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Title: Differences in the diagnosis and management of systemic lupus erythematosus by primary care and specialist providers in the American Indian/Alaska Native population

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Abstract:

Objectives: The objective of this study was to investigate differences in the diagnosis and management of systemic lupus erythematosus (SLE) by primary care and specialist physicians in a population-based registry.

Methods: This study includes individuals from the 2009 Indian Health Service lupus registry population with a diagnosis of SLE documented by either a primary care provider or specialist. SLE classification criteria, laboratory testing, and medication use at any time during the course of disease were determined by medical record abstraction.

Results: Of the 320 individuals with a diagnosis of SLE, 249 had the diagnosis documented by a specialist, with 71 documented by primary care. Individuals with a specialist diagnosis of SLE were more likely to have medical record documentation of meeting criteria for SLE by all criteria sets (ACR, 79% vs 22%; Boston Weighted, 82% vs 32%; and Systemic Lupus International Collaborating Clinics (SLICC), 83% vs 35%; p <0.001 for all comparisons). In addition, specialist diagnosis was associated with documentation of ever having been tested for anti-double stranded DNA antibody and complement C3 and C4 (p<0.001). Documentation of ever receiving hydroxychloroquine was also more common with specialist diagnosis (86% vs 64%, p<0.001).

Conclusions: Within the population studied, specialist diagnosis of SLE was associated with a higher likelihood of having SLE classification criteria documented, being tested for biomarkers of disease, and ever receiving treatment with hydroxychloroquine. These data support efforts both to increase specialist access for patients with suspected SLE and to provide lupus education to primary care providers.

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INTRODUCTION

Systemic lupus erythematosus (SLE) is an autoimmune disease with a variable clinical presentation as well as complex classification criteria that include many different organ systems.[1] The diagnosis of SLE may be challenging even for clinicians experienced with the disease, and is based on laboratory findings coupled with characteristic clinical features. Validation of the diagnosis of SLE in research is performed using classification criteria. The 1982 American College of Rheumatology (ACR) revised classification criteria for SLE, updated in 1997,[2] were developed for high specificity, excluding patients with limited disease. The Boston Weighted criteria were created to increase classification sensitivity in epidemiological studies.[3] The Systemic Lupus International Collaborating Clinics (SLICC) Classification criteria, published in 2012, were developed to better capture the broader spectrum of immunologic and clinical conditions characteristic of SLE.[4] Although these classification criteria sets were designed for use in research, the signs and symptoms in these criteria are also used in the clinical diagnosis of SLE.

Prior research suggests that primary care and specialist physicians differ in their management of SLE.[5,6] SLE guidelines developed by the ACR in 1999[7] highlight the role of primary care providers in facilitating early diagnosis as well as follow-up of stable or mild SLE while working in collaboration with a specialist. More recent SLE guidelines[8,9] and quality indicators[10,11] designed primarily for a specialist audience focus on optimal diagnosis and management of SLE or lupus nephritis. Quality indicators developed in the US and Europe include a broad range of topics related to the care of SLE.[10,11] With respect to laboratory testing, both sets of quality indicators recommend testing for autoantibodies, complement, and urinalysis. Given its effectiveness in controlling skin and joint disease as well as reduction of damage in renal and non-renal SLE, hydroxychloroquine is considered first-line therapy in the management of all patients with SLE.[12-14] Although primary care-specific guidelines for SLE have not been developed, the primary care literature contains some reviews and recommendations for primary care diagnosis and management of SLE in alignment with the 1999 ACR guidelines and others.[15,16]

Regional differences in the number of rheumatologists, as well as a general shortage of practicing rheumatologists, may make de facto specialist diagnosis and management of every individual with SLE challenging.[17,18] Higher SLE prevalence in racial/ethnic minority populations such as the American Indian/Alaska Native (AI/AN) and First Nations populations in the US and Canada,[19,20] which are often located in areas with limited access to rheumatologists, further complicates specialist access for these groups. We hypothesized that patients diagnosed and managed by a specialist would have more ACR criteria documented, increased likelihood of having recommended laboratory testing for SLE performed, as well as increased likelihood of having been treated with any medications for SLE. The objective of this study was to identify differences between primary care and specialist diagnosis and management of SLE in the AI/AN population and to determine features associated with specialist diagnosis.

