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Literature review

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Non-invasive prophylactic ventilation, outcomes and their impacts - a systematic review

Ventilação não invasiva profilática, desfechos e seus impactos – uma revisão sistemática

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RESUMO | INTRODUÇÃO: Ventilação Não Invasiva Profilática (VNIP) é uma modalidade de VNI aplicada a pacientes que foram eleitos para extubação, porém possui alto risco de falha. **OBJETIVO:** descrever e analisar populações favorecidas pela VNIP, impactos e desfechos. **MÉTODO:** Revisão sistemática, buscaram-se ensaios nas bases de dados PubMed, EMBASE e Cochrane Library com os seguintes critérios de inclusão: publicação nos últimos 20 anos, escrito em inglês, espanhol ou português; idade ≥ 18 anos; ventilação mecânica ≥ 48 horas; comparação da VNIP com terapia padrão. Critérios de exclusão: VNIP < 4 horas; e VNIP intermitente. **RESULTADOS:** Resultaram-se oito estudos. Os desfechos foram: reintubação, Insuficiência Respiratória Pós Extubação (IRPE), mortalidade e permanência na UTI. Características relevantes extraídas: uso de VNIP de resgate, níveis de PaCO2, pressão inspiratória máxima e índice de respiração rápida superficial. Os estudos relatam que a aplicação de VNIP em população heterogênea reduz o risco de desenvolver IRPE, porém parece não haver consistência referente à reintubação, mortalidade na UTI, permanência na UTI e hospitalar. Estes marcadores foram apresentados através de resultados controversos entre os estudos revisados. Em pneumopatas especificamente, VNIP parece não ter impacto direto em reintubação e permanência na UTI. **CONCLUSÃO:** Os estudos divergem sobre uso da VNIP em prevenir principais desfechos, mesmo em pneumopatas, porém, seu uso em evitar IRPE é positivo. Sendo assim, necessitam-se estudos em populações com melhor predisposição a sucesso na extubação para comprovar a eficácia da VNIP.

PALAVRAS-CHAVE: Ventilação não invasiva. Extubação. Insuficiência respiratória.

ABSTRACT | INTRODUCTION: Noninvasive Ventilation Prophylactic (NIVP) is a modality of NIV applied to patients who have planned extubation but has a high risk of failure. **OBJECTIVE:** The objective of this study was to describe and analyze populations favored by NIVP, impacts and outcomes. **MATERIAL AND METHODS:** For this, essays were searched in the Pubmed, EMBASE and Cochrane Library databases with the following inclusion criteria: publication in the last 20 years, written in English, Spanish or Portuguese; age ≥ 18 years; mechanical ventilation ≥ 48 hours; and compare NIVP with standard therapy. Exclusion criteria: NIVP < 4 hours and intermittent NIVP. **RESULTS:** Eight studies were resulted. The outcomes were: reintubation, Respiratory Failure Post Extubation (RFPE), mortality and ICU permanence. Relevant features extracted: use of rescue NIV, PaCO2 levels, maximal inspiratory pressure and rapid superficial respiration index. Studies report that the application of NIVP in a heterogeneous population reduces the risk of developing RFPE, but there seems to be no consistency regarding reintubation, ICU mortality, permanence in the ICU and hospital. These markers were presented through controversial results among the reviewed studies. In lung disease specifically, NIPV seems to have no direct impact on reintubation and ICU stay. **CONCLUSIONS:** It is possible conclude that the present studies differ on the use of NIPV to prevent major outcomes such as reintubation and mortality, even in lung disease, but its use in preventing RFPE is positive. Therefore, studies in populations with better predisposition to successful extubation are necessary to prove the efficacy of NIPV.

KEYWORDS: Noninvasive ventilation. Extubation. Respiratory failure.

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Background

Extubation of critically ill patients is an important factor in their clinical course and, as early as possible, should be performed safely and effectively. However, extubation failure can occur between 6 and 23% of planned extubations[1,2]. This factor may originate from Post-Extubation Respiratory Failure (PERF), which most often results from airway obstruction, inadequate cough, copious secretions, encephalopathy, and cardiac dysfunction. Yet, other factors such as age and pneumopathy may increase the chances of failure[2-4].

Reintubation results in a worsening of the patient's prognosis due to the risk of nosocomial pneumonia and augmented mortality. Thus, to avoid this event, noninvasive ventilation (NIV) is suggested depending on the patient's condition[1,2].

