

My prog-MS ezine

For people with progressive MS and other interested people

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Hello and welcome to the latest edition of my ezine about progressive Multiple Sclerosis and MS progression in general. My name is Ian Cook. I'm a secondary progressive MSer from Birmingham, UK. I'm 64.

In this issue are eight pages of prog-MS news stories. There are also two features. One on page 5 is about my recent visit to see a speech and language therapist to help me with my long-standing swallowing problems.

There's also a feature on research into cow's milk, asking whether this is the environmental factor that explains why MS is more common in certain parts of the world like Europe and North America . See page 10 for details.

IN THIS ISSUE



Is milk the elusive environmental factor behind MS? page 10

Tongue stimulator gets approval to help walking, page2

Baclofen Helps Repair Myelin: Study Finds, page 3

News

New tongue stimulator - US approval for device to help walking

The US FDA (Food and Drugs Administration) has approved a new type of medical device to help improve the walking of people with progressive MS.

Helius Medical's Portable Neuromodulation Stimulator (PoNS) helps retrain the neural pathways that provide motor control, as a short-term treatment alongside guided physical exercises such as balancing on one foot or walking on a treadmill.

The PoNS device includes an electrode-lined mouthpiece that is held in the mouth on top of the tongue. It then delivers electrical pulses to the tongue and through the facial nerves to the brain. There, it helps retrain the neural pathways that provide motor control when given as a short-term treatment during guided physical exercises such as balancing on one foot or walking on a treadmill.

Progressive MS can cause widespread demyelination which over time can disrupt the central nervous system's communications between the brain and the rest of the body. The most common issues with walking include unsteady, uncoordinated movements, known as ataxia, which causes people to generally rely on a cane, walker or other assistance.

"MS is one of the most common neurological diseases in young adults," said Christopher Loftus, M.D., acting director of the FDA's Office of Neurological and Physical Medicine Devices. "Today's authorization offers a valuable new aid in physical therapy and increases the value of additional therapies for those who live with MS on a daily basis."

The PoNS system, for adults aged 22 and over, includes a wired, rechargeable controller worn around the neck, similar to some headphone designs.

The FDA reviewed two clinical studies and a real-world data analysis, including a randomized trial comparing the device to a sham unit that did not provide stimulation. After 14 weeks, treated patients showed improvements in gait scores across eight different motor skills. A separate randomized study also showed improvements in sensory organization tests, which gauge a person's ability to use visual and physical cues to maintain a proper balanced posture.

The device was previously granted a breakthrough designation and was awarded a de novo clearance by the FDA. Helius initially submitted the device for use in adults 18 and older, though late last year the FDA requested more information from the company for its application and proposed changes in its labelling.

For details of sources for all news stories go to page 14

MS Spasticity Drug Baclofen Helps Repair Myelin: Study Finds

Baclofen, an approved therapy for spasticity in MS promoted the repair of myelin in a mouse model of the disease, a study has shown.

The findings suggest baclofen — sold as tablets, and as an injectable — may be a potential approach to stimulate myelin repair in people with MS, the researchers noted. Future studies in MS patients treated with baclofen are needed to confirm these findings. The study, "GABAB receptor agonist baclofen promotes central nervous system remyelination," by researchers at the University of the Basque Country, Spain, was published in the journal Glia.

In MS, abnormal immune responses lead to myelin damage and loss (demyelination), impairing nerve cell communication and ultimately resulting in neurodegeneration. In the brain and spinal cord, myelin damage attracts immature oligodendrocyte precursor cells (OPCs) to the lesion site where they mature into myelin-producing oligodendrocytes capable of restoring the myelin sheath. However, in most patients, the efficiency of this process decreases significantly with age and disease progression," the researchers wrote.

Most available MS treatments work by suppressing immune responses, inflammation, and associated relapses, but there are no approved therapies that can promote myelin repair, or remyelination. "Therefore, the development of novel treatments that [boost] remyelination is a major goal of current MS research, and includes the repurposing of existing drugs," the researchers wrote.

