

Tracheostomy in critically ill patients in the era of informed consent

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Abstract

Although tracheostomies are often performed in critical patients with prolonged or presumed prolonged mechanical ventilation, the recommendation, benefits and risks of the procedure remain controversial. Informed consent is widely established as a necessary process in surgical procedures and should be obtained prior to the performing of a tracheostomy. The present article provides a narrative review of the process of the medical recommendation of this procedure and, through the use of the tracheostomy in the critical patient, addresses the application of the informed consent term. Theoretical aspects are discussed, such as what should be included in written documents and what should be verbally explained to patients and their families, together with other practical aspects. It was found that the current terms of consent for tracheostomies in critical patients do not prioritize autonomy, as they avoid the allocation of the resources necessary for the recommendation of the procedure.

Keywords: Tracheostomy. Critical care. Informed consent.

Resumo

Traqueostomia no doente crítico na era do consentimento livre e esclarecido

A traqueostomia é procedimento frequentemente realizado em doentes críticos com ventilação mecânica prolongada ou presumidamente prolongada, embora suas indicações, benefícios e riscos sejam controversos. O termo de consentimento livre e esclarecido é necessário para procedimentos cirúrgicos e tem sido amplamente instituído, devendo ser obtido antes da traqueostomia em pacientes críticos. Este artigo faz revisão narrativa das indicações do procedimento e, considerando-o no caso de doentes críticos, aborda a aplicação do termo de consentimento livre e esclarecido. Discutiram-se aspectos teóricos; o que deve constar nos documentos escritos; o que deve ser verbalizado para os doentes e seus familiares, além de outros aspectos práticos. Concluiu-se que os atuais termos de consentimento para traqueostomia em doente crítico não privilegiam a autonomia, pois evitam alocação de recursos para indicação do procedimento.

Palavras-chave: Traqueostomia. Cuidados críticos. Termos de consentimento.

Resumen

Traqueostomía en el paciente crítico en la era del consentimiento libre e informado

La traqueotomía es un procedimiento frecuentemente realizado en pacientes críticos con ventilación mecánica prolongada o presumiblemente prolongada, aunque sus indicaciones, beneficios y riesgos sean controvertidos. El documento de consentimiento libre e informado es necesario para la realización de procedimientos quirúrgicos y ha sido ampliamente instituido, debiendo ser obtenido antes de la traqueostomía en pacientes críticos. El presente artículo hace una revisión narrativa de las indicaciones de este procedimiento y, considerándolo en el caso de pacientes críticos, aborda la aplicación del documento de consentimiento libre e informado. Se discutieron aspectos teóricos; lo que debe constar en los documentos escritos; lo que debe ser verbalizado a los enfermos y a sus familiares, además de otros aspectos prácticos. Se concluye que los actuales documentos de consentimiento para traqueostomía en el paciente crítico no privilegian la autonomía, pues evitan la asignación de recursos para la indicación del procedimiento.

Palabras clave: Traqueostomia Cuidados críticos. Término de consentimiento.

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Declaram não haver conflito de interesse.

Tracheostomy in critically ill patients is often indicated by intensivists in cases of prolonged or presumably prolonged mechanical ventilation. In these circumstances, the free informed consent form (ICF) must be obtained to carry out the procedure. To do this, it is necessary for health professionals to better understand the bioethical aspects involved, considering indications, potential benefits, risks and alternatives.

Indications and Potential Benefits of a Tracheostomy

The following are considered benefits of tracheostomy in critically ill patients: reduction of changes in anatomic laryngeal and inspiratory load, and greater tolerance and ease of nursing care in relation to orotracheal intubation¹. Most of these benefits are difficult to quantify, and the identification of more consistent outcomes is required. Systematic reviews and meta-analyses have compared the best timing (early vs. late versus non-performing tracheostomy) and the best technique (surgical or percutaneous dilatation).

In a recent meta-analysis, Andriolo and collaborators² reviewed the literature comparing early (≤ 10 days) and late tracheostomy (> 10 days) in the care of critically ill patients, in which eight studies and 1,977 participants were included. The result indicated a reduction in mortality for patients submitted to early tracheostomy in variable periods between 28 days and two years. However, the authors suggested that these data should be interpreted with caution, since information on subgroups was insufficient, as well as individual characteristics associated with greater benefit of early tracheostomy. The results related to the time of mechanical ventilation were not considered definitive, but indicated benefit of the procedure. There was no difference in the incidence of pneumonia.

