ASIG

AUSTRALIAN SCLERODERMA INTEREST GROUP

SCLERODERMA connections

EDITION 10: MAY 2017

greetings,

Welcome to the 2017 edition of Scleroderma Connections. ASIG centres around Australia continue to screen patients with scleroderma, often referred by other rheumatologists, for the complications of this disease. These activities provide a rich source of clinical information for ASIG research, much of which is driven by our hard-working and dedicated Scleroderma Australia-ASIG fellows, Dr Katie Morrisroe and our new fellow for 2017, Dr Laura Ross. In addition, individual ASIG centres also develop their own research programs using data from their own centres or collated ASIG data from across the country. Many of these are included in the list of publications of original research by ASIG members in this newsletter.

In this issue, we are indebted to Dr Joanne Sahhar who has provided two articles: a summary of current plans for research to combat the challenging clinical problem of interstitial lung disease and when to treat it and an overview of recent studies of new therapies for this complication. Katie Morrisroe follows up on her article from last year with an update on her recent studies of health care usage by patients with scleroderma.

Susanna

Susanna Proudman ASIG Chair

Donations

ASIG is grateful for donations that ensure the continuation of the Australian Scleroderma Cohort Study. Our research significantly improves the quality of care we can deliver to our patients, for a wide range of scleroderma-related problems.

A couple from Queensland has generously donated funds to support the development of the Scleroderma Disease Activity Index. Photo of the ASIG research team (from left): Molla Huq, Laura Ross, Katie Morrisroe, Mandy Nikpour, Michelle Wilson, James Hogan

President of Scleroderma Australia, Gene Swinstead (centre), presenting a cheque to ASIG. From left: Molla Huq, Nava Ferdowsi, Mandy Nikpour, Wendy Stevens, Michelle Wilson, Katie Morrisroe, Laura Ross, Alicia Calerdone

presentations.

Australian Rheumatology Association ASM – Darwin, May 2016

Podium

Development of a disease damage index in systemic sclerosis using consensus and data driven methods. Ferdowsi N, Huq M, Burchell J, Mancuso S, Tay T, Stevens W, Rabusa C, Hudson M, Sundararajan V, Prior D, Proudman S, Baron M, Nikpour M.

Survival in scleroderma pulmonary arterial hypertension in the modern treatment era: results from large multicentre cohort study[1]. Morrisroe K, Huq M, Rabusa C, Zochling J, Sahhar J, Roddy J, Proudman S, Stevens W, Nikpour M.

EULAR Annual European Congress of Rheumatology – London, June 2016

Posters

Determinants of unemployment amongst Australian Scleroderma patients: results from large multicentre cohort study[2]. Morrisroe K, Huq M, Rabusa C, Zochling J, Sahhar J, Roddy J, Strickland G, Thakkar V, Proudman S, Stevens W, Nikpour M.

Risk factors for the development of pulmonary arterial hypertension in Australian scleroderma patients: results from a large multicentre cohort study[2]. Morrisroe K, Huq M, Rabusa C, Sahhar J, Zochling J, Roddy J, Strickland G, Thakkar V, Proudman S, Stevens W, Nikpour M.

Pulmonary Hypertension Society ANZ – Melbourne, October 2016

Podium

Survival in scleroderma pulmonary arterial hypertension in the modern treatment era: results from large multicentre cohort study. Morrisroe K, Huq M, Rabusa C, Zochling J, Sahhar J, Roddy J, Proudman S, Stevens W, Nikpour M.

American College of Rheumatology ASM – Washington DC, November 2016

Posters

Work Productivity in Systemic Sclerosis and association with Health-Related Quality of Life. Morrisroe K, Sudararajan V, Stevens W, Sahhar J, Zochling J, Roddy J, Proudman S, Nikpour M, Australian Scleroderma Interest Group (ASIG).

Survival in scleroderma pulmonary arterial hypertension in the modern treatment era: results from large multicentre cohort study. Morrisroe K, Huq M, Rabusa C, Zochling J, Sahhar J, Roddy J, Proudman S, Stevens W, Nikpour M.

