CHIVA method for the treatment of varicose veins (Protocol)

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[Intervention Protocol]

CHIVA method for the treatment of varicose veins

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the efficacy and safety of the CHIVA technique compared with other procedures to treat varicose veins.

BACKGROUND

Description of the condition

Venous insufficiency is the inability to drive venous blood flow to the heart in response to tissue drainage, thermoregulation, and hemodynamic reserve. Venous insufficiency may entail all the factors involved in venous return, the venous wall and valve system, posture, the muscle pump, and respiratory and venule-capillary bed factors. When referring to the syndrome of chronic venous insufficiency (CVI), all signs and symptoms characteristic of this disease of the lower limbs must be addressed. Subjectively, patients report pain, fatigue, heaviness, warmth, swelling, etc., which are more intense when standing and under environmental conditions of heat and humidity (Vanhouette 1997). Objectively, varicose veins, reticular veins, edema, skin changes, and healed or active ulcers, or both, are found.

CVI is a chronic disease of multicausal origin with a slow evolution of symptoms. CVI complications (ulcers, phlebitis, superficial or deep vein thrombosis, skin complications) often appear years or even decades after the onset of symptoms (Kurz 1999). The prevalence of CVI in the general population depends on the outcome considered. It has been estimated that the prevalence of trunk varices ranges from 30% to 40% in the general population (Lee 2003) and that 15% of females and 9% of males have reflux confined to the superficial venous system (Allan 2000). According to Carpentier 2004, varicose veins of any type can be detected in up to 50% of women in the general population.

The introduction of duplex scanning in the study of CVI has allowed in vivo knowledge of venous hemodynamics (Franceschi 1997). In addition to allowing the completion of a morphological study, this exploration facilitates the mapping of the hemodynamics of the venous system, providing precise information on any changes or abnormalities (Cavezzi 2007; Coleridge-Smith 2006; Labropoulos 2005; Lambropoulos 2001; Nicolaides 2000).

Treatment of CVI depends on the state of development of the disease (Agus 2001). There are several therapeutic options that can be used in combination to treat this disease. These therapies cannot cure the disease but can improve symptoms and prevent complications. Treatments for CVI include hygiene and postural measures such as elevation of the legs or walking around to keep the muscle pump working, compression therapy (Nelson 2000; Nelson 2011; O'Meara 2009), topical treatment (Aziz 2011; Cullum 2010; Jull 2008; Kranke 2004; O'Meara 2010; Palfreyman 2006), drug therapy (Martinez-Zapata 2005; O'Meara 2010), sclerotherapy (Tisi 2006), laser therapy (Flemming 1999), radiofrequency ablation (Nesbitt 2011) and surgery (Rigby 2004).

During the 20th century, the first major step in the treatment of varicose veins of the lower limbs was removing the saphenous vein through a metal loop, designed by Keller in 1905. In May 1906, Keller also described the technique of endoluminal stripping. Two years later Babcock first used a flebo-extractor similar to that used today (Lofgren 1977). In 1966, Muller's ambulatory phlebectomy was described (Muller 1966). However, based on the available literature, treatment that involves these techniques cannot prevent varicosity recurrence (Blomgren 2004; Perrin 2000; Winterborn 2004). Besides the possibility of surgical errors, this treatment does not allow for the prevention of the development of new varicose veins (Labropoulos 2005) or the remodeling of the venous network of subcutaneous tissue (Juan 2002). Surgery that removes saphenous veins is generally associated with the presence of varicosities or telangiectasias, and sometimes leads to a clinical cosmetic outcome that is poorer than before surgery. These inconveniences are difficult to justify in patients with clinical grade C2 of the Clinical picture, Etiology, Anatomic distribution and Pathophysiology (CEAP) classification (Porter 1995) (Table 1).

Description of the intervention

In 1988, Franceschi (Franceschi 1988) described a procedure for the treatment of CVI based on hemodynamic performance of the elements that determine the emergence of varicose veins with preservation of the superficial venous system. Francheschi called this procedure the Conservative Hemodynamics of Ambulatory Venous Insufficiency (CHIVA) cure.

Although normally applied via surgery, CHIVA is not a technique but a strategy that can be delivered via surgery, sclerosis, laser or endovascular procedures. The CHIVA method is based on the modification of the hemodynamics of the venous system to eliminate varicose dilatations. This theory is supported by the findings of Mendoza and Escribano (Escribano 2003; Mendoza 2011). The authors demonstrate that CHIVA produces a regression of the diameter size of the saphenous vein (1.6 to 2.6 mm) and the femoral vein (0.4 to 0.7 mm) involved in the venous shunt (Escribano 2003; Mendoza 2011).

How the intervention might work

Primary varicose veins are hemodynamically characterized by the existence of a retrograde circuit or venous-venous shunt (Goren 1996). This circuit consists of a retrograde proximal reflux point (escape point) from which blood from the deep venous system is discharged into the superficial venous system, usually the saphenous veins. The hydrostatic pressure column, between the escape point and the point of re-entry into the deep venous system, generally comprises the saphenous vein and the perforating vein re-entry. This point of venous retrograde re-entry circuit drains back into the deep venous system.

