1. Abstract from review and guidelines of the ESVS January 2015 Eur J Vasc Endovasc Surg (2015) 49, 678e737

 4.8.4. Cure conservatrice et Hémodynamique de l’Insuffisance Veineuse en Ambulatoire (CHIVA)Introduction. CHIVA was described by Franceschi in 1988. It aims to improve the haemodynamics of the superficial venous network by splitting the column of hydrostatic pressure and disconnecting venovenous shunts by interrupting the incompetent trunks at strategic levels (SFJ, perforating veins) depending on a precise pre-operative DUS examination, to obtain a well-drained superficial venous system with low pressure and highflow.

Scientific evidence. One RCT, concerned with treatment of venous ulcers, showed that the group treated by CHIVA had a similar healing rate (100% vs. 96%) and a lower recurrence rate (9% vs. 38%) at 3 years follow up than the group treated by compression. 468

The clinical and DUS recurrence of varicose veins was studied in two RCTs: the results were in favour of CHIVA versus HL/S in both studies, 8% vs. 35% (p<.004) at 10 year follow up in one study 469 and 31.1% vs. 52.7% (p<.001) at 5 year follow up in the other. 470 Some observations must be noted: in the paper by Carandina, there is an important bias concerning the randomization and follow up. 469

In another study all stripping procedures were done under general or epidural anaesthesia whereas the CHIVA treatments were performed under local anaesthesia, which acted as a confounder for the evaluation of the post-operative side effects. 470.

Oriol:

Los pacientes tratados con Stripping o stripping Ecoguiado SOLO SE HIZO anestesia epidural NO General. La valoración de la Morbilidad postoperatoria NO depende de las dos horas de anestesia Epidural. La valoración de la Morbilidad postoperatoria se mide durante los 8-10 días posteriores a la intervención. Trombosis Venosa Profunda. Tromboembolismo Pulmonar, hematomas subcutáneos, hemorragia, Dolor, infección , lesión del nervio safeno y días de baja laboral son las variables de control de postoperatorio.

El dolor postoperatorio no se vera afectado por dos horas de epidural. El dolor quirúrgico postoperatorio mas importante dura 48 horas y posteriormente cede. Los pacientes de los tres grupos distintos operados reciben todos el mismo tratamiento, dosis y tiempo de analgésico. No existen condiciones que puedan condicionar desviaciones en los resultados.

La anestesia eipdural podría condicionar el hecho que los pacientes operados por este método anestésico tuvieran mas trombosis venosas profundas o Tromboembolismos pulmonares pero el porcentaje de estos eventos ha sido 0% en los tres grupos. Por esta razón la Anestesia epidural tampoco ha sido una cuestión diferencial desde un punto estadístico i por lo tanto no ha sido un sesgo.

The most serious limiting concerns in both studies were how “failure” by recurrence was defined: it is unclear if the presence of visible recurrent varicose veins or the presence of refluxing veins during the DUS evaluation or both were considered to define the failure of the treatment.

**Efficacy Measures (extraído del articulo AS 2010)**

The clinical efficacy of the intervention (the primary end point) was evaluated based on recurrence, measured using the Hobbs7 classification: “cure” (absence of VV), “improvement” (presence of VV 􏰃0.5 cm), and “failure” (presence of VV 􏰅0.5 cm, main trunks, or incompetent perforators).

Recurrence was also measured using ultrasonography as a second-level research variable.32 This includes “absent or nonvisible recurrence” (patient clinically cured) and “visible recurrence” (pa- tient in situation of clinical failure), with or without a simple reflux point. Duplex ultrasonography imaging was used to study the location of recurrence by examining different anatomic types of shunts.

La variable principal del estudio es una variable clínica. Las varices son un signo clínico de la enfermedad venosa crónica. En este caso usamos la clasificación de Hobbs.

