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ORIGINAL ARTICLE

Limitation of Vital Support in a Chilean Pediatric Intensive Care Unit: 2004-2014

Limitación de tratamiento de soporte vital en una Unidad de Cuidado Intensivo pediátrica chilena: 2004-2014

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Abstract

Objective: Describe the frequency and characteristics of PICU patients who undergo a process of withholding or withdrawing life-sustaining treatment (LTSV), between 2004 y 2014. Patients and Method: A retrospective, observational descriptive study, using two documents for quality assessment in the PICU of Hospital Roberto del Río: 1) daily individual patient tracking log and 2) daily record of quality indicators, including LTSV, both updated daily at the morning visit. All PICU patients with an ethical dilemma during their PICU stay in which a LTSV was proposed were included. We mention patients rejected for admission in the ICU and those who died in basic units of the hospital with LTSV. Results: In 118 patients of 7821 PICU admissions (1,5%) we determined a LTSV: ONR (Non Resuscitation Order) for all of them, ONI (Non Innovation Order) in 78,8%, withdrawal of some therapeutics in 14,4% and withdrawal of active mechanical ventilation in 6,8%. The basic diagnosis was 23,7% for each neurologic and oncologic diseases. The predominant pathophysiologic condition leading to a LTSV was severe chronic neurologic damage (39%). The length of stay was threefold the mean PICU stay, with a large variability due to expectable individual factors when ethic decisions are involved. Conclusion: LTSV is feasible when the team is involved and this perspective is part of daily clinical analysis. The wide individual variability in the LTSV process is expectable in ethical decisions.

Keywords:
Pediatric critical care patients, ethics, proportionality, quality of life

Introduction

The Intensive Care Unit (ICU) emerged half-century ago, enabling progressively the replacement of vital functions and allowing to improve the survival. The aim was to act as a bridge toward the recovery of health or a decent quality of life^{1,2,3}.

The availability of intensive care and survival of different pathologies, before incompatible with life, have created a new scenario. There is an increasing number of chronic patients admitted to ICU with a special need or leaving with some limitations or disability, modifying progressively the paradigm of intensive care^{4,5,6}.

It is necessary to include an ethic analysis to daily clinical work, posing occasionally the need of a Limitation of Life-Sustaining Treatment (LLST) for some patients^{7,8}. The aim is to work taking into account what may be proportional, and sometimes not proportional or not beneficent for the patient and the society⁹.

In current medical practice, the discussion about a LLST has become an element of good and necessary clinical practices. Despite the efforts to make progress on agreeing on the concept of LLST, the indication must not only consider the prognosis of the patient, but also the very variable clinical and demographic aspects, including the culture in which the patient and the healthcare team are immersed^{10,11}.

The inclusion of the bioethical perspective as part of the clinical work aims to collaborate in the discussion about access, reasonable opportunity and use of critical care, along with the discontinuation of high complexity treatments when they do not seem to be reasonable, respecting at least the principles of non-maleficence, justice, beneficence and autonomy¹².

Chile is in a similar situation of other countries. The number of patients who may not benefit from a stay in ICU increases. The Chilean law of rights and duties in health care from 2012 accepts for terminal patients the right to accept or refuse a medical treatment¹³.

The aim of this study is to describe our experience in the process of LLST in patients admitted to our ICU between 2004-2014.

Patients and Methods

An observational and descriptive, retrospective study that addresses the period between 2004 and 2014 in the ICU of Hospital Roberto del Río, educational public health center of high complexity, that attends a pediatric population of approximately 250.000 children of the northern area of Santiago de Chile and is a referral center.

The ICU has 14 beds and Pediatric Intensivists in charge of a multidisciplinary health team. Since 2000,

different criteria of quality assessment have been implemented, including training the team in Bioethics. Four physicians and a nurse got a formal qualification in Bioethics (diplomas or Master's). At least two of them belong since then to the Hospital Ethics Committee due to their background. The prolonged daily presence of the parents accompanying their children facilitates a good communication and a fluent clinical relationship. They participate in the care of and an informed consent is requested in relevant decisions for their child.