Repurposing compounds already approved — and thus tested for safety — for one health condition and using them in another disease helps accelerate the development of a safe and effective treatment, while reducing costs. In a previous preclinical study, the researchers showed baclofen stimulated OPC maturation via the activation of GABA type B receptors (GABABRs).

GABA is the major suppressive chemical messenger in the brain and spinal cord. It was previously shown to be a key regulator of OPC maturation and myelin production. Baclofen is the best-known GABABR activator. Injecting baclofen directly into the spinal canal in MS patients was reported to improve cognitive function, which correlated with increases in MRI-assessed myelin content, the research team noted. These data highlight that baclofen treatment "following LPC-induced demyelination accelerates the regeneration of myelin sheaths," the researchers wrote.

"This may be an important first step in evaluating the suitability of this drug as a pro-remyelinating/neurorepair agent in MS," they concluded. **For details of all news stories go to page 13**

Mobility improving neural sleeve could be available next year in US

An artificial intelligence-powered, wearable "neural sleeve" which improves mobility for those living with progressive MS is a step closer following collaboration between bio-tech company Cionic and multidisciplinary design firm fuseproject

The Neural Sleeve, aids walking in MS patients and individuals with other conditions that impair mobility. It detects movements during walking and electrically stimulates muscles. In turn, this can help to mitigate walking issues that result from leg muscle weakness or foot drop, which occurs when the front of the foot fails to lift up when taking a step.

US MS patient Beverly Chaidez, who participated in one of the home usability trials Cionic conducted to understand the garment's impact over time, said her ability to walk has greatly improved since she began using the Neural Sleeve.

"When I started the home usability trial, I was only able to walk for about five to 10 minutes at a time, and I used a wheelchair for mobility outside of the home. Today, I can walk for 40 to 50 minutes at a time and I haven't used my wheelchair in over a month. I feel hopeful and optimistic that I can regain a lot of things that I lost," said Chaidez.

In a study, 32 participants with foot drop due to neurological conditions, including eight with MS, showed "strong" improvement in patients' ability to raise their toes above the ground and a reduction in turning in of the foot during swing — two key measures associated with foot drop. The two measures combined resulted in an average improvement of 9 degrees, far exceeding the 5 degrees that are considered clinically significant.

"Building bionic clothing that can augment human movement takes a thoughtful and holistic approach," said Jeremiah Robison, Cionic founder and CEO. "It starts with advanced technology capable of adapting to each user's mobility needs to deliver meaningful outcomes. Then we designed it to be comfortable to wear and effortless to use. From software to soft goods, our team of experts have pushed the boundaries of human-machine interface to deliver the future of assistive technology," he said.

"Ultimately, we are creating not just a single solution, but a platform for bionic clothing that can analyze, predict, and augment human movement for all," Robison added. The company is accepting pre-orders for delivery by early next year (2023). Those interested in the device are invited to take a five-question assessment to determine if the Neural Sleeve is a good fit for them. **For details of all stories go to page 13**



Happy outcome for my swallowing problems

For several years I have suffered problems swallowing. These problems are on occasions extremely worrying. So, on the last visit to see my MS nurse, I mentioned my concerns and a short period later was booked in to see a speech and language therapist locally

Before the visit I did a bit of reading and discovered swallowing problems known as dysphagia affect between 30 and 40 per cent of people with MS. I also discovered swallowing problems are an individual thing and vary from person to person as do solutions. Different techniques appear to work for different people. The important thing with problems is to look at for a pattern, such as time of eating – is swallowing a problem late in the day when fatigued or is it particular foods , that act as 'triggers' that make swallowing more difficult. Armed with this information I approached the visit with confidence I could find help to control these choking episodes and reduce the difficulties I experience.