Footnote:

[1] also presented as a poster at EULAR Annual European Congress of Rheumatology – London, June 2016

[2] also presented as posters at Australian Rheumatology Association ASM – Darwin, May 2016

Research Awards

Laura Ross was awarded a MOVE (Arthritis Victoria) PhD scholarship to develop the Scleroderma Clinical Trials Consortium Activity Index (SCTC-AI) as her thesis project

Survival in scleroderma pulmonary arterial hypertension in the modern treatment era: results from large multicentre cohort study. Morrisroe K, Huq M, Rabusa C, Zochling J, Sahhar J, Roddy J, Proudman S, Stevens W, Nikpour M. Oral presentation at the Pulmonary Hypertension Society ANZ annual meeting October 2016. **Won the prize for Best Oral Presentation.**

Recent ASIG Research Publications

Early mortality in a multinational systemic sclerosis inception cohort. Hao Y, Hudson M, Baron M, Carreira P, Stevens W, Rabusa C, Tatibouet S, Carmona L, Joven B, Huq M, Proudman S, Nikpour M. *Arthritis & Rheumatology.* April 2017.

Long-term efficacy and tolerability of mycophenolate mofetil therapy in diffuse scleroderma skin disease. Boulos D, Ngian G-S, Rajadurai A, Elford K, Stevens W, Proudman S, Owen C, Roddy J, Nikpour M, Youssef P, Hill C, Sahhar J. *International Journal of Rheumatic diseases.* March 2017.

Epidemiology and disease characteristics of systemic sclerosis related pulmonary arterial hypertension: results from a real life screening program. Morrisroe K, Nikpour M*, Proudman S*, the Australian Scleroderma Interest Group (ASIG) (*contributed equally). *Arthritis Research Therapy.* 2017;19:42.

The Australian Scleroderma Interest Group and Database: 10 years of screening to save lives. Nikpour M, Proudman S, Morrisroe K, Sahhar J, Stevens W. *Medical Journal of Australia.* Letters to the Editor. 2017;206(5):229.

Multicentre randomised placebo-controlled trial of oral anticoagulation with apixaban in systemic sclerosis-related pulmonary arterial hypertension: the SPHInX study protocol. Calderone A, Stevens W, Prior D, Nandurkar H, Gabbay E, Proudman S, Williams T, Celermajer D, Sahhar J, Wong P, Thakkar V, Dwyer N, Wrobel J, Chin W, Liew D, Staples M, Buchbinder R, Nikpour M. *BMJ Open.* 2016; 6:e011028.

Measures of disease status in systemic sclerosis: a systematic review. Tay T, Ferdowsi N, Baron M, Stevens W, Hudson M, Proudman SM, Prior D, Nikpour M on behalf of the Damage Index Working Group of the Scleroderma Clinical Trials Consortium. *Arthritis & Rheumatology.* 2016;46(4):473-487.

The association of low complement with disease activity in systemic sclerosis. Esposito J, Brown Z, Stevens W, Sahhar J, Rabusa C, Zochling J, Roddy J, Walker J, Proudman S, Nikpour M. *Arthritis Care & Research.* 2016;18:246.

Single-specificity anti-Ku antibodies in an international cohort of 2140 systemic sclerosis subjects: clinical associations. Hoa S, Hudson M, Troyanov Y, Proudman S, Walker J, Stevens W, Nikpour M, Assassi S, Mayes MD, Wang M, Baron M, Fritzler MJ, Canadian Scleroderma Research Group (CSRG), Australian Scleroderma Interest Group (ASIG), Genetics versus Environment in Scleroderma Outcome Study (GENISOS). *Medicine (Baltimore).* 2016;95(35):e4713.

The Australian Scleroderma Interest Group (ASIG) proposed algorithm for pulmonary arterial hypertension screening in scleroderma: more selective and judicious use of echocardiography. Invited response to letter by Ramchand J *et al.* Nikpour M, Prior D, Proudman S, Stevens W. *Internal Medicine Journal.* 2016;46(6):751.

