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Clinical evaluation of the reference intervals for diabetes in Chinese geriatric population: a cross-sectional cohort study protocol

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ABSTRACT

Introduction Diabetes mellitus (DM) is an important health issue that affects the ageing population. China has the largest geriatric population and the largest number of diabetes cases in the world. This poses a significant challenge for healthcare providers and policymakers. Haemoglobin A1C (HbA1c), which is one of the diagnostic criteria for diabetes, is affected by many factors such as pregnancy, age, race and anaemia. Glycated albumin (GA) is not influenced by factors that affect HbA1c concentrations, although it has been used in the diagnosis of diabetes in a few people. The aim of this study protocol is to determine reference intervals (RIs) of HbA1c and GA for the diagnosis of older adults with diabetes in China and to assess the optimal cut-off values for these parameters from a health economic perspective.

Methods and analysis This cross-sectional survey study will recruit 1278 community-dwelling older adults aged 60–89 in Chengdu City. The data collection process will involve a questionnaire survey, a comprehensive physical examination and the collection of blood samples for laboratory testing. Data analyses will be conducted on the pooled sample and stratified by gender, age or other demographic features if necessary. Rates will be compared using the $\chi 2$ test or Fisher test and receiver operating characteristic (ROC) curves will be used to identify the most effective threshold values for HbA1c and GA for diagnosing diabetes among older adults in China.

Ethics and dissemination The study protocol was approved by the ethics review board of the Bioethics Subcommittee of West China Hospital, Sichuan University (Approval No. 1705 in 2022). The study's results will be disseminated through peer-reviewed journals and scientific conferences.

Trial registration number ChiCTR2300070831

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The first observational investigation aimed at determining reference intervals for diabetes in the elderly Chinese population.
⇒ The cross-sectional design used precludes the establishment of causality.
⇒ Numerous data are collected through self-reports, which may lead to recall bias. To address this issue, data evaluators underwent comprehensive training; however, investigator bias may still exist during the evaluation phase.
⇒ The sample size is restricted to older adults residing solely in the Chengdu City community, thus potentially limiting the generalisability of the findings to the wider population of elderly individuals in China.

INTRODUCTION

Diabetes is a significant public health concern that affects a large percentage of the elderly population. As individuals age, the prevalence of diabetes increases. In fact, more than 25% of individuals over the age of 65 have diabetes and half of older adults have prediabetes.[1] This is particularly relevant in China, which has the largest geriatric population in the world and is currently experiencing rapid population ageing. In 2010, researchers in China reported that over 194 million people were over the age of 60, making up 14.3% of the total population.[2] According to the findings of the seventh national census of China, the elderly population aged 60 and above amounted to 264 million in 2020, accounting for 18.7% of the total population.[3] It is projected that by 2030, the number of individuals over the age of 60 in China will reach 359 million. Additionally, the International Diabetes Federation (IDF) published a report in 2021 indicating that China has 140 million diabetic patients, ranking first in the world.[4] The IDF has also previously noted that China has the highest number of elderly diabetes patients aged 65 and above, with a total of 35.5 million, comprising a quarter of the world's elderly diabetes patients and showing an upward trend.[5]

Elderly individuals with diabetes are more vulnerable to complications, such as cardiovascular disease, kidney disease and neuropathy. Additionally, they are at an increased risk for typical geriatric syndromes, such as polypharmacy, cognitive impairment, depression, urinary incontinence, injurious

falls, persistent pain and frailty, compared with their nondiabetic peers.[6] Therefore, early screening and diagnosis of older adults with diabetes can prevent or delay complications, leading to improved health outcomes and quality of life. Currently, the criteria for diagnosing diabetes in older adults in China are based on the fasting plasma glucose (FPG) and 2-hour plasma glucose (2-h PG) values during a 75 g oral glucose tolerance test (OGTT), according to the WHO criteria from 1999. In addition, haemoglobin A1C (HbA1c), detected in a laboratory using a method that is certified by the National Glycohemoglobin Standardization (NGSP), is also used as the criterion for the diagnosis of old adults with diabetes.[7–10]

It is widely accepted that physiological or pathological changes occur in the human body that occur during the ageing process. Understanding these changes is a prerequisite for developing reliable and accurate reference intervals (RIs),[11] which play an important role in clinical practice for disease diagnosis and health assessment.[12] RIs can vary for various subpopulations due to differences in their physiology, such as in childhood, pregnancy and older adults.

