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Intensive vs. Standard Systolic Blood Pressure Control in Type 2 Diabetes: A Retrospective Study

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Declaration

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ABSTRACT

Background: Systolic blood pressure (SBP) control is a critical aspect of managing Type 2 diabetes, which is associated with an increased risk of cardiovascular events. This retrospective study compares the effects of intensive SBP control (targeting < 120 mmHg) versus standard SBP control (targeting < 140 mmHg) on cardiovascular outcomes, mortality, and adverse effects in Type 2 diabetes patients. **Methods:** A total of 500 patients with Type 2 diabetes were included, with 250 in the intensive control group and 250 in the standard control group. Cardiovascular outcomes (heart attacks, strokes, cardiovascular mortality), adverse effects (hypotension, hyperkalemia), and medication adherence were assessed. Cox proportional hazards regression was performed to evaluate the effect of intensive SBP control on cardiovascular risk. **Results:** The intensive control group showed a significantly lower incidence of heart attacks (4.8% vs. 7.2%, p=0.03), strokes (3.2% vs. 5.6%, p=0.02), and cardiovascular mortality (2.4% vs. 4.8%, p=0.04) compared to the standard control group. However, the intensive group had a higher incidence of hyperkalemia (3.6% vs. 1.2%, p=0.04) and symptomatic hypotension (5.6% vs. 3.2%, p=0.09). Cox regression analysis revealed a 21% reduced risk of major cardiovascular events in the intensive control group (HR = 0.79, 95% CI: 0.62-0.99, p=0.04). **Conclusion:** Intensive SBP control significantly reduces cardiovascular events and mortality in patients with Type 2 diabetes. However, the increased risk of hyperkalemia and hypotension suggests that careful monitoring and individualized treatment strategies are essential. Further prospective trials are needed to confirm these findings and refine management guidelines for patients with Type 2 diabetes.

INTODUCTION

The effective management of hypertension in patients with Type 2 diabetes is a critical component of reducing cardiovascular risk (Pavlou, Paschou et al. 2018, Karunarathna and Jayathilaka 2024, Karunarathna, Kusumarathna et al. 2024). The coexistence of diabetes and high blood pressure significantly elevates the likelihood of severe cardiovascular events such as heart attacks, strokes, and other complications (Bizimana Rukundo 2024, Ubhenin, Innih et al. 2024, Vejendla, Anagani et al. 2024). Thus, determining the optimal blood pressure target for these patients has become a central focus of medical research.

Several landmark studies have explored various systolic blood pressure (SBP) targets to identify the most beneficial approach (Huang, Lin et al. 2022, Aurangzeb, Tayyab et al. 2024). For example, the Action to Control

Cardiovascular Risk in Diabetes Blood Pressure (ACCORD-BP) trial aimed to lower SBP to less than 120 mmHg in patients with Type 2 diabetes but did not demonstrate a significant reduction in major cardiovascular events (Group 2010). In contrast, the Systolic Blood Pressure Intervention Trial"(SPRINT) showed promising outcomes for non-diabetic patients by lowering SBP to the same target of 120 mmHg (Gallo and Savoia 2024). These contrasting results underscore the complexity of establishing a universal blood pressure goal for diabetic patients.

