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Study Protocol

Palliative Extubation Protocol

Protocolo de extubação paliativa

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ABSTRACT

Introduction: Palliative Extubation (PE) is considered to be the discontinuation of mechanical ventilation in patients whose death is inevitable, prioritizing comfort and respecting the patient's wishes. This study focuses on definitions, ethical, and legal issues, as well as challenges faced by healthcare professionals.

Objective: To explore PE as part of the transition in care, emphasizing symptomatic relief and continuity of Palliative Care. A protocol and checklist for PE is proposed to guide professionals through the process.

Method: Review of definitions, ethical, and legal aspects and presentation of a protocol and checklist for PE. Description of PE methods, including withdrawal of ventilatory support and the complexity of the decision.

Results: The decision for PE must respect bioethical principles, patient autonomy and consider prognostic factors. The importance of analgesia and sedation is highlighted.

Discussion: Ethical and legal aspects, such as Resolution 1805/2006 of the Federal Council of Medicine support PE, emphasizing the dignity of the patient and the right to therapeutic refusal. The updating of the Code of Medical Ethics in 2018 reinforces the provision of palliative care in terminal illnesses.

Conclusion: PE is a complex and delicate practice in Intensive Palliative Care. The review highlights the importance of ethical and legal considerations and specific care when making decisions about PE, emphasizing quality in the dying process and relief of suffering.

Keywords: Airway Extubation; Terminal Care; Bioethics; Critical Care; Clinical Decision-Making; Palliative Care; Clinical Protocols; Legislation, Medical.

RESUMO

Introdução: A Extubação Paliativa (PE) é considerada interrupção da ventilação mecânica em pacientes cuja morte é inevitável, priorizando conforto e respeitando desejos do paciente. Este estudo enfoca definições, questões éticas e legais, bem como desafios enfrentados pelos profissionais de saúde.

Objetivo: Explorar a PE como parte da transição no cuidado, enfatizando o alívio sintomático e a continuidade dos Cuidados Paliativos. Propõe-se um protocolo e um checklist para a PE, visando guiar os profissionais no processo.

Método: Revisão de definições, aspectos éticos e legais e apresentação de um protocolo e checklist para PE. Descrição de métodos de PE, incluindo a retirada de suporte ventilatório e a complexidade na decisão.

Resultados: A decisão por PE deve respeitar princípios bioéticos, autonomia do paciente e considerar fatores prognósticos. Destaca-se a importância da analgesia e sedação.

Discussão: Aspectos éticos e legais, como a Resolução 1805/2006 do Conselho Federal de Medicina, suportam a PE, enfatizando a dignidade do paciente e o direito à recusa terapêutica. A atualização do Código de Ética Médica em 2018 reforça a oferta de cuidados paliativos em doenças terminais.

Conclusão: A PE é uma prática complexa e delicada em Cuidados Paliativos Intensivos. A revisão destaca a importância de considerações éticas, legais e cuidados específicos na tomada de decisões sobre PE, enfatizando a qualidade no processo de morrer e o alívio do sofrimento.

Palavras-chave: Extubação; Assistência Terminal; Bioética; Cuidados Críticos; Tomada de Decisão Clínica; Cuidado Paliativo; Protocolos Clínicos; Legislação Médica.

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INTRODUÇÃO

Palliative extubation (PE) is considered to be the process of interrupting mechanical ventilation in patients in situations where death is inevitable and mechanical ventilation appears to be an intervention responsible only for postponing the dying process. It should be carried out, respecting the wishes of the patient or their legal representative, as part of a process of transition from the objective of care, and it is important to prioritize the patient's comfort and protecting their relatives.[1]

The indication of PE should be linked to an emphasis on care focused on symptom management, giving continuity to the interventions provided by Palliative Care. Therefore, the professionals involved in this procedure must have extensive knowledge of symptom control, communication and managing conflicts that may arise in this context.[2] It should also be considered that PE can cause discomfort to the patient if there is not sufficient knowledge and technical preparation for it.[3] In addition, PE is a process that generates the most anguish among health professionals in a critical care unit. In this context, to minimize the suffering of the professional caregiver, it is necessary to demystify erroneous perceptions that involve not only the withdrawal of life support interventions, but also not performing them. It is therefore important to consider:

(1) The main objectives of PE are to reduce the suffering of patients and their families and to offer the best quality in the dying process. As such, this method cannot be considered a medical practice based exclusively on protocols, but must be grounded in ethical, legal, and clinical principles.
(2) withdrawal of ventilatory support is not a form of patient abandonment, since there is continuity of care and maintenance of the doctor-patient bond;
(3) there is no violation of the principle of beneficence insofar as, in certain circumstances, PE can generate greater comfort for the patient and also respect their values and preferences;
(4) mechanical ventilation should not be indicated in order to alleviate dyspnea, as more appropriate pharmacotherapeutic interventions are available for this purpose.

