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Complete List of Authors:	Paudel, Shishir; Manmohan Memorial Institute of Health Sciences, Department of Public Health Khanal, Shankar; Tribhuvan University, Central Department of Statistics Gautam, Sujan; Manmohan Memorial Institute of Health Sciences, Department of Public Health Chalise, Anisha; Tribhuvan University Institute of Medicine, Central Department of Public Health; Center for Research on Environment Health & Population Activities (CREHPA) Koirala, Tara ; Pokhara Super Speciality Health Clinic Marahatta, Sujan; Manmohan Memorial Institute of Health Sciences, Department of Public Health; Nepal Open University,
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Anxiety and Depression among Type-II Diabetes Patients Visiting Diabetes Clinics of Pokhara Metropolitan, Nepal

Shishir Paudel[1], Shankar Prasad Khanal[2], Sujan Gautam[1], Anisha Chalise[3], Tara Nath Koirala[4], Sujan Babu Marahatta[1]

[1] Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal

[2] Central Department of Statistics, Tribhuvan University, Kathmandu, Nepal

[3] Center for Research on Environment Health & Population Activities (CREHPA), Kusunti, Lalitpur, Nepal

[4] Pokhara Super Speciality Health Clinic, Consultant Endocrinologist, Pokhara, Nepal

Authors	Institution Affiliation
1st Author: Shishir Paudel	Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal
2nd Author: Shankar Prasad Khanal	Central Department of Statistics, Tribhuvan University, Kathmandu, Nepal
3rd Author: Sujan Gautam	Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal
4th Author: Anisha Chalise	Center for Research on Environment Health & Population Activities(CREHPA), Kusunti, Lalitpur, Nepal
5th Author : Tara Nath Koirala	Pokhara Super Speciality Health Clinic, Consultant Endocrinologist, Pokhara, Nepal
6th Author : Sujan Babu Marahatta	Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal

CORRESPONDING AUTHOR:

Name: Sujan Babu Marahatta

Email: sujan@nou.edu.np

Contact no: +977-9851126707

Address: Kathmandu, Nepal

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ABSTRACT

Objectives: To estimate the prevalence of anxiety and depression and identify their risk factors among Type-II Diabetes patients visiting diabetes clinics of Pokhara Metropolitan, Nepal.

Design: Cross-sectional study.

Setting: Diabetes clinics of Pokhara Metropolitan, Nepal; From May to July, 2021.

Participants: 283 T2DM patients visiting selected diabetes centers of Pokhara Metropolitan.

Main Outcome Measures: Anxiety and Depression.

Methods: Face-to-face interview was conducted using a structured questionnaire consisting information related to participants' socio-demographic profile, and several factors along with Hospital Anxiety and Depression-anxiety subscale (HADS-A) and Patient Health Questionnaire (PHQ-9) to assess the level of anxiety and depression respectively. Pearson's chi-square tests and binary logistic regression were performed to examine association between dependent and independent variables at 5% level of significance and crude and adjusted odds ratio were reported.

Results: The prevalence of anxiety and depression was noted among 31.4% (95% CI: 26.2%-37.5%) and 36.4% (95% CI: 30.8%-42.0%) of T2DM patients respectively. Anxiety was found to be associated with lower level of perceived social support (AOR:2.442, 95% CI:1.020-5.845), multiple complications (AOR:2.758, 95% CI:1.015-7.334), and comorbidities (AOR:2.110, 95% CI:1.004-4.436), severe COVID-19 fear (AOR:2.343, 95% CI:1.123-4.887), and sleep dissatisfaction (AOR:1.912, 95% CI:1.073-3.047). Likewise, economical dependency (AOR:1.890, 95% CI:1.026-3.482), no insurance (AOR:2.973, 95% CI:1.134-7.093), lower perceived social support (AOR:2.883, 95% CI:1.158-7.181), multiple complications (AOR:2.308, 95% CI:1.585-6.422), and comorbidities (AOR:2.575, 95% CI:1.180-5.617), severe COVID-19 fear (AOR:2.117, 95% CI:1.009-4.573), alcohol use (AOR:2.401, 95% CI:1.199-4.806), and sleep dissatisfaction (AOR:1.995, 95% CI:1.093-3.644) were found to be associated with depression.

Conclusion: This study showed a high prevalence of anxiety as well as depression among T2DM patients. Strengthening social support and focusing on diabetes patients suffering from comorbidity and complications could reduce their risk of mental health problems.

Keywords: Anxiety, Depression, Type 2 Diabetes, Prevalence, Risk Factors, Psychological distress

Strengths and Limitations of this Study

- This is one of the few studies that has assessed the prevalence and risk factors of anxiety among people living with Type-II diabetes mellitus
- The study used recognized screening tools to assess the level of anxiety, depression, and level of perceived social support
- Although the study was performed in the largest Metropolitan City of Nepal, the prevalence of anxiety and depression reported in this study might be slightly higher than the actual prevalence present at the community level, as this was a health institution-based study.

INTRODUCTION

Diabetes mellitus is a systemic disease that affects various body systems causing blindness, kidney failure, and lower limb amputation as its long-term complications.[1-3] The global prevalence of diabetes was estimated at 9.3% in the year 2019 with a prediction that globally 578 million people will have diabetes by the year 2030.[4] Its prevalence has been rising rapidly in low and middle-income countries than that of high-income countries.[5] In Nepal, the World Health Organization diabetes country profile, 2016 estimated the prevalence of diabetes at 9.1%.[6] Furthermore, a systematic review from 2021 based on publications from 2000-2020, noted the pooled prevalence of type-II diabetes (T2DM) in Nepal at 10% with a higher prevalence observed in studies published between the year 2015-2020 at 11.24%.[7]

Mental distress is an emotional state which manifests with a range of depression, anxiety, panic, or somatic symptoms such as sleep problems, headache, and backache.[8] Globally, the prevalence of psychological distress mostly depression and anxiety disorders are higher among people living with diabetes as compared to those without diabetes.[9-11] A systematic review estimated the global prevalence of depression among T2DM patients at 28%, where Asia has the highest rate of depression at 32%.[12] Similarly, another systematic review observed generalized anxiety disorder to be present in 14% of T2DM patients.[13] In Nepal, a cross-sectional study performed among T2DM patients attending tertiary care center in Kathmandu valley found the rate of depression at 40.3% in the year 2013.[14] Similarly, a study published in 2019 revealed the prevalence of depression to be at 22.7% among T2DM patients in community settings of Duhabi-Bhaluwa Municipality of Sunsari District. [15]

Diabetes care mainly consists of self-care aimed to prevent acute and chronic complications. The person living with diabetes is responsible to balance their food intake, physical activities and monitor blood glucose level as much as possible.[16] Mental health complications, mostly anxiety and depression complicates living with diabetes and its management in several ways. Presence of depression and anxiety could worsen the prognosis of diabetes by reducing patients' ability for self-care and increasing non-compliance to treatments while increasing risk of serious short- and long-term complications such as blindness, amputations, stroke, decreased quality of life, and even premature death.[16-19] Additionally, serious anxiety disorders largely overlap with symptoms of hypoglycemia which requires immediate treatment but the diabetes patient might fail to differentiate whether the feelings are of anxiety or hypoglycemia. The preexisting anxiety of injections or blood draws might lead to panic disorders or patients' refusal to monitor their glucose level.[20] Similarly, fear of hypoglycemia, a common source of anxiety and depression for diabetic persons, can lead patients to maintain blood glucose levels above target levels.[20] Even in-current context of COVID-19 pandemic, diabetes patients are taken as one of the vulnerable populations at risk of infection and mortality. There are higher concerns stressed over the mental health and wellbeing of this vulnerable population.[21, 22]

The promotion of mental health and well-being is one of the priorities of the sustainable development goals, yet the health care professionals involved in prevention and treatment of diabetes lack training to address the mental health aspects of diabetes patients. Thus, diagnosis of depression and anxiety among diabetes patients is often missed, leading to severe consequences on patients' health and quality of life. There is a lack of plentiful information about the rates of anxiety and depression among diabetes patients as well as its associated risk factors in South Asia and particularly in Nepal because of the limited studies published to date considering the mental health perspective of diabetes patients. For that reason, this study aimed to assess the prevalence and factors associated with anxiety and depression among type-II diabetes patients visiting diabetes clinics of Pokhara Metropolitan, one of the rapidly urbanizing cities of Nepal with an expectation that the study could provide some valuable insights over mental health issues of diabetes patients in developing nations similar to Nepal.

METHODS AND MATERIALS

Study Design

This was a health facility-based cross-sectional study executed among type-II diabetes patients residing at Pokhara Metropolitan who visited the selected healthcare institutions between May and July 2021.

Participants

All type-II diabetes mellitus patients with at least six months of history of diagnosis, attending the selected diabetes clinics were eligible to be included, while T2DM patients who were not the residents of Pokhara Metropolitan for at least past six months from the date of data collection were excluded.

Sample Size Determination and Sampling Technique

The sample size was determined using the formula for estimation of a proportion, since our major outcome variables were prevalence of anxiety and depression. A community-based cross-sectional study conducted in the eastern part of Nepal reported the prevalence of depression among T2DM patients to be 22.7%. [15] So, using this past prevalence at 5% allowable error and 95% confidence interval, the initially estimated sample size was 264 T2DM patients which was optimized to 291 after adjusting 10% non-response rate.

Two government health institutions (Urban Health Promotion Center and Shishuwa Hospital) and one private clinic (Pokhara Super Speciality Health Clinic) were selected purposively. Urban Health Promotion Center and Shishuwa Hospital are the primary contact points for Social Health Insurance and provide free diabetes-related services as well as referral services. Thus, these are some of the most sought government institutions with an estimated 250-300 T2DM patients visiting monthly. Pokhara Super Speciality Health Clinic is one of the well-known tertiary endocrine referral centers of Pokhara with an average of 500 diabetes patients visiting monthly. The T2DM patients visiting these three healthcare institutions were selected randomly using the technique based on systematic random sampling. For this, every k^{th} patient (800/291=2.74≈3) i.e. 3rd patient waiting in the queue on the day of data collection were enrolled as a participant. If the selected patient refused to participate or fell under exclusion criteria, then the patient next in the queue was approached for participation.

Data Collection

Face-to-face interview technique was used for data collection. The T2DM patients meeting inclusion criteria were approached and provided with the study details. The informed consent was acquired and after his/her approval, the interview was performed**.** Considering the privacy of the participants Pokhara Super Speciality Health Clinic provided the researcher with a separate room next to the doctors' cabin, while a small private space was provided at the corner of the doctors' cabin and in the waiting area in Urban Health Promotion Center and Shishuwa Hospital where the patients were directed for data collection.

The data was collected using a set of closed-ended questions consisting of three sections. The first section consisted of questions regarding the socio-demographic profile of the participants including Multidimensional Scale of Perceived Social Support (MSPSS)[23] translated in Nepali language (MSPSS-N)[24] intending to measure level of perceived social support. Second section consisted of questions regarding the patients' health conditions, diabetes-related attributes and lifestyle-related factors including COVID-19 related variables such as COVID-19 status, vaccination and fear associated with COVID-19 based on a modification of Fear scale of COVID-19[25]. Third section consisted of a nine-item Patient Health Questionnaire (PHQ-9)[26] to measure the level of depression followed by Hospital Anxiety and Depression Scale-anxiety subscale (HASD-A)[27] to measure the level of anxiety.

The PHQ-9 consists of nine items measuring depressive symptoms corresponding to diagnostic criteria for major depressive disorder. Each item was scored on a four-point Likert scale (0–3) with scores ranging from 0 to 27, with higher scores reflecting greater depression severity.[26] The PHQ-9 has been translated in Nepali language and has shown a sensitivity of 0.94 and specificity of 0.80 to measure depression at the cutoff of ≥ 10.[28] The HADS-A consist of seven items measuring anxiety symptoms. Each item is scored on a four-point Likert scale (0-3) with total scores ranging from 0 to 21 with higher scores reflecting greater anxiety and cutoff point of ≥8 illustrating anxiety.[27] The HADS has been validated in Nepali language where HADS-A subscale was found to have a good internal consistency with Cronbach's alpha of 0.76.[29]

Data Processing, Management and Analysis

The collected data were entered in EpiData 3.1 and exported to Statistical Package for Social Sciences (SPSS) version 22 for statistical analysis. The data were summarized in terms of

frequencies and proportions. Bivariate analysis was carried out by applying Chi-square (χ^2) tests to identify the factors associated with anxiety and depression at 95% Confidence Interval (CI) and 5% level of significance i.e. p-value <0.05. The variables found to be significant in bivariate analysis were considered for multivariate analysis using binary logistic regression to determine the adjusted effect of each factor on the dependent variable. Prior to multivariate regression analysis, the multi-collinearity between the independent variables was tested using the Variance Inflation Factor (VIF) test. The Hosmer-Lemeshow test (HL test) for goodness-of-fit was also performed.

Ethical Considerations

The ethical approval for this study was obtained from Institutional Review Committee of Manmohan Memorial Institute of Health Science (Registration no: MMIHS-IRC 583). Written informed consent was obtained from all the participants before conducting the study and all the information was kept confidential.

Patient and Public Involvement

There was no patient and public involvement in the design, or conduct, or reporting, or dissemination plans of our research. The randomly sampled diabetes patients were involved as participants once during the time of data collection after acquiring their informed consent.

RESULTS

A total of 291 T2DM patients were approached for data collection, of which 283 provided complete responses to all the questions, while eight participants left in the middle of the data collection. Thus, the response rate of 97.25% for all questions was acquired and 283 total samples were analyzed for this study. The prevalence of anxiety and depression was noted among 31.4% and 36.4% of T2DM patients respectively (Table 1). Moreover, around one-third (36%) of the participants reported to have experienced suicidal ideation in past two weeks on PHQ-9 of which six participants (2.1%) reported experiencing suicidal ideation nearly every single day.

Table 1: Prevalence of Anxiety and Depression (n=283)

Outcome	n (%)	95% CI	Outcome	n (%)	95% CI
Anxiety Status			**Depression Status**		
Present	89 (31.4)	26.2%-37.5%	Present	103 (36.4)	30.8%-42.0%
Absent	194 (68.6)	62.5%-73.8%	Absent	180 (63.6)	58.0%-69.2%
Anxiety Level			**Depression Level**		
No Anxiety	194 (68.6)	62.5%-73.8%	No Depression	180 (63.6)	57.6 %-68.6%

Mild Anxiety	62 (21.9)	16.6%-27.2%	Mild Depression	71 (25.1)	20.1%-30.7%
Moderate Anxiety	19 (6.7)	3.9%-9.9%	Moderate Depression	22 (7.8)	4.6%-11.0%
Severe Anxiety	8 (2.8)	1.1%-5.3%	Severe Depression	10 (3.5)	1.8%-5.7%

In bivariate analysis, participants' family type, living companionship and perceived level of social support were the only socio-demographic factors found to be associated with anxiety, whereas, living companionship, economic dependency, insurance coverage diabetes care, and perceived level of social support were the only socio-demographic factors found to be associated with depression at 5% level of significance (Table 2).

