DEPARTAMENTO DE MEDICINA LEGAL, TOXICOLOGÍA Y ANTROPOLOGÍA FÍSICA

FACULTAD DE MEDICINA

UNIVERSIDAD DE GRANADA

ESTUDIO EXPERIMENTAL CLÍNICO-FUNCIONAL MEDIANTE DOS MODALIDADES DE VENDAJE NEUROMUSCULAR (KINESIO TAPING) EN EL PACIENTE CON RIESGO EVOLUTIVO DE INSUFICIENCIA VENOSA.

SHORT-TERM EFFECTS OF TWO KINESIO TAPING APPLICATIONS IN PATIENTS WITH RISK OF SEVERE CHRONIC VENOUS INSUFFICIENCY.

TESIS DOCTORAL INTERNACIONAL/INTERNATIONAL PhD THESIS

MªENCARNACIÓN AGUILAR FERRÁNDIZ

SEPTIEMBRE 2012

Editor: Editorial de la Universidad de Granada
Autor: María Encarnación Aguilar Ferrándiz
D.L.: GR 86-2013
ISBN: 978-84-9028-279-3

A mis padres, mi hermana Anita e Ismael

ESTUDIO EXPERIMENTAL CLÍNICO-FUNCIONAL MEDIANTE DOS MODALIDADES DE VENDAJE NEUROMUSCULAR (KINESIO TAPING) EN EL PACIENTE CON RIESGO EVOLUTIVO DE INSUFICIENCIA VENOSA.

Esta Tesis doctoral ha sido realizada bajo la dirección de:

Prof. Dra Dña Carmen Moreno Lorenzo

Prof. Dra Dña Adelaida Mª Castro Sánchez

UNIVERSIDAD DE GRANADA

Departamento de Fisioterapia
Universidad de Granada

Dña Carmen Moreno Lorenzo, PROFESORA TITULAR DEL DEPARTAMENTO DE FISIOTERAPIA DE LA UNIVERSIDAD DE GRANADA

CERTIFICA:

Que la tesis doctoral titulada: **"Estudio experimental clínico-funcional mediante dos modalidades de vendaje neuromuscular (Kinesio Taping) en el paciente con riesgo evolutivo de Insuficiencia Venosa"** que presenta Dña Mª Encarnación Aguilar Ferrándiz al superior juicio del Tribunal que designe la Universidad de Granada, ha sido realizada bajo mi dirección y tutela, siendo expresión de la capacidad técnica e interpretativa de su autora, dando mi conformidad para que sea presentada, leída y defendida para optar al grado de **DOCTOR** con **MENCIÓN INTERNACIONAL** ante el Tribunal que le sea asignado. Y para que conste y surta efecto donde proceda, expido el presente certificado.

Fdo. Dr. Carmen Moreno Lorenzo

En Granada, 3 de Septiembre de 2012

Avenida de Madrid s/n.
18071.Granada.
Tlf:+34958248032

Departamento de Enfermería y Fisioterapia
Universidad de Almería

Dña Adelaida Mª Castro Sánchez, PROFESORA CONTRATADA DOCTORA DEL DEPARTAMENTO DE ENFERMERIA Y FISIOTERAPIA DE LA UNIVERSIDAD DE ALMERÍA

CERTIFICA:

Que Dña Mª Encarnación Aguilar Ferrándiz ha realizado su Memoria de Tesis Doctoral titulada: **"Estudio experimental clínico-funcional mediante dos modalidades de vendaje neuromuscular (Kinesio Taping) en el paciente con riesgo evolutivo de Insuficiencia Venosa"**, bajo mi tutela y dirección para optar al grado de **DOCTOR INTERNACIONAL** por la Universidad de Granada, dando mi conformidad para que sea presentada, leída y defendida ante el Tribunal que le sea asignado para su juicio crítico y calificación. Y para que conste y surta efecto donde proceda, expido el presente certificado.

Fdo. Dra. Adelaida Mª Castro Sánchez

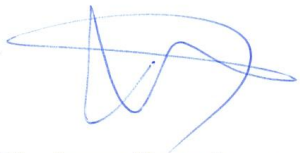
En Almería, 3 de Septiembre de 2012

Carretera de sacramento s/n.
04120. Almería.
Tlf:+34950214516
Fax: 34950214384

El doctorando/a Mª Encarnación Aguilar Ferrándiz y los directores de la tesis "**Estudio experimental clínico-funcional mediante dos modalidades de vendaje neuromuscular (Kinesio Taping) en el paciente con riesgo evolutivo de Insuficiencia Venosa**" Garantizamos, al firmar esta tesis doctoral, que el trabajo ha sido realizado por el doctorando bajo la dirección de los directores de la tesis y hasta donde nuestro conocimiento alcanza, en la realización del trabajo, se han respetado los derechos de otros autores a ser citados, cuando se han utilizado sus resultados o publicaciones.

Granada, a 3 de septiembre de 2012

Director/es de la Tesis



Fdo.: Carmen Moreno Lorenzo

Doctorando

Fdo.: Mª Encarnación Aguilar Ferrándiz

Fdo.: Adelaida Mª Castro Sánchez

ÍNDICE/ TABLE OF CONTENTS

RESUMEN

La Insuficiencia venosa crónica (IVC) es una patología prevalente, con unos signos y síntomas característicos que generan un gran coste socioeconómico e impacto sobre la calidad de vida. El dolor, a pesar de ser un síntoma recurrente en esta patología, ha sido poco estudiado. La terapia de compresión es el método estándar para el tratamiento no invasivo de la IVC, sin embargo, la existencia de una escasa adherencia del paciente a este tipo de tratamiento ha sido descrita.

Kinesio Taping es una nueva técnica de vendaje neuromuscular que puede ejercer efectos sobre la función muscular y articular, disminuir el dolor e influir en la circulación linfovenosa. No se han encontrados estudios previos sobre la aplicación de este vendaje en pacientes con IVC.

Los objetivos principales de esta tesis doctoral son describir las características del dolor en las mujeres posmenopáusicas con insuficiencia venosa crónica y su relación con los factores de riesgo; y evaluar la efectividad de dos modalidades de vendaje neuromuscular (Kinesio Taping) sobre las alteraciones músculoesqueléticas, la sintomatología venosa específica, dolor, severidad y calidad de vida en mujeres posmenopáusicas con riego evolutivo de IVC severa (CEAP C1-C3).

Un total de 259 pacientes con IVC inicial y 40 mujeres sanas que cumplieron los criterios de inclusión, fueron involucradas en los estudios de esta tesis.

Los principales hallazgos y conclusiones son: a) mujeres posmenopáusicas con IVC presentan una intensidad del dolor patológica y una disminución de los umbrales nociceptivos, sugiriendo existencia de sensibilización central. El dolor esta principalmente relacionado con el reflujo venoso periférico y con el dolor y limitación funcional inducido por artrosis de rodilla o cadera, b) el dispositivo Pain Matcher parece ser una técnica válida para la evaluación del dolor crónico venoso, c) la aplicación de un vendaje estandarizado con Kinesio taping en mujeres posmenopáusicas con riesgo evolutivo de IVC severa puede reducir la sintomatología venosa específica, el dolor, la severidad clínica e incrementar la actividad bioeléctrica de gastronemio, d) la modalidad

de vendaje mixta Kinesio taping-compresión periférica, parece mejorar la flexión dorsal del tobillo durante el paso, los parámetros de marcha, el flujo venoso periférico, la sintomatología venosa específica, el edema a nivel de pie y maléolos, el dolor, la severidad clínica, la calidad de vida e incrementar levemente el estado de salud general, en las mujeres posmenopáusicas con riesgo evolutivo de IVC severa, e) Kinesio taping puede tener un efecto placebo en el dolor venoso.

Nuestros hallazgos ayudan a esclarecer los mecanismos implicados en el dolor por insuficiencia venosa crónica y apoyan el uso de Kinesio taping como vendaje alternativo para el manejo de los síntomas de la patología venosa en fases iniciales.

ABSTRACT

Chronic venous insufficiency (CVI) is a prevalent pathology, with some typical signs and symptoms that cause significant socio-economic cost and impact on quality of life. Pain, despite being a recurrent symptom in this pathology, has scarcely been studied. Compression therapy is the standard method for non-invasive CVI treatment; however, it has been indicated that the patient seldom follows this type of treatment.

Kinesio Taping is a new technique of neuromuscular bandaging that can affect muscular and joint function, decrease pain and influence lymph and venous circulation. No previous studies have been found on the application of this bandaging on patients with CVI.

The main objectives of this doctoral thesis are to describe the characteristics of pain in postmenopausal women with CVI and its relationship with risk factors; and assessing the efficacy of two application of neuromuscular bandaging (Kinesio Taping [KT]) on musculoskeletal alterations, specific venous symptomatology, pain, severity and quality of life in postmenopausal women at short-term risk of severe CVI (CEAP C1-C3).

A total of 259 patients with initial CVI and 40 healthy women that fulfilled the criteria for inclusion participated in the studies for this thesis.

The main findings and conclusions are: a) postmenopausal women with CVI present intense pathological pain and lowered nociceptive thresholds, suggesting that there is central sensitization; the pain is principally related with peripheral venous reflux and with the pain and functional limitation induced by knee or hip osteoarthritis; b) the use of the Pain Matcher device seems to be a valid technique for assessing chronic venous pain; c) applying standardised bandaging with KT in postmenopausal women at short-term risk of severe CVI can reduce the specific venous symptomatology, pain and clinical severity and increase the bioelectric activity of the gastrocnemius muscle; d) the method of mixed KT-peripheral compression seems to improve ankle dorsiflexion during walking, gait parameters, peripheral venous flow, specific venous symptomatology, foot and malleolar oedema, pain, clinical severity and quality of life,

while it increases the general state of health slightly, in postmenopausal women at risk of short-term severe CVI; and e) KT can have a placebo effect on venous pain.

Our findings help to clarify the mechanisms involved in pain from CVI and support the use of KT as an alternative bandaging technique for managing the symptoms associated with venous pathology in initial stages.

ABREVIATURAS

IVC	Insuficiencia Venosa Crónica
CEAP	Clasificación Clínica-Etiológica-Anatómica-Fisiopatológica
DT	Desviación Típica
GM	Gastronemio
SVS	Society for Vascular Surgery
AVF	American Venous Forum
EVS	Enfermedad Venosa Severa
VCSS	Indice Clínico de Severidad Venosa
KT	Kinesio Tapin

ABBREVIATIONS

CVI	Chronic Venous Insufficiency
CEAP	Clinical-etiologic-anatomic-pathophysiologic classification
SD	Standard Desviation
GM	Gastrocnemius
SVS	Society for Vascular Surgery
AVF	American Venous Forum
EVS	Enfermedad Venosa Severa
VCSS	Indice Clínico de Severidad Venosa
KT	Kinesio Taping
ROAM	Range Of Ankle Motion
CA	Calf
P	Perimalleolus
PF	Popliteal Fossa
VAS	Visual Analogue Scale
MPQ	McGill Pain Questionnaire
r_s	Spearman Correlation coefficient
WOMAC	Western Ontario McMaster University Osteoarthritis Index
β,	Adjusted coefficient from multiple linear regression analysis
SE	Coefficient standard error
r^2	Regression coefficient of determination
VRT	Venous refill time
VDS	Venous Disability Score
Grade 0	Asymptomatic

Grade 1	Symptomatic, works without external support
Grade 2	Symptomatic, can only work with external support (8 h/day)
Grade 3	Complete employment disability
RLL	Right Lower Limb
LLL	Left Lower Limb
FC	Foot Circumference
MC	Malleolus Circumference
CC	Calf Circumference
PM	Pain Magnitude
PT	Pain Threshold
CIVIQ	Quality of life questionnaire in chronic venous insufficiency
ANCOVA	Analysis of Covariance
PPI	Present Pain Intensity
PRI	Pain Rating Index
DF	Dorsal Foot
EC	External Calf muscle
VPP	Venous Pump Power

INRODUCCIÓN

INTRODUCTION

1. INTRODUCCIÓN

1.1 Insuficiencia venosa crónica: concepto, prevalencia, manifestaciones clínicas y coste socio-económico.

La Insuficiencia venosa crónica (IVC) es una condición patológica del sistema venoso que se caracteriza por una hipertensión crónica periférica de miembros inferiores, como consecuencia del reflujo venoso y/o obstrucción y alteración de la bomba muscular periférica.[1] Esta situación viene determinada por la existencia de anormalidades en la pared venosa y valvular, que producen una incapacidad funcional para conducir el flujo sanguíneo en dirección centrípeta, adaptado a las necesidades de drenaje de los tejidos, termorregulación y reserva hemodinámica, con independencia de la posición y actividad.[2]

La prevalencia de la IVC a nivel mundial es elevada (83,6%), afectando principalmente a los países occidentales.[3] El 63,9% corresponde a sujetos pertenecientes a las clases C1-C6 según la clasificación Clínica-Etiológica-Anatómica-Fisiopatológica (CEAP), siendo más frecuente en el sexo femenino.[3] El rango de posibilidades de enfermedad venosa en la mujer con respecto al hombre va de 4:1 a 10:1, dependiendo de los distintos estudios[4-7], sin embargo, recientemente, Rabe et al[3] 2012 en un estudio multicéntrico sobre 91.545 pacientes de diferentes zonas geográficas manifiestan, que el sexo femenino es más prevalente en los estadios iniciales de la enfermedad (C1-C3), mientras que en las fases de mayor severidad (C4-C6) no existen diferencias en la ratio de afectación hombre-mujer. Álvarez et al[8] 2008, en el estudio DETECT-IVC 2006 sobre población española, encuentran que un 62% de los pacientes que acuden a las unidades de Atención Primaria por otros motivos de consulta, presentan algún tipo de signo de IVC en el examen físico y el 38% de los sujetos se encuentran dentro de los grupos C2-C6, siendo el sexo femenino el más predominante (64%). El promedio de inicio de la enfermedad parece ser más temprano en las mujeres con respecto a los hombres, así la edad media para las primeras es de 34±14 años (DT) frente a 41±14 años (DT) en los varones.[7] Estudios recientes[3] sitúan la edad media en la población general en 50,6±16,9 años. La progresión de la enfermedad se da en un período de

13+11 años (DT)[7], incluyendo en estos intervalos etarios a la población económicamente activa, de ahí su importante repercusión a nivel socio-laboral.

Los síntomas y signos más frecuentes en la IVC son la sensación de pesadez, hinchazón, picor, dolor, calambres musculares, edema y en fases más avanzadas, eczema venoso, hiperpigmentación de la piel, atrofia blanca y ulceración.[8, 9] El dolor, es uno de los síntomas que, a pesar de su frecuencia, ha sido escasamente analizado. La hipótesis principal se basa en que el éstasis periférico incrementa la reacción inflamatoria endotelial, la cual se considera responsable de la estimulación nociceptiva de la pared vascular y tejidos circundantes.[10] Sin embargo, el establecimiento de un proceso de sensibilización central como consecuencia de la cronicidad de la propia patología y el desarrollo de neuropatía periférica, también puede ser uno de los factores relevantes.[11]

Por otra parte se confirma en estos pacientes la existencia de una alteración en la musculatura de la bomba muscular periférica. Qiao et al[12] 2005 estudian los cambios patológicos y metabólicos a nivel del músculo gastronemio (GM) en pacientes con patología venosa, en los que encuentran múltiples alteraciones: atrofia miofibrilar, desnaturalización celular y necrosis, infiltración de células inflamatorias, proliferación venosa interfascicular y dilatación, agrupación de fibras atróficas (especialmente de fibras tipo I) y atrofia moderada-severa de fibras musculares tipo II. Estos autores exponen, que estas alteraciones fisiopatológicas a nivel de GM junto con la hipertensión venosa prolongada están asociadas con la afectación funcional de la bomba muscular de la pantorrilla. En este sentido, estudios recientes[13] sobre el grado de oxigenación de este músculo (GM) en pacientes con diferentes fases de IVC, muestran la existencia de desoxigenación muscular, siendo más marcada en los estadios de mayor severidad (C4-C6). La compresión ejercida por la contracción de bomba muscular periférica sobre el componente venoso, es uno de los mecanismos fundamentales para reducir el éstasis periférico, por tanto, la alteración funcional en esta musculatura se señala como un factor agravante y perpetuador de la enfermedad venosa en el tiempo.[1,12] Otro mecanismo implicado en el retorno venoso, es el rango de movimiento del tobillo, especialmente el movimiento de flexión dorsal, cuya restricción genera un impacto negativo sobre la hemodinámica circulatoria venosa.[14] En este sentido, son numerosos los estudios[15, 16] que ponen de manifiesto la existencia de una reducción del rango de

movimiento del tobillo en pacientes con IVC, correlacionándose la movilidad articular de forma inversa con respecto al grado de severidad de la patología (menor rango articular, mayor grado de afectación venosa). Además, la restricción articular junto con la debilidad de la musculatura de la bomba venosa periférica se asocian con la aparición de patrones de marcha patológica.[17]

Todas estas alteraciones, presentes en la enfermedad venosa, generan un alto coste económico sanitario y un gran impacto sobre la calidad de vida de los sujetos que la padecen. En este sentido se observa que la terapéutica aplicada en úlceras y otras heridas en la piel de estos pacientes, generan en Estado Unidos en el año 2004 un gasto sanitario de 9,7 millones de dólares en costes directos y 2,2 millones en costes indirectos.[18] No obstante, si se considera el tratamiento hospitalario y ambulatorio de este tipo de pacientes, se estima un coste sanitario promedio por paciente de 9.685 dólares cuyo mayor porcentaje corresponde al tratamiento médico domiciliario (48%) y más reducidos los costes que se generan en régimen hospitalario (25%) y ambulatorio (21%).[19] Sin embargo, estos valores subestiman el verdadero coste socio-sanitario puesto que no tiene en cuenta, las anticipaciones en la jubilación a causa de la patología, pérdida de la independencia funcional, sufrimiento o pérdidas laborales.[20] Autores como Gesto et al[16] 2001 observan que en España, un 2,1% de los pacientes con IVC, sufren baja laboral con rango promedio de 30 días y un 1,9% necesitan hospitalizarse una media de 9 días. Posteriormente, Álvarez et al[8] 2008, destacan que en España el 48% de los pacientes que manifiestan signos y síntomas de IVC los describen como con repercusión importante o grave, de forma que la baja laboral y la hospitalización se presentan en un 2,5 y 2% de los casos respectivamente. La media de la baja laboral que comunican, es de 30 días y la de la hospitalización alcanza los 8 días.

Por lo tanto, la insuficiencia venosa es una patología crónica, que afecta a un gran número poblacional, cuyas consecuencias a largo plazo (como son la úlcera venosa, alteraciones cutáneas graves o el riesgo de tromboembolismo periférico) generan un gran impacto socioeconómico.

1.2 Posmenopausia e Insuficiencia venosa crónica.

Las mujeres posmenopáusicas constituyen una población con una elevada prevalencia de insuficiencia venosa crónica, debido a que presentan una combinación de

varios factores de riesgo, como son edad avanzada, embarazos previos, estilo de vida sedentario e incremento de peso.[21] La edad avanzada y un índice de masa corporal elevado se han establecido como factores predictores de la severidad de la enfermedad venosa crónica. [22,23] El riesgo atribuible de patología venosa a la longevidad y el sexo femenino se ha estimado en un 10,7%, sin embargo la evidencia sobre la obesidad es controvertida.[23] A pesar de ello, el incremento de peso es un factor frecuentemente asociado en la etapa posmenopáusica, debido a los procesos ocurridos en fases anteriores. La menopausia en la mujer conlleva una serie de factores, como el sedentarismo, insuficiencia orgánica inespecífica, dieta poco ajustada, estreñimiento, estrés etc, que junto con los cambios hormonales que se producen en esta etapa, favorecen la presencia de trastornos metabólicos e hidroelectrolíticos que conducen, no solo a la obesidad, sino a una importante retención de líquidos (edema).[24] El aumento de peso afecta negativamente incrementando el éstasis periférico, reduciendo el mecanismo *"vis a fronte"* (diafragma en posición inspiratoria) y surgiendo reflujos centrífugos debido a la masa intestinal que comprime las venas ilíacas (afectando directamente a la unión safeno-femoral).[24]

Por otra parte, el número de embarazos que se producen durante el periodo fértil de la mujer, constituye otro factor que incrementa el riesgo de patología venosa en fase posmenopáusica. Durante el embarazo, existen tres factores que tienen efecto negativo sobre el componente circulatorio venoso: el factor endocrinológico, el mecánico y el nutricional.[1,25] Dicha confluencia hace que el 50% de las mujeres embarazadas tengan mayor riesgo de desarrollar IVC.[1] El factor endocrinológico consiste fundamentalmente, en el aumento de la progesterona (10 veces el nivel normal), que conlleva a una vasodilatación y distensibilidad generadora de una sobrecarga gestacional, con pérdida de la tonicidad de la pared venosa (inhibe la contracción del músculo liso). Inicialmente es un trastorno funcional pero posteriormente, puede convertirse en una insuficiencia valvular relativa por falta de coaptación de sus válvulas.[1] El factor mecánico se debe al aumento de la volemia circulante y a la compresión que el útero grávido ejerce sobre la vena cava inferior; principalmente se observa en el último trimestre del embarazo, aunado a la desembocadura de las venas uterinas y obturatrices que aumentan su calibre al doble y desembocan en las venas hipogástrica e ilíaca primitiva, actuando como tapón de la corriente circulatoria proveniente de los miembros inferiores.[1] El factor

nutricional, es el incremento de peso que se produce por el propio proceso y sus repercusiones hemodinámicas.[23]

La reducción en el nivel de actividad física constituye también un factor de riesgo de IVC en el periodo posmenopáusico.[26] La edad avanzada que caracteriza esta etapa, conlleva una serie de cambios como consecuencia del proceso de envejecimiento: artrosis, hipoplasia generalizada del tejido conjuntivo, disminución del tejido celular subcutáneo, atrofia muscular y limitación articular con insuficiencia de la bomba veno-muscular de la pantorrilla.[27] Todo ello, genera patrones de marcha patológicos[17], que implican mayor gasto energético, de forma que la actividad física habitual puede verse reducida. Además, la marcha constituye una actividad fundamental para un adecuado retorno venoso[28], de forma, que todas las posibles alteraciones ortopédicas que puedan comprometer el efecto de compresión que ejerce la musculatura sobre el calibre de la vena (deformidades plantares que impidan la estimulación de la suela venosa de Lejars, o restricciones en el tobillo que imposibiliten la compresión ejercida por la musculatura de la pantorrilla durante el movimiento de flexión dorsal) podrían estar en la base del incremento de éstasis periférico.[28-30] Asimismo, determinadas asunciones culturales han predispuesto a la utilización de un calzado inadecuado por parte del sector femenino, que restringe la movilidad articular y altera la marcha fisiológica (tacón superior a 3,5 cm), lo que incrementa las posibilidades de IVC.[31]

Por otra parte el riesgo de caídas se eleva en fases de edad avanzada, asociado al aumento de la fragilidad, como ocurre en la posmenopausia.[32] El traumatismo de miembros inferiores como consecuencia de las caídas y las operaciones quirúrgicas (síndrome post-trombótico) se consideran factores de riesgo para el desarrollo de la patología venosa. Asimismo, la actividad laboral de los pacientes durante su periodo activo, también puede configurar un factor causal de IVC. La actitud postural al cargar peso, las altas temperaturas, la humedad relativa del ambiente de trabajo, el ortostatismo profesional por largos periodos de tiempo, los desplazamientos reducidos durante la jornada, así como la sedestación prolongada pueden ejercer un efecto negativo sobre el éstasis periférico.[33] Las posiciones de sedestación y bipedestación estática incrementan la presión venosa periférica (80-100 mmHg)[34] y por tanto el éstasis, sin embargo, distintos especialistas consideran que la hipertensión generada por las condiciones de trabajo no es suficiente para el desarrollo de la enfermedad venosa, sino que el fallo

muscular, la existencia de obstrucción del flujo venoso, así como el establecimiento de complejos mecanismos inflamatorios constituyen factores causales de mayor relevancia.[34] Además, si la mujer posmenopáusica presenta antecedentes familiares de enfermedad venosa el riesgo es aún mayor. La existencia de una distribución hereditaria de la patología, es descrita por varios autores y aunque su determinación genética aún no es concluyente, Katrancioglu et al[35] 2010 observan que el polimorfismo PAI-1 alelo 4G se encuentra con una frecuencia significativamente mayor en los individuos con IVC, por lo que existen evidencias de asociación entre ambos.

1.3 Abordaje terapéutico de la Insuficiencia venosa crónica

La enfermedad venosa constituye una entidad patológica que por sus características es susceptible de una gran diversidad de terapéuticas, cuya eficacia presenta cierta controversia. A pesar de que se consiguen mejoras sintomatológicas y funcionales, no existe ninguna forma de tratamiento plenamente eficaz y duradera, aunque algunos autores señalan la cirugía abierta como la única opción con evidencias de eficacia a largo plazo.[36] Es por ello, que el enfoque preventivo supone la línea prioritaria de abordaje de esta patología en estadios iniciales.

