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RESEARCH ARTICLE

Diabetes Mellitus Complications and Associated Factors Among Adult Diabetic Patients in Selected Hospitals of West Ethiopia

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Abstract:

Background / Introduction:

The prevalence of type 1 and type 2 diabetes mellitus (DM) is increasing worldwide. The prevalence might even be higher in low-income countries. As a result, type 1 and type 2 DM and their complications are imposing a high burden on patients (*e.g.* hospitalization, disability and death). In Ethiopia, there are limited studies focusing on the complications of type 1 and type 2 DM. Thus, we assessed the prevalence of type 1 and type 2 DM complications and associated factors in selected hospitals in western Ethiopia.

Methods:

This cross-sectional study included 257 adult patients with DM attending the chronic care clinics of Nedjo general and Nekemte referral hospitals. The study was carried out between March 1 and April 30, 2016 using a pre-tested self-administered questionnaire and chart review.

Results:

Of the 257 patients, 87 (33.9%) had ≥1 DM complication. Acute and chronic complications accounted for 9.3% and 24.5% of the total DM patients, respectively. The age of the patients (p=0.024), family history of DM (p=0.038), DM duration (p=0.015), DM regimen (p=0.041), and the occurrence of other chronic diseases (p=0.006) were significantly associated with DM complications.

Conclusion:

The findings of this study revealed that 1 out of 3 adults with DM have ≥1 complication in our chronic ambulatory care clinics. Diabetic keto-acidosis was the most common acute complication whereas hypertension was the most common chronic complication. The presence of DM complications was associated with the age of the patients, duration of DM, family history of DM, DM regimen and the presence of other chronic diseases.

Keywords: Diabetes, Complications, West Ethiopia, Obesity, Hyperlipidaemia, Hypertension.

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1. INTRODUCTION

Diabetes mellitus (DM) has 2 major types: type 1 and type 2 DM. Etiologically, factors contributing to hyperglycaemia include reduced insulin secretion, decreased glucose utilization and increased glucose production [1, 2].

The number of people with DM has increased about 3-fold between 1980 and 2014, rising from 108 million to 422 million worldwide [3]. The number is expected to scale up from the estimated 415 million in 2015 to 642 million by 2040 [4]. The prevalence is also growing rapidly in low- and middle-income countries [3, 4]. According to the International Diabetes Federation (IDF) about 75% of the people with DM live in low- and middle-income countries [4]. According to a systematic review, the prevalence of DM ranged from 2.6-20% in North African countries in 2013 [5]. The IDF estimated that about 14.2 million people living in Africa (including Ethiopia) had DM in 2015 and that is expected to rise to 32.4 million by 2040 [4]. Ethiopia was among the top 4 African countries with a national prevalence of 2.9%, where a large number of adults live with DM [4]. In 2013, its prevalence was about 5% in Bishoftu town, East Ethiopia [6].

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Although DM-related morbidity and mortality can be prevented by normalizing blood glucose, the level of glucose may increase despite appropriate therapy resulting in complications, such as disturbances in fat metabolism, nerve damage and eye disease [1 - 3]. Patients with some common risk factors, such as long duration of DM, hypertension, poor metabolic control, smoking, obesity and hyperlipidaemia are more prone to DM complications. There is a linear increase in long-term DM complications in both sexes with increasing age and duration of DM. Additionally, the causes of DM complications are related to poor control of DM due to non-adherence, poor attitude towards the disease and its complications, unhealthy diet, insufficient physical activity, and poor management by health care professionals [7 - 11].

Different studies, varying in methodology and DM population, reported a prevalence of DM complications ranging from 20-90.5% [9, 12 - 20, 22 - 24]. Studies in different hospitals in Ethiopia showed that visual disturbance, hypertension, neuropathy and nephropathy were the top 4 chronic complications diagnosed in DM patients in different tertiary hospitals of the country [14, 15, 18, 21]. Acute complications including diabetic ketoacidosis (DKA), hyperosmolar hyperglycaemic state (HHS), and hypoglycaemia were also commonly seen among patients in these hospitals [14, 15]. Furthermore, some of the identified risk factors for DM complications were patient age, gender, type of DM, duration of illness, poor glycaemic control, DM regimen, body mass index (BMI) and negative attitude towards DM as well as poor treatment adherence and knowledge about DM and its management [9, 13 - 16, 17, 20 - 26].

