Bioethics: principles and recommendations on the application of dialysis - palliative care

Gustavo Adolfo Marín Ballestas

Abstract
The prevalence of chronic kidney disease in Colombia increased notoriously in the past years, reaching a number of 510 patients per million population. Both the initiation of and withdrawal from dialysis are a frequent topic of discussion that creates conflict in the search for a balance between quality and quantity of life. We must, therefore, evaluate the criteria, principles and recommendations whereby we make prudent decisions to withdraw patients from dialysis, when we consider that it is a futile treatment. After the withdrawal from dialysis, we must then introduce, as a therapeutic complement, palliative care to relieve pain and symptoms.

Key words: End-stage renal disease, ethical issues, principles and recommendations, withdrawal from dialysis, palliative care (MeSH source).

Bioética: principios y recomendaciones en la aplicación de diálisis - cuidados paliativos

Resumen
La prevalencia de la enfermedad renal crónica en Colombia ha ido en aumento, llegando a una cifra de 510 pacientes por millón de habitantes. Tanto el inicio como la suspensión de la diálisis es un frecuente tópico de discusión que crea conflicto en la búsqueda de un balance entre calidad y cantidad de vida. Debemos evaluar, entonces, los criterios, principios y recomendaciones a través de los cuales debemos tomar decisiones prudentes al suspender la diálisis en los pacientes, cuando consideramos que sería una terapia fútil. Una vez suspendida la diálisis debemos integrar, como complemento terapéutico, los cuidados paliativos aliviando el dolor y los síntomas.

Palabras clave: Enfermedad renal crónica, problemas éticos, principios y recomendaciones, suspender diálisis, cuidados paliativos (fuente DeCS).

“Neither as a man, nor as a physician could he get used to see their fellows die”.
A.Camus

Approximately, more than 600,000 people in the United States receive dialysis treatment as a result of end-stage renal disease.

In Colombia, about 21,000 patients are on dialysis treatment. Our prevalence is on the order of 510 patients per million population (Medellin, 794 patients/million; Antioquia, 615 patients/million). Global figures reveal that more than 800 patients per million population have end-stage renal disease. But, despite beginning their dialysis, the patients have short life expectancy because of their pathology. Adjusted annual mortality rate in the USA is 20%-25%.

Both the initiation of and withdrawal from dialysis is a frequent topic of discussion that creates conflict in the search for a balance between quality and quantity of life. And, additionally, some nephrologists are not completely certain about under what ethical standards and what kind of clinical scenarios the analysis to make that decision should be performed. Between 2001-2010, according to the US Renal Data System (USRDS), withdrawal from dialysis was considered the third cause of death, after cardiovascular disease and infectious complications.

Are these well-made decisions? Will patients have a high comorbidity?

Most patients with end-stage renal disease keep an acceptable quality of life. However, when they remain long periods on dialysis they experience a gradual decline in this, raising the concern of continuity of many and important comorbidities. In the USA, an analysis on 2,746 deaths showed that the 26% of patients’ dialysis were withdrawn before dying, however, uremia was the cause of death only in 4% of these patients. 30% of the patients died in less than three days after withdrawal from dialysis. In their publication, Birmele et al. evidenced death in less than 5 days after discontinuation of therapy. Of the 40 patients, 32 were participants at the time of the decision. Thus, the dichotomy of refusing or discontinuing dialysis treatment in patients arises.

More than 50 years ago, when dialysis and renal transplantation emerged as treatment options for surviving end-stage renal disease, younger and healthier patients were subjected to this type of therapy to save their lives. Later, the aggravating circumstance of an increase of the elder population suffering debilitating medical complexes and problems arose in the last 25 years. For elderly patients with end-stage renal disease and congestive heart failure, annual mortality approaches 60%, with a life expectancy below 6 months, a prognosis as poor as AIDS’s or advanced cancer’s.

I’ll start this paper with the statement of the frequency of appearance, in our environment, of end-stage renal disease, mortality and the emergence of ethical problems with the appearance of dialysis. This paper will deal as well with political and socio-economic aspects in different countries and their implications; and with dialysis treatment in elderly patients to evaluate, then, the criteria, principles and recommendations whereby we must make prudent decisions to withdraw patients from dialysis, when we consider that it is a futile treatment.

