The Moisture Seekers

Sjögren's Syndrome Foundation

www.sjogrens.org

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Naturopathic Approach to Autoimmune Conditions

by Keith Wilkinson, ND, Naturopathic Physician
www.arthritishealth.net / www.integralnatmed.com

From a naturopathic perspective, the body functions as a logical organism that responds in a direct cause and effect relationship to its environment. In the case of Sjögren's and autoimmunity in general, the immune system (the effect) is responding to something that appears to be "foreign" (the cause) in the body. Unfortunately, in the process of trying to remove the foreign substance, the body destroys its own tissue and autoimmunity develops.

From a conventional medicine perspective, much of the treatment focuses on minimizing the symptoms of pain and inflammation using non-steroidal anti-inflammatories (NSAIDs) such as ibuprofen and aspirin, steroidal anti-inflammatories such as prednisone and, in more severe cases, disease-modifying anti-rheumatic drugs (DMARDs) such as methotrexate and plaquenil that inhibit immune function. Because these drugs can

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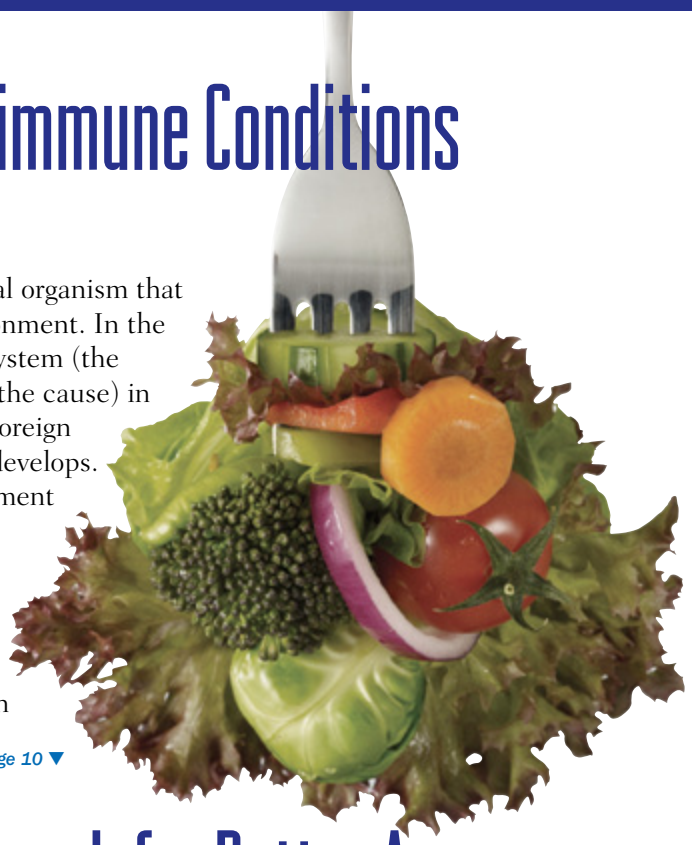

The SSF Supports the Search for Better Answers Through Research Awards

by Katherine Morland Hammitt, SSF Vice President of Research

A major goal of the Sjögren's Syndrome Foundation (SSF) is to support and nurture researchers who are excellent and creative scientists who have novel ideas that could lead to improving the lives of the 4 million Americans and many more worldwide who have Sjögren's. To accomplish this objective, the SSF awards research grants that its Research Review Committee deems the most worthy of funding. This year, seven research grants in Sjögren's were awarded. New projects include a focus on gene therapy and use of a novel approach to make such a therapy viable; development of a diagnostic

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test for early Sjögren's; and investigation into novel molecular pathways that might prove critical to the development of Sjögren's and offer a means for therapeutic intervention.

For only the third time in SSF history, one of the grants awarded was the SSF Innovative Concept Grant. This special grant is not awarded every research grant cycle but is reserved solely for those projects that SSF reviewers deem highly innovative and will test new hypotheses in the hope that promising data is gathered, will be used to obtain additional funding from other sources for continuation of the project and ultimately lead to new knowledge about Sjögren's and, potentially, new therapies. This grant also is reserved for investigators early in their career to encourage top-notch researchers to focus on Sjögren's for years to come.

This year's Innovative Concept Grant winner was made possible by the Leach Family. This family returns for a second time of funding an Innovative Concept Grant and believes in the premise that we will not accomplish a major breakthrough in treatment of Sjögren's unless we support the investigators of tomorrow who will think outside the traditional concepts in Sjögren's research. In addition, the Galewood Foundation continued its critical support this year to assure expansion of the SSF Research Program and funding for top applicants. "The Sjögren's Syndrome Foundation applauds the Leach Family and the Galewood Foundation for their vision and willingness to support these special investigators," says SSF CEO Steven Taylor. "Both have made significant contributions to make a difference and promote research into Sjögren's."

The Leach Family first supported an Innovative Concept Grantee in 2008 and 2009, Umesh Deshmukh, PhD, who has since successfully pursued research in Sjögren's. Since the completion of his SSF research grant in 2009, Dr. Deshmukh has received a major grant from the National Institutes of Health (NIH); added a second appointment with the pharmacology department at the University of Virginia, Charlottesville, Virginia, which has helped catalyze his interest in Sjögren's and drug development; presented at the 2010 American College of Rheumatology Sjögren's Study Group; and authored a lead article for the summer 2011 issue of the *Sjögren's Quarterly*, the SSF publication for professionals with an interest in Sjögren's. "This is exactly what we like to see happen with all of our foundation grants and especially our Innovative Concept Grants," says Denise Faustman, MD, PhD and Chair of the SSF Research Review Committee. "In fact, following our continual examination of the best use of SSF funds to support and promote research in Sjögren's, we will be making all future grants contingent on innovation and the Innovative Concept Grant guidelines. It is critical that we bring in new and promising researchers and provide the seed money for novel ideas which often are not fundable from other sources."

