Predictors of poor glycemic control among type 2 diabetes mellitus patients treated with antidiabetic medications

A cross-sectional study in China

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Abstract
This study aimed to clarify the predictors of poor glycemic control in type 2 diabetes mellitus (T2DM) patients treated with antidiabetic medications in China.

This study was a retrospective, cross-sectional study based on SuValue database. T2DM patients aged 18 years or older performing glycosylated hemoglobin A1c (HbA1c) examinations from January 1st, 2018 to December 31st, 2018 were included and have been treated with antidiabetic medications for at least 6 months. HbA1c < 7.0% was defined as adequate glycemic control. Multivariate analysis was performed for the factors associated with poor glycemic control.

A total of 13972 T2DM patients were included in this study. The adequate glycemic control rate was 44.04% (n=6153). In the multivariate analysis, predictors of poor glycemic control include longer T2DM duration (5–10 years vs <5 years and >10 years vs <5 years, odds ratio [OR] = 1.499 and 1.581, \( P < .001 \) and \( P = .008 \)), myocardial infarction (OR = 1.141, \( P = .041 \)), diabetic neuropathy (OR = 1.409, \( P < .001 \)), secondary hospital (OR = 1.877, \( P < .001 \)), underdeveloped regions (OR = 1.786, \( P < .001 \)), insulin only (OR = 3.912, \( P < .001 \)), combination of oral antidiabetic agents and/or insulin use (\( P < .001 \)).

In conclusion, longer T2DM duration, secondary hospital, myocardial infarction, diabetic neuropathy, undeveloped regions and use of polypharmacy and insulin were associated with poor glycemic control among T2DM patients treated with antidiabetic medications. Patient education and training of health care providers may be short-term strategy to achieve adequate glycemic control.

Abbreviations: EMRs = electrical medical records, HbA1c = glycosylated hemoglobin A1c, OR = odds ratio, T2DM = type 2 diabetes mellitus.

Keywords: glycemic control, glycosylated hemoglobin A1c, type 2 diabetes mellitus

1. Introduction
Prevalence of type 2 diabetes mellitus (T2DM) in China was only 0.67% according to epidemiology study among 300,000 participants in 1980.11 But the proportion of T2DM has increased to 10.4%2 in 2013 with the changes in lifestyle and aging. It is projected that 113.9 million Chinese adults may have T2DM.2,3

Poor glycemic control was associated with a variety of complications such as hypertension and hyperlipidemia.4,5 Most patients with T2DM have at least 1 complication such as diabetic retinopathy, kidney disease, neuropathy, myocardial infarction and stroke, which have contributed remarkably to the burden of mortality and disability worldwide.6 Large randomized trials have demonstrated that intensive blood-glucose control (glycosylated hemoglobin A1c [HbA1c] < 7.0% as control criteria) could reduce the risk of microvascular complications and delay the progression of diabetic retinopathy, nephropathy, and neuropathy in patients with treatment.7 Both Chinese Diabetes Society and American Diabetes Association have published guidelines recommending glucose control of T2DM patients with HbA1c < 7% in adults.8,9 However, it is difficult to control HbA1c level in China. A large-scale study has demonstrated that only 39.7% of patients with treatment had adequate glycemic control with HbA1c < 7.0% in 2010 in China.2 Several reports have demonstrated that older patients and longer duration had been reported to be risk factors for poor glycemic control in Chinese T2DM patients.10,11 In addition, there have been several antidiabetic medications for T2DM patients including oral and injectable medications.8,12,13
However, there is limited data about the economics, hospital level and regions on the poor glycemic control among T2DM patients treated with anti-diabetic medications in China.

SuValue database included electrical medical records (EMRs) of patients from 161 hospitals across 18 provinces in China. Thus, it is possible to analyze the economics, hospital levels and regions on the glycemic control. Based on the SuValue database, we aimed to analyze the status of glycemic control (assessed by HbA1c) in T2DM patients with anti-diabetic medications from January 1 to December 31 in 2018, and conducted analysis for the associated factors with glycemic control.

