Effectiveness and Safety of an Extended ICU Visitation Model for Delirium Prevention: A Before and After Study

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Objectives: To evaluate the effect of an extended visitation model compared with a restricted visitation model on the occurrence of delirium among ICU patients.

Design: Prospective single-center before and after study.

Setting: Thirty-one–bed medical-surgical ICU.

Patients: All patients greater than or equal to 18 years old with expected length of stay greater than or equal to 24 hours consecutively admitted to the ICU from May 2015 to November 2015.

Interventions: Change of visitation policy from a restricted visitation model (4.5 hr/d) to an extended visitation model (12 hr/d).

Measurements and Main Results: Two hundred eighty-six patients were enrolled (141 restricted visitation model, 145 extended visitation model). The primary outcome was the cumulative incidence of delirium, assessed bid using the confusion assessment method for the ICU. Predefined secondary outcomes included duration of delirium/coma; any ICU-acquired infection; ICU-acquired bloodstream infection, pneumonia, and urinary tract infection; all-cause ICU mortality; and length of ICU stay. The median duration of visits increased from 133 minutes (interquartile range, 97.7–162.0) in restricted visitation model to 245 minutes (interquartile range, 175.0–272.0) in extended visitation model ($p < 0.001$). Fourteen patients (9.6%) developed delirium in extended visitation model compared with 29 (20.5%) in restricted visitation model (adjusted relative risk, 0.50; 95% CI, 0.26–0.95). In comparison with restricted visitation model patients, extended visitation model patients had shorter length of delirium/coma (1.5 d [interquartile range, 1.0–3.0] vs 3.0 d [interquartile range, 2.5–5.0]; $p = 0.03$) and ICU stay (3.0 d [interquartile range, 2.0–4.0] vs 4.0 d [interquartile range, 2.0–6.0]; $p = 0.04$). The rate of ICU-acquired infections and all-cause ICU mortality did not differ significantly between the two study groups.

Conclusions: In this medical-surgical ICU, an extended visitation model was associated with reduced occurrence of delirium and shorter length of delirium/coma and ICU stay. (*Crit Care Med* 2017; XX:00–00)

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The ICU visits study investigators are listed in **Supplemental Digital Content 1** (http://links.lww.com/CCM/C730).

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Delirium is a frequent and severe form of acute brain dysfunction that occurs in the critically ill (1–6). It currently represents a major challenge for critical care professionals as it is associated with increased mortality, longer ICU and hospital stay, higher costs of care, and increased risk of long-term cognitive impairment (4–7). Thus, identifying strategies that may reduce the risk and burden of delirium in ICU patients is key to improve outcomes.

Disappointingly, pharmacologic interventions have a limited role in the prevention and treatment of delirium (8). Regarding nonpharmacologic approaches, some evidence indicates that multicomponent interventions including pain control, patient reorientation, sleep hygiene, prevention of sensory deprivation, early mobilization, and establishment of a familiar environment may reduce the frequency of delirium (9–12). Since family engagement plays an essential role in patient well-being, and visitors are associated with lower delirium occurrence (13), evidence-based approaches to prevent delirium such as the ABCDEF bundle have recently evolved to include the family as a means to provide optimal care (9). The presence of the family in the critical care setting is proposed as a means to allow a better sharing of the decision-making process, participating in rounds and patient care, reduction of patient anxiety, and participation in the reorientation and cognitive stimulation of patients (14–17). Additionally, extended ICU visitation policies have been associated with higher levels of patient and family satisfaction (18–21). Recent multicenter data demonstrate that broader family visiting policies are safe and associated with increased ICU efficiency (22). However, extended ICU visitation policies have not been directly tested for their potential to prevent the occurrence of delirium and remain an evidence gap (23).

The aim of the present study was to compare the cumulative incidence of delirium among critically ill patients admitted to a single medical-surgical ICU in the presence of a restricted visitation model (RVM) or an extended visitation model (EVM). Our hypothesis was that an EVM model would reduce the occurrence of delirium among ICU patients when compared with RVM.