Clinical data for the analysis were obtained from 2 reports of routine use in the ICU:

- 1. *Clinical record of daily follow-up:* contains the basic information of the patient in terms of origin, diagnosis, management, evolution, and subsequent destination. The aim is to achieve for the health team a continuity of information during the daily morning visit.
- 2.- Clinical record of quality indicators: since 2004 we register daily the refusal of patients, errors in procedures or medications, transient transfers to another unit, lack of some resource, among others. The record includes LLST considering the date, age, basic diagnosis, condition or diagnosis that motivated the decision and the type of LLST.

From these records, the cases were categorized into 2 groups: 1) patients in which the LLST was decided due to their clinical evolution in the ICU (LLST intra-ICU) and 2) patients refused to be admitted to ICU not meeting the known local admission criteria (LLST pre-ICU).

An eventual need of a LLST is raised openly during the visit by the physician in charge or a member of the team, with the reasons for it. It is discussed and analyzed with the parents and if there is a decision of LLST, this has to be specified in details and with the level of LLST. The agreement is socialized with the health team involved in the patients care. Once the proposed process is clear and fully understood, it is registered in the document of quality indicators and in the medical file, and is implemented in the presence of the parents when the general environment seems to be appropriate (see flow diagram). The Ethics Committee is always available as an instance of harmonic collaboration in controversial cases, rarely used for children in ICU given the local training. Along time the children of the group of LLST pre-ICU were evaluated in advance with higher frequency by their own health team for a greater progressive knowledge of Bioethics, and, in the case of doubts, by the Ethics Committee.

The Scientific Ethic Committee of SSMN, MIN-SAL, approved the study.

Definitions and guidelines used in this ICU

I. Definition of the process of LLST

The process of withdrawing or withholding some therapeutic measures or life-sustaining therapies considered non-proportional to the condition of the patient. The decision should be harmonic, with the parents, in an open and continuous clinical relationship. It must include a therapeutic plan to follow thereafter.

II. Conditions for a LLST analysis

- History, diagnosis, patient's condition, and clear prognosis in the medical record.
- No pending tests.
- Consensus between the health team and the family.
- Planification of the LLST process.
- Planification of the continous care (palliative care).
- Registration in the official Quality and Clinical records.
- Reassessment of the evolution (follow-up).

III. Classification of LLST

- I DNR (Do Not Resuscitate order)
- II NIO (Non Innovation Order): DNR and maintenance of measures already taken
 - III. Withdrawal of measures considered "not-proportional"

May include: parenteral nutrition, vasoactive drugs, antibiotics, immunosuppressive, replacement of vital functions, high-frequency ventilator, noninvasive ventilator, etc.

Must be maintained: basic nutrition/hydration, sedo-analgesia, and any other required therapeutic measure and comfort.

IV. Withdrawal of Mechanical Ventilation (MV)
 Maintaining: basic nutrition/hydration, sedo analgesia, and any other therapeutic or comfort
 measure needed.

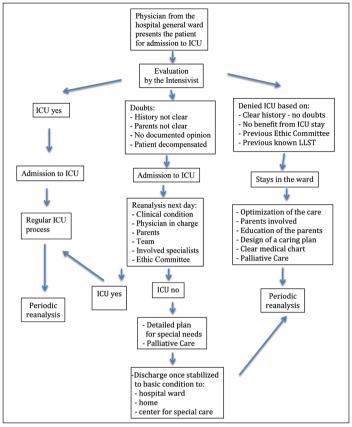
Always demanding:

- 1. Communication between the health team and the family.
- 2. Plan of integral subsequent management adjusted to the necessities.

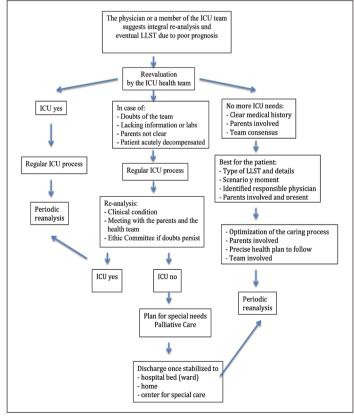
IV. Local criteria for denied admission to ICU

Each patient is analyzed individually with these criteria.