El estudio de la recidiva por DUS es un “second-level research variable”.EL DUS sirv para estudiar la anatomía de la recidiva, sus causas – con o sin punto de fuga-



468Zamboni P, Cisno C, Marchetti F, Mazza P, Fogato L Carandina S, et al. Minimally invasive surgical management of primary venous ulcers vs. compression treatment: a randomized clinical trial. Eur J Vasc Endovasc Surg2003;25:313e8.

469Carandina S, Mari C, De Palma M, Marcellino MG, Cisno C, Legnaro A, et al. Varicose vein tripping vs haemodynamic correction (CHIVA): a long term randomised trial.Eur J Vasc Endovasc Surg2008;35:230e7.

470Pares 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 Surg2010;251:624e31

1. SUGGESTED RESPONSE to write altogether :

As CHIVA European association, here are our comment about the EAVS guidelines (Eur J Vasc Endovasc Surg (2015) 49, 678e737)

The guidelines authors wrote; “In another study (3) all stripping procedures were done under general or epidural anaesthesia whereas the CHIVA treatments were performed under local anaesthesia, which acted as a confounder for the evaluation of the post-operative side effects.” *In fact,* *Stripping procedures were done only under epidural anaesthesia that lasted not more than 2 hours, which didn’t impact the side effects assessed along 8-10 days following the operation which were defined as DVP, PE, hematomas, bruises, safenous nerve injury, pain and days of convalescence. In addition, the potential effect of epidural anaesthesia respect to CHIVA as thromboembolism didn’t occurre. So the different types of anaesthesia didn’t interfere with the statistical analysis of the results.*

The guidelines authors state: “The most serious limiting concerns in both studies were how “failure” by recurrence was defined: it is unclear if the presence of visible recurrent varicose veins or the presence of refluxing veins during the DUS evaluation or both were considered to define the failure of the treatment”. *In the Pares study (3) the first-level research variable of*  *intention-to-treat analysis were the visible clinically visible varicose veins caliber evaluated at 5 years follow-up according to Hobbs classification, so independently of the flow direction. Recurrence was also measured using ultrasonography as a second-level research variable. This includes "absent or non visible recurrence" (patient clinically cured) and "visible recurrence" (pa­tient in situation of clinical failure), with or without a simple reflux point. Duplex ultrasonography imaging was used to study the location of recurrence by examining different anatomic types of shunts*. On the other hand, while the flow direction was not an end point of the trial, the failure by recurrence cannot be defined as a reflux since the reverse flow in the GSV as well as in its incompetent tributary is considered for the CHIVA technique as success when collapsed and no more overloaded by flows fed by other veins through escape points.

 The different types of anesthesia, local for CHIVA general or epidural for Stripping is not a bias if we consider the difference between the two methods relies also on this aspect ( in the CHIVA acronym A means Ambulatory). The review and guidelines of the ESVS January 2015 need some comments. 1 additonal RCT reference CHIVA vs Stripping is not cited in this review (4).

The fact that CHIVA preserves in all cases the GSV, is of first worth because it saves the possibility of arterial by-pass (which is still profitable and vital despite the endo-vascular procedures progresses).

A Cochrane Review (5) was published after this ESVS January 2015 review with the authors conclusion “The CHIVA method reduces recurrence of varicose veins and produces fewer side effects than vein stripping. However, we based these conclusions on a small number of trials with a high risk of bias as the effects of surgery could not be concealed and the results were imprecise due to low number of events. New RCTs are needed to confirm these results and to compare CHIVA with approaches other than open surgery”.

These informations should upgrade the recommendation grade IIb B.

