Lemeshow test, Omnibus test and area under the receiveroperating characteristic (ROC) curve (AUC) were used to assess the goodness-of-fit and discrimination of the predictive model. A 10-fold cross validation was used to assess the model for over-fitting.

Results Unplanned pregnancies (OR 2.84, 95% CI=1.12–7.22), C3 hypocomplementemia (OR 5.46, 95% CI=2.30–12.97), and 24 hr-urinary protein level (0.3 protein <1.0 g/24 hour: OR 2.10, 95%CI=0.63–6.95; protein 1.0 g/24 hour: OR 5.89, 95%CI=2.30–15.06) were selected by the stepwise regression. The Hosmer-Lemeshow test resulted in $p=0.325$; the Omnibus test resulted in $p<0.001$ and the AUC was 0.829 (95% CI=0.744–0.91) in the regression model. The corresponding risk score classification was divided into low risk (0–3) and high risk groups (>3), with a sensitivity of 60.5%, a specificity of 93.3%, positive likelihood ratio of 9.03 and negative likelihood ratio of 0.42.

Conclusions A predictive model for fetal loss in women with SLE was developed using the timing of conception, C3 complement and 24 hr-urinary protein level. This model may help clinicians in identifying women with high risk pregnancies, thereby carrying out monitoring or/and interventions for improving fetal outcomes.

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TYPE II BUT NOT TYPE I INTERFERON SIGNIFIES CLINICAL RESPONSE TO USTEKINUMAB IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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Background Treatment with ustekinumab (UST), an anti-IL-12/23, p40-neutralizing monoclonal antibody, improved global and organ-specific measures of disease activity in a randomized, placebo (PBO)-controlled trial of patients with active SLE (NCT02349061).¹ Type I interferon (IFN-I) and type II IFN (IFN-gamma) are elevated in a subset of SLE patients. Although targeting IFN-I (anifrolumab) has demonstrated inconsistent efficacy and a preliminary study with anti-IFN-gamma mAb (AMG811) failed to establish benefit,^{2 3} we sought to determine if UST affects either pathway and if those effects correlated with a positive SRI-4 response at wk24.

Methods A phase-2, PBO-controlled study enrolled 102 adults with seropositive SLE (SLICC criteria) and active disease (baseline SLEDAI score 6 and 1 BILAG A and/or 2 BILAG B scores) despite standard-of-care therapy.¹ Gene expression analysis using a 21 gene IFN-I gene signature (IGS)⁴ or IFN-gamma signature⁵ was performed by microarray analysis using whole blood PAXgene RNA samples. Serum IFN-gamma and IFN- levels were assessed using MSD (IFN-gamma) and Quantiferix (IFN-).

Results Serum IFN-gamma and IFN- and the IGS were elevated at baseline in SLE compared to healthy controls ($p<0.0001$). IGS was increased in approximately 67% of the

SLE patients at baseline. No decrease was observed with IFN-protein or IGS levels after treatment with either UST or PBO. Whereas the proportion of patients achieving an SRI-4 response at wk24 was numerically greater in the IGS low patients (81.8% UST vs. 54.5% PBO) versus IGS high (48.6% UST vs. 20% PBO), the magnitude of the treatment effect (UST vs. PBO) was similar in both subsets (IGS low effect size=27.3% vs. IGS high effect size=28.6%). Despite similar baseline levels, UST-treated patients achieving an SRI-4 response at wk24 exhibited a significant decrease in IFN-gamma protein versus non-responders ($p<0.05$) at 4 and 8 wks and IFN-gamma gene signature at 4 wks ($p<0.0001$) and 24 wks ($p<0.05$) post-dosing.

Conclusions In this SLE trial population which had significant upregulation of IFN-I at baseline, clinical response to UST was not associated with IFN-I reduction. In contrast, a significant decrease in IFN-gamma protein and gene signature was associated with UST response. These findings suggest that a broad population of SLE patients may respond to UST regardless of baseline IFN-I status. Moreover, UST may have affected TH1 responses in SLE since IFN-gamma levels decreased following treatment.

