# Adverse Events in Intensive Care and Continuing Care Units During Bed-Bath Procedures: The Prospective Observational NURSIng during critical carE (NURSIE) Study

**Guillaume Decormeille, RN[1]**
**Valerie Maurer-Maouchi , RN[2]**
**Gwennaelle Mercier, RN[3]**
**Sylvie Debock, RN[4]**
**Cindy Lebrun , RN[5]**
**Maud Rouhier, RN[6]**
**Elodie Martinez, RN[7]**
**Anne Lise Faure, RN[8]**
**Julien Duviver, RN[9]**
**Samia Hultet-Midelton, RN[10]**
**Francoise De Freitas Pereira, RN[11]**
**Catherine Tuaillon, RN[12]**
**Lea Soulisse, RN[13]**
**Gregoire Demont, RN[14]**
**Atika Youssouf, RN[15]**
**Virginie Dauve, RN[16]**
**Julie Negrel, RN[17]**
**Brice Sauvage, RN[18]**
**Celina Morand, RN[19]**
**Kristell Pedrono, RN[20]**
**Sylvie L'Hotellier, RN[21]**
**Francoise Nicolas, RN[22]**
**Nadine Robquin, RN[23]**
**Philippe Michel, MD[24]**
**Gregoire Muller, MD[25]**
**Nadia Aissaoui, MD[26]**
**Saber Davide Barbar, MD[27]**
**Florence Boissier, MD[28]**
**David Grimaldi, MD[29]**
**Sami Hraiech, MD[30]**
**Gael Piton, MD[31]**
**Gwenaelle Jacq, RN[32]**
**Jean Baptiste Lascarrou, MD[16]; for the SRLF Trial Group**

**OBJECTIVES:** Standard nursing interventions, especially bed-baths, in ICUs can lead to complications or adverse events defined as a physiologic change that can be life-threatening or that prolongs hospitalization. However, the frequency and type of these adverse events are rarely reported in the literature. The primary objective of our study was to describe the proportion of patients experiencing at least one serious adverse event during bed-bath. The secondary objectives were to determine the incidence of each type of serious adverse event and identify risk factors for these serious adverse events.

**DESIGN:** Prospective multicenter observational study.

**SETTING:** Twenty-four ICUs in France, Belgium, and Luxembourg.

**PATIENTS:** The patients included in this study had been admitted to an ICU for less than 72 hours and required at least one of the following treatments: invasive ventilation, vasopressors, noninvasive ventilation, high-flow oxygen therapy. Serious adverse events were defined as cardiac arrest, accidental extubation, desaturation and/or mucus plugging/inhalation, hypotension and/or arrhythmia and/or agitation requiring therapeutic intervention, acute pain, accidental disconnection or dysfunction of equipment, and patient fall requiring additional assistance.

**INTERVENTIONS:** None.

**MEASUREMENTS AND MAIN RESULTS:** The study included 253 patients from May 1, 2018, to July 31, 2018 in 24 ICUs, representing 1,529 nursing procedures. The mean Simplified Acute Physiology Score II was $54 \pm 19$. Nursing care was administered by an average of $2 \pm 1$ caregivers and lasted between 11 and 20 minutes. Of the 253 patients included, 142 (56%) experienced at least one serious adverse event. Of the 1,529 nursing procedures, 295 (19%) were complicated by at least one serious adverse event. In multivariate analysis, the factors associated with serious adverse event were as follows: presence of a specific protocol ($p = 0.011$); tracheostomy ($p = 0.032$); administration of opioids ($p = 0.007$); presence of a physician ($p = 0.0004$); duration of nursing care between 6 and 10 minutes ($p = 0.003$), duration of nursing care between 11 and 20 minutes ($p = 0.005$), duration of nursing care greater than 40 minutes ($p = 0.04$) with a reference duration of nursing care between 20 and 40 minutes.

**CONCLUSIONS:** Serious adverse events were observed in one-half of patients and concerned one-fifth of nurses, confirming the need for caution. Further studies are needed to test systematic serious adverse event prevention strategies.



**DOI: 10.1097/CCM.0000000000004745**

**KEY WORDS:** adverse events; bed-bath; care; hygiene; nursing

## BACKGROUND

In intensive care and continuing care units, nursing procedures are performed several times a day by nurses in collaboration with nursing assistants for patients with organ failure requiring invasive techniques, which limit the patients' capacity to care for themselves. The goals of nursing procedures are not only to maintain personal hygiene but also limit the consequences of immobilization and promote early rehabilitation. Nursing procedures include not only patient personal hygiene and bed bathing but also pressure ulcer prevention, management of spasticity, and patient comfort.

Bed-bath is a complex procedure, which requires presence of at least a nurse and a nursing assistant and comprises several consecutive steps. Turning the patient during bed bathing can result in hemodynamic, respiratory, and/or neurologic changes that may be deleterious or even dangerous for the patient. Turning the patient to the right or left lateral decubitus positions is associated with a risk of accidental displacement/movement of the medical devices necessary for the patient's care. These changes and risks can generate serious adverse events (SAEs), defined as a physiologic change that may be life-threatening, prolong hospitalization, or result in functional sequelae compromising patient safety (1).

Although such nursing procedures are performed daily in all ICUs in France and worldwide, the incidence of SAEs associated with nursing procedures has not been precisely determined, and the risk factors for these SAEs have not been identified. The modalities of bed bathing, its duration, and associated procedures are very heterogeneous (2). Some studies have estimated the incidence of SAEs during hospital transport (1), but few studies have evaluated adverse events occurring during standard nursing procedures (3, 4). de Jong et al (5) studied the incidence of adverse events during bed bathing and personal hygiene procedures in 193 patients, but their single-center study mainly focused on pain-related phenomena. Engström et al (6) found than 23% of procedures were associated with major physiologic changes, such as tachycardia or hypotension, but their study was based on only 16 patients in a single ICU. Finally, Robles Rangil et al (7) studied 90 patients in a single-center study (7).

The objectives of our study were to determine the incidence of SAEs during nursing procedures and identify the risk factors for these SAEs.

