

“The effect of mechanical insufflation – exsufflation on spinal cord injury patients with respiratory problems. A systematic scoping review”

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ABSTRACT

Respiratory dysfunction remains a significant cause of morbidity and mortality after spinal cord injury (SCI). The purpose of this scoping review is to investigate the effectiveness of mechanical insufflation - exsufflation (MI-E) device, for cough augmentation and secretion management, in patients with SCI.

Electronic databases Medline (pubmed), Cochrane, PEDro, DynaMed, CINALH, and electronic libraries Scopus, ScienceDirect and Google Scholar were searched for relevant literature.

Inclusion criteria concerned studies referring to traumatic spinal cord injuries, carried out from 1/1/2000 until 9/12/2021, written in English language. All types of articles were accepted. Studies on children, animals and neuromuscular diseases as well as book chapters and article abstracts were excluded.

The articles were searched systematically. Fifteen studies were found to meet the inclusion criteria. The search revealed 1 randomized control trial (RCT), 5 retrospective studies, 2 cross-sectional studies, 3 observational studies and 4 case reports.

The reviewed evidence of the utilization of MI-E device resulted to improved pulmonary parameters, shorter hospitalization and successful weaning in patients with SCIs. Although, the reviewed evidence is weak and limited, in clinical practice the usage of MI-E device in patients with SCIs, is encouraging.

KEYWORDS: spinal cord injuries, quadriplegia, tetraplegia, mechanical insufflation - exsufflation, cough assist

Introduction

The term ‘spinal cord injury (SCI)’ refers to damage to the spinal cord resulting from trauma (e.g. a car crash) or from disease or degeneration (e.g. cancer) ^[1]. Spinal

cord injuries often cause disabilities and have social and economic impact on those who suffer from it and on the society. An epidemiological study of spinal cord injuries across 22 European countries (2012), record 1840

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deaths, of which 1084 (59%) were males [2]. Deaths from spinal cord injuries account for 2% (95% CI: 1.8% to 2.2%) of the overall injury related mortality. The 61% of the fatal spinal cord injuries occur to the cervical spine area [2].

In addition to deaths, various other problems arise, depending on the extent and the level of the spinal cord damage. A crucial complication of the spinal cord injury is respiratory dysfunction, which is associated with mortality and morbidity and directly depends on the level and the completeness of the trauma [10].

Higher injury levels affect significantly the respiratory muscles. Therefore, the inspiratory capacity and the expiratory muscle force are decreased, resulting in an inadequate cough [3]. Also, cervical cord injury destroys sympathetic pathways and parasympathetic system domains, which leads to mucus increase [4]. In clinical practice, an impaired cough limits the ability to remove the secretions, resulting to atelectasis, infection and finally to death.

In patients with SCIs, there is limited intervention of cough augmentation and secretion management. A technique, which enhances coughing capacity to spinal cord injured patients, is the utilization of the insufflation – exsufflation device.

This device has been commonly used for cough augmentation and secretion removal, in population with neuromuscular diseases [5, 6]. However, in patients with spinal cord injuries, the evidence is limited.

The purpose of this scoping review is to explore the current evidence regarding the effectiveness of the mechanical insufflation - exsufflation device, in spinal cord injured patients, for cough augmentation and secretion management, in order to enhance pulmonary parameters, to avoid intubation or to succeed weaning and to reduce hospitalization. The study followed the recommendations proposed by Arksey and O'Malley [14].

Study questions

1. Does the mechanical insufflation – exsufflation device (MI-E) enhance cough and respiratory parameters to patients with spinal cord injury (SCI)?
2. Is there an appropriate protocol used by the therapists?
3. What are the suitable settings for the MI-E device?

4. Are the weaning time and the hospitalization reduced?

5. What are the complications which follow the utilization of MI-E device?

Search strategy

The scoping review conducted by searching: a) electronic databases of Medline (PubMed), Cochrane, PEDro, DynaMed, CINAHL, b) electronic libraries Scopus, ScienceDirect and c) the link of the Hellenic Academic Libraries. Additionally, Google Scholar was also searched for relevant literature and manual reference list searches of the included studies were also performed (Table 1). The literature searches, the screening as well as the appraisal of the evidence were performed by the first author of this study (KH).

