

Analysis of management protocols regarding ineffective maintenance of organ functions in patients treated at the Intensive Care Unit of the University Hospital in Wrocław

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Abstract

Background: Prolonged support of organ functions without therapeutic benefit represents a serious problem of therapy in intensive care units (ICUs). This kind of treatment, called “futile therapy”, prolongs the process of dying and should be avoided. In Poland, the guidelines and protocol defining the best clinical practice for the avoidance of futile therapy in ICUs was published in 2014. The aim of study was to analyse the protocols concerning futile therapy in the general ICU in the University Hospital in Wrocław, Poland during the years 2015–2018.

Methods: The content of protocols was analysed. The protocols contained information on clinical problems, ethical and social aspects, data on communication with relatives, and therapeutic procedures regarded as futile and consequently withheld or withdrawn.

Results: During the study 1660 patients were treated in the ICU, of whom 557 patients died. Protocols regarding futile therapy were analysed in 146 patients. The diagnosis before starting the protocol was multiorgan failure (56%), permanent CNS injury (39%), respiratory failure (3%), and circulatory failure (2%). The withholding of therapeutic procedures was preferred, and the cases of withdrawal were rare. All patients with protocols died during hospital stay, 81.5% of them in the ICU.

Conclusions: The protocols concerning futile therapy were instituted in 1 in 10 patients treated in the ICU in Wrocław, which comprised was nearly one-fifth of all ICU deaths. The withholding of futile therapeutic procedures was preferred in comparison to withdrawing. Communication with relatives was essential to the process of avoiding futile therapy.

Key words: intensive care unit, futile therapy, withholding, withdrawal.

Anaesthesiol Intensive Ther 2020; 52, 1: 3–9

Received: 05.10.2019, accepted: 29.11.2019

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Intensive care units (ICUs) were founded in the middle of the 20th century as the separate therapeutic stations for patients with reversible failure of vital organs [1]. A classic example was the treatment of respiratory failure caused by the poliovirus using mechanical ventilation [2]. Over time, intensive care developed into a separate medical field; at present, thanks to the technological advances, almost all vital functions can be artificially maintained. In some ICU patients, the support of organ functions does not lead to any basic therapeutic benefits, i.e. satisfactory life after discharge from the ICU. In such cases the maintenance of organ functions only prolongs the process of dying and is of no benefits for patients. Such an approach is

inconsistent with the current medical knowledge and ethics and is called a futile therapy. Many Polish and foreign research studies were focused on determining the principles of avoiding futile therapy [3–8]. In Poland, such principles were presented in the publication entitled “Guidelines regarding the ineffective maintenance of organ functions (futile therapy) in ICU patients incapable of giving informed statements of will” [9]. An essential element of this guidelines is the management protocol regarding futile therapy in ICU, substantiating the criteria to be used to consider the therapy futile and describing the process of withholding or withdrawing futile therapeutic interventions in a given clinical situation. To date, the information regarding

implementation of guidelines into Polish ICU practice has not been published.

The present paper analyses the use of management protocols concerning futile therapy at an intensive care unit of the university hospital between 01.01.2015–31.12.2018.

METHODS

The content of management protocols on futile therapy included in guidelines were analysed. The document presents the official consensus statement, which the medical societies consulted with bioethical and legal opinions. Therefore, our analysis was not additionally approved by the local Bioethics Committee.

The protocol forms were available for the ICU personnel. The protocols were completed in the Intensive Care Unit of the University Hospital in Wrocław, Department of Anaesthesiology and Intensive Therapy, Wrocław Medical University and covered the period of 4 years (01.01.2015–31.12.2018).

The decision about instituting the protocol as the documentation of avoiding futile therapy was made by the ICU attending team, i.e. two specialists in anaesthesiology and intensive therapy in cooperation with the head of the Department. The decision made was discussed with the entire ICU therapeutic team and presented to the patient's families. None of the patients taken into consideration while starting the protocols was capable of deciding about treatment unaided.

The protocol consists of 3 pages (Figure 1). The first one includes personal data of a patient, short introduction to the tenets of avoiding futile therapy and clinical aspects of the decision made. The second page contains ethical and environmental aspects of the decision, information about family members or friends that were informed about the situation, the issues discussed with them, and a list of therapeutic procedures considered futile which will be withdrawn or withheld. The third page of the protocol is the statement substantiating de-escalation of futile

Protocol

Management regarding ineffective maintenance of organ functions (futile therapy) in ICU patients incapable of giving informed statements of will

First name and surname of the patient:

Personal identity number.....

