Evidence Based Medicine in Surgery of Chronic Venous Disease

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Introduction

Purpose of this communication:

This communication aims to make an update of **surgical treatment of varicose veins** based on the Evidence Based Medicine (EBM).

Introduction

Evidence-based Medicine:

1991 Gordon Guyatt: the American College Physicians Journal Club.

1992 was created the Evidence-based Medicine Working Group.

1996 Sackett defined EBM as "conscious, explicit and judicious use of best available scientific evidence in making decisions about patients".

Introduction

Grading recommendations according to evidence

Level of current evidence: A, B, or C

Level of recommendation:

GRADE 1: **"we recommend"** => **strong** recommendation
GRADE 2: **"we suggest"** => **weak** recommendation

Introduction

Parameters based on evidence:

Table I. Grading recommendations according to evidence[a]

Grade	*Description of recommendation*	*Benefit vs risk and burdens*	*Methodologic quality of supporting evidence*	*Implications*
1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, low-quality or very low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A	Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B	Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C	Weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

RCT, Randomized controlled trial.
[a]Adapted from Guyatt et al.[48] Used with permission.

Guyatt G, Gutterman D, Baumann MH, Addrizzo-Harris D, Hylek EM, Phillips B, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an American College of Chest Physicians task force. Chest 2006;129:174-81.

Introduction

Evolution in time, the quality of published studies and their results:

Introduction

Evolution in time, the quality of published studies and their results:

1.- International Committee of Medical Journal Editors (ICMJE):

Uniform Requirements for Manuscripts
CONSORT (Standards of Reporting Trials Consolidate)
Register the study

Introduction

Evolution in time, the quality of published studies and their results:

2.- Cochrane Criteria: Meta-analyses

- **Randomization**
- **Masking of randomization**
- **Blinding**
- **Report results**

Introduction

What is the basic and main study based on guidelines to establish the degree of evidence?

The Randomized Control Trial (RCT)

Introduction

Mainly based on the criteria for recommendation?:

Table I. Grading recommendations according to evidence[a]

Grade	*Description of recommendation*	*Benefit vs risk and burdens*	*Methodologic quality of supporting evidence*	*Implications*
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1B	Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation

Mainly in the RCT and between those who met more strict criteria for study completion.

Introduction

The existence of RCT is the main basis of the Meta-analyses.

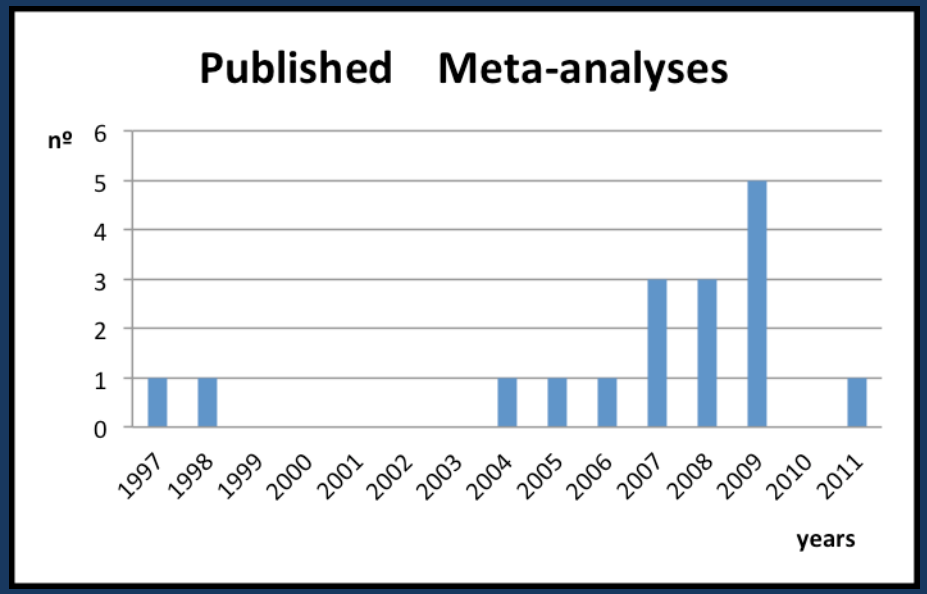
Introduction

Published Meta-analyses on Chronic Venous Disease

1. Murad MH, Coto-Yglesias F, Zumaeta-Garcia M, Elamin MB, Duggirala MK, Erwin PJ, et al. A systematic review and meta-analysis of the **treatments of varicose veins**. J Vasc Surg 2011;53(Suppl 2):51S-67S.
2. Hoggan BL, Cameron AL, Maddern GJ. Systematic review of **endovenous laser therapy versus surgery** for the treatment of saphenous varicose veins. Ann Vasc Surg 2009;23:277-87.
3. O'Meara S, Cullum NA, Nelson EA. **Compression for venous leg ulcers**. Cochrane Database Syst Rev 2009:
4. Leopardi D, Hoggan BL, Fitridge RA, Woodruff PW, Maddern GJ. **Systematic review of treatments for varicose veins**. Ann Vasc Surg 2009;23:264-76.
5. Luebke T, Brunkwall J. Meta-analysis of subfascial endoscopic perforator vein surgery (**SEPS)** for chronic venous insufficiency. Phlebology 2009;24:8-16.
6. Palfreyman SJ, Michaels JA. A systematic review of **compression** hosiery for uncomplicated **varicose veins.** Phlebology 2009;24 (suppl 1):13-33.
7. Luebke T, Brunkwall J. Meta-analysis of **transilluminated powered phlebectomy** for superficial varicosities. J Cadiovasc Surg 2008;49: 757-64.
8. Luebke T, Brunkwall J. Systematic review and meta-analysis of **endovenous radiofrequency** obliteration, endovenous laser therapy, and foam sclerotherapy for primary varicosis. J Cadiovasc Surg 2008;49: 213-33.
9. Luebke T, Gawenda M, Heckenkamp J, Brunkwall J. Meta-analysis of **endovenous radiofrequency** obliteration of the great saphenous vein in primary varicosis. J Endovasc Ther 2008;15:213-23.
10. Jia X, Mowatt G, Burr JM, Cassar K, Cook J, Fraser C. Systematic review of foam **sclerotherapy** for varicose veins. Br J Surg 2007;94: 925-36.
11. Scurr JR, Gilling-Smith GL, Fisher RK. Systematic review of **foam sclerotherapy** for varicose veins (Br J Surg 2007; 94: 925-936). Br J Surg 2007;94:1307-8.
12. Bamigboye AA, Smyth R. Interventions for varicose veins and leg **oedema in pregnancy**. Cochrane Database Syst Rev 2007:CD001066.
13. Tisi PV, Beverley C, Rees A. Injection **sclerotherapy** for varicose veins. Cochrane Database Syst Rev 2006:CD001732.
14.. Mundy L, Merlin TL, Fitridge RA, Hiller JE. Systematic review of **endovenous laser** treatment for varicose veins. Br J Surg 2005;92:1189-94.
15. Tenbrook JA Jr, Iafrati MD, O'Donnell TF Jr, Wolf MP, Hoffman SN, Pauker SG, et al. Systematic review of **outcomes after surgical** management of venous disease incorporating **subfascial endoscopic perforator surgery**. J Vasc Surg 2004;39:583-9.
16. Palfreyman SJ, Lochiel R, Michaels JA. A systematic review of **compression** therapy for venous **leg ulcers**. Vasc Med 1998;3:301-13.
17. Fletcher A, Cullum N, Sheldon TA. A systematic review of **compression** treatment for venous **leg ulcers**. BMJ 1997;315:576-80.

Introduction

Published Meta-analyses on Chronic Venous Disease



Introduction

The existence of RCT is the main basis of the guidelines, too.

Introduction

Published Guidelines on Chronic Venous Disease

1.Peter Gloviczki, MD et all. 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;53:2S-48S.