Table 2. Association of socio-demographic variables with Anxiety and Depression (n=283)

Socio-demographic variables	n (%)	Anxiety		p-value	Depression		p-value
		Presence n(%)	Absence n(%)		Presence n(%)	Absence n(%)	
Age group							
<40 years	30 (10.6)	11 (36.7)	19 (63.3)	0.800	13 (43.3)	17 (56.7)	0.125
40-60	65 (23.0)	19 (29.2)	46 (70.8)		16 (24.6)	49 (75.4)	
50-60	77 (27.2)	22 (28.6)	55 (71.4)		28 (36.4)	49 (63.6)	
≥60 years	111 (39.2)	37 (33.3)	74 (66.7)		46 (41.4)	65 (58.6)	
Gender							
Male	161 (56.9)	54 (33.5)	107 (66.5)	0.384	59 (36.6)	102 (63.4)	0.920
Female	122 (43.1)	35 (28.7)	87 (71.3)		44 (36.1)	78 (63.9)	
Ethnicity							
Brahmin/Chhetri	107 (37.8)	42 (39.3)	65 (60.7)	0.175	38 (35.5)	69 (64.5)	0.409
Janajaties	122 (43.1)	33 (27.0)	89 (73.0)		44 (36.1)	78 (63.9)	
Dalit	33 (11.7)	9 (27.3)	24 (72.7)		10 (30.3)	23 (69.7)	
Religious Minorities	21 (7.4)	5 (23.8)	16 (76.2)		11 (52.4)	10 (47.6)	
Type of Family							
Nuclear	143 (50.5)	53 (37.1)	90 (62.9)	**0.040**	59 (41.3)	84 (58.7)	0.086
Joint/ Extended	140 (49.4)	36 (25.7)	104 (74.3)		44 (31.4)	96 (68.6)	
Living companion							
Living alone	24 (8.5)	13 (55.2)	11 (45.8)	**0.012**	15 (62.5)	9 (37.5)	**0.008**
Living with family	259 (91.5)	76 (29.6)	181 (70.4)		88 (34.0)	171 (66.0)	
Marital Status							
Married	232 (82.0)	72 (31.0)	160 (69.0)	0.489	78 (33.6)	154 (66.4)	0.065
Unmarried/Divorced	13 (4.6)	6 (46.2)	7 (53.8)		8 (61.5)	5 (38.5)	
Widow/ Widower	38 (13.4)	11 (28.9)	27 (71.1)		17 (44.7)	21 (55.3)	
Education							
Illiterate	49 (17.3)	15 (30.6)	34 (69.4)	0.391	21 (42.9)	28 (57.1)	0.298
Literate by Informal Education	42 (14.8)	17 (40.5)	25 (59.5)		18 (43.0)	24 (57.0)	
Literate by Formal Education	192 (67.8)	57 (29.7)	135 (70.3)		64 (33.3)	128 (66.7)	
Economic Dependency							
Dependent	121 (42.8)	41 (33.9)	80 (66.1)	0.446	55 (45.5)	66 (54.5)	**0.006**
Independent	162 (57.2)	48 (29.6)	114 (70.4)		48 (29.6)	114 (70.4)	
Health insurance							
Full coverage	42 (14.8)	9 (21.4)	33 (78.6)	0.287	8 (19.0)	34 (81.0)	**0.004**
Partial coverage	86 (30.4)	27 (31.4)	59 (68.6)		26 (30.2)	60 (69.8)	
No insurance	155 (54.8)	53 (34.2)	102 (65.8)		69 (44.5)	85 (55.5)	
Perceived social support							

Low support	41 (14.5)	20 (48.8)	21 (51.2)	**<0.001**	25 (61.0)	16 (39.0)	**<0.001**
Moderate Support	130 (45.9)	48 (36.9)	82 (63.1)		51 (39.2)	79 (60.8)	
High Support	112 (39.6)	21 (18.8)	91 (81.3)		27 (24.1)	85 (75.9)	

In context of health and lifestyle-related factors, insulin use, presence of complications and comorbidities, prior history of clinically diagnosed mental distress, fear associated with COVID-19, alcohol use and sleep satisfaction were found to be associated with both anxiety and depression status at $p<0.05$. In addition, depression was also found to be associated with the difficulty experienced by T2DM patients to follow dietary recommendations and use of tobacco products. (Table 3). The T2DM patients experiencing anxiety were found to be twice more likely to be depressed (UOR: 2.758, 95% CI:1.641-4.635) in bivariate analysis (Table 4).

Table 3: Association of Health and Lifestyle related variables with Anxiety and Depression (n=283)

Health and Lifestyle related variables	**n (%)**	**Anxiety**		**p-value**	**Depression**		**p-value**
		Presence n(%)	**Absence n(%)**		**Presence n(%)**	**Absence n(%)**	
Duration of Illness							
≤ 4 Years	152 (53.7)	45 (29.6)	107 (70.4)	0.472	49 (32.2)	103 (67.8)	0.117
>4 years	131 (46.3)	44 (33.6)	87 (66.4)		54 (41.2)	77 (58.8)	
Use of Insulin							
Yes	33 (12.0)	17 (51.5)	16 (48.5)	**0.008**	20 (60.6)	13 (39.4)	**0.002**
No	250 (88.0)	72 (28.8)	178 (71.2)		83 (33.2)	167 (66.8)	
Presence of Complications							
None	212 (74.9)	53 (25.0)	159 (75.0)	**<0.001**	63 (29.7)	149 (70.3)	**<0.001**
Single complications	47 (16.6)	23 (48.9)	24 (51.1)		26 (55.3)	21 (44.7)	
Two or more	24 (8.5)	13 (54.2)	11 (45.8)		14 (58.3)	10 (41.7)	
Presence of Comorbidities							
None	126 (44.5)	24 (19.0)	102 (81.0)	**<0.001**	28 (22.2)	98 (77.8)	**<0.001**
Single comorbidity	84 (29.7)	32 (38.1)	52 (61.9)		35 (41.7)	49 (58.3)	
Two or more	73 (25.8)	33 (45.2)	40 (54.8)		40 (54.8)	33 (45.2)	
Difficulty following recommended diet							
Too difficult	63 (22.3)	24 (38.1)	39 (61.9)	0.430	34 (54.0)	29 (46.0)	**<0.001**
A bit difficult	100 (35.3)	29 (30.6)	71 (69.4)		37 (34.0)	63 (66.0)	
Not difficult at all	120 (42.4)	36 (30.0)	84 (70.0)		32 (26.7)	88 (73.3)	
History of Mental illness							
Yes	16 (5.7)	9 (56.3)	7 (43.8)	**0.028**	10 (62.5)	6 (37.5)	**0.025**
No	267 (94.3)	80 (30.0)	187 (70.0)		93 (34.8)	174 (65.2)	
Ever tested for COVID-19							
Tested Negative	31 (11.0)	14 (45.2)	17 (54.8)	0.186	9 (29.0)	18 (64.3)	0.654
Tested Positive	28 (9.9)	7 (25.0)	21 (75.0)		10 (35.7)	22 (71.0)	
Never Tested	224 (79.1)	68 (30.4)	156 (69.6)		84 (37.5)	140 (62.5)	
COVID-19 Vaccine							
Complete vaccination	28 (9.9)	11 (39.3)	17 (60.7)	0.605	9 (32.1)	19 (67.9)	0.285
Incomplete vaccine	65 (23.0)	21 (32.3)	44 (67.7)		29 (44.6)	36 (55.4)	
Didn't receive vaccine	190 (67.1)	57 (30.0)	133 (70.0)		65 (34.2)	125 (65.8)	
COVID-19 Fear							
Low Fear	105 (37.1)	22 (21.0)	83 (79.0)	**0.006**	27 (25.7)	78 (74.3)	**0.013**

Moderate fear	96 (33.9)	32 (33.3)	64 (66.7)		39 (40.6)	57 (59.4)	
Severe Fear	82 (29.0)	35 (42.7)	47 (57.3)		37 (45.1)	45 (54.9)	
Alcohol Use							
Yes	75 (26.5)	31 (41.3)	44 (58.7)	**0.033**	39 (52.0)	36 (48.0)	**0.001**
No	208 (73.5)	58 (27.9)	150 (72.1)		64 (30.8)	144 (69.2)	
Tobacco Use							
Yes	55 (19.4)	22 (41.8)	32 (58.2)	0.065	27 (49.1)	28 (50.9)	**0.029**
No	228 (80.6)	66 (28.9)	162 (71.1)		76 (33.3)	152 (66.7)	
Sleep Satisfaction							
Satisfied	180 (63.6)	45 (25.0)	135 (75.0)	**0.002**	52 (28.9)	128 (71.1)	**0.001**
Not satisfied	103 (36.4)	44 (42.7)	59 (57.3)		51 (49.5)	52 (50.5)	
Depression							
Present	103 (36.4)	47 (45.6)	56 (54.4)	**<0.001**	-	-	-
Absent	180 (63.6)	42 (23.2)	138 (76.7)		-	-	
Anxiety							
Present	89 (31.4)	-	-	-	47 (52.8)	42 (47.2)	**<0.001**
Absent	194 (68.6)	-	-		56 (28.9)	138 (71.1)	

For multivariate analysis, the Variance Inflation Factor (VIF) test among the independent variables was performed where the highest reported VIF was 1.610 so there was no issue of multi-collinearity. Lower level of perceived social support (AOR:2.442, 95% CI:1.020-5.845), presence of single (AOR:2.081, 95% CI:1.002-4.414) and multiple complications (AOR:2.758, 95% CI: 1.015-7.334), presence of single comorbidity (AOR:2.127, 95% CI:1.059-4.272) and multiple comorbidities (AOR:2.110, 95% CI:1.004-4.436), severe fear of COVID-19 infection (AOR:2.343, 95% CI:1.123-4.887), and sleep dissatisfaction (AOR:1.912, 95% CI:1.073-3.047) were found to be the independent predictors of anxiety (Table 4).

Table 4: Independent predictors of anxiety among the diabetes patients (n=283)

Factors	**UOR**	**95% CI**	**p-value**	**AOR[a]**	**95% CI**	**p-value**
Type of Family						
Nuclear	1.701	1.023-2.829	**0.041**	1.458	0.784-2.711	0.233
Joint/ Extended	Ref			Ref		
Living companion						
Living alone	2.846	1.221-6.633	**0.015**	1.108	0.405-3.034	0.842
Living with family	Ref			Ref		
Perceived level of social support						
Low support	4.127	1.902-8.955	**<0.001**	2.442	1.020-5.845	**0.045**
Moderate Support	2.537	1.401-4.591	**0.002**	1.839	0.986-3.520	0.060
High Support	Ref			Ref		
Use of Insulin						
Yes	2.627	1.259-5.481	**0.010**	1.299	0.565-3.166	0.565
No	Ref			Ref		
Presence of Complications						
None	Ref			Ref		
Single complications	2.875	1.499-5.512	**0.001**	2.081	1.002-4.414	**0.049**
Two or more	3.545	1.501-8.387	**0.004**	2.758	1.015-7.334	**0.044**
Presence of Comorbidities						

None	Ref			Ref		
Single comorbidity	2.615	1.399-4.890	**0.003**	2.127	1.059-4.272	**0.034**
Two or more	3.506	1.848-6.652	**<0.001**	2.110	1.004-4.436	**0.048**
History of Mental illness						
Yes	3.005	1.082-8.350	**0.035**	2.132	0.680-6.687	0.194
No	Ref			Ref		
COVID-19 Fear						
Low Fear	Ref			Ref		
Moderate fear	1.886	1.001-3.553	**0.049**	1.491	0.731-3.039	0.272
Severe Fear	2.809	1.478-5.340	**0.002**	2.343	1.123-4.887	**0.023**
Alcohol Use						
Yes	1.822	1.051-3.160	**0.033**	1.639	0.881-3.047	0.119
No	Ref			Ref		
Sleep Satisfaction						
Satisfied	Ref			Ref		
Not satisfied	2.237	1.335-3.748	**0.002**	1.912	1.073-3.047	**0.028**
Depression						
Present	2.758	1.641-4.635	**<0.001**			
Absent	Ref			-	-	-

[a] Logistic regression model adjusted for all variables in the table expect Depression, Nagelkerker R Square 0.310; Hosmer Lemeshow Chi-square 9.793, p=0.280

CI: confidence interval, UOR: Unadjusted odds ratio, AOR: Adjusted odds ratio

In context of Depression, economical dependency (AOR:1.890, 95% CI:1.026-3.482), lower level of perceived social support (AOR:2.883, 95% CI:1.158-7.181), no insurance coverage (AOR:2.973, 95% CI:1.134-7.093), presence of multiple complications (AOR:2.308, 95% CI:1.585-6.422), presence of single comorbidity (AOR:2.262, 95% CI:1.108-4.619), and multiple comorbidities (AOR:2.575, 95% CI:1.180-5.617), difficulty following recommended diet (AOR:2.387, 95% CI:1.100-5.182), severe fear of COVID-19 (AOR:2.117, 95% CI:1.009-4.573), alcohol use (AOR:2.401, 95% CI:1.199-4.806), and sleep dissatisfaction (AOR:1.995, 95% CI:1.093-3.644) were found as the independent predictors for depression (Table 5).

Table 5: Independent predictors of depression among the diabetes patients (n=283)

Factors	UOR	95% CI	p-value	AOR[a]	95% CI	p-value
Living companion						
Living alone	3.239	1.363-7.695	**0.008**	1.586	0.553-4.548	0.391
Living with family	Ref			Ref		
Economic Dependency						
Dependent	1.979	1.210-3.236	**0.007**	1.890	1.026-3.482	**0.041**
Independent	Ref			Ref		
Perceived level of social support						
Low support	4.919	2.295-10.543	**<0.001**	2.883	1.158-7.181	**0.023**
Moderate Support	2.032	1.163-3.551	**0.013**	1.345	0.696-2.599	0.379
High Support	Ref			Ref		
Use of Insulin						
Yes	3.095	1.468-6.528	**0.003**	1.265	0.905-3.171	0.061

No	Ref			Ref		
Presence of Complications						
None	Ref			Ref		
Single complications	2.928	1.535-5.587	**0.010**	1.628	0.739-3.587	0.227
Two or more	3.311	1.397-7.851	**0.007**	2.308	1.858-6.422	**0.046**
Presence of Comorbidities						
None	Ref			Ref		
Single comorbidity	2.500	1.367-4.573	**0.003**	2.262	1.108-4.619	**0.025**
Two or more	4.242	2.274-7.915	**<0.001**	2.575	1.180-5.617	**0.017**
Health insurance coverage						
Full coverage	Ref			Ref		
Partial coverage	1.842	0.751-4.517	0.182	1.792	0.613-4.691	0.287
No insurance	3.410	1.483-7.842	**0.004**	2.973	1.134-7.093	**0.027**
Difficulty following recommended diet						
Too difficult	3.224	1.701-6.112	**<0.001**	2.387	1.100-5.182	**0.028**
A bit difficult	1.615	1.005-2.865	**0.046**	1.112	0.555-2.230	0.764
Not difficult at all	Ref			Ref		
History of Mental illness						
Yes	3.118	1.099-8.848	**0.033**	2.587	0.835-9.025	0.139
No	Ref			Ref		
COVID-19 Fear						
Low Fear	Ref			Ref		
Moderate fear	1.977	1.087-3.594	**0.025**	1.496	0.731-3.060	0.270
Severe Fear	2.375	1.282-4.402	**0.006**	2.117	1.009-4.573	**0.042**
Alcohol Use						
Yes	2.437	1.420-4.184	**0.001**	2.401	1.199-4.806	**0.013**
No	Ref			Ref		
Tobacco Use						
Yes	1.929	1.063-3.500	**0.031**	1.001	0.461-2.174	0.998
No	Ref			Ref		
Sleep Satisfaction						
Satisfied	Ref			Ref		
Not satisfied	2.414	1.460-3.993	**0.001**	1.995	1.093-3.644	**0.025**

[a] Logistic regression model adjusted for all variables in the table expect Anxiety; Nagelkerker R Square 0.358; Hosmer Lemeshow Chi-square 10.073, p=0.260

CI: confidence interval, UOR: Unadjusted odds ratio, AOR: Adjusted odds ratio

DISCUSSION

In this study, the prevalence of anxiety and depression among T2DM patients were 31.4% and 36.4% respectively. This rate of prevalence is slightly lower than a recent study conducted among T2DM patients admitted in the tertiary hospital at Chitwan district in 2019 where anxiety and depression were reported among 57.8% and 49.7% of the participants.[30] This variation in anxiety and depression might be due to the fact that the past study was conducted in hospital-admitted patients. The current prevalence of depression is in line with past prevalence observed among patients visiting diabetes centers in Lalitpur Metropolitan in 2019 where 35.6% of diabetes patients

were found to have depression.[31] However, past community-based study from the Dubabi-Bhaluwa Municipality reported a lower prevalence (22.7%) of depression in the year 2016. [15] These variations in the prevalence might be due to the difference in geographic location, study settings and time factors.

There was a statistically significant relationship existing between the perceived level of social support and patients' anxiety and depression status, as the patients with lower level of perceived social support had twice the odds of anxiety and depression. Similar findings were shared by studies from Saudi Arabia and Ethiopia where higher odds of anxiety and depression were seen in patients with lower social support. [32, 33] As good social support has been observed as a protective factor for anxiety and depression, studies suggest that strengthening social support in patients can improve their psychological wellbeing.[34, 35] Social support plays an important role in management of diabetes. Having poor social support may lead to delay in healthcare-seeking behavior as well as increased emotional distress. [32, 33, 36] This might further inflect an undesirable effect on both physical and mental wellbeing of the patients. Thus, social support in diabetes patients could be strengthened to reduce the risk of mental distress which could be done through frequent engagement of family members at diabetes care settings and formation of peer support groups at the diabetes centers as well as at community levels.

In this study, the presence of comorbidities as well as complications related to diabetes were found to be important predictors for anxiety and depression among T2DM patients. This is in line with past study from Nepal where diabetes patients with comorbid conditions had twice the odds of depression.[37] Likewise, a study from Ethiopia observed that patients worried about diabetes complications had 6.49 folds increase in odds of depression.[38] Similarly, patients with a history of diabetes-related complications were found to have higher odds of anxiety in Mexico.[39] Studies from different parts of the world suggest that, greater the number of additional illnesses present among T2DM patients, greater is the risk of anxiety and depression.[15, 40, 41] Presence of comorbidity and/or complication creates an additional financial burden due to increased treatment cost, physical burden and chronic pain as well as social burden among the T2DM patients. [15, 41, 42] Thus, these might be the contributing factors to impact patients' psychological wellbeing as we also found that economic dependency and absence of health insurance securities were other risk factors for depression among this vulnerable group. Special care should be provided to diabetes

patients suffering from complications and co-morbid conditions and should be provided with certain financial protection, proper health counseling and routine mental health screening services.