- Terminal patient
- Patient in a permanent vegetative state or minimal state of consciousness
- Patients beyond the scope of medical-surgical treatment, in consensus with the medical team, regardless the involved system.



Flujograma LTSV pre-UCI.



Flujograma LTSV intra-UCI.

Exception: if, in relation to an active unavoidable medical intervention (procedure, surgery) a decompensation of his basal state due to the procedure takes place. The exception, discussed with the team and the parents, includes a plan and explicit limits of critical care.

The information was registered in an Excel spreadsheet with the variables of interest: hospital and ICU discharges, age and gender, diagnosis, time spent in ICU (total and in relation to the LLST process), type of LLST, death or discharge, place of death, rejections. An exploratory and descriptive analysis of data was carried out in order to detect record errors and know the distribution of variables. The description of the subject characteristics, just as the type of LLST, was made using absolute numbers and relative frequencies. A graphic of the temporal trend is presented to describe the evolution of these characteristics in relation to LLST.

Results

General hospital production:

In 11 years 134.529 hospital discharges with a death rate of 0.63% occurred. In ICU, 7821 patients were attended (5.8% of hospital discharges) with a mean stay of 5.8 days and an annual mortality rate of 3.9% (304 patients, 35.9% of hospital deaths).

Another place were patients died was the hospital ward in 23.5%, 40% in the Cardiovascular ICU, and 0.6% in the Intermediate Care.

Characteristics of patients with a LLST:

In 118 ICU patients (1.5%) between 0 to 15 years a LLST was agreed (Table 1).

	Total (n)	%
Gender		
Girls	58	49.2
Boys	60	50.8
Age (years)		
0 - < 2	73	61.9
2 - < 5	11	9.3
5 - < 10	14	11.9
10 - < 15	16	13.6
15 y más	4	3.4
Health condition previous to LLST		
Healthy	14	11.9
Chronic disease	104	88.1

The most frequent primary pathology of these patients was hemato-oncologic or neurologic (23.7% both), but with a wide diagnostic variety. In 39% the pathophysiologic condition leading us to determine a LLST was a severe irreversible brain damage (Table 2).

The 118 patients with a LLST used 1915 of 47300 ICU patient days (4.05% of the total, range of length of stay 1-226 days, average 16.2 days).

In 19 patients admitted in the ICU due to medical doubts or lack of clarity in the medical file the stay was 1 day before discharge.

A 59.2% of the length of stay in the ICU (average 9.6 days) was before the decision of LLST took place.

The mean stay in the ICU after the decision of a LLST was 6.6 days, but in 49 patients the stay after LLST was only 1 day, 32 of them died (48.5% of the deaths with a LLST in ICU) and 17 are referred to a step-down facility.

Among the 118 patients with LLST intra-ICU 66 died during their stay in ICU (55.9%), which corresponds to 21.7% of the deaths. The average stay of this group was 4.3 days.

In 44 of the 304 patients who died in the ICU (14.5%) brain death was diagnosed. Only in 6 of them, all severe traumas, a LLST was decided before brain death was defined.

Classification of LLST

The basal determination in all cases of LLST was type I/DNR. The most frequent active indication was Type II/NIO order in 78.8%. The LLST type III and IV with withdrawal of therapeutic measures (partial or including ventilatory support) was 14.4% and 6.8% respectively (Table 3). An active extubation was performed in 3 patients with spinal atrophy type I and in 1 terminal cachectic patient admitted intubated from the Emergency Department. In the first years of the study period, 4 patients were maintained with minimum ventilatory support waiting for the outcome, which was considered equivalent to extubation for the analysis.

In all these cases, the parents were present and involved during the whole process, assisted by the health team.

Characteristics of patients with denied admission to ICU (LLST pre- ICU)

In 79 patients (0.02% of hospital discharges), admission to ICU was denied, not meeting the local criteria for critical care in ICU. They did not have a follow-up for this study. The cause was severe irreversible neurological damage in 76%.

