Online Resource 3. Methods (full description)

This study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement [1]

Study design and subjects

DecubICUs was a worldwide prospective, observational, one-day point prevalence study with an 84-day follow up period of pressure injuries among adult ICU patients. All patients aged 18 years or older and present in an ICU at any time (from 0:00 to 23:59:59 hours) on the day of data collection (15 May 2018) were eligible; there were no exclusion criteria. The study was registered at ClinicalTrials.gov (NCT03270345).

Ethical approval

National Representatives applied for regulatory approval on a national level where applicable and ensured that ethics committee and / or institutional review board approvals or waivers were in place prior to the initiation of the study. Overall, approval or waiver of informed consent for this observational, minimal risk study was expedited and granted by established national, regional or local ethic committees and / or institutional review boards.

Data collection

We engaged National Representatives who advertised the study on a national level, recruited local investigators, maintained intensive communication with the participating sites, and ensured follow up throughout the study period. Local investigators collected the data, provided leadership for the study in their institution, ensured adequate data collection and submission, and acted as guarantor for the integrity and quality of their data.

Data were collected on 15 May 2018 from 0:00 hours to 23:59:59 hours. Data were collected on 15 May 2018 from 0:00 to 23:59:59 hours. An alternative study date was set for Nigeria, Brazil and Libya (delayed ethics approval). Anonymous patient data were collected through a case report form and included demographic and admission data as well as physiological data pertaining to the study day: biological and laboratory parameters, Simplified Acute Physiology Score II [2] (SAPS II) score, risk of pressure injuries according to the Braden scale [3], prevention strategies applied, and pressure injury occurrence following the 2014 international classification system staging definitions [4] The SAPS II provides an estimate of the risk of death based on 12 physiology variables, age, type of admission (scheduled surgical, unscheduled surgical, or medical), and three underlying disease variables (acquired immunodeficiency syndrome, metastatic cancer, and hematologic malignancy) [2]. The Braden scale measures the risk for development of a pressure injury by using 6 subscales: formation: mobility, activity, sensory perception, skin moisture, nutritional state, and friction/shear [3].
Follow up data gathered were survival status and length of ICU and hospital stay until hospital discharge or at day 84 following the study day (7 August 2018). The complete study protocol, including

all data recorded, definitions used, and center and case report forms, is at https://www.esicm.org/research/trials/trials-group-2/decubicus/ and in Online Resource_4.

We used a secured online platform administered by the European Society of Intensive Care Medicine (ESICM and owned by CLINFILE© (www.clinfile.com) with full guarantees of security, reliability and privacy protection for study registration and data reporting. For countries with restricted digital resources, pre-printed forms were downloadable from the study website (https://www.esicm.org/research/trials/trials-group-2/decubicus/) or sent upon demand via postal mail. Completed pre-printed forms were returned to the principal investigators through the channel best suiting the local centers' commodities, and uploaded by SL. The platform was open until 31 January 2019.

Support

To maximise uniformity in reporting, we conceived an education module with a self-test battery of questions on pressure injury staging that was validated for clarity and content by three content experts and published on the study website prior to study initiation (https://www.esicm.org/wp-content/uploads/2018/04/Module-DecubICUs-LR.pdf; Online resource_5). Registered participants were repeatedly encouraged to familiarise themselves with the module prior to the data collection day. The protocol and the data collection forms were available in 10 languages (English, Portuguese, Spanish, German, French, Italian, Turkish, Chinese, Thai, and Russian). All versions were available for download from the study website.

Starting end March 2018 and throughout the entire study period, we regularly mailed motivational and informative newsletters to all registered participants. We integrated a How-to-use guide, an interactive Question & Answer tool and a Frequently Asked Question section into the online platform, and equipped it with the option to run a try-out by entering test cases before the upload of actual study data. Online support via Skype software (Microsoft, WA, US) was permanently available for all urgent queries on the study day and until 18 May 2018.

