorders (non-ICU pt)
	• Co-morbidity include TBI; hypoxia, infection, MI
		• N=22 pts: olanzapine N=11; haloperidol N=11
		• Dose: olanzapine 5-15 mg PO/day; haloperidol 1.5-10 mg PO/day
		• Delirium Rating Scale (DRS) was used
			• Peak response achieved at
			    Olanzapine 6.8 ± 3.5 days
			    Haloperidol 7.2 ± 4.9 days
			• Duration of treatment
			    Olanzapine 23.6 ± 28.3 days
			    Haloperidol 14.6 ± 12.8 days

Schwartz TL 2000	• Retrospective chart review
	• Patients with primary psychiatric
		• N=22 pts: quetiapine N=11; haloperidol N=11
		• Dose: quetiapine
			• Peak response achieved at
			    Quetiapine 6.5 days
			    Haloperidol 7.6 days
			• Duration of treatment

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	disorders (non-ICU pt) • Co-morbidity include TBI; hypoxia, infection, CA	211.4 mg/day; haloperidol 3.4 mg/day • Delirium Rating Scale (DRS) was used	Quetiapine 13 days Haloperidol 10.4 days
Han CS 2004	• Prospective R,DB • Mixed floor, ICU, oncology pt • Duration 7 days	• N=24 pts: risperidone N=12; haloperidol N=12 • Dose: risperidone 0.5 mg BID titrated (1.02 mg/day); haloperidol 0.75 mg BID titrated (1.71 mg/day) • The Memorial Delirium Assessment scale used	• No difference in efficacy or response rate between 2 treatments
Skrobik YK 2004	• Prospective randomized • Med-surg ICU • >24 hr ICU LOS • Duration 5 days	• N=73 pts: olanzapine N=28; haloperidol N=45 • Dose: olanzapine 5 mg PO/day titrated; haloperidol 2.5-5 mg PO Q8h • ICDSC used TID for delirium screening	• Both agents reduced delirium symptoms – no significant difference • 6 pt in haloperidol developed EPS; no ADR reported in olanzapine
Devlin J 2010	• Prospective, D,P, RCT • MICU and SICU • Duration up to 10 days	• N=36 pt (Quetiapine 18 pts; Placebo 18 pts) • Quetiapine 50mg Q12h upto 200mg Q12h • All received PRN Haloperidol • ICDSC ≥4 for delirium	• Shorter time to first resolution of delirium with quetiapine than placebo (1 vs. 4.5 days; p=0.001) • Less time spent in delirium with quetiapine than placebo (36 vs. 120 hrs; p=0.006) • No difference in duration of mechanical ventilation, ICU and hospital LOS, and mortality

THERAPEUTIC RECOMMENDATIONS

The therapeutic effect of haloperidol and atypical antipsychotics appears to be equivalent based on the literature review. Therefore, the ease of administration, pharmacokinetics, potential drug interactions, and safety profile should be considered when making a therapeutic recommendation. The onset of intravenous haloperidol is approximately 60 minutes, and the elimination half life is between 10-36 hours. Haloperidol is metabolized extensively through the liver and does produce an active metabolite. While haloperidol is effective in the treatment of delirium, adverse effects have become the major limitation in its utilization. Major concerns with haloperidol include extrapyramidal side effects (EPS), QT prolongation, and neuroleptic malignant syndrome (NMS). Data has suggested that the incidence of EPS is lower with intravenous compared to oral administration and it is likely associated with prolonged use (18). QT prolongation is generally dose related, however it has been reported with doses as low as 30 mg/day (19-21). This is more pronounced in elderly patients or those with underlying cardiac problems. Several case reports describe development of NMS associated with haloperidol use; patients with traumatic brain injury appear to be more susceptible to this complication (22).

Atypical antipsychotics including risperidone, olanzapine, and quetiapine are the most frequently used agents for delirium management due to their safety profile. Based on pharmacokinetic properties, quetiapine appears to be a better choice for the ICU population due to its shorter half-life and ease to titrate (Table II). The most common side effects with this class are sedation and anti-cholinergic effect (dry mouth, tachycardia, urinary retention, and constipation).

