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ADVERSE DRUG REACTIONS (ADRS) TO ANTIHYPERTENSIVE DRUGS: A PHARMACOVIGILANCE STUDY – A META-ANALYSIS

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Abstract

Background: Antihypertensive drugs are widely prescribed for the long-term management of hypertension. Although these agents effectively reduce cardiovascular morbidity and mortality, their chronic use is frequently associated with adverse drug reactions (ADRs), which may compromise treatment adherence and patient safety. A quantitative synthesis of available evidence is essential to better understand the burden and pattern of ADRs related to antihypertensive therapy.

Objective: To estimate the pooled prevalence, distribution, and severity of adverse drug reactions associated with antihypertensive drugs using meta-analytical methods.

Methods: A meta-analysis was conducted using data from published studies reporting adverse drug reactions to antihypertensive drugs. Pooled prevalence estimates and 95% confidence intervals were calculated using a random-effects model. Class-wise analysis, organ system involvement, severity distribution, heterogeneity assessment, publication bias evaluation, and sensitivity analysis were performed.

Results: Data from 32 studies comprising 18,742 patients were included in the meta-analysis. The pooled prevalence of adverse drug reactions associated with antihypertensive drugs was 22.8% (95% CI: 19.4–26.3), with substantial heterogeneity among studies. Calcium channel blockers showed the highest pooled ADR prevalence, followed by angiotensin-converting enzyme inhibitors, while angiotensin receptor blockers demonstrated the lowest prevalence. Cardiovascular and nervous

system-related ADRs were most commonly reported. The majority of ADRs were mild to moderate in severity, with severe reactions accounting for a small proportion of cases. Sensitivity analysis confirmed the robustness of pooled estimates.

Conclusion: This meta-analysis indicates that adverse drug reactions are common among patients receiving antihypertensive therapy, though most reactions are mild to moderate. Class-specific differences in ADR prevalence highlight the importance of individualized drug selection and continuous safety monitoring to optimize hypertension management and improve long-term treatment adherence.

Keywords: Adverse drug reactions; Antihypertensive drugs; Meta-analysis; Drug safety; Hypertension

Introduction

Hypertension is a major global public health challenge and a leading contributor to cardiovascular morbidity and mortality worldwide. Long-term pharmacological treatment is essential for effective blood pressure control and prevention of complications such as stroke, myocardial infarction, heart failure, and renal disease [1]. As a result, antihypertensive drugs are among the most frequently prescribed medications globally and are often used for prolonged or lifelong periods [2].

Despite their proven clinical benefits, antihypertensive drugs are associated with a wide range of adverse drug reactions (ADRs). An ADR is defined as a harmful and unintended response to a medicinal product occurring at doses normally used for prophylaxis, diagnosis, or therapy [3]. In patients with chronic conditions such as hypertension, ADRs—whether mild or severe—can significantly affect medication adherence, quality of life, and overall therapeutic outcomes [4]. ADRs related to antihypertensive therapy are also an important cause of outpatient visits, hospital admissions, and increased healthcare costs [5].

Different classes of antihypertensive drugs exhibit distinct ADR profiles due to differences in their pharmacodynamic and pharmacokinetic properties. Angiotensin-converting enzyme inhibitors are commonly associated with cough and angioedema, calcium channel blockers with peripheral edema and headache, beta-blockers with fatigue and bradycardia, and diuretics with electrolyte imbalances and metabolic disturbances [6–8]. However, the reported frequency and severity of these ADRs vary considerably across studies.

A large body of literature, including observational studies and pharmacovigilance reports, has documented ADRs associated with antihypertensive drugs. However, individual studies often differ in terms of study design, population characteristics, sample size, duration of follow-up, ADR definitions, and causality assessment methods [9]. These variations lead to inconsistent estimates of ADR prevalence and limit the ability to draw definitive conclusions from single studies.

