

THE OUTLOOK



THE MYOSITIS ASSOCIATION



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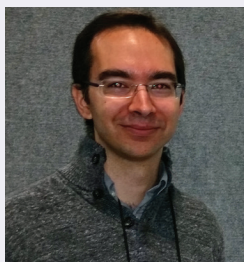
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WINTER 2017
Quarterly Newsletter

THE OUTLOOK

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Christine Lowe (Vice President, MAA) and husband Mark
Photo courtesy of MAA

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**The mission of
The Myositis Association
is to:**

- *Increase program support to the myositis patient and caregiver community*
- *Increase awareness of myositis throughout the general population with emphasis on the medical community*
- *Increase funding for TMA operations and myositis-related research*

Dear TMA member,

With the New Year behind us, it is probably a good time to look back and ahead. The past year offered a lot of promise for myositis patients as more pharmaceutical companies became interested in trying to develop treatments that would benefit myositis patients. Seven companies conducted active clinical trials in 2016 or are planning trials to get underway this year, targeting the different forms of myositis.

While the results from the BYM338 trial for inclusion body myositis did not meet the primary goal of the trial, you will read in this *OutLook* that there were results from this trial that should encourage further investigation. Multiple clinical trials for dermatomyositis and polymyositis were also conducted in 2016 and continue. Additional trials are planned to begin soon, and the degree of interest among pharmaceutical and biotech companies is encouraging.

As we look ahead, TMA is seeking to make improvements in how we facilitate getting information to you. While an article in this *OutLook* notes that TMA offers the most reliable and credible information to patients and physicians, we also recognize that getting the best information to you can be challenging. Recently, we modified our online Community Forum, seeking to improve the user experience. We will soon be updating our website, making it easier to view on smartphones and improving your ability to readily access information important to you.

Other articles in this issue of *OutLook* address how to prepare for future caregiving needs and how to access Veterans Administration benefits to which you are entitled.

All of us have experienced the frustration of bureaucratic barriers when we are anxious to get what we need quickly and efficiently. TMA is trying to help remove those barriers to make your experience more efficient and satisfying. While change can be disruptive, hopefully the end product will justify the inconvenience and frustration experienced in getting to that point.

Please be patient and remain optimistic that better days lie ahead.

Bob Goldberg
Executive Director

TMA welcomes new medical advisors

This year, TMA welcomes two new myositis experts to its Medical Advisory Board. MAB members are selected by their peers and invited to join the Medical Advisory Board by the Board of Directors. Please join us in welcoming our newest medical advisors.



Olivier Benveniste
Photo by Linda Kobert

Olivier Benveniste, MD, PhD started his career doing doctoral work in immunology, researching HIV diseases and vaccines. He expected to become an infectious disease specialist.

As a medical doctor, however, he trained in internal medicine and rheumatology and did a post-doctoral fellowship

in neurology at Oxford University in the United Kingdom with David Hilton-Jones, a specialist in neuromuscular disorders, including inclusion body myositis. Then, he found himself working with rheumatologists and neurologists as part of a multidisciplinary clinical practice at Pitié-Salpêtrière hospital in Paris, a research center that has a historically important cohort of myositis patients.

“When I joined this team, I started to use the tools I learned in immunology with myositis patients,” says Benveniste.

He now serves as head of the Department of Internal Medicine and Clinical Immunology at Pitié-Salpêtrière. He is also one of the most respected myositis experts in the world.

Benveniste is interested in the challenge of working with a disease that has so few effective treatments and is so little understood. He is excited that researchers around the world are starting to work together to understand the acquired immune-mediated myopathies. And he is eager to share the resources from his network in France so the work

of finding solutions for patients can be done more efficiently and without duplication.

“We are at the beginning of a story,” he says. “It is a small world, but there is no huge competition between researchers. That is why I find this field really interesting and challenging.” Working with colleagues who are nice people makes it rewarding for him as well.

Not only does Benveniste enjoy collaborating with colleagues, however, he also recognizes the value of forming connections among patients. As head of one of the most important myositis clinics in France, four years ago he invited one of his patients to lead a support organization similar to TMA’s KIT support group network.

“In France, patient support groups are relatively new,” he says. “Because I have strong links with this new group in France, I was also interested in connecting this group with TMA. I’m very pleased to join your Medical Advisory Board.”

One of the things **Floranne Ernste, MD** most enjoys is working with patients.

