

DESDE EL MÁSTER

**Process of life-sustaining treatment in general hospital:
withholding and withdrawing**

LORENZO SOCIAS CRESPI*

ROSA POYO-GUERRERO LAHOZ*

En esta sección tienen cabida las aportaciones de los alumnos del Máster en Bioética y Derecho de la Universitat de Barcelona, de la presente edición (XIII promoción 2010-2011) así como de ediciones anteriores. Esperamos vuestras contribuciones en obd@pcb.ub.es.

* Intensive Care Unit. Hospital Son Llàtzer. Illes Balears. Spain.

Abstract

Background: Limitation of care (LC) is common practice in intensive care units (ICUs) and is associated with high mortality. There is no consensus on its application or the process in itself, sometimes leading futile prolongation of life and greater suffering.

Objectives: We aimed to study types of LC, associated mortality and factors that influence end-of-life decisions.

Material and method: This was a 2-year (2004-2006) prospective observational study of 97 patients in whom LC was applied. Age, diagnosis on admission, severity scales, life support techniques, sedation and analgesia, modality of LC (withdrawal or withholding) and the justification for LC were recorded.

Results: We applied LC to 6.6 % of the patients admitted to ICU with a mortality rate of 89.6 % (30.3 % of all deaths). The average stay of these patients was 10.5 ± 5.5 days compared to 5.6 ± 4.3 days for patients in whom LC was not implemented ($p < 0.001$). The mean \pm SD length of stay from start of LC until death was 68 ± 50 hours. The most frequent diagnosis on admission was sepsis (30.9%) and the futility was the reason given most often for LC (85%). Withdrawal of life support was used more frequently (65%) than withholding and was associated with higher mortality (95.3%).

Conclusions: The severity criteria on admission to the ICU did not influence the decision to implement LC. Likewise, the modality of LC did not influence patient survival.

Keys Words: limitation of care; withdrawal of life support; withholding life support; futility.

Resumen

Introducción: La limitación del esfuerzo terapéutico (LET) es una práctica frecuente en los Servicios de Medicina Intensiva (SMI) que asocia a una mortalidad elevada. Sin embargo no hay consenso establecido en cuanto a su aplicación ni al proceso en sí derivando en ocasiones a una prolongación fútil de la vida y a un mayor sufrimiento. Analizamos las características epidemiológicas, la modalidad retirada del soporte vital (RSV) frente al no inicio (NISV) del mismo, la mortalidad y la frecuencia de variables que determinan el inicio del proceso de decisión al final de la vida.

Objetivos. Analizar la modalidad más utilizada en la limitación del esfuerzo terapéutico, identificar los factores que la determinan y su implicación en la supervivencia.

Material y método: Estudio observacional, descriptivo y prospectivo durante 2 años (2004-2006) sobre 97 pacientes a los que se aplicó LET. Los datos recogidos fueron: la edad, diagnóstico al ingreso, escalas de gravedad, soporte aplicado, sedación y analgesia, modalidad de la LET y la causa que motivó la toma de decisión.

Resultados: Se aplicó LET al 6,6% de los pacientes ingresados en SMI con una mortalidad del 89,6% (30,3% del total de fallecimientos). La estancia media de estos pacientes fue de $10.5 \pm 5,5$ días frente a $5.6 \pm 4,3$ días en los paciente donde no se les practicó ninguna modalidad de LET ($p < 0,001$) con una estancia media desde el inicio de la LET hasta el fallecimiento de 68 ± 50 horas. El diagnóstico al ingreso más frecuente fue la sepsis (30,9%) y la futilidad fue el motivo de LET más repetido (85%). La RSV se empleó con más frecuencia (65%) que la modalidad NISV y se asoció a mayor mortalidad (95,3%).

Conclusiones: Los criterios de gravedad al ingreso en el SMI no determinan la decisión de aplicar la limitación del esfuerzo terapéutico. Tampoco influyen en la supervivencia de los pacientes la modalidad de LET utilizada.

Palabras clave: limitación del esfuerzo terapéutico; retirada del soporte vital; no inicio del soporte vital; futilidad.

