

THE NDB Research NEWSLETTER

News for Participants in the National Data Bank for Rheumatic Diseases January 2008

Notes from the Director

The NDB begins its 11th year

With your help this project has been the most productive in rheumatology history in terms of publications for rheumatologists and guidance for regulatory agencies like the FDA. You may not know this, but we have also contributed data that is helping to identify genes that increase the risk of developing illnesses like RA. Sometime next year we will tell you more about an additional genetic study that we will be starting. These are exciting times.

About Lupus and Fibromyalgia

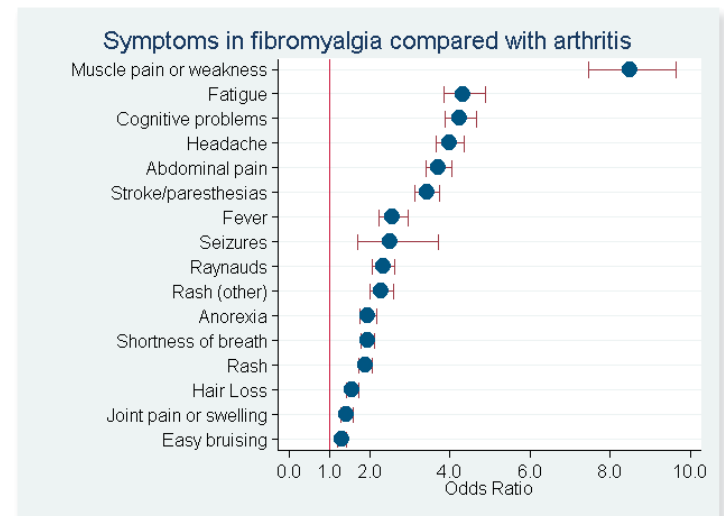
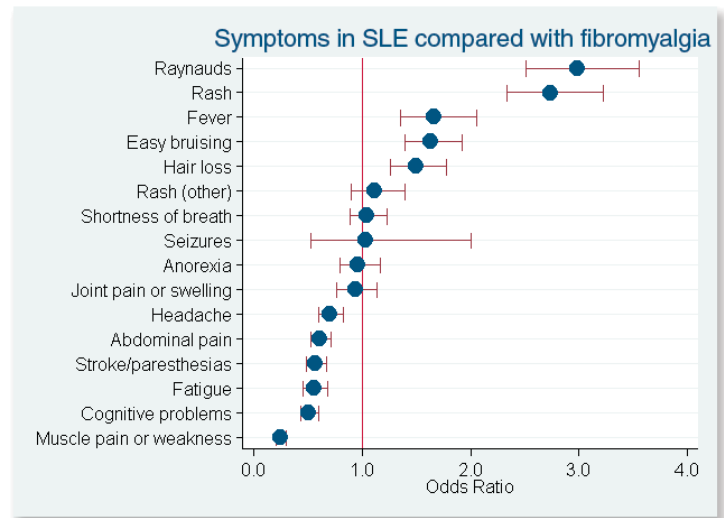
These illnesses are very different, yet have some important features in common. The main features of fibromyalgia are pain over large areas of the body, fatigue, problems with sleep and problems with memory and thinking. People with lupus also have these symptoms, but they also have rashes, kidney problems and laboratory abnormalities, and many other problems. But not all people with lupus have all of the features. You can understand why sometimes doctors have difficulty in distinguishing lupus from fibromyalgia. To make things even more difficult, lupus and fibromyalgia can coexist. And these symptoms exist in other conditions, too. So what's up?

In our previous newsletter we told you the NDB had a lupus data bank. We took the answers to our questions from people with lupus, fibromyalgia, and arthritis to try to sort out the differences between these diseases. Here are some of the results. The first graph (top) compares symptoms in lupus and fibromyalgia. To understand this graph you should know this: The odds ratio on the bottom is a measure of how much more likely it is to have a symptom (listed on the left) if you have fibromyalgia compared with if you have some form of lupus. To the left of the red vertical line (at 1.0) the chances are greater that a symptom exists in fibromyalgia. To the right chances are greater in lupus.

People with lupus have more problems with their hands and fingers turning blue or white (Raynauds), rashes, fever, bruising, and hair loss. By contrast people with fibromyalgia have more headaches, abdominal pain, numbness, fatigue and muscle pain.