2. Khilnani NM, Grassi CJ, Kundu S, D'Agostino HR, Khan AA, McGraw JK, et al. Multi-society consensus quality improvement guidelines for the treatment of lower-extremity superficial venous insufficiency with endovenous thermal ablation from the Society of Interventional Radiology, Cardiovascular Interventional Radiological Society of Europe, American College of Phlebology and Canadian Interventional Radiology Association. J Vasc Interv Radiol 2010; 21:14-31.

3. Gloviczki P, editor. Handbook of venous disorders: guidelines of the American Venous Forum. 3rd ed. London: Hodder Arnold; 2009.

4. Nicolaides AN, Allegra C, Bergan J, Bradbury A, Cairols M, Carpentier P, et al. Management of chronic venous disorders of the lower limbs: guidelines according to scientific evidence. Int Angiol 2008;27: 1-59.

5. Robson MC, Cooper DM, Aslam R, Gould LJ, Harding KG, Margolis DJ, et al. Guidelines for the treatment of venous ulcers. Wound Repair Regen 2006;14:649-62.

6. Agus GB, Allegra C, Antignani PL, Arpaia G, Bianchini G, Bonadeo P, et al. Guidelines for the diagnosis and therapy of the vein and lymphatic disorders. Int Angiol 2005;24:107-68.

7. Rabe E, Pannier-Fischer F, Gerlach H, Breu FX, Guggenbichler S, Zabel M, et al. Guidelines for sclerotherapy of varicose veins (ICD 10: I83.0, I83.1, I83.2, and I83.9). Dermatol Surg 2004;30:687-93.

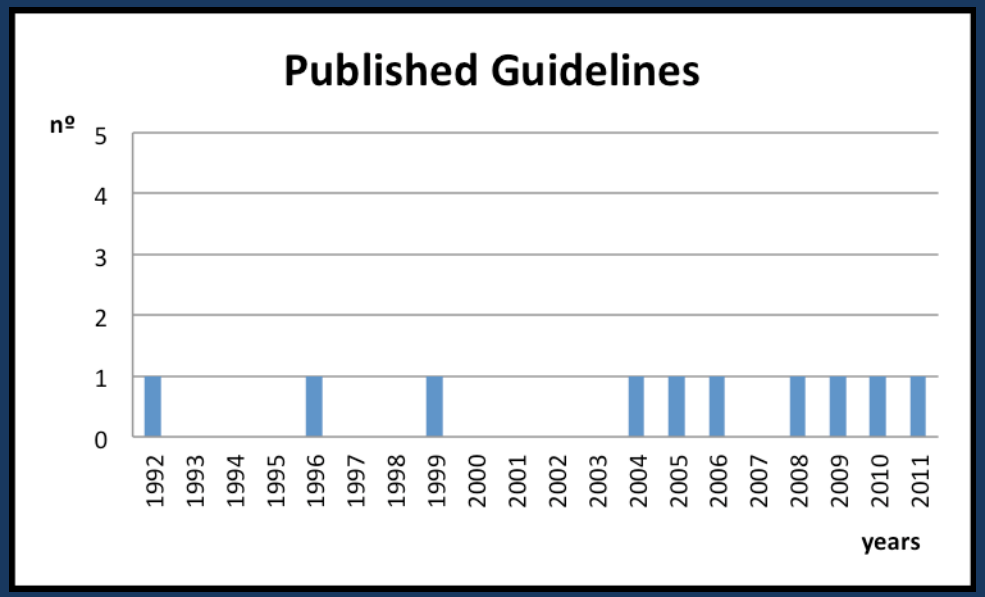
8. Kurz X, Kahn SR, Abenhaim L, Clement D, Norgren L, Baccaglini U, et al. Chronic venous disorders of the leg: epidemiology, outcomes, diagnosis and management: summary of an evidence-based report of the VEINES Task Force. Int Angiol 1999;18:83-102.

9. American Academy of Dermatology. Guidelines of care for sclerotherapy treatment of varicose and telangiectatic leg veins. J Am Acad Dermatol 1996;34:523-8.

10. The Alexander House Group. Consensus paper on venous leg ulcer. J Dermatol Surg Oncol 1992;18:592-602.

Introduction

Published Guidelines on Chronic Venous Disease



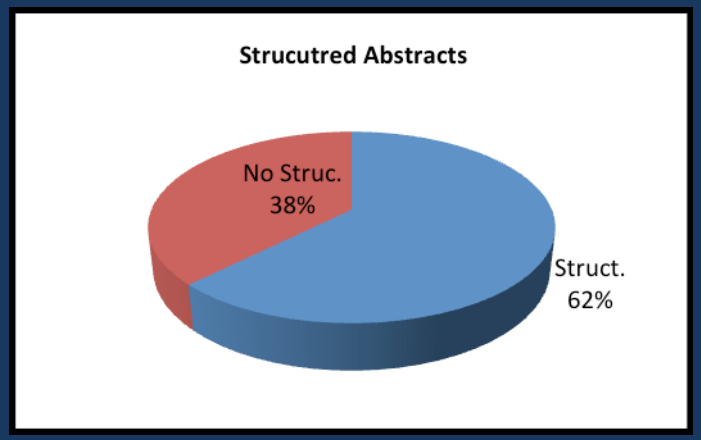
Introduction

The quality of the studies published have improved along the years

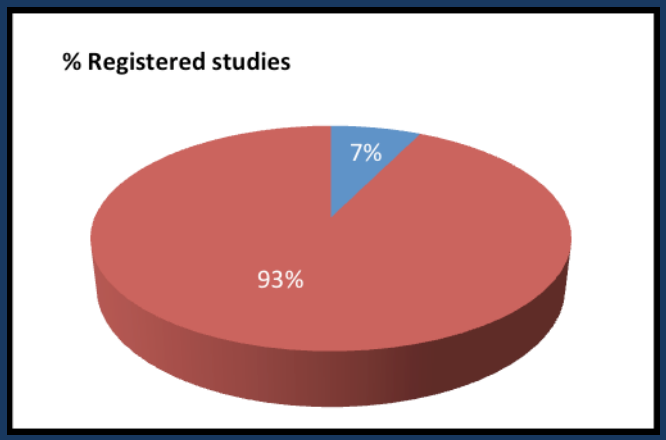
Example: The abstracts quality of the RCT published

Introduction

Quality abstracts

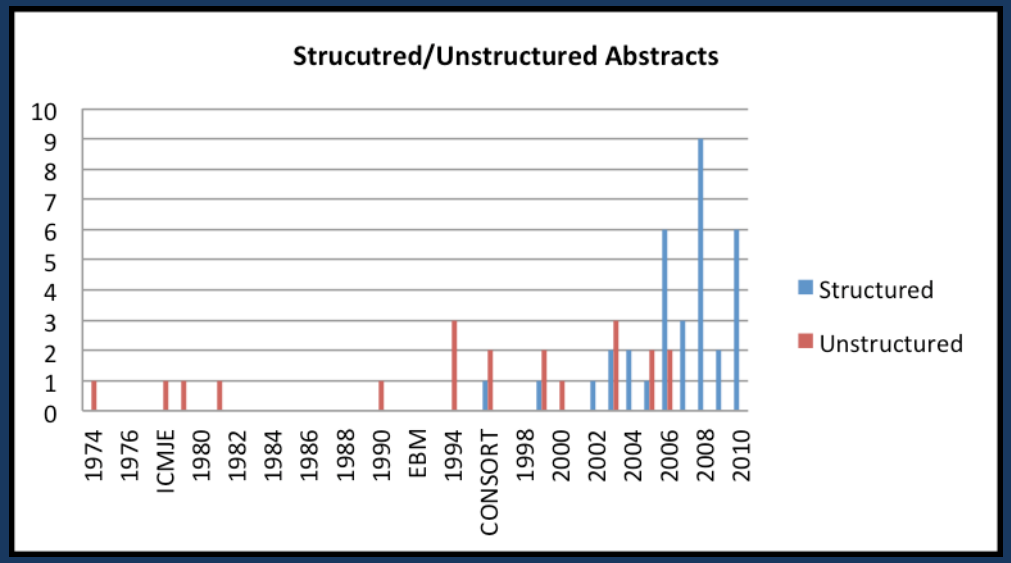


Nº RCT registered



Introduction

Structured and Unstructured Abstracs



Guidelines 2011: the reference

1.Peter Gloviczki, MD et all. 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**.**
Journal of Vascular Surgery 2011;53:2S-48S.

