

Efficacy of noninvasive ventilatory support on exercise tolerance in patients with heart failure: a systematic review

Eficácia do suporte ventilatório não invasivo no incremento da tolerância ao exercício em pacientes com insuficiência cardíaca: uma revisão sistemática

La eficacia del soporte ventilatorio no invasivo en el aumento de la tolerancia al ejercicio en pacientes con insuficiencia cardiaca: una revisión sistemática

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ABSTRACT | The aim of this study was to evaluate the efficacy of noninvasive ventilation (NIV) on improving exercise tolerance of patients with heart failure (HF). A systematic review was performed in PubMed/ MEDLINE, LILACS, Cochrane, CINAHL, Scopus and Web of Science for randomized and quasi-randomized clinical trials, without language and year of publication restrictions. Descriptors were defined as 'heart failure', 'noninvasive ventilation', 'positive-pressure respiration', 'interactive ventilatory support', 'exercise test' in addition to the keywords 'BIPAP', 'CPAP', 'IPAP', 'EPAP', 'NIV' and their Portuguese equivalents. Studies comparing NIV with one or two pressure levels to groups without intervention, other physiotherapy modalities without positive pressure or a sham group were included. Four studies were selected, including HF patients of various etiologies, considering the staging classification of New York Heart Association. Some included work performed allocation concealment, all studies participants underwent blindfolding, but only two trials performed blinding of the evaluators. None of the studies described an intention to treat analysis and did not use appropriate statistical methods. All selected trials assessed functional capacity and in only two, dyspnea was assessed. The intervention protocols of the included trials were heterogeneous, three studies underwent a single intervention with NIV, two immediately before the functional capacity test and another study performed NIV during the exercise evaluation. The last trial held 14 sessions of NIV,

with the functional capacity evaluation being performed on day 0, 4, 9 and 14. There is insufficient evidence on the effectiveness of NIV in increasing exercise tolerance.

Keywords | Heart Failure; Noninvasive Ventilation; Positive-Pressure Respiration.

RESUMO | O objetivo do estudo foi avaliar a eficácia da ventilação não invasiva (VNI) na melhora da tolerância ao exercício em indivíduos com insuficiência cardíaca (IC). Realizou-se uma busca sistemática nas bases de dados PubMed/MEDLINE, LILACS, Cochrane, CINAHL, Scopus e Web of Science por ensaios clínicos randomizados e quasi-randomizados. Os descritores foram: 'heart failure', 'noninvasive ventilation', 'positive-pressure respiration', 'interactive ventilatory support', 'exercise test', além das palavras-chave "BIPAP", "CPAP", "IPAP", "EPAP", "NIV" e seus equivalentes em português. Foram incluídos estudos que comparassem a VNI com um nível de pressão ou com dois níveis de pressão a grupos sem intervenção, a outras modalidades fisioterapêuticas sem pressão positiva ou a um grupo sham. Foram selecionados quatro estudos, incluindo pacientes com IC de diversas etiologias. Os quatro estudos foram randomizados e controlados e realizaram o mascaramento dos participantes. No entanto, apenas dois trabalhos realizaram o mascaramento dos avaliadores. Em nenhum dos artigos selecionados foi feita a análise por intenção de tratar e apenas um não utilizou métodos estatísticos adequados. Todos os estudos avaliaram a

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capacidade funcional e dois avaliaram a dispneia. Os protocolos de intervenção foram heterogêneos entre os estudos, três artigos realizaram uma única intervenção com a VNI. O outro artigo incluído realizou 14 sessões de VNI, sendo realizada a avaliação da capacidade funcional no dia 0, 4, 9 e 14. Devido à baixa qualidade metodológica dos artigos incluídos, não há evidência suficiente sobre a eficácia da VNI no incremento da tolerância ao exercício.

Descritores | Insuficiência Cardíaca; Ventilação Não Invasiva; Respiração com Pressão Positiva.

