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Safety incidents in airway and mechanical ventilation in Spanish ICUs: The IVeMVA study☆

Ángela Alonso-Ovies [a,*], Nicolás Nin [b], Maria Cruz Martín [c], Federico Gordo [d], Paz Merino [e], José M. Añón [f], Blanca Obón [g], Mónica Magret [h], Isabel Gutiérrez [g], and IVeMVA study investigators [1]

[a] Department of Intensive Care Medicine, Hospital Universitario de Fuenlabrada, Madrid, Spain
[b] Department of Intensive Care Medicine, Hospital Español, Montevideo, Uruguay
[c] Department of Intensive Care Medicine, Hospital Universitario de Torrejón, Madrid, Spain
[d] Department of Intensive Care Medicine, Hospital Universitario del Henares, Coslada, Madrid, Spain
[e] Department of Intensive Care Medicine, Hospital Can Misses, Ibiza, Spain
[f] Department of Intensive Care Medicine, Hospital Universitario La Paz-Carlos III, IdiPAZ, CIBERES, Instituto de Salud Carlos III, Madrid, Spain
[g] Department of Intensive Care Medicine, Hospital Clínico, Zaragoza, Spain
[h] Department of Intensive Care Medicine, Hospital Universitario Joan XXIII, Tarragona, Spain

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ABSTRACT

Purpose: To assess incidence, related factors and characteristics of safety incidents associated with the whole process of airway management and mechanical ventilation (MV) in Spanish ICUs.
Materials and methods: Observational, prospective, 7 days cross-sectional multicenter study. Airway and MV related incidents were reported using structured questionnaire. Type, characteristics, severity, avoidability and contributing factors of the incidents were assessed.
Results: Participant ICUs: 104. Inclusion of 1267 patients; 745 (59%) suffered one or more incidents. Incidents reported: 2492 (59% non-harm-events, 41% adverse events).
Individual risk of suffering at least one incident: 66.6%. Incidence ratio (median) of incidents: 2 per 100 patient-hours. 73.7% of incidents were related to MV process, 9.5% to tracheostomy, 6.2% to non-invasive MV, 5.4% to weaning/extubation, 4.4% to intubation and 0.8% to prone position.
Temporary damage was produced in 12% incidents, while 0.8% was related to permanent injuries, risk to the patient's life or contributed to death.
Incidents were considered avoidable in 73.5% of cases. 98% of all incidents had 1 or more contributing factors.
Conclusions: MV is a risk process in critical patients. Although most incidents did not harm patients, some caused damage and a few were related to the patient's death or permanent damage. Preventability is high.

1. Introduction

Management of airway and mechanical ventilation (MV) is one of the most common procedures in ICU. Although the percentage of patients needing MV varies depending on the studies and the specific characteristics of each ICU, it is estimated to oscillate between 40 and 50% of admissions [1-4]. Moreover, respiratory failure and need for MV constitutes one of the principal reasons for admission to ICU [5, 6].

The MV process in critical patients is complex, invasive, and fraught with multiple interactions. This process encompasses a series of phases in which dynamism and interventionism are of utmost importance. This, coupled with the frequent severity of the patient's condition, may produce a multitude of incidents that put patient safety at risk regarding potential or real harm which may trigger severe sequelae or even death.

To date, there have been few published studies on incidents related to MV and airway in ICU. There have been more studies published on the subject of surgical anaesthesia, mainly regarding intubation and airway management [7-11]. In intensive care, much of the data is derived from multicenter patient safety studies (ICUSRS [12], SEE [13], SYREC [14]), or from an individual center [15], or from international epidemiological studies on MV that do not contain a detailed analysis of

Abbreviations: ICU, Intensive Care Unit; MV, Mechanical ventilation; AE, Adverse Event; NHE, Non-harm event; NIMV, non-invasive mechanical ventilation.

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* Corresponding author at: Department of Intensive Care Medicine, Hospital Universitario de Fuenlabrada, Camino del Molino 2, 28492 Fuenlabrada, Madrid, Spain.
E-mail address: a.alonso@salud.madrid.org (Á. Alonso-Ovies).

[1] IVeMVA study investigators are listed in ANNEX 5, in Supplementary data.

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problems concerning patient safety [16, 17]. Other ICU studies focus on some of the phases of the process (principally on airway management) without seeking out incidents from the rest of the phases [18-21].

The objective of the IVeMVA study (Spanish acronym for "Incidents involving Mechanical Ventilation and Airway") is to learn about the incidence of non-harm events (NHEs) and adverse events (AEs) related to the whole process of airway management and MV in Spanish ICU, and also to analyze the types of incidents that occur, their severity, avoidability, the professionals who report them, communication with family members and contributing factors.