MATERIALS AND METHODS

Study Design, Setting, and Patients

A prospective before and after study was conducted at a 31-bed tertiary medical-surgical ICU in Porto Alegre, Brazil. The study was divided into three consecutive periods: first period, 90 days with RVM, from May to July 2015; second period, 30 days without patient enrollment to avoid contamination bias, in August 2015; third period, 90 days with EVM, from September to November 2015.

We enrolled patients greater than or equal to 18 years old with expected length of stay greater than or equal to 24 hours who were consecutively admitted to the ICU during the first and third study periods. Subjects with aphasia, pre-existing delirium, and exclusively palliative treatment at ICU admission were excluded. Subjects who remained unarousable greater than or equal to 48 hours (Richmond Agitation-Sedation Scale [RASS] –4 or –5) (24) and those who were readmitted to the ICU after enrollment in the study were also excluded.

Interventions

During both RVM and EVM, all patients were housed in private ICU rooms and treated in accordance with ABCDEF interventions: prevention and management of pain, daily spontaneous awakening trials coordinated with spontaneous breathing trials, minimization of exposure to benzodiazepines and opioids (except in cases of chronic use), early mobilization, and daily maintenance of orientation to surroundings (1). Visitors were required to wash their hands with antiseptic soap and water and to wear disposable vests and/or personal protective equipment when appropriate. All visitors received oral and written guidance about the standard of good practice for ICU visitation. The number and duration of social visits were determined by the patient or proxies. The visitors were asked to leave the room during some procedures, such as intubation, central venous catheterization, and cardiopulmonary resuscitation.

Two or fewer family visitors per patient at a time were allowed for up to 4.5 hr/d, divided into three periods (9:00 to 11:00 AM, 4:00 to 5:30 PM, and 9:00 to 10:00 PM) in RVM. In EVM, two or fewer at a time were allowed for up to 12 hr/d (9:00 AM to 9:00 PM). The EVM visiting hours were restricted to daytime and evening in order to avoid noise-related sleep disturbances. EVM families were allowed to participate on bedside multidisciplinary rounds.

As an exception, in both study periods, patients were allowed to receive longer visits in the following situations: terminality, conflicts, and delirium.

Outcomes

The primary outcome was the cumulative incidence of delirium during ICU stay. Diagnosis of delirium was made using the confusion assessment method for the ICU (CAM-ICU) (25), which was applied once per 12-hour shift in patients with RASS greater than or equal to –3 by trained nurses. The cumulative incidence of delirium was defined as the presence of delirium on at least one 12-hour shift during ICU stay.

Predefined secondary outcomes included duration of delirium/coma; any ICU-acquired infection; ICU-acquired bloodstream infection, pneumonia, and urinary tract infection; all-cause ICU mortality; and length of ICU stay. Duration of delirium/coma was defined as the number of days during which delirium patients were alive with delirium or coma. This outcome measure best identifies impairment in the duration of normal cognitive status in delirium patients. Patients with a RASS of –4 or –5 were classified as in coma, irrespective of whether the state was induced by sedation or disease. ICU-acquired infections were diagnosed according to Centers for

Disease Control and Prevention guidelines (26–28) by a physician blinded to the study purpose. Time to onset of delirium (time from study enrollment to the first positive CAM-ICU), timing of the first identification of delirium (daytime vs nighttime), duration of delirium, duration of coma, and occurrence of subtypes of delirium (hypoactive, hyperactive, or mixed) were evaluated as post hoc secondary outcomes.

Follow-up, Adherence to Interventions and Covariates

Patients were prospectively followed during ICU stay by investigators who were not associated with the ICU staff. The time frame for verifying the occurrence of outcomes was from study enrollment to ICU discharge or death or a maximum of 14 days.

