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ORIGINALARTICLE

Futility analysis of treatment prolongation in patients with end-stage chronic kidney disease from medical perception

Análisis de la futilidad sobre la prolongación del tratamiento en pacientes con enfermedad renal crónica en fase terminal desde la percepción médica

Análise da futilidade do prolongamento do tratamento em pacientes com doença renal crônica terminalda percepção médica

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ABSTRACT

Introduction: chronic kidney disease is a pathology that reduces the expectancy and quality of life of patients. Doctors are primarily responsible for preserving the patient's life and are responsible for shared decision making. **Objective:** to analyze the perception of medical personnel regarding the prolongation of renal replacement treatment in patients with chronic kidney disease in the terminal phase in the dialysis unit at the General Teaching Hospital of Ambato, Ecuador. **Method:** a qualitative research was carried out, with a semi-structured interview that consisted of questions guided by the theory-hypothesis of the topic. The study sample was made up of doctors from the Dialysis Unit, responsible for the clinical management of patients with chronic kidney disease undergoing dialysis treatment. The protocol was approved by the Human Research Ethics Committee of the Pontificia Universidad Católica del Ecuador, with approval code CEI-88-2020. **Results:** the thematic analysis showed that doctors need to comprehensively ethically and clinically evaluate the patient before maintaining or terminating hemodialysis; the level of knowledge and ethical-clinical skills influence decision making. Furthermore, the application of Beauchamp and Childress' bioethical principles to decision making is vague, morbidly confusing, and therefore irrelevant to this type of decision. **Conclusions:** doctors perceive the need to comprehensively evaluate the patient, taking into account not only the physical but also the psychological, social and economic condition of the patient. They consider it unnecessary to maintain hemodialysis treatment in a patient with a deteriorated quality of life, with reduced autonomy and whose prolonged treatment could cause more pain than benefit.

Keywords: medical futility; professional autonomy; personal autonomy; clinical decision making; principled ethics

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RESUMEN

Introducción: la enfermedad renal crónica es una patología que disminuye la expectativa y calidad de vida de los pacientes. Los médicos son los principales encargados de preservar la vida del paciente y son responsables en la toma de decisión compartida. **Objetivo:** analizar la percepción del personal médico sobre la prolongación del tratamiento sustitutivo renal en los pacientes con enfermedad renal crónica en fase terminal en la unidad de diálisis en el Hospital General Docente de Ambato, Ecuador. **Método:** se realizó una investigación cualitativa, con una entrevista semiestructurada que constó de preguntas guiadas por la teoría-hipótesis del tema. La muestra de estudio estuvo compuesta por los médicos de la unidad de diálisis, responsables del manejo clínico de los pacientes con enfermedad renal crónica en tratamiento de diálisis. El protocolo fue aprobado por el Comité de Ética de investigación en Seres Humanos de la Pontificia Universidad Católica del Ecuador, con código de aprobación CEI-88-2020. **Resultados:** el análisis temático evidenció que los médicos necesitan evaluar ética y clínicamente de manera integral al paciente antes de mantener o dar por terminada la hemodiálisis; el nivel de conocimiento y habilidades ético-clínicas influyen en la toma de decisiones. Además, la aplicación de los principios bioéticos de BeauchampyChildress para la toma de decisiones es vaga, moramente confusa y por tanto irrelevante para este tipo de decisiones. **Conclusiones:** los médicos perciben la necesidad de evaluar integralmente al paciente, al tener en cuenta no solo la condición física sino psicológica, social y económica del paciente. Consideran innecesario mantener un tratamiento de hemodiálisis en un paciente con una calidad de vida deteriorada, con autonomía reducida y cuyo tratamiento prolongado podría causarle más dolor que beneficio.

Palabras clave: futilidad médica; autonomía profesional; autonomía personal; toma de decisiones clínicas; ética basada en principios