El tratamiento preventivo incluye las siguientes medidas: [37, 38]

- Educación y adherencia del paciente al mantenimiento regular de una "Higiene venosa" : alimentación rica en fibra, mantener el índice de masa corporal dentro de la normalidad, evitar ortostatismo o estar sentado por tiempo prolongado, evitar uso de ropa ajustada y calzado con tacón, elevar la parte inferior de la cama a 15-20 cm, realizar ejercicios aeróbicos, marcha y natación, evitar ingestión de anovulatorios y complementos hormonales, lubricar la pierna constantemente evitando rascado u otros traumatismos, durante el día elevar los miembros inferiores 15 cm durante un mínimo de 10 minutos tres veces en el día; por la noche elevar la parte inferior de la cama, evitar la exposición prolongada al calor.

- Terapéuticas que permitan bloquear el reflujo y técnicas para la mejora del sistema de retorno circulatorio mediante el refuerzo de los mecanismos "*vis a tergo"* y "*vis a fronte"*: terapia compresiva y programa de rehabilitación fisioterapéutico pautado.

Estas medidas se utilizan frecuentemente en conjunción con otro tipo de tratamientos como son el consumo farmacológico[39-42](flebotónicos- flavonoides micronizados, diosmina, escina, hesperidina etc- antibióticos, oligoelementos, antioxidantes, medicina herbal), escleroterapia[43,44] o tratamiento quirúrgico[45] (ligadura de safena interna, externa (safenectomía) o ambas combinada con fleboexéresis de vena insuficiente; ligadura y sección de venas comunicantes insuficientes; ligadura y sección de venas perforantes y microcirugía). Los criterios de elección del tratamiento deben estar orientados hacia una multidisciplinaridad y los objetivos deben de ser adaptados en función de la edad del paciente, factores de riesgo, estado de salud general y parámetros clínicos entre otros, sin embargo, el compromiso estético que supone la presentación de varices, ha llevado a priorizar la utilización de técnicas como la escleroterapia o microcirugía.

La nueva guía de práctica clínica basada en la evidencia[36] para la evaluación y tratamiento de las venas varicosas, desarrollada por Venous Guideline Committee of the Society for Vascular Surgery® (SVS) and the American Venous Forum (AVF) en 2011, establece nueve recomendaciones básicas para el abordaje terapéutico de esta afección en función de los riesgos, la carga y el coste económico de la terapéutica (Grado 1: los beneficios superan claramente los riesgos, carga y coste económico; Grado 2: La recomendación es leve, ya que los beneficios están estrechamente equilibrados con los riesgos y carga que supone la acción terapéutica) y en función del nivel de evidencia que la sustenta (Calidad A: alta; B:media; C:baja o muy baja):

1. La evaluación del paciente con venas varicosas o enfermedad venosa severa (EVS), requiere la realización de una historia clínica completa, examen físico detallado y pruebas complementarias como ecografía doppler del sistema venoso superficial y profundo (Grado 1A).

2. Utilización de la escala CEAP (clasificación Clínica-Etiológica-Anatómica-Fisiopatológica de insuficiencia venosa crónica) para la identificación del estadio patológico del paciente (Grado 1A) y el índice clínico de severidad venosa (VCSS) para la evaluación de la eficacia del tratamiento (Grado 1B).

3. Utilización de la terapia compresiva en el paciente con venas varicosas sintomáticas (Grado 2C), sin embargo no se recomienda esta opción de forma primaria si el paciente es candidato a la ablación de la vena safena (Grado 1B).

4. Utilización de la terapia compresiva como tratamiento primario para ayudar a curación de la ulceración venosa (Grado 1B).

5. Utilización regular de la terapia compresiva junto con la ablación de las venas superficiales incompetentes, para disminuir la recurrencia de úlcera venosa (Grado 1B).

6. Para el tratamiento de la incompetencia de la vena gran safena recomiendan la ablación térmica endovenosa (mediante láser o radiofrecuencia) sobre ligadura alta y "stripping" de inversión de la vena safena a nivel de la rodilla (Grado 1B).

7. Realización de flebectomía o escleroterapia para el tratamiento de venas varicosas tributarias (Grado 1B) y sugieren la escleroterapia con espuma como opción terapéutica ante la incompetencia de la vena safena (Grado 2C).

8. No recomiendan el tratamiento selectivo de la incompetencia de las venas perforantes en pacientes con enfermedad varicosa simple (CEAP clase 2; Grado 1B), sin embargo, sugieren el tratamiento de las venas perforantes patológicas (reflujo de 500 ms de duración y diámetro venoso de 3.5 mm) localizadas en la zona de las úlceras cicatrizadas o de úlceras activas (CEAP C5 y C6; Grado 2B).

9. Recomiendan el tratamiento del síndrome de congestión pélvica o varices mediante embolización, escleroterapia o cateterismo de forma aislada o combinada.

Desde el área de la rehabilitación física, el "gold standard" para el tratamiento fisioterapéutico de la IVC consiste en realización de una actividad física adaptada, pautada y orientada a la reeducación de la bomba muscular periférica y estimulación de mecanismos de retorno venoso, junto con una adecuada terapia compresiva.[46] Diferentes estudios[47-50] muestran que la marcha regular, la cinesiterapia activa como el ejercicio de flexión y extensión de la articulación tibio-peronea-astragalina en posición de bipedestación, flexión y extensión de las articulaciones interfalágicas-metacarpofalángicas, la flexión dorsal del tobillo con estiramiento de gastronemio

durante la posición de sedestación, contracción conjunta de toda la musculatura de miembros inferiores mediante bicicleta estática (se aconseja la utilización de bicicleta o pedales estáticos que permitan que el paciente se encuentre en sedestación o decúbito supino, sobre todo en pacientes con patología osteoarticular de rodilla) y trabajo abdomino-diagfragmático (incremento de la fase de inspiración mientras el paciente está en bipedestación y de la fase de espiración cuando el paciente está en decúbito supino) estimulan de forma efectiva los mecanismos de retorno circulatorio y mejoran la hemodinámica venosa. Para la consecución de cambios estructurales, dado el contexto de cronicidad, el protocolo de cinesiterapia debe aplicarse durante largos periodos (mínimo un hora al día, de lunes a viernes, con intervalos de descanso de 10-15 minutos) a una ritmicidad lenta. Además existen otras técnicas fisioterapéuticas que se incluyen en el protocolo de tratamiento de estos pacientes de forma efectiva como es el drenaje manual[51, 52], tratamiento de liberación miofascial[53] y presoterapia neumática intermitente[54]. La presoterapia en sentido anterógrado muestra efectos beneficiosos a corto plazo (un mes de seguimiento) sobre el edema periférico, la congestión venosa y el volumen total del miembro.[54] Asimismo, los programas de hidroterapia termal[55] parecen producir una mejora del éstasis periférico, sin embargo la evidencia científica no aporta información concluyente en este aspecto. Además también se pone de manifiesto la importancia del abordaje de esta patología de una forma global en conexión con el sistema linfático (edema linfovenoso)[56], de ahí que existan evidencias para la utilización del drenaje linfático manual de forma conjunta con las medidas específicas anteriormente mencionadas.[52,56]

Así pues la multiplicidad de tratamientos con indicios de efectividad limitada en la enfermedad venosa crónica, sobre todo en aquellas terapéuticas menos invasivas, pone de manifiesto, la necesidad de nuevas investigaciones bajo metodologías exhaustivas que permitan esclarecer la durabilidad, seguridad y eficacia a largo plazo de estas terapéuticas.

1.3.1 Evidencia científica sobre la utilización de la Terapia compresiva en el tratamiento de la Insuficiencia venosa crónica.

Los dispositivos de compresión (vendajes o medias) tienen la función de aplicar sobre la superficie del miembro una presión que compense las presiones intravasculares

patológicas. Durante la marcha dicha presión se incrementa con la contracción muscular y disminuye durante la relajación, creando un efecto bombeo a nivel superficial y profundo que aumenta la velocidad de retorno, disminuye la hipertensión venosa y favorece la reabsorción de edema.[57,58] Además, al disminuir el calibre de las venas del sistema superficial, fija los trombos a la pared venosa evitando su extensión y migración.[58]

La presión a aplicar con la media o el vendaje compresivo va a depender del estadio evolutivo de IVC en el que se encuentre el paciente. Generalmente en las fases iniciales una presión entre 30 a 50 mmHg es suficiente. Sin embargo, su indicación va a estar supeditada a la existencia de otras patologías asociadas, como es el caso de la enfermedad arterial y su severidad.[59-61] En una reciente revisión realizada por O'Meara et al[62] 2009 sobre los distintos sistemas actuales de medias y vendajes de compresión para la IVC se pone de manifiesto que en cuanto al número de capas y compresión ejercida, los sistemas de varios componentes o capas son más eficaces frente a los de un solo componente, de forma que cuanto mayor es la compresión parece que se incrementan las tasas de curación de úlceras.[62,63] Por otro lado, sistemas de varios componentes que contienen un vendaje elástico parecen ser más efectivos que aquellos cuyos componentes están constituidos principalmente por material inelástico. Los autores concluyen que aunque su uso puede estar relacionado con una disminución del dolor y sensación de pesadez, entre otros efectos positivos, no existe actualmente evidencia científica suficiente que lo sustente, dado la aparición de efectos adversos y un alto índice de retirada según algunos estudios.[62] A pesar de estas conclusiones, existe cierta controversia en cuanto al uso de vendas elásticas-inelásticas, de forma que distintos autores mantienen que los componentes elásticos son más efectivos cuando la afectación es a nivel superficial, mientras que los inelásticos reportan mayores beneficios cuando la alteración es a nivel profundo.[59,60] En esta misma línea se establece un importante debate científico en relación a la aplicación de una presión progresiva o degresiva. En los sistemas convencionales la presión debe ser máxima en pies y tobillos y se aplica desde la base de los dedos del pie hasta la tuberosidad tibial, con gradiente decreciente hasta el extremo proximal, lo que permite al mismo tiempo el juego articular normal.[60] Sin embargo, recientemente Couzan et al[64] 2009, realizan un estudio multicéntrico en 130 pacientes franceses con el objetivo de evaluar un nuevo

concepto progresivo (mayor presión a nivel de pantorrilla, menor presión a nivel de pie y tobillo) de las medias de compresión versus medias de compresión clásicas de presión decreciente para la clase 2 en pacientes con insuficiencia venosa leve sin edema permanente (C0-C1-C2). Los autores observan que tras 15 días de aplicación, la sensación de pesadez desaparece o mejora en el 73% de los casos con nuevas medias frente al 62,5% de los pacientes con medias convencionales. Los autores concluyen que la aplicación de presión degresiva es tan eficiente como la progresiva, si bien se observa en estas últimas mayor adherencia en cuanto a su uso habitual. En esta línea, Mosti y Partsch[65] 2012 concluyen de forma específica, que los pacientes con incompetencia venosa severa obtienen mayores beneficios hemodinámicos con la utilización de vendajes progresivos inelásticos, con mayor presión en pantorrilla que tobillo, especialmente en la bipedestación estática y durante la marcha. Resultados menos alentadores muestran Cohen, AKL y Kahn[66] 2012 en cuanto a la función preventiva de la terapia compresiva frente al síndrome postrombótico, y afirman que la evidencia existente es limitada y de baja calidad debido, entre otras causas, a la falta de estandarización de las escalas de medida, déficit en el sistema de cegamiento de los ensayos clínicos randomizados y la inclusión únicamente de evaluaciones a corto plazo.

A pesar de este déficit de consistencia científica en cuanto a las distintas modalidades de aplicación[67], la terapia compresiva sigue siendo uno de los pilares fundamentales en el tratamiento clínico de la IVC. Su utilización de forma aislada o combinada con otras terapéuticas parece ser eficaz en esta patología[36], sin embargo existe una falta de adherencia del paciente a este tipo de tratamiento. Heinen et al[46] 2007 establecen la existencia de un déficit de adherencia en un 33% de los pacientes que necesitan terapia compresiva y observan como causas más frecuentes la existencia de disconfort, dolor, exudados, irritaciones cutáneas, dificultades en la aplicación y razones estéticas. En este sentido, se manifiestan más recientemente Van Hecke, Grypdonck, y Defloor[68] 2009, y señalan como causas de no adherencia la percepción de dolor, disconfort, dificultades de aplicación, alteraciones de la piel, uso no confortable con la ropa o el calzado, la aplicación incorrecta por parte del paciente o falta de información en cuanto a su uso adecuado por parte de los profesionales de salud.

Por lo tanto la terapia compresiva es una opción terapéutica óptima que requiere de la realización de investigaciones sólidas que permitan por un lado clarificar la

estandarización de los métodos de aplicación y por otra, trabajar en nuevos modelos de vendaje que incrementen la adherencia del paciente a este tipo de tratamiento.

1.3.2 Vendaje Neuromuscular con KinesioTaping®

La técnica Kinesio taping (KT) se origina en Asia en los años 70, y se desarrolla fundamentalmente en Japón y Corea, siendo su máximo creador el Dr. Kenzo Kase. Kenzo desarrolla unas cintas elásticas longitudinalmente, que presentan un preestiramiento del 10% con posible incremento hasta un 140%-160%, compuestas el 100% por fibras de algodón con un pegamento acrílico sensible al calor, a través de las cuales, podía normalizar la función muscular, disminuir el dolor, influir en la circulación linfática y además corregir los problemas articulares.[69] A diferencia de los sistema de vendaje convencionales, la superficie de apoyo de dichas vendas, no es simétrica ni longitudinal, sino que presenta unas ondulaciones en forma de "S" serpenteante, que ayudarán a la formación de "convoluciones" sobre la piel.[70] Además es resistente al agua y se activa con el calor, de ahí que gracias a la propia temperatura corporal, pueda mantenerse durante un mínimo de cuatro días sin que exista una pérdida excesiva de sus propiedades.[71]

Aunque sus mecanismos de actuación aún no son bien conocidos se cree que actúa sobre la función neuromuscular, a través de la estimulación de mecanorreceptores.[71] Las deformaciones (convoluciones) creadas con el vendaje, conllevan un levantamiento de la piel que actúa generando zonas de hipopresión en los tejidos subyacentes.[72] Este hecho hace que se produzca un movimiento de los fluidos desde las zonas de mayor presión hacia las zonas hipopresivas, mejorando así el drenaje circulatorio y ejerciendo un efecto linfático superficial.[73] Además la disminución de la presión intersticial reduce la estimulación nociceptiva, deprimiendo así la sensación dolorosa. Tsai et al[74], en 2009 comprueban como un tratamiento estándar de terapia descongestiva linfovenosa (cuidado de la piel, drenaje manual, compresión neumática) al que se le asocia o bien un vendaje multicapa o bien kinesio tape, obtiene similares resultados a la hora de disminuir el edema. Sin embargo, kinesio tape presenta ventajas frente al vendaje multicapas: mayor aceptación por parte del paciente, menor dificultad al usarse, mayor durabilidad del vendaje y aumento del confort, lo que hace concluir a los autores que el kinesio tape podría remplazar al vendaje multicapa dentro de este tipo

de tratamiento. En este sentido, Lipinska and Sliwinski[75] 2009, en su estudio sobre 104 mujeres con linfedema posmastectomía verifican que el vendaje con kinesio taping no solo mejora la reducción del edema frente al drenaje linfático y el vendaje multicapa sino que también es mayor el aumento de los rangos de movimiento en la extremidad superior. No se han encontrado estudios de la aplicación de KT en pacientes con insuficiencia venosa crónica.

Además del efecto circulatorio, se le atribuye a kinesio tape un efecto mecánico y propioceptivo, mediante el cual puede influir sobre la normalización muscular y posición articular.[71,76] A nivel del tono muscular, gracias a la tendencia de la venda de recogerse hacia su punto inicial de vendaje (por su elasticidad), el anclaje final tiende a retornar hacia el inicio, de forma que podemos conseguir aumentar o disminuir el tono en función de la dirección inferida. De esta forma, si aplicamos el anclaje inicial en el origen del músculo, las fibras musculares tenderán a acortarse, facilitando la activación muscular.[70,71,76] En este sentido se manifiestan diferentes autores, los cuales han encontrado mayor actividad electromiográfica tras la aplicación de KT, en vasto interno del cuadriceps en sujetos sanos[71], en las fibras descendentes de trapecio en pacientes con síndrome subacromial[77], en la musculatura lumbar en sujetos con dolor lumbar crónico[78] y en el cuádriceps en pacientes con dolor patelofemoral[79].Por otra parte, la modalidad de aplicación KT para la corrección funcional, sobre la base del principio de retorno de la venda, proporcionan una información propioceptiva que permite actuar sobre la postura articular y su dirección.[69,70] Así diferentes autores refieren una mejora del rango de movimiento a nivel de hombro[77,80-82], columna cervical[83], flexión de columna lumbar[76], codo[72] y una mejora de la posición en sedestación de los niños con parálisis cerebral[84]. Además se observan efectos positivos sobre la reducción del dolor[80-83,85,86] y kinesiofobia[87].

Por lo tanto, si asumimos que el patrón de retorno de líquidos no es un modelo meramente pasivo si no que existen otros factores que ayudan activamente al retorno circulatorio, como puede ser la contracción muscular o la movilidad el tobillo (ambos alterados en los pacientes con IVC), la aplicación de KT puede ejercer un efecto beneficioso sobre el sistema venoso, no sólo por su propiedades de estimulación linfática sino porque puede permitirnos reforzar la via *vis latere* mediante la

normalización de la musculatura de la bomba muscular periférica y la mejora del rango de movimiento articular del tobillo.

1.4 Justificación del estudio.

Las mujeres posmenopáusicas constituyen un sector poblacional con riesgo evolutivo de patología venosa severa debido a la confluencia de varios factores de riesgo. Los signos y síntomas específicos de IVC han sido ampliamente estudiados, sin embargo, la evidencia científica sobre la percepción subjetiva de dolor, umbrales y su relación con los factores de riesgo es limitada.

La terapia compresiva se establece como uno de los pilares básicos del tratamiento no invasivo de la IVC, sin embargo, existe un déficit de adherencia por parte del paciente a este tipo de tratamiento. Kinesio Taping, es una nueva técnica de vendaje neuromuscular de rápida aplicación y resistente al agua, que permite actuar sobre el componente articular, muscular, y linfovenoso, mejorando el movimiento y reduciendo el dolor. No existen estudios previos sobre la aplicación estandarizada de este vendaje en pacientes con insuficiencia venosa, ni de su combinación con los principios clásicos de compresión periférica.

Así pues la hipótesis inicial de esta tesis doctoral es que el paciente con insuficiencia venosa presenta un dolor característico que podría estar relacionado con los factores de riesgo de esta patología y que la cronicidad del propio proceso podría afectar a los umbrales fisiológicos de dolor. Además el diseño de dos modalidades de vendaje con Kinesio Taping: vendaje KT estandarizado y modelo mixto KT-compresión podrían ejercer un efecto beneficioso a corto plazo sobre las alteraciones músculoesqueléticas, la sintomatología venosa específica, dolor, severidad y calidad de vida en mujeres posmenopáusicas con riesgo evolutivo de IVC.

1. INTRODUCTION

1.1 Chronic venous insufficiency: concept, prevalence, clinical signs and symptoms and socio-economic cost.

Chronic venous insufficiency (CVI) is a pathological condition of the venous system characterised by chronic peripheral hypertension of the lower limbs as a consequence of the venous reflux and/or obstruction and alteration of the peripheral muscle pump.[1] This situation arises because there are abnormalities in the venous and valve wall, which produce a functional incapacity to lead the blood flow towards the centre, adapted to the needs of tissue drainage, thermoregulation and haemodynamic reserve, whatever the position and activity.[2]

The prevalence of CVI world-wide is high (83.6%), affecting mainly the Occidental countries.[3] According to the clinical-etiologic-anatomic-pathophysiologic (CEAP) classification, 63.9% of the cases correspond to subjects belonging to classes C1-C6; it is more frequent in females.[3] The possibilities of venous disease in women compared to men range from 4:1 to 10:1, depending on the study.[4-7] However, Rabe et al[3] 2012 recently indicated, in a multicentre study on 91.545 patients from different geographical areas, that females are more prevalent in the initial stages of the disease (C1-C3), while there are no differences in the male-female ratio in the more severe stages. Álvarez et al[8] 2008, in the DETECT-CVI 2006 study on the Spanish population, found that 62% de the patients that go to Primary Care units because of other reasons presented some CVI sign in the physical examination and that 38% fell within the groups C2-C6, females being the most dominant (64%). The average age at disease onset seems to be earlier in women than in men: the mean age for the former is 34±14 years (SD) as compared with 41±14 years (SD) for men.[7] Recent studies[3] place the mean age in the general population at 50.6±16.9 years. The disease progresses in a period of 13±11 years (SD)[7], including the economically active population in these intervals, which is why its social and employment repercussion is so great.

The most frequent signs and symptoms in CVI are the feeling of heaviness, swelling, itching, pain, muscle cramps, oedema and, in more advanced stages, venous eczema, skin hyper-pigmentation, atrophie blanche and ulceration.[8, 9] Pain is one of the

symptoms that, despite its frequency, has scarcely been analysed. The main hypothesis is that the peripheral stasis increases the endothelial inflammatory reaction, which is considered responsible for the nociceptive stimulation of the vascular wall and surrounding tissues.[10] However, the establishment of a central sensitization, as a result of the pathology itself and of the development of peripheral neuropathy, can also be one of the relevant factors.[11]

Apart from this, it has been confirmed that there is an alteration in the musculature of the peripheral muscle pump in these patients. Qiao et al[12] 2005 studied the pathological and metabolic changes in the gastrocnemius muscle (GM) in patients with venous pathology, in which they found multiple alterations: myofibril atrophy, cell denaturation and necrosis, infiltration of inflammatory cells, interfascicular venous proliferation and dilatation, grouping of atrophic fibres (especially of type I fibres) and moderate-severe atrophy of type II muscle fibres. These authors stated that these physiopathological alterations at the GM level, together with the prolonged venous hypertension, were associated with having the calf muscle pump affected functionally. Recent studies[13] on the oxygenation level of this muscle (GM) in patients in various CVI stages, have shown that muscle deoxygenation exists, with it being more pronounced the more severe the stage was (C4-C6). The compression from the contraction of the peripheral muscle pump on the venous component is one of the key mechanisms for reducing peripheral stasis; consequently, functional alteration of this musculature is indicated as an exacerbating and perpetuating factor of the venous disease over time.[1,12] Another mechanism implicated in the venous return is the range of ankle movement, especially the dorsal flexion movement, whose restriction affects venous circulatory haemodynamics negatively.[14] In this context, there are many studies[15, 16] that have shown that the range of ankle movement is reduced in patients with CVI and that joint movement correlates inversely with the level of severity of the pathology (the more limited the joint range, the greater the venous damage). In addition, joint restriction and muscle weakness of the peripheral venous pump are associated with the appearance of pathological gait patterns.[17]

All of these alterations, present in the venous disease, lead to elevated economic and health costs and a significant impact on the quality of life of the individuals that suffer from it. In this respect, the therapy applied to ulcerations and other skin wounds

in these patients' skin caused, in the United States in 2004, health costs of 9.7 million dollars in direct costs and 2.2 million in indirect costs.[18] However, if we include the hospital and outpatient treatment for this type of patient, an average per patient health cost of $9.685 is estimated, the greatest part of which corresponds to home medical (48%) with more reduced costs generated in the hospital (25%) and outpatient scenarios (21%).[19] Nevertheless, these figure underestimate the true social and health costs, given that they do not consider the early retirement because of the pathology, the loss of functional independence, the suffering and the labour losses.[20] Authors such as Gesto et al[16] 2001 observe that, in Spain, 2.1% of the patients with CVI have to take a mean of 30 days of work leave and 1,9% require hospitalisation for a mean of 9 days. In a later study, Álvarez et al[8] 2008 pointed out that in Spain 48% of the patients that show CVI signs and symptoms describe them as having significant or serious impact, with sick leave from work and hospitalisation are present in 2.5% and 2% of the cases respectively. The mean sick leave reported is 30 days, while that of hospitalisation reaches 8 days.

Consequently, venous insufficiency is a chronic pathology, which affects a great number of the population, whose long-term consequences (such as venous ulcers, severe skin alterations and the risk of peripheral thromboembolism) cause a great socio-economic impact.

