Patient Preference and Adherence Dovepress

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Medicine Usage for Hypertension Management in Type 2 Diabetes Patients in the Rural-Urban Fringe Zone, Suzhou City, Jiangsu Province, China

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Objective: Medicine is critical for blood-pressure control in patients with type 2 diabetes mellitus (T2DM), for evaluation of treatment patterns and effects would offer baselines for future health services.

Methods: A cross-sectional study was conducted from August 2018 to January 2021 in the urban-rural fringe zone of Suzhou City, Jiangsu Province, China. Blood pressure and antihypertensive medication use were collected from T2DM patients combined with hypertension (HTN). Using systolic blood pressure (SBP) and diastolic blood pressure (DBP) <140/85 mmHg as HTN controls, medicine usage patterns were analyzed.

Results: Among the 931 T2DM patients with HTN, 333 (37.0%, 95% *CI*: 33.8%–40.2%) had HTN controlled with SBP and DBP of <140/85 mmHg. Partial following the medicine recommendations for HTN control were observed in this zone, and calcium channel blocker (CCB), angiotensin II receptor blocker (ARB), diuretics and β-receptor blocker (Beta-blocker) were the most frequently used ones, especially for CCB and ARB, which accounted for 67% (625/931) and 55% (509/931), respectively. For combination usage, complete adherence to the recommendation was observed, ie, ARB + CCB and ARB + diuretics were listed as the top two, accounting 30% (282/931) and 16% (153/931), respectively. Combination therapies had HTN control rates ranging from 31.1% to 39.1%, lower than those of monotherapy (>40%). In monotherapies, CCB had control rate of 41.2% (115/279, 95% *CI* 35.4%–47.2%), higher than combination (31.9%, 105/329, 95% *CI* 26.9%–37.3%), as well as ARB; the single reagent had control rate of 42.0% (95% *CI* 33.7%–50.7%), higher than combination (32.2%, 95% *CI* 27.4%–37.3%).

Conclusions: More than 60% of T2DM patients had blood-pressures above the target level and the pattern of medications for HTN control in T2DM patients followed the recommendation of the authorities; however, the effects were not as expected, and more antihypertensive medicines or combinations would not raise the HTN control rate.

Keywords: Management of T2DM, control rate, the urban-rural fringe zone, blood pressure, diabetes complications, coexistent disease

Introduction

According to data from the Seventh National Population Census of China, the aged ≥ 60 years accounted for 18.7% (260.4 million) and 13.3% for aged ≥65 of the total population in 2020, and these two data increased to 19.9% and 14.9% in 2022, respectively.[1,2] About 30% of the aged ≥60 years were diabetes (78.1 million), and more than 95% of them were type 2 diabetes (T2DM).[3] The co-existence of hypertension (HTN) and T2DM has been documented and epidemiological studies have showed that T2DM predisposes to HTN.[4] For instance, approximately 15 million people have both HTN and

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T2DM in China, and up to 75% of adults with diabetes also have hypertension in the USA.[5–7] The risk of T2DM-related mortality has increased dramatically due to the co-existence of HTN, especially for cardio cerebrovascular diseases and the co-existences are also the challenges of the healthcare system in low- and middle-income countries.[4] On the contrary, controlling HTN can significantly reduce the risk of diabetes complications and cardiovascular events.[8]

The National Guidelines for Primary Hypertension Prevention and Control Management suggest that all hypertensive patients should immediately initiate medication treatment along with lifestyle interventions once diagnosed.[9] Under such situation, even if the patient's condition and willingness to temporarily suspend medication, simple lifestyle intervention can be used for up to 3 months. If the control standard is not met, medication should be initiated. When selecting antihypertensive drugs for the co-existence of HTN and T2DM, comprehensive consideration should be given to factors such as antihypertensive efficacy; protective effects on heart, brain, and kidneys; safety and compliance; and impact on metabolism. Therefore, five categories of antihypertensive drugs are recommended as the basic drugs for antihypertensive treatment to reduce overall cardiovascular events and mortality according to the guidelines. The categories of antihypertensive drugs are angiotensin-converting enzyme inhibitors (ACEI), angiotensin II receptor blockers (ARB), β-receptor blockers, calcium channel blockers (CCB), and diuretics (referred to as A, A, B, C, and D).[9]