Due to the current clinical condition, the patient is incapable of consciously expressing his/her will regarding therapeutic management.

In accordance with the current state of medical knowledge, it should be stated that organ failure is irreversible and permanent. Therefore, use or further use of the specific methods maintaining organ functions becomes futile therapy harmful to the patient.

Considering the current clinical condition of the patient, and having been fully familiarised with his/her medical records, as well as having presented the patient's family with the current health situation of the patient, the decision is made that from this moment on the administration of palliative therapy will be most beneficial for the patient. From this moment on, the institution or continuation of the definite forms of treatment aimed at maintaining organ functions will be unfavourable as it will be medically futile, hence will not serve the patient's needs.

This decision has been taken considering clinical, ethical and social aspects; moreover, the therapeutic procedures designed to maintain organ functions, which will be withheld or withdrawn, have been listed.

Clinical aspects:

Underlying diagnosis:

Current clinical condition and therapeutic problems:

Opinions of consultants (if need be):

FIGURE 1. Protocol of futile therapy – page 1

Ethical and social aspects:

Although the therapy maintaining organ functions will be limited, palliative treatment will be administered to provide best comfort. The specialist nursing care will be continued and symptoms such as pain, anxiety, dyspnoea, seizures, and fever will be relieved. The patient will be hydrated and nourished, suitably to his/her needs. Contact with relatives and those of support will be ensured, depending on the patient’s needs and organisational capacity.

To determine the best interests of the patient, the following individuals were talked to:

Family members/close friends: (first name, surname, kinship):

- 1)
- 2)
- 3)
- 4)

The following issues have been discussed:

1. Possible previously expressed statements of will regarding the continuation of procedures maintaining organ functions in a situation comparable to the current one;
2. possible previously expressed wishes of the patient as to management of life-threatening/end-of-life situations that the patient’s family or other close friends are aware of;
3. moral and ethical beliefs accepted by the patient;
4. patient’s current state of awareness and prognosis regarding survival, clinical improvement, recovery and rehabilitation after leaving the intensive care unit;
5. methods of treatment currently applied, including their effectiveness and invasiveness;
6. further management planned.

Therapeutic procedures which will be withheld or withdrawn

Procedure	withheld	withdrawn
Cardiopulmonary resuscitation		
Cardiac electrotherapy		
Renal replacement therapy		
Mechanical circulatory support		
Pharmacological circulatory support		
Mechanical ventilation		
Antibiotic therapy		
Surgical procedures and other invasive procedures		
Parenteral nutrition		
Extracorporeal respiratory support		
Extracorporeal liver support		
Transfusion of blood preparations		

1. Physician - specialist in anaesthesiology and intensive therapy or intensive therapy
 First name and surname:
 Speciality:
 Signature: Date.....

2. Physician - specialist in anaesthesiology and intensive therapy or intensive therapy
 First name and surname:
 Speciality:
 Signature: Date.....

3. Physician in charge of the department
 First name and surname:
 Speciality:
 Signature: Date

FIGURE 1. Cont. Protocol of futile therapy – pages 2 and 3

therapeutic procedures, signed by two specialists in anaesthesiology and intensive therapy and the physician in charge of the department. The content of protocols was statistically analysed. For higher clarity during presentation of outcomes, only the most important clinical diagnosis was selected for analysis.

The questionnaire findings were analysed using Statistica 13.0 PL (Statsoft, Tulsa, USA). Basic descriptive statistics were calculated for quantitative variables; in the case of qualitative variables,

distributions were determined with sample size and contingency tables.

RESULTS

In the years 2015–2018, 1660 patients were treated in the ICU; 557 (33.6%) died. Analysis encompassed 146 properly completed protocols (8.8%). The number of the protocols used in the individual years is presented in Table 1. The group with protocols aged 64.5 years (27–94) on average; male patients constituted 61% (89) and female patients 39% (57). Table 2 reveals the demographic data, average time between ICU admission and use of the protocol as well as average time between protocol commencement and death. The most important initial diagnosis on ICU admission in patients with protocols was presented in Table 3. The predominant diseases were heart failure or systemic infection. The main diagnoses established while implementing the protocols were listed in Table 4. The most common diagnosis was multiple organ failure, followed by permanent damage to the central nervous system (CNS).

