Adverse events in Spanish intensive care units: the SYREC study

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Abstract

Objective. To estimate the incidence and characteristics of adverse events (AEs) and no-harm events (NHEs) in critically ill patients.

Design. Observational, prospective, 24-h cross-sectional study with self-reporting.

Setting. Seventy-nine intensive care units at 76 hospitals.

Measurements. Number of events, risk of AEs and NHEs, types of incidents, severity and avoidability of incidents.

Results. A total of 1017 patients were included in the study; 591 (58%) were affected by one or more incidents. Of the 1424 valid incidents, 943 (66%) were NHEs and 481 (34%) were AEs. The individual risk of suffering at least one incident was 62%, at least one NHE 45% and at least one AE 29%. The median number of incidents, NHEs and AEs was 6, 3 and 2 per 100 patient-hours, respectively. Seventy-four per cent of the incidents were related to medication (24%), equipment (15%), nursing care (14%), accidental withdrawal of vascular accesses and catheters (10%) or airways and mechanical ventilation (10%). AEs resulted in temporary damage in 29% and in permanent damage or damage that compromised patients’ lives or contributed to their death in 4%. Incidents were avoidable in 79% of cases (90% in NHEs and 60% in AEs, P < 0.05).

Conclusions. The individual risk for incidents in critical patients is high. Many incidents did not harm patients, some caused damage and a few were related to the patient’s death. Most incidents were considered avoidable.

Keywords: patient safety, adverse events, incident reporting and analysis

Introduction

The severity of the patients and the complexity of the diagnostic and therapeutic procedures carried out in intensive care units (ICUs) heighten the risk of adverse events (AEs) [1–4]. AE is defined as an incident that results in harm to a patient.

Two 1-day multicentre observational studies coordinated by the European Society of Intensive Care Medicine (ESICM) showed the frequency of different events affecting critical patients. The Sentinel Events Evaluation 1 (SEE 1) [5], analysing the AEs related to medication, catheters and drains, equipment, artificial airways and alarms, reported 38.8 AEs per 100 patient-days. A follow-up study SEE 2 [6], using the same methodological approach to study AEs related to parenteral medication, reported 74.5 AEs per 100 patients-days.

The ESICM elaborated the consensus statement ‘Patient Safety in Intensive Care Medicine: The Declaration of Vienna’ [7] to expressly recognize the need for strategies to prevent or mitigate AEs in critical patients and its professionals’ commitment to improving the quality and safety of critical care.

The organizational model of Spanish ICUs [8], which includes the physical presence of intensivists to direct and coordinate critical care 24 h a day, might have an impact on ICU mortality and ICU stays [9, 10]. Given the particularities of this model and the lack of studies about safety and risk among critically ill patients in Spain, the Spanish Society of Intensive Care Medicine (SEMICYUC), sponsored by the Quality Office of the Ministry of Health and Social Policy, undertook the first study to estimate the incidence of AEs and no-harm events (NHEs), classify them and evaluate their impact and the extent to which they can be avoided: SYREC
(from an acronym for the Spanish title ‘Safety and Risk in Critical Patients’).

Methods

Design

This 24-h observational multicentre study in a prospective cohort was carried out from 8 a.m. on 22 March 2007 to 8 a.m. on 23 March 2007.

Context

After dissemination through SEMICYUC’s website, email and ordinary mail, all Spanish ICUs for adults (220 units) were invited to participate. Hundred accepted of which 21 later withdrew leaving 79 units. Six Latin American units also took part as a convenience sample of those units. ICUs were not asked to provide reasons for not participating. All Spanish ICUs were closed units with a critical care specialist on hand 24 h per day, 365 days per year. This participation rate (32.7%), although low, is similar or even higher than other multicentre national studies.

Inclusion criteria

We included all patients present in the participating ICUs at any time during the observation period, including those admitted or discharged during this period as well as those who died. We included all incidents detected and notified in the ICU during this period as well as those occurring outside the ICU, which resulted in admission to the ICU.

Definitions

The following definitions were used:

- NHE is an incident which did not reach the patient (near miss) or one in which an event reached a patient but no discernable harm resulted [11].
- AE is an incident that results in harm to a patient. Harm implies impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological [11].
- Case or incident: any NHE or AE detected and reported by a health-care professional.

