Addis Ababa University

College of Health Sciences

School of Medicine

Department of Internal Medicine

The risk factors for osteoporosis and falls, their association, and knowledge in patients with Type 1 Diabetes Mellitus

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A thesis to be submitted to the Department of Internal Medicine, School of Medicine, College of Health Sciences, Addis Ababa University, for partial fulfilment of the Sub-Specialty Certificate program in Endocrinology and Metabolism

December 2023.

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December 2023.

Acknowledgement

Words cannot express my gratitude to God.

I would also like to express my sincere gratitude to the following individuals and organizations for their invaluable support and assistance in the completion of this research project:

First and foremost, I would like to express my deepest appreciation to my advisor, Professor Yeweyenhareg Feleke, for her guidance, support, and encouragement throughout the entire research process. Her insights and feedback have been instrumental in shaping the direction and scope of this study.

I would also like to thank the members of the research ethics committee for their valuable feedback and constructive criticism, which helped me to refine and improve the research proposal.

I am also grateful to Nr. Muluwork Gedion, Nr. Kidist Tamru, Nr. Haimanot Tsegaye, Nr. Mihret Mathewos, and Dr. Ribka Beleat for their assistance with data collection and Mr. Mohammed Legas for his assistance with data analysis, without which this research would not have been possible.

In addition, I would like to acknowledge the support and encouragement of my family and friends, who have provided me with emotional and moral support throughout this challenging journey.

Finally, I would like to express my gratitude to Addis Ababa University, College of Health Sciences for providing the resources and facilities necessary to carry out this research.

Thank you all for your invaluable contributions to this project.

Abbreviations and Acronyms

ADA – American Diabetes Association

ACR – Albumin-Creatinine Ratio

BMD – Bone Mineral Density

CKD – Chronic Kidney Disease

DM – Diabetes Mellitus

DXA/DEXA - dual X-ray Absorptiometry

ETB - Ethiopian Birr

FBS – Fasting Blood glucose

FES-I - Falls Efficacy Scale International

FRAX - Fracture Risk Assessment Tool

HgA1c/HbA1c - Glycated hemoglobin

IDF - International Diabetes Federation

NCDs – Non-communicable Diseases

OKAT - Osteoporosis Knowledge Assessment Tool

PER - Protein Excretion Rate

STEPS - STEPwise approach to NCD risk factor Surveillance

USD - United States Dollar

WHO - World Health Organization

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Abstract

Background: Patients with type 1 diabetes have a lower bone mineral density (BMD) and up to 6-fold higher risk of fracture compared to healthy subjects, justifying the classification of the disease as a non-modifiable risk factor for osteoporosis. The literature describes a variety of risk factors for low BMD in patients with type 1 diabetes, with some conflicting evidence. Data on osteoporosis and related factors in patients with type 1 diabetes in Ethiopia, Africa, and other low- and middle-income countries is lacking.

Objectives: To determine the risk factors for osteoporosis and falls, their association, and knowledge in patients with Type 1 Diabetes age 40 years and above.

Methods: An institution-based cross-sectional study was conducted from June 1 to August 31, 2023GC at the diabetes clinic in Tikur Anbessa Specialized Hospital, Addis Ababa. All patients with Type 1 diabetes age 40 years and above attending the diabetes clinic during 2023GC were enrolled. Data was collected through pretested structured interviewer-administered questionnaires and analyzed using SPSS version 26. The statistical association was tested using Pearson's correlation coefficient, chi-square test, bivariate and multivariable logistic regression. Statistical significance was considered at a level of significance of 5%, and an adjusted odds ratio (AOR) with a 95% confidence interval (CI) was used to present the estimates of the strength of the association. Finally, outcomes were presented with tables, figures, and statements.

Results: This study involved a total of 106 participants of which 54.7% were males and 47.2% were between the ages of 40-44 years. Ninety-six percent of the study participants were living with Diabetes for more than 10 years and two-thirds had persistent proteinuria. Fifty-two percent had diabetic eye complications, 10.4% had an eGFR of <60ml/min/1.73m^2 while 9.4% of the participants consumed more than three units of alcohol per day. Only two participants had a high FRAX fracture risk score but 13.2% had a history of previous fragility fracture. Age and duration of diabetes had a positive correlation and eGFR had a negative one with the 10-year probability of a major osteoporosis-related and hip fracture. The magnitude of osteoporosis was 15%. Fifteen percent of the study participants had frequent falls and 13.2% had a high concern of falling. Being female (AOR=1.6, 95% CI=1.42, 5.88), having previous fragility fractures (AOR=1.8, 95% CI=1.04, 9.27), and osteoporosis (AOR=4.1, 95% CI=1.15, 16.49) were associated with frequent falls. Eighty-three percent had poor knowledge about osteoporosis with a higher level of education associated with a higher level of osteoporosis knowledge. The factors associated with osteoporosis

were female gender (AOR=1.8, 95% CI=1.41, 7.69), excess alcohol use (AOR=5.7, 95% CI=1.69, 47.38), diabetic eye complications (AOR=4.7, 95% CI=1.91, 24.35), and frequent falls (AOR=5.6, 95% CI=1.19, 26.15).

Conclusion: Type 1 diabetes carries an increased risk of osteoporosis, falls, and fractures. Being female, having previous fragility fractures and osteoporosis had a positive association with frequent falls, whereas being female, excess alcohol use, diabetic eye complications, and frequent falls were independent determinants of osteoporosis. A significant osteoporosis knowledge deficit was also seen among the participants with a higher level of education being positively associated. A high concern of falling with difficulties maintaining balance were other concerning outcomes.

Keywords: Type 1 Diabetes, Osteoporosis, Falls, FRAX, Osteoporosis knowledge

1. Introduction

Diabetes is a metabolic disease with long-term complications that is characterized by persistently elevated blood glucose levels (1). Globally, the number of diabetics is gradually rising; according to IDF projections, 537 million adults between the ages of 20 and 79 have the disease in 2021. The greatest increase will occur in areas where economies are transitioning from low- to middle-income status, primarily as a result of these countries' growing populations (3). The 2015 National NCDs STEPS survey revealed that 3.2% of Ethiopians had diabetes (5). Around 1.9 million people are estimated to have diabetes as of 2021, according to the IDF (3). According to a 2022 IDF estimate, 19,998 people in Ethiopia have type 1 diabetes (4).

Osteoporosis is the leading cause of bone disease in humans. It is defined by low bone mass and deterioration of bone structure, which increases the risk of fracture (7,8,9). You can divide the risk factors for osteoporosis into modifiable and non-modifiable. Modifiable risk factors include alcohol, smoking, low BMI, poor nutrition – low dietary calcium consumption, vitamin D deficiency, eating disorders, inadequate exercise and frequent falls (15,16). Fixed risk factors include age, height loss, female gender, family history of osteoporosis, previous fracture, ethnicity, estrogen deficiency and amenorrhea, menopause and hysterectomy. They also comprise medications and conditions like diabetes mellitus (15,17).

When compared to healthy subjects, people with type 1 diabetes have a lower bone mineral density (BMD) and a six-fold higher chance of fracture (20,21,22). The early onset of the disease, which frequently occurs before the peak of bone mass accrual, may play a part as seen in postmenopausal women with type 1 diabetes whose onset occurred before age 20 (10,23,24,25). Systematic reviews and meta-analyses revealed that type 1 diabetes increased the chance of hip and non-vertebral fractures (10,26).

One research found no increase in fracture risk in the first five years of diabetes diagnosis, while another found a higher risk with a duration of more than ten years (28,33). Patients with vascular complications had a higher rise in their fracture risk, while their BMD was lower (26). According to the Blue Mountains Eye Study, people who have diabetic retinopathy, have had diabetes for more than ten years, have cortical cataracts that cover less than 25% of the lens, and are taking insulin have an increased chance of all fractures combined (28). Although only about 2% of the

participants had type 1 diabetes, Lee et al. found that neuropathy accounted for about 20% of the chance of hip and other fractures (29).

In older individuals with type 1 diabetes, poorer glycemic control, AGE accumulation, and kidney disease were found to be independent risk factors for lower hip BMD (34). Data from two reviews indicated that factors related with osteoporosis in type 1 diabetes included younger age at diabetes onset, male sex, lower BMI, poor glycemic control, microvascular complications, smoking status, alcohol intake, and menopausal status, BMI, and clustering of autoimmune diseases (35,36).

1.1 Rationale of the Study

There is no data regarding osteoporosis and its associated factors in patients with type 1 diabetes in Ethiopia and Africa. A study on osteoporosis in Africa only mentioned diabetes as a fixed risk factor and not further in detail (37). An Ethiopian study found the musculoskeletal complications of diabetes to be remarkably high, but evaluation for osteoporosis was not performed (50). The available limited literature does not show data from low- and middle-income countries as well. The studies performed also have limitations including the involvement of non-Caucasian ethnic groups and younger patients, scarcity and unavailability of DXA scans, and limited sample size. In a North American study done to assess risk factors for low BMD in older type 1 diabetes participants, they concluded that the findings were not generalizable due to the older age of the participants and 96% being white (34). A study done in the same setting on natural history of osteoporosis and type 1 diabetes involved women in their post-teenage years but 95% were white (24). The number of participants with type 1 diabetes in most similar studies, even when conducted in high-income countries, ranges from 63 to 139 (24,25,36,38,39). The current diabetes guidelines do not provide specific guidance regarding bone health in type 1 diabetes (78). These observations and the unknown magnitude of this problem in our setup raised this research concern. It will also provide baseline data for Africans, for the current treatment gaps and to identify those at higher risk for intervention.

2. Literature review

2.1 Epidemiology of Diabetes Mellitus

Diabetes is described as a chronic, metabolic disorder identified by elevated blood glucose levels, with long term complications occurring in the heart, blood vessels, eyes, kidneys and nerves among others (1). It results from defects in insulin secretion, insulin action, or both, and leads to altered carbohydrate, fat and protein metabolism. Diabetes is found in every population in the world and in all regions (2).

The number of people living with diabetes is steadily increasing worldwide, with IDF estimates indicating 537 million adults, aged 20–79 years, affected in 2021. By 2030 this number is expected to reach 643 million, and 783 million by 2045. The largest increase will take place in regions where economies are moving from low to middle-income status due to the increase in population in these countries. In contrast to having the lowest regional diabetes prevalence (4.5%), the number of people with diabetes in the IDF Africa Region is expected to increase by 134% by 2045, the highest predicted increase of all the IDF regions. Undiagnosed diabetes accounts for more the 50% of people with diabetes in Africa. Deaths due to diabetes or its complications were estimated to be 6.7 million in 2021. The global health expenditure due to diabetes has also been substantial with USD 966 billion spent in 2021 for adults aged 20–79 years. Over 90% of diabetes worldwide is classified under type 2 diabetes, making it the most common type of diabetes (3).

In a 2022 IDF estimate of type 1 diabetes, 8.75 million people were living with the condition worldwide, of which 7.23 million were adults. One fifth (1.9 million) of these individuals live in low-income and lower-middle-income countries (4). Ethiopia was found to have diabetes prevalence of 3.2% based on the 2015 National NCDs STEPS survey (5). A 2021 IDF estimate puts the number of adults with diabetes around 1.9 million (3). Ethiopia was also predicted to have 19,998 individuals living with type 1 diabetes in a 2022 IDF report (4). Diabetes necessitates ongoing medical attention as well as multifaceted risk-reduction techniques beyond glucose control (6).

2.2 Magnitude of Osteoporosis

Osteoporosis is the most common bone disease in humans, representing a major public health problem (7). It is characterized by low bone mass and deterioration of bone structure that causes

bone fragility and increases the risk of fracture (8,9). Fractures are also a public health concern. Fractures at the spine, hip, wrist, and humerus are major osteoporotic fractures (10). Worldwide, osteoporosis causes over 8.9 million fractures annually, resulting in an osteoporosis fracture every 3 seconds (11). Notably, up to 20% of patients die in the first year after a hip fracture, and less than half regain the previous level of function (12).

Using the WHO definition of osteoporosis, the disease affects approximately 6.3% of men over the age of 50 and 21.2% of women over the same age range globally. Based on the world population of men and women, this suggests that approximately 500 million men and women worldwide may be affected (13,14). A systematic review estimated the global & African prevalence of osteoporosis to be 19.7% and 26.9% respectively. Another meta-analysis reported the worldwide prevalence of osteoporosis to be 18.3% with the highest prevalence of 39.5% found in Africa. The prevalence was higher in developing countries (59,60).

2.3 Risk Factors of Osteoporosis

The risk factors for osteoporosis can be classified as modifiable and non-modifiable. Several modifiable risk factors have a direct effect on bone biology, resulting in an overall reduction in bone mineral density (BMD). Still, some of them also increase the risk of fracture independently of their effect on the bone itself. These include alcohol, smoking, low body mass index, poor nutrition – low dietary calcium intake, vitamin D deficiency, eating disorders, insufficient exercise and frequent falls (15,16). Fixed risk factors include age, height loss, female gender, family history of osteoporosis, previous fracture, ethnicity, estrogen deficiency and amenorrhea, and menopause and hysterectomy. Fixed risk factors also include disorders, diabetes mellitus being one, and medications that weaken bone and affect balance (15,17). Secondary osteoporosis refers to osteoporosis caused by certain medical conditions or medications that can cause bone loss, increase fracture risk, directly or indirectly affect bone remodeling or interfere with younger people reaching their peak bone mass. Type 1 Diabetes has been mentioned as one of these causes (7,8,18,19).

