

**The Foundation For a Better QOL
6700 West Loop South, Ste 330
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Current research activities include:

1. “Use of BetterQOL.com to Measure Quality of Life and Track Health Outcomes in Chronic Diseases”

Background: For chronic diseases that do not shorten life expectancy, physicians prescribe drugs to maximize the patient’s quality of life. Unfortunately, in routine clinical care, physicians do not have the resources to measure and track changes in their patients health outcomes. Usually they ask the patients how the medication is working and then make a subjective assessment but a formal measurement of their overall health is not done. Routine screening for comorbid diseases that are common in chronic diseases is also rarely performed. Treatment of comorbid diseases such as depression can improve the patient’s quality of life and affect the overall health outcome.

Method: The Foundation for Better QOL intends to use funding to help develop an online hipaa compliant tool that tracks health outcomes, correlates outcomes to medication changes, screens for comorbid diseases, asks patients about medication compliance, asks pertinent drug and disease review of systems questions, and educates patients on their disease and medications.

Once this technology is widely deployed, The Foundation for Better QOL will analyze aggregate data and identify medications and their use in areas that warrant further study. The Foundation for Better QOL will also make a “scrubbed” database available to researchers who have important research questions that our data can answer.

2. “The efficacy of IV Haloperidol for treatment of New Daily Persistent Headache” and “Role of Tumor Necrosis Factor Alpha in patients with New Daily Persistent Headache before and after treatment with IV Haloperidol”

Background: “New Daily Persistent Headache” affects about 0.1% of all Americans. By definition, these patients have daily headaches and are largely disability. There are no FDA approved therapies for new daily persistent headache. There are no controlled studies currently underway for this disease. Dr. Loftus has presented open label data for four patients treated with IV Haloperidol. ¾ of these patients had a good or excellent response.

Haloperidol has been demonstrated to decrease tumor necrosis factor alpha in the serum. The response of tumor necrosis factor alpha in the CSF to haloperidol treatment has not been measured. Tumor necrosis factor alpha is increased in the CSF in patients with new daily persistent headache.

Methods: The Foundation for a Better QOL intends to determine the levels of tumor necrosis factor alpha in the CSF before and after an IV haloperidol infusion. The Foundation for a Better QOL intends to fund and participate in a double blind placebo controlled study of IV Haloperidol to treat “new daily persistent headache”.

3. **“The efficacy of IV Haloperidol for treatment of Refractory Chronic Migraine”**

Background: IV Haloperidol has been shown useful in aborting migraine status. Intrathecal levels of tumor necrosis factor alpha have been found in patients with refractory chronic migraine. Haloperidol has been demonstrated to decrease tumor necrosis factor alpha in the serum. The response of tumor necrosis factor alpha in the CSF to haloperidol treatment has not been measured.

Methods: Dr. Loftus has used IV haloperidol in his practice for this group of patients. The Foundation for a Better QOL intends to study IV haloperidol in this group of patients as well.

4. **“Efficacy of IV Magnesium in Patients with Chronic Migraine and Frequent Migraine at Various Concentrations and Infusion Rates”**

Background: Chronic migraine is defined as patients who have 15 or more days of headache of which at least 8 fulfill the definition of migraine. Only botulinum toxin – at an approximate cost of \$6,000-\$8,000/yr is FDA approved for this therapy. There have been a handful of studies published in this area. These patients have a very high disability. IV Magnesium has been shown to be useful in a double blind placebo controlled study in the treatment of migraine. Dr. Loftus has used IV magnesium extensively in his practice with these patients and has had good results.

Method: The Foundation for a Better QOL intends to conduct a series of studies to determine the effectiveness of IV magnesium in patients with chronic migraine and frequent migraine. The first work will be to determine the change in concentration of serum magnesium with the use of IV magnesium at different infusion rates. A double blind placebo controlled study will then be conducted to demonstrate the effectiveness of IV magnesium at different infusion rates as well as placebo. We will study both IV magnesium both as an add on agent to existing therapy as well as a single use agent.

5. **Treatment of Palmar and Axillary Hyperhidrosis Using Various Formulations and Concentrations of Botulinum Toxin**

Background: An underserved area of treatment is focal hyperhidrosis, specifically axillary and palmar hyperhidrosis. Hyperhidrosis is extreme sweating in response to anxiety rather than heat. Hyperhidrosis is very socially disabling for patients and palmar hyperhidrosis functionally impairs work for many patients. Botulinum toxin type A in the form of Botox® is the only approved therapy for axillary hyperhidrosis and there is nothing approved for palmar hyperhidrosis. This treatment is effective but quite expensive. Botulinum toxin therapy costs can be minimized by determining optimum concentration of botulinum toxin as well as dose of administration.

There are three additional botulinum toxin formulations that are available in the United States besides Botulinum toxin type A. Optimum concentration and dosing of these formulations have not been determined for treatment of hyperhidrosis.

Method: The Foundation for a Better QOL intends to study the efficacy of all forms of botulinum toxin for palmar hyperhidrosis as well as the optimum concentration and dosing of all formulations for both axillary and palmar hyperhidrosis.