Variables studied

We recorded the following variables:

- Type of incident: incidents were classified into 11 types: medication; transfusion of blood products; artificial airways and mechanical ventilation; accidental withdrawal of vascular lines, catheters, tubes, drains or sensors; equipment failure; diagnostic error; diagnostic tests; nursing care; procedures; nosocomial infection and incidents related to surgery. Table 1 shows examples of each type.
- Severity of the incident: to evaluate the severity of the incident, we used an adaptation of the Ruiz-Jarabo Group’s classification [12], in which categories A and B of the original classification were combined into a single category and a new category, D, was added to classify incidents in which it was impossible to determine the repercussions. Thus, events were classified into nine categories (Table 2).
- Avoidability: based on the expected standard of care, the likelihood of preventability of the AE was subjectively classified on a four-point scale as totally avoidable, possibly avoidable, possibly unavoidable or totally unavoidable.

Procedure

Two coordinators, one physician and one nurse, were designated for each participating centre. Materials for training were distributed to all professionals.

Physicians, nurses and nurse’s aides voluntarily and anonymously communicated NHEs and AEs they witnessed during the study period by filling out a hardcopy questionnaire. Coordinators checked that forms were correctly completed and introduced the data into a database.

Quality control for data collection

The investigators of each hospital detected and eliminated double reporting of the same incident. Three investigators, recognized as experts in patient safety by the SEMICYUC, independently classified each of incidents. Interobserver discordance was resolved by consensus.

Statistical analysis

Data from the questionnaires were stored in a Microsoft Access database and mined statistically using SPSS version 15.0.

For each centre, we obtained the absolute values for the number of patients, the total number of incidents, the number of NHEs, the number of AEs and the remaining variables. For each centre, we calculated the following indicators for each incident: (i) risk of incidents (accumulated incidence): number of incidents divided by the total number of patients, expressed as a percentage or, when the quotient is greater than 1, as a ratio; (ii) individual risk of incidents: number of patients with at least one incident divided by the total number of patients, expressed as a percentage and (iii) rate (density of incidents): number of incidents divided by the total number of hours stay in the ICU (hours of risk),
expressed as the number of incidents per 100 patient-hours in the ICU.

Qualitative variables are presented with frequency distributions and were compared using the $\chi^2$ test. Quantitative variables are summarized as means and standard deviations, or distributions were skewed as medians and interquartile ranges (IQRs). Quantitative variables were compared using Student’s $t$-test for independent samples or, in the case of skewed distributions, using the median test for hypothesis testing. The null hypothesis was rejected when $P < 0.05$.

Overall and specific indicators were summarized as medians and IQR.

Table 1  Examples of type of incidents

<table>
<thead>
<tr>
<th>Type of incident</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication (include medications and fluids)</td>
<td>Prescribing, preparation/dispensing, presentation/packaging, delivery, administration, supply/ordering, storage, monitoring</td>
</tr>
<tr>
<td>Events related to different problems</td>
<td>Wrong: patient, drug, dose/strength of frequency, formulation or presentation, route, quantity, dispensing, label/instruction, storage, etc.</td>
</tr>
<tr>
<td>Transfusion of blood products</td>
<td>Pre-transfusion testing, prescribing, preparation/dispensing, delivery, administration, storage, monitoring, presentation/packaging, supply/ordering</td>
</tr>
<tr>
<td>Events related to different problems</td>
<td>Wrong: patient, blood/blood product, dose or frequency, quantity, dispensing label/instruction, storage, etc.</td>
</tr>
<tr>
<td>Artificial airway and mechanical ventilation</td>
<td>Airway obstruction, displacement of endotracheal tube (dilodgement/advancement), unexpected extubation, atelectasis, reintubation, barotrauma related to mechanical ventilation, accidental withdrawal of mechanical ventilation, bronchoaspiration syndrome, etc.</td>
</tr>
<tr>
<td>Accidental withdrawal of vascular lines, catheters, tubes, drains, sensors</td>
<td>Unexpected withdrawal or disconnection of: central venous catheter, intracranial pressure monitoring devices, arterial catheter, thoracic/ chest tube, pulmonary artery catheter, surgical drain, nasogastric tube, urinary catheter, etc.</td>
</tr>
<tr>
<td>Equipment failure</td>
<td>Infusion pumps, monitors, mechanical ventilators, hemodialysis machines, fiberoptic endoscope, pacemaker, cardioverting/defibrillator equipment, intraaortic balloon pump, etc.</td>
</tr>
<tr>
<td>Events related to different problems</td>
<td>Poor presentation/packaging, lack of availability, inappropriate for task, unclean/unsterile, failure/malfunction, dislodgement/misconnection, removal, user error, wrong managements of alarms, etc.</td>
</tr>
<tr>
<td>Diagnostic error</td>
<td>Wrong medical approach, unavailability or delay in appropriate diagnostic test, misinterpretation of the results of additional tests, wrong additional test, etc.</td>
</tr>
<tr>
<td>Diagnostic test</td>
<td>Radiology, laboratory, endoscopy, neurophysiology, etc.</td>
</tr>
<tr>
<td>Events related to different specialties</td>
<td>No indication, wrong identification of the test or sample, implementation delay, delayed results, wrong result, wrong patient, complication of the test, etc.</td>
</tr>
<tr>
<td>Nursing care</td>
<td>Accidental fall, immobilization, pressure ulcer, nursing care not applied, etc.</td>
</tr>
<tr>
<td>Procedures</td>
<td>Avoidable delay in the onset, improper procedure, inadequate preparation before the procedure, equipment failures, inadequate monitoring, inadvertent organ damage, bleeding, etc.</td>
</tr>
<tr>
<td>Nosocomial infection</td>
<td>Ventilator-associated pneumonia, catheter-related bacteremia, catheter-associated urinary tract infections, etc.</td>
</tr>
<tr>
<td>Incidents related to surgery</td>
<td>Procedure-associated hemorrhage, visceral injury, foreign body, suture dehiscence, surgical wound infection, reoperation unrelated to the above, etc.</td>
</tr>
</tbody>
</table>
Confidentiality and ethical aspects

