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ROLE OF PATIENT-REPORTED OUTCOME MEASURES (PROMs) IN SYSTEMIC LUPUS ERYTHEMATOSUS: A SYSTEMATIC REVIEW

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Abstract: Patient-reported outcomes (PROs) throughout care with individual patients present a critical function in the overall clinical decision-making, which leads to the optimization of the therapeutic plan for Systemic Lupus Erythematosus (SLE) patients. The current study seeks to identify and accurately evaluate all studies appraising patient-reported Health-Related Quality of Life (HRQoL) in patients with SLE. A systematic literature review was performed through SCOPUS database up to January 2021. All potential materials and relevant PROMs were summarized for non-validation studies and perform a methodological quality assessment of identified SLE-specific PROMs studies utilizing the Consensus-based Standards for the selection of health Measurement INstruments (COSMIN). Thirty articles were included in the shortlist to assess PROMs relevant from 3,946 studies initially identified, of which seven materials were used for validation studies focusing on SLE-specific PROMs. High bias (83%) was evident among generic instruments indicating low confidence that the results represent the actual treatment effect. For the validation studies using COSMIN analysis, the reliability of material was determined by the lowest score of all quality items for each criterion of measurement. The systematic review performed is unlikely to determine specific issues concerning the quality of life of the patient due to lack of evidence of its clinimetric importance due to inconsistent study design and PRO reporting in studies. However, studying SLE-specific PROMs has a favorable impact on patients and clinicians concerning its HRQOL, which can further be improved by future researchers when sufficient clinical data and investigations are conducted.

Keywords: Systematic review, Patient-reported outcome measures, Systemic Lupus Erythematosus, Health-Related Quality of Life

INTRODUCTION

Systemic lupus erythematosus (SLE) is a complex, chronic autoimmune disease with multi-systemic involvement, resulting in diverse symptoms that usually target the organs, including the skin, joints, and kidneys. SLE patients' survival rate has improved considerably due to advancements in the therapeutic protocol of the disease that involves a holistic approach in disease symptoms and reducing the adverse drug reactions of the therapy (Mahieu et al., 2016). Despite these therapeutic benefits of certain medications to manage the disease, SLE still has a crucial influence on a patient's daily function and requires prolonged care.

Patients with symptomatic SLE experience a wide range of manifestations that are characterized by fluctuating symptoms, flares and remissions, and are not always measured by objective clinical parameters or laboratory assessment. To overcome these challenges, it is highly recommended to gather and appraise available data on the health-related quality of life (HRQoL), which is the patient's perception about the different domains of health and functional capacity.

The healthcare team, including the clinical decision-makers, are slowly recognizing the importance of obtaining the patients' health-related quality of life through validated and reliable patient-reported outcome (PRO) measures in addition to the assessment of disease activities and damage indices which is the primary therapeutic goal of physicians (Mathias et al., 2018).

Patient-reported outcomes (PROs) are defined as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (Mercieca-Bebber et al., 2018). PROs throughout care with individual patients have a critical role in patient assessment, formulation of clinical decision-making, and tracking patient progress through relevant and corresponding health information data on disease activity and damage index when it comes to the optimization of the therapeutic plan for SLE patients. This approach provides patients' perception and view of health and can significantly influence patient-clinician encounters and pharmaceutical care, impacting the therapeutic alliance and increasing patient engagement.

Furthermore, measurement of the HRQOL through PROs provides SLE patients with a holistic approach and opportunity to participate in their therapy and well-established clinical outcomes used in clinical practice and facilitates two-way communication to the health care team involved in their treatment.

The current study seeks to collect and accurately evaluate all studies appraising patient-reported Health-Related Quality of Life (HRQoL) in patients with Systemic Lupus Erythematosus and to perform a methodological quality assessment of identified SLE-specific PROMs studies utilizing the Consensus-based Standards for the selection of health Measurement INstruments (COSMIN).

MATERIALS AND METHODS

Research Design

This study is designed to perform a systematic review analyzing the roles of patient-reported outcome measures in systemic lupus erythematosus. It utilizes the systematic approach for the literature review, focusing on articles that fit the criteria and give insight into the topic being addressed. From the obtained articles, the researchers gathered and summarized the related findings to make an overall conclusion supporting the objective of the study. Additionally, the systematic review follows the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) diagram.

