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Review

Interventions for the management of lower extremity edema in the elderly people: A review

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ABSTRACT

Aging increases the likelihood of lower extremity edema in older adults. However, few studies have examined effective management methods for lower extremity edema in elderly individuals. This study reviewed the existing literature on the management of lower extremity edema in this population. The study aimed to refine three viewpoints（effectiveness, self-management, and safety）in the management of lower extremity edema in elderly individuals and to examine effective management methods from those viewpoints. A database search identified 375 articles and ultimately used 18 of these articles. The most commonly used method for managing lower extremity edema in elderly individuals was compression therapy using a compression device or stockings, which also showed the possibility of self-management. Compression therapy reduced the circumference and volume of the lower extremities, was associated with weight loss, increased range of motion. These effects also led to improvements in sleep quality, quality of life, and walking distance. However, no studies verified the safety of elderly people with lower extremity edema, such as optimal compression and its effects on hemodynamics. This review has implications for future studies in this area and for elderly patients requiring management of lower extremity edema. In the future, it will be necessary to develop a method for managing lower extremity edema that can be easily self-managed by elderly individuals and verify its safety and effectiveness.

KEY WORDS：elderly, lower extremity edema, management methods, review

Introduction

Elderly people have been shown to have a higher proportion of lower extremity edema than younger individuals. Many elderly people in Japanese long-term care facilities have been reported to have edema somewhere on their bodies, and 88% of patients had edema in their lower extremities[1]. As the elderly

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population increases, there is concern that the proportion of elderly people with lower extremity edema will also increase.

Lower extremity edema has been shown to have adverse effects on physical and mental health. It causes pain[2)3)] and numbness, further limiting the range of flexion and motion of each joint[4)], affecting gait function[2)3)]. In addition, edema reduces the durability of skin tissue, making it more susceptible to damage and ulcers[5)6)]. As a psychological effect, those with lower extremity edema often experience anxiety, discomfort, and shame[5)7)]. Therefore, appropriate management of lower extremity edema is required.

The increased incidence of lower extremity edema in elderly people is linked to many factors related to their physical characteristics. Elderly individuals commonly experience a decrease in the function of each organ leading to edema, such as the heart[8)], kidneys[9)10)], liver[11)], and thyroid gland[12)] (diseased edema). In addition, damage to lymphatic vessels and tissues caused by surgical therapy, radiation therapy, and chemotherapy causes stagnation of blood flow and lymphatic flow, making lower extremity edema more likely to occur[13)] (lymphedema). Lower extremity edema in elderly individuals is also easily caused by decreased activity during the day, prolonged sitting time due to the necessity of a wheelchair, and decreased lower extremity muscle strength and athletic ability[14)] (dependent edema). Therefore, lower extremity edema in elderly individuals is likely to occur due to the presence of multiple factors.

It is critical to invest substantial medical resources that can be utilized by medical professionals with specialized knowledge to appropriately manage lower extremity edema. The total cost of lower extremity edema in the UK is reportedly £1.8 billion[15)] (about 274 billion in Japanese yen), and the exhaustion of medical staff with the necessary expertise is also problematic[15)]. Thus, self-care in the management of lower extremity edema is important to reduce these burdens[16)].

For these reasons, a method for self-management of lower extremity edema in elderly individuals will be required in the future. However, there are some barriers to developing such a method. First, medical professionals and elderly individuals are not fully aware of the importance of managing lower extremity edema. One of the reasons for this is the misunderstanding that proper management of lower extremity edema is not necessary because it occurs as a normal physiological change with aging[17)]. Second, medical professionals are concerned about the impact of self-management on safety, such as overloading the associated hemodynamics[18)], since even the general population of elderly individuals may have a reduced ability to maintain normal hemodynamics.

Therefore, this study comprehensively reviewed the existing literature on the methods for managing lower extremity edema in elderly individuals. The aim was to elaborate on three viewpoints (effectiveness, self-management, and safety) in the management of lower extremity edema in elderly individuals and to examine effective management methods from those viewpoints.

Methods

1. Protocol and registration

The review protocol has not yet been published. We used the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension Reviews checklist (PRISMA-ScR)[19)] to guide this review.

2. Eligibility criteria

We limited our search to articles published in English or Japanese regardless of the clinical setting, including inpatient settings, home care settings, and publication year. The selection criteria for this study were studies verifying the therapeutic effect of conservative treatment for lower extremity edema including individuals aged above 60 years. Proceedings, conference abstracts, letters to the editor, editorials, guidelines, protocols, literature reviews, and meta-analyses were excluded.

3. Information sources

The following bibliographic databases were searched in March 2020: PubMed (MEDLINE), Ichushi-Web (Japanese medical literature), and Cochrane Central. In addition, a hand-search method for managing lower extremity edema was included.

4. Search

The search was performed using a combination of search terms, including “elderly” AND “lower” AND “extremity” AND “edema” AND “management.” In Ichushi-web, we used the same combination of keywords in Japanese.

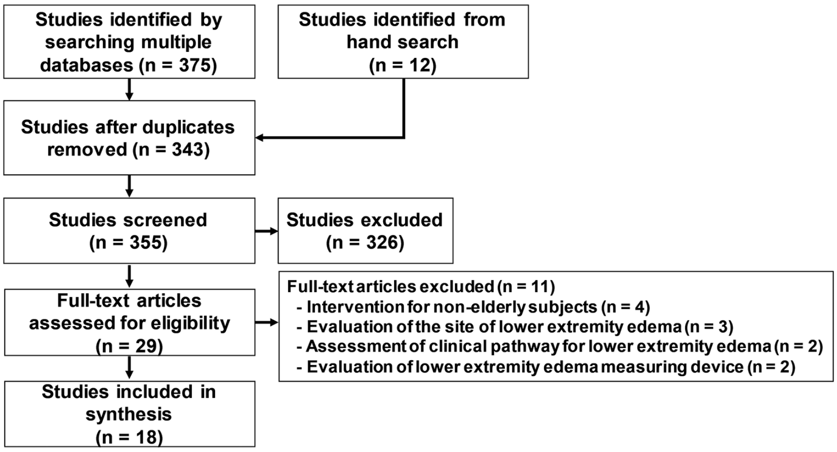

Figure 1 Flowchart of the search and selection process. A PRISMA flowchart of the current review is presented. A total of 18 articles were included in the review.

5. Selection of sources of evidence

Potentially relevant literature was imported into Rayyan for screening[20]. Titles and abstracts were screened by a researcher (F.O.), and those that did not fit the inclusion criteria were excluded. Potentially eligible full-text articles were screened for inclusion by a researcher (F.O.) according to the inclusion criteria. The adequacy of the study choice was discussed by researchers (F.O. Y.I Y.S. and J.S.), and any disagreement was resolved through discussion.

6. Data-charting process

A data-charting form was developed by one author (F.O.) to determine which variables to extract. Data were extracted by a single author (F.O.) and verified by co-authors (Y.I Y.S. and J.S.). Discrepancies in the extracted data were resolved through discussion between the authors.

7. Data items

The following information was extracted: (a) study authors, year of publication, and country; (b) study design/number of participants and age; (c) edema type; (d) methods and purpose (edema management method and evaluation points); and (e) outcome related to edema management (effectiveness, self-management, and safety).

8. Synthesis of results

The extracted data from the included studies were summarized including the attributes, study design, purpose, method, participants, and efficacy of the study in the lower extremity edema management method for elderly individuals.

Results

1. Selection of sources of evidence

The initial search yielded 375 studies. Following the removal of duplicates (n=32), 355 articles remained. Twelve articles identified by hand search were included. Through title and abstract screening, 326 papers were excluded. Among the 29 remaining papers, 11 papers were excluded through full-text screening: four evaluated interventions in non-elderly participants, three evaluated the site of lower extremity edema (no conservative treatment was given for lower extremity edema), two evaluated the clinical pathway of lower extremity edema management, and two were incompatible because they evaluated a measuring device for lower extremity edema. Eighteen articles were included in this review[21-38]. The PRISMA flowchart for the current review is shown in **Figure 1**.