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The World was Buzzing about Sjögren's

More than 350 experts from around the world gathered in Athens, Greece this fall to share and discuss the latest research and clinical advice on Sjögren's. The Sjögren's Syndrome Foundation joined many of its MSAB members and friends there to hear the talks, interact with longtime clinicians and researchers, meet new and upcoming investigators in Sjögren's, strategize with other international groups to raise awareness of Sjögren's around the world, and promote the work of the SSF.

A broad range of areas in Sjögren's were addressed. Clinical topics included conventional and new treatments, management of lymphoma, neurological aspects, evaluation of salivary glands, and the occurrence of Sjögren's in related diseases. Many topics related to the scientific investigation into Sjögren's, and aspects that will encourage clinical trials in Sjögren's also were highlighted. Watch for coverage of subjects of the greatest interest to our readers in *The Moisture Seekers* and *Sjögren's Quarterly* over the coming year!

The symposium kicked off with a special reception to honor Harry Moutsopoulos, MD, Honorary Chair of the symposium who is retiring as Professor and Director of the Pathophysiology Department at the National University of Athens. Dr. Moutsopoulos is a longtime revered clinician and researcher in Sjögren's who has worked closely with the SSF for many years and serves on its medical board. He set the stage for the three days of meetings with a talk on "What Have We Done, and What Should We Learn?" – a very poignant assessment and question about where we should be headed in the future for Sjögren's.

The 11th International Symposium on Sjögren's Syndrome was chaired by Athanasios Tzioufas, MD, an Associate Professor in the Department of Pathophysiology at the School of Medicine, National University of Athens, and Associate Member of the SSF Medical and Scientific Advisory Board (MSAB). Dr. Tzioufas reports that an issue of Journal of Autoimmunity will devote an entire issue to talks from the symposium next year, increasing awareness of the latest work that is taking place in Sjögren's.

The International Symposium on Sjögren's is held approximately every two years. The SSF hosted the IXth symposium in 2006 in Washington, D.C. ■

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2011 Research Grantees Named

SSF Innovative Concept Grant

Gene Therapy for Targeting Salivary Gland Treatment

Michael J. Passineau, PhD

Allegheny-Singer Research Institute,
West Penn Allegheny Health System
Pittsburgh, Pennsylvania

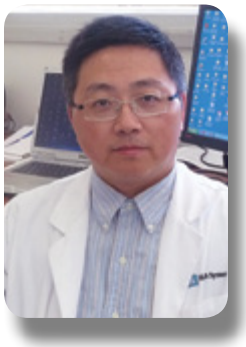
"Ultrasound-assisted gene transfer of IL17R:Fc to the salivary glands as a gene therapy for Sjögren's syndrome"

Supported by the Leach Family

Gene therapy is a particularly exciting approach to Sjögren's, because it can directly target the salivary gland with a gene drug, avoiding the systemic toxicity often seen with traditional pharmaceuticals. The major innovation embodied in this project is the application of a new ultrasound-assisted method of gene drug delivery. Earlier, attempts in salivary gland gene therapy have used a viral vector system, which uses a virus to carry genetic material into an organ. However, this method has proven impractical for long-term therapy. Dr. Passineau hopes that his project will provide a strong rationale for ultimately translating this promising technology to humans. SSF Research Review Committee members stated that Dr. Passineau's project was a unique, innovative and classic high risk-high reward proposal with the potential for moving a gene therapeutic approach closer to reality for Sjögren's.

This SSF grant already has led to the inclusion of Sjögren's as a major focus of a new Autoimmunity Center being launched in 2012 by Dr. Passineau's institute. Co-directors of the Lupus Center of Excellence there, Drs. Joseph Ahearn and Susan Manzi, are leading the establishment of the new center. Ground-breaking is scheduled for January, and the SSF will be on hand to help celebrate. "I think we will have a unique research and clinical care center based primarily in the Western Pennsylvania Hospital, which is being completely renovated and refurbished," says Dr. Passineau.

SSF Research Grant



Novel Molecular Mechanisms Underlying SS Pathogenesis

Shen S. Hu, PhD

UCLA School of Dentistry,
Los Angeles, California

"Interferon-Y induces immunoproteasome in human salivary gland cells"

Studying the molecular and cellular mechanisms involved in Sjögren's will help us understand the cause and processes involved in this disease. The more we know about the events that lead to Sjögren's, the more likely we can develop new therapeutic strategies for patients. In this project, Dr. Hu is investigating the role of interferon-gamma and immunoproteasome in primary SS.

SSF reviewers highlighted the critical importance of this area for Sjögren's research and its clear extension of highly innovative work accomplished previously by others in the field. Reviewers praised the solid and excellent environment for this study, the importance of doing human studies in Sjögren's, and the fact that this award helps to meet the SSF goal of encouraging another excellent investigator in the early stages of his career to focus on Sjögren's.

SSF Research Grant

Identifying an Early Diagnostic Marker in Early Stage Sjögren's

Melinda Larsen, PhD

The Research Foundation of SUNY, University at Albany, Department of Biological Sciences, Albany, New York

"Application of Multiplexing Technology to the Study of Sjögren's Syndrome"

No diagnostic test currently exists for early stage disease in Sjögren's. Several protein targets have been identified that change early in disease development, but the cell types that produce these targets and how they cause disease have not been examined. Dr. Larsen will identify the cell types that produce SS target proteins in the mouse model and test the hypothesis that changes in protein localization precede development of autoimmunity. Finally, she will examine patient tissues to determine if these changes also occur in the human disease as a first step towards the development of a molecular diagnostic test for early stages of SS. Novel multiplexing technology also will be used to examine other potential diagnostic targets.

