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Determinants of Adherence to Medical Therapy in Pregnant Patients with Systemic Lupus Erythematosus

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ABSTRACT

Objective: To assess the determinants of adherence to medical therapy among pregnant patients with Systemic Lupus Erythematosus. **Study Design:** Cross-sectional study. **Duration and Place of Study:** The study was conducted from August 2023 to February 2024 at CMH Multan. **Methodology**: A total of 196 pregnant women diagnosed with SLE were enrolled. Data were collected using a structured interview schedule and the 8-item Morisky Medication Adherence Scale (MMAS-8). Participants were assessed for socio-demographic factors, disease-related characteristics, and factors influencing adherence. Medication adherence was evaluated in relation to educational level, disease awareness, family support, and interaction with healthcare providers. **Results**: The mean age of participants was 29.05 ± 6.01 years, with a higher prevalence in rural areas (68.4%). Results showed that 91.3% of patients were confident in adhering to their medication regimen, but only 74% had satisfactory patient-provider communication. **Conclusion:** Key determinants such as education, disease awareness, communication with healthcare providers, and family support significantly affect medication adherence in pregnant women with SLE.

INTRODUCTION

Systemic Lupus Erythematosus (SLE) is an autoimmune disease with a systemic, recurring, and unpredictable nature, with widespread inflammation in one or many organ systems, including the skin, joints, kidneys, heart, and nervous system.[1] SLE arises when healthy tissue is attacked by an overexcited immune system, with extensive tissue loss and a variety of symptoms, including fever, rashes, arthritic symptoms, and profound exhaustion.[2] SLE most often involves women, particularly during their reproductive years, and pregnancy management in such a scenario is a great concern.[3] SLE pregnancy is complex in terms of disease flares, complications such as preeclampsia and prematurity, and both maternal and fetal complications.[4]

The therapy for SLE during pregnancy is a balancing act between disease-suppressing drugs safe for pregnancy and developing infant.[5] Aspirin in low dosages, hydroxychloroquine, and corticosteroids have been shown to have a minimum disease flaring and little toxicity for infant and can be included in therapy in most cases.[6] In severity, drugs such as azathioprine can be started under medical supervision. Medical professionals have to educate pregnant patients regarding compliance with regimens, with improper use and stoppage of drugs having an impact for infant and mother.[7]

Adherence to therapy reflects the manner in which therapy regimens, such as taking drugs in an orderly sequence, compliance with scheduled appointments, and compliance with life style modifications advised, follow in an orderly sequence.[8] In pregnancy SLE, compliance is particularly important in that its failure can exacerbate disease activity, complicate complications, and jeopardize both maternal-fetal well-being.[9] Despite its importance, compliance in such a population tends to dip below ideal, and a range of obstacles is responsible for such a state of affairs. Forgetfulness, improper instruction, financial constraint, concern regarding complications of drugs, and mental misery with a long-term disease state can generate such a state of affairs.[10]

Healthcare professionals have an important role in enhancing compliance through proper information, allaying apprehensions, and ongoing follow-up during pregnancy.[11]

A range of factors underlies compliance with medical therapy in pregnant SLE patients, both individual and systemic factors in care delivery.[12] On an individual level, awareness of SLE and its therapy and SLE and its therapy awareness have a strong impact, with educated and knowledgeable SLE and its therapy-aware patients and SLE and its therapy-aware patients tending to comply with therapy.[13] Socioeconomics, including educational level, financial level, and access to medical care, have a strong impact, with a patient's financial capacity to pay for drugs and follow-up appointments in their hands.[14] Depression, anxiety, and feelings of stigma can cause non-adherence through a lack of motivation and a lack of efficacy in oneself.[15] On a larger level, patient-provider relation, cultural values, and society's values about pregnancy and disease have an impact on compliance behavior.[15]

This study is crucial due to the unique challenges faced by pregnant women with SLE. Pregnancy adds complexity to the management of SLE, as the disease itself, combined with the potential impact of medications on both the mother and fetus, requires careful treatment planning. Adherence to medical therapy is essential to prevent disease flare-ups, manage symptoms, and ensure the health of both the mother and baby. However, non-adherence can lead to increased risk of complications, such as miscarriage, preterm birth, and organ damage. This study aims to identify factors influencing medication adherence in this population, providing valuable insights to improve treatment outcomes and maternal-fetal health during pregnancy.

