Association of Venous Leg Ulcers With Ankle Range of Motion in People Attending Chiropractic Mobile Clinics in the Dominican Republic

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ABSTRACT

Objective: The goal of the study was to determine if there was an association between chronic venous disorders (CVDs), particularly venous leg ulcers, and ankle range of motion (ROM) in the Dominican Republic.

Methods: Chronic venous disorders were classified using the clinical manifestations portion (C) of the CEAP (clinical manifestations, etiology, anatomy, pathophysiology) method. The legs of participants attending mobile chiropractic clinics in rural, low-income areas in the Dominican Republic were assessed for clinical signs of CVD and venous ulcers. Ankle ROM was then measured, and photographs of the legs were taken. The 6 clinical stages of CVD were divided into 3 groups: normal legs (normal), no ulcer CVD, and ulcer CVD (healed and active). Multiple linear regression of ankle ROM against CVD grouping was used to test the association.

Results: Eight of the 837 patients for whom CVD classification was obtained had venous ulcers (healed or active) on at least 1 leg. About 30% relative reduction in ROM (ankle dorsiflexion plus plantar flexion) was observed between the ulcer group and the normal group. Regression analysis comparing legs with ulcers to healthy legs (normal), adjusted for age, gender, indicator for obesity, and previous leg trauma, revealed a significant decrease of approximately 14° ($P = .0007$) in ankle ROM. Age was also found to be strongly significant in the regression analysis, 1 year of aging was associated with a decrease of 0.16° ($P < .0001$) in ankle ROM (approximately 1.6° in 10 years).

Conclusion: A significant decrease was observed in ankle ROM for participants with active and healed leg venous ulcers compared with those without ulcers. There appeared to be an association between venous leg ulcers and ankle ROM in this sample. (*J Chiropr Med* 2017;16:263-270)

Key Indexing Terms: *Venous Ulcers; Ankle; Range of Motion; Prevalence; Venous Insufficiency; Chiropractic*

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INTRODUCTION

Venous disorders manifest themselves in a range of conditions from telangiectasis, valve incompetence, and varicose veins to later stages, referred to as chronic venous insufficiency (CVI), specifically involving venous hypertension causing pain, swelling, edema, skin changes, and ultimately venous ulcers.¹ CVI accounts for at least 80% of all chronic leg ulcers.² These conditions can lead to major disability and social impairment, are associated with chronicity and relapse³ and, therefore, have a huge impact on the health care system.

There is evidence that venous hypertension and CVI involve 3 major factors: vein patency, competence of valves, and proper calf muscle pump function.^{4,5} The calf muscles must contract and relax to move the ankle through its full

range of motion (ROM), and in a leg with a competent valvular system and patent veins, during plantar flexion specifically, to return blood to the heart from the venous plexus within the calf muscles.⁵ An intact system allows for blood to be propelled toward the heart. A failure of the system creates a deficit in the physiological emptying of the veins and venous hypertension that can then lead to venous ulceration.⁵

In low- and middle-income countries, where health care is not always adequate, venous disorders may not be treated early enough, and wound care may be less than adequate for subsequent ulcers that develop, as was observed by the lead study doctor. Moreover, there is evidence that poor healing rates have been associated with inadequate compression therapy.⁶ In addition, some individuals may not have access to or be able to afford drugs, such as pentoxifylline^{7,8} and iloprost,⁸ used to treat ulcers in high-income communities. Previous studies have examined venous insufficiency and venous ulceration in relationship to ankle ROM in populations with high socioeconomic status.^{9,10}

The primary objective of this study was to determine whether there is an association between chronic venous disorders (CVDs), particularly venous leg ulcers, and ankle ROM in a low-income, rural population of patients. Secondly, we were interested in estimating the prevalence of venous ulcers in this population.

METHODS

Design

This study is a cross-sectional observational multidisciplinary study that involved a chiropractic doctor specializing in joints and their ROM, along with medical doctors trained in vascular disease. Ethical approval for the study was obtained from the Office of Research Administration of the Canadian Memorial Chiropractic College, under Certificate No. 1303X05. In the Dominican Republic, ethical approval is not required for studies done on human subjects in which there is no intervention. Regardless, the study proposal was translated into Spanish and sent to CONABIOS (Consejo Nacional de Bioética en Salud) to apprise the national ethics board of the study.

