THE OUTLOOK

For the inflammatory myopathies

Study needs patients

SUMMER 2007

A ground-breaking international study is recruiting adults and children with polymyositis and dermatomyositis. Researchers are examining the effectiveness of rituximab, a biological agent.

This drug, which has been helpful in adult and pediatric autoimmune diseases such as rheumatoid arthritis and systemic lupus erythematosis, has made a difference for several myositis patients who were involved in smaller studies.

If you are eligible, you will be asked to participate for up to 45 weeks for a total of 14 study visits. The study doctors will be measuring muscle strength and evaluating the symptoms of the disease. Other study tests include electrocardiogram (ECG), physical examination, and blood testing for muscle enzymes, general chemistry and immunological tests.

This is a unique study in many ways. It has centers all over the world, and all study participants will receive the investigational study drug while participating in the study. To find out where patients may go for treatment and follow up, go to www.rimstudy.org. Please contact the site nearest you even if you are not sure if you are eligible.

If you do not live near one of the sites, funds may be available for travel. If you have trouble getting the information you need online, call Sherrie Pryber, BSN, at 412-647-3241, or email her at pryber@dom.pitt.edu.

Two-year IBM diet and exercise study begins

Some Kentucky mice will find themselves among the trendy dieters embracing a low-carbohydrate regimen this year. A two-year study at the University of Kentucky begins shortly, designed to find out what happens when animals with the mouse version of inclusion-body myositis are fed a diet that restricts carbohydrates but includes plentiful protein and sufficient healthy fats. The mice will also be made to exercise.

Mouse IBM is similar to the human type in its long-term effects, Paul Murphy, PhD, Assistant Professor. Department of Molecular and Cellular Biochemistry at the University of Kentucky, said. "The mice develop inclusions

in the muscle, and get progressively weaker as the disease progresses. The main difference is that the mouse immune system is a little different, leading to a slightly different type of inflammation."

The diet, called a "ketogenic" diet, is closely related to the Atkins diet and other diets based on restricting carbohydrates. "In addition to being a popular strategy for people to lose weight, this type of diet is already used to help control some forms of epilepsy," Murphy said.

Murphy says the mice will lose a little bit of weight at first, then stabilize, basically the same as humans on a diet. "If you were trying to make a comparison to people, it would be

roughly equivalent to someone who was a little overweight losing 10-20 pounds," Murphy said.

Murphy and his assistant, Christa Studzinski, who was awarded a two-year fellowship from The Myositis Association, hope the diet will increase the levels of an enzyme that might clear the inclusion bodies

present in the disease. "There is already some preliminary evidence from the Alzheimer's disease field that this may be the case." Murphy, along with colleagues at the Mayo Clinic, developed a test to measure the amount of amyloid beta in the mice after treatment with the special diet and exercise program. "It's a simple biochemical test, similar in principle to an HIV test, except we use a small sample of muscle tissue rather

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TMA, advocacy and IVIG

Advocacy is a term not often fully understood by those living outside the Washington, DC beltway. It means employing people and resources to influence policymakers so that the concerns of the population on whose behalf you are advocating are understood and addressed favorably. It is easier defined than done.

Advocacy includes not just paid lobbyists, but its most important and powerful tool is using people – constituents – to tell their story and let legislators and regulators know of their concerns and their need to have a situation corrected or an idea promoted.

An example of advocacy now underway within The Myositis Association is the effort to get the federal government to fix the injustice caused by changes to reimbursement for IVIG implemented at the beginning of 2005. Patients needing IVIG as a life-saving treatment have been forced to shop around for a provider willing to administer the treatment and able to acquire enough product to treat patients. It is a very complex problem involving nearly every element of the health care system - physicians, hospitals, insurers, producers, distributors, and patients.

TMA has engaged a consulting firm for the past year to work on behalf of those with myositis who need IVIG. Although we may be getting closer to a resolution of the problem, there may not be a final solution. The issue largely stems from the need for the federal government to reduce its healthcare expenses. Ultimately, someone will have to sacrifice for the federal government to be able to reduce expenses and move toward a balanced budget.