1.2 Post-menopause and chronic venous insufficiency.

Postmenopausal women constitute a population with elevated prevalence of CVI, due to the fact that they present a combination of various risk factors, such as advanced age, prior pregnancies, sedentary life style and weight gain.[21] Advanced age and a high body mass index have been established as factors that predict the severity of chronic venous disease.[22, 23] The venous pathology risk attributable to longevity and the female gender have been estimated to be 10.7%; however, the evidence on obesity is subject to controversy.[23] Despite this, weight increase is a factor frequently associated in the postmenopausal stage, due to the processes from prior stages. Menopause in women involves a series of factors, such as sedentarism, non-specific organic insufficiency, rather uncontrolled eating habits, constipation, stress, etc. These factors, together with the hormone changes produced in this period favour the presence of metabolic and

hydro-electrolyte disorders that lead not only to obesity, but to significant fluid retention (oedema).[24] Weight increase has a negative effect, increasing peripheral stasis, reducing the *vis a fronte* mechanism (diaphragm in inspiratory position) and centrifugal reflux arising due to the intestinal mass that compresses the iliac veins (directing affecting the saphenous-femoral union).[24]

Addressing another consideration, the number of pregnancies produced during women's fertile period constitutes another factor that increases the risk of venous pathology in the postmenopausal phase. During pregnancy, there are three factors that impact venous circulation negatively: the endocrinological, mechanical and nutritional factors.[1,25] This confluence makes 50% of pregnant women have higher risks of developing CVI.[1] The endocrinological factor basically consists of a progesterone increase (10 times the normal level), which involves vasodilatation and distensibility that cause a gestational overload, with loss of venous wall tonicity (inhibiting smooth muscle contraction). It is initially a functional disorder, but it later becomes a relative valve insufficiency through the lack of valvular coaptation.[1] The mechanical factor is due to the increase in the circulating volume and the compression the gravid uterus exerts on the lower vena cava; it is observed mainly in the third trimester of pregnancy, joining the débouchement of the uterine and obturator veins, which double their diameter and empty into the primitive iliac and hypogastric veins, acting as a plug of the circulatory stream arriving from the lower limbs.[1] The nutrition factor consists of the weight increase caused by the process itself and its haemodynamic repercussions.[23]

Reduced physical activity level also constitutes a risk factor for CVI in the postmenopausal period.[26] The advanced age characterising this stage involves a series of changes from the aging process: osteoarthritis, generalised conjunctive tissue hypoplasia, decrease in subcutaneous cell tissue, muscle atrophy and joint limitation with insufficiency of the calf venous-muscle pump.[27] All of this causes pathological gait patterns,[17] which leads to a greater energy expenditure, so normal physical activity can become reduced. In addition, walking constitutes a basic activity for appropriate venous return,[28] so all of the possible orthopaedic alterations that can compromise the effect of compression by the musculature on vein diametre (plantar deformities that prevent stimulation of Lejars' venous sole of the foot, or ankle limitations that make calf muscle compression during dorsal flexion impossible) could be the basis for increased

peripheral stasis.[28-30] Likewise, specific cultural assumptions have predisposed women to use inappropriate footwear, restricting joint mobility and altering physiological gait (heels exceeding 3.5 cm), which increases the possibilities of CVI.[31]

Another consideration is that the risk of falling rises in stages of advanced age, associated with increase fragility, as happens in postmenopause.[32] Lower limb traumatism from falls and surgical operations (post-thrombotic syndrome) are considered factors of risk for developing venous pathology. Likewise, the work activity of the patients during their active period can also be a causal CVI factor. Posture when picking up weight, high temperatures, the relative humidity of the work environment, work-related orthostatism for long periods, reduced movement during the shift and prolonged sitting can have a negative on peripheral stasis.[33] Static sitting and standing positions increase peripheral venous pressure (80-100 mmHg)[34] and thus stasis; ihowever, different experts consider that the hypertension caused by labour presence of venous flow obstruction and establishment of complex inflammatory mechanisms constitute causal factors of greater relevance.[34] In addition, if the woman also presents family history of venous disease, the risk is even greater. The existence of a hereditary distribution of the pathology is described by various authors and, although genetic determination is not conclusive yet, Katrancioglu et al[35] 2010 observed that PAI-1 4G allele polymorphism was found with significantly greater frequency in individuals with CVI; consequently, there is evidence of association between both of them.

1.3 Therapeutic approach to chronic venous insufficiency

Venous disease constitutes a pathological entity that, due to its characteristics, is susceptible to a great variety of therapeutic measures, whose present certain controversy. In spite of the fact that symptomatological and functional improvements are achieved, there is no form of treatment that is fully effective and lasting, although some authors point to open surgery as the only option that shows evidence of long-term efficacy.[36] That is why the preventative focus represents the priority approach to this pathology in its initial stages.

Preventative treatment includes the following measures[37,38]:

- Patient education and adherence to regular maintenance of “venous hygiene”: eating a fibre-rich diet, maintaining the body mass index within normal range,

avoiding ortostatism or remaining seated for lengthy period of time, avoiding the use of tight clothing and high-heeled shoes, elevating the lower part of the bed some 15-20 cm, doing aerobic exercises, walks and swimming, avoiding anovulatories and hormone supplements, lubricating the legs constantly and avoiding scratching or other traumatisms, elevating the lower limbs 15 cm for at least 10 minutes, 3 times a day during the day and at night elevating the lower part of the bed, and avoiding prolonged exposure to heat.

- Therapeutic measure that make it possible to block the backflow and techniques to improve the circulatory return system by strengthening the *vis a tergo* and *vis a fronte* mechanisms: compression therapy and a scheduled physiotherapeutic rehabilitation program.

These measures are frequently used in conjunction with other types of treatment such as drugs[39-42] (phlebotonics –micronized flavonoids, diosmin, escin, hesperidin, etc.- antibiotics, oligoelements, antioxidants, herbal medicine), sclerotherapy[43-44] or surgical treatment[45] (ligature of the internal or external saphenous vein (saphenectomy) or both combined with removal of the insufficient vein; ligature and section of insufficient communicating veins; ligature and section of perforating veins and microsurgery). The selection criteria for the treatment should have a multidisciplinary focus and the objectives should be adapted based on patient age, risk factors, general health status and clinical parameters, among others; however, the aesthetic problem represented by the presentation of varicose veins has led to giving priority to the use of techniques such as sclerotherapy or microsurgery.

The new evidence-based clinical practice guidelines[36] for the assessment and treatment of varicose veins developed by the Venous Guideline Committee of the Society for Vascular Surgery® (SVS) and the American Venous Forum (AVF) in 2011 establishes nine basic recommendations for the therapeutic approach to this disorder based on risks, burden and economic costs of the therapeutic measures (Grade 1: the benefits clearly outweigh the risks, burden and economic costs; Grade 2: The recommendation is weak, given that the benefits are closely balanced with the risks and the burden that the therapeutic action involves) and based on the level of evidence that supports it (Quality A: high; B:medium; C: low or very low):

1. Assessment of the patient with varicose veins or severe venous disease (SVD) requires carrying out a complete clinical history, detailed physical examination and supplementary tests such as duplex ultrasound of the deep and superficial venous system (Level 1A).

2. Use of the CEAP scale (clinical-etiological-anatomical-physiopathological CVI classification) to identify the patient's pathological state (Level 1A) and of the venous clinical severity score (VCSS) to assess treatment efficacy (Level 1B).

3. Use of compression therapy for the patient with symptomatic varicose veins (Level 2C); however, this option is not primarily recommended if the patient is a candidate for saphenous vein ablation (Level 1B).

4. Use of compression therapy as the main treatment to help cure venous ulcers (Level 1B).

5. Regular use of compression therapy together with ablation of incompetent superficial veins to reduce the recurrence of venous ulcers (Level 1B).

6. For treatment of the incompetent greater saphenous vein, the recommendation is endovenous thermal ablation (using laser or radiofrequency) over high ligature and inversion stripping of the saphenous vein at the calf level (Level 1B).

7. Performance of a phlebectomy or sclerotherapy to treat tributary varicose veins (Level 1B); the suggestion is for foam sclerotherapy as the therapeutic option for the incompetent saphenous vein (Level 2C).

8. Selective treatment is not recommended for incompetent perforating veins in patients with simple varicose disease (CEAP class 2; Level 1B); however, treatment is suggested for pathological perforating veins (reflux lasting 500 ms and vein diameter of 3.5 mm) located in the area of scarred or active ulcers (CEAP C5 and C6; Level 2B).

9. Treatment of pelvic congestion syndrome or varicose veins embolization, sclerotherapy or catheterization alone or in combination.

As far as physical rehabilitation is concerned, the gold standard for physiotherapeutic CVI treatment consists in carrying out physical activity that is adapted, scheduled and aimed at re-educating the peripheral muscle pump and stimulating venous return mechanisms, together with appropriate compression therapy.[46] Various studies[47-50] have shown that specific activities can effectively stimulate the circulatory return mechanisms and improve venous haemodynamics: regular walking, active kinesiotherapy such as flexing and extending the tibioperoneal-astragalar joint in a standing position, flexing and extending the interphalageal-metacarpophalangeal joints, dorsal knee flexion with gastrocnemius stretching in a sitting position, joint contracture of all the lower member musculature using a stationary bicycle (using a bicycle or pedals that are stationary, which permit the patient to be in sitting or prone position, are recommended, especially for patients with osteoarticular knee pathology) and abdominal-diaphragmatic work (increasing the inhalation stage while the patient is in a standing position and the exhalation stage when the patient is prone). To achieve structural changes, given the context of chronicity, the kinesiotherapy schedule should be applied for long periods (at least an hour a day, from Monday through Friday, with rest periods of 10-15 minutes) at a slow rhythm. In addition, there are other effective physiotherapeutic techniques included in the treatment protocol for these patients, such as manual drainage,[51,52] myofascial liberation treatment[53] and intermittent pneumatic pressotherapy.[54] Antegrade pressotherapy shows beneficial short-term effects (a month of follow-up) on peripheral oedema, venous congestion and total limb volume.[54] Likewise, thermal hydrotherapy programmes[55] seem to improve peripheral stasis; however, scientific evidence does not provide conclusive information in this regard. Besides, the importance of approaching this pathology comprehensively in connection with the lymph system (lympho-venous oedema)[56] has also been shown. That is why there is evidence for the use of manual lymph drainage together with specific measures mentioned previously.[52,56]

The multiplicity of treatments with indications of limited efficacy in chronic venous disease (above all in the less invasive therapies) emphasises the need for new research using in-depth methodologies that make it possible to clarify the durability, safety and efficacy of these therapeutic measures in the long term.

1.3.1 Scientific evidence on the use of compression therapy in treating chronic venous insufficiency.

Compression devices (bandages or stockings) have the function of applying pressure on the limb surface that compensates the pathological intravascular pressure. While walking, this pressure increases with muscle contraction and decreases during relaxation; this creates a pump effect and both the superficial and deep level that increases return speed, lowers venous hypertension and favours reabsorption of oedema.[57,58] Additionally, when the diameter of the superficial system veins are reduced, the thrombi are set against the venous wall, preventing their extension and migration.[58]

The pressure to be applied with the compression stocking or bandage depends on the patient's developmental stage of CVI. In the initial stages, a pressure of between 30 and 50 mmHg is generally sufficient. However, such an indication is conditioned by the existence of other associated pathologies, such as in the case of arterial disease and its severity.[59-61] In a recent review by O'Meara et al[62] 2009 on the different current systems of compression stockings and bandages for CVI, it is revealed that, with respect to the number of layers and the compression exerted, systems with various components or layers are more effective than those having a single component; hence, the greater the compression, it seems that the greater the increase in ulcer cure rates is.[62,63] Another consideration is that multi-component systems containing an elastic bandage appear to be more effective than those whose are primarily composed of non-elastic material. The authors conclude that, although their use could be related to a decrease in pain and sensation of heaviness (among other positive effects), there is no current scientific evidence sufficient to support this, given the appearance of adverse effects and a high removal rate, according to some studies.[62] Despite these conclusions, a certain controversy exists as to the use of elastic/non-elastic bandages; different authors maintain that elastic components are more effective when the problem is at the superficial level, while non-elastic components provide more benefits when the alteration is at a deep level.[59,60] Along the same lines, there has been significant scientific debate in relation to applying progressive or regressive pressure. In the conventional systems, the pressure should be highest in the feet and ankles and it is applied from the base of the toes to the tibial tuberosity, with decreasing gradient up to

the proximal extreme, which permits normal joint play at the same time.[60] However, Couzan et al[64] 2009 recently carried out a multicentre study on 130 French patients to assess a new progressive concept (greater pressure at the calf level, less pressure at the foot and ankle level) of compression stockings, versus classic compression stockings with decreasing pressure, for Class 2 in patients with mild venous insufficiency without permanent oedema (C0-C1-C2). The authors observed that, following 15 days of application, the sensation of heaviness disappeared or improved in 73% of the cases with the new measures, as against 62.5% of the patients with conventional measures. The authors concluded that applying regressive pressure is as effective as progressive, although the latter showed better patient adherence as to normal use. Along these lines, Mosti and Partsch[65] 2012 specifically concluded that the patients with severe venous incompetence obtained greater haemodynamic benefits using non-elastic progressive bandages, with greater calf pressure than in the ankle, especially in the static standing position and during walking. Cohen, Akl and Kahn[66] 2012 found less encouraging results with respect to the preventative function of compression therapy against post-thrombotic syndrome, and they stated that existing evidence is limited and of low quality; this was because of, among other causes, the lack of standardization of the measurement scales, deficits in the blinding systems of the randomized clinical trials and the inclusion of only short-term assessments.

Despite this lack of scientific consistency with respect to the different methods of application, [67] compression therapy continues to be one of the key pillars in clinical CVI treatment. Its use alone or combined with other therapeutic measures seems to be effective in this pathology.[36] However, there is a lack of patient adherence to this type of treatment. Heinen et al[46] 2007 established the existence of a lack of adherence in 33% of the patients that needed compression therapy and observed, as the most frequent causes, the existence of discomfort, paint, exudate, skin irritations, difficulties in the application and aesthetic reasons. In this sense, Van Hecke, Grypdonck and Defloor[68] 2009 more recently agreed with this and pointed to several causes of such non-adherence: perception of pain, discomfort, difficulties in application, skin alterations, discomfort in use with clothing or footwear, incorrect application by the patient or health professionals' lack of information as to the appropriate use.

Consequently, compression therapy is an optimum therapeutic option that requires the performance of solid research that makes it possible, on the one hand, to clarify the standardization of application methods and, on the other, to work on new bandaging models to increase patient adherence to this type of treatment.

1.3.2 Neuromuscular bandaging with Kinesio Taping®

The Kinesio Taping (KT) technique arose in Asia in the 70s and was mainly developed in Japan and Korea, with Dr Kenzo Kase being its foremost creator. Kenzo developed some tapes that were elastic longitudinally, which presented a 10% pre-stretching with possible increases of up to 140%-160%; these tapes were composed of 100% cotton fibres with an acrylic heat-sensitive glue and made it possible to normalise muscular function, reduce pain, affect lymph circulation and even correct joint problems.[69] In contrast to conventional bandaging systems, the support surface with KT bandages was not symmetrical or longitudinal, it presented waves in the form of winding S shapes that helped to form convolutions on the skin.[70] In addition, the tapes were water resistant and heat activated, so thanks to body temperature itself, they could be maintained for at least 4 days without excessive loss of their properties.[71]

Although the mechanisms of KT action are still not well known, it is believed that it acts on neuromuscular function, through mechanoreceptor stimulation.[71] The deformations (convolutions) created with the bandaging involve skin lifting that acts by generating hypopressure areas in the underlying tissues.[72] This leads to the production of a movement of the fluids from the areas of greater pressure toward the hypopressure areas, thus improving circulatory drainage and having a superficial lymph effect.[73] In addition, the decrease in interstitial pressure reduces nociceptive stimulation, depressing the painful sensation. Tsai et al[74] in 2009, demonstrated how a standard lympho-venous decongestive treatment (skin care, manual drainage, pneumatic compression) with associated multi-layer bandage or kinesio tape obtained similar results in reducing the oedema. However, kinesio tape presents advantages over the multi-layer bandaging: greater patient acceptance, fewer difficulties of use, greater bandaging durability and increased comfort; this led the authors to conclude that kinesio tape could replace the multi-layer bandage in this type of treatment. Lipinska and Sliwinski[75] 2009, in their study on 104 women with post-mastectomy lymphoedema, also verified that bandaging

with kinesio taping not only improved the reduction of oedema compared with lymphatic drainage and the multi-layer bandage, the ranges of movement in the upper extremity was also greater. No studies on the application of KT in patients with CVI have been found.

In addition to the circulatory effect, kinesio tape is attributed a mechanical and proprioceptive effect, by means of which it can impact muscle normalisation and joint position.[71,76] At the level of muscle tone, thanks to the tendency of the bandage to retract toward its initial bandaging point (because of its elasticity), the final anchoring tends to return to the initial, so we can achieve an increase or reduction in the tone based on the direction. Consequently, if we apply the initial anchorage in the origin of the muscle, the muscle fibres tend to shorten, facilitating muscle activation.[70,71,76] Statements have been made in this sense by various authors, who have found greater electromyographic activity after applying KT, in the entire vastus medialis muscle in healthy subjects,[71] in the descending trapezius fibres in patients with subacromial syndrome,[77] in the back musculature in subjects with chronic back pain[78] and in the quadriceps in patients with patellofemoral pain.[79] In addition, the method of applying KT for functional correction, based on the principle of the return of the bandage, provides proprioceptive information that allows it to act on joint posture and its direction.[69,70] Different authors have reported improvements in the range of movement at the level of the shoulder,[77,80-82] spine,[83] flexion of the spinal column,[76] elbow[72] and improved sitting position in children with cerebral palsy.[84] Additionally, positive effects have been observed on pain reduction[80-83,85,86] and kinesiophobia.[87]

Consequently, if we assume that the pattern of fluid return is not a merely passive model, but rather that there are other factors that actively help circulatory return, such as muscle contraction or ankle mobility (both altered in patients with CVI), the application of KT can have a beneficial effect on the venous system. This is true not only because of its lymph stimulation properties but also because it can allow us to strengthen the *vis latere* pathway through the normalization of the musculature of the peripheral muscle pump and the improvement of the range of the joint movement of the ankle.

1.4 Justification for the study.

Postmenopausal women constitute a population sector with a short-term risk of severe venous pathology due to the confluence of various risk factors. The specific signs and symptoms of CVI have been studied widely; however, the scientific evidence on subjective pain perception, pain thresholds and their relationship with the risk factors is limited.

Compression therapy has been established as one of the prime pillars of non-invasive CVI treatment. However, there is a lack of patient adherence to this type of treatment. Kinesio Taping is a new neuromuscular bandaging technique that is rapidly applied and water resistant, that makes it possible to act on joint, muscle and lympho-venous components, improving movement and reducing pain. There are no previous studies on standardised application of this bandage in patients with venous insufficiency, nor on its combination with the classic principles of peripheral compression.

The initial hypothesis of this doctoral thesis is that the patient with venous insufficiency presents a characteristic type of pain that could be related to the factors of risk for this pathology, and that the chronicity of the process itself could affect the physiological thresholds of pain. In addition, the design of two methods of bandaging with Kinesio Taping -standardised KT bandaging and the mixed KT-compression model- could have a beneficial short-term effect on the musculoskeletal alterations, specific venous symptomatology, pain, severity and quality of life in postmenopausal women at short-term risk for CVI.

2. BIBLIOGRAFÍA/REFERENCES

1. Labropoulos N, Giannoukas AD, Nicolaides AN, Veller M, Leon M, Volteas N. The role of venous reflux and calf muscle pump function in non thrombotic chronic venous insufficiency. Correlation with severity of signs and symptoms. Arch Surg.1996; 131: 403-6.

2. Wittens CH, de Roos KP, van den Broek TA, van Zelm RT. Guideline "Diagnosis and treatment of varicose veins". Ned Tijdschr Geneeskd. 2009; 153:B7.

3. Rabe E, Guex JJ, Puskas A, Scuderi A, Fernandez Quesada F; VCP Coordinators. Epidemiology of chronic venous disorders in geographically diverse populations: results from the Vein Consult Program. Int Angiol. 2012; 31(2):105-15.

4. De Backer G. Epidemiology of chronic venous insufficiency. Angiology. 1997; 48(7):569-76.

5. Margolis DJ, Berlin JA, Strom BL. Venous leg ulcer: Incidence and prevalence in the elderly. J Am Acad Dermatol.2002; 46(3):381-6.

6. Jantet G. Chronic venous insufficiency: worldwide results of the RELIEF study. Reflux assessment and quality of life improvement with micronized flavonoids. Angiology. 2002; 53(3):245-56.

7. Boccalon H, Janbon C, Saumet JL, Tefani A, Roux T, Vilain C et al. Characteristics of chronic venous insufficiency in 895 patients followed in general practice. Int Angiol. 1997; 16(4): 226-34.

8. Álvarez LJ, Lozano F, Marinel·J, Masegosa JA. Encuesta epidemiológica sobre la insuficiencia venosa crónica en España: estudio DETECT-IVC 2006. Angiología. 2008; 60 (1): 27-36.

9. Rabe E, Stücker M, Esperester A, Schäfer E, Ottillinger B. Efficacy and tolerability of a red-vine-leaf extract in patients suffering from chronic venous insufficiency--

results of a double-blind placebo-controlled study. Eur J Vasc Endovasc Surg. 2011; 41(4):540-7.

10. Bogachev VIu, Shekoian AO. Pain and other symptoms of chronic venous diseases: pathophysiology and therapeutic principles. Angiol Sosud Khir. 2009; 15(3):79-85.

11. Reinhardt F., Wetzel T., Vetten S., Radespiel-Tröger M., Hilz M.J., Heuss D., Neundörfer B. Peripheral neuropathy in chronic venous insufficiency. Muscle Nerve. 2000; 23(6): 883-7.

12. Qiao T, Liu C, Ran F. The impact of gastrocnemius muscle cell changes in chronic venous insufficiency. Eur J Vasc Endovasc Surg. 2005; 30(4):430-6.

13. Yamaki T, Nozaki M, Sakurai H, Soejima K, Kono T, Hamahata A. Advanced chronic venous insufficiency is associated with increased calf muscle deoxygenation. Eur J Vasc Endovasc Surg. 2010; 39(6):787-94.

14. Theys S, Schoevaerdts: Does the venous pump really function by contraction of triceps surae? A myth dispelled 30 years ago by Viel. Kinesither Rev. 2010; 98:27-34.

15. Dix FP, Brooke R, McCollum CN. Venous Disease is Associated with an Impaired Range of Ankle Movement. Eur J Vas Endovasc Surg. 2003; 25(6):556-61.

16. Panny M, Ammer K, Kundi M, Katzenschlager R, Hirschi M. Severity of chronic venous disorders and its relationship to the calf muscle pump. Vasa. 2009; 38(2):171-6.

17. Van Uden CJ, van der Vleuten CJ, Kooloos JG, Haenen JH, Wollersheim H. Gait and calf muscle endurance in patients with chronic venous insufficiency. Clin Rehabil. 2005; 19(3):339-44.

18. Bickers DR, Lim HW, Margolis D, Weinstock MA, Goodman C, Faulkner E et al. The burden of skin diseases: 2004 a joint project of the American Academy of Dermatology Association and the Society for Investigative Dermatology. J Am Acad Dermatol. 2006; 55: 490–500.

19. Olin JW, Beusterien KM, Childs MB, Seavey C, McHugh L, Griffiths RI. Medical costs of treating venous stasis ulcers: evidence from a retrospective cohort study. Vasc Med. 1999; 4: 1–7.

20. Shiman MI, Pieper B, Templin TN, Birk TJ, Patel AR, Kirsner RS. Venous ulcers: A reappraisal analyzing the effects of neuropathy, muscle involvement, and range of motion upon gait and calf muscle function. Wound Repair Regen. 2009; 17(2):147-52.

21. Bromen K, Pannier F, Stang A. Should sex especific differences in venous diseases be explained by pregnancies and hormonae intake? Gesundheitswesen. 2004; 66:170-4.

22. Musil D, Kaletova M, Herman J. Age, body mass index and severity of primary chronic venous disease. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2011;155(4):367-71.

23. Iannuzzi A, Panico S, Ciardullo AV, Bellati C, Cioffi V, Iannuzzo G et al. Varicose veins of the lower limbs and venous capacitance in postmenopausal women: Relationship with obesity. J Vasc Surg. 2002; 36:965-8.

24. Wildman RP, Tepper PG, Crawford S, Finkelstein JS, Sutton-Tyrrell K, Thurston RC et al. Do Changes in Sex Steroid Hormones Precede or Follow Increases in Body Weight during the Menopause Transition? Results from the Study of Women's Health Across the Nation. J Clin Endocrinol Metab. 2012. doi: 10.1210/jc.2012-1614.

25. Kasperczak J, Ropacka-Lesiak M, Musiał-Swider J, Breborowicz GH. Analysis of venous insufficiency risk factors and appearance of clinical symptoms during pregnancy and puerperium in a group of pregnant women with and without symptoms of venous insufficiency of the lower limbs. Ginekol Pol. 2012; 83(3):183-8.