The length of family visits was recorded daily as a measure of adherence to study interventions. Because we encouraged prolonged family visits in patients who developed delirium, the duration of family visits was recorded for these patients from ICU admission to the first episode of delirium or ICU discharge or death.

Hazardous alcohol consumption was defined as alcohol consumption equivalent to greater than or equal to 14 units/wk for women and greater than or equal to 21 units/wk for men (29). An active smoker was defined as a person who currently smoked greater than or equal to five cigarettes per day. Information regarding previous history of stroke and cirrhosis was obtained from medical history and review of medical records. Dementia, depression, anxiety disorder, and schizophrenia were defined according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (30). Chronic use of benzodiazepines, antidepressants, and antipsychotics was defined as daily use of these medications for at least 3 months. Systemic corticosteroid exposure was defined as current use of prednisone greater than or equal to 5 mg/d (or equivalent doses for other corticosteroids). Chronic kidney disease was determined according to the National Kidney Foundation guideline (31). The severity of critical illness within the first 24 hours of ICU admission was evaluated by the Acute Physiology and Chronic Health Evaluation (APACHE)-II (32). Early mobilization was defined as application of physical therapy within the first 48 hours of ICU admission (33).

Statistical Analysis

Details about sample size calculation are showed in **Supplemental Digital Content 2** (http://links.lww.com/CCM/C731). Fisher exact, chi-square, Wilcoxon rank-sum, and Student *t* tests were applied as appropriate to determine whether or not baseline covariates differed between the two study groups. The Wilcoxon rank-sum test was used to compare the two interventions regarding the median length of visits per patient per day. The comparison of outcomes between the two study groups relied on univariate and multivariate Poisson regression models. Covariate adjustment was made using relevant risk factors for the outcome under investigation. These covariates were chosen after a literature review for the most important determinants of outcomes. Relative risk (RR) and adjusted RR (aRR) were estimated along with 95% CIs. Time-to-event data were compared using the log-rank test and presented as Kaplan-Meier curves. A significance level of 0.05 was adopted for all comparisons. No adjustment was made for multiple comparisons. Therefore, secondary outcomes and subgroup analyses should be considered exploratory. SAS version 9.4 (SAS Institute, Cary, NC) was used for statistical analysis.

Ethical Issues

This study was approved by the Research Ethics Committee at Hospital Moinhos de Vento (CAAE42588915.9.0000.5330). The need of written informed consent was waived because the standard of care encompasses both study interventions. Nevertheless, the investigators provided both oral and written information about the study (including option to decline to participate at any time) to patients or their surrogates.

RESULTS

Patients

During the first and third study periods, 360 patients were admitted to the ICU. Thirty-six RVM patients and 38 EVM patients were excluded (**Fig. 1**). In total, 286 eligible patients were enrolled in the study, 141 in RVM and 145 in EVM. The characteristics of patients at baseline and characteristics related to ICU interventions were well balanced between the study groups (**Table 1**).

ICU Visits

In RVM, 14 of 141 patients (9.9%) received visits longer than the limit of 4.5 hours per day at least once. In EVM, due to