Introduction

Limitation of care (LC) is common practice in intensive care units (ICUs) and is associated with high mortality. However, there is no established consensus on when or how it should be applied and, at times, futile attempts to prolong life may lead to greater suffering for the patients. From the ethical point of view, the decision to withhold life support is no different to the decision to withdraw it, as recognized by a number of authors [1,2,3,4].

Often, personal views of the intensivist influence decisions about LC although this is inappropriate from the ethical standpoint and hinders the application of a uniform standard of care. In studies published on the opinion of health-care professionals, prior quality of life (92%) and future predicted quality of life (83%) are taken into account [5]. It is also true that physicians underestimate the quality of life of patients, whereas patients are more optimistic and are more tolerant of their limitations [6]. In practice, although the recommendations are fully clear, withdrawal of life support is only acceptable for reasons of physiological futility such as, for example, brain death, patients with end-stage multiorgan failure and patients in a vegetative state.

In our study, we aimed to compare withdrawal of life support with withholding of life support and analyze the variables that determine the initiation of the decision process at the end of life.

Material and methods

In this prospective, observational, descriptive study conducted between 1 February 2004 and 28 February 2008, we included 97 patients in whom either withdrawal or withholding of life support was practiced. The study was conducted in the Intensive Care Unit of our hospital, with a catchment population of approximately 250,000 people. It has 350 beds, with all medical and surgical specialties represented except neurosurgery and cardiovascular surgery. The ICU has 14 beds and admits, on average, 700 patients/year, with a mean stay of 5.6 days. During the study period, 1458 patients were admitted to the unit. In 97 patients (6.6%), some form of LC was practiced. These patients were studied prospectively until they died or were discharged from the unit.

The following data were collected for each subject: age, sex, diagnosis on admission, Sequential Organ Failure Assessment (SOFA) at the time of inclusion, Acute Physiology and Chronic Health Evaluation (APACHE) II on admission, life support measures during admission (mechanical ventilation, vasoactive drugs, dialysis, antimicrobial therapy, artificial nutrition), type of LC (withdrawal or withholding of life support), number of failing organs when the decision was made, comorbidity, and the rationale for the decision (futility, prior quality of life or suffering). Withholding or withdrawal of life support was defined as the decision not to apply a medical intervention either by not resorting to it (withholding) or renouncing it when the intervention was not meeting its therapeutic goals (withdrawal). Quality of life was defined as the subjective perception of an individual of living in a dignified state. In our study, in accordance with Rivera Fernández et al [7], we defined four levels of quality of life, based on basic physiologic areas: physical activity, dependence on therapeutic measures, and occupational activity. We defined suffering according to the definition proposed by Casell [8]. Futility was defined as

a therapeutic measure considered useless because the objective of providing benefit to the patient was very likely to fail. Other data of interest collected were hospital stay, stay in the ICU, time from admission to the ICU until the decision was made and time from making the decision until death or discharge from hospital.

Statistical analysis

Data were presented as absolute numbers and percentages for categorical variables and mean \pm SD for continuous ones. The χ^2 test was used for comparing non-continuous variables while the means of continuous variables were compared using the Student *t* test for unpaired data. A logistic regression model was used to analyze the factors predictive of mortality. Confounding factors of poor prognosis were considered to be age, sex, APACHE II, organ failure at the time of inclusion and comorbidity. Survival and the influence of type of LC were studied using the Kaplan-Meier method.

Results

Between 1 February 2004 and 28 February 2006 we admitted a total of 1458 patients to the ICU. Their mean age was 65.3 \pm 15.9 years and 64.6% were women. The mean APACHE II score was 15.4 \pm 8.1 and the mean stay was 5.6 \pm 9.6 days. In total, 287 patients died (19.7%). The most common diseases on admission were ischemic heart disease (28.1%), severe sepsis (27.4%) and chronic obstructive pulmonary disease (7%). The mortality rate for each of these diseases was 5.9%, 34.8% and 8.9%, respectively. Of the total number of deaths in the ICU, severe sepsis accounted for 48.4%.