Power calculation

For a risk factor with a prevalence in the study cohort of only 10% (for example patients with a BMI<18.5) and an outcome difference of only 5% (15% vs. 20% in pressure injury occurrence rate) to be statistically significant, a sample size of 5255 patients was required (478 patients with the index risk factor and 4777 without; $\alpha = 0.05$; $\beta > 0.80$). For the current cohort, the post-hoc power is >99.5%.

Data management

The quality and integrity of the data were checked. Missing, extreme or implausible values were sent back to the local investigators for review. Depending on our experiences with the ease and speed of communication, queries were either sent to the national coordinator who in turn contacted the local investigators, or to the local investigators directly. Queries to national coordinators could encompass questions for several local investigators. Due to the fact that investigators could contact the principal investigators during the entire data collection with any questions about data entries and the continuous

follow up of the inputted data by the principal investigators, the number of values remaining missing, extreme or implausible at the data cleaning stage was restricted. A total of 172 mails with queries on data input have been sent.
Where data remained questionable, the primary investigators (SOL & SIB) made a final adjudication about study inclusion in mutual agreement. Missing values mutually judged eligible for study inclusion were imputed with median values or deduced from other variables reported. Remaining missing values were omitted from the statistical analyses.

Statistical analyses

Analyses were performed at the patient level. Overall pressure injury prevalence was calculated as the proportion of the sample who had at least one pressure injury on the study day. ICU-acquired prevalence was calculated as the proportion of the sample who had at least one pressure injury acquired in the ICU on the study day. Prevalence is reported as percentage with 95% confidence interval (CI).

Continuous data is summarised by median with interquartile range, categorical data as number (n) with percentage. We performed univariate analyses using Chi-square, Mann-Whitney U, and Kruskal-Wallis tests, as appropriate, and the Kaplan-Meier procedure with log rank test for survival analysis. Only two variables (age and SAPSII) followed a Gaussian distribution; all others were skewed. Therefore we reported medians with IQRs for all variables and used nonparametric tests. We examined associations with ICU-acquired pressure injuries using a generalised linear mixed-effects regression analysis with the logit link function and including a random effect for country. This method was chosen because of the great variability in standards of care in our international sample. A mixed-effects regression analysis balances this effect, by including a random effect for 'country'. We avoided data transformations in order to ensure that the model results remain realistic rather than optimal but unrealistic [5]. All demographic variables as well as those related to acute illness and chronic conditions were automatically included. Furthermore, additional variables (length of ICU stay before study day, World Bank classification, number of patients per nurse) were included based on both clinical judgement and the literature on risk factors/mortality. As such, all variables were included following an exploratory approach, irrespective of their relationship with pressure injury/mortality in univariate analysis. As the analyses focussed on the identification of associations and not on prediction, feature selection was not applied, particularly given the limited number of predictors (n=24 for pressure injury occurrence, and n=22 for hospital mortality) and the adequate size of the dataset (n= 13 254) that minimises the risk of overfitting. Results are reported as odds ratios (OR) with 95% confidence intervals (CI).

Countries are classified according to the 2016 World Bank classification in low, lower-middle, upper-middle and high economies [6]. Percentages of gross national income spent on healthcare are for calendar year 2016 (World Bank's fiscal year 2018) and according to the World Health Organisation [7].
Number of patients per nurse was calculated by dividing the number of beds occupied throughout three shifts on the study day by the total number of nurses throughout these shifts on the study day.

We conveniently categorised the variable ‘Days in ICU before the study day’ per three days. While the average ICU length of stay may vary among countries and geographical regions, and depend on ICU attributes and patient mix, we relied on the average ICU length of stay of 3.8 days in the United States as reported in the Critical Care Statistics of Society of Critical Care Medicine [8] to use the wording ‘short stay’ to indicate an ICU stay of three days or less.

Statistical analysis was performed using IBM SPSS for Windows 24.0 (IBM Corp., NY, US) and R statistical software 3.6.1. [9].

References

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