The partitioning of RIs is necessary when significant physiological changes need to be distinguished. However, obtaining geriatric RIs presents a major challenge due to the difficulty in selecting healthy individuals who meet the criteria of the C28-A3 guideline, published by the Clinical and Laboratory Standards Institute (CLSI) and the International Federation of Clinical Chemistry (IFCC).[13] In China, the current diagnostic criteria for diabetes in elderly individuals rely on the WHO's 1999 criteria based on plasma glucose levels, although FPG, 2-h PG during 75 g OGTT, and HbA1c are equally valid for diagnostic screening.

However, the epidemiological research that led to the recommendation of HbA1c as a diagnostic tool for diabetes only included adults.[14] The use of HbA1c for diagnosing diabetes also has limitations in conditions such as haemoglobinopathies, haemodialysis, pregnancy, HIV, age, race/ethnicity, genetic background and anaemia. At present, limited evidence is available on RIs for HbA1c in the elderly population with diabetes,[15] while RIs for glycated albumin (GA), a measure that is not influenced by many factors affecting HbA1c levels, have been determined in a few individuals.[16–18] It remains unclear whether RIs for GA are suitable for the diagnosis of elderly adults with diabetes in China.

This study presents a protocol for examining the reference intervals (RIs) of HbA1c and GA in the diagnosis of diabetes among elderly adults in China. To the best of our knowledge, this is the first observational study that assesses the diagnostic threshold values for these measures among this specific population. Additionally, we investigated the most effective cut-off values of HbA1c and GA from a health economic perspective to reduce the patient's burden.

METHODS/DESIGN

Study design and setting

The study is a well-designed cross-sectional survey that employs the epidemiological observation method. The objective is to gather specific data and assess the diagnostic tests for significant examination items (HbA1c and GA) related to diabetes in older adults. The study adheres to the principles of a pragmatic trial, with comprehensive eligibility criteria, a sufficient sample size and study procedures integrated into routine clinical care and conducted by clinical staff. Standardised operational procedures will be followed to collect all biological samples, which will be stored in the biological specimen bank of the West China Hospital of Sichuan University.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Data collection

The data collection process comprises three components: (1) a questionnaire survey, (2) a thorough physical examination and (3)the collection of blood samples for laboratory analysis.

The questionnaire design is based on the National Health and Aging Trends Study (NHATS) developed by Johns Hopkins University, adapted for use with the population in western China.[19] The questionnaire includes inquiries about personal information, social and support networks, social microenvironment, religious beliefs, chronic disease, self-assessed health, dietary habits, household drinking water, smoking habits, consumption of alcohol/tea, physical exercise and daily/leisure activities. Validated assessment tools were employed, including those specifically designed for use in older adults, such as the Activities of DailyLiving (ADL),[20–22] Instrumental Activities of Daily Living (IADL),[21 22] Fatigue, Resistance, Ambulation, Illness and Loss of Weight Index Scale (FRAIL Scale),[23] Social Support Rating Scale (SSRS),[24]Mini Nutritional Assessment Short Form (MNA-SF),[25] Generalized Anxiety Disorder questionnaire (GAD-7),[26] Patient Health Questionnaire-9 (PHQ-9),[27] SARC-F questionnaire[28] and Montreal Cognitive Assessment Scale (MoCA).[29]The contents of the questionnaire, as previously referenced,[30] are detailed in table 1. The included items are provided in the online supplemental appendix. To ensure privacy, each participant will be assigned an identity verification code. Prior to formal implementation, a pretest will be conducted with elderly members of the community to confirm the questionnaire's reliability and validity. This will provide researchers with a better understanding of the participants' overall health status and potential risk factors for certain conditions.

Subsequently, participants will undergo a comprehensive physical examination that includes various tests and measurements for assessing their health status. These include measurements of height, weight, blood pressure

