University of Pittsburgh & UPMC

Scleroderma Center NEWS

Summer 2011

What is Localized Scleroderma ?

by Kathryn Torok, MD

The term scleroderma literally means hardening (skleros) of the skin (derma). "Scleroderma" encompasses both forms of the disease: systemic sclerosis (SSc) and localized scleroderma (LS). Unlike SSc, LS is more commonly found in children. Also unlike SSc, LS does not affect the internal organs or blood vessels, but affects the skin and underlying layers of tissue. The most frequent age of onset of LS is school age, around eight years old. However, LS can be found in children as young as infants and also in adults. It usually takes about a year or two from the time a child first experiences symptoms to when they are seen at the Scleroderma Clinic. At times the skin changes are mistaken for bruises which do not resolve or other conditions which cause discoloration of the skin. The diagnosis of LS is typically made when a child is referred to a dermatologist. As with any progressive disease, the earlier a child begins treatment the better.

Types of Localized Scleroderma

There are four main types of LS: plaque morphea, generalized morphea, deep morphea, and linear scleroderma.

-*Plaque morphea*: This is the most common subtype in adults with LS. A patient with plaque morphea usually has one or two affected areas (lesions) at a time. They can be thick "like alligator skin" in the center with white or yellow discoloration, and have darker colored (brown) borders. When the disease is "active", the lesion can have a red or purple border around it. The skin can also become thin, and veins become more visible with skin thinning.

-*Generalized morphea*: Generalized morphea indicates many plaque morphea lesions on multiple parts of the body, including the chest, abdomen, back, arms and legs.

Deep morphea: Deep morphea affects the lower layers of the skin and the underlying fat (subcutaneous tissue) with the overlying skin being normal. It may be subtle to detect. The lesions look 'scooped out' as the fat underneath the skin weakens and degenerates. Lesions can look like a "divot" or a large dimple.

-*Linear scleroderma*: This is the most common type of LS in children, and unfortunately can have the greatest impact beyond the skin, affecting joints and other underlying tissues. The skin is abnormal in a linear fashion (in a line) and these lesions can affect an arm, leg and/or the face/scalp. When linear scleroderma affects a limb (arm or leg) in a child who is not yet fully grown, the limb can become smaller and shorter than the opposite (unaffected) side. When the linear lesion crosses over a joint it may restrict the motion of the joint (called a "contracture"). Joint contractures require physical therapy and medications to maintain or improve joint motion. When linear scleroderma affects the face or scalp, it is called "en coup de sabre" (meaning like the cut of a sword) or Parry Romberg Syndrome. Oftentimes,

Continued on Page 2...

Kathryn Torok, MD began her career in Pediatric Rheumatology as a Fellow at the Children's Hospital of Pittsburgh (CHP) in 2006. Upon completion of her fellowship, she stayed at Children's and became an Assistant Professor. She helped develop and now serves as director of the CHP Scleroderma Clinic which provides treatment for children with localized scleroderma (LS) and systemic sclerosis (SSc). Along with treating patients, Dr. Torok has been involved in numerous research projects. She is the principal investigator of the National Registry for Childhood Onset Scleroderma, which serves as a national resource of longitudinal data on pediatric patients with this disease. In addition she is involved in the Childhood Arthritis and Rheumatic Disease Research Alliance Network (CARRANet), a North American organization of pediatric rheumatologists who are committed to advancing the health and quality of life of children living with rheumatic diseases and arthritis including the various forms of scleroderma. Dr. Torok has initiated and participated in a number of studies to further evaluate disease activity measurement in pediatric LS. Currently, her main research interest is the study of proteins (cytokines) which are produced by lymphocytes in the skin of patients with LS. Her long-term research goal is to provide better treatment options for LS by targeting cytokines and other factors associated with the active phase of the disease, to minimize or prevent long-term tissue damage. Ideas for effective anti-cytokine therapies for LS may result from this work, changing the way clinicians treat this disease and potentially saving children from life-long physical and emotional disability.

IN THIS ISSUE

What is Localized Scleroderma.....1
Profile on Kathryn Torok, MD.....1
Walk with Tori.....2
Advisory Group Member Profile.....3
Ongoing Studies and Clinical Trials.....4
Research Advances in 2010.....5
Ask the Expert.....6
Donor Acknowledgments.....7
Name the Newsletter Contest.....8
Faculty and Staff Members.....8

children experience hair loss along the lesion and in some cases, facial deformity.