2. Characteristics of sources of evidence

The characteristics of the included studies are provided in **Tables 1-3**. Among the 18 studies included in this review, 15 represented original papers, and three were case studies. Eleven of them were written in English, and the other seven were written in Japanese and published between 2004 and 2019.

The management methods used for lower extremity edema in elderly individuals were compression therapy[21-27] (seven cases), combined physical decongestive therapy[28-32] (five cases), manual lymph drainage[33] (one case), footbath therapy[34)35] (two cases), vibration therapy[36] (one case), position (recumbent)[37]

Table 1 Effects of compression therapy

Study author/year/country	Study design/participants/age	Types of edema	Purpose/methods		Results		
Compression therapy							
			Edema management method	**Evaluation points**	**Effectiveness**	**Self-management**	**Safety**
Tobias Bertsch **2018** **Germany**[21]	**A prospective, single-centre, observational study** N = 94 57 ± 13.9 years (Mean ± SD)	Lymphedema	JOBST Relax®, a custom-made compression garment, when worn by a series of patients with lymphoedema during resting hours and at night.	**1.** Garment's comfort, ease of use, fit, ability to avoid excessive heat and perspiration, its effect on patients' quality of life, and patients' overall satisfaction with it **2.** Safety (occurrences of erythema, skin rash, skin dryness, and pain)	**1.** Eighty-nine patients (97.8%) reported that their quality of sleep was either "very good" or "good" when wearing the garment at night. **2.** Sixty-nine patients (75.8%) reported that the night-time compression garment helped manage their edema "a lot" or "a great deal." **3.** There were notable reductions in the prevalence of skin erythema, skin rash, skin dryness, and pain during the study period. **4.** Fit, wearing comfort, and breathability were deemed "good" or "very good" by at least 86 patients (94.5%). **5.** Seventy-eight patients (85.7%) and 79 patients (86.8%) rated the night-time compression garment as "good" or "very good" in terms of avoiding heat generation and perspiration, respectively.	The percentage of patients who reported they were "not at all dependent" on others for support because of their lymphoedema increased from a baseline of 36% to 51% at the end of the study.	–
Kotaro Suehiro **2014** **Japan**[22]	**Observational study** N = 30 Median: 75 years (Range: 49–93 years)	Dependent edema	Compression therapy (elastic bandage or compression stocking: interface pressure > 30 mmHg, static rigidity index > 10 mmHg) and physical therapy for the purpose of strengthening calf muscles and improving AROM.	Improving AROM (Active Range of Motion Exercise)	**1.** Calf and ankle circumferences were reduced by these treatments (calf: 37.4 ± 5.4 cm vs. 35.2 ± 4.5 cm, p = 0.001, ankle: 25.5 ± 3.1 cm vs. 23.6 ± 2.6 cm, p = 0.001). **2.** All cases of stasis dermatitis and acute lipodermatosclerosis were resolved within two weeks. **3.** Ankle range of motion (AROM), which was determined as the sum of maximum voluntary plantar flexion and dorsiflexion of the ankle, was less than 20° in only 3 of 60 (5%) legs.	–	–
Alison Barker **2019** **United Kingdom**[23]	**Case reports (4 cases)** 81 years 60 years 88 years 82 years	 Diseased edema (Kidney) Diseased edema (Diabetes) Lymphedema Diseased edema (Stroke)	How the product (JOBST® FarrowWrap®) helps reduce edema.	Improve shape, reduce edema, heal ulceration, improve quality of life in relation to the lower extremity, and encourage self-care	**1.** In all cases, there was reduction of edema in the appearance of the lower extremities and healing of the ulcer. As a result, cases of improved quality of life were also reported. **2.** However, since the indicated compression product is of the type from the ankle to below the knee, edema remains on the peripheral side (dorsal of the foot).	–	–

Narumon Chanwimalueang **2015** **Thailand**[24]	**Observational study** N = 340 (lower extrimity group) Mean: 52 years (Range: 6–82 years)	Lymphedema	To present a morphofunctional practicality of Twisting Tourniquet© Technique (TTT) and demonstrate its clinical effectiveness.	Lower extremity volume before and after treatment	**1.** The affected lower extremity volume before and after treatment was 9704 and 7849 mL, respectively. **2.** The edema severity decreased from 61.3% to 30.6% after TTT with an average edema decrement at 1856 mL (range 227–16,378 mL), resulting in a rate of volume reduction at 55.6% (range 17.8–113.5%) within five days.	—	—
Nicole J Chimera **2016** **USA**[25]	**A quasi-experimental time series** N = 20 Older adults group: 56 ± 4.5 years (Mean ± SD)	No edema	Using the Profore Multi-layer Compression Bandaging System (40-60 mmHg).	Blood flow dynamics, lower-extremity edema, and range of motion in healthy older adults compared with healthy young adults	**1.** Static and dynamic dynamic ankle dorsiflexion range of motion significantly increased from precompression to postcompression. **2.** Not statistically significant, calf circumference decreased by 6 cm in the older adult group postcompression.	—	Skin perfusion pressure was significantly higher in the older adult group compared with the younger adult group (89.81 [76.9-102.7] vs. 60.5 [47.6-73.4] ($p = 0.003$).
G Mosti **2015** **Italy**[26]	**A randomized controlled trial** N = 36 71 ± 10.2 years (Mean ± SD) (Range: 52–85 years)	Dependent edema	Using the Inelastic bandages (IBs) and adjustable velcro compression devices (AVCDs®).	Reducing venous leg edema in the initial treatment phase	**1.** At T1 (day 1), the median percent volume reduction was 13% for the IB group versus 19% for the AVCD group; at T7 (day 7), it was 19% vs. 26%, respectively ($p < .001$). **2.** Comfort was reported to be similar with the two compression devices.	The pressure of the IBs was significantly higher compared with the AVCDs at T0 (day 0) (63 vs. 43 mmHg) but dropped by >50% over time while it remained unchanged with AVCDs owing to the periodic readjustment by the patient.	—
Jegy M Tennison **2019** **USA**[27]	**Case report** 64 years	N/A	Using the lower extremity multilayered compression bandaging.	Serial extremity circumference measurements	**1.** The patient's weight decreased from 94.5 kg on day 1 of compression bandaging to 86.3 kg on day 7. The circumferences of the affected extremitys also decreased. **2.** FIM scores for locomotion improved from requiring maximum assistance to ambulate 80 feet on day 1 of compression therapy to requiring only contact-guard assistance to ambulate 170 feet on day 8.	—	—

