Author's response to reviews

Title: A randomized double-blind study protocol comparing polidocanol versus hypertonic glucose for sclerotherapy treatment of reticular veins of the lower limbs

Authors:

Matheus Bertanha (matheus.fameca@ig.com.br)
Carlos EP Lucio Filho (carloseduardofilho@ymail.com)
Jamil VO Mariúba (jamil_mariuba@hotmail.com)
Rafael EF Pimenta (pimentamed36@yahoo.com.br)
Rodrigo G Jaldin (rgibin@uol.com.br)
Marcone L Sobreira (mlsobreira@gmail.com)
Andrei Moroz (moroz@fcafar.unesp.com.br)
Regina Moura (rmoura@fmb.unesp.br)
Hamilton A Rollo (hrollo@fmb.unesp.br)
Winston B Yoshida (winston@fmb.unesp.br)

Version: 2
Date: 5 May 2014

Author's response to reviews: see over
May 01st, 2014

Doug Altman; Curt Furberg; Jeremy Grimshaw
Editors-in-Chief
Trials

Dear Editor,

We are pleased to submit our manuscript entitled: "A randomized double-blind study protocol comparing polidocanol versus hypertonic glucose for sclerotherapy treatment of reticular veins of the lower limbs" by Bertanha et al. for your consideration as a research article in Trials.

The prevalence of chronic venous disease is high, occurring more frequently in females. According to the CEAP definition, the reticular veins included in the C1 class of CEAP classification are mainly associated with aesthetic complaints. Several techniques are used for invasive treatment, such as: mini phlebectomy, laser ablation, and radiofrequency ablation. However, the minimally invasive alternative is the use of a wide range of sclerosing agents, yielding chemical sclerosis of the vein wall. Although this technique is routinely performed around the world, there is not a consensus on the ideal chemical agent regarding efficacy and safety.

In this study, we presented a randomized double-blind clinical trial protocol to evaluate the safety and efficacy of two methods of sclerotherapy treatment of reticular veins in the lower limbs of females between 18 and 69 years. We will enroll 96 patients. The design of this study was evaluate to aims through primary efficacy end point and safety through secondary end point. Thus far, 48 patients have been enrolled. The partial results for these patients were that 25 received treatment, two patients were excluded, 22 returned after 7 days and showed no greater adverse events. It has not been possible to establish the efficacy criteria and no
patients have reached the point of the 60 day return. Thus, these data should help doctors to choose the best chemical agent for the treatment of reticular veins.

We believe that our manuscript highlights novel information in the treatment of reticular veins in lower limbs, justifying publication in Trials.

Our data are novel and have not been submitted to any other scientific journal. All authors are aware and agree to the content of this manuscript. The authors have no financial interest and no conflicts of interest to disclose.

Sincerely,

Winston Bonetti Yoshida, MD, PhD
Full Professor
Dept. of Surgery and Orthopedics, School of Medicine, São Paulo State University (UNESP), Botucatu, SP, Brazil.