

REPORT

ALSUntangled Update 2: Investigating The Hickey Wellness Center

THE ALSUNTANGLED GROUP

Overview

Now six months old, ALSUntangled (1) has 85 followers on twitter, and receives weekly questions about alternative and off-label ALS therapies. Our NING has 40 ALS clinician-scientists from four countries examining these therapies, with 18 active discussions. New discussions underway since our last update (2) include: intravenous glutathione, the Lourdes ALS Miracle, and the Nepsis Institute. Recently, at the request of PALS, one of us travelled to the Hickey Wellness Center (Figure 1). We now present a summary of observations made at this Center.

The Hickey Wellness Center

The Hickey Wellness Center (3) is in Hilton Head Island, South Carolina, USA. It is staffed and run by Dr. Joe Hickey (an internist) and his wife. The Hickeys are enthusiastic, friendly, and accommodating. The Center is located in an attractive part of the island, easily accessible, spacious, modern and clean.

Dr. Hickey believes that ALS and a number of other diseases, including primary lateral sclerosis, myelodysplastic syndrome, renal failure, multiple sclerosis, Parkinson's disease, and fibromyalgia, are caused by heavy metal poisoning. As a result, patients who present with these varied conditions receive similar treatments in his center. No systematic validation of presenting diagnosis is performed; the referring diagnosis is assumed to be correct. Standard blood and urine heavy metal testing is rarely performed in this clinic; Dr. Hickey does not believe such testing is accurate. Instead, patients are assessed for heavy metal burden by 'post-provocation' testing. This involves exposure to chelating agents followed by urine and stool metal testing. The levels of urine and stool metals are compared to 'normal values' taken from people without neurologic symptoms and before provocation. When elevated metals are found, a 'multi-modal treatment' regimen is prescribed. This includes i.v. calcium EDTA given three times weekly. Every three infusions, DMPS is used instead of EDTA to compensate for 'bismuth toxicity'. If

mercury levels are elevated, patients are advised to have their mercury amalgam dental fillings replaced. Supplements including calcium, magnesium, vitamins C and E, N-acetylcysteine, alpha-lipoic acid, coenzyme Q10 (500 mg daily) and creatine (5 g daily) are also recommended, as well as a high protein diet, including 4–6 egg yolks per day (to help stabilize cell membranes and regenerate myelin). Testosterone is added if levels are low.

Prior to chelation, patients are asked to sign a one-page consent form that states: "I understand that this treatment has side-effects that have been explained to me. I understand that this procedure may or may not help me." Dr. Hickey was unable to provide the exact number of PALS treated with the above regimen, but he estimated "30–35." Other than periodic, post-provocation metal testing, no specific outcome measures are followed to determine efficacy; some patients are video-taped in a non-standardized manner, many are simply asked for their gestalt impression of change. Dr. Hickey was unable to provide the exact percentage of PALS who appeared to benefit, but his impression is that "most do." Dr. Hickey was unable to recall adverse events (related to treatment or otherwise) in any of the PALS receiving the above protocol.

Several patients with presumed ALS travelled to the Center to meet with ALSUntangled, and gave us permission to review their available medical records. The diagnosis of ALS appeared sound in three patients; two of these had clearly progressed since starting. The third patient felt subjectively better, and had an improvement in her recorded ALSFRS-R scores while followed for a year in a well-known ALS clinic. Her recorded manual muscle testing scores, however, worsened over this time. Post-provocation metals were initially elevated (compared with non-provoked 'normals') and reduced by chelation in all these patients. Adverse events occurring on the Hickey protocol were evident in medical record reviews, although it was not clear whether these were related to treatment or not. Patients revealed that Center treatments were expensive, and not always covered by insurance; out-of-pocket costs (including travel) were estimated at up to \$30,000

