Intermittent pneumatic compression for prolonged standing workers with leg edema and pain

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Abstract

Even healthy individuals often encounter leg venous symptoms such as heaviness, pain, and swelling especially after prolonged standing work. Intermittent pneumatic compression (IPC) is a widely used simple therapy for preventing deep vein thrombosis and for treating lymphedema and chronic venous insufficiency. However, IPC has not been evaluated for its effect in relieving venous symptoms of healthy people.

This was single center, cross-over study to investigate the effect of IPC for 20 healthy volunteers who usually stand on duty and complain of leg pain and swelling. The primary outcome was pain (measured using a visual analogue scale) and secondary outcomes were leg circumference and volume. Three different interventions included natural rest, sequential mode of IPC, and circular mode of IPC. Outcomes were measured before work and immediately after work (T1), after 30 minutes of intervention (T2), and 30 minutes of rest after intervention (T3).

Pain and leg circumferences were significantly improved at T2 and T3 compared with those at T1. Sequential and circular IPC led to significantly greater improvement in pain and leg circumferences than just natural rest, but there was no difference in its effect according to the 2 modes of IPC. Leg volume was reduced significantly at T2 and T3 as compared with T1 in all 3 interventions, but effects did not differ among 3 intervention groups.

IPC is effective for reducing leg pain and circumferences more than natural rest in healthy adults with prolonged standing work, without causing adverse events.

Abbreviations: IPC = intermittent pneumatic compression, VAS = visual analogue scale.

Keywords: IPC = intermittent pneumatic compression devices, pain

1. Introduction

Prolonged stationary standing is prevalent in occupations such as retail, food service, manufacturing, and within healthcare professions. Previous studies on industrial workers suggested that >1 hour of continuous standing or >4 hours of standing per day is considered unsafe, and may induce various musculoskeletal symptoms.\textsuperscript{[1,2]} Typical negative consequences following prolonged standing include low back pain, knee, ankle, and foot pain, and lower leg fatigue or swelling. An earlier literature review revealed convincing evidence of the detrimental association between prolonged standing and development of musculoskeletal symptoms in the lower back and lower extremities.\textsuperscript{[3]}

Blood pooling is one of the most often reported underlying mechanisms for lower extremity symptoms; other proposed causes include increased intravascular hydrostatic venous pressure, venous stasis due to lack of muscle pump action,\textsuperscript{[4]} and increases in blood flow, skin temperature, and leg volume.\textsuperscript{[4]}

Diffuse leg discomfort or pain with sensations of heavy, weighty, and swollen legs are the core symptoms of venous diseases, with a reported prevalence of 50% in the general population, regardless of the presence of obvious venous pathology.\textsuperscript{[5]} Prolonged standing often leads to a physiologic venous insufficiency which is generally characterized by leg symptoms without an obvious venous cause.

Traditionally, conservative measures such as the use of medical compressive garments, compression bandages, pumps, and other mechanical devices have been used for the treatment of venous symptoms. However, the level of evidence for these interventions remains poor with no definitive national or international guidelines for treatment of these symptoms.\textsuperscript{[6]}

Mechanical intermittent pneumatic compression (IPC) is a simple therapy during which pneumatic cuffs connected to a pump are applied to limbs. IPC works by mimicking the intermittent compression of the limb’s vasculature during muscle contractions.\textsuperscript{[7]}

The common indications for IPC include the prevention of deep vein
thrombosis and the treatment of arterial disease and lymphedema. IPC can also be applied in patients with chronic venous insufficiency whose muscle pump becomes inadequate to clear blood from the veins by dispersing edema.\cite{12} Even with its long clinical application history, there is no standard consensus on the frequency or treatment parameters of IPC according to specific indications.

Until now, the effect of IPC has been targeting patients with pathologic conditions such as chronic venous insufficiency, venous ulcer, and lymphedema. Therefore, it was hard to conclude that the application of the same methods of IPC would equally work for healthy people. The effect of IPC on healthy people has been studied mainly on venous flow velocity or lymphatic flow or oxygenation.\cite{8-12} There is lack of evidence whether IPC device may demonstrate its effectiveness on clinical parameters such as leg pain and leg swelling, and how to apply IPC for healthy people.