PATIENTS AND METHODS:

Study Population:

All individuals in the Indian Health Service (IHS) lupus registry 2009 population were included in this study if a physician diagnosis of SLE was documented in the medical record. The IHS lupus registry has been described previously.[19] Briefly, it is a population-based registry developed as a surveillance project within the IHS in partnership with the Centers for Disease Control and Prevention (CDC) with the goal of determining prevalence (2007) and incidence (2007-2009) of SLE in this population. The registry includes all potential SLE cases residing in communities of interest in three IHS administrative Areas: Alaska, Phoenix, and Oklahoma. In 2009, direct rheumatology care within the IHS or tribal clinics (i.e., an IHS- or tribal clinic-based specialist consultant) was available to patients in the communities included from the Alaska and Phoenix areas, but not in Oklahoma. Field medical record abstraction was performed for all potential cases of SLE included in the IHS lupus registry. A standardized data dictionary was used, and all available medical records were abstracted through 12/31/2009 as previously described.[19] Abstracted data included the final diagnosis of the treating physicians, including any specialist documentation of the final diagnosis; data elements necessary for assessing SLE classification criteria sets; laboratory testing for SLE; and the ever-use of medications indicated for the treatment of

SLE. Data on other aspects of management of SLE, such as preventive care, were not collected given the primary focus of the registry on validating diagnosis of SLE.

This study was reviewed by the Institutional Review Boards (IRBs) of the participating regions and considered exempt research by the Alaska Area IRB, Phoenix Area IRB, and Oklahoma City Area IRB. Tribal approval was obtained from participating tribal health organizations.

Case Definitions:

SLE Diagnosis: A diagnosis in the medical record by a physician of "SLE" or "SLE plus another specified connective tissue disease" was required for inclusion in this study. Because the design of this study evaluated the diagnostic criteria documented in the chart of each case selected, we did not utilize a validated administrative case definition for entry into this analysis. For patients evaluated by more than one physician with disagreement over final diagnosis of SLE (i.e., one physician stated a final diagnosis of SLE, whereas another physician stated a final diagnosis of a different connective tissue disease), the diagnosis was recorded as "SLE plus another specified connective tissue disease" and included in the study. SLE was considered to be diagnosed by a specialist if the final diagnosis was made by a rheumatologist, nephrologist, or dermatologist (or any combination of these three). SLE was considered to be diagnosed by primary care if the final diagnosis was stated by a "family medicine, internal medicine, pediatrics, or women's health" provider without any documented visit to a specialist confirming the diagnosis in the medical record. If at any time a specialist confirmed the diagnosis of SLE in the medical record, the diagnosis was considered to be a specialist SLE diagnosis. If a primary care provider documented a diagnosis of SLE and a specialist documented a different diagnosis, the specialist's diagnosis was used as the final diagnosis.

ACR Classification Criteria: Abstracted data included all elements required for confirmation of the American College of Rheumatology (ACR) revised criteria for SLE.[2]

Boston Weighted Criteria: Except for "Persistently Negative Antinuclear Antibodies (ANA)," abstracted data included all elements required for confirmation of the Boston Weighted SLE Classification criteria.[3] ANA in our study was captured as ever positive or never positive. If it was negative on multiple occasions, this was captured simply as never positive, but the number of tests done was not recorded

Systemic Lupus International Collaborating Clinics (SLICC) Criteria: The SLICC criteria[4] were finalized after the IHS lupus registry had completed data collection. The following elements of the SLICC criteria were not abstracted and therefore not included in this analysis: 1) toxic epidermal necrolysis variant of lupus; 2) maculopapular lupus rash; 3) joint tenderness; 4) duration of pleurisy; 5) acute confusional state; 6) ELISA reference range; 7) degree of anticardiolipin elevation; and 8) CH50. The lack of data on these elements led us to be missing a small subset of the information needed for four of the clinical criteria (acute cutaneous lupus, arthritis, serositis, and neurologic involvement) and to have less detail than recommended for the definition of three of the immunologic criteria (ANA, antiphospholipid antibody, and low complement). The exclusion of these elements is expected to lead to lower sensitivity in cases where the excluded elements were present but not captured by our data abstraction.