In bivariate analysis, we observed that insulin users have twice the odds of experiencing anxiety and thrice the odds of depression as compared to patients who don't have to use insulin. Similar observations were shared by past studies from Nepal where one study noted insulin users to have twice the odds of depression as compared to oral medicine users and another study found a nine-fold increase in depression as compared to non-insulin users.[15, 43] Insulin therapy not only involves painful injections and regular glucose measurement, but also is perceived to be used in severe cases. This perception might influence psychological distress among insulin users.[9, 15, 44, 45] However, in multivariate analyses this statistical relationship between insulin use and both anxiety and depression were ruled out in our study. This might be because a small proportion of insulin users were enumerated by chance in our random sample.

We observed that the participants who were not satisfied with the duration and quality of their sleep had almost twice the odds of being anxious and depressed than those who were satisfied with their sleep. Similar to this finding, a study from China observed that diabetes patients with poor sleep quality had almost twice the odds of anxiety and depression.[46] Short sleep duration could influence psychological distress even in the general population. Diabetes patients suffer from frequent urination which might affect their quality of sleep and sleep satisfaction, leading to discomfort, agitation and stress in long run.[41]

The severe fear of COVID-19 infection was found to be associated with both anxiety and depression. A study from Germany noted diabetes patients tend to perceive a higher susceptibility of COVID-19 infection, think more about its severe course, and even death from COVID-19 than non-diabetes population. However, the same study revealed that there was no increase in anxiety and depressive symptoms among individuals with diabetes.[47] As COVID-19 is an emerging public health concern with limited understanding about its psychological impact on patients with chronic illness who are deemed as a vulnerable group, there is a need for further studies for a better understanding of its association with psychological wellbeing among these vulnerable populations.

Limitations

Despite being one of the few studies to assess the status and risk factors for Anxiety and Depression among type-II diabetes mellitus patients in Nepal, this study is not free from its limitations. Anxiety and depression in this study were assessed through the PHQ-9 and HADS-Anxiety Subscale, which are screening tools. Thus, cross-verification of anxiety and depression from psychiatrists might be a limitation of this study. As this study was a health institution-based study, the prevalence of anxiety and depression might be slightly higher than the actual prevalence present at the community level.

CONCLUSION

The study revealed nearly one-third of the type-II diabetes patients experienced anxiety of varying severity, whereas, nearly two-fifths experienced depressive symptoms. Among the various factors, level of perceived social support, presence of comorbidity and complications, severe fear of COVID-19 infection, and sleep dissatisfaction were the associated risk factors for both anxiety and depression. There is a need to integrate mental health counseling services with present diabetes-related care and support systems to ease patients' physiological wellbeing. Further studies based on qualitative perspective could provide valuable insights over the way social supports and other associated factors are influencing the mental wellbeing of this vulnerable population.

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AUTHOR CONTRIBUTIONS

SP: as the primary investigator, lead the conceptualization of the study, questionnaire development, collected the data, performed preliminary analysis and developed and finalized the manuscript. SBM, SPK and SG: contributed to the manuscript's conceptualization, analysis and interpretation of the findings and supervised the study. AC: contributed in data collection and

analysis, editing and revision of the whole manuscript. TNK: contributed in data collection and review of the manuscript. All authors read and approved the final manuscript.

ETHICAL APPROVAL

The ethical approval for this study was obtained from Institutional Review Committee of Manmohan Memorial Institute of Health Science (Registration no: MMIHS-IRC 583).

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None declared.

COMPETING INTERESTS

None declared.

DATA SHARING

The dataset generated and analyzed during the current study are available from the corresponding author upon reasonable request.

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STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3,4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
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	*6*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6,7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	7
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
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	7
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7,8,9
		(b) Indicate number of participants with missing data for each variable of interest	7
Outcome data	15*	Report numbers of outcome events or summary measures	7,8,9

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	10,11,12
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10,11,12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12,13,14
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	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
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	16

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting.

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Anxiety and Depression among People with Type 2 Diabetes Visiting Diabetes Clinics of Pokhara Metropolitan, Nepal: A Cross-sectional Study

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Anxiety and Depression among People with Type 2 Diabetes Visiting Diabetes Clinics of Pokhara Metropolitan, Nepal: A Cross-sectional Study

Shishir Paudel[1], Shankar Prasad Khanal[2], Sujan Gautam[1], Anisha Chalise[3], Tara Nath Koirala[4], Sujan Babu Marahatta[1]

[1] Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal

[2] Central Department of Statistics, Tribhuvan University, Kathmandu, Nepal

[3] Center for Research on Environment Health & Population Activities (CREHPA), Kusunti, Lalitpur, Nepal

[4] Pokhara Super Speciality Health Clinic, Consultant Endocrinologist, Pokhara, Nepal

Authors	Institution Affiliation
1st Author: Shishir Paudel	Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal
2nd Author: Shankar Prasad Khanal	Central Department of Statistics, Tribhuvan University, Kathmandu, Nepal
3rd Author: Sujan Gautam	Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal
4th Author: Anisha Chalise	Center for Research on Environment Health & Population Activities(CREHPA), Kusunti, Lalitpur, Nepal
5th Author : Tara Nath Koirala	Pokhara Super Speciality Health Clinic, Consultant Endocrinologist, Pokhara, Nepal
6th Author : Sujan Babu Marahatta	Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal

CORRESPONDING AUTHOR:

Name: Sujan Babu Marahatta

Email: sujan@nou.edu.np

Contact no: +977-9851126707

Address: Kathmandu, Nepal

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ABSTRACT

Objectives: To estimate the prevalence of anxiety and depression and identify their risk factors among people with type 2 diabetes visiting diabetes clinics of Pokhara Metropolitan, Nepal.

Design: Cross-sectional study.

Setting: Three diabetes clinics in Pokhara Metropolitan, Nepal; From May to July 2021.

Participants: 283 people with T2DM visiting selected diabetes centers of Pokhara Metropolitan.

Main Outcome Measures: Anxiety and Depression.

Methods: Face-to-face interview was conducted using a structured questionnaire consisting information related to participants' socio-demographic profile, and several factors along with Hospital Anxiety and Depression-anxiety subscale (HADS-A) and Patient Health Questionnaire (PHQ-9) to assess the level of anxiety and depression respectively. Pearson's chi-square tests and binary logistic regression were performed to examine association between dependent and independent variables at 5% level of significance.

Results: The prevalence of anxiety and depression was noted among 31.4% (95% CI: 26.2%-37.5%) and 36.4% (95% CI: 30.8%-42.0%) of people with T2DM respectively. Anxiety was found to be associated with lower level of perceived social support (AOR:2.442, 95% CI:1.020-5.845), multiple complications (AOR:2.758, 95% CI:1.015-7.334), and comorbidities (AOR:2.110, 95% CI:1.004-4.436), severe COVID-19 fear (AOR:2.343, 95% CI:1.123-4.887), and sleep dissatisfaction (AOR:1.912, 95% CI:1.073-3.047). Likewise, economical dependency (AOR:1.890, 95% CI:1.026-3.482), no insurance (AOR:2.973, 95% CI:1.134-7.093), lower perceived social support (AOR:2.883, 95% CI:1.158-7.181), multiple complications (AOR:2.308, 95% CI:1.585-6.422), and comorbidities (AOR:2.575, 95% CI:1.180-5.617), severe COVID-19 fear (AOR:2.117, 95% CI:1.009-4.573), alcohol use (AOR:2.401, 95% CI:1.199-4.806), and sleep dissatisfaction (AOR:1.995, 95% CI:1.093-3.644) were found to be associated with depression.

Conclusion: This study showed a high prevalence of anxiety as well as depression among people with T2DM. Strengthening social support and focusing on people with diabetes suffering from comorbidity and complications could reduce their risk of mental health problems.

Keywords: Anxiety, Depression, Type 2 Diabetes, Prevalence, Risk Factors, Psychological distress

Strengths and Limitations of this Study

- The study used validated screening tools to assess the level of anxiety, depression, and level of perceived social support
- The study was conducted in three most sought health facilities of Pokhara Metropolitan, and the participants were selected based on systematic random sampling technique ensuring the sample represents the people living with type 2 diabetes in this metropolitan.
- The study illustrates a significant relationship existing between mental health status and COVID-19 pandemic in this vulnerable population and at the same time, by adjusting the effect of COVID-19, this study also validates the significance of other independent factors.
- Although the study was performed in the largest Metropolitan City of Nepal, the prevalence of anxiety and depression reported in this study might be slightly higher than the actual prevalence present at the community level, as this was a health institution-based study conducted at the time of COVID-19 pandemic.

INTRODUCTION

Diabetes mellitus is a systemic disease that may affect various body systems leading to blindness, kidney failure, and lower limb amputation as its long-term complications.[1-3] The global prevalence of diabetes was estimated at 9.3% in the year 2019 with a prediction that globally 578 million people will have diabetes by the year 2030.[4] Its prevalence has been rising rapidly in low and middle-income countries than that in high-income countries.[5] A systematic review from 2021 based on publications from 2000-2020, noted the pooled prevalence of type 2 diabetes (T2DM) in Nepal at 10% with a higher prevalence observed in studies published between the years 2015 and 2020, which was at 11.24%.[6]

Mental distress is an emotional state which manifests with a range of depression, anxiety, panic, or somatic symptoms such as sleep problems, headache, and backache.[7] Globally, the prevalence of psychological distress mostly depression and anxiety disorders are higher among people living with diabetes as compared to their counterparts.[8-10] A systematic review estimated the global prevalence of depression among people with T2DM at 28%, where Asia has the highest rate of depression at 32%.[11] Similarly, another systematic review observed generalized anxiety disorder to be present among 14% of people with T2DM.[12] In Nepal, a cross-sectional study performed

among people with T2DM attending tertiary care centers in Kathmandu valley found the rate of depression at 40.3% in the year 2013.[13] Similarly, a study conducted in a community setting of Duhabi-Bhaluwa Municipality of Sunsari District in 2019 revealed the prevalence of depression among people with T2DM to be at 22.7%. [14]

Diabetes care mainly consists of self-care aimed to prevent acute and chronic complications. The person living with diabetes is responsible to balance their food intake, physical activities and monitor blood glucose levels as much as possible.[15] Mental health complications, mostly anxiety and depression complicate living with diabetes and its management in several ways. Presence of depression and anxiety could worsen the prognosis of diabetes by reducing patients' ability for self-care and increasing non-compliance to treatments while increasing the risk of serious short- and long-term complications such as blindness, amputations, stroke, decreased quality of life, and even premature death.[15-18] Additionally, serious anxiety disorders largely overlap with symptoms of hypoglycemia which requires immediate treatment but people with diabetes might fail to differentiate whether the feelings are of anxiety or hypoglycemia. The preexisting anxiety of injections or blood draws might lead to panic disorders or patients' refusal to monitor their glucose levels.[20] Similarly, fear of hypoglycemia, a common source of anxiety and depression for people with diabetes, can lead them to maintain blood glucose levels above target levels.[19] The presence of diabetes is a chronic life-threatening stressor that requires significant mental and physical support and care to cope with elevated feelings of fear and distress. [20] Even in the current context of COVID-19 pandemic, people with diabetes are taken as one of the vulnerable populations at risk of infection and mortality. Thus, the COVID-19 pandemic might have aggregated their existing fear and distress worsening their mental well-being. Considering this circumstance there are higher concerns stressed over the mental health and wellbeing of this vulnerable population.[21, 22]

There is a lack of plentiful information about the rates of anxiety and depression among people with diabetes as well as its associated risk factors in South Asia and particularly in Nepal because of the limited studies published to date considering the mental health perspective of the people with diabetes. Thus, this study aimed to assess the prevalence and factors associated with anxiety and depression among people with type 2 diabetes visiting diabetes clinics of Pokhara Metropolitan, one of the rapidly urbanizing cities of Nepal with an expectation that the study could

provide some valuable insights into mental health issues of these people in developing nations similar to Nepal.

METHODS AND MATERIALS

Study Design

This was a health facility-based cross-sectional study executed among people with type 2 diabetes residing at Pokhara Metropolitan who visited the selected healthcare institutions between May and July 2021.

Participants

All people with type 2 diabetes mellitus with at least six months of history of diagnosis, attending the selected diabetes clinics were eligible to be included, while people with T2DM who were not the residents of Pokhara Metropolitan for at least past six months from the date of data collection were excluded.

Sample Size Determination and Sampling Technique

The sample size was determined using Cochran's formula for the estimation of a proportion ($n=z^2pq/d^2$), since our major outcome variables were prevalence of anxiety and depression. A community-based cross-sectional study conducted in the eastern part of Nepal reported the prevalence of depression among people with T2DM to be 22.7%. [14] So, using this past prevalence at 5% allowable error and 95% confidence interval, the initially estimated sample size was 264 people with T2DM which was optimized to 291 after adjusting 10% non-response rate.

Two government health institutions (Urban Health Promotion Center and Shishuwa Hospital) and one private clinic (Pokhara Super Speciality Health Clinic) were selected purposively. Urban Health Promotion Center and Shishuwa Hospital are the primary contact points for Social Health Insurance and provide free diabetes-related services as well as referral services. Thus, these are some of the most sought government institutions with an estimated 250-300 people with T2DM visiting monthly. Pokhara Super Speciality Health Clinic is one of the well-known tertiary endocrine referral centers of Pokhara with an average of 500 people with diabetes visiting monthly. The people with T2DM visiting these three healthcare institutions were selected randomly using the technique based on systematic random sampling. For this, every k^{th} patient ($800/291=2.74\approx3$) i.e. 3^{rd} patient waiting in the queue on the day of data collection was enrolled as a participant. If

the selected patient refused to participate or fell under exclusion criteria, then the patient next in the queue was approached for participation.

Data Collection

Face-to-face interview technique was used for data collection. The people with T2DM meeting inclusion criteria were approached and provided with the study details. Informed consent was acquired and after his/her approval, the interview was performed**.** Considering the privacy of the participants Pokhara Super Speciality Health Clinic provided the researcher with a separate room next to the doctors' cabin, while a small private space was provided at the corner of the doctors' cabin and in the waiting area in Urban Health Promotion Center and Shishuwa Hospital where the patients were directed for data collection.

The data was collected using a set of closed-ended questions consisting of three sections. The first section consisted of questions regarding the socio-demographic profile of the participants including Multidimensional Scale of Perceived Social Support (MSPSS)[23] translated in Nepali language (MSPSS-N)[24] intending to measure the level of perceived social support. Second section consisted of questions regarding the patient's health conditions, diabetes-related attributes, and lifestyle-related factors including COVID-19 related variables such as COVID-19 status, vaccination, and fear associated with COVID-19 based on a modification of Fear scale of COVID-19[25]. Third section consisted of a nine-item Patient Health Questionnaire (PHQ-9)[26] to measure the level of depression followed by Hospital Anxiety and Depression Scale-anxiety subscale (HASD-A)[27] to measure the level of anxiety.

The PHQ-9 consists of nine items measuring depressive symptoms corresponding to diagnostic criteria for major depressive disorder. Each item was scored on a four-point Likert scale (0–3) with scores ranging from 0 to 27, with higher scores reflecting greater depression severity.[26] The PHQ-9 has been translated in Nepali language and has shown a sensitivity of 0.94 and specificity of 0.80 to measure depression at the cutoff of ≥ 10.[28] The HADS-A consist of seven items measuring anxiety symptoms. Each item is scored on a four-point Likert scale (0-3) with total scores ranging from 0 to 21 with higher scores reflecting greater anxiety and cutoff point of ≥8 illustrating anxiety.[27] The HADS has been validated in Nepali language where HADS-A subscale was found to have a good internal consistency with Cronbach's alpha of 0.76.[29] The data collection tool used in the present study is attached as a supplemental file.

Data Processing, Management and Analysis

The collected data were entered in EpiData 3.1 and exported to Statistical Package for Social Sciences (SPSS) version 22 for statistical analysis. The data were summarized in terms of frequencies and proportions. Bivariate analysis was carried out by applying Chi-square (χ^2) tests to identify the factors associated with anxiety and depression at 95% Confidence Interval (CI) and 5% level of significance i.e. p-value <0.05. The variables found to be significant in bivariate analysis were considered for multivariate analysis using binary logistic regression to determine the adjusted effect of each factor on the dependent variable. Prior to multivariate regression analysis, the multi-collinearity between the independent variables was tested using the Variance Inflation Factor (VIF) test, with a VIF greater than five taken as an indication of multi-collinearity between the independent variables. The Hosmer-Lemeshow test (HL test) for goodness-of-fit was also performed.