Foundation reviewers were highly enthusiastic about Dr. Larsen's grant proposal and cited her excellent training, the productive lab environment and her dedication as a young tenure-track assistant professor poised to move forward in Sjögren's.

Research Grant

Mechanisms in Developing Dry Eye

Sunil Chauhan, DVM, PhD

Schepens Eye Research Institute,
Boston, Massachusetts

"Mechanism and Functional Relevance of Corneal Lymphangiogenesis in Dry Eye Disease"

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For patients with Sjögren's syndrome

DRY-MOUTH SYMPTOMS DON'T HAVE TO BE SO DISTRACTING.

If you experience dry-mouth symptoms due to Sjögren's syndrome, then you already know how distracting these can be to your daily life. It might be time to ask about EVOXAC® (cevimeline HCl), a prescription treatment that works by stimulating the production of your body's own natural saliva.

Talk to your doctor to see if EVOXAC can help, or visit DiscoverEVOXAC.com.

Please see important information about EVOXAC below.

Important Safety Information

What is EVOXAC?

- EVOXAC (cevimeline HCl) is a prescription medicine used to treat symptoms of dry mouth in patients with Sjögren's syndrome.

Who Should Not Take EVOXAC?

- You should not take EVOXAC if you have uncontrolled asthma, allergies to EVOXAC or a condition affecting the contraction of your pupil such as narrow-angle (angle-closure) glaucoma or inflammation of the iris.

What should I tell my Healthcare Provider?

- Tell your healthcare provider if you have any of the following conditions:
  - History of heart disease;
  - Controlled asthma;
  - Chronic bronchitis;
  - Chronic obstructive pulmonary disease (COPD);
  - History of kidney stones;
  - History of gallbladder stones
- Tell your healthcare provider if you are trying to become pregnant, are already pregnant, or are breastfeeding.
- Tell your healthcare provider about all medications that you are taking, including those you take without a prescription. It is particularly important to tell your healthcare provider if you are taking any heart medications especially "beta-blockers".
- If you are older than 65, your healthcare provider may want to monitor you more closely.

General Precautions with EVOXAC

- When taking EVOXAC use caution when driving at night or performing other hazardous activities in reduced lighting because EVOXAC may cause blurred vision or changes in depth perception.
- If you sweat excessively while taking EVOXAC drink extra water and tell your health care provider, as dehydration may develop.
- The safety and effectiveness of EVOXAC in patients under 18 years of age have not been established.

What are some possible side effects of EVOXAC?

- In clinical trials, the most commonly reported side effects were excessive sweating, headache, nausea, sinus infection, upper respiratory infections, runny nose, and diarrhea.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

Please visit www.EVOXAC.com for full Product Information for EVOXAC.

For patients having difficulty affording their Daiichi Sankyo medication, please call the Daiichi Sankyo Patient Assistance Program at 1-866-268-7327 for more information or visit www.dsi.com/news/patientassitance.html.

Evoxac® (cevimeline HCl) 30 mg Capsules

Please see a brief summary of Important Information for EVOXAC on the next page.

Brief Summary – See package insert for full Prescribing Information.

EVOXAC® Capsules

(cevimeline hydrochloride)

INDICATIONS AND USAGE
Cevimeline is indicated for the treatment of symptoms of dry mouth in patients with Sjögren's Syndrome.

CONTRAINDICATIONS
Cevimeline is contraindicated in patients with uncontrolled asthma, known hypersensitivity to cevimeline, and when miosis is undesirable, e.g., in acute iritis and in narrow-angle (angle-closure) glaucoma.

WARNINGS
Cardiovascular Disease:
Cevimeline can potentially alter cardiac conduction and/or heart rate. Patients with significant cardiovascular disease may potentially be unable to compensate for transient changes in hemodynamics or rhythm induced by EVOXAC®. EVOXAC® should be used with caution and under close medical supervision in patients with a history of cardiovascular disease evidenced by angina pectoris or myocardial infarction.

Pulmonary Disease:
Cevimeline can potentially increase airway resistance, bronchial smooth muscle tone, and bronchial secretions. Cevimeline should be administered with caution and with close medical supervision to patients with controlled asthma, chronic bronchitis, or chronic obstructive pulmonary disease.

Ocular:
Ophthalmic formulations of muscarinic agonists have been reported to cause visual blurring which may result in decreased visual acuity, especially at night and in patients with central lens changes, and to cause impairment of depth perception. Caution should be advised while driving at night or performing hazardous activities in reduced lighting.

PRECAUTIONS
General:
Cevimeline toxicity is characterized by an exaggeration of its parasympathomimetic effects. These may include: headache, visual disturbance, lacrimation, sweating, respiratory distress, gastrointestinal spasm, nausea, vomiting, diarrhea, atrioventricular block, tachycardia, bradycardia, hypotension, hypertension, shock, mental confusion, cardiac arrhythmia, and tremors.

Cevimeline should be administered with caution to patients with a history of nephrolithiasis or cholelithiasis. Contractions of the gallbladder or biliary smooth muscle could precipitate complications such as cholecystitis, cholangitis and biliary obstruction. An increase in the ureteral smooth muscle tone could theoretically precipitate renal colic or ureteral reflux in patients with nephrolithiasis.

Information for Patients: Patients should be informed that cevimeline may cause visual disturbances, especially at night, that could impair their ability to drive safely.

If a patient sweats excessively while taking cevimeline, dehydration may develop. The patient should drink extra water and consult a health care provider.

Drug Interactions:
Cevimeline should be administered with caution to patients taking beta adrenergic antagonists, because of the possibility of conduction disturbances. Drugs with parasympathomimetic effects administered concurrently with cevimeline can be expected to have additive effects. Cevimeline might interfere with desirable antimuscarinic effects of drugs used concomitantly.