Setting

Each year a group of 2 clinicians (1 being the lead study doctor) and a number of interns from the Canadian Memorial Chiropractic College travel to the Dominican Republic to provide chiropractic care for musculoskeletal conditions to people across the country. This service is provided free of charge and attracts individuals who cannot afford care for their conditions within their own country. A local medical doctor takes the chiropractic team to communities that he and others have determined to be in greatest need. These communities are located in rural villages or impoverished areas within larger towns and cities. Some communities are underserved with respect to the most basic public health care because there may be no public hospital nearby, and any private hospital is too

expensive for those without access to insurance. Patients will frequently wait the entire day to be seen, having arrived early in the morning after hearing about the outreach on the radio or seeing posters throughout their community.

People attending a Canadian Memorial Chiropractic College outreach clinic were asked to participate in this study. The study sample was made up of Spanish-speaking inhabitants of various towns across the Dominican Republic who chose to attend the free mobile chiropractic clinics of the outreach, held within local community buildings such as churches, community centers, and outdoor covered areas.

Variables

Clinical manifestations (the “C” in the CEAP [clinical manifestations, etiology, anatomy, pathophysiology] classification system) of venous disorders were defined as an independent variable for this study. Total ankle ROM was a dependent variable. Additional variables such as age, gender, body mass index (BMI), and previous (nonrecent) leg trauma were added as risk factors. The measurement methods used to collect the data on these variables are described in detail under Data Collection.

CEAP Classification System for CVDs

In this study, classification of the stages of CVDs was based on the CEAP classification system. This system was created in 1994 by the American Venous Forum and redefined in 2004.¹¹ Most published literature dealing with CVDs uses this classification system.¹¹

As the clinical setting of this study was mobile such that venues were not known in advance by the study team, and electricity might be randomly unavailable for hours at a time during the day, the use of objective diagnostic technology to evaluate involved venous anatomy and pathophysiology dysfunction to confirm venous origin would not have been feasible. Therefore, only the clinical manifestations portion (C) of the CEAP classification system was used, similar to another study by Belczak et al.¹⁰ The C of CEAP involves basic visual inspection and palpation, similar to that which could be done in a physician’s or chiropractor’s office. It does not use diagnostic equipment as would be used for the EAP portions of the classification system.

According to Etufugh and Philips,¹² venous ulcers can be diagnosed mainly clinically, and most ulcers are of venous origin and are an end stage of CVI. Most recently, Agarwal et al¹³ investigated the prevalence of varicose veins, skin trophic changes, and venous symptoms in a northern Indian population. As in this study of a Dominican population, the authors reported that they used observation and patient questions only, rather than diagnostic equipment, to perform the study.

Data Collection

The collection of data can be described as a 4-phase process that involves collaboration between medical

doctors and chiropractors: (1) consent, questionnaire, measurement of weight and height; (2) classification of CVDs; (3) measurement of ankle ROM; and (4) taking photographs of the legs. The collected data were entered twice to ensure good data quality.

At the first phase, all candidates who wished to participate signed a consent form written in Spanish (which was read to them if they were unable to read it themselves). Each participant was assigned a number (ID), and then proceeded to answer a questionnaire that included questions about typical venous leg symptoms, comorbidities, and factors such as previous leg trauma. The questionnaire forms were completed by the participants themselves, provided that they were able to read the questions, or the participants were asked the questions as written by a Dominican medical doctor or, on 1 occasion, by a medical assistant, who manually recorded the answers. The consenting participants had their weight and height measured and recorded by medical assistants or available chiropractic interns.

During phase 2, the participants were assessed by a different medical doctor, who inspected their legs in a standing position after allowing the veins to fill (approximately 2 minutes), to allow for better visualization.¹⁴ Clinical assessment for classification included visual inspection, palpation for pitting edema, and measurement of calf size with a measuring tape. Veins were measured for their width to categorize them as either varicose or reticular. Varicose veins were those that measured >3 mm.¹¹ Evidence of arterial insufficiency, such as loss of foot pulses and trophic skin changes, were recorded, and capillary refill testing was performed by squeezing the toenail beds. A neurologic exam including reflexes and sensation was performed, and if the patient had a history of diabetes, vibration sense and monofilament testing were done to check for sensation loss specific to diabetic neuropathy.