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PAP SCREENING RATES IN SYSTEMIC LUPUS ERYTHEMATOSUS WOMEN AT AN ACADEMIC CENTER COMPARED TO NON-SLE WOMEN WITH RACIAL COMPARISONS

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Background Compared with the general population, women with systemic lupus erythematosus (SLE) tend to have higher rates of cervical neoplasia and pre-malignant lesions and in particular, SLE women treated with immunosuppressant therapies such as methotrexate, azathioprine and mycophenolate mofetil may be at even higher risk when compared to SLE women treated with antimalarials alone. Previous studies have suggested suboptimal cervical cancer screening among SLE patients and racial disparity studies have also shown that black SLE patients endure delayed SLE diagnosis and higher morbidity and mortality from SLE related disease compared to non-black SLE patients.

Methods This was a cross-sectional study using electronic health records to identify women aged 21–65 years old with ICD code of SLE M32.9, positive ANA and who have prescription for hydroxychloroquine on their medication list. We compared this to controls (women 21–65 years of age with a ICD code of asthma ICD J45*, negative ANA and excluded patients with SLE diagnosis). For both groups we excluded patients who underwent hysterectomy with removal of the cervix. We used statistical calculator to ‘N-1’ Chi-squared test

Results Much higher proportion of SLE women are overdue for pap smears compared to non SLE women (60.09% vs

Abstract 252 Figure 1 Pap screening in SLE & non SLE patients

Abstract 252 Table 1 (1) SLE women and pap smear screening rates as well as average age; (2) SLE women and HPV screening rates as well as HPV positivity

SLE women	PAP smear health maintenance in SLE women	Average Age of the patient	
Overdue	363 (60.09%)	48.60 y/o	
Not due	241 (39.90%)	45.57 y/o	
Total	604		

SLE women	Pap smear health maintenance	Tested for HPV	Tested positive for HPV
Overdue	363 (60.09%)	178 (49.03%)	35 (19.66% of those tested)
Not due	241 (39.90%)	209 (86.72%)	60 (28.70% of those tested)
Total	604	387	95

Abstract 252 Table 2 Non-SLE women and HPV screening rates as well as HPV positivity

non-SLE	Pap smear health maintenance	Tested for HPV	Tested positive for HPV
Overdue	1709 (51.21 %)	723 (42.34%)	150 (20.74% of those tested)
Not due	1628 (48.78%)	1398 (85.87%)	330 (23.60% of those tested)
Total	3,337	2,121	480

51.21% $p=0.0022$). Non-SLE women are more likely to be up to date on pap screening compared to SLE women (48.59% vs 39.90% $p=0.0117$). SLE women who are up to date on pap screening and who have had previous positive HPV pap testing had a similar rate of HPV positivity compared to non-SLE patients (28.70% vs 20.60% $p=0.163$). There was a significant difference when we compared black SLE patients to white SLE patients with regards to overdue status (56.60% vs 43.49% $p=0.0197$), overdue status with prior HPV positivity in black SLE versus white SLE patients (70% vs 30% $p=0.0455$) and also higher rate of HPV positivity in black SLE versus white SLE patients (66.02% vs 33.97% $p\leq 0.0001$). When we compared pap overdue black SLE vs black non-SLE we found higher number of black SLE patients were overdue versus black non-SLE (56% vs 46.36%

$p=0.0144$) however the inverse was noted for white SLE and white non-SLE (43.39% vs 53.63% $p=0.0263$).

Conclusions This study suggests that women with SLE are at a significantly higher risk of falling behind on PAP smears when compared to women without SLE. Significant racial disparities between black SLE women and white SLE exist at our institution. Black SLE patients have a significant higher rate of HPV positivity compared to white SLE patients. Increased rate of HPV positivity and lower rates of screening in black SLE patients in conjunction with the known increased risk of cervical neoplasia due to SLE disease itself and due to immunomodulators used to treat SLE signifies that treating physicians should be mindful of the importance of preventative measures, such as cervical screening and HPV vaccination in the SLE population in particular black SLE patients.