“I’m very clinically oriented,” says the Mayo Clinic rheumatologist. “I am always willing to see new patients, and I like complex patients.”

Ernste developed an interest in exploring myositis when she came to Mayo as a resident in internal medicine. TMA medical advisor and pediatric rheumatologist Ann Reed, MD worked there at the time and served as a mentor for Ernste during her residency as well as her rheumatology fellowship.

“I was involved with many of [Dr. Reed’s] projects, and that started my interest,” Ernste says. “The first project I did was an epidemiology study on IBM. From there, we’ve worked together on several other research studies.”



Floranne Ernste
Photo courtesy of Floranne Ernste

As a clinician at Mayo, Erneste works with many dermatomyositis patients, but she also sees those with polymyositis and inclusion body myositis. Often, as a consultant for patients who come to her from other places, she is the person to diagnose the disease and get the patient started on treatments, and then they follow up with their local physician.

“It’s exciting to see these patients when they come back and they’ve benefitted from the treatment,” Erneste says.

Erneste is also excited about the expanding insights into myositis in recent years because of new research findings. Among these are ideas such as the optimal timing for applying different forms of treatment and using autoantibodies to understand how one person’s disease is different from another’s.

Exploring the therapeutic use of biological agents is also an exciting development. Erneste has seen some DM patients respond well, for example, to treatment with rituximab, a monoclonal antibody that works on the immune system and is used to treat rheumatoid arthritis. She also has been involved with clinical trials testing the immunosuppressant tocilizumab in patients with DM and PM.

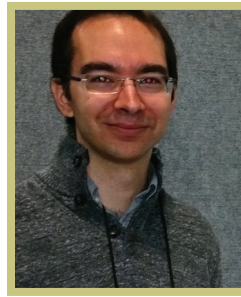
Erneste is looking forward to joining TMA’s Medical Advisory Board.

“It’s a good group of people, and it’s very exciting to be included in that group,” she says. “They’re very knowledgeable about what’s coming up in the research. That was a driving factor for wanting to be part of this team.”

TMA funds new research

In 2016, The Myositis Association offered half a million dollars in new funding for research into causes, treatments, and cures for myositis diseases. Since 2002, TMA has provided nearly \$6 million in funding for projects designed to develop better treatments, possible prevention, more effective rehabilitation, and ultimately a cure.

Of the 15 research applications received in 2016, TMA’s Medical Advisory Board members recommended three promising projects spanning various aspects of the disease.



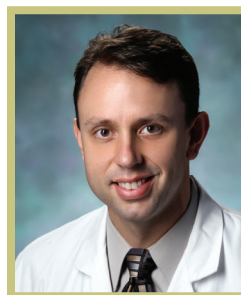
Iago Pinal-Fernandez
Photo by Linda Kobert

in muscle cells. Through this work, he expects to identify unique targets for new therapies.



Janine Lamb
Photo courtesy of The University of Manchester

patients with one form of the disease, inclusion body myositis (IBM). Using a screening technique previously employed in cancer research, Lamb hopes to define the underlying cause of IBM, which will aid development of screening and diagnostic tools, as well as effective treatments for IBM, which currently has no treatment.



Thomas Lloyd
Photo courtesy of The Johns Hopkins University

degenerative disease has been hampered by the fact that no model exists that accurately mimics IBM. Lloyd hopes that development of a mouse model will allow progress to be made toward developing a cure for IBM and other myositis diseases.

Iago Pinal-Fernandez, MD, PhD was awarded a grant to support his post-doctoral fellowship training at the National Institutes of Health. Under the direction of TMA medical advisor Andrew Mammen, MD, PhD, Pinal-Fernandez proposes to analyze specific substances that produce inflammation

A grant was awarded to **Janine Lamb, MD, PhD**, a myositis researcher at the University of Manchester in Oxford, England. Because myositis is thought to be associated with environmental triggers, such as infection, Lamb is looking for evidence of past or current microbial infections in the blood of

TMA medical advisor **Thomas Lloyd, MD, PhD** is also the recipient of a research award. A researcher, clinician, and faculty member at the Johns Hopkins Myositis Center, Lloyd has been working for some time to develop a mouse model for IBM. Research into the cause of this progressive,

TMA: Reliable and credible source of all information myositis

Whether you are newly diagnosed or have been living with myositis for years, The Myositis Association remains your most credible source of information about myositis. TMA makes available to patients, caregivers, and the physician community information about the latest research, current treatments, diagnostic tools, and progress toward a future cure. Utilizing the expertise of its 20-member Medical Advisory Board consisting of neurologists, rheumatologists, dermatologists, and rehab specialists, TMA makes sure the information shared with the public and the myositis research community is accurate and up to date.