Guidelines 2011: search criteria

. previously published **consensus documents**, and **guidelines**, **meta-analyses**

. the **AVF reports** on the Venous Summit at the 2006 and 2009 Pacific Vascular Symposiums

. considered the **recommendations** published in the third edition of the ***Handbook of Venous Disorders, Guidelines of the American Venous Forum***.

Guidelines 2011 Results

The surgery recommendations in order to the grade recommendation and evidence of these guidelines

Guidelines 2011 Results

The surgery recommendations:

GRADE 1A: "we recommend " (high quality evidence)

10. Open venous surgery

10.4 To decrease recurrence of venous ulcers, we recommend ablation of the incompetent superficial veins in addition to compression therapy.

Guidelines 2011 Results

The surgery recommendations:

GRADE 1B: "we recommend" (moderate quality evidence)

10. Open venous surgery

10.2 **To reduce hematoma formation, pain, and swelling**, we recommend **postoperative compression**.

10.3 For treatment of **small saphenous vein incompetence**, we recommend **high ligation of the vein** at the knee crease, about 3 to 5 cm distal to the saphenopopliteal junction, **with selective invagination stripping** of the incompetent portion of the vein.

10.7 We recommend **ambulatory phlebectomy** for treatment of **varicose veins,** performed **with saphenous vein ablation**.

Guidelines 2011 Results

The surgery recommendations:

GRADE 1B: "we recommend" (moderate quality evidence)

11. Endovenous thermal ablation

11.1 **Endovenous thermal ablations** (laser and radiofrequency ablations) are safe and effective, and we recommend them **for treatment of saphenous incompetence.**

11.2 Because of **reduced convalescence and less pain and morbidity**, we recommend **endovenous thermal ablation of the incompetent saphenous vein over open surgery.**

Guidelines 2011 Results

The surgery recommendations:

GRADE 1B: "we recommend" (moderate quality evidence)

12. Sclerotherapy of varicose veins

12.1 We recommend **liquid or foam sclerotherapy for** telangiectasia, reticular veins, and **varicose veins**.

12.2 **For treatment of the incompetent saphenous vein**, we recommend **endovenous thermal ablation over chemical ablation with foam.**

Guidelines 2011 Results

The surgery recommendations:

GRADE 2B: "we suggest"

10. Open venous surgery

10.1 **For treatment of the incompetent great saphenous vein**, we suggest **high ligation and inversion stripping of the saphenous vein to the level of the knee**

10.5 We suggest **preservation of the saphenous vein** using the ambulatory conservative hemodynamic treatment of varicose veins **(CHIVA**) technique **only selectively in patients with varicose veins, when performed by trained venous interventionists.**

Guidelines 2011 Results

The surgery recommendations:

GRADE 2C: "we suggest"

10. Open venous surgery

10.6 We suggest **preservation of the saphenous vein** using the ambulatory selective varicose vein ablation under local anesthesia **(ASVAL**) procedure **only selectively in patients with varicose veins.**

10.9 **For treatment of recurrent varicose veins**, we suggest **ligation of the saphenous stump, ambulatory phlebectomy, sclerotherapy, or endovenous thermal ablation, depending on the etiology, source, location, and extent of varicosity.**

Methodology of this review:

Review of RCT structured abstracts published

Review of the manuscript of the RCT with unstructured abstracts

Review

The RTC is the reference study

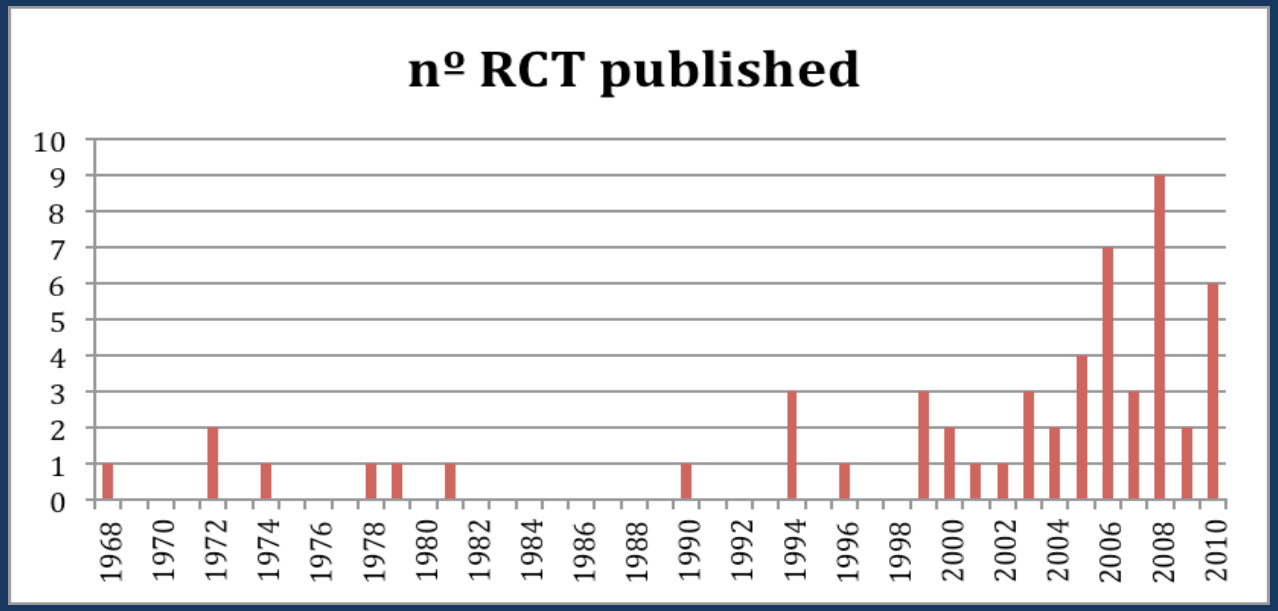
Review

Nº RCT published along the history of the surgery of varicose veins

n=51

Review

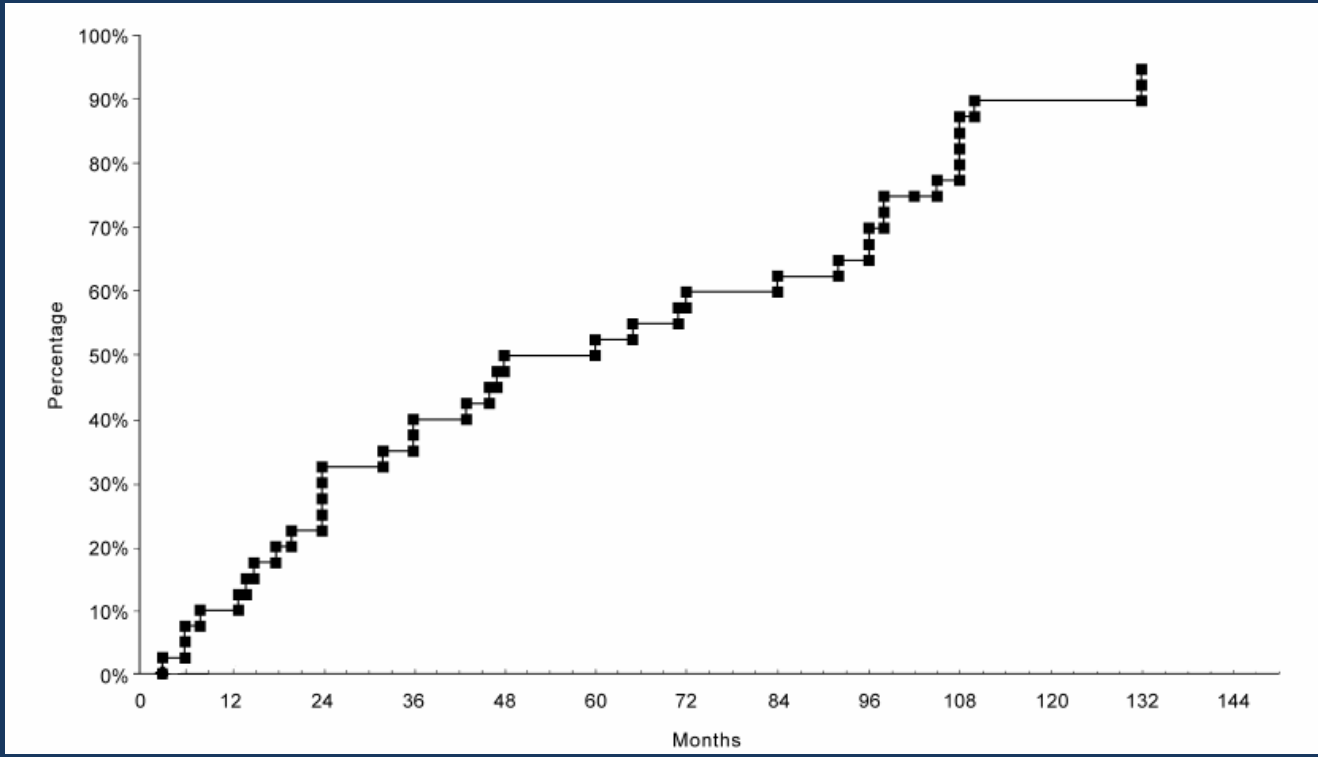
Nº RCT published along the history of the surgery of varicose veins: n=51



Review

Chronic Venous Disease

Time of Follow-up of the Studies and varicose Veins recurrence



1.- Lane ANZ J. Surg. 2003 Aug; 73 (8) p.605-9

Time of Follow-up of the Studies and Varicose Veins recurrence

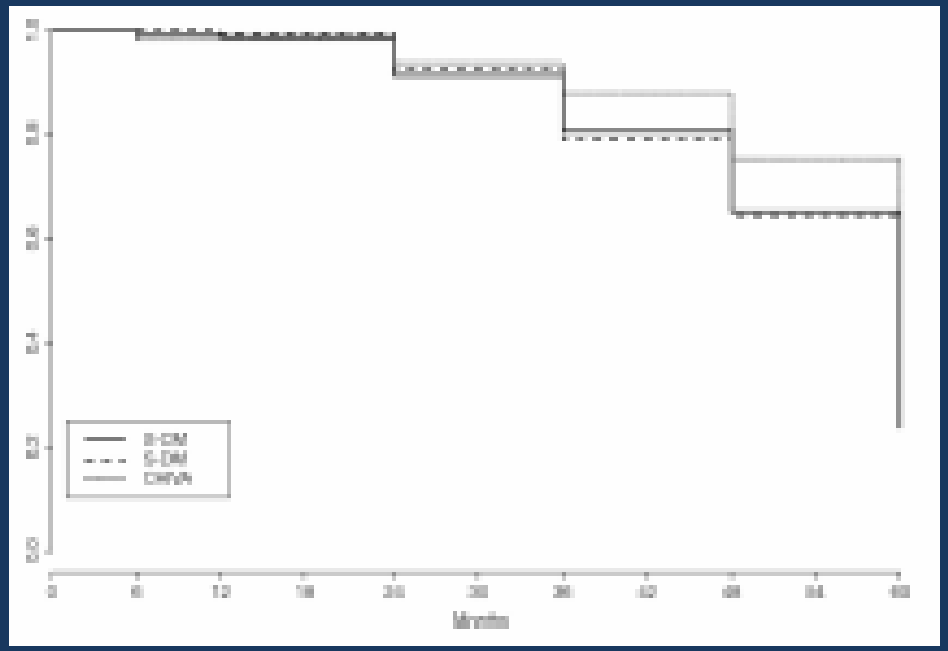


FIGURE 4. Kaplan—Meier Analysis of Clinical Re-currence by Protocol (n =460). About 47.1% of patients in the CHIVA group, 23.5% in the S-CM group, and 31.8% in the S-DM group were free of varicose veins (VV) at 5 years; P <.001 (log- rank test).

Parés JO, Juan J, Tellez R, Mata A, Moreno C, Quer FX, et al. Varicose vein surgery: stripping versus the CHIVA method: a randomized controlled trial. Ann Surg. 2010;251:624-31.

Review

We consider the **recurrence** as the **endpoint** of **half (5 years)** and **long-term (10 years)** studies.

Review

Surgical treatment: classification

		nº RCT	%
Open Surgery	S vs S	24	47,1
	S vs CHIVA	5	9,8
	S vs ASVAL	0	0,0
Ev Term. Ab	S vs EVLA	9	17,6
	S vs RF	5	9,8
Esclerosis	S vs Esc	8	15,7
		51	**100,0**

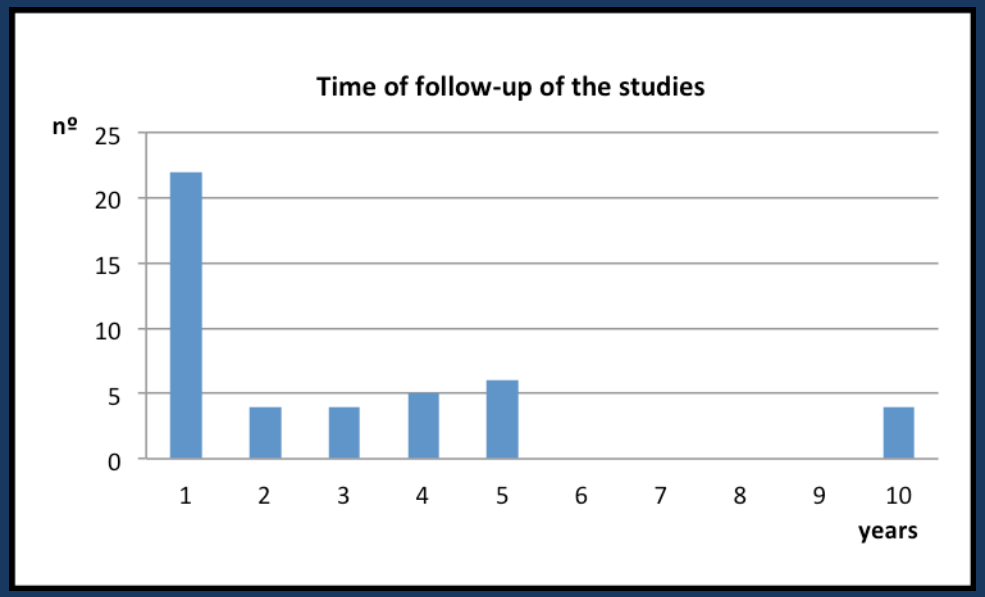
1.Peter Gloviczki, MD et all. The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum.
Journal of Vascular Surgery 2011;53:2S-48S.

