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Effect of inspiratory muscle training in patients with chronic heart failure: a meta-analysis of randomized controlled trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 May 2025 and was last updated on 21 May 2025.

INTRODUCTION

Review question / Objective To further identify the therapeutic effects of inspiratory muscle training (IMT) among chronic heart failure (CHF) patients based on current evidence of randomized controlled trials (RCTs).

Condition being studied Chronic heart failure (CHF) is a progressive, multifactorial disease with a high incidence, mortality rate, and readmission rate, imposing significant economic and psychological burdens on society and families [1, 2]. Global Burden of Disease (GBD) data from 2019 shows that there were approximately 37 million people worldwide in need of rehabilitation due to cardiovascular diseases [3]. Among these, the largest proportion was attributed to heart failure, affecting approximately 35 million people, followed by acute myocardial infarction, which affected about 1.3 million people [4]. Currently, in China, the incidence of cardiovascular diseases is on a significant rise, with nearly 330 million individuals affected. Among Chinese adults aged 35 and above, the prevalence of heart failure is approximately 1.3%, equating to around 8.9 million heart failure patients. Between 2000 and 2015, the incidence of cardiovascular diseases increased by 44% [5]. CHF has a higher overall incidence and mortality rate compared to both healthy individuals and other cardiovascular disease patients. Important risk factors contributing to CHF include diseases such as hypertension, diabetes, obesity, metabolic syndrome, and atherosclerosis [6, 7].
Exercise intolerance and difficulty in breathing are the primary symptoms in patients with chronic heart failure, and they are also the major factors leading to a decreased quality of life in these patients. The mechanisms underlying these symptoms in heart failure patients include not only hemodynamic abnormalities but also changes in peripheral skeletal muscles [8, 9]. A significant body of research has confirmed that aerobic exercise can reverse this alteration and improve the exercise capacity of CHF patients [10, 11]. However, recent studies have found that muscle weakness in CHF patients initially occurs in the

respiratory muscles and then appears in the limbs [12]. In CHF patients with respiratory muscle fatigue, symptoms of breathlessness become more pronounced, and exercise endurance further decreases. Therefore, effectively alleviating the weakness or fatigue of respiratory muscles is crucial for improving the clinical outcomes of CHF patients.

The role of IMT in improving clinical outcomes for patients with various diseases such as the obstructive sleep apnea and chronic obstructive pulmonary disease (COPD) has been widely confirmed [13, 14]. Previous literatures indicated that IMT may improve the clinical outcomes in patient with heart failure [15, 16]. However, these studies were published quite some time ago, and there is insufficient evidence regarding whether IMT could effectively improve outcomes for patients with CHF.

Therefore, we aimed to further determine the effect of IMT on CHF patients based on current evidence provided by randomized controlled trials (RCTs), which may contribute to the clinical application of IMT among CHF patients.

METHODS

Search strategy The PEDro, PubMed, Web of Science, EMBASE and CNKI databases were searched from inception to January 2, 2024 for available RCTs. Following terms were used during the search: inspiratory muscle training, IMT, chronic heart failure, CHF, randomized and randomly. Detailed search strategy was as follows: (inspiratory muscle training OR IMT) AND (chronic heart failure OR CHF) AND (randomized OR randomly). Meanwhile, MeSH terms and free texts were applied, with search fields restricted to tiles, keywords and abstracts. References in included studies were also reviewed for eligibility.

Participant or population Patients were diagnosed with CHF with New York Heart Association (NYHA) class II or III and over 18 years old.

Intervention Patients were randomly allocated to the IMT group or control group. Patients in the intervention group received IMT for at least four weeks and patients in the control group received sham IMT, traditional training or no intervention.

Comparator Primary outcomes were inspiratory muscle function evaluated by the maximal inspiratory pressure (MIP) and pulmonary function including the VO2peak, forced expiratory volume in one second % (FEV1%), forced vital capacity % (FVC%), FVC, FEV1/FVC, and maximal ventilator volume (MVV) and secondary outcomes were exercise performance including the 6 minute-walk test (6MWT) and Borg dyspnea index, quality of life evaluated by the Minnesota Living with Heart Failure Questionnaire (MLwHFQ) and N-terminal pro brain natriuretic peptide (NT-proBNP).

Study designs to be included Randomized controlled trials.

Eligibility criteria Studies met following criteria were included: 1) patients were diagnosed with CHF with New York Heart Association (NYHA) class II or III and over 18 years old; 2) patients were randomly allocated to the IMT group or control group; 3) patients in the intervention group received IMT for at least four weeks and patients in the control group received sham IMT, traditional training or no intervention; 4) primary outcomes were inspiratory muscle function evaluated by the maximal inspiratory pressure (MIP) and pulmonary function including the VO2peak, forced expiratory volume in one second % (FEV1%), forced vital capacity % (FVC%), FVC, FEV1/FVC, and maximal ventilator volume (MVV) and secondary outcomes were exercise performance including the 6 minute-walk test (6MWT) and Borg dyspnea index, quality of life evaluated by the Minnesota Living with Heart Failure Questionnaire (MLwHFQ) and N-terminal pro brain natriuretic peptide (NT-proBNP); 5) above outcomes were compared between the IMT and control groups providing specific data about the baseline and post-IMT values; 6) articles were published in English or Chinese.

Information sources The PEDro, PubMed, Web of Science, EMBASE and CNKI databases were searched from inception to January 2, 2024 for available RCTs.

Main outcome(s) Primary outcomes were inspiratory muscle function evaluated by the maximal inspiratory pressure (MIP) and pulmonary function including the VO2peak, forced expiratory volume in one second % (FEV1%), forced vital capacity % (FVC%), FVC, FEV1/FVC, and maximal ventilator volume (MVV).

Additional outcome(s) Secondary outcomes were exercise performance including the 6 minute-walk test (6MWT) and Borg dyspnea index, quality of life evaluated by the Minnesota Living with Heart Failure Questionnaire (MLwHFQ) and N-terminal pro brain natriuretic peptide (NT-proBNP).

Data management Following information was extracted from included studies: the name of first author, publication year, country, number of cases,

NYHA class level, left ventricular ejection fraction (LVEF), age, parameters about IMT including the initial training pressure, training time, sessions and duration, control care and endpoints with corresponding detailed data.

Quality assessment / Risk of bias analysis Methodological quality was assessed according to the PEDro scale. Studies with a PEDro score of 6 or higher, 4 or 5 and 3 or lower were defined as high-, fair- and low-quality studies.

Strategy of data synthesis Statistical analysis was conducted by RevMan 5.3 version software. Heterogeneity between studies was evaluated by the I2 statistic and Q test. When significant heterogeneity was observed representing as $I2 > 50\%$ and/or $P < 0.10$, the random-effect mode was applied; or the fixed-effect model was used [20, 21]. Continuous data were compared and analyzed as the changes from pre-IMT values to post-IMT values. Mean differences (MDs) with standard deviations (SDs) were combined to calculate the MDs with 95% CIs between the IMT and control groups. If data were presented as means and range values, then they would be converted to means and SDs according to the formula reported by Hozo et al [22]. A P value < 0.05 was considered statistically significant.

Subgroup analysis Not applicable.

Sensitivity analysis Not applicable.

Language restriction No.

Country(ies) involved China (West China Hospital, Sichuan University).

Keywords Inspiratory muscle training; chronic heart failure; clinical effect; meta-analysis; randomized controlled trial.

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