Life-prolonging measures were withdrawn or withheld in 97 patients (6.7%). Eighty-five patients died (30.3% of the total deaths and 89.6% of patients with LC). Consent for LC was obtained from the family in 99%.

The characteristics of the patients for whom LC was implemented are presented in Table 1. Within the withdrawal approach, the most common action was withdrawal of vasoactive drugs (29.2%), followed by mechanical ventilation (18.6%) and oxygen therapy (11%). With regard to withholding of life support, mechanical ventilation was not applied in 15.5% of the patients, followed by continuous replacement techniques in 8.2% and vasoactive drugs in 3%.

With regard to the rationale for decision making, futility was the most common reason, given in 85% of the cases, followed by quality of life in 31.9% and suffering in 6.2%. Disease progression was accompanied by palliative measures with sedatives and analgesics in 95% and 60% of the patients, respectively. On adjustment for age, sex, APACHE II, SOFA at the time of inclusion, number of failing organs, and type of LC, only withdrawal influenced mortality, with an OR of 2.3 (95% CI, 1.4-4.2; $p < 0.001$). Mortality among patients in whom LC was applied was 89.6%. We studied whether there were any factors predictive of survival in patients in whom LC was applied, and did not find any significant differences in comorbidity of the patients or in the number of failing organs at the time of inclusion, although significant differences in the severity criteria were apparent (Table 2). However, on constructing a logistic regression model with adjustment for age, sex, severity criteria (APACHE II, SOFA on admission and number of affected organs), immunosuppression (AIDS, cancer and

corticosteroid administration for a week or more) and the different life support techniques, we did not see any influence on mortality compared to patients who were discharged from hospital.

Follow-up was available for patients who were discharged after LC (12 patients). Six patients died during the first 6 months and 6 were still alive 1 year later. Of those who died, 50% had a good quality of life when they were admitted to the ICU.

Discussion

LC begins the moment that continuing with life support measures is considered futile or of no benefit. General acceptance of this on the part of the medical team and the patient's family is essential for an appropriate and acceptable outcome of the process.

In this study, we found that, although LC is a routine practice in ICUs, in our unit, it was applied in only 6.7% of the patients admitted to our unit. This is lower than the percentage reported in other studies, where it varied between 11% in France [9], 9.9% in Great Britain [10], 10%-9.8% in a study of European Union countries [11] and 9.6% in the Lebanon [12] and Greek 41% [21]. It is however similar to that reported by Esteban et al [4] in their study of application of LC in 7 Spanish ICUs. The lower percentage in our study could be because we did not include patients with a do not resuscitate order.

One of our main findings was that the deaths of patients in whom it was decided to withhold or withdraw life support measures accounted for 30.3% of all mortality—similar to the percentage reported by Wunsch et al [10] but significantly lower than the 45% to 70% reported by other authors [12]. Our results differ from other studies in that a greater proportion of the deaths occurring in the ICU were due to LC [13]. Bearing in mind that the overall mortality of our patients did not differ from the established average (around 19.7% of patients admitted) and that the mean APACHE II in patients for whom life support is maintained was 15 (figures similar to other studies [9,11]), it is not clear why most of the deaths are not due to application of LC. It may partly be due to the fact that patients with do not resuscitate order were not included. On the other hand, mortality within the group of patients for whom LC was decided was 89.6% (95.3% in those with withdrawal and 72.7% in those with withholding of life support). These figures are slightly higher than the study of Ferrand et al [9], who reported mortality of 78% (92% for withdrawal and 57% for withholding).

The lack of an established consensus or widely accepted guidelines means that decision making when treating these patients is a difficult process and is often made using subjective criteria [20]), For these reasons, often with the desire on the part of the families to apply whatever means are necessary, the decision to withhold or withdraw life support in our unit might be taken at a later stage compared to other ICUs in other European countries. Thus, in our study, the mean stay in the ICU was 10.5 days and the delay until adopting LC 8.6 days. Both these are much longer than in other studies [1,11], where the times are 4 and 2 days, respectively. The fact that a high percentage of patients in whom LC was applied were diagnosed with severe sepsis might have had an influence. In such cases, the decisions are generally made later given that this is a potentially curable disease and the resources available were applied until considered futile. It is of relevance that there was a high level of