Determinants of unemployment amongst Australian systemic sclerosis patients: results from a multicentre cohort study. Morrisroe K, Huq M, Stevens W, Rabusa C, Proudman S, Nikpour M. *Clinical and Experimental Rheumatology.* 2016;34(5 suppl 100):79-84.

Risk factors for development of pulmonary arterial hypertension in Australian systemic sclerosis patients: results from a large multicentre cohort study. Morrisroe K, Huq M, Stevens W, Rabusa C, Proudman S, Nikpour M, Australian Scleroderma Interest Group (ASIG). *BMC Pulmonary Medicine.* 2016;16:134.

Subsets in systemic sclerosis: one size does not fit all. Leclair V, Hudson M, Proudman S, Stevens W, Fritzler M, Wang M, Canadian Scleroderma Research Group (CSRG), Australian Scleroderma Interest Group (ASIG), Nikpour M, Baron M. *Journal of Scleroderma and Related Disorders.* 2016;1(3):298-306.

Calcinosis is associated with digital ulcers and osteoporosis in patients with Systemic Sclerosis: A Scleroderma Clinical Trials Consortium Study. Valenzuela A, Baron M, the Canadian Scleroderma Research Group, Herrick A, Proudman S, Stevens W, the Australian Scleroderma Interest Group, Rodriguez-Reyna TS, Vacca A, Medsger Jr. T, Hinchcliff M, Hsu V, Fiorentino D, Chung L. *Seminars in Arthritis and Rheumatism.* pii: S0049-0172(16)30060-9. doi: 10.1016/j.semarthrit.2016.05.008.

Treatment outcome in early diffuse cutaneous systemic sclerosis – the European scleroderma observational study [ESOS]. Herrick A, Pan X, Pertignet S, Lunt M, Hesselstrand R, Silman A, I Stevens W I Roddy J I Proudman S I Sahhar J IDenton CP. *Annals of Rheumatic Diseases.* Accepted 26 Nov 2016

Genetics versus Environment in Scleroderma Outcome Study (GENISOS) Anti-fibrillarin antibodies are associated with native North American ethnicity and poorer survival in systemic sclerosis. Otero C, Assassi S, Hudson M, Mayes M, Estrada-Y-Martin R, Pedroza C, Mills T, Baron M, Stevens W, Proudman S, Nikpour M, Mehra S, Wang M, Fritzler M, Canadian Scleroderma Research Group (CSRG), Australian Scleroderma Interest Group (ASIG). *Journal of Rheumatology.* Accepted 17 January 2017.

Journal of Scleroderma and Related Disorders (JSRD)

JSRD is an international, multi-disciplinary, peer-reviewed publication targeted to scientists and clinicians interested in systemic sclerosis, scleroderma, and other related autoimmune and fibrotic diseases. The journal publishes high quality, original research articles on the epidemiology, natural history, pathophysiology, diagnosis, treatment and outcome of these diseases as well as reviews and thought-provoking editorials and commentaries, with the aim of becoming the leading worldwide reference journal in the field of scleroderma and related diseases. It is the official journal of the World Scleroderma Foundation and the European Scleroderma Trials and Research Group.

Visit www.sclerodermajournal.com for more information

a day in the life of…

Leah McWilliams

Outpatient Clinic Nurse
Royal Adelaide Hospital

This morning, there will be 11 patients attending for their annual visit for the Australian Scleroderma Screening Program. I always admire how pro-active patients with scleroderma are when it comes to attending for their annual echo, pulmonary function test, ECG, blood test and clinic visit.

On arrival, we chat about any pressing issues, then I examine hands and skin and collect that pesky questionnaire! As winter looms, I reiterate the importance of keeping warm, especially the hands and feet. Ensuring you're armed with scripts and a follow up review is also important.

On occasion, someone has a nasty digital ulcer but as I stress that early review and intervention is key, my office number is surely burned into many a contact list. Weekly visits may ensue while we monitor the ulcer and pain closely.