2.4 Type 1 Diabetes Mellitus & Osteoporosis

Most studies have shown that people with type 1 diabetes have lower bone mineral density (BMD) compared with healthy subjects and an up to six-fold increase in fracture risk (20,21,22). Insulin/IGF1

deficiency appears to be a major pathogenetic mechanism leading to impaired osteoblastic bone formation, with or without increased bone resorption. Glucose toxicity, marrow adiposity, inflammation, adipokine and other metabolic alterations may play a role on altering bone turnover (20). Postmenopausal women with type 1 diabetes and onset before age 20 years, had lower trabecular volumetric bone mineral density (vBMD) indicating the early onset of the disease, often before the peak of bone mass accrual might play a role (10,23,24,25,57,63). Eller-Vainicher and coauthors found about 30% of 175 type 1 diabetes patients had low bone mass (osteopenia/osteoporosis) at spine and/or femur (54). Type 1 diabetes was associated with increased risk of incident fracture that began in childhood and extended across the life span, with a disproportionately greater number of lower extremity fractures being sustained. Fractures also occurred 10-15 years earlier than they do in people without diabetes (77).

Systematic reviews and meta-analyses found an increase in the risk of fracture in type 1 diabetes both for hip (RR 4.93, 3.06–7.95) and for non-vertebral fractures (RR 1.92, 0.92–3.99). The risk of hip fractures was higher in Type 1 diabetes compared with type 2 and younger populations. The majority of the reviewed data addressed white populations (10,26,27,70). BMD Z-score was decreased in the spine (mean±SEM −0.22±0.01) and hip (−0.37±0.16) in type 1 diabetes, but the small decrease in BMD does not explain the huge increase in the risk of fractures (26). Elevated prevalence of asymptomatic vertebral fractures was associated with the presence of type 1 diabetes independently of BMD (65).

2.5 Risk Factors in Type 1 Diabetes Mellitus

The increase in fracture risk was higher and BMD lower in patients with complications of diabetes (26). The blue mountains eye study showed increased risk of all fractures combined in those with diabetic retinopathy, diabetes duration of >10 years, cortical cataract involving ≥25% of the lens area and insulin therapy (28,71,72,73). Evaluation of fall frequency among older type 1 diabetes patients showed a higher frequency of falls and injuries with severe hypoglycemia, diabetic peripheral neuropathy, and depression being associated. A threefold higher risk for falls was seen in those with severe hypoglycemia (21,41). Lee et al. reported that neuropathy explained around 20% of the risk of hip and any fractures, though only about 2% of the participants had type 1 diabetes (29).

In young adults, diagnosis of osteoporosis relies not only on aBMD (T-score and not Z-score) but also on multiple fragility fractures (10,20,30). To quantify an individual's absolute fracture risk, the World Health Organization (WHO) developed the FRAX® calculator

(http://www.shef.ac.uk/FRAX). It is a tool used to assess an individual's 10-year probability of experiencing a major osteoporotic fracture (hip, clinical vertebral, humerus, or wrist) or hip fracture specifically. The FRAX score considers several risk factors, including age, sex, body mass index, previous fracture history, parental fracture history, glucocorticoid use, smoking status, alcohol intake, and presence of several medical conditions. Osteoporosis can be defined using the FRAX score as a 10-year probability of a major osteoporotic fracture of 20% or higher, or a 10-year probability of a hip fracture of 3% or higher, in the absence of a prior fragility fracture. However, it is important to note that a FRAX score alone should not be used to diagnose osteoporosis; it is one tool used to assess fracture risk and inform treatment decisions. Diagnosis of osteoporosis typically involves assessment of bone density using techniques such as DXA scan (31,47,57). A study from Germany showed fracture occurrence was similar in type 1 & 2 diabetes groups and related to lower BMD, but unrelated to the threshold T-score, < -2.5 SD (32).

A 2007 World Health Organization report has suggested that fracture risk is not increased within the first 5 years of diabetes (33), while a higher risk was observed with duration of diabetes greater than 10 years in another study, although the proportion of type 2 patients was significant (28).

Glycated hemoglobin (HbA1C) was not linked to BMD and fracture risk in a meta-analysis in 2007 (26), but Poorer glycemic control, AGE accumulation, and kidney disease were found to be independent risk factors for lower hip BMD in older adults with type 1 diabetes (34).

In a review done in 2014, factors found to contribute to osteoporosis in type 1 diabetes include younger age at onset, male sex, lower BMI, poor glycemic control, microvascular complications, and clustering of autoimmune disorders (autoimmune thyroid disease and celiac disease) (35,56,72). A study in 2008 also found adult males with type 1 diabetes have reduced bone density at the hip, femoral neck and spine when compared with age-matched control subjects. As well as, sex hormone binding globulin concentration, smoking status and alcohol consumption, and (for women) menopausal status, each of BMI, serum ionized calcium and serum alkaline phosphatase (negatively) were independently associated with BMD (36,54,56).

In a study done in Tigray among the general population, residing in the rural setting and smoking were positively associated with osteoporosis. In contrast, milk intake greater than four times a week, and when work involves vigorous exercise, appeared to be associated with a reduced risk of osteoporosis (61).

2.6 Causes & Risk factors of falls in patients with Type 1 Diabetes

Every year, more than one-third of people 65 and older fall, and half of these falls are recurring. A significant injury, such as a hip fracture, other fracture, subdural hematoma, other serious soft-tissue injury, or brain injury, occurs in approximately one out of every ten falls. Falls are related to limited mobility, and a reduction in capacity to perform daily activities (42,67). The risk of falls in patients with diabetes was found to be 39%. In the same study, falls occurred more frequently in female patients, with increasing age. with poor diabetic control, in those requiring assistance with mobility: for those mobile with a stick and those who had previously suffered a stroke (43). According to a meta-analysis, older persons with diabetes mellitus are more likely to fall, and this link is stronger in insulin-treated patients (44). Risk factors for falls in patients with diabetes include hypoglycemia, use of medications taken for high blood pressure, peripheral neuropathy and vision loss (45). Studies showed an association with increased fear of falling and fear-associated activity restriction, which modified the risk of falls even in the face of increased fall risk factors (41,68). Abnormalities of balance and gait were shown to be common risk factors for falls among community-dwelling older persons (42,45,67,69).

2.7 Knowledge of Osteoporosis

Routine screening for geriatric illnesses associated with diabetes, such as dementia, depression, falls and hypoglycemia may be especially relevant in older persons due to the possible barriers to diabetes self-management offered by these conditions (46). Patients with osteoporosis should also be encouraged to maintain a healthy lifestyle and avoid behaviors that can increase fracture risk, such as smoking and excessive alcohol consumption (47). Winzenberg and colleagues designed the Osteoporosis Knowledge Assessment Tool (OKAT) for use in Australian 25–44-year-old females. Their study found levels of osteoporosis knowledge were low with a mean score of 8.8 out of 20 (75). A study conducted in India to evaluate knowledge of osteoporosis using a validated questionnaire, the Osteoporosis Knowledge Assessment Tool (OKAT), found significant gaps in knowledge among the subjects at risk (48). A similar study in Cambodia using the OKAT found the average mean score was 9.34 (±3.08) out of 20 and correlated significantly with educational level (74). A Palestinian study of diabetic patients found inadequate knowledge of osteoporosis and recommended education initiatives (49). Another study done in post-menopausal women in Metu, Ethiopia, showed 61.6% of the participants had inadequate

knowledge towards the prevention of osteoporosis. Being younger, employed, better educated, having a personal and family history of osteoporosis and getting information from families and friends increased the odds of having adequate knowledge (62). Similarly, an Iraqi study found that there was a low level of knowledge about risk factors, causes, symptoms, diagnosis, treatment, and prevention of osteoporosis for patient with diabetes mellitus (66).

3. Objectives

3.1 General Objective

To determine the risk factors for osteoporosis and falls, their association, and knowledge in patients with Type 1 Diabetes Mellitus age 40 years and above.

3.2 Specific Objective

- To describe the modifiable risk factors for osteoporosis in patients with Type 1 Diabetes.
- To describe the non-modifiable risk factors for osteoporosis in patients with Type 1 Diabetes.
- To estimate the risk of fracture using the FRAX tool in patients with Type 1 Diabetes.
- To describe the magnitude of osteoporosis in patients with Type 1 Diabetes.
- To determine the association of risk factors and osteoporosis in patients with Type 1 Diabetes.
- To identify the magnitude & risk factors for falls in patients with Type 1 Diabetes.
- To analyze the association of risk factors & falls in patients with Type 1 Diabetes.
- To assess knowledge of osteoporosis in patients with Type 1 Diabetes.

4. Methodology

4.1 Study Setting

The study was conducted from June 1 to August 31, 2023GC at Tikur Anbessa Specialized Hospital. The hospital, found in the capital Addis Ababa, is the largest referral hospital in Ethiopia where specialized clinical services are rendered to the whole nation. It provides sub-specialist level care for patients with diabetes at the diabetes referral clinic. The hospital employs an electronic medical record keeping system where clinical data and laboratory profiles of patients are stored and retrieved when needed. The study was carried out in the diabetes referral clinic of the hospital.

4.2 Study Design

An institution-based cross-sectional study design was used.

4.3 Source & Study population

The source population comprised of all patients diagnosed with type 1 diabetes mellitus who came for follow up at the diabetes clinic of Tikur Anbessa Specialized Hospital in 2023GC. Based on the Department of Internal Medicine monthly clinical audits for the 1 year prior to the start of the study, the number of patients with Type 1 Diabetes Mellitus were 1967. The number of patients with type 1 diabetes age 40 years and above attending the clinics was limited with 194 patients in 2023GC, as such the study population included all 194 patients.

4.4 Eligibility Criteria

Inclusion Criteria

- All patients diagnosed with type 1 diabetes mellitus with age 40 years and above who had at least one prior visit to the diabetes clinic.

Exclusion Criteria

- Incomplete medical records (2 or more missing lab data, missing all 3 of: 24-hour urine protein/urine ACR/Urinalysis).
- Inability/Refusal to give informed consent.

4.5 Sample size determination

All patients with Type 1 diabetes age 40 years and above attending the diabetes clinic during 2023GC were enrolled. Out of 194 patients, 76 did not give consent, 10 had missing lab data and 2 had incomplete data on the data collection tool. Finally, a total of 106 patients were included in the study.

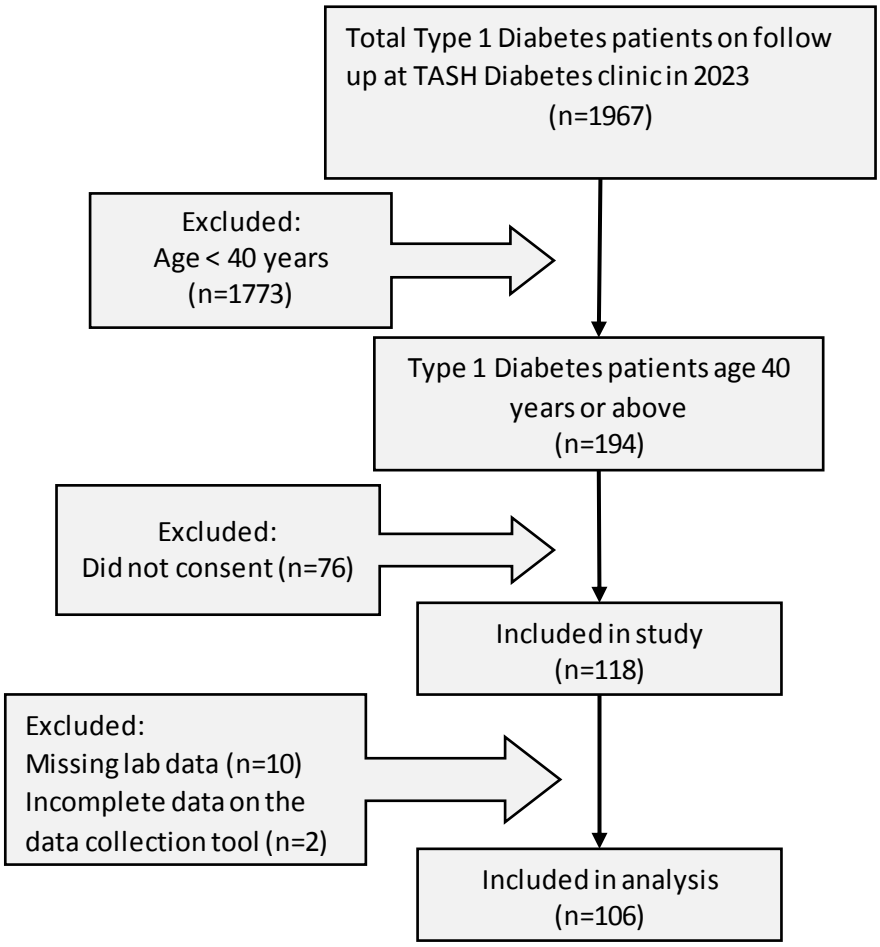

Figure 1. Study Flowchart

4.6 Study Variables

Dependent/Outcome Variables

- Osteoporosis, Falls

Independent/Explanatory Variables

Non-modifiable risk factors

- Age, sex, parental history of hip fracture, previous fragility fracture, menopause, self-reported medical conditions, age at diabetes diagnosis, duration of diabetes, microvascular (neuropathy, nephropathy, retinopathy) and macrovascular (coronary heart disease, cerebrovascular disease, peripheral arterial disease) complications.

Modifiable risk factors

- Insulin dose, physical activity level, excessive alcohol use, smoking status, body mass index, current medications, HbA1c, and frequent falls.