RESUMO

Introdução: a doença renal crônica é uma patologia que reduz a expectativa e a qualidade de vida dos pacientes. Os médicos são os principais responsáveis pela preservação da vida do paciente e pela tomada de decisão compartilhada. **Objetivo:** analisar a percepção do pessoal médico sobre o prolongamento do tratamento renal substitutivo em pacientes com doença renal crônica em fase terminal na unidade de diálise do Hospital Geral Universitário de Ambato, Equador. **Método:** foi realizada uma pesquisa qualitativa, com entrevista semiestruturada composta por questões norteadas pela teoria-hipótese do tema. A amostra do estudo foi composta por médicos da Unidade de Diálise, responsável pelo manejo clínico de pacientes com doença renal crônica em tratamento dialítico. O protocolo foi aprovado pelo Comitê de Ética em Pesquisa com Seres Humanos da Pontifícia Universidade Católica do Equador, com código de aprovação CEI-88-2020. **Resultados:** a análise temática mostrou que os médicos precisam avaliar o paciente de forma abrangente, ética e clínica, antes de manter ou encerrar a hemodiálise; O nível de conhecimento e as competências ético-clínicas influenciam a tomada de decisão. Além disso, a aplicação dos princípios bioéticos de Beauchamp e Childress à tomada de decisões é vaga, mórbidamente confusa e, portanto, irrelevante para este tipo de decisão. **Conclusões:** os médicos percebem a necessidade de avaliar o paciente de forma abrangente, levando em consideração não só a condição física, mas também a psicológica, social e econômica do paciente. Consideram desnecessário manter o tratamento de hemodiálise num paciente com qualidade de vida deteriorada, com autonomia reduzida e cujo tratamento prolongado poderia causar mais dor do que benefício.

Palavras-chave: futilidade médica; autonomia profissional; autonomia pessoal; tomada de decisão clínica; ética baseada em princípios

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INTRODUCTION

According to the World Health Organization (WHO)(1) chronic degenerative diseases are diseases of long duration and generally of slow progression, towards a terminal stage that will eventually end in death; among them is chronic kidney disease (CKD) defined as the progressive, permanent and irreversible loss of glomerular filtration rate over a variable period of time, sometimes even years.[2]

The WHO and the Latin American Society of Nephrology and Hypertension estimate that in Latin America there is a prevalence of CKD of 650 patients per million inhabitants. In Ecuador, statistics from the Ministry of Public Health up to 2015 reveal 11460 patients with CKD, 10 % receive peritoneal dialysis treatment and 90 % hemodialysis; with an estimated life expectancy of 5 to 15 years in patients with treatment.[3]

The progression of the disease and comorbidities represent a challenge for the health care team regarding the choice of the ideal treatment for each patient. The bioethical analysis in the application of clinical treatments on each patient allows reflection, discussion, comparison and dialogue in the decision making process regarding whether to maintain or suspend clinical intervention in those in the terminal phase.[4] Physicians come to present ethical conflicts when choosing the appropriate treatment for each patient due to the endless number of therapeutic procedures that currently exist and that prolong the patient's life.[5]

Prolonging the life of a patient whose organs do not function adequately without support further deteriorates his or her physiopathological, psychological and emotional condition, leading to futility or therapeutic overzealousness.[6,7] Since the emergence of the autonomist context, both patients and their families have demanded the application of treatments that are of little use or of no benefit to the patient's life, resulting in health personnel invoking the term "futility".

The concept of futility refers to the application or prolongation of a procedure or treatment that is useless, ineffective or does not present any effective short or long term benefit for the patient's life.[8] Since the emergence of the term, it has allowed physicians to free themselves from the obligation to apply useless treatments and the patient would be free to refuse or not the application of these treatments.

It presents a number of problems when it is used. First, statistically, the measurement of the probability of survival of applying a treatment is based on the clinical experience of the medical staff in charge of the case, and limited figures between 0 and 50 % are considered, there being a clear discrepancy in establishing a standard probabilistic value to measure the probability of success of a treatment. Second, the application presents several value judgments, since it can be applied only physiologically, which leaves aside the psychological and emotional aspects of the patient.

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Third, the term is subjective and ambiguous, it opens the door for health personnel to justify their unilateral decisions regarding a patient's life and rules out the patient's autonomy in deciding whether or not he/she wishes to undergo treatment and it has been considered that giving this freedom of decision to medical personnel could be manipulated to avoid providing information or rule out the participation of the patient and/or his/her family/legal representative.[9,10]
Sánchez González[9] distinguishes three types of futility:

a) Physiological: treatment incapable of producing a positive physiological effect, or change in the patient.
b) Statistical (probabilistic or quantitative): very low or null probability of achieving a benefit or survival in the patient.
c) Qualitative: difficulty in achieving any benefit or survival goal.

There is no doubt that in order to act ethically in accordance with the principle of justice, the management of CKD should be done in priority order in terms of efficiency and efficacy: prevention, transplantation, peritoneal dialysis and, finally, hemodialysis.[5] However, hemodialysis is the main renal replacement treatment and both public and private access is available. Public access is financed by state funds in both developed and developing countries, a reason that responds to the decentminimum of public health care, i.e. the right of every individual to have access to a free and quality health service.