2. Method

2.1. Design

7-day observational, multicenter study in a prospective cohort carried out from 24/03/2014 to 30/03/2014. During this period, safety incidents related to airway and MV were voluntarily and anonymously collected by any ICU professional (specialist doctors, residents, nurses, nurses' aides, etc.). The principal researchers (intensivists experts in patient safety and MV from the Spanish Society of Intensive Care Medicine, "SEMICYUC") had previously consensually compiled a list of the most common safety incidents related to airway and MV and classified them in six groups: airway intubation, invasive MV, MV in prone position, weaning/extubation, tracheostomy (technique and management) and non-invasive MV (NIMV). (Annex 1).

2.2. Context

All ICU of both public and private Spanish hospitals were invited to participate by email, by the SEMICYUC webpage and by the Electronic Journal of Intensive Medicine (REMI).

2.3. Inclusion criteria

Patients over 18 years, who were already hospitalized or were admitted during the course of the study, were in need of MV (invasive or non-invasive) or were in the weaning phase (including those who were breathing spontaneously but with airway isolation by means of endotracheal tube or tracheal cannula), regardless of whether ventilation support was initiated prior to or during the period under study.

2.4. Definitions

Those proposed by the World Health Organization were used [22]:

- Incidents related to Patient safety: events or circumstances that could have resulted in or did result in unnecessary harm to the patient.
- NHEs: Events which did not inflict harm on the patient, either because they did not impact him/her directly or if they did, were without consequences.
- AEs: events that (unintentionally) caused harm to the patient and occurred either during or as a result of health care attention, and no related to the course or possible complications of the patient's base illness.

2.5. Variables studied

The variables collected were relative to hospital/ICU, patients, MV and incidents (Annex 2). Classification of severity of incidents followed an adaptation of the Ruiz-Jarabo group's "Classification of medication errors" [23] (Annex 3). Contributing factors were collected according the model proposed by the National Patient Safety Agency of the United Kingdom [24] (Annex 4).

2.6. Procedure

A notebook was designed for data collection, containing instructions for registering data and incidents that might occur to patients. A physician and a nurse were designated as coordinators in each ICU to train all the healthcare ICU professionals in the procedures of the study (with educational material provided by the main researchers), to control the data collection and to complete the web electronic data base.

2.7. Data quality control

The incidents registered were reviewed by the study's main researchers. Duplicate data were eliminated by consensus and all data not considered correctly classified was reclassified.

2.8. Statistical analysis

The following absolute values were obtained for each center: number of total events (NHE and AE) associated with MV and AWM as well as the rest of the study's variables. For each of the incidents (NHE/AE) the risk (accumulated incidence) and rate (density of incidence) were calculated.

Data are expressed as the mean ± standard deviation, the median with the interquartile range, and proportions (absolute and relative frequencies) as appropriate. Student's *t*-test or the Mann–Whitney test was used to compare continuous variables, while the $\chi 2$ test or Fisher's exact test was used to compare proportions. A p value of <0.05 was considered to show a statistically significant difference. Version 19.0 of the IBM SPSS program was used for statistical treatment of data.

2.9. Confidentiality and ethical aspects

Compliance with the laws and guidelines on protection of personal data was guaranteed and the anonymity and confidentiality of the incidents registered was maintained. Treatment of the information obtained did not allow identification of the center, reporting professional or patient.

The project was approved by the Ethics Committee of Clinical Research of Aragón (CEICA) on 26/02/2014 (code C.P.-C.I. PI14/0022) and by each of the local Clinical Research Ethics Committees.

3. Results

One hundred and four (104) ICUs participated in the study (83.6% polyvalent, 10.6% mixed, 5.8% monographic) from *94 hospitals* out of a total 237 Spanish hospitals with at least one ICU [25] (39.7%). The characteristics of the participating ICU are reflected in Table 1.

A total of 1267 ICU patients were included out of the 2486 hospitalized during the week of the study (51%, CI 95% 49.1–52.9), 64.2% male, with a median age of 63.4 (SD 14.31). The total number of days of MV or airway isolation was 4491.5 days. Eighty seven (87) patients (7%, CI 95% 5.6–8.4) received NIMV; and 338 patients (27%, CI 95% 24.6–29.4) were tracheostomized (tracheostomy was performed on 83 patients −25%- during the week of the study). Types of patients, reasons for MV and site of airway intubation are shown in Table 2. MV or airway intubation was initiated during the week of the study in 575 patients (45.4%, CI 95% 42.6–48.1).

Two thousand four hundred ninety two (2492) incidents (1475 NHEs, 1017 AEs), involving 745 patients, were reported; in other words, 58.8% of the patients (CI 95% 56.2–61.5) suffered 1 or more incidents. The mean was 1.96 incidents/patient (SD 3.06) and the median was 1 incident/patient (IQR 0–2). The median ratio was 1.68 incidents per patient (IQR 0.9–2.8) (1 NHE, 0.5 AE) with an *incidence ratio of 2 incidents per 100 patients and per hour of MV or airway isolation* (IQR 1.1–3.9) (1.2 NHE, 0.6 AE). *The risk of suffering at least an event for undergoing MV or airway isolation was 66.6%* (IQR 47–83) (48.5% NHE, 38.9% AE). 21% of