Medication Use: All medications were considered positive if documented use was found at any time in the medical record, including either a prescription or documentation of use in physician notes. Ever treatment with the following medications was assessed: hydroxychloroquine, corticosteroids, methotrexate, azathioprine, mycophenolate mofetil, cyclophosphamide, and rituximab. Dose and duration of therapy were not assessed. Belimumab was not FDA-approved at the time the registry began data collection and was not captured.

Laboratory Values: Laboratory studies recommended for evaluation of patients with SLE were considered to have been assessed if documentation of any result was present in the medical record, either by laboratory or physician note documentation. Laboratory tests used in the diagnosis and management of SLE and included in this analysis were:

complement C3 and C4, ANA, anti-double stranded DNA antibody, urinalysis, and IgM or

IgG anticardiolipin or antiphospholipid antibodies (ACL).

Demographics: The age of SLE diagnosis was determined based on the earliest date at

which the diagnosis of SLE was stated by a physician in the medical record. Disease

duration was determined by subtracting year of diagnosis as determined by medical rec-

ord abstraction from the study year (2009). Region was defined as the IHS Area in

which the patient resided during 2009. In case of multiple addresses, the address as

of 7/1/2009 was used.

Statistical Analysis:

All data analysis was performed using Stata software (version 11.2, Statacorp, College

Station, TX). Categorical data were analyzed by chi-square or Fisher's exact tests, as

appropriate. Continuous variables were compared with two-sample t-tests or Mann-

Whitney tests, as appropriate. Multivariate logistic regression analysis was performed

to calculate adjusted odds ratios (OR) and 95% confidence intervals (CI) of being di-

agnosed with SLE by a specialist for the following predictor variables: age, gender,

region (Oklahoma [reference], Alaska or Phoenix), and the documented number of ACR

criteria (less than four vs. four or more). In all tests used, a two-sided p-value of

less than 0.05 was considered statistically significant.

RESULTS:

Demographic characteristics of the 320 patients are shown in Table 1. Study patients

were predominantly female. The median age of diagnosis of cases diagnosed by primary

care was older by about 5 years, and the median disease duration was shorter by about

4 years when compared to cases diagnosed by a specialist. Most cases diagnosed by a

primary care provider were from the Oklahoma region. Approximately half of the pa-

tients had a diagnosis of SLE and another connective tissue disease. Of those, the

most common diagnoses were rheumatoid arthritis (23% and 26% of primary care and spe-

cialist diagnoses, respectively), mixed connective tissue disease (21% and 16%), and

Sjogren's syndrome (1% and 4%) (data not shown). Of the 249 patients diagnosed by a

specialist, 242 (97%) were diagnosed by a rheumatologist alone or by a rheumatologist and another specialist (data not shown). Table 2 summarizes the proportion of patients diagnosed by primary care and specialist providers who met the different SLE classification criteria, as well as the median documented number of ACR criteria. Compared with those diagnosed by a primary care provider, patients diagnosed by specialist providers were more likely to have four or more ACR criteria documented and had a higher median number of ACR criteria documented. Similar differences were seen with the Boston Weighted and SLICC criteria. Table 3 shows the differences in the specific ACR criteria met in patients diagnosed by primary care vs. specialist providers. Of the eleven ACR classification criteria, only three (antinuclear antibody, discoid rash, and neurologic disorder) did not differ significantly between primary care and specialist groups.

Table 4 shows differences in the ever use of medications for SLE, as well as laboratory tests used in the assessment and management of SLE. Compared with those diagnosed by a primary care provider, patients diagnosed by a specialist were more likely to have ever used all medications assessed. The difference was the least significant with respect to corticosteroids. There were fewer than five patients overall who received rituximab, thus data on rituximab were excluded from the table. Primary care and specialist groups differed significantly in laboratory assessment of complement levels C3 and C4, ANA, anti-double-stranded DNA antibody, and anticardiolipin or antiphospholipid antibodies.