On arrival at the language and speech therapist I explained my swallowing/choking concerns in greater detail and the therapist looked into my mouth with a torch, asked me to cough – to see whether I had the strength in my throat to expel any food that might get stuck there. My coughing was judged good enough. The next task was to roll my tongue around my mouth, up and down and from side to side. Everything seemed fine from an anatomical point of view. It was all here and there didn't seem to be any throat blockages that would stop food going down

We then started off the practical swallowing tests with me eating a dry biscuit, followed by drinking a glass of water. Dry foods are always a problem for someone like me but liquids are no problem. In fact they often help me to swallow dry food when saliva doesn't seem enough to soften the food sufficiently for me to swallow it.

Continued on page 6

Continued from page 5 Everything seemed to go down fine. The dry biscuit went down easily as did the glass of water so I mentioned two foods where I have had choking episodes in the past and which I now avoid. These two foods are pickled onions and anything that involves vinegar and secondly soft crème mints where I had the worst choking episode of my life.

Reading around the subject I discovered that vinegar, because of its strongly acidic nature, can act as a throat irritant, and could cause a throat spasm that might cause me to choke. I told the therapist I now avoid pickled onions and she said this was a good move and I should continue to do so. Regarding the soft mint problem I also read that soft mints and jelly like foods can act like a glue in your throat; If demyelination or ageing (I am 64) has caused your muscles to weaken over the years then the cough reflex might not be strong enough to dislodge the problem food. One again, even though my coughing is OK this is probably a food best avoided.

I finally told the therapist I was worried about aspirational pneumonia where food going down "the wrong way" can cause a build up of fluid in your lungs. She didn't think this was a problem in me which was re-assuring so all things considered I felt that although I do have the odd choking episode my problem isn't too severe. The therapist said that if I follow a few simple steps like keeping a good, upright posture when eating, remaining upright for at least 30 minutes after the meal, eating in a relaxed atmosphere, not rushing a meal, chewing thoroughly and avoiding talking while eating I should be ok.

Looking back on my visit I think it helped mainly to reassure me that my problem is manageable and that if I follow a few easy to remember tips my problem should remain one that is controllable. I don't think I will need to have another visit, but I think the visit was half an hour well spent. If you have problems similar to mine I strongly recommend you ask your MS nurse to refer you to see an NHS speech and language therapist. **For further details see page 14**

Picture thanks to Amir-Esrafili (unsplash)

New neuro-protective drug to be trialled in prog MS

US bio-pharma Immunic has enrolled patients in a phase 2 trial in progressive MS patients to explore the use of substance called "vidofludimus calcium" and its neuroprotective potential, as shown by a slowing of brain atrophy and delay in disability worsening, which are often caused by axonal and neural damage.

That is what Immunic CEO Daniel Vitt said in a statement. The company has said an interim analysis is planned for after half of the patients have completed 24 weeks of treatment.

It has been shown that vidofludimus is 2.6 times more potent in inhibiting DHO oxidation by human DHODH (Dihydroorotate dehydrogenase) compared to existing MS drug teriflunomide (Aubagio) . Although both compounds are effective , vidofludimus was better in the inhibition of T-lymphocyte proliferation compared to teriflunomide (Aubagio) an immunomodulatory drug already used in MS treatment.

Dihydroorotate dehydrogenase (DHODH) is an enzyme that in humans is encoded by the DHODH gene on chromosome 16. This protein is a mitochondrial protein located on the outer surface of the inner mitochondrial membrane (IMM). Inhibitors of this enzyme are used to treat autoimmune diseases such as rheumatoid arthritis. Its use in MS is therefore a logical further step in research.

New York-based Immunic posted the full unblinded data from a phase 2 clinical trial of its dihydroorotate dehydrogenase inhibitor vidofludimus calcium in patients with relapsing-remitting multiple sclerosis in September 2020. The peer-reviewed paper, which was published in the journal the Annals of Clinical and Translational Neurology, summarizes findings including the hit on the primary MRI lesion endpoint. Immunic used the release of the paper to share an update on the progress of its candidate since the first data drop from the phase 2 clinical trial**.**

For details of all news stories go to page 14

Aquatic Exercise Found to Ease Fatigue, Improve Balance in prog MS

Aquatic exercise therapy can help to ease fatigue and improve balance in people with progressive MS without notable side effects, according to a review of published studies.