## MATERIAL AND METHODS

NURSIng during critical carE (NURSIE) was an international, institutional, prospective, observational study conducted in 24 intensive care and continuing care units in France, Belgium, and Luxembourg between May 1, 2018, and July 31, 2018.

Patients admitted to intensive care or continuing care units during the previous 72 hours who met at least one of the following severity criteria were included in the study: intubated with an endotracheal tube; tracheostomy cannula; continuous infusion of vasoactive drugs (norepinephrine, epinephrine, dobutamine); noninvasive ventilation for at least 1 hour during the 24 hours prior to screening; or heated humidified high-flow oxygen therapy. Patients were ineligible when they presented any of the following criteria: already included in the study, a medical contraindication to turning the patient to the lateral decubitus position, cessation of active treatment, spinal injury, or bed bathing by the patient himself/herself and expected to stay in the unit for at least 72 hours.

The primary outcome was the proportion of nursing procedures associated with SAEs over the total number of nursing procedures performed during patient follow-up (i.e., 72 hr). Nursing procedures comprised bed bath at least involving positioning of the patient in the lateral decubitus position and care that lasted at least 10 minutes. The secondary outcomes were the incidence of each individual SAE and identification of ICU-, patient-, and nurse-related risk factors for SAEs.

### Data Collection

Three types of data were collected.

ICU data included the type of unit (medical, surgical, or multipurpose), the number of beds, average length of stay, mean Simplified Acute Physiology Score (SAPS) II (8), visiting hours, number of senior physicians, number of residents, number of nurses, number of nursing assistants, number of physical therapists, use of temporary staff, ventilator with a circuit support arm, patient lifters, number of patient positionings per day, timing of nursing procedures, and the presence

of specific protocols. A specific bed-bath protocol was defined by Morris (9) as precise and detailed plans to perform bed-bath for critical care patients. A specific protocol must have been developed, validated, and available in each ICU participating in this study.

Demographic data included age, sex, height, weight, body mass index (BMI), SAPS II score at admission (8), presence of invasive devices, neurologic sequelae (hemiplegia, tetraplegia), duration of mechanical ventilation, ICU length of stay, vital status on discharge from ICU, and vital status on discharge from hospital.

Nursing data included the treatments administered, such as sedation, neuromuscular blocking agents, and vasoactive drugs; caregiver characteristics (level of training, age, length of experience, length of ICU experience); duration of the nursing procedure; number of caregivers; presence of a nurse, nursing assistant, physician, physical therapist, and the patient's family; the patient's level of consciousness (conscious, sedated, intermediate) (10); and global stress assessed by the nurse in charge of the patient (assessed by a numerical score between 0 [no stress] and 10 [intense stress]).

## SAEs

SAEs were defined in accordance with the literature (1). Briefly, an adverse event was defined as any undesirable experience associated with bed-bath. A SAE was defined by the need for therapeutic intervention (increased $FIO_2$, endotracheal suctioning) or medical intervention (life support following cardiac arrest, reintubation following accidental extubation, etc.). Predefined SAEs were as follows:

- cardiac arrest,
- accidental extubation,
- desaturation requiring therapeutic intervention,
- mucus plugging/inhalation requiring endotracheal suctioning,
- accidental disconnection of an implanted device (tube, drain, catheter),
- hypotension requiring therapeutic intervention,
- arrhythmia requiring therapeutic intervention,
- agitation requiring therapeutic intervention,
- equipment dysfunction,
- patient fall,
- need for physician intervention,
- acute pain defined by scores strictly greater than:
  - 5 on the Behavioral Pain Scale (5) and
  - 6 on a visual analog scale (11).

## Ethics

The study protocol was approved by an ethics committee in France (Comité de Protection des Personnes Sud Est IV; Reference 18/003 of 13/02/2018) and by the appropriate authorities in Belgium (ethics committee No. P2018/341) and Luxembourg (CNER No. 201804/02). Patients were provided with oral information, and their consent was sought before inclusion in the study. If the patient was deemed incompetent, his/her loved ones were informed, and their consent was obtained. Once the patient had recovered a satisfactory state of consciousness, he/she was informed, and his/her consent was obtained. Minor patients were also informed, as were their legal representatives, and their consent was also obtained.

## Calculation of the Sample Size

As this was an observational study exploring the incidence of SAEs during nursing procedures, especially bed-bath, this study did not require estimation of the sample size. However, we aimed to recruit at least 200 patients during the study period.

## Statistical Analysis

Discrete data were described by their frequency expressed as a percentage together with the 95% CI. Numerical data were described by the mean (with the 95% CI) and SD. Discrete data were compared using a chi-square test or Fisher exact test, as appropriate. Continuous data were compared by Student *t* test after verification of the equality of variances. Multivariate analysis was performed using mixed effect logistic regression to predict the occurrence of SAE during nursing procedures with the patients as random effect. This mixed model was used to take into account the non-independence between repeated nursing procedures for each patient. Analyses were adjusted for potential confounders defined as factors associated with desaturation at $p$ values less than or equal to 0.2 in the univariate analysis and factors considered to be clinically significant. A backward selection method based on the Akaike information criterion was applied. Odds ratios (ORs) with their 95% CI were calculated. Statistical analyses were performed using R software Version 3.4 (R Foundation for Statistical Computing, Vienna,

Austria; https://www.R-project.org/) with lme4, dyplr, and StatisticalModels packages. No imputation strategy was used for missing data. *p* value of less than 0.05 was considered significant.

## RESULTS

Between May 1, 2018, and July 31, 2018, 24 ICUs (mainly medical and surgical ICUs) with a median of 20 beds participated in the study. ICU characteristics are presented in the **eSupplement** (Supplemental Digital Content 1, http://links.lww.com/CCM/F951).

A total of 253 patients in these ICUs, representing 1,529 nursing procedures, were included in the study. The mean SAPS II of the patients was 53.5 ± 18.8. Patients were intubated in 65.2% of cases, with a central venous catheter in 75.1% of cases and an arterial catheter in 69.96% of cases. ICU characteristics are presented in **Table 1**, and patient characteristics are presented in **Table 2**.

