

Prevalence and Risk Factors of Depression in Chinese Patients With Type 2 Diabetes Mellitus: a Protocol of Systematic Review and Meta-analysis

Xiaobo LIU

Chengdu University of Traditional Chinese Medicine <https://orcid.org/0000-0003-2939-8924>

Chao Dong

The General Hospital of Western Theater Command

Hong Jiang

Xichong County People's Hospital

Dongling Zhong

Chengdu University of Traditional Chinese Medicine

Yuxi Li

Chengdu University of Traditional Chinese Medicine

Huiling Zhang

Chengdu University of Traditional Chinese Medicine

Jun Zhang

Chengdu University of Traditional Chinese Medicine

Jin Fan

Chengdu University of Traditional Chinese Medicine

Juan Li (✉ 785939016@qq.com)

Chengdu University of Traditional Chinese Medicine <https://orcid.org/0000-0002-8530-9001>

Li Guan

Fushun County People's Hospital

Rongjiang Jin

Chengdu University of Traditional Chinese Medicine

Protocol

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Abstract

Background: The prevalence of type 2 diabetes mellitus (T2DM) is growing in China. Both physical and psychological complications occur along with the development of T2DM. The patients with depression account for a significant proportion of T2DM. Depressive symptoms interfere with blood glucose management, leading to poorer treatment outcome and even relate to the occurrence of other serious complications of T2DM population. Among these T2DM patients with depression, early detection and treatment is essential and effective. Knowledge of the current prevalence of depression in T2DM patients as well as associated risk factors may be meaningful for healthcare planning. Therefore, we plan to conduct a systematic review and meta-analysis to evaluate the Chinese prevalence of depression in T2DM and explore associated risk factors.

Methods: We will search literatures recorded in MEDLINE/PubMed, EMBASE, the Cochrane Library, Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), and Wanfang database (Wanfang Data). The grey literatures and reference list will be manually searched. We will include population-based, cross-sectional surveys that investigated the Chinese prevalence of depression in T2DM or/and researched the possible risk factors. Two reviewers will screen studies, extract data and evaluate quality independently. We will assess inter-rater agreement between reviewers for study inclusion, data extraction, and study quality assessment using Kappa statistics. The primary outcome will be the pooled Chinese prevalence of depression in T2DM patients. The secondary outcome will contain the potential risk factors for depression in patients with T2DM. R software (version 3.6.1) and STATA software (version 12) will be used for data analysis.

Discussion: This systematic review will provide comprehensive evidence of the Chinese prevalence and risk factors of depression in patients with T2DM. we expect to provide evidence basis for healthcare practitioners and policy makers to pay attention to the mental health of T2DM. Our data will highlight the need and importance of early detection and intervention for depression in patients with T2DM.

Systematic review registration: PROSPERO CRD42020182979.

Background

Type 2 diabetes mellitus (T2DM) is a common chronic and metabolic disease, accounting for between 90% and 95% of all diabetes cases^[1], and with highest proportions in low- and middle- income countries^[2]. According to international diabetes federation (IDF)^[3] and summary data by Ma RCW^[4], China has the highest diabetes populations and one of the most sharp rises in diabetes prevalence in the world. And the marked increase in diabetes prevalence in China is mainly attributed to T2DM^[4]. The latest statistics showed that the overall prevalence of T2DM in China was 9.1%^[5].

With the progress of the T2DM, clinically important psychological comorbidities including depression are likely to develop^[6, 7]. Depression is characterized by persistent sadness and a loss of interest or pleasure in previously rewarding or enjoyable activities^[8]. Plenty of studies reported a bi-directional relationship between T2DM and depression^[9], which indicating that they are risk factors of each other^[10-12]. Study reported that people with T2DM had a 24% increased risk to develop depression compared to the healthy based on global data^[13]. This is most concerning because comorbid depression in T2DM means poor compliance^[14] and worse quality of life^[15], higher risk of dementia^[16] and cardiovascular event^[17, 18]. In view of the large of T2DM population in China and such an influence of depressive symptoms on mental health and physical health of patients with T2DM, knowledge of the current prevalence of depression in T2DM patients in China and identify high-risk groups are meaningful and urgent.

Results of several developing countries' epidemiological studies showed the prevalence of depression in T2DM ranged from 34% to 54%^[19-21]. 28% T2DM patients have depression at different degrees^[22], and 14.5% have major depressive disorder^[23]. In China, relevant epidemiological investigations have also been carried out in quantity. Numerous cross-sectional surveys of Chinese prevalence of depression in T2DM patients have been conducted, but the results were varied^[24, 25]. Meanwhile, although several studies have reported various risk factors associated with the prevalence of depression in T2DM patients, such as gender, age, educational level, complications and living habit (eg. smoking, drinking history and exercise habit), some of the results were inconsistent^[25-29]. A systematic review (SR) of Chinese prevalence of depression in T2DM conducted by Wang B et al^[30] included 28 studies published up to 2016. However, with more surveys have been published in the recent years, we plan to conduct a SR and meta-analysis to obtain the up to date relevant epidemiological data about the prevalence of depression in T2DM in China and to explore the associated risk factors.