RESUMEN | Esta investigación tuvo por objetivo evaluar la eficacia de la ventilación no invasiva (VNI) en la mejora de la tolerancia al ejercicio en pacientes con insuficiencia cardiaca (IC). Se hizo una búsqueda en las bases de datos PubMed/MEDLINE, LILACS, Cochrane, CINAHL, Scopus y Web of Science por estudios clínicos aleatorizados y cuasi-aleatorizados. Los descriptores fueron: 'heart failure', 'noninvasive ventilation', 'positive-pressure respiration', 'interactive ventilatory support', 'exercise test', además de las palabras clave "BIPAP", "CPAP", "IPAP", "EPAP", "NIV" y sus equivalentes en portugués. Se incluyeron

estudios que compararon la VNI con un nivel de presión o con dos niveles a otras modalidades fisioterapéuticas de presión positiva o al grupo *sham*. Se han elegidos cuatro estudios, que incluyeron pacientes con IC de diversas etiologías. Se han aleatorizados y controlados los cuatro estudios en que se realizó el enmascaramiento de los pacientes. Sin embargo, solamente dos trabajos llevaron a cabo el enmascaramiento de los evaluadores. Ninguno de los ensayos elegidos se ha hecho el análisis con el fin de tratar, y solamente uno no se hizo con métodos estadísticos apropiados. Todos los estudios evaluaron la capacidad funcional, y dos la disnea. Los protocolos de intervención fueron heterogêneos entre los estudios, tres artículos se han hecho una sola intervención con la VNI. El otro artículo incluso se ha hecho 14 sesiones del VNI, lo que se realizó la evaluación de la capacidad funcional el día 0, 4, 9 y 14. Debido a la baja calidad metodológica de los artículos incluídos, no hay comprobación suficiente sobre la eficacia de la VNI en el aumento de la tolerancia al ejercicio.

Palabras clave | Insuficiencia Cardíaca; Ventilación no Invasiva; Respiración con Presión Positiva.

INTRODUCTION

Heart failure (HF) is a growing problem of global proportions that affects more than 20 million people¹. Brazil accounts for approximately two million of this number with an incidence of 240,000 new cases diagnosed annually². This complex syndrome brings about numerous implications both for society, in terms of high socioeconomic costs for the health system and early retirements causing a loss of productivity, as well as for the disease carrier, in terms of the physical and psychological problems that cause them to become socially isolated³.

Changes that HF cause are not only restricted to the cardiac area, since the main symptoms are dyspnea and fatigue⁴, which can limit suffers' tolerance to exercise. However, the population presents an impairment associated to skeletal musculature due to low cardiac output⁵. The progression of these symptoms generates a decrease in the level of physical activity, which further contributes to aggravating these symptoms and exercise intolerance, thereby progressively reducing the population's functional capacity and quality of life, which carries a common clinical condition, which is costly and generally disabling⁶. Furthermore, this heart disease is

associated with frequent hospitalization and re-hospitalization, along with functional impairment that evolves into significant morbidities due to low physical ability and high mortality^{7,8}.

Noninvasive ventilation (NIV) has appeared as a coadjuvant therapy in an attempt to improve patients' functional capacity. NIV has been used as an alternative in order to reduce respiratory effort, increase arterial oxygenation and pulmonary compliance, with the objective of improving exercise tolerance due to its sensitive performance in cardiorespiratory interaction, thereby providing better cardiac and respiratory response during exercise⁸⁻¹¹.

The review aims to assess NIV effectiveness, with continuous pressure or with two levels of pressure, on exercise tolerance in both male and female adult patients with HF.

METHODOLOGY

A systematic review was conducted, consisting of previously selected studies, with the following inclusion criteria: randomized and quasi-randomized controlled clinical trials which used NIV, with continuous pressure

or with two levels of pressure when evaluating functional capacity, comparing them to a control group without intervention, to other physiotherapeutic modalities or to a *sham* group, in adult patients of both sexes with heart failure. The exclusion criterion was considered as studies conducted in periods where the disease was worsening.

