

## Reduced Cardiocirculatory Complications With Unrestrictive Visiting Policy in an Intensive Care Unit Results From a Pilot, Randomized Trial

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**Background**—Observational studies suggest that open visiting policies are preferred by most patients and visitors in intensive care units (ICUs), but no randomized trial has compared the safety and health outcomes of unrestrictive (UVP) and restrictive (RVP) visiting policies. The aim of this pilot, randomized trial was to compare the complications associated with UVP (single visitor with frequency and duration chosen by patient) and RVP (single visitor for 30 minutes twice a day).

**Methods and Results**—Two-month sequences of the 2 visiting policies were randomly alternated for 2 years in a 6-bed ICU, with 226 patients enrolled (RVP/UVP, n=115/111). Environmental microbial contamination, septic and cardiovascular complications, emotional profile, and stress hormones response were systematically assessed. Patients admitted during the randomly scheduled periods of UVP received more frequent ( $3.2 \pm 0.2$  versus  $2.0 \pm 0.0$  visits per day, mean  $\pm$  SEM) and longer ( $2.6 \pm 0.2$  versus  $1.0 \pm 0.0$  h/d) visits ( $P < 0.001$  for both comparisons). Despite significantly higher environmental microbial contamination during the UVP periods, septic complications were similar in the 2 periods. The risk of cardiocirculatory complications was 2-fold (odds ratio 2.0; 95% CI, 1.1 to 3.5;  $P = 0.03$ ) in the RVP periods, which were also associated with a nonsignificantly higher mortality rate (5.2% versus 1.8%;  $P = 0.28$ ). The UVP was associated with a greater reduction in anxiety score and a significantly lower increase in thyroid stimulating hormone from admission to discharge.

**Conclusions**—Despite greater environmental microbial contamination, liberalizing visiting hours in ICUs does not increase septic complications, whereas it might reduce cardiovascular complications, possibly through reduced anxiety and more favorable hormonal profile. (*Circulation*. 2006;113:946-952.)

**Key Words:** aging ■ coronary disease ■ heart failure ■ myocardial infarction ■ shock

Admission to an intensive care unit (ICU) is a potentially stressful event<sup>1</sup> in which pain and physiological dysfunctions from acute disease may be associated with emotional disorders secondary to fear of diagnostic or therapeutic procedures, sleep deprivation, restricted mobility, and limitations to the visits that patients can receive.<sup>2</sup> Limited exploratory studies<sup>3</sup> suggested that all these factors concur to induce a sense of isolation, impair patients' communication capabilities with healthcare staff, and eventually lead, together with well-known somatic risk factors,<sup>4,5</sup> to an "ICU syndrome" and delirium,<sup>6,7</sup> a powerful predictor of ominous prognosis.<sup>8</sup> Hall-Lord et al<sup>9</sup> have conceptualized the role of readily identifiable emotional components in the acutely distressing reaction to ICU admission. However, no study has demonstrated so far that the negative emotional consequences of an

ICU stay can be prevented by enhanced emotional support. In the different perspective of the association between psychological well-being and prognosis of medical illnesses, evidence has been provided that strong emotional support improves survival of older patients after acute myocardial infarction.<sup>10</sup> This evidence is limited to the long-term effect, however, and does not directly refer to the ICU stay.<sup>10</sup>

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Reviews,<sup>11</sup> descriptive surveys,<sup>12</sup> and intervention studies<sup>13,14</sup> have suggested that open visiting policies are preferred by most patients and may improve visitors' satisfaction while reducing their stress. Nonetheless, most ICU staffs maintain restrictive visiting policies in the belief that liberalizing ICU visiting hours may interfere with the provision of