Post-extubatory NIV can be associated with three groups: facilitative, rescue and prophylactic. NIV facilitative is applied to patients who failed the Spontaneous Breathing Test (SBT). However, with the cause of intubation solved, these patients are extubated and noninvasive support is initiated. This modality has solid evidence with well-established clinical trials and favorable results for its application with improved survival and reduced the time of mechanical ventilation (MV) in populations with Chronic Obstructive Pulmonary Disease (COPD)[5,6].

Rescue NIV is used when the patient is extubated and already has an PERF diagnosis given. There is no evidence of impact on mechanical ventilation time or mortality due to its use and it may aggravate the patient's prognosis if reintubation is postponed6. Contrary to those previously mentioned, Prophylactic NIV (NIVP) is mainly used in groups of patients at high risk for extubation failure, even with favorable results in SBT[2,3,6].

From this observation, this systematic review aims to describe which critically ill populations after elective extubation benefit from NIVP as well as the analysis of markers and the impact of NIVP on their outcomes.

Method

This study consists of a systematic literature review following the precepts of the Transparent Reporting of System Reviews and Meta-analyzes - PRISMA guide. For this, randomized clinical trials were searched in the Pubmed, EMBASE and Cochrane Library databases according to the following criteria: be published from January 1990 to August 2019; be written in full in English, Spanish or Portuguese; age ≥ 18 years, clinical trial format, comparison NIVP with standard therapy (oxygen therapy and drug therapies). Studies with application of NIVP for less than 4 hours and intermittent NIVP were excluded.

To return results in a filtered form, terms obtained through Mesh terms were combined with the words "OR" (synonym), "AND" (sum) and "NOT" (negation) in a syntax. The terms determined were: "Noninvasive ventilation", "Continuous Positive Airway Pressure", "extubation", excluding the terms "preterm", "newborn", "infants" and "children".

The systematic search was performed by three authors, divided into 5 phases (as shown in Figure 01): the first phase was the search in the databases cited above with the syntax formulated in order to gather references related to the theme and, concomitantly, a search of the gray literature was performed to aggregate unpublished references. This search resulted in 427 references in conventional databases and none in the gray literature. The second phase was the elimination of duplicate references resulting in 415 references. In the next phase, the third phase was the filtering of articles after reading the title and full abstract. If there were conflicts in the selection of references, there would be discussion between the three authors to define the inclusion of the articles or not. At this stage 398 references were excluded because they did not fit the inclusion criteria. The fourth phase consisted of applying the exclusion criteria for better uniformity of articles, which excluded 10. The fifth phase was the extraction and synthesis of data from the 7 articles. This step was performed by two authors.

Results

The 7 articles were between the periods of 2005 and 2013. Their samples contained from 38 to 406 patients. Most of them evaluated heterogeneous populations, however, two studied the use of the technique in patients with pulmonary disease. NIV application time ranged from 8 hours per day to 48 hours with breaks only for personal hygiene and food. The only similarity in the studies was the standard therapy that was associated with oxygen therapy, but with a different offer.

The assessment of methodological quality consisted of using the Physiotherapy Evidence Database (PEDro) scale, which found three level 5/10, three 6/10 and one 7/10 trials. Even moderate quality studies did not negatively affect data analysis. For primary analysis, data on Table 1 were extracted and exposed about: reintubation, post-extubation respiratory failure, mortality and ICU stay (Table 1).

Secondary data such as use of rescue NIV, PaCO2 levels, Maximal Inspiratory Pressure (PiMAX) and Rapid Shallow Respiration Index (RSBI) were also captured and distributed in table 2, in addition to showing the pressures used and the main results. of the researched studies. Among these values, it is possible to observe the variation between the inspiratory pressures employed, between 10 and 14 on average, being titrated by the studies based on the patient's need to obtain safe pH, ventilatory work and PaCO2 ranges. Outcome variables were also collected in number and percentage of patients. These variables were: reintubation, post-extubation respiratory failure and ICU mortality. The ICU and hospital length of stay data were computed as mean and standard deviation.