TMA's list of Frequently Asked Questions (FAQs) (www.myositis.org/learn-about-myositis/faqs) provides reliable and current information. It has recently been updated, providing more extensive responses to some of the most frequently asked

questions we receive. Among these is a comprehensive description of the current understanding of autoantibodies and what they mean for the different forms of myositis. There is also an extensive set of resources for finding a physician who understands and can treat myositis, as well as articles on antisynthetase syndrome, exercise, dysphagia, and more.

TMA's channel on YouTube (available through a link at the bottom of any page on TMA's website www.myositis.org) now offers 144 videos from TMA. Click on Playlists and you will find the videos grouped by subject matter. You can watch presentations from TMA's Medical Advisory Board members and view videos focused on Exercise, Patient Stories, Research, Support, and Nutrition and Alternative Therapies.

"If you want the most comprehensive, factual and credible information about your form of myositis, you have come to the right place when you visit The Myositis Association's resources," said Bob Goldberg, TMA Executive Director.

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Facing the future

by Nancy Harber

Nancy Harber's husband Charlie had inclusion body myositis (IBM). A registered nurse and an informal consultant, Nancy shares the wisdom she gained as Charlie's long-time caregiver with patients and caregivers struggling with the challenges of myositis. While her experience was specifically with IBM, many of her solutions apply to other forms of myositis as well.

For the first time at this year's Annual Patient Conference, TMA offered a workshop entitled "Caregivers Face the Future." The focus, as you might guess, deals with challenges you might face down the road that you need to try and prepare for.

Until now, our focus has been on trying to understand these diseases and learning to live with them in a meaningful way. As the years have passed, we've seen some positive results in the treatment for dermatomyositis and polymyositis. But with inclusion body myositis, the picture is not as rosy. Most medications have little impact on the disease, although some people do report a slowing down of the progression of symptoms.

So what does it mean for those of us living in the world of IBM? If you remember when you first learned about IBM, you discovered that this disease

has a mind of its own and affects each individual in different ways.

Until the disease is better understood and new treatment modalities are discovered, the future will probably look much like the present. Unfortunately that means those with IBM will probably experience progressive weakness, a few more challenges, and a lot more frustration. So how do we prepare for more of the same, but with less of our own strength to fight back?

Never has it been more important for patient and caregiver (especially if one is a significant other) to be open and honest with each other about what will be desirable in the future. The list of things that can be tried is long—from high tech equipment and several types of physical interventions to fewer interventions, supportive care, and only routine medications. While the decisions about these things cannot be made in a vacuum, ultimately it is the competent individual with the disease who must have the final say.

The time to make these decisions, however, is not when the crisis is upon you and something has to be done *now*. Start talking about these things when there is little pressure for an immediate resolution. Will we need to trade our two-story house for one that is more wheelchair friendly? Should a feeding tube be considered if swallowing becomes a bigger problem? Do you want to move to an assisted living facility or stay at home with additional help?

Whatever you decide is best for you, don't feel guilty. Be reasonable about your choices, and remember that only the person with the disease can determine how much fight is still there. Don't forget, however, that family caregivers have a huge investment in these decisions and need to be part of the process as you think this through.

Fortunately for many people, the needs may not be major, so the decisions will be easier. But for those who will face some major challenges, begin to talk with your caregivers now. And don't forget to involve your physician—s/he may have some new ideas you haven't thought of.

International myositis communities: Passionate about patient support

by Charlia Sanchez

Canada

When she was diagnosed with polymyositis in 2011, Heather Brown struggled with both her symptoms and the limitations they placed on her life. In the first six months after her diagnosis, she refused to visit myositis websites to learn about the disease. She eventually warmed up and connected with other patients online. When she attended TMA's 2013 Annual Patient Conference and 20th Anniversary Celebration in Louisville, Kentucky with her sister, the experience changed her life.

It was at that conference that Heather met Barb Romaniuk, who has dermatomyositis. As first-time conference attendees, the women shared many similar experiences and soon realized they were both from Alberta, Canada. The pair got together a few months later over coffee and decided they needed their own support group.

