University of Dongola

Faculty of Medicine and Health Sciences

Department of Community Medicine

Research Proposal

Prevalence of Vitiligo Among Patients with Type 1 Diabetes Mellitus Attending Al-Jemaih Diabetes Center, Dongola, Northern State, Sudan, 2026

Students	Supervisor
Somaya Omar ALhaj Ahmed Asmaa Abdulaziz Jumaa Sadina	Dr. Noura Eltayb

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1.Introduction

1.1 Background Information

Vitiligo is a chronic acquired depigmenting skin disorder characterized by the loss of functional melanocytes, resulting in well-defined depigmented patches on the skin. It is considered an autoimmune condition and may occur in association with other autoimmune diseases, including Type 1 Diabetes Mellitus (T1DM). Type 1 Diabetes Mellitus is a chronic autoimmune disease characterized by the destruction of pancreatic beta cells, resulting in insulin deficiency. The autoimmune nature of both conditions provides a basis for their possible coexistence.

Vitiligo affects approximately 0.1%–1.0% of the general population worldwide. However, its prevalence is higher among patients with Type 1 Diabetes Mellitus (T1DM), ranging from 1.0% to 7.0%, with a pooled prevalence of about 2.4%. Studies have also shown that patients with T1DM have a higher risk of developing vitiligo compared with the general population.

In the Middle East and Africa (MEA) region, the reported prevalence of vitiligo varies between 0.18% and 5.3%. Vitiligo is frequently associated with other autoimmune conditions, particularly T1DM and autoimmune thyroid diseases.

In Sudan, data on the association between vitiligo and T1DM are limited. Studies from dermatology centers have reported the presence of systemic autoimmune diseases among patients with vitiligo, while diabetes mellitus has also been reported as an associated condition. However, there is still limited local research on the prevalence of vitiligo among patients with T1DM, particularly in Northern State, Sudan. There is limited published data on the prevalence of vitiligo among patients with T1DM in Sudan.

1.2 Problem Statement

Individuals with T1DM are at increased risk of developing other autoimmune diseases because of shared genetic and immunological mechanisms. Vitiligo is a chronic autoimmune disorder,that may occur in association with other autoimmune diseases, including T1DM. [1], systematic review and meta-analysis including 180 studies and 293,889 patients with T1DM reported a pooled prevalence of vitiligo of 2.4% (95% CI 1.2–3.9%) based on 14 studies. The authors also reported moderate to high heterogeneity among the included studies. [1]

The association between diabetes mellitus and vitiligo has been demonstrated in epidemiological studies. A systematic review and meta-analysis reported an association between diabetes mellitus and vitiligo, supporting the occurrence of vitiligo as a comorbidity in patients with diabetes. [2] More recently, a large-scale study using data from 494,109 UK Biobank participants found that diabetes was associated with higher odds of vitiligo (OR 1.53, 95% CI 1.25–1.87). Specifically, T1DM was associated with higher odds of vitiligo (OR 3.73, 95% CI 2.48–5.62). [3]

Vitiligo may also have an important psychosocial and clinical burden. A large retrospective study conducted in the United States found that patients with vitiligo had higher rates of psychiatric and autoimmune comorbidities compared with matched controls. Anxiety was reported in 14.3% of patients with vitiligo compared with 11.0% of controls, while depression was reported in 8.0% compared with 6.3%, respectively. [4]

Despite the documented association between T1DM and vitiligo, there is limited published information regarding the prevalence of vitiligo specifically among patients with T1DM in Sudan. In particular, local epidemiological data from Northern State and among patients attending diabetic centers in Dongola City are .limited

1.3 Rationale

A meta-analysis of 38 studies (226,115 participants) from the Middle East and Africa estimated overall vitiligo prevalence at 3% (95% CI 2–4%). Its authors described regional data as scarce, and none of the included studies were from Sudan [6]. Another meta-analysis (103 studies) reported a relatively high prevalence in Africa, with estimates ranging from 0.004% to 9.98% [7]. In Sudan, the only related study was done in Khartoum (Jabir Abu Eliz Diabetic Center, 2001). It reported vitiligo in 5.6% of the diabetic patients studied, without separating T1DM from T2DM [8]. No study has addressed T1DM specifically, or Northern State and .Dongola

The burden is real. Vitiligo carries a high risk of anxiety and depression [9]. Patients with vitiligo also have another autoimmune disease in 10–15% of cases, compared with 1–2% in the general population [10], so .detecting vitiligo in T1DM may flag a wider autoimmune tendency

1.4 Objectives

General Objective

To study the prevalence of vitiligo among patients with type 1 diabetes mellitus attending Al-JEMAIH Diabetic Center in Dongola City, Northern State, Sudan, in 2026.