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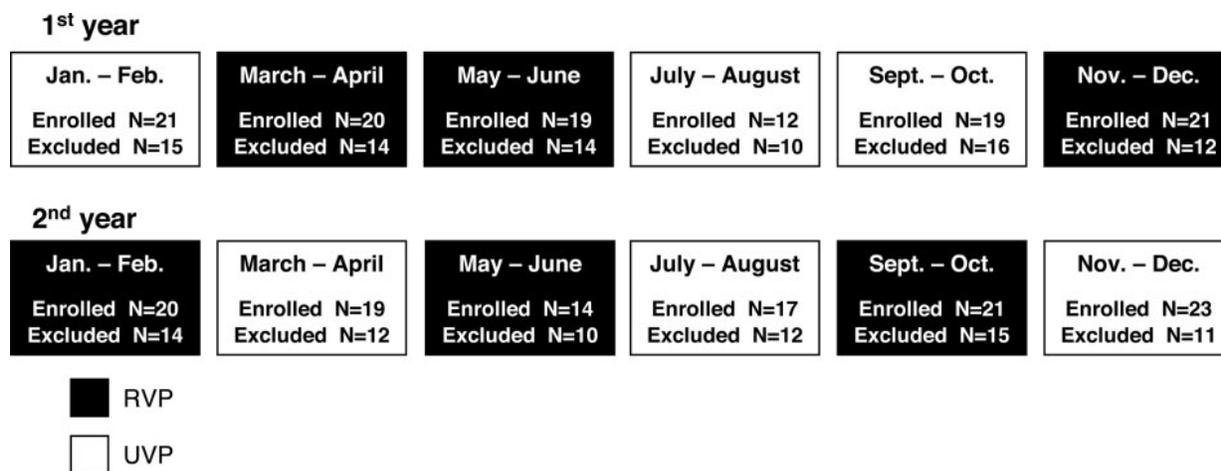
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**Figure 1.** Enrollments and exclusions in the 2-month study periods randomized to RVP or UVP.

care and increase the patient's physiological stress and risk of septic complications.<sup>15</sup> However, because no randomized trial has been conducted so far comparing unrestrictive (UVP) and restrictive (RVP) visiting policies, no conclusive evidence is available yet on their relative advantages or disadvantages.<sup>16</sup>

The present randomized trial was carried out as a pilot study, to address this issue in a cardiology ICU. First, we aimed at testing whether, compared with RVP, UVP is associated with increased environmental contamination, resulting in a greater risk of septic complications. Second, we compared the incidence of major cardiovascular complications and changes in emotional and hormonal profiles between the 2 regimens.

## Methods

### Patient Selection and Randomization

All patients admitted consecutively to our 6-bed cardiology ICU over a 24-month period were screened for eligibility, which was limited by the following exclusion criteria: severe alterations in consciousness, delirium, or cognitive impairment (Mini Mental State Examination score <21)<sup>17</sup>; major psychosis requiring pharmacological treatment; expected ICU stay <24 hours; transferal from another department; readmission after enrollment in the same study; and an unwillingness or inability to provide informed consent. Of 381 patients screened for eligibility over the study period, 155 (40.7%) were excluded. Reasons for exclusion were unconsciousness or poor cognition in 16 (10.3%), psychosis in 8 (5.2%), ICU stay <24 hours in 40 (25.8%), transferal from another department in 53 (34.2%), readmission in 18 (11.6%), and unwillingness or inability to consent in 20 (12.9%).

In this single-center trial, a random sequence of 2-month periods of RVP and UVP was generated with a computer-based procedure that was forced to produce six 2-month periods for each visiting policy for a total duration of 2 years. The randomization sequence was kept concealed to the ICU staff until the beginning of each new period. As shown in Figure 1, enrollments and exclusions were well balanced between RVP and UVP (RVP: enrolled, 115; excluded, 79; UVP: enrolled, 111; excluded, 76;  $P=0.99$ ). In the last week of each 2-month period, no new patient was admitted to the ICU to allow all study participants to be discharged and to allow a 4-day washout phase during which the ICU was cleaned and disinfected. No patient was lost to follow-up over the limited duration of the study, and all participants remained in their initial randomization arm.

### Intervention

In the RVP, a single visitor per patient was admitted for 30 minutes twice a day (from 2:00 to 2:30 and from 7:00 to 7:30 PM). The visitor was required to wash his or her hands for 3 to 5 minutes with antibacterial soap and to wear disposable vests and overshoes in a designated area before the ICU. In the UVP, the number and duration of visits were left to the patient's preference, with the only restriction of 1 visitor at a time. Washing hands and wearing disposable vests and overshoes also applied, as required during the RVP period. The institutional ethics committee approved the design of the trial, which followed the principles of the Declaration of Helsinki. A letter describing the trial design and guidelines for visiting was delivered on admission to visitors and patients, who were required to provide written, informed consent to study procedures and data collection. However, both patients and visitors were masked to the study hypothesis.