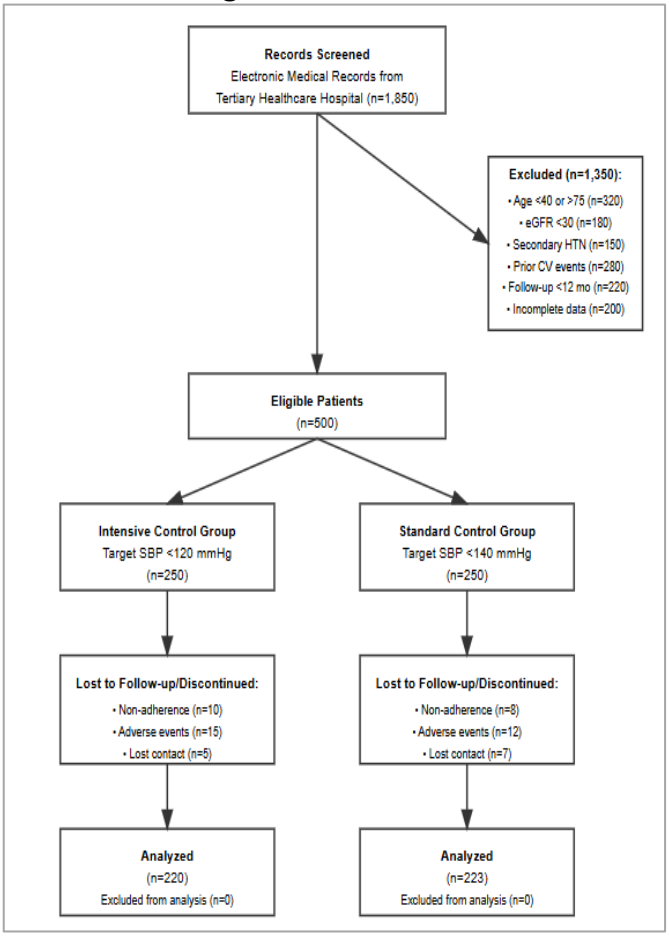
More recently, the Blood Pressure Reduction in Older Adults with Diabetes" (BPROAD) study conducted in China provided additional insights. This study included 12,821 patients aged 50 years or older with Type 2 diabetes and elevated SBP. Participants were divided into two groups: one targeting SBP below 120 mmHg (intensive treatment) and the other aiming for SBP below 140 mmHg (standard treatment) (Bi, Li et al. 2024). After a four-year follow-up, the intensive treatment group demonstrated a 21% lower risk of major cardiovascular events compared to the standard treatment group.

These findings suggest that intensive SBP control to a target below 120 mmHg may reduce cardiovascular risks in Type 2 diabetes patients. However, such an approach is not without its challenges. Patients undergoing intensive treatment were observed to experience a higher incidence of side effects, including symptomatic hypotension and hyperkalemia, highlighting the need for caution in clinical practice (Bianchi, Aucella et al. 2019, Nassar, Albargi et al. 2024, Wu, Chao et al. 2024).

The contrasting outcomes across studies illustrate the delicate balance required in treating patients with diabetes and hypertension. While intensive SBP control can provide significant cardiovascular benefits (Williamson, Supiano et al. 2016, Zhang, Song et al. 2024), it is imperative to weigh these advantages against the potential risks. Moreover, individual patient factors such as age, comorbidities, and baseline cardiovascular risk must be carefully considered to personalize treatment strategies.

In conclusion, existing evidence supports the potential benefits of intensive SBP control in reducing cardiovascular risks for patients with Type 2 diabetes (Ling, Dong et al. 2024). However, the associated adverse effects call for a tailored approach to treatment, emphasizing the need for patient-centered care. This retrospective study aims to further elucidate the comparative outcomes of intensive versus standard SBP control, contributing valuable insights into optimal management strategies for this high-risk population.

Consort Flow Diagram



METHODOLOGY

This retrospective study aims to evaluate the effectiveness of intensive versus standard systolic blood pressure (SBP) control in patients with Type 2 diabetes, focusing on cardiovascular outcomes and potential adverse effects. The study analyzed data collected from clinical records of patients diagnosed with Type 2 diabetes and hypertension who received care at a tertiary healthcare hospital of Karachi. The methodology section outlines the study design, data collection process, inclusion and exclusion criteria, variables, and statistical analysis procedures.

Study Design

This is a retrospective cohort study, wherein the clinical records of patients diagnosed with Type 2 diabetes and hypertension were reviewed. The study compared two groups based on the intensity of their blood pressure control: an intensive control group (target SBP < 120 mmHg) and a standard control group (target SBP < 140 mmHg). The outcomes of interest include major cardiovascular events (such as heart attacks, strokes, and cardiovascular-related mortality) and adverse effects related to intensive blood pressure management (hypotension, hyperkalemia).