Aquatic therapy is a form of exercise therapy done while standing mostly submerged in water. Compared with other kinds of exercise, aquatic therapy has some theoretical advantages for MS patients — being in buoying water can help patients stay supported, and may ease stress on joints, particularly the knees, ankles, and hips.

The research findings have important implications for MS patients, as fatigue is among the main symptoms of the disease and can severely impact quality of life.

The study, "A systematic review with meta-analysis on balance, fatigue, and motor function following aquatic therapy in patients with multiple sclerosis," was published in Multiple Sclerosis and Related Disorders. The work was funded by the University of Tehran, in Iran.

To assess how aquatic therapy affects balance, fatigue, and motor function in people with MS, a team of scientists in Iran and South Africa conducted a review and meta-analysis of the scientific literature. Meta-analysis is a type of study in which researchers pool data from multiple previous papers, providing a more precise estimate of the impact of a given approach.

This meta-analysis included data from six prior studies. Collectively, these studies enrolled 794 people with MS, of whom 493 completed the respective study. All of the trials compared aquatic therapy against conventional non-exercise occupational therapy, and five also included a land-based exercise comparison group.

The team noted that nearly all of the studies that assessed fatigue showed a significant effect of aquatic therapy. The lone exception was a study that lasted only three weeks, which "may not be enough to see beneficial effects of aquatic therapy on fatigue considering the chronicity of fatigue in patients with MS," they added.

Scores on the Berg Balance Scale (BBS) also improved significantly with aquatic therapy compared with conventional interventions, based on data from 58 patients in two studies. The studies generally did not report any safety issues related to aquatic therapy.

The scientists noted that this analysis is limited by the relatively small number of studies available in the analysis, highlighting a need for further research. They also noted that some of the studies enrolled only female participants, so these findings may not apply to all patients. **For more details go to page 14**

Leading a healthy life may delay MS disability progression

Leading a healthy cognitive and physically active lifestyle, including having a normal body weight and well-controlled blood pressure, may increase brain reserve — the brain's ability to adapt after damage — and delay disability progression in MS according to a new study.

The study, "Lifestyle factors in multiple sclerosis disability progression and silent brain damage: A cross-sectional study," was published in the journal Multiple Sclerosis and Related Disorders. In the study, a team of scientists based in Belgium and Switzerland set out to determine whether lifestyle risk factors are associated with MS disease severity, as measured with the Multiple Sclerosis Severity Score (MSSS) — a measure of disability adjusted for disease duration.

Different surveys were used to collect data on the patient's lifestyle. These included the International Physical Activity Questionnaire, which measures physical activity and the amount of time spent sitting, and the Cognitive Reserve Index questionnaire, a test that assesses cognitive reserve based on education, work, and leisure time.

Patients' adherence to the Mediterranean diet, known for its health benefits, as well as smoking and drinking habits, were also evaluated. Additionally, the team examined factors known to affect heart health, such as body mass index (a measure of body fat), blood pressure, cholesterol ratio, and lipid-lowering medications.

The study included a total of 351 people with relapsing-remitting and secondary progressive MS who had not experienced a relapse in the past 30 days. Their mean age was 43 years and 69.8% were female. Results showed that higher cognitive reserve scores and physical activity levels were associated with a lower MSSS, which reflects a longer time to reach a particular level of disability Based on these findings, the team suggested that "adapting a more active lifestyle may be helpful in delaying disability progression."

On the other hand, being overweight or obese and having a higher systolic blood pressure — the pressure within the arteries as the heart beats — were pointed out as factors linked to a higher MSSS. These factors, together with MS type, could explain about 22% of the variability in MSSS.

