



Psychometric Properties of SF-36 in Sickle Cell Disease Patients Attending Outpatient Clinics in Ibadan, Nigeria

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Authors' contributions

This work was carried out in collaboration among all authors. Author AOO conceived the study, led the design of the review and drafted the manuscript. Author AEB contributed to data management and helped to draft the manuscript. Author JL participated in the design of the review and helped to draft the manuscript. All the authors read and approved the final manuscript.

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ABSTRACT

Purpose: This study assessed the psychometric properties of SF-36 and its factor structure in patients with sickle cell disease who are attending outpatient clinics in Nigeria.

Methods: Using a cross-sectional design, this study used a convenience sampling method to collect data from patients who visited the outpatient sickle cell clinics of two major hospitals in Ibadan, south west Nigeria. Reliability and validity were examined and factor analysis was carried out to determine the structure of the instrument in the population.

Results: Reliability of each of the dimensions was above 0.70. Item internal consistency ranged from 0.42 to 0.91 and scaling success ranged between 0.98 - 100%.

Conclusion: The instrument demonstrated acceptable reliability and validity and is suitable for assessing health-related quality of life in the sickle cell disease population.

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ABBREVIATIONS

HRQL : Health-related quality of life.

SCD : Sickle cell disease

SF-36 : The Medical Outcomes Study short form 36 health survey.

1. INTRODUCTION

Eighty-five percent of children born worldwide with sickle cell disease (SCD) are in Africa [1]. The disease, caused by inherited disorders of haemoglobin, is responsible for 6.2% of all under-five mortality in Africa [2–4] with Nigeria having the highest burden of the disease in the world [5,6]. In Nigeria, the prevalence of SCD is 20-30/1000 live births. This inherited sickle haemoglobin gene may also assume a carrier state status when paired with normal HbA for a genotype HbAS or HbAC, described as "sickle cell trait" (SCT). The prevalence of the sickle cell trait in many tropical African countries including Nigeria ranges between 20 and 30% of the population. SCT confers a survival advantage against malaria, the reason it is common in malaria endemic regions such as Nigeria. SCD was described as a "disease of childhood" [7] and until about four decades ago, the median age of survival was 14.3 years [8]. However, medical intervention and public health practices have led to an increase in survival rate [9–14]. SCD has thus evolved over time from a life-threatening disease of children to a chronic disease of adults [15]. Most people with SCD now live into their fifth decade [14,16]. This has shifted priorities from survival to long-term quality of life concerns [17] as the disease may progressively impact on patients' quality of life [18,19].

Quality of life was introduced as a key term in medical indices in 1975 [20]. Health-related quality of life (HRQL) focuses primarily on investigating an individual's view of his or her health status beyond what signs and symptoms may indicate when measuring treatment outcome. Such patient-based assessment along with clinicians' judgements is useful in evaluating medical interventions or effectiveness of medical therapy [20–22]. A major requirement in using self-report measures of health status is establishing the reliability and validity of the instrument in a specific culture and population [23]. Evaluation research and clinical trials are generally criticised on the grounds that they have

failed to measure the impact of healthcare interventions in any convincing way [24,25] because they fail to use validated measurements of quality of life. The emphasis has therefore been on the centrality of psychometric properties such as validity, reliability and method of scaling [26–28].

Measures of HRQL are either generic or disease-specific. The Medical Outcomes Study short form 36 health survey (SF-36) is a generic multidimensional measure designed to measure various components of HRQL [29] for self-administration by persons of 14 years of age or older [30]. The SF-36 is the most frequent measure used to study quality of life in SCD [31, 32]. The validity and reliability of the instrument has been established across age, race and population [30]. Exploratory factor analysis has been used to determine the factor structure of the instrument in 10 different populations [33]. Adults with SCD have reported poorer quality of life on seven of the eight dimensions (except the mental health scale) of the SF-36 compared with the general population [34]. Heo et al. [35] suggested that using SF-36 had advantages above the Sickness Impact Profile (SIP) questionnaire because of its more robust validity and test-retest reliability.