### Data Collection

The social network was investigated by asking patients to indicate how many of their closest relatives or friends they had as potential visitors during their ICU stay. Visitors were asked to record the duration of each visit on a form kept at bedside. Bacterial and fungal contamination of air and surfaces was determined on days 1, 15, and 60 of each randomization period. Air contamination was assessed separately for the central corridor and individual patient's rooms with a surface air system sampler (PBI International) equipped with 36-cm<sup>2</sup> Petri dishes,<sup>18</sup> each containing culture medium specific for different strains. In each sampling procedure, 180 L air was aspirated over 120 seconds far from surfaces and human bodies at a constant height of 1.5 m from the floor. Air contamination, expressed as colony-forming units per volume of aspirated air (m<sup>3</sup>), was calculated as number of colonies per dish times 1000 divided by the volume of aspirated air. Contamination of beds, monitors, and table surfaces in patients' rooms, expressed as colony-forming units per surface of sampled area (cm<sup>2</sup>), was assessed at the same time intervals with contact plates equipped with a graded reticule that gives quantitative information on the extent of the sampled surface. Midday room temperature and humidity were recorded daily.

Septic complications were assessed daily following the criteria of the National Nosocomial Infections Surveillance System.<sup>19</sup> For this purpose, the type and number of invasive procedures were recorded, and asymptomatic bacterial or fungal contamination was assessed by culturing blood, urine, and the tips of vascular and bladder catheters on removal.

Severity of acute and chronic health conditions was assessed on admission with the Acute Physiology and Chronic Health Evaluation II (APACHE II) score.<sup>20</sup> Anxiety and depressive symptoms were evaluated on admission to and discharge from the ICU with the Hospital Anxiety and Depression Scale, which is composed of 2

subscales, each ranging from 0 (no symptoms) to 21 (maximally severe symptoms), with cutoff scores associated with possible or severe disorders of 7 and 14, respectively.<sup>21</sup> Major cardiac arrhythmias (ventricular tachycardia/fibrillation; advanced AV block; asystole), cardiac rupture, and acute cardiac failure (defined as pulmonary edema and/or cardiocirculatory shock) were routinely recorded as cardiovascular complications at any time during the ICU stay. In patients with an admission diagnosis of acute myocardial infarction, Killip class also was assessed daily. Plasma concentrations of thyroid-stimulating hormone (TSH), 8-AM plasma cortisol, and 24-hour vanillylmandelic acid urinary excretion were measured on admission to and discharge from ICU as biological markers of stress.<sup>22–24</sup>

Assessment of microbiological and hormonal outcomes was masked to the study period. To ascertain the cause, autopsy was performed in all cases of death.

### Statistical Analysis

Data were analyzed with SPSS 11.0 for Windows. All analyses were 2 sided and based on the intention-to-treat principle. A value of  $P < 0.05$  was considered statistically significant. In the absence of previous evidence of the possible clinical impact of different visiting policies in ICU, we were unable to determine a specific sample size. We deemed as appropriate a 2-year experiment to obtain an adequate number of periods with the 2 regimens. Baseline categorical variables were compared by the  $\chi^2$  test, whereas their change over time was analyzed with the McNemar test. Dichotomous outcomes were compared between RVP and UVP in logistic regression models adjusted for age, gender, and 2-month period of enrollment. Normally distributed continuous variables (reported as mean  $\pm$  SEM) were compared by the use of the Student *t* test or the paired *t* test as appropriate. The Mann-Whitney test was used for comparing non-normally distributed variables. Changes in continuous variables over time were compared between patients enrolled in the 2 study arms using general linear models for repeated measures, adjusting for demographics and period of enrollment. Factors independently associated with bacterial and fungal contamination were identified with multivariable linear regression models. All statistical analyses were blinded to study period.

The authors had full access to the data and take full responsibility for its integrity. All authors have read and agree to the manuscript as written.