Figure 1. Flowchart of the systematic search for a critical population study using NIVP after elective extubation 2019

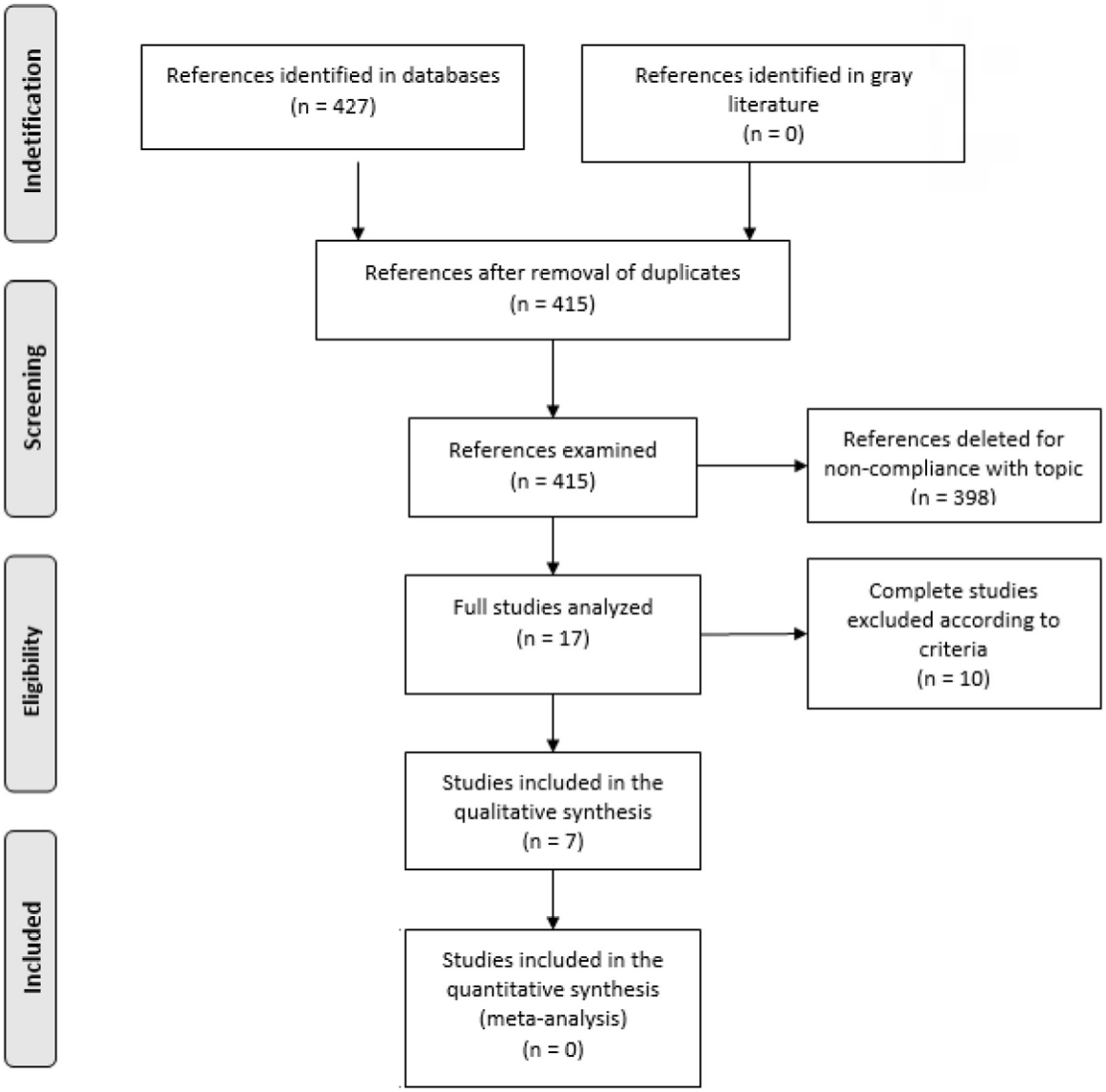

Table 1. Description of randomized controlled trials in a critical population using NIVP after elective extubation 2019

Author	Population	Sample (NIV:Control)	Duration NIV	Qual.	Outcome
Nava S, et al., 2005[3]	Heterogeneous	97(48:49)	8h/day for 48h	5/10	NIV decreased reintubation and mortality
Ferrer M, et al., 2006[4]	Elderly, cardiac patient	162(79:83)	19h	7/10	NIV decreased ARF for 24h post extubation.
Ferrer M, et al., 2009[2]	Pulmonary disease patient with PCO2> 45 during SBT	106(54:52)	18h	6/10	NIV NIV decreased ARF for 24h post extubation, reduction of mortality for 90 days
Khilnani G et al., 2011[7]	COPD hypercapnic	40(20:20)	34,7 h	5/10	No significant changes in reintubation and hospital discharge
Su CL, et al., 2012[8]	Heterogeneous	406(204:202)	12h	6/10	No significant changes in reintubation and mortality
Mohamed K. et al., 2013[9]	Heterogeneous	120(60:60)	12h	6/10	NIV decreased reintubation, including in COPD, reduced length of hospital stay and VAP
Ornico S, et al., 2013[10]	Heterogeneous	38(20:18)	24h	5/10	NIV decreased reintubation, mortality and length of ICU stay