Finally, once we evaluate both the perception of patients and their families about the symptoms to come in their last days, once they are withdrawn from dialysis, we must integrate palliative care as a therapy complement to improve the quality of life of both patients and their families, reaffirming life and considering dying as a normal process, not advancing or delaying death, but relieving pain and symptoms presented by the patient and accompanying the evolution of the disease.

This also allows us to address the patient holistically in psychological, emotional and spiritual aspects, and, provides a support and education system that helps families to cope with the disease so that they are able to be a support, take care of them effectively, and to cope with the pain involved in watching the suffering and loss of their loved ones.

Therefore, it is my goal to give recommendations or guidelines to assist the nephrologist in the process of making decisions such as the withdrawal from dialy-
Euthanasia or renal replacement therapy (RRT), taking into account certain parameters as instruments to support the decision, including patients, their family or their legal representative. Once the decision of stopping dialysis therapy is made, palliative care as alternative therapy is introduced to control the symptoms, such as pain, anguish, and respiratory distress, and, at the same time, to give support to the patients’ families.

All these recommendations, such as palliative care, contribute to the development of an optimal and comprehensive attention to the pain of every human being. Being Bioethics “the systematic study of human behavior in the areas of life and health care sciences, provided this behavior is examined at the light of moral values and principles”4, it must, therefore, establish the guidelines in the exercise of making decisions in our daily practice.

Ethical problems in dialysis5: When we talk about acting ethically we usually mean that we have acted conscientiously. Through our conscience, we judge whether a particular act is good or bad or, what is the same, whether the object of that act is good, or bad or whether the object, purpose and circumstances are good or bad. But, in turn, these acts are good or bad regarding the moral law regulating and measuring human actions. Conscience is a reality from experience. It is therefore intellectual knowledge. True conscience is the conscience that judges goodness or badness of an act in accordance with moral principles. Hence the importance of the construction of conscience to be truly aware of the moral law6. When determining human actions, the object (what is pursued by the action), purpose (intention) and circumstances (factors or changes affecting the human action) are to be considered, and for it to be a good act, all these parameters must be good.

With the introduction of the revolutionary therapies of chronic dialysis and renal transplantation in the late 1950s and early 1960s, the enthusiasm for improving the survival rate of patients who were to die was awakened. Therefore, the appearance of a problem of conscience for doctors was evident. Faced with such demand, it was necessary to select patients for treatment. But, according to what principles? The principles were subject to controversy. The problem is difficult and will continue to be, although one can not always be completely aware of it.

-Is it ethical to select patients for dialysis? As long as the budget is allocated for the treatment of various diseases, we are certainly responsible for determining whether to initiate or not dialysis in a patient with end-stage renal disease. The exclusion based on economic aspects, personality and social utility is unacceptable. Situations where dialysis is excluded are nonuremic dementia, incurable neoplastic disease, end-stages of heart and lung disease, irreversible neurological disease, multiple organ failure with little probability of survival and the need to dominate or sedate the patient during the dialysis session to keep the vascular access properly working. These exclusions are reasonable. However, individual cases with serious problems occur.

I- Dialysis in elderly patients: In industrialized countries, the number of octogenarian patients with chronic renal failure has increased. This age segment has grown annually, 14% in the USA and 16.3% in Canada. The proportion of patients initiating dialysis aged 75 or older increased from 8.2% in 1989-1992 to 21.6% in 1998. In patients older than 80 years, the decision is more difficult, since they have multiple comorbidities and a short life expectancy. USRDS 2006 data shows that the unadjusted probability of survival at 5 years for patients on incident hemodialysis is 53.2% in patients of 40-49 years old and 18.3% in patients of 70 to 79 years old7.

