Lipov, J Trauma Treat 2014, S4
DOI: 10.4172/2167-1222.S4-022

Journal of Trauma & Treatment
ISSN: 2167-1222

Letter to the Editor Open Access

A Randomized, Double-Blind, Placebo-Controlled Trial of Stellate Ganglion Block in the Treatment of Post-Traumatic Stress Disorder: Scientific Poster

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Description

A scientific poster was presented at the 31st Annual Meeting of the American Academy of Pain Medicine on March 25, 2015 titled, "Stellate Ganglion Block (SGB) performed no better than sham treatment in a randomized controlled trial." Dr Robert McLay, the lead author, reported above as the first blinded placebo study done in the San Diego Naval Hospital. Rapid, dramatic and long-lasting improvements in PTSD symptoms have been reported after stellate ganglion block (SGB) but have been limited to anecdotal evidence and uncontrolled trials. He went on to say: "The most obvious explanation would be that the previously-reported benefits for PTSD were attributable to placebo effect" [1]. The background for the use of SGB in treating PTSD is summarized below. The published success rate of using SGB in treating PTSD, as reported in the literature has been, 75% where n=24 [2], and a success rate of over 70% where n=166 [3]. Similar results have been shown in 5 independent institutions. Walter Reed Military Hospital, Dr Mulvaney, et al. [3], Tripler Army Hospital, Dr Alino et al. [4], Long Beach, California Veterans Administration, Dr Alkire et al. [5], Naval Medical Center San Diego, Dr Hickey A [6], Advanced Pain Centers, Dr Lipov [7]. To date, over 1000 SGB's have been done for PTSD with excellent safety and efficacy profile, consistent with the published results noted above. Considering the above reports, we must consider what could account for inconsistency of the results, outside the placebo effect. Most critically could be patient selection. The patient population that was studied by Dr McLay may have been sub optimal for the study conducted since many of the study patients are actively involved in medical board that determines their disability payments [8]. In Dr McLay's population patients had a financial incentive not to report improvement. This is markedly different than the population studied by Dr Mulvaney that were Special Forces trying to return to active duty, or patients in our clinic, that have found us independently and traveled long distances for treatment. Further, when a researcher discusses placebo effect as being dominant vs. "real" effect that implies lack of treatment efficacy. It is true that injections have proven to be very powerful placebos, especially in affecting psychological states, however Dr. McLay's study design may have contributed to his conclusion, out-side the population bias discussed above, which is not consistent with previous reports. Recent studies have demonstrated objective brain changes following SGB. They are: Dr. Jeong report of significant reduction in EEG activity in a rat model when he reported SGB with 0.2 ml 0.25% bupivacaine significantly decreased EEG activities in rats, in a double blind placebo study [9]. A member of the same team, Dr. Yeo, performed a similar experiment in a placebo control human trial . The findings were that, in the SGB group, BIS values (a simplified EEG) significantly decreased after the intervention as compared to baseline ($P<0.05$). The values were also significantly decreased in the SGB group when compared to the values in sham group after the intervention ($P<0.05$) [10]. Another approach to evaluation of SGB effect has been Positron Emission Tomography (PET) Scanner. The findings were as follows: SGB dramatically reduced PTSD symptoms . Importantly, brain regions that correlated with the individual Clinician Administered PTSD Scale (CAPS) scores and their functional improvement following SGB centered on the amygdala and hippocampus, primarily in the right hemisphere. This is consistent with previous reports of the right amygdala/hippocampal areas being relatively overactive when PTSD symptoms are prominent [11].

Below is the summary of the design limitations of Dr. McLay's study:

1) The study did not use an active placebo, a compound that mimics the side effects of the active treatment [12]. In this case, Horner's syndrome (i.e., enophthalmos, ptosis, meiosis, and heterochromia) the patient can easily tell if eye droop occurs or not. This makes blinding problematic since a patient can easily tell if they had a local anesthetic vs. normal saline (normal saline does not produce Horner's syndrome).

2) Forty-two military service members with PTSD were randomized to receive SGB (n=27) or Sham injection (n=15). Due to a 2:1 ratio each placebo would be weighted twice as important vs. SGB.

3) Finally, it is not clear why a study had a total of 42 patients. Typically trails are done in phases. Phase 1 is to determine dosing and side effects of the medication, a step unnecessary for SGB due to a 90-year safety and dosing experience. Phase 2, trials include 100 to 300 participants that have the condition medication is designed to treat. In this phase researchers seek to get more safety data and obtain preliminary evidence of efficacy [9]. Drawing conclusion from a study with a small number of patients is not an optimal way to obtain statically significant efficacydata.