Caption: NIV: Non-Invasive Ventilation; Qual .: Quality; ARF: Acute Respiratory Failure; COPD: Chronic Obstructive Pulmonary Disease; VAP: Ventilator-Associated Pneumonia.

According to the collected data, the reduced reintubation index obtained favorable results in 3 studies[3,9,10] out of 7, followed by decreased mortality (3 studies[4,9,10] out of 6) and ICU stay (1 study[9] out of 6). The PERF index was little exposed in the trials, however, from 3 studies, in 2[2,4] this marker resulted in NIV success compared to the control group (Table 2).

Table 2. Description of the main outcomes in the study on critical population using NIVP after elective extubation 2019

Author	Average Parameters (SD)	ReInt*	PERF*	ICU morthality*	ICU Stay*
Nava S, et al., 2005[3]	IP: 13,1(4,5) EP:5,2(1,6)	4(8):12(24) p = 0,027	NA	3(6):9(18) p = 0,064	8,9(5,7):11,6 (14,9)
Ferrer M, et al., 2006[4]	PI 14(3) PE 5(1)	9(11):18(22) p = 0,12	13(16):27(33) p = 0,029	2(3):12(14) p = 0,015	11(8):13(11) p = 0,14
Ferrer M, et al., 2009[2]	IP: 12 a 20 EP: 5 a 6	6(11):10(19) p = 0,3741	8(15):25(48) p <0,0001	3(6):4(8) p = 0,7132	11(13):10(9) p = 0,5041
Khilnani G et al., 2011[7]	IP: 12,1(1,3) EP: 6,5(1)	3(15):5(20) p = 0,44	NA	NA	2,0(2,1):1,5 (0,8) p = 0,34
Su CL, et al., 2012[8]	IP: 10 a 12 EP: 5	21(10):16 (7,7) p = 0,37	27(13,2):30(14,9) p=0,62	2(0,9):3(1,4) p = 0,64	NA
Mohamed K. et al., 2013[9]	IP: 10(2) EP: 5	9(15):15(25) P = 0,049	NA	4(6,6):10(16,6) p = 0,047	8,3(3,1):11,6 (2,6) p = 0,04
Ornico S, et al., 2013[10]	IP:12 EP: 8	1(5):7(39) p = 0,016	NA	0(0):4(22,2) p = 0,041	16,8(11,6):18 ,4(12,2) p = 0,681

*Caption: * NIV vs Control (%); SD: Standard Deviation; ReIn: Reintubation; NA: Not Assessed; PERF: Post-Extubation Respiratory Failure; NIV: Noninvasive Ventilation; IP: Inspiratory Pressure; EP: Expiratory Pressure*

Other secondary outcomes of the surveys were transcribed in Table 3. These outcomes are related to the use of rescue NIV, PaCO2 measured during SBT or post-extubation, hospital stay, PiMAX, and RSBI. The use of rescue NIV was a practice performed by 3 authors[2,4,8], designed to avoid reintubation of patients who had respiratory failure after extubation. The PaCO2 variable alternated between normal values (37 mmHg) and high values (82.3 mmHG), with no statistical difference between groups. Hospital stay was also unsuccessful in the statistical difference, ranging from 16.1 and 30 days in the NIV group and 18.2 and 29 days in the control group.

Few studies reported PiMAX and RSBI values, but all reported no significant difference between NIV and control groups. Only one study[8] differentiated these values from these variables between patients who failed extubation (PiMAX -27.7 ± 0.9 and -32.4 ± 1.5 and IRRS 73.3 ± 4.6 and 80.1 ± 4.3 NIV and IRRS respectively) and those who were successful (PiMAX -35.2 ± 0.9 and -35.2 ± 0.9 and RSBI 58.6 ± 1.8 and 58.0 ± 1.7, NIV and control respectively). In the PiMAX variable, the NIV group showed a statistical difference between success and failure (p = 0.01), with no similar result in the control group (p = 0.23). In RSBI, both groups showed statistical difference (p = 0.02 and p <0.001, NIV and control respectively).