Specific Objective

To describe the socio-demographic characteristics of patients with Type 1 Diabetes Mellitus included in the .1 .study

.To describe the clinical characteristics of patients with Type 1 Diabetes Mellitus included in the study .2

To describe the clinical characteristics of vitiligo among patients with type 1 diabetes mellit .3

To determine the distribution of vitiligo according to selected socio-demographic and clinical characteristics .4 .among the study participants

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Literature Review 2

The following studies provide relevant evidence concerning the association between vitiligo, type 1 diabetes mellitus, and familial susceptibility.

Nederstigt et al. (2019) conducted a systematic review and meta-analysis to determine the prevalence of associated autoimmune diseases among patients with type 1 diabetes mellitus. The authors searched PubMed, Web of Science, EMBASE, and the Cochrane Library and included 180 studies involving 293,889 patients with type 1 diabetes mellitus. Using a random-effects meta-analysis, the pooled prevalence of vitiligo was estimated from 14 studies. Vitiligo was found in 2.4% of patients with type 1 diabetes mellitus (95% CI: 1.2–3.9%). The authors concluded that autoimmune diseases are common among patients with type 1 diabetes and that vitiligo is one of the associated autoimmune conditions. [1]

Ayanlowo et al. (2009) conducted a hospital-based study at the Lagos University Teaching Hospital, Nigeria, to describe the epidemiological and clinical characteristics of vitiligo. The study included all consecutive vitiligo patients attending the dermatology clinic between October 2003 and October 2006. Vitiligo was diagnosed in 186 patients (2.8%), with a slight female predominance. The face and limbs were the most commonly affected sites. Fifteen patients (0.81%) had features suggestive of associated autoimmune diseases, including Type 1 Diabetes Mellitus. [12]

Grasso and Chiarelli reviewed the overlap between type 1 diabetes (T1D) and other autoimmune disorders in patients under 21 years, drawing on literature from 2010 to 2023 [13]. They explain that T1D shares genetic susceptibility (HLA, CTLA4, PTPN22) and environmental triggers with other autoimmune diseases, and that thyroid disease and celiac disease are the most frequent comorbidities. Vitiligo is reported in 1.6–10% of children with T1D, compared with 0.09–1% in the general pediatric population [13]. The authors suggest that CD4+ T cells may link the two conditions, but note that no common target has been identified. They conclude that most comorbidity data come from small cohorts, and call for larger studies from different countries [13]. .This supports the need for local data on vitiligo among T1D patients in Sudan

3. MATERIALS AND METHODS

3.1 Study Design

A descriptive cross-sectional study will be conducted to determine the prevalence of vitiligo among patients with type 1 diabetes mellitus attending Al-JEMAIH Diabetes Center in Dongola, Northern State, Sudan.

3.2 Study Area

The study will be conducted at Al-JEMAIH Diabetes Center, Dongola, Northern State, Sudan. The center provides healthcare services, follow-up, and management for patients with diabetes mellitus, including children and adults with type 1 diabetes mellitus.

3.3 Study Period

The study will be conducted during September, October, and December 2026.

3.4 Study Population

The study population will consist of patients diagnosed with type 1 diabetes mellitus who attend Al-JEMAIH Diabetes Center during the study period. Both children and adults with type 1 diabetes mellitus who meet the eligibility criteria will be considered for inclusion..

Inclusion criteria:

Confirmed diagnosis of type 1 diabetes mellitus.

Attendance at Al-JAMEEH Diabetes Center during the study period.

Agreement to participate in the study.

Exclusion criteria:

A type of diabetes other than type 1 diabetes mellitus.

Inability to provide the required information and absence of a reliable informant.

Refusal to participate in the study.

A skin condition that makes assessment for vitiligo unreliable.

3.5 Sample Size

The sample size will be calculated using the single population proportion formula for an unknown population size

n = \frac{Z^2P(1-P)} {d^2}

Where:

- n = required sample size
- Z = 1.96 for a 95% confidence level
- P = expected prevalence of vitiligo among patients with type 1 diabetes mellitus
- d = margin of error (5%)

A pooled prevalence of vitiligo of 2.4% among patients with type 1 diabetes mellitus was reported in a systematic review and meta-analysis. Using this prevalence, a 95% confidence level, and a 5% margin of error, the calculated minimum sample size is approximately 36 participants. After adding 10% to account for possible non-response or incomplete data, the final sample size will be approximately 40 participants. [1]

3.6 Sampling Technique

A consecutive sampling technique will be used. All eligible patients with type 1 diabetes mellitus attending the center during the study period will be approached and recruited consecutively until the required sample size of 40 participants is reached.

