

Picking up the pace

The pace at which researchers are learning more about myositis is picking up dramatically. That's what TMA Board Member Dr. Fred Miller reported to members at the Annual Conference, and others echoed that theme. Through better collaboration among professionals and better identification of the cellular players in the disease scenario, breakthroughs in the understanding and treatment of myositis are expected.

Presenters at the Conference predicted improved treatment for dermatomyositis and polymyositis and said possible treatments for inclusion-body myositis may come from studies of the aging and degenerative processes, especially those of Alzheimer's Disease.

However, researchers also reported that myositis is still misdiagnosed and is poorly understood, causing patients to either receive useless treatment with significant side effects or receive less than optimal treatment because of widespread ignorance of the disease. There's evidence that this situation has improved, partly because of TMA's increased communication with the medical community and partly because the TMA-funded research program has raised the myositis profile.

Still, it's important for patients to remain informed and that's the purpose of this Outlook Extra treatment issue. But, as always, the most important part of your care is having an open, comfortable relationship with your doctor. This special edition of the Outlook is meant to encourage this relationship rather than replace it.

Can we talk?

Having trouble communicating with your doctor? We've compiled these pointers from TMA members and physicians:

Ask questions. To get the answers you need, ask all the questions on your mind. Write them down before your appointment so you won't forget anything. Doctors are busy and may not ask for your questions. Ask them at your appointment while the questions are still fresh on your mind.

Listen carefully. Doctors often explain things with scientific language instead of everyday words. Remember any words you don't understand and ask the doctor to explain. If you still have trouble understanding, ask more questions until you are sure of what is meant. There is a lot of information to try to remember, so take notes on what the doctor says. Many patients ask for copies of their medical records to keep at home.

Be informed. Read as much as you can about your illness. You can begin your education about myositis at TMA's web site, using information from the site or asking questions on the Bulletin Board. This will help you better understand your doctor's responses and help you ask better questions on the spot.

Know your medical history. Tell your doctor if you have other medi-

cal problems, and give him or her a written list of your medications. Your health history is important.

Understand your options. If different treatments are discussed, make sure you understand the length, benefits, side effects, and probability of success for each one. You may want to take notes about the treatment information. Sometimes it is helpful to bring someone along to do this for you. Refer to the notes later and write down additional questions as they come up.

Document your progress. As your treatment progresses, keep your own written records of tests performed . . . where, when, and by whom. Note any side effects of medications. Write down any change in your health – good or bad.

Keep your doctor informed. Use your written records (above) when you tell your doctor about any side effects or any changes in your

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Meet the experts

At the Annual Conference, TMA members welcomed some of the world's top myositis experts, who volunteered their time to bring us the latest updates on myositis treatments and research. The Medical Panel consisted of specialists in rheumatology, neurology, and pediatrics.

Dr. Marinos Dalakas is head of the Neuromuscular Diseases Section of the National Institutes of Health. His IBM clinic at NIH forms the basis for much of what other neurologists know about managing IBM. Dr. Dalakas is the chairman of TMA's Medical Advisory Board, has published a huge body of research on myositis diagnosis and management, and just published a summary of treatment and future treatment options for the myopathies.

Dr. Fred Miller is chief of the Environmental Autoimmunity Group, a clinical and basic research group on the NIH campus studying genetic and environmental risk factors for myositis and other autoimmune diseases. He is the Vice Chair of TMA's Medical Advisory Board and a member of TMA's Board of Directors.

Dr. Richard Barohn is chairman of the Department of Neurology at the University of Kansas Medical Center. He maintains a neurology practice and treats a number of myositis patients. Dr. Barohn has a strong interest in teaching young doctors about myositis – both in his position at the University of Kansas and at the American Academy of Neurology – and is active with the Kansas Keep In Touch (KIT) support group.

Dr. Walter Bradley is Chairman of TMA's Medical Advisory Board Research Committee, and a professor and chairman of the neurology department at the University of Miami School of Medicine. Dr. Bradley has published hundreds of research articles on chronic neuromuscular dis-

ease, including myositis, and is a founding editor of the journal *Muscle, Nerve*.

Dr. Ann Marie Reed, is head of pediatric rheumatology and associate professor of pediatrics at the Mayo Clinic in Rochester, Minnesota. Dr. Reed was a founding physician member of TMA, serves on TMA's Medical Advisory Board, and has spoken at some of our previous annual conferences. She has a long-time interest in juvenile myositis, childhood immune diseases, and osteoporosis.

Session presenters

Information sessions at the Conference included a variety of topics and presenters. The presenters enthusiastically gave their time to share knowledge in their own areas of expertise.

Dr. Aziz Shaibani is Director of the Nerve and Muscle Center of Houston, and is a clinical assistant professor of medicine at Baylor College of Medicine. He has lectured on IBM to medical students and residents and has published a number of articles, including a chapter on inflammatory myopathies for a medical textbook.

Dr. Lori Love is a Medical Officer with the Food and Drug Administration. She is Senior Advisor for Clinical Science in the Office of Regulatory Affairs and has contributed to articles on the safety of using supplements and other complementary and alternative therapies.

Kathy Baird is a patient advocate with the ACCESS Program of Accredo Therapeutics, Inc. She has worked for 15 years to help alleviate the stress and financial complications that so often accompany chronic illness. Over time, Kathy has developed strategies for navigating the healthcare system, helping hundreds of families overcome the difficulties of overwhelming medical debt.

Can we talk?

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health that you notice after starting a particular medication. Don't delay if there's a serious change. Your doctor needs your reactions in order to treat you properly.

Be a partner. As a patient, you are paying for and working with the doctor. It's your right to understand your tests, treatment, what to expect with the disease, and what you can do. Your health and your body are the main concern. Work to form an open, comfortable relationship with your doctor - you are partners in your health care.

Many patients call TMA with questions about the best treatment for them. While we are always glad to hear from you and share information, we encourage you to maintain a dialogue with your doctor, who knows your own personal health history.

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IBM: TREATMENT ELUSIVE, BUT FUTURE SHOWS PROMISE

Effective treatment for inclusion-body myositis will come from two fronts, Dr. Marinos Dalakas told attendees at the Annual Conference: from our growing knowledge of the disease process that results in inflammation; and better understanding of the kind of degeneration caused by aging, especially the formation of the beta amyloids observed in IBM and Alzheimer's Disease.

IBM starts and progresses very slowly in most cases. The muscles that cause swallowing are also affected and choking problems are often seen, sometimes even as the first symptom. Although IVIg has been found only sporadically effective in IBM patients, it has helped IBM patients with severe swallowing problems to avoid choking and aspiration.

Doctors often suspect IBM when a patient who has been diagnosed with polymyositis does not respond to therapy. Other clues are involvement of foot, hand, finger and toe muscles, especially foot extensors and finger flexors. Patients with IBM account for the majority of the patients more than 50 years old who are thought to have PM but are unresponsive to therapy.

When doctors diagnose IBM, they look at a combination of serum muscle enzymes, electromyography (EMG), and muscle biopsy. The creatine kinase (CK) is elevated in IBM, but it can also be normal or only slightly elevated. The EMG will show abnormalities, and the muscle biopsy is characterized by inflammation and the appearance of sensitized T cells invading healthy muscle fibers. In IBM, many muscle fibers form holes (called "vacuoles") containing filaments with tiny deposits of amyloid and amy-

loid-related proteins.

Is IBM an autoimmune disease? Opinions vary, but most scientists suspect an autoimmune connection because of the frequent association with other autoimmune diseases, autoantibodies, or viral infections in people with IBM, as well as other factors.

In IBM, CD8+ cytotoxic T cells invade what appears to be intact muscle fibers – a similar scenario to DM. The T cells appear to be sent directly to the muscle.

The picture is complicated even further by degenerative features like vacuoles and accumulation of amyloid or amyloid-related proteins that may either be acting independently or together with the chronic inflammation. Current immunosuppressive treatments do not target the relevant T cells in IBM. Instead, they cause nonselective immunosuppression or immunomodulation.

Most IBM patients will eventually need an assistive device like a cane, walker, or wheelchair, Dr. Dalakas said. The older the age of onset, the more rapidly progressive the course of IBM seems to be.