So how do those of you with fibromyalgia differ from those of you with arthritis? The next graph (bottom) offers some insight.

In this chart, fibromyalgia is to the right of the 1.0 line, and arthritis is to the left. For example, the



odds of having muscle pain or weakness is nine times greater if you have fibromyalgia than if you have arthritis. From the graph you can see that people with fibromyalgia generally have more symptoms than people with arthritis. But the symptoms that are particularly more common in fibromyalgia are muscle pain and weakness, fatigue, problem with memory or thinking, headaches, abdominal pain and numbness or tingling.

These graphs are a part of a study of lupus and fibromyalgia symptoms that the NDB has just submitted for publication. We thought you might be interested because they make it easier to see lupus and fibromyalgia symptoms in comparison.

Notes from the Director (continued)

What is Remission?

In recent years rheumatologists have become interested in something called remission, or when an illness goes away. You may have heard the term used about cancer. It's a simple concept, but it is not always easy to define or identify. Rheumatologists want to measure it because they want to know if new treatments are effective enough to cause remission.

Here is one of the problems. Some studies of rheumatoid arthritis indicate that 35% of

Rheumatologists want to measure remission because they want to know if new treatments are effective enough to cause it.

people who receive new biologic drugs go into remission. Other studies indicate that the remission percentage is closer to 10%. Why the great difference? The major reason is that it all depends how you define remission. And doctors simply don't agree. A committee of the American College of Rheumatology (ACR) decided to try to establish criteria for remission that all rheumatologists will agree on. The committee asked the NDB if we would ask you and your doctors about remission, and we agreed.

In the current questionnaire we ask people with rheumatoid arthritis if they can tell if they are in remission, and then we will see whether their assessment agrees with their doctor's assessment. It is a pretty important question that will help us better evaluate arthritis results.

We need your help with this. Here are the instructions: There is an extra page in the questionnaire this time—the remission page. This is for the paper questionnaire only—there is no remission page on the WebQuest. What we would like you to do is to fill out the single page on the day you are scheduled to go to see your rheumatologist. When you get there please ask

your rheumatologist to fill out the other side without looking at your answers, and then mail the questionnaire back to us in a self addressed envelope that we have enclosed. We'll tell you how it all comes out next time.

For WebQuest users we have another special page. We are testing a new version of the HAQ, or Health Assessment Questionnaire. You will see this page as an option as you complete your web questionnaire. It is optional, but we hope you'll have a couple of minutes for it. The test form has only 24 pretty easy questions.

Would you tell us...?

At the end of each questionnaire there is a place for your comments. We really read them and we respond to many of the comments. So we want you to keep writing to us. I'd particularly like to ask you to tell us about problems that are important to you that we are not asking about. What would you like your doctors to know? How could the medical system be improved for you?

Some new medications

Lyrica is a new treatment that was just approved by the Food and Drug Administration for fibromyalgia. Overall, people who took this drug in the clinical trials improved by about 20%. The results in clinical trials are often different from what is seen in real life. So we will be monitoring use of this drug in the NDB, and we will report soon on benefits and risks that we see.

A large number of clinical trials of lupus treatments are underway, and two or three new biologic treatments for RA might be approved as early as late 2008. We'll report on these therapies in more detail next time.

Helping the NDB in other ways

Achieving the NDB's goals of telling the rheumatology community about patient experience depends on a large group of participants. Here is one way you can help.

Now available for your support group or arthritis, fibromyalgia or lupus meetings....Our pamphlets explain what we do. Each one has a postage-paid postcard to request more information or an enrollment form to join the project. The pamphlets and a small table-top stand are available free from the NDB. Just contact us at webquest@arthritis-research.org or 800-323-5871 ext. 133 or 140. Thank you!



LATEST RESEARCH

Dryness symptoms increased in RA

Eye and mouth dryness conditions affect those who suffer from it in severity ranging from annoying to very painful and debilitating. While simply getting older increases your chance of having dryness symptoms, there may be other causes that are related to rheumatoid arthritis and similar disorders. We decided to investigate whether RA has a role in eye and mouth dryness.

You probably remember our survey questions about eye problems and whether those problems are related to RA. We studied dryness symptoms in NDB participants, and found symptoms to be increased in people with RA. Symptoms also increase with age, and they are associated with certain medications. The severity of one's illness—even non-inflammatory illnesses—is an important predictor of dryness symptoms, as is having fibromyalgia or simply symptoms common to fibromyalgia.