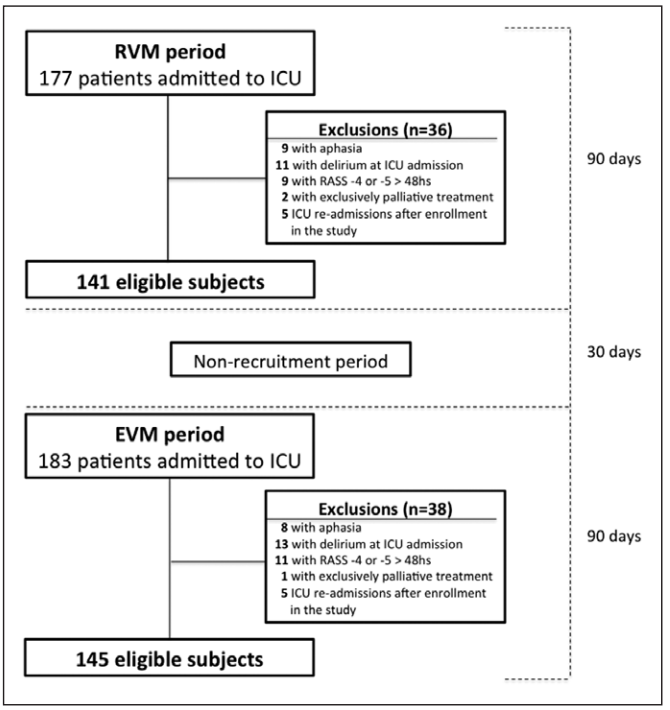

Figure 1. Enrollment of study participants. EVM = extended visitation model, RASS = Richmond Agitation-Sedation Scale, RVM = restricted visitation model.

TABLE 1. Baseline Patient Characteristics

Variables	Restricted Visitation Model (*n* = 141)	Extended Visitation Model (*n* = 145)	*p*
Demographic characteristics			
Male gender, *n* (%)	72 (51.6)	72 (49.6)	0.81
Age (yr), mean ± SD	62.4 ± 20.6	60.5 ± 18.6	0.22
Age ≥ 65 yr, *n* (%)	73 (51.7)	66 (45.5)	0.34
Active smoking, *n* (%)	13 (9.2)	14 (9.6)	0.99
Hazardous alcohol consumption, *n* (%)	6 (4.2)	7 (4.8)	0.99
Living at nursing home, *n* (%)	2 (1.4)	1 (0.7)	0.61
Comorbidities, *n* (%)			
Previous history of stroke	11 (7.8)	7 (4.3)	0.33
Dementia	7 (4.9)	6 (4.1)	0.78
Depression	35 (24.8)	33 (22.7)	0.78
Anxiety disorder	10 (7.0)	15 (10.3)	0.40
Schizophrenia	1 (0.7)	1 (0.7)	0.99
Chronic use of benzodiazepines	26 (18.4)	33 (22.7)	0.38
Chronic use of antidepressants	36 (25.5)	39 (26.9)	0.89
Chronic use of antipsychotics	13 (9.2)	6 (4.1)	0.10
Chronic use of opioids	3 (2.1)	5 (3.4)	0.72
Systemic corticosteroid exposure	8 (5.6)	12 (8.2)	0.38
Cirrhosis	2 (1.4)	1 (0.7)	0.54
Chronic kidney disease	18 (12.7)	18 (12.4)	0.92
Characteristics of acute critical illness			
APACHE-II score, points, mean ± SD	12.7 ± 7.4	12.2 ± 6.9	0.57
APACHE-II score ≥ 15 points, *n* (%)	52 (36.8)	50 (34.4)	0.71
Nonsurgical admission, *n* (%)	85 (60.3)	80 (55.1)	0.40
Elective surgery, *n* (%)	43 (30.5)	47 (32.4)	0.79
Emergency surgery, *n* (%)	13 (9.2)	18 (12.4)	0.44
Interventions during ICU stay, *n* (%)			
Mechanical ventilation	27 (19.1)	29 (20.0)	0.88
Vasopressor	35 (24.8)	41 (28.2)	0.50
Parenteral sedation	40 (28.3)	36 (24.8)	0.59
Benzodiazepine use within the first 24 hr of ICU admission	34 (24.1)	37 (25.5)	0.78
Opioid use within the first 24 hr of ICU admission	62 (43.9)	69 (47.5)	0.55
Renal replacement therapy	12 (8.5)	12 (8.2)	0.99
Indwelling central venous catheter	84 (59.5)	80 (55.1)	0.55
Urinary catheter	91 (64.5)	84 (57.9)	0.33
Early mobilization	121 (85.8)	129 (88.9)	0.42

APACHE-II = Acute Physiology and Chronic Health Evaluation-II.

