Mechanical ventilator liberation protocol. Recommendation based on review of the evidence

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Abstract

Mechanical ventilation is currently the most widely used supportive therapy for the treatment of moderate and severe hypoxemia of any etiology. However, the decision of "when" is the right time to initiate the withdrawal of this support is currently a matter of debate worldwide. Many authors describe that the disconnection process should be gradual and in compliance with standards that provide safety to this process; while other authors report that it is not feasible to establish a universal standard since each patient would have a unique behavior that would be difficult to establish in a protocolized manner.

The present review represents an extensive search for evidence in an attempt to clarify this issue, generating evidence from a consensus of experts at international level, based on a broad review of the literature.

Keywords: Weaning, Spontaneous breathing trial, Rapid shallow breathing index, P0.1

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Levels of recommendation

For this review, we used the "traffic light" criteria to define the level of recommendation according to the evidence reviewed: GREEN for studies with robust designs (systematic reviews, meta-analyses, randomized clinical trials), YELLOW for studies with smaller designs (observational, longitudinal, society recommendations) and finally RED for descriptive studies or studies with robust designs but indicating contraindications for a certain therapy (Figure 1).

EVIDENCE LEVEL

Figure 1: Traffic light criteria

Introduction

Mechanical ventilation (MV) is one of the fundamental pillars of critical patient management. Once the pathology instigating the need for MV is resolved, or at least is in the process of resolving, [1] it is essential to direct efforts so that the patient recovers full ventilatory autonomy and is successfully weaned and liberated from the mechanical ventilator.

What was previously defined as weaning is now called the mechanical ventilator weaning process, [2] and refers to the period of transition and withdrawal of positive pressure ventilatory support once the acute respiratory failure has been resolved. For its realization, the recovery of spontaneous ventilation is a fundamental requirement.

Some authors consider weaning as the process by which ventilatory support is gradually reduced, [3] while others consider it simply as the "release" of the mechanical ventilator. [4]

Tobin [5] proposed six stages in the ventilatory support process, from intubation and initiation of MV through weaning to weaning and successful extubation:

1. Treatment of Acute Respiratory Failure
2. Suspicion that weaning is possible
3. Assessment of readiness for weaning
4. Spontaneous Breathing Trial (SBT)
5. Extubation
6. Possible reintubation

Shortening ventilatory support times translates into a decreased risk of health care-associated morbidities (such as mechanical ventilator-associated pneumonia, ventilator induced lung injury, diaphragmatic dysfunction), and prolonged use increases mortality rates, [6] associated costs [5] and consumption of critical resources. [7]

We propose three stages in the MV release process, which are described in the following algorithm (Figure 2).

1. Initial stage: defined as the transition from a controlled assisted mode to a partial support mode (Pressure Support Ventilation-PSV plus Continuous Positive Airway Pressure-CPAP/PEEP).

2. Weaning stage: is considered to evaluate the subject's ability to breathe spontaneously, in a progressive manner, and is defined as the period in which several tests are performed in order to have a safety range to advance to the "next" step.