Table 2 Effects of combined physical decongestive therapy

Study author/year/country	Study design/participants/age	Types of edema	Purpose/methods		Results		
Combined physical decongestive therapy							
			Edema management method	**Evaluation points**	**Effectiveness**	**Self-management**	**Safety**
Naoki Haruta **2012** **Japan[28]** **(in Japanese)**	**Observational study** N = 72 62 ± 17.8 years (Mean ± SD) (Range: 13–89 years)	Lymphedema	Combined physiotherapy education hospitalization (physiotherapist's manual lymphatic drainage, nurse's elastic bandage wrapping, exercise therapy, skin care, elastic bandage wrapping and dietary guidance)	Evaluation of hospital-based complex decongestive physiotherapy (CDP) education program for lymph edema patients	**1.** Four cases abandoned educational hospitalization (self-convenience, cellulitis, cancer pain). **2.** Significant reduction in circumference of the affected extremity ($p < 0.05$). **3.** As for the long-term prognosis, the circumference was reduced ($p < 0.05$) at the outpatient visit compared to at the time of admission, indicating that the prognosis could be maintained even after discharge.	–	–
Yuuya Kitada **2014** **Japan[29]** **(in Japanese)**	**Case report** 79 years	Lymphedema	Physical therapy (lymph drainage/compression therapy/exercise therapy)	Edema improvement	Decrease in lower extremity circumference one month after intervention (foot dorsal-1.1 cm, outer ankle-1.2 cm, lower leg maximum-5.0 cm, knee point-6.5 cm).	–	–
Takako Hamamoto **2009** **Japan[30]** **(in Japanese)**	**A multicenter prospective observational study** N = 31 Mean: 60 years (Range: 32–88 years)	Lymphedema	Combined physical therapy (skin care, manual lymphatic drainage, compression therapy, exercise therapy, self-care)	Circumference and leg length of 6 points of the lower extremitys and the quality of life	**1.** There is a tendency for lower extremity volume to decrease (no significant difference). **2.** In the QOL evaluation, a significant improvement was observed in the overall evaluation ($p = 0.014$) and the emotional scale ($p = 0.0049$) in Skindex 29, but no significant improvement was observed in SF-36.	–	–
Alis Kostanoglu **2019** **Turkey[31]**	**Observational study** N = 95 56 ± 15.7 years (Mean ± SD)	Lymphedema	Modified combined decongestive therapy (CDT: skin care, manual lymphatic drainage, self-bandage, and exercise therapy	Edema improvement	**1.** The mean reduction amounts of edema volume before and after treatment were 296.05, 784.92, and 1038.50 mL for stages 1, 2, and 3 respectively ($p = 0.001$). There were significant differences between the values before and after treatment in excess extremity volume (EEV) at all stages ($p = 0.001$). **2.** The EEV percentages of the secondary LEL patients were higher than those of the primary LEL patients ($p = 0.04$).	–	–
Alper Tugral **2018** **Turkey[32]**	**Observational study** N = 17 52 ± 15.4 years (Mean ± SD)	Lymphedema	Complex decongestive physiotherap (manual lymph drainage, skin care, compression bandages, and exercise)	To evaluate a new tissue water-specific measurement technique	**1.** CDP reduced lower extremity circumference significantly at each measurement site (R1-R9) along the lower extremity ($p < 0.05$). **2.** Significant reduction was detected in percentage skin water content values measured from thigh, calf, and ankle after the CDP treatment of lymphedema ($p < 0.001$). **3.** General QOL evaluated by LYMQOL VAS also improved (prepost treatment: 5.2 ± 2.1 to 7.1 ± 2.2, $p = 0.003$).	–	–
Manual lymphatic drainage							
Tsunenori Arai **2013** **Japan[33]** **(in Japanese)**	**A quasi-experimental study** N = 56 60 ± 13.6 years (Mean ± SD)	Lymphedema	Manual lymphatic drainage	Lower extremity volume	There was a decrease in lower extremity volume before and after manual lymphatic drainage (81.40 ± 99.50 ml) ($p < 0.000$).	–	–

Table 3　Effects of other therapy for lower extremity edema

Study author/year/country	Study design/participants/age	Types of edema	Purpose/methods: Edema management method	Purpose/methods: Evaluation points	Results: Effectiveness	Results: Self-management	Results: Safety
Footbath therapy							
Mitsumi Ono **2010** **Japan[34]** **(in Japanese)**	**Observational study** N = 6 (Range: 78-102 years)	N/A (The means of transportation was a wheelchair)	Footbath therapy with aromatic oil	To clarify the effects (lower extremity circumferences, pulse, blood pressure, skin condition, presence/absence of chill/cyanosis, and speech)	**1.** Lower extremity circumference: There was a decrease of −0.17 to −0.38 cm in all measurement parts (only 10 cm below the right knee was significantly different [$p < 0.05$]). **2.** Pitting edema: Although it tended to disappear, the dorsal side remained.	–	**1.** Pulse: It decreased from 69.8 times/minute to 68.0 times/minute. **2.** Blood pressure: It decreased from 130.7/75.7 mmHg to 128.8/73.5 mmHg (significant decrease was observed only in systolic blood pressure [$p < 0.05$]).
Chihiro Miwa **2015** **Japan[35]** **(in Japanese)**	**A quasi-experimental study** N = 9 74 ± 8.4 years (Mean ± SD)	No edema	20-minute foot bath	Tympanic temperature with a thermistor, skin blood flow with a laser Doppler flowmeter, and blood pressure and heart rate with an automatic sphygmomanometer were measured	Skin blood flow: Elevated in the lower leg in both groups ($p < 0.05$) (Significant increase in young people compared to the elderly group and increase in thigh skin blood flow only in young people).	–	**1.** Systolic blood pressure: Decreased only in the elderly with a significant difference between the young and elderly groups ($p < 0.05$). **2.** Diastolic blood pressure: Decreased only in the elderly with a non-significant difference between the young and elderly groups. **3.** Heartrate: Increased in both groups but significantly increased only in younger people ($p < 0.05$). **4.** Eardrum temperature: Increased significantly in younger people compared to older people ($p < 0.05$).
Vibration therapy							
Julian M. Stewart **2004** **USA[36]**	**A quasi-experimental study** N = 18 56 ± 5 years (Mean ± SD), (Range: 46-63 years)	No edema	Plantar stimulation with upright tilt table testing	Calf blood flow, venous capacitance, and microvascular filtration, as well as impedance plethysmography to examine changes in leg, splanchnic, and thoracic blood flow while supine at a 35° upright tilt	**1.** 45 Hz plantar vibration increases blood flow in the supine calf (30%), pelvis (26%), and thoracic cavity (20%) ($p = 0.05$). **2.** The threshold for edema increased as lymphatic flow was promoted (24 ± 2 mmHg at 0 Hz, 27 ± 3 mmHg at 15 Hz, and 31 ± 2 mmHg at 45 Hz) ($p < 0.01$).	–	Heartrate was unaffected by plantar vibration, but leg blood pressure increased.
Position (recumbent)							
Sayumi Tsuchiya **2018** **Japan[37]**	**A longitudinal observational design** N = 13 82 to 92 years (Median, 85 years)	Chronic leg edema There are multiple factors that cause edema	Recumbent position at night	Leg circumference measurements, pitting tests and subcutaneous echo-free space (SEFS) grades using ultrasonography were recorded in the dorsum pedis, ankle joint, distal and proximal lower extremitys, and thigh (only the leg circumference measurements and pitting test)	The leg circumference decreased after recumbent position ($p < 0.05$). Pitting edema and SEFS also decreased at some sites in the leg after recumbent position, but edema remained after recumbent position, especially in the dorsum pedis and distal lower extremitys.	–	–
Tapping therapy							
Tomoe Shizuno **2005** **Japan[38]** **(in Japanese)**	**A quasi-experimental study** N = 29 85 ± 7.6years (Mean ± SD) (Range: 71–97 years)	There are multiple factors that cause edema	Edema-reducing effect of tapping on the plantar and calves using a commercially available massage device	The circumference of the feet and legs was measured two times daily over six consecutive days	**1.** During the tapping period, the circumference readings in the morning shortened 8 mm on average compared to those in the previous evening while the shortening was 2 mm on average during the control period. **2.** The mean readings of the morning circumference in the tapping period were significantly shorter when compared with those in the control period ($p < 0.01$).	–	–

(one case), and tapping therapy[38] (one case).

3. Synthesis of results

1) Effects of compression therapy (**Table 1**)

Compression therapy was the most commonly used management method for lower extremity edema in elderly individuals in the reviewed studies. Interfacial pressure was applied to the lower leg at between 30[22] and 60[25] mmHg, with 30 mmHg[22] pressure applied to elderly people with dependent edema, and 40-60 mmHg[25] pressure applied to healthy elderly people without edema. The tools used for compression therapy were compression devices (JOBST Relax®[21], JOBST® Farrow Wrap®[23], Twisting Tourniquet©[24], and Velcro®[26]), compression stockings[22], and bandages[22)25-27]. Of the products used in compression therapy, only compression devices were used for self-care purposes. The effects of compression therapy included reduction in lower extremity circumference, volume[22-24], body weight[27], and improvement in range of motion[22)25], however a study did not show statistically significant difference[25]. Lower extremity edema remained in areas other than the compression site[23]. Reduction of lower extremity edema with compression therapy was shown to improve sleep and quality of life[21)23], promote healing of skin ulcers[23], and increase walking distance[27].

From a safety perspective, no studies evaluated the effects of compression therapy on hemodynamics.