Each nephrologist should assess the social scenario and functional capacity with medical pathologies, which can boost mortality or interfere with adequate and appropriate therapy, since this improves decision-making8-9. In his study, Dominique Joly evaluated octogenarians between 1989-2000 on dialysis (107 patients (group 1)) and not on dialysis (37 patients (group 2)), with a survival rate of 28.9 months in group 1 and 8.9 months in group 2. 60%
II. Recommendations for nephrologists to make a wise decision when refusing or discontinuing dialysis in patients with end-stage chronic renal disease; we must learn to say “No”:

The decision not to offer dialysis is a primary responsibility of nephrologists. If nephrologists fail in making those decisions, this affects patients and their families, the personnel in charge of dialysis and society. The condition of the patient and the medical literature on this topic must be evaluated. They (nephrologists) are able to determine whether dialysis will benefit the patient. If the evidence indicates that dialysis may cause more harm than good, nephrologists should say “no”.

The Renal Physician Association (RPA) and the American Society of Nephrology (ASN), in conjunction with representatives of multiple disciplines and organizations related to dialysis, such as patients, their families, specialists in internal medicine, bioethicists and experts in health policies, formed a working group for the development of a clinical practice guideline, to lead people to an appropriate decision-making both at the initiation of and the withdrawal from dialysis in the last years.

The recommendations are not mandatory, but flexible, and can be adapted to the particular case of each patient. Nine recommendations are included here, however, they needed to be complemented with a consideration to add a greater value and foundation to the exercise of evaluating patients. Of course, this is the first of the ten recommendations exposed below:

II.1 Application of the principle of proportionality, futile treatment: Treatments can be useful or useless, proportionate or disproportionate. A useful treatment provides an improvement to the patient; these are therapeutic measures put in place to achieve a proper management of the disease, which bring a real benefit, which meet a certain goal and which relieve symptoms. Conversely, a useless treatment is the set of therapeutics measures which do not bring a benefit to the condition and pathology that the patient presents, which do not give relief, measures which do not work. These are also known as futile treatment in order to emphasize that it is not effective, that it does not work at all. A futile treatment is known not to work in advance.

Proportionate treatments are the ones where what is sought is proportionate to what needs to be done, proportionate to the difficulties coming with the treatment, how painful and difficult it will be, and the economic costs not only for the patients but for their families. The treatment has a purpose and fulfills it, it is reasonable. Disproportionate treatments are performed for different reasons: lack of medical knowledge, insecurity, fear of being sued, or an irrational demand by the patients’ family who are not willing to accept that we are only able to provide some palliative care to their loved ones.

The use of the term “futility” has increased considerably in recent medical journals, and the diversity of meanings for it is increasing too. There is no universal definition of futility. Moreover, its meaning is difficult to specify. Usually, it is vaguely perceived as something inappropriate, not indicated, useless, ineffective. Daniel Callahan refers to futility as “the problem with no name”:

"everybody knows what it means, but no one manages to give a definition. Authors like Robert Truog describe it as elusive: “They may not be able to define it, but they know it when they see it”.

The simplest definition is proposed by Lo and Steinbrook, who identify futility as uselessness. This first approach to the concept of futility is too vague: useless regarding what? Is it useless because it does not have any physiological effect? Is it useless because it is used only to extend life? Is it useless for the patient to get some benefit?

In order to establish from an objective point of view the futility of a particular medical procedure, it is necessary to observe one of these statements:
a.- There is no reasonable probability of achieving the goal for which the medical procedure is to be applied.

b.- The medical procedure does not alleviate neither the basic disease, nor the intercurrent diseases or symptoms.

c.- There is clear evidence of the fact that the achievable health benefit is exiguous.

d.- It is proved that the disadvantages of the procedure widely exceed the benefits, which can reasonably be considered poor or insufficient. Many authors defend the patient’s autonomy against the medical paternalism that has characterized traditional medicine, but the promotion of a healthy patient’s autonomy does not imply that the doctor becomes a mere provider of medical procedures at patients’ whim. This is not the spirit of proper medicine. The patient has the right and obligation to participate in clinical decisions, but this healthy understanding of patients’ autonomy does not entitle them to impersonate the doctor’s legitimate role, which is supported by science and an upright conscience. Introducing in medical practice objectively futile actions means corrupting the foundation of rationality and the scientific nature of medicine; it would mean mixing the healthy medical acts, which make medical knowledge advance and benefit the patient, with medical acts with no effectiveness discrediting medicine, adding taxes to health costs, instilling false hopes in patients, and making the doctor-patient relationship strained.