Search strategy

Following the COSMIN recommendation, the first step in the methodology is the establishment of a search strategy. To collect as many PROM-based instruments for appraisal, a search strategy emphasizing on sensitivity rather than specificity was developed. All relevant study journals were assessed using SCOPUS, which is linked to several databases, including PubMed, MEDLINE, EMBASE, and Compendex coverage. The focus on PROMs specifically addressing the health-related quality of life was selected to collect a comparable set of measures concerning construct validity. The following search criteria were used to identify relevant studies: "Systemic Lupus Erythematosus" OR "SLE" OR "Lupus" OR "Lupus Erythematosus" OR "Disseminated Lupus Erythematosus") AND ("Patient-Reported Outcome Measures" OR "Patient-Reported Outcomes" OR "PROM" OR "PRO" OR hr-pro OR hrpro) AND ("Quality of Life" OR HRQoL OR qol OR ql OR qol OR hrql).

The literature search was performed from 1946 up to January 2021 and was limited to full-text articles. The search was also limited to materials obtained in the English language. Only studies involving adult population with SLE were included.

Study Screening and Selection

Articles collected through literature screening were initially assessed by abstract by two reviewers (LT and JE) independently and subsequently underwent full-text review for its eligibility. The overall inclusion criteria were original studies with participants diagnosed with SLE, and that uses PROMs to evaluate HRQoL formed either validation or non-validation studies. Excluded were non-English studies, as well as articles that reported on pediatric patients and patients with organ complications as a result of SLE due to patient variability of these groups and treatment management variability of these groups. Studies that are classified as systematic reviews and meta-analyses, as well as editorial comments, letters and case reports were excluded. Identical materials were critically appraised and removed, respectively. Figure 1 shows the preferred reporting items for systematic reviews and meta-analysis (PRISMA) flow diagram.

Data extraction and quality assessment of non-validation and PROM-specific validation studies

Data were extracted from the remaining studies and collected the details of the following characteristics: study design/type, sample size, outcome measures, and PROM-specific details such as PRO concept and PRO instruments used and scoring methodology (Table 1). The methodological quality of each non-validation studies was evaluated using the Cochrane risk-of-bias tool for randomized trials (RoB 2.0), which is structured into a series of domains (bias due to missing outcome data, bias arising from the randomization process, the bias in the selection of the reported result, bias due to deviations from intended interventions, and the bias in the measurement of the outcome) through which bias might be introduced into the study. For PROM-specific validation studies, the quality assessment was performed using the COSMIN analysis consisting of 3 specific SLE-PROMs (LIT, SLEQOL, LupusQoL) in which the quality of each material is evaluated, the results of the studies are extracted, and an overall conclusion was obtained per measurement property with regards to the quality of the instrument based on the appraised pieces of evidence for each measurement instrument. Nine measurement properties, namely, (1) structural validity, (2) internal consistency, (3) cross-cultural validity, (4) measurement invariance, (5) reliability, (6) measurement error, (7) criterion validity, (8) hypothesis testing for construct validity, and (9) responsiveness was assessed by the checklist using standardized assessment framework.