2. Method

2.1. Study design and data source

A retrospective, cross-sectional study of inpatients and out-patients with T2DM was performed from January 1st, 2018 to December 31st, 2018. The EMRs of included patients were extracted from SuValue database which includes EMRs of > 90 million unique patients from 161 hospitals across 18 provinces in China. The ethics approval of this study was exempt because the authorization was obtained for SuValue database.[14]

2.2. Inclusion and exclusion criteria

T2DM patients aged 18 years or older and performing HbA1c examination from January 1st to December 31st in 2018 were included and have been treated with anti-diabetic medications for at least 6 months. Patients diagnosed with gestational diabetes mellitus or with emergency admission 2 weeks ago were excluded.

2.3. Data extraction

Sociodemographic, disease and treatment information including sex, age, hospitals, diagnosis, T2DM duration, anti-diabetic medications and laboratory examination results were extracted from SuValue database. HbA1c < 7.0% was defined as adequate glycemic control. We assessed if a patient had comorbidities (such as hypertension, ischemic stroke and myocardial infarction) or complications (such as diabetic nephropathy, diabetic retinopathy, diabetic neuropathy, diabetic lower extremity arterial disease and diabetic foot disease) according to the diagnosis records.

2.4. Statistical analysis

We grouped included patients into age groups of 18 to 29, 30 to 39, 40 to 49, 50 to 59, 60 to 69, and ≥70 years. T2DM duration was categorized as <5, 5 to 10 and >10 years. Hospitals which patients admitted to were categorized as North and South regions with Qinling-Huaihe river as the boundary line and Eastern, central and Western regions according to previously published article.[15] Regions where hospitals located were categorized as developed regions, medium-developed regions and underdeveloped regions according to local gross domestic product released in local government website. Hospitals were categorized as secondary and tertiary hospital according to the criteria enacted by National Health Commission in China. The categories for anti-diabetic medications were oral anti-diabetic medications only, insulin only, combination of oral anti-diabetic medications and combination of oral anti-diabetic medications and insulin.

Statistical analysis was performed using SPSS 20.0 software. The qualitative data were expressed as percentage and Chi-Squared test was performed for univariate analysis. Multiple logistic regression analysis with “enter” method was performed. We included all variables as factors in the logistic regression model to obtain the adjusted odds ratio (OR) for predicting HbA1c > 7%. The difference was statistically significant with P < .05.

3. Results

3.1. Demographic data and glycemic control

From January 1st to December 31st in 2018, a total of 13,972 patients with T2DM performing for HbA1c examination were included in the study. Most of patients were male (50.19%), aged 60 to 69 years (30.05%), with T2DM duration of <3 years (68.67%), in Southern regions (89.71%), in Eastern regions (39.21%), in secondary hospitals (57.49%), in developed regions.

| Characteristics | NO (%) |
|-----------------|--------|
| Sex | 6976 (50.19%) |
| Age group (yrs) | 6923 (49.81%) |
| 18–29 | 91 (0.66%) |
| 30–39 | 374 (2.69%) |
| 40–49 | 1825 (13.15%) |
| 50–59 | 3277 (23.61%) |
| 60–69 | 4171 (30.05%) |
| ≥70 | 4144 (29.85%) |
| T2DM duration (yrs) | |
| < 5 | 9378 (68.67%) |
| 5–10 | 3965 (29.03%) |
| >10 | 313 (2.29%) |
| Hypertension | 6220 |
| Ischemic stroke | 2773 |
| Myocardial infarction | 3073 |
| Diabetic nephropathy | 1956 |
| Diabetic retinopathy | 956 |
| Diabetic neuropathy | 2649 |
| Diabetic foot | 398 |
| Diabetic lower extremity arterial disease | 37 |