TABLE 1. Percentages of protocols in relations to the number of patients in the individual years

Year	Number of patients	Number of protocols	%
2015	348	29	8.3
2016	420	23	5.5
2017	408	36	8.8
2018	422	58	13.7
In total	1660	146	8.8

TABLE 2. Information on patients with protocols regarding futile therapy

Age	64.5 years on average (27–94)
Gender	Men – 89 (61%) Women – 57 (39%)
Mean time between ICU admission and protocol institution	15.9 ± 14.4 days
Mean time between protocol institution and death	7.8 ± 10.5 days

TABLE 3. Patients with protocols regarding futile therapy – preliminary diagnosis

Cardiovascular system failure (including the condition after cardiac arrest)	28%
Sepsis/Septic shock	25%
Post-surgery complications (undefined)	10%
Central nervous system diseases	9%
Central nervous system injuries	8%
Respiratory disorders	8%
Neoplastic diseases	7%
Hepatic failure	3%
Multiple organ failure	2%

TABLE 4. Patients with protocols regarding futile therapy – diagnosis on protocol implementation

Multiple organ failure	56%
Permanent central nervous system injury	39%
Respiratory failure	3%
Circulatory collapse	2%

Generally, the decisions to implement the protocol were taken by the team of ICU physicians; in 36 cases (24.7%) they consulted with other specialists, mainly neurosurgeons, neurologists, vascular surgeons and general surgeons. Family members were consulted repeatedly. Those informed most frequently were daughters (45%), wives (32%), sons (24%) and husbands (8%). “Family conferences”, i.e. meetings with many family members with many members of therapeutic team, were carried out. Personal conflicts or legal conflicts were avoided; none of the cases with protocols was brought into the court.

The most common procedure to avoid futile therapy was to withhold certain forms of therapy. The general number of withheld forms of therapy was 13-fold higher than the number of withdrawn procedures (Table 5). The procedures withheld most frequently included cardiopulmonary resuscitation and mechanical maintenance of organ functions, which were withheld in 90% of protocols (Table 6).

The decisions to withdraw the therapy were much rarer (Table 6). The procedures most frequently withdrawn included renal replacement therapy and pharmacological support of the cardiovascular system (infusions of catecholamines).

Not all the patients with protocols died in the ICU. In total, 119 died, which constituted 81.5% of deaths of patients with protocols. The remaining patients, $n = 27$, died during further hospital treatment outside the ICU (Table 7). Moreover, the percentage of all deaths of patients with protocols versus the number of ICU deaths was 26.2%.

DISCUSSION

The circumstances leading to futile therapy often occur during ICU treatment. The avoidance of such interventions by physicians is prevalent. According to the questionnaire study published in 1999, involving 16 western European countries, 93% of ICU physicians withheld certain therapeutic interventions and 77% of them withdrawn some procedures during their medical practice due to their futility [10]. The findings of a similar study carried out 12 years later among Polish anaesthesiologists were almost identical (93% and 75%, respectively) [11]. Noteworthy, only 10% of Polish respondents recorded their interventions in hospital records, as compared to 58% in Europe.

The lack of written records of management regarding withholding or withdrawing futile therapy is an obvious medical malpractice. It gives the impression that therapeutic decisions are concealed as if they were improper. On the other hand, futile therapy is generally considered a medical, ethical and legal malpractice [12]. In Poland, medical and ethi-

cal arguments explicitly expressed in the guidelines substantiate the decisions of de-escalation of futile therapy; nevertheless, the legal stance has not been clearly formulated and requires corrections [13]. Therefore, the protocol of management attached to the guidelines was designed to clearly substantiate the medical decisions regarding futile therapy and protect against potential negative consequences of legal action. Similar protocols were constructed in numerous countries to properly document the activities aimed at de-escalation of futile therapy [14, 15].