Exercise capacity is considered to be the primary endpoint (oxygen consumption; distance) evaluated through maximal or sub-maximum effort testing and dyspnea level – evaluated by way of subjective scales. Secondary outcomes were considered as peripheral oxygen saturation (SpO₂), blood pressure (BP) and heart rate (HR).

There was a systematic search for articles published in journals that had been indexed in the following databases: PubMed/MEDLINE, LILACS, Cochrane, SciELO, CINAHL, Scopus and Web of Science. The search strategy used was based on the standards from the Cochrane Handbook for Systematic Reviews of Interventions¹². The descriptors used for the search followed the description from the MeSH/DeCS terms, these being: ‘heart failure’, ‘noninvasive ventilation’, ‘positive-pressure respiration’, ‘interactive ventilatory support’, ‘exercise test’. In addition to these, the following keywords were used: “BIPAP”, “CPAP”, “IPAP”, “EPAP”, “NIV”. There was also another search performed using the same words in the Portuguese language. The terms were combined using the Boolean operators ‘OR’, ‘AND’, ‘NOT AND’. There were no linguistic or publication year restrictions. The search was performed between April and May, 2013.

During the initial phase, the titles and abstracts were independently identified and evaluated by two reviewers (LAC and CRL) on a computer screen, this was done in order to select those who would meet the eligibility criteria. Potentially relevant studies, which raised doubts, were retained for later analysis of the text in their entirety. Whenever there were cases of disagreement in the selection process or article analyses, a third evaluator (DCB) participated in the evaluation.

Data extraction from the selected studies was performed by two independent evaluators. The extracted data were: eligibility criteria, population in the study, flow of participants, intervention details, outcome measures, results and bias risk.

Those studies that met the inclusion criteria were assessed by two independent evaluators as per the qualitative method with the PEDro scale, based on the Delphi

list. The PEDro scale was developed so as to be used during clinical trials, it is currently considered to be one of the most utilized in the field of physiotherapy^{13,14}. The PEDro scale allows a total score of ten points. A score of one point or zero may be assigned for each criterion introduced in the scale.

Upon the data collection’s completion, it was possible to verify whether meta-analysis could be done. However, this was not possible due to the heterogeneity of the studies included and a lack of data.

RESULTS

The search strategy used was extensive and resulted in 1,359 titles. 1,300 of these were excluded as their title did not contain the inclusion criteria. 12 of the 59 remaining studies were discarded for duplicity, 19 more were removed for not conforming with the topic or because they had an inappropriate study design. The remaining 28 studies were selected, assessed by way of abstract analysis, with 18 of these being excluded for not meeting the inclusion criteria. The ten articles that were left had their texts read in their entirety, 6 of which did meet the eligibility criteria, as described in Figure 1.

A total of four studies were included for qualitative synthesis⁸⁻¹¹. The studies included 58 adults who had been diagnosed with heart failure, 18 of these being women and 40 men, whose mean age varied between 33 to 68 years old. These studies originated from Brazil^{8,9,11} and Canada¹⁰, therefore the population was made up of individuals with diverse HF etiologies. However, two of the analyzed studies^{10,11} only included the congestive form of the disease. The staging between the studies differed, three of them^{8,9,11} included patients from the functional class II and III and only one study¹⁰ included individuals from functional class II-IV, using the classification as per the New York Heart Association (Table 1).

Three studies^{8,9,11} evaluated the NIV effect with continuous pressure on exercise tolerance throughout the six-minute walking test, which is a submaximal effort test. Only one of the 10 studies evaluated and compared the NIV effect with two levels of pressure and with continuous pressure on exercise tolerance, having already used the submaximal constant load test cycle in a cycleergometer so as to assess functional capacity. There was also variation as regards the control group: in two studies^{8,9}, individuals did not perform any type of VNI