Since a truly specific therapy is not available, researchers are looking at therapies that are at least more specific. This is made possible, Dr. Dalakas said, by the identification of agents directed against the many proteins and processes surrounding the T cells. Two immunosuppressive drugs, tacrolimus and

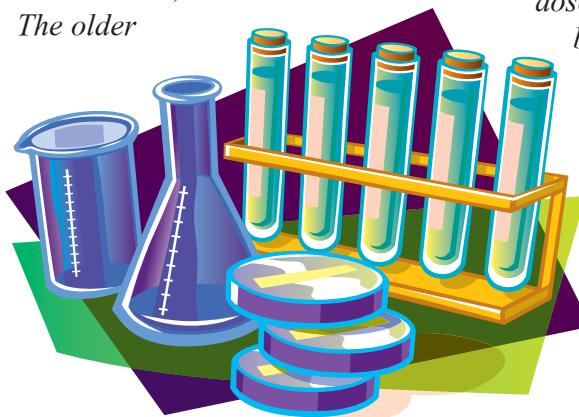
cyclosporine, have shown promise in some difficult cases of inflammatory myopathies. Humanized monoclonal antibodies are now available for experimental use and should be tested in future trials. One humanized monoclonal antibody called Campath (alemtuzumab), directed against a molecule associated with T-cell activation, causes T-cell depletion and will be part of a clinical trial that Dr. Dalakas is about to begin at NIH. Dr. Dalakas spoke briefly about potential new drugs that work against the over-accumulation of beta amyloids, including one called PPI1019, and the work being done by Dr. Valerie Askanas and her Los Angeles team of researchers, partially supported by TMA.

In the question-and-answer session, Dr. Dalakas talked about beta-interferons, used widely in multiple sclerosis. A pilot study with Avonex – a beta interferon – was ineffective in IBM but a controlled multi-center

trial with much higher doses is ready to begin. TMA will help recruit patients for this study when it starts.

At Dr. Dalakas's IBM clinic at NIH, patients are

evaluated and followed for a course of two years. They are shown how to exercise and modify tasks of daily living and how to prevent falls. They are given the choice of taking some over-the-counter prepa-



STEROID THERAPY – WHAT YOU NEED TO KNOW

There's no question that steroid therapy has saved the lives and quality of life of myositis patients, but there's a lot of misunderstanding about these powerful drugs. One common mistake is confusing anabolic steroids, which are widely abused by athletes and body builders, with prescribed corticosteroids. The bad reputation of anabolic steroids is one reason why many patients who may benefit from corticosteroids try to avoid them.

Anabolic steroids

Anabolic steroids are man-made drugs that mimic the male hormone testosterone. They build muscle and increase masculine characteristics. They're sometimes prescribed for patients with too little testosterone or other hereditary and acquired diseases, but the context in which we most often hear about anabolic steroids is their often illegal use to increase body size and athletic performance. Physical and emotional side effects of such abuse can be very serious: increasing the risk of stroke, heart attack, liver cancer, severe acne and a host of other medical problems. They can also cause violent behavior, wild mood swings, paranoia and depression.

Corticosteroids

It's a confusing situation, but anabolic steroids and corticosteroids actually have little in common. Corticosteroids are man-made drugs designed to produce the same effects as cortisol, a steroid hormone produced by the adrenal glands, which rest on top of the kidneys. Cortisol produced by the body helps to maintain various bodily functions. At higher than normal

levels, corticosteroids can reduce inflammation and depress the immune system. Following are some questions that myositis patients commonly ask about corticosteroids:

What are some types of steroids?

Some corticosteroid medications include cortisone, prednisone and methylprednisolone. Prednisone is the most commonly used type of steroid to treat rheumatologic diseases.

How are steroids given?

Steroid medications are available in several forms that vary in how easily they dissolve or how long they stay in the body.

Steroids may be given locally, to the precise place where a problem exists, or systemically, which means throughout the "system" or body. Examples of local steroid treatments include joint injections, eye drops, eardrops and skin creams. Systemic steroid treatments include oral medications (given by mouth) or medication that is delivered directly into a vein (intravenously or IV) or muscle (intramuscularly). Systemic steroids circulate through the blood stream to various body sites.

When possible, local steroid treatments are prescribed instead of systemic steroids.

How do steroids work?

Steroids work by decreasing inflammation and reducing the activity of the immune system.

Inflammation is a process in which the body's white blood cells and chemicals protect us from infection and foreign substances like bac-

teria and viruses. However, in certain diseases, such as myositis, the body's immune system doesn't function properly. This may cause inflammation to work against the body's tissues and cause damage. Inflammation is characterized by redness, warmth, swelling and pain.

Steroids reduce the production of inflammatory chemicals to minimize tissue damage. Steroids also reduce the activity of the immune system by affecting the function of white blood cells.

When are steroids given?

Steroids are used to treat a variety of conditions in which the body's defense system malfunctions and causes tissue damage. Steroids are the main therapy for certain diseases. For other conditions, steroids may only be used sparingly, or when other measures have not been successful.

Steroids are used as the main treatment for certain inflammatory conditions, such as:

- Systemic vasculitis (inflammation of blood vessels)
- Myositis (inflammation of muscle)

Steroids are also used selectively to treat inflammatory conditions like rheumatoid arthritis, lupus, and Sjogren's syndrome, as well as a variety of other conditions.

How will my doctor decide if steroids are the right treatment?

Your doctor will consider your age, physical activity and other medica-



tions you are taking. Your doctor will also make sure you understand the potential benefits and risks of



steroids before you start taking them.

The potential benefits and risks of steroids vary with:

- The nature and severity of the disease being treated;
- The presence or absence of other treatment alternatives; and
- The presence or absence of other significant medical problems.

What are the possible side effects of steroids?

The occurrence of side effects depends on the dose, type of steroid and length of treatment. Some side effects are more serious than others. Common side effects of systemic steroids include:

- Increased appetite, weight gain
- Sudden mood swings
- Muscle weakness
- Blurred vision
- In children, slowed growth
- Increased growth of body hair
- Easy bruising
- Lower resistance to infection
- Swollen, "puffy" face
- Acne
- Osteoporosis (bone weakening disease)
- Worsening of diabetes
- High blood pressure

- Stomach irritation
- Nervousness, restlessness
- Difficulty sleeping
- Cataracts or glaucoma
- Water retention, swelling

Please note: These are the most common side effects. All possible side effects are not included. Contact your doctor if you have questions about your personal situation.

Does everyone have side effects?

Not all patients will develop side effects. How often any side effect occurs varies from patient to patient.

If steroid use is brief (from a few days to a few weeks), it is possible that none of the listed side effects will occur. The side effects listed generally do not appear when occasional steroid injections are given.

How can the side effects of steroids be minimized?

To minimize the side effects of steroids, doctors follow several guidelines:

1. Use steroids only when necessary.
2. Monitor the patient closely to detect the development of serious side effects.
3. If possible, use local steroids for local problems.
4. Use the minimal dose required to gain control of the disease.
5. Reduce the dose gradually as long as the disease remains under control.
6. Monitor blood pressure often and treat if necessary.
7. Prescribe calcium supplements to help maintain bone density. Also consider Vitamin D supplements.
8. Recommend medicines that coat the stomach, especially for juvenile patients, to prevent stomach problems.

Strong treatment, possible side effects

Although some patients sail through prednisone treatment with no visible side effects, most report one or more of these troubling symptoms with long-term use:

- Hypertension
- Glucose intolerance
- Fluid retention and weight gain
- Cataracts or glaucoma
- Higher risk of infection
- Osteoporosis
- Type 2 muscle fiber atrophy

Treating the side effects of prednisone

Dr. Barohn advises other doctors to measure bone density at diagnosis and every 12 months while patients are receiving prednisone. He suggests Vitamin D and calcium even if the scan is normal, recommending calcium supplementation (1 g/day) and Vitamin D (400 to 800 IU/day). If the scan is abnormal at any point, he advises them to begin treatment with a bisphosphonate like Fosamax. Many doctors also begin bisphosphonates for postmenopausal women even without osteoporosis.

Dr. Barohn believes that a low-sodium, low-carbohydrate, high-protein diet can prevent the excessive weight gain associated with prednisone. He encourages physical therapy and an aerobic exercise program. Exercise, which will be discussed at length in the December *OutLook*, helps reduce bone loss and also helps prevent the type 2 muscle fiber atrophy that prednisone may cause. Dr. Barohn also monitors blood pressure, eye problems, fasting blood glucose and serum potassium levels.