They emailed 28 TMA members who lived in Alberta and in May 2014 held their first meeting in Alberta's capital, Edmonton. Ten people attended, and the Edmonton Support Group was formed. The following month, Heather hosted a meeting at her home in Calgary where seven people attended.



MAA Conference dinner
Photo courtesy of MAA



Martin Jarry and Jay Fedosoff,
vice president Myositis Canada
Photo courtesy of Myositis Canada

"It's been great to work with Heather," Barb says. "We have a warm, friendly, and supportive group of members. Getting our group up and running has taken a surprisingly small amount of time and energy. We've grown by one or two members at each meeting."

A few years later in 2015, Myositis Canada formed, serving as an umbrella organization for local support groups that now extend to six provinces. In order to reach out to patients who may not be able to attend physical meetings, Myositis Canada hosts regular meetings via Skype.

The organization's major goals are to link the myositis community in Canada, develop a list of local doctors to whom they can refer patients, and aid in finding participants for clinical trials. They also aim to be the place where patients can go for support and education.

Martin Jarry is Awareness Champion for the Province of Quebec and a strong advocate for the myositis cause. Last year, he drove six hours from his home in Montreal to Toronto to represent both Myositis Canada and TMA at the International Congress for Neuromuscular Diseases, and he plans to be the Myositis Canada presence at the Global Conference on Myositis in Washington, DC in May.

"Participating in these kinds of conferences is a key imperative to increase awareness," says Herb Malcomson, president of Myositis Canada. "It's very close to the source of our Myopeople's journey. The highest need for us is to be available to provide support during that initial diagnosis time."

Australia

Myositis Association Australia (MAA) recently hosted their second National Conference in a lovely seaside venue about 40 miles south of Sydney. More than 90 patients and family members from across the continent attended the three-day event, which featured presentations by myositis experts, including the chair of TMA's Medical Advisory Board, Dr. Dana Ascherman.

"The best part of these conferences is that it provides a venue where people can network and learn at the same time," says Anita Chalmers, MAA's National Secretary. "Most of our attendees at this conference had not met anyone else with myositis."

Providing a way for those who live with myositis to meet others with the disease was the main reason Anita created the organization in 2002. Initially one of TMA's Keep in Touch support groups, the organization incorporated into its own group in 2007 and now includes a network of state and regional organizations from across the country.



Anita Chalmers (National Secretary, MAA) and husband Geoff
Photo courtesy of MAA

State groups usually host luncheons that feature a guest speaker, varying in frequency from once a month to twice a year, depending on how far people have to travel. Regional groups meet for chats over morning tea or lunch. Each association member receives a bimonthly newsletter that publicizes all the group meetings as well as other items, such as member stories, latest developments, helpful hints, and more.

Like TMA, Myositis Association Australia strives to be the initial point of contact for those newly diagnosed with myositis. They serve as a network for



Trevor Neumann (President, MAA) and wife Marilyn
Photo courtesy of MAA

support, provide reliable medical information, connect members with local medical specialists, and link members with relevant clinical trials. They also provide home visits for house-bound members, advocate for special-needs members, and link members to related organizations such as the Muscular Dystrophy Association.

Myositis Association Australia is already looking forward to Myositis Awareness Month in May. They're planning a major fundraising push to support three requests they've received for research funding.

"We need to continue to raise awareness of Myositis in Australia," Anita says. "The disease is not well known, so people are not inclined to support us."

The organization is considering collaborating with other autoimmune groups to sponsor a combined fundraising walk in each state on the same day for maximum publicity. The association is also talking to the Australian Jockey Club about organizing a race called the "Myositis Cup."

Myositis Association Australia is busy raising awareness and thinking of unique ways to appeal to and engage its members. The Australian myositis community continues to grow and remains an important international ally to TMA.

The Myositis Association is working to build global partnerships with international myositis communities. In addition to Myositis Canada (www.myositis.ca) and Myositis Association Australia (www.myositis.org.au), the global myositis network includes organizations in the United Kingdom (www.myositis.org.uk), France (www.facebook.com/groupegimi.fr), Sweden (Stockholm), and Germany.

Getting the VA benefits you deserve

by John McClun

Like many of you, I served my country quietly. As a Vietnam-era veteran, I did my time in that faraway country and returned home untouched physically, but affected nonetheless. I took advantage of some of the Veterans Administration benefits like education and guaranteed home loans. But, as many of us found out, I had no medical benefits because I had no “service-connected disability.” At the time, I really didn’t need medical support, so I continued to work, take care of my family, and live my life.