On the other hand, the patient does not have the right to require a treatment that provides no benefit either. The moral basis of the doctor-patient relationship is the physician’s obligation to ensure some good to the patient. Actions that do not contribute to this goal are not morally demanded.

Proportionate and disproportionate procedures are assessed by comparing the type of therapy, the degree of difficulty and of risk involved, the necessary expenses, and the application possibilities to the result that is expected from all of this, considering the conditions of the patient and his physical and moral strength. In addition to this, some other specific criteria are taken into account, such as the duration of the therapy (acute or chronic); the therapeutic effect (total, partial, or exclusively supportive cure); the eventual complications or side effects; its experimental natural; and financial expenses and necessary investments for staff and required instruments. Other factors are related to the patient’s condition: physical condition prior to the application of the therapy; Is he/she capable of going through a medical intervention? and the patient’s physical condition expected after treatment: What will his/her quality of life be like once the therapy has had the desired effect? Besides physical condition, it is necessary to consider the psychological, psychosocial and spiritual strength the patient has; the degree of diagnostic and prognostic certainty; the expected outcome (effectiveness) and the expected survival.

II.2 Participation in decision-making: A doctor-patient relationship fostering decision-making is recommended for all patients with end-stage renal disease (ESRD). If the patient lacks the ability to make decisions, a patient’s legal representative must be engaged. With the patient’s consent, participation in decision-making can include a family member or friend or another member of the renal care team. The decision is based on appropriate information (adequate, sufficient and clear in its language) about the goal of the treatment, its risks and its benefits.

II.3 Informed consent or rejection: With its three components, which are information, ability to understand or competence and voluntariness, the doctor must thoroughly explain the diagnosis, prognosis and all the treatment options to patients. The explanation of the treatment options must include: available dialysis modalities; nondialytic or conservative management (this must include end-of-life care); time-limited dialysis trials as another option and, lastly, their withdrawal from dialysis and end-of-life care. The decision must be informed and voluntary. The renal team, together with the primary care physician, must ensure that patients or their legal representatives understand the consequences.
of the decision. Informed consent allows a balance between the principle of beneficence (do the best for the patient) and of autonomy (observe his/her freedom of choice).

II.4 Estimating prognosis: To facilitate the process of making the decision to withdraw patients with ESRD from dialysis, the debate about life expectancy and quality of life must be held with the patients or their legal representatives. Moreover, clinical prognosis data are provided by the nephrologist to facilitate discussion. This estimate must be discussed with patients, their families, their legal agent and medical team. For patients with ESRD, this discussion should happen as early as possible in the course of the disease. In patients who have more serious complications which reduce their survival or quality of life, it is appropriate to discuss and re-discuss treatment goals and consider withdrawal from dialysis.

II.5 Conflict Resolution: A systematic approach to resolve conflicts is recommended when there is disagreement regarding the benefit of dialysis between the patient or the legal representative and a member of the renal care team. Conflicts may also arise within the renal care team or between this team and other health care providers. This approach must review and share the process of decision-making in the following potential sources of conflict: I- Lack of communication or understanding about the prognosis. II- Interpersonal disagreements. III- The assessment of the urgency of the dialysis, where this must be performed as long as the resolution of the conflict is sought meanwhile, and if the patient or legal representative requests it.

II.6 Promoting guidelines: The renal care team must try to promote these guidelines in written for all patients on dialysis. These must be honorable. Written guidelines are always preferable to oral ones as these provide legal protection for the renal care team. Communication among doctors and an adequate guidance to patients at the end of life is encouraged. The patients’ ability to make a decision must be assessed, whether the patient has a legal representative must be determined through written guidelines, and advanced care must be discussed with the patient or their legal representative through the assessment of questions such as: If the patient did not have the ability to decide by him/herself, who would he/she trust for decision-making? Under what circumstances, if any, would you be willing to be withdrawn from dialysis? Under what circumstances would you not be willing to live with mechanical ventilation? Where would you prefer to die, and who would you want to be by your side at that moment?