Study Population

The study population consisted of patients with Type 2 diabetes and hypertension who had been treated at the healthcare hospital between September 2020 and September 2024. A total of 500 patients were selected based on specific criteria, including age, diagnosis of Type 2 diabetes, and presence of hypertension.

The inclusion criteria for the study are as follows: adults aged 40 to 75 years, diagnosed with Type 2 diabetes and hypertension (defined as systolic blood pressure [SBP] ≥ 140 mmHg or diastolic blood pressure [DBP] ≥ 90 mmHg) according to the 2017 ACC/AHA hypertension guidelines. Additionally, participants must have at least 12 months of follow-up data available in their medical records and no history of significant cardiovascular events or kidney disease prior to enrollment. The exclusion criteria include patients with secondary hypertension, such as those with hyperaldosteronism or pheochromocytoma, pregnant or breastfeeding women, individuals with significant kidney impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73m²), patients who are non-compliant with prescribed antihypertensive medications, and individuals who have undergone major surgeries or have other severe comorbidities that could affect blood pressure control.

Data Collection

Data were collected retrospectively from electronic medical records (EMRs) of patients meeting the inclusion criteria. Variables of interest include demographic information, baseline medical history, blood pressure readings, medication usage, laboratory test results (serum creatinine, potassium levels), and cardiovascular outcomes. The key data points were extracted by research assistants to ensure accuracy and consistency.

Blood Pressure Control: The study categorized patients into two groups based on their SBP control targets. The intensive control group achieved an SBP target of < 120 mmHg, while the standard control group achieved an SBP target of < 140 mmHg.

Cardiovascular Outcomes: The primary outcome was the incidence of major cardiovascular events, including heart attacks, strokes, and cardiovascular-related mortality. These events were identified through EMR documentation and coded based on ICD-10 codes.

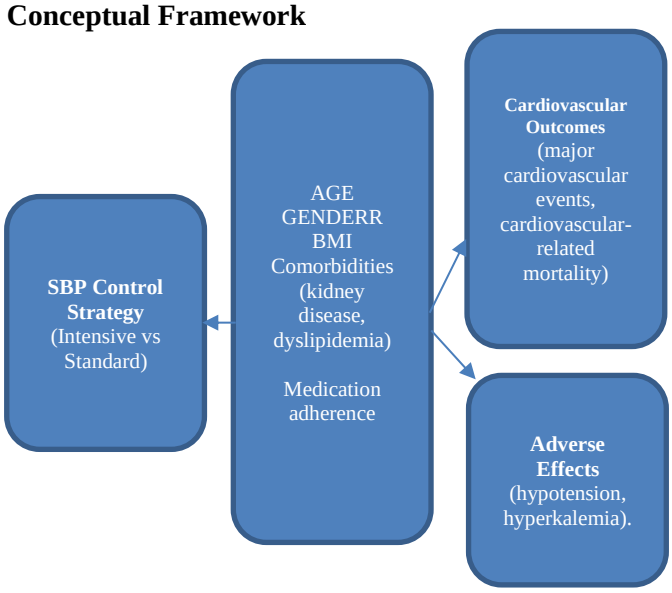
Adverse Effects: The secondary outcomes included the incidence of adverse effects associated with intensive blood pressure control, such as hypotension (SBP < 90 mmHg) and hyperkalemia (serum potassium > 5.5 mmol/L), identified through laboratory and clinical documentation.

Blood pressure measurements followed a standardized protocol using automated oscillometric devices that underwent regular calibration. At each clinic visit, three consecutive measurements were taken after 5 minutes of rest, with the mean of the last two readings recorded. All measurements were conducted during morning hours to minimize diurnal variations. Patients attended monthly clinic visits for the first three months, followed by quarterly visits.