To control HTN combined with T2DM, A (ACEI or ARB) is preferred as the first choice, and C or D should be added to those who do not meet the control standard. However, maintaining the target of BP is still a challenge even with accessibility of drugs.[10] In order to improve health conditions for Chinese people and achieve national health aims, attention should be paid to the population inhabiting rural–urban areas. Data showed that 82.5% (8456/10238) T2DM patients combined with HTN in this area.[11] In 2018, the local government initiated a project for chronic disease management, including T2DM and HTN, in Suzhou, Jiangsu Province. Medication non-adherence or suboptimal adherence to medication is a well-known factor that contributes to poor control of blood pressure.[12] So, based on management registration, the baselines, especially pharmacological regimens for HTN in this area, should be explored, and the treatment patterns for HTN should be studied. Thus, based on these studies, better health services should be offered.

Material and Methods

Subjects

The local government initiated a project on chronic disease management from August 2018 to January 2021. Residents diagnosed with or with a history of T2DM were welcomed to participate in this project. As part of the government program, 1500 T2DM patients were expected; however, in this study, 1207 T2DM patients were included. According to this number, the statistical power of ≥90% would be obtained for cross-sectional study. After registration, basic information was collected, physical examinations and checkups were recorded, and regular follow-ups were performed for T2DM management. Among the registrations for T2DM, 77.1% (931/1207) had a history of hypertension and were selected as subjects for this study (Figure 1).

Three health service centers (urban-rural fringe zones) were implemented in the management as the basic public health service, covering approximately 200000 residents inhabited near a large lake (Taihu Lake). Registered T2DM patients met the following inclusion criteria: (1) adults aged ≥ 30 years diagnosed with diabetes based on fasting plasma glucose (FPG) ≥7.0 mmol/L, or 2h plasma glucose (2hPG) during an oral glucose tolerance test ≥11.1 mmol/L, or a history of T2DM; (2) residents of Suzhou who regularly visited the Community Health Service Center; and (4) willingness to participate in T2DM management. Patients with T1DM, T3cDM, or any other form of diabetes were excluded from the T2DM management. Missing data, without information on diabetes or treatment history, were excluded.

BP Measurements

BP measurements were taken according to the guidelines.[9] In brief, the subjects sat in the room for 5 min, kept calm, and then started to measure. An automatic blood pressure meter was used by the medical staff. During the measurement, the subjects maintained their arms at an altitude of the heart level, and the instrument automatically read the blood pressure