Ethical Considerations

The ethical approval for this study was obtained from the Institutional Review Committee of Manmohan Memorial Institute of Health Science (Registration no: MMIHS-IRC 583). Written informed consent was obtained from all the participants before conducting the study and all the information was kept confidential.

Patient and Public Involvement

None.

RESULTS

A total of 291 people with T2DM were approached for data collection, of which 283 provided complete responses to all the questions, while eight participants left in the middle of the data collection. Thus, the response rate of 97.25% for all questions was acquired and 283 total samples were analyzed for this study. The prevalence of anxiety and depression was noted among 31.4% and 36.4% of people with T2DM respectively (Table 1). Moreover, around one-third (36%) of the participants reported to have experienced suicidal ideation in the past two weeks on PHQ-9 of which six participants (2.1%) reported experiencing suicidal ideation nearly every single day.

Table 1: Prevalence of Anxiety and Depression (n=283)

Outcome	n (%)	95% CI	Outcome	n (%)	95% CI

Anxiety Status			**Depression Status**		
Present	89 (31.4)	26.2%-37.5%	Present	103 (36.4)	30.8%-42.0%
Absent	194 (68.6)	62.5%-73.8%	Absent	180 (63.6)	58.0%-69.2%
Anxiety Level			**Depression Level**		
No Anxiety	194 (68.6)	62.5%-73.8%	No Depression	180 (63.6)	57.6 %-68.6%
Mild Anxiety	62 (21.9)	16.6%-27.2%	Mild Depression	71 (25.1)	20.1%-30.7%
Moderate Anxiety	19 (6.7)	3.9%-9.9%	Moderate Depression	22 (7.8)	4.6%-11.0%
Severe Anxiety	8 (2.8)	1.1%-5.3%	Severe Depression	10 (3.5)	1.8%-5.7%

The age of the participants in this study ranged from 33 to 88 years with a mean age of 56.17±11.81 years. Almost half of the participants (56.9%) were male. Majority (91.5%) reported living with their family and near to half (42.8%) reported to be economically dependent. Nearly half of the participants (54.8%) reported to have no insurance coverage for their treatment. Likewise, one in six participants reported to have a lower level of perceived social support. (Table 2)

Table 2: Socio-demographic profile of the participants (n=283)

Variables	**n (%)**
Age group	
<40 years	30 (10.6)
40-50	65 (23.0)
50-60	77 (27.2)
≥60 years	111 (39.2)
Gender	
Male	161 (56.9)
Female	122 (43.1)
Ethnicity	
Brahmin/Chhetri	107 (37.8)
Janajaties	122 (43.1)
Dalit	33 (11.7)
Religious Minorities	21 (7.4)
Type of Family	
Nuclear	143 (50.5)
Joint/ Extended	140 (49.4)
Living companion	
Living alone	24 (8.5)
Living with family	259 (91.5)
Marital Status	
Married	232 (82.0)
Unmarried/Divorced	13 (4.6)
Widow/ Widower	38 (13.4)
Education	
Illiterate	49 (17.3)
Literate by Informal Education	42 (14.8)
Literate by Formal Education	192 (67.8)
Economic Dependency	
Dependent	121 (42.8)
Independent	162 (57.2)

Health insurance	
Full coverage	42 (14.8)
Partial coverage	86 (30.4)
No insurance	155 (54.8)
Perceived social support	
Low support	41 (14.5)
Moderate Support	130 (45.9)
High Support	112 (39.6)

Out of all 283 participants, almost half (46.3%) reported to have lived with diabetes for more than four years of their life. Almost a quarter (25.1%) of the participants reported to have experienced complications related to diabetes whereas nearly half (55.5%) reported to have other comorbidities existing before they got diagnosed with diabetes. Nearly three out of four (71.0%) participants reported having a fear of COVID-19 infection whereas only 9.9% had complete vaccination status (Table 3).

Table 3: Health and lifestyle related characteristics of the participants (n=283)

Variables	**n (%)**
Duration of Illness	
≤ 4 Years	152 (53.7)
>4 years	131 (46.3)
Use of Insulin	
Yes	33 (12.0)
No	250 (88.0)
Presence of Complications	
None	212 (74.9)
Single complications	47 (16.6)
Two or more	24 (8.5)
Presence of Comorbidities	
None	126 (44.5)
Single comorbidity	84 (29.7)
Two or more	73 (25.8)
Difficulty following recommended diet	
Too difficult	63 (22.3)
A bit difficult	100 (35.3)
Not difficult at all	120 (42.4)
History of Mental illness	
Yes	16 (5.7)
No	267 (94.3)
Ever tested for COVID-19	
Tested Negative	31 (11.0)
Tested Positive	28 (9.9)
Never Tested	224 (79.1)
COVID-19 Vaccine	
Complete vaccination	28 (9.9)
Incomplete vaccine	65 (23.0)
Didn't receive vaccine	190 (67.1)

COVID-19 Fear	
Low Fear	105 (37.1)
Moderate fear	96 (33.9)
Severe Fear	82 (29.0)
Alcohol Use	
Yes	75 (26.5)
No	208 (73.5)
Tobacco Use	
Yes	55 (19.4)
No	228 (80.6)
Sleep Satisfaction	
Satisfied	180 (63.6)
Not satisfied	103 (36.4)

In bivariate analysis, participants' family type, living companionship and perceived level of social support were the only socio-demographic factors found to be associated with anxiety, whereas, living companionship, economic dependency, insurance coverage diabetes care, and perceived level of social support were the only socio-demographic factors found to be associated with depression at 5% level of significance (Table 4).

Table 4. Association of socio-demographic variables with Anxiety and Depression (n=283)

Socio-demographic variables	**Anxiety**		**χ^2 (p-value)**	**Depression**		**χ^2 (p-value)**
	Presence n(%)	**Absence n(%)**		**Presence n(%)**	**Absence n(%)**	
Age group						
<40 years	11 (36.7)	19 (63.3)	1.006 (0.800)	13 (43.3)	17 (56.7)	5.741 (0.125)
40-50	19 (29.2)	46 (70.8)		16 (24.6)	49 (75.4)	
50-60	22 (28.6)	55 (71.4)		28 (36.4)	49 (63.6)	
≥60 years	37 (33.3)	74 (66.7)		46 (41.4)	65 (58.6)	
Gender						
Male	54 (33.5)	107 (66.5)	0.758 (0.384)	59 (36.6)	102 (63.4)	0.010 (0.920)
Female	35 (28.7)	87 (71.3)		44 (36.1)	78 (63.9)	
Ethnicity						
Brahmin/Chhetri	42 (39.3)	65 (60.7)	4.953 (0.175)	38 (35.5)	69 (64.5)	2.889 (0.409)
Janajaties	33 (27.0)	89 (73.0)		44 (36.1)	78 (63.9)	
Dalit	9 (27.3)	24 (72.7)		10 (30.3)	23 (69.7)	
Religious Minorities	5 (23.8)	16 (76.2)		11 (52.4)	10 (47.6)	
Type of Family						
Nuclear	53 (37.1)	90 (62.9)	4.226 (0.040)*	59 (41.3)	84 (58.7)	2.953 (0.086)
Joint/ Extended	36 (25.7)	104 (74.3)		44 (31.4)	96 (68.6)	
Living companion						
Living alone	13 (55.2)	11 (45.8)	6.278 (0.012)*	15 (62.5)	9 (37.5)	7.719 (0.005)*
Living with family	76 (29.6)	183 (70.7)		88 (34.0)	171 (66.0)	
Marital Status						
Married	72 (31.0)	160 (69.0)	1.433 (0.489)	78 (33.6)	154 (66.4)	5.464 (0.065)
Unmarried/Divorced	6 (46.2)	7 (53.8)		8 (61.5)	5 (38.5)	
Widow/ Widower	11 (28.9)	27 (71.1)		17 (44.7)	21 (55.3)	
Education						
Illiterate	15 (30.6)	34 (69.4)	1.880 (0.391)	21 (42.9)	28 (57.1)	2.419 (0.298)
Literate by Informal Education	17 (40.5)	25 (59.5)		18 (43.0)	24 (57.0)	

Literate by Formal Education	57 (29.7)	135 (70.3)		64 (33.3)	128 (66.7)	
Economic Dependency						
Dependent	41 (33.9)	80 (66.1)	0.582 (0.446)	55 (45.5)	66 (54.5)	7.493 (0.006)*
Independent	48 (29.6)	114 (70.4)		48 (29.6)	114 (70.4)	
Health insurance						
Full coverage	9 (21.4)	33 (78.6)	2.498 (0.287)	8 (19.0)	34 (81.0)	11.287 (0.004)*
Partial coverage	27 (31.4)	59 (68.6)		26 (30.2)	60 (69.8)	
No insurance	53 (34.2)	102 (65.8)		69 (44.5)	85 (55.5)	
Perceived social support						
Low support	20 (48.8)	21 (51.2)	15.898 (<0.001)*	25 (61.0)	16 (39.0)	18.458 (<0.001)*
Moderate Support	48 (36.9)	82 (63.1)		51 (39.2)	79 (60.8)	
High Support	21 (18.8)	91 (81.3)		27 (24.1)	85 (75.9)	

*Statistical significance at $p<0.05$

In context of health and lifestyle-related factors, insulin use, presence of complications and comorbidities, prior history of clinically diagnosed mental distress, fear associated with COVID-19, alcohol use and sleep satisfaction were found to be associated with both anxiety and depression status at $p<0.05$. In addition, depression was also found to be associated with the difficulty experienced by people with T2DM to follow dietary recommendations and use of tobacco products. (Table 5). The people with T2DM experiencing anxiety were found to be twice more likely to be depressed (UOR: 2.758, 95% CI:1.641-4.635) in bivariate analysis (Table 5).

Table 5: Association of Health and Lifestyle related variables with Anxiety and Depression (n=283)

Health and Lifestyle related variables	**Anxiety**		**χ^2 (p-value)**	**Depression**		**χ^2 (p-value)**
	Presence n(%)	**Absence n(%)**		**Presence n(%)**	**Absence n(%)**	
Duration of Illness						
≤ 4 Years	45 (29.6)	107 (70.4)	0.518 (0.472)	49 (32.2)	103 (67.8)	2.453 (0.117)
>4 years	44 (33.6)	87 (66.4)		54 (41.2)	77 (58.8)	
Use of Insulin						
Yes	17 (51.5)	16 (48.5)	6.977 (0.008)*	20 (60.6)	13 (39.4)	9.459 (0.002)*
No	72 (28.8)	178 (71.2)		83 (33.2)	167 (66.8)	
Presence of Complications						
None	53 (25.0)	159 (75.0)	16.502 (<0.001)*	63 (29.7)	149 (70.3)	16.345 (<0.001)*
Single complications	23 (48.9)	24 (51.1)		26 (55.3)	21 (44.7)	
Two or more	13 (54.2)	11 (45.8)		14 (58.3)	10 (41.7)	
Presence of Comorbidities						
None	24 (19.0)	102 (81.0)	17.118 (<0.001)*	28 (22.2)	98 (77.8)	22.617 (<0.001)*
Single comorbidity	32 (38.1)	52 (61.9)		35 (41.7)	49 (58.3)	
Two or more	33 (45.2)	40 (54.8)		40 (54.8)	33 (45.2)	
Difficulty following recommended diet						
Too difficult	24 (38.1)	39 (61.9)	1.686 (0.430)	34 (54.0)	29 (46.0)	13.326 (<0.001)*
A bit difficult	29 (30.6)	71 (69.4)		37 (34.0)	63 (66.0)	
Not difficult at all	36 (30.0)	84 (70.0)		32 (26.7)	88 (73.3)	
History of Mental illness						
Yes	9 (56.3)	7 (43.8)	4.839 (0.028)*	10 (62.5)	6 (37.5)	4.992 (0.025)*
No	80 (30.0)	187 (70.0)		93 (34.8)	174 (65.2)	

Ever tested for COVID-19						
Tested Negative	14 (45.2)	17 (54.8)	3.368 (0.186)	9 (29.0)	22 (71.0)	0.850 (0.654)
Tested Positive	7 (25.0)	21 (75.0)		10 (35.7)	18 (64.3)	
Never Tested	68 (30.4)	156 (69.6)		84 (37.5)	140 (62.5)	
COVID-19 Vaccine						
Complete vaccination	11 (39.3)	17 (60.7)	1.005 (0.605)	9 (32.1)	19 (67.9)	2.508 (0.285)
Incomplete vaccine	21 (32.3)	44 (67.7)		29 (44.6)	36 (55.4)	
Didn't receive vaccine	57 (30.0)	133 (70.0)		65 (34.2)	125 (65.8)	
COVID-19 Fear						
Low Fear	22 (21.0)	83 (79.0)	10.325 (0.006)*	27 (25.7)	78 (74.3)	8.614 (0.013)*
Moderate fear	32 (33.3)	64 (66.7)		39 (40.6)	57 (59.4)	
Severe Fear	35 (42.7)	47 (57.3)		37 (45.1)	45 (54.9)	
Alcohol Use						
Yes	31 (41.3)	44 (58.7)	4.625 (0.033)*	39 (52.0)	36 (48.0)	10.733 (0.001)*
No	58 (27.9)	150 (72.1)		64 (30.8)	144 (69.2)	
Tobacco Use						
Yes	23 (41.8)	32 (58.2)	3.405 (0.065)	27 (49.1)	28 (50.9)	4.753 (0.029)*
No	66 (28.9)	162 (71.1)		76 (33.3)	152 (66.7)	
Sleep Satisfaction						
Satisfied	45 (25.0)	135 (75.0)	9.540 (0.002)*	52 (28.9)	128 (71.1)	12.039 (0.001)*
Not satisfied	44 (42.7)	59 (57.3)		51 (49.5)	52 (50.5)	
Depression						
Present	47 (45.6)	56 (54.4)	15.109 (<0.001)*	-	-	-
Absent	42 (23.2)	138 (76.7)		-	-	
Anxiety						
Present	-	-	-	47 (52.8)	42 (47.2)	15.109 (<0.001)*
Absent	-	-		56 (28.9)	138 (71.1)	

*Statistical significance at p<0.05

For multivariate analysis, the Variance Inflation Factor (VIF) test among the independent variables was performed where the highest reported VIF was 1.610 so there was no issue of multi-collinearity. Lower level of perceived social support (AOR:2.442, 95% CI:1.020-5.845), presence of single (AOR:2.081, 95% CI:1.002-4.414) and multiple complications (AOR:2.758, 95% CI: 1.015-7.334), presence of single comorbidity (AOR:2.127, 95% CI:1.059-4.272) and multiple comorbidities (AOR:2.110, 95% CI:1.004-4.436), severe fear of COVID-19 infection (AOR:2.343, 95% CI:1.123-4.887), and sleep dissatisfaction (AOR:1.912, 95% CI:1.073-3.047) were found to associated with anxiety (Table 6).

Table 6: Factors associated with anxiety among people with diabetes (n=283)

Factors	UOR	95% CI	p-value	AOR[a]	95% CI	p-value
Type of Family						
Nuclear	1.701	1.023-2.829	0.041*	1.458	0.784-2.711	0.233
Joint/ Extended	Ref			Ref		
Living companion						
Living alone	2.846	1.221-6.633	0.015*	1.108	0.405-3.034	0.842
Living with family	Ref			Ref		
Perceived level of social support						

Low support	4.127	1.902-8.955	<0.001*	2.442	1.020-5.845	0.045*
Moderate Support	2.537	1.401-4.591	0.002*	1.839	0.986-3.520	0.060
High Support	Ref			Ref		
Use of Insulin						
Yes	2.627	1.259-5.481	0.010*	1.299	0.565-3.166	0.565
No	Ref			Ref		
Presence of Complications						
None	Ref			Ref		
Single complications	2.875	1.499-5.512	0.001*	2.081	1.002-4.414	0.049*
Two or more	3.545	1.501-8.387	0.004*	2.758	1.015-7.334	0.044*
Presence of Comorbidities						
None	Ref			Ref		
Single comorbidity	2.615	1.399-4.890	0.003*	2.127	1.059-4.272	0.034*
Two or more	3.506	1.848-6.652	<0.001*	2.110	1.004-4.436	0.048*
History of Mental illness						
Yes	3.005	1.082-8.350	0.035*	2.132	0.680-6.687	0.194
No	Ref			Ref		
COVID-19 Fear						
Low Fear	Ref			Ref		
Moderate fear	1.886	1.001-3.553	0.049*	1.491	0.731-3.039	0.272
Severe Fear	2.809	1.478-5.340	0.002*	2.343	1.123-4.887	0.023*
Alcohol Use						
Yes	1.822	1.051-3.160	0.033*	1.639	0.881-3.047	0.119
No	Ref			Ref		
Sleep Satisfaction						
Satisfied	Ref			Ref		
Not satisfied	2.237	1.335-3.748	0.002*	1.912	1.073-3.047	0.028*
Depression						
Present	2.758	1.641-4.635	<0.001*			
Absent	Ref			-	-	-

*Statistical significance at p<0.05; [a] Logistic regression model adjusted for all variables in the table except Depression, Nagelkerker R Square 0.310; Hosmer Lemeshow Chi-square 9.793, p=0.280;CI: confidence interval, UOR: Unadjusted odds ratio, AOR: Adjusted odds ratio

In context of Depression, economical dependency (AOR:1.890, 95% CI:1.026-3.482), lower level of perceived social support (AOR:2.883, 95% CI:1.158-7.181), no insurance coverage (AOR:2.973, 95% CI:1.134-7.093), presence of multiple complications (AOR:2.308, 95% CI:1.585-6.422), presence of single comorbidity (AOR:2.262, 95% CI:1.108-4.619), and multiple comorbidities (AOR:2.575, 95% CI:1.180-5.617), difficulty following the recommended diet (AOR:2.387, 95% CI:1.100-5.182), severe fear of COVID-19 (AOR:2.117, 95% CI:1.009-4.573), alcohol use (AOR:2.401, 95% CI:1.199-4.806), and sleep dissatisfaction (AOR:1.995, 95% CI:1.093-3.644) were found to be associated with depression (Table 7).