Each nursing procedure was performed by an average of 2 ± 1 caregivers and lasted an average of 20 ± 13 minutes. Of the 253 patients included, 142 (56% [50–62]) experienced at least one SAE during a nursing procedure. Of the 1,529 nursing procedures performed in these 253 patients, 295 (19.3%) were complicated by at least one SAE (**Fig. 1**). The most common SAEs were desaturation (84/1,523, i.e., 5.5%), arterial hypotension (68/1,523, i.e., 4.5%), agitation (64/1,522, i.e., 4.2%), and acute pain (55/1,522, i.e., 3.6%).

In univariate analysis, factors associated with the development of at least one SAE were (**Table 3**) and (**eTable 1**, Supplemental Digital Content 1, http://links.lww.com/CCM/F951) as follows:

- ICU factors: median ICU length of stay, family visiting policy, number of residents in the ICU, distribution of patient lifter in the ICU, presence of a specific protocol.
- Patient factors: weight, BMI, SAPS II, central venous catheter, presence of a tracheostomy.
- Nursing factors: number of nurses involved in the nursing procedure, presence of a physician during the nursing procedure, global stress level, duration of the nursing procedure, number of caregivers present, patient's level of consciousness, administration of hypnotics, administration of opioids, presence of the family during the nursing procedure.

Factors associated with SAE on multivariate analysis were as follows: presence of a specific protocol (OR,

**TABLE 1.**
**ICU Characteristics**

| Characteristics | Value (*n* = 24) |
|---|---|
| Multipurpose, *n* (%) | 15 (62) |
| Country, *n* (%) | |
| France | 21 (88) |
| Belgium | 2 (8) |
| Luxembourg | 1 (4) |
| Number of beds, mean ± SD | 20 ± 8 |
| Mean length of stay in 2017, d, mean ± SD | 7.5 ± 3.8 |
| Mean Simplified Acute Physiology Score II in 2017, points, mean ± SD | 50 ± 12 |
| Visiting hours, *n* (%) | |
| < 5 hr/d | 3 (12) |
| 5–12 hr/d | 4 (17) |
| > 12 hr/d | 12 (50) |
| 24 hr/24 hr | 5 (21) |
| Number of senior physicians per bed, mean ± SD | 0.4 ± 0.2 |
| Number of residents per bed, mean ± SD | 0.35 ± 0.2 |
| Number of bed per nurse, mean ± SD | 2.3 ± 0.6 |
| Number of bed per nursing assistant, mean ± SD | 1.5 ± 0.5 |
| Number of physical therapists per bed, mean ± SD | 0.1 ± 0.1 |
| Number of temporary staff, *n* (%) | 4 (17) |
| Ventilator with a circuit support arm, *n* (%) | 20 (87) |
| Patient lifter, *n* (%) | |
| In each room | (25) |
| Several in the unit | 7 (29) |
| One only in the unit | 11 (46) |
| Number of times patient positioned per day, *n* (%) | |
| 1 to < 3 | 3 (12) |
| 3 to < 4 | 4 (17) |
| 4 to < 5 | 12 (50) |
| ≥ 5 | 1 (4.2) |
| Nursing procedures in the morning, *n* (%) | 7 (33) |
| Nursing procedures in the afternoon | 22 (92) |
| Nursing procedures at night, *n* (%) | 22 (92) |
| Presence of a specific procedure, *n* (%) | 5 (21) |

**TABLE 2.**
**Patient Characteristics**

| Characteristics | Value ($n = 253$) |
|---|---|
| Age, yr, mean ± SD | 64 ± 14.5 |
| Gender (female), *n* (%) | 109 (43.08) |
| Height, cm, mean ± SD | 167 ± 9.4 |
| Weight, kg, mean ± SD | 76.9 ± 20.2 |
| Body mass index, $kg.m^{-2}$, mean ± SD | 27.4 ± 7.2 |
| Simplified Acute Physiology Score II, points, mean ± SD | 53.5 ± 18.8 |
| Hemiplegia, *n* (%) | 3 (1.19) |
| Tetraplegia, *n* (%) | 4 (1.58) |
| Arterial catheter, *n* (%) | 177 (69.96) |
| Central venous catheter, *n* (%) | 190 (75.1) |
| Endotracheal tube, *n* (%) | 165 (65.2) |
| Tracheostomy, *n* (%) | 12 (4.74) |
| Urinary catheter, *n* (%) | 221 (87.35) |
| Extracorporeal membrane oxygenation device, *n* (%) | 12 (4.74) |
| Renal replacement therapy, *n* (%) | 32 (12.65) |
| Artificial cardiac pacemaker, *n* (%) | 5 (2.0) |
| Chest drain, *n* (%) | 19 (7.51) |
| Abdominal drain, *n* (%) | 34 (13.44) |
| Duration of mechanical ventilation, d, mean (95% CI) | 5.8 (4.96–6.74) |
| Duration of vasoactive drug infusion, d, mean (95% CI) | 2.7 (2.28–3.04) |
| ICU length of stay, d, mean ± SD | 9.4 ± 7.4 |
| Survival after discharge from intensive care, *n* (%) | 190 (75.1) |
| Survival after discharge from hospital, *n* (%) | 167 (66.01) |

1.98; 95% CI [1.17–3.36]; $p = 0.011$), tracheostomy (OR, 3.53 [1.11–11.20]; $p = 0.032$), administration of opioids (OR, 1.71 [1.16–2.52]; $p = 0.006$), presence of a physician (OR, 4.40 [1.94–9.98]; $p = 0.004$), duration of the nursing procedure with a reference duration of between 20 and 40 minutes: from 6 to 0 minutes (OR, 0.50 [0.32–0.79]; $p = 0.0032$), from 11 to 20 minutes (OR, 0.58 [0.40–0.85]; $p = 0.0048$); and duration greater than 40 minutes (OR, 1.89 [1.02–3.50]; $p = 0.0423$). Factors associated with SAE during bed-bath, identified by multivariate analysis, are presented in **Figure 2**.