Studies focusing on DM complications are rare in Africa, particularly in Ethiopia. Some local studies conducted in the country recognized the prevalence of DM complications [14, 15]. On the other hand, since the studies were carried out in tertiary hospitals, they could not clearly indicate the precise picture of DM complications at lower levels, such as in district hospitals. Thus, the current study was focused on assessing the prevalence of DM complications and associated factors in some selected hospitals in western Ethiopia.

2. METHODS

2.1. Study Settings

The setting of this study was in chronic ambulatory care clinics of 2 hospitals in the Wollega Zones, Western Ethiopia. These are Nekemte Referral Hospital (NRH) and Nedjo General Hospital (NGH) in the western part of Oromia at a distance of 331 and 516 Km, respectively from Addis Ababa, the capital of Ethiopia. The NRH has >200 beds and provides health services for 82,000 - 100,000 patients annually. It currently employs about 230 health care professionals. The NGH has about 120 beds, and 210 health care givers provide health care services for about 65,000 patients/annum. The chronic ambulatory care clinics of both NRH and NGH provide health care services for DM, hypertension and cardiac patients independently.

2.2. Study Design and Period

The study was conducted based on a cross-sectional study design. A self-administered questionnaire and chart review in the chronic ambulatory care clinics of NRH and NGH were used to gather data from March 1 - April 30, 2016.

2.3. Study Participants

In the 4 zones of Wollega of the Oromia Regional State, there are 7 general and 1 referral hospitals. The service level provided in all the general hospitals in the zones is almost similar. Hence, among them, 1 general hospital, NGH, was randomly selected, and the only referral hospital in the area (NRH) was included in the study. All adult DM patients (age ≥18 years) who visited chronic care clinics during the study period were included in the study. On the other hand, DM patients with duration of illness of <1 year, with mental problems, pregnant, or who came for a second follow-up visit during the study period (only the first visit's data recorded) were excluded from the study.

2.4. Data Collection Process

In order to gather relevant data for this study, a pre-tested self-administered questionnaire that was developed after we reviewed the literature [16 - 21] and a chart review were used for data collection. To this effect, patients were interviewed, if they were unable to read and/or write. Besides, chart review was made to retrieve data on DM type, family history of DM, duration since diagnosed with DM, acute complications and chronic complications, medication history (drugs taken for DM and other conditions, if any), and blood glucose results (fasting and random blood glucose) measured at the follow-up visit. While 25 questions for socio-demographic characteristics, DM profile and clinical status, and medication history were included in the tool, 23 questions were included for DM knowledge and attitude [27]. During the course of data gathering, 3 different health professionals (2 nurses and 1 pharmacist) trained for this purpose, and employees of the selected hospitals were used to gather data. For the accuracy and completeness of the data, the data gathered each time were checked daily by the investigators during the study period.

2.5. Data Analysis

Once the data are collected, they were checked for completeness, categorized, coded, entered into, and analysed by SPSS software (Windows version 20.0; SPSS Inc, Chicago, IL). Then, descriptive statistics involving standard deviation, mean, frequency and percentages were computed. The Chi-square test was used to determine factors associated with DM complications at a 95% Confidence Level (CI). A two-sided test of significance was used and the level of statistical significance was set at $p<0.05$.

2.6. Operational Definitions

In the current study, the following phrases were operationally defined as:

- Good attitude: patients who answered correctly more than mean score.

- Poor/negative attitude: patients who answered below the mean score.
- Good knowledge: patients who answered correctly more than mean score.
- Poor knowledge: patients who answered below the mean score.
- Acute complications: diabetes complications including DKA, hypoglycaemia and HHS.
- Chronic complications: include micro-vascular (visual disturbance, neuropathy, nephropathy), macro-vascular (hypertension), and non-vascular (gastroparesis, infections, skin changes, and hearing loss) DM complications.
- DKA is clinically defined with random blood sugar ≥250 mg/dL, urine glucose (usually > 3+), urine ketone (usually > 2+), plus sign and symptoms of DKA.

2.7. Ethics Approval and Consent

The study was approved and granted by the Research and Technology V/President office after ethical clearance by the institutional review board of Wollega University. Managements of both hospitals were also contacted through formal letters from the university prior to actual data collection. Moreover, all patients approved their participation in the study by their signatures. They were also informed that the data obtained will be kept confidential and used only for research purposes.