## Results

Of 226 patients enrolled, 115 were randomly admitted during the RVP and 111 during the UVP. Baseline sociodemographic and anthropometric characteristics, cognitive status, cardiovascular risk factors, admission diagnoses, disease severity, prevalence of sensory impairments, and number of invasive procedures were similar between the 2 groups (the Table). In particular, the subgroups with ST-segment-elevation acute myocardial infarction were treated in similar proportions (RVP, 48.8%; UVP, 51.3%;  $P=0.75$ ) with coronary revascularization that, in our health district, is done with primary percutaneous coronary intervention in the vast majority of cases.<sup>25</sup>

### Number and Duration of Visits

Over a similar average length of stay (RVP,  $5.8 \pm 0.4$  days; UVP,  $5.6 \pm 0.3$  days;  $P=0.68$ ), RVP patients received  $2.0 \pm 0.0$  visits per day with an overall duration of  $1.0 \pm 0.0$  h/d; UVP patients received  $3.2 \pm 0.2$  visits per day with a total duration of  $2.6 \pm 0.2$  h/d ( $P < 0.001$  for both comparisons). The overall visiting time covered  $4.1 \pm 0.0\%$  and  $10.9 \pm 0.8\%$  of the whole length of stay in RVP and UVP patients, respectively ( $P < 0.001$ ). Visits from family members ac-

### Demographic and Clinical Characteristics by Visiting Policy

	RVP (n=115)	UVP (n=111)	P
Age, y	67 $\pm$ 1	68 $\pm$ 1	0.63
Aged $\geq 75$ y, %	26.1	27.9	0.76
Male gender, %	69.0	74.8	0.31
Living alone, %	9.0	13.9	0.30
Marital status (married), %	66.1	66.7	1.00
Social network,* n	3.9 $\pm$ 0.8	3.8 $\pm$ 0.9	0.89
Formal education >8 y, %	21.7	21.3	1.00
Wine consumption >0.5 L/d, %	13.9	16.2	0.40
Body mass index, kg/m <sup>2</sup>	25.2 $\pm$ 0.4	25.8 $\pm$ 0.4	0.25
Mini Mental State Examination score	26.6 $\pm$ 0.2	26.7 $\pm$ 0.2	0.78
Cardiovascular risk factors, %			
Current smoking	37.4	34.2	0.30
Diabetes	11.3	17.1	0.25
Dyslipidemia	14.8	21.6	0.23
Hypertension	37.4	33.3	0.58
Admission diagnosis, %			
Acute myocardial infarction	69.6	68.5	
Unstable angina	19.1	20.7	
Decompensated heart failure	4.3	4.5	0.96
Arrhythmias	2.6	3.6	
Other	4.3	2.7	
APACHE II			
Acute Physiology score	2.3 $\pm$ 0.2	2.6 $\pm$ 0.3	0.51
Chronic Health Evaluation score	0.2 $\pm$ 0.1	0.1 $\pm$ 0.1	0.36
Sensory impairments, %			
Hearing loss	0.9	1.8	0.62
Visual loss	4.3	1.8	0.45
Invasive procedures,† n	2.9 $\pm$ 0.2	2.5 $\pm$ 0.2	0.19

\*Number of relatives or friends available for visits.

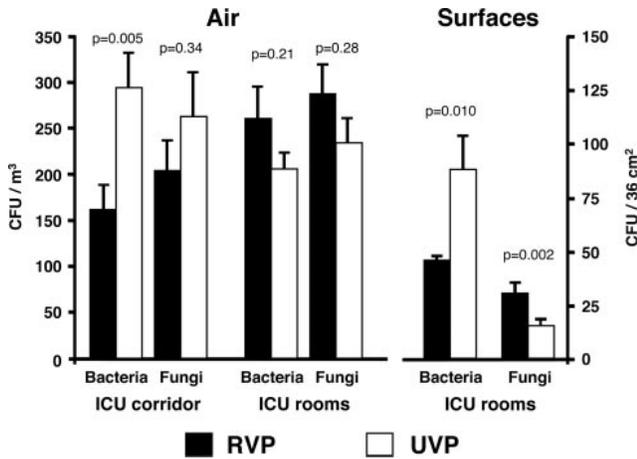
†Invasive procedures include any arterial, venous, urinary bladder, or endotracheal catheter inserted. Continuous variables are presented as mean  $\pm$  SEM.

counted for >90% of all visits received by patients in both periods.