| Region | NO (%) |
|--------|--------|
| Northern region | 12534 (89.71%) |
| Southern region | 1438 (10.29%) |
| Region 2 | |
| Eastern region | 8273 (59.21%) |
| Central region | 681 (4.87%) |
| Western region | 5018 (35.91%) |
| Hospital grade | |
| Secondary | 8033 (57.49%) |
| Tertiary | 5939 (42.51%) |
| Economic development | |
| Developed regions | 11983 (85.76%) |
| Medium-developed regions | 782 (5.60%) |
| Underdeveloped regions | 1207 (8.64%) |
| Treatment modality | |
| Oral anti-diabetic agents only | 1972 (23.36%) |
| Insulin only | 880 (10.42%) |
| Combination of oral anti-diabetic agents | 3689 (43.69%) |
| Combination of oral anti-diabetic agents and insulin | 1902 (22.53%) |
Table 2
Demographic and clinical factors associated with poor glycemic control by univariate analysis.

| Factors                                      | HbA1c < 7.0% level, n (%) | HbA1c ≥ 7.0% level, n (%) | P value |
|----------------------------------------------|---------------------------|---------------------------|---------|
| Total                                        | 6153 (44.04%)             | 7819 (55.96%)             |         |
| Age group (yrs)                              |                           |                           | .045    |
| 18–29                                        | 32 (0.52%)                | 59 (0.76%)                |         |
| 30–39                                        | 167 (2.74%)               | 207 (2.66%)               |         |
| 40–49                                        | 838 (13.73%)              | 987 (12.69%)              |         |
| 50–59                                        | 1485 (24.34%)             | 1792 (23.03%)             |         |
| 60–69                                        | 1809 (29.65%)             | 2362 (30.36%)             |         |
| ≥70                                          | 1771 (29.02%)             | 2373 (30.50%)             |         |
| T2DM duration (yrs)                          |                           |                           | <.001   |
| <5                                           | 4319 (71.77%)             | 5059 (66.23%)             |         |
| 5–10                                         | 1578 (26.22%)             | 2387 (31.25%)             |         |
| >10                                          | 121 (2.01%)               | 192 (2.51%)               |         |
| Hypertension                                 |                           |                           | .375    |
| Ischemic stroke                              |                           |                           | .003    |
| Myocardial infarction                        |                           |                           | <.001   |
| Diabetic nephropathy                         |                           |                           | <.001   |
| Diabetic retinopathy                         |                           |                           | <.001   |
| Diabetic neuropathy                          |                           |                           | <.001   |
| Diabetic foot                                |                           |                           | .086    |
| Diabetic lower extremity arterial disease    |                           |                           | .037    |
| Region 1                                     |                           |                           | .441    |
| Southern regions                             | 5506 (89.48%)             | 7028 (89.88%)             |         |
| Northern regions                             | 647 (10.52%)              | 791 (10.21%)              |         |
| Region 2                                     |                           |                           | <.001   |
| Eastern regions                              | 3959 (63.34%)             | 4314 (65.17%)             |         |
| Central regions                              | 349 (5.67%)               | 332 (4.25%)               |         |
| Western regions                              | 1845 (29.99%)             | 3173 (40.56%)             |         |
| Hospital grade                               |                           |                           | <.001   |
| Secondary                                   | 3174 (51.58%)             | 4859 (62.14%)             |         |
| Tertiary                                    | 2979 (48.42%)             | 2960 (37.86%)             |         |
| Economic development                         |                           |                           | .035    |
| Developed regions                            | 5324 (86.53%)             | 6659 (85.16%)             |         |
| Medium-developed regions                     | 339 (5.51%)               | 443 (6.67%)               |         |
| Underdeveloped regions                       | 490 (7.96%)               | 717 (9.17%)               |         |
| Treatment modality                           |                           |                           | <.001   |
| Oral antidiabetic agents only                | 1329 (33.92%)             | 643 (14.21%)              |         |
| Insulin only                                 | 278 (7.10%)               | 602 (13.30%)              |         |
| Oral antidiabetic agents                     | 1810 (46.20%)             | 1879 (41.52%)             |         |
| Oral antidiabetic agents and insulin         | 501 (12.70%)              | 1401 (30.96%)             |         |

(85.76%) and combination of oral antidiabetic agents (43.69%).
Table 1 showed the characteristics of included T2DM patients.