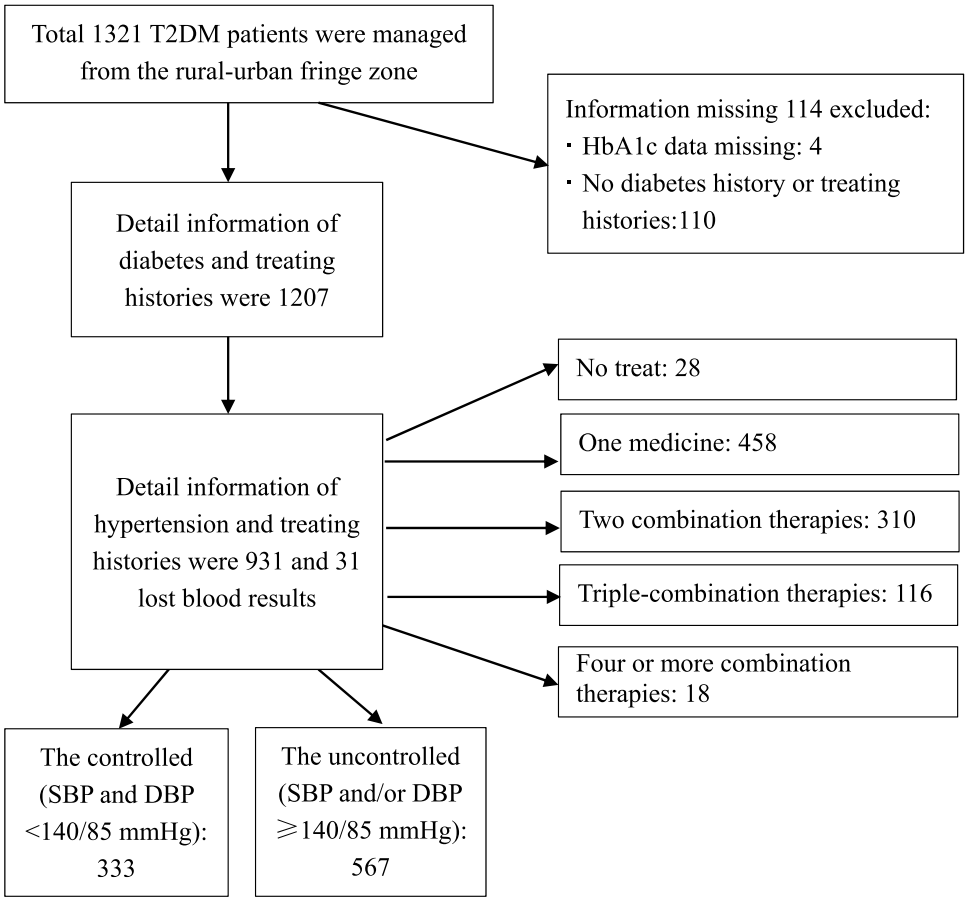

Figure 1 Data process flow for investigating the control of HTN in T2DM in a rural-urban fringe zone in Suzhou city, Jiangsu Province, China.
Abbreviations: HTN, hypertension; T2DM, type 2 diabetes mellitus; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure.

values. Two measurements were taken at each outpatient clinic at an interval of 1–2 minutes, and the average value of the two measurements was used for diagnosis.

Data Collection

This was a cross-sectional study including T2DM patients registered, and a medical staff team was trained and qualified for data collection. Registration was performed at a local hospital. Self-reported basic information, personal habits, and individual disease histories and treatments were collected by face-to-face investigation, and physical checkups and laboratory tests were carried out for body indices, blood, and urea results. In particular, FPG, 2hPG, FPI, and 2hPI levels were measured, and the history of diabetes and medications were investigated.

To investigate the medical use of HTN, considering the non-professional nature of patients, medicine packages were carried to the field and identified by a pharmacist. Pharmacists divided single-pill combination (SPC) medicines into monotherapies for each component according to categories A, A, B, C, and D.[9]

All participants were informed that the data could be used for scientific research and signed consent forms were obtained. For the elderly patients or the illiterate, consent forms were carefully explained and signed under the supervision of medical officer of the hospital. The study was conducted in accordance with the Declaration of Helsinki and approved by the Clinical Research Ethics Committee of the Affiliated Suzhou Hospital of Nanjing University Medical School.

The Controlled HTN in T2DM

Usually, the purpose of hypertension control is to improve the outcome of related cardiovascular and cerebrovascular diseases; therefore, the goal of blood pressure control in elderly patients with T2DM and HTN is <140/85 mmHg (also

called the general control standards). In view of the co-existence of three cardiovascular disease risk factors, namely age, the elderly, T2DM and HTN, the Chinese Diabetes Society adjusted the control standard of diabetes with hypertension to <130/80 mmHg in 2017 (also called strict control standards). For patients with a history of ischemic cardiovascular and cerebrovascular diseases or long-term uncontrolled HTN, the acceptance criterion for the adjustment period was <150/90 mmHg.[13]

In this study, the degree of blood pressure control was based on the following criteria: general control standards, that is, systolic blood pressure (SBP) and diastolic blood pressure (DBP) less than 140 mmHg and 85 mmHg, respectively; strict control standards, with SBP and DBP less than 130 mmHg and 80 mmHg, respectively, and acceptable criteria with SBP and DBP less than 150 mmHg and 90 mmHg, respectively.

Data Processing and Statistical Methods

The data were first checked and then decrypted for personal confidentiality before the analysis. After establishing the database, the data were cleaned to remove unqualified data before the analysis. The distribution of continuous data was checked first, and then the original data were used for calculation of normal distribution. Data were squared or logarithm-transformed for skewed distribution if the condition was permitted (Supplement Figure 1), according to transforming, normal distribution methods would be used. The durations of T2DM and HTN were transformed using the squared method. Quantitative data are presented as the mean ± standard deviation or median with quartile percentiles. Student's *t*-test (or *t*-test) was used for comparisons between the groups. Qualitative data (or counting data) are described as percentages or proportions, and comparisons between groups were performed using the chi-square test. $P < 0.05$ was considered as statistically significant of two sides.

The analysis process of the subjects is shown in Figure 1.