METHODOLOGY

This cross-sectional study was conducted over a six-month period, from August to February 2024, at CMH Multan. A convenience sample of 196 pregnant patients meeting the inclusion criteria was recruited for the study. The sample size was determined using the Epi-info-7 program, with parameters set at an expected frequency of 85% of patients had the confidence to take their medications regularly,[16] an acceptable error margin of 5%, and a confidence coefficient of 95%, resulting in a minimum required sample size of 196 participants.

The inclusion criteria included pregnant women aged 18 to 40 years with an established diagnosis of systemic autoimmune diseases (SAD) who were under treatment for their rheumatic condition. For SLE specifically, diagnosis was made using the 2019 EULAR/ACR Classification Criteria, requiring a positive ANA test as entry criterion and accumulation of 10 or more points across seven clinical and three immunologic domains. Patients who were unable to communicate or unwilling to participate were excluded. For medication adherence assessment in pregnant women, the study used the 8-item Morisky Medication Adherence Scale (MMAS-8) to evaluate adherence to hydroxychloroquine (HCQ) and low-dose aspirin in patients with antiphospholipid antibodies. A score ≥6 was considered as an indicator of good adherence, while a score <3 indicated very poor adherence. Vitamins and dietary supplements were not included in the adherence assessment.

The study utilized two tools to assess the determinants influencing adherence to medical therapy among pregnant patients with Systemic Lupus Erythematosus (SLE). The first tool, a structured interview schedule, gathered socio-demographic and clinical data, as well as patient knowledge regarding SLE and its medications. A 3-point Likert scale was used to assess knowledge levels, with scores of 2 for correct and complete answers, 1 for correct but incomplete answers, and 0 for incorrect or unknown responses. Knowledge scores were categorized as poor (<50%), fair (50–74%), or good (≥75%).

The second tool, a checklist assessing factors affecting medication adherence, included 52 statements across five dimensions: educational, social and economic, healthcare system, condition-related, and therapy-related factors. Responses were recorded as "Yes" or "No" and represented statistically as numbers and percentages.

The study identified key factors influencing adherence, including patients' understanding of their disease and medication necessity, confidence in taking medications regularly, and perceived stigma. Family support in managing medications and healthcare system factors, such as doctors explaining medication use, importance, and side effects, were also considered. Scoring of responses allowed for the quantification of adherence-related barriers, aiding in the identification of key areas for intervention.

Data analysis was conducted via IBM SPSS version 26. Continuous variables were expressed as mean ± standard deviation. Categorical variables were represented as frequencies and percentages. Correlation of education level and duration of SLE with determinants of adherence to medical therapy was also done, with a p-value of ≤ 0.05 considered significant.

RESULTS

The mean age of patients was 29.05 ± 6.01 years, with a mean parity of 2.62 ± 1.82 and a mean duration of SLE of 3.67 ± 1.77 years (as shown in Table-I). Education levels varied, with 46.9% being uneducated, 40.3% having primary education, 6.1% secondary education, and 6.6% higher education. The majority (68.4%) resided in rural areas, while 31.6% lived in urban settings (as shown in Table 1).

Regarding adherence to medical therapy, 71.4% of patients reported having information about their disease, 88.3% understood the necessity of their medications, and

91.3% expressed confidence in taking their medications regularly. Additionally, 88.3% did not feel stigmatized by the disease, and the same percentage received help from family members. While 88.3% reported that doctors explained the use of medications, only 74% felt that doctors allowed them to ask questions (as shown in Table 2).

Correlation analyses revealed significant relationships between education level, duration of SLE, and adherence determinants. Education level showed a significant negative correlation with feeling stigmatized by the disease (p=0.011) and a positive correlation with receiving help from family members (p=0.014). Duration of SLE was positively correlated with understanding the necessity of medications (p=0.000) but negatively correlated with doctors explaining medication use (p=0.029). Information about the disease was significantly correlated with understanding medication necessity (p=0.000), confidence in taking medications regularly (p=0.000), and not feeling stigmatized (p=0.000). Confidence in taking medications was also positively correlated with not feeling stigmatized (p=0.018) and doctors allowing questions (p=0.039) (as shown in Table 3).