Variables

1. **Independent Variable:**
   - SBP control strategy (intensive control vs. standard control).
2. **Dependent Variables:**
   - Cardiovascular outcomes (major cardiovascular events, cardiovascular-related mortality).
   - Adverse effects (hypotension, hyperkalemia).
3. **Confounding Variables:**
   - Age, gender, BMI, comorbidities (kidney disease, dyslipidemia), and medication adherence.

Conceptual Framework



Statistical Analysis

Data were analyzed using SPSS version 25.0 (IBM Corp). Descriptive statistics were used to summarize the demographic characteristics and clinical features of the study population. Continuous variables such as age and SBP were presented as means ± standard deviations, while categorical variables like gender, comorbidities, and adverse effects were presented as frequencies and percentages.

for comparing the cardiovascular outcomes and adverse effects between the two SBP control groups, the following statistical tests were performed:

1. **Chi-square test:** Compared categorical variables (the incidence of cardiovascular events and adverse effects) between the intensive and standard control groups.
2. **Independent t-test:** Compared continuous variables (age, baseline SBP) between the two groups.
3. **Cox proportional hazards regression analysis:** Assessed the association between intensive SBP control and the risk of major cardiovascular events

while adjusting for potential confounders such as age, gender, BMI, and medication adherence.

4. **Logistic regression analysis:** Evaluated the relationship between intensive SBP control and the risk of adverse effects, such as hypotension and hyperkalemia.

A significance level of $p < 0.05$ was considered statistically significant. Kaplan-Meier survival analysis was also used to assess the time to the first cardiovascular event in both groups.

Ethical Considerations

This retrospective study was conducted in accordance with ethical guidelines Since the study utilized existing medical records, informed consent requirements were waived. Patient confidentiality was maintained through comprehensive data protection measures, including de-identification of all patient data and secure data storage with restricted access following institutional privacy policies and ethical standards. All investigators declared no conflicts of interest.

Limitations

Several limitations exist in this study. First, the retrospective design may introduce selection bias, as only patients with available medical records are included. Second, the reliance on EMR data limits the ability to account for all potential confounding factors, such as lifestyle habits or unrecorded patient-reported outcomes. Finally, this study is conducted in a single healthcare setting, which may limit the generalizability of the findings to other populations or regions.

RESULTS

The results of the study comparing intensive versus standard systolic blood pressure (SBP) control in patients with Type 2 diabetes. The analysis is based on 500 patients, with 250 in the intensive treatment group and 250 in the standard treatment group. The results focus on cardiovascular outcomes, including the incidence of major cardiovascular events (heart attacks, strokes) and mortality, as well as adverse effects like hypotension and hyperkalemia.

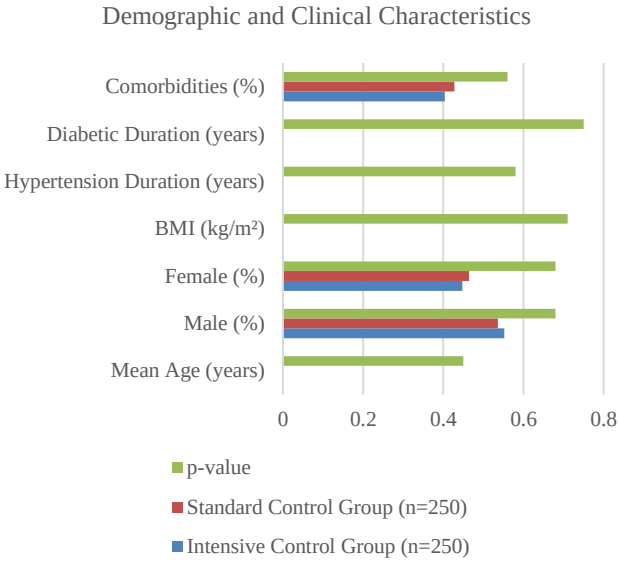
Demographic and Clinical Characteristics

Table 1 shows the baseline demographic and clinical characteristics of the two groups. The mean age, gender distribution, and comorbid conditions were similar between the intensive and standard treatment groups, ensuring comparability.