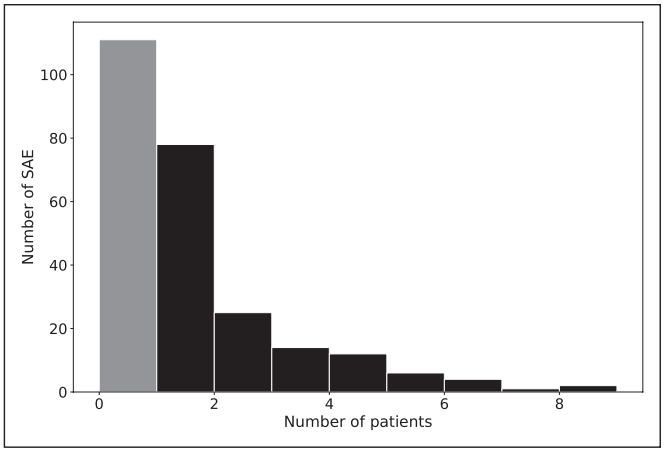


**Figure 1.** Number of patients without or with serious adverse events (SAE) during bed-bath.

The characteristics of nursing procedures complicated by cardiac arrest are presented in **eTable 2** (Supplemental Digital Content 1, http://links.lww.com/CCM/F951). Cardiac arrest occurred during seven of the 1,523 nursing procedures (0.5%). The only factor associated with cardiac arrest on univariate analysis was the presence of a device such as an artificial cardiac pacemaker (three cardiac arrests were observed among the seven patients with such a device).

## DISCUSSION

In our study, a high incidence of SAEs was observed during nursing procedures in intensive care and continuing care units, that is, affecting one in two patients. The most common adverse events, in decreasing order of frequency, were as follows: desaturation, arterial hypotension, agitation, and acute pain. Cardiac arrest occurred during 0.5% of nursing procedures and the subgroup of patients with an artificial cardiac pacemaker appeared to be at particularly high risk. In multivariate analysis, tracheostomy, administration of opioids, duration of the nursing procedure, presence of a physician, length of nursing care, and the presence of a department procedure were associated with higher rates of SAEs.

Nursing procedures and especially bed-bath are the first steps to promote early rehabilitation and skin integrity. Nursing procedures in intensive care patients, especially during the first days after admission, associated with hemodynamic instability, can lead to marked

**TABLE 3.**
**Comparison of Bed-Baths With or Without Serious Adverse Events at the Bed-Bath Level**

| Characteristics | No SAE, *n* = 1,234 | At Least One SAE, *n* = 295 | *p* |
|---|---|---|---|
| Bed-bath factors | | | |
| Number of nurses during nursing procedures, *n* (%) | | | |
| < 3 | 105 (8.51) | 21 (7.12) | 0.36 |
| 3 to < 4 | 806 (65.32) | 176 (59.66) | < 0.001 |
| 4 to < 5 | 197 (15.96) | 56 (18.98) | 0.3 |
| ≥ 5 | 37 (3.0) | 29 (9.83) | < 0.001 |
| Missing data | 89 (7.21) | 13 (4.41) | Not applicable |
| Profession, *n* (%) | | | |
| Nurse | 1,201 (97.33) | 308 (104.41) | 0.08 |
| Nursing assistant | 1,042 (84.44) | 240 (81.36) | 0.72 |
| Other | 131 (10.62) | 25 (8.47) | 0.28 |
| Presence of a physician, *n* (%) | 20 (1.62) | 21 (7.12) | < 0.001 |
| Staff member's age, yr, *n* (%) | | | |
| 18–25 | 442 (35.82) | 101 (34.24) | 0.87 |
| 26–32 | 808 (65.48) | 195 (66.1) | 0.74 |
| 33–40 | 628 (50.89) | 172 (58.31) | 0.09 |
| 41–48 | 337 (27.31) | 69 (23.39) | 0.11 |
| Over 48 | 181 (14.67) | 39 (13.22) | 0.83 |
| Number of years in intensive care, mean ± SD | 7.0 ± 5.0 | 7.0 ± 5.3 | 0.91 |
| Global stress level[a], mean ± SD | 0.6 ± 1.1 | 1.3 ± 1.7 | < 0.001 |
| Duration of nursing procedure (min), *n* (%) | | | |
| < 5 | 41 (3.32) | 10 (3.39) | 0.93 |
| 6–10 | 316 (25.61) | 55 (18.64) | 0.02 |
| 11–20 | 520 (42.14) | 102 (34.58) | 0.02 |
| 21–40 | 281 (22.77) | 87 (29.49) | 0.01 |
| > 40 | 67 (5.43) | 36 (12.2) | < 0.001 |
| Missing data | 9 (0.73) | 5 (1.69) | Not applicable |
| Number of caregivers present, mean ± SD | 2.2 ± 0.6 | 2.4 ± 0.9 | < 0.001 |
| Patient's level of consciousness–conscious, *n* (%) | 538 (43.6) | 103 (34.92) | 0.001 |
| Administration of hypnotic agents, *n* (%) | 436 (35.33) | 141 (47.8) | < 0.001 |
| Administration of opioids, *n* (%) | 483 (39.14) | 163 (55.25) | <0.001 |
| Administration of neuromuscular blocking agents, *n* (%) | 142 (11.51) | 29 (9.83) | 0.41 |
| Administration of neuroleptics, *n* (%) | 37 (3) | 14 (4.75) | 0.13 |
| Administration of anxiolytics, *n* (%) | 36 (2.92) | 10 (3.39) | 0.67 |
| Administration of vasoactive drugs, *n* (%) | 923 (74.8) | 125 (42.4) | 0.53 |
| Presence of the family during nursing care, *n* (%) | 1 (0.08) | 4 (1.36) | 0.001 |

SAE = serious adverse event.

[a]Global stress was assessed by the nurse in charge of the patient during the nursing procedure by using a numerical score between 0 (no stress) and 10 (intense stress).