The psychometric properties of the instrument have been investigated in many general and disease populations [23,36–43]. We found two studies that have attempted to validate and examine the component structure of SCD in a Jamaican population [31,32] but these studies did not examine the eight domains or the factor structure as we have done in this study. Currently in Nigeria, studies on quality of life are rare and no study on the quality of life of SCD patients has been carried out. A study had been carried out in a general population of Yoruba speakers but this was to test the translation equivalence of SF-36 among Yoruba speakers [44]. The aim of the current study was therefore (i) to examine the psychometric properties of SF-36 and (ii) to describe the factor structure of the instrument in the SCD population in Nigeria.

2. METHODS

2.1 Design and Sample

This cross-sectional study was carried out at University College Hospital (UCH) and Adeoyo

General Hospital, Ibadan between January and May 2017. A convenience sample was chosen to recruit participants for the study who routinely came to the clinic for health maintenance. People were approached for participation as they arrived at clinics. Those who were in-patients or in trauma were excluded. Also people who were under intensive care or had any cognitive disability were excluded from the study. The total number of participants in this study was 200.

2.2 Procedure

People with SCD aged 18 years and older who were able to communicate in English or the local language were enlisted to participate. The study was explained to them and they were given a patient information sheet form to read. Those who showed interest in taking part signed an informed consent form and were given the questionnaires to complete.

Participants were asked to rate their health on a 5-point Likert scale from 1 = excellent, to 5=poor with lower scores indicating better health. Participants who required clarification were supported by a trained research assistant. Both the Yoruba [44] and English [30] versions of the instruments were made available to participants to choose whichever was convenient to them. All the participants preferred and completed the English version of the instruments.

2.3 Measures

An investigator-designed questionnaire was used to collect socio-demographic information. The SF-36 version 1 was used to collect information from the participants. The instrument is a health status measure consisting of eight scales from 35 of the 36 items; each scale represents a health dimension. These dimensions are Physical Functioning (PF), Role Physical (RP), Role Emotional (RE), Bodily Pain (BP), Vitality (VT), Mental Health (MH), General Health (GH), and Social Function (SF) and the one item on health transition or changes in health. All eight scales are independent of each other. These scales are alternatively referred to in this article as domains or dimensions. The developers also showed that the scales can be combined into two distinct constructs of the HRQL, the Physical Component Score (PCS) and or 'physical health', and the Mental Component Score (MCS) or psychological or mental health [39].

2.4 Statistical Analysis

The instrument was coded on a scale of 0-100 as recommended in the manual [45] and transformed so that higher values reflect better quality of health [46]. Each dimension or scale was obtained by adding all the items in the scale and dividing by the number of items. For example, the physical functioning (PF) scale was obtained by adding all the 10 items PF01 – PF10 and dividing by 10.

Norm-based scoring can be used to facilitate comparison and interpretation (www.qualitymetric.com). The norm-based scoring was based on the USA 1988 general population and each scale was scored to have a mean of 50 and a standard deviation of 10. This implies that all scores above 50 were interpreted as having a more positive response set to whatever the domain measures. Permission and scoring software license were obtained from QualityMetric Inc. (www.qualitymetric.com) to score the data.

The characteristics of the participants are presented in frequencies, percentages and simple measures of central tendencies. Tests of significance were performed on the domains of the SF-36 for comparison using t-test and one-way analysis of variance. The P value was fixed at 0.05.

A correlation table for inter-correlation items was computed (see Table 2). The correlations between items and the hypothesised scale (item internal consistency) was expected to be at least 0.40 [47] and the correlation between each item and its hypothesised scale (corrected for overlap) should be higher than the correlation between that item and the other scales (item discriminant validity). A scaling success rate was tallied for each item whenever it correlated higher with its hypothesised scale than with all the other scales[48]. Construct validity was based on socio-demographic variables [48,49]. We hypothesised that HRQL will be inversely associated with patients' age, lower socioeconomic level and relatively worse HRQL results for female patients [50]. The floor effect (percentage of patients with worst possible scores, 0) and the ceiling effect (percentage of patients with the best possible score, 100) were obtained for each scale.