Although many patients die within minutes to hours of ventilatory support being withdrawn, a considerable number of patients remain alive for days to weeks, and some can even be discharged home. A study of 148 patients undergoing PE showed a mortality rate of 56% within 24 h, while ¼ of the patients could be discharged home.[4] In another study of 1,505 patients, the average time to death after extubation was 0.93 h (0.25-5.5 h) and the independent predictors for a shorter time interval included non-white ethnicity (Hazard ratio, HR 1.17; 95% Confidence interval, CI 1.01-1.35), insufficient number of organs (HR per organ 1.11; 95% CI 1.04-1.19), use of vasopressors (HR 1.67; 95% CI 1.49-1.88), use of intravenous fluids (HR 1.16; 95% CI 1.01-1.32) and hospitalization in surgical services versus clinical services (HR 1.29; 95% CI 1.06-1.56).[5]

A Brazilian study evaluating 282 patients with limitations to life-sustaining therapies concluded that withdrawal of mechanical ventilation accounted for 11% of all patients with treatment limitations and was not associated with increased hospital mortality after pairing by propensity score of the relevant covariates.[6]

The decision for PE is based on the fundamental principles of bioethics. The patient's autonomy is respected by discontinuing obstinate or disproportionate procedures that go against their values. The criteria of beneficence versus non-maleficence are assessed when it is found that mechanical ventilation is increasing the patient's discomfort and prolonging their death. It should be emphasized that the non-implementation or withdrawal of a treatment has the same value from an ethical and legal point of view.[7–11]

On the other hand, prescribers, when making decisions about end-of-life care, are influenced by the fear of ethical and legal proceedings. This is corroborated by data from a Brazilian article which included 522 intensivists, 106 oncologists and 120 attorneys. In this study, the three groups of professionals were very much in agreement regarding the interruption of mechanical ventilation in a hypothetical end-of-life situation in a patient with advanced neoplasia and with the consent of the family, suggesting that concern about legal issues is overestimated in Brazil.[8-11] Another study carried out in Brazilian Intensive Care Units (ICU) showed that 81% of families of unconscious patients would like doctors to discuss the possibility of withdrawing mechanical ventilation.[10-13]

ETHICAL AND LEGAL ASPECTS OF PALLIATIVE EXTUBATION

Resolution 1805/2006 of the CRM states that "In the terminal phase of serious and incurable illnesses, doctors are allowed to limit or suspend procedures and treatments that prolong the patient's life, guaranteeing them the necessary care to relieve symptoms that lead to suffering, with a view to comprehensive care, respecting the wishes of the patient or their legal representative". [8,9] This resolution was suspended in 2007, but came back into force in 2010 after a decision by Judge Roberto Luiz Luchi Demo, in which it is noted: "After much reflection on the issue raised in this public civil action, I have come to the conviction that CFM

Resolution No.1,805/2006, which regulates the possibility of doctors limiting or suspending procedures and treatments that prolong the life of patients in the terminal phase of serious and incurable illnesses, does not really offend the existing legal system. The authors therefore align themselves with the thesis defended by the Federal Council of Medicine throughout the process and by the Federal Public Prosecutor's Office in its final allegations, since it reflects, from the perspective of the resolution in question, the most appropriate interpretation of the Law in the face of the current state of the art of medicine". This court decision was based on the opinion of the Public Prosecutor Luciana Loureiro Oliveira, who pointed out the view of the Public Prosecutor Diaulas Costa Ribeiro on the matter: "However, the suspension of therapeutic efforts is supported by the Federal Constitution of Brazil (art.1, III, and art.5, III), which recognizes the dignity of the human person as the foundation of the Brazilian democratic state and expressly states: no one shall be subjected to torture or inhuman or degrading treatment; in the Civil Code (art. 15), which authorizes patients to refuse certain medical procedures; in Law 8080/90 (art.7, III), which recognizes the right of the patient to autonomy; and in the Code of Medical Ethics, which repeats these same legal principles.7, III), which recognizes the patient's right to autonomy; and in the Code of Medical Ethics, which repeats these same legal principles and prohibits the doctor from carrying out therapeutic procedures against the patient's will, outside of a life-saving medical emergency, which is not the case with an irreversible condition, with no response to any type of treatment". This opinion also highlights: "... once the end of life has been diagnosed, any additional therapy will appear to be ineffective. Thus, it can no longer be accepted that the doctor should do everything to save the patient's life (beneficence) if this life cannot be saved. Therefore, as the condition is irreversible, it is better – if the patient and their family so wish – not to resort to excessive therapeutic care (because it is ineffective), which will only cause harm to the patient. This is why it can be concluded that, at this stage, the principle of non-maleficence takes a privileged position over the principle of beneficence – since no therapeutic measure can really do the patient any good. Therefore, what palliative medicine advocates, in the context of which is orthothanasia, is that, if it is impossible to save life, the natural – and irreversible – process of death should be allowed to run its course, giving the patient the greatest comfort they can have in their last days (which can be limited to pain relief or even de-hospitalization, if this is the will of the patient themselves and their family)...".[10]