Data acquisition and reporting were anonymous for both patients and personnel. Because the study was observational and no additional interventions were performed, informed consent was considered unnecessary. Each ICU, however, was responsible for obtaining local permissions as necessary.

Results

Description of the participating ICUs

A total of 79 ICUs at 76 hospitals participated. We classified ICUs according to hospital size, as follows: small-sized hospital ICUs, when the hospital had 200 or fewer beds; medium-sized hospital ICUs, when the hospital had between 201 and 499 beds or large-sized hospital ICUs, when the hospital had at least 500 beds. Most participating ICUs belonged to medium- (43%) or large-sized (41%) hospitals. Most ICUs were polyvalent, especially in small- and medium-sized hospitals (Table 3).

Median ICU occupancy on the day of the study was 80% (IQR: 64–99%); ICU occupancy did not differ with the size of the hospital.

Description of the population

A total of 1017 patients were included in the study; 591 patients (58%) were affected by one or more incidents. The affected patients included 381 (64.5%) men and 210 (35.5%) women. The overall mean age of affected patients was 62 years (17 standard deviation), 61 years (16 standard deviation) for men and 62 years (17 standard deviation) for women. No significant differences in incidence were found between sexes.

The percentage of patients affected by incidents was similar in ICUs at small-, medium- and large-sized hospitals. No incidents were reported at four (5%) ICUs.

Description of the incidents

Of the 1424 valid incidents, after exclusion of 43 (3%), 943 (66%) were NHEs and 481 (34%) AEs. Incidents excluded were those not related with patient safety but with perceived quality (temperature, food, etc.) or did not meet the inclusion criteria (incidents occurring before admission without representing the cause of it).

Hospital size was not associated with the number of incidents reported per patient ($P = 0.34$) or with the proportions of NHEs and AEs ($P = 0.57$).

Frequency of the incidents

Expressed as a median, patients in the ICU had a 74% (IQR: 28–141) risk of an NHE and a 40% (IQR: 15–71) risk of an AE. Expressed as medians, the individual risk of a patient suffering at least one incident was 62% (IQR: 0.34–0.57).

Table 2 Classification of the severity of the incidents and examples of each category