II.7 Refusing or withdrawing from dialysis: An approach to dialysis refusal or withdrawal in patients with ESRD includes: I- Patients with ability for decision-making based on complete information, who voluntarily choose to refuse dialysis, or requests that dialysis is stopped. II- Patients who are not able to make decisions, but previously indicated their refusal to dialysis verbally or in written with a clear guideline. III- Patients who have no ability to make decisions and properly designate the legal agent to refuse dialysis or to request their withdrawal from it. IV- Patients with profound and irreversible neurological damage, lacking thought, feelings, determination, behavior, conduct, self-consciousness or consciousness of the environment.

II.8 Special groups of patients: It is reasonable not to initiate or stop dialysis in patients with ESRD, those with a terminal illness of a nonrenal cause, or those whose medical condition precludes the technical process of dialysis. A disease is considered terminal when there is a life expectancy of less than 6 months in patients who are not candidates for solid organ transplants. Within this category we have: terminal liver cirrhosis, severe refractory congestive heart failure, metastatic cancer unresponsive to treatment, terminal lung disease, bone marrow transplant recipients with multiple organ failure, neurodegenerative disease, and all the severe and irreversible forms of dementia.
II.9 Time-limited trial: For patients who require dialysis but have an uncertain prognosis, or those for whom providing dialysis services is not considered viable (they live in remote places or have no family), nephrologists must consider offering a dialysis time-limited trial.

II.10 Palliative care: A patient whose dialysis is to be refused must receive continuous palliative care. Medical, psycho-social and spiritual aspects must be included in the management of end-of-life care with the patients’ consent, and with professionals’ expertise in health care of terminally ill patients.

- What happens to patients after discontinuation of dialysis?

In the case of nephrologists trying to improve their patients’ end-of-life care, when dialysis is discon tinued, it is necessary to be aware of how and under what circumstances they are dying. The majority of elderly patients with serious illnesses died at the hospital, and during the last three days of their lives 55% were still conscious, 40% of them had severe pain most of the time, over 50% had dyspnea and over 80% had fatigue.

The annual mortality rate of patients with ESRD is around 23%, comparable to Non-Hodgkin lymphoma, AIDS, colorectal carcinoma and ovarian carcinoma. Woods showed in a study, through the assessment of the families of 21 patients in New England 6 weeks after their deaths, that 57% of the patients had died in pain. In renal units in the US and Canada, Cohen studied a group of 79 patients with the aim of assessing circumstances and quality of death. Three quarters of patients had 3 to 7 comorbidities, more than half suffered from starvation, and on their last day of life, their families and caregivers reported that 43% of them were conscious, 30% had agitation, 42% of these suffered pain and 5% of them had a very severe pain.

The World Health Organization defines palliative care as follows: “Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threaten ing illness, through the prevention and relief of suffer ing by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual. Palliative care […] affirms life and regards dying as a normal process; intends neither to hasten or postpone death; but offers a support system to help patients live as actively as possible until death; offers a support system to help the family cope during the patients’ illness and in their own bereavement.”

Terminally ill patients often need more attention than those whose disease is curable. Palliative care is characterized like this: - Multi-professionalism, this is conducted with the participation of doctors, nurses, psychologists, priests, etc. - Globalization and customization, taking into account the whole person’s physical, psychological and spiritual aspects. - Therapies and attention are customized for every patient, history and situation. - Assertive communication between professionals, with families, with the patient: it is necessary not to lie, to always tell the truth smoothly and, if needed, gradually. - Proportionality of care and rejection of therapeutic obstinacy. Patients must be intervened as long as this benefits their health, no more and no less.

We must avoid therapeutic obstinacy on the use of useless therapies which are not proportionate to the risks and benefits of the person, prolonging agony rather than offering healing effects.

Patients with ESRD are particularly appropriate candidates for palliative care, as defined by the WHO. ESRD is a life-limiting illness that requires patients and their families to make decisions for the end of life from the time of diagnosis. Deciding whether to undergo RRT or not is the first of many options when patients deal with kidney failure. Those who choose RRT know that their survival depends on the frequency and compliance of dialysis or a successful kidney transplant, as well as of the control of other diseases.

Patients and their families are often well aware that future is uncertain and that death may be close. Patients on RRT often wonder how long their life will extend and whether dialysis can be stopped if their condition deteriorates notably. Given this uncertain-
ty, but usually in a limited course of their ESRD, psychosocial and spiritual support and assistance on advanced care are part of the care component for these patients

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In daily practice, when caring for a person in a situation of terminal illness, the absence of conflict between these four bioethical principles is usual, and the patient will ask for the application of all of them in order to assist all of their needs:

- They need that, although there is no curative treatment, an integral solution is found for their physical, psycho-emotional, social and spiritual problems (principle of beneficence).