TABLE 2. Comparison of Outcomes Before and After Implementation of an Extended ICU Visitation Model

Outcomes	Restricted Visitation Model (*n* = 141)	Extended Visitation Model (*n* = 145)	Unadjusted RR (95% CI)	*p*	Adjusted RR[a] (95% CI)	*p*
Primary outcome, *n* (%)						
Cumulative incidence of delirium	29 (20.5)	14 (9.6)	0.47 (0.26–0.85)	0.02	0.50 (0.26–0.95)	0.03
Secondary outcomes						
Duration of delirium/coma[b] (d), median (IQR)	3.0 (2.5–5.0)	1.5 (1.0–2.0)	0.48 (0.31–0.73)	0.001	0.61 (0.39–0.97)	0.03
Any ICU-acquired infection, *n* (%)	13 (9.2)	8 (5.5)	0.59 (0.24–1.44)	0.25	0.63 (0.24–1.66)	0.35
ICU-acquired pneumonia, *n* (%)	8 (8.5)	6 (4.1)	0.72 (0.25–2.10)	0.55	1.04 (0.34–3.15)	0.94
ICU-acquired bloodstream infection, *n* (%)	3 (2.1)	2 (1.3)	0.64 (0.10–3.87)	0.63	0.70 (0.11–4.24)	0.70
ICU-acquired urinary tract infection, *n* (%)	2 (1.4)	2 (1.3)	0.97 (0.13–6.90)	0.97	1.08 (0.15–7.71)	0.93
ICU mortality, *n* (%)	9 (6.3)	3 (2.1)	0.32 (0.08–1.21)	0.09	0.34 (0.09–1.26)	0.10
Length of ICU stay (d), median (IQR)	4.0 (2.0–6.0)	3.0 (2.0–4.0)	0.87 (0.78–0.98)	0.02	0.89 (0.79–0.99)	0.04

IQR = interquartile range (P25–P75), RR = relative risk.

[a]Delirium adjusted by dementia, Acute Physiology and Chronic Health Evaluation (APACHE)-II score ≥ 15 points and need of continuous parenteral sedation during ICU stay; duration of delirium/coma adjusted by dementia, APACHE-II score ≥ 15 points and need of continuous parenteral sedation during ICU stay; any ICU-acquired infection adjusted by APACHE-II ≥ 15 points and ICU length of stay; ICU-acquired pneumonia adjusted by APACHE-II ≥ 15 points and length of mechanical ventilation; ICU-acquired bloodstream infection adjusted by APACHE-II ≥ 15 points and need of indwelling central venous catheter; ICU-acquired urinary tract infection adjusted by APACHE-II ≥ 15 points and need of urinary catheter; ICU mortality adjusted by APACHE-II score ≥ 15 points; length of ICU stay adjusted by APACHE-II score ≥ 15 points.

[b]*n* = 43 (29 restricted visitation model, 14 extended visitation model) as only patients who developed with delirium were evaluated.

family preferences, 38 of 145 patients (26.2%) never had visits lasting greater than 4.5 hours. Nevertheless, all eligible patients enrolled in RVM (n = 141) and EVM (n = 145) were included in the analyses for the model to which they were assigned. The median duration of visits increased from 133 minutes (interquartile range [IQR], 97.7–162.0) in RVM to 245 minutes (IQR, 175.0–272.0) in EVM ($p < 0.001$). The distribution of median length of ICU visits per patient per day in EVM was significantly different from that recorded in RVM (**Supplemental Digital Content 3**, http://links.lww.com/CCM/C732—legend = Length of ICU visits per patient per day according to the policy of ICU visitation. EVM = extended visitation model, RVM = restricted visitation model). In EVM, daily visits to ICU patients more often lasted between 241 and 300 minutes (67/145 patients [44.1%]) and greater than 300 minutes (33/145 patients [22.7%]). In RVM, most daily visits lasted between 121 and 180 minutes (60/141 patients [42.5%]) and between 61 and 120 minutes (45/141 patients [31.9%]).