3. Consolidation of extubation stage: is the critical period in which there is the probability of the development of factors that could determine the failure of the process. The predictability to achieve the success of this event is the fundamental pillar to reduce the rate of failed extubation and therefore of reintubation, which increases the risk of related hospital mortality by up to 30%. [8]
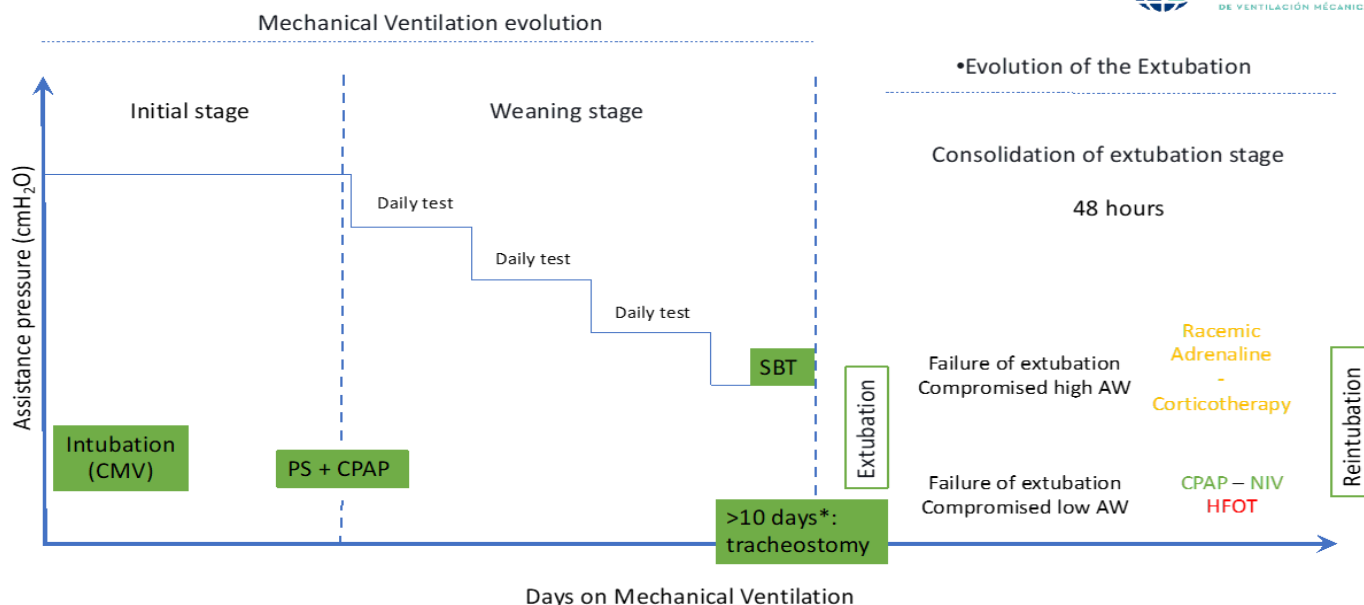
Figure 2. Algorithm of the phases for the release of mechanical ventilation.
CMV: continuous mandatory ventilations, PS: pressure support, SBT: spontaneous breathing trial, AW: airway, NIV: noninvasive ventilation, HFOT: high-flow oxygen therapy

Initial stage

Corresponds to the period in which the patient has achieved clinical stabilization. Once the etiology of the pathology has been identified, stabilization is achieved and it is on the way to resolution, this phase is determined, which marks the beginning of weaning.

The patient who, in the opinion of the ICU team would be in a weaning condition, must meet some eligibility criteria that ensure a high effectiveness of the process, and thus ensure its success. If the following criteria are met, the patient may be considered ready to advance to the next phase:

1. **$Pa/FiO_2 > 150$** [9] and PEEP ≤10 cmH_2O [1]
2. Hemodynamic stability with minimal, or preferably no vasopressor support.
3. Absence of fever or ongoing infection/sepsis
4. Absence of delirium, Glasgow Coma Scale ≥ 8 pts
5. Autonomy and triggering capacity (**P.01**): [10] 0 to -2 cmH_2O; not more than -6 cmH_2O).
6. **Optimized oxygen delivery (DO_2)** defined as oxygen supply (Lactate: 0.5-1.6 mmol/L).
   A. **Hb 7 - 8 mg/dl** (except in chronic anemia, evaluate case by case).
7. Neutral accumulated water balance.
8. Acid-base balance preserved (pH: 7.35 - 7.45; in most cases > 7.25 has been accepted).

9. Plasma electrolytes in normal range (Na 135 to 145 mEq/L, K 3.7 to 5.2 mEq/L).
10. Evaluate the risk-benefit ratio of the use of **systemic corticosteroid therapy** (increases the risk of neuropathy, among others). [11]
    A. **Indicated in the presence of high probability of failure due to high airway involvement**.
11. No new changes in the control chest X-ray.
    - After 24 hours of stability (P/F >150), if **FiO_2 remains <0.6**, PEEP should be reduced at a rate of **2 cmH_2O every 8 hours**. [12]
      o Baseline value: < 10 cmH_2O. [13]
      o Final value: will depend on the existence or not, of previous pathologies of the subject. A minimum value of 5 cmH_2O is considered.
    - If during weaning a progressive increase of FiO_2 >0.1 with respect to the initial PEEP value is required, the **previous PEEP should be programmed**.

It is important to note that, although these would be ideal and safe conditions, many patients could be successfully extubated without having met all the criteria, so they should not be considered as absolutes and it is rather recommended to analyze them as components of an individualized global clinical evaluation

Weaning stage

By definition, weaning [2] is the transition from a controlled assisted mode to a partial support mode (PSV/CPAP). This step should be implemented **as soon as the initial phase is determined,** depending on the patient's overall evolution. It is important to remember that **Synchronized Intermittent Mandatory Ventilation (SIMV)** is less favored mode for weaning because it has been correlated with a higher failure rate of the process. [14] In this phase the patient, at a minimum, should be able to:

1. To ventilate autonomously and spontaneously.
2. Easily arousable or understand and follow commands.
3. Meet minimum criteria of optimal muscular performance, according to the test and protocolized measurement in each ICU.
4. Efficiently maintain airway protection.