2) Effects of combined physical decongestive therapy (**Table 2**)

All studies included lymphedema as a type of edema for which combined physical decongestive therapy was performed[28-33]. The content of the combined physical decongestive therapy consisted of manual lymphatic drainage, compression therapy, exercise therapy, skin and dietary guidance, however the details varied from study to study. In addition, the therapy was carried out by medical professionals with specialized knowledge and skills. This therapy did not involve self-management.

The effects of combined physical decongestive therapy were reported to reduce lower extremity circumference and volume[28-33]. Furthermore, a statistically significant reduction in lower extremity edema was also observed when only manual lymph drainage was performed for a short time[33]. This therapy was also shown to be effective in long-term prognosis and improved quality of life[30)32]. From a safety perspective, no studies evaluated the effects of combined physical decongestive therapy on hemodynamics.

3) Effects of other therapy for lower extremity edema (**Table 3**)

Footbath therapy was shown to reduce the circumference of the lower extremities, but only a portion of the lower extremities showed a significant difference[34]. Pitting edema tended to disappear after footbath therapy but remained on the dorsal side[34]. The effects of footbath therapy on hemodynamics were increased tympanic membrane temperature and cutaneous blood flow in the lower extremity, decreased systolic and diastolic blood pressure, and increased heart rate[35]. These effects on hemodynamics were more likely to occur in elderly than in young individuals[35].

Other management methods performed for lower extremity edema included vibration therapy, postural position, and tapping therapy. Vibration therapy was performed as a quasi-experimental study in people without edema[36]. The results showed that heartrate was not affected by plantar vibration, but the blood pressure in the legs increased. Furthermore, the threshold of edema was raised by increasing the blood flow in the calf, pelvis, and thoracic cavity and improving the lymphatic flow. It was shown that the recumbent position was performed at night to significantly reduce the circumference of the lower extremity[37]. However, the pitting test revealed that the edema persisted. Tapping therapy for lower extremity edema significantly reduced the circumference of the lower extremity[38], and the participants commented on improved sleep quality and comfort. These other therapies did not involve self-management.

Discussion

In this study, we detailed three viewpoints (effectiveness, self-management, and safety) in the management of lower extremity edema in elderly individuals through a literature review and examined effective management methods from those viewpoints. Only five studies were limited to the elderly aged 60 and over with lower extremity edema, all conducted in Japan[29)34)35)37)38]. Therefore, it is necessary to clarify the pros and cons of the lower extremity edema management method for the elderly aged 60 and over in the future.

The most effective management method aimed at self-management of elderly individuals with lower extremity edema was compression therapy using a compression device. Furthermore, for elderly lower extremity edema caused by multiple factors, compression therapy is considered a suitable method regardless of the cause. In existing studies[21)23)24)26)], it is unclear whether older people can put on and take off such devices properly because researchers are wearing them. Improper installation or removal of the compression device can cause medical device-related pressure ulcers[39)] due to excessive pressure on the lower extremity; alternatively, too little pressure fails to improve lower extremity edema. Therefore, it is necessary to clarify the optimal compression pressure for elderly people with lower extremity edema, depending on the type of edema. Previous studies have shown that pressure up to 60 mmHg is suitable for lower extremity compression[40)41)]. However, there is no lower limit, and it is not clear whether this pressure is suitable for the elderly with frailty. The compression pressure used in this study was also 30-60 mmHg, but it is not clear whether this compression pressure is suitable for the elderly. We think that we need a compression device that can be used continuously even with low compression pressure. Therefore, we believe it is necessary to improve and develop a compression device that can be easily used by elderly individuals. Moreover, there is a lack of literature on the safety effects of wearing compression devices for lower extremity edema in elderly individuals. Therefore, it is necessary to clarify the relationship between the optimal compression pressure associated with the management of lower extremity edema in elderly individuals and its effect on hemodynamics to demonstrate its safety.

Combined physical congestion therapy is indicated for lymphedema and requires a medical professional with the expertise and skills to manage it. The combined physical congestion therapy in the reviewed studies reduced lower extremity edema and improved quality of life[28)－32)]. It is necessary to simplify these points to adapt this therapy for self-management by elderly individuals. In addition, no effects on hemodynamics were shown when performing this therapy, and the safety aspect is unclear. Footbath therapy was indicated for edema due to venous stasis; it reduced the circumference of the lower extremities, but the edema tended to remain. Footbath therapy was shown to have hemodynamic effects as the vasodilatory reflex caused by local heating dilates the peripheral blood vessels of the skin and promotes circulation[42)－44)]. Furthermore, blood circulation was promoted by vasodilation and reduction of peripheral vascular resistance due to a decrease in sympathetic tone. Therefore, caution is required when implementing this method in elderly people with impaired hemodynamic function. Vibration therapy showed an increase in blood flow at each site[36)], and blood pressure also increased. This study was conducted on participants in the early stages of old age, but the effects on patients in the late stage of old age require consideration. The recumbent position reduced lower extremity edema by reducing the circumference of the lower extremitys, but the edema remained[37)]. When managing lower extremity edema by posture, there is a concern that activity may decrease due to restrictions in daily life. Therefore, it is necessary to use other management methods together. Tapping therapy was shown to significantly reduce lower extremity edema in participants with lower extremity edema associated with heart disease[38)]. However, the effect on hemodynamics was not measured, and issues related to safety are unclear. Therefore, it is necessary to clarify the relationship between vibration strength and hemodynamics.

Limitation

This study had several limitations. We did not consider the quality of evidence provided by the authors or of the studies assessed in this review. Furthermore, the studies frequently had small sample sizes. These processes may have affected the selection of the evidence. The number of studies on lower extremity edema management methods conducted in the elderly aged 60 and over was limited. Therefore, it may not be a method for managing lower extremity edema specialized for the elderly. In the future, it is necessary to clarify the effect of lower extremity edema management methods focusing on the elderly.

Conclusions

This review provides important implications for future studies on management methods for elderly people with lower extremity edema. The methods used to manage lower extremity edema in elderly individuals – compression therapy, combined physical decongestive therapy, footbath therapy, vibration therapy, position, and tapping therapy – were shown to vary in effectiveness depending on participant characteristics and type of edema. The development of a simple and highly safe compression device is expected in the future to promote self-management of this condition in elderly individuals.

Management based on lower extremity edema by compression therapy is required because of the feasibility and effectiveness of self-management. In the future, it will be necessary to develop and manage compression devices based on the effects on elderly individuals' miscellaneous hand activity, cognitive function, and hemodynamics to independently implement lower extremity edema management for the elderly. It is necessary to verify the developed compression device and management method from the viewpoints of effectiveness, self-care, and safety.

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Disclosure

The authors declare no conflicts of interest. The first author paid all research expenses.

Author's contributions

F.O. and J.S. conceived the study. F.O. designed the search strategy. F.O. searched the databases and screened the records. F.O. screened the full texts. F.O. Y.I. and Y.S. completed all data extraction and conducted quality checks. F.O. drafted the full manuscript. J.S. critically reviewed the manuscript and supervised the entire study process. All authors reviewed and approved the final submission. All authors have read and agreed to the published version of the manuscript.

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高齢者の下肢浮腫管理のための介入：レビュー

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要　旨

高齢者の下肢浮腫保有率は高い。下肢浮腫は、身体面や精神面に悪影響を与えるため、適切な管理が必要である。しかし、これまでにどのような種類の下肢浮腫管理が高齢者に実施され、効果的であったかについては検討されていない。本研究は、高齢者に対して行われた下肢浮腫管理に関する既存の文献をレビューし、3つの視点（有効性、自己管理、安全性）から検討することを目的とした。データベース検索により375件の記事が特定され、最終的に18件の記事が対象となった。高齢者の下肢浮腫管理として最も多く実施された圧迫療法は、自己管理の可能性も示した。下肢浮腫管理を実施した場合の有効性は、下肢周囲径と体積および体重の減少、関節可動域の拡大であった。これらの効果は同時に、睡眠の質および生活の質の向上、歩行距離の改善にもつながることを示した。しかし、安全性を検証した研究は限られていた。今回のレビュー結果は、高齢者の下肢浮腫管理として有効性、自己管理、安全性について、十分な検討が行われていない可能性を示した。今後は、高齢者が容易に自己管理できる下肢浮腫管理を開発し、有効性と安全性を併せた検証を行う必要がある。

キーワード：高齢者、下肢浮腫、管理、レビュー

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Research

Effects of vibration on chronic leg edema in chair-bound older adults: A pilot trial

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ABSTRACT

Leg edema affects many older adults who sit for lengthy periods of time. This study aimed to investigate whether vibration could improve outcomes compared to no treatment and to confirm the feasibility of our vibration method among chair-bound older adults with chronic leg edema.