26. Roaldsen KS, Elfving B, Stanghelle JK, Talme T, Mattsson E. Fear-avoidance beliefs and pain as predictors for low physical activity in patients with leg ulcer. Physiother Res Int. 2009; 14(3):167-80.

27. Wooten MK. Long-term care in geriatrics. Clin Family Pract. 2001;3(3):301-10.

28. Pollack AA, Taylor BB, Myers TT, Wood EH. The effect of exercise and body position on the venous pressure at the ankle in patients having venous valvular defects. J Invest. 1949;28(3):559-63.

29. Theys S, Harichaux P, Clérin M, Schoevaerdts JC, Viel E, Duquesne G et al. Etude préliminaire de la chasseveineuse produite par la flexion dorsale et plantaire de la cheville. Hémodynamique des membres. Toulouse: GEPESC; 1979.

30. Theys S, Schoevaerdts JC. Does the venous pump really function by contraction of triceps surae? A myth dispelled 30 years ago by Viel. Kinésithérapie,la revue.2010; 98(10):27-34.

31. Tedeschi W, Dezzotti NR, Joviliano EE, Moriya T, Piccinato CE. Influence of high-heeled shoes on venous function in young women. J Vasc Surg. 2012.

32. Shim EY, Ma SH, Hong SH, Lee YS, Paik WY, Seo DS et al. Correlation between Frailty Level and Adverse Health-related Outcomes of Community-Dwelling Elderly, One Year Retrospective Study. Korean J Fam Med. 2011; 32(4):249-56.

33. Sancini A, Tomei G, Schifano MP, Nardone N, Andreozzi G, Scimitto L et al. Phlebopathies and occupation. Ann Ig. 2012; 24(2):131-44.

34. Bass A. The effect of standing in the workplace and the development of chronic venous insufficiency. Harefuah. 2007; 146(9):675-6, 734-5.

35. Katrancioglu N, Manduz S, Ozen F, Yilmaz MB, Karahan O, Ozdemir O et al. Type I plasminogen activator inhibitor 4G allele frequency is associated with chronic venous insufficiency. J Int Med Res. 2010; 38(4):1513-8.

36. Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML et al. The care of patients with varicose veins and associated chronic venous diseases:

clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum.J Vasc Surg. 2011; 53(5suppl):2S-48S.

37. Fagrell B. Skin capillary changes in patients with chronic venous Insufficiency. Phlebolymphology. 1995; 8(1):3-8.

38. Neglen P, Eklof B, Kulwicki A, David A, Deschamps T, García M et al. Prevention and treatment of venous ulcers in primary chronic venous insufficiency. J Vasc Surg. 2010; 52(5):15-20.

39. Allaert FA. Meta-analysis of the impact of principal venoactive drugs agents on malleolar venous edema. Int Angiol.2012; 31(4):310-5.

40. Martinez MJ, Bonfill X, Moreno RM, Vargas E, Capellà E. Phlebotonics for venous insufficiency. Cochrane Datebases Syst Rev.2005; 20(3):CD003229.

41. Garner RC, Garner JV, Gregory S, Whattan M, Calam A, Leong D. Comparison of the absorption of micronized (Daflon 500 mg) and nonmicronized 14C-diosmin tablets after oral administration to healthy volunteers by accelerator mass and liquid spectrometry scintillation counting. J Pharm Sci. 2002; 91(1):32-40.

42. Ernst E. Herbal Medicine. Med Clin North Am.2002; 86(1):13-25.

43. Simka M. Principles and technique of foam sclerotherapy and its specific use in the treatment of venous leg ulcers. Int J Low Extrem Wounds.2011; 1083:138-45.

44. Wright DD.What is the current role of foam sclerotherapy in treating reflux and varicosities?. Semin Vasc Surg.2010; 23(2):123-6.

45. Parnaby CN, Welch GH, Stuart WP. An overview of the surgical aspects of lower limb venous disease. Scott Med J. 2009; 54(3):30-5.

46. Heinen MM, van der Vleuten C, de Rooij MJ, Uden CJ, Evers AW, van Achterberg T. Physical activity and adherence to compression therapy in patients with venous leg ulcers. Arch Dermatol. 2007; 143(10):1283-8.

47. Kahn SR, Shrier I, Shapiro S, Houweling AH, Hirsch AM, Reid RD et al. Six month exercise training program to treat post-thrombotic syndrome: a randomized controlled two-centre trial. CMAJ. 2011; 183(1):37-44.

48. Kan YM, Delis KT. Hemodynamic effects of supervised calf muscle exercise in patients with venous leg ulceration: a prospective controlled study. Arch Surg. 2001; 136(12):1364-9.

49. Yang D, Van Dongen YK, Stacey MC. Effect of exercise on calf muscle pump function in patients with chronic venous disease. Br J Surg. 1999; 86(3):338-41.

50. Clerin M, Theys, Schevaerdts JC. Effect of respiratory movements on the venous return in the legs. Phlébologie. 1990; 43(1):67-9.

51. Peschen M, Werner E, Vanscheidt W. Chronic venous insufficiency from pathophysiology to therapy. 3 Physical therapy of venous diseases. Fortschr Med.1996; 114(29):377-9.

52. Molski P, Ossowoski R, Hagner W, Molski S. Patients with venous disease benefit from manual lymphatic manual drainage.Int Angiol. 2009; 28(2):151-5.

53. Ramos-Gónzalez E, Moreno-Lorenzo C,Matarán-Peñarrocha GA, Guisado-Barrilao R, Aguilar-Ferrándiz ME, Castro-Sánchez AM. Comparative study on the effectiveness of myofascial release manual therapy and physical therapy for venous insufficiency in postmenopausal women. Complent Ther Med. 2012; 20(5):297-8.

54. Tsukanov IuT, Tsukanov AIu. The results of pulsed compression therapy by pneumatic massage in patients with chronic venous insufficiency. Angiol Sosud Khir. 2007; 13(2):63-7.

55. Ippolito E, De Luca S, Sommaruga S, Grassellino V, Nappi G. Experimental-clinical study on the effects of hydromassage with thermae oasis's salsobromoiodine water in chronic venous stasis of the lower extremities. Minerva Cardioangiol. 2008; 56(4):401-8.

56. Gironet N, Baulieu F, Giraudeau B, Machet L, Toledano C, Tiguemounine J, Lourette G, Vaillant L. Lymphedema of the limb: predictors of efficacy of combined physical therapy. Ann Dermatol Venereol. 2004; 131(8-9):775-9.

57. Christopoulos D, Nicolaides AN, Belcaro G, Duffy P. The effect of elastic compression on calf muscle pump function. Phlebology 1990; 5:13-9.

58. Motykie GD. Evaluation of therapeutic compression stockings in the treatment of chronic venous insufficiency. Dermatol Surg. 1999; 25(2):116-20.

59. Maybarry JC, Moneta GL. The influences of elastic compression stockings on deep venous hemodynamics. J Vasc Surg.1991; 13:91-100.

60. Mayberry JC, Moneta GL. Fifteen-year results of ambulatory compression therapy for chronic venous ulcers. Surgery. 1991; 109:575-8.

61. Begini JP. Compression treatment of venous and venous/arterial leg ulcers. Soins. 2012; 762:34-6.

62. O'Meara S, Cullum NA, Nelson EA. Compression for venous leg ulcers. Cochrane Database Syst Rev. 2009; 21(1):CD000265.

63. Cullum N, Nelson EA, Fletcher AW, Sheldon TA. Compression bandages and stockings for venous leg ulcers. Cochrane Database Syst Rev. 2000 ;(2):CD000265.

64. Couzan S, Assante C, Laporte S, Mismetti P, Pouget JF. Booster study: comparative evaluation of a new concept of elastic stockings in mild venous insufficiency. Presse Med. 2009; 38(3):355-61.

65. Mosti G, Partsch H. High Compression Pressure over the Calf is More Effective than Graduated Compression in Enhancing Venous Pump Function. Eur J Vasc Endovasc Surg. 2012.

66. Cohen JM, Akl EA, Kahn SR. Pharmacologic and compression therapies for posttombotic syndrome: a systematic review of randomized controlled trials. Chest. 2012;141(2):308-20.

67. Shingler S, Robertson L, Boghossian S, Stewart M. Compression stockings for the initial treatment of varicose veins in patients without venous ulceration. Cochrane Database Syst Rev. 2011; 9(11):CD008819.

68. Van Hecke A, Grypdonck M, Defloor T. A review of why patients with leg ulcers do not adhere to treatment. Journal of Clinical Nursing. 2009; 18:337-49.

69. Kase K, Tatyusuki H, Tomoki O. Development of Kinesio™ tape. In: Kase K, Tatyusuki H, Tomoki O, editors. Kinesio™ Taping Perfect Manual. Kinesio Taping Association; 1996.p.117-8.

70. Kase K, Wallis J, Kase T. Clinical Therapeutic Applications of the Kinesio Taping Method. Tokyo, Japan: Ken Ikai Co Ltd; 2003.

71. Słupik A, Dwornik M, Białoszewski D, Zych E. Effect of Kinesio Taping on bioelectrical activity of vastus medialis muscle. Preliminary report. Ortop Traumatol Rehabil. 2007; 9(6):644-51.

72. Liu YH, Chen SM, Lin CY, Huang CI, Sun YN. Motion tracking on elbow tissue from ultrasonic image sequence for patients with lateral epicondylitis. Med Biol Soc. 2007; 2007:95-8.

73. Shim JY, Lee HR, Lee DC. The use of elastic adhesive tape to promote lymphatic flow in the rabbit hind leg. J Yon Med. 2003; 44 (6): 1045-52.

74. Tsai HJ, Hung HC, Yang JL, Huang CA, Tsauo JY. Could Kinesio tape replace the bandage in decongestive lymphatic therapy for breast-cancer-related lymphedema? A pilot study. Support Care Cancer. 2009; 17:1353-60.

75. Lipinska A, Sliwinski G, Sliwinski Z. Kinesiology taping application and the function of the upper limb in the women after mastectomy. J hand surg. 2009; 34: 139-58.

76. Yoshida A, Kahanov L. The effect of kinesio taping on lower trunk range of motions. Res Sports Med. 2007; 15(2):103-12.

77. Hsu YH, Chen WY, Lin HC, Wang WT, Shih YF. The effects of taping on scapular kinematics and muscle performance in baseball players with shoulder impingement syndrome. J Electromyogr Kinesiol. 2009; 19:1092-9.

78. Paoloni M, Bernetti A, Fratocchi G, Mangone M, Parrinello L, Del Pilar M et al. Kinesio Taping applied to lumbar muscles influences clinical and electromyographic characteristics in chronic low back pain patients. Eur J Phys Rehabil Med. 2011; 47(2):237-43.

79. Macgregor K, Gerlach S, Mellor R, Hodges PW. Cutaneous stimulation from patella tape causes a differential increase in vasti muscle activity in people with patellofemoral pain. J Orthop Res. 2005; 23(2):351-8.

80. Kaya E, Zinnuroglu M, Tugcu I. Kinesio taping compared to physical therapy modalities for the treatment of shoulder impingement syndrome. Clin Rheumatol 30:201-7.

81. Thelen MD, Dauber JA, Stoneman PD. The clinical efficacy of kinesio tape for shoulder pain: a randomized, double-blinded, clinical trial. J Orthop Sports Phys Ther. 2008; 38:389-95.

82. García-Muro F, Rodríguez-Fernández AL, Herrero-de-Lucas A. Treatment of myofascial pain in the shoulder with Kinesio taping. A case report. Man Ther. 2010; 15(3):292-5.

83. Gonzalez-Iglesias J, Fernandez-de-Las-Peñas C, Cleland JA, Huijbregts P, Del Rosario Gutierrez-Vega M. Short-term effects of cervical kinesio taping on pain and cervical range of motion in patients with acute whiplash injury: a randomized clinical trial. J Orthop Sports Phys Ther. 2009; 39:515-21.

84. Simşek TT, Türkücüoğlu B, Cokal N, Ustünbaş G, Simşek IE. The effects of Kinesio® taping on sitting posture, functional independence and gross motor function in children with cerebral palsy. Disabil Rehabil. 2011;33(21-22):2058-63.

85. Lee JH, Yoo WG. Treatment of chronic Achilles tendon pain by Kinesio taping in an amateur badminton player. Phys Ther Sport. 2012; 13(2):115-9.

86. Saavedra-Hernández M, Castro-Sánchez AM, Arroyo-Morales M, Cleland JA, Lara-Palomo IC, Fernández-de-Las-Peñas C. Short-Term Effects of Kinesiotaping Versus Cervical Thrust Manipulation in Patients With Mechanical Neck Pain: A Randomized Clinical Trial. J Orthop Sports Phys Ther. 2012

87. Castro-Sánchez AM, Lara-Palomo IC, Matarán-Peñarrocha GA, Fernández-Sánchez M, Sánchez-Labraca N, Arroyo-Morales M. Kinesio taping reduces disability and pain slightly in chronic non-specific low back pain: a randomised trial. J Physiother. 2012; 58(2): 89-95.

OBJETIVOS

OBJECTIVES

3. OBJETIVOS

3.1 Generales:

- Describir las características del dolor en las mujeres posmenopáusicas con insuficiencia venosa crónica y su relación con los factores de riesgo.

- Evaluar la efectividad de dos modalidades de vendaje neuromuscular (Kinesio Taping) sobre las alteraciones músculoesqueléticas, sintomatología venosa específica, dolor, severidad y calidad de vida en mujeres posmenopáusicas con riego evolutivo de IVC (CEAP C1-C3).

3.2 Específicos:

- Cuantificar la intensidad y umbral del dolor en mujeres posmenopáusicas con insuficiencia venosa crónica, evaluar la influencia de los factores de riesgo en el nivel de dolor y analizar el "Pain Matcher" como técnica complementaria para la valoración del dolor venoso en esta población.

- Evaluar la eficacia de la aplicación de una modalidad de vendaje neuromuscular (KT) estandarizada sobre la sintomatología venosa, calidad de vida, severidad, dolor, edema, actividad electromiográfica de gastronemio y rango de movimiento del tobillo en mujeres posmenopáusicas con IVC leve-moderada.

- Analizar la eficacia de la aplicación de un modelo mixto de vendaje neuromuscular (KT) y compresión periférica sobre el rango de movimiento del tobillo, parámetros de marcha, dolor, edema y calidad de vida en mujeres posmenopáusicas con IVC leve-moderada.

- Objetivar la eficacia de la aplicación de un modelo mixto de vendaje neuromuscular (KT) y compresión periférica sobre el flujo venoso (pletismografía, bioimpedanciometría y temperatura), puntuación de severidad sintomatológica, severidad clínica total, y estado de salud general en mujeres posmenopáusicas con IVC leve-moderada.

3. OBJECTIVES

3.1 General:

- To describe the characteristics of pain in postmenopausal women with chronic venous insufficiency (CVI) and its relationship with risk factors.
- To assess the effectiveness of two methods of neuromuscular bandaging (Kinesio Taping) on muscle-skeletal alterations, specific venous symptomatology, pain, severity and quality of life in postmenopausal women with CVI developmental blood supply (CEAP C1-C3).

3.2 Specific:

- To quantify the intensity and threshold of pain in postmenopausal women with CVI, to assess the influence of the risk factors in the level of pain and to analyse the "Pain Matcher" as a complementary technique for assessing venous pain in this population.
- To assess the efficacy of applying a modality of neuromuscular bandaging (KT) standardised on venous symptomatology, quality of life, severity, pain, oedema, electromyographic activity of the gastrocnemius and range of ankle movement in postmenopausal women with mild-moderate CVI.
- To analyse the efficacy of applying a mixed model of neuromuscular bandaging (KT) and peripheral compression on the range of ankle movement, gait parameters, pain, oedema and quality of life in postmenopausal women with mild-moderate CVI.
- To establish the efficacy of applying a mixed model of neuromuscular bandaging (KT) and peripheral compression on venous flow (plethysmography, bio-impedance analysis and temperature), symptom severity score, total clinical severity and state of general health in postmenopausal women with mild-moderate CVI.

METODOLOGÍA

METHODS

4. METODOLOGÍA/METHODS

Tables 1, 2, 3 and 4 show a summary of the methodology used in the studies included in the PhD thesis.

Table 1. Summary of Material and Methods in study I. (Appendix 1)

PAPER	STUDY DESIGN	PARTICIPANTS	PROCEDURES	MAIN VARIABLES	METHODS
I. Evaluation of pain and its risk factors in patients with chronic venous insufficiency	Controlled cross-sectional study	Postmenopausal women with chronic venous insufficiency (n=139) Healthy controls (n=40)	Screening to identification selection criteria and to collect demographic and risk factor data: - Age - Body mass index -Waist-hip ratio - Aetiology - Professions -Time since CVI onset. -Level of physical activity. -Level of pain associated with knee or hip osteoarthritis. - Anatomical distribution of pain symptoms. - Degree of venous reflux in right and left lower limbs.	6 Variables: - Pain intensity - Sensory pain - Affective pain. - Evaluative pain. -Pain magnitude -Pain threshold	-10-cm visual analogue scale. - McGill pain questionnaire (MPQ). - Pain Matcher device. - Western Ontario McMaster University Osteoarthritis Index (WOMAC). -Photoplethysmography (Vasoquant® VQ4000/A-PPG; ELCAT, Wolfratshausen, Germany)

Table 2. Summary of Material and Methods in study II (Appendix 2)

PAPER	STUDY DESIGN	PARTICIPANTS	INTERVENTION	MAIN VARIABLES	METHODS
II. Kinesio Taping improves venous symptoms, severity, pain and gastrocnemius muscle bioelectrical activity in women with chronic venous insufficiency: a randomised trial.	Double-blinded randomized clinical trial	Postmenopausal women with initial chronic venous insufficiency (n=123): -Standardized KT group (n=62) -Sham KT group (n=61)	Standardized KT model: - Y-shaped strips (origin to insertion) in medial and lateral gastrocnemius (15 to 50% tension) - I-strip to stimulate dorsal ankle flexion (50% tension) Application: three times a week during one month follow-up. Sham KT model: - Y-shaped and I strip in the same positions of standardized bandage but without tension and without respecting the correct anatomical distribution. Application: three times a week during one month follow-up.	24 Variables: - Venous symptoms (pain localizations, venous claudication, swelling, pigmentation, lipodermatosclerosis, Nº of ulcers, colouring, heaviness, muscles cramps and pruritus). -Quality of life -CVI severity -Pain - Peripheral oedema in right and left lower limbs - Total ROAM in right and left lower limbs. - Dorsiflexion ROAM in right and left lower limbs. -Electromyography on lateral and medial gastrocnemius in right and left lower limbs.	- Physical exam. - Quality of Life Questionnaire in Chronic Lower Limb Venous Insufficiency (CIVIQ-20) - Venous Clinical Severity Score (VCSS) - 10-cm visual analogue scale. -Volume of the lower limbs by perimeter (Seca-206 measuring tape of 220 cm). -Goniometer (SG 110, Penny and 203 Giles Biometrics Ltd; UK) - Electromyograph Kine-Pro Motion Wireless surface electromyography (Kine-Pro Hafnarfjodur, 180 Island)

CVI, Chronic venous insufficiency; ROAM, Range of ankle motion; KT, Kinesio Tape.

Table 3. Summary of Material and Methods in study III. (Appendix 3)

PAPER	STUDY DESIGN	PARTICIPANTS	INTERVENTION	MAIN VARIABLES	METHODS
III. Effect of a mixed Kinesio Taping-compression technique on clinical and gait parameters in females with chronic venous insufficiency: Double-blinded, randomized clinical trial.	Double-blinded randomized clinical trial	Postmenopausal women with initial chronic venous insufficiency (n=120): - Mixed KT-compression group (n=60) -Sham KT group (n=60)	Mixed Kinesio Taping-compression model: - Y-shaped strips (origin to insertion) in medial and lateral gastrocnemius (15 to 50% tension) - I-strip to stimulate dorsal ankle flexion (50% tension). - two tapes in malleolar level for peripheral compression (50% tension) Application: three times a week during one month follow-up. Sham KT model: - Y-shaped, I strip and a semicircular tape in the same positions of Mixed Kinesio Taping bandage but without tension and without respecting the correct anatomical distribution. Application: three times a week during one month follow-up.	27 Variables: - Total ROAM in right and left lower limbs. - Dorsiflexion ROAM in right and left lower limbs. - Gait Dorsiflexion ROAM in right and left lower limbs. - Gait parameters: cadence, stride length, step length, stance phase, swing phase, and double support phase in right and left lower limbs. - Peripheral oedema in right and left lower limbs. -Pain intensity. -Pain magnitude. -Pain threshold. -Quality of life	-Goniometer (SG 110, Penny and 203 Giles Biometrics Ltd; UK). - Kine-Pro Motion Wireless surface electromyography (Kine-Pro Hafnarfjodur, 180 Island). -Volume of the lower limbs by foot, malleolus and calf circumference (Seca-206 measuring tape of 220 cm). - 10-cm visual analogue scale. -Pain Matcher device. - Quality of Life Questionnaire in Chronic Lower Limb Venous Insufficiency (CIVIQ-20).

CVI, Chronic venous insufficiency; ROAM, Range of ankle motion; KT, Kinesio Tape.

Table 4. Summary of Material and Methods in study IV. (Appendix 4)

PAPER	STUDY DESIGN	PARTICIPANTS	INTERVENTION	MAIN VARIABLES	METHODS
IV. A Controlled Randomised Trial of a Mixed Kinesio Taping-compression Technique on Peripheral Venous Flow, Venous Symptoms, Pain, Clinical Severity and Overall Health Status in Postmenopausal Women with Chronic Venous Insufficiency.	Double-blinded randomized clinical trial	Postmenopausal women with initial chronic venous insufficiency (n=120): - Mixed KT-compression group (n=60) -Sham KT group (n=60)	Mixed Kinesio Taping-compression model: - Y-shaped strips (origin to insertion) in medial and lateral gastrocnemius (15 to 50% tension) - I-strip to stimulate dorsal ankle flexion (50% tension). - two tapes in malleolar level for peripheral compression (50% tension) Application: three times a week during one month follow-up. Sham KT model: - Y-shaped, I strip and a semicircular tape in the same positions of Mixed Kinesio Taping bandage but without tension and without respecting the correct anatomical distribution. Application: three times a week during one month follow-up.	38 Variables: - Degree of reflux in right and left lower limbs: venous refill tome and venous pump function. - Peripheral oedema in right and left lower limbs: Cell mass, intracellular and extracellular water and fat mass. - Temperature at 3 levels: popliteal fossa, external calf muscle and foot dorsum in right and left lower limbs. - Venous symptoms: heaviness, venous claudication, swelling, muscles cramps and pruritus -Sensory pain. -Evaluative pain. -Affective pain. -Pain rating index. -Present pain intensity. - Pain intensity (cm). -Clinical severity. -Overall Health Status: physical function, physical role, body pain, general health, vitality, social function, emotional role, mental health.	-Photoplethysmography (Vasoquant® VQ4000/A-PPG; ELCAT, Wolfratshausen, Germany) - Bioelectrical impedance meter (Bodycell 1E07004, Carin, Barcelona, Spain) - A thermographic scanner of 0-100◦C (Oregon Scientific - Mod. Naw-880 EXL, Guipuzcoa, Spain). -Physical exam. - McGill Pain Questionnaire (MPQ) - 10-cm visual analogue scale. - Venous Clinical Severity Score (VCSS) - SF-36 quality of life questionnaire on functional state, emotional well-being and general health.

CVI, Chronic venous insufficiency; ROAM, Range of ankle motion; KT, Kinesio Tape.

RESULTADOS

RESULTS

5. RESULTS

5.1 Study I: "Evaluation of pain and its risk factors in patients with chronic venous insufficiency".

5.1.1 *Participant characteristics*

The study population consisted in two groups: patients with CVI (n = 139, mean age [SD] 65 ± 14 years) and a control group of participants without CVI (n = 40, mean age 66 ± 14 years). Baseline demographic characteristics in both groups were similar ($p > 0.159$) for all variables (Table 1). The CVI group was characterized by primary venous pathology (78.5%) beginning more than 10 years previously (56.8%). In most participants the condition was considered class C3 (48.9%), and pain was located most often in the calf, perimalleolus and popliteal fossa (38.2%). The most frequent associations were with prolonged sitting (37.4%) and standing (45.3%) during work, and with reduced physical activity (between 6 and 9 hours/week) (32.4%) (Table 2).

Table 1. Characteristics of patients at baseline and pain outcome measures.

