

My prog-MS ezine

For people with progressive MS and other interested people

Issue 58, January/ February 2025

Hello and welcome to the 58th 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 66. (EDSS 6)

In a slightly early Issue 58, there are eight pages of prog-MS news stories about new trials and research and two features. One on page 5 looks why clinical trials for prog-MS are too short and why making them longer might lead to more disease modifying drugs being available to us prog MSers.

There's another feature on page 10 looking at the subject of "inverse vaccines" It's a simple idea, You just focus on the auto-immunity linked to MS and develop a body tolerance to what is causing it. If this works the body stops attacking itself, MS goes away and we are all cured, hoorah. It has been shown to work in some conditions, so why not MS? Better still, clinical trials are taking place, so watch this space.

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News

New SPMS drug may be available in one-two years

Tolebutinib, a new drug successful in Phase III trials and now being reviewed by European and British medicines agencies could be licensed for non-active secondary progressive MS (naSPMS) over the next year or two.

That is the view of Prof. Gavin Giovannoni of Barts Hospital in London. Writing on his 'MS Selfie' newsletter posted on Substack, Prof. Giovannoni wrote

"The treatment options (for prog-MS) may change shortly -12-24 months- if tolebrutinib gets licensed as a treatment for smouldering MS. So yes, I think tolebrutinib has the potential to transform MS if it receives a license to treat smouldering MS."

Tolebrutinib, a once a day tablet, belongs to a group of medicines called Bruton's tyrosine kinase (BTK) inhibitors. Bruton's tyrosine kinase is an enzyme which is essential for the survival and activation of B-cells.

B-cells are a type of white blood cell (lymphocyte) thought to be involved in the inflammation caused by MS which causes lesions in the brain and spinal cord. BTK also regulates immune cells in the brain called macrophages and microglia which have been linked to MS progression. Tolebrutinib blocks the actions of BTK and it is thought that this will prevent the MS activity which leads to the longer term damage to nerve cells which causes progression.

Results of a clinical trial HERCULES – tolebrutinib compared to placebo, in secondary progressive MS - were revealed at the recent ECTRIMS conference. The study recruited 1,131 participants with non-relapsing (non-active) secondary progressive MS. Treatment was for up to four years.

Initial results presented at ECTRIMS 2024, showed that significantly fewer people on tolebrutinib experienced worsening of disability. Overall, tolebrutinib was found to slow down disability progression by 31% when compared to placebo. The study also looked at disability improvement that was sustained for six months. 10% of participants on tolebrutinib saw improvements in their disability compared to 5% on placebo.

Tolebrutinib-treated participants saw a 38% reduction in active lesions when compared to placebo. However, it wasn't found to significantly slow down brain volume loss (atrophy).

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

Phase 2 trial of foralumab in nonactive SPMS 'ramped up'

Tiziana Life Sciences is ramping up its phase 2 clinical trial testing foralumab nasal spray for the treatment of nonactive secondary progressive MS (naSPMS), with six additional clinical sites across northeastern U.S.

The new sites, all at top U.S. institutions, bring together leaders in medical research and neurology with access to innovative facilities, Tiziana stated in a company press release. The new sites are Yale University in Connecticut, Johns Hopkins University in Maryland, Cornell University and the University at Buffalo, both in New York, University of Massachusetts, and Thomas Jefferson University in Pennsylvania.

According to Tiziana, the goal of adding only sites across the Northeast is for all patients to receive PET scans at a single imaging site, located in New Haven, Connecticut. This ensures that all patients will be examined with the same scan and using consistent imaging protocols, which minimizes variability in scan results.

Tiziana's foralumab targets a protein called CD3, found at the surface of immune T-cells, which simultaneously reduces the activity of inflammatory T-cells and boosts the activity of anti-inflammatory T-cells. This is expected to reduce the activation of other immune cells, such as microglia, and reduce inflammation to slow MS progression.

Foralumab is being tested in 10 people with nonactive SPMS in an expanded access programme. Data so far has shown that 80% of these patients had a reduction in the activity of microglia, which are brain-resident immune cells, in PET scans, and 70% also had less fatigue after six months. Importantly, all patients had either stable or improved disability levels after that period. Based on those findings, the U.S. Food and Drug Administration (FDA) allowed the company to enrol 20 more patients into the expanded access program.