Patients with pulmonary arterial hypertension (PAH) face special challenges such as reduced capacity for exercise and the need for close monitoring for the Medicare Australia applications. Many run into trouble with infections or other illness occurs for which I provide telephone advice throughout the day. At each clinic visit, my first question is usually "how many repeats left on your script?" It's so important to confirm the next application is booked and timed to ensure further scripts are not delayed.

When required, I visit patients in the ward if they have been admitted. A chat with ward staff and clinical pharmacist about a patient's particular needs and medication helps to make the inpatient stay a little easier.

Returning to my office, time is spent following up patients by phone and organising the research projects involving patients with scleroderma. Collating data for research is a continual process. It's the only way progress will be made in combatting scleroderma.

Oh and there is the small issue of moving to a big beautiful new hospital later this year, so a little time is devoted to ordering a few moving boxes…

Leah

new ASIG fellow.

2017 Research Fellow

Dr Laura Ross

Dr Laura Ross is the new Scleroderma Research Fellow at St Vincent's Hospital in Melbourne. She is in her final year of advanced training in rheumatology. She has completed her training at the Austin Hospital and St Vincent's Hospital in Melbourne. Currently she is working with Dr Wendy Stevens in the specialist Scleroderma Clinic at St Vincent's Hospital.

Laura has commenced her PhD under the supervision of Dr Mandy Nikpour. Her project is to develop a Systemic Sclerosis (Scleroderma) Disease Activity Index. This follows on from ASIG's work, led by Dr Nava Ferdowsi and Dr Mandy Nikpour, to develop the Systemic Sclerosis Damage Index (SSc DI). The Activity Index will be able to measure a patient's disease activity at a given time point using clinical features of the disease as well as investigation results. Activity indices have been developed in other rheumatological conditions and are widely used to direct treatment decisions to times of greater disease activity. In other conditions targeting therapy in this way has been shown to improve long term outcomes. The Activity Index will also be used in clinical trials to help develop new therapies for scleroderma.

This project will further ASIG's international collaboration both with the Scleroderma Clinical Trials Consortium (SCTC) and the Canadian Scleroderma Research Group (CSRG), with whom we will work to test and validate our activity index.

mark your calendar.

Members are reminded of the following scientific meetings:

EULAR Annual European Congress of Rheumatology
14th to 17th June, 2017, Madrid, Spain

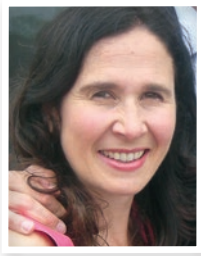
American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting
5th to 7th November, 2017, San Diego, USA

International Workshop on Scleroderma Workshop
5th to 9th August, 2017, University of Pittsburgh, USA

5th Systemic Sclerosis World Congress
15th to 17th February, 2018, Bordeaux, France

What's new in Scleroderma Interstitial Lung disease?

Dr Joanne Sahhar, Rheumatologist, Monash Health, Melbourne, Victoria



Interstitial lung disease (ILD), also known as pulmonary fibrosis, is a common problem in scleroderma (SSc) with breathing test abnormalities occurring in up to 80% of patients. While most patients with ILD have mild, stable disease that does not require treatment, other patients with severe or progressive lung disease can be significantly limited by cough and shortness of breath and can face a reduced life expectancy. The early identification of patients with progressive disease is important in that it allows us to treat patients who are likely to benefit from potentially toxic therapy promptly and avoid exposing patients with stable disease to unnecessary drug toxicity.

Although some risk factors for the development of ILD have been identified, these clinical features do not always reliably predict which patients will develop progressive disease. We know that ILD can affect patients with both limited and diffuse scleroderma and that ILD tends to occur early after disease onset with the greatest decline in lung function occurring in the first 5 and particularly the first 2 years of disease. Certain antibodies, detected in blood tests can be helpful with anti- topo-isomerase (also known as Scl-70) antibodies being associated with an increased risk of ILD.