According to the analysis of withholding or withdrawing futile therapy based on the ICON

TABLE 5. Number of withheld and withdrawn procedures

Total number of protocols	146
Total number of withheld protocols	1164
Number of withheld procedures per 1 protocol	7.8
Total number of withdrawn procedures	89
Number of withdrawn procedures per 1 protocol	0.6

TABLE 6. Procedures of withholding/withdrawing the therapy

Procedure	Withholding/withdrawing therapy	
	% of withholding in relations to the total number of protocols (n)	% of withdrawals in relations to the total number of protocols (n)
Cardiopulmonary resuscitation	97.3 (142)	4.8 (7)
Mechanical circulatory support	97.3 (142)	1.4 (2)
Cardiac electrotherapy	95.9 (140)	2.1 (3)
Extracorporeal respiratory support	94.5 (138)	2.7 (4)
Extracorporeal liver support	94.5 (138)	2.1 (3)
Surgical procedures and other invasive interventions	76.7 (112)	1.4 (2)
Renal replacement therapy	65.8 (96)	19.2 (28)
Pharmacological circulatory support	58.2 (85)	14.4 (21)
Transfusion of blood preparations	56.8 (83)	1.4 (2)
Parenteral nutrition	52.1 (76)	4.8 (7)
Mechanical ventilation	5.5 (8)	0.7 (1)
Antibiotic therapy	2.7 (4)	0

TABLE 7. Number of deaths of patients with protocols

Year (number of protocols)	Number of ICU deaths (deaths in ICU in total)	% of ICU deaths of patients with protocols	% of deaths of patients with protocols to the total number of deaths in the ICU
2015 (29)	27 (117)	93.1	23.1
2016 (23)	18 (150)	78.3	12.0
2017(36)	30 (141)	83.3	21.3
2018 (58)	44 (149)	75.8	29.5
Total number of deaths	119 (557)	81.5	21.4

study, evaluating ICUs worldwide published recently [16], the average frequency of withholding or withdrawing futile therapy was 13% and was similar to that observed in Wrocław (9%). In the Wrocław study, hospital mortality of patients with protocols was 100% while ICU mortality was 81.5%; in the worldwide study, the hospital mortality was 69%. The differences in percentages were associated with inter-country variations in the principles for making the decisions of futile therapy de-escalation. Recently, global steps have been taken to standardise the end-of-life management of patients dying in ICUs. The preliminary findings presented in the WELPICUS study have evidenced that world-wide consensus as to the key definitions and statements regarding end-of-life care in ICU patients can be achieved [17].

In the protocols analysed, the decision to withhold therapy were significantly more frequent, as compared to the decisions of withdrawing the procedures. And this is a prevalent phenomenon. Although both types of management do not differ ethically, in clinical practice, the withdrawal of the therapy already administered is more difficult than withholding of therapy, which is likely to be associated with the lack of detailed protocols of management in such cases [18].

In our opinion, proper communication with the family and relatives of the patient dying in the ICU is pivotal. In the cases discussed, special attention was paid to comprehensive and multifaceted discussions between the staff and family members. The mean time between the protocol initiation and death was 8 days, which seems to be enough to establish in-depth contact with the patient's family. Much has to be done to optimise the proper strategy of communication with the family and friends of terminally ill patients dying in ICUs [19].

The study limitations are as follows: 1) the study involves a single centre; therefore, it does not provide complete country-wide information on the use of protocols of management regarding futile therapy in ICUs, 2) the protocol described in the guidelines is only a suggestion; it has not been validated or verified and presumably requires some amendments and modifications.

Nevertheless, the study is the first broader analysis concerning the implementation of the guidelines to ICU practice in Poland and should be an incentive to carry out multi-centre research studies. The clinical observations should lead to the protocol optimisation of management and to updating the guidelines. A desirable objective is to formally regard the amended version of guidelines with the protocol as part of standard medical record documentation required at intensive care units.

CONCLUSIONS

In the years 2015–2018, the protocols of management regarding futile therapy were used in 9% of patients treated in the Intensive Care Unit of the Teaching Hospital in Wrocław. All patients with protocols died during the hospital treatment. Withholding of resuscitation and mechanical maintenance of organ functions was found to be significantly more frequent than withdrawing of the procedures already undertaken. Multi-centre analysis of the use of protocols of management regarding futile therapy is recommended to optimise the care of patients dying in the ICU.

ACKNOWLEDGEMENTS

1. Financial support and sponsorship: none.
2. Conflicts of interest: none.

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