We are determined to see that it is not those with myositis who need to make this sacrifice. Nobody should be denied medications that are truly irreplaceable. IVIG is one of those treatments for those with dermatomyositis and polymyositis.

Let your legislators know that you expect to be able to access care for your disease and that it is their responsibility to see that you are not denied appropriate and irreplaceable treatment such as IVIG.

Help Steve get to Sturgis, SD!

On August 3rd, Steve Morris, a middle-school teacher from California, will hop on his Harley and head for the Black Hills of South Dakota for a motorcycle rally in Sturgis. Steve has a rare form of myositis, and last year he was in a wheelchair. He wants to help others suffering from myositis by "riding for those who can't," and raising money for The Myositis Association and a cure.

His students and fellow teachers gave Steve the first \$1,000 to kick off his campaign. If you send a donation of \$50 or more, Steve will include your name or the person you are honoring on the back of the t-shirt he and the other bikers will wear on their ride. You will also receive one of the tshirts for yourself.

TMA will be following Steve's progress on this 3,000 mile journey and will be arranging media coverage along his route. To help send Steve to Sturgis, go to www.myositis.org, or send a check to The Myositis Association (1233 20th St., NW, Suite 402, Washington, DC 20036). Please note that your donation is for the Steve Morris Biking Campaign and in whose name you are contributing.

Two-year IBM diet and exercise study begins

continued from cover

than blood. Since all the mice get the disease, we don't do a before and after test—we just test them all at the end and compare the treated mice to the untreated ones. Hopefully, the treated ones get better."

Murphy was approached by Dr. Frank LaFerla from the University of California at Irvine about the IBM mice LaFerla was studying. "I was very enthusiastic about the idea. It has always amazed me that for a disease as common as IBM, so few people are involved in studying it," Murphy said. He believes that the worldwide focus on Alzheimer's disease research has produced a great many ideas that could be treatments for IBM, and these ideas should be examined.

"For instance," he said, "several potential Alzheimer's disease therapies are in clinical trial right now, and one or more of these might benefit those suffering from inclusion-body myositis."

Both Studzinski and Murphy are veterans of Alzheimer's disease research. Murphy's interest in inclusion-body myositis began when he was struck by the research of TMA Medical Advisor Valerie Askanas. "I've been working in the AD field since the early 90s, about the time when Valerie Askanas was reporting key observations that suggested that IBM and AD might be related," he said.

When studies showed that exercise had a significant benefit for mice with symptoms of Alzheimer's, Murphy jumped at the chance to investigate its benefits in mice with IBM. He met Studzinski a few years ago when she gave a talk on her dietary studies with dogs, and they both realized that there were also a number of dietary angles that hadn't been explored in AD. Since the idea of moderate exercise as a therapy for IBM patients had been around for a while, Murphy thought it might be a good idea to try both approaches, diet and exercise, at the same time.

"I'm looking forward to working with a different disease with some of the same features," Studzinski said. "I've been working with Alzheimer's disease for most of my professional career." She received her PhD in pharmacology in May from the University of Toronto, and has worked with many animal studies.

One notable study with implications for Alzheimer's disease was conducted in aging dogs. Studzinski added antioxidants to their food, in the form of fruits and vegetables. "The dogs just loved it," she said. When this simple dietary change improved their cognition significantly, she was intrigued at the possibility of dietary intervention in chronic and degenerative diseases.

It's interesting to try to measure the cognition levels of dogs, who have varying degrees of intelligence to begin with. "We used the same type of tests that are used to measure cognitive decline in monkeys," she said. One such test is presenting animals with covered wells in their food trays. Over time, they'll go right to the well that really has the food in it. "Dogs seem to love being tested," she said. One test for cognition in mice is to see how quickly they recognize an escape platform hidden in a small pool, approximately an inch below the surface of the water.

Since the IBM testing measures muscle strength rather than cognition, the mice will be measured on the rotarod, a test Studzinski learned recently from Murphy. "As the name suggests, this is a slowly rotating rod," said Murphy. "We use it to assess the strength and coordination of their leg muscles." The same mice who get the ketogenic diet (a kind of readily available mouse chow, Studzinski says) will also be rewarded for exercise on the "rotarod," an exercise wheel.