The keywords used were: “spinal cord injuries, quadriplegia, tetraplegia, mechanical insufflation exsufflation, cough assist”.

DynaMed, CINAHL, Scopus, ScienDirect and HeAL-link were searched through a common platform of the National and Kapodistrian University of Athens.

Inclusion criteria

Only papers with traumatic spinal cord injuries were accepted and the electronic search timeframe ranged between 1/1/2000 to 9/12/2021. There were no exclusions based on the age, gender or the level of injury. The included articles were in English and due to lack of high quality RCTs, all types of research articles were included.

Exclusion criteria

Studies which used children, animals, and other neuromuscular diseases were excluded. Also, book chapters, abstracts and grey literature were excluded. Finally, the reviews were excluded, because their reviewed articles were also found by the search strategy of the present review.

Risk of bias

Although the assessment of the methodological quality of the literature is not necessary in scoping reviews [7] an attempt was made in this review to quality appraise the included studies. The only randomized control trial that found and included in this review was quality appraised with the PEDro scale [8], while the Sackett scale was used

to classify the studies to different levels of evidence [9].

Discussion

The search strategy revealed 454 articles in total. After screening the titles and the abstracts, 392 articles were excluded as not relevant. The full-text of the 62 articles was reviewed, and 15 were found to meet the inclusion and exclusion criteria (flowchart).

The results were: 1 randomized control trial (level 2b), 5 retrospective studies (level 3), 2 cross-sectional studies (level 4), 2 observational studies (level 4), 1 observational study (level 5), and 4 case reports (level 5) (table 2). The methodological quality of the RCT was quite low (1/10 in PEDro scale). The retrieved articles were grouped and presented, according to the above-mentioned questions.

Sample characteristics

The sample of the studies ranged from 1 to 86 adult patients. In two studies, the sample size was not mentioned [15, 36]. In total, the sample size of the twelve studies combined was 290 patients. Approximately, the 80% of the patients were males and the 20% females. The age of the sample patients ranged from 16-75 years. Neurological level of injury ranged from C1-T3 [15, 18, 21, 22, 23, 24, 25, 26, 37, 40, 41] and Asia Impairment Scale (AIS) / American Spinal Injury Association (ASIA) classification ranged from A-D. Five studies were referred to AIS / ASIA A injuries [15, 18, 22, 23, 41] and three studies included injuries of AIS / ASIA A-D [21, 24, 26]. Most common SCI was classified in AIS / ASIA A. However, one study did not include injuries of AIS / ASIA A [25].

Of the fifteen studies, five included acute SCIs [15, 22, 23, 24, 41], one study subacute [18], two chronic SCIs [25, 26], one study had mixed acute and chronic SCIs [27] and in four studies the chronicity of the SCI and its neurological level was unspecified [17, 27, 37, 40]. Additionally, two studies included mixed population [17, 40] (subjects with neuromuscular diseases, obesity hypoventilation syndrome, restrictive pulmonary syndromes and SCI). Finally, two of the fifteen studies explored therapists' experiences on using mechanical insufflation – exsufflation device [16, 19].

Patients' and therapists' experience / questionnaires

Four of the fifteen studies used as measurement tools, questionnaires [16, 19, 26, 27] and they were retrospective studies. One survey was referred to patients and examined their comfort by a 5-point Likert scale and tech-

nique preference (MI-E and endotracheal suctioning) by questions [26]. Two articles were referred to therapists and their experiences on using MI-E to patients with SCI [16, 19]. Finally, one survey, which was used questionnaire, had mixed sample, therapists and patients with SCI [27].

Schmitt et al. [27] and Garstang et al. [26] reported that patients were satisfied and preferred the MI-E device rather than the endotracheal suctioning for secretion removal. Moreover, these authors found that there was lack of the device utilization in many institutions.

Similarly, Rose et al [19] questioned Canadian and UK therapists about the utilization of MI-E device. They found moderate awareness of the guidelines for the assessment of cough effectiveness and airway-clearance interventions, which hinder therapists' adoption and performance [34]. Also, Cough peak flow (CPF) reported as the most common cough assessment for both countries.