Outcomes	CVI Group	Control group	*p*-value
Age (years)	65.66±13.6	66.60±14.0	0.703
Body mass index (kg/m^2)	28.30±4.5	29.01±4.6	0.392
Waist-hip ratio	.89±0.6	.88±0.4	0.159
VAS (0-10) [a]	5.44±2.5	1.66±0.4	0.001*
McGill pain score			
Sensory (0-33)	5.22±6.9	3.47±3.1	0.001*
Affective (0-12)	2.79±2.06	3.01±1.7	0.424
Sensory+affective (0-45)	9.27±3.88	8.02±3.1	0.108
Pain Matcher magnitude (0-60)	10.85±4.01	1.87±0.8	0.001*
Pain Matcher threshold (0-60)	6.09±1.1	11.20±2.3	0.001*

Data are expressed as the mean ± standard deviation (SD). CVI, chronic venous insufficiency. [a] (x-x) Range of normal scores for the variable.* $p<0.05$

T**able 2.** Potential predictive risk factors and pain localization in the chronic venous insufficiency group.

Outcomes	Frequency	%
CVI etiology		
Congenital	0	0.0
Primary	109	78.5
Secondary	30	21.5
Time since CVI onset		
≤ 10 years	60	43.2
> 10 years	79	56.8
Work activity		
Housewife	24	17.3
Profession involving prolonged sitting	52	37.4
Profession involving prolonged standing	63	45.3
Physical activity		
0 to <3 h/week	24	17.3
3 to <6 h/week	28	20.1
6 to <9 h/week	45	32.4
9 to <12 h/week	35	25.2
≥12 h/week	7	5
WOMAC score (0-100)		
15 ≥ x ≤30	38	27.3
31 ≥ x ≤46	56	40.3
47≥ x ≤62	36	25.9
63≥ x ≤78	9	6.5
CEAP classification		
C1	8	5.7
C2	17	12.2
C3	68	48.9
C4	15	10.7
C5	16	11.8
C6	15	10.7
Pain localization		
CA	15	10.8
P	4	2.9
PF	22	15.8
CA and P	25	17.9
CA and PF	20	14.6
CA, P and PF	53	38.2

Categorical variables are expressed as absolute and relative frequencies. CEAP, clinical, etiological, anatomical, and pathophysiological scale; CVI, chronic venous insufficiency; CA, calf; P, perimalleolus; PF, popliteal fossa.

5.1.2 Pain in chronic venous insufficiency

Patients with CVI had more pain than control participants regardless of which measurement technique was used. Mean scores in the CVI group were 5.44 ± 2.5 for VAS, 5.22 ± 6.9 for the MPQ sensory dimension and 10.85 ± 4.01 for pain magnitude matching. These scores were significantly higher ($p < 0.01$) than in the control group: 1.66 ± 0.4 for VAS, 3.47 ± 3.1 for the MPQ sensory dimension and 1.87 ± 0.8 for pain magnitude matching. The pain threshold in the CVI group (6.09 ± 1.1) was significantly lower ($p < 0.01$) than in the control group (11.20 ± 2.3) (Table 1).

Patients in both groups with lower pain thresholds had the highest scores in the pain magnitude matching test. The significance of this negative correlation was greater in the CVI group ($r_s = -0.938$, $p < 0.001$) than in the control group ($r_s = -0.806$, $p < 0.01$) (Figure 1).

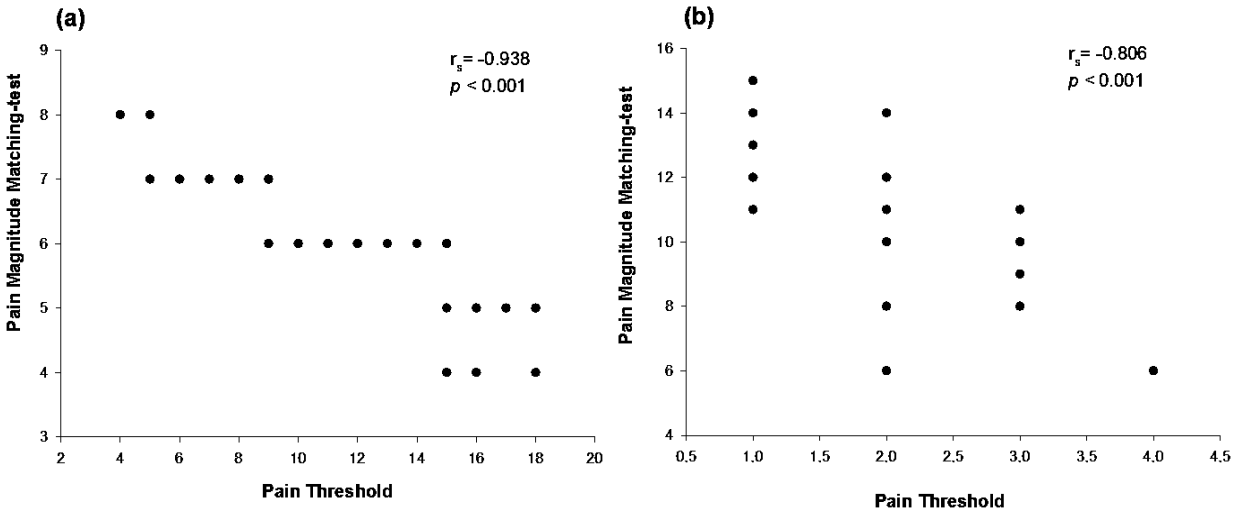


Figure 1. Scatter-plot showing the relationship between the pain threshold and pain magnitude matching assessed with the Pain Matcher device in 139 patients with chronic venous insufficiency (A) and 40 control participants (B).

5.1.3 *Risk factors for pain in chronic venous insufficiency*

Bivariate correlation analysis showed a relationship between VAS, MPQ, pain magnitude matching and physical activity level, profession and pain from knee or hip osteoarthritis (WOMAC score). All three pain scores were higher in individuals with

lower levels of physical activity (VAS: $r_s = -0.420$, $p < 0.001$; MPQ: −0.297, $p < 0.001$; pain magnitude matching: $r_s = -0.416$, $p < 0.001$), prolonged standing or sitting (VAS, MPQ, pain magnitude matching $p < 0.001$, Kruskal–Wallis test) and osteoarthritis pain and functional limitation (VAS: $r_s = 0.351$, $p < 0.001$; MPQ: 0.214, $p < 0.011$; pain magnitude matching: $r_s = 0.335$, $p < 0.001$). In addition, pain scores correlated inversely with venous refill time in both the right (VAS: $r_s = -0.955$, $p < 0.001$; MPQ: $r_s = -0.377$, $p < 0.001$; pain magnitude matching: $r_s = -0.918$, $p < 0.001$) and left lower limbs (VAS: $r_s = -0.934$, $p < 0.001$; MPQ: −0.401, $p < 0.001$; pain magnitude matching: $r_s = -0.894$, $p < 0.001$). Thus patients with a lower venous refill time and therefore greater venous stasis had higher levels of pain (Figure 2). However, none of the three pain outcome measures showed any significant associations with age, CEAP classification, body mass index, waist-hip ratio, time since onset or etiology ($r_s \leq 0.123$, $p \geq 0.317$).

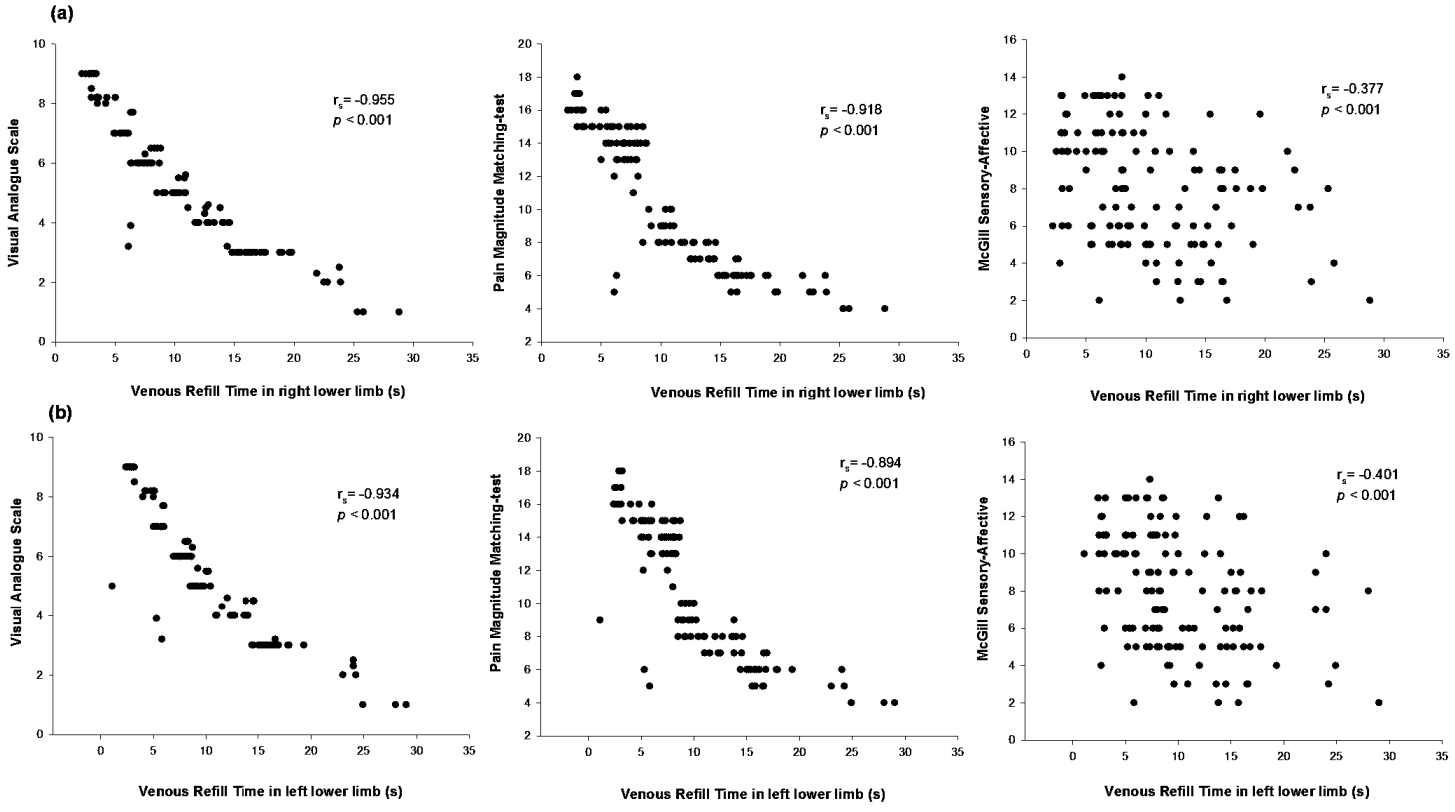


Figure 2. Scatter-plot showing the relationship between venous refill time and the McGill Pain Questionnaire results, visual analogue scale score and pain magnitude matching in the right (A) and left (B) lower limbs in 139 patients with chronic venous insufficiency.

Multivariate regression analysis showed that venous refill time and WOMAC osteoarthritis index were significantly associated with pain measured as VAS and with Pain Matcher scores (Tables 3 and 4). However, none of the risk factors studied here was associated with pain as evaluated with the MPQ (Table 3).

Table 3. Predictive risk factors of pain intensity assessed with a visual analogue scale and the McGill Pain Questionnaire in chronic venous insufficiency.

	Visual analogue scale (r^2 = 0.893)			McGill Pain Questionnaire (r^2 = 0.194)		
Independent variables	β	SE	*p*-value	β	SE	*p*-value
Etiology[a]	0.055	0.140	0.405	1.425	0.582	0.056
Profession[b]	-0.239	0.158	0.601	-0.687	0.657	0.298
Age	-0.005	0.007	0.847	0.018	0.027	0.518
Body mass index	0.011	0.015	0.386	0.049	0.061	0.428
Waist-hip ratio	-0.426	0.952	0.239	6.307	3.947	0.113
Time since onset	-0.010	0.007	0.543	-0.003	0.030	0.927
CEAP	0.014	0.050	0.690	0.191	0.206	0.357
Physical activity	-0.011	0.026	0.536	-0.165	0.107	0.127
WOMAC	0.030	0.005	0.001	0.010	0.021	0.647
VRT	-0.275	0.018	0.001	-0.079	0.075	0.291

β, adjusted coefficient from multiple linear regression analysis; SE coefficient standard error; r^2, regression coefficient of determination; CEAP, clinical, etiological, anatomical, pathophysiological scale; WOMAC, Western Ontario McMaster University Osteoarthritis Index; VRT, venous refill time.

[a] Primary vs secondary.

[b] Housewife vs prolonged sitting and standing.

Table 4. Predictive risk factors of pain intensity assessed with the Pain Matcher device in chronic venous insufficiency.

Independent variables	Pain magnitude (r^2 = 0.789)			Pain threshold (r^2 = 0.194)		
	β	SE	*p*-value	β	SE	*p*-value
Etiology[a]	0.051	0.402	0.898	-0.163	0.127	0.202
Profession[b]	-0.637	0.454	0.163	0.206	0.143	0.152
Age	0.009	0.019	0.621	0.001	0.006	0.859
Body mass index	0.024	0.042	0.567	-0.002	0.013	0.900
Waist-hip ratio	-3.591	2.724	0.190	-0.228	0.859	0.791
Time since onset	-0.016	0.021	0.443	0.006	0.007	0.374
CEAP	0.145	0.142	0.310	-0.032	0.045	0.477
Physical activity	-0.033	0.074	0.655	-0.016	0.023	0.507
WOMAC	0.037	0.014	0.011	-0.017	0.005	0.001
VRT	-0.517	0.052	0.001	0.121	0.016	0.001

β, adjusted coefficient from multiple linear regression analysis; SE coefficient standard error; r^2, regression coefficient of determination; CEAP, clinical, etiological, anatomical, pathophysiological scale; WOMAC, Western Ontario McMaster University Osteoarthritis Index; VRT, venous refill time.

[a] Primary vs secondary.

[b] Housewife vs prolonged sitting and standing.

5.1.4 Pain Matcher assessment of venous pain

Evaluations of venous pain intensity obtained with Pain Matcher showed a strongly positive correlation with VAS score (r_s = 0.966, $p < 0.001$) (Figure 3). There was also a positive relationship between pain magnitude matching values and MPQ sensory dimension results (r_s = 0.529, $p < 0.001$) and between pain magnitude matching values and total MPQ results (r_s = 0.368, $p < 0.001$).

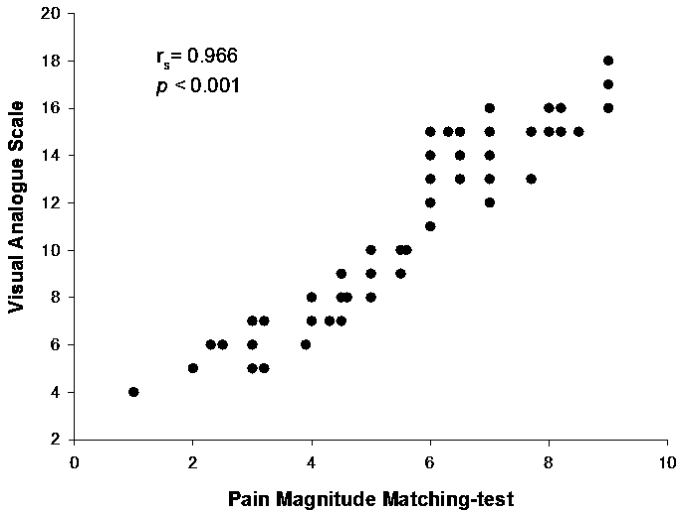


Figure 3. Scatter-plot showing the relationship between visual analogue scale score and pain magnitude matching in 139 patients with chronic venous insufficiency.

5.2 Study II: "Kinesio Taping improves venous symptoms, severity, pain and gastrocnemius muscle bioelectrical activity in women with chronic venous insufficiency: a randomised trial".

Out of the 160 women recruited for the study, 123 women with a mean (SD) age of 66 (±8) years met the inclusion criteria and were randomly assigned to the placebo control group (n=61) or experimental KT group (n=62). A flow chart of the recruitment and follow-up of participants is depicted in figure 4 and details the reasons for study exclusion. Baseline demographic characteristics were similar between groups for all variables (Table 5).

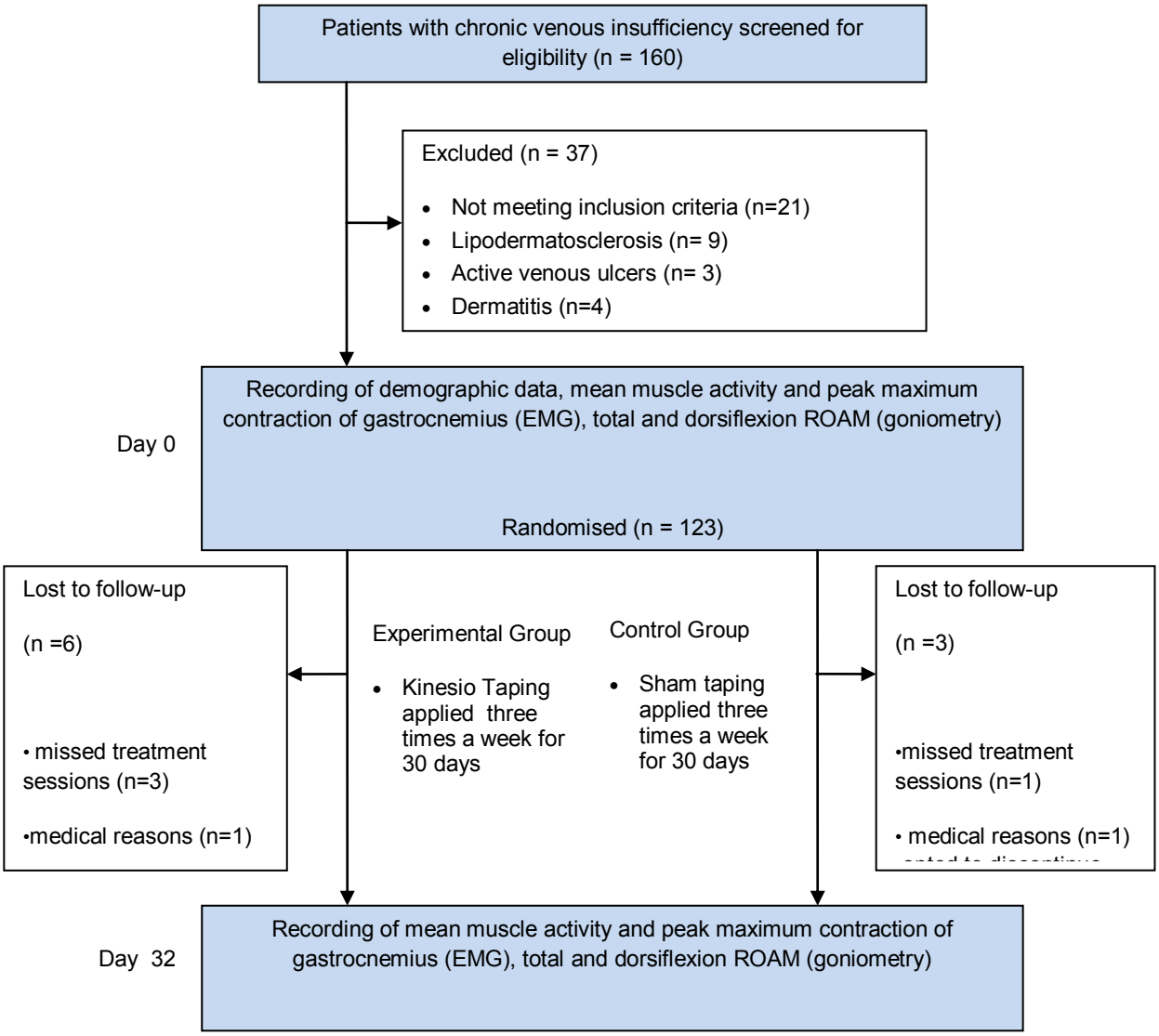


Figure 4. Design and flow of participants through the trial.

Table 5. Mean (SD) or number (%) of the groups of characteristics of patients at baseline.

	Experimental Group (*N =56)*	***Control Group (****N = 58)*
Age (*yr*) mean (SD)	66.05(13.7)	63.32(14.3)
CVI Aetiology, number (%)		
Congenital	0(0)	0(0)
Primary	47(83.9)	46(79.3)
Secondary	9(16.1)	12(20.7)
CEAP Classification, number (%)		
C1	3(5)	3(5)
C2	4(7.5)	9(15)
C3	49(87.5)	46(80)
Time since CVI onset, number (%)		
≤ 10 yrs	14(25)	16(27.6)
> 10 yrs	42(75)	42(72.4)
Work Activity, number (%)		
Housewife	13(23.2)	17(29.3)
Profession involving prolonged sitting	24(42.8)	22(37.9)
Profession involving prolonged standing	20(35.7)	19(32.8)
Physical activity, number (%)		
0 to <3 h/week	4(7.2)	10(17.2)
3 to <6 h/week	9(16.1)	12(20.7)
6 to <9 h/week	16(28.6)	19(32.7)
9 to <12 h/week	21(37.5)	15(25.9)
≥12 h/week	6(10.6)	2(3.5)
Medical comorbidities, number (%)		
Diabetes	8(14.3)	9(15.5)
Hypertension	16(28.6)	14(24.1)
Osteoarticular disease	20(35.7)	18(31.1)
Heart failure	10(17.8)	13(22.4)
Dyspnoea	2(3.6)	4(6.9)

CEAP, Clinical, etiological, anatomical, and pathophysiological scale; CVI, Chronic Venous insufficiency.

5.2.1 Effect of intervention

Tables 6 and 7 exhibit the results for, quality of life, severity, pain, leg volume, and ROAM in the experimental and control groups.

Table 6. Number (%) for venous symptoms and its statistical significance between groups.

Outcomes measures		***Baseline***		***One month post-treatment***		
		EG	*CG*	*EG*	*CG*	*P*
		N = 56	*N = 58*	*N = 56*	*N = 58*	
Clinical CVI manifestations						
Pain localization	P	6(10.7)	4(6.7)	13(23.2)	6(10.3)	0.001*
	CA	2(3.6)	3(5.2)	10(17.8)	3(5.1)	
	PF	9(16.1)	6(10.3)	5(8.9)	7(12.1)	
	CA & P	10(17.9)	16(25.9)	20(35.7)	14(24.1)	
	CA & PF	9(16.1)	12(20.7)	6(10.7)	11(18.9)	
	CA, P & PF	20(35.6)	18(31.2)	2(3.5)	17(29.5)	
Venous claudication	Non	17(30.3)	23(39.6)	31(55.3)	23(39.6)	0.042*
	Mild	20(35.7)	24(41.4)	14(25)	26(44.8)	
	Moderate	12(21.4)	8(13.8)	4(7.1)	6(10.3)	
	Severe	7(12.6)	3(5.2)	7(12.3)	3(5.2)	
Swelling		50(90)	51(87.5)	35(62.5)	48(82.7)	0.020*
Pigmentation		0(0)	0(0)	0(0)	0(0)	1.000
Lipodermatosclerosis		0(0)	0(0)	0(0)	0(0)	1.000
Nº of ulcers		0(0)	0(0)	0(0)	0(0)	1.000
Coloring	Normal	41(72.5)	44(75)	49(87.5)	41(70.7)	0.038*
	Ochre	15(27.5)	14(25)	7(12.5)	17(29.3)	
	Cyanosis	0(0)	0(0)	0(0)	0(0)	
Heaviness		52(92.5)	48(82.7)	31(55.3)	44(75.8)	0.030*
Muscles cramps		39(70)	39(67.5)	18(32.1)	41(70.7)	0.001*
Pruritus		11(20)	7(12.5)	4(7.1)	7(12.1)	0.529

*p< 0.05

EG, experimental group; CG, control group; CVI, Chronic Venous insufficiency; P, perimalleolus; CA, Calf; PF, Popliteal fossa.

Table 7. Mean (SD) for Quality of life, Severity, Pain, Volume, Range of Ankle Motion (ROAM) and mean (SD) difference within-between groups (95% CI).