Phases of Localized Scleroderma

There are two phases of LS, an active phase and a damage phase. In the active phase, lesions are very inflamed and can be red or warm. New lesions develop and existing lesions become larger. The amount of time that areas are affected and the severity of inflammation are felt to contribute the most to damage and disability in LS. Initiating treatment during the active phase of the disease is extremely beneficial and can lessen the extent of the damage phase. During the damage phase, the affected skin can become thick, hard, and discolored. This usually causes skin and underlying tissues to weaken and degenerate (fat, muscle, tendons and even bone). This can cause significant deformity and severe functional impairment in actively growing children.

Diagnosis

LS is usually diagnosed by a dermatologist or a rheumatologist who is familiar with the typical appearance of the skin changes. However, a skin biopsy may be needed in some cases. Biopsies show both excessive amounts of collagen, the substance responsible for thickening, and activated immune system cells such as lymphocytes, which are not normally found in the skin. At the Scleroderma Clinic, patients have blood drawn, which is assessed for certain types of antibodies associated with LS, along with other markers of disease activity.

Treatment

Patients with only one plaque (lesion) are sometimes treated with topical medications (lotions or ointments rubbed directly onto the affected skin), typically a cortisone containing cream. Patients with multiple morphea lesions or linear scleroderma usually require systemic medication. These include cortisone by mouth (like prednisone), methotrexate, and other medications which help "calm down" the overactive immune system. Overall, children tolerate the medications well. Systemic treatment usually stops the disease from progressing within a few months. Changes can be seen in the appearance of lesions; the skin gets softer, redness decreases, and joints move better.

Current Research on Localized Scleroderma

LS, like SSc, is considered an autoimmune disease, in which the patient's immune system mistakenly starts to attack itself. Lymphocytes relocate to the skin and are plentiful in the affected tissues in biopsy samples when viewed under a microscope and over-produce inflammatory mediators (proteins such as cytokines) which contribute to skin damage. There is little known about the exact inflammatory proteins involved in LS. Currently, Dr. Torok and the other investigators at the Scleroderma Center are researching the inflammatory molecules which are present during the active and damage phases of the disease. A better understanding of what happens in the affected tissues in LS, especially during the very early active phase, may open new avenues for more specific therapies, such as anti-cytokine agents which have been successfully used in the treatment of adult and childhood onset rheumatoid arthritis. For more information on Dr. Torok's LS studies, please contact her research coordinator Christina Kelsey at christina.kelsey@chp.edu or 412-692-6478.

Famous Quote:
"The only place success comes before work is in the dictionary."
Vince Lombardi

Walk With Tori

Tori Anderson
is a popular country radio personality at 104.7 WAYZ FM in Greencastle, PA. She is on the air Monday thru Friday from 10am to 3pm EST. You can listen to Tori online at wayz.com.

Tori is organizing a walk to benefit research at our Scleroderma Center.

Date: Sunday, September 11, 2011
Location: Doubs Woods Park, Hagerstown, Maryland
Time: Registration starts at 1 p.m. Walk begins at 3 p.m.

Tori has been a patient of Dr. Medsger since 2008. She states, "I was diagnosed with scleroderma 3 years ago, but I will not let it define who I am. I will, however, do everything I can to make sure it doesn't affect another human being."

Not only is Tori active working at the radio station and volunteering her time to fundraise for scleroderma research, she is married with 3 children, 3 grandchildren, and one on the way. She enjoys singing with the group Possum Holler and is the organist/pianist at her church.

Please support scleroderma research and "Walk with Tori". Another way you can help the cause is by donating items for a silent auction. You can receive more information regarding donations and the walk by emailing walkwithtori@gmail.com or by calling Tori or Joe Dill at 1-301-733-TORI(8674).


Virginia and Everette Curlee

Advisory Group Member Profile Virginia Curlee,"Never Give Up"

Just as each case of scleroderma is unique, so is each person it affects. One such person is Virginia Curlee. Back in the late 80s, Virginia was diagnosed with breast cancer. While undergoing chemotherapy, she knew there was something else happening inside her body. She was soon diagnosed with scleroderma. However doctors at that time were apprehensive about treating it. Their only options were still experimental and they were unsure of what the interaction would be with her chemotherapy and breast cancer.