This is in line with Prevost et al [16], who used a questionnaire to assess the MI-E utilization (protocols, guidelines, MI-E parameters, cough assessment). They found that one-third of the Ontario hospitals researched had an MIE device. The device applied in various pressures. The most common (54%) pressure spans were 35 cmH₂O to 40 cmH₂O. Similar results were found by Schmitt et al [27]. However, the use of protocols and guidelines were: 70% had a specific protocol and 29% had staff competencies, in contrary to Schmitt et al [27] who found: 56% had a specific protocol and 63% had staff competencies. The MI-E device was commonly assessed by Vital Capacity (VC), Peak Cough Flow (CPF), maximal inspiratory/expiratory pressures.

Hospitalization

Hospitalization was evaluated in patients with SCIs by Crew et al. [21]. This was a retrospective cohort study of 40 patients with SCIs who were prescribed MI-E devices for outpatient use. There was a nonsignificant reduction in respiratory hospitalization rates by 34% (0.314/y before MIE vs 0.208/y after MIE; p = 0.21). A post hoc subgroup analysis showed a significant reduction in respiratory hospitalizations per year for patients with smoking history (p=0.03). Furthermore, Ehsanian et al. [41] present the pharyngeal clearance maneuver, a technique which uses a modified application of the mechanical insufflation-exsufflation device to remove secretions above the tracheostomy cuff during cuff deflation. The proposed

technique eliminates the risk of pneumonia from aspiration of accumulated secretions and contributes to success rates of ventilator liberation. Also, the reduction in risk of aspiration potentially allows the patient to recover neurologically, to be active and to reduce the risk of mortality associated with pneumonia [42].

Pulmonary Parameter Outcome.

Pulmonary parameters were evaluated in almost all studies. CPF was the most common indicator. The only randomized control trial was the review of Pillastrini et al. [15] examining the effect of MI-E on respiratory volumes and flows during bronchial clearance. The experimental group was treated with manual respiratory physiotherapy in conjunction with MI-E (pressure: 15 cmH₂O - 45 cmH₂O). The control group was treated with manual respiratory physiotherapy only. At the end of the treatment the experimental group showed a significant increase in Forced Vital Capacity (FVC), Forced Expiratory Volume in 1 s (FEV1) and Peak Expiratory Flow (PEF) (P<0.01). The control group did not change significantly. That was in line to the findings of Bach et al [20].

The observational study by Sugiyama et al. [25] evaluated the effects of MI-E on volume change of the chest wall and each compartment, in 14 male patients with cervical spinal cord injury using optoelectronic plethysmography. The compliance was evaluated by the summation of the volume of the upper thorax (V_{UT}), the volume of the lower thorax (V_{LT}), and the volume of the abdomen (V_{AB}): V_{chestwall} = V_{UT} + V_{LT} + V_{AB}. The volume of the chest wall and the upper and lower thorax compartments were significantly greater during MI-E ≥ ±30 cmH₂O compared to deep breath. However, the appliance of MI-E had no significant difference to the volume of the upper and lower thorax and abdomen compartment in the pressures range between ±30 and ±50 cmH₂O. Goldman et al. [36] described the compliance of the abdominal wall of quadriplegic participants. They found that compliance was 2 times greater than the normal subjects. FVC, FEV, maximal Inspiratory/Expiratory Pressures (P_Imax, P_Emax) and CPF were also improved.

Moreover, Chang et al [23] in a case report, presented their experience of a successful weaning by using M-mode ultrasonography and a cough-assist device for secretion removal in a quadriplegic patient neurological level C2 (near complete quadriplegia). The case was a

man 65 years old. Criteria for weaning were diaphragm assessment and the parameter PCF. However, his respiratory muscles were weak and secretion removal was inadequate. Diaphragm was evaluated by M-mode ultrasonography and PCF was enhanced by MI-E device. Extubation was successful and the patient was stable with good vital signs and arterial blood gases from 2 hours after extubation for 5 days and then he was transferred to his hometown hospital. This is further supported by studies that suggest that the MI-E is preferable by the patients with SCIs than other techniques [26, 27, 37]. Furthermore, the utilization of MI-E can induce low rates of ventilator pneumonia and has reduced the complications of the respiratory impairment [37]. Vital capacity, forced vital capacity, peak cough flow and arterial blood gases were also, improved.