No statistically significant differences were found between patients diagnosed with SLE alone versus SLE and another connective tissue disease with respect to age, disease duration, region of residence, proportion with documentation of meeting ACR criteria, Boston weighted criteria, abridged SLICC criteria, and all three sets of criteria (data not shown). Patients with SLE and another connective tissue disease were more likely to be female (92% vs 84%, p=0.033), to have met at least one set of criteria (89% vs 80%, p=0.035) and to have ever received hydroxychloroquine (88% vs 73%, p =0.001) and methotrexate (58% vs 19%, p<0.001).

Predictors of specialist diagnosis of SLE were assessed using multivariate logistic regression and are presented in Table 5. There was no statistically significant association of specialist diagnosis with age or gender. Patients residing in either the Alaska or Phoenix region or those with documentation of four or more ACR criteria were more likely to have a specialist diagnosis of SLE.

DISCUSSION:

In this study using data from the IHS lupus registry, a population-based registry of AI/AN people with SLE diagnosed by any provider, we found differences between primary care and specialist diagnosis and management of SLE. A specialist diagnosis of SLE was associated with increased likelihood of fulfilling the ACR and other classification criteria, a higher median number of documented ACR criteria, higher likelihood of having had recommended laboratory testing for SLE, and a higher likelihood of ever having been treated with hydroxychloroquine.

Even in areas of relatively high prevalence SLE is an uncommon disease. Primary care providers may not diagnose or manage many patients with SLE in their practices. Compounding issues with disease familiarity are the complex classification criteria and variable presentations and courses of patients with SLE. For these reasons, all patients suspected of having SLE would ideally be evaluated by a physician familiar with the diagnosis and management of the disease, typically a rheumatologist. Yet for some patients from rural populations, access to specialist care, including rheumatology, remains limited.[21] Access to rheumatology specialty care also may be restricted in other populations with limited access to health care, given the limited supply and uneven distribution of rheumatologists in the United States.[18] In this study, the majority of patients diagnosed by primary care providers (~80%) resided in an area without direct access to IHS or tribal clinic-based rheumatology consultation services at the time the registry was created. This suggests that when specialists are more available, they are included in the diagnosis of SLE.

Management of SLE is often complex. Providers must distinguish disease activity from damage, as well as recognizing the more urgent need for aggressive therapy in the set-

ting of organ or life-threatening disease. Compounding this complexity is the propensity for atypical presentation within the AI/AN population.[22] The 1999 ACR guidelines on the referral and management of adults with SLE focus on the importance of early and routine specialist involvement in patient care,[7] suggesting that the major role of the primary care provider is to refer to a specialist early and to monitor patients with mild, stable disease. Others have argued the management of even stable SLE should be delegated to rheumatologists alone.[23]

Prior research has revealed differences between specialist and non-specialist management of SLE.[5,6,24] In Puerto Rico, Molina et al. examined laboratory testing and prescription patterns in patients with SLE seeing a rheumatologist versus seeing a primary care provider alone and found that rheumatologists were more likely to order anti-dsDNA and serum complements, but that urinalysis and anticardiolipin antibodies were ordered in similar proportions in each group.[5] Of note, only 13-14% of patients had anticardiolipin antibodies ordered, a smaller proportion than either group in our study (21% in primary care and 38% in specialist group).[5] Molina et al. also found that hydroxychloroquine was more commonly prescribed by rheumatologists than PCPs (32.6% vs. 18.5%), but that even among rheumatologists, this prescription rate was low.[5] Encouragingly, we found that 65% of patients evaluated by a primary care provider had ever received hydroxychloroquine. It is likely that primary care providers are less familiar than specialists with the general recommendation for the use of hydroxychloroquine in the management of SLE, but the familiarity may differ by setting of practice. Lerang et al.[24] compared patients managed by rheumatologists to patients managed by other internal medicine specialists in Norway and found that those managed by rheumatologists were more likely to be treated with hydroxychloroquine (78% vs. 12%) and to have been tested for antiphospholipid antibodies (94% vs. 68%). These findings are similar to our study, although the proportions with favorable management differed.