### Environmental Contamination and Septic Complications

The average temperature (RVP,  $24.7 \pm 0.1^\circ\text{C}$ ; UVP,  $24.7 \pm 0.1^\circ\text{C}$ ;  $P=0.79$ ) and humidity (RVP,  $59.1 \pm 1.5\%$ ; UVP,  $61.4 \pm 1.0\%$ ;  $P=0.20$ ) in ICU rooms were similar in the 2 study periods.

At the systematic microbial survey, the air in the ICU corridor was significantly less contaminated with bacteria in RVP than in UVP periods, whereas air contamination in patients' rooms was similar (Figure 2). Surfaces in patients' rooms were significantly more contaminated with bacteria in UVP and with fungi in RVP periods (Figure 2). At multivariable regression analysis, bacterial contamination of surfaces was positively associated with air bacterial contamination ( $P=0.038$ ), room temperature ( $P=0.001$ ), and UVP ( $P=0.001$ ), whereas humidity and surface fungal contamina-



**Figure 2.** Microbial (bacteria and fungi) contamination of air and surfaces in the ICU during the RVP and UVP periods. Data are mean±SEM. CFU indicates colony-forming units.

tion, the only other covariates entered in this model, were not significant predictors of bacterial contamination of surfaces and therefore were backward deleted from the final regression model. On the other hand, fungal contamination of surfaces was positively associated with fungal air contamination ( $P=0.001$ ), room humidity ( $P=0.001$ ), and RVP ( $P=0.01$ ) and not with room temperature and bacterial contamination.

Despite the lower bacterial contamination in the RVP period, the cumulative incidence of pneumonia, urinary tract infections, generalized sepsis, and overall septic complications was similar in the 2 experimental groups, also after adjustment for age, gender, and period of enrollment (Figure 3).

**Cardiovascular Complications and Mortality**

All major cardiovascular complications were more frequent in the RVP than UVP periods, the difference being statistically significant for pulmonary edema or shock. Overall, the relative risk of any type of cardiovascular complication was approximately double in RVP than in UVP periods (Figure 3). In a separate analysis of the 156 patients (RVP, n=80; UVP, n=76) with acute myocardial infarction, we compared the Killip class distribution between admission to and dis-

charge from the ICU. In the RVP periods, the difference between admission and discharge was not significant ( $P=1.00$ ), with 6.7% of patients admitted in Killip class 1 deteriorating to class 2 to 4 on discharge, and 26.7% of those admitted in class 2 to 4 improving to class 1 on discharge. Conversely, in the UVP periods, only 3.4% of patients admitted in Killip class 1 deteriorated to class 2 to 4, whereas 58.8% of those admitted in class 2 to 4 improved to class 1 on discharge ( $P=0.039$ ).

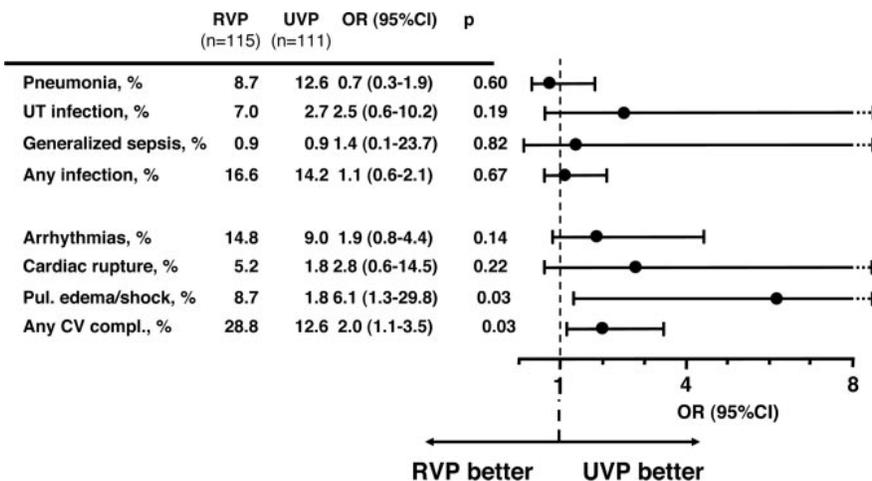
In-hospital mortality was 5.2% (n=6) in patients randomly admitted during RVP periods and 1.8% (n=2) in those admitted during UVP periods ( $P=0.28$ ).