Table 1 The core components of the questionnaire investigation

Questionnaire outline	Description of content
Basic personal details	Name, gender, age, ID number, birthplace, duration of local residency, local domicile address, contact numbers (including her/himself and relatives), educational qualifications and experiences, citizenship, language (minority language), prior occupation (before age 60), etc.
Social support network	Number of male and female births, family context, family management, familial esteem, in-home care, family functioning Interpersonal relationships between neighbours and friends aid and support, marital status and spousal circumstances, etc.
SSRS scale	Assessment of social support encompassing interactions with friends, neighbours, family members, seeking assistance, engaging in conversation, etc.
Social microenvironment	Familial dwelling space, revenue stream, annual household income and financial satisfaction
Religious belief	Faith tradition, religious practices
Chronic disease background	Classification of chronic diseases, inpatient care, health insurance, previous year's medical expenses, satisfaction with healthcare status, prompt medical treatment, etc.
Self-evaluation of health	Restriction of activity, physical condition, affective state, pain, self-awareness, etc.
Dietary habits	Daily meal frequency, the quantity of food, meal combinations, breakfast eating habit presence/absence, salt consumption, techniques of cooking, rate of eating, preference for taste and dietary intake patterns
MNA-SF scale	BMI, psychology, calf circumference, mid-arm circumference diet, etc.
Domestic potable water	Category/origin of drinking water
Smoking	Smoking status and duration, initiation age for smoking, type of cigarette, history of smoking cessation, family history of smoking, passive smoking exposure status
Alcohol consumption	History of alcohol consumption, age at first alcohol consumption, frequency and type of alcohol consumption
Tea consumption	Current and past consumption of tea, age at first tea consumption, type of tea, daily consumption (mL)
Physical activity	Current and past engagement in physical activity, age at commencement and cessation of physical activity
Daily and recreational activity	Domestic chores, agricultural activities, breeding of poultry animals, reading, playing mahjong, TV, radio, talk in tearooms, etc.
ADL scale	Assessment of daily living skills, encompassing eating, ambulation, dressing, bathing, etc.
IADL scale	Objective assessment of instrumental activities of daily living, encompassing cooking, medication management, shopping and telecommunications
FRAIL scale	Debilitation, resistance, ambulation, illness, reduced body weight
GAD-7 scale	Assessment of anxiety symptoms, encompassing nervousness, worry, irritability, and fear, etc.
PHQ-9	Assessment of the severity of depressive symptoms, including feelings of sadness, loss of interest in activities, alterations in appetite and sleep patterns
SARC-F questionnaire	Sarcopenia screening, including strength, assistance in walking, rising from a chair, climbing stairs and falls
MoCA	Cognitive function assessment, including attention, memory, language, visuospatial abilities and executive function

ADL, Activities of DailyLiving; BMI, Body Mass Index; GAD-7, Generalised Anxiety Disorder-7; IADL, Instrumental Activities of Daily Living; MNA-SF, Mini Nutritional Assessment-Short Form; MoCA, Montreal Cognitive Assessment Scale; PHQ-9, Patient Health Questionnaire-9; SSRS, Social Support Rating Scale.

and BMI, as well as assessments of cardiovascular, respiratory, neurological and musculoskeletal systems. Before conducting the tests, all test instruments were calibrated following the manufacturer's guidelines.

Participants will receive instructions to refrain from engaging in any intense physical activity and to maintain a regular diet for 3 days leading up to the test. The test will take place in the morning following an overnight fast of 8 to 12 hours. Blood samples will be collected at baseline and 2 hours following the ingestion of glucose solution to measure the blood glucose levels. Furthermore, baseline blood samples will also be used to measure the participants' HbA1c and GA.

Study participants

Participants will be recruited from the population of older adults residing within the community of Chengdu City. The eligibility criteria for inclusion in the study are as follows:

1. Participants agreed to participate in the study and provided written informed consent.
2. The study included participants aged between 60 and 89 years old, with equal representation of males and females. The age distribution was 5:2:1 for the age groups of 60–69, 70–79 and 80–89.
3. The participants have resided in the local area for a minimum of 6 months.

4. Participants are willing and committed to completing all the inspection contents in the project, including FPG, HbA1c and GA. Participants without a self-reported diagnosis of diabetes history were tested with OGTT, while participants with a self-reported history of diabetes underwent a 2-hour postprandial blood glucose test.

Exclusion criteria

1. Participants who were unwilling to sign the informed consent form or complete the assessment components independently were excluded from the study.
2. Individuals who are younger than 60 years old (as indicated on their ID card).
3. Individuals with liver or kidney dysfunction, disability, dementia or cancer.
4. Individuals with diseases that can affect blood glucose, HbA1c and GA such as abnormal haemoglobin disease, haemolytic disease, thyroid dysfunction or nephrotic syndrome.
5. A history of long-term drug use, specifically glucocorticoids, can impact blood glucose levels, HbA1c and GA.