Then IT happened. I heard that word we’ve all come to know so well: myositis. At first the doctors thought it was polymyositis, but then they discovered I had inclusion body myositis. It doesn’t matter: myositis is devastating to your body, and it’s incurable.

As I became more and more hampered by the disease, I turned to the VA for help with the needs I knew would be beyond my capabilities and my insurance company to provide. But as a middle-income adult, I made too much to qualify for VA medical support without paying full cost. And I didn’t have a “service connected disability,” the VA’s catch phrase for providing care to veterans whose health was affected while serving on active duty.

So, like many other vets, I fell into what the VA calls “Priority Group 8,” an honorably discharged veteran who can pay for the care that the VA provides. Then I found out about the “catastrophic disability” rating for veterans at one of TMA’s Annual Patient Conferences. It was at a seminar led by Ray Lesoine that I found out that you don’t have to have a service-related disability to qualify for catastrophic disability.

The VA defines a catastrophically disabled veteran as “a veteran who has a permanent, severely disabling injury, disorder, or disease that

compromises the ability to carry out the activities of daily living to such a degree that he/she requires personal or mechanical assistance to leave home or bed, or requires constant supervision to avoid physical harm to self or others.” (statement from VHA Directive 2010-054 – www.nasvh.org/Conferences/2014WinterHandouts/VHA-Dir-2010-054.pdf)

Catastrophic disability is measured against either the Katz or Functional Independence Measurement scales. Both scales measure how well you perform normal daily activities, such as dressing, toileting, bathing, eating, and mobility. You may qualify with either polymyositis, dermatomyositis, or inclusion body myositis, as long as you meet the requirements.

This rating designates you as “Priority Group 4” and exempts you from copayments for hospital care, outpatient medical care, and medications. Often, however, a Veteran Service Officer may not know how to proceed with a catastrophically disabled application, as they rarely encounter this type of request.

The most important form when applying for these benefits is the VHA form 10-0383, which is the basic form you will need to have a VA clinician, physical therapist, or hospital clinician fill out.



John McClun at dedication ceremony for veterans memorial in Williston, FL on November 11, 2015
Photo by Bonnie McClun

Once a physical therapist rates you as not able to accomplish the activities of daily living (ADL) or instrumental activities of daily living (IADL), you will be reclassified to Priority Group 4, unless you rate higher because of another condition.

All Priority Group 4 veterans are also eligible for veteran-directed care, which allows the VA to pay your partner or anyone you choose for your care. Paying your partner for your care is worth several thousands of dollars per year. This is an excellent choice if you and your spouse have been using your savings to help cover your medical needs.

Once in veteran-directed care, you will be given a flexible budget to spend on items such as home health care (including paying your spouse to care for you), getting help with meals or medicine, transportation for social activities, and a host of other needs. As a Priority Group 4 veteran, the VA will also provide support for housing modification, durable medical equipment, and assistance with vehicle modification.

My path to Priority Group 4 rating started with a call to 1-877-222-VETS (8387) to discuss what forms I needed to file for this qualification. On this call, I asked how I could apply for the Priority Group

4, Catastrophically Disabled rating. Of course, I was asked all the usual questions: when did I serve, was I honorably discharged, did I have a “service connected disability,” what classification did I have? I also had several questions of my own: what would a Priority Group 4 rating get me, how long does it take, and how much would I receive?

After learning everything they could tell me, I researched all I could find. I did not apply on the telephone but instead visited my VA eligibility clerk at my local VA Medical Center. I would encourage others to do this as well, unless you live too far away. You will want to be known as a person rather than just a telephone number.

I hope this information makes it easier for you to file for VA medical benefits. We certainly don’t deserve to suffer with this terrible disease, but we do deserve the benefits for having served our great country. The VA will provide you and your care partner with excellent care, regardless of what you’ve heard on the news. Be persistent and you will get the benefits you deserve.

For more information and a link to the necessary forms, go to <http://helpdesk.vetsfirst.org/index.php?pg=kb.page&id=2198>

TMA FAQs

My insurance won’t pay for the drug my doctor prescribed. What are my options?