These ethical questions and confusions among medical personnel lead to conflict in the application of the bioethical principles established in the principled theory of Beauchamp and Childress: "autonomy, non-maleficence, beneficence and justice".[11] The principles are based on the bioethical principle on which all ethics of clinical practice and research is based: respect for human dignity; and they respond to a common morality that defends an ethics of reasonable and enforceable minimums for all individuals.

The interruption or non-application of this treatment in a patient with end-stage CKD should be done after clinical evaluation and based on the ethical principle of non-maleficence, avoiding acting when the prejudice is greater than the possible benefit that the patient would receive; that is, the limitation of hemodialysis in the terminal patient can be carried out respecting the ethical principles of non-maleficence, autonomy, justice and beneficence.[9] However, respect for the patient's decision is less when it is necessary to act to achieve the maximum benefit despite the fact that the patient is not in total agreement, which leads to futility and violates the principle of nonmaleficence.[5,12]

Autonomist ethics considers that decision making should not be unilateral, but shared, giving the patient participation in decisions and giving greater weight to his preferences or wishes and wills, and considering it as part of the patient's right to obtain all the desired information on his state of health in order to actively participate in the decisions regarding the interventions he will receive.[13,14]

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Although in many occasions it is not possible to reach an agreement, because due to emotional and in some cases cultural issues, it is more important for the family to keep the patient alive than to assume the possible long-term consequences of maintaining him/her with a treatment that accelerates thedeterioration of his/her life[15,16]; therefore, the decision making should not be absolute but with certain restrictions(9) that establish the limits that avoid therapeutic ingratiation and futile treatments.[14]

Physicians' perceptions of futility show that they focus on evaluating the quality and quantity of life, the psychological effects and the possible risks-benefits expected from maintaining the intervention in patients.[9] Furthermore, it is important to know that part of the perception of the medical team involves their values and emotions, which can influence the decision on the patient's life, but which can be "perfected" with clinical practice and experience.[2] Therefore, the medical team must recognize and assume their values and ethical perceptions based on professional experience and what is ethically correct in order to make the decision that fits the patient's clinical condition and personal situation. In this sense, the medical staff should always establish therapeutic objectives for the benefit of the survival, preservation or restoration of the quality of life of these patients.[12]

As they are patients with reduced autonomy, health personnel must take this as a determining factor in decision making, based mainly on respect for the most essential right of every human being: the right to life. However, the health care team should be clear from the technical point of view that, although clinical treatment should be withdrawn, it is much more complicated to make such a decision, since the execution of this practice leaves them with a feeling of letting the patient die.[6]

Motta de Morais,et al. [17] reveal that on many occasions this "feeling" is due to the terminological confusion that both medical students and physicians have when defining the prolongation of treatment and life; and it has been shown that its correlation with the time that the physician shares with the patient and the patient's age, results in factors that trigger painful feelings such as the feeling of helplessness, and/or increased anxiety and uncertainty[18] which directly affects decision making in the continuity or suspension of medical treatments that affect the estimated time of life of the patient.

In Ecuador, studies on the bioethical implications behind the perceptions of health professionals on this topic are scarce. This study seeks to answer the question: What are the perceptions of medical personnel on the prolongation of renal replacement therapy in patients with end-stage chronic kidney disease in the dialysis unit?

METHOD

The research used a qualitative methodology, with a semi-structured interview consisting of questions guided by the theory-hypothesis of the topic.

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The population consisted of medical professionals working in the dialysis unit of the General Teaching Hospital of Ambato, Ecuador, who are responsible for the clinical management of patients with chronickidney disease undergoing dialysis treatment. Fifteen interviews were needed to achieve information saturation.

The analysis was carried out from the perspective of thematic analysis and was tabulated using Atlas.ti[9] software.

The protocol was approved by the Human Research Ethics Committee of the Pontificia Universidad Católica del Ecuador, with approval code CEI-88-2020, and the semi-structured interviews were carried out after the authorization obtained in the informed consent.

RESULTS

40 % of the participants were between 21- 30 years old, 20 % between 31-.40 years old, 15 % between 41- 60 years old, and 1 % over 60 years old. 60 % of the physicians were of female gender and had a medical specialty, among: Nephrology, Internal Medicine, Cardiology, Gynecology and Intensive Care. Physicians' perception of futility was reflected in five categories:

Dialysis unit admission factors

Physicians considered that there are extrinsic factors that influence when prioritizing the admission of a patient to receive treatment: family support to the patient, the patient's personal economic resources, social factors and the physician's point of view about each patient's health condition, as mentioned in the following sentence: "since, for example, in patients over 90 years of age who have some pathologies that are difficult to control, there should be a good assessment of whether or not they can enter dialysis"; they also considered that the State is the one who provides the necessary economic resources to public institutions to ensure access and maintenance of renal replacement treatment.