DYSPHAGIA: WHEN MYOSITIS IS HARD TO SWALLOW

This article was compiled from the following presentations and articles: Aziz Shaibani, MD, FACP, from the 2003 Annual Conference; Lisa Orloff, MD, from the 2001 Annual Conference; and previous articles written for *The Outlook for the Inflammatory Myopathies*, TMA's quarterly newsletter.

Most people swallow without even thinking about it. But for those who can't seem to do it without coughing or choking, swallowing can be very frustrating.

Symptoms begin slowly: You may become aware of coughing or choking more often while you're eating, or losing weight without meaning to do so. You may notice a change in your voice after eating, a change in your breathing, a discharge from your nose, a feeling that food is stuck in your throat, heartburn or reflux, or recurring pneumonia. All of these are signs of trouble swallowing, or dysphagia.

How common is dysphagia in myositis patients? One-third of myositis patients develop problems with swallowing. Though swallowing is a reflex, you can control a part of it, says Aziz Shaibani, MD, FACP, Director of the Nerve and Muscle Center of Texas. For instance, it is much easier to swallow foods you like, Dr. Shaibani told the myositis patients in his session in Houston. He outlined the stages of normal swallowing:

- Oral, including oral preparatory (chewing your food) and oral transit (tongue against the roof of your mouth, pushing back)
- Pharyngeal (larynx closes, forcing your food down)

- Esophageal (food is squeezed through your throat to your stomach, your airway reopens)

If you have dysphagia, you have trouble getting through at least one of these stages, explained Dr. Shaibani. You may drool or get food in your nose if you have problems in the oral stage. You may choke if the difficulty is in the pharyngeal stage, or you may vomit if your abnormality is in the esophageal stage. The oral stage is the one you can control, while the other two are involuntary or reflex stages, harder to improve. Members gave real examples from their lives:

"My dysphagia seems to be the result of a flaw in the final stage of swallowing," says Mike, who has IBM. "That is, I can initiate the swallowing process with no problem and get the food started down. But there is a point, right near the opening to the windpipe, where the food tends to stay, and only patience, and small amounts of liquid, will get it to go down further." This happens more toward the end of a meal, he says.

Incomplete swallowing shouldn't be ignored, said Dr. Shaibani. Bits of food may get into the lungs, causing an infection if you can't cough the food out. This infection may lead to aspiration pneumonia, a more serious problem. Treatment of the pneumo-

nia depends on how severe your symptoms are and what other medicines you are taking.

Treatments and helpful suggestions

There are some practical steps you can take, along with some medical procedures. Be sure to take in plenty of food and water to avoid more problems, including dehydration, malnutrition and pneumonia, says Dr. Shaibani. Your doctor may recommend a nutritionist to make sure you are taking in enough calories each day. It's important to maintain a good weight for you. Losing weight can be a sign that your body is not getting the nutrients it needs.

"Do not wait until it is difficult to sort it out," says Dr. Shaibani. Go to your doctor, who may question what foods cause you the most trouble, if the problem seems to be

getting worse, and if you notice

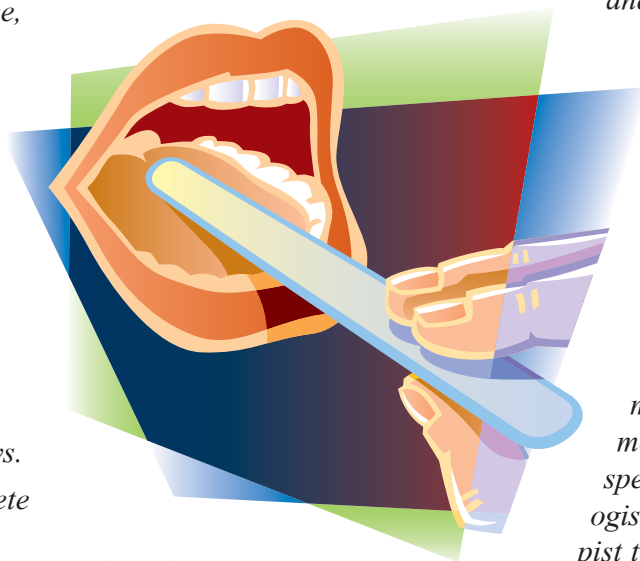
the difficulty all the time or

just on occasion.

He or she may recommend a

speech pathologist or therapist to examine your head, neck, mouth and tongue;

test your gag reflex; x-ray your chest to look at your lungs; or order a modified barium swallow. For the barium swallow, or videofluoro-



scopic swallowing study, you swallow a barium solution that coats the inside of your esophagus. This allows the x-ray to see the muscle activity of your esophagus as you go through the swallowing process. Doctors can see where an obstruction is so they'll know how to treat you. Your doctor may decide to do other tests, depending on your own situation.

If dysphagia is the first sign that alerted you to your disease, the medicines you use to treat the myositis itself may be enough to stop your trouble swallowing. There are medicines that can help specifically with dysphagia, including intravenous immunoglobulin (IVIg). Antidepressant medications may help, says Dr. Shaibani, since certain emotional conditions, like anxiety, can trigger dysphagia. Your doctor will choose the medicine that best treats the cause of your dysphagia, keeping in mind the other medicines you may be taking for your myositis.

Actually thinking about swallowing may help, says Dr. Lisa Orloff, a throat surgeon in San Diego. Clear your throat before you swallow, she recommends, so any residue left over from what you just tried to swallow won't leak into your airway. "If you start out with a clear throat," she says, "you're less likely to aspirate."

You can make simple changes yourself to improve your swallowing and avoid more problems:

- Chew your food well and take smaller bites and sips. Eat slowly.
- Hold your breath while you swallow.
- Eat when you are fully alert, not tired, so you'll pay attention to

each bite. Try to stay away from distractions like the television. Don't talk while you eat.

- Eat six smaller meals each day. This can be less tiring than three larger meals.
- Do lip and tongue exercises. Also work on your jaw and face muscles. Different exercises can help you strengthen the muscle or improve your coordination for swallowing.
- Change the consistency of your food to find what works best for you. Also consider how very cold or very hot foods affect your swallowing, then adjust your foods accordingly.
- Limit your dairy foods, which can cause thicker saliva. Choose citrus juices to reduce thickness.
- Find the head position that helps you avoid problems swallowing. Tuck your chin down to change your head angle, which lifts parts of the back of your throat, or tilt it up to use gravity in your favor. One side of your throat may be stronger than the other, says Dr. Orloff, so use it more.
- Sit up straight while you're eating and for an hour or so afterwards to help direct the food toward your stomach.
- Maintain healthy teeth and gums to help prevent aspiration pneumonia.

When other treatments just don't help

Sometimes the medicines and changes in how you eat don't solve

the problem. There are still options for you.

Several TMA members have tried dilatation, a procedure to expand the width of your esophagus. If the passageway is too narrow, this will help you swallow. Doctors pass a soft device into your throat to stretch it with increasing sizes of dilators.

The cricopharyngeal myotomy is also a procedure used to open your throat. Doctors cut the muscle fibers in your esophagus. These fibers are like rubber bands, so cutting them will widen the opening so your food can pass through more easily.

Some myositis patients have feeding tubes inserted into their stomachs, but this is typically one of the last options a doctor chooses. With the feeding tube, you miss out on the part of the swallowing that causes the trouble in the first place. This helps you take in the proper amount of food so you can avoid further problems.

"It's not what most people think," says Dr. Todd Levine, a Phoenix neurologist who treats a number of myositis patients. "It's not a giant tube going down your throat but a very small button – about the size of your navel – going directly into your stomach." You can use this tube to supplement what you eat regularly, so you don't have to give up eating altogether. This procedure is sometimes called a PEG (Percutaneous Endoscopic Gastrostomy), a common, simple surgery. The tube can be removed once the symptoms of dysphagia are no longer there.

See page 28 for list of terms commonly associated with dysphagia and its treatment.



MYOSITIS EXPERTS DISCUSS TREATMENTS IN INFORMAL, INTERACTIVE CHATS

In September, TMA initiated the first in a series of “chats with the experts,” and the two chats hosted so far have been extremely popular with members. Since many of the questions were about current and future treatments for myositis, we include some relevant questions and their answers here for those who missed them or don’t have access to the TMA web site. Find the full transcripts on the site at www.myositis.org. Look for details on the next chat with Dr. Fred Miller. He plans to address treatments for myositis and their side effects.