In 2018, the Code of Medical Ethics was updated and states in Article 41, Sole Paragraph, "In cases of incurable and terminal illness, the physician must offer all available palliative care without undertaking useless or obstinate diagnostic or therapeutic actions, always taking into account the express wishes of the patient or, if this is not possible, those of their legal representative".[11]

Regarding respect for patient autonomy, Federal Council of Medicine (CFM) Resolution No.2,232/2019 establishes ethical standards for therapeutic refusal by patients and conscientious objection to the doctor-patient relationship.[11]

SUSPENSION OF MECHANICAL VENTILATION

The decision to suspend mechanical ventilation is complex and involves assessing both the multi-professional team's understanding of the process and the interpretation of the values by the patient/family binomial.

Whenever palliative extubation is defined, other disproportionate therapies and/or procedures, which do not aim to prevent or control symptoms, should be withdrawn beforehand. These therapies/procedures include renal replacement therapy, vasopressor support, administration of blood products, antibiotics, intravenous fluids, or an artificial diet (enteral or parenteral), as well as requests for laboratory tests and diagnostic examinations.

The literature mentions two methods for interrupting invasive ventilatory assistance. Extubation or reducing ventilator parameters by maintaining the orotracheal tube and minimum parameters such as support pressure 6-8 cm H_2O, fraction of inspired oxygen (FiO_2) 21% and minimum positive end-expiratory pressure (PEEP) 5 cm H_2O or without PEEP (ZEEP). Although extubation is more advisable, reducing pressure/volumetric parameters and/or the fraction of inspired oxygen is also accepted, depending on the context in which the decision is made.[14]

When opting for PE, the prescriber must bear in mind that the outcome could be an adequate breathing pattern that allows discharge from the ICU or the maintenance of minimally effective breathing that leads to death in a short space of time.[14] For this reason, it is advised that after extubation the patient remains in the ICU for a period of 24-48 h before possible discharge from the sector. The patient's quality of life is essential and for this purpose, systematic assessment, and control of discomfort with appropriate titration of analgesics, sedatives, and adjuvants at every step of the process is paramount.

Figure 1 shows the recommended basic steps for PE to be carried out. A suggested protocol for palliative weaning of palliative care patients is illustrated in Figure 2. Figure 3 provides a checklist for performing PE.[3,14–17]

FUNDAMENTAL STEPS TO BE TAKEN WHEN FACED WITH THE POSSIBILITY OF DISCONTINUING MECHANICAL VENTILATION

- Certification that the maintenance of mechanical ventilation is inappropriate because the patient is in an irreversible end-of-life situation, or the sequelae of previous illnesses and/or critical illness are unacceptable according to the patient's values;
- Checking that the teams agree on the need for palliative extubation;
- Assessment of the patient's/family's understanding and acceptance of the procedure;
- Enabling, where appropriate, a visit from the family's or hospital's spiritual leader;
- Provision, where possible, of support from the palliative care team;
- Description of all stages of the process in the medical record;
- Assessment of discharge to the room or palliative care unit, 24-48 h after extubation, depending on the patient's stability; and
- Continuous observation and maintenance of the necessary care to ensure the patient's comfort and well-being.

Figure 1. Fundamental steps to be taken when faced with the possibility of discontinuing mechanical ventilation.
Source: Adapted from references 3,14–17.