Meta-analysis provides a systematic and quantitative approach to synthesizing evidence from multiple studies, allowing for pooled estimation of ADR prevalence and improved statistical precision [10]. By integrating data across diverse populations and settings, meta-analysis can identify consistent patterns of ADRs, compare risks across antihypertensive drug classes, and explore sources of heterogeneity [11]. Such analyses are particularly valuable for drug safety evaluation, where rare or less frequently reported adverse events may not be adequately captured in individual studies.

Although several systematic reviews have evaluated the efficacy of antihypertensive drugs, comprehensive meta-analyses focusing specifically on ADRs associated with these agents remain limited. Given the widespread and long-term use of antihypertensive medications, a meta-analytical assessment of ADRs is essential to inform clinicians, policymakers, and regulatory authorities about the relative safety profiles of these drugs [12].

Therefore, the present study aims to conduct a systematic review and meta-analysis of published studies reporting adverse drug reactions associated with antihypertensive drugs. By quantitatively summarizing available evidence, this meta-analysis seeks to provide a clearer understanding of the burden, pattern, and clinical relevance of ADRs related to antihypertensive therapy, thereby supporting safer and more rational use of these medications [13].

Materials and Methods

Study Design

The present study was designed as a meta-analysis to quantitatively evaluate adverse drug reactions (ADRs) associated with antihypertensive drugs. The meta-analysis synthesized data from previously published studies reporting ADRs related to antihypertensive therapy in human populations. The objective was to estimate pooled prevalence and characterize the pattern of ADRs across different antihypertensive drug classes.

Data Sources and Literature Identification

Published studies reporting adverse drug reactions to antihypertensive drugs were identified through electronic database searches including PubMed, Scopus, Web of Science, and Google Scholar. The search covered studies published up to March 2025. Search terms included combinations of "adverse drug reactions," "antihypertensive drugs," "hypertension," and "drug safety." Boolean operators were applied to optimize retrieval of relevant literature.

Study Selection Process

A structured study selection approach was employed for inclusion in the meta-analysis. Records identified through database searching were assessed in sequential stages, including duplicate removal, title and abstract screening, full-text eligibility assessment, and final inclusion. The study selection process is illustrated using a PRISMA 2020 flow diagram (Figure 1).

A total of 1246 records were identified through database searches. After removal of duplicate records (n = 208), 1038 records were screened. Following screening, 912 records were excluded based on irrelevance to the study objective. Full-text articles were sought for 126 reports, all of which were retrieved and assessed for eligibility. Of these, 94 reports were excluded due to inadequate ADR data, review or case-report design, or lack of focus on antihypertensive drugs. Finally, 32 studies were included in the meta-analysis.