This study was a randomized pilot trial which was conducted from August to November 2015. Nursing home residents aged ≥65 years with chronic lower extremity edema who spent more time sitting than standing or laying during the day were randomly assigned to either the intervention or control group. The intervention group underwent vibration therapy three times a day for 2 weeks. The pitting test was performed at 22 sites, and participants' pitting scores were calculated based on the pitting depth. Changes in pitting scores before and after the intervention periods were compared between the intervention and control groups.

The median age of the intervention (n=7) and control (n=7) groups was 86 and 84 years, respectively. The median total pitting score change in the intervention group was -0.4 (interquartile range: -5.3—1.8), which was significantly lower than that of the control group (2.0 [interquartile range: 1.0—5.3], p=0.01). During the investigation, no adverse events occurred. There were also no participant withdrawals from the investigation.

The results indicate that vibration can help reduce the progression of chronic leg edema in chair-bound older adults. It was also confirmed the feasibility of our vibration method.

KEY WORDS: chair-bound, edema, older adults, vibration

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Introduction

Leg edema is caused by various kinds of diseases[1] and can occasionally occur following long periods of sitting or standing in healthy persons. This can be effectively alleviated by lying down or calf muscle pumping[2]. However, older adults can easily develop leg edema that can become chronic due to long hours of sitting, along with cardiovascular dysfunction, decreased lower limb muscle strength, skin tension, and nutritional conditions attributable to aging[1].

A previous study that investigated the prevalence of leg edema in older adults in nursing home discovered that 92% of older adults who sit for >12 h a day had leg edema（n=36）[3]. Moreover, one study reported that >50% of edema in older adults remains untreated[1]. These reports indicate that edema among older adults is not adequately treated.

Older adults experience various problems associated with chronic leg edema. Leg edema causes feelings of weariness and heaviness[4], it may cause decreases in daily activity as well as an increase in the risk of falling due to a limited range of ankle movement[5]. Edematous skin is also easily damaged and prone to pressure injuries and skin tears[6]. Given these problems, effective management for chronic leg edema in older adults is required.

Two issues arise when providing care to older adults with leg edema. First, providing continuous care to reduce edema is difficult because the current care methods necessitate the nursing staff's time. For example, leg elevation exercises[7] and typical treatments such as foot baths and massages are performed. Second, the standard care method for edema[8], compression therapy, may be limited in its use in older adults as vulnerable skin can easily be injured if the compression stockings are inappropriately worn. Further, older adults often have difficulty in wearing them[9]. There is also a high prevalence of arterial blood flow insufficiency[10-12].

This study focused on vibration therapy as a care method. Essentially, the vibration improves blood flow and lymphatic flow. It includes vasodilation due to axon reflex[13] or increased secretion of endothelium-derived nitric oxide[14]. These factors then increase the blood flow and reduce the venous pressure, which expands the anchoring filaments that promote interstitial fluid reabsorption to the superficial lymphatic vessels[15]. Previous experiments showed that vibration effectively reduced upper limb lymphedema when provided as an additional care for simple lymphatic drainage[16] and improved the leg fluid flow among premenopausal women[15]. As mentioned above, the chronic edema in older adults is caused by a different mechanism than lymphedema. Furthermore, edema is more likely to occur in the lower limbs than in the upper limbs due to the influence of gravity, and it is unclear whether vibration is effective enough to reduce edema in the lower limbs. Therefore, the effects of vibration therapy on chronic leg edema in chair-bound older adults remain unclear.

The present study aimed to investigate whether vibration could improve outcomes compared to no treatment and to confirm the feasibility of our vibration method in chair-bound older adults with chronic leg edema. Our hypothesis was that the pitting score, leg volume, and subcutaneous echo-free space grade would improve more in the intervention group than in the control group.

Methods

1. Study design

This study was a pilot trial and used a non-blinded, randomized control, parallel comparison design. For participant allocation, a permuted block（4 persons/block）randomization method was used to ensure balanced assignments. A computer-generated list of random numbers was employed and the allocation ratio was 1:1. The research assistant devised the random allocation sequence, enrolled participants, and assigned them to interventions. The study was conducted from August to November 2015 at a nursing home in Kanazawa City, Japan. The name of the trial register is UMIN Clinical Trials Registry. The clinical trial registration number is UMIN000017716.

2. Participants

Participants were nursing home residents with chronic leg edema from a single facility. Chronic edema was defined as subcutaneous tissue swelling that continued for ≥3 months based on a previous study[4].

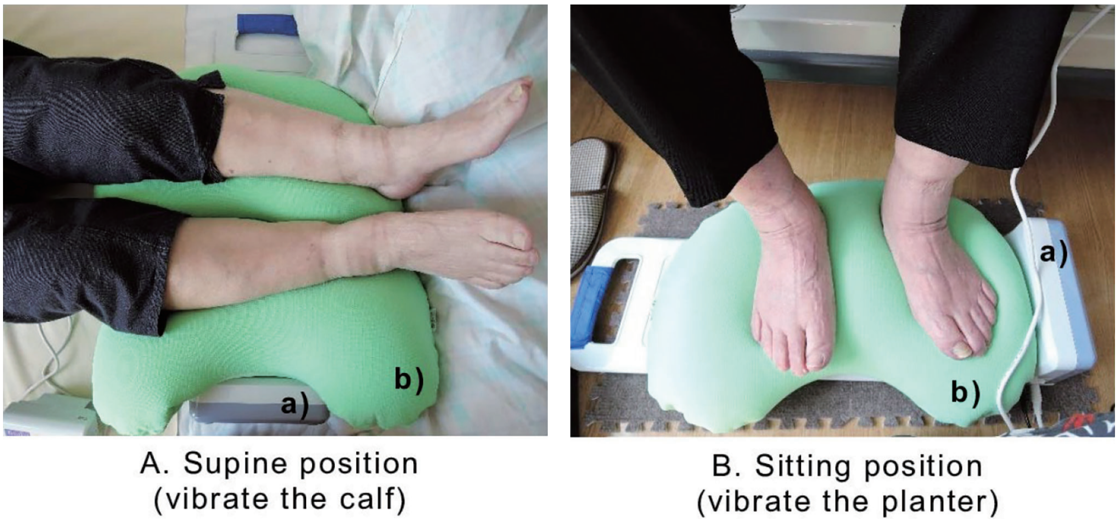

Figure 1　Intervention method using a vibration device
a) Vibration device, b) Polystyrene beads cushion
Vibrations were provided in supine position (A) or sitting position (B). The size of the vibration device (Rela feel, Global-Micronics Co., Ltd. Kashiwa, Japan) was 616×182×114 mm (length×width×height). The vibrator was placed under the legs with cushions (270 mm long, 430 mm wide, 120 mm thick) between the vibrator.

Pitting depth was classified using a 0 (no edema) to 4+ pitting edema. The scale was as follows: 0=0 mm; 1+=0.1-1.9 mm; 2+=2-3.9 mm; 3+=4-5.9 mm; and 4+=≥6 mm depending on the physical examination method[17]. The nursing staff assessed the participants for pitting edema every day, and the researcher performed the pitting test twice before and after three months to confirm the presence of chronic edema. Participants classified as having chronic leg edema were those with a pitting depth of ≥1+, on at least one site of their legs. We informed the participants about the research and evaluated their eligibility. The inclusion criteria comprised nursing home residents aged ≥65 years, as well as those who spent more time sitting than standing or lying during the day. The exclusion criteria comprised residents who were diagnosed with aneurysm or thrombosis, were not diagnosed with chronic leg edema, were otherwise considered unsuitable by a physician or nurse, or were unable to grant consent.