3.2. Univariate analysis and multivariate analysis of factors associated with poor glycemic control

Among 13972 T2DM patients, the proportion of adequate glycemic control with HbA1c < 7% was 44.04% (n = 6153). Univariate analysis showed that poor glycemic control was associated with age (P = .045), T2DM duration (P < .001), ischemic stroke (P = .003), myocardial infarction (P = .002), diabetic nephropathy (P < .001), diabetic retinopathy (P < .001), diabetic neuropathy (P < .001), diabetic lower extremity arterial disease (P = .037), Western regions (P < .001), secondary hospital (P < .001), underdeveloped regions (P = .035), and insulin use/polypharmacy (P < .001, Table 2).

In the multivariate analysis, longer T2DM duration (5–10 years vs < 5 years and > 10 years vs < 5 years, OR = 1.499 and 1.581, P < .001 and P = .008), myocardial infarction (OR = 1.141, P = .041), diabetic neuropathy (OR = 1.409, P < .001), secondary hospital (OR = 1.877, P < .001), underdeveloped regions (OR = 1.786, P < .001), insulin only (OR = 3.912, P < .001), combination of oral antidiabetic agents (OR = 2.129, P < .001), combination of oral antidiabetic agents and insulin (OR = 5.250, P < .001) were associated with poor glycemic control. All age groups (30–39, 40–49, 50–59, 60–69, ≥70), ischemic stroke, diabetic nephropathy, diabetic retinopathy and diabetic lower extremity arterial disease were not associated with the poor glycemic control (P > .05) (Table 3).

4. Discussion

This was a retrospective, cross-sectional study of glycemic control in T2DM patients who admitted to hospitals between January 1st, 2018 and December 31st, 2018. Our study showed that 44.04% of T2DM patients achieved adequate glycemic control (HbA1c < 7%), which was higher than 32.6% between 2010 and 2012 in China in previous report (HbA1c < 7% or fasting plasma glucose < 7.0 mmol/L)[10] but was lower than 53.6% in 8 European countries (HbA1c < 7%).[16] Longer T2DM duration,
diabetic neuropathy, myocardial infarction, use of polypharmacy and insulin, secondary hospital and underdeveloped regions increased the risk of poor glycemic control.

Both univariate and multivariate analysis showed that T2DM duration ≥5 years was associated with poor glycemic control in this study. These results were similar with previous reports that patients with longer duration of T2DM had been shown to have higher levels of HbA1c. The reason may be due to the disease progression, progressively loss of pancreatic beta cell function, resistance to medication and increased dose and medication types. In addition, diabetic neuropathy and myocardial infarction were associated with poor glycemic control in this study. Similarly, in previous report in India, neuropathy, nephropathy and retinopathy were associated with poor glycemic control. The longer duration of T2DM may result into the complications. Insulin therapy in T2DM patients was initiated when failing on oral anti-diabetics agents due to the escalating deterioration in the function of pancreatic β-cells. Thus, similarly with duration, insulin use and polypharmacy were also predictors for poorer glycemic control. Polypharmacy could increase the potential risk of drug-drug interactions and non-adherence to treatment regimens. The insulin adherence and persistence are generally poor among Chinese T2DM patients. Patients may not realize the severity of T2DM and do not know the treatment regimes very well. In addition, poor communication resulted from limited clinic time between caregivers and patients may contribute into the poor insulin adherence and persistence in China. Thus, patient education may be a good strategy for adequate glycemic control in T2DM patients in China.

Univariate and multivariate analysis showed that underdeveloped area predicts the poor glycemic control, which is similar with previous report that proportion of patients with adequate glycemic was lowest in underdeveloped regions. The poor glycemic control rate was higher in developing countries comparing with USA and European countries (63.0% vs 47.8% vs 46.4% ). In underdeveloped country, the diagnosis of T2DM was made when patients present with retinopathy, nephropathy and other complications, resulting in a consequent loss of treatment efficacy. In our study, most of patients were short duration with less than 10 years while most of them are with complications. It has been reported that peer health coaching significantly improved HbA1c in the coached group comparing with usual care group. Therefore, patient education is necessary in underdeveloped regions to reduce the poor glycemic control rate.