DR. WALTER BRADLEY,

Chair of TMA’s Research Committee and Chairman of the University of Miami’s Department of Neurology, was the first expert to participate in a TMA chat room. He spoke candidly about conventional and new treatments, particularly for IBM.

Anti-T-lymphocyte globulin treatment

Q. Dr. Bradley, we have been seeing news about using anti-T-lymphocyte globulin for IBM – can you comment on that?

A. ALG can remove T cells, which are important in the damage of the muscle in IBM, and also in PM. There has been a small trial that showed promise. However the treatment is not without risks and side effects, and a larger trial is required before it is possible to recommend this experimental treatment to everyone with IBM.

Stem cells and gene therapy

Q. Doctor, will you comment on stem cells as possible use in treat-

ment of IBM?

A. Muscle has stem cells of its own, called satellite cells. These normally replace damaged muscle fibers. Probably muscle weakness begins when the satellite cells begin to wear out. It is possible that stem cells from a donor of some sort might help muscle repair. However, so far this has not worked in trials of treatment in muscular dystrophy. Therefore, we do not yet have the technology to make it work in any disease.

Q. How far away is gene therapy for any of these diseases?

A. Gene therapy is a real hope for the genetic diseases of muscle, particularly the muscular dystrophies. But we still have a long way to go to find the way to get the good gene into the muscle effectively, and without danger. How long? Perhaps 5 years.

Q. Does gene therapy mean stem cells?

A. Gene therapy means wrapping the DNA containing the good gene into a virus, or some other vehicle to carry it into the cells. Not strictly using stem cells.

Q. Gene therapy – does this mean we should all be advocating more support for stem cell research?

A. Personally, I believe we should indeed all be advocating stem cell research. This is a major hope for many neurological diseases like ALS, Parkinson’s disease, stroke, etc. The US administration’s view that we have enough stem cell lines is incorrect; none can be used for experimental treatment of humans because they were grown in contact

with animal cells.

We need more cell lines, and much more research funding.

Q. What’s wrong with umbilical cord cells?

A. Umbilical stem cells are like blood stem cells. Eventually we may learn how to turn them into muscle cells or neurons. But we cannot do so at present.

Current research

Q. Is there any research that you are particularly excited about?

A. An open-ended question if ever there was. We need to advance our understanding of IBM; we still do not know what causes it. One theory is that it is a biochemical degeneration. I believe this is an epidemic of IBM, and consider a chronic viral infection as possible. However, I am something of a heretic!

For biochemical degeneration, I meant that the theory is that there is something wrong in the biochemistry (how all the chemical processes work) of the muscle fibers. Many possibilities exist, including abnormalities of the mitochondria, of how the muscle cell deals with its debris (the garbage disposal is broken!), and so on.

Research into ways to treat IBM is advancing, and new drugs are being tried. ALG, mentioned above, is only one of these exciting new treatment trials.

Research into DM

Q. Is there any promising research being done for DM?

A. DM seems to be mainly an autoimmune disease producing



damage of the small capillaries of the muscle, probably from antibodies that damage them. Work on IVIG, synthesized antibodies to block the production of the disease-related autoantibodies, antibodies to block the chemicals released by damaged blood vessels, are all exciting new research tools.

Use of creatine

Q. Can you comment on the use of creatine for IBMers?

A. Creatine is used by the muscle to store high energy ATP that can then be used later for work of the muscle. Creatine can



increase muscle strength and decrease fatigue, though by only about 10 to 15 percent. It is worth having but not a cure.

Information on interferon

Q. What is the latest information concerning interferon?

A. Beta interferons are now used in the treatment of MS, an autoimmune disease. There are trials of the interferons in other autoimmune neurological diseases, and perhaps this will be tried in myositis.

Diet and exercise

Q. Dr. Bradley, do you recommend certain types of diet or exercise for your myositis patients?

A. Re diet: a good nutritious diet,

no wild fads. Do not gain excessive amounts of weight, but don't starve yourself. Exercise is good, even of weak muscle.

Q. Can you do harm by too much exercise?

A. Muscle has a way to tell you it has exercised enough. It hurts! Perhaps, if you push beyond the pain, this can be harmful. Most exercise that is used to treat these diseases is not to this level.

For the second chat,

DR. ANTHONY AMATO, Vice Chair of the Neurology Department at Harvard University Medical School, fielded questions about the incidence of polymyositis. Dr. Amato teaches neurologists about myositis, and he recently published a paper stating that PM is actually very rare, and best diagnosed by ruling out DM, IBM and other dystrophies.

Dr. Amato: I became interested in myositis in 1986 during my early training. Although PM is frequently reported as the most common myositis, that has not been my experience or that of many other experts – Robert Griggs, Jerry Mendell, Marinos Dalakas.

Most of the patients referred to me with a PM diagnosis usually have some other type of muscle disorder: inclusion-body myositis being the most common. Other patients have had forms of limb girdle muscular dystrophy, which can be associated with inflammation on muscle biopsy. Still others have had unrecognized dermatomyositis or a non-specific myositis.

This is also the experience of other experts in the field. A recently published study in Neurology last month reported that of the nearly 240 patients diagnosed in The

Netherlands with a type of myositis, only 9 had PM. Further, on follow up of these patients, 4 out of 9 patients initially diagnosed with PM had their diagnosis changed to IBM.

Diagnosis and treatment

Q. Dr. Amato, other than prednisone what has been the drug that you have had the most success with concerning PM?

A. Methotrexate

Q. Is PM characteristic of Rheumatoid Arthritis but with muscle weakness, and would drugs for RA be beneficial to someone with PM?

A. Drugs for RA are often tried for PM (for example, prednisone and methotrexate). The newer TNF-alpha blockers may be beneficial and I am trying to get a study started in patients with PM and DM.

Q. I was diagnosed with PM in 1998 and have tried methotrexate, Imuran, cyclosporine, and am now on CellCept, but have had very little benefit. Only with high doses of prednisone do I see a marked improvement. Any ideas what I should be looking at next, either with drugs or different diagnoses?

A. If you have not had a marked improvement with prednisone, methotrexate, cyclosporine, Imuran, and CellCept, then an alternative diagnosis such as inclusion-body myositis (IBM) should be entertained. IBM is the MOST common muscle disease in people over 50 years of age.

Other possible diagnoses

Q. In the study, what were some of the diagnoses of the other non-myositis patients?

A. Other diagnoses that can mimic

NAVIGATING THE HEALTHCARE SYSTEM

Gaining ACCESS to health-care coverage

Kathy Baird has learned to negotiate the healthcare system through years of living with her own chronic illness as well as her family's health problems. She now works to pass this knowledge on to others as a part of the ACCESS team. ACCESS, or Advocating for Chronic Conditions, Entitlements and Social Services, is a division of Accredo Health, and its services come at no cost to you and are completely confidential.

By calling 1-888-700-7010, you can get help negotiating the often-confusing and difficult healthcare system. If you've lost health insurance, have medical bills you can't pay, or are looking for a job, ACCESS can help.

There are other free counseling services such as that offered by FFF Enterprises (see "Making IVIg available to you," next page.)

At the Annual Conference, Ms. Baird shared her thoughts and ideas. She compared piled up medical bills to a nightmare in your closet, an image from one of her favorite children's book. "As consumers, what do we do?" she asked. "We go where we're told, and we pay what we're billed." The healthcare system has gotten out of control because we have let it, she said.

She suggested a management plan: keep a list of every medical bill with dates, account numbers, original full amounts due, amounts that have been paid, who has made these payments, and the balance remaining. List these from smallest to largest. From this list, decide how you can best manage paying

the bills. Where is the money available – family, friends, savings? This whole process may take time, especially if your bills have built up over time.

Contact each provider yourself, she said, and do it as soon as possible. Offer a fixed amount, less than the amount remaining, to be paid immediately as payment in full, or ask for interest-free payments. If you're polite and can maintain your composure,



you will likely have better results, she said. Once you've come to an agreement with the providers, stick to what you've agreed to pay each week or month.