Results

As part of the long-term management of T2DM in the rural–urban fringe zone located in Suzhou city, Jiangsu province, this cross-sectional study included 1321 patients, covering about 10% of diabetic population in this area. Among them, 4 (0.3%) lost plasma HbA1c data and 110 (8.3%) without information on diabetes history or treatment histories were excluded (Figure 1).

The 931 T2DM patients with hypertension were aged 66 ± 8 years (min-max: 38–90 years) and 302 were male (32.4%). The patients had T2DM disease duration of 8.2 ± 1.0 years (min-max: 0.1–32.5 years) and HTN disease duration of 10.7 ± 1.1 years (min-max: 0.1–56.1 years). No obvious associations were observed between age and disease duration or between T2DM disease duration and HTN duration (Supplemental Figure 2).

According to Chinese management guidelines, under the strict control standards, less than 1/5 (16.6%, 149/900, 95% *CI*: 14.2%–19.1%) of T2DM patients with SBP and DBP <130/80 mmHg; Using the general control standards, 37.0% (333/900, 95% *CI*: 33.8%–40.2%) T2DM patients with HTN was controlled with SBP and DBP <140/85 mmHg. Using the acceptance criteria for the adjustment period of SBP and DBP <150/90 mmHg, the control rate was 60.2% (542/900, 95% *CI*: 56.9%–63.4%)(Figure 2).

Among medicines for HTN control in T2DM patients in this rural-urban fringe zone, CCB, ARB, diuretics and B-blockers were the most frequently used, especially for CCB, ARB, which accounted for 67% (625/931) and 55% (509/931) respectively (Table 1). Combinations were mostly observed for these medicines. For example, approximately one-half of CCB were single-used for HTN control in T2DM patients, obviously higher than most of the other reagents (the nearest monotherapy between CCB and ARB with $\chi^2 = 36.172$, $P < 0.001$).

ARB, B-blockers, CCB and diuretics were commonly used as combinations. For example, CCB and ARB were the most commonly observed combinations for HTN, accounting for 30% (282/931) of patients under management (Table 2). Nearly 60% (167/282) of CCB and ARB combinations were two-drug combinations (Table 3). Diuretics combined with ARB were the second most common, with a proportion of 16% (153/931); however, approximately 65% (99/153) of this combination had three or more combinations. The combination of diuretics and CCB accounted for the majority (94%, 97/103) of the triple or more combinations.

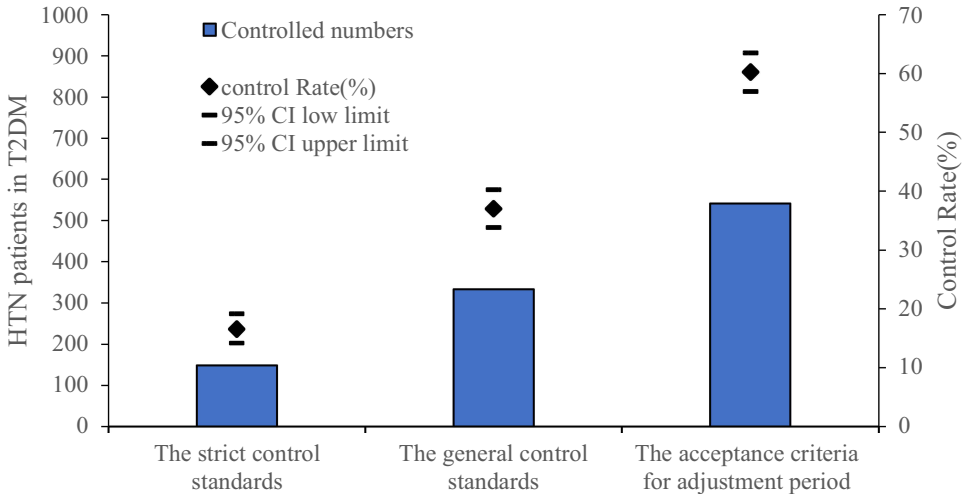

Figure 2 The HTN control numbers and rates inT2DM patients with difference standard The strict control standards means SBP and DBP <130/80 mmHg; the general control standards means SBP and DBP <140/85 mmHg; the acceptance criteria for adjustment period means SBP and DBP <150/90 mmHg.

