

Time-limited trial – searching for rational solutions in the functioning of intensive care units

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Abstract

Introduction: Evaluating futility carries the burden of subjectivity; we do not have scales that verify the impartiality of decisions. It is very difficult to decide on the fate of a patient who shows up intubated at the intensive care unit (ICU). The uncertainty of the prognosis at the beginning of a critical illness does not allow the doctor to predict the effect of therapy in terms of survival, regaining the previous quality of life, and independent functioning.

Material and methods: There are 3 options to choose from: ICU admission and all invasive procedures; refusal of ICU admission, with a sense of making decisions based on incomplete information; and a time-limited trial, which allows testing invasive procedures aimed at the potential improvement of the patient's health and the reassessment of gains and losses after a specific, defined period. It seems that the last solution is fair and acceptable to the patient/family and medics.

Results: A time-limited trial is part of the concept of personalized medicine, which puts the patient at the centre of our actions. A time-limited trial is a practical proposition for patients with a doubtful prognosis and uncertainty concerning the effects of invasive and aggressive therapies.

Conclusions: Patients with a limited life expectancy and exhausted physiological reserves are ideal candidates for the implementation of the described method.

Key word: intensive care, futility therapy, time-limited trial.

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INTRODUCTION

Pro-life supporters demand the protection of life from conception to natural death. However, the progress of medicine has contributed to the medicalization of death, leaving the question: "What does natural death mean today? Is life support in intensive care units (ICU) in line with respect for life?" The topic of futile therapy has been part of the debate on end-of-life problems for several years. Looking for an ethical solution to this difficult issue, we want to discuss the concept of the time-limited trial (TLT).

Medical futility is defined as the use of significant resources without the rational hope of returning the patient to a state of relative independence or being interactive with the environment. It is criticized by ethicists for its lack of objectivity. We do not have scales that verify the impartiality of decisions. Evaluating futility carries the burden of subjectivity.

Ethicists believe that fragility is a fairer evaluation criterion [1].

MATERIAL AND METHODS

Futility statistics

The debate over futile therapy focuses on the ICU where capacity is always insufficient and life-sustaining treatment is routinely provided. Futile therapy is part of end-of-life care [2]. In ICUs, there is often the problem of the rules for distributing medical procedures based on honesty, justice, benefit, non-harm, and dignity. The situation is so complicated that maintaining the patient's autonomy and obtaining informed consent is impossible in 95% of critically ill patients [3]. According to the teachings of Hippocrates, the physician should refuse to treat

those who are defeated by the disease, realizing that medicine is powerless in these cases [4]. The statistics of futility are appalling; 66–89% of the nursing staff employed in ICUs participated in futile therapy [5]. Paradoxically, people who consider themselves believers often mistakenly consider discontinuation of therapy as unethical and identify it with euthanasia; however, it merely stops the unnatural prolongation of death [5].

According to the surveyed physicians, 20% of patients hospitalized in ICUs receive futile therapy; 73% of the surveyed physicians believe that they often admit ICU patients who do not have a prognosis of survival longer than a few weeks. Such decisions are explained by the earlier implementation of life-saving procedures (intubation, resuscitation, infusion of catecholamines in the hospital emergency department) before referral to the ICU. The attending physician works under time pressure and does not have sufficient information about the patient's health condition. Under these conditions, the last intensive care bed in the hospital is occupied [5, 6]. In the United States in 2000, 24.3% of ICU patients were hospitalized in the last month of life, while in 2015 – 29%. The same data show that between 2000 and 2013, the number of residents of nursing homes with dementia and mechanical ventilation doubled, which did not improve the treatment results [7]. It has been unequivocally proven that we deal with overtreatment in patients with advanced diseases and poor prognosis. Intensive therapy in these cases is associated with minimal benefit and prolonged suffering [8].

Unrealistic expectations for medicine

Twenty per cent of Americans die during or immediately after ICU admission, and the number of patients dying in ICUs in developed countries is constantly increasing. The dominant problem is overtreatment, with its side effects in the form of depression of relatives and occupational burnout of the staff [9]. Nowadays, we are dealing with the so-called medicalization of death, i.e. capturing death by medicine. We are witnessing attempts to push the finite limit of life to infinity. The beginning of this concept, popularized by the media, was the use of a ventilator, followed by organ transplants. The economy of hope causes the patient to develop unrealistic expectations concerning therapy and a significant improvement in health and quality of life. Patients rely on advanced medical technologies and believe that life and death are in the hands of medical science, not nature. The patient dies because medicine has failed, not because life is limited by death. Death has been placed in the hands of doctors who also have difficulty accepting it. They treat it as a failure. Prolonged dying may be consid-

ered a cure for failure, which is the patient's death. In the 21st century, we are witnessing a significant change. Previously, critically ill patients lived shorter lives and died quickly, while today they live longer and die more slowly. The cost of prolonged dying is measured in dollars and suffering [10, 11].