"Nearly every facility has a charity form," she said. Most forms are 2 to 3 pages long, including spaces for income and expenses. Don't fill out this form as it is, she said. Customize it by attaching a list of your medical bills – keeping track of expenses for a week or so to capture a truer picture of your actual expenses – and write a hardship letter. In this letter, explain your circumstances. Include everything so

that your situation sticks out from the rest – appeal to the person deciding who will receive these funds. These forms are objective, with formulas to measure need, but the person or committee making the decision is subjective, she said.

ACCESS will walk you through the steps you need to take, or the staff members will go through the process for you.

Paying for prescriptions

Many people don't have adequate prescription drug coverage, if any at all. This leaves you open to the very high cost of certain prescriptions you need to treat your condition.

There are several options for you – using drug discount cards, buying prescriptions online, and purchasing from Canada.

Discount cards

There are a number of companies offering cards to buy prescriptions with some discount. Make sure the card you choose covers the medicines and services you need. Cards are available through local pharmacies, larger drug companies, senior associations, and more. Pfizer offers the Pfizer for Living Share Card, for instance. This allows you to buy medicines manufactured by Pfizer for \$15 per 30-day supply. There is no fee to apply, and requirements include that you are enrolled in Medicare, you don't have prescription drug coverage, you aren't eligible for Medicaid or any state-funded plan, and your

income is less than \$18,000 per year (\$24,000 for couples).

TogetherRx was founded by some of the other large drug manufacturing companies and offers 20 to 40 percent savings on medicines, including up to 15 percent on generic medicines at certain pharmacies. Again, you must be enrolled in Medicare, your annual income is less than \$28,000 (\$38,000 for couples), and you cannot have other prescription drug coverage.

Drug manufacturers may offer their own discount cards, so check their web sites or call the company to find out if one is available for you. Patient Assistance Programs, also offered through manufacturers, provide free medicines to those who are eligible. There are web sites and phone numbers to help you find these programs in your area. (See Patient Assistance Programs in Resources, at right.)

Prescriptions on the web

Buying your prescriptions online has a lot of obvious advantages – not having to drive to the store, saving money over pharmacy prices. But there are some important precautions to take before buying. Watch for high shipping costs and other additional fees tacked onto the prescription price. You can check the Food and Drug Administration site at www.fda.gov for guidelines on using online pharmacies. You can also report any problems you've had with these online stores to the FDA.

U.S.-made medicines from Canada

There are stores on the Internet allowing you to buy FDA-approved medicines at lower prices. Again, you need to be wary of things that seem too good to be true. You can save from 30 to 90 percent on brand name prescription drugs from

Canadian sites; generic medicines remain cheaper overall in the United States. Shipping these prescriptions across country borders is not legal, though the FDA has concentrated its enforcement of these laws on more questionable Canadian agencies and not the practice in general.

To ensure safety, check for the name, address and phone number of the online pharmacy, and make sure it has a license number. Be sure they ask for your prescription and health history questionnaire before filling your order. The medicines should arrive in their original packages with the original safety seals intact.

Making IVIg available to you

If other medicines don't control your disease, intravenous immunoglobulin is often a logical choice. IVIg infusions, however, can cost far beyond your means. And insurance companies aren't always willing to pay for these treatments. FFF Enterprises offers access to reimbursement, infusion and pharmacy advisors at 1-800-843-7477.

Medicare will help cover IVIg therapy under specific circumstances – for polymyositis and dermatomyositis patients who have not responded to corticosteroid therapy, who cannot taper to a reasonable dose, who experience serious side effects from therapy, and who have not improved with at least one immunosuppressive therapy. There has been one study in particular suggesting that IVIg is beneficial in the treatment of sporadic IBM, as it stabilizes the disease and offers slight improvement in daily activities. The authors encourage its use to improve the quality of life for those with sIBM. (“High-dose immunoglobulin therapy in sporadic inclusion body myositis: a double-blind,

placebo-controlled study” from the *Journal of Neurology*, 2000)

Other healthcare programs

You may be eligible for other insurance coverage, including Medicare and Medicaid. Medicare's web site at www.medicare.gov offers help locating prescription drug and patient assistance programs in your state, including any Medicare plans with prescription coverage. Medicaid is available to those with lower incomes and varies from state to state. The Federal government gives broad guidelines for Medicaid coverage, and states set their own standards, including whether prescribed drugs are covered.

Resources:

ACCESS: www.accredohealth.net/ati/access/access.html or 1-888-700-7010

Centers for Medicare and Medicaid Services: www.cms.hhs.gov or 1-877-267-2323

FDA (Buying Prescription Medicines Online: A Consumer Safety Guide): <http://www.fda.gov/cder/drug/consumer/buyonline/guide.htm>

FFF Enterprises: Theo L. Wagner, Reimbursement Director, 1-800-843-7477 ext 1164 or Twagner@fffenterprises.com

Patient Assistance Programs: www.helpingpatients.org (PhRMA) or 1-202-835-3400; www.rxassist.org or 1-877-844-8442; www.RxHope.com or 1-908-850-8004; www.medicare.gov (then click on “Search tools” for options)

Pfizer: www.pfizersharecard.com or 1-800-459-4156

TogetherRx: www.TogetherRx.com or 1-800-865-7211



"GENERICS" HELP KEEP MEDICATION COSTS MANAGEABLE

The Cleveland Clinic compiled this information for its web site and has given TMA permission to share it with you. We have edited the article slightly for length. Find the complete article at www.clevelandclinic.org.

Prescription medications can be a major expense for everyone, especially older persons or those with chronic conditions such as myositis. Switching from brand-name, or "branded," drugs to their generic equivalents can result in considerable savings, but many people are leery about doing so because they fear that generics may not be as safe and effective.

Assuming that consumers purchase generic drugs from reputable sources, they have nothing to worry about, according to Mandy Leonard, PharmD, Cleveland Clinic doctor of pharmacy. "There's nothing wrong with generic drugs. Generics are the same as the branded drugs, and will save people—especially those without appropriate healthcare coverage—a lot of money," says Dr. Leonard. "You don't have to take a branded product if a generic is available."

Choosing generics over brand-name agents can result in cost savings of 40 to 80 percent. Experts estimate that the generic version of a \$72 average branded prescription drug costs roughly \$17.

Generic drugs – close copies of branded products

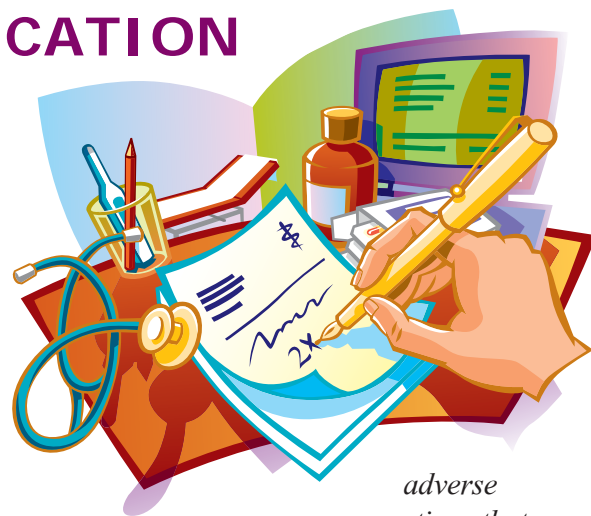
By law, all generic drug products must meet specifications for identity, strength, quality, purity and potency. Through the Food and Drug Administration (FDA), the

U.S. government oversees the manufacture of all FDA-approved drugs produced in the United States. The FDA requires drug makers to maintain stringent manufacturing standards to ensure the safety of drugs. Just as the brand-name manufacturers do, generic manufacturing processes and drug products undergo FDA inspections and testing to ensure that the manufacturing process produces a pure, safe copy of a brand-name drug.

Generic drugs that contain the same active ingredients, in the same dosage form, given by the same route of administration, and that consist of the same strength as the brand-name counterpart are called "therapeutically equivalent." The Center for Drug Evaluation and Research (CDER), a division of the FDA, determines whether a generic drug can be called a therapeutic equivalent to the brand-name drug. Generic drugs that are rated as therapeutically equivalent are allowed to differ with respect to shape, flavor, and preservatives, but must produce the same effects as their brand-name counterparts.

The preservatives used in the various generic equivalents, however, may cause differing responses to the medicine, or elicit an allergic, gastrointestinal, or other type of response simply because they are different than the preservatives used in the brand-name version. This can also be the case with the flavorings or coloring used in generic drugs. Reactions to these ingredients, however, are rare, says Dr. Leonard.

