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Effect of Health Care on Quality of Life among Human Immunodeficiency Virus Infected Adults With and Without Visceral Leishmaniasis in northwest Ethiopia: A Longitudinal Follow-Up Study

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Abstract. There has been a scarcity of data on the effect of health care on the quality of life (QoL) of human immunodeficiency virus (HIV)– and visceral leishmaniasis (VL)– coinfected patients over time. We sought to assess the change that health care brings about in the QoL of HIV patients with and without VL and its predictors in 6 months. A total of 465 HIV patients without VL and 125 HIV–VL-coinfected patients were enrolled in the longitudinal follow-up study from October 2015 to September 2016. Data on QoL at baseline and in 6 months were collected by trained nurses through face-to-face interviews using a short Amharic version of World Health Organization QoL instrument for HIV clients. Multiple linear regressions were used to assess the predictors of health-related QoL. There was an improvement in all of the domains of QoL at the sixth month follow-up compared with the baseline for both groups of patients ($P < 0.001$). Lack of social support and income were associated with the low improvement in QoL in most of the domains in both groups. Compared with patients having severe acute malnutrition, patients having moderate acute malnutrition and normal nutritional status were better in most of the QoL domains in both groups of patients. Both antiretroviral and anti-VL treatments showed improvement in all dimensions of QoL. Income, social support, and nutritional status were the predictors for most of the QoL domains.

INTRODUCTION

Visceral leishmaniasis (VL) is transmitted by the bite of female phlebotomine sand flies. The causative agents of VL are the members of the *Leishmania donovani complex*.[1] VL is typically fatal if left untreated. In immuno-competent individuals, effective VL drug treatment reduces *Leishmania* amastigotes to a level undetectable in spleen or lymph node aspirates. An effective lifelong cellular immune response normally develops and residual parasites are suppressed unless immunodeficiency exists.[2] VL accelerates human immunodeficiency virus (HIV) replication and disease progression.[3] The current prevalence of HIV in Ethiopia is 1.1%[4] among the general population. However, the prevalence of HIV among VL-infected patients in Ethiopia is 17.75%.[5]

Ethiopia has started free antiretroviral therapy (ART) for advanced HIV disease since 2003[6] and subsequently scaled-up progressively to the current test and treat strategy.[7] A qualitative study conducted on quality of life (QoL) among HIV–VL coinfections reported that challenges related to the living environment, financial limitations, and poor therapeutic outcomes of VL drugs were factors most negatively affecting their QoL.[8] Several longitudinal follow-up studies on HIV-infected patients reported that patient QoL improved after ART was started, and most of the gains of QoL were achieved by the third month of the therapy.[9–13] There is, however, a knowledge gap on the change of QoL over time among HIV–VL-coinfected patients.

Quality of life is affected by several clinical and sociodemographic factors. Some of the predictors of QoL among HIV patients are baseline $CD4^+$ lymphocyte count,[11,14] time since HIV diagnosis,[14] poor social support,[15] depression,[9,16–18] unemployment,[19] old age,[20] and female gender.[21] Thus, there is a scarcity of data on the predictors of QoL among HIV–VL-coinfected patients in the Ethiopian context.

A qualitative study on perceived QoL among HIV–VL-coinfected migrant male workers in northwest Ethiopia reported the complexity and multidimensional nature of poor QoL.[8] In line with this, we also conducted a cross-sectional quantitative QoL survey among HIV-infected patients with and without VL in northwest Ethiopia from October 2015 to September 2016.[22] The stated cross-sectional study also showed that HIV–VL-coinfected patients had poorer QoL than HIV-infected patients without VL. In this study, we present the effect of health care on QoL among the same group of patients after 6 months of treatment of their respective diseases.

METHODS

Study settings and design. From October 2015 to September 2016, a total of 465 HIV patients without VL and 125 HIV–VL-coinfected patients who were taking ART in three hospitals (Humera, Metema and the University of Gondar) and the Abdrafi health center in northwest Ethiopia were enrolled in the longitudinal follow-up study. The details of the study areas are described elsewhere.[22]

Study population. The patient selection process is described elsewhere.[22] In brief, at the three hospitals and the health center, for each HIV–VL-coinfected patient, three HIV-infected patients without VL were selected using the simple random sampling technique. The registration list of HIV-infected clients was used as a sampling frame for random selection of HIV-infected patients. OpenEpi computer generator was used to select study participants. All HIV–VL-coinfected patients were in the intensive phase of anti-VL treatment during admission to follow-up. The exclusion criteria for both groups were age less than 15 years, presence of opportunistic infections other than VL, or known

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chronic illness, such as hypertension. Patient follow-up was conducted monthly from the baseline.