These tests should be performed daily until it is concluded that the ideal conditions for continuing the process are in place (Table 1). Additionally, the spontaneous ventilation test is performed.

Table 1: Clinical evaluation to be performed in the weaning stage
SAS: Sedation-Agitation Scale; RASS: Richmond Agitation-Sedation Scale; GCS: Glasgow Coma Scale; PEEP: Positive End Expiratory Pressure; Vd/Vt: dead space fraction

Sedation/Awareness	Respiratory	Hemodynamic
- SAS 4 - RASS -2 - 1 - GCS > 8 pts	- Establish a Pressure Support needed to maintain Vt 6 - 8 ml/kg of ideal weight. - PEEP ≤10 cmH_2O - Arterial gases: rule out hypoxemia ($PaO_2 \geq$ 60 mmHg). - Evaluate adequate thoracic excursion and without use of accessory musculature. - Volumetric Capnography: Vd/Vt < 0.6 - Respiratory rate < 30–35 /min	- Systolic blood pressure >90 - <180 mmHg - Diastolic blood pressure < 90 mmHg - Mean arterial pressures > 60 mmHg - Heart rate < 100 bpm - On low dose of vasopressor therapy equivalent to norepinephrine drip < 0.1 mcg/Kg/min

It is considered that there are **3 types of "weaning"** [15]

- **Simple**: when the subject succeeds in being extubated after the first trial of spontaneous breathing.
- **Difficult**: when the subject manages to be extubated after 2 or 3 trials of spontaneous breathing; or less than 7 days after the first trial.
- **Prolonged:** when the subject could not be extubated after 3 attempts, or when the process takes more than 7 days.

Spontaneous Breathing Trial (SBT)

In this phase, the patients can demonstrate that they are capable of freeing themselves from the mechanical ventilator.

Traditionally the Frequency/V_T index (Rapid Shallow Breathing Index - RSB) is used to quantify the ventilatory autonomy capacity ideally on no ventilatory support through T-tube; but, considering that a recent clinical trial showed that there is no difference when using T-tube or PSV+CPAP/PEEP, [16] and given the high aerosolization capacity implied by the use of the **T-tube**, the exhaled **air must be filtered**, especially in contagious respiratory pathologies. The option for these cases would be:

- SBT can be performed with **PSV + CPAP/PEEP (7 and 5 cmH_2O respectively) and $FiO_2 \leq 0.4$** [17–22] for 30 minutes. [23] If the test fails, it should be performed 24 hours later, until the best time to extubate the patient is determined. [24] The 24-hour wait corresponds to a period in which the ICU team evaluates and corrects the causes of SBT failure and allow the patients muscles rest and recovers from fatigue.[25]
- It is debatable to use **1 hour of "rest"** (in PSV+/- CPAP/PEEP) after the test and prior to extubation, [25] since there is contradictory evidence on this point. [26]
- The use of assisted proportional ventilation could be beneficial in this phase, when this resource is available, since this tool has been shown to be an alternative with similar results. [27]

It is recommended to monitor some variables (**predictors**) during the procedure, between 30 and 120 minutes [28]:

1. **Airway defense capacity**: adequate cough, [29] evaluated by:
   A. **Peak Flow** [30] performed with the patient connected to the mechanical ventilator I (60 L/min with Pressure Support: 7 cmH$_2$O and PEEP 5 cmH$_2$O), or with a peak Flow meter connected directly to the endotracheal tube.
   B. Low amount of secretions (< 2.5 ml/suction). [31]
   C. Frequency of suctioning [29]: no more than 1 suction within 2 hours.