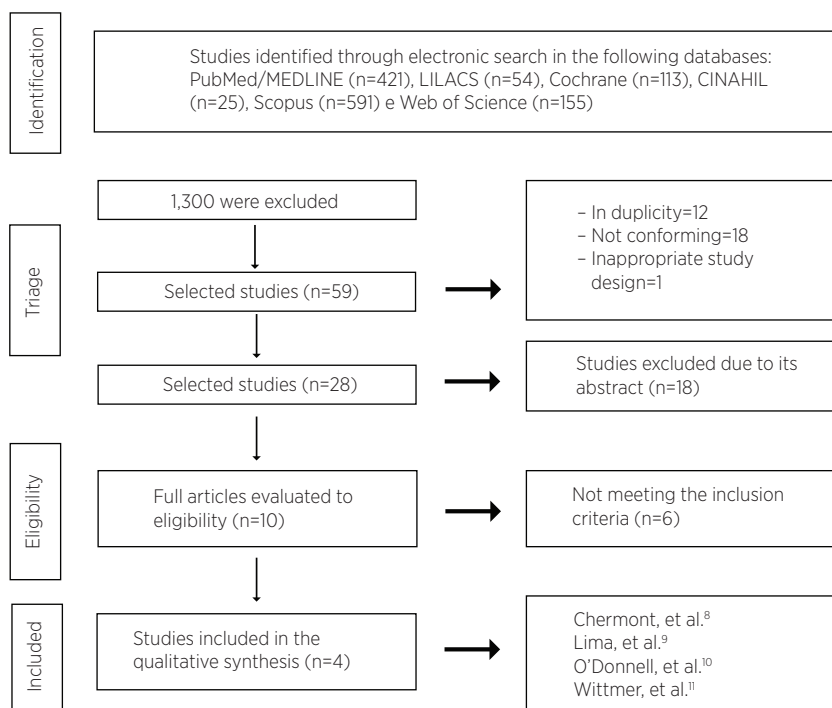


Figure 1. Search and selection of studies from systematic review according with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)

in the two studies; however, during the other two studies^{10,11}, the individuals performed the NIV in the form of a placebo, with low blood pressure levels.

Regarding patient selection control, all the aforementioned studies performed randomization⁸⁻¹¹, but only one of the included studies⁹ specified the method used (random drawing in a sealed envelope). Whereas, in regards to allocation anonymity, one study⁹ reported that the envelope used to achieve this was opaque; none of the analyzed studies⁸⁻¹¹ specified whether an independent person performed the allocation.

In one article¹¹ there was a selective description of the outcome, in addition to their results only being expressed in gain percentage (value after treatment – value before treatment/value before treatment \times 100). This same study analyzed their results by comparing the same group before and after the intervention. Only one article¹¹ referred to a sample loss, while none of them performed an intention-to-treat analysis. All the articles⁸⁻¹¹ blindfolded the participants involved, but only two did the same to the test's evaluator^{8,11}. The studies' scores, in accordance with the PEDro scale, can be seen in Table 2.

As for the outcome evaluation, with the exception of one study¹¹, where results were not clearly shown, the functional capacity was reproducibly evaluated in three studies⁸⁻¹⁰. Regarding the dyspnoea outcome, only two

studies proposed examining the data^{9,10}, with both using the Borg Dyspnoea scale. In one of the articles⁸, data was collected through the Borg Dyspnoea scale every two minutes during the 6-Minute Walk Test, however this data was not presented. With regards to the secondary outcomes, two studies^{9,10} evaluated the oxygen saturation outcome and three^{8,9,10} evaluated blood pressure (BP) and heart rate (HR) (Table 2).