Data collection procedures and follow-up. The diagnoses of VL and HIV were based on the national guidelines.[23] The World Health Organization (WHO) case definition of VL was used as a starting point.[24] A patient whose illness met this case definition and had no previous VL treatment was diagnosed by a serologic test called recombinant K 39 (rK39). The rK39 strip test is an ideal qualitative test with high sensitivity, specificity, and diagnostic accuracy of VL.[25] The test was conducted according to instructions provided by the manufacturers. In brief, 20 µL serum was placed on a pad. After this, two to three drops of wash buffer (provided) was added to the pad and the mixture was allowed to migrate up the strip by capillary action. The result was read within 10 minutes. Patients with previous history of VL underwent spleen or lymph node aspiration, and parasitological confirmation of VL was carried out. Patients with HIV infection but not fulfilling the clinical signs and symptoms of the WHO case definition for VL were considered as not having VL.[24]

During each clinical visit, the patients were meticulously evaluated by trained nurses for drug side effects, general health status, and symptoms of opportunistic infections. $CD4^+$ lymphocyte count and WHO clinical staging were extracted from patient records at baseline. The health-related QoL (HRQoL) was measured at baseline and after 6 months of follow-up through face-to-face interviews using the short Amharic version of the WHO QoL instrument for HIV clients (WHOQoL-HIV-Bref).[26] The HRQoL instrument, WHOQoL-HIV-Bref, is described elsewhere.[9,22] In brief, it consisted of 31 Likert scale questions in six domains of QoL such as Physical health (four items), psychological health (five items), social relationship (four items), environmental health (eight items), level of independence (four items), and spiritual health (four items). In addition to the above questions, we included two questions about general QoL and perceived general health. The Kesseler-10 scales were used to measure common mental disorder (CMD).[27] This instrument is described elsewhere.[9,22]

Data analysis. Each completed questionnaire was checked visually for completeness before data entry. The data were entered into Excel; data cleanup and cross-checking was performed and analyzed by using Statistical Package for Social Science version 21 (IBM Corp, Armonk, NY). Domain scores in the WHOQoL-HIV-Bref were scaled in a positive direction with a higher score denoting good QoL. The mean scores of items within each domain were used to calculate the domain score. The mean scores were then multiplied by four to make domain scores comparable with the scores used in the WHO QoL (WHOQoL-100). We used *t* tests and F tests to compare the means between groups.

Quality of life was treated as a continuous variable. Common mental disorder was categorized as normal (score < 20), moderate (score 20–24), severe (score 25–29), and very severe (score above 30).[27] Paired *t* test was used to compare repeated measurements of QoL at baseline and in 6 months. Independent variables associated with each of the six HRQoL domains were first identified using bivariate linear regression analysis. Then, all variables which yielded *P* values of < 0.2 were fitted in the multivariable linear regression model. We checked for violations of regression model assumptions by the inspection of plots of residuals versus predicted values, outliers, and multicollinearity. The results of the regression analysis were expressed in an unstandardized coefficient (beta). Beta coefficients were measured in units of standard deviation and referred to the average change in the dependent variable for a unit increase in the predictor variable. The Beta coefficients enabled us to compare the strength of the relationships between predictor variables and dependent variables in the multivariable linear regression analysis. *P* values of < 0.05 were considered indicative of statistical significance.

RESULTS

After 6 months of follow-up, 439 (94.4%) of the 465 HIV-infected patients and 75 (60%) of the 125 HIV–VL-coinfected patients were considered in the analysis. Fifty eight (9.5%) were the overall lost to follow-up of the 590 participants. Eighteen (14.4%) of the 125 HIV–VL-coinfected patients were confirmed dead. Baseline $CD4^+$ lymphocyte count between patients who completed the study and those who were lost to follow-up was not significantly different. Most of the HIV patients without VL who were lost to follow-up had a WHO stage I or II clinical status.