Additionally, McCaughey et al. [18] conducted a case report to evaluate the combination of the Abdominal Functional Electrical Stimulation (AFES) with the MI-E, during a 14 week period, in a tetraplegic patient. FVC and PEF were measured before and after the intervention. The parameters of the MI-E device were chosen according to clinical judgement and the pressures used were lower when compared to the standard clinical practice [27,33], because the patient was not in the need of intensive secretion removal. The patient made 5 unassisted insufflation - exsufflation cycles and another 5 assisted cycles by AFES and MI-E. There was no statistically significant difference between stimulated and unstimulated expiratory volume (EV) (P=0.64) and peak expiratory flow (PEF) (p=0.44). Nevertheless, in most of the sessions, stimulated EV and PEF were higher than the unstimulated and therefore, there was the potential for these parameters to be clinically significant. Nevertheless, judging by the increased respiratory volumes, the combination of AFES and MI-E perhaps is more valuable in secretion removal than MI-E alone. Also, AFES and MI-E were synchronized with 96.7% accuracy.

Finally, Fauzi et al. [22] in their case report described two males with spinal cord injuries. In this review there will be reference only to the one man, who had a traumatic injury. The second man had a cord tumor and according to exclusion criteria, he will be excluded. The first man had a C5 fracture dislocation (ASIA A) and difficulty in weaning. His therapy regime in the ICU was respiratory physiotherapy, endotracheal suctioning, mucol-