Table 1

Patient Demographics

Demographics		**Mean ± SD / n (%)**
Age (years)		29.046±6.01
Parity		2.622±1.82
Duration of Systemic lupus erythematosus (years)		3.668±1.77
Education Level	Uneducated	92 (46.9%)
	Primary	79 (40.3%)
	Secondary	12 (6.1%)
	Higher	13 (6.6%)
Residential Status	Rural	134 (68.4%)
	Urban	62 (31.6%)

Table 2

Determinants of Adherence to Medical Therapy

Determinants of Adherence to Medical Therapy	**Frequency**	**%age**
Information about their disease	140	71.4%
Understood the necessity of their medications	173	88.3%
Confidence to take their medications regularly	179	91.3%
Did not feel stigmatized by the disease	173	88.3%
Receiving help from family members	173	88.3%
Doctors explained the use	173	88.3%
Doctors allowed them to ask questions	145	74%

Table 3

Correlation of Education Level and Duration of SLE with Determinants of Adherence to Medical Therapy

Variables		**Education Level**	**Duration of SLE**	**Information about their disease**	**Understood the necessity of their medications**	**Confidence to take their medications regularly**	**Did not feel stigmatized by the disease**	**Receiving help from family members**	**Doctors explained the use**	**Doctors allowed them to ask questions**
Education Level	Pearson Correlation	1	0.028	-.274**	-0.124	0.057	-.181*	.174*	0.044	-0.068
	Sig. (2-tailed)		0.702	0.000	0.082	0.425	0.011	0.014	0.543	0.345
	N	196	196	196	196	196	196	196	196	196
Duration of SLE	Pearson Correlation	0.028	1	0.068	.248**	0.017	-0.003	0.086	-.156*	-0.020
	Sig. (2-tailed)	0.702		0.347	0.000	0.815	0.963	0.228	0.029	0.777
	N	196	196	196	196	196	196	196	196	196
Information about their disease	Pearson Correlation	-.274**	0.068	1	.366**	.447**	.331**	0.015	-0.020	.320**
	Sig. (2-tailed)	0.000	0.347		0.000	0.000	0.000	0.834	0.780	0.000
	N	196	196	196	196	196	196	196	196	196
Understood the necessity of their medications	Pearson Correlation	-0.124	.248**	.366**	1	.226**	.212**	-0.084	-0.133	0.109
	Sig. (2-tailed)	0.082	0.000	0.000		0.001	0.003	0.244	0.063	0.128
	N	196	196	196	196	196	196	196	196	196
Confidence to take their medications regularly	Pearson Correlation	0.057	0.017	.447**	.226**	1	.169*	-0.112	0.000	.148*
	Sig. (2-tailed)	0.425	0.815	0.000	0.001		0.018	0.117	0.997	0.039
	N	196	196	196	196	196	196	196	196	196
Did not feel stigmatized by the disease	Pearson Correlation	-.181*	-0.003	.331**	.212**	.169*	1	-0.084	-0.034	0.109
	Sig. (2-tailed)	0.011	0.963	0.000	0.003	0.018		0.244	0.632	0.128
	N	196	196	196	196	196	196	196	196	196
Receiving help from family members	Pearson Correlation	.174*	0.086	0.015	-0.084	-0.112	-0.084	1	-0.034	-0.036
	Sig. (2-tailed)	0.014	0.228	0.834	0.244	0.117	0.244		0.632	0.621
	N	196	196	196	196	196	196	196	196	196
Doctors explained the use	Pearson Correlation	0.044	-.156*	-0.020	-0.133	0.000	-0.034	-0.034	1	0.073
	Sig. (2-tailed)	0.543	0.029	0.780	0.063	0.997	0.632	0.632		0.310
	N	196	196	196	196	196	196	196	196	196
Doctors allowed them to ask questions	Pearson Correlation	-0.068	-0.020	.320**	0.109	.148*	0.109	-0.036	0.073	1
	Sig. (2-tailed)	0.345	0.777	0.000	0.128	0.039	0.128	0.621	0.310	
	N	196	196	196	196	196	196	196	196	196

DISCUSSION

The results indicated that a high value for the proportion of patients knowing that they have to use drugs (88.3%) and thinking about taking drugs regularly (91.3%), and such high values can be attributed to proper guidance and counseling of a patient. Yet, a relatively low value for opportunity to inquire proportion (74%) reflects an improper communication between a patient and a provider, and such an improper communication can generate a barrier in adherence. High value for educational level and less feeling of stigma (p=0.011) reflects a role for overcoming adherence-related psychosocial barriers through health education. In addition, positive values between disease duration and medication necessity awareness (p=0.000) can have a cumulative role for long-term disease care and patient empowerment.