Sampling method and size

1. The study examines the population of elderly residents in both urban and rural areas of Chengdu, with a proportion of 16:9.
2. Data collection will be conducted at each research site with the assistance of government departments and community organisations at all levels of the project site. This will initiate social mobilisation and publicity for the study. As a form of compensation, our team will provide free medical check-ups (valued at approximately $50) and long-term health monitoring, including free hospital referrals if necessary, to all participants.
3. The sample size calculation was conducted using PASS 2021 (NCSS, Kaysville, Utah), taking into consideration the findings of a literature review, variations in diabetes research methodology and the requirements of subject recruitment scenarios. The required sample size is determined by considering both the prevalence/incidence rate (P) and the allowable error (δ). Cohort studies must also consider the potential for participant dropout, which necessitates a 20% increase in the required sample size. Consequently, a total of 1278 subjects will be needed (figure 1).

Data quality control and management

Since the participants are 60 years of age or older, paper questionnaires will be used for data collection in this study. On the day of data collection, the questionnaires will be verified by two independent investigators who will randomly select and verify 30% to 50% of them. If any responses are missing or unclear, the participant will be contacted by phone to confirm. This rigorous process identifies errors or inconsistencies in the data and ensures the reliability and validity of the results.

The database was established using Epidata V.3.1, and independent double entry was used. The two separate databases were cross-checked using the 'consistency check' function of the software. Any discrepancies found between the two databases were corrected on a case-by-case basis until the two databases were fully consistent.

All collected biological specimens will undergo preprocessing and labelling on the same day. The labelling process will include adding information such as the individual's name, gender, age and a unique code based

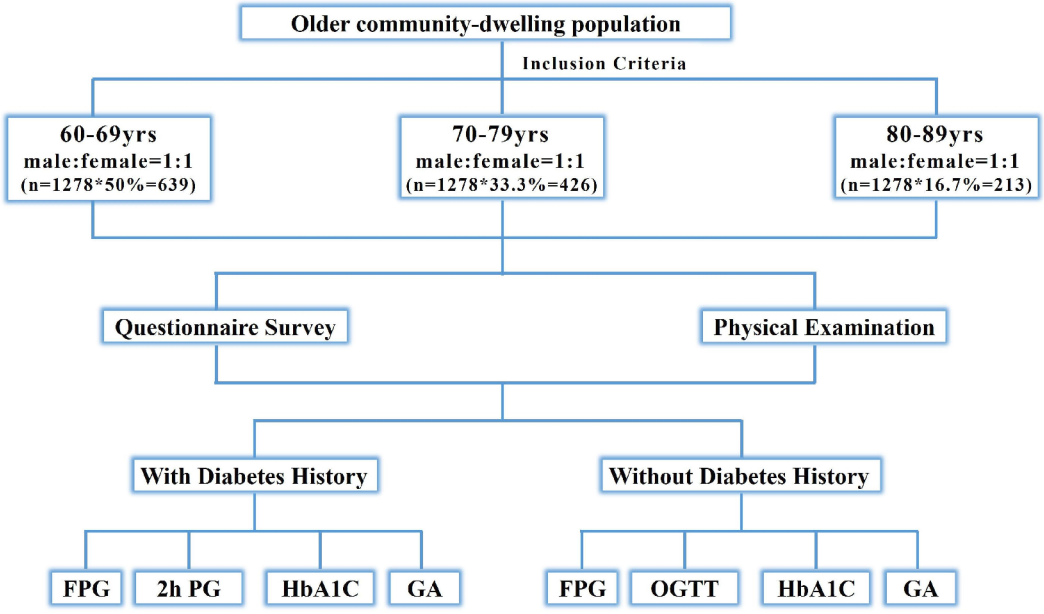

Figure 1 Conceptual framework of the study. FPG: fasting plasma glucose; GA: glycated albumin; HbA1C: haemoglobin A1C; OGTT: oral glucose tolerance test; 2-h PG: 2-hour plasma glucose.

on the original barcode and QR code of each cryopreservation tube. The specimens will then be stored in an ultralow temperature refrigerator at −80°C to ensure their long-term preservation. To maintain the quality of the specimens during intracity transportation, a transfer box will be used to maintain a temperature of 4°C and prevent haemolysis. Temperature control records will be maintained throughout the entire process. All biological samples that meet ethical standards will be placed in the biological sample bank at West China Hospital of Sichuan University for long-term conservation. Additionally, random inspections (1%–3%) of the location data of cryopreservation tubes will be conducted following each transfer to ensure that the storage location of biological specimens remains unchanged due to transfer operations (ie, change, move and loss of storage location information).

The primary investigator holds the ultimate responsibility for managing the data, which includes storage, application and utilisation. The data management plan follows guidelines related to medical ethics, fairness and bias. Therefore, before using the data, it will undergo deidentification by eliminating sensitive information, such as participant name, gender, age, identification number and home address. All data will be retained for a decade to facilitate future analysis and investigation.