Virginia and her husband Everette were desperate to find someone who could help her. "We saw one of her doctors in Charlotte, North Carolina in the fall of 1989 and I told him how I hated watching my wife's body being eaten up by scleroderma," Everette remembers. "He told me to give him two weeks and he'd find someone who could help." Meanwhile, during those two weeks, Virginia was at the beauty salon and happened to pick up a copy of *Family Circle* magazine while she waited. Inside, she came across an article that would change her life. The story, "Glenda Fights Back" profiled a woman with scleroderma who was being treated by Dr. Thomas Medsger. She took the magazine home and showed it to Everette. Soon after, the doctor contacted the Curlees and told them that he found a physician who was an expert in scleroderma – his name was Dr. Thomas Medsger. "When we heard Dr. Medsger's name twice in that short amount of time, I just knew we'd have to see him!" Everette explains.

They traveled to Pittsburgh from their native North Carolina in November of 1989. "Finding the right doctor is crucial," Virginia explains. "From the first time I met Dr. Medsger, he gave me hope. That's the most wonderful thing a doctor can do for someone who was in my situation." That first meeting lasted three hours, during which a treatment plan was devised for Virginia. At her next visit six months later, they found that, while her condition wasn't necessarily improving, it was no longer deteriorating. They considered this a big win, which kept her hopes high. They began returning every three months and, within the next three month period, her condition began improving. By 1997, she had almost no sign of scleroderma, aside from minor infrequent flare ups. "Dr. Medsger has done so much for people," Virginia exclaims. "He's put in so much time with us and with all of his other patients. We're so grateful!"

"I remember when I first heard the term 'scleroderma'," Everette says. "I thought, 'what in the world is THAT?' So many people aren't aware of what it is unless they know someone who has it." Everette and Virginia are doing their part in educating people about the disease and their experience with it. "Hopefully one day we'll find a cure," Virginia says. "I certainly hope in my lifetime it happens. We are hoping that people who have had family with scleroderma will help us continue the research that's currently being done by Dr. Medsger to help us find a cure."

Virginia and Everette still live in Charlotte and visit Pittsburgh – and Dr. Medsger – frequently. "We've become friends," Everette says. "Without Dr. Medsger, I truly don't think I'd have Miss Virginia here with me today." The Curlees have been married for 50 years and began their own construction company– Evco Construction Company, Inc. – in 1973. Everette and Virginia still work there, along with their two adult children, Kim and Berry. In addition, they enjoy square dancing, although work has taken up much of the time they used to have to square dance. "We still do go to the square dancing conventions each year in hosting cities across the United States.," Virginia explains. Along with their daughter Kim, the Curlees have also been instrumental in the non-profit organization Grand Square International which focuses on the promotion and preservation of square dancing as an American art form.

"Hopefully one day we'll find a cure," Virginia says. "I certainly hope in my lifetime it happens. We are hoping that people who have had family with scleroderma will help us continue the research that's currently being done by Dr. Medsger to help us find a cure."

More importantly, as for what Virginia would tell others who are diagnosed with scleroderma, she says simply, "Never give up. It is that hope, and the groundbreaking research and treatment of Dr. Medsger that will make the future bright for those with scleroderma."

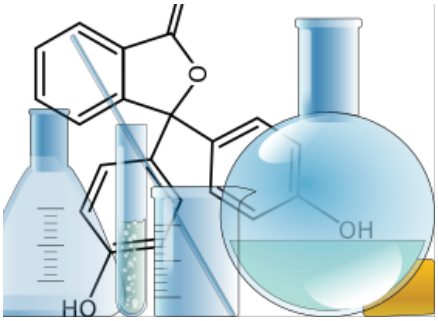
Ongoing Studies and Clinical Trials

The Pittsburgh Scleroderma Center is currently participating in five studies, including one multi-center trial of a medication which addresses a particular scleroderma-related problem. If you live in our geographic area, Pittsburgh is a logical site to consider for participation. If you live in another part of the country, you may wish to contact the participating site closest to you for additional details.