4.7 Data Collection Techniques

Data was collected from consenting patients using a structured interviewer-administered questionnaire including the FRAX tool (31), the short Falls Efficacy Scale International (FES-I), the 4-Stage Balance Test and the Osteoporosis Knowledge Assessment Tool (OKAT).

To estimate the FRAX score, first the 11 parameters were checked to be complete on the data collection tool (Femoral neck BMD not done in this study), next country was specified as Ethiopia on the FRAX tool website (https://frax.shef.ac.uk/FRAX/tool.aspx?country=83) (31), after that the data for each patient was entered, and finally the 10-year probability of hip fracture and major osteoporotic fracture were estimated and documented.

The knowledge about osteoporosis is evaluated using a 20-item instrument addressing the understanding of osteoporosis, knowledge of risk factors, preventive factors and treatment availability. This instrument is derived from Osteoporosis Knowledge Assessment Tool (OKAT) to adapt to actual situation in Ethiopia. The OKAT was translated from English to Amharic by a person proficient in both languages. This version was assessed by a senior Endocrinologist and a few modifications of the questionnaire to suit the Ethiopian context were made. Knowledge scores are created by assigning a "1" to each correct response and a "0" to each incorrect or do not know response. The items are summed for a range of 0 to 20, with higher scores indicating greater knowledge (74,75)

Data on clinical and laboratory profiles of the participants was obtained through review of electronic medical records or patient charts. All missing clinical and laboratory records were

collected during the visit. The questionnaire was prepared in English and translated to Amharic. Finally, it was translated back to English to check its consistency. Data was collected by trained nurses & a general practitioner.

4.8 Data Quality & Management

To ensure the quality of data, training was given to data collectors on-site for 2 days before the study to ensure consistency and reduce intra- and inter-observation differences on the measurement of variables. The collected data was checked for completeness and consistency on each day of data collection. Supervision and monitoring were done every day by the principal investigator, Dr. Paulos Efrem, and at intervals by the advisor, Professor Yeweyenhareg Feleke.

4.9 Data Processing and Analysis

After data collection using structured interviewer-administered questionnaires, each form was checked for completeness and entered into SPSS version 26 for analysis.

Descriptive statistics included mean with SD for continuous variables, while frequency and percentage tables were used for categorical data.

To measure the statistical relationship between risk factors and 10-year probability of hip fracture and major osteoporotic fracture in patients with Type 1 Diabetes age 40 years and above, Pearson's correlation coefficient was used with P value ≤ 0.05 indicating statistical significance.

To assess the association between the mean & SD of sociodemographic characteristics & osteoporosis knowledge chi-square test was used with P value ≤ 0.05 indicating statistical significance.

To identify determinants of osteoporosis among patients with type 1 diabetes, binary logistic regression analysis was done. First, bivariate analysis was done to identify the variables associated with osteoporosis. Variables with P value < 0.25 in bivariate analysis were selected as candidate variables to be entered together into multivariable analysis to control for confounders. Lastly, variables with P-value < 0.05 in multivariable analysis were employed as statistically significant and AOR with 95% CI was identified to measure the strength of the associations. The result was presented by using text, tables and graphs.

4.10 Operational Definition

Osteoporosis: Osteoporosis is diagnosed based on history of fragility fracture or calculated 10-year fracture risk (79).

10-year risk of major osteoporotic fracture: A FRAX-calculated 10-year risk of 20% or more for a major osteoporosis-related fracture and/or a 3% or more for a hip fracture.

Fragility fracture: a fracture resulting from low energy trauma such as a fall from standing height or less, most commonly occurs at the hip, spine, or wrist.

Excessive alcohol use: consumption of 3 or more drinks a day.

Menopause: the permanent cessation of menstrual periods, determined retrospectively after a woman has experienced 12 months of amenorrhea.

Frequent falls: ≥2 falls in the past 12 months.

The Osteoporosis Knowledge Assessment Tool (OKAT): is a set of 20 questions in which scores are generated by giving 1 point to every correct answer and 0 points for incorrect or 'not known' answers (75). It measures osteoporosis knowledge with scores

- <10: Poor knowledge
- 10-15: Satisfactory knowledge
- >15: Good knowledge

Short Falls Efficacy Scale International (FES-I): is a set of 7 questions, each scored from 1 to 4, designed to assess how concerned a patient is about the possibility of falling and is scored out of 28 with scores

- 7-8: Low concern
- 9-13: Moderate concern
- 14-28: High concern

4 step balance test: An older adult who cannot hold the tandem stance or either of the 2 prior stances (stance 1- feet side by side &/or stance 2- instep of one foot touching the big toe of the other foot) for at least 10 seconds each is at increased risk of falling.

Persistent proteinuria/Albuminuria: will be categorized based on the available updated laboratory data using one of urine dipstick test, spot urine albumin-creatinine ratio (ACR), or 24-hour urine protein excretion rate (PER) (51,52,53).

Table 1. Categories of proteinuria and albuminuria.

Measure	Categories		
	Normal to mildly increased (A1)	Moderately increased (A2)	Severely increased (A3)
ACR (mg/g)	<30	30-300	>300
PER (mg/24 hours)	<150	150-500	>500
Urine dipstick test	Negative to trace	Trace to +1	+1 or greater

ACR: spot urine albumin-creatinine ratio, PER: 24-hour urine protein excretion rate.

4.11 Ethical Considerations

The study was done in conformity with ethical guidelines. The purpose and importance of the study was explained and informed consent was obtained from each study participant. Confidentiality was maintained at all levels of the study.

All results have been communicated to the treating physicians. All study participants have been informed that participation in this study would have neither incentives nor direct benefits. Participants who were unwilling to participate in the study and those who wished to quit their participation at any stage were informed to do so without any restriction.

The project was evaluated by the Department of Internal Medicine IRB and an ethical clearance has been obtained.

4.12 Plan for Dissemination of Research Finding

The result of this study will be presented in scientific conferences and published in a reputable international journal. A copy will also be placed in the CHS library as a reference.

5. Results

5.1 Sociodemographic characteristics of the study participants

A total of 106 participants were involved in this study with a response rate of 100%. The majority (47.2%) of the study participants were in the age group of 40-44 years with mean and SD of 46.57±7.26 years respectively. Fifty-five percent of the study participants were male and 92.5% of them were urban residents. Over a third of the study participants had secondary school education and 41.5% of them were self-employed. Concerning the monthly household income, 13.2% of them had no monthly income while 17% of them earned ≥10,000 Ethiopian birr.

Table 2. The sociodemographic characteristics of participants with type 1 diabetes age 40 years and above.

Variable	Frequency	Percent
Age		
40-44 years	50	47.2
45-49 years	28	26.4
50-54 years	17	16
55-59 years	4	3.8
60-64 years	3	2.8
≥65 years	4	3.8
Sex		
Male	58	54.7
Female	48	45.3
Residence		
Urban	98	92.5
Rural	8	7.5
Marital status		
Single	19	17.9
Married	75	70.8
Divorced	9	8.5
Widowed	3	2.8
Educational level		
No formal education	2	1.9
Primary education	30	28.3
Secondary education	38	35.8
Higher education	36	34
Occupation		
Government employee	28	26.4
Self-employed	44	41.5
Homemaker	12	11.3
Farmer	1	0.9
Pensioner	4	3.8
Unemployed	17	16
Household monthly income		

No income	14	13.2
500-5000 birr	47	44.3
5000-10000 birr	27	25.5
≥10000 birr	18	17.0

5.2 Modifiable risk factors for osteoporosis of the study participants

All of the study participants were treated with insulin and 67% of them received a combination of NPH and regular insulin. Close to one-third of the study participants were taking an insulin dose of ≥1IU/kg and practiced a sedentary lifestyle. More than half of the study participants had an increased body mass index, with the majority being overweight. On the contrary, 4.7% were underweight. Eighty-seven percent of the participants had an HgA1c of ≥7% while 40.6% had a fasting blood sugar of ≥130mg/dl. There was only 1 current smoker among the participants while 9.4% consumed more than three units of alcohol a day. Fifteen percent of the study participants had ≥2 falls over the last 12 months.

Table 3. Modifiable risk factors for osteoporosis of participants with type 1 diabetes age 40 years and above.

Variable	Frequency	Percent
Total daily insulin dose		
<1 IU/kg	70	66
≥1 IU/kg	36	34
Body mass index		
Underweight	5	4.7
Normal	45	42.5
Overweight	45	42.5
Obese	11	10.4
HgA1c		
<7%	14	13.2
≥7%	92	86.8
Physical activity		
Vigorous	17	16
Moderate	55	51.9
Sedentary	34	32.1
Smoking status		
Never smoked	101	95.3
Ex-smoker	4	3.8
Current smoker	1	0.9
More than three units of alcohol per day		
Yes	10	9.4
No	96	90.6

Frequent falls		
Yes	16	15.1
no	90	84.9
Additional medications (n=15)		
Osteoporosis treatment	2	13.3
Thiazide diuretic	2	13.3
Loop diuretic	3	20
Oral glucocorticoid	2	13.3
Proton pump inhibitor	4	26.7
Thyroxine	3	20
SGLT2 Inhibitor	5	33.3

5.3 Non-modifiable risk factors for osteoporosis of the study participants

Females comprised 45.3% of the participants. Ninety-six percent of the study participants were living with Diabetes for more than 10 years and 44.3% of the study participants were diagnosis with diabetes before the age of 20 years. Sixteen percent of the study participants had neuropathy and 16% had diabetic nephropathy. Fifty-two percent of the study participants had diabetic eye complications. Diabetic retinopathy was reported from 80% and cataracts from 23.6% of the participants with diabetic eye complications. Around eight percent of the study participants with comorbidities were experiencing menopause. Four percent of the study participants had a history of parental hip fracture and 13.2% had a history of previous fragility fracture. Only two participants had a high FRAX fracture risk score.

Table 4. Non-modifiable risk factors for osteoporosis of participants with type 1 diabetes age 40 years and above.

Variable	Frequency	Percent
Sex		
Male	58	54.7
Female	48	45.3
Duration of diabetes mellitus		
<10 years	4	3.8
≥10 years	102	96.2
Age at DM diagnosis		
≤10 years	8	7.5
11-20 years	39	36.8
21-30 years	44	41.5
31-40 years	13	12.3
≥41 years	2	1.9
Diabetic eye complications		
Yes	55	51.9

No	51	48.1
Types of diabetic eye complication (n=55)		
Diabetic retinopathy	44	80
Cataract	13	23.6
Glaucoma	3	5.4
Diabetic nephropathy		
Yes	17	16
No	89	84
Neuropathy		
Yes	17	16
No	89	84
Types of chronic disease (n=80)		
Dyslipidemia	71	88.8
Hypertension	48	60
Menopause	6	7.5
CLD	1	1.3
Untreated long-standing hyperthyroidism	1	1.3
Previous fragility fracture		
Yes	14	13.2
no	92	86.8
Parent hip fracture		
Yes	4	3.8
No	102	96.2
FRAX high fracture risk		
Yes	2	1.9
No	104	98.1

5.4 The correlation between the 10-year probability of a major osteoporosis-related fracture and independent variables

In this finding, age of the study participants had significant positive relation at r (104) = 0.735, p=0.000. This implies that as age increases, the 10-year probability of a major osteoporosis related fracture increases. The duration of diabetes mellitus also has a significant positive relation at r (104) =0.426, p=0.000, implying that as the duration of diabetes increases, the 10-year probability of a major osteoporosis related fracture increases. The other significant positive correlations with major osteoporosis related fracture were HgA1c and triglyceride levels as depicted in the table below. The estimated GFR had a weak negative correlation with the 10-year probability of a major osteoporosis related fracture.

Table 5. The correlation between the 10-year probability of a major osteoporosis related fracture and independent variables of participants with type 1 diabetes age 40 years and above.

The correlation between the 10-year probability of a major osteoporosis related fracture and continuous independent variables		10-year probability of a Major osteoporosis-related fracture
Age	Pearson Correlation	.735**
	Sig. (2-tailed)	**.000**
	N	106
Duration of Diabetes	Pearson Correlation	.426**
	Sig. (2-tailed)	**.000**
	N	106
HgA1C in %	Pearson Correlation	.514**
	Sig. (2-tailed)	**.047**
	N	106
Triglyceride	Pearson Correlation	.999**
	Sig. (2-tailed)	**.000**
	N	106
eGFR by CKD-EPI equation	Pearson Correlation	-.191**
	Sig. (2-tailed)	**.050**
	N	106
**. Correlation is significant at the 0.01 level (2-tailed).		
*. Correlation is significant at the 0.05 level (2-tailed).		

5.5 The correlation between the 10-year probability of a hip fracture and independent variables

In this finding, age of the study participants had a significant positive relation at r (104) = 0.684, p=0.000. This implies that as age increases, the 10-year probability of a hip fracture increases. The duration of diabetes mellitus had a significant relation at r (104) =0.434, p=0.000, implying that as the duration of diabetes increases, the 10-year probability of a hip fracture increases. On the other hand, eGFR showed a weak negative relation with the 10-year probability of a hip fracture at r (104) =-0.192, p=0.048.

Table 6. The correlation between the 10-year probability of a hip fracture and independent variables of participants with type 1 diabetes age 40 years and above.

The correlation between probability of hip fracture and continuous independent variables		10-year probability of a Hip fracture
Age	Pearson Correlation	.684**
	Sig. (2-tailed)	**.000**
	N	106
Duration of Diabetes	Pearson Correlation	.434**
	Sig. (2-tailed)	**.000**
	N	106
eGFR by CKD-EPI equation	Pearson Correlation	-.192*
	Sig. (2-tailed)	**.048**
	N	106
**. Correlation is significant at the 0.01 level (2-tailed).		
*. Correlation is significant at the 0.05 level (2-tailed).		

