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Teratogenic medication use associated with favourable odds of contraception counselling in a cohort of women with systemic lupus erythematosus at a large tertiary academic medical centre

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ABSTRACT

Objective SLE primarily affects women of childbearing age, who have an increased risk of pregnancy complications, especially in the setting of active disease. Contraception counselling is particularly important given the teratogenicity of some medications used for SLE treatment. Our study describes the frequency of contraception counselling provided by multiple subspecialties to women with SLE and investigates associations between teratogenic medication use and receiving contraception counselling.

Methods This was a cross-sectional retrospective study of women (aged 15–46 years) diagnosed with SLE who were seen in various outpatient clinics at a large tertiary academic medical centre over a 2-year period. Demographic data were retrieved via the university-affiliated central data repository, and additional data, including documentation of contraception counselling, were obtained via manual chart abstraction. Univariable associations between variables and contraception counselling were assessed to produce unadjusted ORs and 95% CIs. Multivariable models were generated to evaluate independent associations between variables and contraception counselling.

Results Data from 478 women (52% African American, 25% Caucasian) with SLE were included. Rheumatology was the subspecialty to document contraception counselling most frequently (57%). Nearly 80% of women received counselling from at least one subspecialty, 44% from at least two. Factors associated with having lower odds of receiving contraception counselling were older age and Caucasian race. Women on teratogenic medications (methotrexate, mycophenolate mofetil/mycophenolic acid, cyclophosphamide) had higher odds of receiving contraception counselling from at least one subspecialty (OR 2.01; 95% CI 1.23 to 3.26), from two or more subspecialties (OR 2.18; 95% CI 1.50 to 3.17), and from rheumatology (OR 1.86; 95% CI 1.27 to 2.73).

Conclusions In this study, women with SLE on teratogenic medications had higher odds of receiving contraception counselling from rheumatology and from at least two subspecialties. Multidisciplinary approaches to enhance contraception counselling should be encouraged.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ SLE primarily affects women of childbearing age, who have an increased risk of pregnancy complications such as pregnancy loss and pre-eclampsia. Some medications prescribed to treat SLE manifestations are teratogenic. Contraception counselling in this vulnerable population is therefore important.

WHAT THIS STUDY ADDS

⇒ We found that women who were older or who were Caucasian had lower odds of receiving contraception counselling. Women who were on teratogenic medications were more likely to receive contraception counselling from multiple subspecialties.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Results from our study can inform more streamlined contraception counselling efforts for patients with SLE across medical subspecialties.

INTRODUCTION

SLE primarily affects women of childbearing age, who have an increased risk of pregnancy complications such as pre-eclampsia and pregnancy loss, especially in the setting of active disease.[1] A study found that 40% of pregnant women with SLE had unplanned pregnancies and these pregnancies were more likely to be conceived during periods of higher SLE activity and result in adverse pregnancy outcomes.[2] Unplanned pregnancy has also been identified as an independent risk factor for fetal loss in patients with SLE.[3] There are additional risks related to the teratogenicity of immunosuppressive medications used for SLE treatment. Therefore, contraception counselling should be promoted to encourage pregnancy planning

Table 1 Characteristics of patients in the SLE cohort (N=478)

Characteristics	n	%
Demographics		
Age (range=15–46), mean±SD years	33.6	±8.0
Race		
(Missing)	26	5.4
African American	248	51.9
Caucasian	118	24.7
Other	66	13.8
Asian	15	3.1
American Indian/Native Alaskan	5	1.0
Positivity of antiphospholipid antibodies (missing=91)	152	31.8
Counselling		
Specialty of contraception counselling (not mutually exclusive)		
Rheumatology	272	56.9
OB/GYN	155	32.4
Nephrology	97	20.3
Family medicine	48	10.0
Internal medicine (IM)	45	9.4
Other	40	8.4
Haematology	22	4.6
Pharmacy	15	3.1
Number of counselling specialties		
0	103	21.5
1 (most common groups (n=): rheumatology (92), OB/GYN (36), family (12), nephrology (11))	165	34.5
2 (rheumatology+OB/GYN (45), rheumatology+nephrology (24))	127	26.6
3 (rheumatology+OB/GYN+nephrology (12), rheumatology+nephrology+IM (9))	60	12.6
4 (rheumatology+OB/GYN+nephrology+other (6))	21	4.4
5 (rheumatology+OB/GYN+nephrology+IM+other)	1	0.2
6 (rheumatology+OB/GYN+nephrology+other+haematology+pharmacy)	1	0.2
At least 1 counselling specialty	375	78.5
At least 2 counselling specialties	210	43.9
At least 3 counselling specialties	83	17.4
Immunosuppression		
Immunosuppression use (not mutually exclusive)		
Hydroxychloroquine (HCQ)	412	86.2
Mycophenolate mofetil/mycophenolic acid (MMF/MPA)	143	29.9
Monoclonal antibody (mAb) (missing=1)	73	15.3
Methotrexate (MTX)	33	6.9
Cyclophosphamide (CYC) (missing=1)	10	2.1
Teratogenic (MMF/MPA, MTX, CYC)	183	38.3
Number of immunosuppressive medications		
(Missing)	2	0.4
0	23	4.8
1 (most common groups (n=): HCQ (230), MMF/MPA (18), mAb (11))	266	55.6
2 (HCQ+MMF/MPA (102), HCQ+mAb (30), HCQ+MTX (18))	159	33.3
3 (HCQ+MMF/MPA+mAb (15), HCQ+mAb+MTX (9))	28	5.9
At least 1 immunosuppressive medication (missing=2)	453	94.8
At least 2 immunosuppressive medications (missing=2)	187	39.1