Observational Studies

Banking of Biological Samples and Collection of Clinical Data for Connective Tissue Disease (CTD) Research: Connective tissue diseases are chronic diseases that involve damage of connective tissues such as the lining of the joints, blood vessel walls, muscle, skin, and certain internal organs. These diseases are also known as autoimmune diseases because the body's immune system mistakenly attacks its own tissues. Treatment has improved over the past 20 years, but there is still much that is not understood about the complications and causes of these diseases. The purpose of this project is to set up and maintain a Rheumatology Biological Specimen Bank of blood and tissue samples and a parallel Research Databank of computerized medical information. For example, we are interested in obtaining and banking blood and skin samples (from biopsies) on patients with scleroderma. Inclusion Criteria: all ages, male or female, diagnosed by a Pittsburgh Scleroderma Center physician with either systemic sclerosis or localized scleroderma or a normal healthy individual not genetically related to a patient with scleroderma willing to provide a blood or skin sample. Close to 100% of our scleroderma patients participate in this study and have generously provided blood samples.

Vascular Changes in Early Diffuse Scleroderma: Raynaud phenomenon (RP) is a condition resulting in discoloration of the fingers and/or the toes after exposure to cold temperatures or emotional stress. Raynaud is the most frequent initial symptom of systemic sclerosis (SSc). This suggests that vascular (blood vessel) injury and dysfunction occurs very early in SSc patients. Injury to the endothelial cells, which form the innermost lining of the blood vessel, is believed to be the initial event for many types of vascular injury. In this study we are evaluating endothelial cell function in patients with early diffuse SSc (characterized by rapid development of skin thickening beginning with the hands and extending to the arms and trunk) to see if it is abnormal early in the disease course. With this study we hope to better understand the endothelial cell and artery blood vessel stiffness changes that occur in early SSc. Improved understanding of the pathogenesis (step by step development of a disease) and damage in SSc may lead to improved treatment of the disease. We will be comparing early diffuse SSc patients to healthy



controls, matched by age and gender. Therefore healthy individuals, such as a spouse or non-relative of a SSc patient, are also needed to complete this study. The study will involve noninvasive ultrasound testing of the vasculature. This is an investigator-initiated trial at the University of Pittsburgh only.

PHAROS: Pulmonary hypertension (PH) is increased blood pressure in the blood vessels of the lungs. In SSc patients, this is caused by thickening of these vessels. It is one of the more serious complications of SSc. Patients with early PH may have little warning before they develop severe shortness of breath (which is called dyspnea). The tests doctors commonly order now don't always catch the early warning signs, but they are the best tests currently available. This study will follow SSc patients who are at risk to develop PH and those who have been recently diagnosed with PH. Investigators will gain a better understanding of who is likely to develop PH and their response to different therapies. This study will hopefully lead to earlier treatment or possibly prevention of PH. There are currently 15 SSc research centers in the United States, including the University of Pittsburgh, enrolling adult patients with limited or diffuse SSc into the PHAROS Registry. Patients who consent will provide information from their SSc-related medical records for the duration of the 5 year study. They will provide a single blood sample for research. They will complete questionnaires every 6 months (or more frequently if necessary), which can be sent by mail, or can be done on-line. Medical records will be collected every time patients undergo standard tests and procedures such as pulmonary function tests or echocardiograms. The information collected by this Registry will be used to develop a standard for diagnosing and treating one of the most serious complications people with SSc encounter.

For information on these studies, please contact our Research Coordinator, Dana Ivanco, at 412-648-7040 or des2@pitt.edu.

Systemic Sclerosis Twin Study: This research is being done to determine the role that environmental and inherited factors play in the development of systemic sclerosis (SSc). Several studies suggest the role of environmental factors as 'triggers' for SSc. In addition, familial cases of SSc are rare yet SSc occurs in siblings of SSc subjects more frequently than in the general population. The study of twins is the "gold standard" for determining whether a disease is due to shared genes or shared environmental factors. The logic behind the approach is that if inheritance is important in the development of a disease, then one would expect identical twins to

both develop SSc since they inherit the same sets of genes from their parents. If only one twin of an identical twin pair develops the disease, then the disease is not primarily due to inherited genes and is more likely due to environmental factors and/or genetic changes that occur after birth. For this study we are enrolling both identical and fraternal (non-identical) twins in which one or both twins have SSc. *For more information on the SSc Twin Study, please contact our Research Coordinator, Maureen Laffoon, at 1-800-603-8960 or laffoonm@pitt.edu.*