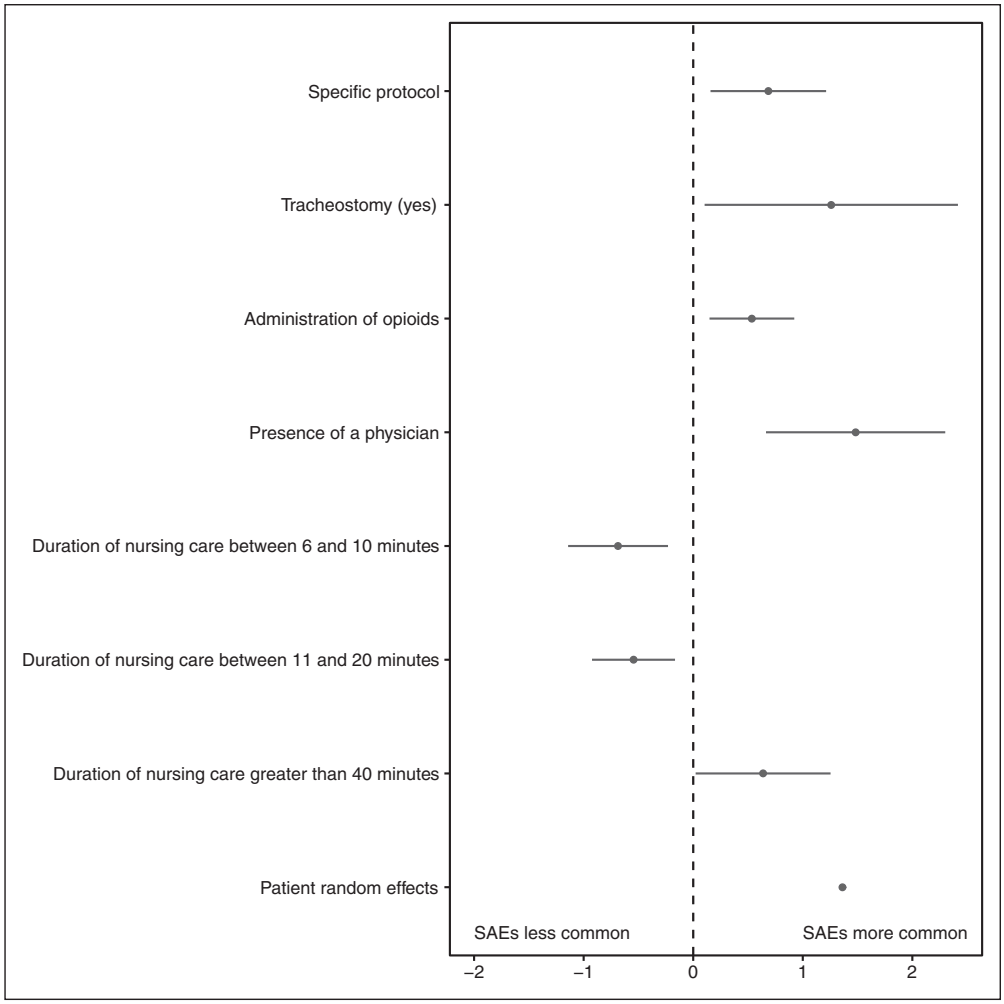


**Figure 2.** Multivariate analysis of factors associated with serious adverse event (SAE) occurrence.

variations in hemodynamic and/or respiratory variables. Lewis et al (12) observed that lateral decubitus positioning was associated with a significant decrease in mixed venous oxygen saturation. Only limited data have been published concerning the changes associated with these nursing procedures. For example, Bailey et al (13) reported a 1% rate of procedure-related adverse events, primarily positioning (without a personal care and hygiene component) of patients monitored throughout their stay (and not only during the first 72 hr) and not presenting any markers of severity, which was a prerequisite in our study. Pohlman et al (14) observed that 16% of patient positioning procedures were complicated by SAE, but the patients included in their study had fewer and less severe morbidity. Patient positioning was performed an average of three to four times a day (i.e., once every 6–8 hr), which can be considered to be suboptimal with respect to international guidelines recommending that patients be turned every 2 hours (15, 16), but which predate the advent of more effective devices, notably antibedsore mattresses. Last, prolonged (> 16 hr) prone positioning was associated with a statistically higher risk of bedsores (17).

Nursing care involves numerous procedures that can be schematically subdivided as follows: treatment adjustments prior to certain procedures (pain-relieving plasters, mobilization of fracture site), lateral positioning, and nursing care procedures designed to enhance patient comfort, followed by personal hygiene and turning. Each of these procedures can be responsible for adverse events and can collectively complicate care, making it more difficult to predict potential adverse events and also resulting in underestimation of the incidence of adverse events, as reported by Engström et al (6). In our study, the SAEs most commonly observed, in decreasing order of frequency, were as follows: desaturation, arterial hypotension, agitation, and acute pain. Interestingly, acute pain was the fourth most common SAE, but it can be targeted by therapeutic interventions, as highlighted by de Jong et al (5) and Kalfon et al (18), although opioid administration is also associated with SAEs.

As the patients included in our study were critically ill, an association between SAEs and various variables was expected: administration of opioids, duration of the nursing procedure, and presence of a physician during the nursing procedure. On the one hand, the presence of a physician can be related to the patient's unstable state during bed-bath, but it may also constitute a distraction for the nurse and nursing assistant performing the bed-bath. In contrast, the association between SAEs and the use of a specific protocol for nursing

procedures can be interpreted in three ways. First, a specific protocol constitutes a response to a previously identified problem and may also be related to other factors, such as burden of care, number of staff members, and severity of the patient's illness. Second, ICUs are particularly aware of procedure-related adverse events, and we observed a Hawthorne (or observer) effect resulting in more frequent recording and reporting of adverse events in the ICUs participating in this study (19). Third, a patient positioning protocol has a direct impact on the SAE rate, because a protocol results in more standardized practices. Standardized practice provides a reassuring framework for inexperienced nurses but probably limited the personalized care provided by more experienced nurses, as it has been shown that intensive care nurses' decision-making processes are based on clinical reasoning centered on the perception and analysis of clinical and contextual information (20, 21) and that the nurse's experience is a key to the relevant action (22). Only experienced nurses are able to step outside an imposed routine in order to include a notion of lasting efficacy. Sometimes, for experienced nurses, the most effective measure consists of doing nothing and ensuring that nothing is done or waiting to restore balance before continuing the bed-bath. Standardization of patient positioning according to a protocol may sometimes run counter to safe, effective, and personalized care. Based on these identified and modifiable factors, further studies could be conducted in order to improve the safety of nursing procedures in ICU patients, as in the ongoing trial (NCT02881645).