**Emotional Profile and Hormones**

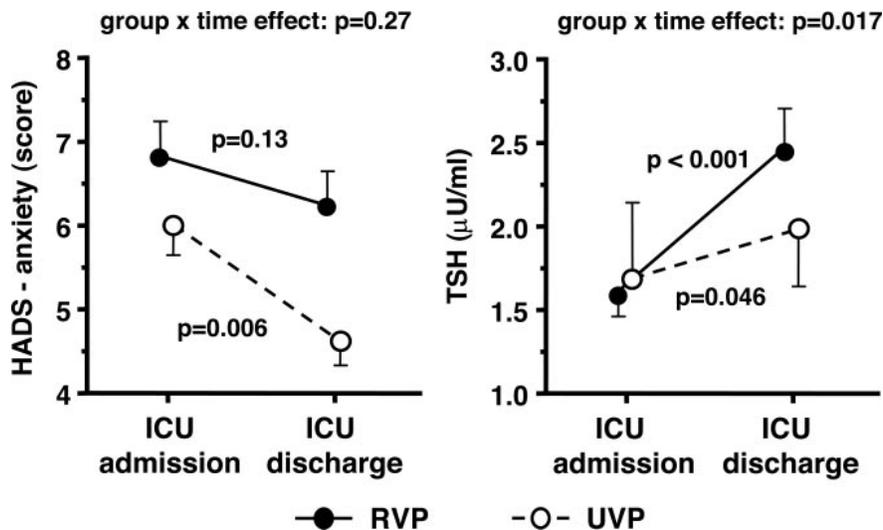
Anxiety score was similar at baseline in the 2 groups and was reduced significantly in the UVP group from ICU admission to discharge, whereas a slight, nonsignificant reduction was observed in the RVP group. Overall, the 2 groups showed a similar change when anxiety scores were compared between admission and discharge (Figure 4). Depression score did not change between admission and discharge in either group (RVP:  $3.9\pm 0.3$  on admission versus  $3.9\pm 0.3$  at discharge,  $P=0.79$ ; UVP:  $2.9\pm 0.3$  on admission versus  $3.1\pm 0.3$  at discharge,  $P=0.39$ ). Compared with admission, plasma TSH was significantly higher at discharge in both groups; the difference was more marked in the RVP group, as indicated by a significant group-time interaction (Figure 4). Plasma cortisol concentration (RVP:  $542\pm 28$  nmol/L on admission versus  $452\pm 15$  nmol/L at discharge,  $P<0.001$ ; UVP:  $603\pm 48$  nmol/L on admission versus  $443\pm 15$  nmol/L at discharge,  $P<0.001$ ) and 24-hour vanillylmandelic acid urinary excretion (RVP:  $5.8\pm 0.3$  mg/24 h on admission versus  $4.6\pm 0.2$  mg/24 h at discharge,  $P<0.001$ ; UVP:  $5.4\pm 0.3$  mg/24 h on admission versus  $4.2\pm 0.2$  mg/24 h at discharge,  $P<0.001$ ) were reduced to a similar extent (group-by-time interaction,  $P=0.16$  and  $P=0.97$ , respectively) in the 2 groups from admission to discharge.

**Discussion**

The main findings of the present study are that, despite greater bacterial contamination of the environment, liberalizing ICU visiting hours is not harmful in terms of increased



**Figure 3.** Incidence, with OR and 95% CI, of septic and major cardiovascular complications in patients enrolled during the RVP and UVP periods adjusted for age, gender, and time of enrollment. RR indicates relative risk; UT, urinary tract; pul., pulmonary; and CV compl., cardiovascular complication.