Patients may not develop symptoms of ILD until disease is advanced. ASIG researchers have previously shown that if more than 20% of the lung is affected on high resolution CT scanning of the chest and/or lung volumes on breathing tests are reduced to less than 70% of predicted values or fall more than 15% in a year, lung disease is likely to be progressive and hence benefit from early treatment. Therefore, it is important that all patients with scleroderma undergo yearly screening with breathing tests to monitor lung function and CT scans of the chest to confirm fibrosis if lung function deteriorates. Serial breathing tests are also helpful in monitoring response to treatment. However breathing test results can be variable and sometimes be affected by other conditions such as anaemia and chest wall skin thickening. Serial CT chest scans are associated with significant cost and toxicity through radiation and have not been shown to be useful in monitoring disease over time. Other tests are needed to help management of ILD.

ASIG researchers are currently working on a project looking at the value of biomarkers in detecting early disease, predicting progression of ILD and monitoring response to treatment. In ILD, injury to the lung leads to thickening in the thin walled air sacks in the lungs and reduced oxygen exchange. When this occurs, specific proteins and cytokines may leak into the circulation and be measurable in the blood of affected patients.

In small studies, a range of biomarkers has been identified at increased levels in patients with scleroderma lung disease compared with patients with scleroderma but no lung disease. Moreover, correlations between levels of biomarkers in the blood, fall in lung function on breathing tests and extent of fibrosis on HRCT chest have been identified. At present, no single biomarker has been shown to reliably identify an increased risk of progression of ILD in a prospective study.

ASIG researchers, led by Dr Joanne Sahhar from Monash Health and A/Professor Peter Youssef from Royal Prince Alfred Hospital, Sydney, have commenced a collaborative study with lung specialist Tamera Corte and PhD student, Dr Adelle Jee, to examine the utility of a range of biomarkers in ILD.

This study will utilise the clinical data and sera collected from patients in the Australian Scleroderma Cohort Study from ASIG centres across Australia. The study will be funded by a grant from Arthritis Australia (provided by Scleroderma Australia) and by funds from Roche Pharmaceuticals. A systematic review of the literature on biomarkers in lung fibrosis has been completed by Dr Jee and biomarker testing will commence early in 2017.The results of biomarker testing will then be examined to determine whether there is a "biomarker footprint" for ILD. If identified, this footprint could then be examined together with baseline breathing tests and CT chest and correlated with outcomes in patients with SSc ILD to create a model which could improve prediction of disease progression. Testing for such biomarkers could provide a cheap, non- invasive investigation which could be repeated over time to assist in the detection and management of ILD.

We look forward to the development of improved methods of detecting, monitoring and treating patients with SSc ILD and in turn, improving quality of life for patients living with this disease.

watch this space!

In addition to those already cited, listed below is a selection of the studies currently in the pipeline to watch out for in the coming year:

VCAM1 as a therapeutic target in scleroderma. Brown M, Kenna T, Proudman S, Stevens W, Nikpour M

Incidence and prevalence of muscle disease in systemic sclerosis. Proudman S, Limaye V, Maundrell A

Genetics of Scleroderma. Brown M and Cremin K

The utility of biomarkers of interstitial lung disease in systemic sclerosis. Youssef P, Sahhar J, Adelstein S, Nguyen M

Interferon-λ3 rs12979860 genotype is associated with pulmonary fibrosis in patients with systemic sclerosis. Metwally M, George J, Manolios N, Mohammed E

The clinical relevance of ANCA in systemic sclerosis. Nikpour M, Moxey J

FCGR3B Genetic Copy Number Variation in Systemic Sclerosis. Lester S, Nguyen L

Validation of modified Rodnan skin score, a measure of skin thickness, as an enrichment criterion for clinical trials in systemic sclerosis. Proudman S, Stevens W, Nikpour M, Khanna D

The economic burden and determinants of healthcare use in systemic sclerosis: a data linkage study. Morrisroe K, Nikpour M

The economic burden of ambulatory care for patients with systemic sclerosis. Morrisroe K, Nikpour M

Determinants of health-related quality of life in a multi-national systemic sclerosis inception cohort. Morrisroe K, Hudson M, Baron M, Stevens W, Nikpour M, INSYNC

New treatment options for Scleroderma Interstitial Lung Disease

Dr Joanne Sahhar, Rheumatologist, Monash Health, Melbourne, Victoria

New findings related to the treatment of scleroderma interstitial lung disease (ILD) have emerged in the last year. The ***Scleroderma Lung Study II***, a multicentre study from the US, was published in *The Lancet* in July 2016 and showed that in 142 patients randomised to receive treatment for ILD with cyclophosphamide for 1 year or mycophenolate mofetil for 2 years that lung outcomes were the same but that mycophenolate was associated with much less toxicity.