Our study presents several limitations

The definition of SAEs included events that could be interpreted in various ways according to the reason for the patient's admission to ICU (desaturation for a patient with acute respiratory distress syndrome, arterial hypotension for a patient with septic shock), although this definition has already been used in previous similar studies (1). Our definition only included bed-bath associated with therapeutic intervention, as even transient physiologic variations can impact patient outcome. Additionally, the planned data collection did not include evaluation of any effects on patient mortality or morbidity related to one or more SAEs (23) or the patient's well-being, which can be a primary objective in certain clinical settings (24). Stress was self-assessed by the nurse in charge of the procedure using a 0–10 numerical scale without the use of a validated scale such as assessment of job strain (25).

## CONCLUSIONS

An SAE occurs during almost 20% of nursing procedures and in more than 50% of patients during the first 72 hours of their ICU stay. Risk factors for SAEs have been identified, and further studies are needed to test specific prevention strategies.

## ACKNOWLEDGMENTS

We thank Matthieu Lloung, Florence Neels, Chantal Sevens, and Martin Lavillonnière of the Société de Réanimation de Langue Française (SRLF) for their help with administrative work, and Laurent Poiroux for editing the article. We thank Younes Youssfi for his help in statistical analysis. The SRLF Trial Group members are as follows: N. Aissaoui, Medical ICU, European University Hospital Center, Paris (France); C. Alves, Rehabilitation Care Unit, University Hospital Center La Pitié Salpêtrière, Paris (France); T. Abaziou, Medical Surgical ICU, University Hospital Center, Toulouse (France); S.D. Babar, Medical ICU, General Hospital Center, Nimes (France); F. Boissier, Medical ICU, University Hospital Center, Poitiers (France); P.E. Danin, Medical-Surgical ICU, University Hospital Center, Nice (France); V. Dauve, Medical ICU, University Hospital Center, Nantes (France); S. Debock, Réanimation Polyvalente. CHU- Charleroi Marie Curie. Université Libre de Bruxelles. 140, chaussée de Bruxelles. 6042- Charleroi (Belgium); G. Decormeille, Medical Surgical ICU, University Hospital Center, Toulouse (France); F. De Freitas Pereira, Medical ICU, University Hospital Center La Pitié Salpêtrière, Paris (France); J. Delemazure, Rehabilitation Care Unit, University Hospital Center La Pitié Salpêtrière, Paris (France); J. Dellamonica, Medical-Surgical ICU, University Hospital Center, Nice (France); G. Demont, Médecine Intensive Réanimation, CHU Lille, F-59000 Lille; Université de Lille, Faculté de Médecine, 59000-F Lille (France); M. L. Durand Marie-Luce, Medical ICU, University Hospital Center La Pitié Salpêtrière, Paris (France); J. Duviver, Medical Surgical ICU, Centre Hospitalier de la Dracénie, Dax (France); A.L. Faure, Medical Surgical ICU, Centre Hospitalier Dax, Dax (France); P. Fillatre, Medical Surgical ICU, General Hospital Center, Saint Brieux (France); G. Jacq, Medical Surgical ICU, General Hospital Center, Versailles (France); M. Jeannot, Medical-Surgical

ICU, Centre Hospitalier de Valence, Valence (France); A. Joosten, Réanimation Polyvalente. CHU- Charleroi Marie Curie. Université Libre De Bruxelles. 140, chaussée de Bruxelles. 6042- Charleroi (Belgium); J. F. Georger, Medical Surgical ICU, General Hospital Center, Villeneuve Saint George (France); D. Grimaldi, Medical-Surgical ICU, ERASME, Bruxelles (Belgium); C. Guerineau, Medical Surgical ICU, Centre Hospitalier Sud Francilien, Corbeil Essonne (France); M. Guillot, Medical ICU, University Hospital Center, Nice (France); G. Hékimiana, Medical ICU, University Hospital Center La Pitié Salpêtrière, Paris (France); S. Hultet-Midelton, Medical ICU, European University Hospital Center, Paris (France); S. Hraiech, Medical ICU, University Hospital Center, Marseilles (France); A. Lamont, Medical-Surgical ICU, ERASME, Bruxelles (Belgium); J.B. Lascarrou, Medical ICU, University Hospital Center, Nantes (France); C. Lebrun, Medical ICU, Centre Hospitalier Universitaire Ambroise Paré, Paris (France); S. L'hotellier, Medical ICU, University Hospital Center, Nice (France); E. Martinez, Medical Surgical ICU, Centre Hospitalier Sud Francilien, Corbeil Essonne (France); V. Maurer-Maouchi, Réanimation polyvalente, Centre hospitalier Emile Mayrisch, rue Émile Mayrisch L-4240 Esch-Sur-Alzette. Luxembourg (Luxembourg); B. Megarbane, Medical ICU, University Hospital Center Lariboisière, Paris (France); G. Mercier, Medical-Surgical ICU, ERASME, Bruxelles (Belgium); P. Michel, Medical Surgical ICU, General Hospital Center Rene Dubos, Cergy Pontoise (France); P. Mora, Medical ICU, University Hospital Center Lariboisière, Paris (France); C. Morand, Medical ICU, University Hospital Center, Poitiers (France); L. Mouton, Réanimation polyvalente, Centre hospitalier Emile Mayrisch, rue Émile Mayrisch L-4240 Esch-Sur-Alzette. Luxembourg (Luxembourg); G. Muller, Medical Surgical ICU, Regional Hospital Center, Orléans (France); S. Mylhane, Rehabilitation Care Unit, University Hospital Center La Pitié Salpêtrière, Paris (France); J. Negrel, Medical ICU, University Hospital Center, Nice (France); S. Nseir, Médecine Intensive Réanimation, CHU Lille, F-59000 Lille; Université de Lille, Faculté de Médecine, 59000-F Lille (France); K. Pedrono, Medical Surgical ICU, General Hospital Center, Saint Brieux (France); N. Peron, Medical ICU, University Hospital Center Lariboisière, Paris (France); M. Piallat, Medical-Surgical ICU, Centre Hospitalier de Valence, Valence (France); M. Piagnerelli, Réanimation Polyvalente. CHU- Charleroi Marie Curie. Université Libre de Bruxelles, 140, chaussée de Bruxelles. 6042- Charleroi (Belgium); G. Piton, Medical ICU, Centre Hospitalier Universitaire, Besancon (France); T. Rastegar, Réanimation polyvalente, Centre hospitalier Emile Mayrisch, rue Émile Mayrisch L-4240 Esch-Sur-Alzette. Luxembourg (Luxembourg); V. Rivals, Medical ICU, University Hospital Center Lariboisière, Paris (France); N. Robquin, Medical Surgical ICU, General Hospital Center, Villeneuve Saint; M. Rouhier, Medical ICU, Centre Hospitalier Universitaire, Besancon (France); P. Santiago, Medical-Surgical ICU, Centre Hospitalier de Draguignan, Draguignan (France); B. Sauvage, Medical Surgical ICU, Regional Hospital Center, Orléans (France); V. Schittekatte, Medical-Surgical ICU, ERASME, Bruxelles (Belgium); L. Soulisse, Medical ICU, University Hospital Center Lariboisière, Paris (France); C. Tuaillon, Rehabilitation Care Unit, University Hospital Center La Pitié Salpêtrière, Paris (France); S. Troin, Medical-Surgical ICU, Centre Hospitalier de Draguignan, Draguignan (France); A. Vieillard Baron, Medical ICU, Centre Hospitalier Universitaire Ambroise Paré, Paris (France); A. Youssouf, Medical ICU, University Hospital Center, Marseilles (France).