3. Data collection

1) Intervention

The intervention group underwent vibration therapy for two weeks. The size of the vibration device (Rela feel, Global-Micronics Co., Ltd. Kashiwa, Japan) was 616×182×114 mm (length×width×height). The controller had been attached to adjust the modulation cycle and vibration time. The frequency and horizontal vibration acceleration were set at 47 Hz and 1.78 m/s^2, respectively, as per the permissible range for the minimum health and safety requirements[18]. Previous studies reported that this device can be safely used on older adults[19]. When participants sat, the vibrator was placed under the plantar surface of the foot, and when they laid down, it was placed under the posterior calf with a polystyrene beads cushion (270 mm long, 430 mm wide, 120 mm thick) placed between the calf and the vibrator (**Figure 1**). During the morning and daytime vibration therapy sessions, participants were either sitting or lying down depending on their lifestyle. At night, patients were lying down. The therapy was administered three times: in the morning (06:00-09:30), throughout the day (12:30-14:30), and at night (18:00-21:00), with each vibration lasting 15 minutes according to the results of a previous study[16]. The control group did not receive any intervention, such as leg vibration or elevation.

2) Demographic data

Data for participants' characteristics included age, sex, medical history, present illness, height, weight, body mass index (BMI), total serum protein, serum albumin, dietary intake, and medication. These data were collected from medical and nursing records. We

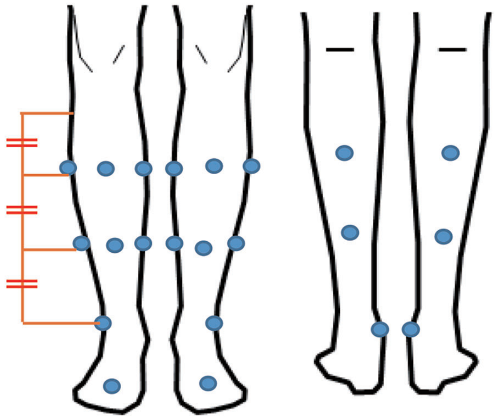

Figure 2　Pitting test
The investigator applied an even amount of pressure on 22 measuring sites.

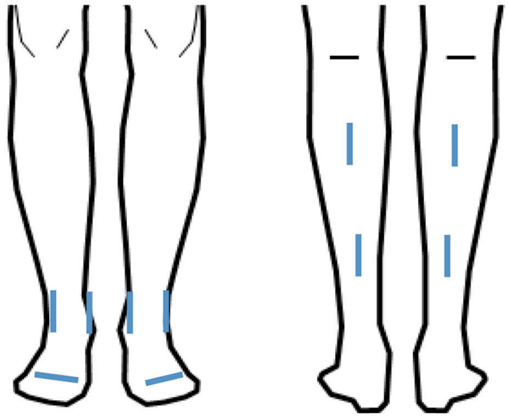

Figure 3　Ultrasound images
The principal researcher obtained ultrasound images at 10 sites.

recorded data for participants' daytime activities using a participant-observer method, this included the time spent walking, sitting, and lying down. The principal researcher performed a Stemmer's test by pinching and lifting a skin fold at the base of the second toe. If the skin can be pinched and lifted, the Stemmer's sign is negative, whereas if it cannot be pinched and lifted, the sign is positive. A positive Stemmer's sign indicates subcutaneous tissue fibrosis[20].

3) Outcome measurements

The primary outcome was the pitting score evaluated using palpation. Secondary outcomes were leg volume evaluated using leg circumferences and subcutaneous echo-free space grade (SEF) evaluated using ultrasound imaging. We adopted the pitting test and leg volume measurement, since these methods were commonly used for edema evaluation. SEF was used to evaluate interstitial fluid in subcutaneous tissue, which cannot be evaluated by conventional indicators. All variables were measured before and after the intervention period by a trained researcher.

The pitting test was performed following the procedure described in a previous study[20]. The investigator applied an even amount of pressure on 22 measuring sites, in the right and left lower extremities, with the right thumb for 10 s (**Figure 2**). All measurements were provided by one researcher. To calculate the test-retest reliability of the pressure, the researcher pressed the pressure measurement device (Palm Q, CAPE CO., LTD, Yokosuka, Japan) 10 times and measured the pressure of pitting. The intraclass correlation coefficients (1, 1) of the pressure was 0.923. The inter-rater reliability of pitting test was high in the previous study conducted by Dai et al.[21]. Pitting depths were classified 0 to 4+, and were converted to pitting scores: pitting 0, 0 point; pitting 1+, 1 point; pitting 2+, 2 points; pitting 3+, 3 points; and pitting 4+, 4 points. The points were added to obtain a total score for each leg.

The leg volume was determined using the following validated formula to calculate the truncated cone volume[22]. $V=V_1+V_2$, $V_1=1/3\pi h\ (r_1r_1+r_1r_2+r_2r_2)$, and $V_2=1/3\pi h\ (r_2r_2+r_2r_3+r_3r_3)$, where V_1 represents the volume of the ankle to distal leg; V_2 represents the volume of the distal to proximal leg; r_1 is the ankle radius, r_2 is the distal leg radius, and r_3 is the proximal leg radius; and h is the leg length (one-third of the length of the lateral ankle to the fibular head apex).

SEF is a qualitative method to analyze ultrasound images. The principal researcher obtained ultrasound images at 10 sites on the right and left lower extremities (**Figure 3**). The dorsalis pedis was a short-axis image, whereas the remainder were long-axis images. An ultrasound console (Noblus, Hitachi Aloka Medical, Ltd., Mitaka, Japan) and linear transducer (L64, frequency range: 5-18 MHz) with the following identical settings were used: gain, 15; dynamic range, 70 dB; and focus point, 0.5 cm. Using a modified approach established by Suehiro et al (**Figure 4**), SEF was classified into five grades: 0, 1, 2-type A, 2-type B, and 2-type C. This method had been validated to assess edema in subcutaneous tissue in the study[23]. Leg images were classified by the principal researcher and another

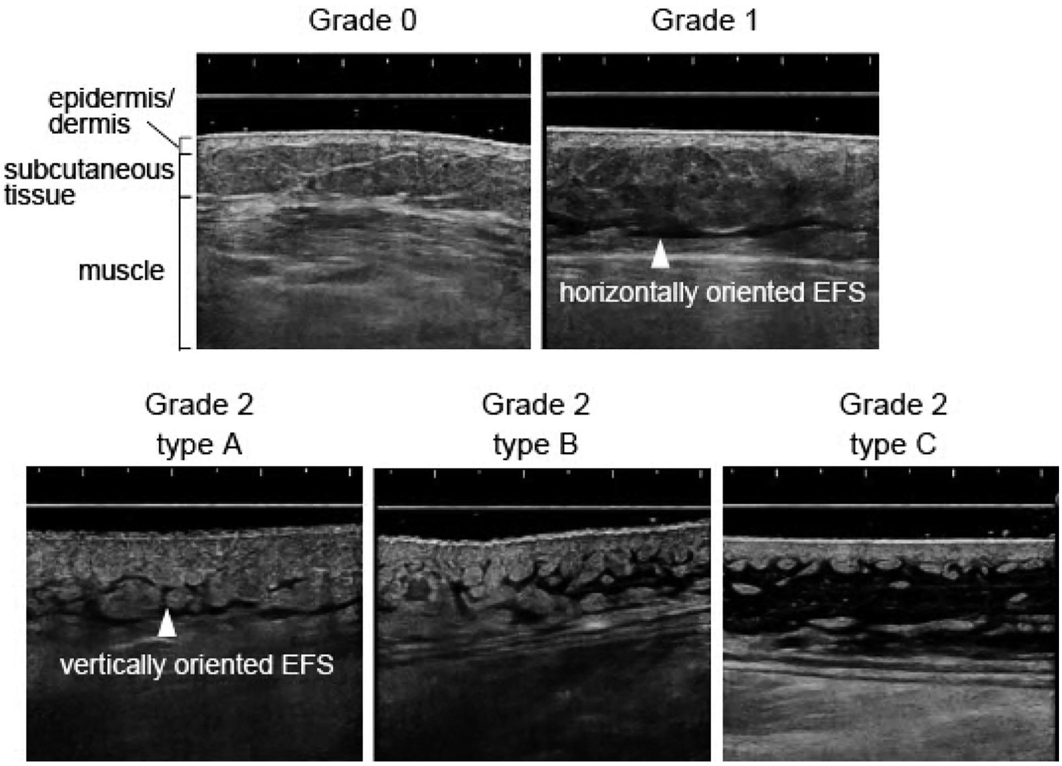

Figure 4　Modified subcutaneous echo free space grade
Grade 0 : No echo free space (EFS).
Grade 1 : Horizontally oriented (<45 degrees to the skin) only.
Grade 2/type A : Presence of vertically oriented (≥45 degrees to the skin), EFS bridging the horizontally oriented EFSs, EFS occupies less than 20% of subcutaneous tissue area.
Grade 2/type B : Presence of vertically oriented (≥45 degrees to the skin), EFS bridging the horizontally oriented EFSs, EFS occupies 20% or more, but less than 80%.
Grade 2/type C : Presence of vertically oriented (≥45 degrees to the skin), EFS bridging the horizontally oriented EFSs, EFS occupies 80% or more.