PALLIATIVE EXTUBATION PROTOCOL

Preparing for palliative extubation

- Prepare the team members and ensure that the attending physician is aware of and agrees with the plan;
- Review planned procedures in detail with team members and plan continuity of care;
- Remind the team that all actions are aimed at guaranteeing the patient's dignity. Reaffirm that the patient and their family are the focus of care;
- Ensure the patient's comfort;
- Check that the patient is adequately provided with analgesics and sedated and that they are not on neuromuscular blockers;
- Assure the family that neither they nor the patient will be abandoned by the team. Clarify the possibility of an irregular end-of-life ventilatory pattern and noises such as wheezing. Make visits more flexible and stimulating;
- Ensure that spiritual care is offered, according to the needs of the patient/family.

6 h before removal of mechanical ventilation

- Prepare the environment and control excessive noise or any other factor that compromises the tranquility of the space;
- Remove unnecessary equipment and inappropriate medication;
- Reduce hydration and administer, when indicated, furosemide and corticoids to prevent post-extubation stridor;

Figure 2. Palliative extubation protocol.
Source: Adapted from references 3,14–17.

PALLIATIVE EXTUBATION PROTOCOL (Cont.)

- Evaluate the use of hyoscine/ scopolamine/atropine SL to reduce secretions;
- Consider the need for hygiene or bathing before the procedure;
- Monitor, control, and prevent symptoms: pain, dyspnea, agitation, delirium. Use specific scales to monitor symptoms;
- Assess and adjust comfort medications such as midazolam, propofol, morphine, fentanyl; and
- Discontinue diet. Nasogastric tube siphoning;

30 min before removal of mechanical ventilation

- Position the patient in the supine position, with the headboard at 30-40 degrees;
- Aspirate secretions before removing the orotracheal tube;
- Check for analgesia and sedation and adjust medications by bolusing and/or increasing the flow rate before, during and after extubation;
- Turn off equipment alarms;
- Sequentially reduce FiO_2 to 21% and ZEEP or PEEP 5 cm H_2O. Maintain minimum support pressure (6-8 cm H_2O);
- Assess the necessity to repeat medications such as corticoids, hyoscine, furosemide etc.
- Keep analgesia (opioid, morphine 1st line) and sedatives (midazolam, 1st line) ready to control symptoms. Note: Previously administered medications, such as fentanyl and propofol can be maintained;
- If the patient is uncomfortable, medicate and increase the ventilator parameters until the symptoms are controlled,

Figure 2. Cont.
Source: Adapted from references 3,14–17.

CHECKLIST FOR PALLIATIVE EXTUBATION

Extubation decision (meet all criteria)

( ) The patient will benefit clinically
( ) There is information, acceptance, and preparation of the team and the attending physician
( ) The procedure is in line with the patient's/family's values and/or preferences
( ) The patient and/or family were adequately informed and were accepting of the method
( ) There is no BMN effect
( ) The environment was deemed suitable for the procedure
( ) Continuity of care has been planned
( ) Visits were allowed to be flexible before, during and after the procedure
( ) Psychological/spiritual support for patient/family has been ensured

Figure 3. Palliative extubation checklist.
Source: Adapted from references 3, 14-17.

CHECKLIST FOR PALLIATIVE EXTUBATION

6 h before extubation

( ) The environment has been prepared to allow the process to go smoothly

( ) The family has been prepared for potential complications after extubation

( ) The need for hygiene procedures before extubation has been assessed

( ) The need for removal of monitoring devices has been reassessed

( ) Potentially inappropriate medications (inotropic, chronotropic, dialysis and other medications) have been withdrawn

( ) Enteral feeding has been withdrawn and SNG has been maintained in siphonage

( ) Discomfort has been monitored

( ) The need for additional medication has been assessed

( ) The ventilation modality has been readjusted

30 min before extubation

( ) Briefing conducted with team on preparation

( ) Patient's position (head elevated 30-40 degrees) has been checked

( ) Secretions have been aspirated

( ) Analgesia and sedation have been checked and adjusted

( ) Rapid access to the drugs needed for patient comfort have been checked

( ) Ventilatory modality (FiO_2 21%, ZEEP or PEEP 5 cm H_2O, minimum support pressure 6-8 cm H_2O) have been checked

EXTUBATE

Maintain comprehensive patient/family care

Figure 3. Cont.
Source: Adapted from references 3, 14-17.