2. **PaO$_2$/FiO$_2$** greater than 150, FiO$_2$ less than 0.6.
3. **TTi** (Respiratory muscle tension-time index) (Ti/T tot) x (Pdi/Pdi max) < to 0.15 Pdi: transdiaphragmatic pressure. [32,33]
4. **NIF/MIP**: (Negative inspiratory force, Maximum inspiratory pressure) a range between -10 and -20 cmH$_2$O [30] is considered acceptable.
5. **ΔHb**: If Hb at the 30th minute of the test increases 6% with respect to baseline (at the beginning of the test), it implies cardiac failure and therefore extubation should be desisted. [34,35]
6. **BNP** > 275 pg/mL without previous heart disease; or in patients with previous heart failure, a value > 12% over the initial value - before and at the end of SBT. [36]
7. **Echocardiogram**: Ideally, if available, perform this procedure and evaluate RA volume and right ventricle ejection fraction. [37]
8. **Hemodynamics**: should remain normotensive (MAP <100 mmHg) and normocardial (HR < 100 bpm).
9. **Respiratory work**: should not present increased RR, (25 - 30), adequate pump work: visualize thoracic excursion and do not present use of accessory musculature.
10. **Ultrasound evaluation of the diaphragm**: measurement of diaphragmatic thickness allows assessment of the thickening fraction (TF). A TF > 30% is associated with greater success in weaning. [38]

If the patient effectively fulfills these conditions, they are considered ready to be extubated.

It is important to emphasize that the use of these predictors should be in accordance with the local protocols of each unit; it is recommended to use those with which the medical team is most familiar. Finally, it is not necessary to comply with all the variables mentioned above.

- **Failed extubation**
  Failed extubation is defined as the need for reintubation within 48 hours after its execution. [39] Failure is usually multifactorial, it could be of common etiology with those of failed weaning or could also be caused by upper airway obstruction. [17]

- **Failed weaning**
  This occurs if during the SBT process the patient develops a certain degree of deterioration that prevents progressing towards the extubation process. There are some variables that determine failed weaning. (Table 2)

According to current reports, the average number of days on mechanical ventilation in patients with Covid-19 for example, was around 14 days. In this context, there is a pragmatic recommendation to consider progressing weaning through **tracheostomy,** [40] however, it will always be subject to the experience and management of each unit according to their internal protocols.

Table 2: Variables that determine failed weaning

Respiratory	Cardiovascular	Neurologic
- Tachypnea - Increased work of breathing - Desaturation and increase in FiO$_2$ requirement - Hypoxemia	- Tachycardia or arrhythmias - Hypertension / hypotension - Altered Δ Hb	- Confusional state (delirium) [41] - Diaphoresis - Agitation/delirium

Extubation process

To ensure an adequate and safe process, the following is recommended:

- Have the patient in the fowler position, at a **45° angle**.
- Perform **bronchial hygiene** before the spontaneous ventilation test.
- Maintain the **same FiO_2 level** previously used in invasive ventilation and before performing the spontaneous breathing test.
- Perform **leak test with deflated cuff** and comparatively monitor the difference between inspired and exhaled volumes.

Extubation consolidation stage

After a successful weaning process, extubation follows, which can also be successful or failure. Extubation failure is defined as inability to maintain spontaneous breathing after removal of the artificial airway; and the need for reintubation within a specified period of time, within 24-72 hours. [42,43] In most studies, weaning failure is defined as failure of spontaneous ventilation or need for reintubation within 48 hours after extubation. [17,34] Extubation failure has also been defined as reintubation or death within 7 days after extubation. [44]

The reasons for extubation failure are often multifactorial and are listed in Table 3.

Table 3: Variables that could determine extubation failure

Prolonged MV (>7 days)
Acquired weakness in the ICU
Impaired respiratory function (atelectasis, post-extubation pulmonary edema, upper airway obstruction, hypercapnia, hypoxemia and/or decreased hemoglobin saturation, increased work of breathing, absolute inability to mobilize secretions)
Cardiovascular disturbances (rhythm disturbances, significant changes in blood pressure, severe systolic dysfunction of the left ventricle).
Neurological disturbances (loss of consciousness, poor ventilatory pump response due to underlying disease)
Psychological disturbances (fear of assuming spontaneous ventilation, uncontrollable panic, delirium). [45]

One cause that can lead to reintubation is edema of the structures that were in contact with the artificial airway. The use of **corticosteroids** does not seem to reduce the need for reintubation; however, their use has been recommended as a predictor for the identification of subglottic edema during the leak test before extubation. [44] However, in the context of Covid-19 patients, it has been seen that the use of systemic corticosteroids used prophylactically decreases the risk of stridor post extubation, so that a short cycle for 24 hours prior to repeating the cuff leak test could be recommended for patients at high risk of reintubation. This is similar to what happens in patients with laryngeal stridor. [46]