5.6 The magnitude of osteoporosis among the study participants

The finding of the study revealed that the magnitude of osteoporosis was 15% as shown in the figure below.

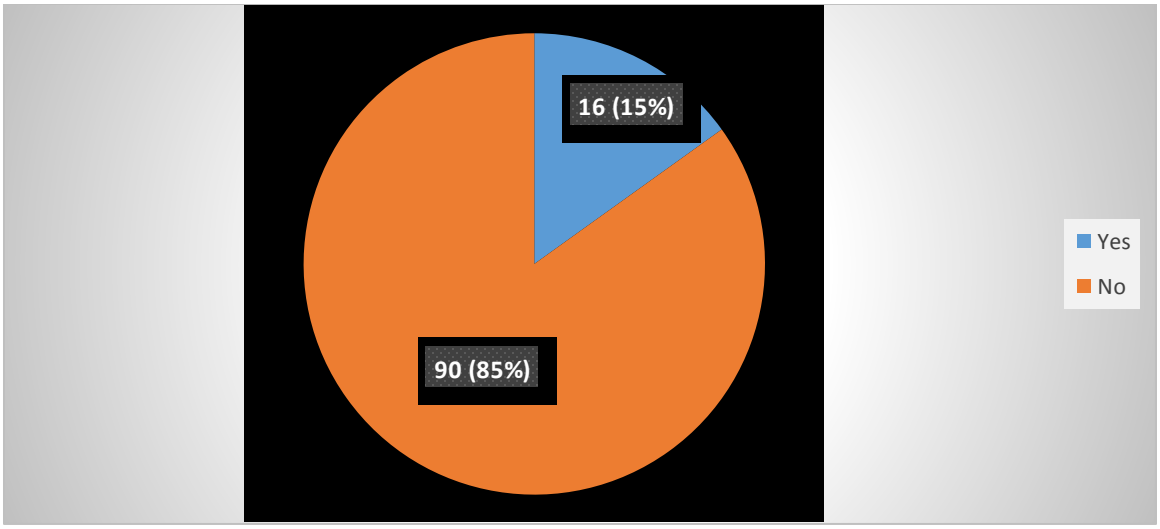

Figure 2. The magnitude of osteoporosis among participants with type 1 diabetes age 40 years and above.

5.7 Falls and Balance characteristics of the study participants

Fifteen percent of the study participants had ≥2 falls over the last 12 months and 13.2% had a high concern of falling on the short falls efficacy scale. One-fourth of the study participants were unable to maintain the 4 positions on the 4-stage balance test used to measure static balance.

Table 7. Falls and Balance characteristics of participants with type 1 diabetes age 40 years and above.

Variable	frequency	Percent
Frequent falls		
Yes	16	15.1
no	90	84.9
Short falls efficacy scale		
Low concern	59	55.7
Moderate concern	33	31.1
High concern	14	13.2
The 4-stage balance test		
Passed	79	74.5
Failed	27	25.5

5.8 The determinant factors leading to frequent falls among the study participants

The study revealed that participant having previous fragility fractures and osteoporosis were associated with frequent falls by bivariate logistic regression. The multivariable logistic regression showed that female participants had a 1.6-fold increased risk of frequent falls than males (AOR=1.6, 95%CI=1.42, 5.88) and participants who had a previous fragility fracture had a 1.8-fold increased risk of frequent falls compared to the opposite compartment (AOR=1.8, 95%CI=1.04, 9.27). Study participants with osteoporosis had a 4.1-fold increased risk of frequent falls compared to the opposite compartment (AOR=4.1, 95%CI=1.15, 16.49).

Table 8. The bivariate and multivariable logistic regression analysis of factors associated with frequent falls among participants with type 1 diabetes age 40 years and above.

Variable	frequency of fall		p-value	COR with 95%CI	P-value	AOR with 95%CI
	yes	No				
Sex						
Male	7	51	1		1	
female	9	39	0.142	1.7(0.58, 4.91)	0.049	**1.6(1.42, 5.88)**
Level of physical activity						
Vigorous	4	13	1		1	
Moderate	6	49	0.199	0.39(0.09, 1.62)	0.087	0.24(0.05, 1.23)
Sedentary	6	28	0.619	0.69(0.17, 2.89)	0.344	0.45(0.09, 2.35)
Comorbid disease						
Yes	14	66	0.238	2.5(0.54, 12.04)	0.343	2.2(0.43, 11.10)
no	2	24	1		1	

Previous fragility fracture						
Yes	5	9	0.029	4.1(1.16, 14.45)	0.042	**1.8(1.04, 9.27)**
no	11	81	1		1	
Osteoporosis						
Yes	6	10	0.011	4.8(1.44, 16.05)	0.043	**4.1(1.15, 16.49)**
No	10	80	1		1	
DM Neuropathy						
Yes	4	13	0.206	1.9(0.55, 7.07)	0.652	1.4(0.31, 6.59)
No	12	77	1		1	

5.9 Osteoporosis knowledge assessment of the study participants

In this study, 17% of the study participants had satisfactory knowledge about osteoporosis while 83% had poor knowledge. None of the participants had good knowledge about osteoporosis.

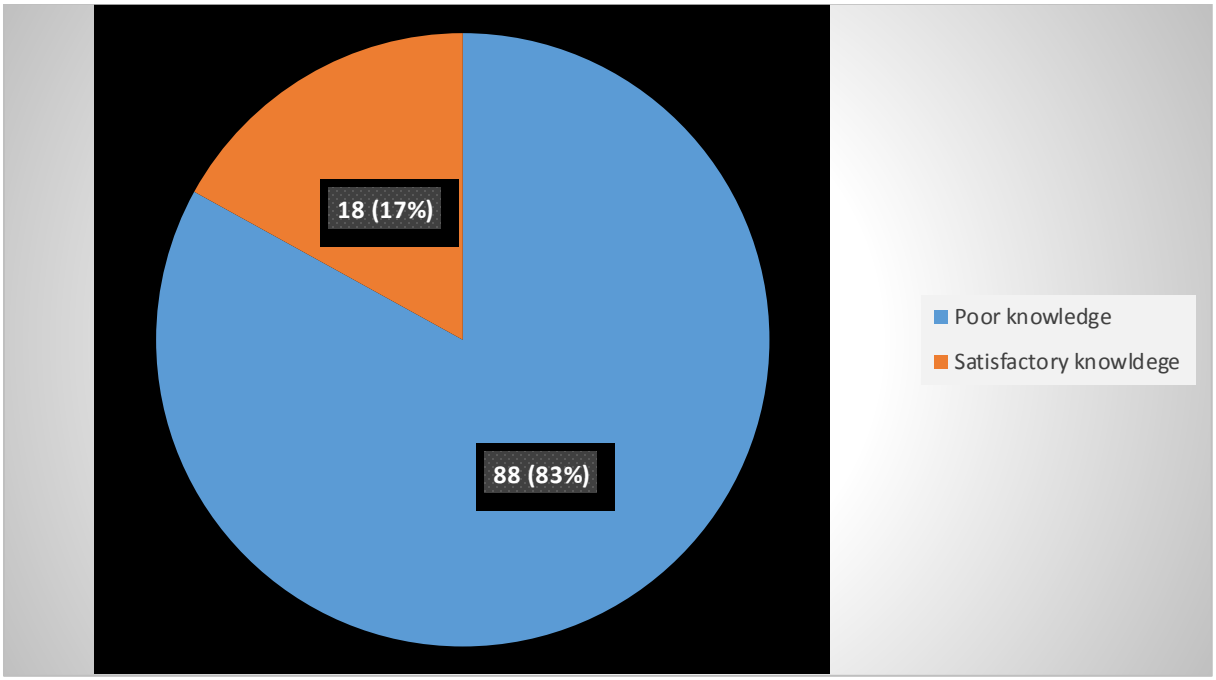

Figure 3. Osteoporosis knowledge assessment tool (OKAT) score of participants with type 1 diabetes age 40 years and above.

The study showed the mean OKAT score was 6.17±3.34, indicating poor osteoporosis-related knowledge. Among the 20 statements of the OKAT-derived questionnaire, the 1st statement "Osteoporosis leads to an increased risk of bone fractures" was the question that was answered correctly the most, while the 2nd statement "Osteoporosis usually causes symptoms (e.g. pain) before fractures occur" the least.

The majority of participants incorrectly answered 15 out of 20 questions on the OKAT (>50% of the participants gave the wrong answer for the questions). Concerning to the specific findings,

more than half of the participants know about the majority of women having osteoporosis by age 80 years, that an adequate calcium intake can be achieved from two glasses of milk a day and that sardines and broccoli are good sources of calcium for people who cannot take dairy products. One fifth of the participants believe there are no effective treatments for osteoporosis available in Ethiopia.

Table 9. Osteoporosis knowledge assessment tool results of participants with type 1 diabetes age 40 years and above.

Variable	Frequency (%)		
	Yes	No	Did not know
Osteoporosis leads to an increased risk of bone fractures.	**77(72.6) ***	5(4.7)	24(22.6)
Osteoporosis usually causes symptoms (e.g. pain) before fractures occur.	51(48.1)	**8(7.5) ***	47(44.3)
Having a higher peak bone mass at the end of childhood gives no protection against the development of osteoporosis in later life.	**16(15.1) ***	23(21.7)	67(63.2)
Osteoporosis is more common in men.	14(13.2)	**20(18.9) ***	72(67.9)
Cigarette smoking can contribute to osteoporosis.	**50(47.2) ***	4(3.8)	52(49.1)
White women are at highest risk of fracture as compared to other races.	**19(17.9) ***	23(21.7)	64(60.4)
A fall is just as important as low bone strength in causing fractures.	**68(64.2) ***	9(8.5)	29(27.4)
By age 80, the majority of women have osteoporosis.	**54(50.9) ***	5(4.7)	47(44.3)
From age 50, most women can expect at least one fracture before they die.	**41(38.7) ***	15(14.2)	50(47.2)
Any type of physical activity is beneficial for osteoporosis.	70(66)	**10(9.4) ***	26(24.5)
It is easy to tell whether I am at risk of osteoporosis by my clinical risk factors.	**37(34.9) ***	17(16)	52(49.1)
Family history of osteoporosis strongly predisposes a person to osteoporosis.	**23(21.7) ***	35(33)	48(45.3)
An adequate calcium intake can be achieved from two glasses of milk a day.	**54(50.9) ***	16(15.1)	36(34)
Sardines and broccoli are good sources of calcium for people who cannot take dairy products.	**55(51.9) ***	7(6.6)	44(41.5)
Calcium supplements alone can prevent bone loss.	24(22.6)	**38(35.8) ***	44(41.5)
Alcohol in moderation has little effect on osteoporosis.	**26(24.5) ***	33(31.1)	47(44.3)
A high salt intake is a risk factor for osteoporosis.	**23(21.7) ***	27(25.5)	56(52.8)
There is a small amount of bone loss in the ten years following the onset of menopause.	17(16)	**12(11.3) ***	77(72.6)
Hormone therapy prevents further bone loss at any age after menopause.	**9(8.5) ***	13(12.3)	84(79.2)
There are no effective treatments for osteoporosis available in Ethiopia.	23(21.7	**22(20.8) ***	61(57.5)

***Correct answers highlighted in bold.**

A significant difference (P=0.049) was found between the total score of OKAT and the educational level of the participants. It was observed that higher level of education was associated with a higher level of osteoporosis knowledge.

Table 10. The association of characteristics of patients with Type 1 Diabetes age 40 years and above with the total scores of OKAT.

Variable	Frequency	Percent	mean± SD	P-value
Age of the study participants in years				0.313
40-44	50	47.2	6.54±3.08	
45-49	28	26.4	5.57±3.51	
50-54	17	16	5.65±4.35	
55-59	4	3.8	7±4.24	
60-64	3	2.8	6.33±4.62	
≥65	4	3.8	7±4.83	
Sex of the study participants				0.438
Male	58	54.7	6.07±3.19	
Female	48	45.3	6.29±3.54	
Residence of the study participants				0.376
Urban	98	92.5	6.14±3.32	
Rural	8	7.5	6.50±3.74	
Marital status of the study participants				0.336
Single	19	17.9	7.26±2.96	
Married	75	70.8	6.04±3.24	
Divorced	9	8.5	5.78±4.02	
widowed	3	2.8	3.67±5.51	
Educational level of the study participants				**0.049**
No formal education	2	1.9	5.50±4.95	
Primary education	30	28.3	7.37±3.01	
Secondary education	38	35.8	5.29±3.31	
Higher education	36	34	6.14±3.40	
Occupation of the study participants				0.824
Government employee	28	26.4	5.39±3.19	
Self-employee	44	41.5	6.43±3.43	
Homemaker	12	11.3	7.42±3.03	
Farmer	1	0.9	8.0	
Pensioner	4	3.8	6.50±3.36	
unemployed	17	16	5.71±3.42	
Household monthly income in birr				0.853
no income	14	13.2	5.29±3.15	
500-5000	47	44.3	6.55±3.56	
5000-10000	27	25.5	5.63±3.39	
≥10000	18	17.0	6.67±2.77	

5.10 Determinants of osteoporosis among the study participants

In this study, the strength of association was measured by using odd ratio and 95% confidence interval. Accordingly, alcohol utilization, visual impairment, diabetic eye complications and frequent falls were associated with osteoporosis by bivariate logistic regression. The multivariable logistic regression revealed that study participants who were female had a 1.8-fold increased risk of osteoporosis compared to males (AOR=1.8, 95%CI=1.41, 7.69), study participant who drink more than three units of alcohol per day had a 5.7-fold increased risk of osteoporosis compared to those who consume less alcohol (AOR=5.7, 95%CI=1.69, 47.38) and study participant having diabetic eye complications had a 4.7-fold increased risk of osteoporosis compared to the opposite compartment (AOR=4.7, 95%CI=1.91, 24.35). The study participants who had frequent falls had a 5.6-fold increased risk of osteoporosis compared to the opposite compartment (AOR=5.6, 95%CI=1.19, 26.15).