Chart 1 details the doses of analgesic and sedative medications used during and after the PE process in adult patients. Chart 2 refers to pediatric medications. The scales recommended for monitoring the main symptoms are shown in Chart 3.[3]

CONCLUSION

Palliative extubation is a complex and sensitive procedure within the context of Intensive Palliative Care. The review covered in this article highlights the importance of in-depth ethical and legal considerations and specific care when deciding on PE. The procedure is not just a matter of following protocols, but rather of being based on sound ethical, legal, and clinical principles. It is crucial to understand that PE seeks not only to alleviate the patients' suffering, but also to respect their values and preferences, ensuring them a dignified and comfortable death. The updating of the Code of Medical Ethics in 2018 reinforces this necessity, focusing on the provision of palliative care for terminal illnesses. Moreover, Brazilian legislation, such as Resolution 1805/2006 of the Federal Council of Medicine, supports PE, recognizing the patients' right to therapeutic refusal in end-of-life situations. Ultimately, PE requires an interdisciplinary approach, effective communication, and meticulous attention to symptoms, ensuring maximum comfort and dignity for the patient in the dying process.

Chart 1. Analgesia and sedation for palliative extubation in adults.

Analgesia medication before, during and after the palliative extubation process		
Patients with no prior opioid use	Patients receiving morphine	Patients receiving fentanyl
First option: start morphine: 2 mg intravenous (IV) bolus. Repeat the IV bolus dose every 10 to 15 min if necessary (if needed). Add morphine IV in continuous infusion – 1 mg/h. In case of discomfort, give a bolus of 50% of the hourly dose every 10 min and increase the continuous infusion by 25-50% every 10 min (if needed). ***or*** Start fentanyl 20 µg IV bolus. Repeat the IV bolus dose every 5 min (if needed). Combine IV fentanyl with continuous infusion 20 µg/h. In the event of discomfort, bolus 50% of the hourly dose every 10 min and increase the continuous infusion by 25 to 50% every 10 min (if needed).	Administer a bolus dose 2× the hourly dose of the continuous infusion. Repeat the IV bolus dose every 15 min (if needed) and increase the IV dose of the continuous infusion by 100% if it is necessary to receive 2 or more boluses.	Administer a bolus dose of the hourly dose of the continuous infusion. Repeat the IV bolus dose every 5 min (if needed) and increase the continuous infusion IV dose by 100% if 2 or more boluses are required.
Sedation medication before, during and after the palliative extubation process		
Patients with no prior use of sedatives	Patients receiving midazolam	Patients receiving propofol/(dexmedetomidine)
First option: start midazolam 2 mg IV bolus. Repeat (if needed) the IV bolus dose every 2 to 5 min. Add midazolam IV in continuous infusion 1 mg/h.	Administer a bolus dose of 1 to 2× the hourly dose of the continuous infusion. Repeat the IV bolus dose every 5 min (if needed) and increase the continuous infusion IV dose by 25 to 30%. If needed, two or more boluses are required in 1 h, it is suggested to double the hourly continuous infusion.	If the patient is comfortable with previously prescribed medication, these can be maintained.

Chart 2. Analgesia and sedation for palliative extubation in pediatrics.[18,19]

Analgesia medication before, during and after the palliative extubation process		
Patients with no previous opioid use	Patients receiving morphine	Patients receiving fentanyl
First option: start morphine: 0.05 - 0.1 mg/kg/dose IV slowly. Repeat the IV bolus dose every 10 to 15 min (if needed). Associate morphine IV in continuous infusion 0.01 mg/kg/h and increase as necessary. ***or*** Fentanyl in equivalent doses.	Administer a 25% higher dose.	Maintain medication and increase dose according to clinical assessment.
Sedation medication before, during and after the palliative extubation process		
Patients with no prior use of sedatives	Patients receiving midazolam	Patients receiving clonidine/(dexmedetomidine)
First option: start midazolam 1-3 mg/dose IV bolus. Repeat (if needed) the IV bolus dose every 5 min. Add midazolam IV in continuous infusion 1-5 µg/kg/min, until dyspnea is controlled.	Maintain the dose for patient comfort and dose in bolus according to clinical evolution.	In case the patient is comfortable with previously prescribed medicines, these should be maintained.

Chart 3. Scales used to assess the main symptoms.

Most prevalent symptom	**Symptom assessment (systematic use of scales is essential)**
Pain	Behavioural Pain Scale (BPS) or Care Pain Observation Tool (CPOT) which score values related to easy expression, limb movements, adaptation to ventilation, muscle tension and vocalization.
Dyspnea	Respiratory Distress Observation Scale (RDOS) to assess respiratory distress. The following can be interpreted as respiratory distress: tachypnea, tachycardia, facial expression, use of accessory muscles, paradoxical breathing, and nasal beat.
Agitation	Sedation-Agitation Score (SAS) or Richmond Sedation/Agitation Scale (RASS).
Delirium	Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)

Source: Adapted from reference 3.

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