In conclusion, it is unfortunate, that a small study in a suboptimal population that has not gone through the peer review of a formal article may pre- vent patients who may have a marked improvement in their PTSD symptoms from receiving SGB. Critical to note is that the current PTSD therapies are succeeding at a rate below 30% [13], to date SGB seems to be the most promising development for treating PTSD available today. The SGB efficacy should be judged by an adequately powered RCT study with a truly representative population, in fact this study is now funded and is in the process of being conducted. A Triangle research institute has received a $2 million grant from the

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Received March 31, 2015; **Accepted** September 12, 2015; **Published** September 20, 2015

Citation: Lipov E (2015) A Randomized, Double-Blind, Placebo-Controlled Trial of Stellate Ganglion Block in the Treatment of Post-Traumatic Stress Disorder: Scientific Poster. J Trauma Treat S4: 022. doi:10.4172/2167-1222.S4-022

U.S. Department of Defense to test a medical procedure (SGB) to treat post-traumatic stress disorder. Three military hospitals were chosen to participate in the study: Womack Army Medical Center at Fort Bragg, Tripler Army Medical Center in Honolulu, Hawaii, and Landstuhl Regional Medical Center in Landstuhl, Germany [14].

References

1. McLay R, Hanling S, Drastal CA, Adams G, Hickey A (2015) A Randomized, Double-Blind, Placebo-Controlled Trial of Stellate Ganglion Block in the Treatment of Post-Traumatic Stress Disorder. The American Academy of Pain Medicine 126.
2. Navaie M, Keefe MS, Hickey AH, McLay RN, Ritchie EC, et al. (2014) Use of Stellate Ganglion Block for Refractory Post-Traumatic Stress Disorder: A Review of Published Cases. J Anesth Clin Res 5: 403.
3. Mulvaney SW, Lynch JH, Hickey MJ, Rahman-Rawlins T, Schroeder M, et al. (2014) Stellate Ganglion Block Used to Treat Symptoms Associated With Combat-Related Post-Traumatic Stress Disorder: A Case Series of 166 Patients. Mil Med 179: 1133-1140.
4. Alino J, Kosatka D, McLean B, Hirsch K (2013) Efficacy of stellate ganglion block in the treatment of anxiety symptoms from combat-related post- traumatic stress disorder: a case series. Mil Med 178: 473 -477.
5. Alkire MT, Hollifield M, Khoshsar R, Nguyen L, Alley SR, et al. (2014) Prolonged Relief of Chronic Extreme PTSD and Depression Symptoms in Veterans Following a Stellate Ganglion Block. American Society of Anesthesiology.
6. Hickey A, Hanling S, Pevney E, Allen R, McLay RN (2012) Stellate Ganglion Block for PTSD. Am J Psychiatry 169: 760.
7. Lipov EG, Navaie M, Brown PR, Hickey AH, Stedje-Larsen ET, et al. (2013) Stellate ganglion block improves refractory post-traumatic stress disorder and associated memory dysfunc- tion: a case report and systematic literature review. Mil Med 178: e260-e264.
8. Personal communication from a physician, the name is not disclosed due to possible career impact of this individual
9. Seunghyun J, Jeon Y, Yeo J, Baek W (2014)The effects of stellate ganglion block on the electroencephalogram in rats. J Anesth 28: 601-605.
10. Yeo J, Jeon Y (2015) Effects of stellate ganglion block on sedation as assessed by bispectral index in normal healthy volunteers. Pain Physician 18:173-178.
11. Alkire MT, Hollifield M, Khoshsar R (2015) Neuroimaging Suggests that Stellate Ganglion Block Improves Post-Traumatic Stress Disorder (PTSD) Through an Amygdala Mediated Mechanism. To be presented at American Society of Anesthesiology.
12. Benedetti F(2014) Placebo Effects (2ndedn) Oxford Print , USA.
13. Hoge CW (2001) Interventions for war-related posttraumatic stress disorder:meeting veterans where they are. JAMA 306: 549-551.
14. http://www.newsobserver.com/news/state/north-carolina/arti- cle19090185.html accessed 4/20/15.

This article was originally published in a special issue, **Post Traumatic Stress Disorders** handled by Editor(s). Dr. Allison N. Sinanan, Stockton University, NJ, USA