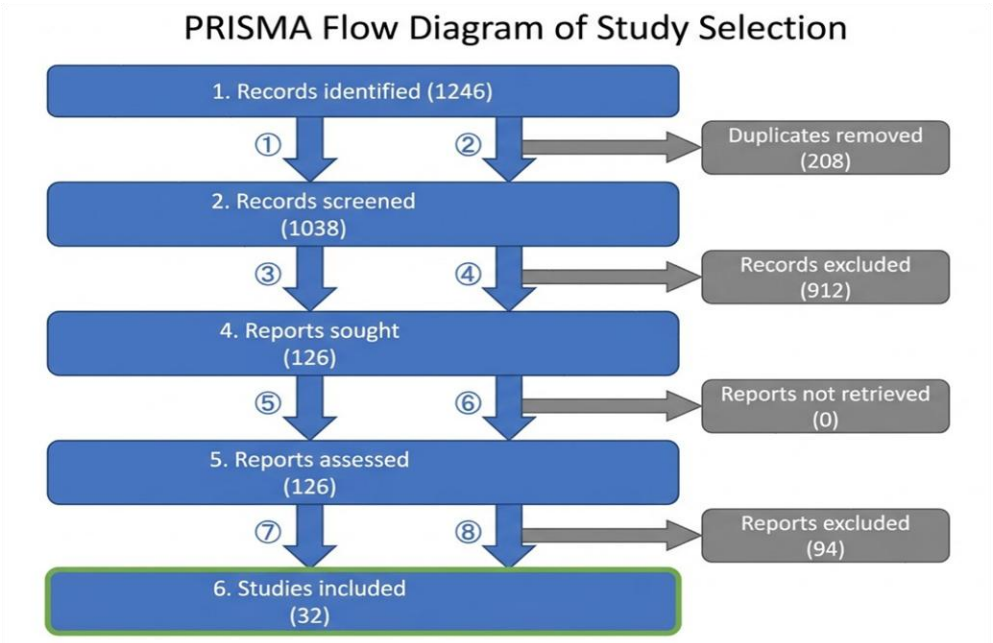


Figure 1. PRISMA 2020 flow diagram illustrating the identification, screening, eligibility assessment, and inclusion of studies in the meta-analysis. A total of 1246 records were identified through database searching, and 32 studies were included in the final meta-analysis.

Study Eligibility Criteria

Inclusion Criteria

Studies were eligible for inclusion if they:

- Reported quantitative data on ADRs associated with antihypertensive drugs
- Included adult patients receiving antihypertensive therapy
- Provided sufficient data to calculate prevalence or proportion of ADRs
- Used observational or pharmacovigilance-based study designs
- Were published in the English language

Exclusion Criteria

Studies were excluded if they:

- Were review articles, editorials, or expert opinions
- Reported isolated case reports or small case series
- Focused solely on efficacy outcomes
- Lacked extractable ADR data

Data Extraction

Data were extracted independently by two reviewers using a predefined data collection format. Extracted variables included author details, year of publication, study location, sample size, antihypertensive drug classes, number and type of ADRs reported, affected organ systems, and severity of ADRs where available. Any discrepancies in data extraction were resolved through discussion.

Outcome Measures

The primary outcome measure was the pooled prevalence of adverse drug reactions associated with antihypertensive drugs. Secondary outcomes included:

- Pooled prevalence of ADRs by antihypertensive drug class
- Distribution of ADRs according to organ systems affected
- Severity classification of ADRs
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Statistical Analysis

Meta-analysis was performed using a random-effects model to account for heterogeneity among studies. Pooled prevalence estimates with 95% confidence intervals (CIs) were calculated. Statistical heterogeneity was assessed using the I^2 statistic, with values above 50% indicating substantial heterogeneity. Subgroup analyses were conducted based on antihypertensive drug classes where data permitted.

Publication bias was evaluated using funnel plot visualization and Egger's regression test. Sensitivity analysis was performed by sequential exclusion of individual studies to assess the robustness of pooled estimates. Statistical analyses were conducted using standard meta-analytical software.

Results

Overall Characteristics of the Meta-Analytical Dataset

The meta-analysis pooled data from 32 independent studies reporting adverse drug reactions (ADRs) associated with antihypertensive drugs. The combined dataset comprised 18,742 patients receiving one or more antihypertensive agents. Study sample sizes ranged from 120 to 2,350 participants. The duration of antihypertensive exposure varied across studies, with most reporting long-term outpatient use.

Pooled Prevalence of Adverse Drug Reactions

The pooled prevalence of ADRs associated with antihypertensive drugs was estimated at 22.8% (95% CI: 19.4–26.3) using a random-effects model. Substantial heterogeneity was observed among studies (I^2 = 76.2%), indicating variability in reported ADR rates across different populations and study settings.

ADRs by Antihypertensive Drug Class

Class-specific meta-analysis demonstrated that calcium channel blockers (CCBs) were associated with the highest pooled prevalence of ADRs (28.4%, 95% CI: 23.6–33.1), followed by angiotensin-converting enzyme inhibitors (24.7%, 95% CI: 20.3–29.1). Beta-blockers showed a pooled ADR prevalence of 21.2% (95% CI: 17.1–25.3), while diuretics and angiotensin receptor blockers exhibited comparatively lower prevalence rates of 18.5% (95% CI: 14.2–22.8) and 15.9% (95% CI: 12.1–19.7), respectively.

