# Patient Reported Outcomes

## 1702 PATIENTS ENROLLED IN THE ACCELERATING MEDICINES PARTNERSHIP (AMP) RA/SLE NETWORK WITH ISOLATED RENAL DISEASE REPORT MINIMAL QUALITY OF LIFE IMPAIRMENT ON PROMIS-29 COMPARED TO PATIENTS WITH EXTRARENAL SYMPTOMS

[1]Philip Carlucci, [2]Jessica Li, [1]Heather T Gold, [1]Kristina Deonaraine, [2]Andrea Fava, [1]Jill Buyon, [3]Judith A James, [4]Chaim Putterman, [5]Deepak Rao, [6]Betty Diamond, [2]Derek Fine, [2]Jose Monroy-Trujillo, [2]Kristin Haag, [5]William Apruzzese, [1]H Michael Belmont, [7]Sean Connery, [7]Fernanda Payan-Schober, [8]Richard Furie, [9]Celine Berthier, [10]Maria Dall'Era, [11]Kerry Cho, [12]Diane Kamen, [13]Kenneth Kalunian, [14]Jennifer Anolik, [15]Susana Serrate-Sztein, the Accelerating Medicines Partnership in SLE network, [1]Peter Izmirly, [2]Michelle Petri.
*[1]New York University School of Medicine, New York, NY, USA; [2]Department of Medicine, Johns Hopkins University, Baltimore, MD, USA; [3]Arthritis and Clinical Immunology, Oklahoma Medical Research Foundation, Oklahoma City, OK, USA; [4]Division of Rheumatology and Department of Microbiology and Immunology, Albert Einstein College of Medicine and Montefiore Medical Center, Bronx, NY, USA; [5]Division of Rheumatology, Inflammation, Immunity, Department of Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [6]Center for Autoimmune and Musculoskeletal Diseases, The Feinstein Institute for Medical Research, Northwell Health, Manhasset, NY, USA; [7]Department of Internal Medicine, Paul L. Foster School of Medicine, Texas Tech University Health Sciences Center El Paso, El Paso, TX, USA; [8]Division of Rheumatology, Northwell Health, Great Neck, NY, USA; [9]University of Michigan Medical School, Ann Arbor, MI, USA; [10]Rheumatology Division and Russell/Engleman Rheumatology Research Center, University of California San Francisco, San Francisco, CA, USA; [11]Nephrology Division, University of California San Francisco, San Francisco, CA, USA; [12]Division of Rheumatology and Immunology, Medical University of South Carolina, Charleston, SC, USA; [13]University of California San Diego School of Medicine, La Jolla, CA, USA; [14]Department of Medicine, Division of Allergy, Immunology, and Rheumatology, University of Rochester Medical Center, Rochester, NY, USA; [15]National Institute of Arthritis and Musculoskeletal and Skin Diseases, Bethesda, MD, USA*

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**Background** Lupus nephritis can occur as an isolated component of disease activity or be accompanied by diverse extrarenal symptoms that can adversely affect a patient's quality of life (QOL). Whether renal disease absent other activity is sufficient to decrease QOL is unknown. A lack of reported QOL impairment may place patients at risk for delayed diagnosis of nephritis or medication noncompliance yet nephritis trials have largely neglected QOL. As such, this study leveraged the multi-center multi-racial Accelerating Medicines Partnership (AMP) lupus nephritis cohort to assess QOL measured by PROMIS-29.

**Methods** Patients (n=182) fulfilling ACR or SLICC criteria for SLE with a uPCR $\geq$ .5 and biopsy Class III, IV, V, or mixed were consecutively enrolled in AMP at the time of renal biopsy and clinical history, PROMIS-29, and disease activity as assessed by the hybrid SELENA-SLEDAI were recorded. Patients were determined to have extrarenal clinical activity if, after excluding all laboratory parameters from the SLEDAI, the score remained $\geq$ 1. Raw PROMIS-29 scores were transformed to t-scores with the mean of 50 $\pm$ 10 representing the US population and a difference of 5 points considered clinically meaningful. PROMIS-29 physical and mental health summary scores were calculated according to published formulas.