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Circumstances or situations with the potential to result in an incident in which no incident occurred because they were detected and corrected before an incident occurred.</td>
<td>Example: inadvertently an antibiotic has been prescribed to a patient that is allergic. The nurse realizes the mistake and avoids the administration.</td>
</tr>
<tr>
<td>B</td>
<td>Incidents that involved but did not harm the patient and did not require monitoring or require intervention.</td>
<td>Example: accidental disconnection of the ventilator immediately detected.</td>
</tr>
<tr>
<td>C</td>
<td>Incidents that involved but did not harm the patient but required monitoring and/or intervention to check whether the patient had been harmed.</td>
<td>Example: erroneous administration of antiarrhythmic medication.</td>
</tr>
<tr>
<td>D</td>
<td>Incidents in which it was impossible to determine the extent of harm.</td>
<td>Example: no early antibiotic administration in severe sepsis.</td>
</tr>
<tr>
<td>E</td>
<td>Incidents that contributed to or caused temporary harm and required intervention.</td>
<td>Example: pneumothorax after central venous catheter insertion.</td>
</tr>
<tr>
<td>F</td>
<td>Incidents that contributed to or caused harm or prolonging hospitalization.</td>
<td>Example: ventilator-associated pneumonia.</td>
</tr>
<tr>
<td>G</td>
<td>Incidents that contributed to or caused permanent harm.</td>
<td>Example: cerebral haematoma due to wrong dose of anticoagulants that causes residual hemiparesis.</td>
</tr>
<tr>
<td>H</td>
<td>Incidents that compromised the patient's life and required intervention to keep the patient alive.</td>
<td>Example: accidental extubation in patient with difficult airway.</td>
</tr>
<tr>
<td>I</td>
<td>Incidents that contributed to or caused the patient's death.</td>
<td>Example: cardiac tamponade after percutaneous mitral valvuoplasty, which causes the patient's death.</td>
</tr>
</tbody>
</table>

*Adaptation of the Ruiz-Jarabo Group's classification [12], in which categories A and B of the original classification were combined into a single category and a new category (D) was added to classify incidents in which it was impossible to determine the effects.
44–80), of suffering at least one NHE 45% (IQR: 28–64) and of suffering at least one AE 29% (IQR: 15–50).

The median number of incidents was 131 (IQR: 56–256) per 100 patient-days in the ICU. The median number of NHE was 83 (IQR: 42–206) per 100 patient-days in the ICU and of AE was 48 (IQR: 20–86) per 100 patient-days in the ICU.

Type of incident

Seventy per cent of the incidents reported were related to medication, devices, nursing care, accidental withdrawal of vascular accesses and catheters or artificial airways and mechanical ventilation (Table 4).

Incidents related to medication; artificial airways and mechanical ventilation; accidental withdrawal of vascular accesses, catheters and drainages; equipment and diagnostic tests were mainly NHEs (P < 0.05). Incidents related to diagnostic error, nursing care, procedures and surgery were mainly AEs (P < 0.05). All nosocomial infections and pressure ulcers were, by definition, AEs.

Severity and avoidability

AEs resulted in temporary damage in 29% and in permanent damage or damage that compromised patients’ lives or contributed to their death in 4%. Figure 1 shows the breakdown of incidents by severity.

The AE contributed to or caused the patient’s death in nine cases, representing one death per patient-days of follow-up and a risk of 0.88 per 100 ICU patients.

Incidents were classified as either ‘totally avoidable’ or ‘possibly avoidable’ in 79% of cases. A greater proportion of NHEs than AEs was classified as ‘totally avoidable’ or ‘possibly avoidable’ (90% versus 60%, P < 0.05).

Discussion

The SYREC study is the first to identify and characterize the main incidents related to health care in Spanish ICUs. To identify priority areas of risk is an important first step in improving the safety of our patients.
Our results confirm that the ICU is a high-risk area. Although methodological differences and the scant presence of critically ill patients in classic epidemiological studies [13, 14] make comparison with these studies difficult, other studies carried out in ICUs support our results [3, 4, 9, 15, 16].

To situate our study in the context of safety for critical patients, it is essential to consider the inherent differences in methodology among studies and problems due to a lack of consensus about the terminology. Using clinical surveillance and a very loose definition of incident, Donchin et al. [17] detected incidents in all patients. The rates of AE reported in studies using direct observation (20–46%) [2, 16, 18] are much higher than those reported from studies using voluntary notification (1–20%), which have a high underreporting bias [19, 20].

SYREC used the same source of data as SEE [5], voluntary notification of incidents during a 24-h period, although SEE classified incidents in only five categories. SEE found a mean rate of 38.8 incidents per 100 patients per day, excluding common incidents related to nursing care, diagnostic tests and nosocomial infection that are reported in our study.

The most frequent type of incident in our study was related to medication. These results agree with those reported for other studies and are to be expected, considering that medication is one of the main therapeutic resources in critically ill patients. Many drugs used in critically ill patients entail high risk and are administered intravenously, and this increases the likelihood of mistakes and AEs.

ICUs are also characterized by high technology and equipment that can place patients at risk from malfunctioning or inappropriate use. Incidents related to technology and devices were among the most common in our study, and these findings corroborate those reported by other authors [22, 23].