Review

Surgical treatment: classification

		S. vs ?	nº RCT	%
Ablation. GSV	Open Surgery	S vs S	24	
	Ev Term. Ab	S vs EVLA	9	
		S vs RF	5	
	Esclerosis	S vs Esc	8	
			46	90,2%
Preserv. GSV	Open Surgery	S vs CHIVA	5	
		S vs ASVAL	0	
			5	9,8%
			51	100%

Time of Follow-up of the published RCT



Review

RCT on Varicose Veins witch 1ari objective is recurrenece
With 10 years follow-up

Phleboextraction vs. SFL or ESC : Phleboextraction is better than the others

29. Winterborn RJ et all. Causes of varicose vein recurrence: late results of a randomized controlled trialof stripping the long saphenous vein. J Vasc Surg. 2004 Oct;40(4):634-9.

31. Belcaro G et all. Foam-sclerotherapy, surgery, sclerotherapy, and combined treatment for varicoseveins: a 10-year, prospective, randomized, controlled, trial (VEDICO trial). Angiology. 2003 May-Jun;54(3):307-15.

35. Belcaro G, et all. Endovascular sclerotherapy, surgery, and surgery plus sclerotherapy in superficial venous incompetence: a randomized, 10-year follow-up trial—finalresults. Angiology. 2000 Jul;51(7):529

Phleboextaction vs CHIVA: CHIVA is better than Phleboextraction

54. S. Carandina, et all. Varicose vein stripping vs haemodynamic correction (CHIVA): a long term randomised trial. Eur J Vas Endovasc Surg 2008; 35: 230-7.

Review

RCT on Varicose Veins witch 1ari objective is recurrenece
With 5 years follow-up

Phleboextraction vs. SFL or short PH.: Phleboextraction is better than SFL
Phleboextr. = Short Phleboextraction

37. Dwerryhouse S et all. Stripping the long saphenous vein reduces the rate of reoperation for recurrentvaricose veins: five-year results of a randomized trial. J Vasc Surg. 1999 Apr;29(4):589-92.

41. Holme K et all. Partial or total stripping of the great saphenous vein. 5-year recurrence frequency and 3-year frequency of neural complications after partial and total stripping of the great saphenous vein. Ugeskr Laeger. 1996 Jan 22;158(4):405-8.

Phleboextaction vs CHIVA: CHIVA is better than Phleboextraction

53. JO. Parés, et all. Varicose vein surgery. Stripping versus the CHIVA method: a randomized controlled trial. Annals of Surgery 2010; 251: 624-31.

55. E. Iborra, et all. Comparative study of two surgical techniques in the treatment of varicose veinsof the lower extremities: results afeter five years of monitoring. Angiología 2006; 58: 459-68.

Review

RCT on Varicose Veins witch 1ari objective is recurrenece With 4 years follow-up

Phleboextraction vs. EVLA. : Not Statistically significant.

2. Christenson JT et all. Prospective randomized trial comparing endovenous laser ablation and surgery for treatment of primary great saphenous varicose veins with a 2-year follow-up. J Vasc Surg. 2010 Nov;52(5):1234-41.

3. Rasmussen LH et all. Randomised clinical tEur J VascEndovasc Surg. 2010 May;39(5):630-5. Epub 2010 Jan 12.rial comparing endovenous laser ablation with stripping ofthe great saphenous vein: clinical outcome and recurrence after 2 years.

8. Disselhoff BC et all. Randomized clinical trial comparing endovenous laser ablation of the greatSaphenous vein with and without ligation of the sapheno-femoral junction: 2-year results. Eur J VascEndovasc Surg. 2008 Dec;36(6):713-8. Epub 2008 Oct 10.

9. Disselhoff BC et all. Randomized clinical trial comparing endovenous laser with cryostripping for greatsaphenous varicose veins. Br J Surg. 2008 Oct;95(10):1232-8.

Phleboextaction vs flushing, Trivex, SFL: Not Statistically significant.

10. Winterborn et ell. Randomised trial of flush saphenofemoral ligation for primary great saphenousvaricose veins. Eur J VascEndovasc Surg. 2008 Oct;36(4):477-84. Epub 2008 Aug 20.

30. Aremu MA et all. Prospective randomized controlled trial: conventional versus powered phlebectomy. J Vasc Surg. 2004 Jan;39(1):88-94.

45. Hammarsten J et all. Long saphenous vein saving surgery for varicose veins.A long-term follow-up. Eur J VascSurg. 1990 Aug;4(4):361-4.

Review

RCT on Varicose Veins witch 1ari objective is recurrence with 3 years follow –up:

Phleboextraction vs. RF or SFL+Ph.: Phleboextraction is better than the others

26. Perl J et all. Radiofrequency endovenous obliteration versus stripping of the long saphenous vein in the management of primary varicose veins: 3-year outcome of a randomized study. Ann Vasc Surg. 2005 Sep;19(5):669-72.

42. Rutgers PH et all. Randomized trial of stripping versus high ligation combined with sclerotherapy inthe treatment of the incompetent greater saphenous vein. Am J Surg. 1994 Oct;168(4):311-5.

CHIVA vs Compression in úlcers: CHIVA is better than Compression

56. Zamboni, et all. Minimally invasive surgical management of primary venous ulcers vs. compression treatment a randomized clinical trial. Eur J Vasc Endovasc Surg. 2003; 25 (4: 313-8)

Review

RCT on Varicose Veins witch 1ari objective is recurrence with 2 years follow –up:

Most of these studies referrer to the quality of life, postoperative complications, etc but not about the recurrence.

CHIVA today

CHIVA today

The Cochrane Library

A systematic review of efficacy and safety of CHIVA method

Systematic review of efficay and safety of CHIVA method over other procedures to treat varicose veins.

Dr. Sergi Bellmunt[1], Dra. Mª José Martínez-Zapata[2],
Dr. José María Escribano[3], Dr. Jaume Dilmé[1].

[1]Hospital de Sant Pau.
[2]Centro Cochrane Iberoamericano. IIB Sant Pau. CIBERESP.
[3]Hospital Vall d'Hebron, Barcelona. España.

Acknowledgements

Associazione Umanizzazione della Chirurgia in memoria di Achille Lampugnani

Introduction

Maximum precision and maximum exposure

- Cochrane collaboration:
  "International organization, independent, nonprofit".

Its main objective is to "ensure that there is information on the impact of health interventions carried, on a rigorously form and regularly updated, and it is readily accessible to everyone."

How?: Meta-analysis

Systematic review

- Summarizes the results of available studies and carefully designed (controlled trials) and provides a high level of evidence on the effectiveness of interventions.

Objetives

Objetive

To evaluate **the efficacy and safety of CHIVA method** compared with other procedures for the treatment of varicose veins.

Material and Methods

Steps to develop a Cochrane review

- Record title.

  The organization must authorize the registration of a title, based on:
  - Justification of interest
  - Protocol

- Ensuring quality standards thanks to an appropriate methodology.

The Cochrane Peripheral Vascular Diseases (PVD) Group
Title Registration Form

Please complete this form to outline your proposal for a Cochrane systematic review. Email the completed form to marlene.stewart@ljmf.ac.uk, or send to Marlene Stewart, Managing Editor, Cochrane Peripheral Vascular Diseases Group, Public Health Sciences, The Medical School, The University of Edinburgh, Teviot Place, Edinburgh EH8 9AG. Tel: +44 131 6503406, Fax: +44 131 6506904

Before completing this form:

- Make sure that your proposal falls within this group's scope, and that it has not already been covered in another Cochrane review. Check existing registered titles at www.cochrane.org/reviews/en/topics.
- Note that all authors must follow the *Cochrane Handbook for Systematic Reviews of Interventions* (see www.cochrane.org/resources/handbook).
- Be aware that preparing a Cochrane review requires a significant, long-term commitment. At least two authors are required before a title can be registered.