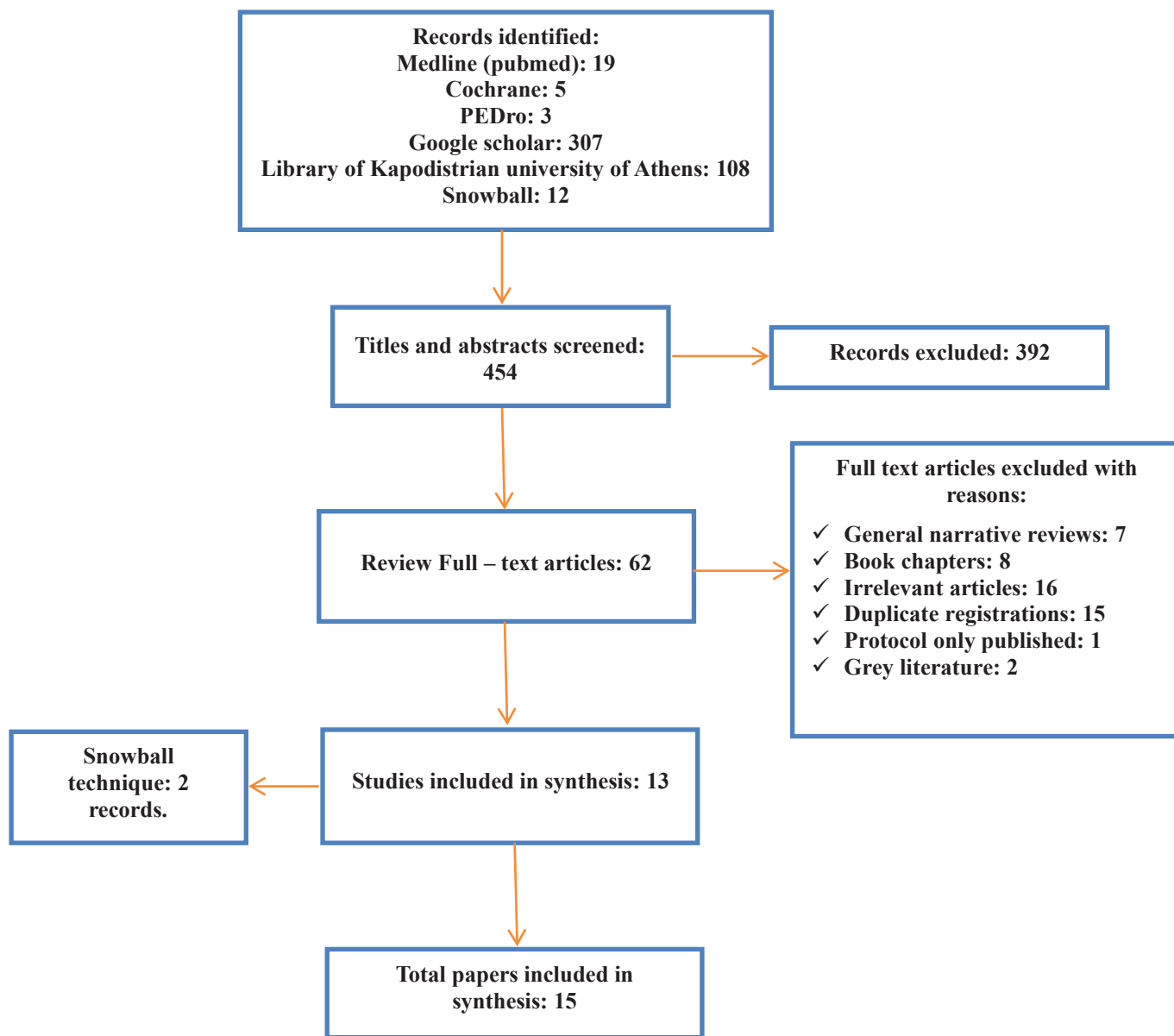


Figure1: Flowchart

ytic agents and MIE therapy. The utilization of MIE was assessed by PCF. He weaned to room air at four months postoperatively. There was a significant increase in FVC and FEV1 by the MI-E utilization similar to the findings reported by Pillastrini et al. [15].

Weaning / decanulation

Four surveys included in this review studied the weaning time and decannulation in patients with SCIs.

Bach et al. [17] studied the efficacy of MI-E on decannu-

lation of 61 patients with severe respiratory muscle insufficiency. The patients with SCIs were only 4 and their mean age was 43.4 years. The VC of 61 patients increased significantly (p < 0.001) from presentation to immediately pre-decannulation and in the 3 weeks post-decannulation. For patients with SCIs, vital capacity mean, was 775ml (SD =358), 3 weeks post-decannulation. All patients, apart from one with SCI were decannulated. Saturation of pO₂ (SpO₂) and CPF were also improved.

A year later, the research team of Bach [40] found that

unweanable subjects, with respiratory muscle failure can firstly be extubated to continuous noninvasive ventilatory support (CNVS) and MIE. Then they can normalize their O₂ saturation and increase their vital capacity (VC) in order to facilitate their extubation ($p < 0.001$). Ninety seven of ninety eight subjects were successfully extubated despite 45 having been CNVS-dependent for 4 months to 18 y before being intubated. Weaning from CNVS to part-time noninvasive ventilatory support (NVS) was achieved by all 52 subjects who had not been CNVS-dependent before intubation. Bach and the other researchers accept that the use of the MI-E device is beneficial to any patient with airway secretions and inadequate cough flows.

Additionally, Wong et al. [24] conducted a retrospective study to examine the efficacy of High Tidal Volume Ventilation (HVtV), Intrapulmonary Percussive Ventilation (IPV) and MIE treatments on the respiratory status of patients with acute high level cervical injury. The sample consisted of 24 patients and 23 were weaned to room air in an average time of 16.3 days (SD 20.8). The above intervention improved respiratory parameters within 7 days of its application. A secondary outcome was tidal volume (average tidal volume after application: 1037.50 mL; SD 140.8). HVtV, IPV and MIE for mucus removal for the patients with SCIs were suggested as a clinical guideline of the Consortium for Spinal Cord Medicine. However, according to Schimtt et al. [27] only the 64% of the therapists of the Acute Rehabilitation Facility, were using the MIE device. Wong et al [24] also used the three interventions to almost all patients and they could not distinguish which one was more effective.

Finally, Lyszner et al. [37] made an effort to establish MI-E guidelines for patients with SCIs. They found low rate of ventilator pneumonia (<1%) and low incidence of atelectasis, when the MI-E was used. Weaning success was about 97%, for injuries below C4 with the MI-E utilization.