An estimated 78 interventions per patient per day are performed in the ICU, most by nursing staff [17], which underlines the importance of nursing care in these patients. In our study, incidents related to nursing care were the third most common type. The high frequency of this type of incident is probably related to increased likelihood of reporting due to the widespread implementation of safe practices in this context and the numerous registries to record specific incidents such as falls and pressure ulcers.

Incidents related to the accidental withdrawal of catheters and tubes accounted for 10% of the total; this percentage is similar to the rates reported by Needham et al. [24] and Pronovost et al. [25] through the ICU Safety Reporting System. In the SEE study [5], this type of incident was the most common among the five types considered (27%). Although these incidents rarely cause harm, it is important to consider the risk involved in inserting a new catheter or tube [26].

Likewise, incidents related to artificial airways and mechanical ventilation (10%) were common. Airways management in ICU patients is complex, and mechanical ventilation is used in a high percentage of patients for a longer period of time than in other environments.

These five categories account for 74% of the incidents reported. Nosocomial infection, which is very prevalent in other studies [3], accounted for only 8% of the incidents in our study. Voluntary notification is not the best way to study this type of incidents, which are better detected through reviewing clinical histories or nosocomial infection surveillance systems [27].

Incidents related to diagnostic tests, procedures, diagnostic error, surgery or transfusion of blood products were reported much less frequently. However, the low frequency of reported incidents of this type does not diminish their importance. The low rate of incidents related to transfusion reported reflects the success of blood surveillance systems and should encourage the design and implementation of safety systems. Incidents related to surgery, which were few but severe, underline the importance of multidisciplinary collaboration.

Incidents related to diagnostic error deserve special attention. These were few (1%) but had a high impact. The deployment of new diagnostic devices and techniques and the increasing importance of technology in hospitals cannot eradicate this type of error. This problem involves multiple factors and studies need to be designed specifically to evaluate its magnitude as well as its causes and long-term consequences [28].

The impact of the incidents occurring in ICUs varies widely. Regardless of the severity scale used, most studies, including ours, detect a high incidence of NHEs. Twice as many NHEs were reported than AEs, as might be expected in a study with voluntary notification. The studies that report the highest proportion of severe AEs are based on the review of clinical histories, because it is unusual to record NHEs. Observational studies detect a higher percentage of AEs, which professionals might be reluctant to report [15].

In nine patients, the cause of death was related to an AE, which translates to a risk of 9 per 100 ICU patients. Although mortality is an objective variable, its relation with AE is not. The few studies that evaluate mortality after safety problems show that AEs have more severe consequences in critical patients than in other environments [29]. The individualized analysis of these cases showed that these patients
had a high risk of death, and the AE was considered un-
avoidable in seven of the nine cases.

In the SYREC study, the incidents reported have been
considered mainly as avoidable. Our results show that sever-
ity and avoidability are inversely related, although other
studies do not confirm this relationship [30].

Probably the voluntary reporting has influenced this state-
ment, because the professional may feel intimidated when
taking over as avoidable cases that have caused serious harm
to the patient. Nevertheless, the percentage of incidents
reported that were classified as avoidable by the professionals
themselves reflects a cultural change and an opportunity for
improvement in this area.

The study of the local epidemiology of AEs is the first step
to improving security. The identification of specific risk areas
should be followed by the implementation of improvement
actions that will allow further studies to confirm the effective-
ness in decreasing the incidence of AEs in the critically ill.

Limitations

Our methodology results in a series of limitations. First,
there are professional difficulties in classifying the incidents
into a specific category and the subjectivity of the concept of
avoidability, despite the use of scales. We sought to minimize
this limitation by providing definitions before beginning the
study and reviewing the incidents for quality assurance; how-
ever, there are no tools that would enable all incidents to be
precisely classified or to determine to what extent they are
avoidable. Second, the ICUs where the study was carried out
were not selected randomly. The ICUs that chose to partici-
pate were probably those with the greatest interest in patient
safety, leading to a selection bias, as in other studies [5].
Third, the Hawthorne effect might have influenced the results
by favouring safer practices on the day of the study and
thus avoiding the occurrence of AEs. Fourth, the short
duration of the study (24 h) makes it difficult to establish the
final impact of the AE and might lead to an underestimation
of the severity of some of them.

Conclusions

The SYREC study shows a high individual risk for incidents
in critical patients. Most incidents were related to medication,
equipment, nursing care, accidental withdrawal of catheters
and other devices or artificial airways and mechanical ventila-
tion. Although many of the incidents did not result in harm
to the patient, a significant percentage caused damage and a
few were even related to the patient’s death. Most incidents
were considered avoidable.

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