Of those in this study group, some of you had ongoing dryness, and others experienced the symptoms sporadically. We found that RA meant a 33% increased risk for sporadic dryness and a 46% increase for persistent dryness.

Sjögren's syndrome is an auto-immune disease (like RA) that directly attacks tear and saliva glands. Sjögren's is also associated with RA, so we needed make sure we weren't just looking at

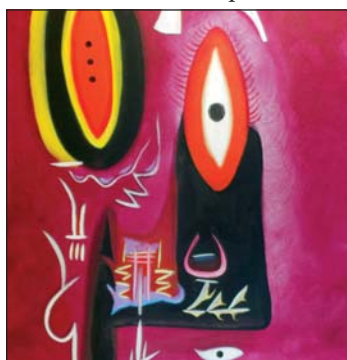
Sjögren's. We found only about 25% of RA patients with dryness symptoms also had Sjögren's syndrome. This shows that RA itself is independently associated with dryness.

A number of arthritis-related medications list dryness as a side effect. We confirmed this in our study. The treatments include pain relievers, anti-anxiety medications, anti-depressants, sleeping medications, some stomach pain treatments, diuretics, and anti-hypertensives.

One interesting finding is that disease activity or severity contributes to dryness symptoms. The more severe the disease, the greater risk of dryness. This was true even with non-inflammatory rheumatic diseases, like osteoarthritis. In addition, dryness is more common in those who have had total joint replacements, work disability or other severe effects because of their conditions. So, it appears that illness severity, or some unknown effects of illness severity, rather than RA alone

is the important association with dryness symptoms.

In summary, using your answers to the questionnaires, we found that dryness is increased in RA and that the risk of dryness is increased by illness severity and some treatments. Any factor that increases illness severity or distress, including fatigue and body pain, results in an increase in dryness.



Detail from "Dry Eye Syndrome" by Brian Fey.

Welcome New Participants!

Everyone who works for the NDB and all of the doctors and researchers who benefit from our research are extremely grateful for the dedication of you, the participants, to helping this project. Many of you have been with us for several years or more. But every 6 months we are also glad to see many new people join us. Here is a quick primer on the NDB for the new and a refresher for the old timers.

The NDB is a non-profit organization that performs research in rheumatoid arthritis, osteoarthritis, fibromyalgia, lupus and other rheumatic diseases. The research is designed to improve the treatment and outcomes of these conditions.

The NDB is an independent organization that conducts its own research without influence from pharmaceutical, insurance, financial or other outside interests. Our

research is so well respected that we are often hired to provide independent drug safety verification to the government.

Your personal information will always remain private. We do not sell or share any identifying information about NDB participants. Before we work with researchers or collaborate with other research groups we remove any of your answers that could be used to identify you.

Nearly all of our research is available for you to read on our website.

We are glad to answer your general questions about rheumatic diseases and treatments, but we are not able to give personal medical advice.

NDB research is different in an important way: Participants report on themselves;

data is not collected by doctors or medical staff. With patient-reported data, researchers get a perspective that short, small clinical trials can not provide. Our long-term study offers a much broader view of treatment and results. Clinical trials are good at identifying common side effects, but rare or subtle problems, or problems that take longer to develop, are better detected by studies like the NDB. The same is true of long-term effectiveness of a treatment.

So, welcome to the NDB, or thanks again for your continuing participation! If you ever have any questions or need help with your questionnaire, feel free to contact us.

LATEST RESEARCH

A Little Weight Loss Can Greatly Reduce Knee Pain

This comes to us from the Missouri Arthritis Rehabilitation Research and Training Center (MARRTC). It was written by Ferdous Al-Faruque, MARRTC Staff. You can learn more about MARRTC at <http://marrtc.missouri.edu/>.

Losing 15 pounds could alleviate knee pain in people with knee osteoarthritis by 50 percent, finds a new study by Johns Hopkins University. "That was really surprising to us," said Susan Bartlett, principal investigator and an associate professor of medicine at Johns Hopkins. "We thought that weight loss would be helpful, we certainly thought that it would take more than 15 pounds to have an improvement of 50 percent, because even our best drugs only reduce pain by about 30 percent."

People in the study were middle-aged adults and mostly women. Participants had knee osteoarthritis and were either overweight or obese. They were asked to gradually add 30 minutes of walking to their daily routine or take a total of 10,000 steps a day.