Year	Neurologic	Cardiologic	Respiratory	Oncologic	Gastro- intestinal	Genetic	Metabolic	Mesenqui- mopathy	Infection
2004	6	0	5	4	1	0	0	1	0
2005	6	1	2	1	2	1	0	0	0
2006	5	2	1	5	2	0	1	0	0
2007	4	0	0	5	0	0	0	1	1
2008	5	1	0	1	2	0	1	0	1
2009	2	2	1	0	0	0	0	0	0
2010	5	2	1	3	0	1	0	0	0
2011	6	2	1	1	2	1	0	0	0
2012	4	0	1	1	1	0	1	1	0
2013	1	1	0	3	0	0	1	0	0
2014	2	0	1	2	0	0	0	0	0
Total	46 (39%)	11 (9.3%)	13 (11%)	26 (22%)	10 (8.5%)	3 (2.5%)	4 (3.4%)	3 (2.5%)	2 (1.7%)

Characteristics of patients who died in a hospital

In 11 years, 167 of the 199 patients who died in a non-critical care bed (83.9%) had a written LLST in the medical file. The most frequent underlying condition was a severe irreversible neurological damage.

There is a tendency over the years of less LLST intra-ICU cases. The number of denied admissions to ICU decreased with less requests from the hospital ward, but the rate of patients who died there with a LLST remains over 80% during the observation period (Graphic 1).

Who raised the need for a LLST was not determined for each case, considering it part of an continuous clinical process, with daily analysis of caring needs in relation to the patient condition, with an active team deliberation along with the parents. The time needed for the decision and final acceptance of LLST was variable up to 35 days for the longest (a patient with spinal atrophy I), until the parents not only accepted the need, but also decided to participate.

There was no judicial action related to the clinical process of LLST. In other words, the clinical team together with the parents advanced through the process without legal conflicts.

Discussion

This study shows the local experience and feasibility of performing a LLST in some patients with an irreversible and life-limiting pathology of ominous prognosis related to ICU. The LLST is raised for both denied admission to ICU and the limitation of the use

Table 3. Incidence of LLST 2004-2014 (number of patients per year)						
Year	DNR	NIO	Partial withdrawing	Withdrawing of mechanical ventilation		
2004	17	12	3	2		
2005	13	10	1	2		
2006	16	15	1	0		
2007	11	11	0	0		
2008	11	7	3	1		
2009	5	3	2	0		
2010	12	7	5	0		
2011	13	13	0	0		
2012	9	5	2	2		
2013	6	5	0	1		
2014	5	5	0	0		
Total	118 (100%)	93 (78.8%)	17 (14.4%)	8 (6.8%)		

of certain measures (considered by the team as nonbeneficent or nor proportional to the individual's condition) once the patient is admitted to ICU.

The analysis of a bioethic perspective, as a complement to the routine clinical and administrative analysis, is necessary and contributes to a good medical practice. It was part of a progressive training of the ICU health team since 2000, spreading to the rest of the hospital over time.

The determination of a LLST in this study was lower than in other studies. This may be explained be-

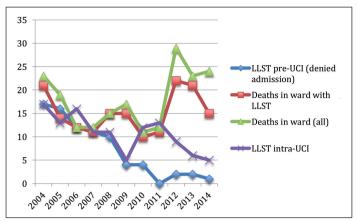


Figure 1. Number of patients with LLST intra-ICU and pre-ICU. Deaths in the hospital ward with and without LLST.

cause they don't explicit the number of cases with denied admission to ICU^{8,10,14}. Spanish experiences in Pediatric ICU show similar numbers to ours, with a LLST in 29.8% and 31.2% of deceased ICU patients^{15,16}.

The participation of the family in the LLST process in our ICU was a condition for its occurrence, a fact supported by literature¹⁷. Given the presence and permanent communication between the parents, the treating physician, and the team it is hard to determine if the physician or the parents initiated the deliberation about the need to rethink the therapeutic plan for the child, due to his adverse evolution. The presence of the family in publications from Brazil and Argentina a decade ago is lower than in ours, probably because of local cultural factors at that time (between 10% and 36%, always for us)^{8,18,19}. Taking care of the clinical relationship or physician-patient relationship provides the communicational basis that may influence a consensus^{20,21}.