Medicines and HTN Control

Using SBP and DBP <140/85 mmHg as the control standards, the results showed that the control rate was 37.0% (333/900, 95% *CI*: 33.8%–40.2%). Considering the therapy pattern of monotherapy or combination of reagents, more numbers were with lower HTN control rates (Table 4). Combination therapy with the control rate of HTN ranged from 31.1% to 39.1% (Figure 3), which was lower than that of monotherapy with HTN control rates of more than 40%. For example,

Table 1 Treatment Medicines for HTN Control in Patients with T2DM in a Rural-Urban Fringe Zone in Suzhou City, Jiangsu Province, China

	Frequency	Monotherapy (%)*	Combination therapy			
			2	3	4	5
CCB	625	283(45.3)	217	106	18	1
ARB	509	142(27.9)	242	106	18	1
Diuretics	192	7(3.6)	78	88	18	1
Beta-blocker	115	13(11.3)	51	33	17	1
ACEI	43	4(9.3)	28	10	1	0
Others	19	9(47.4)	4	5	0	1

Notes: ACEI, angiotensin-converting enzyme Inhibitor; ARB, angiotensin II receptor blocker; Beta-blocker, β-receptor blocker; CCB, calcium channel blockers *Percentage in monotherapy means single usage of this regent accounted for all of its usage.

Table 2 Combination Matrix of Medicines for HTN Control in Patients with T2DM in a Rural-Urban Fringe Zone in Suzhou City, Jiangsu Province, China

	CCB	ARB	Diuretics	Beta-blocker	ACEI	Others
CCB		282	103	70	23	9
ARB	282		153	66	5	6
Diuretics	103	153		33	21	2
Beta-blocker	70	66	33		2	1
ACEI	23	5	21	2		0
Others	9	6	2	1	0	

Notes: ACEI, angiotensin-converting enzyme Inhibitor; ARB, angiotensin II receptor blocker; Beta-blocker, β-receptor blocker; CCB, calcium channel blockers.

Table 3 Combination Usages of Medicines for HTN Control in Patients with T2DM in a Rural-Urban Fringe Zone in Suzhou City, Jiangsu Province, China

	2	≥3	Total
ARB+ CCB	167	115	282
ARB + Diuretic	54	99	153
Diuretic +CCB	6	97	103
CCB+Beta-blocker	27	43	70
ARB+Beta-blocker	19	47	66
Diuretic+Beta-blocker	5	28	33
CCB+ACEI	14	9	23
ACEI+Diuretic	12	9	21

Notes: ACEI, angiotensin-converting enzyme Inhibitor; ARB, angiotensin II receptor blocker; Beta-blocker, β-receptor blocker; CCB, calcium channel blockers.

Table 4 Comparisons Between Monotherapy and Combination Therapy of HTN Control Regents in Patients with T2DM in a Rural-Urban Fringe Zone in Suzhou City, Jiangsu Province, China

	Monotherapy			Combination therapy			χ^2	*P*
	Controlled	Uncontrolled	Control rate(95% CI)	Controlled	Uncontrolled	Control rate(95% CI)		
CCB	115	164	41.2(35.4–47.2)	105	224	31.9(26.9–37.3)	5.659	0.017
ARB	58	80	42.0(33.7–50.7)	114	240	32.2(27.4–37.3)	4.215	0.040
Diuretic	2	4	33.3(4.3–77.7)	57	115	33.1(26.2–40.7)	0.185**	0.666
Beta-blocker	7	6	53.8(25.1–80.8)	35	59	37.2(27.5–47.8)	1.321	0.250
ACEI	0	4	0.0(0.0–60.2)*	15	23	39.5(24.0–56.6)	1.038**	0.308
Others	4	5	44.4(13.7–78.8)	3	7	30.0(6.7–65.2)	Fisher exact	0.649

Notes: ACEI, angiotensin-converting enzyme Inhibitor; ARB, angiotensin II receptor blocker; Beta-blocker, β-receptor blocker; CCB, calcium channel blockers Controlled means SBP<140 mmHg and DBP<85mmHg; Uncontrolled means SBP≥140 and/or DBP≥85mmHg*, one-sided, 97.5% confidence interval; **, Yates corrected.

single regent had a control rate of 41.2% (115/279; 95% *CI* 35.4%–47.2%), which was higher than the combination of 31.9% (105/329, 95% *CI* 26.9%–37.3%)($\chi^2 = 5.659$, $P = 0.017$). This was also true for ARB, and the single reagent had a control rate of 42.0% (95% *CI* 33.7%–50.7%), which was higher than the combination with a rate of 32.2% (95% *CI* 27.4%–37.3%) ($\chi^2 = 4.215$, $P = 0.040$).

