

A systematic review of pneumatic compression for treatment of chronic venous insufficiency and venous ulcers

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Introduction: As part of a reconsideration of coverage policy, the Centers for Medicare and Medicaid Services requested a systematic review of the evidence on the use of pneumatic compression devices in the home environment for treatment of chronic venous insufficiency (CVI) and venous ulcers.

Methods: Articles were found with a systematic literature search of MEDLINE, EMBASE, and AMED (Allied and Complementary Medicine) databases, hand searches of reference lists, and suggestions of experts.

Results: Eight trials that met the inclusion criteria, including several randomized control trials, were found. Most studies were small and may have been underpowered. However, several were well-designed randomized controlled trials. Three studies showed that the devices could alleviate symptoms of CVI. No studies directly measured whether the devices could prevent the occurrence of venous ulcers. Some studies on the treatment of venous ulcers did not show a benefit for pneumatic compression, but other studies showed a benefit for the devices in healing long-standing chronic ulcers that had not healed with other methods. No studies directly compared single-chamber and multiple-chamber devices or studied whether the effectiveness of the pump was dependent on types of treatment used concurrently with the pump. Few adverse events were reported in the trials. Patients generally expressed satisfaction with the pneumatic compression devices, and several studies reported higher compliance than with other compression methods.

Conclusion: The available data cannot be relied on to inform the optimal choice of compression therapy or optimal protocol for patients with CVI or venous ulcers. Methodologically rigorous research designed to answer these questions would be useful for treatment decisions. The Centers for Medicare and Medicaid Services considered the results of this study and issued a decision that pneumatic compression will only be covered for patients with refractory edema with significant ulceration of the lower extremities after a 6-month trial of standard therapies, such as compression stockings, has failed. (*J Vasc Surg* 2003;37:539-44.)

The Centers for Medicare and Medicaid Services (CMS; formerly the Health Care Financing Administration) requested a technology assessment on the use of pneumatic compression devices for the treatment of venous insufficiency and chronic ulcers. This manuscript is based on the technology assessment/systematic review that was submitted to CMS.

At the time of the request, CMS was reconsidering its coverage policy; the policy was to cover pneumatic compression devices for patients with refractory edema with significant ulceration of the lower extremities with failure to heal after 6 months of treatment with other methods, such as compression bandages. CMS requested that the Agency

for Healthcare Research and Quality find and evaluate evidence related to the use of intermittent pneumatic compression devices for the treatment of venous insufficiency and leg ulcers in the home.

BACKGROUND

Chronic venous insufficiency (CVI) of the lower extremities is a condition caused by abnormalities of the venous wall and valves that leads to obstruction or reflux of blood flow in the veins.¹ Symptoms and signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers. Severe and persistent edema leads to secondary lymphedema and trapped fluid. The calf becomes permanently enlarged and hard, and ulcers occur more frequently and are more difficult to heal.²

Approximately 3% to 11% of the adult population has skin changes and edema from CVI.¹ Studies of the prevalence of venous leg ulcers found that venous ulcers occur in approximately 0.18% to 1.3% of the adult population, with only 50% with healing by 4 months, 20% with open ulcers at 2 years, and 8% with open ulcers at 5 years.¹

Wide consensus exists in the literature that compression is a necessary part of all treatments for CVI and venous ulcers. A list of reviews and guidelines related to the use of compression is given in Appendix 1 (online only). Compression is commonly provided with stockings; these stockings are not covered by Medicare because they do not fall into any Medicare statutorily defined benefit category.

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Many elderly patients have reduced strength and dexterity that makes it difficult to put on the stockings.³⁻⁶ Compression may also be provided with an Unna's boot or with different types of elastic bandages. Some patients have reported difficulty with these methods as well.^{7,8}

Compression to the limb may be provided with pneumatic compression devices. Pneumatic compression devices consist of an inflatable boot and a pneumatic pump that fills the boot with compressed air. The boot is intermittently inflated and deflated, with cycle times and pressures that vary between devices. The boots may have a single chamber that is inflated to a single pressure or multiple chambers that are individually inflated in sequential order, to produce a "milking" effect on the limb. The latter type of device may have preset pressures in each chamber or pressures that are individually set for each chamber. Individually controllable pressures would allow patients to lower the pressure in chambers directly over the site of an ulcer.

