January 2016 Update for Therapies and Advocacy Efforts by the US Institute for Advanced Sinus Care & Research

Dear ENS Community,

We are growing increasingly optimistic about our therapies for ENS and hopes for a cure in the future. Attached in an update of our efforts over the last six months.

1. How have the results of PRP/Matristem therapy been progressing?

We now have treated 180 patients from 25 countries. Of these, 148 patients or 82% of patients have reported an improvement in their symptoms. 17 patients (9%) have not reported any followup, 11 patients (6%) have reported no improvement at all, and 4 (2%) patients have reported getting worse.

Of the 148 patients who have reported an improvement, approximately 25 (17%) have reported a life changing/dramatic improvement, 102 (69%) have reported a moderate benefit, and 21 (14%) have reported a mild benefit. Almost 100% have reported fluctuation in their symptoms; most report an initial improvement and then some initial loss of the initial benefit and then a later gradual improvement. 32 of 148 (22%) patients have reported a temporary benefit with complete loss of their initial improvement over the course of weeks to months after the initial benefit. Many of these patients have only had 1 or a few injections.

I have seen visible regrowth of turbinates in over 30 patients, increased moisture and mucus production in over 50 patients. Many patients have reported improved sleep, cessation of their suffocation symptoms, decreased anxiety, resolution of dysautonomia and significant improvement in their global health. I continue to believe each injection seems to provide an additive benefit, however there might be an exponential benefit during the first three injections. We have had 15 patients who have completed between 4 and 12 injections and have reported return to their pre-surgical level of health. I am now confident in the therapy and engaging in efforts to perform a controlled study and publish results supporting the use of PRP/Matristem. The costs are substantial to perform a Level 1B study. They will cost me approximately 10,000 for Institutional Review Board fees, $15,000 for study coordination/data collection, and $75,000 for treatment materials. We are actively engaging in fundraising efforts to support the completion of this study.

2. What is the new therapy you will be implementing in 2016?

We have purchased a new, cutting-edge system for platelet rich plasma (PRP) system extraction. This system utilizes a laser and advanced centrifuge to enrich PRP to levels four times greater than our current system. As a result, we are hopeful that this system will lead to near-physiologic levels of chemotaxis and stem cell signalling. Due to the added expense of this system, our costs will increase per treatment from $1850 to $1985 for initial treatments and from $1500 to $1635 for repeat injections. However, we are hopeful that patients will need fewer injections to restore their turbinate function and hopefully reduce overall costs for each patient.

3. How have your efforts been in developing new stem-cell based therapies for ENS?

We participated in a conference call with Dr. Anthony Atala, who is probably the leading stem-cell scientist in the world in October. Dr. Atala invited me to his laboratory to discuss future therapies for ENS. Dr. Atala is a urologist by training and has been able to regrow penile tissue in his lab; penile tissue is cavernous erectile tissue very similar to inferior turbinate tissue. We also hope to participate in the World Stem Cell Summit in 2016, and develop contacts with industry partners to expedite the development of therapies to regrow new turbinates for patients who have suffered irreversible turbinate damage.

4. How did your meeting with the Blue Tail Medical Group go?

In October, we met with one of the leading orthopedic stem cell groups that are performing therapies for arthritis and joint damage. There we learned new techniques to utilize bone marrow and fat for stem cell harvest. We are actively working to vet these therapies and implement these therapies for our patients.

5. How was the American Rhinologic Society annual meeting?

The meeting was very promising. There continues to be greater recognition that ENS is a problem. Dr. James Palmer, Chief of Rhinology at the University of Pennsylvania lamented that ENS was his greatest fear that kept him concerned at night. Many panels within the ARS are discussing ENS as a real problem and leading discussions on the best way to solve this problem.

6. Any new changes to your practice?

While our practice has become extremely busy, we will continue to devote more time to education and prevention efforts. We will try to develop a web series that will provide weekly lectures on the web on the basic science, clinical practice, and general education of sinus and turbinate disease. We will also continue to perform second opinion phone consults for patients with ENS. One thing that I have become more aware of over the last year, is that many patients with severe nasal problems are not necessarily suffering from ENS, but suffering from poor surgery that may have missed the original nasal problems. We have performed several operations unrelated to ENS based on reviews of people's ct scans. Overall, we are hopeful that 2016 will be a promising year where significant progress is made towards preventing and curing ENS.

Best wishes, and happy new year to you all.

Sincerely,
Subinoy Das, MD, FACS