Protocols/ settings of MI-E device

There was variation in the settings and the way that the MI-E device was used. In five studies, the time of inhale and exhale was 2 and 3 sec respectively [15, 18, 21, 23, 26]. In the other eight studies, there was no mention about the inhale and exhale time [17, 19, 22, 24, 25, 27, 40, 41]. However, the

ideal insufflation time to provide higher exsufflation volume and flow, according to Sancho et al. [33] is 3 sec. Insufflation time less than 3 sec probably will not expand the lungs completely. However, according to Prevost et al. [16] most of the therapists (40%) apply more than 3 sec inspiration time.

In the present review, the applied pressures of the device ranged from ± 15 cmH₂O to ± 70 cmH₂O. Insufflation-exsufflation spans $< \pm 35$ cmH₂O achieve expiratory flows less than 160 L/min, which are inadequate to expand completely the lungs [34]. Moreover, Winck et al. found significant improvement in blood oxygen saturation only after 40 cmH₂O [39]. Prevost et al. [16] described that pressures of ± 35 to ± 40 cmH₂O were used by most of the therapists. Bach et al. [17, 40] in both of their studies, used the MI-E device in pressure range of 50 – 70 cmH₂O and Ehsanian et al. used the MI-E device in lower pressure range (40–60 cmH₂O) [41].

Additionally, in the study of Rose et al. [19] the device settings were not mentioned.

Therefore, based on the current evidence, it is not clear about which are the most suitable device settings for insufflation time and pressure range.

Considering of the frequency that the device was applied, Prevost et al [16] reported that when patients were stable, most of the therapists performed MI-E two times per day. In contrast, during infection, 3, 4 or more times per day may be needed. Also, Wong et al. [24] and Bach et al. [17] suggest its use every 2 to 4 hours around the clock. Bach et al. [40] in their recent study of 2015 applied MI-E device every hour around the clock.

Moreover, according to Prevost et al. [16] and Schmitt et al. [27] most therapists followed a specific protocol, which however was not described or justified.

In six studies, MI-E was combined with other therapies, such as Intrapulmonary Percussive Ventilation (IPV), High frequency percussive ventilation (HFPV), bronchoscopy, mucolytic agents, chest physiotherapy, endotracheal suctioning and Abdominal Functional Electrical Stimulation [15, 16, 18, 22, 23, 24].

Finally, in the study of Lyszner et al. [37], the pressures of the MI-E, which were used, were the following: For patients with tracheostomy the applied pressure was ± 35 cmH₂O and for patients with mask or mouthpiece interface the applied pressure was ± 15 cmH₂O. The pressures were gradually increased until the limit of 55 cmH₂O. The

time of insufflation was 2 to 3 sec and of exsufflation 3 to 4 sec. There were 4 -5 cycles max.

MI-E complications

The complications of the use of MI-E devices are not common and can include: nausea, bradycardia, tachycardia, and abdominal distension [11]. Additional, exsufflation can cause a rapid decrease of intrathoracic pressure and consequently may provoke gastroesophageal reflux and aspiration [12]. However, in clinical practice, this complication is rarely reported [13]. Finally, Sivasothy et al, have described barotrauma as complication [38].

Strength and limitations


This is the first review that systematically searched and summarized the evidence regarding the use of MI-E device in SCI patients. However, the poor methodological quality and the different study designs of the included studies increase the risk of bias. Most of the studies were observational and case studies and there was only 1 low quality RCT (PEDro 1/10).

Additionally, the included studies had generally small

and heterogeneous sample sizes and lacked control groups of randomization procedures. Also, various protocols and parameters of MI-E device were used and in most of the studies the methodology was not described clearly.

Finally, the introduction of systematic bias in this review due to inclusion of literature published only in English is unlikely, due to fact that English is the main language used in conventional medicine publications [28-32].

Conclusion

In this scoping review, an attempt was made to identify and summarize the evidence regarding the utilization of MI-E device in patients with spinal cord injury. Most studies suggested that the use of the MI-E device in patients with SCI's, resulted to better pulmonary parameters, shorter hospitalization, and successful weaning and this is encouraging. However, no firm conclusions can be drawn due to the current limited, heterogeneous, and low-quality evidence. It is imperative that further high-quality research is required to explore the efficacy of the MI-E device in SCI patients. 

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