Drugs which inhibit CYP2D6 and CYP3A3/4 also inhibit the metabolism of cevimeline. Cevimeline should be used with caution in individuals known or suspected to be deficient in CYP2D6 activity, based on previous experience, as they may be at a higher risk of adverse events. In an *in vitro* study, cytochrome P450 isozymes 1A2, 2A6, 2C9, 2C19, 2D6, 2E1, and 3A4 were not inhibited by exposure to cevimeline.

Carcinogenesis, Mutagenesis and Impairment of Fertility:
Lifetime carcinogenicity studies were conducted in CD-1 mice and F-344 rats. A statistically significant increase in the incidence of adenocarcinomas of the uterus was observed in female rats that received cevimeline at a dosage of 100 mg/kg/day (approximately 8 times the maximum human exposure based on comparison of AUC data). No other significant differences in tumor incidence were observed in either mice or rats.

Cevimeline exhibited no evidence of mutagenicity or clastogenicity in a battery of assays that included an Ames test, an *in vitro* chromosomal aberration study in mammalian cells, a mouse lymphoma study in L5178Y cells, or a micronucleus assay conducted *in vivo* in ICR mice.

Cevimeline did not adversely affect the reproductive performance or fertility of male Sprague-Dawley rats when administered for 63 days prior to mating and throughout the period of mating at dosages up to 45 mg/kg/day (approximately 5 times the maximum recommended dose for a 60 kg human following normalization of the data on the basis of body surface area estimates). Females that were treated with cevimeline at dosages up to 45 mg/kg/day from 14 days prior to mating through day seven of gestation exhibited a statistically significantly smaller number of implantations than did control animals.

Pregnancy:
Pregnancy Category C.
Cevimeline was associated with a reduction in the mean number of implantations when given to pregnant Sprague-Dawley rats from 14 days prior to mating through day seven of gestation at a dosage of 45 mg/kg/day (approximately 5 times the maximum recommended dose for a 60 kg human when compared on the basis of body surface area estimates). This effect may have been secondary to maternal toxicity. There are no adequate and well-controlled studies in pregnant women. Cevimeline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:
It is not known whether this drug is secreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from EVOXAC®, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use:
Safety and effectiveness in pediatric patients have not been established.

Geriatric Use:
Although clinical studies of cevimeline included subjects over the age of 65, the numbers were not sufficient to determine whether they respond differently from younger subjects. Special care should be exercised when cevimeline treatment is initiated in an elderly patient, considering the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in the elderly.

ADVERSE REACTIONS
Cevimeline was administered to 1777 patients during clinical trials worldwide, including Sjögren's patients and patients with other conditions. In placebo-controlled Sjögren's studies in the U.S., 320 patients received cevimeline doses ranging from 15 mg tid to 60 mg tid, of whom 93% were women and 7% were men. Demographic distribution was 90% Caucasian, 5% Hispanic, 3% Black and 2% of other origin. In these studies, 14.6% of patients discontinued treatment with cevimeline due to adverse events.

The following adverse events associated with muscarinic agonism were observed in the clinical trials of cevimeline in Sjögren's syndrome patients:

Adverse Event	Cevimeline 30 mg (tid) n*=533	Placebo (tid) n=164
Excessive Sweating	18.7%	2.4%
Nausea	13.8%	7.9%
Rhinitis	11.2%	5.4%
Diarrhea	10.3%	10.3%
Excessive Salivation	2.2%	0.6%
Urinary Frequency	0.9%	1.8%
Asthenia	0.5%	0.0%
Flushing	0.3%	0.6%
Polyuria	0.1%	0.6%

*n is the total number of patients exposed to the dose at any time during the study.

In addition, the following adverse events (≥3% incidence) were reported in the Sjögren's clinical trials:

Adverse Event	Cevimeline 30 mg (tid) n*=533	Placebo (tid) n=164	Adverse Event	Cevimeline 30 mg (tid) n*=533	Placebo (tid) n=164
Headache	14.4%	20.1%	Conjunctivitis	4.3%	3.6%
Sinusitis	12.3%	10.9%	Dizziness	4.1%	7.3%
Upper Respiratory Tract Infection	11.4%	9.1%	Bronchitis	4.1%	1.2%
Dyspepsia	7.8%	8.5%	Arthralgia	3.7%	1.8%
Abdominal Pain	7.6%	6.7%	Surgical Intervention	3.3%	3.0%
Urinary Tract Infection	6.1%	3.0%	Fatigue	3.3%	1.2%
Coughing	6.1%	3.0%	Pain	3.3%	3.0%
Pharyngitis	5.2%	5.4%	Skeletal Pain	2.8%	1.8%
Vomiting	4.6%	2.4%	Insomnia	2.4%	1.2%
Injury	4.5%	2.4%	Hot Flushes	2.4%	0.0%
Back Pain	4.5%	4.2%	Rigors	1.3%	1.2%
Rash	4.3%	6.0%	Anxiety	1.3%	1.2%

*n is the total number of patients exposed to the dose at any time during the study.

The following events were reported in Sjögren's patients at incidences of <3% and ≥1%: constipation, tremor, abnormal vision, hypertonia, peripheral edema, chest pain, myalgia, fever, anorexia, eye pain, earache, dry mouth, vertigo, salivary gland pain, pruritus, influenza-like symptoms, eye infection, post-operative pain, vaginitis, skin disorder, depression, hiccup, hyporeflexia, infection, fungal infection, sialoadenitis, otitis media, erythematous rash, pneumonia, edema, salivary gland enlargement, allergy, gastroesophageal reflux, eye abnormality, migraine, tooth disorder, epistaxis, flatulence, toothache, ulcerative stomatitis, anemia, hypoesthesia, cystitis, leg cramps, abscess, eructation, moniliasis, palpitation, increased amylase, xerophthalmia, allergic reaction.