The leak volume (or **cuff leak test**) has been defined as the difference between inspired and exhaled tidal volume and is expressed in leak percentages taking as 100% the average inspired tidal volume [47]; values of air leak less than 110 ml on average approximately in 6 breaths, as well as values less than 10% of the tidal volume [48] indicate a high risk of post-extubation laryngeal stridor. A recent multicenter study found that stridor following extubation occurs in less than 10% of unselected critically ill patients. Furthermore, the various pneumotachometer cuff leak tests show

limited diagnostic performance for the stridor detection, so given the high false positive rate, routine leak testing may expose the patient to undue prolonged mechanical ventilation. [49] However, it is important to consider that the variable that most predicts the risk of developing edema, stridor or reintubation is the leak volume. [50] In the presence of any respiratory pathology that implies a high level of contagion, given the high level of aerosolization, it is not recommended to perform this test. In case the leak volume test is positive, a new test should be performed 4 hours after the administration of systemic glucocorticoids. [51]

Diaphragmatic dysfunction assessed by ultrasound has not been associated with an increased risk of extubation failure. Difficult weaning has been associated with ICU-acquired muscle weakness, an abnormality that also affects the diaphragm. [52]

Cough, one of the main mechanisms of airway protection may be depressed or weak, which may contribute to extubation failure due to inability to manage secretions. In a multivariate analysis, ineffective cough was the only factor that remained

independently associated with extubation failure. [42] This result is closely related to another study showing that clinically assessed ineffective cough was a stronger predictor of extubation failure than ICU-acquired muscle weakness. [53] This assessment tool as a predictor of extubation failure may be limited by the risk of aerosolization of certain respiratory pathologies; and therefore, can be replaced by **Peak Flow** measurement.

Metabolic, endocrine, and nutritional disorders and anemia can also be contributors to extubation failure. [54]

What to do when extubation fails?

Failure of extubation requires immediate intervention by the ICU team. It should always be oriented to the implementation of ventilatory support, either **invasive MV** or **noninvasive MV (CPAP/BLPAP)**, and some groups of investigators have tried the use of **HFOT**, although it has failed to consolidate as a solid and safe tool (Figure 3).
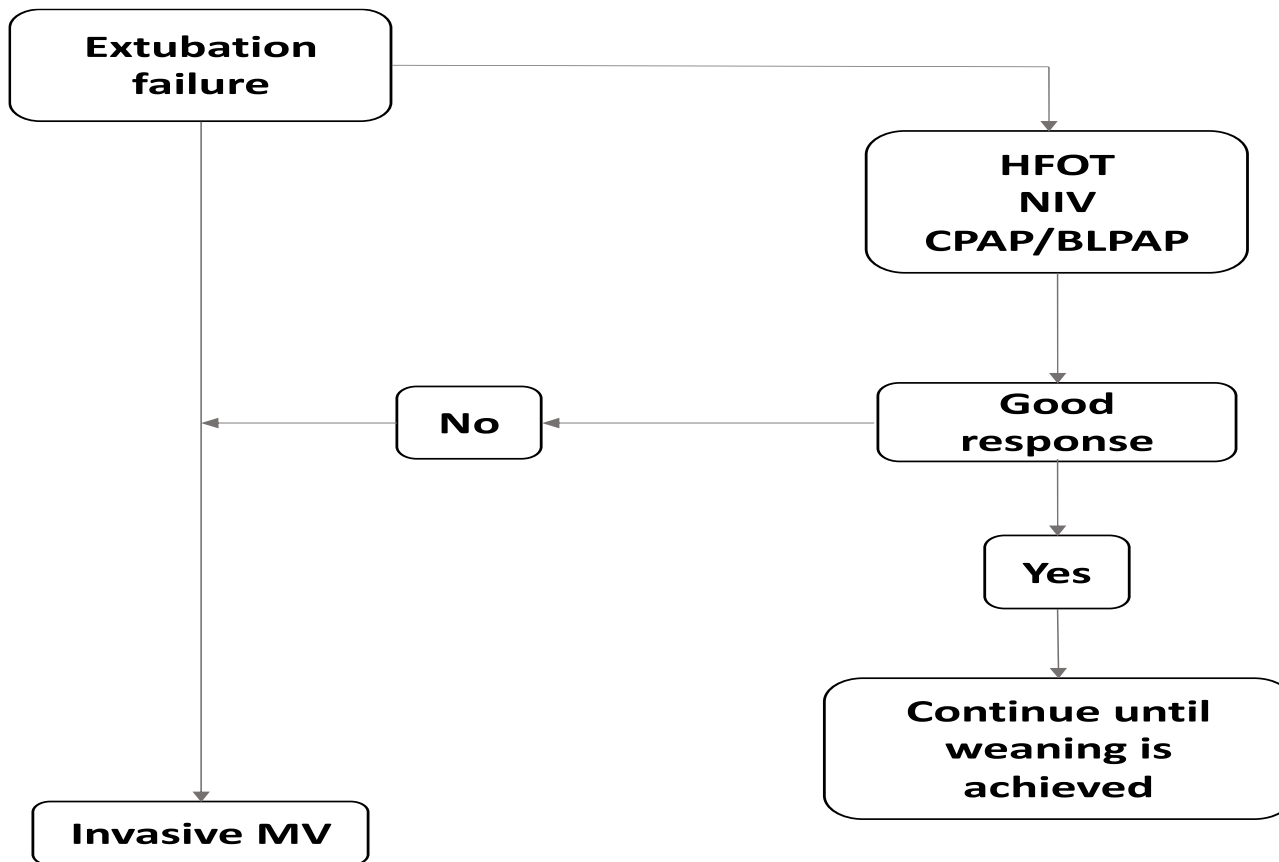