The positive data also supported the launch of the ongoing Phase 2 clinical trial (NCT06292923), launched at Brigham and Women's Hospital of Harvard Medical School in Massachusetts. The trial dosed its first participant late last year.

The study is enrolling as many as 54 MS patients who experience continuous disease progression despite treatment with available therapies. Participants are receiving foralumab, at a dose of 50 mcg or 100 mcg, or a placebo, in three-week cycles.

Foralumab has been granted the FDA's fast track designation for the treatment of nonactive SPMS. That status is designed to accelerate the development and review of medications that have the potential to fill unmet needs.**For details of all news stories go to page 1**4

Non-invasive brain stimulation could boost balance and walking

Adding non-invasive brain stimulation to physical therapy may help people with MS improve their balance and walking ability, a study shows.

Benefits from physical therapy with and without brain stimulation were observed, but most improvements only remained significant after six months in those who had also received brain stimulation.

"Our results suggest that the addition of [brain stimulation] prior to exercise treatment provides a significant improvement in walking speed and balance in people with MS which lasts longer, compared to exercise alone," the researchers wrote. Their study, "Noninvasive brain stimulation enhances the effect of physiotherapy for balance and mobility impairment in people with Multiple Sclerosis," was published in the journal 'Multiple Sclerosis and Related Disorders'.

Problems with balance and walking are common symptoms of MS. Physical therapy, or physiotherapy, which involves exercising under the guidance of a physical therapist, can help people with MS manage these symptoms. One common form of brain stimulation is 'transcranial direct current stimulation' (tDCS), which involves applying an electrical current to the outside of the head to target the part of the brain that mainly controls movement, called the motor cortex, the idea being to make it more active and adaptable so it can better take in physical therapy's benefits.

A research team in Australia enrolled 40 adults with MS in a small clinical trial (ACTRN12628001836224) to take part in a six-week physical therapy program designed to improve gait and balance. Before each session, half the patients received 20 minutes of tDCS targeting the area of the motor cortex involved in limb movements, while the others received sham stimulation.

The 36 patients who completed the study were assessed a week after the intervention and most of them underwent a follow-up assessment six months later. Patients in both groups saw significant improvements in standard measures of walking ability and balance, showcasing the impact of physical therapy for improving mobility in MS. But those given tDCS were generally more likely to have improvements last after six months than those who'd received the sham procedure. These patients also saw significant gains in physical and mental quality of life after six months.

"Our results suggest that the addition of tDCS before exercise provides a significant improvement in walking speed and balance in people with MS, which lasts longer compared to exercise alone," a spokesperson said. **For details of all news stories go to page 14**



Why time matters in prog-MS drugs trials

Readers of Multiple Sclerosis News Today may have noticed a recent story saying a Hungarian study had shown a large majority of people with relapsing-remitting MS who took Tysabri (natalizumab) had no evidence of disease activity (NEDA) for up to six years.

At this point you are probably inclined to say: "So what?" After all, Tysabri isn't offered as a treatment option for us prog-MSers. However, at the same time as the Hungarian study was published, another academic paper appeared in the journal Neurotherapeutics with the catchy title: "Long-term effectiveness of natalizumab (Tysabri) in secondary progressive multiple sclerosis: A propensity-matched study."

This paper, written by Italian academics, looked at a group of prog-MSers who were treated with Tysabri for four years between 2012 and 2018 and compared them with a similar group treated with beta-interferon. It found that treatment with Tysabri in SPMS patients showed more favourable disability outcomes compared to beta interferon over a period of four years (48 months). All of which begs the question: If the findings of this Italian study are correct then shouldn't Tysabri be being offered to us progressive MSers? And if not, why not?

Well, the reason why us prog MSers aren't offered Tysabri is probably due to a 2018 trial of the drug in progressive MS. The trial called 'Ascend' was two years (24 months) long and it failed to meet its primary endpoints – things like improvements in walking, etc. However, Tysabri did reduce progression on its upper-limb component. In other words, it was working on the smaller upper limbs, but not the bigger lower limbs. So, what was going on?.