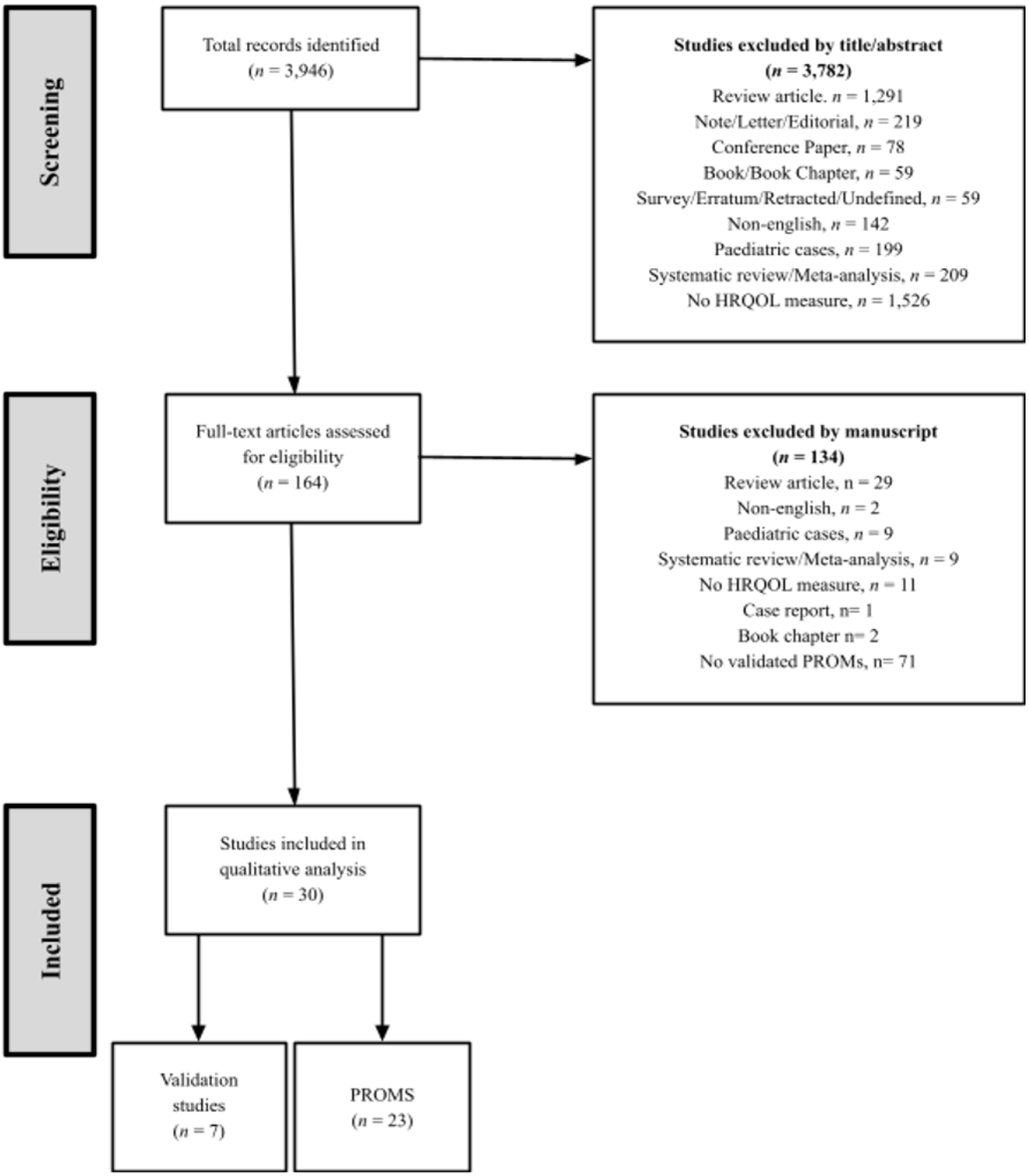

Figure 1. Preferred reporting items for systematic review and meta-analysis (PRISMA) flow diagram

Table 1. Summary of Study Characteristics for Non-validation Studies

Characteristics		**n**	**%**
Year of publication	*2001-2010*	1	4.3
	2011-2021	22	95.7
Origin of the study	*Europe*	7	30.4
	Asia	1	4.3
	North America	11	47.8
	Intercontinental	4	17.4
Study Type	*Randomized-controlled trials*	5	21.7
	Prospective longitudinal studies	5	21.7
	Cross-sectional	12	52.2
	Non-randomized-controlled trials	1	4.3
Number of study sites	*1*	14	60.9
	2	3	13
	3	1	4.3
	4	2	8.7
	≥5	3	13
Sample size	*1-100*	1	4.3
	101-200	10	43.5
	201-300	4	17.4
	301-400	2	8.7
	>400	6	26.1
PRO as an outcome measure	*Primary outcome*	18	78.3
	Secondary outcome	2	8.7
	Primary and Secondary outcome	3	13
Number of PROs measure	*1*	18	78.3
	2	4	17.4
	>2	1	4.3
When PRO was measured	*Suspected SLE patients*	0	0
	SLE patients	23	100
PRO instruments used	*Generic PRO*		
	EuroQoL-5D	3	13
	Short-form 36	15	65.2
	PROMIS-10	5	21.7
	SF 12	1	4.3
	SLE specific PRO		
	LupusQoL	2	8.7
	LupusPRO	2	8.7
	LIT	1	4.3
Distribution of PROs	*Clinic*	16	69.6
	Phone	1	4.3
	Email	3	13
	Not specified	3	13

RESULTS AND DISCUSSION

A total of 3,946 studies were initially evaluated by title and abstract review, and after the removal of ineligible literature by following the exclusion criteria, 164 were selected for detailed examination and assessed for eligibility. A total of 30 articles were selected for a full review utilizing PROMs, of which 7 works of literature were selected as validation studies focusing on SLE-specific PROMs. Reasons for exclusion were as follows: PRO questionnaires were mostly insufficient in detail, or no HRQoL measures were also not explained in some materials. Further information on literature exclusion is shown in Figure 1.