Factor analysis was carried out to determine the structure of SF-36 in the Nigerian population of SCD patients. The principal component analysis was followed with varimax rotation on the 35

items. A factor was assumed relevant if its eigen value was greater than unity.

All data analyses were performed with SPSS software, version 23.0 (IBM SPSS Inc., Chicago IL).

3. RESULTS

3.1 Sample Characteristics

The mean age of participants was 27.9 years (SD: 6.95) and 58.5% of them were female. Also, 75.5% were single, 20.5% married and 4% either divorced or widowed. The ratio of patients with HbSS to HbSC was 85:15. The educational profile of the sample population was high with only 9.5% having below secondary education and 42.2% having tertiary education. Only 36% indicated that they had full time or part time employment and 92.9% were either living with relatives or friends.

The mean scores with corresponding standard deviations are shown in Table 1. Higher scores

represented better health, the highest score was in Mental Health while the lowest score was for Role Physical. Role Emotional had the highest deviation from the mean followed by the Role Physical. When compared with the norm-based scoring, the HRQL of SCD patients in Nigeria fell far below the norms in all the domains except in Vitality (VT) which was slightly above average (mean = 50.96, SD= 9.93).

The psychometric properties and scaling analysis are displayed in Table 2. Reliability was higher than 0.70 for all the domains, internal consistency and discriminant validity were also acceptable. The scaling test recorded 100% in all the domains except the GH domain where GH05 'my health is excellent' correlated higher with MH ($r = 0.68$) compared with its hypothesised scale ($r = 0.58$). The ceiling (the proportion of patients with best possible scores) was high for both RP and RE domains, 30 and 42.5 respectively. Both domains also recorded high floor (proportion of patients with worst possible score) 22.5 and 20 respectively.

Table 1. Quality of life domain scores of SF-36 in a SCD sample population, Ibadan, Nigeria

Scale	Conventional score*		Norm-based score**	
	Mean	Std. deviation	Mean	Std. deviation
Physical functioning (PF)	58.250	25.356	38.62	10.98
Role physical RP	53.625	38.289	41.88	11.36
Role emotional (RE)	61.333	39.319	44.01	11.63
Social functioning (SF)	64.563	27.676	41.33	12.33
Bodily pain (BP)	66.188	25.088	47.58	9.50
Vitality (VT)	62.850	21.157	50.96	9.93
Mental health (MH)	71.680	20.227	48.07	11.58
General health (GH)	67.362	21.422	47.48	11.66

* Score based on the 0-100 transformation

**Score based on US 1988 general population with mean 50 and SD 10

Table 2. Test of reliability and scaling parameters of SF-36 among SCD population, Ibadan, Nigeria

Scale	No. of items	Reliability cronbach (α)	item internal consistency ^a	Item discriminant validity ^b	Ceiling / floor ^c	Success /totals ^d	Scaling success (%)
PF	10	0.866	0.422 - 0.783	0.00-0.37	5.0 / 2.5	80/80	100
RP	4	0.771	0.731 - 0.796	0.17-0.51	30 / 22.5	32/32	100
RE	3	0.731	0.796 - 0.817	0.09-0.62	42.5 / 20	24/24	100
SF	2	0.774	0.9-0.906	0.15-0.47	18.0 / 1.0	16/16	100
BP	2	0.702	0.873-0.883	0.08-0.50	17.5 / 0.0	16/16	100
VT	4	0.715	0.688 - 0.805	0.02-0.51	1.5 / 0.0	32/32	100
MH	5	0.712	0.529 - 0.819	0.08-0.49	6.0 / 0.0	40/40	100
GH	5	0.716	0.575 - 0.775	0.07-0.68	5.0 / 0.0	39/40	98

a. Correlation between items and hypothesised scale

b. Correlation between items and other scales

c. Proportion of patients with best possible score (ceiling) and worst possible score (floor).

d. Number of hypothesised correlation higher /total number of correlations

Poorer health-related quality of life was observed for women in all the domains except in GH and about the same in MH (see Table 3). These differences were significant in BP ($t = 3.806$, $p < 0.001$) and SF ($t = 2.112$, $p < 0.036$). Married participants reported worse health in RE compared with others.