The answer may lie in another paper, a 2017 paper titled 'Is multiple sclerosis a length-dependent central axonopathy? The case for therapeutic lag and the asynchronous progressive MS hypotheses'. This paper, published in 'Multiple Sclerosis and Related Disorders' argued that MS is a 'length-dependent central axonopathy'. In other words demyelination hits the longer limbs (legs) earlier and more severely than the shorter limbs (arms) The reason for this, it was **Continued on page 6**

Continued from page 5 argued, is that longer limbs have more myelin to be demyelinated than shorter limbs.

The academics writing up the 2018 Ascend trial results didn't refer to or comment on this 'length-dependent central axonopathy' argument advanced a year earlier in 2017 but they did say the following: "Longer-term trials are needed to assess whether treatment of secondary progressive multiple sclerosis might produce benefits on additional disability components," It was argued by independent observers that if Ascend had gone on for four years rather than two, then improvement in lower limbs might have started to be seen.

Of course, longer term trials are expensive and for this reason they never take place, leaving those of us with non-active prog-MS, the forgotten few in the MS world, untreated and in the eyes of the medics untreatable. That's certainly true as long as the average prog MS drug trial remains at just two years.

That said, I did wonder if the recent Italian study might change things and make neurologists re-consider Tysabri as a treatment option for those of us with progressive MS. If you want an argument for having longer trials in prog-MS you only have to read the 'abstract' for the 2017 study which said as follows:

'Trials of anti-inflammatory therapies in non-relapsing progressive multiple sclerosis (MS) have been stubbornly negative. . . We argue that this might be because trials have been too short and have focused on assessing neuronal pathways, with insufficient reserve capacity, as the core component of the primary outcome. Delayed neuroaxonal degeneration primed by prior inflammation is not expected to respond to disease-modifying therapies targeting MS-specific mechanisms.

' However, anti-inflammatory therapies may modify these damaged pathways, but with a therapeutic lag that may take years to manifest. .. . we propose that clinically apparent neurodegenerative components of progressive MS may occur in a length-dependent manner and asynchronously. If this hypothesis is confirmed it may have major implications for the future design of progressive MS trials.'

In other words, trials for secondary progressive MS longer should be longer than two years and if they were you might then see more positive results. Tell that to your neuro next time you see them and ask them to read the 2017 and 2024 papers listed on page 14

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For further details of sources for feature see page 14.

Cannabis drugs help MS spasticity, says 'meta-analysis'

Sativex and other cannabis-based drugs appear to work well for controlling spasticity, a common MS symptom that occurs when muscles stiffen or tighten, a meta-analysis of findings in published studies reports.

The 'meta-analysis, essentially a study of many other studies, showed that cannabis-based products significantly reduced spasticity on two validated measures, the MS spasticity Numerical Rating Scale (NRS) and the Ashworth Scale. But the researchers said larger studies into cannabis-based treatments of spasticity for MS patients are needed. The researchers, all from Iran, wrote the review article, "Cannabinoids for spasticity in patients with multiple sclerosis: A systematic review and meta-analysis," which was published in the journal 'Multiple Sclerosis Journal – Experimental, Translational and Clinical'.

For their meta-analysis the team from Tehran University of Medical Sciences searched the literature for studies related to this topic. After careful review, they selected 31 studies, including six randomized trials. The vast majority of these studies came from Europe, with two being from the U.S. The number of patients in them ranged between eight and 1,845, and the studies' duration ranged between four weeks and one year. All but four studies investigated nabiximols (Sativex).

A meta-analysis was conducted to examine the pooled effects of cannabinoids on spasticity across all studies. Data showed that the cannabis-based products significantly reduced spasticity on two validated measures, the MS spasticity Numerical Rating Scale (NRS) and the Ashworth Scale. "Nabiximols was the most common cannabinoid which was used to control MS-related spasticity, and it was effective," the researchers wrote.

Still, they noted considerable variation among the studies, meaning that while cannabinoids worked for many, the results varied from patient to patient.