"Usually, allergies to the dyes used in generics are the only



adverse reactions that arise, but such instances are rare, since most generic products are white in color. Obviously, some individuals will have some unique allergies. But overall, in the general population, there should be no worries about this," says Dr. Leonard. The bottom line: in terms of their safety and effectiveness for treating an illness or condition, generics are virtually identical to their brand-name counterparts.

Generics cheaper to produce

Generic drugs are cheaper to produce than branded products because they do not require the research and development necessary to get a new, branded product on the market.

Getting a brand-name drug to market can take years and a large investment of money. New drugs are developed under patent protection, which gives the company that develops the drug the right to be the only seller of that medication for a set period of time. Legally, the rights to market and sell the drug exclusively extend 20 years beyond the filing date for the patent.

When patents for brand-name drugs expire, generic drug makers can apply for permission from the FDA to manufacture and sell copies of the brand-name versions. Generic drug makers incur no

development costs, so when they manufacture and sell a drug, they can charge significantly less for it. The branded products have, in effect, paved the way for the generic products to be mass produced.

In addition, when a patent for a branded product expires, any and all pharmaceutical manufacturers can produce a generic version. When several companies manufacture the same generic drug, the competition can drive down prices.

A boost from the government

The increased availability of lower-cost generic drugs can benefit all consumers, particularly older persons or those with chronic conditions.

Even the government has recognized the need to hasten and improve the availability of generic drugs to consumers. Recently, the Bush administration implemented a new rule designed to speed up the process by which generic drugs are available once a patent expires. This change became effective on August 18, 2003, and is expected to save consumers roughly \$35 billion over the next 10 years by making generic drugs available faster. The FDA has announced that it will be working to streamline the approval process for generic drugs in the near future.

Many health insurance plans are offering incentives to doctors and patients for switching from brand-name agents to generics.

Perhaps with a little help from the government, and a slight shift in consumer confidence toward

Continued on page 25

TAKING YOUR MEDICATIONS

As a patient, you need to take a hands-on approach to your treatment. Here are a few tips from the Cleveland Clinic:

Before medication is prescribed, tell your doctor:

- If you are allergic to any medications.
- If you are currently taking any other medications (including over-the-counter medications).
- If you are pregnant or think you might be pregnant.
- If you have problems taking any medications.

Medication guidelines

Note: These are general guidelines. Be sure to ask your doctor or pharmacist for guidelines specific to your medication.

- Keep a list of all your medicines and their doses with you.
- Take all medicines exactly as prescribed by your doctor.
- Do not stop taking your medications unless you talk to your doctor first. Stopping your medication too early can cause the symptoms to return or make it more difficult to treat your condition.
- Do not double or change the dose of your medication.
- If you miss a dose of your medication at the scheduled time, don't panic. Take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and return to your regular schedule.
- Do not keep medicine that is outdated or no longer needed. Throw old medicines away.
- Store medications in a dry area away from moisture (unless your doctor or pharmacist tells you the medicine needs to be refrigerated).
- Always keep medications out of the reach of children.

- Contact your doctor immediately if you experience any unusual side effects after taking your medication.
- Do not share your medications with others.
- If you store your medications in a container, label it with the medication name, dose, frequency and expiration date.
- Keep your medications in your carry-on luggage when you travel. Do not pack your medications in a suitcase that is checked, in case the suitcase is lost. Label all medicines clearly.
- Take extra medication with you when you travel in case your plans change and you need to stay away longer than expected.

Questions to ask about your medications

Be sure you know the answers to these questions before you start taking any new medication:

- What is the name of the medication?
- Why do I need to take it?
- How often should I take it?
- What time of day should I take it?
- Should I take it on an empty stomach or with meals?
- Where should I store the medication?
- What should I do if I forget to take a dose?
- How long should I expect to take the medication?
- How will I know it is working?
- What side effects should I expect?
- Will the medication interfere with driving, working or other activities?
- Does the medication interact with any foods, alcohol or other medications (including over-the-counter medications)?



NEW MYOSITIS DRUGS DISCUSSED BY RHEUMATOLOGISTS

Dozens of researchers presented their work in myositis-related investigations last month at the annual meeting of members of the American College of Rheumatology. These informal presentations – called “poster” sessions – highlight current research that hasn’t been published yet. Posters at the November conference included studies of treatments for various forms of myositis and its complications and side effects. A few are summarized here.

Mycophenolate Mofetil (CellCept)

Researchers at the University of Mississippi Medical Center in Jackson called this new immunosuppressive agent a safe and promising therapy for adult inflammatory myopathies. Drs. Vikas Majithia, Suzanne Sanders and Valee Harisdangkul noted that the drug is safe and usually well tolerated and has been used in other autoimmune diseases. They conducted a small trial to study its use in myositis.

They used the drug to treat six patients with inflammatory myopathies, and recorded the results. All of the patients were adult women with either PM or DM, and all were receiving 20 to 60 mg of prednisone daily. Conventional immunosuppressive drugs like methotrexate, azathioprine (Imuran) and hydroxychloroquine (Plaquenil) had been tried in all the patients, and they either had little or no response, or had developed side effects serious enough to discontinue treatment. The team started mycophenolate mofetil in

doses of 500 mg twice a day and increased the amount to 1 gram twice a day.

The results were impressive, said the researchers. All the patients had marked improvement in their lab tests; all but one showed a marked improvement in strength. The average length of time for the women to respond after treatment was eight weeks, and they all tolerated it well during periods from six months to two years without any significant side effects.

The researchers conclude that mycophenolate may be an alternative to conventional immunosuppressive agents in patients who don’t respond to, or don’t tolerate, the usual treatments for myositis

Cyclophosphamide

Treatment of interstitial lung disease – a serious complication of PM and, less often, DM – with a six-month course of intravenous pulse cyclophosphamide was reported by a team of French researchers. In patients with the anti-JO1 antibody, the rate of this serious complication is 60 to 80 percent. Seven patients with progressive disease due to myositis received six cycles of monthly IV pulse cyclophosphamide with an initial one-month course of prednisolone, then tapered to a maintenance dosage.

The study group included five women and two men who were between the ages of 32 and 63 years when they experienced the first symptoms of PM, and there was one DM patient. Five of the patients were unresponsive to a one-month high-dose course of



prednisolone alone or in association with methotrexate and azathioprine before receiving the cyclophosphamide. In more than half the patients, lung functions were stabilized.

The researchers concluded that cyclophosphamide was useful in some cases of myositis with interstitial lung disease, most notably those treated early in the disease process.

Treatment of interstitial lung disease with tacrolimus

Drs. M. Wilkes, S. Sereika, N. Fertig, M. Lucas, A. Perez, and C. Oddis of the University of Pittsburgh studied the efficacy of tacrolimus in patients with anti-aminoacyl-tRNA synthetase (anti-aaRNS) associated interstitial lung disease and myositis. Ninety-eight patients with anti-aaRNS autoantibodies were identified from approximately 600 patients. Fifteen patients with anti-aaRNS associated ILD who had been treated with tacrolimus between 1992 and 2003 were reviewed retrospectively.

Researchers used a variety of lung tests to measure improvement in the interstitial lung disease; and muscle testing, blood testing and the ability to reduce steroid treatment to assess muscle strength improvement. Significant improvement was observed in all pulmonary parameters measured, and ten (77%)

Continued on next page

patients maintained normal muscle strength or improved muscle strength over time.

There were few side effects, though hypertension was noted as one, and the researchers concluded that tacrolimus is well-tolerated and effective for managing refractory ILD and myositis in anti-aarNS positive myositis patients.



EXPERT CHATS,

Continued from page 19

PM other than what I noted above include toxic myopathies (example, from being on cholesterol-lowering agents, thyroid disease, proximal myotonic myopathy).

Diagnostic testing

Q. Dr. Amato, what about IBM in people under 50, and what would be the difference in diagnostic tests?

A. Rarely IBM can present in patients under 50. The clinical exam should be able to distinguish IBM from other diseases.

Other symptoms

Q. Could PM affect the diaphragm, or would that be a result of long-term steroid use?

A. I have not seen PM affect the diaphragm.

Q. Does anyone else have peripheral neuropathy with PM?

A. Peripheral neuropathy is more common in IBM than PM, and if one has normal CK, as I said earlier, PM is not likely.

Normal or abnormal CK

Q. I have been dealing with my PM for 19 years and have had normal CK (creatin kinase) when controlled with medicines. Are you

saying that CK is always abnormal with patients with PM without meds or with them?

