

## INFORMED CONSENT ABOUT VARICOSE VEINS TREATMENTS

### *Ethical, Legal and , Scientific and Professional Issue*

The Great Saphenous Vein (GSV), in normal and varicose people, can be harvested to treat a life-threatening coronary or lower limb arterial disease. Indeed, GSV in varicose patients is eligible even if refluxing which is confirmed by the use of GSV stripped in varicose patients cold stored and sold as allograft for arterial by-passes in other patients, even if not as good as autologous.

Paradoxically, most of the time, no information is given to the patient about the benignity of the varicose disease, the possible future vital necessity of his GSV as arterial by-pass, the possible conservative and efficient treatment with elastic stockings or GSV conservative surgery. Studies confirm the refluxing GSV eligibility for arterial by-pass\*. Only destructive treatments are proposed: Great Saphenous Vein (GSV) surgical (Stripping) or endovenous destruction (sclerosis, foam, laser, radio-frequency, glue, steam). This is contrary to the informed consent law, particularly regarding the possible vital future need of the GSV for arterial by-pass. In addition, exhaustive conservative treatments from abstention to stockings and conservative surgery should be proposed.

\* *Moritz A, Grabenwöger F, Raderer F, Ptakovsky H, Magometschnigg H, Ullrich R, Staudacher M. Use of varicose veins as arterial bypass grafts. Cardiovasc Surg. 1993 Oct;1(5):508-12*

\* *Lofgren EP. In Bergan JJ, Yao JST AND (eds) AND Surgery of the veins 1985. 285-299*

\* Cohn JD<sup>1</sup>, Korver KF. Selection of saphenous vein conduit in varicose vein disease. Ann Thorac Surg. 2006 Apr;81(4):1269-74.

\* Delfrate R. Thanks to the CHIVA strategy, may the histoarchitecture of great saphenous vein- sparing, make it suitable as graft for bypasses? Veins and Lymphatics. 2019, 8(1). <https://doi.org/10.4081/vl.2019.8227>

**A- Aorto-Coronary saphenous by-pass comparable to left internal thoracic artery (LITA).** 2 studies show that no-touch technique of saphenous vein harvesting provides significantly higher patency than the conventional technique and that was still comparable to that of the LITA:

1-No touch technique of saphenous vein harvesting: Is great graft patency rate provided? Papakonstantinou NA<sup>1</sup>, Baikoussis NG<sup>2</sup>, Goudevenos J<sup>3</sup>, Papadopoulos G<sup>4</sup>, Apostolakis E<sup>5</sup> Thorac Cardiovasc Surg. 2015 Oct;150(4):880-8. doi: 10.1016/j.jtcvs.2015.07.027. Epub 2015 Jul 15.

2-The no-touch saphenous vein for coronary artery bypass grafting maintains a patency, after 16 years, comparable to the left internal thoracic artery: A randomized trial. Samano N<sup>1</sup>, Geijer H<sup>2</sup>, Liden M<sup>2</sup>, Fremes S<sup>3</sup>, Bodin L<sup>4</sup>, Souza D<sup>5</sup>. TRIAL REGISTRATION: ClinicalTrials.gov NCT01686100. Copyright © 2015 The American Association for Thoracic Surgery. Published by Elsevier Inc. All rights reserved.

**B-Infra-popliteal Saphenous by-pass is still the best method to treat a critical limb ischemia.** 2 Meta-analysis show that infra-popliteal venous by-pass remains the best method:

1-Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia

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*Anai Espinelli S. Durazzo, MD,b Carlos Alberto Bragança Pereira, PhD,c and Nelson De Luccia, MD,b ( J Vasc Surg 2008;47:975-81.)*

*2-Meta-analysis of popliteal-to-distal vein bypass grafts for critical ischemia*

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*Nelson De Luccia, MD, PhD,a and Carlos Alberto Bragança Pereira, PhD,b Santos and São Paulo, São Paulo, Brazil ( J Vasc Surg 2006;43:498-503.)*

**C- The level of performance of cold-stored venous allograft is inferior to autologous vein sources.** Paradoxically, the GSV is often described as “sick” and not eligible for by-pass, so to be destroyed, though sold as by-pass by companies. Outcomes of cold-stored venous allograft for below-knee bypasses in patients with critical limb ischemia.

*1 Ganichot F, Jurus C. Allogreffes veineuses conservées à 4°C dans les pontages sousinguinaux: résultats à long terme dans 170 cas. Ann Chir Vasc 2000 ;14 : 553-560*

*2 Streichenberger R, Barjoud H, Adeleine P, Larese A, Nemoz C, Chatelard P, Nedey C, Sabben. Allogreffes veineuses conservées à 4°C dans les pontages sousinguinaux: résultats à long terme dans 170 cas. Ann Chir Vasc 2000 ;14 : 553-560*

*3 Masmajan S, Deslarzes-Dubuis C, Petitprez S, Longchamp A, Haller C2, Saucy F, Corpataux JM, Déglise S. Ten Year Experience of Using Cryopreserved Arterial Allografts for Distal Bypass in Critical Limb Ischaemia. Eur J Vasc Endovasc Surg. 2019 Jun;57(6):823-831*

*4 Ziza V, Canaud L, Gandet T, Molinari N, Alonso W, Chastan R, Branchereau P, Picard E. Outcomes of cold-stored venous*