Table 11. The bivariate and multivariable logistic regression analysis of factors associated with osteoporosis of participants with type 1 diabetes age 40 years and above.

Variable	Osteoporosis		p-value	COR with 95% CI	P-value	AOR 95% CI
	yes	No				
Sex of the study participants						
Male	7	51	1		1	
female	9	39	0.142	1.7(0.57, 4.91)	0.041	**1.8(1.41, 7.69)**
Residence						
Urban	15	83	1		1	
rural	1	7	0.132	0.79(0.09, 6.89)	0.962	1.1(0.08, 14.46)
Monthly income						
No income	3	11	1		1	
500-5000	11	36	0.877	1.2(0.26, 4.75)	0.589	0.62(0.11, 3.48)
5000-10000	2	25	0.212	0.29(0.04, 2.01)	0.220	0.27(0.03, 2.20)
>10000	0	18				
Total cholesterol						
<200mg/dl	14	71	1			
≥200mg/dl	2	19	0.132	0.53(0.11, 2.56)	0.339	0.39(0.06, 2.71)
More than 3 units of alcohol/day						
Yes	3	7	0.018	2.7(1.64, 11.94)	0.016	**5.7(1.69, 47.38)**
No	13	83	1		1	
Neuropathy						
Yes	4	13	0.296	1.9(0.55, 7.07)	0.422	1.9(0.37, 10.43)
no	12	77	1		1	
Visual impairment						
Yes	7	30	0.023	1.6(0.53, 4.58)	0.850	1.2(0.29, 4.39)

No	9	60	1		1	
Diabetic eye complication						
Yes	12	43	0.043	3.3(1.98, 10.94)	0.042	**4.7(1.91, 24.35)**
No	4	47	1		1	
Frequent falls						
Yes	6	10	0.011	4.8(1.44, 16.05)	0.029	**5.6(1.19, 26.15)**
No	10	80	1		1	
Four-stage balance test						
Passed	11	68	1		1	
Failed	5	22	0.166	1.4(0.44, 4.49)	0.713	0.75(0.16, 3.46)

6. Discussion

Our research showed the magnitude of osteoporosis in patients with Type 1 diabetes was 15%. Factors associated with osteoporosis were female gender, excess alcohol use, diabetic eye complications and frequent falls. Only two participants had a high FRAX fracture risk score while 13.2% had a history of previous fragility fracture. Age and duration of diabetes had a positive association and eGFR had a negative relation with the 10-year probability of major osteoporosis related and hip fracture. Fifteen percent of the study participants had frequent falls and 13.2% had a high concern of falling. Being female, having previous fragility fractures and osteoporosis were associated with frequent falls. Eighty-three percent had poor knowledge about osteoporosis with the mean OKAT score of 6.17±3.34. A higher level of education was associated with a higher level of osteoporosis knowledge.

The magnitude of osteoporosis in patients with Type 1 diabetes was 15% in this study. A systematic review estimated the global & African prevalence of osteoporosis to be 19.7% and 26.9% respectively. Another meta-analysis reported the worldwide prevalence of osteoporosis to be 18.3% with the highest prevalence of 39.5% found in Africa (59,60). These reviews indicate a substantial prevalence of osteoporosis among the general population which is significantly higher than the findings in our study, despite an increased magnitude being anticipated considering the older age of the participants and the presence of secondary causes of osteoporosis like Type 1 diabetes.

Our finding was similar to a study done in Germany where 15.8% of the participants with type 1 diabetes had osteoporosis (38). Eller-Vainicher and coauthors found about 30% of 175 type 1 diabetes patients had low bone mass (osteopenia/osteoporosis) at spine and/or femur (54). A study in India also showed individuals with type 1 diabetes had a lower BMD as compared to controls (39). Nevertheless, the number of patients with osteopenia included in these 2 studies and the use of DXA scan as a means of diagnosis may be reasons for which the magnitude in our study was comparatively lower.

Macrovascular complications of diabetes were not as common as expected even though the duration of diabetes of close to all the participants exceeded 10 years. Diabetic eye complications were the most common diagnosed microvascular complications among the participants, though

two-thirds of them had persistent proteinuria, among which only 16% were diagnosed and on follow up while the rest remained undiagnosed.

The age of participants and duration of diabetes had a positive correlation with the 10-year probability of major osteoporosis related & hip fractures. Similarly, age modified the effect of diabetes on hip fracture risk in a 2021 study (57). On the other hand, the estimated GFR had a negative correlation with the 10-year probability of major osteoporosis related & hip fractures. This indicates complications like CKD having a positive impact on fracture risk. A few studies addressed nephropathy, reporting lower BMD in patients with albuminuria than without. (26,34,35,56,72) A study done in Italy showed mildly reduced kidney function was independently associated with low femur BMD in patients with type 1 diabetes, showing the importance for bone loss at the femur in type 1 diabetes. (54) This could also be considered an impact of the increased duration of diabetes on the fracture risk, though the other complications did not show any correlation (28,33). More than half of the study participants had an increased body mass index which may reduce fracture risk, though not significantly associated. Elsewhere, BMI was found to significantly ameliorate the increase in fracture risk (26,35,54,56).

In our study, only 1.9% of the participants had an increased risk of fracture based on the FRAX score while 13.2% had a history of previous fragility fracture. The overall rate of osteoporotic fractures was 10.4% of all patients presenting to Tikur Anbessa Specialized Hospital with fractures between January 2018 and December 2021 (63). Another hospital-based study in Tigray found the overall prevalence of osteoporotic fractures was 9.3%. (64) Although both studies indicate similar findings, they were done in non-diabetic individuals. A 2019 Italian study reported 18.5% of patients with type 1 diabetes had at least one fragility fracture. (70)

Considering the discrepancy between the FRAX scores and previous fragility fractures of the patients, one possibility is FRAX underestimates fracture risk in this population group. Individuals with diabetes mellitus have an excessive risk of hip fractures, and this relationship is more pronounced in type 1 diabetes (27). Elevated prevalence of asymptomatic vertebral fractures was associated with the presence of type 1 diabetes independently of BMD (65). Diabetes status was also found to be predictive of future hip and major osteoporotic fractures independent of FRAX probability and its associated risk factors including BMD. Additionally, FRAX does not incorporate risk factors for falls, which may explain the higher fracture risk for any given FRAX-

based probability in diabetics (57). There is compelling evidence that bones in patients with type 1 diabetes are characterized by poor mineralization and smaller and thinner size with reduced bone strength and quality, which can lead to a higher fracture incidence at any site, predominantly at femoral neck. (56)

Fifteen percent of the study participants had ≥2 falls over the last 12 months and 13.2% had a high concern of falling on the short falls efficacy scale. Twenty-nine percent of participants with type 1 diabetes reported falls within the past 12 months and 41% participants were fearful of falls in a US study (41). The risk of falls in patients with diabetes was found to be 39% in another study (43). This difference is mainly due to the age of the participants being over 65 years, as a third of this population sustain falls yearly with over 50% having recurrent falls (42,67). Additionally, approximately 1 in 10 falls result in trauma or fracture. Although done in patients with type 2 diabetes, a study showed an association with increased fear of falling and fear-associated activity restriction, which modified the risk of falls even in the face of increased falls risk factors (68).

One-fourth of the study participants had difficulties maintaining their balance during static balance assessment. Abnormalities of balance and gait were shown to be common risk factors for falls among community-dwelling older persons and those with type 2 diabetes (42,45,67,69). Studies evaluating balance characteristics of patients with type 1 diabetes are lacking.

On multivariable analysis, female participants, those with previous fragility fractures and osteoporosis were found to have increased risk of frequent falls. Falls occurred more frequently in female patients with diabetes in a study from the United Kingdom (43). Being fearful of falls in patients with type 1 diabetes was reported from a Danish study, with diabetes related complications, hypoglycemic events, and antihypertensive treatment all leading to falls (21).

Severe hypoglycemia, diabetic peripheral neuropathy, and depression were associated with falls in adults with type 1 diabetes in the US (41). However, this was not apparent in this study. Since all the participants had type 1 diabetes, treatment with & use of a higher dose of insulin can be one of the reasons for greater risk of falls, since there is a strong association between the two in previous studies. (43,44)

This study confirmed a relevant knowledge deficit among patients with type 1 diabetes, with 83% having poor knowledge about osteoporosis. Similarly, the Osteoporosis Knowledge Test (OKT)

was used to assess 300 patients with diabetes in Palestine and found poor knowledge in the majority with females having a significantly higher overall OKT score (49). An Australian study using the Osteoporosis Knowledge Assessment Tool (OKAT), the same tool used in our study, found levels of osteoporosis knowledge were low in Australian 25–44-year-old females with a mean score of 8.8 out of 20 (75). A similar study in Cambodia using the OKAT found the average mean score was 9.34 (±3.08) out of 20 and correlated significantly with educational level (74). A study in Indian postmenopausal women using the OKAT also showed 60% had poor knowledge about osteoporosis (48).

A study done in post-menopausal women in Metu, Ethiopia, showed 61.6% of the participants had inadequate knowledge towards the prevention of osteoporosis. Being younger, employed, better educated, having a personal and family history of osteoporosis and getting information from families and friends increased the odds of having adequate knowledge (62). Similarly, an Iraqi study found that there was a low level of knowledge about risk factors, causes, symptoms, diagnosis, treatment, and prevention of osteoporosis for patient with diabetes mellitus (66), which was quite similar to our findings. A Hungarian study using the OKAT found the average mean score was 9.99 ± 4.04 out of 20 in non-health care professional young women and correlated significantly with age, educational level and health care professionals (76). We also observed that higher level of education was associated with a higher level of osteoporosis knowledge. The findings between the studies may reflect of our own but the studied populations were young or post-menopausal females in most.

The multivariable analysis of this study identified four factors as independent determinants of osteoporosis among the study participants with Type 1 DM. Being female, excess alcohol use, presence of diabetic eye complications and frequent falls increased the risk of osteoporosis.

The relationship between female sex and increased risk of osteoporosis was in agreement with studies from USA (15), France (55) and Ethiopia (63) but not with one done in Sweden (72) where both men and women with type 1 diabetes were at increased risk for hip fracture. Older age and post-menopausal state could be the reasons behind this finding.

Similar to our study, other researchers have reported increased risk of osteoporosis with excess alcohol use (36,47) and frequent falls (15,16).

The presence of diabetic eye complications was positively associated with developing osteoporosis which was concordant with multiple studies (26,28,35,72,73) but not with a Danish study (71) that indicated the entire complex of diabetes with complications to be the reason for the increase in risk of fractures rather than the diabetic eye disease, which was just one of the markers of complicated diabetes. Compensatory mechanisms (e.g., laser treatment, glasses) may also have ameliorated some of the consequences of impaired vision.

In a study done in Tigray among the general population, rural residence and smoking were positively associated with osteoporosis. In contrast, milk intake greater than four times a week, and when work involves vigorous exercise, appeared to be associated with a reduced risk of osteoporosis (61). But these factors were not associated with osteoporosis in our study.

Other researchers have reported increased risk of osteoporosis with increased daily insulin dose (54,55,71) but not in our study. A higher insulin dose may reflect the presence of difficult to control diabetes with a more pronounced inflammatory milieu, possibly leading to bone damage.

This was the first comprehensive assessment of osteoporosis risk factors, knowledge and falls in patients with type 1 diabetes age 40 years and above in Ethiopia. This study confirmed the presence of a higher magnitude of osteoporosis, falls and a relevant knowledge deficit among patients with type 1 diabetes age 40 years and above.

Although optimal preventive measures still need to be defined, the co-occurrence with other diabetes complications suggests that tighter metabolic control might reduce the risk (70,71,72).

7. Conclusion

In conclusion, type 1 diabetes carries an increased risk of osteoporosis, falls and fractures. Being female, having previous fragility fractures and osteoporosis had a positive association with frequent falls, whereas being female, excess alcohol use, diabetic eye complications and frequent falls were independent determinants of osteoporosis. A significant osteoporosis knowledge deficit was also seen among the participants with a higher level of education being positively associated. A high concern of falling with difficulties maintaining balance were other concerning outcomes.

8. Limitations

Being the first study in this context, there are a few limitations. First, bone turnover markers and BMD were not used for osteoporosis diagnosis which may cause us to miss patients with the clinical tools. Second, the study was carried out in a single center and the sample size was limited affecting the representativeness. Third, the study is subjected to social desirability bias as the questionnaire contained some sensitive questions about behavioral risk factors for osteoporosis and recall bias as certain questions relied on self-reported data. Finally, lack of prior research studies on the topic, sampling technique used and a large number of participants who refused to give consent could be additional considerations.

9. Recommendations

The untreated population of individuals with osteoporosis is referred to as 'The Osteoporosis Treatment Gap' and recent studies have sought to introduce interventions to reduce it. An example could be the use of fracture risk assessment tools (such as FRAX), which use clinical variables to provide a measure of fracture risk and assist clinicians in identifying 'at risk' individuals. Although alone it cannot do much, it must be paired with a screening program. Following screening, risk stratification based on WHO recommendations should be done to determine interventions (58). Given the findings, there may be public health benefits in targeting this population group. In addition to prioritization of screening for osteoporosis during routine visits, education regarding prevention and treatment modalities could achieve a reduction in osteoporosis-related complications like fracture.