Research questions

This SR and meta-analysis will answer the following key research questions:

- What is the epidemiological status of depression in T2DM in China?

What are the risk factors associated with development of the depression in T2DM?

Methods/design

Study registration

This SR protocol have been priori registered on PROSPERO at 30 April 2020 (registration ID: CRD42020182979). Our protocol is reported in according to the Preferred Reporting Item for Systematic Review and Meta-analysis-Protocol (PRISMA-P) statement (Additional file 1) and referred to the MOOSE guidelines for Meta-Analyses and Systematic Reviews of Observational Studies^[31]. The results of this SR will be reported according to the PRISMA statement and MOOSE guidelines.

Inclusion criteria

We will include studies based on the following criteria:

Studies characteristics

- Population-based, cross-sectional surveys investigated the Chinese prevalence of depression in patients with T2DM or/and researched the possible risk factors associated with development of depressive symptoms, regardless of sample size;
- Studies published in English or Chinese.

Participant characteristics

- Chinese adults (≥ 18 -year-old) diagnosed with T2DM based on self-reported physician's diagnosis, medical records or glucose level testing (fasting plasma glucose ≥ 7.0 mmol/L and/or 2 hours plasma glucose ≥ 11.1 mmol/L)^[32];
- T2DM patients were defined as depression by screening instruments which have been verified to have good validity and reliability in Chinese population (eg. Patient Health Questionnaire-9, Hamilton Depression Scale, Self-rating Depression Scale, Center for Epidemiologic Studies Depression Scale, Beck depression inventory, Composite International Diagnostic Interview, the Geriatric depression)^[33];

3) No restrictions on gender and geographical region.

Type of outcome measurements

- Our primary outcome will be the pooled Chinese prevalence of depression in T2DM patients;
- The secondary outcome will contain the potential risk factors for depression in patients with T2DM in China, such as gender, age, educational level, complications and living habit (eg. smoking, drinking history and exercise habit).

Exclusion criteria

We will exclude studies meeting one of the following criteria:

1) Hospital-based studies;

2) Randomized trials, case studies, qualitative studies, systematic reviews, protocols, commentaries, editorials and conference abstracts;

3) Full text can't be obtained or data that can't be extracted;

4) Repeated publications (we will include study with the most complete data).

Databases and search strategy

Electronic databases including MEDLINE/PubMed, EMBASE, the Cochrane Library, Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), and Wanfang database will be searched. Both Medical Subject Headings (MeSH) and free text words related to China, diabetes and depression will be used for searching relevant articles. The search strategy of PubMed was shown in Additional file 2. Suitable strategies will be applied in other electronic database in accordance with respective retrieval rules. We will search reference lists of included articles and relevant SRs for additional eligible studies. Grey literature will also be manually searched such as conference proceedings and academic degree dissertations.

Study selection

We will use reference management software (ENDNOTE X9) to manage the all articles collected from literature search. After filtering out the duplicate records, two independent reviewers (HLZ and JZ) will screen the titles and abstracts of the rest records to acquire potentially eligible studies preliminary. Then, full texts will be obtained and checked independently by two reviewers (XBL and JF) to identify the eligible studies. All screening processes will be based on inclusion and exclusion criteria. Any disagreements will be discussed with a third reviewer (JL) to meet a consensus. We will provide a list of excluded studies and justify the exclusions. PRISMA flow diagram will be presented to describe the screening and selection processes.

Data extraction

Once eligible studies are identified, two reviewers (YXL and DLZ) will independently extract the data using a prepared data extraction form. The extracted data from each study will include:

1. Study characteristics: title, journal, conducted year(s), country, geographical region, method of data collection, criteria used to define diabetes and depression, source of funding;
2. Participants information: mean age, gender, history of diabetes, education level, living habit (eg. smoking, drinking history and exercise habit), diabetes treatment (eg. diet control, oral medicine, use of insulin), and other relevant reported demographic, health, and diabetes-related information;
3. Critical data: sample size, the number of subjects with depression, response rate, the reason for non-response, potential risk factors associated with development of depression in T2DM with their respective subjects' number and/ or respective odds ratio (OR) and 95% confidence interval (CI).

If necessary, we will contact the corresponding authors by e-mail for any incomplete information and data. Finally, the extracted data will be cross-checked, a third reviewer (JRJ) will participate in discussion if there are any disagreements.

Quality assessment

Two reviewers (LG and CD) will assess the quality of included studies dependently by the Agency for Healthcare Research and Quality (ARHQ) methodology checklist which is devised for cross-

sectional/prevalence study quality^[34, 35]. ARHQ methodology checklist consists of 11 items, and each item will be answered with “Yes”, “No” or “Unclear”. An item will be scored “1” if answered with “Yes” and scored “0” if answered with “Unclear” or “No”. A study will be defined as high-quality if the total scores greater than 7 points. Assessment results will be cross-checked, and disagreement will be determined by a third reviewer (JL).