Characteristics of Included Studies

Of 23 non-validation studies selected, the majority were performed from (2011-2021). (95.7%) in North America (47.8%) and as single-centered studies (60.9%). The majority of the articles were classified as cross-sectional studies (52.2%) in which only five articles are classified as randomized-controlled trials (4.3%). Among all PROMs evaluated, the 36-item Short Form survey (SF-36) generic measure was featured the most frequently (65.2%). The majority of the study samples were found to have a sample size between 101-200 (43.5%), followed by six articles describing a population of >400 (26.1%).

Risk of Bias Assessment

Most studies included in the review demonstrated a high bias towards randomization, outcome measurement, and the selection of reported results, and low bias towards deviation from the intended intervention and missing outcome data. Figure 2, shown below, summarizes the risk of bias assessment for each study. Several studies do not have information about allocation sequence or were not sufficiently concealed. Since blinding was poorly performed, the high bias attributed to the outcome measurement was significantly influenced by knowledge of the intervention received, and most results were selected from patient-reported outcome measurements within the outcome domain. The overall risk of bias illustrated in Figure 3 reveals that 19 (83%) studies show high risk, 1 (4%) shows some concerns, and only 3 (13 %) studies show low risk.

Validation Studies and COSMIN Analysis

Table 2 summarizes the scores for each measurement property of 7 PROM-validation studies. Of these studies, four reported on the Lupus Impact Tracker (LIT), One reported on the SLE Quality of Life (SLEQOL), and two on the Lupus Quality of Life (LupusQoL). The assessment scored “adequate” content validity for all studies, whereas only four studies scored "very good" to "adequate" structural validity. The soundness of content was determined by probing both patients and professionals regarding relevance, comprehensiveness, and comprehensibility of the PROMs for the construct, target population, and intended context of use. The assessment of PROM development was not considered since not all identified PROM-validation studies include pilot testing. All studies were found to be "inadequate" for cross-cultural validity, reliability, and measurement error; whereas, only one study showed "very good" criterion validity depicting poor internal structure. Of three studies tested for internal consistency, two scored "inadequate," and one was "doubtful." Only two studies were tested for construct validity and responsiveness, one of which resulted in "very good," whereas the other was "doubtful" and "inadequate," respectively. The results of measurement properties were not pooled and compared for good measurement properties due to the limited number of PROM-validation studies and thereby hindering the endorsement of SLE-specific PROM.

	D1	D2	D3	D4	D5	Overall
Dietz et al., (2020)	×	+	+	×	×	×
Elefante et al., (2020)	—	+	+	×	×	—
Kasturi et al., (2018)	—	+	+	×	×	×
Gavilán-Carrera et al., (2020)	×	+	+	+	×	×
Jolly et al., (2019)	+	+	+	+	+	+
Román Ivorra et al., (2019)	+	+	+	×	+	×
Patterson et al., (2018)	×	+	+	+	×	×
Jolly et al., (2016)	×	+	+	+	+	×
Inoue et al., (2017)	×	—	—	×	×	×
Magro-Checa et al., (2017)	×	+	+	×	×	×
Golder et al., (2017)	×	+	+	×	×	×
Mahieu et al., (2016)	×	+	+	×	×	×
Fidler et al., (2016)	×	+	+	×	×	×
Jolly et al., (2017)	+	+	+	+	×	×
Gordon et al., (2013)	×	+	+	×	×	×
Petri et al., (2013)	+	+	+	+	×	×
Moldovan et al., (2011)	×	+	+	×	×	×
Aggarwhal et al., (2009)	×	+	+	×	×	×
Lindblom et al., (2021)	+	+	+	+	+	+
Borg et al., (2021)	+	+	+	+	+	+
Kasturi et al., (2019)	×	+	+	+	×	×
Piga et al., (2017)	×	+	+	+	×	×
Lai et al., (2016)	×	+	+	+	—	×

Domains:

D1: Bias due to randomization

D2: Bias due to deviations from intended intervention

D3: Bias due to missing data

D4: Bias due to outcome measurement

D5: Bias due to selection of reported result

Judgement

× High

— Some concerns

\+ Low

Figure 2. Risk of Bias Assessment for Non-validation Studies

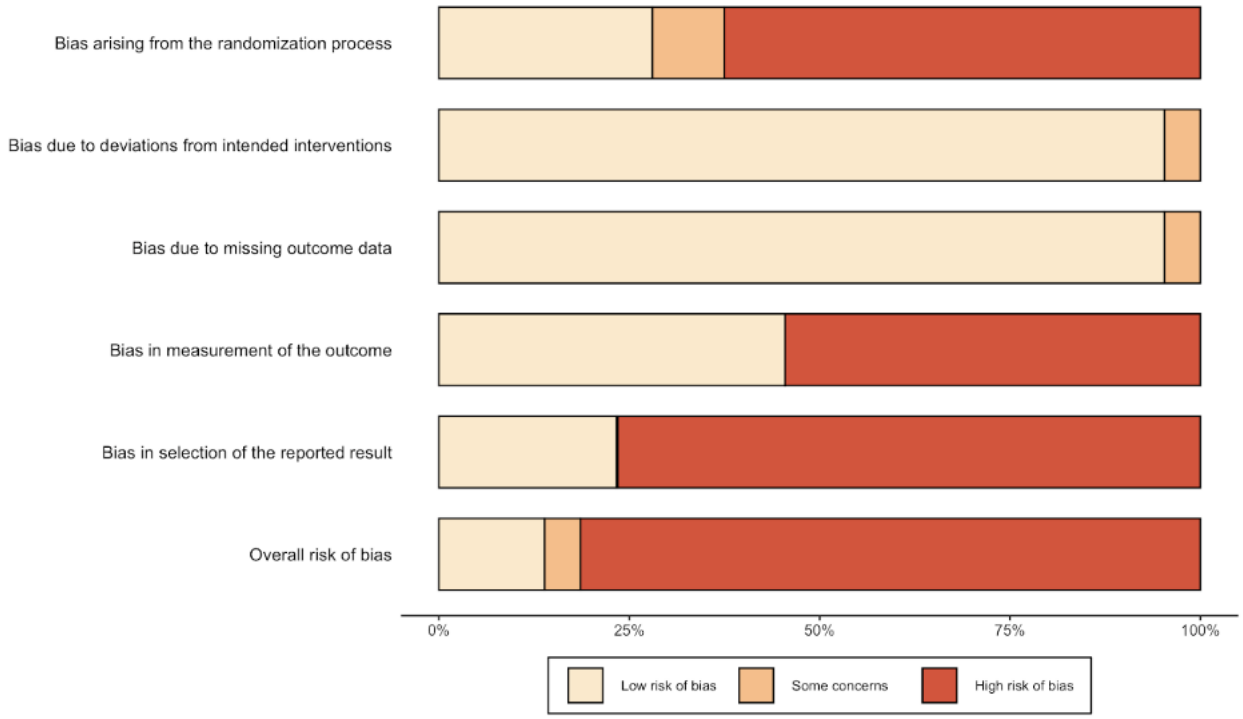

Figure 3. Summary of Overall Risk of Bias for Non-validation Studies

Table 2. Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) analysis of selected validation studies per Patient Reported Outcome Measure (PROM).

Measurement Properties	*Lupus Impact Tracker (LIT)*				*SLE Quality of Life (SLEQOL)*	*Lupus Quality of Life (LupusQOL)*	
	Elefante, 2020	Brandt, 2017	Schneider, 2017	Devilliers, 2016	Louthrenoo, 2020	Kasturi, 2017 (US)	Pamuk, 2014 (TR)
Content Validity	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate	Adequate
Structural validity	Adequate	Very good	Adequate	Inadequate	Very good	Inadequate	Inadequate
Internal consistency	–	–	Inadequate	–	–	Inadequate	Doubtful
Cross-cultural validity	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate
Reliability	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate
Measurement Error	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate	Inadequate
Criterion Validity	Inadequate	Inadequate	Inadequate	Inadequate	Very good	Inadequate	Inadequate
Construct validity	–	Very good	Doubtful	–	–	–	–
Responsiveness	–	Very good	Inadequate	–	–	–	–

Discussion

The role of patient-reported outcomes measurement (PROMs) to measure the health-related quality of life (HRQoL) in multifactorial diseases such as systemic lupus erythematosus (SLE) has increasingly gained attention in the medical and scientific community. In this study, generic (EuroQoL-5D, SF-36, PROMIS-10, SF 12) and specific (LupusQoL, LupusPRO, LIT, SLEQOL) PROM-based instruments for HRQoLin SLE were identified, and the measurement properties of SLE-specific PROMs were systematically reviewed based on the COSMIN method.