At the same time, admission will also depend on intrinsic factors, such as: life expectancy, adherence, psychological state of the patient, efficacy of the treatment, self-determination and the patient's right to autonomy to receive or not the treatment, taking into consideration that "depending on the patient, he has the right to decide whether or not he wants to continue certain treatment" (Figure 1).

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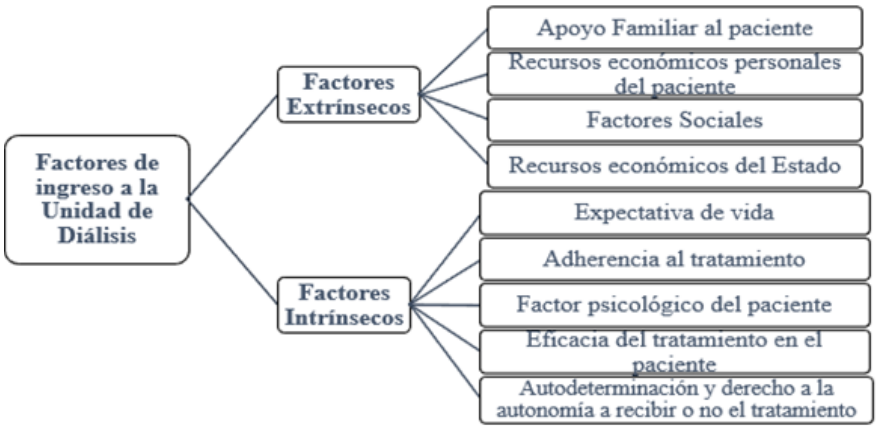

Figure 1 Factors of admission to the Dialysis Unit, Hospital General Docente de Ambato.

Treatment prioritization

According to the interviews, two subcategories were established to determine prioritization:

1) According to the personal perspective of each patient: age, family support and adherence to treatment, for example - "if it is a patient who is young and his quality of life is going to be good and he is an economically active patient obviously those patients have to be prioritized over another patient who does not have the same conditions."
2) According to the Institution: physician's point of view, local epidemiological analysis, technical, human and economic resources. - The institution should be able to determine the incidence and prevalence of these patients so that the economic aspect can also be planned accordingly" (Fig. 2).

Figure 2 Medical perception of the prioritization of renal replacement therapy in the Dialysis Unit, Hospital General Docente de Ambato

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Prolongation of treatment

The physicians considered that the patient should be evaluated individually when fulfilling their duty to maintain life and consider all the factors related to the patient "to continue giving the patient the therapy until the last moment of life, improving the whole global sphere, the whole integral sphere of the person as a patient. So as physicians, what we have to do is to give him quality of life and present him with all the alternatives we have to do so." The patient's decision regarding the prolongation of treatment contains ethical dilemmas that they must resolve before making a decision (Figure. 3).

Figure3 Physician perception of treatment prolongation in patients with end-stage chronic kidney disease

Perception of the patient's quality of life

Part of the competencies of the medical team is to evaluate the patient's quality of life in order to guarantee the continuity of treatment since "this is what leads us to decide whether or not the patient continues the therapy, because if the quality of life is worsened by the therapy, there is no family support or it is very difficult, the patient himself does not want to and has a deplorable quality of life, we set up a dialysis or therapy committee and thus we decide whether or not to continue the therapy". Therefore, "the technical criterion, the medical criterion, the scientific criterion must prevail so that it can influence the decision to do dialysis or not to do dialysis and thus prolong life"; and to consider within the evaluation of the quality of life the perspective that the patient has on this to avoid falling into therapeutic incarceration (Figure 4).