The following events were reported rarely in treated Sjögren's patients (<1%): Causal relation is unknown:

Body as a Whole Disorders: aggravated allergy, precordial chest pain, abnormal crying, hematoma, leg pain, edema, periorbital edema, activated pain trauma, pallor, changed sensation temperature, weight decrease, weight increase, choking, mouth edema, syncope, malaise, face edema, substernal chest pain

Cardiovascular Disorders: abnormal ECG, heart disorder, heart murmur, aggravated hypertension, hypotension, arrhythmia, extrasystoles, t wave inversion, tachycardia, supraventricular tachycardia, angina pectoris, myocardial infarction, pericarditis, pulmonary embolism, peripheral ischemia, superficial phlebitis, purpura, deep thrombophlebitis, vascular disorder, vasculitis, hypertension

Digestive Disorders: appendicitis, increased appetite, ulcerative colitis, diverticulitis, duodenitis, dysphagia, enterocolitis, gastric ulcer, gastritis, gastroenteritis, gastrointestinal hemorrhage, gingivitis, glossitis, rectum hemorrhage, hemorrhoids, ileus, irritable bowel syndrome, melena, mucositis, esophageal stricture, esophagitis, oral hemorrhage, peptic ulcer, periodontal destruction, rectal disorder, stomatitis, tenesmus, tongue discoloration, tongue disorder, geographic tongue, tongue ulceration, dental caries

Endocrine Disorders: increased glucocorticoids, goiter, hypothyroidism

Hematologic Disorders: thrombocytopenic purpura, thrombocythemia, thrombocytopenia, hypochromic anemia, eosinophilia, granulocytopenia, leucopenia, leukocytosis, cervical lymphadenopathy, lymphadenopathy

Liver and Biliary System Disorders: cholelithiasis, increased gamma-glutamyl transferase, increased hepatic enzymes, abnormal hepatic function, viral hepatitis, increased serum glutamate oxaloacetic transaminase (SGOT) (also called AST-aspartate aminotransferase), increased serum glutamate pyruvate transaminase (SGPT) (also called ALT-alanine aminotransferase)

Metabolic and Nutritional Disorders: dehydration, diabetes mellitus, hypercalcemia, hypercholesterolemia, hyperglycemia, hyperlipemia, hypertriglyceridemia, hyperuricemia, hypoglycemia, hypokalemia, hyponatremia, thirst

Musculoskeletal Disorders: arthritis, aggravated arthritis, arthropathy, femoral head avascular necrosis, bone disorder, bursitis, costochondritis, plantar fasciitis, muscle weakness, osteomyelitis, osteoporosis, synovitis, tendinitis, tenosynovitis

Neoplasms: basal cell carcinoma, squamous carcinoma

Nervous Disorders: carpal tunnel syndrome, coma, abnormal coordination, dysesthesia, dyskinesia, dysphonia, aggravated multiple sclerosis, involuntary muscle contractions, neuralgia, neuropathy, paresthesia, speech disorder, agitation, confusion, depersonalization, aggravated depression, abnormal dreaming, emotional lability, manic reaction, paroniria, somnolence, abnormal thinking, hyperkinesia, hallucination

Miscellaneous Disorders: fall, food poisoning, heat stroke, joint dislocation, post-operative hemorrhage

Resistance Mechanism Disorders: cellulitis, herpes simplex, herpes zoster, bacterial infection, viral infection, genital moniliasis, sepsis

Respiratory Disorders: asthma, bronchospasm, chronic obstructive airway disease, dyspnea, hemoptysis, laryngitis, nasal ulcer, pleural effusion, pleurisy, pulmonary congestion, pulmonary fibrosis, respiratory disorder

Rheumatologic Disorders: aggravated rheumatoid arthritis, lupus erythematosus rash, lupus erythematosus syndrome

Skin and Appendages Disorders: acne, alopecia, burn, dermatitis, contact dermatitis, lichenoid dermatitis, eczema, furunculosis, hyperkeratosis, lichen planus, nail discoloration, nail disorder, onychia, onychomycosis, paronychia, photosensitivity reaction, rosacea, scleroderma, seborrhea, skin discoloration, dry skin, skin exfoliation, skin hypertrophy, skin ulceration, urticaria, verruca, bullous eruption, cold clammy skin

Special Senses Disorders: deafness, decreased hearing, motion sickness, parosmia, taste perversion, blepharitis, cataract, corneal opacity, corneal ulceration, diplopia, glaucoma, anterior chamber eye hemorrhage, keratitis, keratoconjunctivitis, mydriasis, myopia, photopsia, retinal deposits, retinal disorder, scleritis, vitreous detachment, tinnitus

Urogenital Disorders: epididymitis, prostatic disorder, abnormal sexual function, amenorrhea, female breast neoplasm, malignant female breast neoplasm, female breast pain, positive cervical smear test, dysmenorrhea, endometrial disorder, intermenstrual bleeding, leukorrhea, menorrhagia, menstrual disorder, ovarian cyst, ovarian disorder, genital pruritus, uterine hemorrhage, vaginal hemorrhage, atrophic vaginitis, albuminuria, bladder discomfort, increased blood urea nitrogen, dysuria, hematuria, micturition disorder, nephrosis, nocturia, increased nonprotein nitrogen, pyelonephritis, renal calculus, abnormal renal function, renal pain, strangury, urethral disorder, abnormal urine, urinary incontinence, decreased urine flow, pyuria

In one subject with lupus erythematosus receiving concomitant multiple drug therapy, a highly elevated ALT level was noted after the fourth week of cevimeline therapy. In two other subjects receiving cevimeline in the clinical trials, very high AST levels were noted. The significance of these findings is unknown.