- They need not to be unnecessarily harmed using therapeutic or diagnostic procedures that were proven useless or futile, or which are deemed disproportionate (principle of non-maleficence).

- They need to be treated with confidence, respecting their privacy and autonomy, to be informed if they wish so, and their opinion to be taken into account at the time of deciding what is best for them (principle of autonomy).

- They need that, if there is a universal health care system (as in our region), it covers their needs, irrespective of any circumstances, and that they are never discriminated (principle of justice).

Other ethical principles in palliative medicine that should not be different to the ones that govern our daily actions in life, are: Principle of human dignity, as an intrinsic worth of human beings, which is at the crossroads of all principles; Principle of truthfulness, as guarantor for the best relationship with patients and their families, for their confidence, respect for their life, their existence, their needs; Principle of proportionality, where the principles of beneficence and justice, necessary for decision-making, are involved; Principle of double effect or of the indirect voluntary, which when being applied requires assessment in light of the progress of science; Principle of predictability, which allows decisions according to the natural evolution of the disease, and allows to prepare the patient and the family on a better adaptation to upcoming events, including their personal needs in different aspects; and Principle of non-abandonment, which involves solidarity and fidelity which puts to test our own humanity, where the forces of our own values are.

Conclusion

We must, therefore, begin by raising awareness, better understanding and education regarding this problem in our environment at the different hospitals and renal clinics across our country, where patients come continuously to require our support and integral management of kidney disease. We must not lose objectivity and, armed with clear criteria, make these types of decisions maintaining dignity and alleviating human suffering until the last moment. We still have a lot to do and achieve for this group of patients and their families, starting from the ethical problems related to dialysis and culminating in the making of an appropriate decision as to refuse or stop dialysis, including in the overall context of patients the guidelines that bring us closer to the right decision.

It is time now to prepare for the making of such decisions, since it is an ethical obligation to know the moral law applied to the individual lifestyle, in a given, a professional environment (professional ethics). We must be based on the sensible assessment of proportionality or futility of the process, with tools of clinical evidence, such as RPA/ASN guidelines, the identification of prognostic factors which are strongly predictive of early death in dialysis patients, such as low levels of albumin, poor functional status, comorbidity, e.g. myocardial stroke and lower limb amputation. Albumin under 3.5 g/dl is associated with a probability of death at one year of 50%. Severe functional compromise is associated with 3.46 times more risk of early death. Patient with myocardial stroke is associated with a mortality
at one year of 60%. Above-knee amputation is associated with a mortality at one year of 73%.

Of course, what we still have to do is work as much as possible for this group of patients, who were withdrawn from dialysis, to die with dignity, with no anxiety, with no pain, without respiratory distress, as it sadly happens. We are willing to take the challenge with the support of palliative care.

Palliative medicine, because of its great humanitarian component and defense for the respect of life and dignity, is the most effective way to care for patients who are in a situation of terminal illness, since the philosophy on which it is based guarantees, among other things, a strict and consistent implementation of the fundamental bioethical principles. Palliative care, thus, is the way to avoid abandonment of our patients. However, it is still true that the road ahead is long, especially if we are to make political and governmental institutions understand the need and the incalculable value it brings to the benefit of the human dignity in the final stage of life.

All the staff at renal clinics, including doctors, nurses, psychologists, technicians, pharmacists, medical secretaries, janitors, nutritionists and social workers, should be educated in palliative care techniques. The potential benefits of this approach both for patients and their families are worthy, despite the high amount of effort and time. Therefore, palliative care should be a standard practice in nephrology.

We can also conclude that it is of vital importance to include palliative care as part of residents’ curriculum training in nephrology.

Let’s keep in mind this quote from the founder of hospice movement:

“**You matter because you are you, and you matter to the end of your life. We will do all we can not only to help you die peacefully, but also to live until you die.**”

*(Cicely Saunders)*

**Interest conflict**

The authors declare no conflict of interest.

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