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Annexes

Annex 1: Information sheet

I, the undersigned, want to do a study on the magnitude of osteoporosis and its associated factors among patients with type 1 diabetes mellitus. The elevated risk of this patient group and unknown magnitude of this problem in our setup gave rise to research concern. The clinical data will be collected using a structured questionnaire.

I agree to accept responsibilities for:

- The scientific, ethical and technical conduct of the research project,
- Requesting amendment for ANY change on the protocol that might need to happen during execution of the project, and obtain written approval for the request from Department of Internal Medicine-IRB,
- Submitting scientific publications that emanate from the project, and
- Reporting any unprecedented protocol violation within seven days of the event if the project is approved as a result of this application.

Postgraduate Candidate: Paulos Efrem

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Signature: ……

Date of Submission: December 14, 2023

This thesis has been submitted with my approval as advisor.

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Signature: ……

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Addis Ababa, Ethiopia.

Annex 2: Informed consent form

You are invited to take part in this research as your age is 40 years and above and you are living with type 1 diabetes. There will be 106 individuals taking part in this research. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully and feel free to ask if it is not clear or to discuss it with anyone you wish. Please take time to decide whether you want to take part in this research. We would like to stress that taking part in this study is entirely voluntary, you can refuse to take part in this study, or you can withdraw your participation from the study at any time without any consequences to you.

Patients with type 1 diabetes have a lower bone mineral density leading to a 6-fold higher risk of fracture compared to healthy subjects, justifying the classification of the disease as a non-modifiable risk factor for osteoporosis. Data on osteoporosis and related factors in patients with type 1 diabetes in Ethiopia, Africa, and other low- and middle-income countries are lacking. These observations and the unknown extent of this problem in our setup raised these research concerns.

The objectives of this study are to determine the risk factors of osteoporosis and falls, their association, and knowledge in patients with Type 1 Diabetes Mellitus age 40 years and above.

The research will be conducted from June 1 to August 31, 2023GC. Data will be collected through structured questionnaires.

If you decide to take part in this study, you will be asked to complete the questionnaire administered at your respective clinic.

All data collected from the study will be kept confidential. Presentations of the study's results at meetings/conferences or their publication in a scientific journal will not include your name.

There will be no payment for participation in this study.

If you have any questions related to the study before/during participation in the study, you can consult the contact person listed below.

1. Paulos Efrem (MD, Internist, Endocrinology Fellow)

   Phone: +251 703 859 692

   Email: paulos.efrem@aau.edu.et

Certificate of Consent I have read the foregoing information. I have had an opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily consent to participate in this research study. _____ Initials of the participant _____ Signature of the participant Date _____ day/month/year	 I confirm that the participant was given an opportunity to ask questions about the study and all the questions have been answered correctly. I confirm that my consent has been given voluntarily. _____ Printed name of the person taking the consent _____ Signature of the person taking the consent Date _____ day/month/year

አባሪ 2፡ በመረጃ የተደገፈ የፈቃድ ቅጽ

እድሜዎት 40 አመትና ከዚያ በላይ የሆነ እና ከአይነት 1 የስኳር ህመም ጋር ስለሚኖሩ በዚህ ጥናት ላይ እንዲሳተፉ ተጋብዘዋል። በዚህ ጥናት ውስጥ 106 ግለሰቦች ይሳተፋሉ። ከመወሰንዎ በፊት ጥናቱ ለምን እንደሚደረግ እና ምን እንደሚያካትት መረዳት ለእርስዎ አስፈላጊ ነው። እባክዎ የሚከተለውን መረጃ በጥንቃቄ ያንብቡ እና ግልጽ ካልሆነ ለመጠየቅ ወይም ከሚፈልጉት ሰው ጋር ለመወያየት ነፃነት ይሰማዎ። በዚህ ጥናት ውስጥ ለመሳተፍም ወይም ላለመሳተፍም ለመወሰን ጊዜ ይውሰዱ። በዚህ ጥናት ውስጥ መሳተፍ ሙሉ በሙሉ በፈቃደኝነት ላይ የተመሰረተ መሆኑን ልናሳስብ እንወዳለን፣ በዚህ ጥናት ላይ አለመሳተፍም ትችላላችሁ ወይም በማንኛውም ጊዜ ተሳትፎዎን ከጥናቱ ማንሳት ይችላሉ። ይህ በእናንተ ላይ የሚያመጣው ምንም አይነት ችግር አይኖርም።

አይነት 1 የስኳር በሽታ ያለባቸው ታካሚዎች ዝቅተኛ የአጥንት ማዕድን መጠን ይኖራቸዋል። ይህም ከጤናማ ሰዎች ጋር ሲነፃፀሩ በ 6 እጥፍ ከፍ ያለ የአጥንት መሰበር እድላቸው እንዲፈጠር ምክንያት በመሆኑ በሽታው ለአጥንት መሳሳት ከማይስተካከሉ መንስኤዎች መካከል መሆኑን ያረጋግጣል። በኢትዮጵያ፣ በአፍሪካ እና በሌሎች ዝቅተኛ እና መካከለኛ ገቢ ባላቸው አገሮች ውስጥ ዓይነት 1 የስኳር በሽታ ላለባቸው ታካሚዎች የአጥንት መሳሳት በሽታ እና ተያያዥ ምክንያቶች ላይ የመረጃ እጥረት አለ። እነዚህ ምልከታዎች እና የዚህ ችግር መጠን ያልታወቀ መሆኑ በእኛ መዋቅር ውስጥ እነዚህን የምርምር ጥያቄዎችን አስነስቷል።

የዚህ ጥናት ዓላማዎች አይነት 1 የስኳር በሽታ ባለባቸው ታካሚዎች ላይ የአጥንት ማዕድን መጠን መቀነስ እና የአጥንት መሳሳት በሽታን መጠን እና ተያያዥ ምክንያቶችን ለመወሰን እንዲሁም የመሰበር አደጋን መገምገም ናቸው።

ጥናቱ ከሰኔ 1 እስከ መስከረም 30 ቀን 2015 ዓ.ም. በመረጃ መጠይቆች ይሰበሰባል።

በዚህ ጥናት ላይ ለመሳተፍ ከወሰኑ በስኳር ህመም ክሊኒክ ጉብኝትዎ ጊዜ የሚሰጠውን መጠይቅ እንዲሞሉ ይጠየቃሉ።

በጥናቱ የተሰበሰቡ ሁሉም መረጃዎች በሚስጥር ይቀመጣሉ። የጥናቱ ውጤት በጥናታዊ ስብሰባዎች ላይ ወይም በሳይንሳዊ መጽሄት ላይ በሚታተሙበት ጊዜ የተሳታፊውን ስም አያካትቱም።

በዚህ ጥናት ውስጥ ለመሳተፍ ምንም ክፍያ አይኖርም።

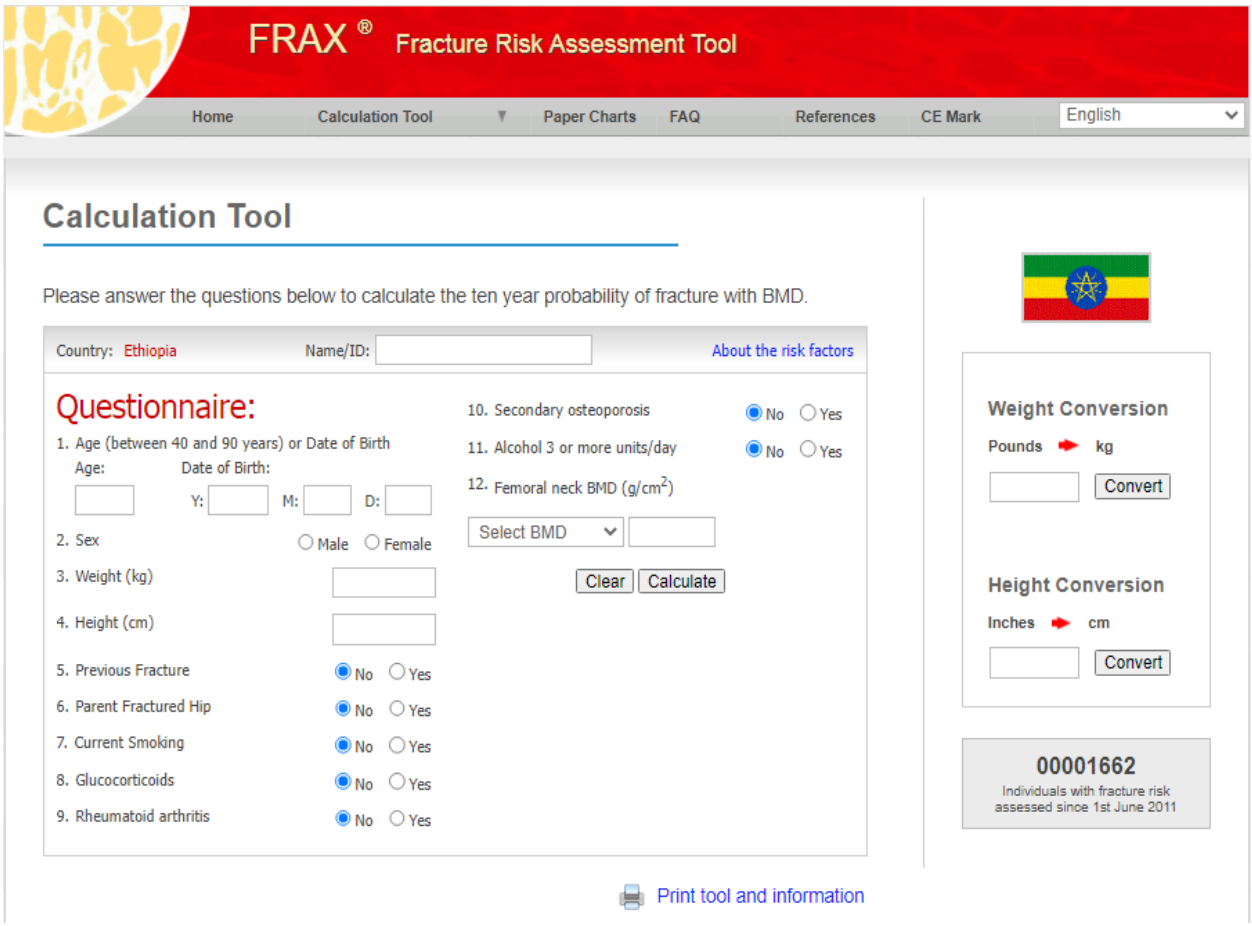
በጥናቱ ከመሳተፍዎ በፊት/በመሳተፍ ከጥናቱ ጋር የተያያዙ ማንኛቸውም ጥያቄዎች ካሉዎት ከዚህ በታች የተመለከተውን ሰው ማማከር ይችላሉ።

1. ዶ/ር ጳውሎስ ኤፍሬም

ስልክ፡ +251 703 859 692 ኢሜል፡ paulos.efrem@aau.edu.et

የፍቃድ የምስክር ወረቀት ከላይ ያለውን መረጃ አስቀድሜ አንብቤዋለሁ። ጥያቄዎችን ለመጠየቅ እድል አግኝቻለሁ እናም ሁሉም ጥያቄዎቼ መልስ አግኝተውኛል። በዚህ የምርምር ጥናት ለመሳተፍ በፈቃዴ ተስማምቻለሁ። _____ የተሳታፊው ስም ፊደሎች _____ የተሳታፊው ፊርማ ቀን _____ ቀን / ወር / ዓመት	ተሳታፊው ስለ ጥናቱ ጥያቄዎችን ለመጠየቅ እድል እንደተሰጠው እና ሁሉም ጥያቄዎች በትክክል እንደተመለሱ አረጋግጣለሁ።. ስምምነቱን በፈቃደኝነት መሰጠቱን አረጋግጣለሁ። _____ ፈቃዱን የወሰደው ሰው ስም _____ ፈቃዱን የወሰደው ሰው ፊርማ ቀን _____ ቀን / ወር / ዓመት

Annex 3: Fracture Risk Assessment Tool (FRAX)



Annex 4: Questionnaire on the Magnitude of osteoporosis and its associated factors among patients with type 1 diabetes mellitus

Code _____

I-care number _____ Date of interview _____/2023

Section 1: Demographics

1. Age? _____years
2. Gender?
    a. Male
    b. Female
3. Residence?
    a. Urban
    b. Rural
4. Current marital status?
    a. Single
    b. Married
    c. Divorced
    d. Widowed
5. What is your level of education?
    a. No formal education
    b. Primary school
    c. Secondary school
    d. Higher education
6. What is the occupation you practiced over the past 12 months?
    a. Government employee
    b. Self-employed
    c. Homemaker
    d. Farmer
    e. Pensioner
    f. Unemployed
7. What is your average household monthly income? _____Birr

Section 2: Diabetes History

8. How long have you had diabetes? ____ years
9. How old were you when you were diagnosed with diabetes? _____years
10. What type of treatment are you currently taking for your diabetes? Choose all that apply.
    a. Insulin (_____years)
    b. SGLT2i (_____years)
    c. Other, specify _____
11. Which type of insulin do you use?
    a. NPH only
    b. NPH with Regular insulin
    c. Glargine insulin with Regular insulin
    d. Mixed insulin
    e. Other, specify_____
12. What is your total daily dose of insulin? _____IU