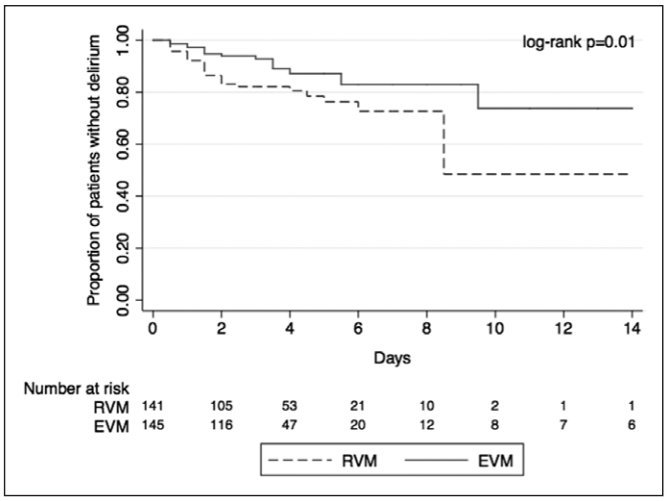

Figure 2. Delirium-free survival during ICU stay. EVM = extended visitation model, RVM = restricted visitation model.

Primary Outcome

Delirium occurred in 14 of 145 patients (9.6%) during EVM and in 29 of 141 patients (20.5%) during RVM (aRR, 0.50; 95% CI, 0.26–0.95) (**Table 2**). Survival free of delirium during ICU stay was also significantly higher in EVM versus RVM patients (**Fig. 2**). A sensitivity analysis excluding RVM patients who received visits greater than 4.5 hr/d and EVM patients who never had visits greater than 4.5 hours confirmed the lower occurrence of delirium in EVM versus RVM patients (aRR, 0.44; 95% CI, 0.21–0.92).

Subgroup analysis for the primary outcome (**Fig. 3**) showed that patients greater than or equal to 65 years old (RR, 0.43; 95% CI, 0.22–0.87), surgical patients (RR, 0.51; 95% CI, 0.27–0.97), patients without psychiatric disorders (RR, 0.34; 95%