In our study, secondary hospitals were significantly related with poor glycemic control. Thus, training of health-care providers should also be strengthened in secondary hospitals to achieve the goal of improvement in glycemic control. Health-care providers should emphasize on early diagnosis, systematic screening for complications and proper and timely treatment according to related guidelines.

The strength of current study was that data were reliable based on EMRs and we analyzed the glycemic control status all over China. However, there were several limitations in this study. First, some factors that may influence the glycemic control were not available on the electronic medical records such weight, lifestyle and medication adherence. Second, although we extracted the EMRs of primary hospital, no patient was included according to related guidelines. Third, the methodology for HbA1c may be different across different laboratories for the lack of standardization for HbA1c in China.

In conclusion, self-management and intensive monitoring should be especially concerned in T2DM with longer duration, diabetic neuropathy, myocardial infarction and polypharmacy and insulin use in underdeveloped regions and in secondary hospitals. Patient education and training of health care providers may be short-term strategy to achieve adequate glycemic control.

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### Author contributions

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**Table 3: Logistic regression analysis of factors associated with poor glycemic control among patients with type 2 diabetes mellitus.**

| Factors                        | Adjusted OR (95% CI) | P value |
|-------------------------------|----------------------|---------|
| Age (yrs)                     |                      |         |
| 18–29                         | Ref                  |         |
| 30–39                         | 0.969 (0.505–1.85)   | .922    |
| 40–49                         | 0.961 (0.532–1.737)  | .895    |
| 50–59                         | 0.925 (0.516–1.659)  | .794    |
| 60–69                         | 1.012 (0.564–1.813)  | .969    |
| ≥60                           | 0.932 (0.519–1.673)  | .813    |
| T2DM duration (yrs)           |                      |         |
| <5                            | Ref                  |         |
| 5–10                          | 1.499 (1.337–1.682)  | <.001   |
| >10                           | 1.581 (1.125–2.221)  | .008    |
| Ischemic stroke               |                      |         |
| Yes                           | 1.096 (0.961–1.249)  | .173    |
| No                            | Ref                  |         |
| Myocardial infarction         |                      |         |
| Yes                           | 1.141 (1.005–1.296)  | .041    |
| No                            | Ref                  |         |
| Diabetic nephropathy          |                      |         |
| Yes                           | 0.913 (0.787–1.061)  | .236    |
| No                            | Ref                  |         |
| Diabetic retinopathy          |                      |         |
| Yes                           | 1.006 (0.822–1.232)  | .953    |
| No                            | Ref                  |         |
| Diabetic neuropathy           |                      |         |
| Yes                           | 1.409 (1.231–1.611)  | <.001   |
| No                            | Ref                  |         |
| Diabetic lower extremity arterial disease |         |         |
| Yes                           | 0.655 (0.234–1.833)  | .421    |
| No                            | Ref                  |         |
| Hospital level                |                      |         |
| Secondary                     | 1.877 (1.692–2.082)  | <.001   |
| Tertiary                      | Ref                  |         |
| Economic development          |                      |         |
| Developed regions             | Ref                  |         |
| Moderately developed area     | 1.213 (0.985–1.493)  | .069    |
| Underdeveloped area           | 1.786 (1.478–2.158)  | <.001   |
| Treatment modality            |                      |         |
| Oral antidiabetic agents only | Ref                  |         |
| Insulin only                  | 3.912 (3.253–4.704)  | <.001   |
| Combination of oral antidiabetic agents |      |         |
| 2.129 (1.882–2.407)           | <.001   |
| Combination of oral antidiabetic agents and insulin | | <.001 |
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Writing – review & editing: Chendong Wen, Yan Liu, Hongshan Ma.

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