Table 7: Factors associated with depression among people with diabetes (n=283)

Factors	UOR	95% CI	p-value	AOR[a]	95% CI	p-value
Living companion						

Living alone	3.239	1.363-7.695	0.008*	1.586	0.553-4.548	0.391
Living with family	Ref			Ref		
Economic Dependency						
Dependent	1.979	1.210-3.236	0.007*	1.890	1.026-3.482	0.041*
Independent	Ref			Ref		
Perceived level of social support						
Low support	4.919	2.295-10.543	<0.001*	2.883	1.158-7.181	0.023*
Moderate Support	2.032	1.163-3.551	0.013*	1.345	0.696-2.599	0.379
High Support	Ref			Ref		
Use of Insulin						
Yes	3.095	1.468-6.528	0.003*	1.265	0.905-3.171	0.061
No	Ref			Ref		
Presence of Complications						
None	Ref			Ref		
Single complications	2.928	1.535-5.587	0.010*	1.628	0.739-3.587	0.227
Two or more	3.311	1.397-7.851	0.007*	2.308	1.858-6.422	0.046*
Presence of Comorbidities						
None	Ref			Ref		
Single comorbidity	2.500	1.367-4.573	0.003*	2.262	1.108-4.619	0.025*
Two or more	4.242	2.274-7.915	<0.001*	2.575	1.180-5.617	0.017*
Health insurance coverage						
Full coverage	Ref			Ref		
Partial coverage	1.842	0.751-4.517	0.182	1.792	0.613-4.691	0.287
No insurance	3.410	1.483-7.842	0.004*	2.973	1.134-7.093	0.027*
Difficulty following recommended diet						
Too difficult	3.224	1.701-6.112	<0.001*	2.387	1.100-5.182	0.028*
A bit difficult	1.615	1.005-2.865	0.046*	1.112	0.555-2.230	0.764
Not difficult at all	Ref			Ref		
History of Mental illness						
Yes	3.118	1.099-8.848	0.033*	2.587	0.835-9.025	0.139
No	Ref			Ref		
COVID-19 Fear						
Low Fear	Ref			Ref		
Moderate fear	1.977	1.087-3.594	0.025*	1.496	0.731-3.060	0.270
Severe Fear	2.375	1.282-4.402	0.006*	2.117	1.009-4.573	0.042*
Alcohol Use						
Yes	2.437	1.420-4.184	0.001*	2.401	1.199-4.806	0.013*
No	Ref			Ref		
Tobacco Use						
Yes	1.929	1.063-3.500	0.031*	1.001	0.461-2.174	0.998
No	Ref			Ref		
Sleep Satisfaction						
Satisfied	Ref			Ref		
Not satisfied	2.414	1.460-3.993	0.001*	1.995	1.093-3.644	0.025*

*Statistical significance at p<0.05; [a] Logistic regression model adjusted for all variables in the table except Anxiety; Nagelkerker R Square 0.358; Hosmer Lemeshow Chi-square 10.073, p=0.260;CI: confidence interval, UOR: Unadjusted odds ratio, AOR: Adjusted odds ratio

DISCUSSION

In this study, the prevalence of anxiety and depression among people with T2DM were 31.4% and 36.4% respectively. This rate of prevalence is slightly lower than a recent study conducted among people with T2DM admitted in the tertiary hospital of Chitwan district in 2019 where anxiety and depression were reported among 57.8% and 49.7% of the participants.[30] This variation in anxiety and depression might be due to the fact that the past study was conducted in hospital-admitted patients. The current prevalence of depression is in line with past prevalence observed among people visiting diabetes centers in Lalitpur Metropolitan in 2019 where 35.6% of the people with diabetes were found to have depression.[31] However, a past community-based study from the Dubabi-Bhaluwa Municipality reported a lower prevalence (22.7%) of depression in the year 2016.[14] These variations in the prevalence might be due to the difference in geographic location, study settings, and time factors. In the global context, a similar rate of anxiety and depression has been noted among these vulnerable population in countries of different economies such as China[32], Saudi Arabia[33, 34], Mexico[35], Malaysia[36], Pakistan[37], and India[38].

There was a statistically significant relationship existing between the perceived level of social support and the anxiety and depression status of the people, as the people with a lower level of perceived social support had twice the odds of anxiety and depression. Similar findings were shared by studies from Saudi Arabia and Ethiopia where higher odds of anxiety and depression were seen among people with lower social support. [34, 39] As good social support has been observed as a protective factor against anxiety and depression, studies suggest that strengthening social support in these people can improve their psychological well-being.[40, 41] Social support plays an important role in the management of diabetes. Having poor social support may lead to delay in healthcare-seeking behavior as well as increased emotional distress. [34, 39, 42] This might further inflect an undesirable effect on both physical and mental well-being of the people. Thus, social support in people with diabetes could be strengthened to reduce the risk of mental distress which could be done through frequent engagement of family members at diabetes care settings and formation of peer support groups at the diabetes centers as well as at community levels.

In this study, the presence of comorbidities as well as complications related to diabetes were found to be important factors associated with anxiety and depression among people with T2DM. This is in line with a past study from Nepal where people with diabetes having comorbid conditions had

twice the odds of depression.[43] Likewise, a study from Ethiopia observed that people worried about diabetes complications had 6.49 folds increase in odds of depression.[44] Similarly, people with a history of diabetes-related complications were found to have higher odds of anxiety in Mexico.[35] Studies from different parts of the world suggest that the greater the number of additional illnesses present among people with T2DM, the greater the risk of anxiety and depression.[14, 45, 46] Presence of comorbidity and/or complication creates an additional financial burden due to increased treatment costs, physical burden, and chronic pain as well as social burden among the people with T2DM. [14, 46, 47] Thus, these might be the contributing factors to impact their psychological well-being as we also found that economic dependency and absence of health insurance securities were other risk factors for depression among this vulnerable group. Special care should be provided to people with diabetes suffering from complications and co-morbid conditions and should be provided with certain financial protection, proper health counseling, and routine mental health screening services.

In bivariate analysis, we observed that insulin users have twice the odds of experiencing anxiety and thrice the odds of depression as compared to patients who don't have to use insulin. Similar observations were shared by past studies from Nepal where one study noted insulin users had twice the odds of depression as compared to oral medicine users and another study found a nine-fold increase in depression as compared to non-insulin users.[14, 48] Insulin therapy not only involves painful injections and regular glucose measurement but also is perceived to be used in severe cases. This perception might influence psychological distress among insulin users.[8, 14, 49, 50] However, in multivariate analyses this statistical relationship between insulin use and both anxiety and depression was ruled out in our study. This might be because a small proportion of insulin users were enumerated by chance in our random sample.

We observed that the participants who were not satisfied with the duration and quality of their sleep had almost twice the odds of being anxious and depressed than those who were satisfied with their sleep. Similar to this finding, a study from China observed that people with diabetes with poor sleep quality had almost twice the odds of anxiety and depression.[32] Short sleep duration could influence psychological distress even in the general population. People with diabetes suffer from frequent urination which might affect their quality of sleep and sleep satisfaction, leading to discomfort, agitation, and stress in long run.[46]

The severe fear of COVID-19 infection was found to be associated with both anxiety and depression. A study from Germany noted that people with diabetes tend to perceive a higher susceptibility to COVID-19 infection, think more about its severe course, and even die from COVID-19 than other general population. However, the same study revealed that there was no increase in anxiety and depressive symptoms among individuals with diabetes.[51] Moreover, another study from Germany noted that the rate of anxiety and depression increased at the time of COVID-19 outbreak.[52] As COVID-19 is an emerging public health concern with limited understanding about its psychological impact on patients with chronic illness who are deemed as a vulnerable group, there is a need for further studies for a better understanding of its association with psychological well-being among these vulnerable populations. The fear of COVID-19 pandemic has been found to have significant relationships with anxiety and depression, but by adjusting its effect we also observed that the presence of the COVID-19 pandemic does not invalidate the relationship of anxiety and depression with other factors.

Limitations

Despite being one of the few studies to assess the status and risk factors for Anxiety and Depression among people with type 2 diabetes mellitus in Nepal, this study is not free from its limitations. As the study was executed during the time of COVID-19 pandemic, the observed rate of anxiety and depression might be slightly overestimated due to the effect of the pandemic, requiring further studies. A larger sample size would have benefited the precision of our confidence interval but due to the time constraints and lockdown imposed due to COVID-19 pandemic, the research team failed to cover a larger sample and only covered the estimated sample size. The patients were sampled from selected health institutions which might have introduced some selection bias. Anxiety and depression in this study were assessed through the PHQ-9 and HADS-Anxiety Subscale, which are screening tools. Thus, cross-verification of anxiety and depression from psychiatrists might be a limitation of this study. As this study was a health institution-based study, the prevalence of anxiety and depression might be slightly higher than the actual prevalence present at the community level.

CONCLUSION

The study revealed nearly one-third of the people with type 2 diabetes experienced anxiety of varying severity, whereas, nearly two-fifths experienced depressive symptoms. Among the various

factors, the level of perceived social support, presence of comorbidity and complications, severe fear of COVID-19 infection, and sleep dissatisfaction were the associated risk factors for both anxiety and depression. There is a need to integrate mental health counseling services with present diabetes-related care and support systems to ease patients' physiological well-being. Further studies based on qualitative perspective could provide valuable insights into the way social supports and other associated factors are influencing the mental well-being of this vulnerable population.

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AUTHOR CONTRIBUTIONS

SP: as the primary investigator, lead the conceptualization of the study, questionnaire development, collected the data, performed preliminary analysis and developed and finalized the manuscript. SBM, SPK and SG: contributed to the manuscript's conceptualization, analysis and interpretation of the findings and supervised the study. AC: contributed in data collection and analysis, editing and revision of the whole manuscript. TNK: contributed in data collection and review of the manuscript. All authors read and approved the final manuscript.

ETHICAL APPROVAL

The ethical approval for this study was obtained from Institutional Review Committee of Manmohan Memorial Institute of Health Science (Registration no: MMIHS-IRC 583).

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COMPETING INTERESTS

None declared.

DATA SHARING

The dataset generated and analyzed during the current study are available from the corresponding author upon reasonable request.

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Questionnaire

Eligibility Criteria:

Q1: How long have you known that you have diabetes?

Years_____ Months_____ If date is provided _____

Q2: How long have you been residing at Pokhara Metropolitan?

Years_____ Months_____ If date is provided _____

Section-A: Demographic Information

Q3. Age……. completed years **Q4. Gender…….**

Q5. Ethnicity

0. Dalit 1. Disadvantaged Janajatis 2. Disadvantaged non-dalit Terai caste groups
3. Religious Minorities 4. Relatively advantaged Janajatis 5. Upper caste groups

Q6. Marital Status

0. Single (Unmarried) 1. Married 2. Separated
3. Divorced 4. Widowed 5. Other (specify)…….....

Q7. **The total number of family members** (living together in the household sharing the same kitchen)……..

Q8. Type of Family

0. Nuclear 1. Joint 2. Extended

Q9. Educational Level

0. Illiterate 1. Literate with informal education 2. Primary Level
3. Secondary Level 4. Higher Secondary Level 5. Undergraduate and above

Q10. What was your main occupation within the past year?

0. Unemployed 1. Agriculture 2. Service(Private/Government)
3. Daily wage laborer 4. Own a business 5. Oversees employment
6. Home Maker 7. Retired (Pension) 8.Retired (without Pension)
9. Others (Specify)……

Section-B: Health-related characteristics

Q11. What types of treatment are you currently using?

0. No treatment 1. Oral tablet 2. Insulin
3. Both tablet and insulin 4. Only dietary management 5. Other.....

Q 12. Do you use Insulin for treatment of Diabetes management?

1. Yes 2. No

Q 13. How difficult do you feel to follow the dietary recommendation for the management of your diabetes?

0. Too difficult 1. A bit difficult 2. Not difficult at all

Q 14. Is there any health insurance to cover the diabetes related cost

0. Yes, cover full cost 1. Yes, but covers partial cost 2. . No there is no insurance

Q 15. Do you have any complications resulted due to diabetes?

0. Yes 1. No If yes continue, if No go to Q18

Q 16. What are the complications resulted due to diabetes? (Multiple choices)

0. Cardiovascular disease 1. Neuropathy 2. Nephropathy
3. Retinopathy 4. Skin conditions 5. Hearing impairment 6. Other_____

Q 17. Number of complications_____

Q 18. Do you have any other chronic illness other than these complications?

0. Yes 1. No

If yes continue, if No go to Q 21

Q 19. What are the chronic illness other than these complications that you have which was before you were diagnosed with Diabetes? (Multiple choices)

0. Hypertension
1. Hyperlipidemia
2. Chronic Kidney condition (not resulted after Diabetes)
3. Cardiovascular disease not resulted after Diabetes
4. COPD
5. Thyroid
6.Other_____

Q 20. Number of additional illness (comorbidities) _____

Q 21: Section D- Patient Health Questionnaire (PHQ-9)				
Over the last 2 weeks, how often have you been bothered by any of the following problems? (Use "√" to indicate your answer)				
	Not at all	Several Days	More than half the days of week	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3
3. Trouble falling or staying asleep or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself- or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual?	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way?	0	1	2	3

Q 22: Section E- Hospital Anxiety and Depression Scale-Anxiety Subscale

Please tick the statement about how you have been feeling in the past week. Don't take too long over you replies: your immediate is best.

A1. I feel tense or 'wound up':
3. Most of the time
2. A lot of the time
1. From time to time, occasionally
0. Not at all

A2. I get a sort of frightened feeling like 'butterflies' in the stomach
3. Very Often
2. Quite Often
1. Occasionally
0. Not at all

A3. I get a sort of frightened feeling as if something awful is about to happen
3.Very definitely and quite badly
2. Yes, but not too badly
1.A little, but it doesn't worry me
0. Not at all

A4. I feel restless as I have to be on the move:
3.Very much indeed
2. Quite a lot
1 .Not very much
0. Not at all

A5. Worrying thoughts go through my mind:
3. A great deal of the time
2. A lot of the time
1. From time to time, but not too often
0. Only occasionally

A6. I get sudden feeling of panic

3. Very Often 2. Quite Often
1. Not very often 0. Not at all

A7. I can sit at ease and feel relaxed

0. Definitely 1. Usually
2. Not often 3. Not at all

Section F: History of Disease and Lifestyle Factors

Q23. Have you ever been diagnosed with any mental distress such as depression, anxiety or so on?

0. Yes 1. No

If Yes, specify.....

Q24. In your family, has anyone in the last three generations been diagnosed with any mental distress such as depression, anxiety or so on?

0. Yes 1. No 2. Don't Know

If Yes, specify.....

Q25. In the past one month have you ever used any tobacco products (smoking, chewing tobacco) ?

0. Yes 1. No

Q26. In the past one month have your ever consumed any hard drink or alcohol?

0. Yes 1. No

Q27. How many hours in an average do you sleep in a day? (based on the average of past one week)

Sleep hours.....hrs per day

Q28. Are you satisfied with your sleep quality and duration?

0. Satisfied 1. Not Satisfied

Section G: COVID-19 Status

Q.29. Have you ever got tested for COVID-19?

0. Yes 1. No

Q.30 what was the result

0. Positive 1. Negative 2. Never Tested

Q.31 Have you received any COVID-19 vaccine?