Clinical Trials

Rituxan Study: Rituxan is an immune suppressing drug currently used by hematologists for certain malignancies such as lymphoma. It is also approved for use in rheumatoid arthritis. Rituxan eliminates B cells from the blood stream. These cells participate in immune responses and may be responsible for some types of immune injury to tissues in patients with rheumatoid arthritis, lupus, and other related diseases, including SSc. It is typically given by vein twice, two weeks apart. This study is directed at SSc patients who have confirmed pulmonary hypertension (PH or high blood pressure in the lungs) for less than 5 years, regardless of how much skin thickening they have. Half of the patients will receive Rituxan and half placebo. A right heart catheterization both before the study (to determine eligibility) and after 6 months on treatment (or placebo) is required. Other PH medications can be continued throughout the study. Patients will be followed for 1 year or until the B cells in their blood have returned. *For more information on this study, please visit http://clinicaltrials.gov, or contact our Clinical Research Coordinator, Dana Ivanco, at 412-648-7040 or des2@pitt.edu*

Other Clinical Trials: The Scleroderma Center will participate in all future trials which our physicians believe offer reasonable hope for improvement of SSc-related problems. As with all clinical trials, patients who enroll are not required to remain in the study if there are significant side effects or if their disease progresses.

Piecing Together the Scleroderma Puzzle: Research Advances in 2010

by Carol Feghali-Bostwick, PhD

The 2010 national meeting of the American College of Rheumatology (ACR) was held November 7-11 in Atlanta, GA. The meeting included presentations by investigators from numerous countries. Many podium and poster presentations provided information on advances in scleroderma/systemic sclerosis (SSc) research.

Research in progress included pre-clinical investigations of the effect of new drugs on the development of scleroderma-like conditions in mice, the effect of growth factors, genes, and drugs on cells derived from patients with SSc, the identification of circulating factors in the blood of patients with scleroderma that may correlate with various clinical aspects of the disease, further delineation of the potential role of the innate immune system in the development of SSc, and the identification of individual changes in the DNA code that may be associated with SSc. A detailed description of the numerous presentations is beyond the scope of this article, and technical summaries of most of the presentations are available on the ACR web site.

Almost all SSc patients have a positive anti-nuclear antibody (ANA) by the standard immunofluorescence (IF) method. Screening using new non-IF methods led to a false negative ANA rate of up to 40% in SSc patients.

Advances were made in understanding the outcome of the two most common lung complications in SSc, interstitial lung disease (ILD) and pulmonary hypertension (PH). One study showed that patients with both severe ILD and secondary PH had a faster decline in lung function than those with mild ILD alone. The former group (ILD + PH) was also more likely to fail to respond to a single drug (an endothelin receptor antagonist or a phosphodiesterase type-5 inhibitor) and required the addition of a second therapeutic agent. Furthermore, knowing the patient's disease subtype and autoantibody helped in identifying patients at higher risk for developing ILD compared to those more likely to develop PH. For example, patients with anti-Scl-70 antibodies are more likely to develop ILD whereas those with anti-centromere antibodies are more likely to develop PH. Although these antibody associations have been known for years , this observation was further confirmed in patients enrolled in the PHAROS study (described on page 4). Although the best screening test for PH is the echocardiogram, a study including both academic centers and community rheumatology practices concluded that the key elements required to diagnose PH, such as the right ventricular systolic pressure, are not reported consistently by cardiologists performing echocardiograms. Better education and teamwork between rheumatologists and cardiologists is needed .

In a form of scleroderma known as SSc *sine* (without) scleroderma, in which patients have internal organ involvement but no obvious skin involvement, investigators found that Raynaud symptoms, arthritis, and esophageal complications precede the development of ILD and that antibodies to Th/To and U1/U2 RNP are the most common autoantibodies seen in these patients. On the other hand, ILD is rare in patients with anti-RNA polymerase antibody, which is normally found in SSc patients with kidney complications.

One study reported on the serious complications encountered in patients participating in the

Continued on Page 6...

Scleroderma Lung Study (SLS). Over a period of 9 years, patients who had previously enrolled in this one-year study of cyclophosphamide (Cytoxan) versus placebo had a surprisingly high mortality rate of 27%. Seven patients developed forms of cancer that are not usually associated with immunosuppressive treatment. A total of 22 patients required oxygen therapy and 2 had lung transplantation.