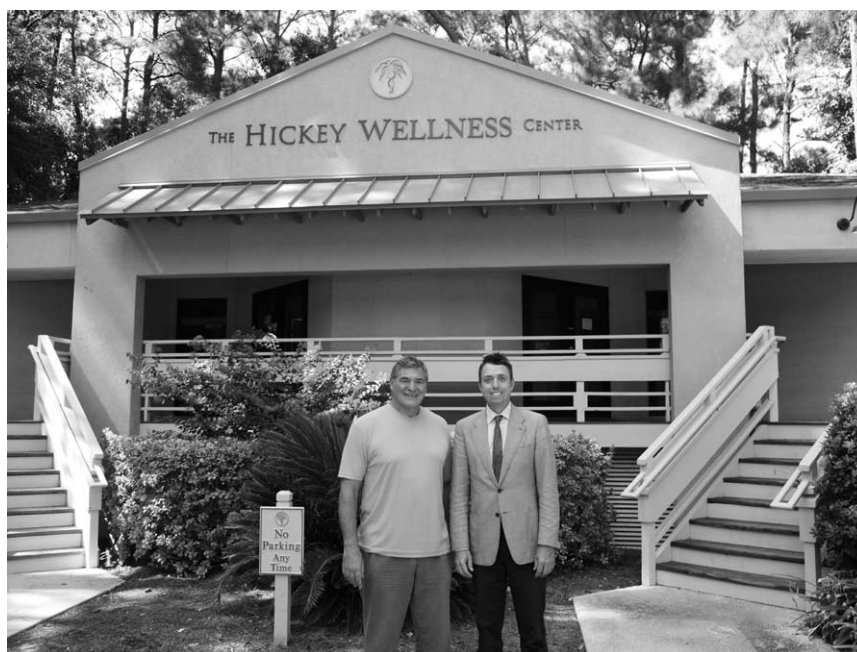


Figure 1. Dr. Joe Hickey (left) and Dr. Bedlack in front of the Hickey Wellness Center.

per year. As a result of the costs, patients admitted their compliance with the protocol was variable. All patients were complimentary of Dr. Hickey's bedside manner, and his respect for their desire to pursue an alternative treatment for their ALS. Most were no longer seeing their neurologist because they felt that they were not given any hope by them, and/or that their inputs regarding their own therapy were not welcomed or respected.

Conclusion

The Hickey Wellness Center infrastructure is clean and professional. Dr. Hickey has a good bedside manner, and clearly believes in his protocol (indeed he himself is on it, and has had his own fillings removed). However, at this time, we are not convinced of a link between heavy metal toxicity and ALS. The metal testing performed in the Center is un-interpretable given the lack of 'normal' post-chelation metal ranges. Similarly, concerning are the lack of validated diagnoses, an appropriately detailed informed consent form, a consistent protocol across patients, objective outcome measures, or even adverse event tracking. As a result of these problems, ALSUntangled cannot currently condone most of the Hickey Wellness Center's approach toward ALS. We do endorse two of Dr. Hickey's practices: stressing hope, and once all the important information about an alternative therapy has been provided, respecting a patient's wish to pursue it even if it is against our advice.

The ALSUntangled Group currently consists of the following members: Richard Bedlack, Orla Hardiman, Bjorn Oskarsson, Alberto Ascherio, Robert Bowser, Vivian Drory, Jeremy Shefner, Terry Heiman-Patterson, Noah Lechtzin, Melanie Leitner, Robert Miller, Hiroshi Mitsumoto, Todd Levine, James Russell, Khema Sharma, David Saperstein, Leo McClusky, Daniel MacGowan, Jonathan Licht, Ashok Verma, Michael Strong, Catherine Lomen-Hoerth, Rup Tandan, Michael Rivner, Lisa Krivickas, Steve Kolb, Meraida Polak, Stacy Rudnicki, Pamela Kittrell, Muddasir Quereshi, George Sachs, Gary Pattee, Tahseen Mozaffar, Michael Weiss, John Kissel, Merit Cudkowicz, Jonathan Goldstein, Jeffrey Rothstein, Bryan Traynor, Dan Pastula.

Note: this paper represents a consensus of those who commented. The opinions expressed in this paper are not necessarily shared by every investigator in this group.

References

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3. Hickeycenter.com. The website of the Hickey Wellness Center; 2009 (cited September 13, 2009). Main section (1 page). Available from <http://www.hickeycenter.com>.