EVIDENCE MODEL

Figure 1 outlines an evidence model for the action of pneumatic compression pumps. In this model, pneumatic pumps affect the physiologic processes underlying CVI and venous ulcers, leading to beneficial health outcomes such as reduced edema, prevention of lymphedema, and increased rates of ulcer healing. Pneumatic compression may also lead to adverse events. In this assessment, we searched for data on the use of pneumatic compression in the home environment for patients with venous insufficiency of the lower extremities or leg ulcers from CVI. Studies on patients with lymphedema were excluded because pneumatic compression devices for lymphedema were the subject of a separate Medicare coverage decision.

Many studies investigate the effect of pneumatic compression on intermediate outcomes on the basis of assumptions about the underlying physiology of CVI and venous ulcers. However, these physiologic processes are poorly understood.⁹ One theory of the action of pneumatic compression is that use of the device increases oxygen tension. Studies have shown that venous ulcers, like other wounds, have low oxygen tension and that wounds associated with an oxygen tension of less than 20 mm Hg are unable to heal.^{10,11} Some researchers have found that intermittent pneumatic compression increases oxygen tension in venous ulcers,¹² and others found no difference in oxygen tension with pneumatic compression.¹¹ Another theory is that pneumatic compression increases blood flow (measured with the clearance of small-molecular weight radiolabeled markers or a laser Doppler fluxmeter) and/or lymphatic clearance (measured with the clearance of large-molecular weight radiolabeled markers) at the site of the ulcer. However, different studies found conflicting results on the clearance of large and small molecules with the use of pneumatic compression.¹³⁻¹⁵ Differences between studies may be explained by different protocols of pneumatic compression, different methods of measurement, and different patient populations. More research is needed in this area.

Many studies have measured the effects of different cycle times, pressures, and multichamber versus single-chamber devices on physiologic measurements on healthy volunteers and patients (reviewed by Allsup¹⁶). These studies found that the use of multichamber devices and higher pressures led to greater increases in venous blood flow than single-chamber devices and lower pressures, respectively. However, one study found no additional increases in blood velocity at pressures above 35 mm Hg at the ankle, and another study found that blood velocity continued to increase at pressures above 55 mm Hg at the ankle. Compression with single-chamber devices led to trapping of venous blood in the distal veins, whereas sequential gradient compression results in more complete emptying of the deep veins.¹⁷ Venous system refilling time was approximately 45 seconds in two different studies, which led to a recommendation of a cycle time of approximately 70 seconds to allow the venous system to refill while the devices were deflated.¹⁶ Many of these studies were done on healthy volunteers or a population with the devices to prevent deep vein thrombosis, which led to questions of the applicability of these results to a patient population with CVI. In addition, the poor understanding of the physiologic processes underlying CVI and the mechanism of action of the devices makes interpretation of these studies difficult.

Reporting of adverse events is poor in many areas of medical research,¹⁸ which results in insufficient knowledge about the true spectrum and frequency of adverse events. This is likely to be the case for pneumatic compression devices as well. Peroneal neuropathy and compartment syndrome, where circulation and function of tissues within a closed space are compromised by increased pressure, leaving muscles and nerves susceptible to injury, have been reported with the use of pneumatic compression to prevent deep vein thrombosis.¹⁹ Genital edema has been reported when pneumatic compression devices are used for lower limb lymphedema.²⁰ Pneumatic compression is contraindicated in patients with significant arterial insufficiency, edema from congestive heart failure, active phlebitis, deep vein thrombosis, or the presence of localized wound infection or cellulitis.²¹ These may be relative rather than absolute contraindications. For example, arterial disease may be a relative contraindication; compression with stockings or bandages may be used in these patients at lower pressures.²² Very high compression reduces blood supply to the skin and may lead to pressure damage, and even moderate pressures in patients with impaired blood supply to the legs may result in pressure damage.²³

METHODS

The systematic review was carried out by the Agency for Healthcare Research and Quality (AHRQ) Technology Assessment staff trained in systematic review methodology. The technology assessment was reviewed by four content experts before it was sent to CMS.

The questions and inclusion and exclusion criteria for the systematic review were developed in collaboration with staff from CMS. CMS was given the opportunity to review

and comment on the draft manuscript at the same time the draft was sent to external reviewers. The authors considered the comments of CMS and the external reviewers and modified the manuscript on the basis of the comments. The content of the final report and decisions regarding publication in a peer-reviewed journal rested solely with the authors.

