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# New study from Liverpool on Antisecretory Factor in regards to Menière's Disease 6 out of 10 significantly improved!



Dr. Tristram Lesser, Master of Surgery, Fellow of College of Surgeons, Medical director at the Department of Otorhinolaryngology – Head and Neck and Skull Base Surgery, University Hospital Aintree, Liverpool.

#### Liverpool is not just about the Beatles Story and the Liverpool Football Club. Here we also find the Liverpool University Hospital Aintree.

The director of the ENT-clinic, Dr. Tristram Lesser MS, FRCS, has directed a study of the effect of Antisecretory Factor (AF) on Menières disease, a study that was published in October 2013.

## DOUBLE BLIND

Our reporter Carl-Olof Börjeson travelled to Liverpool for an interview with Dr. regards to Menière's disease through almost 20 years. – The study was designed in

The Liverpool study is the second randomized double blind study with significant results that confirm an initial pilot study, which also had significant results. Consistent results are now available from two university hospitals in two different cities in two different countries; Antisecretory Factor effectively reduces pain, vertigo and other problems associated with Menière's disease.

Tristram Lesser about the study. – Our investigation includes 39 patients (age 22-80) diagnosed with Menière's disease, in a randomized, double blind, placebo-controlled crossover study. The result was measured with the Functional Level Scale, a 6-level measuring scale that has been accepted and applied internationally with such a way that patients received either SPC or placebo in identical packages for 3 months of use. Neither the doctor nor the patient knew what the contents of the packages were. After an intermission ("wash-out period") of two weeks the patients received the other of the two alternatives for another three months of use.

Menière's disease or Menière's syndrome is a disease of the inner ear, which was first described by the French doctor Prosper Menière in 1861.

The onset of disease is typically at the age of 40, in rare cases during childhood. Women and men are equally susceptible.

At the ENT clinic in Liverpool, it is estimated that there is a disease prevalence of 3 patients per 8000 inhabitants, where 1 is referred to the clinic while the other 2 are treated in primary care.

Menières disease is caused by increased pressure in the inner ear. It is due to accumulation of endolymph in the ductus and saccus endolymphaticus of the ear. A so-called endolymphatic hydrops occurs. Endolymph is present in both the cochlea and the vestibular

system and since these organs are connected, symptoms arise from both the hearing and balance organs.

Menière's disease involves vertigo attacks, hearing impairment of one ear, a feeling of pressure or fullness and tinnitus. The severity of the disease is estimated according to the Functional Level Scale, in use since 1995.



#### AAO-HNS Ménière's Disease Functional Level Scale

1. My dizziness has no effect on my activities at all.

2. When I am dizzy I have to stop what I am doing for a while, but it soon passes and I can resume activities. I can continue to work, drive, and engage in any activity I choose without restriction. I have not changed any plans or activities to accommodate my dizziness.

3. When I am dizzy, I have to stop what I am doing for a while, but it does pass and I can resume activities. I continue to work, drive, and engage in most activities I choose, but I have had to change some plans and make some allowance for my dizziness.

4. I am able to work, drive, travel, take care of a family, or engage in most essential activities, but must exert a great deal of effort to do so. I must constantly make adjustments in my activities and budget my energies. I am barely making it.

5. I am unable to work, drive, or take care of a family. I am unable to do most of the active things that I used to. Even essential activities must be limited. I am disabled.

6. I have been disabled for 1 year or longer and/or I receive compensation (money) because of my dizziness or balance problem.

\*) Committee on Hearing and Equilibrium guidelines for the diagnosis and evaluation of therapy in Menière's disease. American Academy of Otolaryngology–Head and Neck Foundation, Inc. Otolaryngol Head Neck Surg 1995;113:181-5.

# IMPRESSIVE IMPROVEMENT FROM 5 TO 2

The result is positive. A shift on the Functional Level Scale from 5 to 2 is a very significant improvement, especially for those patients who took part in the study who had tried and failed previous treatment, before the SPC treatment.

The Menière patients who participated in the study are part of the minority of patients who have been referred to a specialist clinic. The majority of cases, who are less severe, are managed by primary care. – The patients reported a significant improvement with SPC Flakes. Quite a few of the patients said that they could feel a difference in the form of increased symptoms when they switched from (as they understood it) active SPC to placebo.

# "Treatment with SPC appears to be well tolerated by most patients (91%) without any complications. More than half (59%) of the study cohort reported subjective improvement in functional level."

### FEWER OPERATIONS

Tristram Lesser tells us about an unexpected consequence of the SPC treatment.

- In particular difficult cases of the disease with frequent and severe relapses, patients can end up being so bothered and hearing impaired that they are willing to sacrifice hearing entirely on one ear, in order to become free of symptoms and pain.

- The treatment that is sought in these cases is an injection of an ototoxic antibiotic, Gentamycin, which kills the hair cells of the inner ear and stops the pain impulses to the brain. An Australian colleague and I have previously launched an improvement of the method where a Gentamycin depot is placed in the ear instead of an injection.

- But even if the pain is gone after gentamycin treatment, discomfort remains in the form of a feeling of pressure in the ear.

- I have noted a dramatic decrease in the number of these operations and it is due to SPC, which has reduced the symptoms of the patients, improved their quality of life and has enabled them to cope without

an operation so far, concludes Tristram Lesser...... Antisecretory Factor-Inducing Therapy Improves Patient-Reported Functional Levels in Meniere's Disease Samuel C. Leong, MPhil, FRCS(ORL-HNS); Surya Narayan, MS, DLO, FRCS(ORL-HNS); Tristram H. J. Lesser, MS, FRCS

Annals of Otology, Rhinology & Laryngology 2013; 122: 619-624. © 2013 Annals Publishing Company. All rights reserved. From the Skull Base Unit, Department of Otorhinolaryngology–Head and Neck Surgery, University Hospital Aintree, Liverpool (Le- ong, Lesser), and the Department of Otorhinolaryngology, Royal Blackburn Hospital, Blackburn (Narayan), England. Winner of the George Seed Prize 2012-2013 for best academic paper, presented by the North of England Otolaryngology Society.Correspondence: Samuel C. Leong, MPhil, FRCS(ORL-HNS), Dept of Otorhinolaryngology–Head and Neck Surgery, Skull Base Surgery, University Hospital Aintree, Liverpool L9 7AL, United Kingdom.