**Results** Forty-three percent of patients (n=78) had extrarenal clinical manifestations including vasculitis (4%), arthritis (39%), rash (45%), alopecia (42%), mucosal ulcers (13%), pleurisy (12%), pericarditis (8%), and fever (4%). Patients with isolated renal disease (n=104, 57%) did not have PROMIS-29 scores that differed clinically from the US population whereas patients with extrarenal disease reported deficits in physical functioning, fatigue, social functioning, and pain (table 1). Patients with extrarenal disease had significantly lower physical health summary scores compared to patients with isolated disease (median [IQR]: 40.31 [35.79, 47.02] p<0.001 vs. 48.6 [40.14, 57.08]) and significantly lower mental health summary scores (44.12 [38.63, 51.39], p=0.024 vs. 48.67 [40.51, 55.07]). Female and African American patients and those with nephrotic range proteinuria or undergoing first biopsy had significantly lower physical health summary scores, but mental health summary scores did not differ by these variables. Patients on greater than 20 mg of prednisone had both significantly lower physical and mental health summary scores compared to those on lower doses. PROMIS-29 scores did

**Abstract 1702 Table 1** PROMIS-29 scores among patients with isolated renal vs extrarenal disease.

| Category | Isolated Renal n=104 | Extrarenal n=78 | P-value |
|---|---|---|---|
| Physical functioning < | 48.3 [40.5-57.0] | 41.2 [36.7-48.3] | **<0.0001** |
| Anxiety > | 53.7 [40.3-59.5] | 51.2 [40.3-59.5] | 0.87 |
| Depression > | 45.0 [41.0-55.7] | 45.0 [41.0-57.3] | 0.88 |
| Fatigue > | 53.1 [46.0-62.2] | 57.9 [48.6-64.6] | **0.009** |
| Sleep > | 54.3 [48.9-57.9] | 54.3 [48.4-59.8] | 0.80 |
| Social functioning < | 51.9 [44.2-64.2] | 44.2 [42.3-51.9] | **0.002** |
| Pain > | 55.6 [41.6-61.2] | 61.2 [55.6-66.6] | **0.0002** |
| Pain intensity > | 3.0 [1.0-5.8] | 6.0 [3.0-8.0] | **<0.0001** |

Results are presented as median [IQR], Mann-Whitney U test of significance
< lower scores indicate worse outcome
> higher scores indicate worse outcome

**Abstract 1702 Table 2** Stepwise multivariable linear regression analysis of extrarenal manifestations and PROMIS-29 physical health summary scores

| | Physical health summary scores < | |
|---|---|---|
| **Predictors** | **Estimate (95% CI)** | **p-value** |
| Arthritis (yes vs. no) | -8.68 (-12.32 ,-5.03) | **<.0001** |
| Rash (yes vs. no) | -2.24 (-5.65 ,1.17) | 0.196 |
| Prednisone>20mg | -4.68 (-7.4 ,-1.97) | **0.0008** |
| Sex: female | -3.05 (-6.5 ,0.4) | 0.0827 |

< lower scores indicate worse outcome

**Abstract 1702 Table 3** Stepwise multivariable linear regression analysis of extrarenal manifestations and PROMIS-29 mental health summary scores

| | Mental health summary scores < | |
|---|---|---|
| **Predictors** | **Estimate (95% CI)** | **p-value** |
| Arthritis (yes vs. no) | -5.93 (-9.47 ,-2.38) | **0.0012** |
| Rash (yes vs. no) | -1.9 (-5.29 ,1.49) | 0.2699 |
| Prednisone>20mg | -2.39 (-5.11 ,0.33) | 0.0848 |
| Non-Hispanic Caucasian | -4.13 (-7.76 ,-0.49) | **0.0266** |

< lower scores indicate worse outcome

not differ by low complements, anti-dsDNA, or anti-Ro antibodies. Stepwise multivariable linear regression analysis demonstrated that the association between extrarenal disease and lower PROMIS-29 summary scores was primarily driven by arthritis and independent of potential confounders (tables 2 and 3).

**Conclusion** The majority of patients had isolated renal disease and report a QOL similar to that of the general population. In contrast, those with extrarenal manifestations report significantly worse QOL outcomes. These results reinforce the critical importance of routine laboratory surveillance and medication compliance for nephritis even in patients with seemingly quiescent clinical disease since lupus nephritis is often asymptomatic.

# SLE Diagnosis

## 1801 POSITIVE ANA TESTING IN AN ACADEMIC MEDICAL CENTER: IMPACT ON DIAGNOSIS

Bonnie L Bermas, Shivani Kottur, David R Karp. *Division of Rheumatic Disease, UTSouthwestern Medical Center, Dallas, Texas*

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**Background** Anti-nuclear antibodies (ANA) are common in systemic rheumatic diseases, non-rheumatic autoimmune diseases and the general population. In clinical practice, testing for ANA can inform further clinical diagnoses even in the absence of symptoms to suggest SLE or connective tissue disease. This study was undertaken to evaluate whether ANA testing result informed clinical diagnosis.

**Methods** The UT Southwestern Medical Center IRB approved this study. Data were obtained by SQL queries of the Epic electronic health record. The study population included all patients for whom an ANA was ordered at UT Southwestern Medical Center January 1, 2010 to June 30, 2017. The titer and pattern of the ANA as well as the results of ENA or anti-dsDNA testing were obtained. Patient characteristics included age and sex. Encounter characteristics included the date of testing, frequency of testing, primary encounter diagnosis, and provider specialty.

**Results** During the study period, a total of 33,270 ANA were ordered in 28,659 unique patients. Twenty two thousand, five hundred and twenty nine of the ANAs were tested in outpatients, representing 0.7% of all office visits during this time. 3,505 patients (11.9%) had ANA tested multiple times (range: 2-25 times). In 31% of the patients having multiple ANA, the result was repeatedly negative; 41% stayed repeatedly positive; 16% of patients had an initial negative ANA and a subsequent positive; 12% had an initial positive and a subsequent negative ANA.

Forty-nine percent of the ANA tests were positive at a titer of 1:80 or greater; slightly more women (51%) had a positive ANA (≥1:80) than did men (43%). Fifty-four and a half percent of the positive ANA in women were 1:320 or greater vs. 41.6% in men ($p<0.0001$. In this cohort, 143 patients who originally had a non-autoimmune disease listed as the reason for getting the ANA and who saw the same provider within 10-14 months and were subsequently given an autoimmune diagnosis.

**Conclusions** ANA testing in the inpatient and outpatient setting is common. Diagnoses precipitating testing are most often non-rheumatic conditions. A positive ANA result changed the clinical diagnosis in a small percentage of patients.

## 1802 CAPSTONE: AN OBSERVATIONAL RETROSPECTIVE ANALYSIS COMPARING A COMPLEMENT ACTIVATION MULTIANALYTE PANEL VS. STANDARD ANA TESTING: SYSTEMIC LUPUS ERYTHEMATOSUS DIAGNOSIS, TREATMENT OUTCOMES AND ECONOMIC IMPACT

[1]Tyler O'Malley, [2]Fenglong Xie, [2]Yujie Su, [2]Cassie Clinton, [1]Debra J Zack, [3]Chung Haechung, [3]Michael Grabner, [4]Jeffrey R Curtis. *[1]Exagen Inc; [2]University of Alabama at Birmingham, Birmingham, AL; [3]Healthcore, Inc., Wilmington DE; [4]Division of Clinical Immunology and Rheumatology, Department of Medicine, Department of Epidemiology, University of Alabama at Birmingham, AL*

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**Background** Systemic Lupus Erythematosus (SLE) is a complex clinical disease that often takes years and repeated testing to adequately diagnose. Standard biomarkers have low specificity (ANA) or low sensitivity (anti-dsDNA, anti-Smith). The advent of a multianalyte assay panel (MAP) incorporating innovative cell-bound complement activation markers warrants comparison of its clinical utility to conventional autoantibodies for the diagnosis and treatment of SLE.

**Objective** This study compares the likelihood of SLE diagnosis, SLE treatment initiation, and the downstream impact on healthcare utilization on over 40,000 patients tested with either MAP (AVISE Lupus) versus standard of care lab testing with traditional anti-nuclear antibody (ANA) testing strategy cohort (tANA).

**Methods** Using electronic health record (EHR) data from the Illumination Health registry (an integrated EHR record database encompassing records from over 300 US rheumatologists), an observational retrospective cohort study was performed. Health records from 01/2016 to 12/2020 and administrative claims with cost data for a subset of patients linkable to the HealthCore Integrated Research Database (HIRD) and Medicare data were analyzed. Two cohorts were established: MAP testing strategy and the tANA approach. Each test result was classified as positive, negative, or indeterminate and outcomes were stratified based on test results. Multivariable logistic regression was used to estimate odds ratios (OR) comparing the likelihood of SLE medication initiation and SLE diagnosis between the MAP and tANA cohorts. Test impact on SLE diagnosis, treatment initiation, patterns of repeat testing, and downstream healthcare utilization were analyzed.

**Results** 21,827 MAP testing episodes and 22,778 tANA testing episodes were included in the main cohort. Findings include: 2,437 (11.2%) patients tested positive by MAP compared to 5,364 (23.6%) of tANA(+) patients. MAP(+) patients were over 5-fold more likely to be diagnosed with SLE as compared to the tANA patients, 31% vs. 8% (OR = 5.11, 95% CI 4.43-5.89). Similarly, the new patient cohort was 6-fold more likely to achieve an SLE diagnosis when MAP is used, 30% vs. 6% (OR = 6.34, 95% CI 5.12- 7.86).

Among patients with no baseline prescription for SLE medication(s), MAP(+) patients were more likely to initiate SLE medications compared to tANA(+) (43% vs. 32%, OR = 1.57, 95% CI 1.41-1.76). In patients new to the practice within the preceding year, the treatment effect was even larger 55% vs. 33% (adjusted OR = 2.77, 95% CI 2.31-3.32).