Gaining access to new or unconventional treatments is an ongoing problem for people with any chronic disease. Health insurance companies typically publish a “formulary” that lists the drugs, both generic and brand name, that your plan will cover. Prescription formularies are developed based on efficacy, safety, and cost-effectiveness of the medications. Drugs listed in the formulary are known as “preferred” drugs; those not listed are referred to as “non-preferred” drugs. When your doctor orders a medication that is not listed in the formulary, the insurance company may deny coverage for this medication. This can be frustrating for both your doctor and you. Always remember that you have the right to appeal your insurer’s decision. TMA advocates for its members who need specialty drugs by supporting patients’ rights legislation and offering guidance on how to navigate this dilemma. TMA’s FAQ page offers guidelines and resources for dealing with insurance company denials and many other questions at www.myositis.org/learn-about-myositis/faqs.



Nutrition for inflammatory disease

Many TMA members find that they feel better when they pay attention to what they eat. But some folks are confused when we suggest that they try to “boost” their immune system through diet. They are taking immune suppressant medications, such as prednisone, after all, which are designed to depress the body’s immune response. Wouldn’t making the immune system stronger only make their disease worse?

The muscle weakness, skin rash, and other symptoms of myositis are the result of an overactive immune system that causes chronic inflammation. Many myositis patients find that eating a diet that reduces inflammation improves their disease and even helps them decrease or get off of immunosuppressant medications.

TMA board member and DM patient Dr. Renee Lantner presented an evidence-based discussion of food and inflammation at the 2016 Annual Patient Conference, so we asked her to share some of her favorite “anti-inflammatory” recipes.

Quinoa Pilaf

Quinoa (keen-wah) is a versatile and nutritious grain, high in protein, gluten-free, and easy to digest.

- 1 cup of dry quinoa, rinsed and drained in a fine-mesh sieve
- 2 cups water or broth
- 1 cup cooked chicken, turkey, or tuna chunks
- 1 cup or more of chopped or sliced carrots, zucchini, green beans, broccoli, and/or cauliflower
- 1 teaspoon salt
- 1-3 teaspoons Italian herb mix
- 1-2 tablespoons of olive oil
- 1 sliced avocado as garnish

Bring quinoa and liquid to a boil and reduce to a simmer for about 15 minutes. Keep your eye on it to make sure it does not dry out before it is cooked. You may need to add more liquid. It will be cooked when a white ring appears in the individual grains and the liquid is all absorbed.

Stir in the next five ingredients. Garnish with avocado slices and serve.





Quick and Easy Bean Dish

Good for vegans, vegetarians, those on dysphagia diets
Serves 4-6

2-3 cans any beans (kidney, pinto, black, garbanzo),
rinsed and drained

1 large or 2 small cans of diced tomatoes, low-salt
preferred, not drained

1 tablespoon each of cinnamon, coriander, cocoa powder,
and cumin (okay to leave some out, flavor will just
be different)

1 tablespoon tomato paste, optional

1 teaspoon garlic or onion powder, optional

½ -1 teaspoon black pepper, optional

1 teaspoon salt (omit if on low-sodium diet)

Shredded cheese, such as cheddar or Mexican blend, optional can use low-sodium version,
vegans can use non-dairy cheese.

Cooked rice or noodles, optional.

Mix all ingredients except the cheese and rice or noodles in a medium to large pot and bring to simmer on
medium heat. Meanwhile, prepare rice or noodles. Once beans are heated, ladle over rice or noodles and
top with cheese, if desired. This freezes and reheats very well.

Easy Broiled Salmon Fillets

Salmon is one of the healthiest fish due to its high content of
omega-3 fatty acids and vitamin D. Choose US-farmed Atlantic,
Alaska, or wild-caught salmon or Arctic char; *avoid* farm-raised
Atlantic fish from Chile.

6-8 ounce salmon or Arctic char fillets, one per person

Vegetable oil, such as canola

Salt, optional

Black pepper, optional

Lemon wedges, optional

Place broiler rack in oven in top position. Place broiling pan
or cast-iron skillet (ideal) on rack; if not using cast-iron, add
1 tablespoon of oil to pan and swirl to coat. Preheat broiler on
high for 5 minutes.

Meanwhile season fillets with salt and pepper, if desired. Once pan is
heated, place salmon carefully on pan, skin side down. Broil for 8 minutes
and remove from oven. Squeeze lemon juice over fish and serve.



BYM338 research report available

A number of TMA members participated in the recent clinical trial for BYM338, a human monoclonal antibody, administered by injection, whose generic name is bimagrumab. Developed by Novartis Pharmaceuticals to treat pathological muscle loss and weakness, the experimental drug was given “breakthrough” status for treatment of sporadic inclusion body myositis by the Food and Drug Administration, a designation that put it on a fast-track through the FDA’s development and regulatory review process.