Study outcomes

1. The reference intervals (RIs) for HbA1c for the diagnosis of diabetes among older adults in western China.
2. Reference intervals (RIs) for GA for the diagnosis of diabetes among older adults in western China.
3. The optimal cut-off values of HbA1c and GA for diagnosing diabetes among older adults in western China from a health economic perspective.

Statistical analysis

The data analysis will use SPSS V.22.0 and RV.3.6.1. Descriptive statistical analyses will be conducted on sociodemographic features and medical examination data to generate percentages, averages and SD. Rates will be compared using the $\chi 2$ test, and the Fisher test will be used if the conditions for the $\chi 2$ test are not met. For variables with scores on any of the psychometric or behavioural scales, the rank-sum test will be employed. The level of significance will be set at $p<0.05$. To determine the optimal cut-off values of HbA1c and GA in the diagnosis of diabetes among older adults in western China, receiver operating characteristic (ROC) curves will be used.

Dissemination

The study's results will be disseminated through presentations at multiple research conferences and publication in peer-reviewed journals.

Trial status

The study was registered with the Chinese Clinical Trial Registry on 24 April 2023, with ID: ChiCTR2300070831. Recruitment began on 1 April 2023 and is expected to be completed by 1 April 2024.

Future plans

On completing the recruitment of subjects, we will proceed with the planned collection of pertinent data, comprising (1) a questionnaire survey,(2) a comprehensive physical examination and (3) the acquisition of blood samples for laboratory analysis. Analysis of blood samples to derive data on HbA1c and GA aids in the establishment of reference intervals (RIs) for these biomarkers in the geriatric population of western China and facilitates the development of receiver operating characteristic (ROC) curves to ascertain optimal cut-off values for diagnosing diabetes mellitus in this cohort. The full study is projected to be finalised by the conclusion of 2025.

DISCUSSION

Diabetes is a significant public health concern among elderly individuals in China due to the increasing prevalence of diabetes and population ageing. Therefore, it is crucial to address the unique needs of older adults with diabetes. This study protocol aims to determine the reference intervals (RIs) of HbA1c and GA for diagnosing diabetes in older adults in China while evaluating their optimal cut-off values from a health economic perspective. The results of this investigation will provide valuable information on the diagnostic accuracy of HbA1c and GA for detecting diabetes among elderly individuals in China, thereby assisting healthcare providers in accurately diagnosing diabetes and administering appropriate treatment. Additionally, this study will offer insights into the economic implications of using HbA1c and GA as diagnostic tools for diabetes in older adults in China, which would benefit policymakers in making decisions concerning the allocation of healthcare resources and developing cost-effective diabetes management strategies. However, it is important to note that HbA1c may be affected by factors such as anaemia and haemoglobinopathies, while the availability of GA measurement is limited, and its use in clinical practice is still evolving. As a result, HbA1c and GA should not be viewed as the optimal diagnostic tools for diabetes in the geriatric population although they can provide valuable information.

ETHICS APPROVAL

The Biomedical Ethics Review Committee of West China Hospital of Sichuan University approved the current study protocol (Approval No. 1705 in 2022) on 23 November 2022 and written ethical approval was obtained. The investigator will ensure that the study adheres to the principles of the Declaration of Helsinki. The proposed research will follow the conditions and principles of the International Conference on Harmonization Good Clinical Practice and comply with national laws and regulations. Prospective participants will receive a comprehensive

information sheet about the study and will be required to provide written consent before being officially recruited.

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Contributors All the authors listed meet the ICMJE criteria for authorship. Each author has made substantial contributions to the work , such as the design of the work, the acquisition, analysis or interpretation of data for the work. All authors have approved the manuscript that is enclosed.CL Zhou and JL contributed equally to this paper. Writing: CL Zhou and JL; study design: FL and XC Wu; project coordination: XC Wu, XH Qi and FL; data acquisition: XH Qi and XC Wu; data quality control: CL Zhou and JL; data management: XC Wu and FL; guarantor: FL.

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Disclaimer Our sources of funding had no role in the design of cohort profile, and will not be any impact on data collection, analysis, writing and decision to submit or publish the research results.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. It was approved by the ethics review board of the Bioethics Subcommittee of West China Hospital, Sichuan University (Approval No. 1705 in 2022), registered with the China Clinical Trial Registration Centre (registration number: ChiCTR2300070831). Participants gave informed consent to participate in the study before taking part.

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