Table 3. Description of secondary data in critical population using NIVP after elective extubation 2019

Author	RNIV	Average PaCO2(DP)*	Hospital Stay Average (DP)*	PiMAX*	RSBI (f/Vt)*
Nava S, et al., 2005[3]	No	(Post) 41,7(4,2):39,4(5,6)	23,3(16,4):25,5 (21,4) p = ?	NA	NA
Ferrer M, et al., 2006[4]	Yes	(SBT) 38(5):37(5)	30(23):29(18) p = 0,65	NA	NA
Ferrer M, et al., 2009[2]	Yes	(SBT) 55(6):53(5)	29(27):25(17) p =0,2988	NA	66(26):65 (23)
Khilnani G et al., 2011[7]	No	(Post)82,3(11,2): 80,0(13,2)	16,1(6,2):18,2 (7,9) p 0,34	NA	NA
Su CL, et al., 2012[8]	Yes	NA	NA	35,2(0,9):27,7(0,9) (p=0,01) vs 35,2(0,9):32,4(1,5) (p=0,23) ⁋	58,6(1,8):58,0 (1,7) (p=0,02) vs 73,3(4,6): 80,1(4,3) (p<0,001) ⁋
Mohamed K. et al., 2013[9]	No	(Post) 39.9(6,3):42,8 (7,7)	NA	33(11,6):34(13,7)	93,9(31,8): 95,9 (34,1)
Ornico S, et al., 2013[10]	No	NA	NA	NA	NA

Caption: SD: Standard Deviation; NIV: Noninvasive Ventilation;RNIV: Rescue Noninvasive Ventilation; * Success versus Failure; ⁋: NIV versus Control; Post: Post Extubation; SBT: Spontaneous Breathing Training; PiMAX: Maximum Inspiratory Pressure; RSBI: Rapid Shallow Breathing Index; NA: Not Assessed.

Some studies[2,4,7,9] referred their full or partial attention to the population who suffer from pulmonary diseases and it is necessary to include these data in table 4, which discusses reintubation, post-extubation respiratory failure, ICU mortality, ICU stay and hospital mortality. These studies show no statistical difference in reintubation and ICU stay between NIV and control groups, but the results regarding post-extubation respiratory failure, ICU mortality and hospital mortality were controversial.

Table 4. Results in pulmonary disease in a critical population using NIVP after elective extubation 2019

Author	ReIn*	PERF*	ICU mort.*	ICU Stay*	Hospital mort. (days)*
Ferrer M, et al., 2006[4]	3(11):6(27) p=0,27	4(15):9(41) p=0,083	0(0):4(18) p=0,035	NA	1(4):9(41) p=0,003
Ferrer M, et al., 2009[2]	6(11):10(19) p = 0,3741	8(15):25(48) p <0,0001	3(6):4(8) p = 0,7132	11(13):10(9) p=0,50	6(11):11(22) p=0,25
Khilnani G et al., 2011[7]	3(15):5(20) p = 0,44	NA	NA	2,0(2,1):1,5(0,8) p = 0,34	NA
Mohamed K. et al., 2013[9]	1(5,25):5(31,2) p=0,019	NA	NA	NA	NA

Caption: * NIV: Control (%);ReIn: Reintubation;; PERF: Post-Extubation Respiratory Failure; Mort.: Mortality; NA: Not Assessed; SD: Standard Deviation; NIV: Noninvasive Ventilation;

Discussion

In heterogeneous populations, the analysis of the studies suggests that NIVP decreases the risk of PERF, but has no consistency in preventing reintubation, decreasing ICU mortality rate and reducing ICU and hospital stay, as these markers are presented through controversial results in the reviewed studies.

In the population who suffer from pulmonary diseases specifically, NIVP did not suggest an impact on preventing reintubation and decreasing ICU stay compared to the control group. In the PERF variables, ICU and hospital mortality showed inconsistent results. The indication of NIVP varied according to the studies, however, they are united in patients electing MV for more than 48 hours, having acute respiratory failure type I[2,4,9-10] or type II[7] as cause of the intubation added to success in SBT. Some authors have determined that pulmonary disease[2,7] or populations at high risk of reintubation[3,4] would benefit from NIVP with positive outcomes.