The designation also inspired a great deal of hope in the myositis patient community that a treatment for sIBM was finally at hand.

Unfortunately, last year, TMA received word that Novartis had terminated the trial, citing lack of clinical evidence to support its continuation. While some participants claimed they did experience benefits from the treatment—feeling stronger, better able to stand up from a chair, stronger grip—the data collected by researchers related to muscle strength and physical function did not meet the study’s primary clinical endpoint.

According to a statement from the company, “There was no statistically significant or numerically consistent difference between bimagrumab treatment and placebo in measurements related to muscle function, including the 6-minute walking test (6MWT), quadriceps quantitative muscle testing (QMT), hand grip strength, or pinch grip strength.”



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A report on the study was released in November at the annual meeting of the American College of Rheumatology. You can read the report here: <http://acrabstracts.org/abstract/a-randomized-double-blind-placebo-controlled-study-of-bimagrumab-in-patients-with-sporadic-inclusion-body-myositis/>.

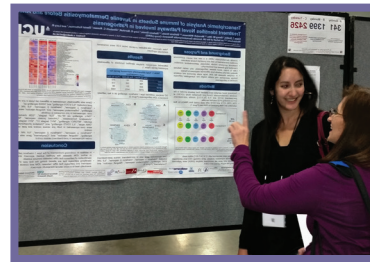
TMA spoke with researchers involved in the clinical trial at the ACR meeting. They remain hopeful that the drug might still benefit patients with IBM. Novartis continues to study uses for the drug, such as to aid healing in older adults after hip surgery and for those with sarcopenia, a muscle wasting disease in the elderly. If bimagrumab is approved for these diseases, it may be possible for physicians to also prescribe it “off label” for patients with sIBM. TMA will continue to track the progress of this research and report the findings.

AAV1-FS344 is granted “Orphan Drug” designation by FDA

Milo Biotechnology announced in October that the FDA has granted Orphan Drug designation for their product AAV1-FS344 for the treatment of inclusion body myositis. This special designation provides incentives for pharmaceutical companies to invest in the research and development needed to bring promising drugs and biologics to the market, despite the likelihood that they will not bring large profits.

AAV1-FS344 is a gene therapy-delivered follistatin protein that increases muscle strength and function. It has been shown to improve walking ability in patients with Becker muscular dystrophy. It is currently in a Phase I/II trial at Nationwide Children’s Hospital in Columbus, Ohio for adult patients with sporadic inclusion body myositis, clinical work that was funded in part by TMA. Initial data from this early trial was promising, and the company plans to move forward with a multi-center clinical trial.

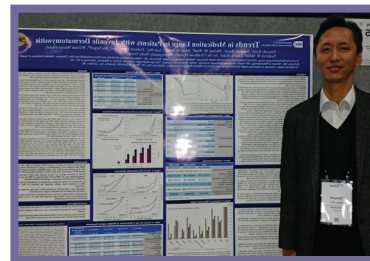
TMA grant recipients present their findings



Claire Deakin
Photo by Linda Kobert

Claire Deakin, PhD, a postdoctoral fellow at University College in London, received a TMA fellowship grant in 2015 to study genetic markers that may be

common in children with dermatomyositis. Deakin has another year to go on this project, but she presented some of her findings to date at the November 2016 meeting of the American College of Rheumatology. She has identified several pathways that are altered during the first year of treatment of JDM. Her work will continue as it investigates pathways associated with different clinical courses.



Takayuki Kishi
Photo by Linda Kobert

Takayuki Kishi, MD, PhD of Tokyo Women’s Medical University Hospital, Tokyo, Japan also received a TMA fellowship grant in 2014 to identify treatment trends for patients

with juvenile dermatomyositis. He’s trying to identify patient response to various treatments in order to understand what therapies are most successful. Kishi too presented findings from this research at the November 2016 meeting of the American College of Rheumatology, which took place in Washington, DC. According to his study, prednisone continues to be the mainstay of therapy for treating JDM, and the use of corticosteroid-sparing treatments, such as methotrexate and intravenous immunoglobulin, has increased over the last two decades.



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CONFERENCE FEES

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Refund Policy: Refund requests for TMA registration fees received in writing by July 24 will be issued a full refund; requests received after July 24 and by August 21 will be issued a 50% refund. No refunds after August 21.

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