Great heterogeneity was noted in each study by observing the intervention protocols therein. One VNI session was performed in each of the three studies^{8,9,10}; two studies^{8,9} held theirs immediately before the functional capacity test (FCT) and the other study¹⁰ carried it out during the FCT. 14 VNI sessions were performed in the other article¹¹, with the functional capacity evaluation being performed on days zero, 4, 9 and 14. The studies differed not only in terms of the number of sessions, but also in relation to the pressure used, while in two studies^{9,11}, the continuous positive airway pressure (CPAP) was fixed at 10cmH₂O and 8cmH₂O respectively. The other two studies^{8,10} performed a pressure titration. One study⁸ titrated based on the individual's satisfaction from a previous evaluation, while adopting a CPAP of 3 to 6cmH₂O. The other study included¹⁰ a pressure titration based on benefits found from a previous evaluation, having adopted a similar value for the continuous pressure and the phase with two levels of

Table 1. Characteristics of the included studies

Author and country	Population	Age±mean (years)	Diagnosis	Criteria used for staging	Intervention protocol
Chermont, et al. ⁸ Brazil	G: 4 women and 8 men	G: 56±12	HF (6 ischemic and 6 idiopathic) LVEF<45%	NYHA II/III: 4/8	Therapy type: NIV – CPAP (4–6cmH ₂ O) (individualized pressure), through nasal mask in supine position at 45°, before the 6MWT. Placebo: ventilatory support (0–1cmH ₂ O) in supine position at 45°, before the 6MWT. Frequency: once every experimental situation, on different days (no interval is reported). Duration: NIV and placebo – 30 minutes. Functional capacity test: 6MWT. Instrument: CPAP (Tranquility, Healthdyne Technologies, Marietta, GA)
Lima, et al. ⁹ Brazil	NIV: 2 women and 4 men; Control: 1 woman and 5 men	NIV: 47.5±9.1; Control: 45.1±12.1;	HF (5 hypertensive, 5 ischemic, 2 others) LVEF<45%	NYHA II/III: 2/10	Therapy type: NIV– CPAP (10cmH ₂ O) before the 6MWT; Control – no ventilatory support. Frequency: once. Duration: NIV– 30 minutes. Functional capacity test: 6MWT. Instrument: CPAP (no specification)
O'Donnell, et al. ¹⁰ Canada	G: 1 woman and 11 men	G: 61±4.	CHF (ischemic and idiopathic)	NYHA II-IV	Therapy type: NIV 1 – CPAP (4.8±0.2cmH ₂ O) during constant-load cycle endurance performance; Placebo – CPAP (1cmH ₂ O) during constant-load cycle endurance performance (75% of maximal work capacity). Frequency: once every experimental situation, with a 1-hour interval in between. Duration: CPAP/PS/Placebo during constant- load cycle endurance performance. Functional capacity test: constant-load cycle endurance performance. Instrument: Respiroics ventilator (Respiroics Murrysville, PA)
Wittmer, et al. ¹¹ Brazil	NIV: 6 women and 6 men; Control: 4 women and 6 men	NIV: 59.8±3.7; Control: 52.7±11.14	CHF (13 idiopathic, 1 alcoholic NYHA II and III, 8 after rheumatic fever)	NYHA II e III	Therapy type: NIV–CPAP (8cmH ₂ O), 100-meter walk every day, breathing exercises; Control–100- meter walk every day, breathing exercises. Frequency: NIV and Control–14 sessions. Duration: NIV–30 minutes of CPAP. Functional capacity test: 6MWT. Instrument: CPAP (no specification)

HF: heart failure; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; 6MWT: Six-Minute Walk Test; NIV: non-invasive ventilation; CPAP: continuous positive airway pressure; G: Group; CHF: congestive heart failure; PS: pressure support

pressure, the mean adopted pressure was 4.8cmH₂O. In three articles^{8,10,11}, the intervention groups were described in detail, including important information such as positioning during NIV administration and the interface used. The intervention groups and their respective protocols, the outcomes and the methods used by the authors to measure, and the results from the intervention can be seen in Table 1. Two studies had a cross-over design, one of these⁸ did not reference the ‘wash-out’ period between the experimental and placebo. The other¹⁰ opted to perform three sub maximal effort tests – two experimental and one placebo – on the same day, with a one-hour rest period between them.

Sample calculation was only performed in one study⁸, which used data from the literature to do it. None of the articles defined the clinically important difference in the evaluation of functional capacity or dyspnea.

Furthermore, among the articles analyzed here, none of them presented a conflict of interest.