Declaring futility

A physician who declares futility serves the patient and the family. But if the patient/family objects to the decision of the doctor who wants to declare the therapy futile, then the decision is treated as a death sentence, after a short trial, and without the possibility of appeal. The doctor opposes the family's desire to do everything when there is nothing left to do. According to the family, the doctor plays the role of God, with power incomparable to that of a judge in a civil or criminal trial. In the face of enormous responsibility, doctors have very little protection from the system – only guidelines, recommendations, and opinions [12].

RESULTS

New role of the anaesthesiologist

The Intensive Care Units Organization in Poland makes the anaesthesiologist responsible for hospitalized patients. Doctors of other specialties act as consultants. At the beginning of the existence of this specialty, anaesthesiologists played a very limited role as service providers, but over time their duties have significantly evolved. The anaesthesiologist began to act as a consultant, deciding on preoperative preparation and selection of anaesthesia and treatment methods in the early postoperative period. Currently, there is a need for specialists in perioperative medicine, but also intensive care specialists; doctors who will be the patient's advocate not only in the perioperative period but also during critical illness and their stay in the ICU [13].

Mechanisms for making difficult decisions

Nobel Prize-winning Israeli-American psychologist and economist Daniel Kahneman describes two distinct information-processing systems that explain the reasons for acting against one's interests in certain difficult life situations. The first system is fast, automatic, susceptible to environmental influences, and habitual. It takes over the decision-making process in complex, overwhelming situations when time pressure or other pressures accompany decision-making. Decision-making in this system is typical for both the doctor and the patient or

his/her relatives in the case of a critical illness requiring admission to the ICU, especially in situations of ongoing advanced or terminal illness underlying the critical condition. The second system is based on slow, reflective processing of information, taking into account the goals. It promotes the wait-and-see attitude [14].

It is very difficult to decide on the fate of a patient who shows up intubated at the ICU door. The uncertainty of the prognosis at the beginning of a critical illness does not allow the doctor to predict the effect of therapy in terms of survival, regaining the previous quality of life, and independent functioning. During the first contact between the doctor and the patient/family, it is difficult for them to trust each other. Patients or their families need time to understand their situation. This is possible during the first days of stay in the ICU when the outcome of treatment can be predicted with high probability. Intensive care unit physicians struggle with a common sense of moral obligation to use an intensive procedure if it is available. They follow the principle of acting in response to a problem that arises. If it is technically possible to replace the function of an organ, appropriate therapy should be implemented. There is a so-called clinical momentum, where symptoms are linked to intervention, and one intervention leads to another [15]. In the daily professional rush, one must find time and answer the question of whether such action serves the patient.

Third option – time-limited therapy

It is worth asking the question: What do you do if the patient referred to the ICU is a person with advanced disease, with a limited quality of life, without physiological reserves, and in a critical condition? There are 3 options to choose from: a) ICU admission and all invasive procedures; b) refusal of ICU admission, with a sense of making decisions based on incomplete information; c) TLT, which allows the testing of invasive procedures aimed at potential improvement of the patient's health and reassessment of gains and losses after a specific, defined period [15]. It seems that the last solution is fair and acceptable to the patient/family and medics. The place of TLT is in the narrow margin of admission, between patients too ill to benefit from ICU stay (indications for palliative care) and critically ill patients with some chance of returning to an acceptable health state. Time-limited trial consists of agreement between doctors and the patient/family on the use of intensive care procedures for the treatment of a critical condition within a strictly defined time, after which it is necessary to assess the patient's condition based on pre-defined parameters. The purpose of treatment and observation for a certain period is to assess the patient's

response to the applied therapies and, if necessary, to predict the prognosis in terms of quality of life. The implementation of the strategy requires consideration of the expectations of the patient/family. The proposed procedure promotes a consensus between the therapeutic team and the patient/family. It focuses on listening patiently to expectations and making decisions without time pressure [6, 16]. Patients and their families must understand from the beginning that subsequent clinical decisions will depend on the body's response to the implemented invasive therapies. Implementing TLT requires a detailed protocol. The key is to define the clinical problem and determine the prognosis. The preferences of the patient/family are an important element but not in terms of a "must live" statement. The treatment team is responsible for defining the parameters of improvement/deterioration of the clinical condition, e.g. weaning from mechanical lung ventilation, reduction/discontinuation of doses of catecholamines, number of failing organs, change in scores used in intensive care (APACHE, SOFA), lactate concentration, and state of consciousness. It is necessary to determine the time of observation of treatment effects, i.e. the date of the next assessment of the patient's clinical condition (e.g. 3 days: hypoxaemic encephalopathy, 3–7 days: end-stage cardiovascular failure, 7–14 days: severe CNS stroke; 15 days: cancer, not in the final stage). Physicians must also provide a plan for managing the patient after the allotted time. If the patient's condition has improved, treatment should be continued, and if no effective health response is obtained within the defined time, discontinuation of intensive care should be considered and palliative treatment should be implemented to alleviate suffering and ensure comfort [16].