Discussion

Diabetes mellitus (DM) is a serious and costly disease that has become a public health problem worldwide. The coexistence of HTN and T2DM is common worldwide, and such combinations lead to a higher risk of cardiovascular and renal complications. The risk of diabetes-related mortality has increased dramatically owing to the coexistence of HTN.[14] Diabetic patients are twice as likely to have HTN as non-diabetic patients. Similarly, patients with HTN are more likely to develop diabetes than those with normotensive people.[5] In this paper, 77.1% (931/1207) had history of hypertension in T2DM, and the results are similar to those reported in USA that up to 75% of adults with diabetes also have hypertension.[7] Epidemiological studies have documented that T2DM predisposes to HTN,[4] however, in this paper, no correlations between T2DM duration with age and HTN duration was observed.

For primary prevention, optimal SBP and DBP control could reduce the risk of T2DM. The National Guidelines for Primary Hypertension Prevention and Control Management suggest that all patients with hypertension should immediately initiate medication treatment along with lifestyle interventions once diagnosed.[9] However, the effect of control was not as expected. Using the general standard as recommended, less than 40% of T2DM patients with HTN had controlled SBP and DBP of <140/85 mmHg. For strict control standards, the rate was even worse, and less than one-fifth of the

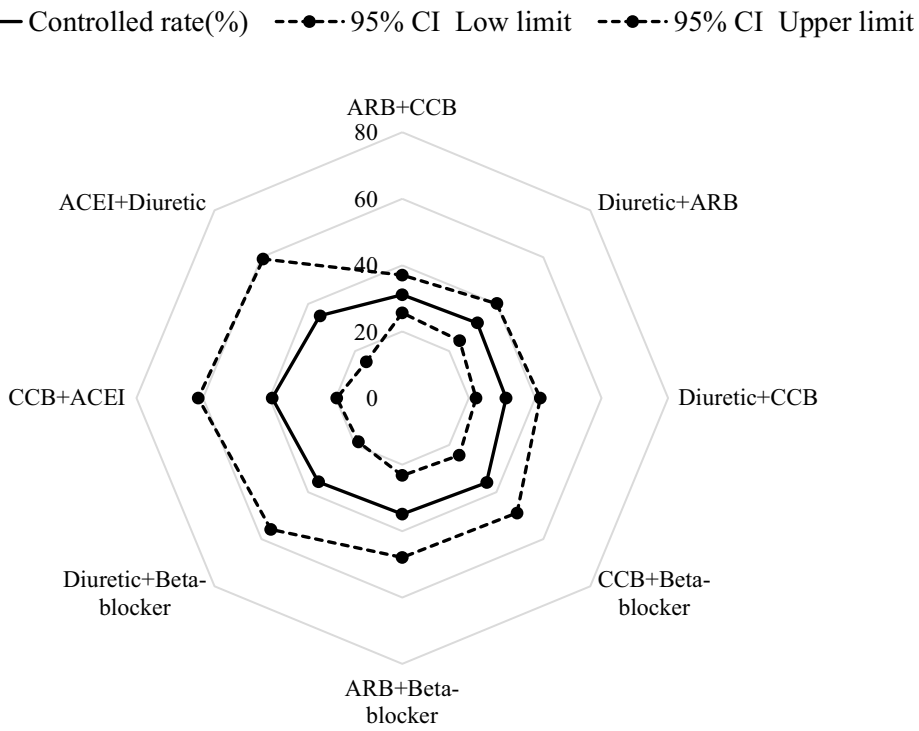

Figure 3 HTN control in T2DM patients for two-drug combinations in a rural-urban fringe zone in Suzhou City, Jiangsu Province, China.
Abbreviations: ACEI, angiotensin-converting enzyme Inhibitor; ARB, angiotensin II receptor blocker; Beta-blocker, β-receptor blocker; CCB, calcium channel blocker.

patients had SBP and DBP <130/80 mmHg. This result is very close to the results in India, in which the target BP for persons with diabetes was achieved by only 39.9% of T2DM patients.[10] It is obvious that target BP levels were far from being achieved in a majority of patients with T2DM, and effective measures need to be employed for the population located in the rural–urban fringe zone.