Outcome/ Group		**Baseline**	**One Month Post-treatment**	**Within-Group Mean difference**	**Between-Group Mean difference**
CIVIQ (*0-100*)[a]					
Experimental		65.5(9.1)	66.2(8.9)	-0.96 (0.1 to -2.1)	-1.2(3.5 to-5.8)
Control		63.3(10.9)	63.6(11.4)	-0.3(0.6 to -1.2)	
VCSS (*0 to 30*)					
Experimental		5.5(1.2)	3.6(1.6)	1.8 (1.6 to 2.1)	-1.3(-0.8 to -1.8)
Control		5.1(1.3)	4.9(1.5)	0.1(-0.2 to 0.3)	
VAS (*0 to 10*)					
Experimental		5.7(2.1)	3.6(1.4)	2.1(1.9 to 2.5)	-1.74 (-2.3 to -1.15)
Control		5.6(2.3)	5.3(1.8)	0.32(0.07 to 0.57)	
Volume (cm^3)					
Experimental	RLL	2290.3(265.8)	2285.3(276.9)	5.1 (-1.0 to 11.1)	-3.6(-107.1 to 114,2)
	LLL	2276.7(249.4)	2268.3(250.3)	7.5(-1.6 to 16.6)	-19.7 (85.8 to 125.2)
Control	RLL	2292.3(324.4)	2288.9(327.6)	3.4(-0.7 to 7.6)	
	LLL	2299.9(322.1)	2287.9(313.4)	10.9(-11.9 to 33.7)	
Total ROAM (º)					
Experimental	RLL	67.9(4.1)	67.9(4.1)	0.1(-0.2 to 0.3)	-0.2(1.4 to -1,8)
	LLL	67.1(4.3)	66.9(4.7)	0.2 (-0.5 to 0.9)	-0.02(1.7 to -1.7)
Control	RLL	68.0(4.7)	67.9(4.5)	0.1(-0.1 to 0.3)	
	LLL	66.2 (4.3)	66.3(4.6)	-0.2(0.1 to -0.5)	
Dorsiflexion ROAM (º)					
Experimental	RLL	20.3(3.1)	22.4 (2.7)	-0.1(0.3 to -0.5)	-0.1(0.8 to -1.1)
	LLL	20.9(3.4)	21.1(3.0)	-0.2(0.2 to -0.7)	0.8(-0.4 to 2.0)
Control	RLL	20.5 (2.7)	20.5 (2.4)	-0.03(0.2 to-0.3)	
	LLL	20.3(3.47)	20.3 (3.5)	-0.02(-0.4 to 0.4)	

CIVIQ, Chronic Lower Limb Venous Insufficiency Questionnaire; VCSS, Venous Severity Score; VAS, visual analogue scale; [a]primary outcome.

At 4 weeks post-treatment, significant between-group differences were observed in venous symptoms, and the experimental group alone showed improvements versus pre-treatment values in claudication ($p<0.015$), swelling ($p<0.002$), colouring ($p<0.047$), heaviness perception ($p< 0.001$), muscle cramps ($p<0.001$), and pruritus ($p<0.016$), with significant reductions of 15-37.2 % in these symptoms. Pain distribution was also significantly reduced in the experimental group ($p<0.001$), with the majority experiencing pain relief at one or two sites but with a persistence of pain at perimalleolar and calf levels.

The experimental group evidenced an improvement in CVI severity (95%CI, 1.6 to 2.1 points) but showed no significant pre-post-treatment changes in quality of life or lower limb volumes.

Within-group comparisons demonstrated significant differences in pain score between baseline and 4 weeks post-treatment in both groups, although the improvement was significantly greater in the experimental group (95%CI, 1.9 to 2.5) than in the controls (95%CI 0.07 to 0.57).

The Student's *t*-test showed statistical significance for the dependent variable root-mean-square (**Figure 5**), finding more electrical activation in the experimental versus placebo group for the external and internal calf muscle of both lower limbs (right lower limb: LG 95% CI=2.99 to 5.84, MG 95% CI=1.02 to 3.42; left lower limb: LG 95% CI=3.00 to 6.25, MG 95% CI=3.29 to 5.3). Within-group analysis for this variable showed significant pre- versus post-treatment improvements in the experimental group (right lower limb: LG 95 % CI= -3.18 to -5.19, MG 95%CI=-2.16 to -3.81; left lower limb: LG 95%CI=-2.42 to -5.67, MG 95%CI= -3.08 to -4.98) but not in the placebo group (right lower limb: LG 95%CI=-0.22 to 0.3, MG 95%CI=-0.12 to 0.24; left lower limb: LG 95%CI=-0.11 to 0.79, MG 95%CI=-0.35 to 0.40).

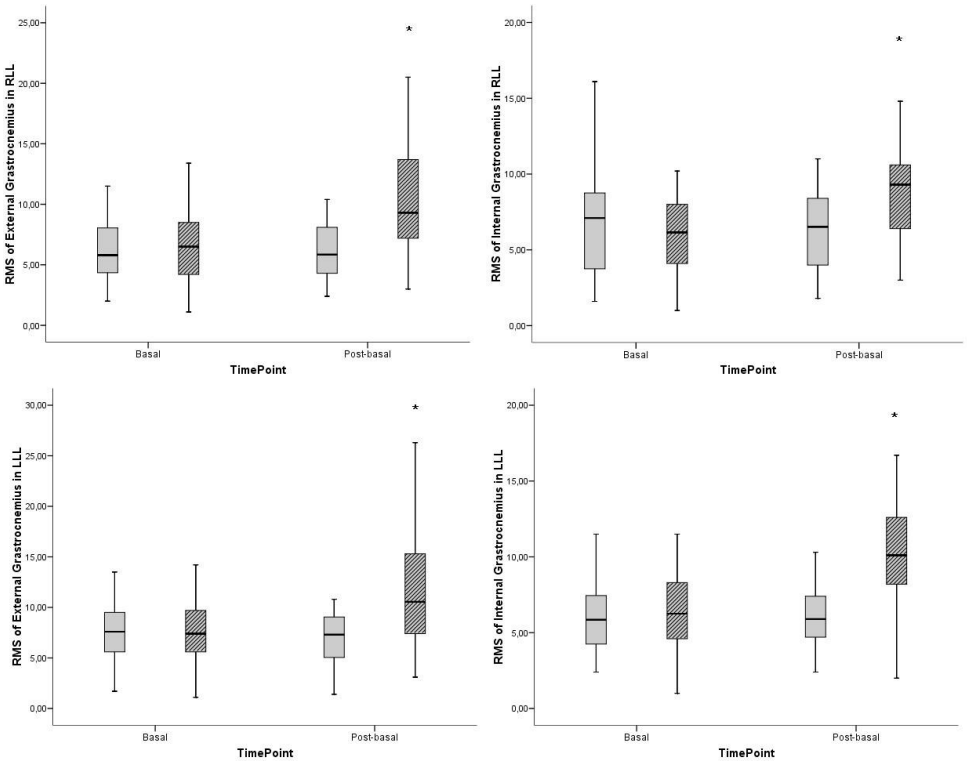


Figure 5. Mean activation of external and internal gastrocnemius muscles in both lower limbs, expressed as percentage of maximal voluntary isometric contraction (%MVIC) at baseline and post-application in control (grey box) and experimental groups (striped box). *P-value< 0.05 (95 % confidence interval). RMS, root-mean-square; RLL, right lower limb; LLL, left lower limb.

Similar results were obtained for the dependent variable peak of maximal contraction (**Figure 6**), finding a significantly greater improvement in the experimental versus placebo group (right lower limb: LG 95%CI= 4.8 to 22.7), MG 95%CI= 2.67 to 24.62; left lower limb: LG 95%CI= 2.37 to 20.44, MG 95%CI= 2.55 to 25.53) and significant within-group improvements in the experimental group (right lower limb: LG 95%CI=-8.18 to -14.06, MG 95%CI=-4.90 to -5,79; left lower limb: LG 95%CI=-5,96 to -10.40, MG 95%CI=-6.42 to -9.04) but not in the placebo group (right lower limb: LG 95%CI=-1.03 to 1.54 [P<.0.690], MG 95%CI=-1.04 to 1.88; left lower limb: LG 95%CI=-0.63 to 1.40, MG 95%CI=-0.82 to 3.69).

There were no significant post-treatment differences between or within groups in total or dorsiflexion ROAM values.

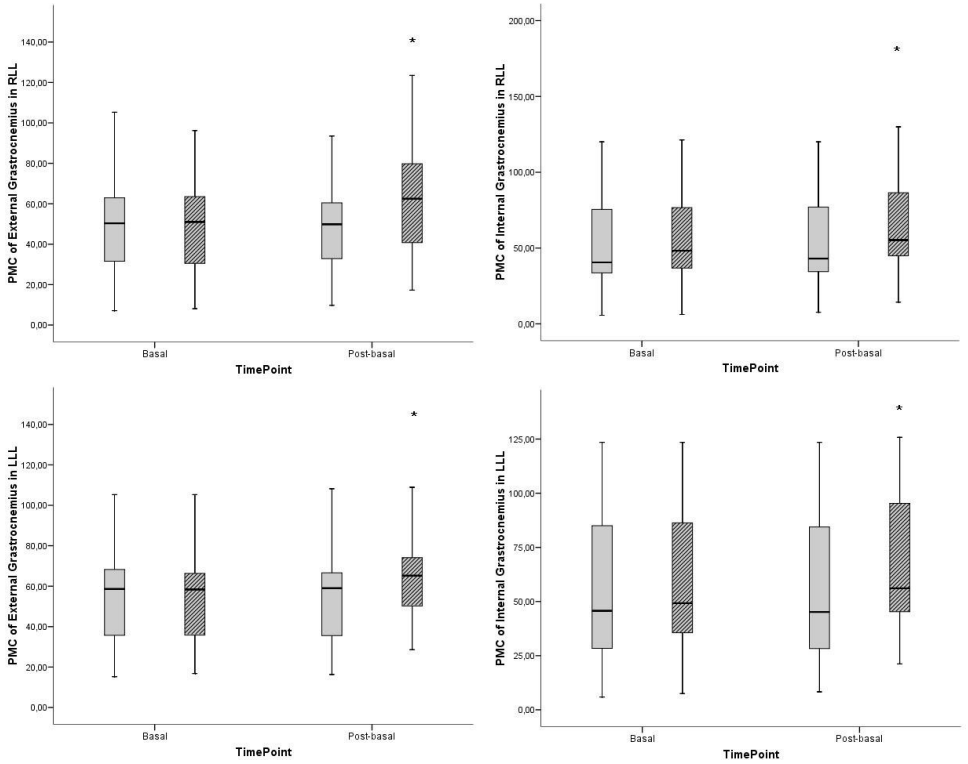


Figure 6. Maximum peak contraction of external and internal gastrocnemius muscles in both lower limbs, expressed as percentage of maximal voluntary isometric contraction (%MVIC) at baseline and post-application for control (grey box) and experimental (striped box) groups. PMC, peak of maximal contraction; RLL, right lower limb; LLL, left lower limb.*P-value< 0.05 (95 % confidence interval).

5.3 Study III: "Effect of a mixed Kinesio Taping-compression technique on clinical and gait parameters in females with chronic venous insufficiency: Double-blinded, randomized clinical trial".

Out of the 130 patients recruited for the study, 120 patients with mean (SD) age of 65 (±13) years met the inclusion criteria and were randomly assigned to one of two intervention groups; placebo control group (n=60) and experimental KT group (n=60). A flow chart of the recruitment and follow-up of the patients is depicted in **Figure 7** and details the reasons for study exclusion. Baseline demographic characteristics (P<.414) were similar between groups for all variables (**Table 8**).

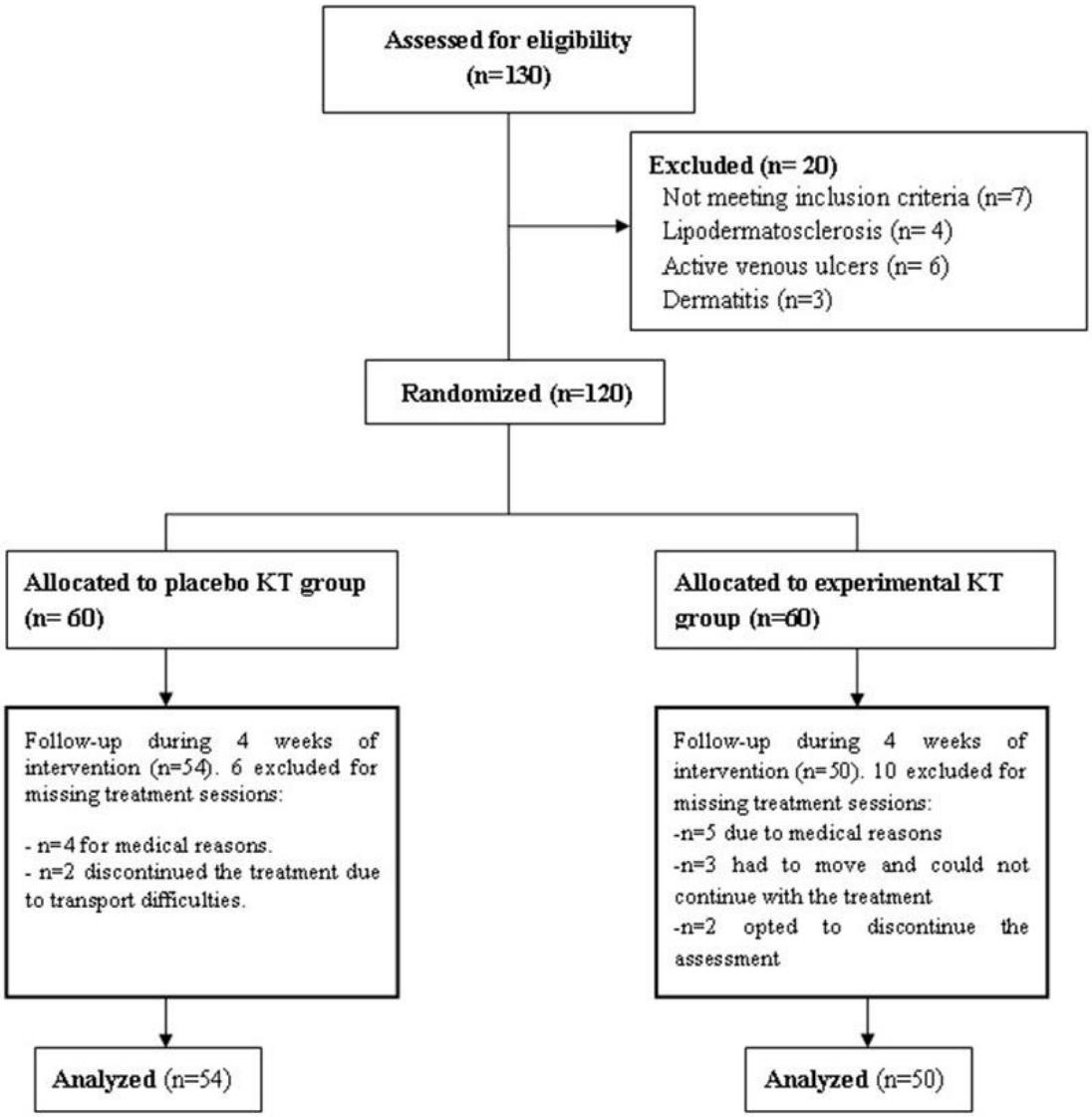


Figure 7. Flow diagram of the recruitment and follow-up of patients in the study

Table 8. Characteristics of patients at baseline

	Experimental Group N =50		*Control Group N = 54*		*P-value*
Mean age	64.40±13.1		66.48±12.7		.414
Age range	60-68		63-70		
Body mass index (kg/m^2)	26.86±4.8		27.69±4.6		.434
Time since CIV onset (years)	18.9±11.2		17.51±8.4		.472
	Freq	%	*Freq*	%	
CIV etiology					.802
Congenital	0	.0	0	.0	
Primary	39	78	41	75.9	
Secondary	11	22	13	24.1	
VDS					.659
Grade 0	0	.0	0	.0	
Grade 1	39	78	43	22	
Grade 2	11	22	11	20.4	
Grade 3	0	.0	0	.0	
Previous treatments					.822
None	13	26.0	10	18.5	
Pharmaceuticals	5	10.0	6	11.1	
Elastocompression	14	28.0	13	24.1	
Surgery	0	.0	1	1.9	
Laser	0	.0	0	.0	
Physiotherapy	0	.0	0	.0	
Pharmaceuticals plus elastocompression	12	24.0	13	24.1	
Pharmaceuticals plus laser	0	.0	0	.0	
Pharmaceuticals plus surgery	4	8.0	7	13.0	
Elastocompression plus surgery	2	4	4	7.4	

Values are expressed as absolute and relative frequencies (N=108) for categorical variables and as means and standard deviations (SD) for continuous variables. No differences between groups (P>.414). CIV, Chronic Venous insufficiency; VDS, Venous Disability Score; Grade 0, asymptomatic; Grade 1, symptomatic, works without external support; Grade 2, symptomatic, can only work with external support (8 h/day); Grade 3, complete employment disability.

The Student's t-test showed statistical significance for the dependent variable dorsiflexion ROAM during gait (**Table 9**), finding differences between groups in results for right (RLL) and left (LLL) lower limbs (RLL p=0.001; LLL p=0.024). Within-group analysis of this variable showed significant differences between baseline and final treatment conditions in the experimental group (RLL p=0.001; LLL p=0.001) but not in the placebo group (p≥0.497).

Table 9. Differences between and within groups in Range of Ankle Motion (ROAM).

Outcome/ Group		Baseline	One Month Post-treatment	Within-Group Mean difference	*p* Value	Between-Group Mean difference	*p* Value
Total ROAM(º)							
Experimental	RLL	66.42±2.82	66.77 ± 3.13	0.02(-0.15,0.19)	0.811	-0.23(-2.03,1.57)	0.798
	LLL	65.20 ± 4.03	65.18 ± 3.99	0.02(-0.16, 0.20)	0.821	0.56(-1.05,2,17)	0.492
Control	RLL	67.28± 4.46	67.44 ± 4.45	-0.16(-0.34, 0.07)	0.677		
	LLL	65.70 ± 4.22	65.74 ± 4.27	0.04 (-0.32, 0.25)	0.796		
Dorsiflexion ROAM(º)							
Experimental	RLL	20.45±2.56	20.62 ± 2.53	-0.20(-0.56, 0.16)	0.268	-0.10 (-1.14,0.94)	0.847
	LLL	20.36 ± 3.36	20.40 ± 3.40	-0.04(-0.52, 0.44)	0.868	0.36 (-0.92,1.64)	0.579
Control	RLL	20.31±2.96	20.51 ± 2.80	-0.20(-0.48, 0.07)	0.147		
	LLL	20.54 ± 3.46	20.76 ± 3.18	-0.22(-0.67, 0.23)	0.329		
Gait dorsiflexion ROAM(º)							
Experimental	RLL	93.04 ± 1.69	90.42 ± 1.19	2.62 (2.20, 3.03)	0.001*	2.98 (2.40, 3.57)	0.001*
	LLL	92.72 ± 2.12	90.22 ± 1.26	2.53 (2.11, 2.93)	0.001*	2.81 (2.22.3.41)	0.024*
Control	RLL	93.03 ± 1.88	93.35 ± 1.74	-0.05(-0.36, 0.25)	0.718		
	LLL	92.90 ± 1.84	93.15 ± 2.73	-0.09(-0.35, 0.17)	0.497		

*p< 0.05

Values are expressed as mean ± SD for baseline and one month post-treatment and as mean difference (95% confidence interval) for within- and between-group. ROAM, range of ankle motion; RLL, right lower limb; LLL, left lower limb.

Similar results were obtained for cadence (p=0.001), stride length (RLL p=0.001; LLL p=0.001), step length (RLL p=0.001; LLL p=0.001), and stance phase (RLL p=0.042; LLL p=0.020) (**Table 10**), finding significant differences between groups in both legs. Within-group variations between baseline and 4-week follow-up

showed significant changes in these variables in the experimental group (p=0.001) but not in the placebo group (p≥0.070).

Table 10. Differences between and within groups in Gait parameters.

Outcome/ Group		Baseline	One Month Post-treatment	Within-Group Mean difference	*p* Value	Between-Group Mean difference	*p* Value
Cadence (steps/min)							
Experimental		65.60 ± 8.39	70.57 ± 8.42	-4.97(-5.18,-4.76)	0.001*	-3.53(-6.46,-0.59)	0.019*
Control		66.92 ± 6.80	67.05 ± 6.63	-0.12(-0.45,0.20)	0.455		
Stride length (cm)							
Experimental	RLL	37.60 ± 5.01	73.18 ± 9.53	-35.58(-34.28,-36.87)	0.001*	-37.23(-34.73,-39.73)	0.001*
	LLL	37.64 ± 4.95	73.40 ±9.42	-35.76(-34.48,-37.04)	0.001*	-36.37(-33.89,-38.85)	0.001*
Control	RLL	74.63 ±7.69	74.83 ± 7.49	-0.20(-0.59,0.18)	0.260		
	LLL	74.05 ±7.50	74.01 ± 7.44	0.04(-0.23,0.31)	0.784		
Step length (cm)							
Experimental	RLL	24.68 ± 3.30	38.58 ±5.09	-13.90 (-13.38,-14.42)	0.001*	-14.82(-13.39,-16.24)	0.001*
	LLL	24.84 ± 3.32	38.62 ±5.03	-13.78 (-13.25,-14.27)	0.001*	-14.21(-12.77,-15.65)	0.001*
Control	RLL	39.43 ±4.17	39.48 ± 4.00	-0.04(-0.27,0.19)	0.742		
	LLL	39.11 ± 4.12	39.07 ± 4.05	0.04(-0.16,0.23)	0.699		
Stance phase (ms)							
Experimental	RLL	917 ± 0.17	1005 ± 0.16	-88(-98,-80)	0.001*	-80(-160,-1)	0.042*
	LLL	904 ± 0.11	966 ± 0.12	-62(-70,-54)	0.001*	-99(-160, -40)	0.020*
Control	RLL	923 ± 0.11	925 ± 0.03	-2(-61,57)	0.955		
	LLL	902 ± 0.01	867 ±0.18	36(-3,74)	0.070		
Swing phase (ms)							
Experimental	RLL	561 ± 0.07	555 ± 0.07	6 (1, 11)	0.056	19 (-7, 44)	0.146
	LLL	563 ± 0.07	562 ± 0.06	1 (-4, 6)	0.586	6 (-19, 31)	0.630
Control	RLL	572 ± 0.06	574 ± 0.05	-1(-4, 1)	0.296		
	LLL	569 ± 0.06	568 ± 0.08	2 (- 10, 15)	0.740		
Double support phase (ms)							
Experimental	RLL	239 ± 0.03	236 ± 0.03	2 (-10, 15)	0.655	1(-1, 21)	0.075
	LLL	235 ± 0.04	237 ± 0.03	-2 (-10, 7)	0.683	4(-7, 15)	0.486
Control	RLL	245 ± 0.02	246 ± 0.03	-1(-3, 2)	0.525		
	LLL	243 ± 0.04	241 ± 0.02	2 (-1, 5)	0.102		

*p< 0.05

Values are expressed as means ± SD for baseline and one month post-treatment and as mean difference (95% confidence interval) for within- and between-group. RLL, right lower limb; LLL, left lower limb.

Finally, the group-by-time interaction (Student's *t*-test) showed significant post-treatment differences between groups in foot (RLL p=0.005; LLL p=0.014) and malleolus (RLL p=0.041; LLL p=0.011) circumference, VAS (p=0.001), PM (p=0.001) and CIVIQ (p=0.001) (**Table 11**). Within-group comparisons demonstrated significant differences between baseline and 4 weeks post-treatment for all variables (p=0.001) in the experimental group and for pain outcomes alone in the control group (VAS p=0.001; PM p=0.001). The improvement in pain scores between before and

after treatment was significantly greater in the experimental group (VAS 3.07±1.8; PM 3.20±1.2) than in the control group (VAS 0.36±0.7; PM 1.40±0.7).

Table 11. Differences between and within groups in lower limbs circumferences, pain, and quality of life.