The CHIVA method is a minimally invasive surgery procedure, usually performed under local anesthesia, based on the findings of a careful analysis of the hemodynamic superficial venous network by echo-doppler.

The principles underlying the CHIVA method are:

1. fragmentation of the venous pressure column;

2. disconnecting the venous-venous shunts;
3. preservation of the perforators re-entry;
4. abolition of undrained superficial varicose veins.

The aim of the CHIVA treatment is to decrease the hydrostatic column pressure to disrupt venous-venous shunts without removing the saphenous vein and the venous drainage of the superficial tissues of the limb.

Why it is important to do this review

There are some clinical trials that provide evidence about the efficacy of the CHIVA strategy compared with stripping (the gold standard treatment) (Carandina 2008; Iborra 2006; Pares 2010). CHIVA is one of the few strategies that treat varicose veins without seeking their destruction.

OBJECTIVES

To evaluate the efficacy and safety of the CHIVA technique compared with other procedures to treat varicose veins.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials (RCTs).

Types of participants

Males and females over 18 years of age suffering from CVI, CEAP stage from 2 to 6.

Types of interventions

RCTs that assess the technique of CHIVA compared with other procedures to treat varicose veins, such as drugs, compressive measures, laser therapy, radiofrequency, stripping, sclerotherapy or any other.

Types of outcome measures

Primary outcomes

Recurrence of varicosity, defined as the appearance of new varicose veins after a minimum length of follow-up of one year.

Secondary outcomes

Re-treatment, defined as patients' need for a new intervention due to persistent varicose veins or new varicose veins in the same leg and the same area.

Clinic or aesthetic changes after a minimum length of follow-up of one month after the intervention as assessed by the following.

- Objective signs:
  - free from reflux, checked by echo-doppler;
  - edema measured by the dichotomous variable 'edema' and the continuous variables 'ankle perimeter circumference' and 'volume of the leg';
  - skin manifestations such as venous ulcers and trophic alterations, which may include telangiectasia (small red points on the skin caused by permanently opened tiny blood vessels), reticular veins (dilated veins which show as a net-like pattern on the skin), varicose veins (permanently dilated veins), or lipodermatosclerosis (a hardening of the skin which may gain a red or brown pigmentation and is accompanied by wasting of the subcutaneous fat).
- Subjective symptoms:
  - pain;
  - cramps;
  - restless legs;
  - itching;
  - feeling of heaviness in the legs;
  - swelling;
  - paresthesias (abnormal sensations, such as prickling, burning, tingling).
- Global assessment measures:
  - disease-specific quality of life (QoL) scales (e.g. CVIIQ or Veines-qol) or satisfaction of participants, or both.

Side effects

- participants who experience adverse events during the trial, as reported by questionnaire or related by the participants and specified within the publication, such as hematoma, infection, superficial or deep venous thrombosis, lung embolism, nerve injury.

Search methods for identification of studies

Electronic searches

The Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator (TSC) will search the Specialised Register and the Cochrane Central Register of Controlled Trials (CENTRAL), part of *The Cochrane Library*, www.thecochranelibrary.com. See Appendix 1 for details of the search strategy which will be used to search CENTRAL. The Specialised Register is maintained by the

TSC and is constructed from weekly electronic searches of MEDLINE, EMBASE, CINAHL, AMED, and through handsearching relevant journals. The full list of the databases, journals and conference proceedings which have been searched, as well as the search strategies used are described in the Specialised Register section of the Cochrane Peripheral Vascular Diseases Group module in *The Cochrane Library* (www.thecochranelibrary.com).

The following trial databases will be searched by the TSC for details of ongoing and unpublished studies:

- World Health Organization International Clinical Trials Registry http://apps.who.int/trialsearch/;
- ClinicalTrials.gov http://clinicaltrials.gov/;
- Current Controlled Trials http://www.controlled-trials.com/.

Searching other resources

We will scrutinize reference lists of identified RCTs, systematic reviews and meta-analyses in order to find further trials.

Data collection and analysis

Selection of studies

Two authors (SB and MJM) will independently assess the eligibility of the studies identified in the search. If there are any disagreements, a third author will independently evaluate the study and will discuss it with the rest of the team. We will classify eligible studies as included or excluded. If study classification is unclear, we will contact the authors to obtain any pertinent clarification.

Data extraction and management

Two authors (SB and MJM) will collect data independently on a previously tested standardized form. Data will include methodological quality, characteristics of study participants, characteristics of the intervention and control groups, and outcome characteristics of each group of participants. One review author (MJM) will enter the data into Review Manager 5.1 and will perform the appropriate analyses.

Assessment of risk of bias in included studies

Two authors (SB and MJM) will assess the quality of the studies, specifically examining the randomization method (sequence generation and allocation concealment); whether the intervention was masked (blinded) to the participants, investigators and outcome assessors; incomplete outcome data; percentage of patients lost to follow-up; estimate of sample size; and whether the study included an intention-to-treat (ITT) analysis.