There are five categories of antihypertensive drugs were recommended as the basic drugs for antihypertensive treatment, including ACEI enzyme inhibitors, angiotensin receptor blockers, calcium channel blockers, and diuretics (referred to as A, A, B, C, D). For the coexistence of HTN and T2DM, it is recommended that class A (ACEI and ARB) be the first choice and class C or class D should be added for uncontrolled.[9] In this rural-urban fringe zone, it was observed that the recommendation was partically followed. For example, class A was not the most common, but class CCB was. In this paper, CCB, ARB, diuretics and B-blockers were the most frequently used medicines, especially for CCB, ARB, which accounted for 67% (625/931) and 55% (509/931) respectively, about 8% to 11% higher than the national results.[15] For combination usage, full adherence to the recommendation was observed, that is, ARB+ CCB and ARB + Diuretics were listed as the top two, with proportions of 30% (282/931) and 16% (153/931), respectively.

Although medicines were selected and combinations were used, the control effect of HTN in T2MD was not as expected, especially for combinations. Combination therapy with the control rate of HTN ranged from 31.1% to-39.1%, which was lower than that of monotherapy with an HTN control rate of more than 40%. For example, single regent had a control rate of 41.2% (115/279; 95% *CI* 35.4%–47.2%), which was higher than the combination of 31.9% (105/329, 95% *CI* 26.9%–37.3%) (χ^2 = 5.659, P = 0.017). This was also true for ARB; the single reagent had a control rate of 42.0% (95% *CI* 33.7%–50.7%), which was higher than the combination with a rate of 32.2% (95% *CI* 27.4%–37.3%) (χ^2 = 4.215, P = 0.040). The control effect was almost the same as that of monotherapy with recommended drugs. Studies show that a single-pill combination (SPC) may increase adherence and control effects;[16,17] however, what could be included in the combinations still needs to be explored.

DM and HTN share common comorbidities, and their frequent co-existence is not a coincidence but due to shared pathogenic mechanisms. T2DM and HTN were found to be associated with a significantly increased risk of CVDs, and they may work as additive or multiplicative interactions.[10,18] Therefore, controlling HTN is of great clinical and public health importance for T2DM management. Future research would propose a longitudinal design or intervention-based research could provide more robust data on treatment efficacy.

A few limitations of this study should be noted when interpreting the results. The study was based on data from registration claims, with limited information on the patients' clinical status. Also, as one observational study, self-reported information would cause potential biases; however, the study is a long term project, and information would be checked several times. Thus, potential biases would be limited. Furthermore, reasons for HTN control were not explored in this study. Medication non-adherence or suboptimal adherence to medications is a well-known factor that contributes to poor control of blood pressure and glycemic levels,[10] which means uncontrolled HTN may also have been caused by medication non-adherence in this study. Although claims data provides accurate information on medication dispensation, the lack of these factors may have biased our assessment. The paper is based on prescription/dispensation data submitted by healthcare providers; therefore, patients' actual administration behaviors were unknown. This study focused on combination usage, which is also called a free–equivalent combination,[16] so SPC was divided into monotherapy for each component according to categories when analyzing, and the effects of SPC were not studied, which may have been underestimated. In addition, reagent dosage was not included in the study because mistakes may have been reported by the patients themselves.

Conclusion

More than 60% of the patients with T2DM in our study had a BP above the target level. The pattern of using medications for HTN control in T2DM in the rural–urban fringe zone almost followed the recommendation of the authority; however, their effect was not as expected and more antihypertensive medicines would not raise the HTN control rate, and how to improve blood pressure control rate still need further research.

Abbreviations

T2DM, type 2 diabetes mellitus; HTN, hypertension; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin II receptor blocker; Beta-blocker, β- receptor blocker; BP, blood pressure; SBP, systolic blood pressure; DBP, diastolic blood pressure; CCB, calcium channel blocker; SPC, single-pill combination.

Data Sharing Statement

All data generated or analysed during this study are included in this published article.

Ethics Statement

The study involving human participants was conducted in accordance with the Declaration of Helsinki and approved by the Clinical Research Ethics Committee of the Affiliated Suzhou Hospital of Nanjing University Medical School (NO. IRB20170205OI).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study. The person(s) providing consent have been shown the article contents to be published.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no conflicts of interest regarding the publication of this article.

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