Outcome/ Group		Baseline	One Month Post-treatment	Within-Group mean difference	*p* Value	Between-Group mean difference	*p* Value
FC (cm)							
Experimental	RLL	22.88 ± 1.29	22.15 ± 1.34	0.73 (0.56,0.92)	0.001*	0.76 (0.23, 1.29)	0.005*
	LLL	22.59 ±1.39	22.00 ± 1.25	0.59 (0.40, 0.79)	0.001*	0.68 (0.14, 1.28)	0.014*
Control	RLL	22.81 ±1.28	22.91 ± 1.34	-0.10(-0.24,0.04)	0.148		
	LLL	22.54 ±1.42	22.68 ± 1.52	-0.14(-0.38,0.10)	0.256		
MC (cm)							
Experimental	RLL	23.05 ±2.71	21.71 ± 2.53	1.34 (1.15, 1.52)	0.001*	1.07 (0.04,2.1)	0.041*
	LLL	22.88 ±2.55	21.49 ± 2.40	1.40 (1.18,1.63)	0.001*	1.29 (0.31,2.29)	0.011*
Control	RLL	22.84 ±2.74	22.79 ± 2.76	0.05(-0.06,0.16)	0.394		
	LLL	22.79 ± 2.65	22.78 ± 2.64	0.01(-0.12,0.14)	0.884		
CC (cm)							
Experimental	RLL	26.74 ± 2.81	25.88 ± 2.79	0.85(0.55,1.15)	0.001*	0.32(-0.77,1.41)	0.564
	LLL	27.15± 2.80	26.03 ± 2.59	1.12(0.76, 1.49)	0.001*	0.76(-0.31, 1.83)	0.164
Control	RLL	26.22 ± 2.84	26.20 ± 2.82	0.01(-0.12,0.14)	0.865		
	LLL	26.78 ± 2.82	26.79 ±2.90	-0.02(-0.18,0.15)	0.841		
VAS (0-10)							
Experimental		5.58 ± 2.09	2.51 ± 1.54	3.07 (2.56, 3.57)	0.001*	2.41(1.71, 3.12)	0.001*
Control		5.29 ± 2.33	4.92 ± 2.02	0.36 (0.16, 0.56)	0.001*		
PM (0-60)							
Experimental		11.08 ± 3.85	7.88 ± 3.40	3.20 (2.86, 3.54)	0.001*	1.51 (0.09, 2.93)	0.038*
Control		10.79 ± 4.21	9.39 ± 3.86	1.41(1.23, 1.59)	0.001*		
PT (0-60)							
Experimental		5.14 ± 1.22	5.51 ± 1.93	-0.37 (-0.84, 0.11)	0.127	-0.14 (-0.84, 0.56)	0.692
Control		5.54 ± 1.41	5.37 ± 1.64	0.17 (-0.31, 0.64)	0.483		
CIVIQ (0-100)							
Experimental		66.36± 11.7	72.48 ± 9.2	-6.12 (-7.56, -4.68)	0.001*	-8.76 (-12.55,-4.96)	0.001*
Control		63.80 ± 10.3	63.72 ± 10.2	0.07 (-0.59, 0.73)	0.823		

*p< 0.05

Values are expressed as means ± SD for baseline and one month post-treatment and as mean difference (95% confidence interval) for within- and between-group. FC, foot circumference; MC, malleolus circumference; CC, calf circumference; VAS, visual analogue scale; PM, pain magnitude; PT, pain threshold; CIVIQ, quality of life questionnaire in chronic lower limb venous insufficiency.

5.4 Study IV: "A controlled randomised trial of a mixed Kinesio Taping-compression technique on venous symptoms, pain, peripheral venous flow, clinical severity and overall health status in postmenopausal women with chronic venous insufficiency".

Recruitment started in September 2008 and ended in December 2009. Out of the 130 patients recruited for the study, 120 postmenopausal females (mean (SD) age of 65

(13) years) with initial CVI (C1, C2, or C3 CEAP scale) met the inclusion criteria, consented to participate in the study and were randomly assigned to 1 of 2 intervention groups: placebo control group (n = 60) and experimental KT group (n = 60). Figure 8 depicts the flow of patients through the study, giving the reasons for ineligibility. Baseline demographic characteristics (P < .066) were similar between groups for all variables (Table 12).

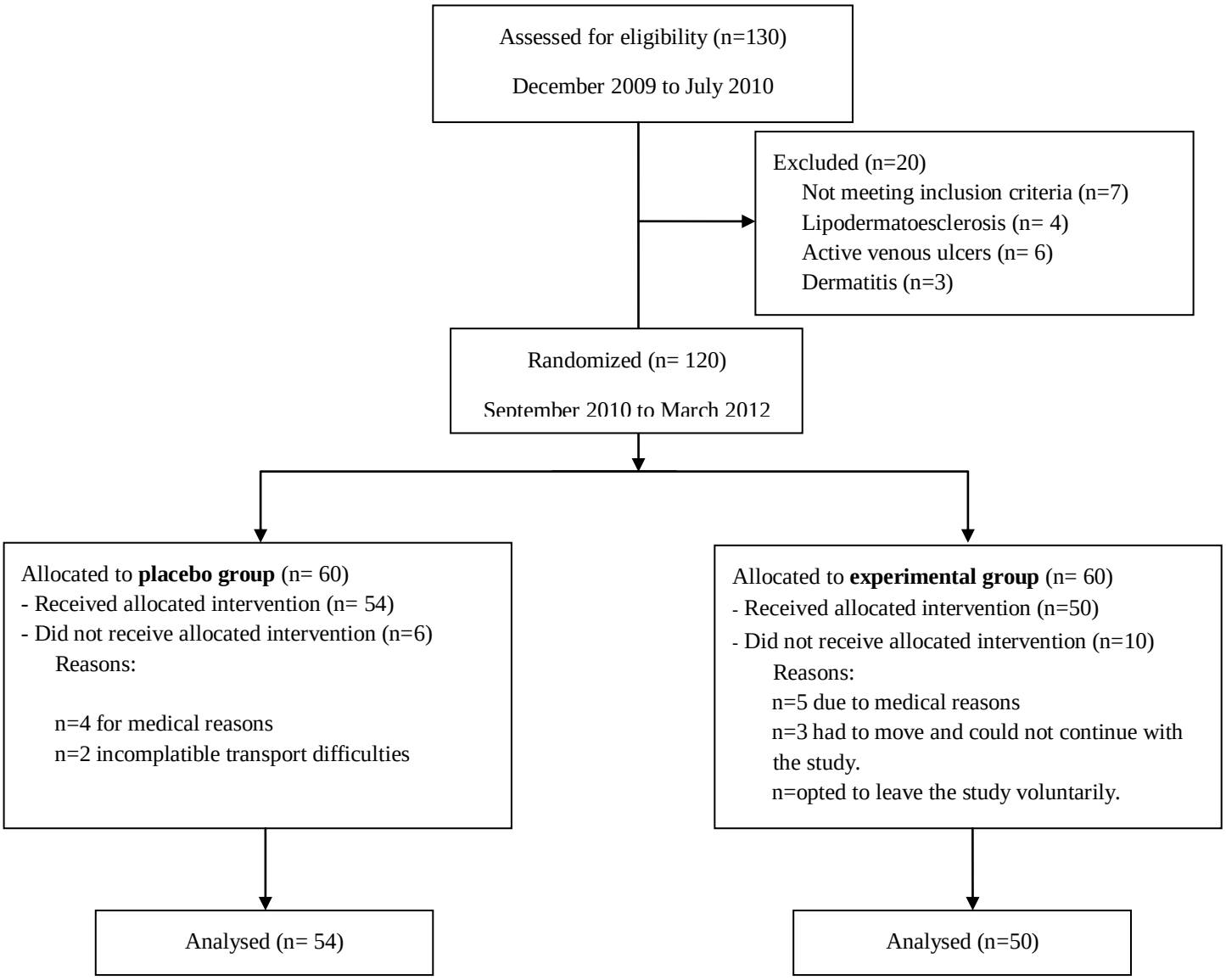


Figure 8. Flow of patients who participated in the study.

Table 12. Characteristics of patients at baseline

	Experimental Group		*Control Group*		*P-value*
	n=50		*n=54*		
Age (y) (mean ± SD)	64.40 ± 13.1		66.48 ± 12.7		0.414
Body mass index (kg/m^2)(mean ±SD)	26.86 ± 4.8		27.69 ± 4.6		0.434
Time since CIV onset (y) (mean ± SD)	18.9 ± 11.2		17.51 ± 8.4		0.472
	Freq	%	*Freq*	%	
CIV aetiology					0.802
Congenital	0	0.0	0	0.0	
Primary	39	78.0	41	75.9	
Secondary	11	22.0	13	24.1	
VDS					0.659
Grade 0	0	0.0	0	0.0	
Grade 1	39	78.0	43	22.0	
Grade 2	11	22.0	11	20.4	
Grade 3	0	0.0	0	0.0	
Predisposing factors					
Family history	29	58.0	34	62.9	0.066
Orthostatism at work	37	74.0	39	72.2	0.596
Exposure to heat	1	2.0	2	3.7	0.960
Lower limb trauma	13	26.0	9	16.7	0.250
Sedentarism	20	40.0	22	40.7	0.085
Inadequate clothing and footwear	9	18.0	16	29.6	0.305
Pretreatment status					0.112
Major improvement	0	0.0	0	0.0	
Slight improvement	3	6.0	2	3.7	
Stabilisation	14	28.0	19	35.1	
Worsening	32	64.0	33	61.1	
Major worsening	1	2.0	0	0.0	

Values are expressed as absolute and relative frequencies (n=104) for categorical variables and as means ± standard deviation for continuous variables. Abbreviations: CIV (Chronic Venous insufficiency) and VDS (Venous Disability Score. Grade 0: asymptomatic; Grade 1: symptomatic, works without external support; Grade 2: symptomatic, can only work with external support (8 h/day); Grade 3: complete employment disability).

5.4.1Venous symptoms and pain

Within-group analysis of venous symptoms showed significant differences between baseline and final treatment conditions (4 weeks) in the experimental group for all venous symptoms (P = .001) with the exception of pruritus. No significant changes were observed in the placebo group ($P \geq 0.200$) (Table 13). Post-treatment analysis (ANCOVA) between groups showed a significantly lower score in the experimental *versus* placebo group in heaviness ($F = 20.32$; $P = .002$), venous claudication ($F = 8.57$; $P = .004$), swelling ($F = 22.58$; $P = .001$) and muscle cramps ($F = 7.14$; $P = .008$).

Paired comparisons with baseline values demonstrated significant differences in all pain variables at 4 weeks post-treatment in the experimental group ($P = .001$) but only in MPQ sensory ($P = .032$) and VAS ($P = .016$) outcomes in the control group. The improvement in pain scores (Table 3) between before and after treatment was significantly greater in the experimental group (MPQ sensory 3.32 (1.88); VAS 3.12 (1.77)) than in the control group (MPQ sensory .28 (0.76); VAS .37 (.78)). ANCOVA showed statistically significant intergroup differences in MPQ sensory ($F = 35.50$; $P = .001$), MPQ affective ($F = 5.85$; $P = .032$), MPQ sensory & affective ($F = 10.46$; $P = .009$ and VAS ($F = 23.94$; $P = .001$) scores. Table 13 shows within and between-group changes scores (with 95% CI) for venous symptoms, pain and its within-group significance level.

Table 13 . Baseline, post-treatment, pre-post-treatment differences and change scores in each group (95% confidence interval) for venous symptoms and pain.

Outcome/ Group	Baseline	One Month Post-treatment	Paired t-test *P*	Within-Group Score Change	Between-Group Score Change
Heaviness (0-3)					
Experimental	2.22 ± 0.65	1.24 ± 0.59	0.001*	0.98 (0.80, 1.15)	-0.81(-1.11, -0.52)
Control	2.02 ± 0.73	2.11 ± 0.84	0.341	-0.09 (-0.28, 0.10)	
Venous claudication (0-3)					
Experimental	1.65 ± 0.75	0.98 ± 0.55	0.001*	0.64 (0.47, 0.80)	-0.61 (-0.89, -0.33)
Control	1.61 ± 0.79	1.59 ± 0.83	0.766	0.02 (-0.10, 0.14)	
Swelling (0-3)					
Experimental	2.06 ± 0.68	1.10 ± 0.64	0.001*	0.96 (0.79, 1.12)	-0.90 (-1.17, -0.63)
Control	1.98 ± 0.87	2.00 ± 0.80	0.849	-0.02 (-0.21, 0.18)	
Muscle cramps (0-3)					
Experimental	1.00 ± 0.86	0.30 ± 0.58	0.001*	0.70 (0.52, 0.88)	-0.81(-1.11,0.52)
Control	1.02 ± 0.87	1.11 ± 0.90	0.200	-0.09 (-0.23, 0.05)	
Pruritus (0-3)					
Experimental	0.26 ± 0.59)	018 ± 0.48)	0.209	0.08 (-0.05, 0.21)	-0.08 (-0.28,0.13)
Control	0.29 ± 0.66)	0.25 ± 0.59)	0.159	0.03 (-0.01, 0.09)	
MPQ Sensory (1-53)					
Experimental	4.96 ± 1.75)	1.94 ± 1.07)	0.001*	3.02 (2.50, 3.54)	-2.37 (-2.96,-1.79)
Control	4.57 ± 1.94)	4.31 ± 1.81)	0.022*	0.26 (0.06, 0.46)	
MPQ Affective (1-9)					
Experimental	2.62 ± 1.78	2.64 ± 1.65	0.647	0.08 (-0.27, 0.43)	-0.23 (-0.90,0.43)
Control	2.73 ± 1.82	2.77 ± 1.75	0.371	-0.05 (-0.11, 0.19)	
MPQ Evaluative (1-4)					
Experimental	1.60 ± 0.64	1.06 ± 0.23	0.001*	0.54 (0.36, 0.71)	-0.62 (-0.83,-0.41)
Control	1.66 ± 0.58	1.68 ± 0.69	0.821	-0.01 (-0.18, 0.07)	
MPQ PRI (1-66)					
Experimental	9.18 ± 3.20	5.54 ± 2.25	0.001*	3.64 (2.97, 4.30)	-3.24 (-4.45,-2.03)
Control	8.96 ± 3.99	8.77 ± 3.72	0.255	0.18 (-0.14, 0.51)	
MPQ PPI (1-5)					
Experimental	2.24 ± 1.01	1.26 ± 0.56	0.001*	0.98 (0.70, 1.56)	-0.92 (-1.25,-0.60)
Control	2.28 ± 1.03	2.18 ± 1.04	0.341	0.09 (-0.10, 0.28)	
VAS (0-10)					
Experimental	5.63 ± 2.07	2.51 ± 1.54	0.001*	3.12 (2.61, 3.63)	-2.40 (-3.09,-1.70)
Control	5.28 ± 2.36	4.91 ± 1.99	0.016*	0.37 (0.16, 0.59)	

*p< 0.05

Values are expressed as means ± standard deviation for baseline and 1 month post-treatment and as mean score change (95% confidence interval) for within- and between-group values. Abbreviations: MPQ (McGill pain questionnaire), PPI (present pain intensity), PRI (pain rating index) and VAS (visual analogue scale).

5.4.2 Peripheral venous flow

At the end of the 4-week treatment period, the experimental group showed a significant improvement *versus* baseline in VRT (right: $P = .001$; left: $P = .001$) and VPP (right: $P = .011$; left: $P = .003$) values and a significant reduction in extracellular water (right: $P= .021$; left: $P = .015$) for both lower limbs. However, the placebo group showed no significant differences versus baseline values. In addition, post-treatment analysis (ANCOVA) showed that the experimental group presented significantly less extracellular water (right: $F = 35.55$, $P = .004$; left: $F = 23.84$, $P = .001$) and higher VRT (right: $F = 9.45$, $P = .012$; left: $F = 14.86$, $P = .001$) and VPP (right: $F = 35.55$, $P = .004$; left: $F = 17.39$, $P = .001$) values *versus* the placebo group for both lower limbs. Table 14 shows within and between-group changes scores (with 95% CI) for all venous functional parameters and its within-group significance level.

Table 14. Baseline, post-treatment, pre-post-treatment differences and change scores in each group (95% confidence interval) for functional venous parameters.

Outcome/ Group		Baseline	One Month Post-treatment	Paired t-test *P*	Within-Group Score Changes	Between-Group Score Changes
VRT (s)						
Experimental	Right	15.67 ± 6.53	21.36 ± 7.34	0.001*	-5.68 (-7.37,- 3.99)	5.10 (2.39,7.80)
	Left	17.16 ± 7.19	25.54 ± 9.91	0.001*	-8.38 (-10.77,-5.77)	9.36 (6.04, 12.69)
Control	Right	16.38 ± 6.80	16.26 ± 7.01	0.560	0.12 (-0.29, 0.52)	
	Left	16.20 ± 7.03	16.17 ± 7.20	0.907	0.02 (-0.35, 0.40)	
VPP (Vo%)						
Experimental	Right	2.28 ± 0.94)	3.51 ± 1.16	0.011*	-1.22 (-1.05,-.94)	1.13(0.73,1.53)
	Left	2.33 ± 0.98)	3.66 ± 1.46	0.003*	-1.32 (-1.68,-.96)	1.27(0.78,1.76)
Control	Right	2.30 ± 0.93)	2.37 ± 0.90	0.183	-0.07 (-0.19,0.03)	
	Left	2.31 ± 1.01)	2.39 ± 1.20	0.200	-0.06 (-0.18,0.04)	
Cell mass (kg)						
Experimental	Right	24.38 ± 4.13	24.81 ± 3.29	0.288	-0.43 (-1.2,-0.37)	-1.21(-0.09, 2.5)
	Left	24.74 ± 4.05	25.09 ± 3.09	0.267	-0.35 (-98,0.29)	-1.24 (-0.10,-2.6)
Control	Right	23.39 ± 3.79	23. 59 ± 3.43	0.332	-0.20 (-0.60,0.21)	
	Left	23.72 ± 3.92	23.84 ± 3.77	0.498	-0.12 (-0.49,0.24)	
Fat mass (kg)						
Experimental	Right	33.34 ± 10.96	33.27 ± 10.89	0.700	.06 (-0.27,0.41)	2.71(-0.80,6.2)
	Left	33.23 ± 10.95	33.48 ± 10.80	0.378	-0.25 (-0.81,0.31)	2.86 (-0.69, 6.4)
Control	Right	30.82 ± 7.11	30.56 ± 6.91	0.237	0.26 (-.18,0.71)	
	Left	31.04 ± 7.08	30.62 ± 7.25	0.134	0.41 (-.13,0.97)	
Intracellular water (l)						
Experimental	Right	22.45 ± 3.66	22.89 ± 3.30	0.141	-0.43 (-1.02, 0.15)	.77 (-0.46, 2.01)
	Left	22.26 ± 3.37	22.21 ± 2.74	0.851	0.06 (-0.56, .67)	.06 (-0.46, 2.03)
Control	Right	22.11 ± 3.39	22.12 ± 3.02	0.968	-0.01 (-0.38, .36)	
	Left	22.11 ± 3.39	22.15 ± 3.68	0.945	-0.04 (-1.21, 1.13)	
Extracellular water (l)						
Experimental	Right	5.93 ± 1.51	3.43 ± 1.44	0.021*	2.51 (2.22, 2.79)	-2.11(-2.67, -1.56)
	Left	5.86 ± 1.61	3.29 ± 1.43	0.015*	2.57 (2.28, 2.86)	-2.03(-2.59, -1.45)
Control	Right	5.64 ± 1.43	5.54 ± 1.42	0.280	0.10(-0.08, 0.28)	
	Left	5.34 ± 1.39	5.32 ± 1.47	0.913	0.01 (-0.22, 0.25)	
Temperature PF (ºC)						
Experimental	Right	32.95 ± 1.46	32.97 ± 1.40	0.902	-0.01 (-0.24, 0.21)	0.14 (-0.44, 0.73)
	Left	33.25 ± 1.50	33.11 ± 1.99	0.357	0.13 (-0.15, 0.40)	0.28 (-0.48, 1.04)
Control	Right	32.88 ± 2.16	32.83 ± 1.59	0.724	0.05 (-0.23, 0.33)	
	Left	32.93 ± 1.98	32.84 ± 1.91	0.436	0.10 (-0.15, 0.36)	
Temperature EC (ºC)						
Experimental	Right	31.98 ± 1.48	32.04 ± 1.65	0.712	-0.05(-0.34, 0.23)	0.20(-0.49, 0.91)
	Left	32.24 ± 1.30	32.32 ± 1.74	0.900	0.02 (-0.29, 0.34)	-0.04(-0.85, 0.77)
Control	Right	32.00 ± 2.62	31.83 ± 1.94	0.289	0.17(-0.15, 0.49)	
	Left	32.24 ± 2.93	32.26 ± 2.37	0.926	-0.01 (-0.25, 0.23)	
Temperature DF (ºC)						
Experimental	Right	30.89 ± 1.57	30.96 ± 1.82	0.651	-0.07 (-0.38, 0.23)	-0.09(-0.92, 0.73)
	Left	30.85 ± 2.03	30.62 ± 2.77	0.187	0.23 (-0.12, 0.58)	0.07(-0.78, 0.93)
Control	Right	30.77 ± 2.77	31.06 ± 2.35	0.163	-0.29 (-0.71, 0.12)	
	Left	30.59 ± 2.52	30.55 ± 2.36	0.763	0.04 (-0.23, 0.31)	

*p< 0.05

Values are expressed as means ± standard deviation for baseline and 1 month post-treatment and as mean score change (95% confidence interval) for within- and between-group values. Abbreviations: DF (dorsal foot), EC (external calf muscle), PF (popliteal fossa), VPP (venous pump power) and VRT (venous refill time).

5.4.3 Severity of venous disease and overall health status

At 4 weeks after the treatment, the experimental group showed significant differences versus baseline in severity (P = .001), physical function (P = .010) and body pain (P = .012). No significant changes were observed in the placebo group. After treatment (ANCOVA analysis), the experimental group showed significantly higher scores in physical function (F = 9.15; P = .003) and body pain (F = 3.36; P = .043) and less severity (F = 18.47; P = .001) in comparison to placebo group. Table 15 shows within and between group changes in scores (with 95% CI) for severity and overall health status and its within-group significance level.

Table 15. Baseline, post-treatment, pre-post-treatment differences and change scores in each group (95% confidence interval) for severity and overall health status.

Outcome/ Group	Baseline	One Month Post-treatment	Paired t-test *P*	Within-Group Score Change	Between-Group Score Change
VCSS (0-30)					
Experimental	5.62 ± 1.06	3.28 ± 1.19	0.001*	2.34 (2.03, 2.65)	-1.83 (-2.32, -1.33)
Control	5.22 ± 1.16	5.11 ± 1.35	0.451	0.11 (-0.18, 0.40)	
Physical function (0-100)					
Experimental	75.92 ± 6.89	80.96 ± 6.99	0.010*	-5.74 (-6.84, 4.63)	6.08 (3.38, 8.79)
Control	75.01 ± 7.22	74.87 ± 6.93	0.733	0.14 (-0.72, 1.01)	
Physical role; (0-100)					
Experimental	52.80 ± 8.72	51.98 ± 9.51	0.069	0.82 (-0.05, 0.69)	-0.68 (-4.38, 3.01)
Control	53.28 ± 8.93	52.66 ± 9.49	0.193	0.61 (-0.31, 1.53)	
Body pain (0-100)					
Experimental	49.26 ± 7.70	52.34 ± 8.62	0.012*	-3.08 (-4.13, -2.03)	3.81 (.58,7.04)
Control	48.94 ± 8.16	49.07 ± 8.10	0.825	-0.13 (-1.30, 1.04)	
General health (0-100)					
Experimental	57.56 ± 8.28	56.84 ± 7.44	0.226	0.72 (-0.46, 1.09)	1.13 (-1.9, 4.20)
Control	55.83 ± 8.08	55.70 ± 8.29	0.748	0.13 (-0.68, 0.93)	
Vitality (0-100)					
Experimental	51.88 ± 8.58	52.66 ± 9.39	0.120	-0.78 (-1.77, 0.21)	-1.32 (-4.68,2.04)
Control	53.74 ± 10.3	54.15 ± 9.09	0.345	-0.40 (-1.26, 0.45)	
Social function (0-100)					
Experimental	75.34 ± 7.23	74.90 ± 7.47	0.511	0.44 (-0.89, 1.77)	1.51 (-1.61,4.60)
Control	72.42 ± 8.15	73.39 ± 8.51	0.153	-0.96 (-2.31, 0.39)	
Emotional role (0-100)					
Experimental	49.56 ± 7.84	48.58 ± 8.10	0.073	0.98 (-0.09, 2.05)	-0.97 (-4.20,2.26)
Control	50.11 ± 7.86	49.55 ± 8.53	0.287	0.55 (-0.48, 1.59)	
Mental health. (0-100)					
Experimental	56.12 ± 8.38	57.08 ± 8.29	0.067	-0.96 (-1.96, 0.04)	-2.53 (-6.01,0.94)
Control	58.94 ± 9.25	59.61 ± 9.47	0.193	-0.66 (-1.68, 0.34)	

*p< 0.05

Values are expressed as means ± standard deviation for baseline and 1 month post-treatment and as mean score change (95% confidence interval) for within- and between-group values. Abbreviations: VCSS (venous clinical severity score).

DISCUSIÓN

DISCUSSION

6. DISCUSION/DISCUSSION

6.1 Pain in Chronic Venous Insufficiency, Risk factors and Pain Matcher. (Complete discussion with appropriate references are shown in appendix 1)

Our study shows that patients with CVI had a significantly lower Pain Matcher pain threshold than individuals without CVI, and significantly increased pain magnitude matching, VAS scores and MPQ sensory dimension findings. The increased pain level was related mainly to the greater degree of peripheral venous reflux (or less venous refill time) and the presence of pain and functional limitations from osteoarthritis, but not with CEAP classification. Moreover, we also demonstrated that the Pain Matcher appears to be a useful device for assessing chronic venous pain.