Age group 31-40 years reported worse health in RP, RE, GH and MH compared to younger ages but no difference from those aged above 40. Those with higher education reported worse quality of life in all domains except PF and SF compared with those with secondary education or lower. The differences were however not significant except in RP and GH. Living situation associated only with SF. Those living with others reported significantly better health than those living alone.

The factor analysis identified eight factors (see Table 4) which accounted for 64.4% of the total variance. The Eigen-values ranged between 8.5 and 1.3. Most of the items loaded as expected. The items of the MH scale were shared between factors 3 and 4 and one of the factors of GH (GH05) was loaded on factor 4. PF10 also loaded separately from the other 9 items; some cross-loadings were also observed for 3 items namely PF09, SF02 and VT03.

4. DISCUSSION

Our findings show that many dimensions of SF-36 depended on age (RP, RE, GH, MH), gender (BP, SF), marital status (RE), level of education (GH, RP) and living situation (SF). Males have better reported health than females in all the domains except in GH which is similar to findings in the UK general population [51]. The difference was significant in BP and SF. Women reported worse BP ($P < 0.001$) than men similar to findings in the Nigerian population of Yoruba speakers [44]. Married participants reported worse RE compared with others, a similar result for RP was observed in the general population of Jordan [52]. The finding that those living with others reported far better health in SF than those living alone, is probably a reflection of the positive impact of social support on people with SCD. People with SCD who have tertiary education reported significantly worse health-related quality of life in role physical (RP) and general health (GH). This may be due to their having higher life expectations which the condition has limited them from attaining. Family support seemed strong in line with African

cultural ties with 92.9% either living with relatives or friends, this reflected in the better life especially in social functioning (SF). The fact that less than 40% (compared to about 14.2% in the Nigerian population at the time of data collection) indicated that they had full time or part time employment may be due to their inability to get or retain a job as a result of their condition.

The RP and RE domains showed high ceiling (30% and 42.5% respectively) and floor (22.5% and 20%) effects. Although Bollinger et al. [53] argued that ceiling and floor effects should be less than 20% to assure that the scale captured the full range of potential responses, evidence have however shown that RP and RE tend to have ceiling and floor effects above this level. For example, Failde and Ramos [38] obtained 55% and 65% ceiling for RP and RE respectively and 22% and 33% floor effects in coronary artery disease patients. Cruz et al. [36] and Sullivan et al. [23] also observed higher than 20% floor and ceiling effects for these domains in coronary artery disease and in a general population of older Swedes respectively. These scales also found large standard deviations, which we also observed in the present study. Similar high standard deviations were obtained in earlier studies [23,38,40,54] which were a reflection of the high floor and ceiling effects they found. McHorney et al. [40] explained that these two domains, RP and RE, are the most "coarse" of all the eight domains. They suggested that the response categories for the items in these domains could be increased to establish a finer gradation in role disability beyond mere presence or absence of limitations [38,40]. We found that the VT scale had the best distribution with negligible floor and ceiling effects, similar to findings elsewhere [23].

The factor analysis reflects an eight-factor structure as posited by the developer with Eigen value greater than unity and over 60% variance accounted for [55]. Most of the items loaded as expected. We however note that the MH dimension loaded on two factors. This loading was similar to the results of Failde and Ramos [38]. Also, one of the items of GH loaded separately, this seems a better structure in SCD unlike in coronary artery disease where two of the items loaded separately [38]. Moorer et al. [37] also reported their inability to get all factors of MH assigned to one domain and those of GH assigned to the same domain. They however reported that these few violations were within the limit of chance [37].