TABLE II

	Dosage forms	Oral bioavail-ability	Peak	Half life	Metabolism	Dosing
Risperidone	- Tablet - Orally-disintegrating tablet - Solution	70%	1 hr	20-30 hrs	- Hepatic - Active metabolite	- 1 mg PO Q12 hr - Increased in increments of 0.5-1 mg/day every 2-3 days - Max daily dose 6 mg - Renal and hepatic adjustment (0.5 mg Q12h)
Olanzapine	- Tablet - Orally-disintegrating tablet	57%	6 hrs	21-54 hrs	- Hepatic - Active metabolite	- 2.5 mg PO QHS - Increase in increments of 5 mg/day - Max daily dose 20 mg - No renal adjustment
Quetiapine	- Tablet - Extended-release tablet	9%	1.5 hrs	6 hrs	- Hepatic - Active metabolite	- 25 mg PO Q12 hr - Titrated in increments of 25 mg/day every 24 hours - Max daily dose 800 mg - No renal adjustment

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Appendix 1: Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)

	Positive	Negative
Feature 1: Acute Onset or Fluctuating Course Positive if you answer 'yes' to either 1A or 1B.	**Positive**	**Negative**
1A: Is the patient different than his/her baseline mental status? or **1B**: Has the patient had any fluctuation in mental status in the past 24 hours as evidenced by fluctuation on a sedation scale, GCS, or previous delirium assessment?	**Yes**	**No**
Feature 2: Inattention Positive if either score for 2A or 2B is less than 8. Attempt the ASE letters first. If patient is able to perform this test and the score is clear, record this score and move to Feature 3. If the patient is unable to perform this test or the score is unclear, then perform the ASE pictures. If you perform both tests, use the ASE pictures' results to score the Feature.	**Positive**	**Negative**
2A: ASE Letters: record score (enter NT for not tested) Directions: Say to the patient, *"I am going to read you a series of 10 letters. Whenever you hear the letter 'A,' indicate by squeezing my hand."* Letters from the following letter list in a normal tone. **S A V E A H A A R T** Scoring: Errors are counted when patient fails to squeeze on the letter "A" and when the patient squeezes on any letter other than "A."	**Score (out of 10):** _____	
2B: ASE Pictures: record score (enter NT for not tested) Directions are included on the picture packets.	**Score (out of 10):** _____	
Feature 3: Disorganized Thinking Positive if the combined score is less than 4.	**Positive**	**Negative**

3A: Yes/No Questions
(Use either Set A or Set B, alternate on consecutive days if necessary):
    Set A   **Set B**
1. Will a stone float on water?   1. Will a leaf float on water?
2. Are there fish in the sea?   2. Are there elephants in the sea?
3. Does one pound weigh more   3. Do two pounds weigh more than one
   than two pounds?   pound?
4. Can you use a hammer to   4. Can you use a hammer to cut wood?
   pound a nail?
Score _____ (patients earns 1 point for each correct answer out of 4)
	Combined Score (3A+3B):
	
	_____
	
	(out of 5)	

3B: Command Say to the patient, *"Hold up this many fingers"* (examiner holds two fingers in front of patient) *"Now do the same thing with the other hand"* (not repeating the number of fingers). *If patient is unable to move both arms, for the second part of the command as the patient to "Add one more finger."* **Score** _____ (patients earns 1 point for each correct answer out of 4)		
Feature 4: Altered Level of Consciousness Positive if the actual RASS score is anything other than zero.	**Positive**	**Negative**
Overall CAM-ICU (Features 1 and 2 must be positive and either Feature 3 or 4 positive)	**Positive**	**Negative**

Richmond Agitation-Sedation Scale
(RASS)

+4	Combative	Combative, violent, immediate danger to staff
+3	Very agitated	Pulls or removes tube(s) or catheter(s); aggressive
+2	Agitated	Frequent nonpurposeful movement, fights ventilator
+1	Restless	Anxious, apprehensive but movements are not aggressive or vigorous
0	Alert and calm	
-1	Drowsy	Not fully alert, but has sustained awakening to voice (eye opening & contact > 10 sec)
-2	Light sedation	Briefly awakens to voice (eye opening & contact < 10 sec)
-3	Moderate sedation	Movement or eye opening To voice (but no eye contact)
-4	Deep sedation	No response to voice, but movement or eye opening to physical stimulation
-5	Unarousable	No response to voice or physical stimulation

Sedation and Delirium Assessments:
A Two Step Approach

Step One: Sedation Assessment *(RASS)*

If RASS is -4 or -5, then **Stop & Reassess** patient at later time
If RASS is above - 4 (-3 through +4) then **Proceed to Step 2**

Step Two: Delirium Assessment *(CAM-ICU)*

Feature 1: Acute onset of mental status changes
or a fluctuating course

And

Feature 2: Inattention

And

Feature 3: Disorganized Thinking   Or   **Feature 4:** Altered Level of Consciousness

= DELIRIUM
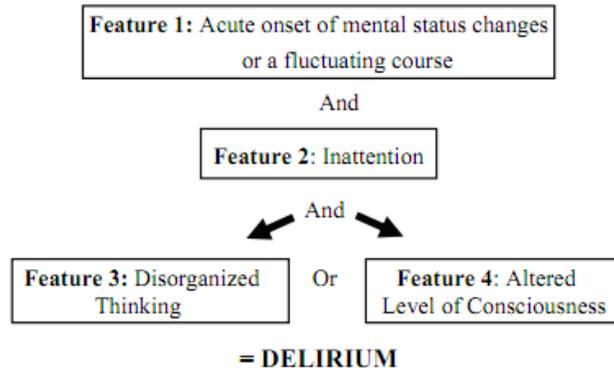
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Appendix 2: Intensive Care Delirium Screening Checklist (ICDSC)