DISCUSSION

Due to the methodological heterogeneity of clinical trials⁸⁻¹¹ in terms of the protocols employed and with there being no clear presentation of the results, NIV effectiveness was not evident along with increased exercise tolerance in patients with HF. In addition, all studies analyzed their outcomes based solely on statistical significance; therefore, it was not possible to calculate the magnitude of the treatment effect. The methodological aspects of the articles included deserve consideration.

Some methodological artifices are used in order to reduce the risk of bias. The best way to minimize

Table 2. Outcome evaluation

Author and country	PEDro	Form of assessing outcomes	Functional capacity (instrument)	Dyspnea (instrument)
Chermont, et al. ⁸ Brazil	8	After intervention phase and placebo phase (intergroup analysis)	Distance (6MWT) NIV: 507±33m Placebo: 446±36m p≤0.001	Not evaluated
Lima, et al. ⁹ Brazil	7	Before and after for the intervention group and for the control group (intra- and intergroup analysis)	Distance (6MWT) NIV: 534±89.91m Control: 420.6±73.8m p≤0.03	Borg NIV: 11±0.8 Control: 13.1±1.16 p≤0.009
O'Donnel, et al. ¹⁰ Canada	7	After the intervention phases and the placebo phase (intergroup analysis)	VO ₂ (constant-load cycle endurance performance; Egometrics 800S; SensorMedics) PS: 1.47±0.14min N/S CPAP: 1.46±0.14L/min NS Control: 1.5±0.14L/min	Borg PS: 5.5±0.5 NS CPAP: 5.1±0.5 NS Control: 5.2±0.5
Wittmer, et al. ¹¹ Brazil	5	On days zero, 4, 9 and 14 for the intervention group and for the control group (intergroup analysis)	Distance (6MWT) NIV before: 344±25m NIV after: increase of 28% – p≤0.05 Control before: 341±16m Control after: not informed – p≤NS	Not evaluated
Chermont, et al. ⁸ Brazil	After intervention phase and placebo phase (intergroup analysis)	NIV: 99±4bpm Placebo: 91±4bpm p≤0.03 Instrument not specified	NIV: 129±6mmHg Placebo: 136±8mmHg p≤0.312 Instrument not specified	Not evaluated
Lima, et al. ⁹ Brazil	Before and after for the intervention group and for the control group (intra- and intergroup analysis)	NIV: 99.6±13bpm Control: 117.8±19.3bpm p≤0.086 Instrument not specified	NIV: 140±12.6mmHg Control: 150±8.9mmHg p≤0.145 NIV: 101.6±13.2mmHg Control: 105±5.4mmHg p≤0.583 Instrument not specified	NIV: 96.1±1.8% Control: 93.6±1.5% p≤0.02 Instrument not specified
O'Donnel, et al. ¹⁰ Canada	After the intervention phases and the placebo phase (intergroup analysis)	PS: 119±7bpm NS CPAP: 122±8bpm NS Control: 121±7bpm Electrocardiographic monitor (Cardiovit CS-6/12Z; Schiller, Baar, Switzerland)	Not evaluated	PS: 97.6±0.3% NS CPAP: 97.5±0.2% NS Control: 97.6±0.3% Pulse oximeter (503 pulse oximeter; Criticare Systems, Waukesha, WI, USA)
Wittmer, et al. ¹¹ Brazil	On days zero, 4, 9 and 14 for the intervention group and for the control group (intergroup analysis)	Not evaluated	Not evaluated	Not evaluated