3. RESULTS

3.1. Socio-demographic Characteristics of Patients

A total of 257 diabetic patients were included in the study during the 2 month period. The majority of the patients were males (58%) and married (68%). The mean age of patients was 40 (±15.75) years (Table **1**).

3.2. DM and Other Related Profiles of Patients

More than half (57.6%) were type 1 DM patients with a duration of illness <5 years (51.8%). In addition, few patients (14.8%) reported a family history of DM and used alcoholic drinks (15.6%), and about one-third (30.4%) of patients had other chronic diseases in addition to DM (Table **2**).

Table 1. Socio-demographic characteristics of diabetic patients in two hospitals in western Ethiopia, 2016 (n = 257).

Variable		Frequency (%)
Sex	Male	148 (57.6)
	Female	109 (42.4)
Age interval (in years)	≤30	88 (34.2)
	31-45	74 (28.8)
	>45	95 (37)
Marital status	Unmarried	56 (21.8)
	Married	175 (68.1)
	Divorced	6 (2.3)
	Widowed	20 (7.8)
Educational status	Illiterate	72 (28)
	1-8 grade	80 (31.1)
	9-12 grade	63 (24.5)
	Diploma	25 (9.7)
	University degree and above	17 (6.6)
Current job	Government employee	39 (15.2)
	NGO employee	12 (4.7)
	Merchant	17 (6.6)
	Farmer	75 (29.2)
	Housewife	52 (20.2)
	Others	62 (24.1)

NGO: Non-Governmental Organization

Table 2. Medical profiles of patients with diabetes in two hospitals in western Ethiopia, 2016 (n = 257).

Variables		Frequency (%)
Type of DM	Type 1	148 (57.6)
	Type 2	109 (42.4)

(Table 2) contd.....

Variables		Frequency (%)
Duration of illness (in years)	<5	133 (51.8)
	5-9	81 (31.5)
	10-14	31 (12)
	≥15	12 (4.7)
Family history of DM	Yes	38 (14.8)
	No	214 (83.3)
	Unknown	5 (1.9)
History of cigarette smoking	Yes	18 (7)
	No	239 (93)
History of using alcohol	Yes	40 (15.6)
	No	217 (84.4)
Level of PE[a]	No PE	95 (37)
	Less to moderately frequent PE	79 (30.7)
	Regular PE	83 (32.3)
Presence of other chronic diseases	Yes	78 (30.4)
	No	179 (69.6)

PE physical exercise: less to moderate PE means 30 min/day exercise for 1-4 days/week; regular PE means 30 min/day for 5 or more days/week.

Although insulin was used for both type 1 and type 2 DM management, insulin only regimen, specifically neutral protamine Hagedorn (NPH) insulin, was prescribed for the majority (59.5%) of patients (Table **3**).

3.3. Prevalence of DM Complications

Concerning the prevalence of DM complications, 87 DM patients out of 257 had ≥1 complication (overall prevalence = 33.9%). Sixty-three (24.5%) patients had ≥1 chronic complication. The overall prevalence was not different with regard to DM types. In contrast, acute DM complications (14.2 *vs* 2.8%) were more common in type 1 DM than type 2 DM patients. Chronic DM complications (31.2 *vs* 19.6%), family history of DM (21.1 *vs* 10.1%), and other chronic diseases (49.5 *vs* 16.2%) were more common in type 2 DM patients. Most type 1 DM patients were younger with age ≤30 years (57.4%) while type 2 DM patients were older with age >45 years (67.9%). Type 1 DM patients, nevertheless, had slightly better knowledge (61.5%), but poorer attitude (52.0%) towards DM and its complications compared with type 2 DM patients (Table **4**).

Hypertension 34 (41.5%) was the most common chronic complication reported in DM patients, followed by visual disturbance 17 (20.7%) and nephropathy 13 (15.9%), respectively (Table **5**). On the other hand, DKA 16 (66.7%) was the most common acute complication identified in patients. Hypoglycaemia was reported in 8 (33.3%) patients; there was no documented HHS case.