Additional adverse events (relationship unknown) which occurred in other clinical studies (patient population different from Sjögren's patients) are as follows:

cholinergic syndrome, blood pressure fluctuation, cardiomegaly, postural hypotension, aphasia, convulsions, abnormal gait, hyperesthesia, paralysis, abnormal sexual function, enlarged abdomen, change in bowel habits, gum hyperplasia, intestinal obstruction, bundle branch block, increased creatine phosphokinase, electrolyte abnormality, glycosuria, gout, hyperkalemia, hyperproteinemia, increased lactic dehydrogenase (LDH), increased alkaline phosphatase, failure to thrive, abnormal platelets, aggressive reaction, amnesia, apathy, delirium, delusion, dementia, illusion, impotence, neurosis, paranoid reaction, personality disorder, hyperhemoglobinemia, apnea, atelectasis, yawning, oliguria, urinary retention, distended vein, lymphocytosis

The following adverse reaction has been identified during post-approval use of EVOXAC®. Because post-marketing adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Post-Marketing Adverse Events: *Liver and Biliary System Disorders:* cholecystitis

MANAGEMENT OF OVERDOSE
Management of the signs and symptoms of acute overdosage should be handled in a manner consistent with that indicated for other muscarinic agonists: general supportive measures should be instituted. If medically indicated, atropine, an anti-cholinergic agent, may be of value as an antidote for emergency use in patients who have had an overdose of cevimeline. If medically indicated, epinephrine may also be of value in the presence of severe cardiovascular depression or bronchoconstriction. It is not known if cevimeline is dialyzable.

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I Stood Up. . .

Support from family and friends. . .

Like so many other Sjögren's patients, Lisa Faricelli knows how discouraging it can be when talking to family, friends and the general and medical community about Sjögren's… she knew she had to do something to raise awareness.

After learning more about the *Sip for Sjögren's* events, Lisa Faricelli decided to organize an event in the Greater Philadelphia region. It didn't take much convincing to recruit her husband, Jack, and their children to join her efforts. Knowing that many hands make light work, she then asked friends and Philadelphia support group members to also come on board. Their goal was to hold the event in September 2011. They began securing sponsorships and silent auction items immediately.

The attendees were pleasantly surprised to taste the subtle differences in the 10 waters from around the world.

The committee's hard work raised more than $14,000.

You, too, can volunteer to organize a *Sip for Sjögren's* event in your community.

sip for Sjögren's

a fine water tasting event

"Research Grants" continued from page 4 ▼

Autoimmune attack of tear-secreting glands and the ocular surface leads to dry eye disease, a hallmark of Sjögren's. This can lead to significant discomfort, visual impairment and even blindness. The precise mechanism of dry eye development, however, is poorly understood. Dr. Chauhan proposed that dry eye induces the growth of corneal lymphatic vessels which facilitate migration of corneal immune cells to the lymphoid tissues where they activate autoimmunity. Once it is determined how the lymphatic vessels in the cornea are formed, blocking this formation could then provide a powerful tool for suppressing the generation of autoreactive immune cells and ocular surface inflammation in Sjögren's.

Dr. Chauhan was awarded a second-year grant renewal to continue his project this year. A manuscript is currently in preparation for publication on the initial findings.

UCSF Documents, Media & Mail

Research Grant

Epigenetics

Lindsey Criswell, MD, MPH, Dsc

University of California, San Francisco, San Francisco, California

"Epigenetic Profiling of Multiple Cell and Tissue Types in Sjögren's Syndrome"

The cause of Sjögren's is clearly complex with important contributions from both genetic and environmental factors. In addition to genes playing a role in developing Sjögren's, epigenetics, or inherited changes in the way genes express themselves, can be involved. This new and explosive field of science will significantly transform our understanding of Sjögren's and could lead to more effective approaches to prevention, diagnosis and treatment.

During the first year of her grant, Dr. Criswell determined the best mechanisms for extracting, sorting and storing genetic material. The SSF has renewed her grant for a second year, and now Dr. Criswell is collecting blood samples from SS patients as well as non-SS patients for comparison and will determine the unique epigenetic profiles associated with Sjögren's.

Research Grant

Genetics

Kathy L. Moser, PhD

Oklahoma Medical Research Foundation, Oklahoma City, Oklahoma

"The Genetic Basis of Human Sjögren's Syndrome"

With the discovery of the human genome in the 21st century, candidate genes that might play a role in developing disease can now be investigated. Dr. Moser developed the Genome Wide Association Study (GWAS) to do just that in Sjögren's. After analyzing potential genes associated with Sjögren's during the first year of her SSF grant, Dr. Moser's grant was renewed for a second year so she could continue to explore genes thought to be connected with Sjögren's and increase the number of people tested. She also will expand her analyses of existing data to explore gene expression and genetic associations with clinical traits. Dr. Moser expects to firmly establish robust associations within several genetic regions and pinpoint new regions that warrant further study. Overall, these studies represent the largest genetic studies performed to date in SS. Two articles have been submitted for publication during the second year of the grant.

Research Grant

Immunology, Lymphocytic Infiltration and Gene Therapy

Cuong Nguyen, PhD

University of Florida, Gainesville, Florida

"Suppression of TH17 cells using IL-27 gene therapy: A potential therapeutic approach for the treatment of Sjögren's syndrome patients"

Supported by the Galewood Foundation

An abnormal feature of Sjögren's is the accumulation of immune cells in the saliva- and tear-producing glands. In the first year of his grant, Dr. Nguyen addressed the question of whether a newly-described immune cell population known as TH17 cells is responsible for glandular destruction. He also is investigating the use of gene therapy to reduce TH17 activity. With the approval of the SSF to continue his grant for a second year, Dr. Nguyen continues to make progress with his hypothesis and to focus on use of a cytokine known as Interleukin-27 (IL-27) which usually controls TH17 cells but does not do so in autoimmune disease. If the gene therapy approach using IL-27 works in an animal model of primary Sjögren's, the process could then lay the foundation for similar gene therapy in human patients.