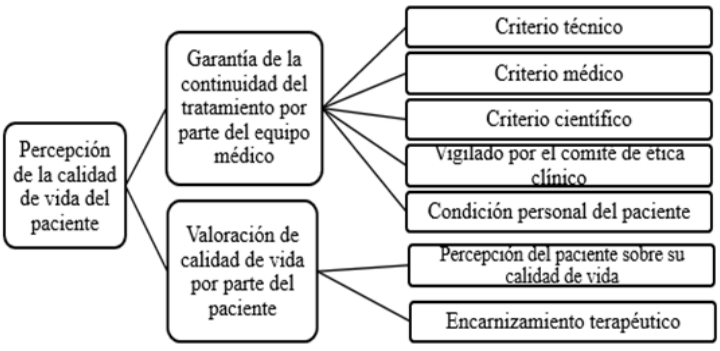

Figure 4 Medical perception of the quality of life of patients with end-stage chronic kidney disease

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Decision on the patient's life

The perceived futility of the medical decision depends on the patient's autonomy, quality of life and treatment. The decision is the patient's own and based on the patient's own factors: quality of life, economic factors, comorbidities, life expectancy, emotional and psychological condition, family support, religious beliefs; "at the end of the day it is the patient who makes the final decision and it is based on him/her that the decision will be made". However, they considered that the decision of the multidisciplinary team should be ethical, that is to say, "within the bioethical principles, the most important of which is patient autonomy. That allows you to follow equally with the other principles of beneficence, non-maleficence, justice and equity" (Figure 5).

Figure 5 Physician perception of life decision-making in patients with end-stage chronic kidney disease

DISCUSSION

Physicians perceive it necessary to ethically and clinically evaluate an end-stage patient in a comprehensive manner before maintaining or terminating hemodialysis, since they agree that, although its general objective is to maintain life, intervention should be limited in patients whose condition is very deteriorated.[19] Nevertheless, several studies agree that futile therapeutic intervention should not be instituted, but neither should it be withdrawn since it is considered therapeutic obstinacy and therefore an act of incorrect clinical practice.[20]

The level of knowledge and ethical-clinical skills is a necessary factor in making decisions about the life of patients with end-stage CKD, since they usually present irreversible or terminal comorbidities;[21]when deciding whether or not to keep the patient on hemodialysis treatment, physicians consider the age and comorbidities of the patient as essential to avoid performing a futile intervention that would prolong the patient's pain.[22,23]

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The physicians consider that there are two types of factors to be considered for admission to hemodialysis treatment: extrinsic, which are related to access to health services offering suchtreatment, considering the greatest limitation to be sufficient material resources to attend all patients and to guarantee integration and consolidation of shared decision-making as an attribute of quality and social legitimacy of the services.[13] Intrinsic or patient-specific, such as: age, life expectancy, comorbidities, psychological factors, autonomy and future quality of life, of which they considered the patient's decision to maintain or withdraw treatment to be fundamental, although this could conflict with the physician's clinical decision, since many patients choose to terminate treatment, even though they may have a longer life expectancy in the future.[22]

As for the prioritization of treatment, it depends largely on the health institution, since in the case of public institutions, despite offering the service, they may not have sufficient technical, human and economic resources to cover the demand of patients with CKD. It is essential that the health team knows how to establish the correct clinical diagnosis in order to make a timely referral to the specialist for a comprehensive clinical assessment and thus facilitate and anticipate the correct choice of treatment.[22,23]

On the other hand, the choice of treatment should take into account the patient's wishes, physiological, psychological, emotional, socioeconomic and home management of the disease. Integrating each of these factors will improve care to define the planning, adherence and continuity of treatment for each patient.[24]

Regarding the perspective on the prolongation of treatment, the medical staff considers that there are three main factors that could lead to prolonging hemodialysis in the patient with end-stage CKD: technical and ethical competence of the physician, several authors consider that it should be regulated and subject to rules to guarantee the protection of the patient's rights for a correct decision making on the life of the individual, which should be done in consensus with the entire health team treating the patient to justify the prolongation or suspension of clinical treatment through a management protocol and for assertive communication to family members, avoiding procedures that result more painful to the patient.[25,26]

Decision-making supervised by an ethics committee allows the patient's rights to be respected, the application of ethical principles to prevent the health team from violating the patient through futile treatments or slow passive euthanasia; it is also the nexus for communicating all the information about the patient to family members in a clear and simple manner.[27]

Factors directly related to the patient, the physician in the first instance considers the physical-physiological-psychological condition and the integral sphere of the patient to decide the type of intervention, since in a patient in terminal phase with comorbidities to continue the treatment would accelerate the process of death; however, they mention that in many occasions in spite of the physician expressing his desire to terminate the intervention in these conditions, the patient and/or his relatives express the desire to continue with the intervention in spite of the risks that this represents in the short and long term.[28,29]

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Ethical issues

Several authors agree that the decision about the patient's life is an integral decision between the patient, his family members or responsible delegate, the multidisciplinary health team and the hospital ethics committee with the aim of always acting in benefit of the patient's health and integrity.[25] In the application of bioethical principles, the principle of autonomy prevails, that is, the patient's self-determination about his own life, the desire to continue or not the treatment for personal, religious or social reasons; being the responsibility of the health team to give all the necessary information to the patient.[21,30] It is the responsibility of the treating physician to guide the patient and his family members to make an informed decision, and not only through the signature of the informed consent as a legal proof of acceptance of the intervention.[31] It is the responsibility of the treating physician to guide the patient and his family for an informed decision, and not only through the signature of the informed consent as a legal proof of acceptance of the intervention.