3.4. Factors Associated with Type 1 and Type 2 DM Complications

The presence of DM complications was associated with various factors as summarized in Table **6**. Accordingly, Chi-square test indicated that the age of patients (p = 0.024), family history of DM (p = 0.038), duration of DM (p = 0.015), DM regimen (p = 0.041), and presence of other chronic diseases (p = 0.006) had a significant association with DM complications. Furthermore, the rate of DM complications increased with increasing age and duration of DM. The prevalence of complications was relatively higher in women (39.4%) than men (29.7%), but the difference was not significant. Likewise, DM type, specific DM drugs, overall knowledge and attitude scores showed no significant association with DM complications.

Table 3. The regimen and specific drugs used to treat diabetic patients in two hospitals in Western Ethiopia, 2016 (n = 257).

Variables		Frequency (%)
Diabetes regimen	Insulin only	153 (59.5)
	Oral hypoglycaemic agents	90 (35)
	Oral hypoglycaemic agents and insulin	14 (5.4)
Specific drugs	Glibenclamide	13 (5.1)
	Metformin	22 (8.6)
	Metformin and glibenclamide	55 (21.4)
	Metformin and NPH insulin	14 (5.4)
	NPH insulin	153 (59.5)

Table 4. Distribution of variables by diabetes type among patients in two hospitals in Western Ethiopia, 2016 (n = 257).

Variables		DM Type		
		Type 1 (%)	Type 2 (%)	Total
Presence of ≥1 complication	Yes	50 (33.8)	37 (33.9)	87 (33.9)
	No	98 (66.2)	72 (66.1)	170 (66.1)
Acute complications	Yes	21 (14.2)	3 (2.8)	24 (9.3)
	No	127 (85.8)	106 (97.2)	233 (90.7)
Chronic complications	Yes	29 (19.6)	34 (31.2)	63 (24.5)
	No	119 (80.4)	75 (68.8)	194 (75.5)
Sex	Male	88 (59.5)	60 (55)	148 (57.6)
	Female	60 (40.5)	49 (45)	109 (42.4)
Age interval (in years)	≤30	85 (57.4)	3 (2.8)	88 (34.2)
	31-45	42 (28.4)	32 (29.4)	74 (28.8)
	>45	21 (14.2)	74 (67.9)	95 (37.0)
Family history of DM	Yes	15 (10.1)	23 (21.1)	38 (14.8)
	No	132 (89.2)	82 (75.2)	214 (83.3)
	Unknown	1 (0.7)	4 (3.7)	5 (1.9)
Presence of other chronic disease	Yes	24 (16.2)	54 (49.5)	78 (30.4)
	No	124 (83.8)	55 (50.5)	179 (69.6)
Duration of illness (in years)	<5	63 (42.6)	70 (64.2)	133 (51.8)
	5-9	51 (34.5)	30 (27.5)	81 (31.5)
	10-14	26 (17.6)	5 (4.6)	31 (12.1)
	≥15	8 (5.4)	4 (3.7)	12 (4.7)
Knowledge score	Poor Knowledge	57 (38.5)	44 (40.4)	101 (39.3)
	Good Knowledge	91 (61.5)	65 (59.6)	156 (60.7)
Attitude score	Poor/Negative attitude	77 (52.0)	46 (42.2)	123 (47.9)
	Good/Positive attitude	71 (48.0)	63 (57.8)	134 (52.1)

Table 5. Prevalence of chronic complications among diabetes patients in two hospitals in Western Ethiopia, 2016 (n = 257).

Chronic Complications	Frequency (%)
Hypertension	34 (41.5)
Visual disturbance	17 (20.7)
Nephropathy	13 (15.9)
Peripheral neuropathy	8 (9.8)
Erectile dysfunction	7 (8.5)
Diabetic foot ulcer	1 (1.2)
Infection	1 (1.2)
Dental problem	1 (1.2)

Table 6. Association of different factors with type 1 and type 2 diabetes complications among patients in two hospitals in Western Ethiopia, 2016 (n = 257).

Variables		Presence of ≥1 complication			p
		Yes	No	Total	–
Sex	Male	44	104	148	–
	Female	43	66	109	0.104
Age interval	≤30	20	68	88	–
	31-45	30	44	74	0.024
	>45	37	58	95	–
Marital status	Single	27	55	82	
	Married	60	115	175	0.830

(Table 6) contd.....