acceptance on the part of the families when deciding jointly to initiate LC. This is in contrast to Esteban et al [4], who reported that the family was not consulted about the decision for LC in 28.3% of the cases. The high degree of consensus achieved in our study may be because LC was initiated later thereby allowing the family members more time to accept and adapt to the life-threatening situation of the patient. Another factor might be that in our unit, it is always the treating physician who informs the family of the situation, and a bond of trust is generally established between them. Probably as a result of this consensus and the high degree of acceptance, we recorded the moment in which—jointly in a unit meeting and in consultation with the family—it was decided to apply LC in 99.8% of the medical records. This contrasts with the study reported by Vincent et al [13] of ICUs in different European countries (in particular Spain, Italy and Greece), in which the decision for LC is not usually recorded.

With regard to deciding on LC, of note is that withdrawal was adopted in 65.9% of the patients versus 34% in whom life-support measures were withheld. This is in agreement with data obtained in studies carried out in southern Europe compared to other European regions and the United States where no differences were found between adopting one or other type of measure [1,9,11]. This discrepancy may be due to different religious beliefs, customs, and moral convictions in each country.

Withdrawal of life support is generally associated with higher mortality and earlier death. In our study, the estimated mean time from making the decision until death was 41 hours in the case of withdrawal and 96 hours in the case of withholding. We did not find any significant differences in the number of failing organs, APACHE II or SOFA that might explain this difference, as suggested in the study of Sprung et al [11] and Vincent et al [13]. According to these authors, the patients in whom LC in the form of withdrawal of life support is applied are usually the most critical or unstable.

Overall, the time between starting LC and death or discharge was 68 hours, which is much longer than the time reported by Sprung et al [11] and Wunsh et al [10], Jensen et al [21], (15, 2 hours, 36 hours, respectively). A number of explanations could be offered for these observations. In some cases, we delayed the process to help the family adapt to the loss of a loved one. At other times, the delay was to allow the implicated family members time to arrive at the bedside or to avoid death during the early hours of the morning. On the other hand, it may be that the process of withdrawal of life-support measures was slow and progressive or that the LC involved withholding or withdrawing less aggressive measures.

Among the reasons given for deciding on LC, the most frequent was futility (85%) followed by poor quality of life (31.9%) and suffering (6.1%). This is in line with the findings of other studies [1, 16, 18, 21,22]. It seems clear that the balance between applying aggressive measures and poor patient prognosis is a concept that is widely accepted in our group. Recently Cabré et al proposed a model showed that in population with multiorgan failure those older than 60 years and with SOFA score higher than 9 for at least 5 days were unlikely to survive [19].

Like Wood et al [14] and Smedira et al [2] we found that suffering was not a principal factor when making end-of-life decisions. Costs were not included as a limiting factor because we did not consider them decisive, as reflected in other studies conducted, like ours, in public centers financed by the national social security system [13,16]. However, it is true that when withholding life-support

measures, the most aggressive and costly were considered (mechanical ventilation followed by renal replacement techniques).

There is regional and international variability in the approaches to end-of-life care. Randall and Vincent report the end-of-life care requires adequate training, good communication between the clinician and family, and the collaboration of a well functioning interdisciplinary team [20.] More studies are necessary to investigate the attitude of the medical teams, the perceptions of the patients and their family members, prognosis, future quality of life, etc, as well as clearer ethical and legal criteria to establish guidelines to support and standardize application of LC with the ultimate aim of providing patients with a fundamental right—a dignified death.

Our study is subject to several limitations that might interfere with the interpretation of the results. This was a prospective, observational study in which the attitudes of the physicians may have been influenced by knowing that they were under observation. Thus the patient records may have been filled out with greater care or the families consulted more often, giving the appearance of a longer decision process than in other studies. However, the general impression of in our unit is that our attitude before and after the study did not change significantly. In addition, we have not recorded important data such as the participation of nursing staff, religious orientation, degree of relationship of the family members who agree on decision making with us, etc. Likewise, we have not recorded the patients for whom a do not resuscitate order was applied. This could mean that both the number of patients to whom LC was applied and the associated mortality are lower than other studies.