Over the 6 months of follow-up, 3/75 (4%) patients with HIV-VL coinfection were reported to have VL relapses. Moreover, 2 (2.7%) of HIV–VL-coinfected patients and 96 (18.8%) of all patients missed either their anti-VL treatment or ART at least once (Table 1).

Change in QoL. A significant improvement was identified after 6 months of treatment in all participants regarding their HRQoL across all dimensions (i.e., physical, psychological, social relationships, environmental, level of independence, and spiritual) (Tables 2 and 3).

The improvement of QoL in the physical, spiritual, and level of independence domains was more pronounced for HIV–VL-coinfected patients compared with HIV patients without VL infection. For instance, there was a 3.1 unit difference between HIV–VL-coinfected and HIV-infected patients without VL in the physical dimension of QoL. The change in QoL of the remaining domains (psychological, social relationships, and environmental) was not statistically significant between the two groups (Table 4).

Predictors of change in QoL. Table 5 shows the results of the multivariable linear regression analysis for the predictors of the HRQoL domains, respectively. The collinearity statistics in the final multivariate regression models did not suggest multicollinearity.

Lack of source of income was associated with lower HRQoL on the psychological, level of independence, and environmental domains in both groups of participants. Likewise, lack of social support was associated with lower HRQoL in all except the spiritual domain of HIV-infected patients. Having no social support was associated with low HRQoL on psychological, social, and environmental domains of HIV–VL-coinfected patients.

Compared with patients having (SAM), patients having (MAM) and normal nutritional status had better HRQoL in most of the domains among both groups of participants. Adherence to ART and anti-VL treatments was not associated with any of the domains of HRQoL in both groups.

DISCUSSION

The study focused on determining the change in QoL and its predictors among HIV–VL-coinfected and HIV-infected

TABLE 1
Sociodemographic and clinical characteristics of HIV–VL-coinfected and HIV-infected patients without VL in northwest Ethiopia, 2016

Variables	HIV–VL-coinfected patients (*N* = 75)	HIV-infected patients without VL (*N* = 439)	*P* value
Age in years, mean (SD)	34.5 (±7.7)	36.4 (±8.9)	0.490
Gender			< 0.001
Male	71 (94.7%)	168 (38.3%)	–
Female	4 (5.3%)	271 (61.7%)	–
Employment*			< 0.001
Farmer	25 (33.3%)	26 (5.9%)	–
Daily laborer	34 (45.3%)	67 (15.3%)	–
Used	10 (13.3%)	126 (28.7%)	–
Merchant	2 (2.7%)	47 (10.7%)	–
Housewife	3 (4.0%)	111 (25.3%)	–
Unemployed	1 (1.3%)	62 (14.1%)	–
Have income source			< 0.001
Yes	22 (29.3%)	236 (53.8%)	–
No	53 (70.7%)	203 (46.2%)	–
Have social support			0.712
Yes	40 (53.3%)	224 (51%)	–
No	35 (46.7%)	215 (49%)	–
WHO Staging*			< 0.001
Stage I	–	290 (66.1%)	–
Stage II	–	69 (15.7%)	–
Stage III	–	72 (16.4%)	–
Stage IV	75 (100%)	4 (1.8%)	–
Mean (median) CD4$^+$ count* (cells/µL)	134.8 (90)	453.6 (419)	0.131
Missed at least one dose of anti-VL treatment	2 (2.7%)	–	–
Missed at least one dose of antiretroviral therapy	18 (24.0%)	78 (17.8%)	0.201
Antiretroviral drug regimen			0.149
Efaviranze-based	50 (66.7%)	241 (54.9%)	–
Nevirapen-based	24 (32.0%)	185 (42.1%)	–
Other	1 (1.3%)	13 (3.0%)	–
Common mental disorder			< 0.001
Normal	24 (32.0%)	348 (79.3%)	–
Moderate	15 (20.0%)	62 (14.1%)	–
High	15 (20.0%)	16 (3.6%)	–
Very high	21 (28.0%)	21 (28.0%)	–
Nutritional status†			< 0.001
SAM	24 (32%)	33 (7.5%)	–
MAM	47 (62.7%)	125 (28.5%)	–
Normal	4 (5.3%)	275 (62.6%)	–
Obese	–	6 (1.4%)	–
Confirmed dead	18 (14.4%)	–	–
Lost to follow-up	32 (25.6%)	26 (5.6%)	< 0.001

BMI = body mass index; CD4$^+$ = cluster of differentiation 4$^+$; HIV = human immunodeficiency virus; MAM = moderate acute malnutrition; SAM = severe acute malnutrition; SD = standard deviation; VL = visceral leishmaniasis; WHO = World Health Organization.