Variables		Presence of ≥1 complication			p
		Yes	No	Total	–
Family history of DM	Yes	16	22	38	–
	No	67	147	214	0.038
	Unknown	4	1	5	–
Presence of other chronic disease	Yes	36	42	78	–
	No	51	128	179	0.006
DM type	Type 1	50	98	148	–
	Type 2	37	72	109	0.978
Duration of illness (in years)	<5	34	99	133	–
	5-9	35	46	81	–
	10-14	11	20	31	0.015
	≥15	7	5	12	–
DM regimen	Insulin	51	102	153	–
	Oral hypoglycaemic agents	27	63	90	–
	Oral hypoglycaemic agents and Insulin	9	5	14	0.041
Specific drugs	Glibenclamide	3	10	13	–
	Metformin	9	13	22	–
	Metformin and Glibenclamide	15	40	55	0.090
	Metformin and NPH Insulin	9	5	14	–
	NPH insulin	51	102	153	–
Knowledge score	Poor knowledge	34	67	101	–
	Good knowledge	53	103	156	0.969
Attitude score	Poor/negative attitude	39	84	123	–
	Good/positive attitude	48	86	134	0.512

4. DISCUSSION

In this study, the magnitude of type 1 and type 2 DM complications was determined and the common ones were described. Additionally, various factors associated with DM complications were presented.

Among the 257 diabetic patients included in the study, most of them were type 1 DM, and were on NPH insulin for treatment. This finding is inconsistent with those reported by other studies in Jimma, Dessie, and the United Arab Emirates (UAE) [14, 15, 17], where type 2 DM was predominant among patients. According to a systematic review conducted in Ethiopia, type 1 DM is more common in rural parts while type 2 is prevalent in urban areas of the country [18]. This might be a reason for the predominance of type 1 DM in our study, as most of the DM patients in both hospitals were from rural areas. Another explanation for high prevalence of type 1 DM and low type 2 DM in our study could be because early type 2 DM patients are relatively asymptomatic and may not seek medical advice and the age distribution in this study showed that the mean age of patients was 40 (±15.75) years, of which 63% were ≤45 years.

About one-third (33.9%) of diabetic patients in the current study had ≥1 complication. This is similar to the finding reported from the UAE (29.5%) [17]. The prevalence reported in other studies; however, was higher compared with ours (Ethiopia: in Jimma 83% [14] and in Dessie 59.7% [15], Nigeria 52% [24], Libya 68.7% [9] and Iran 57.5% [16]). Generally speaking, it is well known that long duration of DM is related to the occurrence of more complications. This in turn might have contributed to the relatively low prevalence reported in our study, as more than half (51.8%) of the patients had a duration of illness of <5 years. Poor documentations of data in patient records, variations in patient health-seeking behaviour, missed diagnosis, and underreporting of sensitive issues like erectile dysfunction could also be responsible for the discrepancy.

In this study, approximately one-tenth (9.3%) of the DM patients had acute complications which occurred more frequently in type 1 (14.2 *vs* 2.8%) than in type 2 DM. Of the type 1 DM complications, 66.7% had DKA. This study revealed that the prevalence of acute complications in DM patients is lower than the rates observed in the Jimma (30.5%) and Dessie (28.2%) hospitals [14, 15]. However, of the type 1 DM complications, similar findings were reported for DKA in both studies (Jimma 71% and Dessie 68.3%) [14, 15]. According to our study, DKA is a problem in both types of DM with an increased ratio in type 1 (14/16 patients with DKA had type 1 DM). Similar findings with this were also reported by previous studies conducted in Ethiopia [14, 15]. Prevention of DKA has better outcomes than its treatment and can be achieved by maintaining good blood glucose control. A study [28] revealed significant reductions of glycosylated haemoglobin (HbA_{1c}) and DM-related distress in type 2 DM, where patients were provided with accurate information about their risk of developing DM-related complications, along with appropriate counselling. Therefore, health care givers should focus on providing education to increase patient knowledge and attitude towards DM complications in order to reduce the burden of DM.

Moreover, our study indicated that a quarter (24.5%) of diabetic patients had ≥1 chronic complication. However, this is

lower than the findings reported in several studies: Dessie (58.8%), Jimma (52.5%) and Iran (57.5%) [14 - 16]. This discrepancy might have occurred due to variations in the prevalence of DM types (*i.e*. type 1 was predominant in our study), level of practice in hospitals on diagnosing complications and documentations as well as poor knowledge and attitudes of DM patients. Furthermore, in our study, type 2 DM patients had more chronic complications than type 1 DM patients (31.2 *vs* 19.6%), which might be due to the fact that most type 2 DM patients remain asymptomatic initially until diagnosis when they come up with ≥1 chronic complication. The prevalence of chronic complications among type 2 DM patients, in our settings, is higher than that reported in a study from Ghana (20%) [19], but lower compared with findings reported in Bangladesh (90.5%), Pakistan (81.4%), Libya (68.7%), multinational (53.5%) studies and Nigeria (37%) [9, 13, 20, 22, 23].