The two-year study should provide some clues to possible therapies for IBM that will do no harm and be readily available. "Even though my degree is from the Department of Pharmacology, I am really drawn to these dietary studies," she said. "From this field, we're more likely to find ideas that will help large numbers of people, regardless of their tolerance for medications and their ability to pay."

RESEARCH GUIDELINES

Animal research has changed as computer models are used more. Some of the changes are outlined below, courtesy of Americans for Medical Progress, a non-profit advocacy group.

• The most common laboratory animals are rodents, reptiles, insects and fish. Combined, the numbers of dogs, cats and primates in research constitute less than 1% of the animals studied.

• Over the past 50 years, the total number of animals in research has declined by some 30%. However, with the revolution in technology creating transgenic animals, the number of mice, rats and fish in research has increased.

• Federal law requires that new medicines be tested first in two species of animals before going into human clinical trials.

Scientists are committed to seeking realistic alternatives to animal models, and are focused on the "3Rs": Replace the use of animals whenever possible, Reduce the number of animals needed to a minimum, and Refine tests to cause the least possible distress.

MYOSITIS AND CANCER: WHAT'S THE CONNECTION?

It's scary for patients to hear the word "cancer," especially when they're still adjusting to the diagnosis of myositis, said Dr. Andy Mammen, a Johns Hopkins neurologist and co-director of the Myositis Center at Hopkins. A recent article in the *New York Times* focused on this connection, along with the difficulty of diagnosing myositis.

Mammen believes the cancer screening done for all dermatomyositis and polymyositis patients at the Center is an important step in their care. Although the relationship between the two diseases isn't yet completely understood, cancer is found in more patients with these diseases than in the normal population, with the risk in dermatomyositis being higher. Studies have placed the percentage of myositis patients having cancer in a range beginning at 6 percent and increasing, varying significantly in different studies.

Mammen likes a study led by Dr. C.L. Hill at the Boston University Arthritis Center because it examined myositis patients in Scandinavian countries. In these countries, the National Health Service coordinates reporting so every case of myositis is included.

The Boston University team analyzed national data from Sweden, Denmark and Finland. All patients with dermatomyositis and polymyositis who were at least 15 years old were identified by the respective National Boards of Health in a time span that ranged from 1964 to 1989. The myositis patients were then matched to the national cancer registries, and to national death registries for the same periods.

Dermatomyositis and cancer

The researchers identified 618 cases of dermatomyositis, of whom 198 had cancer. In that group, 115 developed cancer after diagnosis of dermatomyositis. This disease was strongly associated with malignant disease, particularly ovarian, lung, pancreatic, stomach and colorectal cancers; and non-Hodgkin lymphoma.

Polymyositis and cancer

Of the 914 cases of polymyositis, 107 had cancer. In 95 of those patients, the cancer was found after the diagnosis of polymyositis. Polymyositis was associated with a raised risk of non-Hodgkin lymphoma, and lung and bladder cancers. The authors characterized this as a "modest increase in the overall risk of malignant disease."

There does not seem be any increase in cancer in inclusion-body myositis patients, Mammen said.

"We screen everyone who is diagnosed with polymyositis or dermatomyositis," he said. The screenings most commonly done are for chest and abdominal cancers. Women are referred for a mammogram to find breast cancer and men for a blood test to determine the presence of prostatespecific antigens. "We're looking for markers in the blood that give us clues to the presence of cancer, specifically CA-125 and CEA," he said.

This correlation is not a coincidence, Mammen said. Myositis does not "cause" cancer. "Most likely, the immune system has acted to protect the patient from cancer and sets off the chain of events that results in myositis," he said. Once our bodies identify the cancer proteins and attack them, they may turn their attack towards healthy tissues, like the muscles.

Paraneoplastic syndromes

You may hear the term "paraneoplastic" or "paraneoplastic syndromes" used in connection with dermatomyositis and polymyositis. These syndromes include a small number of rare diseases triggered by a person's immune system response to a neoplasm, which is another name for a cancerous tumor.