3.7 Data Collection

Data will be collected using a structured interviewer-administered questionnaire. The questionnaire will consist of the following sections:
Section A: Sociodemographic data
Section B: Diabetes-related information
Section C: Vitiligo-related information

- **Clinical Assessment**

Participants will be clinically assessed for the presence of vitiligo by examining the skin for characteristic depigmented patches.
Where possible, the diagnosis will be confirmed by a qualified clinician/dermatologist according to the clinical features of vitiligo. The participant will then be classified ,Completed questionnaires will be checked daily for .completeness and consistency. Data will be entered carefully and checked for errors before analysis

Pilot Study

A pilot study will be conducted before the commencement of the main study among a small number of patients with type 1 diabetes mellitus who meet the study eligibility criteria. The pilot study will be used to assess the clarity and feasibility of the data collection tool, estimate the time required for data collection, and identify any difficulties related to the clinical assessment of vitiligo. Necessary modifications to the data collection tool and study procedures will be made .based on the findings of the pilot study before commencement of the main study

3.8 Data Analysis

Data will be entered, cleaned, and analyzed using IBM SPSS Statistics Version 31.0.2. Descriptive statistics will be used to summarize the data. Categorical variables will be presented as frequencies and percentages. Continuous variables will be summarized using Mean and standard deviation or Median and interquartile range, depending on the distribution of the data. The prevalence of vitiligo among patients with type 1 diabetes mellitus will be calculated as the proportion of participants diagnosed with vitiligo among the total number of study participants and expressed as a percentage. The results will be presented using tables and appropriate charts.

3.9 Bias

Potential sources of bias will be considered and minimized during the study. Selection bias will be reduced by using consecutive sampling and recruiting all eligible patients with type 1 diabetes mellitus who attend Al-JEMAIH Diabetic Center during the study period until the required sample size is reached.
Information and measurement bias will be minimized by using a standardized data collection questionnaire and applying a consistent clinical assessment method for the diagnosis of vitiligo. Suspected cases will be assessed and, where possible, confirmed by a qualified clinician or dermatologist
Recall bias may occur when participants are asked about the onset or duration of vitiligo. This will be minimized by using clear and specific questions and by reviewing available medical records where applicable.

The study variables 3.10

Dependent variable .1

(Presence of vitiligo

Independent variables .2

Age

Sex

Duration of Type 1 Diabetes Mellitus

Age at diagnosis of Type 1 Diabetes Mellitus

Family history of autoimmune diseases

Duration of vitiligo, if present

Age at onset of vitiligo, if present

Site(s) of vitiligo lesions, if present

3.11 Ethical Clearance

Ethical approval will be obtained from the relevant university Institutional Review Board or Research Ethics Committee before the study commences. Administrative authorization will also be sought from the appropriate health authorities and the selected study facility in Dongola City.
All participants will receive comprehensive information regarding the study purpose, procedures, potential benefits, and foreseeable risks. Written informed consent will be obtained before participation. Participation will be voluntary, and participants may decline to participate or withdraw at any time without penalty or impact on the medical care they receive.
Participants' confidentiality and privacy will be maintained throughout the study. Personal identifiers will be replaced with unique study identification codes, and all data will be stored securely, with access restricted to authorized members of the research team. The information collected will be used exclusively for academic and research purposes.
The study will involve completing a questionnaire and a clinical assessment for vitiligo and will not include therapeutic interventions. For participants under 18 years of age, written informed consent will be obtained from a parent or legally authorized guardian. Age-appropriate assent will also be obtained from the minor, where applicable.

3.12 Work Plan (Gantt Chart)

Activity	18–30 Sep	1–31 Oct	1–30 Nov	1–31 Dec	1–4 Jan
Literature review	■				
Questionnaire preparation	■				
Proposal submission	■				
Data collection		■			
Data analysis		■	■		
Result writing and Discussion			■		
Report writing			■	■	
Final presentation/seminar					■

7. Budget

The estimated study budget will include printing, transportation, communication, and other research-related expenses. The exact costs will be completed according to actual local prices and available resources.

Budget Item	Quantity	Unit Cost (SDG)	Total Cost (SDG)
Printing	200 papers	200	40000
Transportation	21 days	8000	168000
Communication	3 months	60000	180000
Other research-related expenses	anaylysis	120000	120000
Total	_	—	508000

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