"We encouraged them to break that into small bouts of walking, so rather than go out and walk for 30 minutes, we really encouraged them to do more of what is known as lifestyle exercise," said Bartlett. "Park further in a parking lot and walk a couple of extra minutes in to work in the

morning or walk a couple of extra minutes out at the end of the day."

She said that it was important to break up the walking into small episodes to prevent excessive pressure on their knees.

"They could walk 10 minutes three times a day or walk for five minutes six times a day, however they wanted to do it," said Bartlett. "Most of them just looked for creative ways during the day to be active."

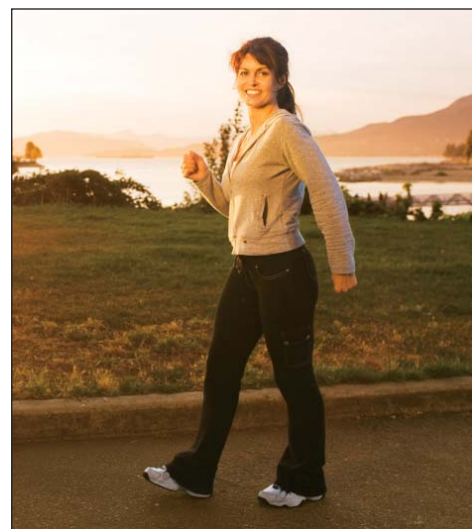
After four months in the study, participants lost an average of 15 pounds or 7.3 percent of their starting weight.

After one year, researchers checked the progress of the participants. They found that 20 percent of the participants lost more weight, but 46 percent had regained weight.

"Even with weight regain, they were still enjoying many of the benefits," said Bartlett. "Their pain was still 30 percent less than at the baseline, and their ability to function was 40 percent better even with the weight regain."

She added the results of this research were good news for doctors and patients.

"It's a very new message for physicians and for their patients to be able to say, everything helps," Bartlett said. "You'll



see improvements with the first 5 pounds, you'll see more improvements with 10 pounds, and by the time you've lost 15 pounds, you're able to help your knees much better than any medication I can give you."

Bartlett says reducing that pain is easy and inexpensive.

"Get yourself a pedometer, it's only about \$10, work up slowly over a few weeks or months to 10,000 steps," she advises people with knee osteoarthritis. "It's a great way to improve your health, reduce the pain that you have from your arthritis, and enjoy the benefits without having to go to a gym, buy a membership, or wear special clothing."

Lottery Winners!

Return your research questionnaire within two weeks of receiving it and be eligible for one of three \$1,000 awards. The research data bank can best contribute to research when the questionnaires are completed and returned as soon as possible. Anyone who completes the questionnaire within two weeks of receiving it will be eligible for the award – given as a token of our gratitude in help with rheumatology research. The \$1,000 winners from the last questionnaire were Elizabeth Bucknam, Williamstown, NJ; Mary Bauman, St. Joseph, MO; George Kent, Riverside, RI. Winning smaller amounts were June Hegland, Saint Louis Park, MN; Mary Ann Wilichowski, Marathon, WI; Warren Bissell, Simpson, KS. Congratulations to all!

Meet the Participants

CREST Syndrome, or Limited Scleroderma as it is also called, is a rheumatic disease with a mix of conditions whose symptoms can be mild or severe. Jean Harrison, an NDB participant, shares her experience with CREST in a new edition of Meet the Participants.

If you are interested in sharing your story with the NDB community, please contact us.

Meet the Participants: Jean Harrison

When my rheumatologist diagnosed CREST, my first thought was “What on earth is that?” He explained that each letter stood for a different arthritic disease and that I may not have any of them as bad as one could be.

I am 75 years young and was diagnosed with osteoarthritis when I was in my early fifties. It was 1989 when my doctor said that I had CREST, also. He explained this to me, and I searched other places for information, which was hard to find. Finally, I got a computer and I searched all over for info, which is on lots of medical sites.

I asked the doctor how long before I might be unable to get out and about. He said I should have at least ten years. My husband and I decided that if that was the case, we would make the most of those ten years. In 1990, we took a four week tour of Europe. I retired in 1992. The next few years we traveled all over the USA by car, including Alaska. Oh, how I wish we could still travel!