*allograft for below-knee bypasses in patients with critical limb ischemia. J Vasc Surg. 2015 Oct;62(4):974-83.*

5 Hartranft CA, Noland S, Kulwicki A, Holden CR, Hartranft T. Cryopreserved saphenous vein graft in infrainguinal bypass. *J Vasc Surg.* 2014 ; 60(5) :1291-1296

#### **D- The CHIVA vs Stripping and EndoVenous Ablation reduces recurrence of varicose veins and produces fewer side effects than vein stripping.**

*1-CHIVA method for the treatment of chronic venous insufficiency. Bellmunt-Montoya S1, Escribano JM, Dilme J, Martinez-Zapata MJ. Cochrane Database Syst Rev. 2015 Jun 29;(6):CD009648. doi: 10.1002/14651858.CD009648.pub3." The CHIVA method reduces recurrence of varicose veins and produces fewer side effects than vein stripping"*

*2-Hemodynamic classification and CHIVA treatment of varicose veins in lower extremities (VVLE)*

*Hua Wang<sup>1</sup>, Qianyi Chen<sup>1</sup>, Zhewei Fei<sup>1</sup>, Endong Zheng<sup>2</sup>, Zhanghui Yang<sup>2</sup>, Xiaowang Huang<sup>2</sup>. <sup>1</sup>Department of Vascular Surgery, Xinhua Hospital Affiliated to Shanghai Jiaotong University School of Medicine Chongming Branch, Chongming 202150, China; <sup>2</sup>Department of General Surgery, Cangnan People's Hospital, Wenzhou 325800, Zhejiang. Int J Clin Exp Med 2016;9(2):2465-2471*

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*/ISSN:1940-5901/IJCEM0016552 "Conclusion: CHIVA treatment has significant better curative effect than traditional surgery and endovenous therapy in the treatment of varicose veins. CHIVA treatment induced less damage, quicker health recovery, high safety factor and lower complications. Thus, CHIVA treatment can be widely used in clinical restoration than general minimally invasive operations".*

#### **E- Cytokines/chemokines levels are significantly reduced in**

**the CHIVA treated patients as compared to the CVI patients before surgery**

*Modulation of Circulating Cytokine-Chemokine Profile in Patients Affected by Chronic Venous Insufficiency Undergoing Surgical Hemodynamic Correction.* Veronica Tisato,<sup>1</sup> Giorgio Zauli,<sup>2</sup> Sergio Giancesini,<sup>1,3</sup> Erica Menegatti,<sup>1,3</sup> Laura Brunelli,<sup>1</sup> Roberto Manfredini,<sup>4</sup> Paolo Zamboni,<sup>1,3</sup> and Paola Secchiero  
*Journal of Immunology Research* Volume 2014, Article ID 473765, 10 pages <http://dx.doi.org/10.1155/2014/473765>

#### **F- Conflicts of interest are questioned:**

*The Endovenous Literature: A Perfect Storm of Limited Effectiveness Data, Rapid Technological Evolution and Potential Conflict of Interest* David C. Bosanquet, Christopher P. Twine *Eur J Vasc Endovasc Surg* (2017) 54 , 771 .

DOI: <http://dx.doi.org/10.1016/j.ejvs.2017.09.009>

“The literature supporting the endovenous revolution has left clinicians and commissioning bodies in a difficult position. There are many dubiously-powered randomised studies comparing heterogeneous endpoints of limited clinical value, for a condition where the predominant aim of treatment, improvement in quality of life (QoL), has been overlooked for too long. There is a wide selection of treatment options of varying costs which are constantly being updated. Lastly, a potential conflict of interest can occur because endovenous treatment can be lucrative for both device companies and the clinician”.

#### **G- Mini-invasive venous treatments doesn't mean safe.**

*1- Morbidity and mortality after thermal venous ablations.* Malgor RD1, Gasparis AP, Labropoulos N. *Int Angiol.* 2016 Feb;35(1):57-61. Epub 2015 Feb 12

“EVA has gained high acceptance worldwide but the risks tend to be overlooked. Despite a very low complication rate, mortality has been reported. The complications found in MAUDE represent only

*a fraction as the majority of the practitioners are not aware of this database. Further investigation by a large national registry is warranted to better define the real magnitude of EVA complications”.*

*2- Assessment of thrombotic adverse events and treatment patterns associated with varicose vein treatment. Thomas F*

*O'Donnell, Michael Eaddy, Aditya Raju, Kimberly Boswell, David Wright. *J Vasc Surg Venous Lymphat Disord*. 2015*

*Jan;3(1):27-34. doi: 10.1016/j.jvsv.2014.09.007.Epub 2014 Nov 3.*

*There were 985,632 unique subjects diagnosed with varicose veins; of them, a total of 131,887 subjects met all of the study criteria: 63,033 (47.8%) having multiple therapies; 22,980 (17.4%) having laser ablation; 21,637 (16.4%) having radiofrequency ablation; 12,708 (9.6%) having sclerotherapy; and 11,529 (8.7%) having surgery.*

**Conclusions:** *Thrombotic complications associated with invasive varicose vein treatments in the real-world setting may be higher than what has been reported in clinical trials, particularly in regard to DVT after endovenous thermal ablation therapy. A better understanding of these patterns of adverse events may have an impact on new strategies to safely and effectively manage patients with varicose veins.*