"Our study suggests an association between a 'brain healthy lifestyle' with disability progression in MS. A cognitive and [physically] active lifestyle alongside a normal body weight and blood pressure may help to prevent future disability in MS," the researchers concluded. **For further information on news stories go to page 14**



Is milk the elusive environmental factor that causes MS?

All MSers will know that the search for the elusive environmental agent that plays a part in causing the disease is endless.

Sunlight, vitamin D and diet have been much researched. One subject that comes up periodically and probably deserves more study is cow's milk. It is well known that MS is more common in countries where cow's milk is drunk and incredibly one study carried out in Denmark in 2013 and published in BMJ Open showed a high frequency of MS among "dairy operators," who had an incidence of MS twice as high as the rest of the study's population.

Five years later in 2018 a German academic Stefanie Kürten from the Institute of Anatomy at University Hospital Bonn looked further into a possible link between cow's milk and M. She explains: "We injected mice with different proteins from cow's milk. We wanted to find out if there was a constituent that they were responding to with symptoms of disease."

And the research did indeed find what was being looked for. When researchers administered the cow's milk constituent casein together with an effect enhancer to the animals, the mice went on to develop neurological disorders. Electron microscopy showed damage to the insulating layer around the nerve fibres, the myelin. The fat-like substance prevents short circuits and additionally significantly accelerates stimulus conduction.

The insulating sheath was also massively perforated in the mice -- apparently triggered by casein administration. "We suspected that the reason was a misdirected immune response, similar to that seen in MS patients," explains Rittika Chunder, who is a postdoctoral fellow in Prof. Kürten's research group. "The body's defences actually attack the casein, but in the process they also destroy proteins involved in the formation of myelin." Such cross-reactivity can occur when two molecules are very similar, at least in parts. The immune system then in a sense mistakes one for the other "We compared casein to different molecules that are important for myelin production," Chunder says. "In the process, we came across a protein called MAG. (Myelin Associated Glycoprotein) It looks markedly similar to casein in some respects -- so much so that antibodies to casein were also active against MAG in the lab animals." **Continued on page 11**

.Continued from page 10

This means that in the casein-treated mice, the body's own defences were also directed against MAG, destabilizing the myelin. But to what extent can the results be transferred to people with MS? To answer this question, the researchers added casein antibodies from mice to human brain tissue. These did indeed accumulate in the cells responsible for myelin production in the brain.

Certain white blood cells, the B cells, are responsible for antibody production. The study found that the B cells in the blood of people with MS respond particularly strongly to casein. Presumably, the affected individuals developed an allergy to casein at some point as a result of consuming milk. Now, as soon as they consume fresh dairy products, the immune system produces masses of casein antibodies. Due to cross-reactivity with MAG, these also damage the myelin sheath around the nerve fibres.

However, this only affects MS patients who are allergic to cow's milk casein. "We are currently developing a self-test with which affected individuals can check whether they carry corresponding antibodies," says Kürten, "At least this subgroup should refrain from consuming milk, yogurt, or cottage cheese."

It is possible that cow's milk also increases the risk of developing MS in healthy individuals. Because casein can also trigger allergies in them -- which is probably not even that rare. Once such an immune response exists, cross-reactivity with myelin can in theory occur. However, this does not mean that hypersensitivity to casein necessarily leads to the development of multiple sclerosis, the professor emphasizes. This would presumably require other risk factors. This connection is nevertheless worrying, Kürten says: "Studies indicate that MS rates are elevated in populations where a lot of cow's milk is consumed."

Interestingly when I carried out a 93 food IgG (Immunoglogulin) food intolerance screening test some years ago I found that cow's milk was the animal product that I had the highest level of sensitivity to. While I would be the first to admit that this is not conclusive proof of cow's milk being the environmental factor that has played a part in my MS, but given Professor Kürten's work and the earlier Danish research it is food for thought, and arguably time for me to cut out cow's milk from my diet.