In MS, damage to nerve cells in the brain and spinal cord causes a range of disease symptoms that can vary widely from one patient to another. But spasticity, marked by stiff, tight muscles, and sudden spasms that often limit a patient's daily life, tends to be among the more typical ones. Spasticity can be controlled with medications, but side effects are frequent and benefits typically don't last long. Many patients turn to cannabinoids — the active compounds found in the cannabis plant — to help with muscle stiffness or tightness.

Nabiximols, an oral spray that combines the two most common cannabinoids, is approved in Canada and most of Europe under the brand name Sativex to treat MS spasticity in adults who don't respond well to or cannot tolerate other medications. However, the safety and efficacy of nabiximols and other cannabis-based products "are not clearly understood," the researchers wrote. **For further details of all news and features go to page 14**

Older MS patients may not need to stay on DMTs, says new study

Research suggests that relapses and new Magnetic Resonance Imaging (MRI) changes become fewer as people age, especially in MS patients over 55 suggesting their need for DMTs (Disease Modifying Therapies) also diminishes.

That's according to a study carried out at the university of Colorado in the US. The researchers argue that the need to continue MS medicines that reduce relapses and new MRI lesions may also decrease especially in those who have not had relapses or MRI scan changes for prolonged times.

It has been known for some time that older MS patients typically experience fewer relapses compared to younger patients. Research suggests this may, in part, be due to the immune system weakening with age, a process known as 'immunosenescence'. This natural decline can make older patients more susceptible to unwanted 'side effects' from some Disease Modifying Therapies (DMTs,) such as infections. Additionally, other medical conditions, such as heart disease, diabetes, and cancer, are more prevalent later in life and may increase the risk of DMT side effects, changing the risk-benefit profile of medications they may either be currently taking, or considering for their MS.

Therefore, the researchers argue, it is crucial to explore whether older patients can safely stop taking DMTs without increasing their risk of relapses or new brain lesions. The results were inconclusive and the researchers were unable to say whether patients who stopped DMTs did as well as those who continued. An extension study to gather more information is currently taking place.

The existing study included participants from multiple study sites. The study included 259 MS patients aged 55 and older who were taking DMTs. These patients had not experienced a relapse for at least five years or new brain lesions for at least three years. The average age of participants was 63, with 83% being women.

The research team also assessed whether stopping DMTs affected patients' level of disability. Participants were randomly assigned to either stop or continue taking their DMTs. They underwent MRI scans at the start of the study and at 6, 12, and 24 months to check for new or changing brain lesions.

After two years, 5% of patients who continued taking DMTs had a relapse or new brain lesion, compared to 12% of those who stopped taking DMTs. The researchers were unable to say that stopping DMTs wasn't worse than continuing DMTs in this group of patients. However, there was no significant difference in changes in the level of disability between the two groups. **For details of all news stories go to page 14**

New research explains how fats can speed MS progression

A diet with too much fat — especially the saturated fats abundant in fried and processed foods — can speed up MS progression, according to new US research.

"This new information gathered from a new study in a mouse model of the disease points to a specific metabolic pathway through which dietary fats can worsen MS symptoms," Damien Marechal, PhD, coauthor of the study at City University of New York (CUNY), said in a university news story. The study, "Neuroprotective effect of neuron-specific deletion of the C16 ceramide synthetic enzymes in an animal model of multiple sclerosis," was published in the journal 'Glia'.

Diet is known to have profound and complex impacts on human health. It's generally recommended that MS patients try to eat a well-balanced diet that provides all necessary nutrients without consuming too much fat or sugar. Saturated fats in particular, which are known to increase the risk for heart disease, have been suggested to have detrimental effects in MS. But the biological details of how these fats might worsen MS have not been clear. Now, an international team led by U.S. scientists has shed new light on the toxic effects of saturated fats in mice with experimental autoimmune encephalomyelitis (EAE), a lab-induced disease that's often used to model MS.

The researchers found that mice fed a diet high in palm oil — a source of saturated fats that's present at high levels in many processed and fatty foods — had more severe disease. This included worse motor symptoms and more damage to nerve fibres in the brain and spinal cord. The animals also had greater levels of fat molecules called ceramides.