A. CK is always abnormal in PM prior to treatment. If the PM is controlled with medications, then the CK can be normal.

Q. In general, will CK tend towards normal with most drug treatment in PM?

A. CK will go down with treatment in PM. However, this does not mean that a lower CK level on prednisone implies someone has PM because we will see the same thing (lower CK on steroids) in IBM or dystrophy patients who get started on steroids.

Future expectations

Q. What sort of life expectancy differences can you expect with PM?

A. Most patients with PM/DM have normal life expectancies.

Q. I have had IBM for about 10 years with no treatment for most of the time. I have weakness mostly in the quadriceps (from the beginning) and arms as of late. Could you give me some idea how the IBM will progress and time frame?

A. I have tried everything for IBM and unfortunately I have not found any medication to be effective as yet. We are doing a lot of research in trying to better understand what causes IBM so we can come up with treatments that work. Currently, if someone with IBM is not in a drug study, I do not recommend treatment as the side effects of these medications outweigh any expected benefit.

As you can see from these excerpts, TMA members are learning a lot from the experts in the chat rooms. Please plan to join us for future chats.



IBM TREATMENTS,

Continued from page 13

rations – L-carnitine, Coenzyme Q10 and creatine.

At the Conference, Dr. Dalakas said potential IBM treatment will be tested on patients associated with the clinic. To find out more about the NIH IBM clinic, go to TMA's web site at www.myositis.org and find the open trials link in the health professionals section. You may also call the Patient Recruitment and Public Liaison Office at 1-800-411-1222 or email prpl@mail.cc.nih.gov.



GENERICS,

Continued from page 22

generic drugs, the cost-saving potential of generic agents will be fully realized.

“A lot of consumers want the branded drugs, and think that only the branded product will work for them. That's incorrect,” says Dr. Leonard. “The generic drugs are the same products, and they will work in the same way.”



COMPLEMENTS TO CONVENTIONAL TREATMENTS

When traditional treatments don't seem to be working, many patients look to complementary, alternative or integrative therapies to help.

Lori Love, MD, PhD, Senior Advisor for Clinical Science at the Food and Drug Administration, addressed complementary and alternative medicine (CAM) at the Annual Conference.

Complementary therapies are used in addition to your conventional treatments – like vitamin supplements or aromatherapy – so you continue taking the medicines your doctor prescribes to treat your myositis. Alternative therapies are used in place of traditional medicines. This includes choosing a special diet over chemotherapy or radiation to treat cancer, said Dr. Love. For integrative therapies, traditional therapies are combined with CAM therapies that have some scientific evidence that they are safe and effective.

Patients have reported positive results with different forms of CAM therapies, but there are some precautions you should take before starting anything new. “Natural is not necessarily safe,” said Dr. Love. Some natural products will cause adverse effects if taken with certain medicines. Dr. Love urged everyone at the Conference to tell his or her doctor before beginning any type of therapy or supplementation. “Any of these products can potentially have interactions,” she said. “There are changes in how you metabolize certain products with your age, gender or health condition.”

Dr. Love provided her perspective as a physician, but added in the question-and-answer session that she is also someone who has der-

matomyositis and lupus. She shared some advice after living with these overlap syndromes: “You need to recognize what your limitations are and respect them.” She also stressed the importance of nurturing the partnership between you and your physician and between you and your family. “Attitude is important,” she continued. “It's important to have something in your life where you can be expressive and creative.”

As a patient, she has tried some CAM therapies, including acupuncture and traditional Chinese medicine. She controls her diet, exercise and stress levels, and takes a multi-vitamin and calcium with Vitamin D supplements. She has chosen to restrict her diet to mostly plant-based foods and adds specific herbs to her foods. “I find that ginger is helpful for digestive purposes,” she said. She reemphasized the need to tell your doctor: “You need to let your doctor know. It has to be a joint decision.”

Complementary therapies

Creatine

Creatine has often been mentioned in connection with myositis. It is an amino acid produced by the body and is involved in muscle contraction. Older patients with neuromus-

cular diseases, like myositis, have lower levels of creatine, so it has been considered a possible supplement.

Some doctors recommend creatine for their myositis patients since creatine has been found in healthy people to increase lean body mass and strength. Mark Tarnopolsky, a Canadian researcher, tested creatine in a number of patients, including some with inflammatory myopathies. The patients took 10 grams (g) of creatine daily for 5

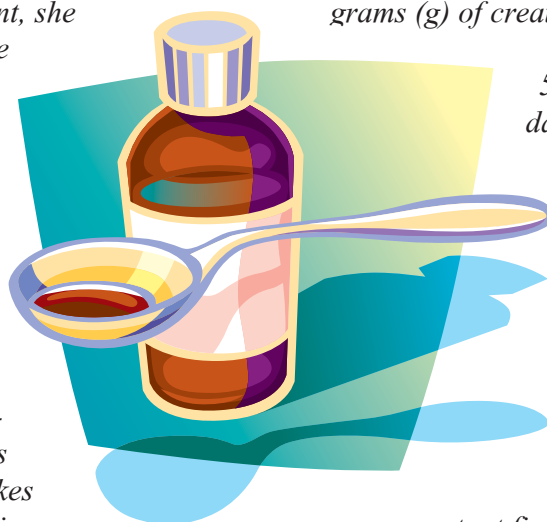
days, followed by 5 g daily for 5 days. He noted an increase in handgrip, ankle movement and knee extension as well as in lean body mass with this short-term use of creatine.

This is an important finding since those with myositis lose muscle progressively.

L-carnitine and Coenzyme Q10 (CoQ10)

These supplements are often used in high doses and are available in chewable wafers or pills. Both are relatively non-toxic, so trying them is a reasonable option for most patients. CoQ10 is an antioxidant, protecting your body against free radicals like cancer cells and others involved in aging.

“Some of these patients may be right at the point where a slight improvement will make a significant difference in their quality of life, so it's logical that they would want to try one of these,” said Dr.



Marinos Dalakas, Chair of TMA's Medical Advisory Board. "All of these supplements make some sense, although they haven't been studied properly." These supplements will not cure myositis, but physicians hope they can slow the progression of the disease.

Drs. Valerie Askanas and King Engel of the University of Southern California's Keck School of Medicine recommend L-carnitine with CoQ10: one gram of L-carnitine 4 to 5 times a day, with 100 to 150 mg of CoQ10 four times a day. Both should be taken with food.

Glucosamine and chondroitin

Glucosamine and chondroitin are substances made naturally by the body. Glucosamine is thought to inhibit inflammation and encourage cartilage growth; chondroitin strengthens cartilage. There is anecdotal evidence that glucosamine works well in one-third of the patients taking it, with another third having some response to the medicine. The final third has no response at all, said Dr. Love.

Exercise and other physical complements

Exercise is an important part of any therapy routine, but you need to tailor what you do to how you're feeling. Don't overdo it, especially when you're in a flare. Concentrate on range-of-motion and some strengthening exercises, and move forward with more exercises as you feel better. Exercise will be discussed in more detail in the December issue of *OutLook*.

Other touch therapies, also called manipulative and body-based therapies, include massage, warm stone therapy, acupuncture, and acupressure. Studies have looked at brain imaging during massage and

without massage. "It is known that massage can activate some of the brain pathways that are involved with making endorphins, which are the body's own anti-pain molecules," said Dr. Love. "There is something there." The same holds true for exercise and other outside interests, she said.

As a patient, Dr. Love tried acupuncture and acupressure, which she found helpful when she was in an acute phase of the dermatomyositis. "You have to keep doing it or the benefit stops," she said. Other TMA members have tried warm stone and massage therapy, reporting that both are very soothing and relaxing to them.

Alternative therapies

Alternative therapies are complete systems, used apart from conventional treatments. Alternative systems include homeopathic and naturopathic therapies, as well as many others that have been used throughout history.

Homeopathic practitioners use substances that would typically cause the symptoms you're trying to control. By highly diluting the substances, homeopathic practitioners believe the mixture will actually cure the symptoms it would typically cause.