Literature was searched in the medical databases MEDLINE, EMBASE, and AMED (Allied and Complementary Medicine) from the inception of the databases to March 8, 2001, with keywords related to pneumatic compression, venous insufficiency, and venous ulcers. A full description of the literature search is given in Appendix 2 (online only). This search found 91 articles, seven of which contained relevant clinical trials. Reference lists of review articles were hand searched, but no additional articles were found. An expert reviewer suggested an additional study that was included in the review.

Data was extracted from the studies directly into an evidence table (Table I, online only) by one assessor. A second assessor verified the extracted data. The assessors noted key attributes of each study that affect relevance and validity in the comments column of the evidence table.

RESULTS

Results by study

Ginsberg et al²⁴ studied the effect of pneumatic compression in patients with CVI associated with severe post-phlebotic syndrome. All patients were given pneumatic pressure devices, and patients were randomized to either a therapeutic pressure of 50 mm Hg or a placebo pressure of 15 mm Hg for 20-minute sessions twice daily. After 1 month, patients were crossed over to the alternate pressure. Results were measured with a symptom questionnaire; on this questionnaire, higher scores correspond to fewer symptoms, with a score of 70 for the least severely affected patients. The mean symptom score increased from 14.4 with the placebo pressure to 16.5 ($P = .007$) with the therapeutic pressure. The authors state that this difference is clinically significant, but it is very small.

Arcelus and Caprini²⁵ measured clinical improvement in 18 patients aged 23 to 62 years with CVI. Compression was provided with a sequential gradient device, 4 hours per day, 35 to 50 mm Hg for 11 seconds, with 60 seconds between cycles. Clinical improvement was measured with a questionnaire about symptoms before and after the use of the pump. Symptoms included swelling, discomfort, discoloration of the skin, cosmetic problems, decreased activity tolerance, depression, sleep problems, and interference with work. The study measured a significant decrease in the scores, indicating a significant clinical improvement with the use of the pump. Patients rated their pre-pump symptoms retrospectively after using the pump; answers on retrospective questionnaires may be subject to recall bias. Older patients rated the device as more inconvenient, suggesting the potential for lower compliance.

Pflug²⁶ measured the improvement in signs and symptoms of 252 patients with venous edema (188 mild; 64 severe) with the single-chamber device at least 3 hours daily. No demographic information is given about these patients, and no definition of "signs" or "symptoms" is given. More than 90% of the patients had improvements of signs and symptoms. Statistical significance was not measured.

Rowland²⁷ measured the time to ulcer healing, change in ulcer size, and change in lower limb volume. The study was a crossover randomized controlled trial (RCT). Patients were switched to the alternative therapy after 2 to 3 months, depending on the rate of healing. Sixteen patients were originally enrolled, and five patients withdrew from the study after the first or second visit (three from the pump group and two from the bandage group). Patients in the pneumatic compression group received treatment with a single-chamber device, 1 hour each morning and evening. Control patients received high stretch bandaging. There was no difference in intention-to-treat analysis of ulcer healing rate and lower limb volume between the groups. Patients reported that the device was easier to use and more comfortable than the bandaging. Only three patients had complete healing by the end of the study. The authors comment that the power of the study may be too low to detect a real difference.

Schuler et al²⁸ studied the effect of a sequential gradient compression system compared with Unna's boot in a RCT of 54 patients ranging in age from 31 to 85 years. Patients were instructed to use the pneumatic compression devices for 1 hour in the morning and 2 hours in the evening with their legs elevated (12 seconds of compression, 60-second interval, 50 mm Hg at the ankle). Patients wore stockings between pumping sessions. There was no significant difference in fraction of patients who achieved complete healing in 6 months, average healing rates, or pain scores.

Smith et al²⁹ studied the effect of a sequential gradient compression device used 4 hours per day in a RCT of 45 patients ranging in age from 42 to 78 years. Patients in the experimental and control groups received compression stockings (30 to 40 mm Hg compression at the ankle) and were instructed to wear stockings during pumping sessions. One of 24 patients had healing within 3 months in the control group compared with 10 of 22 patients in the pneumatic compression group ($P = .009$). The median healing rate was 2.1% of ulcer area per week in the control group compared with 19.8% of ulcer area per week in the pneumatic compression group ($P = .046$). This was an intention-to-treat analysis.