0. Yes, Received vaccine 1. No, didn't received vaccine

Q.32 Have you received complete two doses?

0. Complete vaccine dose 1. Incomplete vaccine dose 2. Didn't received vaccine

Q 33: Please respond to each item by ticking (√) one of the five (5) responses that reflects how you feel, think or act toward COVID-19

Fear of COVID-19 Items	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. I am most afraid of Corona	1	2	3	4	5
2. It makes me uncomfortable to think about Corona	1	2	3	4	5
3. My hands become clammy when I think about Corona	1	2	3	4	5
4. I am afraid of losing my life because of Corona	1	2	3	4	5
5. When I watch news and stories about Corona on social media, I become nervous or anxious.	1	2	3	4	5
6. I cannot sleep because I'm worrying about getting Corona infection/ reinfection.	1	2	3	4	5
7. My heart races or palpitates when I think about getting Corona infection/ reinfection.	1	2	3	4	5

Q 34.Section C. Multidimensional Scale of Perceived Social Support

We are interested in how you feel about the following statements. Read each statement carefully. Indicate how you feel about each statement by selecting one for seven options at each statement-making a circle.

	Very Strongly Disagree	Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
1. I get the emotional help & support I need from my family	1	2	3	4	5	6	7
2. I can talk about my problems with my family.	1	2	3	4	5	6	7
3. My family really tries to help me.	1	2	3	4	5	6	7
4. My family is willing to help me make decisions.	1	2	3	4	5	6	7
5. I have friends with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
6. I can talk about my problems with my friends.	1	2	3	4	5	6	7
7. My friends really try to help me.	1	2	3	4	5	6	7
8. I can count on my friends when things go wrong	1	2	3	4	5	6	7
9. There is a special person who is around when I am in need.	1	2	3	4	5	6	7
10. There is a special person with whom I can share joys and sorrows.	1	2	3	4	5	6	7
11. I have a special person who is a real source of comfort to me	1	2	3	4	5	6	7
12. There is a special person in my life who cares about my feelings.	1	2	3	4	5	6	7

Thank you for your participation

To Be filled by Investigator

Remark by the data collector	…… Signature of the Data collector

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3,4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
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	*6*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6,7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	7
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
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	7
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7,8,9
		(b) Indicate number of participants with missing data for each variable of interest	7
Outcome data	15*	Report numbers of outcome events or summary measures	7,8,9

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	10,11,12
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10,11,12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12,13,14
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	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
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	16

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting.

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Anxiety and depression among people with type 2 diabetes visiting diabetes clinics of Pokhara Metropolitan, Nepal: a cross-sectional study

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Anxiety and depression among people with type 2 diabetes visiting diabetes clinics of Pokhara Metropolitan, Nepal: a cross-sectional study

Shishir Paudel[1], Shankar Prasad Khanal[2], Sujan Gautam[1], Anisha Chalise[3], Tara Nath Koirala[4], Sujan Babu Marahatta[1,5]

[1] Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal

[2] Central Department of Statistics, Tribhuvan University, Kathmandu, Nepal

[3] Center for Research on Environment Health & Population Activities (CREHPA), Kusunti, Lalitpur, Nepal

[4] Pokhara Super Speciality Health Clinic, Consultant Endocrinologist, Pokhara, Nepal

[5] Nepal Open University, Nepal

Authors	Institution Affiliation
1st Author: Shishir Paudel	Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal
2nd Author: Shankar Prasad Khanal	Central Department of Statistics, Tribhuvan University, Kathmandu, Nepal
3rd Author: Sujan Gautam	Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal
4th Author: Anisha Chalise	Center for Research on Environment Health & Population Activities(CREHPA), Kusunti, Lalitpur, Nepal
5th Author: Tara Nath Koirala	Pokhara Super Speciality Health Clinic, Consultant Endocrinologist, Pokhara, Nepal
6th Author: Sujan Babu Marahatta	Department of Public Health, Manmohan Memorial Institute of Health Sciences, Kathmandu, Nepal

Correspondence to:

Sujan Babu Marahatta

sujan@nou.edu.np

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ABSTRACT

Objectives: To estimate the prevalence of anxiety and depression and identify the associated factors among people with type 2 diabetes (T2DM) visiting diabetes clinics of Pokhara Metropolitan, Nepal.

Design: Cross-sectional study.

Setting: Three diabetes clinics in Pokhara Metropolitan, Nepal, from May to July 2021.

Participants: 283 people with T2DM visiting selected diabetes centers of Pokhara Metropolitan.

Outcome measures: Anxiety and depression were the outcome measures. Face-to-face interviews were conducted using a structured questionnaire comprising information related to participants' socio-demographic profile and several factors along with Hospital Anxiety and Depression-Anxiety subscale (HADS-A) and Patient Health Questionnaire (PHQ-9) to assess the levels of anxiety and depression, respectively. Pearson's chi-square tests and binary logistic regression were performed to examine association between dependent and independent variables at 5% level of significance.

Results: The prevalence of anxiety and depression were 31.4% (95% CI 26.2%-37.5%) and 36.4% (95% CI 30.8%-42.0%), respectively. Anxiety was found to be associated with a lower level of perceived social support (adjusted odds ratio [AOR] 2.442, 95% CI 1.020-5.845), multiple complications (AOR 2.758, 95% CI 1.015-7.334) and comorbidities (AOR 2.110, 95% CI 1.004-4.436), severe COVID-19 fear (AOR 2.343, 95% CI 1.123-4.887), and sleep dissatisfaction (AOR 1.912, 95% CI 1.073-3.047). Economical dependency (AOR 1.890, 95% CI 1.026-3.482), no insurance (AOR 2.973, 95% CI 1.134-7.093), lower perceived social support (AOR 2.883, 95% CI 1.158-7.181), multiple complications (AOR 2.308, 95% CI 1.585-6.422) and comorbidities (AOR 2.575, 95% CI 1.180-5.617), severe COVID-19 fear (AOR 2.117, 95% CI 1.009-4.573), alcohol use (AOR 2.401, 95% CI 1.199-4.806), and sleep dissatisfaction (AOR 1.995, 95% CI 1.093-3.644) were found to be associated with depression.

Conclusion: This study showed high prevalence levels of anxiety and depression among people with T2DM. Strengthening social support and focusing on people with diabetes suffering from comorbidity and complications could help to reduce their risk of mental health problems.

Keywords: Anxiety, Depression, Type 2 Diabetes, Prevalence, Risk Factors, Psychological distress

Strengths and limitations of this study

- The study used validated screening tools to assess the levels of anxiety, depression, and perceived social support.
- The study was conducted in the three most sought after health facilities of Pokhara Metropolitan, and the participants were recruited via a systematic random sampling technique, ensuring that the sample represented the people living with type 2 diabetes in the metropolitan area.
- Although the study was performed in one of the largest metropolitan cities of Nepal, the prevalence of anxiety and depression reported in this study might be higher than the actual prevalence present at the community level, as it was a health institution-based study conducted at the time of the COVID-19 pandemic.

INTRODUCTION

Diabetes mellitus is a systemic disease that may affect various body systems leading to blindness, kidney failure, and lower limb amputation as its long-term complications.[1-3] As of 2019, nearly one in ten people were living with diabetes with a prediction that globally 578 million people will have diabetes by the year 2030.[4] Its prevalence has been skyrocketing in low and middle-income countries than in high-income countries.[5] A systematic review from 2021 based on publications from 2000-2020 noted the pooled prevalence of type 2 diabetes (T2DM) in Nepal at 10 percent with a higher prevalence observed in studies published between the years 2015 and 2020, which was at 11.24 percent.[6]

Mental distress is an emotional state which manifests with the symptoms ranging from somatic symptoms such as sleep problems, headache, and backache to depression, anxiety, and distress.[7] Globally, the prevalence of psychological distress, primarily depression and anxiety disorders are higher among people living with diabetes as compared to their counterparts.[8-10] A systematic review estimated the global prevalence of depression among people with T2DM at 28 percent, with Asia having the highest rate of depression at 32 percent.[11] Similarly, another systematic review observed generalized anxiety disorder to be present among 14 percent of people with

T2DM.[12] In Nepal, a cross-sectional study performed among people with T2DM attending tertiary care centers in Kathmandu valley found the rate of depression to be 40.3 percent in the year 2013.[13] Similarly, a study conducted in a community setting of Duhabi-Bhaluwa Municipality of Sunsari District in 2019 revealed the prevalence of depression among people with T2DM to be 22.7 percent. [14]

Diabetes care mainly consists of self-care aimed to prevent acute and chronic complications. The person living with diabetes is responsible for balancing their food intake, physical activities and monitoring blood glucose levels as much as possible.[15] Mental health complications, mainly anxiety and depression, complicate living with diabetes and its management in several ways. The presence of depression and anxiety could worsen the prognosis of diabetes by reducing the patients' ability for self-care and increasing non-compliance to treatments while increasing the risk of serious short- and long-term complications such as blindness, amputations, stroke, decreased quality of life, and even premature death.[16, 17] Additionally, severe anxiety disorders largely overlap with symptoms of hypoglycemia which requires immediate treatment. However, people with diabetes might fail to differentiate the feelings of hypoglycemia with anxiety. The preexisting anxiety of injections or blood draws might lead to panic disorders or patients' refusal to monitor their glucose levels.[18] Similarly, fear of hypoglycemia is a common source of anxiety and depression for people with diabetes and can lead them to maintain blood glucose levels above target levels.[18] The presence of diabetes is a chronic life-threatening stressor that requires significant mental and physical support and care to cope with elevated feelings of fear and distress.[19] Even in the current context of COVID-19 pandemic, people with diabetes are taken as one of the vulnerable populations at risk of infection and mortality.[20] Thus, the COVID-19 pandemic might have aggregated their existing fear and distress, worsening their mental well-being. Considering this circumstance there are more serious concerns stressed over the mental health and well-being of this vulnerable population.[21, 22]

There is a lack of ample information about the rates of anxiety and depression among people with diabetes along with its associated risk factors in South Asia and particularly in Nepal due to the limited studies published to date considering the mental health aspect of the people with diabetes. Thus, this study aimed to assess the prevalence and factors associated with anxiety and depression among people with type 2 diabetes visiting diabetes clinics of Pokhara Metropolitan, one of the

rapidly urbanizing cities of Nepal, with an expectation that this study will provide valuable insights into mental health issues of these vulnerable population in developing nations similar to Nepal.

METHODS

Study design

This was a health facility-based cross-sectional study executed among people with type 2 diabetes residing at Pokhara Metropolitan who visited the selected healthcare institutions between May and July 2021.

Participants

All people with type 2 diabetes mellitus with at least six months' history of diagnosis, attending the selected diabetes clinics were eligible participants. On the other hand, people with T2DM who were not residents of Pokhara Metropolitan for at least the past six months from the date of data collection were excluded.

Sample size determination and sampling technique

The sample size was determined using Cochran's formula for estimation of a proportion ($n=z^2pq/d^2$). A community-based cross-sectional study conducted in the eastern part of Nepal reported the prevalence of depression among people with T2DM to be 22.7 percent. [14] So, using this past prevalence at 5 percent allowable error and 95 percent confidence interval, the initially estimated sample size was 264 people with T2DM, which was optimized to 291 after adjusting 10 percent non-response rate.

Two government health institutions (Urban Health Promotion Center and Shishuwa Hospital) and one private clinic (Pokhara Super Speciality Health Clinic) were selected purposively. Urban Health Promotion Center and Shishuwa Hospital are the primary contact points for Social Health Insurance (SHI) and provides free diabetes-related services under the SHI scheme and also provide referral services. Thus, these were some of the most sought government institutions with an estimated 250-300 people with T2DM visiting monthly. Pokhara Super Speciality Health Clinic was one of the well-known tertiary endocrine referral centers of Pokhara with an average of 500 people with diabetes visiting monthly. The people with T2DM visiting these three healthcare institutions were selected randomly using the technique based on systematic random sampling. For this, every k^{th} patient (800/291=2.74≈3) i.e. third patient waiting in the queue on the day of data

collection, was enrolled as a participant. If the selected patient refused to participate or fell under exclusion criteria, then the patient next in the queue was approached for participation.

Data collection

Face-to-face interview technique was used for data collection. The people with T2DM meeting inclusion criteria were approached and provided with the study details. Informed consent was taken from the participants before initiating the interviews**.** Considering participants' privacy, Pokhara Super Speciality Health Clinic provided the researcher with a separate room next to the doctors' cabin. Likewise, a small private space was provided at the corner of the doctors' cabin in Urban Health Promotion Center and Shishuwa Hospital, where the patients were directed for data collection.

The data was collected using a set of closed-ended questions consisting of three sections. The first section consisted of questions regarding socio-demographic profile of the participants including Multidimensional Scale of Perceived Social Support (MSPSS)[23] translated into Nepali language (MSPSS-N)[24] intending to measure the level of perceived social support. The second section consisted of questions regarding patient's health conditions, diabetes-related attributes, and lifestyle-related factors including COVID-19-related variables such as COVID-19 status, vaccination, and fear associated with COVID-19 based on a modification of the Fear scale of COVID-19[25]. The third section consisted of a nine-item Patient Health Questionnaire (PHQ-9)[26] intended to measure the level of depression followed by a Hospital Anxiety and Depression Scale-anxiety subscale (HASD-A)[27] intended to measure the level of anxiety.

The PHQ-9 consists of nine items measuring depressive symptoms corresponding to diagnostic criteria for major depressive disorder. Each item was scored on a four-point Likert scale (0–3) with scores ranging from 0 to 27, with higher scores reflecting greater depression severity.[26] The PHQ-9 has been translated into Nepali language and has shown a sensitivity of 0.94 and specificity of 0.80 to measure depression at the cutoff of ≥ 10.[28] The HADS-A consists of seven items measuring anxiety symptoms. Each item is scored on a four-point Likert scale (0-3) with total scores ranging from 0 to 21 with higher scores reflecting greater anxiety and a cutoff point of ≥ 8 illustrating anxiety.[27] The HADS has been validated in Nepali language where the HADS-A subscale was found to have a good internal consistency with Cronbach's alpha of 0.76.[29] The data collection tool used in the present study is included as a supplemental file.

Data processing, management and analysis

The collected data was entered in EpiData 3.1 and exported to Statistical Package for Social Sciences (SPSS) version 22 for statistical analysis. The data was summarized in terms of frequencies and proportions. Bivariate analysis was carried out by applying Chi-square (χ^2) tests to identify the factors associated with anxiety and depression at 95% Confidence Interval (CI) and 5% level of significance i.e., p-value <0.05. The variables found to be significant in bivariate analysis were considered for multivariate analysis using binary logistic regression to determine the adjusted effect of each factor on the dependent variable. Prior to multivariate regression analysis, the multi-collinearity between the independent variables was tested using the Variance Inflation Factor (VIF) test, with a VIF greater than five taken as an indication of multi-collinearity between the independent variables. The Hosmer-Lemeshow test (HL test) for goodness-of-fit was also performed.

Ethical considerations

The ethical approval for this study was obtained from the Institutional Review Committee of Manmohan Memorial Institute of Health Science (Registration no: MMIHS-IRC 583). Written informed consent was obtained from all the participants before conducting the study and all the information was kept confidential.

Patient and public involvement

None.

RESULTS

A total of 291 people with T2DM were approached for data collection, of which 283 provided complete responses to all the questions, while eight participants left in the middle of the data collection. Thus, the response rate of 97.25% for all questions was acquired, and 283 total samples were analyzed for this study. The prevalence of anxiety and depression was found to be 31.4 percent and 36.4 percent among people with T2DM respectively (Table 1). Moreover, around one-third (36%) of the participants reported having experienced suicidal ideation in the past two weeks on PHQ-9, of which six participants (2.1%) reported experiencing suicidal ideation nearly every single day.