The cancer-fighting antibodies or white blood cells known as T cells mistakenly attack normal cells in the nervous system. Muscle weakness is one of the symptoms of a paraneoplastic syndrome, and the one most familiar to myositis patients, but there are other symptoms accompanying certain types of cancer. One of the confusing aspects is that the symptoms themselves are most often noticed before tumor detection, which can complicate diagnosis.

Mammen and other scientists believe that our immune system may react to tumors so small they may never be detected, attacking and removing them, just as it fights viruses, bacteria and other invaders. "It's possible that some of us may have successfully fought off tumors that have never gotten large enough for detection and may never return," he said. In the process, though, there may be people with resulting immune system problems like myositis. Other autoimmune diseases that have a cancer association are myasthenia gravis and, to a much lesser extent, rheumatoid arthritis.

Clues from the antibodies

Mammen said one highly cancer-predictive autoantibody has been detected (anti-155-40 ab). People with this autoantibody are particularly likely to have a cancer diagnosis. In several analyses, including a look at the records kept by Johns Hopkins, dermatomyositis patients were not likely to have cancer if they were included in the Jo-1 subgroup. In one study of 256 patients with myositis, there were no patients with this antibody type to be diagnosed with cancer. Other patients with the typical myositisassociated antibodies and myositisspecific antibodies identified in the initial blood tests (anti-PM-Scl, -U1-RNP, -U3-RNP, -Ku antibodies) were also unlikely to have cancer-associated myositis. American and Hungarian studies suggest those who have both diseases are likely to be older when diagnosed and to have more severe muscle and skin involvement.

There are other surprises as studies of the two diseases go forward, Mammen said: "For instance, in one study, patients with skin cancer who also have myositis did better in battling their cancer than skin cancer patients without myositis." Several studies have reported that myositis is well managed once the cancer is successfully treated.

Watch for reoccurrence

In one Japanese report, Dr. T. Osako led a study of a patient with reoccurring breast cancer. At the Japanese Foundation for Cancer Research in Tokyo, doctors treated a 68-year-old woman with dermatomyositis who was found to also have breast cancer. The symptoms of dermatomyositis had diminished and steroids were tapered, after the breast cancer was removed.

When the inflammation measured by blood tests and the skin symptoms of DM returned, doctors immediately suspected a recurrence of cancer. Tests showed the cancer had indeed returned. This study suggests that an immediate check-up is needed for early detection of recurrence when dermatomyositis flares up again after breast cancer surgery.

Children and cancer

The association of cancer to dermatomyositis and polymyositis in adults creates concern in parents whose children have juvenile myositis (JM). The cancer-myositis relationship is one of several features of adult-onset myositis that differs from childhood-onset disease. "Fortunately the link between JDM and cancer is very rare," write Robert Rennebohm, MD, and others in *Myositis and You*, a publication of The Myositis Association.

Cancer can develop when people take certain medicines, like methotrexate or cyclophosphamide, but here again the chances are extremely rare in children. Cancer typically occurs only



when several of these medicines are used in combination or for an extended period of time, write Lisa Rider, MD, and her co-authors.

One case study described a child with juvenile dermatomyositis (JDM) who presented with enlarged lymph nodes. The authors state that although cancer is uncommon in JDM patients, it should be considered when lymph nodes are abnormally enlarged or inflammatory markers elevated.

The good news for children and parents: Many studies and reviews maintain that JM is not associated with an increased risk of developing cancer.

Myositis and cancer: TMA resources

Read the New York Times article, "An elusive diagnosis and one that comes with a risk of cancer", in TMA's newsroom. Chat online with Dr. Andy Mammen, October 16, 2 p.m. Eastern Time at www.myositis.org

NOTES FROM THE TMA COMMUNITY FORUM

TMA's bulletin board users comment that their physicians have been extremely conscientious in referring them for cancer screening at diagnosis. One dermatomyositis patient, determined later to be cancer-free, said her doctor was so sure she must have an underlying tumor that he ran every cancer-screening test possible. The only thing left, she said, was to cut her up in little pieces.