The mean age of our subjects (29.05 ± 6.01 years) is in agreement with that of Clowse et al. [17] with a mean age of 29.05 years, and with Zucchi et al. [18] with a mean age of 35.6 years. As in our investigation, and in contrast with Zucchi et al.[18] and in agreement with the meta-analysis of Clowse et al.[17] in our investigation, female subjects in reproductive age, a group pertinent to SLE care in pregnancy, took part.

The high rural dwelling value (68.4%) in our investigation identifies a function for geographical and socioeconomic factors in care access, and such factors can impact adherence, a function corroborated also by Mahmoud et al. [16] who, in an investigation, revealed that patient-related factors such as psychological factors and lack of information can serve as a barrier for adherence.

Regarding adherence, 71.4% of subjects in our study mentioned having information about disease, and 88.3% knew why drugs have been taken, a fact similar to that of Zucchi et al. [18] in whom high adherence level in well-informed subjects was observed. That fact confirms the conclusion of Chambers et al. [19] in whom an important role for patient education and information delivery in adherence improvement was stressed. In our study, 91.3% of subjects mentioned confidence in taking drugs regularly, a fact similar to that of Bălălău et al. [20] in whom an important role for adherence in pregnancy improvement in SLE subjects was stressed.

Our study, in fact, even found a significant, negative correlation between educational level and disease stigmatization (p=0.011), in agreement with Mahmoud et al. [16] who stressed educational interventions for adherence enhancement. In a similar manner, positive correlation between disease duration and awareness regarding taking drugs (p=0.000) is in agreement with Clowse et al. [17] in whom disease duration is positively correlated with disease awareness.

In terms of doctor-patient conversation, our study found 88.3% of respondents concurring that physicians mentioned the use of drugs, but 74% concurring that physicians gave them an opportunity to contribute in asking for information. That observation mirrors concerns in a report in Chambers et al. [19] in that patient involvement and incorrect information produce non-adherence. Besides, Zucchi et al. [18] supported a role for contact between doctor and patient in attaining adherence, namely during pregnancy, in under picking a similar role for increased conversation in our work.

A notable observation variation is a significant positive association between educational level and having family supporting them with a supportive role (p=0.014), and an indicative role for family in adherence, specifically in rural environments with potentially limited access to care. Mahmoud et al. [16] discussed psychological and information-related barriers, but our observation brings to fore the family's supportive role, specifically in environments with limited access to care.

Our study confirmed a negative relation between educational level and feeling stigmatized (p=0.011), and, therefore, a less educated patient can have a greater opportunity for feeling stigmatized for having such a disease, and in consequence, can have an adherence problem with therapy. Stigma, in its function in interfering with therapy adherence, has been addressed in studies in the past, for instance, work performed by Chambers et al. [19] but our study’s relation with educational level introduces new information about overcoming stigma with educational intervention.

Additionally, our analysis revealed that confidence in taking drugs positively correlated with not being stigmatized (p=0.018) and with permission of physicians for questions (p=0.039), and thus, underlines the intersection between medical and psychological care factors. Where, in contrast, studies such as Zucchi et al. [18] have long-established that psychological factors such as anxiety have an impact on adherence, our analysis sets out that confidence in taking drugs can best be developed through communicative and supportive medical care, and is a significant role in enhancing adherence, in long-term diseases such as SLE.

So, our study validates the multidimensional nature of SLE pregnant women adherence with medication and places strong emphasis on patient information, patient education, and social networks. As our study is consistent with most significant studies in the field, it brings new information about the level of education, disease duration, and stigma, but future studies, including larger and mixed samples, will have to validate and extend our present picture of complex factors in adherence with medication and work out specific interventions for improvement in patient outcomes.

One limitation of our study is its single-center design, and its generalizability to larger groups could potentially have been limited. Besides, its relatively small group could have compromised part of its statistics' power for its correlations. It measured adherence through selfreport, and adherence could potentially have been underreported and over reported due to recall bias. Future studies will have to conduct multi-center trials with larger and more diverse groups, and objective adherence measurement in an effort to make its results even more reliable.

CONCLUSION

Our study concluded that a variety of factors impact medication adherence in pregnant SLE patients, including level of education, disease duration, and patient-provider communication. Higher disease awareness, family support, and less stigma towards SLE and its consequences have been seen to have a positive impact in terms of adherence. What emerges most clearly in these studies is the value of educational interventions, direct communications with providers, and consideration of psychosocial factors in enhancing adherence and improving outcomes in pregnant SLE patients.

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