Beside few patients with acute catastrophic pathology such as trauma, children in a process of limitation of LST had a life-limiting irreversible chronic pathology with a broad spectrum of diagnosis. This is consistent with the premise in bioethics that all decisions are due to an individual global health condition. However, both for the primary basic diagnosis and the motivating physiopathologic condition motivating a LLST, neurologic and oncologic pathology was predominant as expected and similar to other experiences.

The stay of patients with LLST triples our mean stay in ICU. The 59.2% of this time spent previous to LLST may reflect the effort to recover the patients before a reassessment takes place. Nevertheless, a group of 19 patients, although admitted for clinical uncertainty, stood only 1 day in ICU and were then referred to another unit with a new plan, adapted to their clinical condition.

It is remarkable that the LLST does not imply death in ICU, with 44.1% being able to be delivered to the ward for proportional care.

In patients with brain death LLST was not raised. In six mentioned brain dead patients a LLST is determined due to the catastrophic condition before brain death was diagnosed. This reference is made because this differs from other experiences.

Unlike other experiences, we addressed a LLST starting from a DNR for all, accompanied in specific cases by a NIO or withdrawing, revealing an active attitude in bioethics terms. The reason is that the aim of the Cardio Pulmonary Resuscitation (CPR) goes beyond the recovery of vital signs²².

In relation to denied admission to ICU, over the years a progressive decline of the request to the Intensivists, with maintenance of a high proportion of the deaths occurring in the wards in patients with a LLST draws attention. Patients who died with LLST in a basic bed due to a decision of the team double those with a denied admission who stay in the ward. This may reflect an improved bioethic knowledge of the physicians of the hospital, accepting limits, or a request to the Ethic Committee of the institution when necessary.

The need of a LLST in some patients of ICU, going over to palliative care with a fair and reasonable treatment under a multidisciplinary support, is sometimes unavoidable^{9,21}. The factors that influence the process are diverse, including cultural, educational, and spiritual aspects. This leads to an, expected, great variability in the decision-making process round the world^{12,23,24,25}.

The discussion about alternatives and "what to do" in life-limiting pathologies is increasing^{7,8,18,26,27}. Factors as an individual personal concept of life quality, culture, religion, prognosis, family's opinion, local availability of critical care, increasing health cost, rational use of ever-scarce resources, among others, can influence the acceptance or restriction of admission to an ICU in different scenarios around the world.

Generating a global framework of medical and professional responsibility, the President's Commission of United States established in 1983 that patients do not have the right to require professional services incompatible with lex artis²⁸. This has been ratified in the Andalucía Guide⁶, establishing that the judgment about LLST and futility is primarily professional.

There is still a wide variability both in the indication and in the process analyzing an eventual LLST. The published works show different perspectives, which make them hard to compare. Multicenter international experiences show a wide disparity in classification, systematization, and criteria to determine a LLST²⁴.

There were no trials or lawsuits during the study

period, which at least indicates that we were able to achieve a consensus between the parents and the team.

To our knowledge, this is the first experience in pediatrics that describes a pediatric population in which a process of LLST is proposed and analyzed in the context of quality assessment.

The recommendation is to progress in the inclusion of the bioethic knowledge and analysis in daily clinical work, enhancing the clinical ability to take the best decision, with fundaments, for the management of each patient as an unique individual.

Conclusion

Performing a LLST is feasible when the team incorporates this perspective into the daily clinical work. A wide variability of population characteristics was observed in terms of age, diagnosis, length of stay, and highlights the importance of the individuality in ethical matters. The NIO in patients with irreversible severe brain damage was the most frequent LLST. The admission request to ICU of patients with bad prognosis has decreased progressively while the decision to make a LLST in the ward increased. The decision of a LLST is not equivalent to death in the ICU.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed ac-

cording to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

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Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

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