Section 3: Physical Examination & Laboratory Results

13. Weight _____Kg
14. Height _____cm
15. BMI _____kg/m^2
16. SBP _____mmHg
17. DBP _____mmHg
18. Recent hemoglobin A1C _____%
19. Recent FBS_____mg/dl
20. Total serum cholesterol _____mg/dl
21. Serum HDL cholesterol _____mg/dl
22. Serum LDL cholesterol _____mg/dl
23. Serum triglycerides _____mg/dl
24. Serum creatinine _____mg/dl
25. 24-hour urine protein excretion _____mg

Section 4: Osteoporosis Risk Factors

26. Physical activity level
    a. Vigorous (75 minutes a week eg. running)
    b. Moderate (150 minutes a week eg. Walking at a fast pace)
    c. How much time do you spend sitting on a usual day? (home, work, transportation) _____hours
27. Smoking status?
    d. Never
    e. Ex-smoker. Smoked _____ cigarettes daily, for _____years
    f. Current smoker. Smoke _____ cigarettes daily, for _____years
28. Do you consume more than 3 units of alcohol a day?
    g. Yes
    h. No
29. Self-reported history of medical conditions (ever), Choose all that apply.
    a. Osteogenesis imperfecta
    b. Untreated long-standing hyperthyroidism
    c. Hypogonadism
    d. Malabsorption
    e. Chronic liver disease
    f. Rheumatoid arthritis
    g. Hypertension
    h. Dyslipidemia
    i. Epilepsy
    j. Menopause, if yes, age at menopause _____ years
    k. None of the above
30. Current medications (Use of medication within the past year), Choose all that apply.
    a. Osteoporosis prevention or treatment
    b. Anticonvulsants
    c. Aromatase inhibitors
    d. Thiazide diuretics
    e. Loop diuretics

f. Oral contraceptives
g. Hormone replacement therapy
h. Testosterone
i. Oral glucocorticoids: currently taking or exposed for 3 months at a dose of prednisolone 5mg PO/day
j. Proton pump inhibitors
k. Thyroid replacement
l. SGLT2 inhibitors or Metformin
m. None of the above

FRAX - Fracture Risk Assessment Tool

No.	Risk Factors	Response	
1	Age ***see above**		
2	Sex ***see above**	Male ☐	Female ☐
3	Weight (in Kg) ***see above**		
4	Height (in cm) ***see above**		
5	*Previous fragility fracture (arising from trivial trauma)*	Yes ☐	No ☐
6	*Parent fractured hip*	Yes ☐	No ☐
7	Current smoking ***see above**	Yes ☐	No ☐
8	Glucocorticoids (currently taking or exposed for 3 months at a dose of prednisolone 5mg PO/day) ***see above**	Yes ☐	No ☐
9	Rheumatoid Arthritis ***see above**	Yes ☐	No ☐
10	Secondary Osteoporosis **(Yes for all- Type 1 DM)**	**Yes** √	No ☐
11	Alcohol 3 or more units/day ***see above**	Yes ☐	No ☐
12	*BMD femoral neck (g/cm^2)* **#if available**		

The 10-year probability of **(calculated)** Major osteoporosis-related fracture _____%

Hip fracture_____%

Section 5: Acute & Chronic Diabetes Complications

31. Any neuropathy?
    a. Yes, review chart _____
    b. No
32. If no previous assessment, do Monofilament test – assess 10 sites/foot & if no response at 4 sites Positive)
    a. Positive
    b. Negative
33. Any visual impairment?
    a. Yes
    b. No
34. Any diabetic eye complications?
    a. Yes, specify 1. Diabetic retinopathy 2. Cataracts 3. Glaucoma
    b. No
35. Any nephropathy?
    a. Yes, review chart _____
    b. No

36. Any PAD?
    a. Yes, review chart _____
    b. No
37. Any Coronary Heart Disease?
    a. Yes, review chart _____
    b. No
38. Any Cerebrovascular Disease?
    a. Yes, review chart _____
    b. No
39. Any recent hypoglycemia?
    a. Level 1 (mild) - between 54 – 69mg/dl or shaking, sweating, rapid heartbeat, increased hunger
    b. Level 2 (moderate) - less than 54mg/dl or confusion, irritability, sleepiness
    c. Level 3 (severe) - loss of consciousness, seizure, coma or requiring help from others

Section 6: Falls & Balance Assessment

40. Frequent falls (≥2 falls in the past 12 months)?
    a. Yes
    b. No

Short Falls Efficacy Scale International (FES-I)

Now we would like to ask some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently do not do the activity, please answer to show whether you think you would be concerned about falling IF you did the activity. For each of the following activities, please tick the box which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

		Not at all concerned 1	*Somewhat concerned 2*	*Fairly concerned 3*	*Very concerned 4*
1	Getting dressed or undressed	*1* ☐	*2* ☐	*3* ☐	*4* ☐
2	Taking a bath or shower	*1* ☐	*2* ☐	*3* ☐	*4* ☐
3	Getting in or out of a chair	*1* ☐	*2* ☐	*3* ☐	*4* ☐
4	Going up or down stairs	*1* ☐	*2* ☐	*3* ☐	*4* ☐
5	Reaching for something above your head or on the ground	*1* ☐	*2* ☐	*3* ☐	*4* ☐
6	Walking up or down a slope	*1* ☐	*2* ☐	*3* ☐	*4* ☐
7	Going out to a social event (e.g. religious service, family gathering or club meeting)	*1* ☐	*2* ☐	*3* ☐	*4* ☐

Total Score _____

The 4-Stage Balance Test

Instructions to the patient

- I am going to show you four positions
- Try to stand in each position for 10 seconds
- You can hold your arms out, or move your body to help keep your balance, but do not move your feet
- For each position I will say, "Ready, begin." Then, I will start timing. After 10 seconds, I will say, "Stop."

	1. Stand with your feet side-by-side	Time:_____seconds
	2. Place the instep of one foot so it is touching the big toe of the other foot.	Time:_____seconds
	3. Tandem stand: Place one foot in front of the other, heel touching toe.	Time:_____seconds
	4. Stand on one foot.	Time:_____seconds

If the patient can hold a position for 10 seconds without moving their feet or needing support, go on to the next position.

If not, STOP the test.

Patients should not use an assistive device (cane or walker) and they should keep their eyes open.

Section 7: The Osteoporosis Knowledge Assessment Tool (OKAT)
Please answer each of the following questions with True, False or Don't know.

No.	Question	True	False	Do not know
1	Osteoporosis leads to an increased risk of bone fractures.			
2	Osteoporosis usually causes symptoms (e.g. pain) before fractures occur.			
3	Having a higher peak bone mass at the end of childhood gives no protection against the development of osteoporosis in later life.			
4	Osteoporosis is more common in men.			
5	Cigarette smoking can contribute to osteoporosis.			
6	White women are at highest risk of fracture as compared to other races.			
7	A fall is just as important as low bone strength in causing fractures.			
8	By age 80, the majority of women have osteoporosis.			
9	From age 50, most women can expect at least one fracture before they die.			
10	Any type of physical activity is beneficial for osteoporosis.			
11	It is easy to tell whether I am at risk of osteoporosis by my clinical risk factors.			
12	Family history of osteoporosis strongly predisposes a person to osteoporosis.			
13	An adequate calcium intake can be achieved from two glasses of milk a day.			
14	Sardines and broccoli are good sources of calcium for people who cannot take dairy products.			
15	Calcium supplements alone can prevent bone loss.			
16	Alcohol in moderation has little effect on osteoporosis.			
17	A high salt intake is a risk factor for osteoporosis.			
18	There is a small amount of bone loss in the ten years following the onset of menopause.			
19	Hormone therapy prevents further bone loss at any age after menopause.			
20	There are no effective treatments for osteoporosis available in Ethiopia.			

Total Score _____

Thank you for your time.

አባሪ 3፡ አይነት 1 የስኳር በሽታ ባለባቸው ታካሚዎች መካከል የአጥንት መሳሳት መጠን እና ተያያዥ ምክንያቶች መጠይቅ

ኮድ _____ የሲስተም ካርድ ቁጥር _____ መጠይቅ የተደረገበት ቀን _____

ክፍል 1፡ የስነ ሕዝብ አወቃቀር

1. ዕድሜ? _____ ዓመት
2. ጾታ? (በማየት ይመዝግቡ)
    1. ወንድ
    2. ሴት
3. የመኖሪያ ቦታ?
    1. ከተማ
    2. ገጠር
4. አሁን ያለው የጋብቻ ሁኔታ?
    1. ያላገባ/ች
    2. ያገባ/ች
    3. የተፋታ/ች
    4. ባል/ሚስት የሞተበት/ባት
5. የትምህርት ደረጃዎን ይግለጹ?
    1. አልተማርኩም
    2. የመጀመሪያ ደረጃ
    3. ሁለተኛ ደረጃ
    4. ከፍተኛ ትምህርት
6. የስራዎ ሁኔታ ባለፉት 12 ወራት ምንድን ነበር?
    1. የመንግሥት ሠራተኛ
    2. የግል ስራ
    3. የቤት እመቤት
    4. ገበሬ
    5. ጡረተኛ
    6. ስራ አልነበረኝም
7. የቤተሰብዎ አማካይ ወርሃዊ ገቢ ስንት ነው? _____ብር

ክፍል 2፡ የስኳር በሽታ ታሪክ

8. ለምን ያህል ጊዜ ከስኳር ህመም ጋር ኖረዋል?_____ዓመት
9. የስኳር በሽታ እንዳለቦት ሲታወቅ ዕድሜዎ ስንት ነበር? _____ዓመት
10. በአሁኑ ጊዜ ለስኳር ህመምዎ ምን ዓይነት ህክምና እየወሰዱ ነው? (ተገቢውን ሁሉ ይምረጡ።)
    1. ኢንሱሊን (_____ ዓመት)
    2. SGLT2 ኢንሂቢተር (_____ ዓመት)
    3. ሌላ፣ ይግለጹ_____
11. የትኛውን አይነት ኢንሱሊን ነው የሚጠቀሙት?
    1. ኤንፒኤች ብቻ
    2. ኤንፒኤች ከሬጉላር ኢንሱሊን ጋር
    3. ግላርጂን ኢንሱሊን ከሬጉላር ኢንሱሊን ጋር
    4. የተቀላቀለ ኢንሱሊን (ሚክስታርድ)
    5. ሌላ፣ ይግለጹ_____
12. አጠቃላይ ዕለታዊ የኢንሱሊን መጠንዎ ስንት ነው? _____ዩኒት

ክፍል 3፡ የአካል ምርመራ እና የላቦራቶሪ ውጤቶች

13. ክብደት _____ ኪ.ግ
14. ቁመት _____ ሳንቲ ሜትር
15. ቢኤምአይ _____ ኪግ/ሜ^2 (ይዘለል)
16. የደም ግፊት _____/_____mmHg
17. የቅርብ ጊዜ ሄሞግሎቢን ኤ1ሲ (HgA1C) _____%
18. የቅርብ ጊዜ FBS_____mg/dl
19. አጠቃላይ የደም ኮሌስትሮል (Total cholesterol) _____ mg/dl
20. ኤችዲኤል ኮሌስትሮል (HDL-C) _____ mg/dl
21. ኤልዲኤል ኮሌስትሮል (LDL-C)_____ mg/dl
22. የደም ትራይግሊሰራይድ (TG)_____ mg/dl
23. የደም ክሪያቲኒን (Cr) _____ mg/dl
24. 24-ሰዓት የሽንት ፕሮቲን መጠን_____ mg

ክፍል 4፡ ለአጥንት መሳሳት የሚዳርጉ ምክንያቶች

25. የአካል ብቃት እንቅስቃሴ ደረጃ (አንዱን ይምረጡ)
    1. ከፍተኛ (በድምር 75 ደቂቃ በሳምንት ለምሳሌ በፍጥነት መሮጥ)
    2. መጠነኛ ((በድምር 150 ደቂቃ በሳምንት ለምሳሌ ፈጣን የእግር ጉዞ)
    3. በተለመደው ቀን ምን ያህል ጊዜ ተቀምጠው ያሳልፋሉ (በቤት፣ በስራ ቦታ፣ ትራንስፖርት ላይ) _____ሰዓት
26. ሲጋራ ይጠቀማሉ?
    1. በጭራሽ
    2. አቁሜአለሁ። በቀን_____ሲጋራ ለ_____አመት
    3. እጠቀማለሁ። በቀን_____ሲጋራ ለ_____አመት
27. በቀን ከ3 ብርጭቆ/መለኪያ ወይም ከዚያ በላይ አልኮል ይጠቀማሉ?
    1. አዎ
    2. አልጠቀምም
28. የተጓዳኝ በሽታዎች ሪፖርት (በመቼውም ጊዜ የነበሩ) የሚመለከተውን ሁሉ ይምረጡ
    1. አስቲዮጄኔሲስ ኢምፐርፌክታ
    2. ለረጅም ጊዜ የቆየ ያልታከመ ሃይፐርታይሮይዲዝም
    3. ሃይፖጎናዲዝም
    4. ማላብዞርፕሽን
    5. ሥር የሰደደ የጉበት በሽታ (CLD)
    6. የሩማቶይድ አርትራይተስ (RA)
    7. የደም ግፊት
    8. ዲስሊፒዲሚያ (የኮሌስትሮል መጨመር)
    9. የማንቀጥቀጥ በሽታ
    10. ማረጥ፣ አዎ ከሆነ፣ ስንት ዓመታት ሆነው _____
    11. የለም
29. በአሁኑ ጊዜ የሚጠቀሙት መድሃኒቶች (በአለፈው 1 አመት ውስጥ የተጠቀሙትም) የሚመለከተውን ሁሉ ይምረጡ
    1. ለአጥንት መሳሳት ህክምና የሚሰጡ
    2. ለማንቀጥቀጥ በሽታ የሚሰጡ
    3. አሮማቴዝ ኢንሂቢተርስ
    4. ታይዛይድ ዳዩሪቲክስ: HCT
    5. ሉፕ ዳዩሪቲክስ: ላሲክስ