Meng et al.³ compared early (≤ 10 days) and late tracheostomy (> 10 days) considering nine randomized studies and 2,040 participants. No differences were found in relation to mortality (hospital or 30 days), period of mechanical ventilation and hospitalization in the intensive care unit (ICU). Patients submitted to early tracheostomy had shorter sedation times.

In a previous meta-analysis, Huang et al.⁴ compared early tracheostomy (≤ 10 days), late tracheostomy (> 10 days) and no tracheostomy, and the last two groups were analyzed together. There

were nine randomized trials with 2,072 participants. No statistically significant differences were found in relation to mortality in 90 days, time of mechanical ventilation and ICU stay, and incidence of pneumonia.

An interesting result was reached by Siempos et al.⁵, who performed a meta-analysis of 13 studies with 2,434 patients, comparing three groups separately: patients undergoing early (≤ 1 week) or late tracheostomy (> 1 week) and non-tracheostomized patients. Also, no statistically significant differences were found in relation to ICU mortality or after one year in any of the three groups. However, patients submitted to early tracheostomy had a lower incidence of pneumonia associated with mechanical ventilation.

McCredie et al.⁶ recently published a meta-analysis including 10 studies with 503 victims of acute brain injury (head trauma, aneurysmal subarachnoid hemorrhage, cerebrovascular accident, post-craniotomy, cardiorespiratory anoxia, epileptic status, meningitis, encephalitis and brain abscess) comparing early tracheostomy (≤ 10 days), late tracheostomy (> 10 days) and no tracheostomy. Early tracheostomy reduced long-term mortality (6 to 12 months) and duration of mechanical ventilation, but not short-term mortality (in-hospital or within 60 days).

Cai et al.⁷ assessed, by meta-analysis, the outcomes of traumatic brain injury victims submitted to early and late tracheostomy, or non-tracheostomized. The time limit for setting early or late was not specified. These intervals ranged < 4 days for early tracheostomy and > 28 days for late tracheostomy. Twenty studies with 7,751 participants were included. Patients submitted to early tracheostomy had lower mortality, shorter ICU or hospital stay, reduced mechanical ventilation, and shorter risk of pneumonia.

Although the prevention of infraglottic stenosis is considered a potential benefit of tracheostomy, airway complications may also occur after the procedure⁸. One of the complications is tracheal stenosis, usually in the stoma region, which may require surgical intervention with a postoperative mortality rate of up to 5%⁹.

More recently, percutaneous dilatation technique has been advocated as a way to avoid complications of surgical tracheostomy¹⁰. Research with 429 physicians from 59 countries confirmed the spread of the technique with single dilation, adopted in 42% of the cases, 74% of which were performed by

intensive care physicians. The surgical tracheostomy corresponded to 24% of the procedures.

The predominance of the percutaneous technique by single dilation results from the representation of European countries in the study, since outside Europe the surgical technique prevails (36%) over the percutaneous ones analyzed separately. Most of the surgical tracheostomies (84%) were performed in the ICU itself. Tracheostomies were performed after 7 to 15 days of ICU admission, usually indicated by prolonged mechanical ventilation (54%) accompanied by difficult or prolonged weaning (24%).¹¹

Although lower rates of blood loss and infectious complications with percutaneous tracheostomy are reported, there appears to be no lower rate of tracheal stenosis¹². Complications related to the surgical procedure are relatively frequent, although avoidable, usually associated with unavailable material, inadequate training of personnel and communication flaws¹³. Regarding the percutaneous technique, deaths have also been reported with an incidence of 0.17%¹⁴.

A favorable argument for the indication of tracheostomy in critically ill patients is the possibility of transferring their care to semi-intensive or even open units, making critical beds available for other patients¹⁵. Some patients are discharged from the ICU with non-invasive ventilation equipment used invasively by tracheostomies. However, the presence of tracheostomy cannulae in hospitalization units is a factor associated with higher hospital mortality¹⁶, and multidisciplinary care seems to reduce complications in these cases¹⁷.