Mulder and Reis⁸ studied the effect of a sequential gradient compression device in a historic control study on 10 patients with an average age of 68 years. Patients were their own control; they entered the study after 42 days of failed Unna's boot therapy. Patients were instructed to use the sequential compression devices for 1 hour each morning and 2 hours each evening. Two patients dropped out, one for equipment failure and one for lack of compliance. There was a significant decrease in wound area over time in

patients remaining in the study ($P < .01$), with only one patient with complete healing in 120 days. Mulder and Reis⁸ report that patients were followed for 1 year after study termination and that two patients who discontinued pump use had recurrent wounds that healed after a return to pump use.

Hazarika and Wright³⁰ studied the effect of a single-chamber device in a prospective controlled study of 21 patients with an age range from 50 to 82 years. No indication was given on how patients were chosen for treatment or control. Patients used the device once daily for 2 to 3 hours at "comfortable" pressure settings (30 to 80 mm Hg). Most control patients had no change or worsening of ulcers; several pneumatic compression patients had improved ulcers, and a few of those who reported low compliance had ulcers that did not change or increased in size. Statistical significance of the results was not reported.

Results by question

Following is a summary of results in response to specific questions posed by CMS about the effectiveness of pneumatic compression pumps.

At what point in therapy should the pneumatic compression devices be introduced? Three studies^{25,26,31} showed an improvement in signs and symptoms of CVI with the use of pneumatic compression devices. No studies were specifically designed to test whether use of the devices could prevent ulcers. Two patients who discontinued use of the compression device in one study⁸ had recurrence of ulcers that healed when use of the device was reinitiated. This is consistent with circumstantial evidence from studies that compression with stockings and bandaging systems prevents recurrence of venous ulcers.³²

Most patients in the studies of ulcer healing had chronic ulcers that had not healed for several months or more. Therefore, no conclusions can be made about whether pneumatic compression can improve rates of ulcer healing in new ulcers compared with other therapies.

One RCT and two other studies^{8,29,30} found that pneumatic compression devices increased rates of healing in chronic ulcers that had not healed for several months or more with other methods. Two other RCTs^{27,28} found no difference compared with control methods. This may be because of differences in treatment of control patients; however, a previous review had found no difference in ulcer healing rates among high compression methods, such as stockings, bandages, and Unna's boot. This may also be because of differences in protocol (see question 2).

Overall, the results suggest that patients with CVI who have not yet had ulcers develop may have a small benefit from the use of pneumatic compression. No data exist on patients with new ulcers, and data are mixed on whether pneumatic compression pumps aid healing of chronic ulcers that have not responded to other therapies for several months or longer.

What protocol should be used to maximize effectiveness of the pneumatic compression devices? No studies directly compared the effectiveness of single-cham-

ber devices with gradient multichamber devices. Both types of devices had a beneficial effect compared with control methods in some studies and no difference compared with control methods in other studies. Several researchers have made physiologic arguments favoring multichamber gradient devices. Results from different physiologic studies conflict, and more research is needed in this area.

Three of the studies^{8,28,29} on patients with ulcers used sequential gradient multichamber devices; it was not specified whether these were the type with individual pressure control in each chamber. Pressures and cycle times were mostly set as recommended by the manufacturer. Recommendations for these parameters are from physiologic studies. None of the studies directly compared the effects of different pressures or cycle times on health outcomes, such as ulcer healing rates. In most studies, patients were instructed to use the device for several hours each day.

Some studies replace other compression treatments with pneumatic compression, and other studies use the pneumatic compression device in conjunction with other methods of compression. There are many other variables in the studies. For example, one RCT by Schuler et al²⁸ that showed no additional benefit for the devices asked control patients to sit for 3 hours daily with elevated legs. Another RCT by Smith et al²⁹ that showed a benefit of the devices over the control methods only asked the control patients to elevate legs while sitting with no specific time period mentioned. Smith et al²⁹ comment that they cannot rule out that some of the effect may be from pneumatic compression patients sitting with elevated legs for longer periods. Another variable was how the stockings were worn. Patients wore stockings in both studies; however, in the study by Schuler et al,²⁸ patients were asked to remove their stockings during pumping sessions, and in the study by Smith et al,²⁹ patients wore stockings during pumping sessions.