Table 3. HRQL mean scores and socio-demographic characteristics of SCD study sample, Ibadan, Nigeria, 2017

	N	PF	RP	RE	GH	BP	SF	VT	MH
Gender									
Male	83	62.17 (24.1)	54.82 (36.3)	65.06 (36.8)	64.11 (20.9)	73.95 (22.3)	69.43 (26.2)	64.34 (21.2)	71.52 (19.0)
Female	117	55.47 (26)	52.77 (39.8)	58.69 (41)	69.67 (21.5)	60.68 (25.6)	61.11 (28.3)	61.79 (21.2)	71.79 (21.1)
<i>P</i> – value		.066	.711	.260	.071	<.001	.036	.404	.924
Age									
18-30	146	59.21 (26.7)	59.93 (36.7)	68.49 (37.5)	69.80 (20.9)	66.95 (25.8)	66.61 (27.5)	62.29 (22.3)	73.92 (18.9)
31-40	41	57.44 (20.8)	33.54 (37.3)	38.2 (36.2)	57.31 (21.5)	62.20 (23.5)	56.71 (28.7)	61.63 (18.3)	64.88 (19.7)
Above 40	13	50.00 (27.7)	46.15 (38.0)	53.85 (42.0)	71.63 (18.4)	70.19 (22.6)	66.35 (24.1)	72.31 (14.2)	68.00 (21.9)
<i>P</i> – value		.445	<.001	<.001	.003	.473	.125	.248	.032
Living situation									
Living alone	18	54.44(26.2)	55.56 (37.9)	51.85 (46.0)	66.46 (17.7)	61.81 (19.4)	45.14 (23.5)	61.11 (20.9)	64.67 (19.0)
Living with others	182	58.62 (25.3)	53.43 (38.4)	62.27 (38.6)	67.45 (21.8)	66.62 (25.6)	66.48 (27.4)	63.02 (21.2)	72.37 (20.3)
<i>P</i> – value		.506	.823	.285	.851	.439	.002	.716	.123
Marital status									
Married	41	54.76 (24.8)	43.90 (37.8)	48.78 (40.9)	67.2 (20.5)	67.68 (21.6)	57.93 (27.8)	64.76 (18.4)	73.76 (18.2)
Not married (single, divorced, widowed)	159	55.15 (25.5)	56.13 (38.1)	64.57 (38.4)	67.41 (21.7)	65.80 (21.9)	66.27 (27.5)	62.36 (21.8)	71.14 (20.7)
<i>P</i> – value		.324	.068	.021	.956	.670	.085	.519	.462
Education									
≤ Secondary school	116	57.33 (25.4)	58.41 (37.3)	61.78 (40.83)	72.65 (18.7)	67.24 (24.3)	63.25 (28.8)	64.52 (22.8)	72.69 (20.6)
> Secondary school	84	59.52 (25.4)	47.02 (38.9)	60.71 (37.4)	60.06 (22.9)	64.73 (26.2)	66.37 (26.1)	60.54 (18.5)	70.29 (19.8)
<i>P</i> – value		.547	.038	.850	<.001	.486	.434	.189	.408