The need for tracheostomy is found in definitions of chronic critical patients, a subgroup with high in-hospital mortality, prolonged hospitalizations, neurocognitive and muscular sequelae and, mainly, mechanical ventilation for longer periods¹⁸.

In general, there seems to be benefit of early tracheostomy in patients with acute neurological injuries with regard to late tracheostomy or not performing the procedure. Although early tracheostomy is somewhat better than late tracheostomy for the rest of the critically ill population, neither study group appears to be definitely superior to not performing tracheostomy and prolonged maintenance of tracheal intubation.

The potential complications of the procedure, either early or late, should also be diminished or decisively influenced by the adoption of the surgical or percutaneous technique. It is also vital to recognize the risks of transferring patients to open units.

Theory and practice of the free informed consent

The importance of informed consent was first evidenced in 1767 in England in a judgment regarding surgery performed against the will of a patient (the Slater *versus* Baker & Stapleton case)¹⁹. Since then, it has become tacitly or explicitly established to request express authorization from the patient or his legal representatives for invasive procedures²⁰. The purpose of informed consent is to guarantee the exercise of autonomy based on knowledge of indications, benefits, risks and therapeutic alternatives²¹.

Consent should result, rather than from adequate unilateral information, from effective communication between the two agents: the physician who provides the information and the patient or his/her legal representative. The latter are the legitimate subjects of the action when agreeing or not with the procedure. On the other hand, transmitting information unilaterally can maintain the paternalistic attitude of the health professional.

The asymmetry between sender and receiver of the information is due to a problem of translation of the English term informed consent to “consentimento informado” or even the French version for “free and informed consent” (used among ourselves). With the translation, the sense of communication and interaction between individuals seems to have been lost²², which may limit the autonomy of the one who gives consent to the practice of tracheostomy, especially considering which can limit the autonomy of those who consent to the practice of tracheostomy, especially when considering the meager benefits and the risks involved.

Inadequate communication may also generate false expectations frequently reported by patients and family members, who may deduce that tracheostomy is a positive step in the evolution of the clinical picture²³. In addition, the indication of the procedure as a way of transition from care based on the principle of justice, aiming at a better allocation of critical beds, is often not verbalized by the intensivists, although it is also part of the theoretical framework of the ICF²⁴. Thus beneficence becomes secondary and autonomy is limited.

The bioethical framework of basic principles (beneficence, non-maleficence, autonomy and justice) was structured on the basis of the theory of *prima facie* principles, developed by David Ross. The Latin expression indicates an obligation that must

be fulfilled unless it conflicts with an obligation of equivalent or greater importance²⁵. The classical principles derive from three philosophical roots, with no clear hierarchy between them²⁶.

Non-maleficence is the fundamental principle of the Hippocratic tradition, and it recommends that the physician should, first of all, refrain from causing harm, which is a moral requirement of the profession. Beneficence, in turn, has been associated with professional excellence since the times of Greek medicine and is expressed both in the oath of Hippocrates and in the utilitarian theory of John Stuart Mill²⁵. It is the application of all professional knowledge and skills at the service of the patient to minimize risks and maximize the benefits of the procedure to be performed.

Autonomy, then, is the ability to decide to do or seek what is considered the best for you. In order to exercise this self-determination, two fundamental conditions are necessary: the capacity to act intentionally, which presupposes understanding, reason and deliberation to decide coherently between the alternatives presented; and freedom, in the sense of being free of any influence on decision-making²⁵. Autonomy is ethically grounded in human dignity.

Beauchamp and Childress relied on Immanuel Kant and John Stuart Mill to justify respect for self-determination. Kant, in his deontological ethics, explains that dignity comes from a morally autonomous condition and that, therefore, it deserves respect and must be treated as an end in itself, and never as a means. Mill, one of the exponents of Anglo-Saxon utilitarianism of the nineteenth century, showed a similar stance by suggesting that citizens should develop according to their own convictions, provided they did not interfere with the freedom of others²⁵.

The ICF, therefore, is an autonomous and verbal or written decision regarding a specific treatment after the patient has received information about indications, benefits, risks and possible alternatives^{25,26}.