Table 1: Prevalence of anxiety and depression (n=283)

Outcome	n (%)	95% CI	Outcome	n (%)	95% CI
Anxiety status			**Depression status**		
Present	89 (31.4)	26.2%-37.5%	Present	103 (36.4)	30.8%-42.0%
Absent	194 (68.6)	62.5%-73.8%	Absent	180 (63.6)	58.0%-69.2%
Anxiety level			**Depression level**		
No Anxiety	194 (68.6)	62.5%-73.8%	No Depression	180 (63.6)	57.6 %-68.6%
Mild Anxiety	62 (21.9)	16.6%-27.2%	Mild Depression	71 (25.1)	20.1%-30.7%
Moderate Anxiety	19 (6.7)	3.9%-9.9%	Moderate Depression	22 (7.8)	4.6%-11.0%
Severe Anxiety	8 (2.8)	1.1%-5.3%	Severe Depression	10 (3.5)	1.8%-5.7%

The age of the participants in this study ranged from 33 to 88 years, with a mean age of 56.17±11.81 years. Almost half of the participants (56.9%) were male. A large majority (91.5%) of the participants reported living with their family, and nearly half of them (42.8%) reported being economically dependent. More than half of the participants (54.8%) reported to have no insurance coverage for their treatment. Likewise, one in six participants (14.5%) reported having a lower level of perceived social support. (Table 2)

Table 2: Socio-demographic profile of the participants (n=283)

Variables	n (%)
Age group	
<40 years	30 (10.6)
40-50	65 (23.0)
50-60	77 (27.2)
≥60 years	111 (39.2)
Gender	
Male	161 (56.9)
Female	122 (43.1)
Ethnicity	
Brahmin/Chhetri	107 (37.8)
Janajaties	122 (43.1)
Dalit	33 (11.7)
Religious minorities	21 (7.4)
Type of family	
Nuclear	143 (50.5)
Joint/extended	140 (49.4)
Living companion	
Living alone	24 (8.5)
Living with family	259 (91.5)
Marital status	
Married	232 (82.0)
Unmarried/divorced	13 (4.6)
Widow/widower	38 (13.4)
Education	
Illiterate	49 (17.3)
Literate by informal education	42 (14.8)
Literate by formal education	192 (67.8)

Economic dependency	
Dependent	121 (42.8)
Independent	162 (57.2)
Health insurance	
Full coverage	42 (14.8)
Partial coverage	86 (30.4)
No insurance	155 (54.8)
Perceived social support	
Low support	41 (14.5)
Moderate support	130 (45.9)
High support	112 (39.6)

Out of all 283 participants, almost half (46.3%) reported to have lived with diabetes for more than four years of their life. A quarter (25.1%) of the participants reported having experienced complications related to diabetes, whereas more than half (55.5%) reported having other comorbidities existing before they got diagnosed with diabetes. Nearly three out of four (71.0%) participants reported having a fear of COVID-19 infection (Table 3).

Table 3: Health and lifestyle-related characteristics of the participants (n=283)

Variables	**n (%)**
Duration of illness	
≤ 4 years	152 (53.7)
>4 years	131 (46.3)
Use of insulin	
Yes	33 (12.0)
No	250 (88.0)
Presence of complications	
None	212 (74.9)
Single complications	47 (16.6)
Two or more	24 (8.5)
Presence of comorbidities	
None	126 (44.5)
Single comorbidity	84 (29.7)
Two or more	73 (25.8)
Difficulty following a recommended diet	
Too difficult	63 (22.3)
A bit difficult	100 (35.3)
Not difficult at all	120 (42.4)
History of mental illness	
Yes	16 (5.7)
No	267 (94.3)
Ever tested for COVID-19	
Tested negative	31 (11.0)
Tested positive	28 (9.9)
Never tested	224 (79.1)
COVID-19 vaccination	
Complete vaccination	28 (9.9)
Incomplete vaccination	65 (23.0)

Didn't receive vaccine	190 (67.1)
COVID-19 fear	
Low fear	105 (37.1)
Moderate fear	96 (33.9)
Severe fear	82 (29.0)
Alcohol use	
Yes	75 (26.5)
No	208 (73.5)
Tobacco use	
Yes	55 (19.4)
No	228 (80.6)
Sleep satisfaction	
Satisfied	180 (63.6)
Not satisfied	103 (36.4)

In bivariate analysis, participants' family type, living companionship and perceived level of social support were the socio-demographic factors found to be associated with anxiety. Similarly, living companionship, economic dependency, insurance coverage for diabetes care, and perceived level of social support were the socio-demographic factors found to be associated with depression at 5% level of significance (Table 4).

Table 4: Association of socio-demographic variables with anxiety and depression (n=283)

Socio-demographic variables	Anxiety		χ^2 (p-value)	Depression		χ^2 (p-value)
	Presence n(%)	Absence n(%)		Presence n(%)	Absence n(%)	
Age group						
<40 years	11 (12.4)	19 (9.8)	1.006 (0.800)	13 (12.6)	17 (9.4)	5.741 (0.125)
40-50	19 (21.3)	46 (23.7)		16 (15.5)	49 (27.2)	
50-60	22 (24.7)	55 (28.4)		28 (27.2)	49 (27.2)	
≥60 years	37 (41.6)	74 (38.1)		46 (44.7)	65 (36.1)	
Gender						
Male	54 (60.7)	107 (55.2)	0.758 (0.384)	59 (57.3)	102 (56.7)	0.010 (0.920)
Female	35 (39.3)	87 (44.8)		44 (42.7)	78 (43.3)	
Ethnicity						
Brahmin/Chhetri	42 (47.2)	65 (33.5)	4.953 (0.175)	38 (36.9)	69 (38.3)	2.889 (0.409)
Janajaties	33 (37.1)	89 (45.9)		44 (42.7)	78 (43.3)	
Dalit	9 (10.1)	24 (12.4)		10 (9.7)	23 (12.8)	
Religious minorities	5 (5.6)	16 (8.2)		11 (10.7)	10 (5.6)	
Type of family						
Nuclear	53 (59.6)	90 (46.4)	4.226 (0.040)*	59 (57.3)	84 (46.7)	2.953 (0.086)
Joint/extended	36 (40.4)	104 (53.6)		44 (42.7)	96 (53.3)	
Living companion						
Living alone	13 (14.6)	11 (5.7)	6.278 (0.012)*	15 (14.6)	9 (5.0)	7.719 (0.005)*
Living with family	76 (85.4)	183 (94.3)		88 (85.4)	171 (95.0)	
Marital status						
Married	72 (80.9)	160 (82.2)	1.433 (0.489)	78 (75.7)	154 (85.6)	5.464 (0.065)
Unmarried/divorced	6 (6.7)	7 (3.6)		8 (7.8)	5 (2.8)	
Widow/widower	11 (12.4)	27 (13.9)		17 (16.5)	21 (11.7)	
Education						
Illiterate	15 (16.9)	34 (17.5)	1.880	21 (20.4)	28 (15.6)	2.419

Literate by informal education	17 (19.1)	25 (12.9)	(0.391)	18 (17.5)	24 (13.3)	(0.298)
Literate by formal education	57 (64.0)	135 (69.6)		64 (62.1)	128 (71.1)	
Economic dependency						
Dependent	41 (46.1)	80 (41.2)	0.582	55 (53.4)	66 (36.7)	7.493
Independent	48 (53.9)	114 (58.8)	(0.446)	48 (46.6)	114 (63.3)	(0.006)*
Health insurance						
Full coverage	9 (10.1)	33 (17.0)	2.498	8 (7.8)	34 (18.9)	11.287
Partial coverage	27 (30.3)	59 (30.4)	(0.287)	26 (25.2)	60 (33.3)	(0.004)*
No insurance	53 (59.6)	102 (52.6)		69 (67.0)	85 (47.5)	
Perceived social support						
Low support	20 (22.5)	21 (10.8)	15.898	25 (24.3)	16 (8.9)	18.458
Moderate support	48 (53.9)	82 (42.3)	(<0.001)	51 (49.5)	79 (43.9)	(<0.001)
High support	21 (23.6)	91 (46.9)	*	27 (26.2)	85 (47.2)	*

*Statistical significance at p<0.05.

Insulin use, presence of complications and comorbidities, prior history of clinically diagnosed mental distress, fear associated with COVID-19, alcohol use and sleep satisfaction were found to be associated with both anxiety and depression status at p<0.05. In addition, depression was also found to be associated with difficulty experienced by people with T2DM to follow dietary recommendations and use of tobacco products. (Table 5). The people with T2DM experiencing anxiety were found to be twice more likely to be depressed (unadjusted odds ratio 2.758, 95% CI 1.641-4.635) as compared to their counterparts (Table 5).

Table 5: Association of health and lifestyle-related variables with anxiety and depression (n=283)

Health and lifestyle-related variables	Anxiety		χ^2 (p-value)	Depression		χ^2 (p-value)
	Presence n(%)	Absence n(%)		Presence n(%)	Absence n(%)	
Duration of illness						
≤ 4 years	45 (50.6)	107 (55.2)	0.518	49 (47.6)	103 (57.2)	2.453
>4 years	44 (49.4)	87 (44.8)	(0.472)	54 (52.4)	77 (42.8)	(0.117)
Use of insulin						
Yes	17 (19.1)	16 (8.2)	6.977	20 (19.4)	13 (7.2)	9.459
No	72 (80.9)	178 (91.8)	(0.008)*	83 (80.6)	167 (92.8)	(0.002)*
Presence of complications						
None	53 (59.6)	159 (82.0)	16.502	63 (61.2)	149 (82.8)	16.345
Single complications	23 (25.8)	24 (12.4)	(<0.001)*	26 (25.2)	21 (11.7)	(<0.001)*
Two or more	13 (14.6)	11 (5.7)		14 (13.6)	10 (5.6)	
Presence of comorbidities						
None	24 (27.0)	102 (52.6)	17.118	28 (27.2)	98 (54.4)	22.617
Single comorbidity	32 (36.0)	52 (26.8)	(<0.001)*	35 (34.0)	49 (27.2)	(<0.001)*
Two or more	33 (37.0)	40 (20.6)		40 (38.8)	33 (18.3)	
Difficulty following a recommended diet						
Too difficult	24 (27.0)	39 (20.1)	1.686	34 (33.0)	29 (16.1)	13.326
A bit difficult	29 (32.6)	71 (36.6)	(0.430)	37 (35.9)	63 (35.0)	(<0.001)*
Not difficult at all	36 (40.4)	84 (43.3)		32 (31.1)	88 (48.9)	
History of mental illness						
Yes	9 (10.1)	7 (3.6)	4.839	10 (9.7)	6 (3.3)	4.992

No	80 (89.9)	187 (96.4)	(0.028)*	93 (90.3)	174 (96.7)	(0.025)*
Ever tested for COVID-19						
Tested negative	14 (15.7)	17 (8.8)	3.368 (0.186)	9 (8.7)	22 (12.2)	0.850 (0.654)
Tested positive	7 (7.9)	21 (10.8)		10 (9.7)	18 (10.0)	
Never tested	68 (76.4)	156 (80.4)		84 (81.6)	140 (77.8)	
COVID-19 vaccination						
Complete vaccination	11 (12.4)	17 (8.8)	1.005 (0.605)	9 (8.7)	19 (10.6)	2.508 (0.285)
Incomplete vaccination	21 (23.6)	44 (22.7)		29 (28.2)	36 (20.0)	
Didn't receive vaccine	57 (64.0)	133 (68.6)		65 (63.1)	125 (69.4)	
COVID-19 fear						
Low fear	22 (24.7)	83 (42.8)	10.325 (0.006)*	27 (26.2)	78 (43.3)	8.614 (0.013)*
Moderate fear	32 (36.0)	64 (33.0)		39 (37.9)	57 (31.7)	
Severe fear	35 (39.3)	47 (24.2)		37 (35.9)	45 (25.0)	
Alcohol use						
Yes	31 (34.8)	44 (22.7)	4.625 (0.033)*	39 (37.9)	36 (20.0)	10.733 (0.001)*
No	58 (65.2)	150 (77.3)		64 (62.1)	144 (80.0)	
Tobacco use						
Yes	23 (25.8)	32 (16.5)	3.405 (0.065)	27 (26.2)	28 (15.6)	4.753 (0.029)*
No	66 (74.2)	162 (83.5)		76 (73.8)	152 (84.4)	
Sleep satisfaction						
Satisfied	45 (50.6)	135 (69.6)	9.540 (0.002)*	52 (50.5)	128 (71.1)	12.039 (0.001)*
Not satisfied	44 (49.4)	59 (30.4)		51 (49.5)	52 (28.9)	
Depression						
Present	47 (52.8)	56 (28.9)	15.109 (<0.001)*	-	-	-
Absent	42 (47.2)	138 (71.1)		-	-	
Anxiety						
Present	-	-	-	47 (45.6)	42 (23.3)	15.109 (<0.001)*
Absent	-	-		56 (54.4)	138 (76.7)	

*Statistical significance at p<0.05.

For multivariate analysis, the Variance Inflation Factor (VIF) test among the independent variables was performed, where the highest reported VIF was 1.610, indicating that there was no issue of multi-collinearity. Lower level of perceived social support (adjusted odds ratio [AOR] 2.442, 95% CI 1.020-5.845), presence of a single (AOR 2.081, 95% CI 1.002-4.414) and multiple complications (AOR 2.758, 95% CI 1.015-7.334), presence of a single (AOR 2.127, 95% CI 1.059-4.272) and multiple comorbidities (AOR 2.110, 95% CI 1.004-4.436), severe fear of COVID-19 infection (AOR 2.343, 95% CI 1.123-4.887), and sleep dissatisfaction (AOR 1.912, 95% CI 1.073-3.047) were found to be associated with anxiety (Table 6).

Table 6: Factors associated with anxiety among people with diabetes (n=283)

Factors	UOR	95% CI	p-value	AOR[a]	95% CI	p-value
Type of family						
Nuclear	1.701	1.023-2.829	0.041*	1.458	0.784-2.711	0.233
Joint/extended	Ref			Ref		
Living companion						
Living alone	2.846	1.221-6.633	0.015*	1.108	0.405-3.034	0.842
Living with family	Ref			Ref		
Perceived level of social support						

Low support	4.127	1.902-8.955	<0.001*	2.442	1.020-5.845	0.045*
Moderate support	2.537	1.401-4.591	0.002*	1.839	0.986-3.520	0.060
High support	Ref			Ref		
Use of insulin						
Yes	2.627	1.259-5.481	0.010*	1.299	0.565-3.166	0.565
No	Ref			Ref		
Presence of complications						
None	Ref			Ref		
Single complications	2.875	1.499-5.512	0.001*	2.081	1.002-4.414	0.049*
Two or more	3.545	1.501-8.387	0.004*	2.758	1.015-7.334	0.044*
Presence of comorbidities						
None	Ref			Ref		
Single comorbidity	2.615	1.399-4.890	0.003*	2.127	1.059-4.272	0.034*
Two or more	3.506	1.848-6.652	<0.001*	2.110	1.004-4.436	0.048*
History of mental illness						
Yes	3.005	1.082-8.350	0.035*	2.132	0.680-6.687	0.194
No	Ref			Ref		
COVID-19 fear						
Low fear	Ref			Ref		
Moderate fear	1.886	1.001-3.553	0.049*	1.491	0.731-3.039	0.272
Severe fear	2.809	1.478-5.340	0.002*	2.343	1.123-4.887	0.023*
Alcohol use						
Yes	1.822	1.051-3.160	0.033*	1.639	0.881-3.047	0.119
No	Ref			Ref		
Sleep satisfaction						
Satisfied	Ref			Ref		
Not satisfied	2.237	1.335-3.748	0.002*	1.912	1.073-3.047	0.028*
Depression						
Present	2.758	1.641-4.635	<0.001*			
Absent	Ref			-	-	-

*Statistical significance at p<0.05. [a] Logistic regression model adjusted for all variables in the table except Depression, Nagelkerker R Square 0.310; Hosmer Lemeshow Chi-square 9.793, p=0.280; CI: confidence interval, UOR: Unadjusted odds ratio, AOR: Adjusted odds ratio.

Economic dependency (AOR 1.890, 95% CI 1.026-3.482), lower level of perceived social support (AOR 2.883, 95% CI 1.158-7.181), no insurance coverage (AOR 2.973, 95% CI 1.134-7.093), presence of multiple complications (AOR 2.308, 95% CI 1.585-6.422), presence of a single (AOR 2.262, 95% CI 1.108-4.619), and multiple comorbidities (AOR 2.575, 95% CI 1.180-5.617), difficulty following the recommended diet (AOR 2.387, 95% CI 1.100-5.182), severe fear of COVID-19 (AOR 2.117, 95% CI 1.009-4.573), alcohol use (AOR 2.401, 95% CI 1.199-4.806), and sleep dissatisfaction (AOR 1.995, 95% CI 1.093-3.644) were found to be associated with depression (Table 7).