Dr. Nguyen authored numerous publications during the first year of his grant and currently has two more in the works.

Your donations make the difference in research into Sjögren's!

The SSF Research Program is made possible by the generous donations from our members. Donations large and small make a tremendous difference in the number and dollar amount of grants we can award. Just as importantly, lack of donations make a difference in the number of grants we cannot award, our ability or inability to obtain future answers in Sjögren's, and the number of researchers we have to turn away who then move to other fields of study. Our goal is to nurture the investigators of tomorrow, help keep those in Sjögren's focused on Sjögren's, and encourage creative and new ways of thinking about this disease.

The SSF also expresses its deep gratitude to the many expert volunteers who review research applications for the Foundation and whose donation of time, knowledge and experience is immeasurable. ■

LETTER FROM SSF CEO STEVEN TAYLOR

2011 – Another Banner Year

As another year draws to a close, I am once again reminded about all the wonderful advancements the Sjögren's Syndrome Foundation has seen in awareness, education and research over the past year.

The SSF was honored and humbled when Venus Williams announced that she had Sjögren's back in August. Her announcement was heard worldwide and has already made an impact on the way Sjögren's is viewed in the healthcare and general community. The SSF has seen a steady rise in visitors to our website, calls to our office for information as well as an increase in the number of physicians wanting to learn more about Sjögren's! Venus' announcement changed Sjögren's forever and we are truly grateful for her willingness to publicly share her story. The SSF will have more on Venus' story in future issues of TMS, but I know you all join with me in thanking her for inviting the world into her journey with Sjögren's!

It was also another record-setting year for our research initiatives. Not only did we increase the amount of money awarded for Sjögren's research grants, but we also increased our commitment to other initiatives including our Clinical Trials Consortium and our Clinical Practice Guidelines initiative. These programs are pillars to the future of Sjögren's and how physicians will treat their patients. We are excited about working with various pharmaceutical companies on developing a pharmacological method for Sjögren's while also working on Sjögren's guidelines for how physicians should treat Sjögren's once a patient is diagnosed.

And finally, the SSF is always proud of the wonderful educational seminars and conferences we offer, but also for the valuable information that is available on our website and through the SSF. In addition, we were busy this past year educating physicians and dentists about Sjögren's. We attended various healthcare professional conventions and were proud of the resounding interest we saw among these specialists. The SSF is also truly appreciative of the professionals who volunteered their time to speak at our conferences and healthcare professional conventions.

So as you sit down this New Year's and look towards 2012, I hope you know how thankful we are for each of you — thankful for your continued support of the Sjögren's Syndrome Foundation as well as thankful for your willingness to share your Sjögren's story with family and friends. Telling everyone and anyone about Sjögren's will help us increase awareness. And for those who have stepped up and helped organize an event in their community, volunteered to be an awareness ambassador, oversaw a Sjögren's support group or attended an SSF event this past year – we thank you! Thanks for helping us realize our vision of making Sjögren's a household name!

"Naturopathic Approach" continued from page 1 ▼

provide quick pain relief and slow disease progression, they are a necessary tool in the treatment of autoimmunity. However, in order to understand the possible underlying causes to autoimmune conditions, naturopathic medicine is also a necessary tool. Because of its broad focus on diet, lifestyle, environmental exposure, gastrointestinal health, physical and emotional stress, etc., naturopathic medicine can take a more "upstream" approach to understand what may be triggering the body's autoimmune reaction and the necessary steps to restore health. The following are some general naturopathic approaches to working with autoimmunity.

Anti-Inflammatory Diet

As a foundation for health, a naturopathic doctor nearly always will begin treatment by addressing the patient's diet. To a naturopath, food not only provides fuel for the body but is a powerful "medicine" that can be used to restore and maintain health. By maximizing foods that inhibit inflammation and consuming a whole-foods plant-based diet, the patient can see the tremendous impact of nutrition on one's health. From here the real investigative work to find the root causes of the autoimmunity begins.

Food Allergy

One area to start is by looking at food allergies. To many people, food allergy means the anaphylactic immediate reactions seen with foods such as peanuts or shellfish. However, in the case of autoimmunity, patients could have food reactions that are delayed by several days. The "gold standard" for assessing food allergy is through a food elimination and re-challenge diet. By eliminating foods that are common allergens (milk, eggs, grains, peanuts, gluten, food additives, preservatives, etc.) and eating a diet of simple foods, inflammatory reactions caused by the allergenic foods are allowed to subside. Once the patient is on a simplified diet, foods can be slowly reintroduced. Noting improvement of symptoms during the elimination phase or worsening of symptoms during the re-introduction phase, provides valuable information about the role foods may be playing in the autoimmune process.

In addition to the food elimination diet, food allergies also can be assessed through blood analysis. If the body is having a delayed/chronic reaction to certain foods, the immune system will make immunoglobulin G (IgG)-class antibodies against the food. By testing blood against 90+ different food types, IgG Food Allergy panel testing can also provide a quick assessment of the possible role of food allergies in the autoimmune condition.

Gut Health

It may not seem obvious, but the gut is actually a tube going through the body that is open to the outside environment via the mouth. Because of this, over 60% of the body's immune system (lymphatic tissues/nodes, immune cells, etc.) resides in the gut. A healthy GI provides "surveillance" against pathogens and functions as a barrier to prevent passage of foreign particles into the body interior. However, in the case of autoimmunity, there often is intestinal inflammation that challenges the surveillance and then compromises the barrier function due to improper cell-to-cell junctions lining the gut wall. These improper cell junctions lead to a condition called "leaky gut" where undigested and potentially antigenic food particles and/or foreign pathogens can be released into the blood stream leading to autoimmune reactions. Additionally, the gut flora, which is vital for GI health, often is out of balance or dysbiotic, creating further challenges for the immune system.

