5.0mg, where the placebo group (a group not receiving the real drug, but some inactive substance) after the extension was switched to fingolimod 1.25mg or 5.0mg; all others continued with their original dose. Patients received continuous oral fingolimod treatment at 1.25mg dose and those who initially received the 5.0mg dose and were switched to 1.25mg in the second year of the study. After 36 months of continuous fingolimod treatment, annualized relapse rate (ARR) remained low and 68-73% of patients remained relapse free. The majority of each group was free from Gadolinium lesions (88-89%) or new T2 lesions (70-78%) on MRI. The most frequent side effects of the drug were nasopharyngitis, headache, fatigue, and influenza. After 3 years of follow up, there was a major improvement in clinical and MRI activity in patients on fingolimod.

Fampridine-SR

A research group from University of Rochester, New York reported results from a trial of Fampridine-SR, a sustained-release formulation of 4-aminopyridine that temporarily enhances nerve signaling. Since the previous studies showed beneficial effect of Fampridine on walking and leg strength, the goal of this research was to confirm the usefulness and safety in patients with walking difficulties due to multiple sclerosis (MS). For nine weeks 120 people received Fampridine, and 119 were on placebo. The first outcome they looked at was improvement in the time taken to walk 25 feet. The group that was on treatment had 43% of patients that showed consistent improvement in walking speed, versus about 9% of those on placebo. In the ones who had gotten better with the drug, walking speed improved by about 25% from baseline. The drug was well tolerated and the side effects (insomnia, dizziness, constipation, and nausea) were similar to those found in the previous studies of Fampridine in MS.

FTY720 clinical trial

Presented were 3-year results from a phase 2 study of oral fingolimod (FTY720) in patients with relapsing remitting multiple sclerosis. Oral fingolimod in FTY720 clinical trial is administered once-daily in doses 1.25mg and 5.0mg, where the placebo group (a group not receiving the real drug, but some inactive substance) after the extension was switched to fingolimod 1.25mg or 5.0mg; all others continued with their original dose. Patients received continuous oral fingolimod treatment at 1.25mg dose and those who initially received the 5.0mg dose and were switched to 1.25mg in the second year of the study. After 36 months of continuous fingolimod treatment, annualized relapse rate (ARR) remained low and 68-73% of patients remained relapse free. The majority of each group was free from Gadolinium lesions (88-89%) or new T2 lesions (70-78%) on MRI. The most frequent side effects of the drug were nasopharyngitis, headache, fatigue, and influenza. After 3 years of follow up, there was a major improvement in clinical and MRI activity in patients on fingolimod.

The 1.25mg dose had a good safety profile and ongoing phase 3 studies will further evaluate the benefit/risk of oral fingolimod 1.25mg and 0.5mg in relapsing MS.
Rituxan (Rituximab)

Rituximab is a monoclonal antibody which reduces the number of CD20+ immune B cells (one of the types of white blood cells) from the circulation. It has been shown that IV Rituxan (rituximab) was successfully applied in relapsing MS patients. Unfortunately, a new study showed overall negative results with primary-progressive patients. A group of clinicians from Ohio State University, Columbus, OH, presented results of a trial involving 439 people with primary-progressive MS, showing that the drug did not slow disease progression when compared with inactive placebo. There were some positive findings regarding MRI. Patients on treatment had significantly less lesions after the trial. Also, patients who were younger or who had enhancing lesions on their MRI scans did much better with treatment. This treatment in primary progressive MS patients should be further investigated in the future.

Campath (Alemtuzumab)

In patients with very aggressive MS, potent drugs like Alemtuzumab are being analyzed. Alemtuzumab is a monoclonal antibody that removes most of the white blood cells.

In the CAMMS223 clinical trial, 334 patients were divided randomly into 3 equal groups. Two of the groups received Campath (alemtuzumab) in two different doses. The third group received Rebif. After over two years, Campath was 75% more effective than Rebif at reducing relapses, and 65% more effective than Rebif at preventing sustained disability progression. Number of clinically disease-free patients was much larger in the group that was receiving alemtuzumab than Rebif at years 1, 2 and 3 (71% alemtuzumab versus 38% Rebif). Also the phase 3 program was described.