An important element of the proposed strategy is the time of making the decision on its implementation. The optimal solution is based on 2 moments. The first of them is on admission to the ICU, when the doctor works under time pressure with very limited knowledge of the patient's health condition, knowing only the cause/symptoms of the critical illness that is the reason for the referral to the ICU. The second moment is during the patient's stay in the ICU, when unexpected complications occur or in the event of an unforeseen course of treatment implying uncertainty as to the outcome of therapy [6].

DISCUSSION

The implementation of the TLT regimen consists of 5 steps:

1. Detailed diagnosis and prognosis, type of planned intensive care;
2. Knowing the preferences of the patient/family;

3. Proposing specific parameters to assess the effects of the implemented therapy;
4. Determining the duration of therapy until the next evaluation of its results;
5. Scheduling a meeting between the patient/family and the doctors to present the results of intensive care [15, 17].

The prerequisite for the success of the entire project is the precision of the procedure. Preparation is based on an excellent knowledge of the patient's medical history. Key persons responsible for the implementation of TLT should be selected from the treatment team. People responsible for decision-making concerning the patient should be selected. The meeting with the patient's family must take place as soon as possible after admission to the ICU. It should begin by introducing all the participants of the meeting and explaining its purpose. It is necessary to develop a consensus between the parties, and mutual trust is a necessary condition. During the TLT, it is necessary to regularly inform the family about the effects of treatment. In the case of a positive response to treatment, further steps should be proposed. If the patient's condition deteriorates, it is necessary to start negotiations about another form of TLT or the use of palliative therapy. In contact with the patient/family, one should present a conciliatory attitude, listen to the arguments of the other party, and try to work out a compromise [18]. It is necessary to discuss the balance of risks and benefits, limit unnecessary or harmful therapies, and adjust the scope and methods of treatment to the set goal. It is necessary to jointly define the rational limits of therapy in each case to reduce suffering that does not bring any benefit [8].

The time-limited trial is a difficult and unpopular therapy. The reasons for its failure are various. Medical personnel do not have the tools necessary to prepare a plan, and there are no protocols, checklists, or templates. The patient/family and treatment team have difficulty sharing the treatment plan. Patients and their families are afraid of abandoning effective therapy in a situation where, in their opinion, it has a chance of success. Working in the on-call mode means that medical professionals who inform the family about the patient's health status are constantly changing. And finally, a very prosaic problem, i.e. difficulties with setting the date of the next meeting. According to the surveyed physicians, withdrawing is not ethically equivalent to withholding treatment, which does not facilitate the implementation of the TLT strategy. Ethicists treat both forms equally [6, 17]. Treatment failure may be additionally determined by the patient's clinical condition deteriorating too quickly or the lack of unanimity in the therapeutic team and/or in the patient's family [9].

The term 'time-limited trial' suggests a kind of research work, an experiment, but the word 'therapy' prevents this interpretation. Time-limited trial is part of the concept of personalized medicine, which puts the patient at the centre of our actions. The patient/family should remain aware of hope but also of the need to prepare for the worst.

CONCLUSIONS

A time-limited trial is a practical proposition for patients with a doubtful prognosis and uncertainty concerning the effects of invasive and aggressive therapies. Patients with a limited life expectancy and exhausted physiological reserves are ideal candidates for the implementation of the described method. Studies published in 2021 clearly showed that the use of the TLT strategy in patients with advanced disease shortened their stay in the ICU and reduced the use of invasive procedures without affecting hospital mortality and family satisfaction [8]. Conversations with the family about TLT should start at the time of admission to the ICU if there is uncertainty about the effects of intensive care due to the general medical burden of the patient. In this way, unrealistic expectations and false hope among family members can be avoided. Chinese doctors have created a checklist with the acronym F-R-A-I-L, which helps identify patients dedicated to the TLT strategy. The checklist includes Functional impairment, Recurrent hospitalizations, Advanced malignancy or chronic disease, Irreversible organ failure, and Long hospital stay. Meeting the F-R-A-I-L criteria predicts frailty, and limited recovery potential and mediocre response to treatment. Having the checklist does not relieve experienced specialists from making final decisions when they have all the relevant information, after a thorough review of the medical history. A time-limited trial is an ethical alternative to the 2 extreme, radical solutions, i.e. the implementation of unlimited intensive care or refusal of service [19].

A time-limited trial can, if properly conducted, determine the high quality of services in the ward and provide patients with the care they desire and which offers them the greatest benefit [16]. It is also consistent with the doctrine of the Catholic Church. The review of the state of knowledge on TLT in the presented paper reveals the lack of Polish-language literature, which confirms the authors' belief that there is a need to discuss this topic also in our country.

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