Table 7: Factors associated with depression among people with diabetes (n=283)

Factors	UOR	95% CI	p-value	AOR[a]	95% CI	p-value
Living companion						
Living alone	3.239	1.363-7.695	0.008*	1.586	0.553-4.548	0.391
Living with family	Ref			Ref		

Economic dependency						
Dependent	1.979	1.210-3.236	0.007*	1.890	1.026-3.482	0.041*
Independent	Ref			Ref		
Perceived level of social support						
Low support	4.919	2.295-10.543	<0.001*	2.883	1.158-7.181	0.023*
Moderate support	2.032	1.163-3.551	0.013*	1.345	0.696-2.599	0.379
High support	Ref			Ref		
Use of insulin						
Yes	3.095	1.468-6.528	0.003*	1.265	0.905-3.171	0.061
No	Ref			Ref		
Presence of complications						
None	Ref			Ref		
Single complications	2.928	1.535-5.587	0.010*	1.628	0.739-3.587	0.227
Two or more	3.311	1.397-7.851	0.007*	2.308	1.858-6.422	0.046*
Presence of comorbidities						
None	Ref			Ref		
Single comorbidity	2.500	1.367-4.573	0.003*	2.262	1.108-4.619	0.025*
Two or more	4.242	2.274-7.915	<0.001*	2.575	1.180-5.617	0.017*
Health insurance coverage						
Full coverage	Ref			Ref		
Partial coverage	1.842	0.751-4.517	0.182	1.792	0.613-4.691	0.287
No insurance	3.410	1.483-7.842	0.004*	2.973	1.134-7.093	0.027*
Difficulty following recommended diet						
Too difficult	3.224	1.701-6.112	<0.001*	2.387	1.100-5.182	0.028*
A bit difficult	1.615	1.005-2.865	0.046*	1.112	0.555-2.230	0.764
Not difficult at all	Ref			Ref		
History of mental illness						
Yes	3.118	1.099-8.848	0.033*	2.587	0.835-9.025	0.139
No	Ref			Ref		
COVID-19 fear						
Low fear	Ref			Ref		
Moderate fear	1.977	1.087-3.594	0.025*	1.496	0.731-3.060	0.270
Severe fear	2.375	1.282-4.402	0.006*	2.117	1.009-4.573	0.042*
Alcohol use						
Yes	2.437	1.420-4.184	0.001*	2.401	1.199-4.806	0.013*
No	Ref			Ref		
Tobacco use						
Yes	1.929	1.063-3.500	0.031*	1.001	0.461-2.174	0.998
No	Ref			Ref		
Sleep satisfaction						
Satisfied	Ref			Ref		
Not satisfied	2.414	1.460-3.993	0.001*	1.995	1.093-3.644	0.025*

*Statistical significance at p<0.05. [a] Logistic regression model adjusted for all variables in the table except Anxiety; Nagelkerker R Square 0.358; Hosmer Lemeshow Chi-square 10.073, p=0.260; CI: confidence interval, UOR: Unadjusted odds ratio, AOR: Adjusted odds ratio.

DISCUSSION

In this study, around one third of the people with T2DM were found to have anxiety (31.4%) and depression (36.4%). This rate of prevalence is slightly lower than the prevalence observed by a recent study conducted among people with T2DM admitted in the tertiary hospital of Chitwan district in 2019, where anxiety and depression were reported among 57.8 percent and 49.7 percent of the participants respectively.[30] This variation in anxiety and depression might be due to the fact that the past study was conducted in hospital-admitted patients. On the other hand, this prevalence is higher than the prevalence of depression (22.7%) among T2DM patients as observed by a community-based study in Dubabi-Bhaluwa Municipality in the year 2016. [14] However, the current prevalence of depression is in line with past prevalence observed among people visiting diabetes centers in Lalitpur Metropolitan in 2019, where 35.6 percent of the people with diabetes were found to have depression.[31] These variations in the prevalence might be due to the difference in geographic location, study settings, and time factors. In the global context, a similar rate of anxiety and depression has been noted among this vulnerable population in countries of different economies such as China[32], Saudi Arabia[33, 34], Mexico[35], Malaysia[36], Pakistan[37], and India[38].

There was a statistically significant relationship existing between the perceived level of social support and the anxiety and depression status of the people, as the people with a lower level of perceived social support had twice the odds of anxiety and depression than those with higher level of perceived social support. Similar findings were shared by studies from Saudi Arabia and Ethiopia, where higher odds of anxiety and depression were seen among people with lower social support. [34, 39] As good social support has been observed as a protective factor against anxiety and depression, studies suggest that strengthening social support in these people can improve their psychological well-being.[40, 41] Social support plays an important role in the management of diabetes. Poor social support may lead to delays in healthcare-seeking behavior as well as increased emotional distress. [34, 39, 42] This might further inflect an undesirable effect on the persons' physical and mental well-being. Thus, social support in people with diabetes could be strengthened to reduce the risk of mental distress, which could be done through frequent engagement of family members in diabetes care settings and formation of peer support groups at the diabetes centers as well as at community levels.

In this study, the presence of comorbidities as well as complications related to diabetes were observed as an important factors associated with anxiety and depression among people with T2DM. This is in line with a past study from Nepal, where people with diabetes having co-morbid

conditions had twice the odds of depression as compared to their counterparts.[43] Likewise, a study from Ethiopia observed that people who worried about diabetes complications had six folds increase in odds of depression.[44] Similarly, people with a history of diabetes-related complications were found to have higher odds of anxiety in Mexico.[35] Studies from different parts of the world suggest that the greater the number of additional illnesses present among people with T2DM, greater the risk of anxiety and depression.[14, 45, 46] The presence of comorbidity and/or complication creates an additional financial burden due to increased treatment costs, physical burden, and chronic pain as well as social burden among the people with T2DM. [14, 46, 47] Thus, these might be contributing factors to impact their psychological well-being as it was also found that economic dependency and absence of health insurance securities were other risk factors for depression among this vulnerable group in this study. Special care should be provided to people with diabetes who are suffering from complications and co-morbid conditions. In addition, it is also essential to ensure certain financial protection, proper health counseling, and routine mental health screening services targeting this vulnerable population.

In bivariate analysis, we observed that insulin users had twice the odds of experiencing anxiety and thrice the odds of experiencing depression as compared to those not using insulin. Similar observations were shared by the past studies from Nepal, where one study found that insulin users had twice the odds of depression as compared to oral medicine users, and another study found a nine-fold increase in depression among insulin users as compared to non-insulin users.[14, 48] Insulin therapy not only involves painful injections and regular glucose measurement but also is perceived to be used in severe cases. This perception might influence psychological distress among insulin users.[8, 14, 49, 50] However, in multivariate analyses this statistical relationship between insulin use and both anxiety and depression was ruled out in our study. This might be attributed to a small proportion of insulin users enumerated by chance in our random sample.

We observed that the participants who were not satisfied with the duration and quality of their sleep had almost twice the odds of being anxious and depressed than those who were satisfied with their sleep. Similar to this finding, a study from China observed that people with diabetes with poor sleep quality had almost twice the odds of anxiety and depression.[32] Short sleep duration could influence psychological distress even in the general population. People with diabetes suffer from frequent urination, which might affect their quality of sleep and sleep satisfaction, leading to discomfort, agitation, and stress in long run.[46]

The severe fear of COVID-19 infection was found to be associated with both anxiety and depression. A study from Germany noted that people with diabetes tend to perceive a higher susceptibility to COVID-19 infection, think more about its severe course, and even die from COVID-19 than other general population. However, the same study revealed that there was no increase in anxiety and depressive symptoms among individuals with diabetes.[51] In contrast, another study from Germany noted that the rate of anxiety and depression increased at the time of the COVID-19 outbreak.[52] As COVID-19 is an emerging public health concern with limited understanding about its psychological impact on patients with chronic illness who are deemed as vulnerable groups, there is a need for further studies for a better understanding of its association with psychological well-being among these vulnerable populations. The fear of COVID-19 pandemic has been found to have a significant relationship with anxiety and depression. While adjusting its effect, we also observed that the presence of COVID-19 pandemic does not invalidate the relationship of anxiety and depression with other factors.

Limitations

Despite being one of the few studies to assess the status and risk factors for anxiety and depression among people with type 2 diabetes mellitus in Nepal, this study is not free from its limitations. As the study was executed during the COVID-19 pandemic, the observed rate of anxiety and depression might be slightly overestimated due to the effect of the pandemic, requiring further studies. Although a larger sample size would have benefited the precision of the confidence interval, due to the time constraints and the lockdown imposed during the COVID-19 pandemic, the research team failed to cover a larger sample and only covered the minimum required sample size. The patients sampled were from selected health institutions which might have introduced some selection bias. As this study was a health institution-based study, the prevalence of anxiety and depression might be slightly higher than the actual prevalence present at the community level.

CONCLUSION

The study revealed nearly one-third of the people with type 2 diabetes experienced anxiety of varying severity, and nearly two-fifths experienced depressive symptoms. Among the various factors, the level of perceived social support, presence of comorbidity and complications, severe fear of COVID-19 infection, and sleep dissatisfaction were the associated risk factors for anxiety and depression. Integrating mental health counseling services with present diabetes-related care

and support systems is essential to ease patients' physiological well-being. Further studies based on qualitative perspective could provide valuable insights into the way social supports and other associated factors are influencing the mental well-being of this vulnerable population.

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CONTRIBUTORS

SP: as the primary investigator, lead the conceptualization of the study, and questionnaire development, collected the data, performed analysis and developed and finalized the manuscript. SBM, SPK and SG: contributed in conceptualization, analysis and interpretation of the findings and supervised the study. AC: contributed in data collection and analysis, editing and revision of the manuscript. TNK: contributed in data collection. All authors read and approved the final manuscript.

ETHICAL APPROVAL

The ethical approval for this study was obtained from the Institutional Review Committee of Manmohan Memorial Institute of Health Science (Registration no: MMIHS-IRC 583).

FUNDING

None declared.

COMPETING INTERESTS

None declared.

DATA AVAILABILITY STATEMENT

The dataset generated and analyzed during the current study is available from the corresponding author upon reasonable request.

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Questionnaire

Eligibility Criteria:

Q1: How long have you known that you have diabetes?

Years_____ Months_____ If date is provided _____

Q2: How long have you been residing at Pokhara Metropolitan?

Years_____ Months_____ If date is provided _____

Section-A: Demographic Information

Q3. Age……. completed years **Q4. Gender…….**

Q5. Ethnicity

0. Dalit 1. Disadvantaged Janajatis 2. Disadvantaged non-dalit Terai caste groups
3. Religious Minorities 4. Relatively advantaged Janajatis 5. Upper caste groups

Q6. Marital Status

0. Single (Unmarried) 1. Married 2. Separated
3. Divorced 4. Widowed 5. Other (specify)…….....

Q7. **The total number of family members** (living together in the household sharing the same kitchen)……..

Q8. Type of Family

0. Nuclear 1. Joint 2. Extended

Q9. Educational Level

0. Illiterate 1. Literate with informal education 2. Primary Level
3. Secondary Level 4. Higher Secondary Level 5. Undergraduate and above

Q10. What was your main occupation within the past year?

0. Unemployed 1. Agriculture 2. Service(Private/Government)
3. Daily wage laborer 4. Own a business 5. Oversees employment
6. Home Maker 7. Retired (Pension) 8.Retired (without Pension)
9. Others (Specify)……

Section-B: Health-related characteristics

Q11. What types of treatment are you currently using?

0. No treatment 1. Oral tablet 2. Insulin
3. Both tablet and insulin 4. Only dietary management 5. Other.....

Q 12. Do you use Insulin for treatment of Diabetes management?

1. Yes 2. No

Q 13. How difficult do you feel to follow the dietary recommendation for the management of your diabetes?

0. Too difficult 1. A bit difficult 2. Not difficult at all

Q 14. Is there any health insurance to cover the diabetes related cost

0. Yes, cover full cost 1. Yes, but covers partial cost 2. . No there is no insurance

Q 15. Do you have any complications resulted due to diabetes?

0. Yes 1. No If yes continue, if No go to Q18

Q 16. What are the complications resulted due to diabetes? (Multiple choices)

0. Cardiovascular disease 1. Neuropathy 2. Nephropathy
3. Retinopathy 4. Skin conditions 5. Hearing impairment 6. Other_____

Q 17. Number of complications_____

Q 18. Do you have any other chronic illness other than these complications?

0. Yes 1. No

If yes continue, if No go to Q 21

Q 19. What are the chronic illness other than these complications that you have which was before you were diagnosed with Diabetes? (Multiple choices)

0. Hypertension
1. Hyperlipidemia
2. Chronic Kidney condition (not resulted after Diabetes)
3. Cardiovascular disease not resulted after Diabetes
4. COPD
5. Thyroid
6.Other_____

Q 20. Number of additional illness (comorbidities) _____

Q 21: Section D- Patient Health Questionnaire (PHQ-9)				
Over the last 2 weeks, how often have you been bothered by any of the following problems? (Use "√" to indicate your answer)				
	Not at all	Several Days	More than half the days of week	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3
3. Trouble falling or staying asleep or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself- or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual?	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way?	0	1	2	3

Q 22: Section E- Hospital Anxiety and Depression Scale-Anxiety Subscale

Please tick the statement about how you have been feeling in the past week. Don't take too long over you replies: your immediate is best.

A1. I feel tense or 'wound up':
3. Most of the time
2. A lot of the time
1. From time to time, occasionally
0. Not at all

A2. I get a sort of frightened feeling like 'butterflies' in the stomach
3. Very Often
2. Quite Often
1. Occasionally
0. Not at all

A3. I get a sort of frightened feeling as if something awful is about to happen
3.Very definitely and quite badly
2. Yes, but not too badly
1.A little, but it doesn't worry me
0. Not at all

A4. I feel restless as I have to be on the move:
3.Very much indeed
2. Quite a lot
1 .Not very much
0. Not at all

A5. Worrying thoughts go through my mind:
3. A great deal of the time
2. A lot of the time
1. From time to time, but not too often
0. Only occasionally

A6. I get sudden feeling of panic

3. Very Often 2. Quite Often
1. Not very often 0. Not at all

A7. I can sit at ease and feel relaxed

0. Definitely 1. Usually
2. Not often 3. Not at all

Section F: History of Disease and Lifestyle Factors

Q23. Have you ever been diagnosed with any mental distress such as depression, anxiety or so on?

0. Yes 1. No

If Yes, specify.....

Q24. In your family, has anyone in the last three generations been diagnosed with any mental distress such as depression, anxiety or so on?

0. Yes 1. No 2. Don't Know

If Yes, specify.....

Q25. In the past one month have you ever used any tobacco products (smoking, chewing tobacco) ?

0. Yes 1. No

Q26. In the past one month have your ever consumed any hard drink or alcohol?

0. Yes 1. No

Q27. How many hours in an average do you sleep in a day? (based on the average of past one week)

Sleep hours.....hrs per day

Q28. Are you satisfied with your sleep quality and duration?

0. Satisfied 1. Not Satisfied

Section G: COVID-19 Status

Q.29. Have you ever got tested for COVID-19?

0. Yes 1. No

Q.30 what was the result

0. Positive 1. Negative 2. Never Tested

Q.31 Have you received any COVID-19 vaccine?

0. Yes, Received vaccine 1. No, didn't received vaccine

Q.32 Have you received complete two doses?

0. Complete vaccine dose 1. Incomplete vaccine dose 2. Didn't received vaccine

Q 33: Please respond to each item by ticking (√) one of the five (5) responses that reflects how you feel, think or act toward COVID-19

Fear of COVID-19 Items	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1. I am most afraid of Corona	1	2	3	4	5
2. It makes me uncomfortable to think about Corona	1	2	3	4	5
3. My hands become clammy when I think about Corona	1	2	3	4	5
4. I am afraid of losing my life because of Corona	1	2	3	4	5
5. When I watch news and stories about Corona on social media, I become nervous or anxious.	1	2	3	4	5
6. I cannot sleep because I'm worrying about getting Corona infection/ reinfection.	1	2	3	4	5
7. My heart races or palpitates when I think about getting Corona infection/ reinfection.	1	2	3	4	5

Q 34.Section C. Multidimensional Scale of Perceived Social Support

We are interested in how you feel about the following statements. Read each statement carefully. Indicate how you feel about each statement by selecting one for seven options at each statement-making a circle.

	Very Strongly Disagree	Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
1. I get the emotional help & support I need from my family	1	2	3	4	5	6	7
2. I can talk about my problems with my family.	1	2	3	4	5	6	7
3. My family really tries to help me.	1	2	3	4	5	6	7
4. My family is willing to help me make decisions.	1	2	3	4	5	6	7
5. I have friends with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
6. I can talk about my problems with my friends.	1	2	3	4	5	6	7
7. My friends really try to help me.	1	2	3	4	5	6	7
8. I can count on my friends when things go wrong	1	2	3	4	5	6	7
9. There is a special person who is around when I am in need.	1	2	3	4	5	6	7
10. There is a special person with whom I can share joys and sorrows.	1	2	3	4	5	6	7
11. I have a special person who is a real source of comfort to me	1	2	3	4	5	6	7
12. There is a special person in my life who cares about my feelings.	1	2	3	4	5	6	7

Thank you for your participation

To Be filled by Investigator

Remark by the data collector	…… Signature of the Data collector

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1,2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3,4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
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	*6*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6,7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	7
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
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	7
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7,8,9
		(b) Indicate number of participants with missing data for each variable of interest	7
Outcome data	15*	Report numbers of outcome events or summary measures	7,8,9

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	10,11,12
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10,11,12
Discussion			
Key results	18	Summarise key results with reference to study objectives	12,13,14
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	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
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	16

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting.