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Decision-Making in Uncertainty – Time-Limited Trials

An overview of time-limited trials (TLT), collaborative agreements between the treating team and the patient to apply life-sustaining therapies to help reduce prognostic uncertainty and foster trust between teams and patients and/or patient surrogates.

the prognosis may change – sometimes drastically – while a patient is treated in an intensive care unit (ICU), even the most thorough decisions as to indications suffer from prognostic uncertainty (Michalsen et al. 2023a; Simpkin and Schwartzstein 2016). It is, therefore, often difficult to assess whether life-sustaining treatments are (still) beneficial for the patient or whether their burden exceeds their benefits. Withdrawing such treatments can be a grave decision. At the same time, though, it is hardly ethically justifiable not to start a life-sustaining therapy out of (prognostic) uncertainty. How to resolve this impasse?

ing four phases: considering, planning, supporting, and reassessing.

Considering a TLT, the medical team needs to assess the patient's prognosis, the medically sensible treatment options, and the level of uncertainty under the circumstances prevailing. At the same time, it is essential to evaluate and discuss the patient's wishes and values, including the burden caused by and the probable restrictions and limitations after the intensive care treatment. For example, a patient with a respiratory condition may accept non-invasive ventilation during but not dependency on it after his/her stay in the ICU.

Planning the TLT, the medical team will approach the patient and/or the surrogate(s), especially explaining the time frame and the criteria of a positive TLT outcome, i.e. usually the improvement of the patient's condition (Jöbges et al. 2024; Kruser et al. 2024; Michalsen et al. 2023b). Choosing the right timeframe for a TLT is difficult, and suggestions in the literature vary depending on the patient's health status before treatment in the ICU, his/her present condition, and his/her treatment preferences (Jöbges et al. 2024; Kruser et al. 2024; Michalsen et al. 2023b; VanKerkhoff et al. 2019; Vink et al. 2018). The medical team needs to clarify that the therapeutic goal will need to be changed if the condition of the patient does not improve as defined by medical criteria (Jöbges et al. 2024; Kruser et al. 2024; Michalsen et al. 2023b). Finally, the conditions of the TLT need to be documented in the health record.

Introduction

Medical indication and a patient's consent form the basis of every diagnostic or therapeutic medical measure (Milliken and Sadovnikoff 2023). In intensive care medicine, particularly, making an appropriate medical indication can be a highly complex decision that requires sufficient clinical experience and knowledge, potentially consuming extensive diagnostic and therapeutic resources (Milliken and Sadovnikoff 2023; Neitzke et al. 2019). Indications often must be made at a time when not all the information required for a comprehensive treatment plan is available. Furthermore, next to the medical assessment, the treating team needs to take the patient's wishes and values into account for indication-making (Milliken and Sadovnikoff 2023; Girbes 2023). Also, the individual prognosis constitutes an important part of an indication. And as

Time-Limited Trials

A time-limited trial (TLT) is a collaborative obliging agreement between the treating team and the patient to use life-sustaining therapies in a defined time period when reaching the original treatment goal is highly improbable. Its goal is to reduce prognostic uncertainty and, if necessary, change the therapeutic goal thereafter, often to comfort care only (Michalsen et al. 2023a; Simpkin and Schwartzstein 2016; Jöbges et al. 2024; Kruser et al. 2024; Michalsen et al. 2023b; Chang et al. 2021; VanKerkhoff et al. 2019; Vink et al. 2018). A TLT should always rest on a shared decision between the medical team and the patient or his/her surrogate decision-maker(s). Kruser and co-workers (2024) defined some critical elements for developing and implementing a TLT in intensive care medicine. According to this approach, a TLT consists of the follow-

Ideally agreed upon in consensus, the TLT will be supported by the whole team as well as by the patient and his/her family. In case of major changes in the patient's status, though, the duration of and/or the treatment measures during the TLT need to be re-evaluated.

Reassessing the TLT after the time period agreed upon, the clinicians and the patient and/or his/her surrogates meet again to discuss the patient's response to therapy according to the predefined clinical criteria. If the patient's condition improves during the TLT, the original treatment goal will be upheld, and therapeutic measures will be taken accordingly. If, however, the patient's condition does not improve – whereby a standstill equals non-improvement – the therapeutic goals usually should be changed to comfort care only. A second TLT must be restricted to special situations, as otherwise, decisional inertia will ensue (Jöbges et al. 2024; Michalsen et al. 2023b).

In summary, it is not mandatory for a TLT to follow a strict protocol, but its core elements are (1) considerable prognostic uncertainty, (2) a commitment to certain therapeutic measures for a limited time period, and (3) a subsequent reassessment of the situation followed by the decision to either continue life-sustaining measures or to change the treatment goal to comfort care only (Jöbges et al. 2024; Kruser et al. 2024; Michalsen et al. 2023b; VanKerkhoff et al. 2019; Vink et al. 2018). Another elementary component of a TLT is, obviously, adequate communication within the treating team as well as between the team and the patients and their relatives.

Case Report

A 55-year-old somnolent female patient was admitted to the ICU with acute liver failure and hepatic encephalopathy. Because of a hemiparesis, a computed tomography was performed, showing a big intracranial haemorrhage most likely caused by severe coagulopathy. The neurosurgeon consulted decided that surgery was not indicated.

The patient was treated in the ICU for several weeks, improving slowly. However, she was not able to communicate her wishes or values, nor had she appointed a surrogate decision maker before admittance. Communication with the family was considerably difficult because of a language barrier. At one point, the patient developed a fever caused by a urinary tract infection and pneumonia, and her condition deteriorated rapidly. At this time, some members of the nurses' team were concerned that the patient was no longer benefitting from ICU treatment but rather suffering needlessly. Subsequently, the local ethics committee was involved in a case discussion.

▲▲ a TLT is a suitable instrument to prevent early surrender as well as continued suffering due to overtreatment ▼▼

According to specialists involved in the patient's care, the neurological rehabilitation would take time but would be possible, and the liver function would most likely return to normal. They agreed that antibiotic therapy was necessary to treat the infection and could show an effect in approximately five days.

The interprofessional team decided that given the potential to regain a reasonable quality of life, it would be in the patient's best interest to continue care directed towards recovery. Because of the uncertainty about the effect of the antibiotics, a TLT of five days was suggested. The patient's family was informed about this procedure and agreed. During the TLT period, the patient's status had improved, and therefore, curative care was continued. A few days later, however, the patient showed signs of intestinal bleeding and went into haemorrhagic shock. As the bleeding could not be stopped, the treating team decided to change the treatment goal to

comfort care only, and the patient died a few hours later.

Benefits and Challenges of TLTs

A key aspect of a successful TLT is adequate communication, both within the team and between the team and patient and/or the family (Kruser et al. 2024). As has been shown recently, a good ethical climate, including respectful and open communication between all ICU team members, is an important team asset as it helps diminish disproportionate care and moral distress (Van den Bulcke et al. 2020; Benoit et al. 2018). Explicitly recognising prognostic uncertainty helps navigate difficult treatment phases and arrive at individually appropriate treatment goals. When their realisability becomes highly questionable, a TLT is a suitable instrument to prevent early surrender as well as continued suffering due to overtreatment (Kruser et al. 2024; Michalsen et al. 2023b; VanKerkhoff et al. 2019; Michalsen et al. 2021; Simpkin and Schwartzstein 2016). As TLTs are primarily led by ICU clinicians, they do not require routine clinical ethics consultation.

As communication is a key feature, agreeing on a TLT can be especially difficult where language barriers or cultural differences are predominant (Metaxa et al. 2023). Another critical aspect is deciding on the right time to initiate a TLT. In our case report, it was the moral distress of nurses within the team that led to this decision. However, the freedom to raise concerns about the (present) extent of treatment depends on the work environment, as alluded to earlier. Finally, deciding on the criteria for a positive outcome of a TLT can be a complex process on its own. Advisably so, the outcome should be based on objective and reproducible parameters and the overall clinical impression – certainly not on single vital signs or laboratory values (Jöbges et al. 2024; Kruser et al. 2024). It is important to follow through according to the prior agreement after the end of the TLT and not be persuaded into another

TLT and yet another TLT (Kruser et al. 2024). If inadequately implemented, a TLT may contribute to conflicts within the team and with patients and/or surrogates. Furthermore, some prognostic uncertainty will persist despite accurate implementation of a TLT and frequent re-evaluations of the patient's course. However, decisions as to the extent of treatment need to be taken. Therefore, prognostic irrefutability should never be a goal.

Conclusion

A time-limited trial (TLT) is a collaborative agreement between the treating team and the patient to apply life-sustaining therapies in a defined time period with the overarching goal of reducing prognostic uncertainty and strengthening decision-making in the face of uncertainty. The duration and the criteria of a positive or a negative outcome – reflecting the continuation with or the change of the present treatment goal – need to be chosen with

prudence and in consensus between the team and the patient and/or his/her legal representatives. Implementing a TLT may help reduce prognostic uncertainty and foster trust between teams and patients and/or patients' surrogates. Both patients' needless suffering due to overtreatment and moral distress within the teams will be diminished.

Conflict of Interest

None.

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