* Baseline data.

† Nutritional status (BMI) will be assessed using weight and height data for patients ≥ 19 years of age, whereas WHO Anthro and Anthro Plus software (Geneva, Switzerland) will be used to calculate a BMI-for-age *Z*-score for those aged ≥ 5–19 years. For patients ≥ 19 years of age, SAM and MAM were defined as BMI < 16 and 16 to < 17, respectively. For patients aged ≥ 5–19 years, SAM was defined as BMI-for-age Z-score < –3 and MAM as < –2 but > –3 SD.

patients over 6 months of treatment. As a result, all of the domains of HRQoL of both groups significantly improved from baseline to 6 months of treatment, and factors such as income source, social support, and nutritional status of patients were significantly associated with HRQoL domains.

Indeed, when HRQoL improvements were estimated using separate and paired *t* tests, the change in all the domains of HRQoL scores after 6 months of treatment of both groups was positive. We considered that 6 months of HIV treatment brings improvement in HRQoL because several clinical trials have already pointed out that the improvement in QoL of HIV-infected patients started after 6 months to 1 year of HIV treatment.[28–30] The long-term effect of different treatments for HIV-infected patients has also been addressed in many

TABLE 2
Change in QoL among HIV–VL-coinfected patients after 6 months of treatment in northwest Ethiopia, 2016

QoL domain	Mean (SD) at baseline	Mean (SD) after 6 months	Mean differences (95% CI)	*P* value
Physical health	10.42 (±3.5)	17.3 (±2.8)	5.7 (4.8–6.7)	< 0.001
Psychological health	10.68 (±3.6)	15.1 (±2.8)	2.8 (1.9–3.6)	< 0.001
Social health	9.71 (±3.1)	12.6 (±3.2)	2.1 (1.2–2.9)	< 0.001
Environmental health	9.66 (±3.1)	13.4 (±2.9)	2.8 (2.1–3.6)	< 0.001
Level of independence	9.46 (±3.2)	14.7 (±2.8)	4.1 (3.4–4.9)	< 0.001
Spiritual health	11.49 (±3.3)	16.3 (±2.9)	4.1 (3.3–5.0)	< 0.001

CI = confidence interval; HIV = human immunodeficiency virus; SD = standard deviation; QoL = quality of life; VL = visceral leishmaniasis.

TABLE 3

Change in QoL among HIV-infected patients after 6 months of treatment in northwest Ethiopia, 2016

QoL domain	Mean (SD) at baseline	Mean (SD) after 6 months	Mean differences (95% CI)	*P* value
Physical health	17.43 (±2.8)	18.5 (±2.1)	1.1 (0.8–1.3)	< 0.001
Psychological health	12.60 (±3.4)	13.9 (±3.7)	1.3 (1.0–1.6)	< 0.001
Social health	11.44 (±3.4)	12.3 (±3.5)	0.9 (0.6–1.1)	< 0.001
Environmental health	11.53 (±2.9)	12.8 (±3.2)	1.2 (0.9–1.5)	< 0.001
Level of independence	13.34 (±2.8)	14.8 (±3.2)	1.4 (1.1–1.7)	< 0.001
Spiritual health	15.06 (±3.4)	17.1 (±2.8)	2.0 (1.7–2.3)	< 0.001

CI = confidence interval; HIV = human immunodeficiency virus; SD = standard deviation; QoL = quality of life.

studies, leading to various conclusions. One study[31] reported that HIV-infected patients have been showing significant improvement in QoL after 96 weeks of treatment. Other studies[32,33] reported no overall change in QoL of HIV-infected patients after several years of treatment.

According to this work, all domains of HRQoL significantly improved after 6 months of treatment in both groups of participants. However, the improvement in the physical, spiritual, and level of independence domains were more evident for HIV–VL-coinfected patients compared with HIV-infected patients without VL infection. This significant improvement could be explained by the contribution of VL symptoms relief during the anti-VL treatment by augmenting the expected improvement in baseline symptoms after ART initiation. Multi-country studies also demonstrate that the major gain in the QoL among patients with HIV infection occurs in the first 3 months of initiating ART.[10–13] This study gives additional evidence on the major gains in QoL among patients with HIV–VL coinfection and HIV patients in ART treatment without VL.