To assess GI function, stool analysis can be performed which assesses the presence of beneficial bacteria, pathogens, GI inflammation, digestion function, leaky gut, etc. To restore gut function, various treatments are available including amino acids and proper fats to restore gut tissue, probiotics to restore proper flora, botanicals and supplements for a variety of mechanisms.

Environmental Medicine

The naturopathic approach to environmental medicine recognizes that everyone is exposed to chronic low-dose pollutants in air, water, and food. These pollutants pose a toxic load that the body must regularly rid itself of through the pathways of elimination (i.e., feces, urine, perspiration, and respiration). Unfortunately, if the body's excretory functions are inhibited or if one is exposed to levels that overwhelm normal elimination, it poses a burden on the body that often can show up as autoimmunity.

In working with an environmentally sensitive patient, the first task is to reduce ongoing exposure to pollutants. This is accomplished through taking a detailed patient history and then working with the patient to establish avoidance plans. Next, the current toxic load on the body can be assessed through heavy metal challenge testing, oxidative stress makers, metabolic testing, etc. Since the liver is the major organ used for the biotransformation of toxins, testing also can be done to assess adequate liver function.

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During this festive time of the year, help us continue to be a light of hope for millions of Sjögren's syndrome sufferers.

When making a donation this holiday season, consider restricting your gift to research so that we can once again increase our financial commitment to awarding more research grants in 2012 than ever before.

Each year our research committee has to turn away promising Sjögren's research grant applications because of lack of funding. We want to ensure that we fund as many grants as possible, and with your support we can do that.

For those who have made a research gift this past year, we thank you for your continued support. Each and every gift helps us reach our goal. Please also remember, you can always ask others to make a research donation as well. Family and friends may consider supporting an organization that is important to you – you just have to ask them.

Together we all can make a difference!

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"Naturopathic Approach" continued from page 10 ▼

After baseline testing is completed, environmental treatment can be as simple as improving bowel function through dietary modification and additional fiber or more comprehensive through treatments such as heavy metal chelation, improving liver function with supplementation and botanical medicine, improving nutrient status through supplementation and IVs, etc.

In addition to the physical contributors to environmental toxicity, the psycho/social aspects of daily living also pose a "toxic" load that must be processed by the body. By recognizing the effects of stress on the body and creating mechanisms for dealing with stress, the total body burden from all environmental stressors can be reduced.

Summary

Autoimmune disease is a complex process that poses a challenge for any physician. By addressing immediate needs through conventional medicine and using naturopathic medicine to uncover possible causes for the disease process, a truly comprehensive care option is available for the patient. Naturopathic physicians are located in all 50 states. However, scope of practice and medical board oversight vary by state. When looking for a naturopathic physician, it is important to ask if they have completed medical training at a four-year in-residence naturopathic medical school. Since Sjogren's and other autoimmune conditions can be complex diseases, it is also important to ascertain the prospective physician's experience with conditions similar to yours. Naturopathic medicine offers a different approach to understanding and treating autoimmunity. It may take a bit of effort to find a naturopathic physician with autoimmune expertise, but given the additional options it provides, it is well worth the effort.

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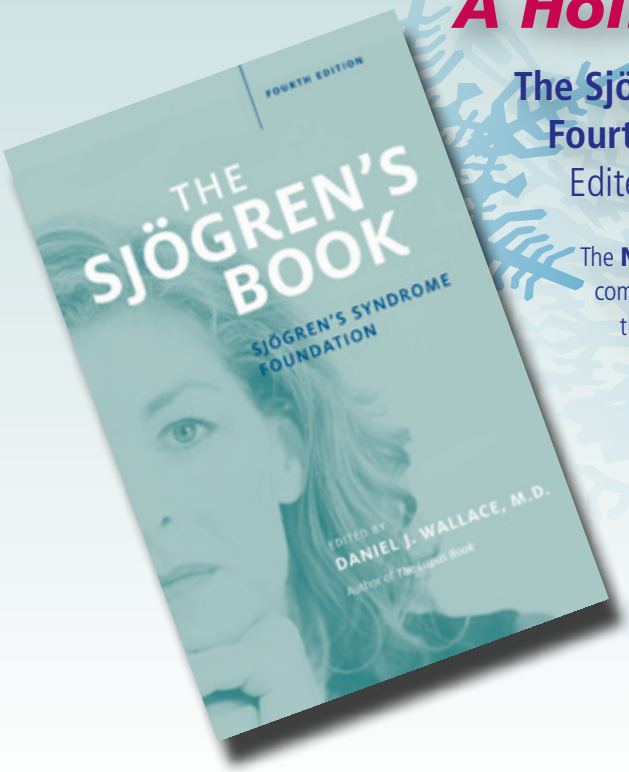

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"Charting the Course"

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As a Sjögren's patient, it's easy to feel confused or overwhelmed by the abundance of information available about the illness and how it affects your body. But here is your opportunity of "Charting the Course" for an educational journey to take control of your health and day-to-day living by learning from the best minds dealing with Sjögren's. This April, join fellow Sjögren's patients and their family members as well as healthcare professionals and other experts who specialize in Sjögren's at the 2012 SSF National Patient Conference in La Jolla, California.

SSF programs are the best Sjögren's patient education opportunities in the country. They have helped thousands gain a better understanding of Sjögren's and will help you, too. This two-day event will feature an array of presentations from the country's leading Sjögren's experts – physicians, dentists, eye care providers, and researchers – who will help you understand how to manage all key aspects of your disease. Presentation topics will include:

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