One study[3] presented the high-risk population as: MV for more than 48 hours, successful SBT, one or more of the high risk of reintubation criteria: More than one consecutive spontaneous breath test failure; chronic heart failure, PaCO2> 45 mmHg after extubation, more than one comorbidity (excluding chronic heart failure); ineffective cough; upper airway stridor requiring no immediate intubation. Another clinical trial[4] met criteria such as: age greater than 65 years, heart failure as a cause of intubation or increased severity translated through the Acute Physiology and Chronic Health Evaluation (APACHE)-II score greater than 12.

The main outcome found in all studies was reintubation. Only three studies[3,9,10] found statistically significant results for reintubation prevention. Some authors[2,4] justify the main causes of reintubation as respiratory failure (mainly due to increased PaCO2), excess airway secretion and heart failure.

Some of these studies[2,4,8] performed rescue NIV in both groups that did not require immediate intubation. Patients allocated to the NIVP group received this support after completing the intervention protocol and developed post-extubation respiratory failure within 72 hours. In the control group, patients who had this condition within 72 hours, the rescue NIV modality was applied.

Reintubation in many cases precedes PERF. This variable was studied by three authors[2,4,8] and observed positive results for the use of NIVP. These authors believe that with the application of Rescue NIV modality in those who did not need to be immediately reintubated, there was a reversal in some cases of PERF, which may explain the non-statistical significance of the reintubation variable in these studies. Two clinical trials[2,4] specifically quantified these values and found efficacy at 100% and 35% versus 47% and 35% of respiratory failure reversal in the NIV and control groups respectively, thereby reducing the reintubation rate.

Other factors such as PaCO2, PiMAX and RSBI may have contributed to extubation failures. Khilnani, et al.[7] recruited patients with mean PaCO2 of 82.3 and 80.0 mmHg (NIV and control groups, respectively) with a pH of 7.22, similar in both groups. This did not have positive results in the use of NIVP, it is believed that PaCO2 values above 60 plus pH between 7.20 and 7.25 may increase the possibilities of reintubation[12].

The PERF was also stratified by the author mentioned above[8], which found a statistical difference in terms of success and failure in the results of the NIV groups (56.6±1.8 and 73.3±4.6 p=0.02) and control (58.0±1.7 and 80.1±4.3 p<0.001). This marked difference between the two groups may be related to the proximity of the 100 breaths/L values, ie, the closer the 100 breaths/L values, the more susceptible to extubation failure in these patients[14]. Mohamed, on the other hand, et al.[9] even with PERF in their study with results of 93.9±31.8 and 95.9±34.1 in the NIV and control groups, respectively, favored positive results in the use of NIVP impacting on reintubation, mortality in the ICU and ICU stay. This PERF result may be related to the ventilatory support that NIVP, by having values close to 100 breaths/L, provided to patients in this group. In the study by Ferrer, et al.[2], their PERF values were 66±26 and 65±23 in the NIV and control groups, respectively, but the results in the reintubation variable were similar and can be explained by another cause for 72h after extubation.

Regarding the reduction in ICU mortality, the vast majority of studies[2,3,8] appointed that there was no statistical difference between the groups, three authors obtained positive results[4,9,10] in this variable, thus these findings can be explained through the indices of reduced reintubation in the NIV group in two studies[9,10]. In contrast, the other authors may not have found relevance in the data due to the increased severity of patients who are reintubated.

This systematic review has some limitations: low number of articles collected. Even with cautious formulating an appropriate syntax and searching the gray literature, this review featured only seven clinical trials; few variables reported in all studies; comparison of outcomes, only reintubation index was evaluated in all studies; diverse protocols for the application of NIVP; there is no description in the literature about a standardization in the application of the technique (initiation, duration and use or not of rescue NIV), this may have impacted the outcomes analyzed.

Conclusion

This systematic review suggests that NIVP reduces post-extubation respiratory failure, but has no impact on preventing reintubation in heterogeneous and pulmonary disease populations. Other outcomes such as mortality, ICU stay and length of hospital stay did not present consistent data. Therefore, to solidify this practice in ICU routines, it is important to conduct further studies to determine specific populations that can benefit directly from NIVP.

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Author contributions

Duarte HB wrote the manuscript, outlined the method and approved the final version. Mendes KMB wrote the manuscript, outlined the method and approved the final version. Pereira AP reviewed the literature and approved the final version. Dias LC reviewed the literature and approved the final version. Menezes CS wrote the manuscript and approved the final version.

Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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