	Points
1. Altered level of consciousness (SAS Score) Note: May need to reassess patient if recent administration of sedation therapy 	

Behavior	Score
Unarousable: minimal or no response to noxious stimuli	1
Very sedated: arouses to physical stimuli only	2
Sedated: difficult to arouse, awakens to verbal stimuli or gentle shaking	3
Calm and cooperative: calm; awakens easily	4
Agitated: anxious or agitated but calms down to verbal instructions	5
Very agitated: Does not calm down on verbal reminder, requires physical restraints	6
Dangerous agitation: pulling at tubes/removes catheters/thrashing side to side; hits staff	7

	Points
➢ Exaggerated response to normal stimulation: SAS = 5, 6, or 7 → score 1 point ➢ Normal wakefulness: SAS = 4 → score 0 points ➢ Response to mild or moderate stimulation (follows commands): SAS = 3 → score 1 point **Score 0 if altered level of consciousness related to recent sedation/analgesia** ➢ Response only to loud voice and pain: SAS = 2 **Stop assessment ➢ No response: SAS = 1 **Stop assessment	

2. Inattention - Score 1 point for any of the following abnormalities:
    A. Difficulty in following commands OR
    B. Easily distracted by external stimuli OR
    C. Difficulty in shifting focus
Does the patient follow you with their eyes?	

3. Disorientation - Score 1 point for any one obvious abnormality: A. Mistake in either time, place or person ***Does the patient recognize ICU caregivers who have cared for him/her and not recognize those that have not? What kind of place are you in?***	

4. Hallucinations or Delusions - Score 1 point for either:
    A. Equivocal evidence of hallucinations or a behavior due to hallucinations
      (Hallucination = perception of something that is not there with NO stimulus) OR
    B. Delusions or gross impairment of reality testing
      (Delusion = false belief that is fixed/unchanging)
Any hallucinations now or over past 24 hrs? Are you afraid of the people or things around you? [fear that is inappropriate to clinical situation]	

5. Psychomotor Agitation or Retardation - Score 1 point for either:
    A. Hyperactivity requiring the use of additional sedative drugs or restraints in order to control
      potential danger (e.g. pulling IV lines out or hitting staff) OR
    B. Hypoactive or clinically noticeable psychomotor slowing or retardation
Based on documentation and observation over shift by primary caregiver	

6. Inappropriate Speech or Mood - Score 1 point for either:
    A. Inappropriate, disorganized or incoherent speech OR
    B. Inappropriate mood related to events or situation
Is the patient apathetic to current clinical situation (i.e. lack of emotion)? Any gross abnormalities in speech or mood? Is patient inappropriately demanding?	

7. Sleep/Wake Cycle Disturbance - Score 1 point for:
    A. Sleeping less than four hours at night OR
    B. Waking frequently at night (do not include wakefulness initiated by medicalstaff or loud
      environment) OR
    C. Sleep ≥ 4 hours during day **Based on primary caregiver assessment**	

8. Symptom Fluctuation - Score 1 point for:
    A. Fluctuation of any of the above items (i.e. 1 – 7) over 24 hours (e.g. from one shift to
      another) **Based on primary caregiver assessment**	

TOTAL ICSDC SCORE (Add 1 – 8)	

Delirium is defined as an ICDSC score > 4 PLUS clinical judgment

Figure 1: ICU Delirium Assessment and Management

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                    ┌─────────────────┐
                    │  Assessment of  │
                    │ Sedation Score  │
                    │   (SAS Score)   │
                    └─────────────────┘
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                          ╱     ╲
                         ╱   Is   ╲                          ╭──────────────────╮
                        ╱ SAS Score╲────── Yes ─────────────▶│ Reassess sedation│
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                    │    checklist    │                               │
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                    │  If clinically  │
                    │consistent,patient│
                    │  has delirium   │
                    └─────────────────┘
                             │
                             ▼
                          ╱     ╲
┌──────────────────┐     ╱   Is   ╲     ┌──────────────────┐
│Haloperidol 5-10 mg│◀─Yes─╱ patient>60╲─No─▶│Haloperidol 5-10 mg│
│IV  Q 2 hr prn    │     ╲  yrs of age?╱     │IV  Q 2 hr prn    │
└──────────────────┘      ╲         ╱        └──────────────────┘
         │                 ╲       ╱                   │
         │                                             │
         │        ┌──────────────────────────┐         │
         └───────▶│    Consider adding       │◀────────┘
                  │Quetiapine 50 mg NG/OG Q12hr;│
                  │titrate every 24 hour by 25 mg/dose│
                  └──────────────────────────┘
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