1. Zamboni P, Cisno C, Marchetti F, Mazza P, Fogato L Carandina S, et al. Minimally invasive surgical management of primary venous ulcers vs. compression treatment: a randomized clinical trial. Eur J Vasc Endovasc Surg2003;25:313e8.
2. Carandina S, Mari C, De Palma M, Marcellino MG, Cisno C, Legnaro A, et al. Varicose vein tripping vs haemodynamic correction (CHIVA): a long term randomised trial.Eur J Vasc Endovasc Surg2008;35:230e7.
3. Pares 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 Surg2010;251:624e31
4. Iborra-Ortega E, Barjau-Urrea E, Vila-Coll R, Ballon-Carazas H, Cairols-Castellote MA. Comparative study of two surgical techniques in the treatment of varicose veins of the lower extremities: results after five years of follow-up [Estudio comparativo de dos técnicas quirúrgicas en el tratamiento de las varices de las extremidades inferiores: resultados tras cinco años de seguimiento]. Angiología 2006;58(6):459-68.
5. Sergi Bellmunt-Montoya, Jose Maria Escribano, Jaume Dilme, Maria José Martinez-Zapata CHIVA method for the treatment of varicose veins. Cochrane Database of Systematic Reviews , Issue . Art. No.: . DOI Review number: 1671

C- The Cochrane review ABSTRACT recall

Main results

No new studies were identified for this update. We included four RCTs with 796 participants (70.5% women). Three RCTs compared

the CHIVA method with vein stripping, and one RCT compared the CHIVA method with compression dressings in people with

venous ulcers. We judged the quality of the evidence of the included studies as low to moderate due to imprecision caused by the low

number of events and because the studies were open. The overall risk of bias across studies was high because neither participants nor

outcome assessors were blinded to the interventions. The primary endpoint, clinical recurrence, pooled between studies over a followup of 3 to 10 years, showed more favorable results for the CHIV A method than for vein stripping (721 people; RR 0.63; 95% CI 0.51

to 0.78; I

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= 0%, NNTB 6; 95% CI 4 to 10) or compression dressings (47 people; RR 0.23; 95% CI 0.06 to 0.96; NNTB 3; 95%

CI 2 to 17). Only one study reported data on quality of life (presented graphically) and these results significantly favored the CHIVA

method.

The vein stripping group had a higher risk of side effects than the CHIVA group; specifically, the RR for bruising was 0.63 (95% CI

0.53 to 0.76; NNTH 4; 95% CI 3 to 6) and the RR for nerve damage was 0.05 (95% CI 0.01 to 0.38; I

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= 0%; NNTH 12; 95%

CI 9 to 20). There were no statistically significant differences between groups regarding the incidence of limb infection and superficial

vein thrombosis.

Authors’ conclusions

The CHIVA method reduces recurrence of varicose veins and produces fewer side effects than vein stripping. However, we based these

conclusions on a small number of trials with a high risk of bias as the effects of surgery could not be concealed and the results were

imprecise due to low number of events. New RCTs are needed to confirm these results and to compare CHIVA with approaches other

than open surgery

Oriol:

La principal causa de que el análisis de la Cochrane valora los resultados de cualidad media baja es una cuestión de descripción metodológica escasa o no adecuada de los artículos publicados.

Cochrane tiene un manual público en el que se detallan los requisitos que deben aplicar los revisores cuando valoran un artículo medico y en concreto un RCT. 600 páginas…LO descubrí una vez publicada la revisión COCHRANE….

Durante la revisión de los RCT CHIVA vs Stripping los revisores pidieron aclaraciones a los autores de detalles no redactados en los RCT’s. Pero no pidieron todos los detalles que eran susceptibles de corrección. Una pena ya que de este modo hubiéramos obtenido una cualidad metodológica media alta o alta!!!!

MIERDA!!!!

Creo que muy poca gente que escribe artículos RCT conoce este hecho… Dudo que los RCT publicados en relación a los métodos destructivos se hayan escrito teniendo en cuenta estos consejos…

La intención del artículo a los diez años es corregir este error de redacción metodológica – es decir , volver a redactar toda la metodología con el fin que – a pesar de que se trata de un estudio randomizado no farmacológico- la posibilidad de Bias sea la mínima y tengamos la oportunidad de ser valorados, finalmente sin escusas, en el lugar que CHIVA se merece. Por la gran idea que es y por los resultados que demuestran los RCT publicados.

De todos modos seguro que encuentran una excusa para que no sea así.

Lo voy a intentar. Necesitaré vuestra ayuda.

Un abrazo

Oriol