6. የወሊድ መከላከያ ክኒን
7. የሆርሞን ምትክ (ኤስትሮጀን) ሕክምና
8. ቴስቶስትሮን
9. ግሉኮርቲሲኮይድ: (በአሁኑ ጊዜ የሚወስዱ ወይም ቢያንስ ለ3 ወራት ፕሬኒሶሎን/Prednisolone 5mg በቀን የወስዱ ወይም የተጋለጡ)
10. የጨጓራ: ፕሮቶን ፓምፕ ኢንሂቢተርስ
11. ታይሮክሲን
12. SGLT2 ኢንሂቢተር ወይም ሜትፎርሚን
13. የለም

<u>የስብራት ስጋት ግምገማ መሣሪያ (ፍራክስ)</u>

ቁጥር	ለስብራት የሚዳርጉ ምክንያቶች	ምላሽ	
1	ዕድሜ ***ከላይ ይመልከቱ**	_____አመት	
2	ጾታ ***ከላይ ይመልከቱ**	Male ☐	Female ☐
3	ክብደት (በኪግ) ***ከላይ ይመልከቱ**	_____ኪሎ ግራም	
4	ቁመት (በሳ.ሜ.) ***ከላይ ይመልከቱ**	_____ሳንቲ ሜትር	
5	*ከዚህ ቀደም ያጋጠመ ስብራት (በቀላል ጉዳት ምክንያት)*	አዎ ☐	የለም ☐
6	*የወላጅ የዳሌ ስብራት ከነበረ*	አዎ ☐	የለም ☐
7	ሲጋራ ያጨሳሉ ***ከላይ ይመልከቱ**	አዎ ☐	የለም ☐
8	ግሉኮርቲሲኮይድ (በአሁኑ ጊዜ የሚወስዱ ወይም ቢያንስ ለ3 ወራት ፕሬኒሶሎን/Prednisolone 5mg በቀን የወስዱ ወይም የተጋለጡ) ***ከላይ ይመልከቱ**	አዎ ☐	የለም ☐
9	የሩማቶይድ አርትራይተስ (RA) ***ከላይ ይመልከቱ**	አዎ ☐	የለም ☐
10	ሁለተኛ ደረጃ ኦስቲዮፖሮሲስ (ለሁሉም አዎ- ዓይነት 1 ስኳር)	**አዎ** √	የለም ☐
11	በቀን ከ3 ብርጭቆ/መለኪያ ወይም ከዚያ በላይ አልኮል ይጠቀማሉ ***ከላይ ይመልከቱ**	አዎ ☐	የለም ☐
12	*ቢኤምዲ (BMD) የዳሌ አጥንት አንገት (g/cm^2)* #**ከተገኘ**	_____	

የ10-አመት የስብራት እድል (የሚሰላ): ዋና ከለአጥንት መሳሳት ጋር የተያያዘ ስብራት _____%
የዳሌ ስብራት _____%

ክፍል 5፡ አጣዳፊ እና ሥር የሰደዱ የስኳር በሽታ ጉዳቶች

30. ማንኛውም በስኳሩ ምክንያት የመጣ የነርቭ በሽታ?
    1. አለ፣ የታካሚውን ፋይል ይገምግሙ _____
    2. የለም
31. ምርመራ ተደርጎ የማያውቅ ከሆነ: የሞኖፊላመንት ምርመራ ውጤት (ከ10 ቦታ በአንድ እግር 4ቱ ከነደለ)
    1. ጉድለት አለ
    2. ጉድለት የለም
32. የማየት እክል አለ?
    1. አለ
    2. የለም
33. ማንኛውም በስኳሩ ምክንያት የመጣ የዓይን በሽታ?

1. አለ፣ ይግለጹ 1. የስኳር በሽታ ሬቲኖፓቲ 2. የዓይን ሞራ ግርዶሽ 3. ግላኮማ
2. የለም

34. ማንኛውም በስኳሩ ምክንያት የመጣ የኩላሊት በሽታ?
1. አለ፣ የታካሚውን ፋይል ይገምግሙ _____
2. የለም

35. ማንኛውም የእግር ደም ስር በሽታ?
1. አለ፣ የታካሚውን ፋይል ይገምግሙ _____
2. የለም

36. ማንኛውም የልብ በሽታ?
1. አለ፣ የታካሚውን ፋይል ይገምግሙ _____
2. የለም

37. ማንኛውም የስትሮክ በሽታ?
1. አለ፣ የታካሚውን ፋይል ይገምግሙ _____
2. የለም

38. በቅርብ ጊዜ የተከሰተ የስኳር መውረድ?
1. ደረጃ 1 (መለስተኛ) - ከ54-69mg/dl ወይም የእጅ መንቀጥቀጥ፣ ማላብ፣ የልብ ምት መፍጠን፣ ረሃብ
2. ደረጃ 2 (መካከለኛ) - ከ54mg/dl ያነሰ ወይም ግራ መጋባት፣ መነጫነጭ፣ እንቅልፍ ማጣት
3. ደረጃ 3 (ከባድ) - ራስን መሳት፣ ሙሉ ሰውነትን ማንቀጥቀጥ፣ ኮማ ወይም የሌሎችን እርዳታ የሚያስፈልግ ከሆነ

ክፍል 6፡ የመውደቅ እና ባላንስ ግምገማ

39. ባለፉት 12 ወራት ውስጥ 2 እና ከ2 ጊዜ በላይ መውደቅ?
1. አለ
2. የለም

<u>የመውደቅ እድልን መለኪያ ኢንተርናሽናል - አጭር መጠይቅ</u>

አሁን የእርስዎን የመውደቅ እድልን በተመለከተ ምን ያህል እንደሚያሳስብዎት አንዳንድ ጥያቄዎችን መጠየቅ እንፈልጋለን። እባክዎ ወትሮም እንቅስቃሴውን እንዴት እንደሚሰሩ በማሰብ መልስ ይስጡ። በአሁኑ ጊዜ እንቅስቃሴውን ካልሰሩ፣ በሚሰሩበት ጊዜ መውደቅ ያሳስበኛል ብለው ይገምቱ እንደሆነ በማሰብ ይመልሱ። ለሚከተሉት ተግባራት፣ ይህን እንቅስቃሴ ካደረጉ ሊወድቁ እንደሚችሉ ምን ያህል ስጋት እንዳለዎት በማሳየት ለእራስዎ አስተያየት በጣም ቅርብ የሆነውን ሳጥን ላይ ምልክት ያድርጉ።

		በፍፁም አያሳስበኝም 1	*በትንሹ ያሳስበኛል 2*	*በመጠኑ ያሳስበኛል 3*	*በጣም ያሳስበኛል 4*
1	ልብስ መልበስ ወይም ማውለቅ	*1* ☐	*2* ☐	*3* ☐	*4* ☐
2	ገላን መታጠብ ወይም ሻወር መውሰድ	*1* ☐	*2* ☐	*3* ☐	*4* ☐
3	በወንበር ላይ መቀመጥ ወይም መነሳት	*1* ☐	*2* ☐	*3* ☐	*4* ☐
4	ደረጃን መውጣት ወይም መውረድ	*1* ☐	*2* ☐	*3* ☐	*4* ☐
5	ከቁመት በላይ ወይም በመሬት ላይ የሆነ ዕቃ ላይ ለመድረስ መሞከር	*1* ☐	*2* ☐	*3* ☐	*4* ☐
6	ዳገትን መውጣት ወይም ቁልቁለትን መውረድ	*1* ☐	*2* ☐	*3* ☐	*4* ☐
7	ወደ ማህበራዊ ዝግጅት መውጣት (ለምሳሌ የሃይማኖት አገልግሎት፣ የቤተሰብ መሰባሰብ ወይም የክለብ ስብሰባ)	*1* ☐	*2* ☐	*3* ☐	*4* ☐

የድምር ውጤት _____

ባለ 4-ደረጃ የባላንስ ምርመራ

ለታካሚው መመሪያዎች

- አራት የባላንስ ምርመራዎችን አሳዮታለሁ
- በእያንዳንዱ ቦታ ለ10 ሰከንድ ለመቆም ይሞክሩ
- እጆችዎን ወደ ውጭ መያዝ ወይም ባላንስዎን ለመጠበቅ ሰውነትዎን ማንቀሳቀስ ይችላሉ, ነገር ግን እግሮችዎን አያንቀሳቅሱ
- ለእያንዳንዱ ምርመራ፣ "ዝግጁ፣ ጀምሩ" እላለሁ። ከዚያ, ጊዜ እጀምራለሁ. ከ10 ሰከንድ በኋላ፣ "አቁሙ" እላለሁ።

	1. እግሮችዎን ጎን ለጎን አድርገው ይቁሙ	ጊዜ:_____ ሰከንድ
	2. የአንዱን እግር መወጣጫ የሌላኛውን እግር አውራ ጣት እንዲነካ አድርገው ያስቀምጡ	ጊዜ:_____ ሰከንድ
	3. የታንደም መቆሚያ: አንድ እግርን ከሌላው ፊት ለፊት ያስቀምጡ, ተረከዙ አውራ ጣት እንዲነካ አድርገው	ጊዜ:_____ ሰከንድ
	4. በአንድ እግር ብቻ ይቁሙ	ጊዜ:_____ ሰከንድ

በሽተኛው እግራቸውን ሳያንቀሳቅሱ ወይም ድጋፍ ሳይፈልጉ ለ10 ሰከንድ የመጀመሪያውን የባላንስ ምርመራ መስራት ከቻሉ ወደ የሚቀጥለው ምርመራ ይሂዱ ካልሆነ ምርመራውን ያቁሙ።

ታካሚዎች አጋዥ መሳሪያ (ዱላ ወይም መደገፊያ) መጠቀም የለባቸውም እና ዓይኖቻቸውን ክፍት ማድረግ አለባቸው።

ክፍል 7፡ የአጥንት መሳሳት እውቀት ምዘና መሣሪያ

እባኮትን የሚከተሉትን ጥያቄዎች እውነት፣ ሀሰት ወይም አላውቅም ብለው ይመልሱ።

ቁጥር	ጥያቄ	እውነት	ሀሰት	አላውቅም
1	የአጥንት መሳሳት ለስብራት የመጋለጥ እድልን ይጨምራል።			
2	የአጥንት መሳሳት በአብዛኛው ጊዜ ከስብራት በፊት ምልክቶችን (ለምሳሌ ህመም) ያመጣል።			
3	በልድነት መጨረሻ ላይ ከፍተና የአጥንት ክብደት መኖሩ በኋለኛው ህይወት ውስጥ የአጥንት መሳሳትን ለመከላከል አይጠቅምም።			
4	የአጥንት መሳሳት በወንዶች ላይ በብዛት ይታያል።			
5	ሲጋራ ማጨስ የአጥንት መሳሳት እንዲፈጠር አስተዋጽኦ ያደርጋል።			
6	ነጭ ሴቶች ከሌሎች ዘሮች ጋር ሲነፃፀሩ ከፍተና የመሰበር እድል አላቸው።			
7	መውደቅ ከዝቅተኛ የአጥንት ጥንካሬ እኩል ስብራት እንዲፈጠር ምክንያት ነው።			
8	ከ80 ዓመት በኋላ በአብዛኛዎቹ ሴቶች ላይ የአጥንት መሳሳት ይታያል።			
9	ከ50 ዓመት በኋላ አብዛኛዎቹ ሴቶች ቢያንስ አንድ ስብራት ሊያጋጥማቸው ይችላል።			
10	ማንኛውም አይነት የአካል ብቃት እንቅስቃሴ የአጥንት መሳሳትን ለመከላከል ይጠቅማል።			
11	ለአጥንት መሳሳት ተጋላጭ መሆኔን በቀላሉ ከማያቸው ምልክቶች ማወቅ እችላለሁ።			
12	በቤተሰብ የአጥንት መሳሳት ያለበት ሰው መኖር አንድን ሰው ለአጥንት መሳሳት ያጋልጣል።			
13	በቂ የካልሲየም መጠን ለማግኘት በቀን ሁለት ብርጭቆ ወተት መውሰድ ይበቃል።			
14	ሳርዲን ዓሳ እና ብሮኮሊ የወተት ተዋጽኦዎችን መውሰድ ለማይችሉ ሰዎች የካልሲየም ምንጭ ናቸው።			
15	ተጨማሪ ካልሲየም ክኒን ብቻ መስጠት የአጥንት መሳሳትን ይከላከላል።			
16	በመጠኑ አልኮልን መጠቀም በአጥንት መሳሳት ላይ ያለው ተጽእኖ አነስተና ነው።			
17	ከፍተኛ የጨው መጠን መጠቀም ለአጥንት መሳሳት ምክንያት ነው።			
18	የወር አበባ ከቆመ በቀጣዮቹ አስር አመታት ውስጥ አነስተኛ መጠን ያለው የአጥንት መሳሳት አለ።			
19	የሆርሞን ምትክ (ኤስተሮጅን) ሕክምና የወር አበባ ከቆመ በኋላ ባለ እድሜ ላይ ተጨማሪ የአጥንት መሳሳት ይከላከላል።			
20	ኢትዮጵያ ውስጥ ለአጥንት መሳሳት ውጤታማ የሆኑ ህክምናዎች የሉም።			

የድምር ውጤት _____

ለጊዜዎት አመሰግናለሁ።