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Abstract 252 Table 3 (1) Comparing SLE vs non-SLE using 'N-1' Chi-squared test; (2) Comparing black SLE patients to white SLE patients using 'N-1' chi-squared test

	SLE = n (%)	non SLE = n (%)	p-value
Overdue	363 (60.09%)	1,709 (51.21%)	$P = 0.0022$
Not due	241 (39.90%)	1,628 (48.59%)	$P = 0.0117$
Overdue with prior HPV positivity	35 (19.66%)	150 (20.74%)	$P = 0.8871$
Not due with prior HPV positivity	60 (28.70%)	330 (20.60%)	$P = 0.1630$
Overdue in black population	180 (56.60%)	688 (46.36%)	$P = 0.0144$
Overdue in white population	138 (43.39%)	796 (53.63%)	$P = 0.0263$
Overdue with prior HPV positivity in black population	21 (70%)	77 (55.39%)	$P = 0.2308$
Overdue with prior HPV positivity in white population	9(30%)	62(44.60%)	$P = 0.4114$
Not due with prior HPV positivity in black population	138 (66.02%)	168 (59.94%)	$P = 0.2746$
Not due with prior HPV positivity in white population	71 (33.97%)	127 (43.05%)	$P = 0.2118$

	Black	White	P value
Overdue	180 (56.60%)	138 (43.39%)	$P = 0.0197$
Overdue with prior HPV positivity	21 (70%)	9 (30%)	$P = 0.0455$
Not due with prior HPV positivity	138 (66.02%)	71(33.97%)	$P < 0.0001$

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VALIDATION AND RELIABILITY OF A DISEASE-SPECIFIC QUALITY OF LIFE MEASURE IN PATIENTS WITH CUTANEOUS LUPUS ERYTHEMATOSUS

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Background Cutaneous lupus erythematosus (CLE) is a potentially disfiguring, chronic autoimmune disease with variable skin manifestations, negatively affecting the quality of life (QoL) of patients. Patient-reported outcome (PRO) measures used in assessing QoL in CLE patients have been either generic or developed without input from patients with CLE. The objective of this study was to demonstrate the reliability and validity of a disease-specific QoL measure for CLE the cutaneous lupus erythematosus quality of life (CLEQoL).

Methods A total of 101 patients with a diagnosis of CLE were recruited at outpatient dermatology clinics at the University of Texas Southwestern Medical Center and Parkland Health and Hospital System in Dallas, TX. Each patient was asked to complete the CLEQoL and Short Form 36 (SF-36). The CLEQoL contains 29 questions from the SKINDEX, a generic skin disease QoL measure, three questions relating to photosensitivity and alopecia (adapted from the SKINDEX-29 +3), and four questions from the vitiligo-specific quality of life (VitiQoL) (figure 1). These questions were validated via focus groups of patients with CLE. Internal consistency was

used as a measure of reliability. Validity was measured in two ways structural validity via exploratory factor analysis and convergent validity via Spearman correlations between CLEQoL and SF-36. Patient demographic and disease characteristics were collected. Data was analyzed using SPSS and significance was set to $p < 0.05$.

Results The average age of our CLE patients was 48 ± 13 with discoid lupus ($n=72$, 71.3%) being the most predominant CLE subtype. Patients were mostly female ($n=88$, 87.1%) and African-American/Black ($n=59$, 58.4%). Internal consistency ranged from 0.67 to 0.95. A total of five domains, functioning, emotions, symptoms, body image/cosmetic effects and photosensitivity, were extracted with a total explained variance of 71.06%. CLEQoL-related domains correlated with SF-36 domains (r ranging from -0.39 to -0.65). The Cutaneous Lupus Activity and Severity Index (CLASI) activity scores correlated positively with the CLEQoL functioning ($r=0.24$, $p<0.05$), emotions ($r=0.26$, $p<0.05$), and symptoms ($r=0.32$, $p<0.05$) domains. CLASI damage scores correlated positively with the CLEQoL body image/cosmetic effects ($r=0.41$, $p<0.001$) and photosensitivity ($r=0.25$, $p<0.05$).

Conclusions The CLEQoL was found to be a valid and reliable PRO measure for assessing QoL in patients with CLE. Demonstrating that the CLEQoL has strong psychometric properties is an important step towards the development of a disease-specific PRO measure for future CLE clinical trials.

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