Some studies not reviewed here had patients come to a clinic to receive pneumatic compression sessions. For example, McCulloch et al³³ found that patients who received an hour of pneumatic compression twice weekly had significantly improved rates of ulcer healing compared with control patients.

Overall, there are no data that can be relied on to develop a protocol to maximize the effectiveness of the pneumatic compression pumps.

Are there absolute indications or contraindications to use of pneumatic compression therapy? Indications for the use of pneumatic compression that have been addressed in studies are CVI with edema and CVI with chronic ulceration that had not healed in several months or more with other treatments.

Few adverse events were reported in the clinical trials. However, a few patients dropped out from several trials; this may be because of adverse events. One patient in the study of Schuler et al²⁸ had cellulitis develop with the use of a sequential gradient compression system. One study reported that patients were generally able to use the devices at home,²⁶ but another study reported that some elderly patients had a fear of the devices.³⁰

Pneumatic compression is contraindicated in patients with significant arterial insufficiency, edema from congestive heart failure, active phlebitis, deep vein thrombosis, or the presence of localized wound infection or cellulitis. These may be relative rather than absolute contraindications.

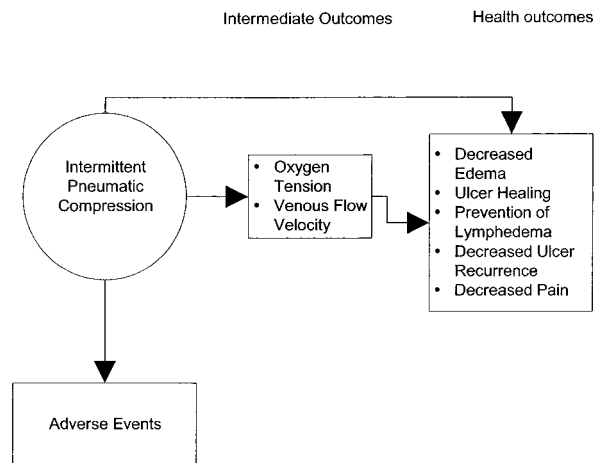
CONCLUSION

Compression therapy is an important part of treatment for CVI and venous leg ulcers. Often patients do not comply with compression therapies, such as stockings, bandages, and Unna's boot, because of difficulty with use of the therapies.

Long-term use of pneumatic compression devices in the home environment may be an alternative to other compression therapies for patients who are unable or refuse to comply with other methods. In addition, pneumatic compression may be effective for patients who have previously failed treatment with other compression devices, either in addition to, or instead of, these other methods. Trials of pneumatic compression devices for the treatment of CVI and venous leg ulcers include few patients and may not have enough power to detect differences. Several studies have randomized designs with well-defined outcome measures and results that reach statistical significance. The results are mixed. There are many protocol differences between studies, including choice of compression system for control patients.

A previous review found no evidence of different effectiveness for different types of compression, such as stockings, bandages, or Unna's boot.²³ However, other variables, such as length of time spent with legs elevated or whether stockings are worn during pumping sessions, might affect results. Several studies did show significant improvement with the use of pneumatic compression devices of long-standing chronic ulcers that had not healed with other methods. Few adverse events were recorded. Some patients expressed fear of using the devices, but patients who agreed to use the devices generally expressed satisfaction and reported higher compliance than with other compression methods.

This systematic review has several potential limitations. The scope of the systematic review was narrowly defined by the policy question asked by CMS. Therefore, the focus of the systematic review was data directly studying the effectiveness of pneumatic compression devices. However, a more broadly defined systematic review that presents an overview of care of patients with venous insufficiency and venous ulcers, including assessment and a full range of treatments, might be useful to clinical decision making. Another potential limitation is the scope of the literature review. We have tried to ensure that the literature search had as little bias as possible by searching three different electronic databases and searching for grey literature through suggestions of experts and hand searches of references in review articles. For practical reasons, we did exclude articles in languages other than English. Ideally, articles in all languages should be included. However,



Evidence model for the action of pneumatic compression pumps.

researchers in other areas have found that 78% of identified meta-analyses have language of publication restrictions and that there is no evidence that language restricted meta-analyses lead to biased estimates of intervention effectiveness.³⁴

CMS considered the results of this technology assessment and decided not to change the coverage policy. Pneumatic compression will only be covered for patients with refractory edema with significant ulceration of the lower extremities after a 6-month treatment with standard methods, such as compression stockings, has failed.³⁵

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