Figure 3: Extubation failure management Flow. BLPAP: bilevel positive airway pressure, CPAP: continuous positive airway pressure, HFOT: high flow oxygen therapy

NIV is the simplest and most plausible tool in this context, as it currently has very strong evidence that has been shown to avoid reintubation. [55,56]

In the consensus article by Boles and colleagues [9] a plausible statement about the use of NIV in relation to extubation failure is expressed, it could be useful as:

1. An **alternative modality** for patients intolerant to the weaning trial

2. A **prophylactic measure** after extubation for patients at high risk of reintubation but who do not develop extubation failure.

3. A **treatment option** for patients who have been extubated but develop extubation failure within 48 hours.

However, the following scenarios should be considered:

- When NIV is used as an alternative modality for patients intolerant to the weaning trial, the

ideal indication is in patients with COPD. It has been found that NIV can facilitate early weaning from MV in COPD patients, but only in centers that have experience with this type of therapy. [57] A systematic review and meta-analysis of randomized clinical trials (RCTs) found that the use of NIV after planned extubation significantly decreases the reintubation rate in patients with COPD and patients at high risk of extubation failure; however, in another study [58] no difference in reintubation rate was found between NIV and conventional oxygen therapy. In patients with acute respiratory failure of etiology other than COPD, NIV has been reported to avoid reintubation at 48 hours if applied immediately after elective extubation, compared to the high-flow oxygen therapy group. [59,60]

- When NIV is used as a prophylactic measure after extubation, for patients at high risk of reintubation but who do not develop extubation failure, its use could be beneficial, especially in patients with chronic respiratory disease with hypercapnia [61] or obesity.

- When used as a treatment option for patients with post-extubation respiratory failure, the routine use of NIV does not prevent the need for reintubation and shows a trend towards increased mortality. [62] **Delayed reintubation** in these patients may be associated with increased mortality. [63,64]

Regarding the use of support other than NIV, there is information on the use of conventional oxygen therapy and **HFOT** in the event of extubation failure.

A systematic review and meta-analysis of RCTs in adult patients after extubation suggests that **low-flow oxygen therapy** is the first-line post-extubation treatment for postoperative patients without extubation failure. [65]

For post-surgical patients, **HFOT** was found to be non-inferior to NIV in patients at risk of extubation failure, [65] but individualized evaluation of its use is recommended. In contrast, an open-label, randomized controlled trial found that, compared to conventional humidified oxygen therapy, HFOT did not reduce the rate of reintubation. [66] In a recent trial, NIV was compared with HFOT in 182 patients considered to be at **very high risk** of reintubation [55] patients treated with NIV had a significant 15.5% reduction in reintubation rate and 6.5 fewer days of hospital stay. Based on this and the evidence previously presented, the use of **NIV** over HFOT is recommended to consolidate weaning. [67,68]

Recently, the use of **Mechanical Power** (MP) has been used as an early predictor of weaning failure, mainly associated with the pulmonary dynamic component as a transcendental discriminating factor. [69]

Conclusion

The weaning process and its consolidation should be guided mainly by the physiology and the clinical condition of each patient, in a personalized manner. The use of the different tools presented in this work are clearly guidelines to reduce the margin of failure of this complex procedure. It is necessary to carry out studies with a robust design to consolidate these statements.

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