Within the brain, a specific fat in palm oil is converted into a toxic molecule called ceramide C16. The conversion of fat into this toxic molecule is mediated by two enzymes, CERS5 and CERS6. To study whether this toxic ceramide was causing the worsened disease severity in mice fed the diet rich in palm oil, the researchers engineered mice to lack these two enzymes. That meant that fats couldn't be converted into ceramide C16. When these engineered mice were fed a high-fat diet, they had markedly less severe symptoms and less nerve fibre damage than was seen in healthy mice fed the diet.

"When both [CERS5 and CERS6] enzymes were deleted in neurons, mice showed a milder EAE course, even when challenged with a high-fat diet enriched in palmitic acid, which serves as precursor for ceramide C16 synthesis," the researchers wrote. **For further information go to page 14**



Could a vaccine cure MS?

One approach to treating MS is often overlooked but is surprisingly simple, some might even say simplistic. You simply focus on the auto-immunity linked to MS and develop a body tolerance to what is causing it. If this works the body stops attacking itself, MS goes away and we are all cured, hoorah.

In practical terms researchers develop something called an “inverse vaccine”. Unlike traditional vaccines that give the immune system a glimpse of the problematic substance to fight off, inverse vaccines introduce the problematic substance through a process that encourages the immune system to tolerate or simply ignore it. In MS, for example, this problematic substance would be myelin, or something in myelin and our bodies learn to “tolerate” it and not attack it.

This theory of exposing the body to the problematic substance has recently been tried out in food allergies with some success in things like peanut allergy. But there are major challenges in extending this idea to auto-immune diseases or immune mediated diseases such as MS. While MS is seen as a de-myelinating disease, with myelin being the obvious auto-antigen, the unanswered question is: what substance or substances in myelin causes auto-immunity?

The obvious candidate is myelin basic protein (MBP) as this is present in both the central nervous system (CNS) and peripheral nervous system (PNS) and in large amounts. However, MBP still makes up only 30 per cent of total myelin, so there is good reason for not just looking at MBP but rather at something in the other 70% of myelin that isn’t MBP?

The idea of looking at proteins other than MBP has been adopted by Norwegian bio-pharma Nykode Therapeutics. Its inverse vaccine called TV004 aims to boost immune system tolerance to another protein found in myelin called MOG or myelin oligodendrocyte glycoprotein.

Continued on page 11

Continued from p10 MOG is abundant in the Central Nervous System but less so in the Peripheral Nervous System, and as MS is predominantly a CNS rather than a PNS disease then MOG is a good candidate in the search for developing an inverse vaccine to MS. Better still, early research has shown TV004, through generating tolerance to MOG, was able to prevent the development of MS in a mouse model of the disease. It was found TV004 infusions before "mouse MS" was induced protected mice from mouse MS, with very mild or no symptoms over 28 days.

Another Inverse Vaccine approach comes from Swiss biopharma Anokion, and has the backing of pharmaceutical giant Pfizer who have stumped up $35m. The Anokion researchers point out a basic challenge in inverse vaccines, namely that although several inverse vaccines succeed in animal experiments they often fail in human trials.

The reason is that it's hard to determine exactly what self-antigen the human body is reacting to, and whether it's reacting to more than one. This is a potential problem in the Nykode research where myelin or MOG (myelin oligodendrocyte glycoprotein) seems to be the obvious auto-antigen but only clinical trials in humans will prove whether this is the reality.

The Anokion vaccines use engineered proteins and a sugar to encourage the liver to label the self-antigen as a friend, not a foe. This can suspend the immune attack, halting and potentially reversing disease progression, a process outlined in a recent study. In terms of the self-antigen that ANK-700 is working on, Anokion says the following: " it encompasses a previously identified myelin antigen that is implicated in driving Multiple Sclerosis," so it's not clear whether it is MOG or something else.

Human trials in MS are underway, with help of that $35 million from Pfizer. ANK-700, is currently in phase 1 trials at 15 locations in the US. Early results have shown a trend toward immune tolerance and Anokion anticipates having full results very soon.

So, while the idea of a reverse vaccine is very much a wild-card in MS research, early results available in early 2025 may give some indication of whether this new approach could lead to the cure, MS research's holy grail which, like the Crusaders of old, we are all ardently seeking.