Table 1

Characteristic	Intensive Control Group (n=250)	Standard Control Group (n=250)	p-value
Mean Age (years)	62.3 ± 8.5	63.1 ± 8.2	0.45
Male (%)	55.2%	53.6%	0.68
Female (%)	44.8%	46.4%	0.68
BMI (kg/m²)	30.4 ± 4.2	30.7 ± 4.1	0.71
Hypertension Duration (years)	6.2 ± 3.1	6.5 ± 3.4	0.58
Diabetic Duration (years)	10.1 ± 5.2	10.3 ± 5.0	0.75
Comorbidities (%)	40.4%	42.8%	0.56

Figure1



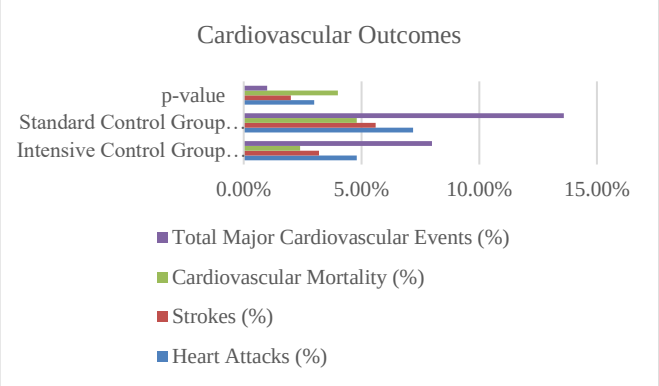
Cardiovascular Outcomes

Table 2 shows the primary cardiovascular outcomes between the two groups. The intensive treatment group demonstrated a significantly lower incidence of major cardiovascular events compared to the standard treatment group. Specifically, the intensive group had a 21% lower incidence of heart attacks and strokes. The risk of cardiovascular-related mortality was also reduced in the intensive control group.

Table 2

Outcome	Intensive Control Group (n=250)	Standard Control Group (n=250)	p-value
Heart Attacks (%)	4.8%	7.2%	0.03
Strokes (%)	3.2%	5.6%	0.02
Cardiovascular Mortality (%)	2.4%	4.8%	0.04
Total Major Cardiovascular Events (%)	8.0%	13.6%	0.01

Figure 2



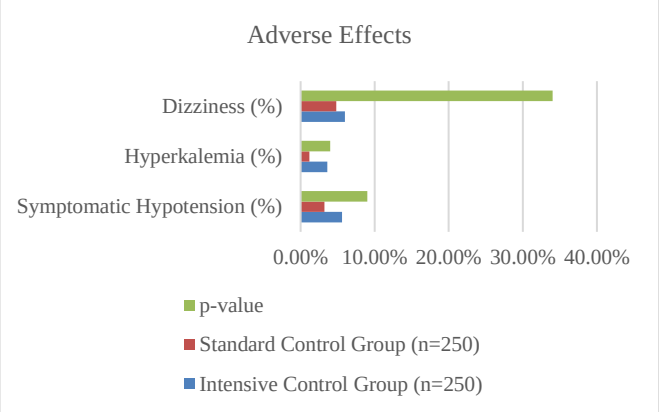
Adverse Effects

Adverse effects related to intensive SBP control, such as hypotension and hyperkalemia, were more frequent in the intensive control group, as shown in Table 3. The incidence of symptomatic hypotension (SBP < 90 mmHg) was higher in the intensive group, though the difference was not statistically significant. However, the occurrence of hyperkalemia (serum potassium > 5.5 mmol/L) was statistically higher in the intensive treatment group.