**Figure 4.** Changes from ICU admission to ICU discharge in anxiety score (Hospital Anxiety and Depression Scale [HADS]) and in TSH in patients enrolled during the RVP and UVP periods. Data are mean  $\pm$  SEM, adjusted for demographics and period of enrollment. In each panel, the probability value for the interaction term "group $\times$ time" is shown.

septic complications, which are usually given by bacteria in the immune competent host; rather, it might be beneficial in terms of reduced cardiovascular complications. Our results also suggest that this benefit might be ascribed to a lower level of anxiety associated with a somewhat more favorable hormonal profile.

To the best of our knowledge, this is the first pilot, randomized trial aimed at formally comparing the effect of RVP and UVP in an ICU on clinically valuable outcomes.<sup>16</sup> Studies suggest that most ICU patients express their preference for a less restrictive visiting policy that is flexible enough to meet their needs and those of their family members.<sup>12</sup> Nevertheless, open and flexible visiting policies are far from having been implemented, and the idea of liberalizing ICU visiting hours is still challenged and generates considerable resistance among nurses and physicians.<sup>15</sup> Notably, in our experience, when patients and families were offered unrestricted ICU visiting hours, the duration of visits more than doubled for patients with comparable sociodemographic characteristics. This confirms the results of structured interviews of patients and families on ICU visiting that showed that open visiting policies would be largely preferred by the vast majority of them.<sup>12</sup>

Air bacterial contamination was significantly greater during the UVP than the RVP periods in the ICU corridor, the area most intensely traveled by visitors and staff, but it was similar in patients' rooms in the 2 regimens. Bacterial contamination of surfaces in patients' rooms was greater during the UVP, with a lower concentration of fungi that can be interpreted as being the result of their natural competition with bacteria. Overall, our microbiological data suggest that the increased number and duration of visits during the UVP period were associated with increased environmental contamination by bacteria. Nonetheless, the cumulative incidence of any type of septic complication was similar during the 2 periods. This finding challenges the idea that restricting visiting hours may contribute to infection control in ICUs and suggests that environmental contamination is not a major determinant of septic complications, which are best prevented with careful hand washing when staff members move from 1 patient to another.<sup>26</sup>

Compared with UVP, RVP patients had a 2-fold greater risk of major cardiovascular complications, particularly of pulmonary edema or shock, but also, although not significantly, of arrhythmias and cardiac rupture. The potential cardiocirculatory benefit associated with UVP was further highlighted by the significantly greater improvement in Killip classification in patients admitted with acute myocardial infarction in the UVP periods. It might be hypothesized that the lower incidence of cardiovascular complications recorded in the UVP periods resulted from a closer surveillance provided by visiting relatives to patients, fostering faster and more accurate reactions by the ICU staff. However, it is unlikely that a well-trained staff would rely on relatives' alerts to provide better care in an ICU setting, where concerns have been expressed that excessive presence of visitors might interfere with the provision of adequate care.<sup>15</sup>

In the early phase of acute myocardial infarction, anxiety is a particularly common emotional reaction that, in observational studies,<sup>27</sup> is independently associated with an increased risk of major cardiovascular complications, either short or long term.<sup>28</sup> Increased vasomotor tone and left ventricular stress, ectopic activity, and platelets endothelial adhesion are among the possible consequences of autonomic activation<sup>29</sup> that may justify the association of anxiety and acute stress with increased complications. The concern that the patient should be left alone to rest assumes that family presence at bedside increases patients' stress level. However, some empirical literature has suggested that attendance of family and friends may in fact reduce heart rate in patients admitted to an ICU for acute coronary syndromes.<sup>30</sup> In agreement with these observations, our findings are consistent with reduced anxiety in the UVP group. Indeed, in our patients, in whom acute coronary syndromes accounted for >75% of admission diagnoses, the UVP was associated with a significant reduction in anxiety score that did not occur with the RVP over an identical ICU stay. This difference, although not significant at trend comparison over time, was associated with a different time course of 1 stress-related hormone represented by a significantly larger increase in TSH in the RVP than in the UVP group. We therefore propose that the increase in the

number and length of reassuring and soothing family visits has produced a reduction in anxiety that, in turn, might have been associated with less stress, dampened hormonal activation, and eventually fewer cardiovascular complications. However, the interpretation of TSH data may be controversial. A reduction in the pulsatile secretion of TSH and of several other hormones released by the anterior pituitary gland has been reported in prolonged stress states and has been recognized as a possible contributor to the protein-wasting syndrome that may occur with prolonged ICU stay.<sup>23</sup> On the other hand, a brisk and sustained increase in TSH has been reported in response to acute stress in normal volunteers.<sup>22</sup> Therefore, our result might be interpreted as the hallmark of a more rapid reduction in acute stress in UVP patients over a substantially short ICU stay, as also suggested by the significant reduction in anxiety score.