Proposed title (see Handbook section 4.2.1)

CHIVA method for the treatment of varicose veins

Contact person (see Handbook section 4.2.3)

Name: Sergi Bellmunt-Montoya

Review proposal and inclusion criteria: (see Handbook chapter 5)

Motivation for the review:	Many techniques have been developed for the treatment of varicose veins.
Review objective:	We want to set the efficacy of CHIVA method compared with other treatments.
Types of study: (section 5.5)	Randomised controlled trials (RCTs).
Participants / population: (section 5.2)	Patients with varicose veins
Intervention: (section 5.3)	CHIVA method Comparison: All the other treatments: medical treatment (pharmacological and compressive) and surgical procedures (stripping, laser, radiofrequency and sclerotherapy)
Outcomes and adverse effects: (section 5.4)	Primary: Recurrence Secondary: Clinical improvement, Quality of live improvement, aesthetic improvement, wound healing, sick leave, technique satisfaction. Adverse effects: heamatoma, infection, superficial and deep venous thrombosis, pulmonary embolism, nerve injury, scars and matting.
Subgroup analyses: (section 9.6)	NO

Cochrane Peripheral Vascular Diseases Review Group

CHIVA method for the treatment of varicose veins

You've registered a title……now what?

I would like to welcome you to the Cochrane Peripheral Vascular Diseases (PVD) Group and thank you for registering your title with the group. A draft version of your protocol is due at the editorial base in Edinburgh by **5 November 2010**, although we will be pleased to receive it before then.

Undertaking a systematic review can seem like a daunting task and this information pack has been put together to guide you through the systematic review process and to help you locate useful information.

1) Review Identification Number

The identification number for your review **SB1671**.

“CHIVA method for the treatment of varicose veins”

Inclusion criteria:

Population and diseas:
Patients with venous insufficiency stages of clinical CEAP 2 to 6.

Study type:
Randomized clinical trials.

Intervention:
CHIVA method versus medical treatment (pharmacological and compression) or surgical (stripping, Laser, radiofrequency and sclerotherapy)

"CHIVA method for the treatment of varicose veins"

- **Study variables:**
  - *Primary endpoint*
    Clinical Recurrence
  - *Secondary variables*

    Eco-Doppler Recurrence
    Clinical improvement
    Quality of life
    Cosmetic improvement
    Ulcer healing
    Adverse effects: hematoma, infection, superficial or deep venous thrombosis, pulmonary embolism, nerve injury.

"CHIVA method for the treatment of varicose veins"

- **Search strategy**
  - Search electronic data bases including:
    - Cochrane Peripheral Vascular Diseases Review Group's Specialized Register
    - Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library
    - MEDLINE
    - EMBASE
    - DARE

“CHIVA method for the treatment of varicose veins”

Assessment of risk of bias

- Sequence randomization generation
- Masking of randomization
- Blinding of interventions
- Report data variables of the study

Results

Search bibliographic databases

- **MEDLINE (Pubmed 17.08.2010)**

•	#8	"Varicose Veins"[Mesh]	13394
•	#9	varicose vein*[tw]	11941
•	#10	varice*[tw]	26176
•	#11	((#8) OR #9) OR #10	38770
•	#12	CHIVA[tw]	43
•	#13	Conservative Haemodynamic Management of Varicose Vein*[tw]	7
•	#14	Conservative Hemodynamic Management of Varicose Vein*[tw]	7
•	#15	Conservative Hemodynamic Management[tw]	2
•	#16	Conservative Haemodynamic Management[tw]	0
•	#17	hemodynamic correction[tw]	50
•	#18	haemodynamic correction[tw	9
•	#19	((((((#12) OR #13) OR #14) OR #15) OR #16) OR #17) OR #18	96

- #20 (#11) AND #19

39

Search bibliographic databases

- **EMBASE (Ovid 17.08.2010)**
-

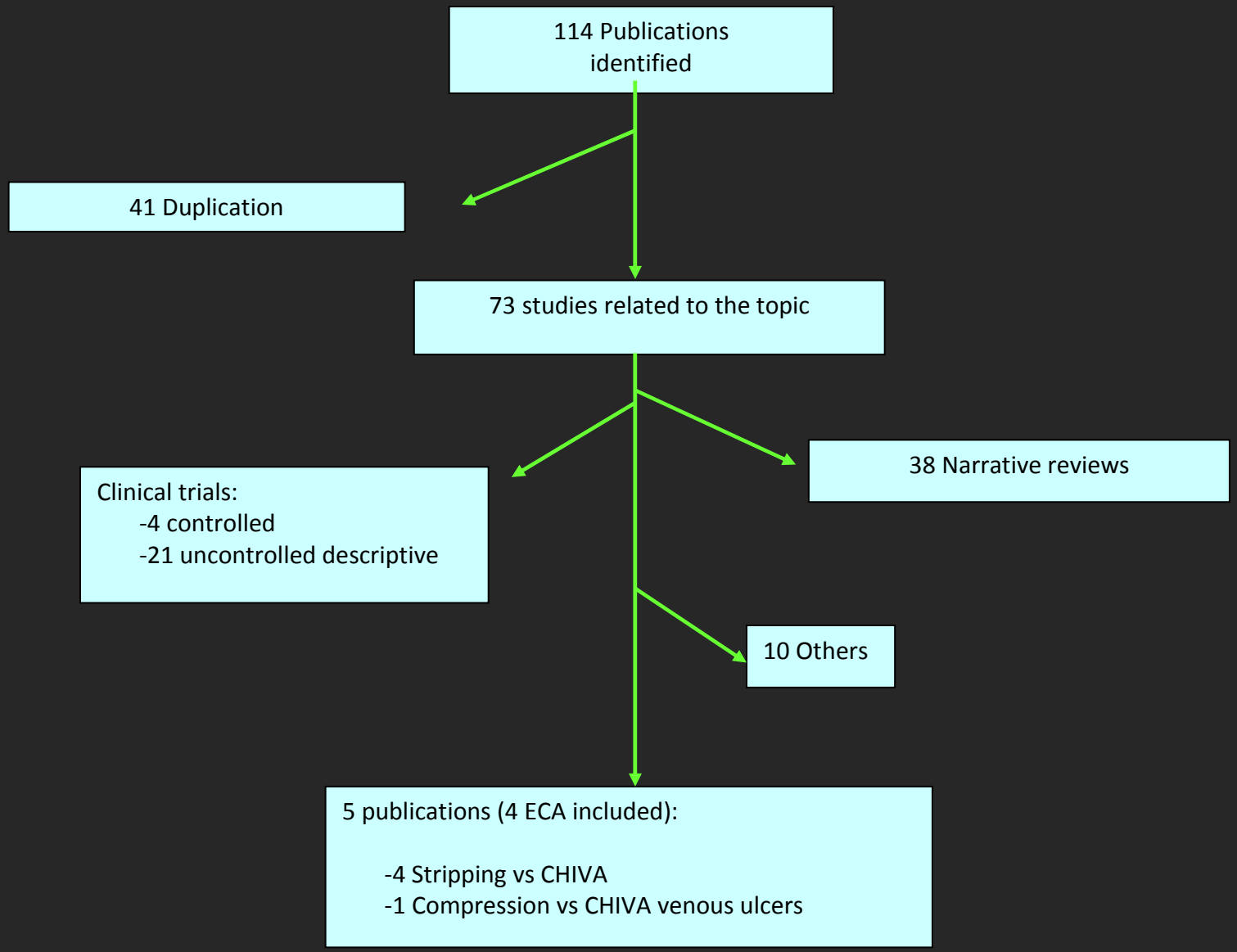
•	1	exp varicosis/	33919
•	2	varicose vein*.mp.	5922
•	3	varice*.mp.	33880
•	4	1 or 2 or 3	52602
•	5	CHIVA.mp.	87
•	6	Conservative Hemodynamic Management of Varicose Vein*.mp.	3
•	7	Conservative Hemodynamic Management.mp.	3
•	8	hemodynamic correction.mp.	56
•	9	5 or 6 or 7 or 8	137
•	10	4 and 9	67