This study was planned as single group repeated measures controlled study to verify the effect and safety of IPC on leg pain and swelling in healthy volunteers who stand at work for >8 hours and maintain their work environment during the study. The authors aimed to compare the effect of IPC with natural supine resting, and to compare the most common 2 modes of IPC.

2. Methods

2.1. Study population

For this study, healthy male and female adults aged 19 years or older with a job that required prolonged standing were recruited. Per the “Health Guide for People who Work Standing” published by the Korea Occupational Safety and Health Agency,\cite{13} occupations that require prolonged standing include salespersons or cashiers at wholesale and retailers such as large discount stores, workers in the food and lodging industries, salespersons at highway service areas, casino dealers, workers in the laundry and hairdressing industries, workers in assembly lines, workers in the packaging industry such as within warehouses, construction workers, healthcare workers, and education workers at schools and private institutes. The study inclusion criteria were current occupations that required standing for at least 8 hours a day, self-reported leg pain and swelling by potential participants, demonstrating an adequate understanding of the purpose and procedures of the study, and voluntarily expressing willingness to participate in the study. The exclusion criteria were age < 19 years, diminished cognitive function that hindered the ability to accurately express the area and level of pain, suspected neurological disease following a physical examination, hyposthesia, leg surgery within the past 6 months, an obvious history of venous or arterial disease, self-reporting as currently being pregnant or breastfeeding, a positive urine pregnancy test, planning to conceive during the clinical trial period (for female participants only), and other individually applied criteria at the discretion of the principal investigator. This study was approved by the institutional review board (CUH 2018-04-036-002), and written informed consent was obtained from all participants.

2.2. Study device

IPC is defined as compression of the extremities using pneumatic pressure administered through an IPC device. IPC specifically facilitates blood and lymph circulation through repetitive expansion and contraction of several chambers as a result of changes in pneumatic pressure. In this study, we used an IPC device with 5 chambers (LUXURY-ZAM, WelbuTech, Seoul, Korea). The range of pressure possible within the chamber ranges from 0 to 265mm Hg, and there are 2 IPC modes of application (sequential and circular modes). In the sequential mode, the set pressure is first pumped into the distal chamber, then the pressure is pumped into the proximal chamber, and then the distal chamber is deflated. In the circular mode, the set pressure is pumped into the distal chamber, followed by the proximal chamber without decompression of the chamber that is filled with the set pressure, followed by the proximal chamber without decompression of the distal chamber, and all chambers are deflated at once after all chambers are inflated. The same pressure was applied to all chambers, and pneumatic compression proceeded to the next chamber once the set pressure was reached inside a chamber as determined by a pressure sensor. During the clinical trial, the pressure in each chamber was set by the participants within the range of 90 to 130mm Hg, such that the pressure did not cause excessive pain or feel uncomfortable.

2.3. Study design

This study was designed as a single-group repeated-measures controlled trial. People who worked standing on their feet for prolonged periods to identify those with leg pain and swelling were screened. Participants who were enrolled in the study following the screening completed 3 study visits. For each visit, participants presented at the clinical trial facility before work (and within 24 hours of screening for visit 1), and then proceeded to their work. For visit 1, they reported back to the clinical trial facility after their workday and rested for 60 minutes in the supine position. For visit 2 (within 7 days of visit 1), used the IPC device in the sequential mode for 30 minutes at a pressure of 90 to 130 mm Hg in the supine position following their work-day, and then rested for 30 minutes. Finally, at visit 3 (within 7 days of visit 2), they used the IPC device in the circular mode for 30 minutes at a pressure of 90 to 130 mm Hg in the supine position following their work day, and then rested for 30 minutes. A total of 7 visits were required, including the screening visit, visit 1 (within 24 hours of screening, comprising visits before and after work), visit 2 (within 7 days of visit 1, comprising visits before and after work), and visit 3 (within 7 days of visit 2, comprising visits before and after work). The clinical trial was concluded after visit 3 (Fig. 1).