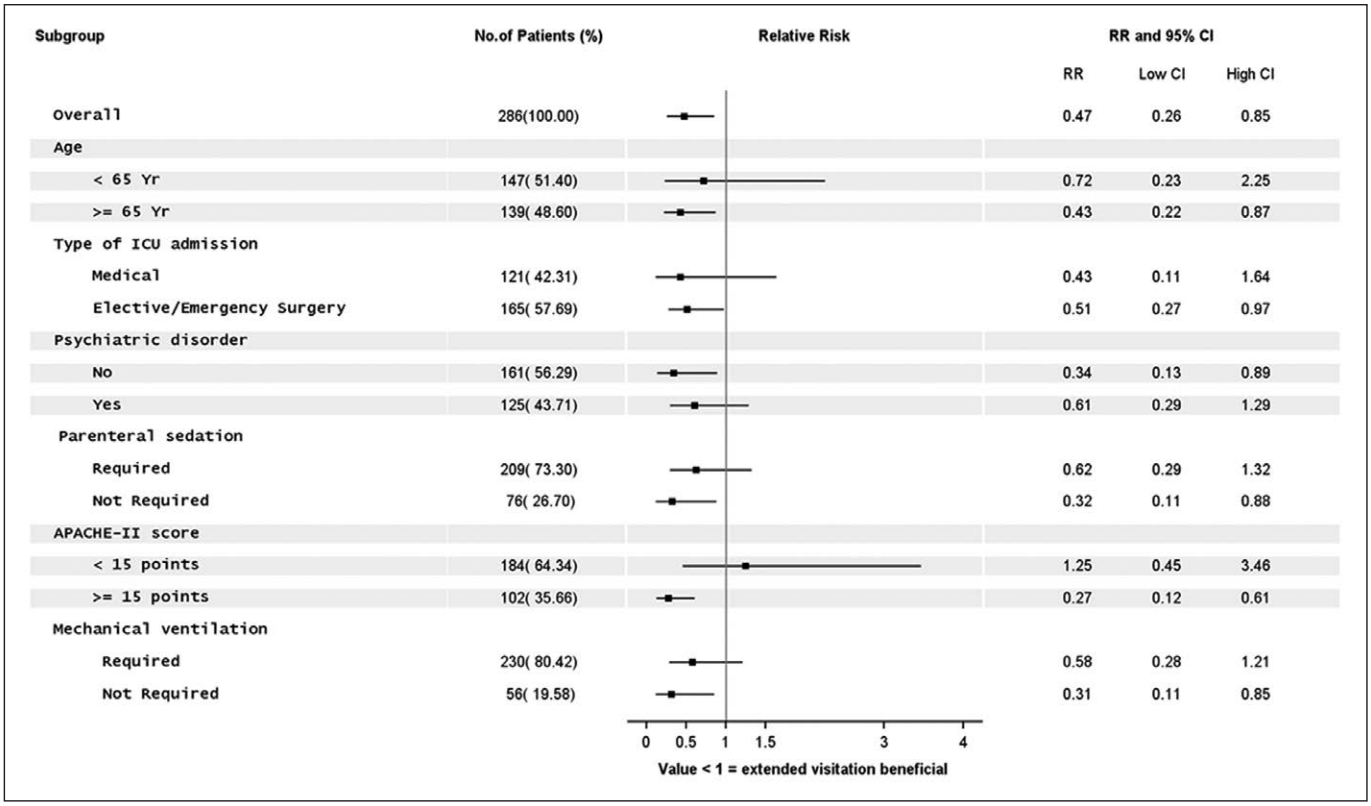

Figure 3. Incidence of delirium according to the policy of ICU visitation: subgroup analysis. APACHE-II = Acute Physiology and Chronic Health Evaluation-II, RR = relative risk.

CI, 0.13–0.89), patients who did not require parenteral sedation (RR, 0.32; 95% CI, 0.11–0.88), patients with APACHE-II score greater than or equal to 15 points (RR, 0.32; 95% CI, 0.14–0.72), and patients who did not require mechanical ventilation (RR, 0.31; 95% CI, 0.11–0.85) were those who benefited most from EVM. A post hoc subgroup analysis showed similar occurrence of delirium for EVM with visits lasting less than or equal to 4.5 hr/d versus EVM patients with visits lasting greater than 4.5 hr/d (RR, 1.12; 95% CI, 0.35–3.59).

Secondary Outcomes

Among secondary outcomes (Table 2), median duration of delirium/coma was lower for EVM versus RVM patients (1.5 d [IQR, 1.0–3.0] vs 3.0 d [IQR, 2.5–5.0]; $p = 0.03$). The median length of ICU stay was shorter for EVM versus RVM patients (3 d [IQR, 2.0–4.0] vs 4 d [IQR, 2.0–6.0]; $p = 0.04$). The rate of ICU-acquired infections and ICU mortality did not differ significantly between the two study groups. The effects of interventions on post hoc secondary outcomes are showed in **Supplemental Digital Content 4** (http://links.lww.com/CCM/C733). The duration of delirium was lower for EVM versus RVM patients (1 d [IQR, 1.0-1.0] vs 2 d [IQR, 1.2–3.2]; $p = 0.007$). Duration of coma, time to onset of delirium, timing of the first identification of delirium and occurrence of specific subtypes of delirium did not differ significantly between the two study groups. Delirium patients had longer median length of ICU stay in comparison with patients who did not develop delirium (7.0 d [IQR, 4.0–12.0] vs 3.0 d [IQR, 2.0–4.0]; $p < 0.001$) (**Supplemental Digital Content 5**, http://links.lww.com/CCM/C734).