Any ulcers found were measured for size and number. Ulcers were categorized as venous based on location (gaiter area of the leg¹²) and appearance (border, depth and exudate)¹⁵ and by ruling out signs of arterial insufficiency and diabetic neuropathy. The doctor also examined for signs of recent trauma, Achilles scars, and other factors that could artificially limit ankle ROM.

A venous classification was assigned to each leg by this doctor based primarily on the clinical appearance of the legs and if necessary, the questionnaire. The classifications were as follows: C0 = no visible or palpable signs of venous disease, C1 = telangiectasis or reticular veins, C2 = varicose veins (distinguished from reticular veins by a diameter of ≥ 3 mm), C3 = edema, C4a = pigmentation or eczema, C4b = lipodermatosclerosis or atrophie blanche, C5 = healed ulcer, C6 = active ulcer. A subscript for the presence or absence of venous leg symptoms, as a further delineation of the C (as can be done within the CEAP system), was not assigned.

Diagrams of both legs with all leg lesions (including scars) were drawn for each participant to enable later comparison of these diagrams with photographs taken at the final phase. If any type of ulcer was found, the patient was told to see a medical doctor in the community to have wound care follow-up. When the classification phase was complete, the participant was instructed to go to the ROM measurement area.

During phase 3, the chiropractic doctor performed all ROM measurements using a previously tested modified inclinometer.¹⁶ The device consisted of a commercially available Baseline bubble inclinometer (Fabrication Enterprises, White Plains, New York) attached to a long wooden stick. This inclinometer enabled measurement of the total ROM (total of dorsiflexion plus plantar flexion from a set neutral—0—position)¹⁶ to establish the relative differences in ROM between CVD groupings.

The design of the device was developed based on a similar modified inclinometer used by Gerhardt et al¹⁷ to measure ROM. However, their inclinometer used a commercially available extension arm, which would not have been sturdy enough for our expected field conditions. This study's modified inclinometer was therefore developed to be a sturdy and simple-to-use device, providing the ability to make a large number of ankle ROM measurements reliably in a short time. The extended arm of the modified inclinometer helped to control for toe movement contribution to ankle ROM. Our device was designed and tested by this same chiropractic doctor in a prior pilot study,¹⁶ and was found to have very good intra-examiner reliability (intraclass correlation coefficient [ICC] = 0.88; 95% confidence interval [CI] = 0.72–0.95).

According to Gerhardt et al,¹⁷ inclinometers “read angle position relative to gravity or to a set neutral—0—position.” The bubble inclinometer used in this study did not have the ability to establish the vertical gravity—0—position¹⁸ to determine the absolute values for dorsiflexion and plantar flexion separately. However, with the objective to be able to compare relative total ROM, use of a set neutral—0—position was determined to be appropriate.

The method for measuring ROM in this study was based on that by Gerhardt et al.¹⁷ The participant was instructed to place 1 knee on a chiropractic table such that the lower leg was 50% on the table and the foot hung off the table. The participant remained standing on the other leg. The participant was told to bear weight on the standing leg and to maintain an upright position. Instruction was given to the individual about plantar flexion and dorsiflexion of the ankle, of the elevated foot, without extension or flexion of the toes. Effort was made to maintain the foot/toes of the participant in contact with the wooden arm of the modified inclinometer. The dorsiflexion and plantar flexion readings were called out to an independent person (who may have differed from day to day), who recorded the verbalized values to keep the chiropractor blinded to the classification

assigned to the legs by the MD in phase 2 and to reduce interruption between plantar and dorsiflexion measurements. The chiropractor also called out any incidence where the participant could not actively complete the measurement because of neurologic deficit, such as foot drop or cerebral palsy, or an inability to follow instructions likely caused by cognitive impairment.