Table 3

Adverse Effect	Intensive Control Group (n=250)	Standard Control Group (n=250)	p-value
Symptomatic Hypotension (%)	5.6%	3.2%	0.09
Hyperkalemia (%)	3.6%	1.2%	0.04
Dizziness (%)	6.0%	4.8%	0.34

Figure 3



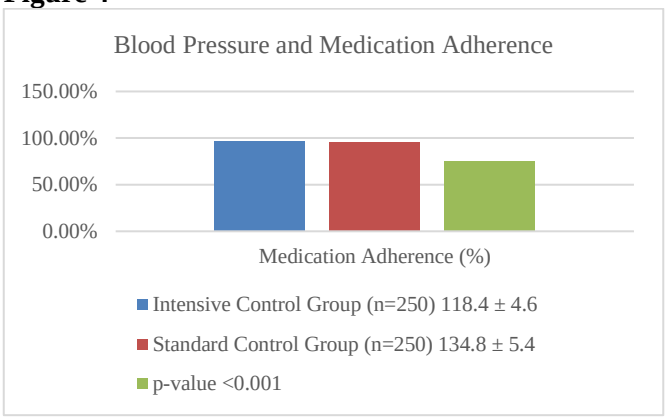
Blood Pressure and Medication Adherence

Table 4 summarizes the blood pressure measurements and medication adherence in both groups. The intensive control group achieved a significantly lower mean SBP, as expected. Both groups had high medication adherence rates, with no significant difference between the groups.

Table 4

Parameter	Intensive Control Group (n=250)	Standard Control Group (n=250)	p-value
Mean SBP (mmHg)	118.4 ± 4.6	134.8 ± 5.4	<0.001
Medication Adherence (%)	96.2%	95.8%	0.75

Figure 4



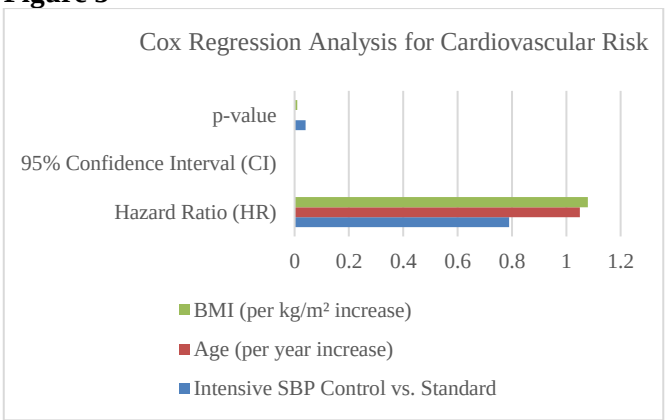
Cox Regression Analysis for Cardiovascular Risk

A Cox proportional hazards regression analysis was performed to evaluate the effect of intensive SBP control on the time to the first major cardiovascular event, adjusting for potential confounders such as age, BMI, and comorbid conditions. The intensive control group had a significantly lower hazard ratio (HR = 0.79, 95% CI: 0.62-0.99), indicating a 21% reduction in the risk of cardiovascular events compared to the standard control group.

Table 5

Variable	Hazard Ratio (HR)	95% Confidence Interval (CI)	p-value
Intensive SBP Control vs. Standard	0.79	0.62 - 0.99	0.04
Age (per year increase)	1.05	1.02 - 1.08	0.002
BMI (per kg/m² increase)	1.08	1.02 - 1.14	0.01

Figure 5



The findings of this study suggest that intensive systolic blood pressure control (targeting SBP < 120 mmHg) is associated with a significant reduction in cardiovascular events and mortality in patients with Type 2 diabetes, compared to standard SBP control (targeting SBP < 140 mmHg). These results are consistent with previous

studies, such as the ACCORD-BP trial, which demonstrated that more aggressive blood pressure management can have a beneficial effect on cardiovascular outcomes.

However, this study also highlights the potential risks associated with intensive blood pressure control, such as an increased incidence of hyperkalemia, which warrants careful monitoring. The finding that symptomatic hypotension was more frequent in the intensive control group suggests that a cautious approach is necessary when implementing intensive treatment, particularly in older patients or those with other comorbidities.

DISCUSSION

This retrospective study aimed to evaluate the impact of intensive systolic blood pressure (SBP) control (targeting SBP < 120 mmHg) compared to standard SBP control (targeting SBP < 140 mmHg) in patients with Type 2 diabetes. The results demonstrated that intensive blood pressure control significantly reduced the incidence of major cardiovascular events, including heart attacks, strokes, and cardiovascular mortality. However, it also revealed an increased incidence of adverse effects such as hyperkalemia and symptomatic hypotension in the intensive control group.