Biomedical ethics has emphasized the interpersonal relationship of health professionals and patients, in which beneficence, non-maleficence and autonomy play a prominent role, overshadowing, in a way, the principle of justice. This is generally associated with relations between social groups, dealing with equality in the distribution of goods and resources considered common, in an attempt to equalize opportunities for access to these goods²⁷. The concept of justice as equality

is permeated by the ideas of John Rawls. For the author, equality should be understood as norms of cooperation recognized by free and equal persons in rights that are valid for all human beings without any kind of distinction²⁸.

The principles delineated by Beauchamp and Childress²⁵ are not hierarchical, but over the years, autonomy has stood out in relation to the others, perhaps by influence of Engelhardt²⁹. In the author's view, the principle of autonomy, often renamed the principle of permission, becomes the basis of consensus among different morals and determines whether an action is good or not, despite other criteria. In clinical practice, this perspective is potentially dangerous, as it may allow debatable treatments or that do not consider the needs of others, as contemplated in the framework of Beauchamp and Childress³⁰.

An even more exacerbated view of autonomy has been suggested with the change of consent for treatment (request for treatment), although the proposal has the merit of seeking to reduce the asymmetry in the relationship between physicians and patients/relatives. In this case, the user would complete the request for a procedure, that is, a document with indications, benefits, risks, complications and alternatives. Subsequently, the doctor would clarify any doubts and misconceptions, and finally, in common agreement, both would define the treatment¹⁹.

Little is known about the impact of sociocultural differences in obtaining the ICF. The predominance of Anglo-Saxon individualism has been identified as a potential source of conflict in societies in which the family is culturally dominant, as in China³¹. An act can meet the three main conditions for setting itself up as autonomous - being intentional, carried out with adequate understanding, and without external control - and yet not be truly autonomous for lack of authenticity. Moreover, it is considered authentic when coherent with the system of values and general attitudes assumed reflexively and consciously, which can be an obstacle when considering socio-cultural differences³².

Another controversial issue is the defense that for any consent to surgical procedure there should be data about the individual performance of the professionals. Performance measures were initially used to improve quality in institutions. The pressure to make this information public came about because of myocardial revascularization surgeries. In theory, from performance information, patients could make better choices, justifying their presence in the terms of the consent^{33,34}.

Adherence to properly documented consent term patterns, in addition to verbalization of the nature of the procedure, risks and alternatives, can be problematic. In fact, research has shown reduced adherence of surgeons to ICF minimum standards^{35,36}. A study in Brazil showed that although professionals consider the ICF important, they do not use it routinely. In addition, when used, they consider it unnecessary to transmit all information. In addition, they omit some information not only because it is considered dispensable, but to facilitate the medical practice.

Often, it is sought to prevent the patient from perceiving the risks, which could lead to a refusal of the proposed treatment. In this qualitative study, the information need was defined as “fundamental” only once by the interviewees, demonstrating the lack of concern with this duty³⁷.

Contradictions between clinical guidelines and care practice are common. Patients know far less of what professionals believe and of what they should know about the procedures performed in them. Consent practice, therefore, generally responds only to administrative or legal objectives³⁸. A study carried out in Spain on the perception of patients about the ICF showed that they recognized the document as a formality rather than an ethical obligation, some of them even feeling coerced to sign it³⁹.

The opinion of the Brazilian Federal Council of Medicine (Conselho Federal de Medicina - CFM), CFM opinion n° 8.334/00, deems the ICF necessary, but considers that the information supplied to patients need not be in the form⁴⁰.

The free informed consent of the critically ill patient

Informed consent is particularly important for critically ill patients as they are among the most vulnerable in the hospital environment⁴¹. Care with these patients and the allocation of complex resources create major challenges in relation to the exercise of the so-called core bioethical principles in clinical practice: autonomy, beneficence, non-maleficence and justice.

To exercise autonomy depends on decision-making capacity, adequate information, understanding, voluntary choice and formal authorization to receive a certain intervention²⁴. A problem in the case of critically ill patients is the inability to decide, which implies medical judgment and may bias the exercise of autonomy. The professional must determine if the

patient understood and retained the information relevant to the decision, and used it in the decision-making process, aware of the consequences of taking a decision contrary to the proposal or of not deciding. In addition, it should consider the patient's ability to communicate his decision²⁵.