During the final phase, the ROM examiner proceeded to photograph the ID number assigned to each participant and the legs of any participant with classifications C1 to C6. The examiner was told to photograph the legs without being told what classification had been assigned. The participants were photographed in several different positions using a macrolens to capture the appearance of any and all lesions, including specific characteristics of any ulcers.

After the study was completed, all photographs were subsequently and independently analyzed by 2 study doctors to ensure that the proper classification was done. Any disagreements were discussed, and consensus was reached based on their individual clinical experience and information found in the venous literature. Furthermore, the photographs of the ulcers were then shown to an independent general surgeon in the Dominican Republic, who gave his opinion as to their classification as either likely venous or other in nature. All decisions previously made regarding ulcer type were confirmed by this surgeon. This dual level of assessment was done to ensure that the classification process was robust.

After the participant had completed the study, he or she was shown to the chiropractic part of the mobile clinic for care of musculoskeletal complaints. Because treatment of the musculoskeletal system could have included manipulation to the extremities, the study was done first to prevent introducing a confounding factor into the ankle ROM measurements.

Sample Selection

All participants from the age of 9 years were invited to participate because it has been reported that venous disease can be found even in adolescents.¹⁹

Power analysis calculation for estimating prevalence in observational studies revealed that $n = 1056$ patients should be recruited²⁰ for a study aimed to estimate the prevalence with a margin of error $d = 0.006$ and predefined ulcer prevalence equal to $p = 0.01$, as reported in other studies.^{12,14,21} Based on past experience, between 1000 and 1100 patients were typically seen on these outreaches, and so this was a feasible number of patients that could be expected during the outreach. With respect to the analysis of the association, for which the use of linear multiple regression was envisioned, the commonly used rule of thumb requires 2 to 10 subjects per variable (SPV),²² such that the expectation was that recruiting between 1000 and 1100 patients should be sufficient to answer the research questions in mind with a good level of confidence. Because no

selection mechanism was applied during the sample recruitment, and the patients were seen across the whole country, we believe the study participants provided good coverage of a population with low socioeconomic status in the Dominican Republic.

Statistical Analysis

The CVD severity variable was defined to take 3 values: 0 = normal (healthy legs, C0); 1 = no ulcers (C1–C4[a,b]); 2 = ulcers (active and healed, C5–C6).

Because total ankle ROM is a continuous variable, a multiple linear regression model was fitted to measure the association between the severity of CVD and total ankle ROM. The regression was adjusted for age, gender, previous (nonrecent) leg trauma, and indicator for obesity, defined as $BMI \geq 30 \text{ kg/m}^2$. The regression model was fitted using the method of generalized estimating equations (GEE) to account for a correlation between the legs in the same person.²³ R software²⁴ was used to perform the analyses.

RESULTS

Nine hundred twenty patients attended this particular outreach clinic during the period of study. Of them, 838 consented to participate in the study. Basic descriptive statistics for all consenting participants are summarized in Table 1. The participants constituted a diverse age group (ages), with slightly more females than males. Twenty-four percent were found to be obese, having a $BMI \geq 30 \text{ kg/m}^2$, and 28% had had previous (nonrecent) leg trauma. CVD classification was obtained for 837 consenting participants,

Table 1. Basic Descriptive Statistics of the Study Sample ($n = 838$)

Variable	No. (%)
Gender	
Male	314 (38)
Female	523 (62)
N/A	1 (0)
Age	
<40	183 (22)
40–49	153 (18)
50–59	193 (23)
60–69	177 (21)
70–79	99 (12)
≥ 80	33 (4)
Body mass index, kg/m^2	
<18.5 (underweight)	37 (4)
18.5–24.9 (normal)	268 (32)
25–29.9 (overweight)	320 (38)
≥ 30 (obese)	199 (24)
N/A	14 (2)
Previous (nonrecent) leg trauma	
Had previous trauma	182 (22)
Did not have previous trauma	653 (78)
N/A	3 (0)

N/A, not available (missing data).

Fig 1. Algorithm of study participation. MSK, musculoskeletal; ROM, range of motion.

as data for 1 participant appeared to be missing, probably because of a technical error. Eight hundred thirty-five of the participants were then taken for measurement of ROM, as 2 were excluded because each had only 1 leg. Of these 835 participants, 25 were excluded from the subsequent analysis for issues identified during their CVD classification or ROM measurement. Fig 1 is an algorithm of study participation. No participants presented wearing any form

of compression stocking. Table 2 summarizes the numbers of people in each C category of the CEAP for each leg.