Continued

Table 1 Continued

Characteristics	n	%
Contraception		
Type of contraception (n=)		
None documented (106) or documented as not using (38)	144	30.1
Levonorgestrel IUD (65), Nexplanon (27), copper IUD (10), patch (1) or ring (1)	104	21.8
Tubal ligation/salpingectomy (58) or partner vasectomy (6)/orchiectomy (1)	65	13.6
Depo-Provera injections (32) or progestin-only OCPs (16)	48	10.0
Condoms	35	7.3
Abstinence	32	6.7
Combination OCPs	30	6.3
Currently pregnant (8), menopausal (7) or same sex partner (5)	20	4.2

mAb: includes rituximab and belimumab.
IUD, intrauterine device; OB/GYN, obstetrics/gynaecology; OCPs, oral contraceptives.

during periods of quiescent disease and avoid the risks of unintended pregnancy.[4 5]

Limited evidence exists on contraception counselling in women with SLE. Data suggest that fewer than half of women with SLE report receiving contraception counselling within the past year, most often from a rheumatologist (64%) or obstetrician/gynaecologist (36%).[4 6 7] In a 2014 study, a majority of patients with SLE reported that their reproductive health concerns were not sufficiently addressed during their appointments, also noting discrepancies in providers' recommendations.[8] These findings highlight a need for improved contraception counselling for patients with SLE and underscore the important role of specialist providers in addressing this discrepancy.

Additionally, within the medical community, knowledge gaps seem to exist regarding reproductive health concerns of women with SLE. Some medications regarded as low teratogenic risk are discontinued during pre-conception or pregnancy, perhaps due to limited understanding that disease exacerbation can potentially carry more risks than using these medications during pregnancy.[9] Yazdany *et al* found that women with SLE using teratogenic medications were 'no more likely to have received contraceptive counselling to have used contraception consistently, or to have used more effective contraceptives' than those not taking teratogenic medications.[4] A survey by Clowse *et al* found that rheumatologists overestimated the effectiveness of condoms and DMPA (depot medroxyprogesterone acetate), and only 37% correctly identified mycophenolate mofetil (MMF) as teratogenic.[10] There is a need for more comprehensive education efforts across multiple specialties to enhance the care of women with SLE.

In this study, we aimed to describe the frequency of contraception counselling provided by multiple subspecialties to women with SLE and identify factors associated with receiving contraception counselling. We also specifically investigated associations between teratogenic medication use and receiving contraception counselling.

METHODS

Study setting and population

This was a cross-sectional retrospective chart review conducted at the University of North Carolina (UNC), a large, tertiary academic medical centre in Chapel Hill, North Carolina. Ours was part of a larger analysis performed by our UNC obstetrics/gynaecology (OB/GYN) colleagues who investigated overall trends in contraception use and contraception counselling in women with SLE.[11] We specifically focused on associations with contraception counselling across multiple subspecialties, given the multidisciplinary nature of care often provided to patients with SLE.

With the assistance of the university-affiliated central data repository North Carolina Translational and Clinical Sciences Institute, we identified our population of women, aged 15–46 years, who had an International Classification of Disease (ICD) code M32 of SLE, who were seen between June 2016 and June 2018 in rheumatology, nephrology, OB/GYN, haematology, internal medicine, family medicine and pharmacy outpatient clinics. Among the subspecialties that were included in this study, the rheumatology clinic has a separate pharmacy clinic that provides medication counselling. Patients with a history of hysterectomy, bilateral oophorectomy or menopause were excluded.