Search bibliographic databases

- **CENTRAL (The Cochrane Library 2010, August issue)**
-

#1	MeSH descriptor Varicose Veins explode all trees	706
#2	varicose vein*	687
#3	varice*	2152
#4	(#1 OR #2 OR #3)	3059
#5	CHIVA	9
#6	Conservative Haemodynamic Management of Varicose Vein*	1
#7	Conservative Hemodynamic Management of Varicose Vein*	1
#8	Conservative Hemodynamic Management	7
#9	Conservative Haemodynamic Management	23
#10	hemodynamic correction	72
#11	haemodynamic correction	61
#12	(#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11)	156
#13	(#4 AND #12)	**11**

Study selection



Characteristics of included studies

Study	Patients			Interventions	Follow-up duration (years)
	N	Age	CEAP Clinic		
Carandina 2008	150	Adults <70 a	2-6	2 groups: Stripping versus CHIVA	10 years
Iborra 2000/2006	100	Mean 47-50 (DS 7-10) years	2	2 groups: Stripping versus CHIVA	5 a
Pares 2010	501	Mean 48-50 (DS 12) years	2-6	3 groups: Stripping with marked clinically versus CHIVA Stripping with Eco-doppler versus CHIVA	5 a
Zamboni 2003	45	Adults <80 a	6 Úlcers 10-12 cm^2 (range 3 to 12)	2 groups: Comprenssion versus CHIVA	3a

Risk of bias

	Randomization	Masking of randomization	Blinding	Report results
Carandina	Adequate	Adequate	No	Adequate
Iborra	Adequate	Adequate	No	**Partial**
Parés	Adequate	Adequate	No	Adequate
Zamboni	Adequate	**Not reported**	No	**Partial**

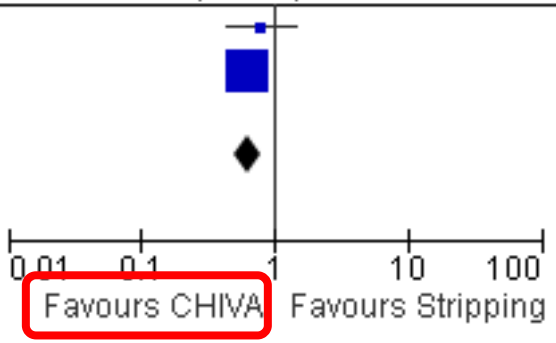
Meta-analysis

Clinical recurrences of varicose veins

Study or Subgroup	CHIVA Events	CHIVA Total	Stripping Events	Stripping Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Iborra 2006	14	51	17	49	13.4%	0.79 [0.44, 1.43]
Pares 2010	52	167	168	334	86.6%	0.62 [0.48, 0.79]
Total (95% CI)		**218**		**383**	**100.0%**	**0.64 [0.51, 0.81]**
Total events	66		185			

Heterogeneity: Chi² = 0.57, df = 1 (P = 0.45); I² = 0%

Test for overall effect: Z = 3.78 (P = 0.0002)



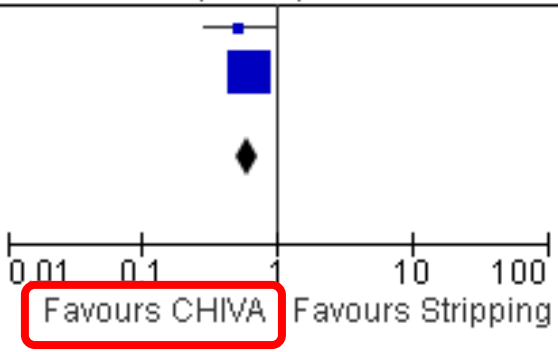
Meta-analysis

Recurrence: evaluation by eco-doppler

Study or Subgroup	CHIVA Events	CHIVA Total	Stripping Events	Stripping Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Carandina 2008	13	70	19	54	13.0%	0.53 [0.29, 0.97]
Pares 2010	67	167	216	334	87.0%	0.62 [0.51, 0.76]
Total (95% CI)		**237**		**388**	**100.0%**	**0.61 [0.50, 0.74]**
Total events	80		235			

Heterogeneity: Chi² = 0.24, df = 1 (P = 0.62); I² = 0%

Test for overall effect: Z = 5.08 (P < 0.00001)



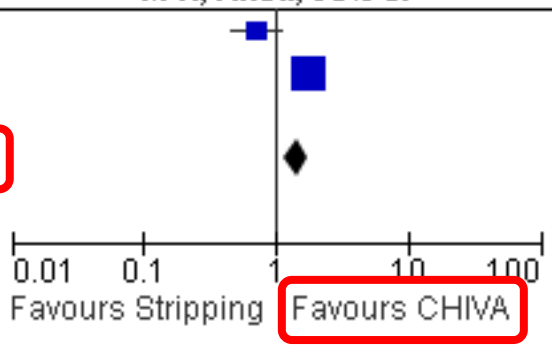
Meta-analysis

Healing without clinical symptoms

Study or Subgroup	CHIVA Events	CHIVA Total	Stripping Events	Stripping Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Iborra 2006	20	51	27	49	33.0%	0.71 [0.47, 1.09]
Pares 2010	74	167	84	334	67.0%	1.76 [1.37, 2.27]
Total (95% CI)		**218**		**383**	**100.0%**	**1.42 [1.14, 1.75]**
Total events	94		111			

Heterogeneity: Chi² = 12.97, df = 1 (P = 0.0003); I² = 92%

Test for overall effect: Z = 3.21 (P = 0.001)