In another study, researchers compared the antibody response of SSc patients to the influenza vaccine. Overall, patients had a good response to the vaccine and generated protective antibodies, however the response in patients with ILD was significantly lower than that in patients without ILD. The vaccine was found to be safe and continues to be recommended for SSc patients.

Follow-up results on treatments and clinical trials were also presented. Similar to last year's presentations at the ACR meeting, conflicting results were presented regarding the effectiveness of imatinib mesylate (Gleevec) in SSc. Although the drug slightly improved skin thickening in some reports, it showed no beneficial effects in others. Most investigators concurred that the adverse side effects of imatinib were significant. Mycophenolate mofetil (MMF) has also been discussed at the ACR meeting for several years. A presentation this year indicated slight beneficial effects of the drug on skin involvement, muscle disease severity and quality of life after one year of treatment.

Advances were also made in juvenile localized scleroderma (LS). Two large international pediatric rheumatology groups, the Childhood Arthritis & Rheumatology Research Alliance (CARRA) which encompasses North America and the Pediatric Rheumatology European Society (PRES), are collaborating in an effort to standardize evaluation of skin involvement and identify both clinical and laboratory data that can be used to evaluate treatment effectiveness. The CARRA – Rx project is being launched in the United States. This is an NIH sponsored project to develop consensus treatment plans for LS and includes comparing different combinations of methotrexate (MTX), corticosteroids (CS), and MMF. A recent European study showed that children with localized scleroderma who were treated with oral MTX and oral CS had fewer relapses (disease recurrences) than those given oral CS with placebo, suggesting that MTX is effective. MTX was well tolerated by patients with juvenile LS.

In the basic research field, progress was reported in understanding the fibrotic process that results from excessive production of collagen and other extracellular matrix molecules by cells known as fibroblasts, the mechanism of activation of immune cells, levels of cytokines (hormones of the immune system) and their correlations with various clinical aspects of SSc, genetic associations with features of SSc reported by studies from different countries, responses of animal models of fibrosis to different conditions and treatments, as well as other advances.

Once again, several key contributions at this year's ACR meeting were the result of research conducted by current and past Scleroderma Foundation grant recipients. Their work, in combination with that of investigators from all over the world, continues to add new pieces to help us solve the scleroderma puzzle.

Ask the Expert

If you have a question regarding scleroderma that you would like answered by our Scleroderma Center team of experts, please send it to laffoonm@pitt.edu. If your question is selected, the question and answer will be published in a future issue of the newsletter.

Lori S. From Jeannette, PA asks the following:

Question: **Is cancer associated with systemic sclerosis?**

Answer by Dr. Medsger: In our Pittsburgh Scleroderma Center experience over the last 4 decades, 256 (7%) of 3465 SSc patients have developed cancer after the onset of SSc. In both large and small series of SSc patients reported in the medical literature, the risk of developing cancer is slightly, but only slightly, increased compared with the risk in the general population. There are several particular associations which patients should know about, as follows:

1. Breast cancer seems to be more frequently diagnosed during the first two years after the onset of diffuse SSc than would be expected.

2. Tongue cancer is more frequent in SSc patients.

3. Lung cancer is more frequent in SSc patients who have long-standing pulmonary fibrosis (interstitial lung disease or ILD). This cancer is independent of cigarette smoking. So cancer development is in some way linked to the changes which occur in lung cells as a result of many years of the scarring process. This same increased risk is present in persons with ILD who do not have SSc.

4. Lymphoma is probably more frequent in SSc patients. One possible link is that lymphoma is a recognized complication of Sjogren syndrome and 20 – 30% of SSc patients also have this disorder.

5. There is no known increased risk of any cancer including skin cancer, in localized scleroderma (LS).

Note: Dr. Medsger has given the talk on cancer and scleroderma at the Scleroderma Foundation's annual patient conference for the last 3 years.

Thank You

We would like to thank the following donors for their support of scleroderma research

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Name the Newsletter Contest

Are you Creative? Then you should enter our "Name the Newsletter" contest. Send in a name for our newsletter to laffoonm@pitt.edu by September 1, 2011.

The winner will be recognized in the next issue of the newsletter and receive a gift certificate to a restaurant of his/her choice.

A future issue of our newsletter will feature a contest to design a logo for our Scleroderma Center.

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