Pic p10, Thanks to Drew Hays on Unsplash. **For details of all features go to page 14.**

News

Higher bile acid levels in blood linked to slower MS progression

Higher blood levels of bile acids — molecules found in the digestive fluid bile, which helps absorb fat in the gut — are associated with a slower progression of MS as indicated by imaging scans, a study by U.S. researchers reported.

In a small clinical trial in people with progressive MS, daily supplementation with a bile acid called tauroursodeoxycholic acid, or TUDCA, lowered the blood levels of certain pro-inflammatory immune cells.

"TUDCA supplementation in [progressive MS] is safe, tolerable, and has measurable biological effects that warrant further evaluation in larger trials with a longer treatment duration," the researchers wrote. The study, "Bile acid metabolites predict multiple sclerosis progression and supplementation is safe in progressive disease," was published in the journal MedRXIV

Bile acids are molecules generated in the liver that mainly help the digestive system absorb fats, or lipids. But they can also modulate certain metabolic processes and interact with receptors found in cells in the brain and immune system.

Research has shown that multiple sclerosis patients, mainly those with progressive MS, have lower blood levels of bile acid metabolites. Meanwhile, animal studies have suggested that supplementation with bile acids can offer some protection and ease disease severity.

In the latest research a team of researchers at the Johns Hopkins University School of Medicine in Maryland examined whether bile acid levels correlated with measures of disease progression in MS patients. The analysis included 107 patients with available MRI brain scans, and 192 who underwent repeated retinal scans using optical coherence tomography, (OCT).

The results showed that higher levels of primary bile acids — those synthesized in the liver — at the study's start were associated with significantly slower shrinkage, or atrophy, across the whole brain, and in various regions within the brain over time.

Building on these findings, the team conducted a small Phase 1/2 clinical trial (NCT03423121) to test the impact of TUDCA in adults with progressive MS. Supplemented patients experienced significant increases in TUDCA blood levels as well as in levels of several other bile acids, as expected. In addition, TUDCA significantly reduced several types of immune T-cells versus the placebo, and altered the composition of microbes in the gut. These are known as gut microbiota. Future studies are planned. **For details of all stories go to page 14**

News

Urinary tract infection top reason for MS hospital admission

People with MS are primarily admitted to the hospital due to urinary tract infections, and evidence suggests being hospitalized contributes to disability progression. a new study shows.

The study, “Reasons for Hospital Admission in Individuals With Multiple Sclerosis,” was published in the International Journal of MS Care by three researchers at Duke University Hospital in Durham, North Carolina, US.

Evidence suggests being hospitalized contributes to disability progression in MS, but “there are limited data on the reasons for their hospital admissions,” wrote the researchers, who examined data from 210 adults admitted to Duke University Hospital from 2018 to 2019 to uncover trends that lead to admissions and identify areas for possible intervention. The patients’ mean age was 54.4 and there were about three times as many women as men.

A total of 28.3% MS patients admitted had secondary progressive MS, and 14.2% had primary progressive MS. The MS type wasn’t recorded for nine patients (4.2%). Nearly two-thirds (62.4%) used devices, such as canes, walkers, or wheelchairs, to assist with movement, indicating a high disability level in this patient group.

The most common reason for hospitalization was urinary tract infection (10.3%). Because people with MS often have bladder problems, including frequent urination or difficulty urinating, “it is not surprising that a [urinary tract infection] was the most common reason for admission,” the researchers wrote. Neurological problems without an identifiable cause were the second most common reason for a hospital admission (9.2%), followed by an MS relapse (7.6%), and falls, difficulty walking, and stiffness combined (6.2%).

Nearly half the patients (48.2%) admitted to the hospital weren’t taking a DMT. These patients had a similar age as those who were receiving treatment, but the reasons for being admitted differed.

The most common reasons for admission in untreated patients were relapses (15.7%), urinary tract infection (11%), and lung infection (7.9%), neurological problems with no clear cause (13%), and skin infection (5.8%) in treated patients. On average, patients stayed in the hospital 6.1 days, a length of stay comparable to that of the general population (5.5 days). Some patients returned within 30 days of discharge (14.9%), a rate also similar to the general population’s (15.5%). For those patients, the most common reasons for readmission were pain (25%) and infection (22.5%).

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References further details, etc

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For details of ANK 700 check out the Anokion website. See also

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