DISCUSSION

In this single-center prospective before and after study performed in a medical-surgical adult ICU, an extended visitation policy was associated with lower cumulative incidence of delirium.

The impact of EVM on prevention of delirium is scientifically plausible and may be explained by various mechanisms. Extended visitation allows longer and more frequent contact between patients and their families (16–19). Furthermore, EVM allows more flexible visitation schedules, favoring patient and family-centered care and promoting family engagement in the care of ICU patient. This routine may improve communication between patients and ICU staff, providing a better understanding of patient risk factors for delirium. Also, patient stress and anxiety may be reduced and patient reorientation may be optimized, while reassurance and comfort measures are promoted and treatment adherence is reinforced. These benefits have been associated with lower occurrence of delirium in studies evaluating multicomponent nonpharmacologic interventions to prevent delirium and constitute the rationale for the F component of the ABCDEF bundle (1, 4, 9–12). A study addressing risk factors for developing delirium (13) detected a 3.7-fold higher delirium incidence in ICU patients who received no visits. A two-fold lower incidence of cardiovascular complications

has been described in ICU patients admitted during an unrestricted visitation policy compared with those admitted under a restricted visitation policy (34). In our study, the subgroup findings of greater benefit in delirium prevention for patients greater than or equal to 65 years old and those with APACHE-II score greater than or equal to 15 may be related to the greater susceptibility of these patients developing delirium (4, 6). Specifically, the explanation for the benefit found in surgical patients, patients without psychiatric disorder, and patients who did not require mechanical ventilation and parenteral sedation is not clear. However, these variables may represent proxies of lower exposure to sedation. We hypothesize that the interaction between patients and family members could have been potentiated in situations in which less sedation was applied (35); alternatively, greater sedation may have confounded delirium detection and its precision (36).

Although the average length of ICU visits per patient per day during EVM period was longer than the RVM period, it remained relatively short considering the 12-hour period when visits were possible. Nevertheless, the few studies examining family member visit duration in the context of unrestricted ICU visitation are in agreement with our results. In one study, family members usually stayed for 1–2 hours per day during the first 5 days (16). In another, the mean visiting time was 2.6 hours per patient per day (34). Greater flexibility as to visiting hours may have altered their behavior; this was not tested in either study.

Regarding possible risks associated with EVM, our study failed to show increased risk of ICU-acquired infections or adverse events that could potentially increase ICU length of stay or ICU mortality. Extended visitation policies are associated with greater environmental microbial contamination (34) but similar risk of ICU-acquired infection (34, 37). The reduction in ICU length of stay with EVM in our study may be attributed to the reduced occurrence of delirium, which is a well-recognized risk factor for prolonged ICU stay (4, 6). This fact is reinforced by our findings of longer ICU length of stay for patients with delirium.

Some limitations must be acknowledged. First, the study design is susceptible to biases such as changes over time and Hawthorne effect: these factors could lead to overestimation of the effectiveness of the intervention. Second, we did not control important risk factors for delirium such as the overall sedation requirements and exposure to opioids and benzodiazepines during the whole ICU stay. Third, we did not evaluate the impact of EVM on ICU bedside staff: previous studies showed that ICU workers sometimes perceive visits as a source of increased workload, disorganization of care and stress (38–40). Fourth, generalization of our findings may be limited by the study's single-center character.

Strengths of our study include prospective design, use of strategies to avoid contamination bias, follow-up by an independent research team, and the measurement of variables and outcomes according to previously defined objective criteria.

Beyond being safe and associated with better patient outcomes, an extended visitation policy, by helping to respect and preserve the patient's ties with family, is an important mean to keep patient humanity at such a difficult moment. This component of patient- and family-centered care is an achievable aim with many potential benefits to patients and families (41–43).

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