In this study, income and social support were found to be significantly associated with most of the domains of HRQoL for both groups. This finding is in line with other studies which reported that socioeconomic status and social support are very important predictors of QoL of HIV patients.[19] Therefore, this study gives additional evidence for designing financial and social support to improve the QoL of both patient groups. In contrast, a study conducted 4 years ago to assess changes in QoL among tuberculosis (TB) and TB–HIV-coinfected patients reported no association between QoL domains with income, and social support.[9]

In this study, gender did not significantly influence QoL for both groups. This finding is in line with the results of previous work.[9] Given the predominant economic dependence of females in the region, one can anticipate a much lower HRQoL among HIV-infected females than males; and some studies have also reported findings in line with such assumptions.[13,21] However, the finding in our study and the other previous work with concordant finding with the present study.[9] This can be explained by two mechanisms. The relatively increasing presence of government and nongovernment organizations working on socioeconomic and political empowerment interventions for HIV-infected females could be one plausible reason. The second potential explanation could be attributed to the small proportion of women among the HIV–VL-coinfected group.

In this study, patients with MAM and normal nutritional status compared with SAM had a better HRQoL in most of the domains in both groups after confounding variables were controlled. This finding is important for ART programs because obtaining sufficient nutritious foods was associated with better HRQoL,[17] whereas food insecurity negatively affected health-care utilization and thereby HRQoL among HIV-infected patients in Africa.[34] This suggests that nutritional support could be an important strategy toward improving the QoL of patients with VL and/or HIV in Ethiopia.

In contrast, this work did not demonstrate HRQoL to be associated with low baseline $CD4^+$ lymphocyte count,[13] CMD[9], and WHO stage.[17] However, unlike the previous studies conducted while national and regional treatment guidelines were recommending ART at a very low $CD4^+$ lymphocyte count (< 200–350 cell/μL) and advanced WHO stage, the current national and regional treatment guidelines advocate test and treat.[7] This has led to the reduction of early posttreatment complications of HIV, such as immune reconstitution inflammatory syndrome, drug side effects, and drug–drug interaction which are all known to be more prevalent when ART is started late during advanced HIV disease. Therefore, the effect of baseline $CD4^+$ lymphocyte count and WHO stage to influence on HRQoL could be undermined.

The finding of this study should be interpreted with some limitations because of the lost to follow-up due to unknown reasons, particularly among HIV–VL-coinfected groups. Most of the lost to follow-up HIV–VL-coinfected patients were migrant daily laborers. We made efforts to trace these patients based on the registered addresses but we could not manage to get them. Besides, the administration of the questionnaire during the face-to-face interview might have resulted in a social desirability bias, no matter how much confidentiality was maintained throughout the follow-up. Furthermore, socialsupport was assessed using a single-item measure.

TABLE 4

Comparison of QoL among HIV–VL-coinfected and HIV-infected patients without VL after 6 months of treatment in northwest Ethiopia, 2016

QoL domain	Mean difference for HIV–VL coinfected	Mean difference for HIV-infected without VL	Mean differences of differences (95% CI)	*P* value
Physical health	5.7 (4.8–6.7)	1.1 (0.8–1.3)	3.1 (2.0–4.2)	< 0.001
Psychological health	2.8 (1.9–3.6)	1.3 (1.0–1.6)	0.1 (–0.8 to 1.0)	0.780
Social health	2.1 (1.2–2.9)	0.9 (0.6–1.1)	0.1 (–0.8 to 0.9)	0.881
Environmental health	2.8 (2.1–3.6)	1.2 (0.9–1.5)	0.2 (–0.7 to 1.1)	0.676
Level of independence	4.1 (3.4–4.9)	1.4 (1.1–1.7)	1.2 (0.4–2.1)	0.005
Spiritual health	4.1 (3.3–5.0)	2.0 (1.7–2.3)	1.2 (0.2–2.3)	0.024

CI = confidence interval; HIV = human immunodeficiency virus; QoL = quality of life; VL = visceral leishmaniasis.