Data analysis

We will calculate the primary outcome of prevalence with 95% CI of depression in T2DM patients by pooling the proportion of T2DM with depression in each included study. Meanwhile, to explore potential risk factors, we will calculate the OR values and 95% CI of the reported risk factors for depression in T2DM patients, and it will be considered statistically significant when OR value and 95% CI is not equal to 1 and $P < 0.05$ ^[36]. The statistical heterogeneity among studies will be assessed by the Cochran's Q test and the I^2 statistic. P value < 0.10 for the Q test and an $I^2 > 50\%$ will be set as the threshold for statistically significant heterogeneity. Since heterogeneity is expected, we will use random-effects model to pool all outcomes. We will assess inter-rater agreement between reviewers for study inclusion, data extraction, and study quality assessment using Kappa statistics. Strength of agreement will be divided into 6 categories according to Kappa statistics: poor (< 0.00), slight ($0.00-0.20$), fair ($0.21-0.40$), moderate ($0.41-0.60$), substantial ($0.61-0.80$), or almost perfect ($0.81-1.00$)^[37]. All statistical analyses will be performed using R software (version 3.6.1) and STATA (version 12.0) software.

Subgroup analysis

In the subgroup analyses, we will obtain respective prevalence of depression in T2DM patients according to the characteristics which are consistent with potential risk factors, such as gender, age, educational level, complications and living habit (eg. smoking, drinking history and exercise habit) and other characteristics (based on authors' report). In addition, subgroup analyses based on different ways of defining depression (eg. Patient Health Questionnaire-9, Hamilton Depression Scale, or Self-rating depression scale) and quality of included studies (score > 7 and score ≤ 7) will be carried out.

Meta-regression analysis

If there are statistically significant heterogeneity, meta-regression analysis will be used to investigate the potential sources of heterogeneity. Based on available data points and number of included studies, we plan to conduct meta-regression analyses by type of depression screening instruments, age (average age), gender (proportion of women), year of study conduct and so on.

Publication bias

If there are ≥ 10 studies in primary outcome and in each potential risk factors, we will use Funnel plots and Egger's test to assess publication bias.

Discussion

In China, the ever-increasing prevalence of T2DM brings a great challenge for public health^[5, 38]. According to the results of cross-section studies, the prevalence of T2DM patients with depression in China ranges from 10% to 50%^[25-29]. Variety in the prevalence of depression may be due to the differences in sample population and screening instruments of studies. For example, the prevalence of depression in T2DM screened by Patient Health Questionnaire-9 and Zung Self-rating Depression Scale in 2 different districts of Shanghai were 18.8% and 35.1%, respectively^[39, 40]. Part of the studies reported that female T2DM patients has higher prevalence of depression than man^[25, 27], and people over 60 years old was a risk factor for depression in patients with T2DM^[25], while others' results did not support gender and age are associated with depression in T2DM patients^[28, 39]. Given that, only after understanding the present epidemiological status of depression in T2DM in China and identifying high-risk patients of depression can we offer more targeted intervention strategies for them.

Study has shown that an early self-management education can improve depressive status, resulting in better blood glucose control in patients with newly diagnosed T2DM^[41]. This means an early attention and intervention can be beneficial for the psychological outcomes of people with T2DM, especially those at high risk for depression. In addition, for T2DM patients whose depressive symptom was screened out, subsequent monitoring of depression symptoms and intensive treatment of depression are important and appear to successful^[42]. For examples, both physical activity intervention and cognitive behavioral therapy are beneficial in improving depression for patients with T2DM^[43, 44]. Therefore, detection and treatment of depression as early as possible are crucial for T2DM population.

Our SR will provide a pooled Chinese prevalence of depression in patients with T2DM by quantitative analysis, expecting to provide evidence basis for healthcare practitioners and policy makers to comprehensively consider the psychosomatic symptoms in the diagnosis and treatment of T2DM. And through exploring the risk factors associated with development of depression in T2DM, the high-risk population of depression might be benefit from early interventions. To sum up, our data will highlight the need and importance of early detection and intervention for depression in patients with T2DM.

Abbreviations

T2DM: type 2 diabetes mellitus; IDF: international diabetes federation; PRISMA-P: Preferred Reporting Item for Systematic Review and Meta-analysis-Protocol; MOOSE: Meta-analysis Of Observational Studies in Epidemiology; PROSPERO: Prospective Register of Systematic Reviews; MeSH: Medical Subject Headings; CBM: Chinese Biomedical Literature Database; CNKI: China National Knowledge Infrastructure; VIP: Chinese Science and Technology Periodical Database.

Declarations

Ethics approval and consent to participate

Not required.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Author's contributions:

XBL, CD and HJ wrote the manuscript; RJJ, JL and LG conceptualized the study; XBL and YXL designed the search strategy and will perform searches; HLZ, JZ, XBL and JF will select studies; YXL and DLZ will extract the data; LG and CD will assess the quality of included studies.

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Not applicable.

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