Leg pain (measured via the visual analogue scale [VAS]), leg volume, and leg circumference were measured 4 times at each of the study visits (T0: morning visit, T1: immediately after the afternoon visit, T2: 30 minutes after the intervention in the afternoon visit, and T3: 60 minutes after the afternoon visit). Participants were also monitored for any adverse events. Participants were instructed to refrain from any activity that may reduce leg swelling during work, such as the use of compression stockings or resting on their backs for a prolonged period during the workday. Further, they had to engage in work that required at least 8 hours of standing, from the start to the end of their workday.

2.4. Outcome measures

2.4.1. Primary outcome. The primary outcome of our study was a pain score measured via the conventional 100mm VAS with 2 end point descriptor, which is by far the most frequently used pain assessment tool. Participants were asked to rate how
their leg pain is by placing a mark somewhere along the scale between the 2 extremes from 0 for no pain to 100 for the worst pain.\(^{[14]}\)

### 2.4.2. Secondary outcomes.

The secondary outcome of this study was leg swelling as measured by leg volume and circumference. Specifically, leg volume was measured in both legs using the water displacement method\(^{[15]}\) and was recorded in milliliters. Leg circumference was also measured in both legs, with the limb in a relaxed position. We measured the circumference of each foot, at 2 cm above the medial malleolus, at 10 cm below the inferior pole of the patella, at 10 cm above the superior pole of the patella,\(^{[16]}\) and recorded each measurement to 2 decimal places.

### 2.5. Safety

Participants were instructed to report any adverse events that occurred during the study period, along with their severity and causal relations with respect to the study device. The symptoms and signs, date of onset, severity, course (continuous or intermittent), outcome, seriousness, relationship, and actions taken were recorded in the case report form for any adverse study-related events.

### 2.6. Statistical analysis

All statistical analyses were conducted using SPSS 24.0 software (SSPS Inc., Chicago, IL, USA). For each study visit, the primary outcome (VAS) and secondary outcomes (leg volume and leg circumference) were compared across T0, T1, T2, and T3. Normality was tested with the Shapiro-Wilk test. Normally distributed data were analyzed with repeated measures analysis of variance (RM-ANOVA) followed by a post-hoc test to determine whether significant differences occurred with respect to treatment interventions. Non-normally distributed data were analyzed with the nonparametric Friedman test followed by a Wilcoxon signed-rank test to determine whether significant differences occurred with respect to treatment interventions. Bonferroni correction was performed for the post-hoc test or Wilcoxon signed-rank test to ensure that the alpha was maintained at 0.05.

### 3. Results

#### 3.1. Subject demographics

All participants were healthy adults. The study included 20 participants with a mean age of \(37.8 \pm 9.8\) years. Demographics of the participants were described in Table 1.

#### 3.2. Provocation of edema after work

All leg swelling parameters (volume and circumference) and pain measured in the afternoon after work (T1) were significantly higher than those measured before work in the morning (T0), showing that significant leg swelling and pain were provoked at T1 among all participants (Tables S1, Supplemental Digital Content, http://links.lww.com/MD/G253, S2, Supplemental Digital Content, http://links.lww.com/MD/G254, and S3, Supplemental Digital Content, http://links.lww.com/MD/G255).

#### 3.3. Pain score as the primary outcome

The pain score at T1 (measured immediately after working while standing for a prolonged period) was aggregated across study visits for a mean score of 33.5; scores were similar across the 3 study visits. At T2, measured after a 30-minute intervention, the score decreased by 5 following the resting intervention, by 17 following the sequential mode intervention, and by 16.5 following the cyclical mode intervention. These results at T2 showed significantly reduced pain following all 3 interventions compared with the pain score measured at T1 (\(P = .041, P < .001, P < .001\), respectively). At T3, after 30 minutes of additional resting, all 3 interventions also demonstrated significantly