PEDro: PEDro scale; NIV: non-invasive ventilation; 6MWT: Six-Minute Walk Test; PS: pressure support; CPAP: continuous positive airway pressure; NIV before: baseline value of the non-invasive ventilation group; NIV after: post-test value of the non-invasive ventilation group; Control before: baseline value of the control group; Control after: post-test value of the control group. VO₂: oxygen consumption. NIV: non-invasive ventilation; PS: pressure support; CPAP: continuous positive airway pressure

selection bias, while certifying the treatment effect, is to perform the randomization process and allocation anonymity adequately. A treatment could possibly be overestimated by up to 40% when these items are not suitably performed^{15,16}. Furthermore, randomly allocating participants in a study means that there is a balance to group characteristics, thereby avoiding confusion factors¹⁶. Concerning the selection control of the participants, it was observed that all the studies included⁸⁻¹¹ reported a randomization process; however, only one of the articles⁹ described the adopted process, despite it being an unsuitable method. In regards to allocation anonymity, one study⁹ reported

that an opaque envelope was used to maintain secrecy, however none of the analyzed studies specified whether or not the allocation was performed by an independent person. By knowing the importance of these methodological aspects, since they avoid overestimating the effect of the treatment, it is possible that different results may be evidenced in studies that correctly perform randomization and allocation anonymity, thereby indicating a lesser effectiveness of the technique.

Moreover, in trying to minimize selection bias by the studies, well delimited inclusion criteria were established in order to homogenize the studied sample.

However, in one of the studies¹¹, there was a difference between the basal values of ejection fraction (EF) for the study groups, with the highest EF being for the intervention group when compared to the control group. EF is an important variable that can interfere with the blood supply and, consequently, with the functional capacity of the evaluated individuals¹⁷.

Blindfolding participants, despite not being possible in all situations, is as necessary as randomization or allocation anonymity, since it decreases the likelihood that the investigators' expectations might interfere in the treatment's real benefit¹⁸. All studies included in this review performed participant blindfolding⁸⁻¹¹, while despite examiner and outcome evaluator blindfolding being possible in all the analyzed studies, it only took place in two papers^{8,11}. This item is necessary because it prevents execution and measurement bias.

Only one clinical trial⁸ performed a sample calculation that was based on data from the literature. Sample calculation is important so that inferences and extrapolations can be made, from the results found, for the general population. Only one of the included articles⁹ was classified as a pilot study in its title. More controlled and randomized clinical trials with sample calculations are therefore suggested in order to ensure sufficient power, as well as greater external validity of the findings.

Another important item that can minimize result overestimation is the intention-to-treat analysis, which compares patients in the group where they were primarily allocated, regardless of sample loss¹⁹. The application of this analysis is only possible when complete data are available for all randomized individuals. Only one study¹¹ reported patient loss, but the patient inclusion and exclusion flowcharts were not presented in any of the analyzed studies. This lack of clarity in showing the individual inclusion and exclusion and in results pertaining to each outcome leads to a risk of bias. Data being absent is a significant bias when estimating the effect²⁰, which configures the selective description of the outcome. This occurs due to the fact that studies with positive results are published with greater ease. Because of this, greater clarity and objectivity is required in the presentation of results regarding the outcomes, in the conduct of the volunteer during the research, in the correct handling of data, while performing the same between the groups after the intervention and not before and after in the same group.

There was an observed weakness in the internal validity of the studies after qualitatively evaluating the presented results, since many strategies that could be employed to minimize the risks of bias were not correctly used. Decision-making is fundamental in the current evidence-based practice concept, which requires that the best levels of evidence are chosen along with the clinical experience of the professional and the patient's choice²⁰. Accordingly, studies that possess a wider methodological scope must be performed in order to better support the use of the NIV as a coadjuvant therapy along with exercise in individuals with HF.

CONCLUSION

This systematic review was inconclusive in terms of proving the effectiveness of the NIV along with increased exercise tolerance in patients with HF. Based on the evaluated studies, the conclusion is that methodological quality is low due to the high risk of bias, as observed in the available studies on this subject, as a result it is not possible to make a recommendation regarding NIV in this context. Therefore, it is recommended that randomized and controlled clinical trials follow a stricter methodological process, with appropriate sampling power, which will in turn control allocation anonymity and evaluator blindfolding. Greater clarity is also required in terms of data presentation, this is important so that analyzing the extent of the treatment's effect easier for the critical and important outcomes.

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