Similarly, a study led by Dr Claire Owen from Monash, utilising data from the Australian Scleroderma Cohort Study which was published in Clinical and Experimental Rheumatology in 2016 showed that maintenance therapy with mycophenolate or azathioprine was associated with similar lung outcomes but that mycophenolate was much better tolerated than azathioprine.

Now that mycophenolate, which used to be expensive and difficult to access, has become available on the PBS, many physicians are using mycophenolate as first line treatment for SSc ILD and it is anticipated that this should result in a reduction in the treatment related toxicity that we have seen in patients treated with cyclophophamide and azathioprine.

Promising data have also emerged in trials of new drugs in patients who have ILD without scleroderma, so-called idiopathic pulmonary fibrosis or IPF. Clinical trials of nintedanib in IPF over 1 year have shown modest improvement in lung function compared with placebo and this drug is now PBS approved for use in Australia for IPF. A study of nintedanib in SSc ILD, the ***SENSCIS*** study, is underway around the world including Australia, and will be completed late in 2018.

> "Promising data have also emerged in trials of new drugs in patients who have ILD without scleroderma, so-called idiopathic pulmonary fibrosis or IPF."

The recent phase 2 ***FaSScinate*** study showed improvement in lung function in patients with SSc ILD treated with tocilizumab, an agent that is currently used to treat rheumatoid arthritis. On the strength of these findings, a phase 3 study of tocilizumab, the ***FoccuSSced*** study is in progress overseas to examine the effect of tocilizumab on skin and ILD in SSc.

The ***ATSIS*** trial of autologous stem cell transplantation also demonstrated benefits in patients with SSc ILD, but given the high treatment-related mortality, this therapeutic option is considered only in selected patients who have failed to respond to other treatment options.

Quantifying the healthcare burden of Scleroderma in Australia

Dr Katie Morrisroe, Scleroderma Australia ASIG, St Vincent's Hospital Melbourne

We are delighted to update you on the status of our nationwide data linkage project to quantify the healthcare burden of scleroderma in Australia and to share with you some of our results. Thus far, we have received de-identified linked data from the Victorian hospital and emergency department databases and from the Medical Benefits Scheme (MBS).

Our preliminary data show that scleroderma is associated with substantial healthcare utilisation and associated cost. Within Victoria alone, more than 80% of people living with scleroderma were admitted to hospital at least once between 2011 and 2015 with an associated cost of AUD$12,734,394.95. A complication of scleroderma was the main reason for hospital admission, with disorders of the gastrointestinal tract being the most common reason for admission. Furthermore, over half of the people living with scleroderma in Victoria presented to the emergency department with an associated cost of AUD$200,664.87. Chest pain followed by abdominal pain was the main reason for emergency department presentation.

> "Within Victoria alone, more than 80% of people living with scleroderma were admitted to hospital at least once between 2011 and 2015 with an associated cost of AUD$12,734,394.95."

Attending outpatient clinics and allied health visits have a very important role in the management of scleroderma, so called multidisciplinary care. We were able to quantify the use of these services using MBS data. Between 2011-2015, the most frequently visited medical professional by people living with scleroderma in Victoria was their general practitioner, while the most common allied health provider was a podiatrist. During this period, the use of MBS-funded ambulatory care amounted to AUD$6,993,367.19.

As you can see, our data highlight that scleroderma is associated with substantial healthcare use and cost. We hope that our results will encourage further research into this area and ensure equitable resource access to all those living with scleroderma in Australia.

Further information about ASIG can be found at:
https://rheumatology.org.au/patients/asig.asp

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