Table 4. Rotated component matrix of SF-36 items in SCD sample, Ibadan, Nigeria

Component	1	2	3	4	5	6	7	8
PF01	0.568	0.091	0.06	0.193	0.048	-0.026	0.061	-0.31
PF02	0.684	0.191	0.12	-0.108	-0.203	0.147	0.119	-0.059
PF03	0.76	0.08	0.095	-0.013	0.05	0.135	-0.15	0.018
PF04	0.695	0.24	0.061	-0.104	0.013	0.305	0.018	0.024
PF05	0.721	0.099	0.092	0.001	0.028	0.132	0.008	0.298
PF06	0.718	-0.017	0.055	0.178	0.202	-0.078	-0.085	0.195
PF07	0.693	0.221	-0.06	0.009	0.142	-0.024	0.126	-0.035
PF08	0.673	0.201	-0.087	0.024	0.073	0.143	0.151	0.158
PF09	0.596	0.087	-0.009	-0.001	0.057	-0.098	0.128	0.602
PF10	0.246	-0.133	0.179	-0.017	-0.025	0.055	-0.165	0.766
RP01	0.282	0.636	0.021	0.144	0.272	-0.049	0.039	0.042
RP02	0.137	0.714	0.222	0.085	-0.009	0.123	-0.015	-0.051
RP03	0.168	0.649	0.093	0.251	0.024	-0.013	0.038	0.077
RP04	0.107	0.701	0.052	0.07	0.069	0.285	0.092	-0.104
RE01	0.132	0.699	0.042	-0.122	0.305	0.149	0.13	-0.023
RE02	0.06	0.724	0.31	0.059	-0.015	-0.047	-0.021	0.043
RE03	0.232	0.619	0.185	0.013	0.001	0.215	-0.121	-0.142
BP01	-0.054	0.137	0.063	0	0.782	0.011	0.164	0.148
BP02	0.136	0.085	0.201	0.012	0.768	0.17	0.113	-0.039
SF01	0.298	0.168	0.216	0.257	0.594	0.083	-0.078	-0.331
SF02	0.313	0.102	0.535	0.186	0.472	-0.03	-0.234	-0.13
MH01	0.041	0.283	0.499	0.134	0.092	0.072	-0.036	0.227
MH02	0.058	0.328	0.699	0.163	0.002	0.261	-0.039	0.207
MH03	-0.119	0.175	0.03	0.654	0.074	0.241	0.056	0.028
MH04	-0.02	0.251	0.727	0.213	0.238	0.051	0.061	0.022
MH05	0.101	0.002	0.22	0.756	0.049	0.041	0.266	-0.109
VT01	0.059	-0.121	-0.12	0.248	0.033	0.103	0.682	-0.063
VT02	0.056	0.144	-0.006	0.342	0.067	0.187	0.727	0.051
VT03	0.025	0.127	0.615	0.1	0.143	0.024	0.505	-0.132
VT04	0.098	0.069	0.488	-0.132	0.157	-0.017	0.66	-0.099
GH01	-0.014	0.235	-0.122	0.344	0.252	0.588	0.262	0.17
GH02	0.157	0.086	0.192	0.123	0.148	0.688	0.199	0.151
GH03	0.204	0.073	-0.082	0.277	0.096	0.654	0.082	-0.312
GH04	0.203	0.235	0.293	-0.052	-0.106	0.63	-0.079	-0.012
GH05	0.088	0.179	0.269	0.836	0.011	0.065	0.15	0.008

Note: Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization. Items in bold indicate loadings of items on factors

Overall, we note that the instrument met the recommended psychometric standards [30] and therefore can be used in the Nigerian population of people with SCD. The Cronbach's alpha of 0.70 and above in all the domains supports the recommendations of the developers for internal consistency [40].

5. LIMITATIONS

This was a hospital-based study and considering the out of pocket healthcare finance system which operates in Nigeria, access to healthcare may be unaffordable to a significant proportion of people with SCD who have low socioeconomic status or weak social support. This means that

only those who attended hospital were captured in this study and as such we may have only obtained data from healthier individuals. Moreover, this is a cross sectional design which did not allow for the assessment of the responsiveness of the instrument to changes in the individual clinical status of the patients over time.

6. CONCLUSION

Our study is the first to investigate the properties of SF-36 in sickle cell disease group in Nigeria. The instrument demonstrated appropriate factor structure with valid and reliable features to measure HRQL among people with SCD. This

result also suggests that similar studies can be carried out in other disease populations in the country which could be compared with our study.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

The University of Sunderland Ethical board and the University of Ibadan/University College Hospital (UI/UCH) Ethics Committee approved the study. Furthermore, official permission was obtained from the management of Adeoyo General Hospital.

AVAILABILITY OF DATA AND MATERIALS

A datasheet will be available from the corresponding author on request.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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