1 *Service de Réanimation polyvalente, Hopital de Rangueil, 1 avenue du Professeur Jean Poulhes, Toulouse, France.*

2 *Réanimation polyvalente, Centre hospitalier Emile Mayrisch, rue Émile Mayrisch L-4240 Esch-Sur-Alzette, Luxembourg.*

3 *Service de Réanimation polyvalente, ERASME, Route de Lennik 808, Bruxelles, Belgique.*

4 *Centre Hospitalier de Charleroi, Boulevard Zoé Drion 1, Charleroi, Belgique.*

5 *Service de Médecine Intensive Réanimation, Centre Hospitalier Universitaire Ambroise Paré, 9 avenue du Général de Gaulles, Boulogne Billancourt, France.*

6 *Centre Hospitalier Universitaire, 2 place Saint Jacques, Besançon Cedex, France.*

7 *Centre Hospitalier du Sud Francilien, 40 avenue Serge Dassault, Corbeil Essonne Cedex, France.*

8 *Centre Hospitalier, Boulevard Yves du Manoir, Dax, France.*

9 *Centre Hospitalier de la Dracénie, Route de Montferrat, BP249, Draguignan Cedex, France.*

10 *Service de Médecine Intensive Réanimation, Hopital Européen George Pompidou, 20 rue Leblanc, Paris, France.*

11 *Service de Médecine Intensive Réanimation, Hôpital Universitaire La Pitié-Salpêtrière, 47-83 boulevard de l'hôpital, Paris, France.*

12 *SRPR Sevrage Ventilatoire Post Réanimation, Hôpital Universitaire La Pitié-Salpêtrière, 47-83 boulevard de l'hôpital, Paris, France.*

13 *Service de Réanimation Médicale et Toxicologique, Centre Hospitalier Universitaire Lariboisière, 2 rue Ambroise Paré, Paris, France.*

14 *Réanimation polyvalente, Centre Hospitalier Universitaire, Lilles, France.*

15 *Service de Médecine Intensive Réanimation, Centre Hospitalier Universitaire, Chemin des Bourrely, Marseille, France.*

16 *Service de Médecine Intensive Réanimation, Centre Hospitalier Universitaire, 30 Boulevard Jean Monnet, Nantes Cedex, France.*

17 *Service de Médecine Intensive Réanimation, Centre Hospitalier Universitaire, 151 route de Saint Antoine, Nice, France.*

18 *Service de Médecine Intensive Réanimation, Centre Hospitalier Régional, 14 avenue de l'Hopital, Orléans, France.*

19 *Service de Médecine Intensive Réanimation, Centre Hospitalier Universitaire, 2 rue de la Milétrie, Poitiers, France.*

20 *Service de Médecine Intensive Réanimation, 1 rue de la Marne, Saint Brieuc, France.*

21 *Service de Médecine Intensive Réanimation, Centre Hospitalier Universitaire, 1 place de l'hôpital, Strasbourg Cedex, France.*

22 *Service de réanimation polyvalente, Centre Hospitalier de Valence, 179 avenue du maréchal Juin, Valence, France.*

23 *Service de Médecine Intensive Réanimation, Centre Hospitalier Intercommunal Villeneuve Saint George, 40 allée de la Source, Villeneuve Saint George Cedex, France.*

24 *Service de Médecine Intensive Réanimation, Centre Hospitalier René Dubos, 6 avenue de l'Ile de France, Cergy Pontoise, France.*

25 *Service de Médecine Intensive Réanimation, Centre Hospitalier Régional, 14 avenue de l'Hopital, Orléans, France.*

26 *Service de Médecine Intensive Réanimation, Hôpital Européen George Pompidou, 20 rue Leblanc, Paris, France.*

27 *Service de Médecine Intensive Réanimation, Hôpital Universitaire Carémeau, Place du Pr Robert Debré, Nîmes Cedex 9, France.*

28 *Service de Médecine Intensive Réanimation, Centre Hospitalier Universitaire, 2 rue de la Milétrie, Poitiers Cedex, France.*