Many other alternative therapies are tailored to your own symptoms and health history. Practitioners develop individual therapies such as therapeutic touch, traditional Chinese medicines, and naturopathic medicines in accordance with your body's healing

forces and energy.

Some patients alter their diets instead of choosing conventional treatments. This is an effort to cleanse their bodies without the use of medicines, and they'll often cut out certain foods while adding others, especially certain herbs with anti-inflammatory properties. These herbs include ginger, cumin, and coriander, among others.

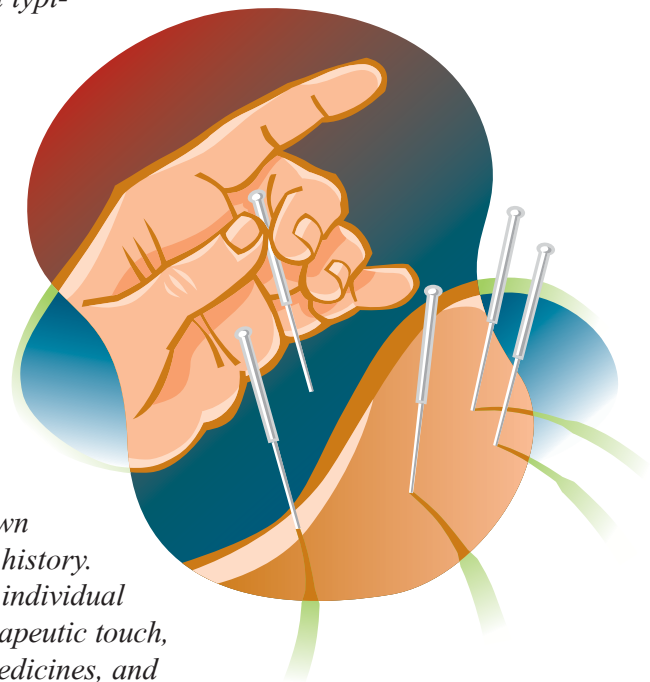
Web sites and other resources

Food and Drug Administration:
www.fda.org

National Center for Complementary and Alternative Medicine (NIH):
<http://nccam.nih.gov/>

Office of Dietary Supplements (NIH): <http://dietary-supplements.info.nih.gov/>

MedWatch, Food and Drug Administration (to report adverse effects of products):
www.fda.gov/medwatch;
1.800.FDA.1088



GLOSSARY OF TERMS

The following are general definitions for terms used throughout this publication. They may be explained in more detail within the text of the articles. These terms may have other definitions depending on the situation.

alternative therapy: any therapy used in place of conventional, or more traditional, treatments; examples are special diets instead of chemotherapy for cancer or homeopathic remedies.

amyopathic dermatomyositis: (also called DM sine myositis) dermatomyositis with only skin symptoms, like a rash, without weakness or pain in muscles.

antibody: protein produced by the body that acts against antigens in immune response.

antigen: foreign protein that stimulates an immune response in the body.

anti-rheumatic: medicine that acts against diseases with inflammation or pain in muscles or joints.

aspiration: inhaling food or other substance into your larynx below the vocal chords toward your lungs.

aspiration pneumonia: infection in your lungs caused by bits of food being inhaled into your lungs.

autoimmune disease: disease in which the body's immune system works against its own healthy tissues.

biologic agent: product, like glob-

ulin or antigen, used to prevent or treat disease.

biological dose: the amount of cortisol your body would normally produce if you hadn't been on a long course of high-dose prednisone.

calcinosis: hard, often painful lumps of calcium that form under the skin's surface, especially in juvenile dermatomyositis.

complementary therapy: any therapy used in addition to treatment prescribed by your physician. Examples are massage, aromatherapy, and tai chi.

contracture: stiffening of the joint, causing it to shorten and stay bent.

conventional therapy: traditional treatments that are more commonly prescribed by physicians. For most with myositis, for instance, conventional therapy is prednisone or methotrexate.

corticosteroids: medicines aimed to reduce inflammatory response, and to relieve redness, swelling, itching, and discomfort.

creatin kinase: enzyme found in the blood in elevated levels after muscle injury. Creatine kinase levels are often used to determine if a person has myositis or how a specific treatment is working.

cricopharyngeal myotomy: surgical procedure to widen the opening in your throat.

deglutition: act of swallowing.

dilatation: procedure to stretch the esophagus to widen the opening for food to pass through.

dysphagia: trouble swallowing; difficulty moving food or liquid from your mouth to your stomach.

efficacy: effectiveness of a particular medicine to treat disease or condition for which it is being tested.

esophagus: tube that passes food from your pharynx to your stomach.

first-line treatment: medicine that the doctor chooses to try as the first treatment for your condition. First-line treatment for JM is usually high-dose prednisone.

flare: return of past symptoms or increase in current symptoms after a period of remission or slower disease activity. This may occur when tapering medicine too quickly or overexerting yourself through exercise or stress.

generic: type of drug manufactured to mimic brand name medicine at less cost. Generic medicines are typically less expensive than their brand name counterparts.

Gottron's sign: (also Gottron's papules) unusual redness of the knuckles with a raised, scaly eruption.

heliotrope rash: blue-purple discoloration on the upper eyelids with edema.

idiopathic inflammatory myopathy: disease of the muscle, causing swelling of the muscle fibers, with no known cause.

immune system: your body's system that protects you from foreign substances through immune response. In myositis, the immune system is thought to be overactive, causing your body to attack its own healthy tissue.

immunomodulation: change in the immune system by a particular agent (like methotrexate).

immunosuppressant: medicines that lower the body's ability to fight infection by slowing the body's immune system from fighting healthy tissues.

inflammation: response to injury that results in redness, swelling, pain, and sometimes loss of function.

integrative therapy: combination of complementary therapy to treat symptoms and conventional therapy to treat underlying disease.

intravenous: method of giving medicine through a needle directly into your vein.

intravenous port: device that remains in your vein to make giving medicines by needle less painful or uncomfortable.

larynx: muscle and cartilage that holds your vocal chords.

local: affecting only a part of the body where medicine is applied, given. Local treatments include topical creams for DM skin rash.

lymphocyte: cell originating from stem cells that play a role in immunity.

maintenance dose: very small amount of medicine a person may need in order to keep symptoms from returning or worsening.

mechanic's hands: dilated capillary loops at the base of the fingernails with irregular, thickened, and distorted cuticles, or cracked, "dirty" horizontal lines at the lateral and palmar areas of the fingers.

modified barium swallow: test for which you swallow a barium solution, which shows up white on an X-ray because of its density. This is also called a videofluoroscopic swallowing study.

monoclonal antibodies: antibodies from a single cell, in large numbers, that act against a particular antigen. Enbrel and Remicade are two medicines that target tumor necrosis factor (TNF), a protein that is believed to increase in myositis patients.

PEG: relatively simple procedure, where a doctor inserts a feeding tube into your stomach. This treatment usually has good results.

pharynx: area leading from your mouth and nose to your larynx and esophagus.

pulse: dose of medicine given intravenously (through IV needle) over a short period of time.

range-of-motion exercise: type of exercise to keep flexibility and movement in joints.

refractory: resistant or unresponsive to treatments.

relapse: return of symptoms after a period of remission or no additional disease activity.

remission: period of time when patient shows no symptoms of disease and has been off all medicines

for six months or longer.

retrospective: type of study that looks at patients' past experiences to determine if a certain treatment has worked.

rheumatic disease: disease in which there is swelling or pain in the muscles or joints.

second-line treatment: medicine chosen after a patient fails to respond to the first medicine given. Methotrexate is often a second-line treatment after prednisone.

shawl sign: a flat red rash on the back and shoulders.

staph infection: bacterial infection that grows deep below the skin.

stricture: narrowing of a tube.

systemic: therapy that affects the body as a whole, as in medicines taken orally or intravenously.

taper: process of slowly lowering your dosage of medicine to reach a maintenance dose or stop taking the medicine completely.

tumor necrosis factor (TNF): protein that destroys cells that appear to be abnormal and stimulates inflammation.

type 2 muscle fiber atrophy: (also steroid myopathy) weakness caused by long-term use of corticosteroid medicines.

vacuoles: holes in the muscle fibers evident in muscle biopsies of IBM patients.

vasculitis: swelling of blood vessels under the skin that cause a visible rash.