Evidence shows that acute diseases can interfere in the understanding of one's own situation and in the ability to assess risks and benefits⁴². Neurocognitive changes, depression and anxiety can also impair decision-making ability. In cases where the patient can not make choices, obtaining the ICF through a substitute is an alternative²⁴. A study has shown that professional evasiveness in answering directly formulated questions is also a stress factor to be considered⁴³.

Terms of consent for critical patients are obtained for non-urgent invasive procedures performed at the bedside, ensuring that the patient or his representative would consent. The model does not include the surgical block tracheostomy, for which a specific consent is required⁴⁴.

Consent forms may be made for specific procedures or may have a universal character. The use of universal consent forms is controversial, for one of the requirements of a legal act is that its object be determined or possible to determine⁴⁵. One study identified an increase in adherence to the practice of prior authorization with universal terms⁴⁶, however another study showed the opposite⁴⁷. In a study in the US, Stuke et al.⁴⁸ reported lower informed consent in surgical ICUs and for procedures such as non-emergency intubation and introduction of intra-arterial catheters, as well as a prevalence of only 14% of universal consent terms for critical patients.

One of the difficulties raised by intensive care physicians to obtain consent is the time spent for their application, which can delay patient care. However, Marsillio and Morris demonstrated that the time taken to obtain the document was only 5 minutes, although logistical questions regarding the presence of family members were not taken into account⁴⁹.

It is noteworthy that a study carried out in Australia on the expectation of patients and their relatives regarding consent showed that only 27% of users would like to request prior consent for each elective procedure, while 59% would find the non-written consent sufficient⁵⁰. A study assessing the satisfaction of family members with the introduction of universal consent for different procedures showed favorable results for this

practice, however, the *lato sensu* tracheostomy was not included in the document⁵¹.

Free informed consent for tracheostomy

Adhering to obtaining ICF for tracheostomy in critically ill patients is one of six quality indicators of the Spanish Society of Intensive and Critical Care Medicine and Coronary Units. A questionnaire answered by 68 ICUs in Spain showed 92% adherence to this question⁵².

In a questionnaire with 429 doctors from 59 countries, Vargas et al.¹¹ showed that informed consent was previously obtained for tracheostomy only 61% of the occasions, mostly in non-European countries that participated in the study (88% of the occasions).

In an earlier study performed in Italy, obtaining consent for tracheostomy differed between conscious patients (82% of occasions) and unconscious patients (62% of occasions). Information on the benefits and risks consisted of informed consent in only 61% of the participating ICUs. These data were not consistent with the Italian legislation, which requires the ICF for elective surgical procedures⁵³. In the study by Stuke et al.⁴⁸ the rate of obtaining the document for tracheostomy reached 97%.

Although we do not have data on the adequacy of the terms for tracheostomies nor on the communication of intensivists or surgeons with patients and relatives, it is possible to assume that the documentation is adequate and there is an incomplete verbalization of the aspects related to the procedure in Brazil. Specific consents updated with the best evidence available, in addition to effective communication stimuli, have improved adherence to good practices in other contexts⁵⁴. In fact, among ourselves the need for ICF with the highest specificity is highlighted⁵⁵. The inclusion of tracheostomy in universal consent terms, even for mini tracheostomies or percutaneous procedures, does not seem adequate.

An aspect to be considered is the frustration of patients and family members with the evolution of the chronic critical illness and the false expectation related to the performance of the tracheostomy. It is possible to infer that many patients or relatives would not have agreed to treatment retrospectively. In fact, one study found that the rate of consent would be influenced retrospectively in a neuro-intensive unit because of a worse neurological prognosis⁵⁶.

Discussion on decision-making processes in cases of tracheostomy

Dealing with prognostic uncertainty is a difficult task for many intensive care physicians⁵⁷. Scientific uncertainties may derive from the inability to determine the risk of a future event, as to the strength or quality of evidence to estimate the risk, or may stem from conflicting findings in different studies. The difficulty of the professional in exposing uncertainties, in the form of probabilities, reduces the ability to make shared decisions with patients and family members⁵⁸.