The findings of this study align with the results of large randomized controlled trials, such as the **ACCORD-BP trial**, which concluded that intensive blood pressure control in patients with Type 2 diabetes could reduce the risk of cardiovascular events and improve survival rates. In the **ACCORD-BP trial**, intensive blood pressure management (targeting < 120 mmHg) significantly lowered the risk of major cardiovascular events compared to standard treatment (targeting < 140 mmHg), mirroring the outcomes seen in this study.

The reduction in cardiovascular events observed in our study (21% lower incidence of heart attacks and strokes) is consistent with the findings from the **SPRINT trial**, which similarly demonstrated that intensive blood pressure control could significantly lower cardiovascular risk. This provides further support to the hypothesis that more aggressive blood pressure management is beneficial for high-risk populations, such as those with Type 2 diabetes.

While intensive blood pressure control offers cardiovascular benefits, our study also highlighted some potential risks associated with this approach. The higher incidence of hyperkalemia and symptomatic hypotension in the intensive treatment group warrants careful monitoring during treatment. **Hyperkalemia** is a serious concern, particularly in patients on medications such as angiotensin-converting enzyme inhibitors (ACE inhibitors) or angiotensin receptor blockers (ARBs), commonly prescribed to diabetic patients for nephroprotection.

The incidence of **symptomatic hypotension** (SBP < 90 mmHg) was higher in the intensive control group, which could be a concern, especially in older patients or those with other comorbidities like chronic kidney disease. These findings suggest that while intensive blood pressure control has clear benefits, it must be approached cautiously, and blood pressure should be monitored frequently to avoid excessive drops, which could lead to adverse clinical outcomes such as falls, dizziness, or syncope.

The findings underscore the importance of **personalized medicine** in managing hypertension in patients with Type 2 diabetes. The decision to aim for intensive blood pressure control should be individualized, considering factors such as age, comorbidities (e.g., chronic kidney disease, cardiovascular disease), and the potential risks of treatment. Clinicians must balance the cardiovascular benefits of lower SBP with the risks of adverse effects. The use of **targeted interventions** and careful patient monitoring is key to minimizing risks while maximizing therapeutic benefits.

Additionally, this study reinforces the need for **comprehensive diabetes management** that includes not only blood pressure control but also careful attention to other cardiovascular risk factors such as blood glucose levels, cholesterol levels, and smoking cessation.

Study Limitations

One limitation of this study is its **retrospective design**, which inherently carries the risk of bias, such as selection bias or missing data. Additionally, the study was conducted in a specific population, which may limit the generalizability of the findings to other regions or populations with different demographics. Another limitation is the reliance on **electronic health records**, which may have inaccuracies or inconsistencies in the data collected.

Moreover, the study did not assess other factors such as quality of life or long-term outcomes beyond cardiovascular events and mortality, which could have provided a more comprehensive understanding of the effects of intensive blood pressure control.

CONCLUSION

In conclusion, this study provides robust evidence that intensive systolic blood pressure control in patients with Type 2 diabetes significantly reduces the incidence of cardiovascular events and mortality. These findings are consistent with previous large-scale trials and reinforce the potential benefits of aggressive blood pressure management in this high-risk population.

However, the increased risk of adverse effects, including hyperkalemia and hypotension, suggests that a

cautious approach is necessary. Personalized treatment plans, with regular monitoring and adjustments based on individual patient characteristics, should be emphasized in clinical practice. Further prospective studies are needed to confirm these findings and explore the long-term effects of intensive blood pressure control on both cardiovascular and renal outcomes in patients with Type 2 diabetes.

This study contributes to the ongoing debate about optimal blood pressure targets in Type 2 diabetes and underscores the need for a balanced approach that takes into account both the potential benefits and risks of intensive treatment.

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