For details of all news and features go to page 13

Photo p1 and p10 Engin Akyurt Unsplash

News

Global Prevalence of SPMS Seen to Vary Extremely Widely

Worldwide, about 22 in every 100,000 people live with secondary progressive multiple sclerosis (SPMS), a review study analyzing data across various countries reported.

Its researchers found substantial variability in SPMS rates country-by-country, with countries closer to the poles generally reporting higher prevalence than those near the equator. Rates also appear to be influenced by differences in how healthcare systems across countries report this type of multiple sclerosis (MS).

The study, "Systematic literature review and meta-analysis of the prevalence of secondary progressive multiple sclerosis in the USA, Europe, Canada, Australia, and Brazil," was published in BMC Neurology.

A total of 86 studies with at least moderate quality in terms of patient sampling, sample size, outcome measurements, and interpretation of results were included in the review. Most (76 studies) were conducted in Europe, with over a dozen studies each in Spain and Italy. No epidemiological studies in the U.S. had reported specifically on SPMS prevalence.

The researchers conducted a meta-analysis where they pooled data from all of these studies together in order to estimate the overall prevalence of SPMS worldwide. The overall combined prevalence of SPMS was 22.42 out of every 100,000 people.

However, substantial variability in SPMS prevalence was evident from country to country. Brazil had the lowest estimated prevalence, at 1.68 out of every 100,000 people. The prevalence in Canada was estimated to be 55.02 out of 100,000, while in Australia it was 10.32 out of 100,000.

In Europe overall, the prevalence was estimated to be 24.74 out of 100,000, but there was marked variation country-by-country. The highest prevalence in any country was reported in Sweden — 75 out of 100,000 — while Portugal had the lowest rate, at 7.88 per 100,000 people.

Some of this geographical variability is likely explained by latitude, the researchers said, since the risk of MS is known to be higher for populations living further from the equator. However, they stressed that these differences cannot account for all of the variation seen here, since some data "directly conflict with any interpretation of the results based on latitude or longitude." For instance, Spain and Italy are at similar distances from the equator, but the estimated prevalence was nearly two times higher in Italy: 22.49 vs. 11.89 out of every 100,000 people. **For details of all stories go to page 14**

News

EMBOLD Study of ATA188 in Progressive MS Given Go-ahead

An independent committee of experts has recommended that the Phase 2 portion of the EMBOLD clinical trial continue as planned. The trial is testing Atara Biotherapeutics' experimental medication ATA188 in progressive MS.

"We look forward to completing the EMBOLD study as we aspire to demonstrate a potentially transformative profile for ATA188 in patients with progressive MS who have high unmet need and limited options," Pascal Touchon, Atara's president and CEO, said in a company press release.

ATA188 is a T-cell-based therapy designed to kill cells infected with the Epstein-Barr virus (EBV). Best known as the cause of infectious mononucleosis ("mono"), an emerging body of evidence has shown a strong link between EBV infection and MS risk.

The Phase 1/2 EMBOLD trial (NCT03283826) is testing the experimental therapy's safety and effectiveness in people with primary and secondary progressive MS (PPMS, SPMS). In the first portion of the trial, 24 patients were treated and followed for a year. The results indicated the treatment was well tolerated and hinted that it may promote remyelination, or myelin repair.

The second phase is planned to enrol 80 PPMS and SPMS patients who would be randomly assigned to receive ATA188 or a placebo for a year. The main goal of this part is to evaluate the treatment's effect on Expanded Disability Status Scale (EDSS) scores after one year.

Like other clinical trials, EMBOLD has an Independent Data and Safety Monitoring Committee (IDSMC) — a group of independent experts tasked with reviewing data from the trial as it's ongoing. IDSMCs ensure the safety of participants in clinical trials and make recommendations based on interim analyses.

"We are pleased to have completed the target enrolment for the EMBOLD study and look forward to sharing the topline results as planned at an appropriate forum in October 2023." Said Jakob Dupont, MD, head of global research and development at Atara.

For details of all news stories see page 14

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page 5-6 swallowing

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