The initial section of this review concerned data mining of records that involved clinimetric assessment of PROM-based instruments to assess HRQoLin SLE. SCOPUS was used as the only referencing database resulting in 3,946 potential unique records. Restricting search efforts to SCOPUS while exploiting its linkage to several databases such as PubMed, MEDLINE, EMBASE, and Compendex, abridge the search scheme not only by automatically removing overlap in search hits but also ensuring much database coverage as possible. The next stage of reviews involved a full-text evaluation of 164 reports of PROM-based instruments and their measurement properties. However, many records were not eligible for inclusion due to non-validated PROM-based instruments (53%). This demonstrates that, while PROMs are routinely used in SLE management, many of these instruments are problematic with regards to validity, and thereby warranting further studies.

The latter stage of this review involved assessing the risk of bias and the level of evidence for every measurement index of the generic and SLE-specific PROM-based instruments from the former stage of review, respectively. High bias (83%) was evident among generic instruments indicating low confidence that the results represent the actual treatment effect. This denoted that generic PROM-based instruments could not effusively capture the changes in HRQoL, sanctioning recommendations towards SLE-specific PROM-based instruments. For the validation studies using COSMIN analysis, the reliability of material was determined by the lowest score of all quality items for each criterion of measurement. The SLE-specific instruments lacked a clear description of the measurement model used and were judged with inadequate internal structure. It is noteworthy that many articles referred to previous records to describe the study population instead of reporting it, which could lead to under or overestimation of the instruments. The COSMIN analysis results on SLE-specific PROM-based instruments were not combined due to the limited number of the included SLE-specific articles.

The strength of this review includes the reproducibility of a well-developed search methodology for finding and assessing review literature with the use of a clear set of inclusion and exclusion criteria. The decision to include and exclude journal articles at any stage of data extraction was also validated by different individuals' experts on the field to increase the reliability and minimizes the bias in the screening process. However, this systematic review did not conduct a grey literature search, which potentially omits unpublished but relevant materials. The electronic search has also been limited to the SCOPUS database and uses keywords determined by authors as a filter on the search strategy; and lastly, inadequate abstracts from journal articles may lead to premature exclusion during the initial screening process.

Currently, there is limited evidence on PROMs used in SLE, such as LupusQoL, LupusPRO, LIT, and SLEQoL, which is an expected gap because of the complexity of the disease, this scenario limits the clinicians to completely integrate and optimize the use of this tool in individual patients. Researchers need further studies about the health-related quality of life impact of systemic lupus erythematosus to patients having different characteristics to provide high-quality outcomes in validity and reliability of patient-reported outcome measures. The majority of PROMs evaluated did not have sufficient evidence for their use

with pregnant women, which is considered a high-risk population that has SLE. In order for researchers to appropriately associate the needs and treatment progress of pregnant women with SLE, new formulated and validated SLE-specific PROMs to reflect important issues to a specific population. The ideal study design in conducting SLE-related research is randomized-controlled and double-blinded to establish transparency of evidence synthesis results and findings. Researchers may also need to conduct further feasibility and acceptability studies to enhance the perspective of patient and clinician toward integration of SLE-specific PROMs. In the future, when these investigations are achieved, it will be easier to choose the most suitable PROM. Therefore, PROMs for measuring HRQoL in SLE patients in the field of clinical research will excellently be based on hard evidence contributing to each measurement properties of PROMs.

CONCLUSION

The systematic review of 30 studies for qualitative analysis of SLE specific PROMs, which focus on assessing HRQoLin SLE patients, particularly the generic outcomes measure, is unlikely to determine specific issues concerning the quality of life of the patient due to lack of evidence of its clinimetric importance due to inconsistent study design and PRO reporting in studies. The incorporation of disease-specific PROMs in SLE patients could have positive outcomes in physical health and psychological distress, and well-being. It is likely to improve intervention in clinical research trials, which may enhance HRQoL in these populations. The use of PROMs is continuously increasing its importance, but up until now, it has not been successfully established in routine use among clinicians focusing on SLE.

The review has identified the importance of having a holistic approach in the measurement of the clinical outcome of SLE patients by using comprehensive tools that cover all aspects of quality of life and are not confined to PROMs. However, a systematic review of PROMs has a favorable impact on patients and clinicians, which can further be improved by future researchers when sufficient clinical data and investigations are conducted.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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