Data collection

Documentation of race/ethnicity, contraception, immunosuppressive medication and contraception counselling by different subspecialties was obtained by manual chart abstraction. Teratogenic immunosuppressive medications were defined as cyclophosphamide (CYC), MMF/mycophenolic acid (MPA) and methotrexate (MTX).

As per Silverstein *et al*, any contraceptive method that was documented within 2 years of the study period, without documentation of cessation, was included in the study. Contraception counselling was defined as either

documentation in a clinic note or a discussion of contraception in discharge instructions.[11]

Statistical analysis

Counts and percentages were produced for categorical variables, while mean and SD were computed for continuous variables. Univariable associations between variables and contraception counselling were assessed to produce unadjusted ORs and 95% CIs. To assess independent associations of covariables with contraception counselling, multivariable logistic regression was separately modelled for the log odds of contraception counselling (1) from at least one subspecialty, (2) from at least two subspecialties and (3) from rheumatology. Age, race and immunosuppressive medications were included in the models to produce adjusted ORs and 95% CI. A fourth multivariable, cumulative proportional odds logistic model was used to treat the contraception counselling outcome as ordinal for the number of subspecialties using four levels, from zero to three or more specialties.

Some (5.6%) information for race and immunosuppressive medications was missing in our dataset and was assumed to be missing at random. For the multivariable analyses, multiple imputation using fully conditional specification logistic regression was used to impute these missing categorical covariables. Models were averaged over 25 imputed datasets.

All analyses were performed with SAS V.9.4 (SAS Institute). Statistical significance was determined at p=0.05.

RESULTS

Data from 478 women with SLE were included. The mean age of our study population was 34 years, with 52% African American and 25% Caucasian. Of the 478 women, 38% were prescribed a teratogenic medication. Nearly 80% of women received counselling from at least one subspecialty (57% from rheumatology) and 44% of women received contraception counselling from at least two subspecialties (table 1).

The univariable analysis showed that women who were on average older (OR for a 10-year increase, 0.64; 95% CI 0.48 to 0.85) or were Caucasian (OR compared with African American women, 0.51; 95% CI 0.30 to 0.86) had lower odds of receiving contraception counselling. Women on two or more types of immunosuppressive medication had higher odds of receiving contraception counselling (OR compared with one or none, 1.84; 95% CI 1.14 to 2.97) (table 2). Women on teratogenic medications (ie, MTX, MMF/MPA, CYC) had higher odds of receiving contraception counselling from at least one subspecialty (OR 2.01; 95% CI 1.23 to 3.26), from two or more subspecialties (OR 2.18; 95% CI 1.50 to 3.17), and from rheumatology (OR 1.86; 95% CI 1.27 to 2.73) (table 2).

The multivariable analysis showed that women using teratogenic immunosuppressive medications had higher odds of receiving contraception counselling from additional subspecialties (model 4 cumulative OR 2.09; 95% CI 1.48 to 2.95) independent of age, race or use of other immunosuppressive medications (table 3). Multivariable analyses modelling (1) at least one subspecialty, (2) at least two subspecialties and (3) rheumatology all showed similar results.

DISCUSSION

We found that women with SLE on teratogenic medications had higher odds of receiving contraception counselling from rheumatology and from multiple subspecialties. To our knowledge, ours is the first study to investigate contraception counselling across multiple subspecialties for patients with SLE. Patients with SLE often regularly see other specialists besides their rheumatologist, so streamlining counselling efforts across subspecialties is crucial.

We found that women who were older and who were Caucasian had lower odds of receiving contraception counselling. These findings resemble those from Ferguson *et al* who found that women were who were older, white and had high disease activity were less likely to receive contraception counselling.[9] While fertility does decline with age, pregnancy is still common after age 40 years; the birth rate for women aged 40–44 years has increased on average by 3% annually from 1985 to 2020.[12] Therefore, contraception counselling in this population should be addressed. The association we found between race and contraception counselling is likely complex and warrants further focused investigation.

Besides the inclusion of multiple subspecialties, this study has other strengths. Our sample size was large and the utilisation of a large central data repository to assess objective data helped avoid potential biases.

Our study also has some limitations. Since all patients were seen at one healthcare centre, our results may not be generalisable to the population at large. Focusing on one healthcare centre may have also excluded care received from external healthcare providers during the study period. Reliance on ICD diagnosis codes for SLE, rather than specific clinical classification and diagnostic criteria, could have potentially underestimated the size of our population due to billing/coding discrepancies. Additionally, we did not investigate SLE disease activity measures and their impact on contraception counselling efforts.