### Table 1

| Demographics of participants. |
|------------------------------|
| **Number** |
| 20 |

| **Male: female** |
| 1: 19 |

| **Age, y** |
| 37.8 ± 9.8 |

| **Height, cm** |
| 160.2 ± 5.7 |

| **Weight, kg** |
| 60.3 ± 14.6 |

| **Body mass index, kg/m²** |
| 23.4 ± 4.2 |

| **Blood pressure (systolic/diastolic)** |
| 117 ± 11 / 73 ± 9 |

| **Heart rate** |
| 80 ± 10 |

| **Body temperature** |
| 36.6 ± 0.0 |

| **Occupation** |
| Nurse |
| 13 |
| Nursing assistant |
| 2 |
| Sales person |
| 1 |
| Professor |
| 1 |
| Nutritionist |
| 1 |
| Researcher |
| 1 |
| Occupational therapist |
| 1 |

Values are presented as mean ± standard deviation.
reduced pain among study participants when compared with the pain scores evaluated at T1 ($P = .002$, $P < .001$, $P < .001$, respectively) (Fig. 2), and at T2 ($P = .021$, $P = .025$, $P = .046$, respectively). In all 3 intervention groups, there were significant pain reduction between T1 and T2, T1 and T3, and T2 and T3 (Table S4, Supplemental Digital Content, http://links.lww.com/MD/G256).

There were significant differences between the 3 interventions with respect to pain reduction (specifically, between T1 and T2 and between T1 and T3, but not between T2 and T3). The post-hoc test showed that differences in pain reduction between T1 and T2 and between T1 and T3 were only observed when comparing the resting and sequential mode interventions as well as the resting and the circular mode interventions, but there was not any differences in leg pain reduction between the sequential and circular IPC modes (Tables S4, Supplemental Digital Content, http://links.lww.com/MD/G256 and S5, Supplemental Digital Content, http://links.lww.com/MD/G257).

3.4. Leg volume as a secondary outcome

At T2, participants’ right leg volumes decreased by an average of 95 mL after 30 minutes of rest, by 133 mL after 30 minutes of sequential mode IPC, and by 123 mL after 30 minutes of circular mode IPC, when compared with the leg volume measured at T1. All of these differences were statistically significant. At T3, after 30 minutes of additional rest, participants’ right leg volumes further decreased by an average of 179 mL after the resting intervention, by an average of 201 mL after the sequential mode intervention, and by an average of 211 mL after the circular mode intervention, when compared with the leg volumes measured at T1. In other words, the right leg volume decreased continuously after T2, and differences between T1 and T3 were statistically significant for all 3 interventions (Fig. 3A).
At T2, participants’ left leg volumes decreased by an average of 121 mL following 30 minutes of resting, by an average of 132 mL after 30 minutes of sequential mode IPC, and by an average of 103 mL after 30 minutes of circular mode IPC when compared with the leg volumes measured at T1, and all of these differences were statistically significant. At T3, after 30 minutes of additional resting, left leg volumes decreased by an average of 200 mL after resting, by an average of 202 mL after sequential mode IPC, and by an average of 201 mL after the circular mode IPC, when compared with the leg volumes at T1. In other words, the left leg volume continuously decreased after T2, and the differences between T1 and T3 were statistically significant for all 3 interventions (Fig. 3B). Time effect of 3 interventions was significant through T1 to T3 in resting, sequential, circular groups, however, there were no significant differences in volume reduction between 3 intervention groups (right leg, *P* = .362 for group comparison of T1–T2, *P* = .198 for group comparison of T1–T3; left leg, *P* = .122 for group comparison of T1–T2, *P* = .995 for group comparison of T1–T3) (Table S6, Supplemental Digital Content, http://links.lww.com/MD/G258).

3.5. Leg circumference as a secondary outcome

Leg circumference was measured at the foot, ankle, 10 cm below the knee, 10 cm above the knee, and 20 cm above the knee after resting as well as sequential, and circular mode IPC interventions. Leg circumferences at all the measured points, with the exception of the right foot, 20 cm above the knee for the right leg, and 20 cm above the knee for the left leg, were significantly decreased at T2 when compared with the leg circumferences measured at T1 (ΔT1–T2) (Fig. 4). All circumferences, with the exception of 20 cm above the knee for both legs, were significantly decreased at T3 when compared with the leg circumference measured at T1 (ΔT1–T3) for the sequential and circular mode interventions, though not for the resting group (Fig. 5). When comparing study interventions, there were significant differences across interventions for leg circumferences in all areas for changes occurring between T1–T2 and T1–T3, but not for changes occurring between T2 and T3. Post-hoc tests showed that ΔT1–T2 and ΔT1–T3 significantly differed between the resting and sequential interventions, but not between the sequential and circular interventions (Tables S7, Supplemental Digital Content, http://links.lww.com/MD/G259, S8, Supplemental Digital Content, http://links.lww.com/MD/G260, S9, Supplemental Digital Content, http://links.lww.com/MD/G261, and S10, Supplemental Digital Content, http://links.lww.com/MD/G262).