Eight of the 837 patients for whom CVD classification was obtained had venous ulcers (healed or active) on at least 1 leg. Descriptive statistics for the average ankle total ROM and sample sizes for the 3 CVD groups for each leg are summarized in Table 3 for the 810 relevant participants. The results in Table 3 reveal a 31% to 33% relative

reduction in average ankle ROM between the ulcer group and the normal group, consistent in both legs. This finding was confirmed by a strongly significant decrease of approximately 14° ($P = .0007$) in ankle ROM found in the regression analysis when comparing legs with ulcers to healthy legs (normal), adjusted for age, gender, indicator for obesity, and previous leg trauma. There was no significant difference in ankle ROM between legs with venous disorders but no ulcers (considered in this study to be classification C1 to C4b) and legs in the normal group.

Age was also found to be strongly significant in the regression analysis: there was a decrease of 0.16° ($P < .0001$) in ankle ROM for each year of aging (approximately 1.6° in 10 years). In addition, previous (nonrecent) leg trauma was associated with a significant decrease of approximately 1.8° ($P = .0275$) in ankle ROM, and obesity indicator was associated with a significant decrease of approximately 2° ($P = .0199$) in ankle ROM. The model did not reveal any association between gender and ROM.

DISCUSSION

This study was motivated by an observation made by a lead study investigator during her visits to the Dominican Republic. She observed that leg ulcers were neither bandaged nor covered in compression stockings. When asked, the patients described minimal wound care. Patients who attended the outreach clinic lived in an environment potentially demanding greater mobility for work and other activities, often involving traveling by foot or motorbike because of a lack of affordable transportation. Access to health care was limited for this patient group. Based on the experience of the outreach team, the researcher hypothesized there might be an association between the presence of venous leg ulcers and ankle mobility in this population.

The focus of this interprofessional study was to establish the association between CVD, particularly venous ulcers, and ankle ROM, for a large observational sample of participants from various locations throughout the Dominican Republic. Previous studies established this association for very selective populations^{4,9,10} (eg, white populations, populations with high socioeconomic status) and were characterized by relatively small sample sizes (not larger

Table 2. CEAP Classifications and Numbers of Participants in Each Class Based on Leg

Leg	C0	C1	C2	C3	C4a, C4b	C5	C6
Left	235	310	161	51	48	2	3
Right	230	316	162	50	48	2	2

C0, no visible or palpable signs of venous disease; C1, telangiectasis or reticular veins; C2, varicose veins; C3, edema; C4a, pigmentation or eczema; C4b, lipodermatosclerosis or atrophie blanche; C5, healed ulcer; C6, active ulcer; CEAP, classification method (clinical manifestations, etiology, anatomy, pathophysiology).

Table 3. Average Ankle Total Range of Motion and Sample Sizes for 3 CVD Groups^a

	Range of Motion (Sample Size)		
	Normal	CVDs, No Ulcers	CVDs, Ulcers
Left leg	53.64° (235)	50.53° (570)	36.00° (5)
Right leg	54.88° (230)	52.23° (576)	37.75° (4)

CVD, chronic venous disorder.

^a Normal (CEAP classification C0), CVD no ulcers (C1–C4b), CVD ulcers (C5 and C6).

than a few dozen participants). In contrast, our study sample consisted of 838 participants recruited from rural and low-income individuals who were seeking free chiropractic care offered by our mobile clinics. This sample was diverse with respect to age, gender, and BMI. The prevalence of venous ulcers (healed or unhealed) in this study was approximately 0.96%, which is comparable to the 1% found in Western countries as quoted by Fowkes et al.²¹ Regression analysis of the data revealed a statistically significant decrease in ankle ROM for participants with active and healed leg venous ulcers as compared with participants with healthy legs.