One of the main limitations of this study was the reliance on clinic notes and discharge paperwork to define contraception counselling. This could have led to the overestimation of contraception counselling in our population (80%), which deviates from most reports closer to 40%.[4 13] Additionally, Silverstein *et al* found that 52% of patients who declined contraception were on a teratogenic medication.[11] We could not ascertain the quality or comprehensiveness of the contraception counselling delivered to patients in this study, and therefore do not know if patients not on contraception underwent more

Table 2 Univariable associations between various factors and receiving contraception counselling

Exposures	Categories	No contraception counselling (n=103, 22%) n (%) or mean±SD	Any contraception counselling (n=375, 78%) n (%) or mean±SD	OR (95% CI)	None or one contraception counselling specialty (n=268, 56%) n (%) or mean±SD	At least 2 contraception counselling specialties (n=210, 44%) n (%) or mean±SD	OR (95% CI)	No rheumatology contraception counselling (n=206, 43%) n (%) or mean±SD	Rheumatology contraception counselling (n=272, 57%) n (%) or mean±SD	OR (95% CI)
Age	Continuous years, 10 years older	35.7±8.3	33.0±7.8	**0.64 (0.48 to 0.85)**	34.8±8.1	31.9±7.6	**0.63 (0.50 to 0.79)**	34.8±7.9	32.6±7.9	**0.71 (0.56 to 0.90)**
Race	African American	41 (17)	207 (83)	1.00 (ref)	132 (53)	116 (47)	1.00 (ref)	99 (40)	149 (60)	1.00 (ref)
	Caucasian	33 (28)	85 (72)	**0.51 (0.30 to 0.86)**	76 (64)	42 (36)	**0.63 (0.40 to 0.99)**	56 (47)	62 (53)	0.74 (0.47 to 1.14)
	Other/Asian/ AI/NA	21 (24)	65 (76)	0.61 (0.34 to 1.11)	46 (53)	40 (47)	0.99 (0.61 to 1.62)	39 (45)	47 (55)	0.80 (0.49 to 1.31)
Immuno-suppression	No HCQ	16 (24)	50 (76)	1.00 (ref)	40 (61)	26 (39)	1.00 (ref)	29 (44)	37 (56)	1.00 (ref)
	HCQ	87 (21)	325 (79)	1.20 (0.65 to 2.20)	228 (55)	184 (45)	1.24 (0.73 to 2.11)	177 (43)	235 (57)	1.04 (0.62 to 1.76)
	No MMF/MPA	81 (24)	254 (76)	1.00 (ref)	204 (61)	131 (39)	1.00 (ref)	157 (47)	178 (53)	1.00 (ref)
	MMF/MPA	22 (15)	121 (85)	**1.75 (1.04 to 2.95)**	64 (45)	79 (55)	**1.92 (1.29 to 2.86)**	49 (34)	94 (66)	**1.69 (1.13 to 2.54)**
	No mAb	88 (22)	316 (78)	1.00 (ref)	226 (56)	178 (44)	1.00 (ref)	179 (44)	225 (56)	1.00 (ref)
	mAb	15 (21)	58 (79)	1.08 (0.58 to 1.99)	41 (56)	32 (44)	0.99 (0.60 to 1.64)	26 (36)	47 (64)	1.44 (0.86 to 2.41)
	No MTX	100 (22)	345 (78)	1.00 (ref)	256 (58)	189 (42)	1.00 (ref)	196 (44)	249 (56)	1.00 (ref)
	MTX	3 (9)	30 (91)	2.90 (0.87 to 9.69)	12 (36)	21 (64)	**2.37 (1.14 to 4.94)**	10 (30)	23 (70)	1.81 (0.84 to 3.89)
	No CYC	100 (21)	367 (79)	1.00 (ref)	262 (56)	205 (44)	1.00 (ref)	202 (43)	265 (57)	1.00 (ref)
	CYC	2 (20)	8 (80)	1.09 (0.23 to 5.21)	5 (50)	5 (50)	1.28 (0.37 to 4.47)	3 (30)	7 (70)	1.78 (0.45 to 6.96)
	No teratogenic	76 (26)	219 (74)	1.00 (ref)	187 (63)	108 (37)	1.00 (ref)	144 (49)	151 (51)	1.00 (ref)
	Any teratogenic	27 (15)	156 (85)	**2.01 (1.23 to 3.26)**	81 (44)	102 (56)	**2.18 (1.50 to 3.17)**	62 (34)	121 (66)	**1.86 (1.27 to 2.73)**
Number of immuno-suppressive medications used	0	8 (35)	15 (65)	1.00 (ref)	18 (78)	5 (22)	1.00 (ref)	14 (61)	9 (39)	1.00 (ref)
	1–3	94 (21)	359 (79)	2.04 (0.84 to 4.95)	248 (55)	205 (45)	**2.98 (1.09 to 8.15)**	190 (42)	263 (58)	2.15 (0.91 to 5.08)
	0–1	73 (25)	216 (75)	1.00 (ref)	182 (63)	107 (37)	1.00 (ref)	140 (48)	149 (52)	1.00 (ref)
	2–3	29 (16)	158 (84)	**1.84 (1.14 to 2.97)**	84 (45)	103 (55)	**2.09 (1.43 to 3.03)**	64 (34)	123 (66)	**1.81 (1.23 to 2.64)**