3.6. Safety

Although we created a comprehensive system for monitoring and recording adverse events potentially occurring during this study, no serious adverse events were noted in the study population. We
observed mild adverse events in 3 participants (dizziness and headache in 1 participant, foot discomfort in 1 participant, and dizziness, foot discomfort, palpitations in another participant). Foot discomfort after application of IPC was considered to be causally related to the intervention, and dizziness and palpitation were considered to probably be causally related to the intervention. These adverse events were reported as mild events because they were relieved within 20 minutes after application of the device without any medical treatment.

4. Discussion

This study found that the use of an IPC device leads to a significant reduction in pain and swelling among healthy adults who regularly work standing for prolonged periods when compared with pain reduction seen with resting alone. The positive effects of the IPC intervention with regard to leg pain and swelling did not differ between modes of IPC administration (sequential and circular). Further, applying an IPC device at a pressure of 90 to 130 mm Hg did not cause any significant adverse events and is thus safe for use.

Before measuring main outcomes after work, participants visited in the morning to measure the baseline pain and swelling (T0). Compared with baseline data, pain, and swelling (volume and circumferences) were significantly increased after work (Tables S1–3, Supplemental Digital Content, http://links.lww.com/MD/G253, http://links.lww.com/MD/G254, http://links.lww.com/MD/G255). This result can give the evidence of physiologic venous insufficiency that healthy individuals without specific medical history can develop the venous stasis symptoms such as pain, swelling caused by prolonged standing occupational environments.

The primary outcome, pain score measured in this study (the VAS) ranged from 10.5 to 13.5 (with 100 considered to be the most severe pain possible) in the morning before work, and rose by 20 points to an average of 33.5 after work across study visits. The pain score decreased by 5 points after 30 minutes of supine resting, and by 17 and 16.5 points after 30 minutes of the IPC circular and sequential modes, respectively. After 30 minutes of additional resting, the pain score decreased by 9.5 for the resting intervention and by 21 and 19 for the IPC circular and sequential interventions, respectively. These results showed that applying IPC decreased the pain score to a similar level as leg pain measured in the morning, before work. Thirty minutes of IPC followed by 30 minutes of resting after a period of prolonged standing could reduce leg pain developing throughout the day to the baseline level, and thus, can be more beneficial than simply resting in the supine position after work.

The secondary outcome, leg circumferences were significantly increased in all areas after work, compared with those before work. Natural rest, sequential, and circular mode of IPC were all effective for reducing leg circumferences with significant group difference. Natural rest did not completely reduce the swelling to the baseline level observed in the morning, while, leg circumferences in most areas were reduced to the baseline level or even lower following 30 minutes of IPC and 30 minutes of resting. These differences were more evident in the proximal parts (10 and 20 cm above the knee) than in the distal parts of the leg. Applying IPC showed superior effect on leg circumferences than natural rest with no difference between sequential and circular mode.

In terms of leg volume, leg volumes after work were significantly increased by 68 to 150 mL, compared with that before work but decreased significantly following resting, as well as circular and sequential IPC interventions. In all 3 cases, leg volumes decreased by an average of 95 to 133 mL after 30 minutes of each respective. After 60 minutes of each respective intervention, leg volumes decreased by an average of 179 to 211 mL (i.e., to less than baseline). All 3 interventions of rest, sequential, and circular mode of IPC were effective for reducing leg volume after prolonged standing. However, there were no significant differences between interventions.

Regarding hemodynamic changes caused by standing, previous studies conducted among healthy participants reported that standing for 10-minute intervals increased the hydrostatic venous pressure around the ankle by 90 mm Hg and increased leg volume by approximately 50 mL.