The Pain Matcher measurements of pain threshold in our patients with CVI are consistent with previous studies that reported lower thresholds in patients with chronic pain, acute oral pain and whiplash-pain disorders than in healthy individuals. In addition, pain threshold in CVI was negatively associated with the intensity of pain, suggesting that central sensitization induced by nociceptive inputs is involved The Pain Matcher device is used at a remote nonpainful site without tissue damage, and thus provides general information about nociceptive rather than local inputs. Increased pain sensitivity in nonpainful regions has been suggested to be a disorder of pain modulation in conditions that involve long-lasting pain and may indicate secondary hyperalgesia. A hypothetical explanation for the lower pain threshold is that stasis in CVI may augment the leukocytic-endothelial inflammatory reaction, considered the main stimulator of nociceptors in the venous wall and paravasal tissue. This chronic inflammatory process may sensitizes Aδ and C fibers peripherally and may trigger the central activation of different mediators including cyclo-oxygenase enzymes. These enzymes can increase neurotransmitters such as glutamate, thereby increasing the likelihood that NMDA receptors will be activated. This dysfunction in the NMDA-dependent disinhibition of temporal summation may contribute to central sensitization in these patients. In addition, ischemia due to venous microangiopathy and increased endoneurial pressure may result in nerve impairment, which may in turn account for underlying neuropathic

pain. The sensitization phenomenon is an underappreciated cofactor in CVI, and it should be taken into account in attempts to develop effective approaches to pain management in these patients.

In our study, pain in CVI was not related with CEAP classification, suggesting that the patients experience a general increase in pain which is independent of other associated disorders such as leg ulcers or severe dermatological conditions that can occur at higher CEAP classes. Our finding is consistent with other research that reported no relationship between pain assessment and disease severity according to CEAP class. The central sensitization of pain may explain the higher CEAP classes (C1-C3) for venous pain in patients with initial stages of CVI in whom the condition has been present for a long time. However, in their evaluation of deep tendon reflexes, vibration, proprioception and light touch in patients with mild (C2) and severe (C5) CVI, Padberg et al. concluded that there was evidence of sensory neuropathy, but the signs were significantly worse in patients with severe CVI.

Discrepancies between studies may also be influenced by the type of quantitative sensory testing; the method used by Padberg and colleagues involved the lower limbs, and sensory abnormalities were associated with the extent of skin trophic changes. On the other hand, although the CEAP classification is the most widely used system internationally, it has limitations that may account, in part, for our results. Recently Rabe and Pannier (2012) concluded that this classification cannot be considered a severity scale because C2 summarizes all types of varicose veins, and the C3 class may make it difficult to distinguish between venous and other causes of edema. These authors further noted that corona phlebectatica is not included in the classification. Accordingly, the explanation for the lack of a clear relationship between the degree of pain and the CEAP classification may lie in shortcomings in the reliability of the scale itself. Future research should compare the degree of pain in relation to other pain scales such as the Venous Clinical Severity Score in order to refine the clinical management of this symptom in patients with CIV.

Our multivariate analysis showed that in the present study the level of venous pain was related mainly with peripheral venous reflux and functional limitations from

osteoarthritis. Reflux is the main risk factor for pain in CVI. Conway et al also found that aches and pains were more frequent in patients with saphenofemoral junction reflux. Similar results were obtained by Broholm et al, who found that patients with patent veins and functional valves had higher quality of life scores and less pain than patients with reflux and occluded veins. Margolis et al analyzed the relationship between venous leg ulcers and concomitant medical conditions, and found a statistically significant association between osteoarthritis and venous leg ulcers of recent onset. This relationship may be linked through disturbances in mobility and range of motion, factors that influence in the level of pain. Additionally, other authors demonstrated that patients with osteoarthritis had significantly higher VAS pain scores and tactile hypoesthesia and significantly decreased pain threshold (indicative of mechanical allodynia) compared to healthy persons. Thus, pain in patients with venous CVI may be influenced by alterations associated with osteoarthritis.

Our bivariate analysis suggested that other risk factors such as reduced physical activity and prolonged standing or sitting seem to influence pain levels. Mobility and range of motion are affected in patients with CVI. These alterations are related with gastrocnemius impairment and a reduced range of ankle motion, especially dorsiflexion, which is thought to be required for normal functioning of the calf muscle pump. Several studies showed that the periodic contraction of this muscle significantly decreases venous stasis, and that ankle motion restriction can have a negative impact on venous hemodynamics. These factors may explain the association between reduced physical activity and pain in these patients. Certain sitting or standing positions can facilitate venous stasis; thus, slowed venous circulation may contribute to higher pain scores in these patients.

This study shows that in a sample of patients with CVI, there was a significant correlation between pain intensity measured as VAS score, MPQ and pain magnitude matching; this result suggests that there is an association among these measures. Similar results were found in patients with other pathologies, and earlier studies have consistently noted that assessments of electrical pain threshold and pain magnitude with the Pain Matcher were highly reproducible. Although one study has questioned the validity of electrical stimulus magnitude matching, recent studies in labor pain indicate

that the Pain Matcher is a reliable tool for assessing pain threshold, although VAS seems more sensitive than the Pain Matcher for recording changes in pain intensity. It should be borne in mind that in a sensitized state, C fibers discharge at low frequencies of around 1–10 Hz, which are in the same range of stimulation as the Pain Matcher device. This device therefore seems to be suitable to evaluate pain threshold in central sensitized states.

6.2 Short-term effects of standardized KT in Chronic Venous Insufficiency. (Complete discussion with appropriate references are shown in appendix 2)

A standardized KT can improve significantly venous symptoms, CVI severity, pain and electromyographic activation of peripheral vein pump muscles during in women with CVI after 4 weeks in comparison to those receiving a placebo KT application for the same time period. However, KT had no effect on quality of life, leg oedema, or ROAM.

The improvements in venous symptoms and CVI severity observed may be attributable to the increased gastrocnemius myoelectric activity that the KT therapy induced. Inadequate action of calf veno-muscular pumps leads to the reduction in venous emptying that underlies CVI. Various authors have demonstrated that improved muscle contraction after a specific exercise program,exerts a beneficial effect on venous return and on the ejection of calf venous blood. According to KT theory, the tape reduces or increases muscle tone by moving and raising the skin in one or other direction , but González-Iglesias and colleagues proposed that the effects of KT were dependent on the tension produced by this type of dressing, regardless of the direction of skin traction. The present findings support the latter proposition, because the tension of the tape and resulting movement restriction would amplify venous compression by the peripheral calf muscle during dorsiflexion, exerting a positive circulatory effect that would contribute to the observed improvement in venous symptoms.

However, neither quality of life nor lower limb volume was improved by KT in our study population. The improvement in quality of life was only 2.1 points or lower on the CIVIQ scale, whereas compression stockings were reported to achieve a

minimum improvement of 10 points. However, previous studies on quality of life in CVI assessed outcomes after a minimum 3-4 months of treatment with compression bandages or stockings, whereas our intervention was only for 4 weeks. Future investigations should evaluate the impact of long-term treatments on the quality of life. Although the subjective perception of swelling was improved after our KT therapy, the total lower limb volume showed no significant change, suggesting that the activation and compression effects of KT on peripheral muscles were not sufficient to improve oedema. Further work is needed to improve the compression capacity of our KT procedure e.g., by increasing tape tension or adding peripheral compression devices.

The effect of taping on pain (i.e. an improvement of 2.1 cm on VAS) was consistent with a clinically worthwhile effect of 2 cm. However, the maximum improvement was 2.5 cm, which is relatively low given the VAS range of 0 to 10 cm. There was no change in lower limb volume that might explain this slight pain improvement. Numerous authors have found that KT application reduces pain, but the action mechanisms remain unknown. Castro-Sánchez and colleagues recently proposed various hypothetical mechanisms, including: interference with the transmission of painful stimuli: activation of the descending pain inhibitory pathway (gate control theory); interaction between sensory modalities and interconnecting intermodal/cross-modal networks; action on C-fibres *via* keratinocyte activation and an increase in neural feedback. In addition, besides these theoretical models, the simple traction of the tape on the skin may provide cutaneous proprioceptive feedback *via* increased stimulation of cutaneous mechanoreceptors and muscle afferents, which could be responsible for the reduction in pain sensation. Furthermore, movement restrictions imposed by mechanical taping (despite the elasticity of KT) may influence pain levels. Thus, restriction by the taping of gastrocnemius muscle movement and its compression effect may have contributed to the pain relief obtained by KT in our study. Peripheral stasis can potentiate a leukocyte-endothelial inflammatory reaction, which is considered the main stimulator of nociceptors of the venous wall and paravasal tissue. By increasing compression of the calf, the tape diminishes stasis and hence the level of nociceptive stimulation.

Post-KT EMG activity findings are in agreement with previous reports of changes in myoelectric muscle activity in people with disease and healthy individuals after KT application. However, EMG findings have been controversial, and other authors have questioned the effects of taping on muscle activation. Discrepancies in results may also be related to the small sample sizes of the latter studies, which were conducted in young healthy volunteers and reported on the immediate effects of taping but not on its medium or long-term effects. Although some authors described a decrease in EMG effects after four days of application, our finding of a positive impact on muscle activity after continued use of the tapes (changed 3 times a week) for 4 weeks suggests that KT has a cumulative effect.

Our hypothesis that KT would improve ROAM in females with CVI is not supported by our results, suggesting that the tape does not have a mechanical effect. Karadaq and colleagues also found no improvement in ROAM after KT application to correct spastic equinus in stroke patients. In contrast, other authors reported positive effects on the range of motion in different diseases . These discrepancies with our study may be related to the longer time since onset of the venous disease in the present series (>10 years in 68% of our study population), whose restricted ankle movement may therefore have become a stable orthopaedic alteration refractory to physiotherapy. However, although KT may not produce a structural joint improvement, it may have propioceptive effects on the joint position by facilitating dorsiflexion during gait. Further studies using imaging techniques are warranted to record movement and joint position after KT application.

Although our 4-week course of treatment did not achieve improvements in all outcome measures, KT possesses certain characteristics that can be expected to improve compliance with this therapy in comparison to other compression systems. It can be rapidly applied, is air-permeable and water-resistant and can be worn for several days without removal. KT may therefore be especially useful in people with mild-CVI who find it difficult to adhere to conventional compression methods. Besides allowing the wearers to shower or bathe without removing the tapes, their water-resistant property means that KT can be used in combination with aquatic therapy rehabilitation programmes, unlike other peripheral compression techniques.

This study of a large sample of women with mild CVI is the first to contribute scientific evidence on the application of Kinesio Taping guidelines in this type of population. Further research is warranted to support the design of optimal taping procedures for people with CVI and to evaluate their effectiveness in combination with other physiotherapeutic treatments or hydrotherapy exercise programmes.

6.3 Short-term effects of mixed Kinesio Taping-compression technique in Chronic Venous Insufficiency. (Complete discussion with appropriate references are shown in appendix 3 and 4).

At four weeks after application of a mixed KT-compression model in CVI patients their ankle dorsiflexion during gait, cadence, stride/step length, and stance phase time were significantly increased and their foot and malleolus edema, degree of reflux (higher VRT and VPP), venous symptoms, pain, severity, physical function and body pain, and quality of life significantly improved in comparison to pre-treatment values and to the outcomes of a placebo KT application.

Although we observed no change in ROAM in the present thesis, the mixed technique achieved an amplification of the angle of ankle dorsal flexion during gait. In a similar manner, Simşek et a observed that KT had no direct effects on gross motor function or functional Independence in cerebral palsied children but improved their sitting posture. Therefore, the mid-term effect of this bandaging modality appears to be mainly propioceptive. The mechanisms underlying improvements in joint position with this type of bandage may include mechanical restraint-induced neural facilitation and stimulation of Golgi receptors. In fact, it has been proposed that dorsiflexion be included in preventive physiotherapy guidelines for deep vein thrombosis and CVI, because it increases the compression of the sural triceps on the venous component. Hence, facilitation of this flexion during gait can have a positive circulatory effect, which is important for the rehabilitation of these patients. Further research is required to elucidate the impact of this taping technique on venous hemodynamics.

Application of this mixed KT-compression model improved key gait parameters at one month in our group of postmenopausal women with CVI, increasing their cadence, stride and step length, and stance phase time. Several studies have reported a slower walking speed, longer step/stride times, and fewer steps per week in CVI patients than in controls. Increases in cadence and stride and step length are considered positive developments in patients with walking impairment. The beneficial effect of origin-to-insertion KT may result from an improvement in clinical parameters alongside a possible increase in peripheral muscle pump activity. An increase in electromyographic muscle activity has been reported after this type of KT application on the vastus medialis in healthy subjects and in patients with patellofemoral pain, impingement syndrome, and chronic lumbar pain. The improvements obtained in our experimental group may also be due to the stimulation of dorsal flexion. Thus, it has been found that the placement of ankle-foot orthosis can improve the balance of patients with limitation of this movement during walking. On the other hand, peripheral compression can also have beneficial effects on the cardiorespiratory system and therefore on gait quality. Thus, Heising et al observed superior myogenic vessel activity and cardio-respiratory parameters in CVI patients who wore compression stockings or compression bandages than in those who did not. Further research is needed to study the effects of this bandaging system on peripheral muscle pump activity and cardio-respiratory function.

Our hypothesis that KT-mixed model would improve edema, venous pain and quality of life in females with CVI is supported by our results. The reduction in the circumference in both lower limbs was significantly greater at foot and ankle than leg level. It has been reported that edema in patients with initial or low-grade CVI, which frequently appears in the evening, is mainly distal and can therefore be reduced by wearing low compression stockings. The application of external compression can help to diminish or reverse the skin and vascular changes described in these patients, by forcing fluid from the interstitial spaces back into the vascular and lymphatic compartments. Multi-component systems containing an elastic bandage, such as KT, appear more effective than those composed mainly of inelastic constituents. Despite the elasticity of KT, movement restrictions imposed by mechanical taping could improve contractions of the gastrocnemius muscle, which is altered in CVI patients. Numerous

studies have suggested that periodic contractions of gastrocnemius significantly contribute to improving calf muscle pump function and decreasing venous stasis. Compression bandaging is therefore an important measure to treat peripheral stasis, to prevent venous thromboembolism and leg ulcers and should be taken into account in clinical management guidelines for physiotherapist practitioners.

6.4 Placebo effect on venous pain

The placebo group also experienced a post-treatment improvement on pain (in the two randomized studies), though smaller than experimental group, suggesting that this technique has a placebo effect on pain intensity.

Pain perception is subjective and involves both physical and psychological processes. The input of visual (colours) and proprioceptive cutaneous afferents from Kinesio Taping may endow the technique with pain effects related to positive expectations of the therapeutic outcome. Sawkins and colleagues reported that sensory feedback generated by the placebo tape instilled the belief that the tape would have a positive effect on injuries, improving perceptions of stability, confidence, and reassurance. In addition, placebo treatment was found to induce endogenous opiates *via* activation of different brain areas and to facilitate descending inhibition of nociceptive reflexes through the periaqueductal gray substance. Hence, a placebo effect may contribute to the effectiveness of KT.

6.5 Limitations

The main limitation of our studies was that no men were included in our sample, and this means that our data cannot be generalized to the male population. A further limitation is the short duration of the KT application, and there is a need for studies on the effects of multiple applications over a longer time period. The study protocol was not prospectively registered, and the possibility of selective reporting cannot be ruled out. In addition, the severity of CVI was assessed with the CEAP classification in the cross-sectional study; as previously discussed, this scale has some limitations with

regard to this particular condition. Moreover, use of the Pain Matcher is associated with unpleasantness which may induce some bias in participants' pain assessments.

Finally, the EMG study offers an indirect measure of muscle activity as an indication of function during movement but has no diagnostic. Although the EMG normalisation method used in our study has been applied by most authors, the EMG signal and strength are exceptionally unstable in contractions against a maximum resistance of > 80% and other methods have been proposed, including submaximal contraction or the GAIN method, especially in people with pain, whose maximum effort can be very difficult to assess. Nevertheless, the EMG normalisation approach was feasible and appropriate in the study population, who experienced no increase in pain with maximum plantar flexion.

CONCLUSIONES
CONCLUSIONS

7. CONCLUSIONES

- Nuestros resultados muestran que las mujeres postmenopáusicas con insuficiencia venosa crónica presentan una percepción de la intensidad del dolor superior a la población general y una disminución del umbral nociceptivo, lo que sugiere la existencia de mecanismos de sensibilización central. El dolor en esta patología esta principalmente relacionado con el reflujo venoso periférico y con el dolor y la limitación funcional inducida por procesos degenerativos concomitantes (artrosis rodilla o cadera). El dispositivo Pain Matcher parece ser una herramienta válida para la evaluación del dolor crónico venoso.

- La aplicación de un vendaje estandarizado con Kinesio taping para la estimulación de la bomba muscular periférica y la flexión dorsal del tobillo, en mujeres postmenopáusicas con riesgo evolutivo de IVC severa, durante un mes de tratamiento, reduce la sintomatología venosa específica, el dolor, la severidad clínica e incrementa la actividad bioeléctrica del músculo gastronemio durante la marcha, sin embargo, sus efectos sobre la calidad de vida, el edema periférico y el rango de movimiento del tobillo siguen siendo inciertos. Además, Kinesio taping puede tener un efecto placebo para el dolor venoso.

- La modalidad de vendaje mixta Kinesio taping-compresión periférica, mejora la flexión dorsal del tobillo durante el paso, los parámetros de marcha, el edema a nivel de pie y maléolos, el dolor venoso y la calidad de vida, tras un mes de tratamiento, en las mujeres postmenopáusicas con riesgo evolutivo de IVC severa. Esta modalidad de vendaje puede tener un efecto placebo en el dolor venoso.

- La aplicación de un modelo de vendaje mixto Kinesio taping-compresión periférica mejora el flujo venoso periférico, la sintomatología venosa específica, dolor, severidad clínica e incrementa levemente el estado de salud general tras un mes de tratamiento, en las mujeres posmenopáusicas con riesgo evolutivo de IVC severa.

Nuestros hallazgos ayudan a esclarecer los mecanismos implicados en el dolor por insuficiencia venosa crónica y apoyan el uso de Kinesio taping como vendaje alternativo para el manejo de los síntomas de la patología venosa en fases iniciales.

7. CONCLUSIONS

- Our results show that postmenopausal women with chronic venous insufficiency present a perception of the intensity of pain higher than that of the general population and a decrease of the nociciptive threshold, which suggests that there are mechanisms of central sensitization. Pain is this pathology is mainly related with the existence of peripheral venous reflux and pain and functional limitations from knee or hip osteoarthritis. The Pain Matcher device appears to provide a valid technique for assessing chronic venous pain.

- A standardised Kinesio taping application to enhance gastrocnemius muscle function and ankle dorsiflexion in posmenopausal females with short-term risk of severe CVI, may reduce venous symptoms, pain and their clinical severity and enhance gastrocnemius muscle activity during walking at one month, but its effects on quality of life, peripheral oedema, and range of ankle motion remain uncertain. In addition, Kinesio Taping may have a placebo effect on venous pain.

- A mixed Kinesio Taping-compression procedure can improve ankle dorsiflexion during walking, gait parameters, peripheral edema, venous pain, and quality of life in posmenopausal females with short-term risk of severe CVI until at least one month post-treatment. Moreover, this technique appears to exert a certain placebo effect on pain perception.

- A mixed KT-compression technique may improve venous symptoms, pain, peripheral venous flow and clinical severity and produce a slight increase in overall health status in posmenopausal females with short-term risk of severe CVI until at least one month post-treatment.

Our findings help to highlight the mechanism of pain in chronic venous insufficiency and support the use of Kinesio Taping such as an alternative bandage in the management of initial venous disease related symtoms.

IMPLICACIONES CLÍNICAS

- El hallazgo de instauración de mecanismos de sensibilización central para el dolor en las pacientes con IVC inicial pone de relevancia la importancia de establecer un abordaje precoz y preventivo de esta patología. Aunque en estas fases iniciales no hayan aparecido procesos de ulceración y alteraciones dermatológicas graves, en los que se han descrito la existencia de neuropatía periférica, la propia cronicidad del proceso puede conducirnos a un estado de sensibilización que implicaría el establecimiento de terapéuticas de mayor complejidad. Desde la fisioterapia, este hallazgo orienta a establecer un abordaje holístico del dolor, no sólo mediante las técnicas convencionales para disminuir el éstasis periférico y la reeducación de la bomba muscular de la pantorrilla, sino técnicas analgésicas específicas como la estimulación espinal con electroterapia, técnicas de desensibilización y electroanalgesia local para la alodinia mecánica tras la cicatrización de las úlceras o técnicas para el trabajo de la neuroplasticidad cortical del dolor (terapia de simulación frente al espejo y "motor imagery").

- El dolor, es uno de los problemas frecuentemente asociados a la no adherencia de los dispositivos de compresión, por lo tanto controlar este síntoma podría ayudar a mejorar la tolerancia del paciente frente a esta terapéutica

- La asociación del dolor con los procesos degenerativos concomitantes como la artrosis de rodilla o cadera, conlleva que el tratamiento vascular de fisioterapia debe de ser adaptado a las limitaciones impuestas por estas alteraciones y al mismo tiempo incluir técnicas dirigidas específicamente al tratamiento del dolor y limitación funcional derivado de los mismos.

- El vendaje estandarizado o mixto con kinesio taping parece ejercer un efecto positivo sobre la sintomatología y alteraciones coadyuvantes de la insuficiencia venosa crónica en estadios iniciales, de forma que podría constituir una alternativa de tratamiento, sobre todo en aquellos casos de intolerancia a los dispositivos convencionales de compresión. Además presenta una serie de ventajas, frente a los sistemas de vendaje tradicional, son fáciles de aplicar, resistentes al agua y estéticamente más aceptados por el paciente. La propiedad de resistir al agua

permite por un lado que el paciente pueda permanecer con el vendaje durante el aseo personal, de tal forma que no se interrumpe el efecto de compresión periférica durante las actividades de la vida diaria y por otra parte este sistema nos permitiría la aplicación de compresión durante los protocolos de rehabilitación con hidroterapia. Recordemos que para la reeducación de la bomba muscular periférica mediante la realización de los ejercicios físicos pautados es imprescindible la aplicación de un dispositivo de compresión de forma concomitante, por lo tanto, si disponemos de un sistema que permita realizar esta compresión en el medio acuático, los beneficios aportados por el agua (ej. tratamiento con sales para la mejora del edema, terapia de contraste frio-calor, principio de flotación, etc.) pueden verse incrementados por los beneficios aportados por la compresión.

CLINICAL MESSAGES

- The finding that mechanisms of central sensitization for pain in the patients with initial CVI makes the importance of establishing an early and preventative approach to this pathology even more relevant. Even though no ulcer processes and severe dermatological alterations have appeared in these initial stages, if the existence of peripheral neuropathy has been described, the chronicity itself of the process can lead to a state of sensitization that would involve establishing more complex therapeutic measures. Speaking from the perspective of physiotherapy, this finding positions us to establish a holistic approach to pain. This approach should involve not only through conventional techniques to reduce peripheral stasis and to re-educate the calf muscle pump but also to establish specific analgesic techniques such as spinal stimulation with electrotherapy, desensitization techniques and local electroanalgesia for the mechanical allodynia following ulcer scarring or techniques for the work on cortical neuroplasticity and pain (simulation therapy in front of a mirror and motor imagery).

- Pain is one of the problems frequently associated with non-adherence to compression devices. Consequently, controlling this symptom could help to improve patient tolerance to this therapeutic measure.

- The association of pain with the concomitant degenerative processes such as knee or hip osteoarthritis means that the vascular physiotherapy treatment should be adapted to the limitations imposed by these alterations, while it should also include techniques specifically aimed at treating the pain and the functional limitation derived from such changes.

- Standardised or mixed bandaging with kinesio taping seems to have a positive effect on the symptoms and alterations of CVI in initial stages. Consequently, it could constitute a treatment alternative, especially in cases of intolerance to conventional compression devices. It also presents a series of advantages over the traditional bandaging systems: kinesio tapes are easy to apply, resistant to water and aesthetically more acceptable to the patient. The fact that they are water resistant makes it possible, on the one hand, for the patient to keep them on during personal grooming, so the effect of peripheral compression is not interrupted during

daily life activities. On the other hand, this system makes it possible to apply compression during the protocols of rehabilitation with hydrotherapy. It should be remembered that, to re-educate the peripheral muscle pump by performing set physical exercises, the concomitant application of a compression device is essential. Consequently, if we have a system that lets us carry out this compression in an aquatic environment, the benefits provided by the water (for example, treatment with salts to improve oedema, heat-cold contrast therapy, flotation principle, etc.) can be increased with the benefits provided by the compression.

APPENDIX 1

Evaluation of pain and its risk factors in patients with chronic venous insufficiency

APPENDIX 2

Kinesio Taping improves venous symptoms, severity, pain and gastrocnemius muscle bioelectrical activity in women with chronic venous insufficiency: a randomised trial.

APPENDIX 3

Effect of a mixed Kinesio Taping-compression technique on clinical and gait parameters in females with chronic venous insufficiency: Double-blinded, randomized clinical trial.

APPENDIX 3

A controlled randomised trial of a mixed KinesioTaping-compression technique on venous symptoms, pain, peripheral venous flow, clinical severity and overall health status in postmenopausal women with chronic venous insufficiency.