researcher with experience in analyzing ultrasound images of leg edema. The SEF values were converted to SEF scores: grade 0, 0 point; grade 1, 1 point; grade 2-type A, 2 points; grade 2-type B, 3 points; and grade 2-type C, 4 points. The points were added to achieve the total score for each leg.

4. Data analysis

Mann-Whitney U tests were used to compare differences in age, height, weight, and BMI between the intervention and control groups. Fisher's exact tests were used to compare differences in other characteristics between the two groups. In order to analyze the pitting score, leg volume, and SEF, the total number of participant legs was calculated and employed. Edema severity at baseline, pitting score changes, leg volume changes, and SEF score changes were analyzed for the intervention and control groups using Mann-Whitney U tests. Differences in pitting scores, leg volumes, and SEF scores at pre- and post-intervention in each group were analyzed using the Wilcoxon signed rank test. Values are shown as median (interquartile range [IQR]).

To determine if chronic leg edema was controlled, participants were divided into edema-controlled and uncontrolled groups. Controlled edema indicated a lower or similar total pitting score at post-intervention than at pre-intervention, uncontrolled edema had the opposite effect. Chi-square tests were used to assess the association between the intervention and edema control groups. All analyses were performed using the Statistical Package for the Social Sciences version 19 (IBM-SPSS, Inc. Chicago, IL, USA) and $p<0.05$ was considered significant.

5. Ethical consideration

The present study was conducted in accordance with the Helsinki declaration and was approved by the Medical Ethics Committee of Kanazawa University

(number: 599-1). A written informed consent was obtained from the participants and their families. All measurements and intervention sessions were performed by two registered nurses to ensure participants' safety. Moreover, participants' vital signs were evaluated pre-intervention and post-intervention every day.

Results

1. Participant characteristics

The participants' flow is shown in Figure 5. A total of104 participants were recruited. Of these, 83 subjects were excluded because they did not give consent (n=40), spent more time lying than sitting during the day (n=17), and were considered unsuitable for participation (n=26). Consequently, participants who met the criteria (n=21) were divided into the intervention group (n=10) and the control group (n=11). Of these, 7 participants were excluded because they were unable to complete the study in the intervention group (n=3) and the control group (n=4) as a result of limited study duration. The median (IQR) age in the intervention and control groups was 86 (85−87.5) and 84 (80−89.5) years, respectively. Male participants comprised 14.3% (n=1) in the intervention group and 57.1% (n=4) in the control group. The median (IQR) BMI was 23.4 (22.2−25.1) and 22.6 (22.1−25.0) kg/m^2 in the intervention and control groups. Differences in participant characteristics were not significant between the groups (**Table 1**). Some participants in the intervention group (n=2) and the control group (n=1) took diuretic medicine, while some participants in the intervention group (n=4) and the control group (n=6) took medication that caused edema as a side effect. They continued to take the medication during this research. Differences in the edema status at baseline in the pitting score, leg volume, and SEF were not significant between the two groups (**Table 1**).

2. Primary outcome

The total pitting score at post-intervention was significantly higher than that at pre-intervention in the control group (median 9.5 [IQR: 4.5−15.5] vs. 8.0 [3.5−11.5], p=0.04) (**Table 2**). The median total pitting score change in the intervention group was − 0.4 (IQR: − 5.3−1.8), which was significantly lower than that of the control group (2.0 [IQR: 1.0−5.3], p=0.01) (**Table 3**). A significant interaction was found ($\chi^2(1)=5.25$, p=0.02). The intervention group was more likely to have controlled edema (n=9 (legs), 64.3%) than the control group (n=3 (legs), 21.4%).

3. Secondary outcomes

The leg volume and total SEF did not significantly differ at pre-intervention and post-intervention in both groups (**Table 2**), and they did not significantly differ between the two groups (**Table 3**).

4. Feasibility of the vibration method

During the investigation, no adverse events such as skin injuries or pulmonary thromboembolisms occurred. There were also no participant withdrawals from the investigation (**Figure 5**).

Discussion

This was the first study to evaluate the effects of vibration for chronic leg edema among chair-bound older adults. Results of the present study indicate that vibration can effectively prevent the progression of chronic leg edema.

The median total pitting score change in the intervention group was significantly lower than that in the control group. Moreover, the total pitting score at post-intervention was significantly higher than that at pre-intervention in the control group, indicating that chronic leg edema in older adults worsens without vibration. Furthermore, these results were consistent with those reported by a previous study, showing that edema severity significantly increased over time in older adults with chronic leg edema[24].

Differences in the secondary outcome were not significant; we evaluated the following causes. The edema severity changes in the foot could not be measured because leg volumes were calculated except for the dorsal pedis and older adults with decreased walking ability often have severe edema in their ankles or feet[25]. Thus, volume changes in the feet possibly occurred but were not recorded. Regarding SEF, edema status was assessed using the modified SEF grade; as this scale has five grades which has been already existed, it could not reflect detailed interstitial fluid changes. Moreover, the proportion of positive Stemmer signs at baseline was high, which indicates the patient has subcutaneous tissue fibrosis[20]. Therefore, a tissue

Table 1 Participants' characteristics

	Intervention (n=7)	Control (n=7)	*p*
Age (years), median (IQR)	86 (85 – 87.5)	84 (80 – 89.5)	0.31
Male, n (%)	1 (14.3)	4 (57.1)	0.13
Body mass index (kg/m^2), median (IQR)	23.4 (22.2 – 25.1)	22.6 (22.1 – 25.0)	0.41
Disease, n (%) (based on ICD-10)			
Mental and behavioral disorders	4 (57.1)	3 (42.9)	0.50
Diseases of the circulatory system	4 (57.1)	6 (85.7)	0.28
Endocrine, nutritional, and metabolic diseases	2 (28.6)	5 (71.4)	0.14
Diseases of the digestive system	0 (0.0)	1 (14.3)	0.50
Diseases of the genitourinary system	1 (14.3)	1 (14.3)	0.77
Diseases of the musculoskeletal system and connective tissue	4 (57.1)	1 (14.3)	0.27
Neoplasms	0 (0.0)	0 (0.0)	–
Taking diuretic medicine, n (%)	2 (28.6)	1 (14.3)	0.50
Taking medicine that cause edema as side effect, n (%)	4 (57.1)	6 (85.7)	0.28
Standing time of a day (minutes), median (IQR)	15 (0 – 37)	0 (0 – 30)	0.09
Sitting time of a day (minutes), median (IQR)	740 (662 – 747)	675 (630 – 753)	0.80
Lying time of a day (minutes), median (IQR)	660 (660 – 762)	708 (638 – 772)	0.85
Total serum protein (g/dL), median (IQR)	7.0 (6.6 – 7.0)	7.0 (6.3 – 7.1)	1.00
Serum albumin (g/dL), median (IQR)	3.8 (3.7 – 3.9)	3.7 (3.6 – 3.9)	0.78
Positive Stemmer sign, n (%)	5 (71.4)	6 (85.7)	0.50
	Intervention (n=14†)	Control (n=14†)	
Total pitting score (points)	14.0 (10.3 – 16.8)	9.5 (6.0 – 14.5)	0.25
Leg volume (cm^3)	1079.3 (1031.5 – 1251.3)	1083.7 (984.7 – 1183.2)	0.80
Total SEF (points)	7.5 (5.3 – 8.0)	8.0 (4.3 – 9.0)	0.43