29 *Service de Réanimation polyvalente, ERASME, Route de Lennik 808, Bruxelles, Belgique.*

30 *Service de Médecine Intensive Réanimation, Centre Hospitalier Universitaire, Chemin des Bourrely, Marseille, France.*

31 *Service de Médecine Intensive Réanimation, Centre Hospitalier Universitaire, 2 place Saint Jacques, Besançon Cedex, France.*

32 *Service de Médecine Intensive Réanimation, Centre Hospitalier de Versailles, 177 rue de Versailles, Le Chesnay, France.*

*ClinicalTrials.gov Identifier: NCT03475238.*

*Drs. Decormeille and Lascarrou designed the study and wrote the protocol. All authors contributed to patient recruitment. All authors collected data. Drs. Aissoui and Lascarrou analyzed and interpreted the data. PM performed statistical analysis. Dr. Lascarrou wrote the article. All authors read and approved the final article.*

*Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website (http://journals.lww.com/ccmjournal).*

*The data for this study are available on reasonable request to the corresponding author.*

*Supported, in part, by the French Society of Intensive Care.*

*The authors have disclosed that they do not have any potential conflicts of interest.*

*For information regarding this article, E-mail: jeanbaptiste.lascarrou@chu-nantes.fr*

## REFERENCES

1. Brouard F, Muller G, Michel P, et al: Étude du transport INTrA-hospitalier du MAlade de réanimation (TINTAHMAR). *Réanimation* 2016; 25:161–170
2. Coyer FM, O'Sullivan J, Cadman N: The provision of patient personal hygiene in the intensive care unit: A descriptive exploratory study of bed-bathing practice. *Aust Crit Care* 2011; 24:198–209
3. Rising CJ: The relationship of selected nursing activities to ICP. *J Neurosci Nurs* 1993; 25:302–308
4. Boortz-Marx R: Factors affecting intracranial pressure: A descriptive study. *J Neurosurg Nurs* 1985; 17:89–94
5. de Jong A, Molinari N, de Lattre S, et al: Decreasing severe pain and serious adverse events while moving intensive care unit patients: A prospective interventional study (the NURSE-DO project). *Crit Care* 2013; 17:R74
6. Engström J, Bruno E, Reinius H, et al: Physiological changes associated with routine nursing procedures in critically ill are common: An observational pilot study. *Acta Anaesthesiol Scand* 2017; 61:62–72
7. Robles Rangil MP, Córcoles Gallego T, Torres Lizcano M, et al: Frecuencia de eventos adversos durante el aseo del paciente crítico. *Enfermería Intensiva* 2002; 13:47–56
8. Le Gall JR, Lemeshow S, Saulnier F: A new Simplified Acute Physiology Score (SAPS II) based on a European/North American multicenter study. *JAMA* 1993; 270:2957–2963
9. Morris AH: Treatment algorithms and protocolized care. *Curr Opin Crit Care* 2003; 9:236–240
10. Claassen J, Velazquez A, Meyers E, et al: Bedside quantitative electroencephalography improves assessment of consciousness in comatose subarachnoid hemorrhage patients. *Ann Neurol* 2016; 80:541–553
11. Chanques G, Payen JF, Mercier G, et al: Assessing pain in non-intubated critically ill patients unable to self report: An

adaptation of the behavioral pain scale. *Intensive Care Med* 2009; 35:2060–2067

12. Lewis P, Nichols E, Mackey G, et al: The effect of turning and backrub on mixed venous oxygen saturation in critically ill patients. *Am J Crit Care* 1997; 6:132–140
13. Bailey P, Thomsen GE, Spuhler VJ, et al: Early activity is feasible and safe in respiratory failure patients. *Crit Care Med* 2007; 35:139–145
14. Pohlman MC, Schweickert WD, Pohlman AS, et al: Feasibility of physical and occupational therapy beginning from initiation of mechanical ventilation. *Crit Care Med* 2010; 38:2089–2094
15. Krishnagopalan S, Johnson EW, Low LL, et al: Body positioning of intensive care patients: clinical practice versus standards. *Crit Care Med* 2002; 30:2588–2592
16. Goldhill DR, Badacsonyi A, Goldhill AA, et al: A prospective observational study of ICU patient position and frequency of turning. *Anaesthesia* 2008; 63:509–515
17. Guérin C, Reignier J, Richard JC, et al; PROSEVA Study Group: Prone positioning in severe acute respiratory distress syndrome. *N Engl J Med* 2013; 368:2159–2168
18. Kalfon P, Baumstarck K, Estagnasie P, et al; IPREA Study group: A tailored multicomponent program to reduce discomfort in critically ill patients: A cluster-randomized controlled trial. *Intensive Care Med* 2017; 43:1829–1840
19. Wickström G, Bendix T: Commentary. *Scandinavian J Work Environment Health* 2000; 26:363–367
20. Bucknall TK: Critical care nurses' decision-making activities in the natural clinical setting. *J Clin Nurs* 2000; 9:25–35
21. Aitken LM: Critical care nurses' use of decision-making strategies. *J Clin Nurs* 2003; 12:476–483
22. Currey J, Botti M: The influence of patient complexity and nurses' experience on haemodynamic decision-making following cardiac surgery. *Intensive Crit Care Nurs* 2006; 22:194–205
23. Forster AJ, Kyeremanteng K, Hooper J, et al: The impact of adverse events in the intensive care unit on hospital mortality and length of stay. *BMC Health Serv Res* 2008; 8:259
24. Reignier J, Feral-Pierssens AL, Boulain T, et al; French Society of Emergency Medicine (Société Française de Médecine d'Urgence, SFMU) and French Intensive Care Society (Société de Réanimation de Langue Française, SRLF): Withholding and withdrawing life-support in adults in emergency care: Joint position paper from the French intensive care society and French society of emergency medicine. *Ann Intensive Care* 2019; 9:105
25. Karasek R, Baker D, Marxer F, et al: Job decision latitude, job demands, and cardiovascular disease: A prospective study of Swedish men. *Am J Public Health* 1981; 71:694–705