Christine Nixon was also found to be free of cancer, but her dermatologist ordered test after test to make sure. She endured screenings "from her chin to her belly button: lungs, mammogram, gastroscopy." Her doctor also ordered a colonoscopy and pap smear. "It was very wearisome, but I knew it had to be done," Nixon said.

Vickie Pierson, a 44-year-old dermatomyositis patient, had undergone stage II melanoma surgery three months before her diagnosis. After the diagnosis, her physician referred her for additional cancer screenings. A colonoscopy found several precancerous polyps which were removed. Pierson also elected to have her ovaries removed after a large benign ovarian tumor was found. A couple of other dermatomyositis patients nearing the end of their child-bearing years elected to have hysterectomies after irregularities were found.

Other dermatomyositis patients report detailed screenings where physicians did find very early evidence of cancer and took steps to remove very small tumors. All of them were very grateful for the attention from their physicians. "I worried terribly," said Nixon, "but I realized that worry was not going to save me."

The Myositis Bookshelf: The Chronic Illness Workbook by Patricia Fennell

People with chronic illness feel misunderstood for the same reason that more doctors are going into emergency medicine than rheumatology. Our culture appreciates the acute disease, the drama of the surgery or overnight cure, the return of the patient from the brink of death to normal, active life.

That's because Americans are action-

The

Workbook

STRATEGIES and SOLUTIONS

for TAKING BACK YOUR LIFE

Patricia A. Fennell, MSW, LCSW-R

and achievement-oriented, writes Chronic Illness Patricia Fennell in The Chronic Illness Workbook: "Our society prefers acute illnesses because they have a distinct beginning, middle and end." Fennell goes on to give the reasons why our culture can't seem to make a place for the chronically ill. We want to believe that modern medicine, science and technology can "fix" everything, even when the evidence that it can't is all around us.

Hospital dramas and modern cultural expectations lead us to believe that there is such a thing as a "cure" for everything from birth defects to shyness. When the cure is not forthcoming, both doctors and their chronically-ill patients feel uncomfortable, guilty that they've somehow failed.

In the Workbook, Fennell addresses many of the issues that The Myositis Association members discuss every day on the bulletin boards. She begins, appropriately, with the voices of chronic illness. One patient mentions the trauma and fear she felt with the sudden onset of the disease: one reports an exchange with a friend that ended with these words: "It's like the Joan I knew is dead. I don't recognize you anymore. It's like you're a completely different person."

In another case, a partner's husband was stung by the loss of the help he was accustomed to from his wife, and the complete lack of spontaneity that characterized their life after diagnosis.

Other voices reported withdrawal and impatience by doctors and other healthcare professionals, facing resentment at work, and becoming preoccupied with fears about the future.

One of the worst features of our cultural attitude towards chronic illness is that it causes many patients to become obsessed with their

health. "If it never gets better the way everyone, including yourself, wants you to, you may end up thinking about your illness all the time," Fennell writes. "Are you a person who has an illness, or is the illness all that you are? Probably the most traumatic effect of society's intolerance of chronic illness is this obsession that patients can have."

The picture is not totally bleak, though. Fennell gives the reader several wonderful tools for constructing a meaningful life that recognizes the limitations that challenge those who don't know from day to day how they will feel. Fennell is credited with being the creator of the "four-phase approach," a system designed to help patients move away from the shame and bitterness they often feel. She presents strong, positive models and

clear, sensible advice for practical as well as emotional problems.

One of Fennell's main goals is to give people the skills to integrate their experience into a meaningful new life rather than hopelessly pursuing an unattainable former life. It's true that society stigmatizes chronic illness, that doctors are sometimes impatient with it, that friends, employers and spouses may not react well, but then what?