Conclusions

In conclusion, the most commonly applied type of LC was withdrawal of life support. We did not find any factors on admission predictive of the choice of type of LC. Withdrawal of life support was more strongly related to mortality than withholding.

Further studies are required in this field to help the clinician in making decisions that are still difficult due to the lack of clear standars on the futility of certain treatments

List of abbreviations

APACHE, Acute Physiology and Chronic Health Evaluation; ICU, intensive care unit; LC, limitation of care; SOFA, Sequential Organ Failure Assessment.

Keys messages

Intensive Care Service should establish protocols of withholding and withdrawing in your clinical practice

There aren't factors on admission predictive of the choice of type of LC.

Competing interests

The authors declare that they have no competing interests.

This article there are not financial interests.

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Table 1. Characteristics of the population according to type of limitation of care

	WDLS	WHLS	P
Number	64	33	
Age	71.3 ± 11.8	71.8 ± 16.9	NS
Sex, female	21 (32.8%)	13 (39.4%)	NS
APACHE II	21.6 ± 7.3	20.6 ± 6.9	NS
SOFA on implementing LC	8.4 ± 3.8	7.7 ± 4.3	NS
Stay in ICU (hours)	313.5 ± 401.9	240.4 ± 172.9	NS
Stay until decision made (hours)	273.2 ± 400.5	144.2 ± 166.2	0.02
Stay from decision until death or discharge from hospital (hours)	40.5 ± 7.3	96.3 ± 70.3	0.01
Hospital stay (hours)	399.8 ± 433.5	377.1 ± 321.6	NS
No. organs affected initially	2.6 ± 1.5	2.6 ± 1.6	NS
Diagnosis on implementing LC (%)			
Septic shock	16 (25%)	15 (45.4%)	NS
Cardiogenic shock	8 (12.5%)	10 (30.3%)	NS
COPD	5 (7.8%)	5 (15.1%)	NS
Stroke/cerebral anoxia	24 (37.5%)	1 (3%)	NS
Respiratory distress	7 (10.9%)	0	NS
Cancer	4 (6.2%)	2 (6%)	NS
Initial multiorgan failure			
Cardiovascular	35 (54.6%)	19 (57.5%)	NS
Respiratory	38 (59.3%)	16 (48.4%)	NS
Renal	26 (40.6%)	16 (48.4%)	NS
Hepatic	20 (31.2%)	10 (30.3%)	NS
Hematologic	10 (15.6%)	5 (15.1%)	NS
Digestive	19 (29.6%)	8 (24.2%)	NS
Number of organs			
≤ 2 organs	37 (57.8%)	15 (45.5%)	0.05
3 organs	10 (15.6%)	8 (24.2%)	NS
4 organs	8 (12.5%)	6 (18.1%)	NS
≥ 5 organs	9 (14%)	4 (12.1%)	0.05
Techniques during LC			
Mechanical ventilation	38 (59.3%)	12 (36.3%)	0.02
Inotropics	5 (7.8%)	6 (18.1%)	NS
Dialysis	3 (4.6%)	0	NS
Antibiotics	25 (39%)	12 (36.3%)	NS
Artificial nutrition	18 (28.1%)	17 (51.5%)	NS
Tracheotomy	7 (10.9%)	1 (3%)	NS
Dead	61 (95.3%)	24 (72.7%)	0.003
Alive	3 (4.7%)	9 (27.3%)	

Abbreviations: WDLS, withdrawal of life support; WHLS, withholding of life support.

Table 2. Severity criteria of the patients with LC

	Dead	Alive	<i>P</i>
Number of patients	85	12	
Age (years)	71 ± 13.9	74.9 ± 13.19	NS
APACHE II	21.7 ± 7.3	17.4 ± 5.2	0.03
SOFA on implementing LC	8.5 ± 3.4	5.8 ± 3.8	0.03
Number of organs on implementing LC	2.7 ± 1.5	1.6 ± 1.6	0.04
Initial SOFA ≥ 11	31	1	0.05