ORs and 95% CIs are shown in **bold** when the null effect is excluded at alpha=0.05. OR >1 indicates higher odds of contraception counselling defined; OR <1 indicates lower odds of contraception counselling defined, compared with the reference group.
AI/NA, American Indian/Native Alaskan; CYC, cyclophosphamide; HCQ, hydroxychloroquine; mAb, monoclonal antibody (includes rituximab and belimumab); MMF, mycophenolate mofetil; MPA, mycophenolic acid; MTX, methotrexate.

Table 3 Multivariable associations between various factors and receiving contraception counselling

Model by outcome*					
		Model 1: any contraception counselling	Model 2: at least two contraception counselling specialties	Model 3: rheumatology contraception counselling	Model 4: cumulated over multiple to no counselling specialties
Covariables	Comparison	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)
Age	Age: 10 years older	**0.65 (0.48 to 0.87)**	**0.65 (0.51 to 0.83)**	**0.72 (0.56 to 0.91)**	**0.66 (0.53 to 0.81)**
Race	Caucasian (ref=African American)	**0.58 (0.34 to 0.99)**	0.75 (0.47 to 1.19)	0.80 (0.51 to 1.25)	0.73 (0.49 to 1.09)
	Other/Asian/AI/NA (ref=African American)	0.58 (0.31 to 1.08)	0.97 (0.58 to 1.60)	0.75 (0.45 to 1.25)	1.03 (0.66 to 1.62)
Immunosuppression	Hydroxychloroquine (ref=not)	1.24 (0.66 to 2.35)	1.31 (0.76 to 2.28)	1.12 (0.65 to 1.93)	1.29 (0.80 to 2.08)
	Monoclonal Ab (ref=not)	1.18 (0.62 to 2.24)	1.06 (0.62 to 1.79)	1.52 (0.89 to 2.59)	1.02 (0.65 to 1.61)
	Any teratogenic (ref=not)	**1.97 (1.20 to 3.24)**	**2.11 (1.43 to 3.11)**	**1.81 (1.22 to 2.67)**	**2.09 (1.48 to 2.95)**

Results are based on 25 multiple imputed datasets.
Monoclonal Ab includes rituximab and belimumab.
Any teratogenic immunosuppression includes cyclophosphamide, methotrexate, mycophenolate mofetil and mycophenolic acid.
aORs and 95% CIs are shown in **bold** when the null effect is excluded at alpha=0.05. aOR >1 indicates higher odds of contraception counselling defined; aOR <1 indicates lower odds of contraception counselling defined, compared with the reference group.
*Models 1–3 results are from three separate multivariable logistic models and model 4 is from a multivariable, cumulative proportional odds logistic model for a four-level, ordinal, polytomous outcome of no contraception counselling, one contraception counselling subspecialty, two contraception counselling specialties, and three or more counselling specialties.
Ab, antibody; AI/NA, American Indian/Native Alaskan; aOR, adjusted OR.

robust contraception counselling efforts. Previous studies have suggested that contraception counselling increases the use of effective contraception and may also reduce rates of unintended pregnancy, but studies comparing the effectiveness of counselling techniques are still needed.[4]

Yazdany *et al* developed a quality measure to document contraception counselling for all women with SLE of childbearing potential when initiating teratogenic medications.[14] The HOP-STEP (Healthy Outcomes in Pregnancy with SLE Through Education of Providers) Programme strives to empower providers (primarily rheumatologists) to counsel patients on reproductive health planning.[15] Future studies could perhaps apply these principles across multiple subspecialties to enhance the delivery of contraception counselling to women with SLE.

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