It is the responsibility of the treating physician to guide the patient and his family in making an informed decision, and not only through the signature of the informed consent form as legal proof of acceptance of the intervention.[31] Likewise, the interviewees reflect that in order to guide the patient in this decision it is necessary for them to be trained in bioethics and clinical management protocols in decision-making.

The clinical assessment should measure by means of scales the patient's perception of his own quality of life to determine the prolongation or suspension of hemodialysis, mainly in older adult patients who usually depend on third parties to perform any activity, perceiving that the treatment generates more pain than benefit to their health, are disoriented, and are subjected to the hospital due to the complications of the disease and/or its comorbidities.[32] In addition, the need to establish the patient's own perception in order to reevaluate the clinical intervention and guarantee the continuity of treatment through three criteria became evident: technical, professional (decision and intervention proposals, ethical-clinical skills, assessment of transfer to critical care or palliative care), scientific (clinical management protocols for CKD, scientific evidence).

However, in order for this guarantee to be respected, since 2010 the medical practice guidelines on dialysis promote that all medical activity for the benefit of the patient must be supervised and approved by a hospital care ethics committee to ensure that patient autonomy prevails, the right to have a dignified life and death; a factor that is necessary and must be implemented in the institution.[33]

From the perspective of the principled theory of Beauchamp and Childress,[34] the application of the principles for the resolution of ethical conflicts over the patient's life can be theoretically useful, since it would make it possible to support medical decisions ethically and legally. However, the literature considers that the application of this theory as a determinant for decision making is vague, morally confusing and therefore irrelevant for this type of decision where the benefits and burdens of short and long term treatment for the patient must be weighed.

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For a responsible and ethical decision making on the patient's life, the use of the Hastings Center Guide is recommended, which considers that there are no treatments or curative measures that are intrinsically ordinary or extraordinary,[35] which puts into consideration that the assessment of the treatment to be applied must be made according to the patient's specific situation; and the three steps of Calipari, which allow a process of moral assessment of the patient:"

1) Evaluate the proportionality of the treatment based on the analysis of clinical factors and medical assessment.
2) Subjective analysis of the patient.
3) Qualifying synthesis according to four possible resolution scenarios".[36]

The technological advances of the last decade have facilitated the prolongation of the life of people through life support treatments of certain organs; however, the application of such treatments can be futile when applied in terminally ill patients whose life expectancy and survival is short.

As for knowledge of bioethics, academic training has trained them to maintain the patient's life at all costs, despite the fact that the patient may express a desire to terminate the treatment, which shows little knowledge of bioethics, thus putting at risk the dignity and respect for the patient's autonomy of decision; this is why they should be trained in clinical ethics.

The interviews showed that bioethical principles are applied when making decisions on the prolongation of treatment in these patients, from the admission assessment to their discharge; therefore, such assessment should respond to the principle of non-maleficence, considering all possible treatment options, since this way they guarantee access to a quality health service to patients.

As for the principle of justice, the adequate fulfillment of this principle depends in part on the resources available to the hospital, since if the institution does not have such resources, the right of all patients to access health services is violated and, therefore, it would have to further limit who can or cannot access the service, categorizing as a priority those patients with a greater probability of long-term survival and without comorbidities in an advanced or terminal stage.

CONCLUSIONS

Physicians perceive the need for an integral evaluation of the patient, taking into account not only the physical condition but also the psychological, social and economic condition of the patient, since they consider that a patient with terminal chronic kidney disease who does not have family support, with an economic condition that limits access to both drugs and services, with terminal comorbidities that would accelerate the process of death or with psychological problems that could harm the maintenance of dialysis treatment could not be admitted to a dialysis unit. In addition to considering it unnecessary to maintain hemodialysis treatment in a patient with a deteriorated quality of life, with reduced autonomy and whose prolongation of treatment could cause more pain than benefit.

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