Major health risk while on this drug is an immune thrombocytopenic purpura (ITP). This is a disorder characterized by low numbers of platelets (cell fragments involved in the formation of blood clots) and correlated increased risk of uncontrolled bleeding. Six of 216 patients developed ITP. One died. The other five have recovered. The clinicians argue that this side effect is manageable if patients are closely monitored. Other risks are: fatigue, rashes, lymphopenia, autoimmune thyroid disorders, neutropenic pneumonia.

Tysabri (Natalizumab)

The newest data on Tysabri was also presented at the Congress. As of June 2008, over 31,000 patients are now being prescribed Tysabri all over the world, and 13,900 have been taking the drug for at least 1 year, and 6,600 for at least 18 months.

Two recently reported cases of PML (progressive multifocal leukoencephalopathy) were discussed as well. PML is a viral infection of the brain that usually leads to death or severe disability.

Dr Ralf Gold, from University Clinic Bochum at St. Josef Hospital, Bochum, Germany described one of two cases. This patient was receiving Tysabri as a monotherapy (not in combination with other therapies). He described how the diagnosis of the PML was made and the treatment that was used in a 52-year-old patient from Germany who had been taking Tysabri for 14 months. He was diagnosed with MS 16 years ago.

Predictors of MS

It is important but hard to predict the severity of disease, recovery and location of attacks in MS patients. Dr Emmanuelle Waubant from UCSF, San Francisco, CA approached these questions looking at certain clinical and demographic predictors. It was found that non-white race/ethnicity and younger age is strongly linked with severe first and second attacks. Secondly, and most importantly, a severe initial event predicted more severe second and third events. Similarly, poor initial recovery predicted more severe second and third events. Third, there was an increased chance of patients’ second and third relapses occurring in the same anatomical location as the first event. Finally, non-white race/ethnicity and younger patients also had a higher risk of relapse during the first year of...
onset. Whether genetic or biological factors are responsible for this pattern remains to be determined.

Magnetic resonance imaging (MRI) is a powerful tool for assessing the disease stage and severity but also can help in predicting the disease course and clinical decline. A group from National Institutes of Health, Bethesda, MD conducted a study that followed 31 people with relapsing-remitting MS for 5 years. They wanted to see if different MRI techniques can predict clinical worsening. It was found that MRI measures of tissue damage (atrophy and whole brain MTR- a measure of tissue integrity) show correlation with clinical worsening. This correlation was not seen in conventional MRI measures (contrast enhancing lesion and T2 lesion load).

**Cognitive impairment and MRI**

A group of clinicians and scientists from Italy used a highly advanced MRI technique called double inversion recovery (DIR) to look at the lesions in the gray matter of the brain (cortex) that are usually not so well visible on regular MRI. They evaluated the amount of damage in the cortex and possible connection with cognitive problems (including memory problems, attention, speed of information processing and verbal fluency), fatigue and depression. 70 MS patients were tested for cognition, fatigue and depression. Their brain scans were analyzed for several MRI measures: T2 lesions, Gadolinium enhancing lesions, brain atrophy and cortical lesion volume. It was found that cognitive impairment, but not fatigue or depression, was associated with high number of intracortical lesions (lesions inside the cortex). Other MRI measures for assessing brain damage were not linked to cognitive impairment. This suggests that more research studies, both clinical and MRI based, need to be done for detection, treatment and prevention of cognitive problems in MS.

Meet The Staff: Ms. Shamika Mitchell, MA

Joined the Baylor Neurology Family.

Shamika graduated from Kashmere Senior High School and then attended Remington College and completed her Medical Assistant Certificate. She is also a licensed phlebotomist and is an asset to our Baylor Family here.

She has outside hobbies and great interest in Yoga, Fine Arts and is an active member in her Community and Fifth Ward Missionary Baptist-Church where she is a faithful member of their choir and praise dance team.

She states that since working with MS Patients she has found a greater love for the medical profession and has desire to complete her schooling and become an LVN.

Shamika Mitchell came to the Maxine Mesinger Clinic in January of this year from Total Woman Healthcare. She decided to venture into Neurology from Women’s Health and then
“Making life livable for persons with MS.”

National MS Society Corner

Save the Dates for the 2009 MS WALKS!

Saturday, November 7, 2009
Walk MS Kemah

Saturday, November 14, 2009
Walk MS Katy

Saturday, November 14, 2009
Walk MS The Woodlands

Sunday, November 15, 2009
Walk MS Downtown Houston

Downtown Aquarium – site change!

www.WalkMSTexas.org