Well, the ten year prediction hasn't come to pass, for which I am so thankful to God. It has been eighteen years since the diagnosis. My husband has Parkinson's, and I help him as much as possible, aided by some part time help for him.

I grew up in South Carolina and have lived in North Carolina since 1966. The rheumatologist that I see is 40 miles away, and I drive there alone and sometimes with others. This gives me opportunities to also do some shopping and maybe eat out. I do the grocery shopping, go to club meetings and we visit with friends and family.

About five years ago, I found out that a friend had CREST also. She and I do not know anyone else that has it so we get together frequently and compare symptoms and talk about living with it. This has brought us closer together. She seems to have it worse than I do even though I was diagnosed before her. On top of that, she has other serious illnesses which add to her problems.

Several years ago, I received an invitation from the NDB to participate in filling out a questionnaire pertaining to arthritis. It is interesting to read the questions pertaining to my arthritis and I enjoy filling in the answers and seeing how things change from time to time. So, when I got an email asking if anyone would care to write an article, I thought “Why not, it may be fun.” It feels good to write my thoughts.

Here is some basic information about CREST, and how it has affected me.

C - Calcinosis: Deposits of calcium under the skin of the fingers and body. I get sores (ulcers) on finger joints, These can be quite painful and if I hit them on something, it really hurts. In the sores, there is calcium, which looks like pus.

R - Raynaud's Phenomenon: This and the calcinosis sores bother me most of all. The blood vessels react to cold and stress. The fingers turn white and cold. I do whatever I can to warm them. While warming, they gradually they turn purple, then pink. I try to keep my hands warm with gloves and avoid handling cold items. My husband goes into the freezer for me, and I wear gloves in the grocery store.

E - Esophageal dysfunction: Difficulty in swallowing, acid reflux. This calls for a prescription antacid. I have not had to raise the head of my bed, which is one way to relieve this symptom.

S - Sclerodactyly: The most dreaded (for me) of all the problems associated with CREST is tightening and hardening of the skin on the fingers. This is the hallmark of the disease called scleroderma. My fingers are all bent, some to the side and some toward the palm. I cannot make a fist. My fingers are fat and tight. I have been told that my fingers look like sausages!

C, R & S all cause problems with some housework. It is painful to do yard work. It is difficult to lift heavy items. Thankfully, I can drive, but after a while the fingers, hands and arms do start hurting.

T - Telangiectasia: Red spots on fingers, palms, face and inside the mouth. The ones on my hands come and go but the ones on my face stay there.

Having at least two of the CREST conditions is usually enough to make the diagnosis.

Important Information about Email

For patients using WebQuest, email is our primary method of getting in touch with you. Even if you're not using WebQuest, we'd like to be able to send you important information by email.

We cannot emphasize enough how important it is for you to let us know whenever you change your email address. To update your email address go to our website and look in the participant's links, or call us.

Here's a VERY IMPORTANT step you can take to make sure our email gets to you: Add us to your email address book. Our address is webquest@arthritis-research.org. This will ensure that our mail makes it through the spam blockers. You will need to do this every time you change your email address. Thank you!



Questionnaire changes

As mentioned in the Director's Notes, many of you will get a new page on remission in your paper questionnaire. Please pay careful attention to the instructions. WebQuest users will not get the remission page.

Most WebQuest users will have an optional page called the PROMIS Health Assessment Questionnaire. You will recognize most of the questions, but there are some minor differences. We're trying to assess whether this version works as well as the version we have been using.

WebQuest users may also notice some improvements to the graphical layout of the questions. We hope these changes make the questionnaire a bit easier for you.

Reminders

While working on your questionnaire, if you have ANY questions about the questionnaire, please contact us right away by email or phone. These might be about technical difficulties or how to interpret a question. If you put your immediate questions in the comments section we probably won't see it in time to answer.



WebQuest

WebQuest is the online version of the questionnaire. The questions are the same as those you get on the paper questionnaire. People who are comfortable using computers should find it easier than the paper version. If you would like to try it, follow the links from our home page, www.arthritis-research.org and make the request, or send us an email at webquest@arthritis-research.org



Refer a Friend

Here's a really easy way to let a friend know about the NDB. Just give us your friend's email address and we'll send out an email invitation to join the study. Go to <http://www.arthritis-research.org/enrollfriend.htm>

FOR MORE INFORMATION OR TO PARTICIPATE

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