STROBE Statement—checklist of items that should be included in reports of observational studies

RESEARCH ARTICLE: Health-related quality of life of adults with cutaneous leishmaniasis at ALERT Hospital, Addis Ababa, Ethiopia
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	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1 and 2	"A **cross-sectional study** was done using the Amharic version of the Dermatology Life Quality Index"
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1 and 2	"This study aimed to assess the health-related quality of life (HRQoL) using the Amharic version of the Dermatology Life Quality Index (DLQI) in adults diagnosed with active CL" (in summary). The HRQoL impairment associated with CL is significant.
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2 and 3	"CL is associated with reduced health-related quality of life (HRQoL) of affected individuals due to the appearance of active skin lesions or the permanent scarring on exposed body sites" "There is paucity of data on HRQoL of individuals with CL in Ethiopia".
Objectives	3	State specific objectives, including any prespecified hypotheses	3	"We aimed to assess the HRQoL associated with active CL"
Methods				
Study design	4	Present key elements of study design early in the paper	3	"A cross-sectional study was performed…"
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3	"This work was done at the dermatology department of ALERT Hospital, Addis Ababa, Ethiopia between December 2018 and December 2021." "The validated Amharic version of the DLQI [18] was completed for each participant prior

				to treatment by a trained interviewer."
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	3	"Individuals aged 18 years or older diagnosed with active CL (confirmed by microscopy and/or culture) who gave written informed consent were enrolled". "Inclusion was not consecutive as staff were not always available to recruit and not all affected individuals spoke Amharic."
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3	HRQoL in patients with CL is measured by DLQI score (outcome measure): a higher DLQI score indicates greater impairment of HRQoL. Exposure / predictors/ effect modifiers: - the type of CL ("The treating health care professionals classified participants as having LCL, MCL or DCL") - Demographic and clinical data - Location of lesions ("sites of skin lesions were categorised into regions as being on the head and neck or the torso and/or limbs or both regions. The head and neck skin lesions were further categorised into those affecting the face (not the lips or nose), lips or nose. Potential confounders are sociodemographic characteristics, area of residence, and location of the lesions.
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	3	Participant: Patient diagnosed with active CL as confirmed by microscopy and/or culture Type of CL: as diagnosed by treating physician. Location of CL lesion: as described by treating physician and participant. Demographic data: as described by participant: age; sex; residence ie rural or ueban
Bias	9	Describe any efforts to address potential sources of bias	3	As much as possible consecutive recruitment of Amharic speaking participants diagnosed with CL were conducted. No other selection criteria were applied
Study size	10	Explain how the study size was arrived at	4	Not applicable – 10 participants per question is usually sufficient to evaluate the effects of a condition on HRQoL. We had aimed at 150 participants minimum. We recruited 302.

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4	Descriptive statistics were used to compare medians and explored differences between gender, age, area of residence, affected body parts and type of CL with the assumptions that there is a difference in HRQoL scores between the different groups.
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	4	A comparison of scores between two groups was made using the Mann–Whitney U inspected rank test, and for three or more groups the Kruskal–Wallis H test. Adjusted multivariable ordinal logistic regression analysis was performed to identify the independent predictors of effect of CL on HRQoL. We used a model based on clinical phenotype, location of lesions, sex, age and residence P-values less than 0.05 were considered statistically significant.
		(*b*) Describe any methods used to examine subgroups and interactions	4 and 5	Regression analysis was used to examine subgroup analysis
		(*c*) Explain how missing data were addressed	3	Participants with missing data were to be excluded but no data were missing.
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy		Not applicable
		(*e*) Describe any sensitivity analyses		Not applicable
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	3	All 302 individuals diagnosed with active CL and approached to participate were recruited after giving consent. We did not keep a record of excluded individuals. They would have been excluded because of age (younger than 18) or inability to speak Amharic (the language of the questionnaire used)
		(b) Give reasons for non-participation at each stage	NA	All individuals approached consented to participate
		(c) Consider use of a flow diagram	NA	Not necessary as study is straightforward design
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	4	"The median age of 132 participants was 29 years (IQR 21; 45), 56.0% male (169/302) and 66.6% urban dwellers (201/302). The body region most affected was the head and neck in 270 (89.4%), of which involve the nose in 151 (50%), 134 other sites on the face in 122 (40.4%), and the lips in 35 (11.6%). The

				proportion of clinical phenotypes 135 were 62.6% LCL (189/302), 34.4% MCL (104/302), and 3.0% DCL (9/302) (Table 1)."
		(b) Indicate number of participants with missing data for each variable of interest	4	No missing data
		(		
Outcome data	15*			
		Cross-sectional study—Report numbers of outcome events or summary measures	4	The overall median DLQI score for the study participants was 10 (IQR 8). The range of DLQI scores was 2 to 29. Median DLQI scores were higher in participants diagnosed with DCL (median 18) compared to participants with MCL (median 11) and LCL (median 9) (Table 1 and Figure 1). Similarly, participants in the 30-39 year age group had higher DLQI scores (median 14; IQR 9).
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	5	In the multivariate analysis, clinical phenotype of CL, age of participants and the affected body region remained significantly associated with DLQI scores (Table 6). The odds of having low HRQoL was eight times higher in DCL cases (P = 0.003) compared to those with LCL. Younger,20 to 49 years, age groups and those having their head and face region affected had higher odds of having very poor HRQoL compared to those in 50 years and above, and those that have lesions on their Trunk and/or limbs. There was no significant difference in DLQI scores between male and female participants (P = 0.260) or rural and urban dwellers (P = 0.354).
		(*b*) Report category boundaries when continuous variables were categorized	4 and 6	Individuals rate the impact of their dermatological condition in the past week as "not at all, scored 0", "a little, scored 1", "a lot, scored 2", "very much, scored 3", The size of the HRQoL effect of active CL as measured by DLQI score ranged from small effect to extremely large effect (Table 3).
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-7	Table 3. The size of effect on HRQoL associated with clinical phenotype of cutaneous leishmaniasis. Table 4. Percentage of total possible domain score and median/ Interquartile range (IQR) of DLQI domains scores by sex of participants.

				Table 5. Percentage of total DLQI domain score and median/ Interquartile range by clinical phenotype of participants.
Discussion				
Key results	18	Summarise key results with reference to study objectives	6	'All participants with active CL experienced an effect on their HRQoL, which ranged from small effect to extremely large effect. Almost half of the participants reported either very large (36.4%) or extremely large (11.3%) effect on HRQoL.'
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8	'This study is a cross sectional prior to treatment, we cannot comment on possible treatment related changes in HRQoL. The clinical classification was based on the judgement of the dermatologist who assessed the patient rather than standardized case definitions."
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	7	"This study shows significant reduction in HRQoL for individuals with untreated CL in Ethiopia. Despite the differences in sociocultural grouping, study setting and causative Leishmania species, affected individuals are concerned with the extent of damage caused by CL. CL clinical phenotypes were associated significantly with different DLQI scores. Individuals with DCL had 8.8 times higher odds of having poor HRQoL compared to patients with LCL, which may be due to the extent of skin involvement and subsequent changes. Refai et al., observed that in Sri Lankan individuals with active LCL those with plaques and ulcerated lesions had higher DLQI scores than those with papules and nodules [21]. In Iran, Vares et al. found that those with ulcerated lesions had lower quality of life compared to those with nonulcerated lesions [14].:
Generalisability	21	Discuss the generalisability (external validity) of the study results		This study can be generalizable to cases with CL. This is not discussed in our paper
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2	Armauer Hansen Research Institute (Norad and Sida Core funding) funded this work.

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.