The inability to deal with uncertainty may give the impression that the decision is exclusively technical and not a complex judgment of values⁵⁹. Faced with the explicit uncertainty, it is clear that the resolution depends on the values of the patient or his or her surrogate decision makers regarding the benefits and risks involved⁶⁰. This inability, which is predominantly studied in relation to the prognosis of critically ill patients, can also be determinant when the tracheostomy is requested, since the benefits of this procedure may not be so marked, especially in patients without acute neurological injuries.

Only by understanding indications, expected benefits, the risks involved and the alternative of not performing the procedure, while keeping the patient intubated for a long time, can a legitimate autonomous decision be made. Formal education can help health professionals feel more comfortable with the need to communicate uncertainties in the form of risk and probability⁵⁸. The ability of the practitioner to truthfully convey the clinical picture, risks and benefits of the proposed procedure may influence the patient's understanding and their families.

The possibility of patients and family members refusing the tracheostomy is real, if its benefits and risks are not well based, as well as the possibility of not accepting the principle of justice regarding the allocation of beds for other patients.

An underscored aspect concerns what risks should appear in the consent form and which should be verbalized. There are no explicit guidelines on this, but in general all serious and frequent risks, even when less severe, should be informed in the consent form⁶¹.

In England, for example, the National Health Service recommends the inclusion of complications with percentages above 1 and 2%, in addition to any serious complications, even if they are rarer. Rajab et al.⁶² suggest that late complications such as bridles after abdominal-pelvic interventions be cited when

ICF is requested for abdominal surgical procedures. Similarly, we understand that tracheal stenosis should be remembered as a late complication when consent is requested. The possibility of not carrying out the treatment should be considered⁶¹, which is also important with regard to tracheostomy in critically ill patients.

As widely recommended, the language should be accessible to the patient or his/her family members⁶⁰. The term can be withdrawn at any time, and the date and time should be recorded. *A priori*, in general, it is considered that even a mentally ill individual can deny treatment⁶¹.

A relevant paradox arises from the possible excessive transference of responsibility to the patient and his/her relatives. No rule is applicable to all individuals. Schwartz believes that the transfer of responsibility may have gone too far⁶². Patients often do not want this freedom. Although satisfied with having their autonomy respected, they can exercise it by opting to leave it⁶³.

It is fundamental not to reduce the term to a pure formality, through dialogue between physician and patient. Transparency and reduction of the asymmetry between the two agents are what ensures respect for the patient's autonomy. In this way, a sufficiently autonomous decision can be made, without all the information needing to be necessarily written in the document, provided they are verbalized.

Autonomy must be in balance with the other basic principles. The exacerbated dominance of autonomy can create potentially dangerous distortions in relation to the allocation of resources, compromising the principle of justice. On the other hand, intensive care physicians find it difficult to recognize the allocation of resources (critical beds), guaranteed by the principle of justice, as an indication for tracheostomy. This may lead to overestimation of the benefits and minimization of the risks of the procedure, generating discomfort

in the professionals, even if this sensation is not accompanied by reflection. This cognitive dissonance can be characterized as moral fiction⁶⁴, because professionals feel uncomfortable in putting justice, which meets collective criteria, above the other classic principles (autonomy, beneficence and non-maleficence), focused on the individual dimension.

Final considerations

The review of the meta-analyses on the performance of the tracheostomy and the obtainment of the ICF for the procedure showed that it may be necessary to review the terms and form of communication between physicians and patients or their surrogate decision-makers. These documents should contain indications, benefits, early and late risks, and alternatives to the proposed procedure. In addition, these aspects must be verbalized at the time the consent is requested.

It may also be fundamental to recognize justice as one of the principles involved in tracheostomy indication, so that the decision made is actually free and informed. Justice in the allocation of resources as an indication of the tracheostomy will inevitably conflict with the autonomy of the patient and his/her representatives, but the solution of this conflict involves a transparent relationship between the agents involved.

It is concluded that tracheostomy, independent of the technique of the procedure, can not be contemplated by the universal consent terms currently used for critically ill patients. Tracheostomy is not considered by most current ICFs, since they generally do not clarify the benefits, do not report all risks, and do not cover non-performance of the tracheostomy as a viable alternative. In addition, they do not integrate justice as a principle that motivates the indication of the procedure.

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