Foot discomfort after application of IPC was considered to be causally related to the intervention, and dizziness and palpitations in another participant. Although no international consensus exists on the recommended IPC pressure or mode of application for treating leg pain, leg swelling, and other conditions, a pressure of 30 to 60 mm Hg is recommended for patients with lymphedema.

A recently published systematic review recommended a dosage time of 45 to 60 minutes to apply pressures between 30 and 60
mm Hg in a sequential IPC program. However, this study provided low-level evidence of moderate quality.[22] In patients with chronic venous edema, a dose-dependent relationship was reported between high pressure and leg edema.[24] However, when comparing groups receiving a high pressure intervention (120 mm Hg) and a low pressure intervention (60 mm Hg) as well as a control group without IPC among patients with chronic venous insufficiency and primary lymphedema, swelling was reduced most significantly in the high pressure group.[21] Furthermore, applying IPC at 100 to 120 mm Hg for 3 years in patients with stage II–III lymphedema in the lower limb did not lead to notable complications.[26] In their 2013 study, Zaleska et al.[27] reported that a high pressure of about 120 mm Hg and at least 50 seconds of compression are required to produce efficient tissue fluid pressure and generate proximal flow. In a study that examined lymph circulation after varying combinations of IPC interventions, including simultaneous inflation of 6 chambers, sequential inflation of chambers, sequential deflation from the proximal to distal (6–1), and sequential deflation in the order of 6, 4, 2, 5, 3, and 1, along with varying pressures (45 and 90 mm Hg), no differences were shown in lymph circulation according to the method of inflation, deflation, or the level of pressure among healthy people.[12] Participants in our study were healthy adults with leg swelling and pain caused by prolonged standing work; thus, a relatively high pressure of 90 to 130 mm Hg was applied, which led to swelling and pain reduction without any serious adverse events. Thus, based on our study in combination with previous research, high pressure IPC dosage for about 30 minutes seems to be an appropriate intervention for leg pain and swelling following prolonged standing at work. Since equal effects of swelling and pain reduction were attained following the sequential mode, when the distal chamber was deflated, when inflating the proximal chambers, when implementing the circular mode, and when the distal chamber was not deflated, people using IPC to relieve leg pain and swelling may therefore make a choice based solely on their preferences.

Although previous studies have reported positive effects of IPC on venous insufficiency, this study is novel and innovative because of distinctive features: we recruited workers who stand >8 hours daily compared with those in previous studies investigating the effect of IPC only after short period of standing. We conducted the interventions in a supine position, rather than while sitting, to effectively assess and compare the effect of resting versus IPC. We measured leg volume and circumference in addition to subjective pain scores to determine the effects more accurately. We directly compared the effects of the 2 most frequently applied IPC treatment modes.

5. Limitations

One limitation of this study was that it may have included patients with chronic venous insufficiency, such as those with venous reflux or stasis, despite an attempt to enroll healthy adults without an underlying past history of chronic venous insufficiency. This is because we could not confirm the absence of vascular or lymph problems via testing during the screening process. In addition, though we publicly recruited participants with occupations that involved prolonged standing, the majority of our recruited participants were nurses, and 19 were women, which may be evidence of selection bias, and may also reduce the generalizability of our findings with regard to male workers or workers within other occupations.

6. Future directions

Through this study, the effect of IPC was compared with that of natural supine rest for physiologic leg edema and pain in healthy individuals. In a follow-up study, comparing the effect of IPC with other widely used methods for lymphedema or chronic venous insufficiencies, such as compression stocking, would provide more information on the therapeutic potency of IPC in relieving leg edema and pain.

7. Conclusions

This study revealed that significant leg pain and edema after prolonged standing could be relieved by application of IPC device in healthy individuals. The application of IPC was safe and effective for reducing leg pain and leg circumferences compared with natural supine resting. Leg volume was reduced after the use of IPC; however, the effect of volume reduction was similar to supine resting. Application of IPC with a pressure of 90 to 130 mm Hg was safe without significant adverse events, and the commonly used sequential and circular modes of IPC were equally effective for reducing leg pain, volume, and circumferences among healthy adults.

Author contributions

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