Because of the small sample size, which is the major limitation of our study, the robustness of our findings on individual cardiac outcomes is limited, and we were unable to demonstrate whether the UVP is also associated with a significant reduction in mortality. From our results, the estimated sample size required to detect a significant difference in mortality ( $\alpha=0.05$ ; power=0.9) would be at least 306 patients per group. Moreover, we did not measure the time devoted to patients' care by the staff and the cumulative incidence of delirium in the 2 periods, nor did we take into account any indicator of stress to staff, which might be increased by UVP. Similarly, we did not take into account any indicator of the satisfaction or dissatisfaction of patients and visitors. However, the global impression reported by personnel, patients, and visitors was favorable, to the point that, after completion of the experimental protocol, the visiting schedule in our cardiology ICU has been widened substantially. A further study limitation is the fact that, because of the study design, it was not possible to keep assessors of clinical outcomes masked to study period. Our analyses of the hormonal impact of the 2 visiting regimens were also limited in that we did not measure cortisol as 24-hour urine excretion but only as 8:00 AM plasma concentration, which may account for the lack of any significant difference in cortisol levels between RVP and UVP. We are aware that seasonal variations can profoundly affect microbial contamination, staffing and management practices in an ICU, and ultimately patients' overall health outcomes. This, in turn, might have confounded the results of this study. Nevertheless, we believe that such a confounding should have been limited by the random sequence of assignment of the experimental intervention—which, in fact, resulted in comparable values of temperature and humidity in the 2 regimens—and by adjusting our analyses for 2-month periods of enrollment. Finally, the results of this Italian single-center study may not be generalized to other geographic and sociodemographic contexts.

Despite these limitations, we conclude that, beyond being neither caring nor compassionate,<sup>15</sup> restricting visiting hours might be unjustified and unnecessary for protecting the sickest patients in the ICU because it does not reduce the rate of infectious complications. Our findings suggest that liberalizing the visiting hours seems to be more protective because

it is associated with a reduction in severe cardiovascular complications. Whether such a protective effect may translate into reduced in-hospital mortality is an issue to be addressed in larger randomized trials, which might also confirm the robustness of our preliminary findings.

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### Disclosures

None.

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### CLINICAL PERSPECTIVE

Although observational studies suggest that open visiting policies are preferred by most patients and visitors in intensive care units (ICUs), the safety and health outcomes of unrestrictive and restrictive visiting policies (UVP, RVP) have never been compared in randomized trials. We conducted a pilot, randomized trial in an ICU, with the purpose of comparing health outcomes associated with a UVP regimen, in which each patient could freely choose frequency and duration of visits, and an RVP regimen, characterized by visiting times not exceeding 30 minutes twice a day. In a random sequence of 2-month periods of the 2 visiting policies, 226 patients (RVP, n=115; UVP, n=111) were enrolled over a 2-year period. Environmental microbial contamination, septic and cardiovascular complications, emotional profile, and stress hormones response were systematically assessed. Patients admitted in UVP periods did receive more and longer visits. The UVP regimen was associated with higher environmental microbial contamination, but not with more septic complications. Interestingly, the risk of cardiocirculatory complications was 2.0 times greater in the RVP periods, which were also associated with a nonsignificantly higher mortality rate. The UVP regimen was associated with greater reduction in anxiety score and significantly lower increase, from admission to discharge, in hormonal stress profile. We conclude that, despite greater environmental microbial contamination, liberalizing visiting hours in ICUs does not increase septic complications, although it might reduce cardiovascular complications, possibly through reduced anxiety and more favorable hormonal profile. These encouraging results should be confirmed in larger studies.

## Reduced Cardiocirculatory Complications With Unrestrictive Visiting Policy in an Intensive Care Unit: Results From a Pilot, Randomized Trial

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