Continuous data were tested with Mann-Whitney U tests. Categorical data were analyzed by Fisher's exact tests.
*$p < .05$
†Numbers indicate the number of legs which are evaluated.
IQR : Interquartile range
ICD-10 : International Statistical Classification of Diseases and Related Health Problems

Table 2 Edema status changes at pre- and post-intervention

	Intervention (n=14†)			Control (n=14†)		
	Pre	Post	*p*	Pre	Post	*p*
Total pitting score (points)	14.5 (11.8 – 18.0)	11.5 (7.0 – 18.6)	0.06	8.0 (3.5 – 11.5)	9.5 (4.5 – 15.5)	0.04*
Leg volume (cm^3)	1079.3 (1031.5 – 1251.3)	1055.5 (994.6 – 1260.4)	0.45	1083.7 (984.7 – 1183.1)	1085.7 (942.5 – 1216.2)	0.98
Total SEF (points)	7.5 (5.3 – 8.0)	6.5 (4.5 – 8.0)	0.36	8.0 (4.3 – 9.0)	6.0 (5.0 – 9.3)	0.59

Values indicate that median (Interquartile range).
*$p<.05$ (Wilcoxon signed rank test).
†Numbers indicate the number of legs which are evaluated.
SEF : subcutaneous echo-free space grade

Table 3 Comparison of edema status changes between the intervention and control groups

	Intervention (n=14†)	Control (n=14†)	*p*
Total pitting score changes (points)	-0.4 (-5.3 – 1.8)	2.0 (1.0 – 5.3)	0.01*
Leg volume changes (cm^3)	0.01 (-72.74 – 31.50)	0.85 (-18.37 – 30.93)	0.57
Total SEF changes (points)	0.0 (-1.0 – 0.3)	0.0 (-1.3 – 1.0)	0.84

Values indicate that median (Interquartile range).
*p<.05 (Mann-Whitney U test).
†Numbers indicate the number of legs which are evaluated.
SEF : subcutaneous echo-free space grade

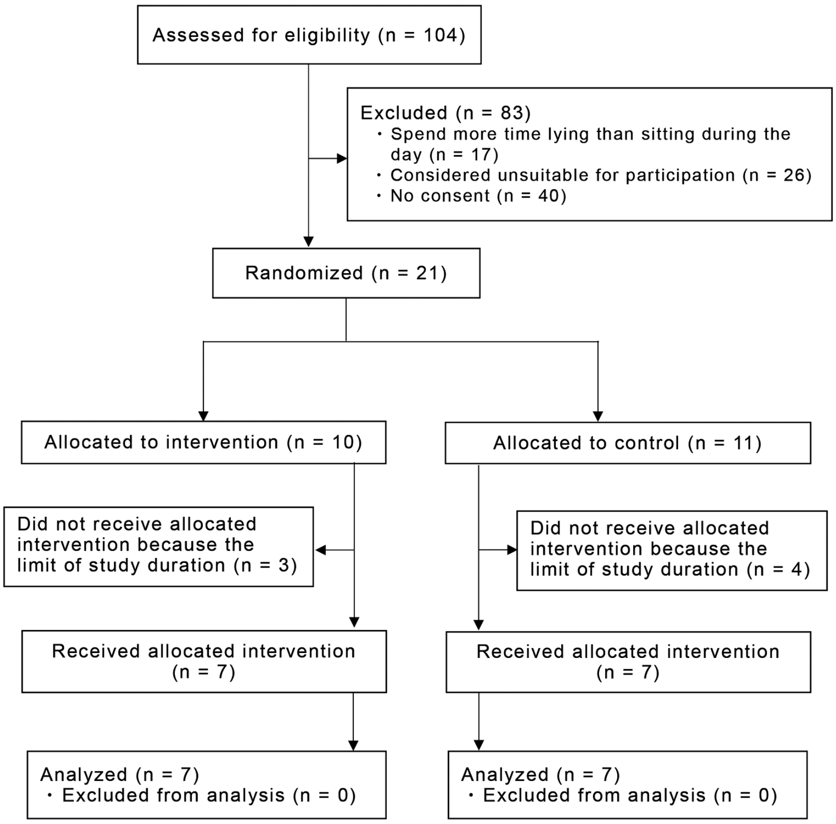

Figure 5 Participants flow diagram

change may not have appeared in the morphological echo image. In future studies, it is necessary to consider a more appropriate evaluation method for the ultrasound images of lower limb edema in older adults.

Given that this is the first study that used vibration for treating chronic leg edema in chair-bound older adults, and no adverse events such as abnormal cardiovascular function or skin damage was caused by the intervention, vibration therapy can be adopted as a preventive measure. Furthermore, the vibration intensity used in this study has been proven safe for humans, including older adults, in previous studies[19].

This study has certain areas for improvement. First, during the vibration administration sessions, some participants were in a sitting position because it was performed under a condition that did not interfere with the participants' daily life. Previous studies showed that planter vibration increased the leg fluid flow[15]. However, extreme knee flexion has been shown to decrease the ankle brachial systolic pressure index[26]. Therefore, it is preferable for participants to lie down when receiving vibration therapy. Second, because the vibration device used in this study was used with cushions and the control group participants were not provided with leg elevation, the effect of leg elevation could not be isolated in the intervention group. Finally, the sample size was small as this was a pilot trial. The result of the leg volume and SEF may have been different if the sample size was larger.

Conclusion

The participants in the intervention group were more likely to have their edema controlled, as their median total pitting score change was significantly lower than that in the control group. Moreover, the total pitting score at post-intervention was significantly higher than that at pre-intervention in the control group. These results indicate that vibration can prevent the deterioration of chronic leg edema in chair-bound older adults. This pilot study provides sufficient evidence for a larger clinical trial.

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Preprint disclosure

The preprint has been submitted to ResearchGate. https://www.researchgate.net/publication/343777032_Effects_of_vibration_on_chronic_leg_edema_in_chair-bound_older_adults_A_randomized_pilot_trial

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長時間座位保持高齢者の下肢慢性浮腫に対する加振の効果：パイロット研究

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要　旨

長時間座位保持高齢者は下肢浮腫の有病率が高いが、十分なケアが行われていない。本研究では、簡便で継続的に実施可能な方法として振動療法に着目した。研究目的は、長時間座位保持高齢者において、下肢に振動を加えることで下肢慢性浮腫を改善できるかを明らかにすること、振動療法の実行可能性を検討することである。

研究デザインはランダム化比較パイロットスタディである。特別養護老人ホーム入居中の 65 歳以上の高齢者のうち、日中の座位時間が立位・臥位時間よりも長い者を対象とした。介入群は 1 日 3 回 2 週間振動療法を受けた。浮腫の程度は、圧痕テストを使用し圧痕の深さを 0 から 4+で評価した。両下腿・足部の計 22 か所で実施し、各肢のピッティングスコアを圧痕テストに基づいて算出した。介入期間前後のピッティングスコアの変化を、介入群と対照群の間で比較した。

介入群（n=7）と対照群（n=7）の年齢の中央値は、それぞれ 86 歳と 84 歳であった。介入群のピッティングスコア変化量の中央値は-0.4（四分位範囲：-5.3-1.8）であり、対照群（2.0［四分位範囲：1.0 ─ 5.3］）よりも有意に低かった（p=0.01）。研究期間中の有害事象の発生はなく、途中で辞退した者はいなかった。

本研究結果より、振動療法は長時間座位保持高齢者の下肢慢性浮腫の悪化を防ぐことができ、下肢浮腫を有する長時間座位保持高齢者への実行可能性があると考える。

キーワード：座りきり，浮腫，高齢者，振動