TABLE 5
Multivariable linear regression analysis of predictors of HRQoL of HIV-infected patients with and without VL in northwest Ethiopia, 2016

	HRQoL domains											
	Physical domain (β-coefficient)		Psychological domain (β-coefficient)		Social domain (β-coefficient)		Spiritual domain (β-coefficient)		Level of independence (β-coefficient)		Environmental domain (β-coefficient)	
Patient characteristics	HIV–VL (*N* = 75)	HIV (*N* = 439)	HIV–VL (*N* = 75)	HIV (*N* = 439)	HIV–VL (*N* = 75)	HIV (*N* = 439)	HIV–VL (*N* = 75)	HIV (*N* = 439)	HIV–VL (*N* = 75)	HIV (*N* = 439)	HIV–VL (*N* = 75)	HIV (*N* = 439)
Gender	–	–	–	–	–	–	–	–	–	–	–	–
Male					−0.59							
Female					Ref.							
Income source					–			–				
Yes	Ref.	Ref.	Ref.	Ref.		Ref.	Ref.		Ref.	Ref.	Ref.	Ref.
No	−1.14	−0.35	−1.35*	−1.15**		−0.76**	−0.96		−1.87**	−1.07**	−2.05**	−2.28**
Social support												
Yes	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
No	−0.30	−0.77**	−1.41*	−2.89**	−4.11**	−4.39**	−1.21	−0.32	−0.47	−1.55**	−1.54**	−2.19**
Adherence of ART	–	–	–	–	–	–	–	–	–		–	
Yes										Ref.		Ref.
No										−0.18		−0.09
Adherence of anti-VL	–	–	–	–	–	–		–		–		–
Yes							Ref.		Ref.		Ref.	
No							−1.73		−2.57		−1.11	
Nutritional status												
SAM	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.	Ref.
MAM	2.33**	1.28**	1.21	1.45*	1.47*	1.27*	0.86	1.15*	1.93**	1.17*	1.22	0.94
Normal	2.53	1.48**	1.99	1.42*	1.03	1.08*	1.66	0.81	3.06*	1.38*	−0.15	0.85
Obese	–	2.02*	–	0.39	–	0.21	–	2.74*	–	1.17	–	0.25
P value of multivariate regression model	*P* = 0.001	*P* = 0.001	*P* = 0.002	*P* = 0.001	*P* = 0.001	*P* = 0.001	*P* = 0.055	*P* = 0.069	*P* = 0.001	*P* = 0.001	*P* = 0.001	*P* = 0.001
Adjusted R2	0.197	0.085	0.172	0.219	0.546	0.449	0.080	0.011	0.256	0.125	0.263	0.318

ART = antiretroviral therapy; HIV = human immunodeficiency virus; HRQoL = health related quality of life; MAM = moderate acute malnutrition; Ref. = reference category; SAM = severe acute malnutrition; VL = visceral leishmaniasis. **P* = value < 0.05; ***P* = value < 0.01.

CONCLUSION AND RECOMMENDATIONS

Our study shows that both ART and anti-VL treatments improve all of the dimensions of HRQoL for HIV–VL-coinfected patients. Income, social support, and nutritional status were found to be the predictors of most of the domains of HRQoL. The change in QoL in the physical, spiritual, and level of independence domains was more pronounced among HIV–VL-coinfected patients compared with HIV-infected patients without VL coinfection.

Although health care was found to improve HRQoL among both HIV-infected and HIV–VL-coinfected patients, clinical care was not the only variable that determined HRQoL as we have identified that having social support, presence of income source, and avoiding severe malnutrition improved HRQoL among the study groups. We recommend the integration of psychosocial, financial, and nutritional support with the existing national health-care programs of VL and HIV to improve the HRQoL of such patients.

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Ethical approval and consent to participate: Ethical clearance letter No. 2015/996 was obtained from the Institutional Review Board of the University of Gondar. Then, an official letter was obtained from the administrative bodies of Gondar University, Humera, and Metema hospitals and Abdrafi Health Center. The purpose of the study was well explained to the study participants and informed consents were secured. Confidentiality was maintained at all levels of the study by avoiding the use of names and other identifiers. Participants' involvement in the study was voluntary; participants who were unwilling to participate and those who wished to quit were allowed to do so without any restrictions.

Availability of data and materials: The datasets supporting the conclusions of this article are available on request to the corresponding author. Because of data protection restrictions and confidentiality, we do not make participant data publicly available.

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