



## SCIENTIFIC LETTER

### Preliminary results of the ADENI-ICU trial: Analysis of decisions of refuse admission in intensive care units as a limitation of life support treatments; multi-center, prospective, observational study<sup>☆</sup>



### Resultados preliminares del estudio ADENI-UCI: análisis de las decisiones de no ingreso en unidades de cuidados intensivos como medida de limitación de los tratamientos de soporte vital; estudio multicéntrico, prospectivo y observacional

Dear Editor:

Traditionally, the lack of analysis of the factors associated with the processes involved in refusing admission to intensive care units (ICU) has been reason for complaint.<sup>1</sup>

Back in the month of February 2018 the ADENI-UCI study started recruiting patients to analyze the decisions made by these patients to refuse admission at the ICU as a measure of limitation of life support treatment (LLST) in our setting.

This analysis is part of the ADENI-UCI study, a prospective, observational, multicenter trial conducted in Spain that started recruiting patients back in February 2018. The cut-off date occurred 120 days after starting recruitment in order to assess the capacity of recruitment of the centers involved in the study (June 8th, 2018). All intensive care medicine units (ICMU) were invited to participate through SEMICYUC Bioethics Working Group.

When it comes to the scope and the population study, the ADENI-ICU trial included ICMUs distributed across 21 Spanish provinces. These ICMUs varied depending on the size of their ICUs (depending on the number of wards available), the diseases and conditions treated, the presence of intermediate

care units, the availability of extended intensive care services (EICS), and also on the ratio between the staff and the number of wards visited during morning hours and on-call hours.

Each participant ICU committed itself to registering consecutively, and for a period of six (6) months, the LLST-based decisions made by those patients to refused ICU admission.

The study will include a general description of the study variables including the distributions of absolute and relative frequencies of qualitative variables and measures of central tendency and dispersion (average, standard deviation, mean, minimum, maximum, interquartile range) of quantitative variables. Also, it will include 95% confidence intervals (CI) for the main quantitative variables of the results associated with the primary endpoint.

Absence data will not be taken into consideration and they will be considered lost data. When inferential analysis is needed, parametric tests will be used for the continuous variables and non-parametric tests for the ordinal, categorical or non-parametric variables. Hypothesis tests used will be bilateral in all cases and with a .05 level of significance. For those variables that are not adjusted to a normal (or parametric) distribution, the Mann–Whitney *U* test for unpaired samples or the Wilcoxon test for paired samples will be used. For the analysis of contingency tables and to draw the proportion and/or distribution of frequencies, the chi-squared test (or Fisher's exact test when needed) will be used.

The size of the sample will be defined by the transient nature of the study. In this case, each participant center will be recruiting patients consecutively for 6 months starting with the recruitment of the very first patient. The total duration of the study will be one full year finishing February 2019. The last month to start the study registry will be September 2018.

During the first 120 days of inclusion in the ADENI-UCI study a total of 502 patients from 36 participant ICUs were recruited. The average age was  $76 \pm 12$  years old, and the percentage of male patients was around 60%. In approximately 60% of the cases registered the patients were grouped into classes C and D of the Knauss score, and three (3) out of every four (4) patients showed a Karnofsky Performance Scale index below 60.

The decision to refuse ICU admission was made during the first assessment of the patient made by the intensivist over 90% of the time and while on-call in almost 60% of the cases.

<sup>☆</sup> Please cite this article as: Escudero-Acha P, Palomo Navarro M, Leizaola Irigoyen O, Vidal Tegeador B, González Romero D, Misis del Campo M, et al. Resultados preliminares del estudio ADENI-UCI: análisis de las decisiones de no ingreso en unidades de cuidados intensivos como medida de limitación de los tratamientos de soporte vital; estudio multicéntrico, prospectivo y observacional. *Med Intensiva*. 2019;43:317–319.

Assessments from the surgical areas would be considered just a formality below 12%.

At the time of the assessment, in almost 20% of the ICUs here were less than two (2) beds available.

Severe chronic disease was the most common cause to refuse admission.

Patients were informed on the decision made less than 20% of the time, a percentage that grew up to 80% when the decision was told to the family. The decision to refuse ICU admission was attached to the patient's clinical history in almost 90% of the cases.

We strongly believe that the data presented here show the great job done during the study follow-up.

Although these are preliminary data from a descriptive analytical study and even through there are different possibilities of discussion, we would like to highlight a few key aspects here.

In the first place, there is a significantly high number of times when the decision to refuse ICU admission is made during the first consultation. Also, we should say here that the decisions to apply LLST were made through the correct assessment of our critical patients' complex clinical setting and based on our capacity to discuss all possibilities with the patient at the right time.<sup>2</sup>

However, it seems reasonable to emphasize that families, treating physicians, and extended intensive care services (EICS) should anticipate what may be coming with patients who are potentially critical and have a chronic condition to obtain greater participation and more recommendations with time to spare.

Secondly, the small role that the patient's own will play in this type of decisions is really striking. In this sense, we should mention here that there may be situations when patients just don't have the capacity to make any decisions and cases when their preferences are barely known by anybody else.<sup>3,4</sup> In the third place, and even though this is going to be controversial, in these cases the doctor's consideration of futility and the lack of availability of a bed at the ICU are totally out of the patient's scope of action. Therefore, the doctor could be making this decision without the patient or family's consent,<sup>5</sup> because the decision would be considered a cruel and inadmissible load to bear for the family.<sup>6,7</sup>

Nevertheless, we agree that this decision should be made not only by everyone involved but also in line with the family,<sup>8</sup> a situation that actually happens in almost 80% of the decisions made in our setting as our results clearly indicate. In any case, these data cast the shadow of a doubt when it comes to whether the interview with the family was only to inform them on what had previously been decided or whether an actual conversation ever took place.<sup>3</sup>

## Authors

González Castro and P. Escudero Acha conducted the surveys and wrote the manuscript.

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