Risk factors that have been associated historically with venous disease and ulcers include obesity, gender and previous pregnancies,²⁵ older age, previous leg injuries, deep venous thrombosis, and phlebitis.⁸ In our study, we used some of these same factors (obesity, gender, age, and previous nonrecent leg trauma) to adjust for the association between leg ulcers and ankle ROM. Of these 4 factors, age, obesity, and previous (nonrecent) leg trauma exhibited a significant contribution to the decrease in ankle ROM.

There is agreement in the literature^{4,9,10} that venous leg ulcers are associated with a decrease in ankle ROM. Simka states that calf muscle pump function (MPF) in some patients is related to decreased mobility of the ankle joint caused by painful ulceration in the ankle area.⁵ Klyscz et al²⁶ state that chronic venous congestion affects not only the skin, causing ulcerations, but also the Achilles tendon and joint capsules of the talocrural and talocalcaneal joints. This leads to a reduction in mobility and possibly even a foot equinus position, which in turn impairs calf MPF. This latter syndrome is called arthrogenic compressive syndrome.

Although some studies report on the benefit of exercise intervention on MPF²⁵ and ankle mobility,²⁷ Klyscz et al²⁶ comment that exercises alone do not change the “hemodynamically insufficient” gait patterns that people with arthrogenic compressive syndrome display. Their study²⁶ focused on passive mobilization of the ankle joint of elderly patients with CVI and arthrogenic compressive syndrome by a therapist and simultaneous exposure of the lower extremity to vibrations from a biomechanical stimulation machine. This intervention caused significant improvement in ankle range and gait, and participants tolerated the intervention well. They also found that transcutaneous oxygen tension in the border around venous leg ulcers increased significantly, which was clinically noticeable as improved wound healing.²⁶

The machinery used in Klyszcz et al's study would not likely be available or would be too costly for people in low- or middle-income countries such as the Dominican Republic. To our best knowledge, no studies have determined the effect of low-cost manipulative and other manual therapy of the ankle, alone or in combination with exercises, on MPF and on ROM in persons with CVI or venous ulcers, and therefore, this question remains open.

Limitations

Restricted field conditions and lack of electrical power prevented us from using diagnostic equipment that would allow classification of the stages of venous disorders using the full CEAP system. Because these conditions were anticipated in advance, we used the expertise of general medical doctors in both the data collection and the classification of CVD and venous ulcers, together with a general surgeon who provided a secondary and independent evaluation of the ulcer photographs. Ideally, we would have liked to have had a vein specialist as part of our team, but 1 was not available to us. Thus, reduced accuracy in classification was a limitation of this study. A larger sample size in this study, 6000 to 9000 participants, would have allowed a higher precision of our secondary objective of a prevalence estimate. This study did not cover the analysis of risk factors for venous disease or ulcers in this population as part of the analysis of prevalence. Future studies could focus on the role of low-cost manipulative therapy of the ankle to improve ROM and, further, to measure any improvement in muscle pump function.

CONCLUSION

In this sample population in the Dominican Republic, venous ulcers of the legs, classified using primarily the clinical (C) portion of the CEAP venous classification system, were found to be associated with a reduction in ankle total ROM measured with a modified inclinometer.

FUNDING SOURCES AND CONFLICTS OF INTEREST

No funding sources or conflicts of interest were reported for this study.

CONTRIBUTORSHIP INFORMATION

Concept development (provided idea for the research): P.A.T., A.F., R.A.L.

Design (planned the methods to generate the results): P.A.T., A.F., N.G.

Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): P.A.T., R.A.L., V.L.

Data collection/processing (responsible for experiments, patient management, organization, or reporting data): P.A.T., N.G., A.F., V.L., R.A.L.

Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): V.L., P.A.T.

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Writing (responsible for writing a substantive part of the manuscript): P.A.T., V.L., N.G.

Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): P.A.T., V.L., N.G., A.F., R.A.L.

Other (translation of institutional review board and all forms used into Spanish): A.F., N.G., R.A.L.

Practical Applications

- Chiropractors and other manual therapists serving patient groups in low- and middle-income communities should examine their patients' legs for clinical signs of venous insufficiency.
- They should measure for, and consider treating, any ROM deficit using conservative manual therapy.
- Patients can then be educated on the association between ankle ROM and venous leg ulcers and encouraged to maintain good ROM through exercise and other therapy.

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