It's the "then what" that Fennell presents in The Chronic Illness Workbook. Because it's a workbook, there are lessons and charts, with lists to make and items to check off. She encourages readers to examine everything in their lives to determine what they can let slide and what they can't. One of her objectives is to make sure her readers focus their dwindling energy on the most important-rather than the least important-activities in their lives. Everyone who has experience with chronic illness will recognize the four phases the author discusses:

- Phase One—Contain the crisis
- Phase Two—Stabilize and begin restructuring your life
- Phase Three—Maintain insight, develop meaning, construct a new self
- Phase Four—Integrate your illness into a new and meaningful life

Of course, there are a number of steps in each of these phases, with pointers and exercises that should help any patient move with greater understanding from one phase to the other.

The Chronic Illness Workbook is available in the Marketplace at www.myositis.org.

Exercise and myositis: find the right type and frequency

TMA was unable to present the scheduled chat on exercise with Michael Harris-Love because of chat room overload. We asked Dr. Harris-Love to answer some of your most frequently-asked questions, submitted in advance. Two of the most commonly asked are about exercise for people in wheelchairs, and how often to exercise. Dr. Harris-Love answers below.

I am in a wheelchair. Is there anything I can do for exercise?

Yes, here are a few points to consider:

• Work with your physical therapist and physician to determine the muscle groups that are a priority. (In general, this will be obvious – but the rehab team can help identify "helper" muscle groups that may escape your attention.)

• Identify exercises for muscle groups that you can work on your own and exercises for muscle groups that will require the assistance of a caregiver. This will allow you to work independently while giving due diligence to the more difficult exercises when help is available.

• Get comfortable working in the side-lying position. For many people who use wheelchairs or various forms of powered mobility, this will be the position of choice during your exercise sessions. However, the challenge is that the caregiver must be aware of proper body mechanics while assisting with the exercises.

• Don't forget isometric exercise. You may recall that this is the type of exercise that involves a muscle contraction without limb motion. A common form of isometric exercise prescribed by physical therapists is a "quad set." While I believe that isometric exercise has been pushed too heavily as the best form of exercise for people with myositis, this form of exercise does have its place in treatment regimens. For people with painful joints, or profound muscle weakness where it is dif-

ficult to generate any limb movement, isometric exercise is a valuable alternative.

Should I exercise every day, every other day? Should I alternate muscle groups?

Alternating muscle groups or exercise days is an excellent idea for those pursuing a vigorous exercise program. Remember, muscles respond to exercise while you rest and recover – not when you are in the gym.

However, only people working at moderate to high intensities need to make a concerted effort to alternate muscle groups for the purpose of muscle recovery. This is the exercise paradox: the higher the intensity, the less frequent the workouts. For the majority of people with myositis this will not be the case, since few people with myositis will work out at high intensities that justify training the knee extensors (this is just an example) only once or twice a week.

If you're like most people with myositis, you will probably engage in strength training from 3-5 days per week training all targeted muscle groups each session. A minority of clients with severe muscle weakness will engage in some strength training daily. Why is this? Remember the exercise paradox: since your exercise intensity is lower, you can train more often. In a sense, your exercise sessions are serving to replace the customary activity that you need to maintain your muscle mass.

There is one exception to alternating muscle groups during training that I should mention: extreme fatigue. If you have significant muscle weakness that justifies daily strengthening exercise, but you are unable to complete exercise for all muscle groups in a single session, then you may benefit from splitting your routine within a given day. For

example, you may opt to exercise your upper extremities in the morning, and then your lower extremities in the evenings. Another popular "split training" method is to do all pulling motions in one session, and then all pushing motions in another session.

Finally, the rate of recovery is more rapid for aerobic and stretching exercises – these activities can be performed daily by everyone.

To see the complete list of questions and their answers, go to My TMA, the member's only section of the website, www.myositis.org.

EZ-Step

The portable EZ-step reduces stair height by approximately 50% thus making it easier to use stairways. Check www.ez-step.com for more information.

Price is \$69.95 plus \$9.95 shipping and handling.

See you at The Myositis Association Conference in Seattle, Sept 6-9. Please stop by our booth!

For each portable EZ-step sold to a Mysositis Association member, EZ-Step, Inc. will donate \$15 to The Myositis Association. Be sure to mention this ad when ordering.



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