Once this information has been gathered, the authors will classify each study into one of the three levels of risk of bias: low, unclear or high risk of bias, based on the criteria specified in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).

Measures of treatment effect

For each study we will consider relative risks (RRs) for dichotomous variables and mean differences (MDs) for continuous variables. If the continuous variables in the studies are measured in different scales, we will calculate the standardized mean difference (SMD). We will also calculate the number needed to treat for an additional beneficial outcome (NNTB) and the number needed to treat for an additional harmful outcome (NNTH).

Unit of analysis issues

The unit of analysis will be the individual participants randomized in the included clinical trials. We will collect and analyze a single measurement for each outcome from each participant .

Dealing with missing data

We will contact study authors if more information is needed, as well as to clarify any doubts that may arise regarding missing data. The main analysis will be an 'available case analysis', analyzing data as provided in the individual studies.

Secondarily, we will also complete an intention-to-treat sensitivity analysis of dichotomous variables, imputing data using a worst case scenario. We will enter missing values for participants who withdrew or were lost to follow-up as negative events.

Assessment of heterogeneity

We will examine the characteristics of each study to detect clinical heterogeneity. We will deem an I^2 statistic greater than 50% as substantial heterogeneity. We will also study the sources of heterogeneity.

Assessment of reporting biases

If a reasonable number of studies (more than 10) are included in the review, we will assess publication bias by means of a funnel plot.

Data synthesis

We will determine the global effect estimate for each variable through a meta-analysis of the individual effect measures of each outcome. We will apply the statistical method of Mantel-Haenszel for dichotomous measures and the inverse variance for continuous measures using a fixed-effect model. If I^2 is greater than 50%, we will use a random-effects model. If heterogeneity is greater than 75%, we will not pool the results. We will perform all statistical analyses using Review Manager 5.1.

Subgroup analysis and investigation of heterogeneity

The authors anticipate the following as sources of clinical heterogeneity and plan to conduct subgroup analyses comparing:
1) type of procedure that was used to implement the CHIVA method, i.e. open surgery, endovascular surgery, sclerosis or laser technique;
2) type of comparison assessed, i.e. CHIVA versus drugs, CHIVA versus leg compression, CHIVA versus any surgery (laser therapy, stripping, radiofrequency, etc.).

Sensitivity analysis

We will use sensitivity analysis to assess the strength of the results and to explain possible heterogeneity between the studies. We will re-analyze data by:
1. comparing unpublished studies (if there are any) versus published studies;
2. comparing studies with high risk of bias versus low risk of bias;
3. analyzing data by intention to treat.

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. CEAP Clinical Classification (C)

Class	Clinical Indication
0	No visible or palpable signs of venous disease
1	Telangiectases or reticular veins
2	Varicose veins
3	Edema
4	Skin changes ascribed to venous disease (e.g., pigmentation, venous eczema, lipodermatosclerosis)
5	Skin changes as defined here with healed ulceration
6	Skin changes as defined here with active ulceration

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor Varicose Veins explode all trees
#2 (varicos* near3 (vein* or veno*))
#3 (tortu* near3 (vein* or veno*))
#4 (incomp* near3 (vein* or veno*))
#5 (insuffic* near3 (vein* or veno*))
#6 (saphenous near3 reflux)
#7 MeSH descriptor Saphenous Vein, this term only with qualifier: SU
#8 (GSV)
#9 MeSH descriptor Venous Insufficiency explode all trees
#10 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)
#11 (CHIVA):ti,ab,kw
#12 ambulatory near5 Hemodynamic
#13 Conservat* near5 Hemodynam*
#14 ambulatory near5 surg*
#15 ambulatory near5 strip*
#16 haemodynamic near5 surgery
#17 hemodynamic near5 surgery
#18 MeSH descriptor Ambulatory Surgical Procedures, this term only
#19 MeSH descriptor Surgical Procedures, Minimally Invasive, this term only
#20 (#11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19)
#21 (#10 AND #20)

HISTORY

Protocol first published: Issue 2, 2012

CONTRIBUTIONS OF AUTHORS

Conceiving the review: SB, JME

Designing the review: SB, MJM

Co-ordinating the review: MJM

Designing electronic search strategy: Cochrane PVD Group editorial base

Screening search results: SB, MJM

Obtaining copies of trials: SB, MJM

Appraising quality of papers: SB, MJM

Abstracting data from papers: SB, MJM

Data management for the review: MJM

Entering data into RevMan: MJM

Analysis of data: MJM

Interpretation of data: all authors

Writing the review: MJM, SB , JME

Draft the final review: all authors

Guarantor for the review: SB, MJM

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

- Iberoamerican Cochrane Center, Spain.

External sources

- Chief Scientist Office, Scottish Government Health Directorates, Scottish Government, UK.

The PVD Group editorial base is supported by the Chief Scientist Office.

- Associazione "Umanizazione" della Chirurgia, Italy.

This organization is a not-for-profit organization that promotes formative and scientific sessions (scientific meetings, workshops etc.) principally in relation to venous hemodynamics of the lower limbs. This organization partially finances this review because it has an interest in the independent assessment of the CHIVA method but it does not have influence on the review process.