In the present study, hypertension (41.5%), visual disturbance (20.7%), and nephropathy (15.9%) were the 3 most identified chronic complications in descending order. This was consistent with reports of other studies conducted in Ethiopia [14, 15, 21] and Libya [9]. Yet, different patterns to ours were reported in a multinational study, Pakistan, and Nigeria [13, 20, 22] where peripheral neuropathy, nephropathy, and retinopathy ranked 1st, 2nd and 3rd, respectively. The difference in DM population, medications used to control high blood glucose as well as the level of knowledge, attitude and practice of DM patients might be responsible for the discrepancy.

Further analysis of the data in the study also indicated a significant association between the presence of DM complications and risk factors including the age of patients, family history of DM, duration of DM, DM regimen and presence of other chronic diseases. This is consistent with other studies conducted in different contexts [9, 13 - 15, 17, 22, 23]. It was stated that an increase in the age of patient and duration of DM resulted in an increased occurrence of complications [9, 14, 17, 23]. A comparable pattern was observed in our study. In agreement with other studies in Ethiopia [14, 15], the occurrence of DM complications was not significantly different between men and women. In contrast, sex was a determinant factor in reports from Libya and UAE [9, 17]. This contradiction may be due to the differences in DM population, health seeking behaviour, or patient education levels. Nevertheless, the type of DM was not associated with the presence of complications unlike that reported in the previous studies [14, 15].

In general, as this study was cross-sectional, cause-effect relationships and outcomes of DM complications could not be determined. Besides, clinical findings from chart review and questionnaire based techniques were used to determine complications and associated factors in DM patients. It should be noted that missed or undocumented diagnosis could cause underreporting of complications. Moreover, the HbA_{1c} test was not done. Thus, we did not determine the association between the level of blood glucose control and the occurrence of DM complications. This study also has not assessed how the patients store their insulin. These are some of the potential limitations of this study.

CONCLUSION

We found that 1 out of 3 adults with type 1 or type 2 DM attending chronic ambulatory care clinics of selected hospitals in Western Ethiopia have ≥1 complication. The presence of DM complications was associated with the age of the patients, duration of illness, family history of DM, treatment, and the presence of other chronic diseases.

RECOMMENDATION

Awareness of DM complications and risk factors in conjunction with regular patient education should be provided in hospitals. Additionally, measures for optimal blood glucose control should be in place to prevent the long-term complications of DM. The effort is also needed from all stakeholders to diminish the overall burden of this disease. Moreover, prospective studies should be conducted in the region to indicate the severity and outcomes of DM complications.

LIST OF ABBREVIATONS

DKA	=	Diabetic Keto-acidosis;
DM	=	Diabetes Mellitus;
HbA_{1c}	=	Glycosylated Haemoglobin;
HHS	=	Hyperosmolar Hyperglycaemic State;
IDF	=	International Diabetes Federation;
NGH	=	Nedjo General Hospital;
NRH	=	Nekemte Referral Hospital

AUTHORS' CONTRIBUTION

AT Korsa: conceived the research idea, study design, data collection, data entry and analysis, interpreted the data, draft and reviewed the manuscript. ES Genemo, HG Bayisa: designed the study, collected data and analysis, and reviewed the manuscript. MG Dedefo: designed the study, data entry and analysis, interpreted the data, and reviewed the manuscript. All authors have read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved and granted by the Research and Technology V/President office after ethical clearance by the institutional review board of Wollega University with reference number of WU:95,260/ST1-37. Managements of both hospitals were also contacted through formal letters from the university prior to actual data collection. Moreover, all patients approved their participation in the study by their signatures. They were also informed that the data obtained will be kept confidential and used only for research purposes.

HUMAN AND ANIMAL RIGHTS

Not applicable.

CONSENT FOR PUBLICATION

Informed consent has been obtained from all the participants.

AVAILABILITY OF DATA AND MATERIAL

The data supporting the findings of the article are available from the corresponding author MGD upon reasonable request.

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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