Our study has some limitations. First, the IHS lupus registry, from which these data were obtained, was designed to determine the incidence and prevalence of SLE in this population, not to assess SLE severity, longitudinal outcomes, or all aspects of qual-

ity of care. Thus, our study does not have measures of disease activity, severity, damage, or all potential quality indicators available for analysis. Medication history and laboratory values were assessed based on an "ever-use" or "ever-assessed" basis, and data on duration or dose of medications or frequency and timing of laboratory assessments were not available. Relatedly, because of our design and desired outcomes, this study did not us a previously validated administrative definition of SLE to identify cases within the national IHS database. Second, this study relied on information in the medical record to determine if, and by what means, a specialist or primary care provider had ever made the diagnosis of SLE. Although a detailed medical record abstraction was performed for each patient, it is possible some patients considered here as primary care SLE diagnoses did in fact receive an in-person, specialist consultation for which documentation was not available in the medical records. This could possibly have occurred outside the IHS health care system. Alternately, an undocumented telephone consultation between the primary care provider and a rheumatologist or other specialist could have occurred. Of note, it was not possible to determine how many patients within the IHS Lupus Registry sought care outside the IHS. When available in the IHS medical record, outside specialist medical records were included in this study. Documentation of patient history and physical exam findings formed the basis of much of our analysis. Specialists, who presumably would be more familiar with classifying SLE, may be more likely to specifically mention the features associated with SLE classification criteria in their medical record documentation. In addition, it is possible that primary care physicians refer patients meeting a greater number of ACR criteria at a higher rate than those patients who have fewer criteria present and possibly milder disease. Third, in the medical record abstraction for this study, patients with a diagnosis of SLE and a diagnosis of another connective tissue disease were included in this study as SLE patients. The most common other diagnoses were rheumatoid arthritis and mixed connective tissue disease, suggesting that these were patients with arthritis or other features of an overlap syndrome as a component of their disease. In most of these cases, the laboratory testing and medications used would be similar to patients with SLE alone, but the inclusion of patients with other connective tissue diseases may have affected our results. Other similar studies did not specifically exclude patients with other connective tissue disease[5,24] and our re-

sults were comparable to those studies, suggesting that this limitation did not have a major impact on our study. Furthermore, we did not find any statistically significant differences between the SLE alone and SLE and other connective tissue disease groups, other than a higher proportion ever treated with both methotrexate and hydroxychloroquine in the SLE and other connective tissue disease group, possibly driven by arthritis. Fourth, because "ever-use" or "ever-tested" was recorded to assess medications and laboratory testing, the intent of prescriber may not have been the treatment of SLE. For some of the less SLE-specific medications or tests (such as corticosteroids and urinalysis), it is possible that these were given or performed for a different reason. Because we were using previously collected registry data for this study, we were not able to distinguish the rationale for treatment or testing. Despite these limitations, the use of "real-world" data from a population-based registry where some patients do not have access to specialists is a significant strength of this study and allows us to address questions that cannot be addressed in a university-based cohort of SLE patients.

Our study shows significant differences in the diagnosis and management of systemic lupus erythematosus between specialist and primary care providers. Specific differences found were the proportion of patients meeting classification criteria, ever-use of medications for SLE, and ever-testing for recommended lupus laboratory studies. The majority of patients diagnosed with SLE by a primary care provider resided in communities without direct access to specialist care, suggesting that patients with SLE are referred to specialists when available. For populations with limited access to specialist care, our findings suggest that research should focus on improving access to specialists or providing additional support to primary care providers in the diagnosis and management of SLE.

Key Messages:

- Specialist diagnosis is associated with an increased likelihood of meeting classification criteria for SLE.
- Specialist diagnosis is associated with increased use of recommended medications and laboratory tests for SLE.
- Increased access to specialists and primary care provider education on SLE are both recommended.

Conflict of Interest Statement:

All authors declare no financial conflict of interest.

Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily reflect the official position of the US Centers for Disease Control and Prevention or the Indian Health Service.

Table 1: Demographics of SLE Patients by Diagnosing Provider

	Diagnosed by Primary Care	Diagnosed by Specialist	
	n = 71	n = 249	p-value
Sex, % female	89%	88%	0.86
Age at diagnosis, years, median	43.5	38.1	0.001
Duration of SLE in 2009, years, median	5.4	9.7	0.017
Diagnosis			
SLE alone, %	52%	42%	0.137
SLE and other CTD, %	48%	58%	
Region			
Alaska, %	9%	44%	
Oklahoma, %	80%	12%	<0.001
Phoenix, %	11%	44%	

Table 2: Classification Criteria Met by SLE Patients Diagnosed by Diagnosing Provider

Criteria	Diagnosed by Primary Care	Diagnosed by Specialist	
	n = 71	n = 249	p-value
Number of ACR criteria documented, median (min, max)	2 (0,6)	5 (1,9)	<0.001
Met 4 or more ACR criteria, %	23%	79%	<0.001
Met Boston Weighted criteria, %	32%	82%	<0.001
Met Abridged SLICC criteria, %	35%	83%	<0.001
Met 1 or more set of criteria (ACR, Boston, and/or SLICC), %	56%	93%	<0.001
Met all 3 sets of criteria (ACR, Boston, and SLICC), %	23%	76%	<0.001

Table 3: Proportion of patients diagnosed by primary care providers vs. specialists meeting each individual ACR criterion, in order from most to least common by primary care provider.[a]

Criterion	Diagnosed by Primary Care n = 66	Diagnosed by Specialist n = 249	p-value
Antinuclear antibody	88%	94%	0.091
Hematologic disorder	59%	82%	<0.001
Arthritis	33%	70%	<0.001
Immunologic disorder	32%	59%	<0.001
Malar rash	18%	34%	0.015
Serositis	17%	43%	<0.001
Photosensitivity	11%	49%	<0.001
Renal disorder	11%	33%	<0.001
Oral Ulcers	3%	35%	<0.001[b]
Discoid rash	2%	8%	0.091[b]
Neurologic disorder	0%	3%	0.212[b]

a. Excludes patients with diagnosis of SLE who met 0 ACR criteria (n=5 diagnosed by primary care provider and 0 diagnosed by specialist).

b. Denotes p-value obtained by Fisher's exact testing

Table 4: Ever use of medications and laboratory testing in SLE patients diagnosed by primary care provider vs. specialist

	Diagnosed by Primary Care	Diagnosed by Specialist	
	n = 71	n =249	p-value
Medication			
Hydroxychloroquine, %	65%	86%	<0.001
Corticosteroids, %	75%	85%	0.039
Methotrexate, %	20%	47%	<0.001
Azathioprine	11%	25%	0.012
Mycophenolate mofetil	0%	18%	<0.001 [a]
Cyclophosphamide	0%	7%	0.017 [a]
Laboratory Testing			
C3, ever, %	52%	84%	<0.001
C4, ever, %	52%	83%	<0.001
Antinuclear antibody, ever, %	89%	99%	<0.001 [a]
Urinalysis, ever, %	97%	96%	0.74 [a]
Anti-dsDNA testing, ever, %	73%	93%	<0.001
ACL testing, ever, %	21%	38%	0.01

a. Denotes p-value obtained by Fisher's exact testing

Table 5: Multivariate associations with specialist diagnosis of SLE

Predictor Variable	OR	95% CI	p-value
Age	0.96	0.95, 1.00	0.056
Gender			
Male[a]	(base)		
Female	1.14	0.36, 3.57	0.83
Region:			
Oklahoma [b]	(base)		
Alaska	20.9	7.8, 55.9	<0.001
Phoenix	12.6	5.1, 31.0	<0.001
Number of ACR SLE criteria			
Less than 4 [b]	(base)		
4 or more	5.4	2.5, 11.6	<0.001

a. Values are adjusted odds ratio (95% confidence interval). Odds ratios are from multivariate models regressing the outcome of specialist diagnosis of SLE on all listed variables. Age is analyzed as a continuous variable, while all other variables are categorical.
b. Reference category.

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