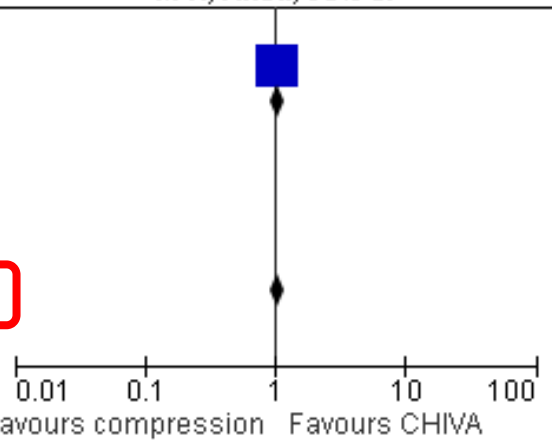


Comment: Great heterogeneity statustucs, 92%

Analysis

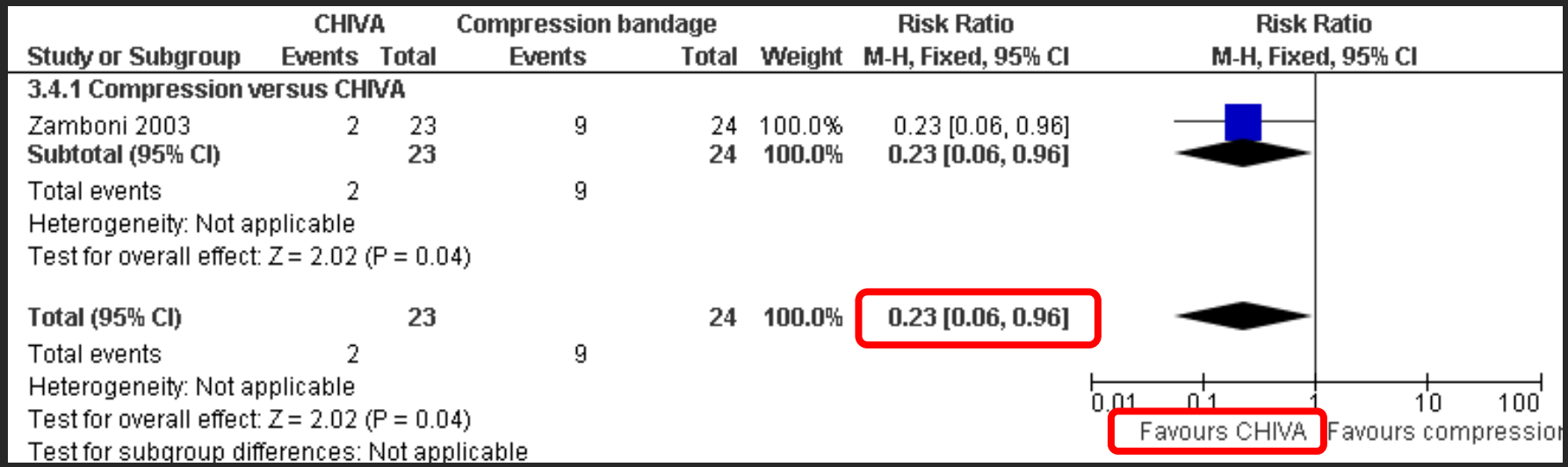
Venous ulcer healing

Study or Subgroup	CHIVA Events	CHIVA Total	Compression bandage Events	Compression bandage Total	Weight	Risk Ratio M-H, Fixed, 95% CI
1.4.1 Compression versus CHIVA						
Zamboni 2003	23	23	23	24	100.0%	1.04 [0.93, 1.17]
Subtotal (95% CI)		**23**		**24**	**100.0%**	**1.04 [0.93, 1.17]**
Total events	23		23			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.70 (P = 0.49)						
Total (95% CI)		**23**		**24**	**100.0%**	**1.04 [0.93, 1.17]**
Total events	23		23			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.70 (P = 0.49)						
Test for subgroup differences: Not applicable						



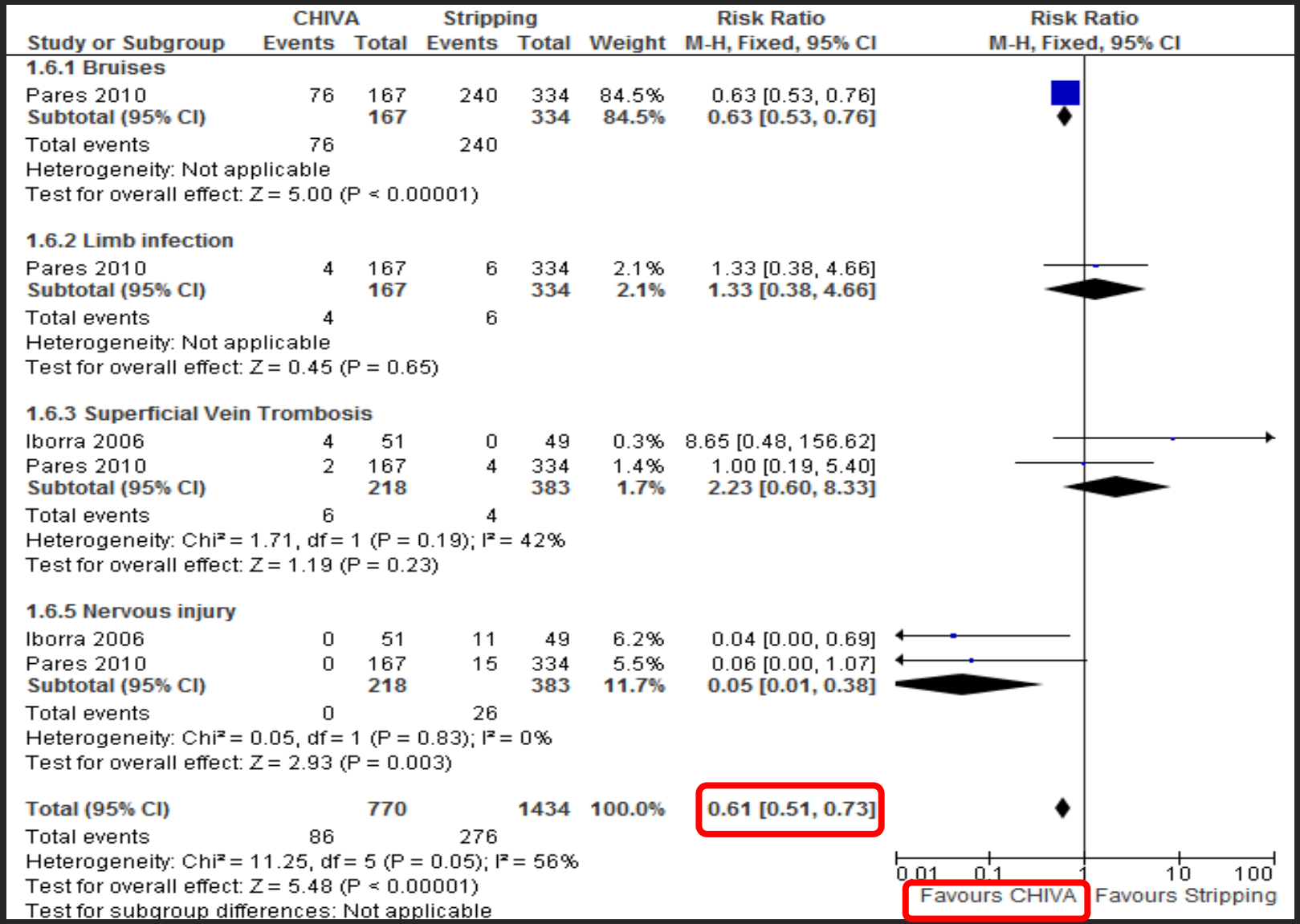
Analysis

Venous ulcer recurrence



Meta-analysis

Adverse events



Preliminary and final conclusions

Conclusions

- CHIVA method is more effective than long-term vein stripping and decreasing clinical recurrences of varicoses veins and venous ulcers.

- With regard to adverse events: the stripping, there are more nerve damage, and subcutaneous hematoma, whereas in the method CHIVA exists superfical venous thrombosis.

References selected studies

1. E. Iborra, et all. Randomized clinical trial comparing two surgical techniques for treatment of varicose veins: immediate results.
Angiología 2000; 6: 253-8.

2. E. Iborra, et all. Comparative study of two surgical techniques in the treatment of varicose veinsof the lower extremities: results afeter five years of monitoring.
Angiología 2006; 58: 459-68.

3. S. Carandina, et all. Varicose vein stripping vs haemodynamic correction (CHIVA): a long term randomised trial.
Eur J Vas Endovasc Surg 2008; 35: 230-7.

4. Zamboni, et all.Minimally invasive surgical management of primary venous ulcers vs. compression treatment a randomized clinical trial. Eur J Vasc Endovasc Surg. 2003; 25 (4: 313-8)

5. JO. Parés, et all. Varicose vein surgery. Stripping versus the CHIVA method: a randomized controlled trial.
Annals of Surgery 2010; 251: 624-31 .

Near Future Achievements

Quality of Evidence and Degree of Recommendation

Cochrane currently set the grade level of evidence of the Study as

GRADE "1 A" to the CHIVA method.

Conclusion

Final Conclusion:

Hopefully in the next guidelines, the scientific committee will be strong enough argument to agree with the Meta-analysis that has produced the Cochrane and put the **CHIVA method** in grade **1A recommendation,** as it deserves.

The end

Thanks' very much for your attention

Introduction

Varicose Vein Surgery
Stripping Versus the CHIVA Method: A Randomized Controlled Trial

Josep Oriol Parés, MD, Jordi Juan, MD, Rafael Tellez, MD, Antoni Mata, MD, Coloma Moreno, MD, Francesc Xavier Quer, MD, David Suarez, PhD, Isabel Codony, MD, and Josep Roca, MD.

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