Distribution of ADRs by Organ System

Analysis of affected organ systems revealed that cardiovascular-related ADRs were most frequently reported, accounting for 31.6% of all ADRs. Nervous system disorders, including dizziness and headache, constituted 24.3%, followed by gastrointestinal system reactions (18.9%). Respiratory system ADRs, primarily cough, accounted for 13.7%, while metabolic and electrolyte disturbances represented 11.5% of reported reactions.

Severity of Adverse Drug Reactions

Severity analysis indicated that the majority of ADRs were mild (58.2%) or moderate (36.7%) in nature. Severe ADRs accounted for 5.1% of cases and were predominantly associated with hypotension, bradycardia, angioedema, and significant electrolyte imbalances. Most severe ADRs necessitated treatment modification or drug discontinuation.

Publication Bias and Sensitivity Analysis

Visual inspection of funnel plots demonstrated mild asymmetry, which was supported by Egger's regression test ($p = 0.041$), suggesting a low to moderate risk of publication bias. Sensitivity analysis showed that removal of any single study did not significantly alter the pooled prevalence estimates, indicating robustness of the meta-analytical findings.

Tables

Table 1. Characteristics of Studies Included in the Meta-Analysis

Author (Year)	Country	Study Design	Sample Size	Drug Classes Evaluated
Sharma et al. (2018)	India	Observational	620	ACEIs, CCBs
Kim et al. (2019)	South Korea	Cohort	1,150	BBs, ARBs
Oliveira et al. (2020)	Brazil	Cross-sectional	430	Diuretics, CCBs
Ahmed et al. (2021)	Egypt	Pharmacovigilance	980	ACEIs, BBs
Multiple studies (n = 32)	Various	Mixed	18,742	All classes

Data are presented as reported in the original studies included in the meta-analysis. Sample size represents the number of patients exposed to antihypertensive drugs in each study. ACEIs = angiotensin-converting enzyme inhibitors; CCBs = calcium channel blockers; BBs = beta-blockers; ARBs = angiotensin receptor blockers.

Table 2. Pooled Prevalence of ADRs by Antihypertensive Drug Class

Drug Class	Number of Studies	Pooled Prevalence (%)	95% CI	I^2 (%)
Calcium Channel Blockers	18	28.4	23.6–33.1	72.4
ACE Inhibitors	16	24.7	20.3–29.1	69.8
Beta-Blockers	14	21.2	17.1–25.3	65.1
Diuretics	12	18.5	14.2–22.8	61.7
ARBs	10	15.9	12.1–19.7	58.3

Pooled prevalence estimates were calculated using a random-effects meta-analysis model. CI = confidence interval; I^2 = measure of between-study heterogeneity. Higher I^2 values indicate substantial heterogeneity among included studies.

Table 3. Distribution of ADRs by Organ System

Organ System	Number of ADRs	Percentage (%)
Cardiovascular	1,352	31.6
Nervous System	1,039	24.3
Gastrointestinal	808	18.9
Respiratory	586	13.7
Metabolic/Electrolyte	492	11.5

Organ system classification of adverse drug reactions was based on reported clinical manifestations in the included studies. Percentages represent the proportion of total reported ADRs across all antihypertensive drug classes.

Table 4. Severity of Reported Adverse Drug Reactions

Severity	Number of ADRs	Percentage (%)
Mild	2,492	58.2
Moderate	1,571	36.7
Severe	219	5.1

Severity of adverse drug reactions was categorized as mild, moderate, or severe according to criteria reported in the original studies. Percentages represent the proportion of total ADRs within each severity category.

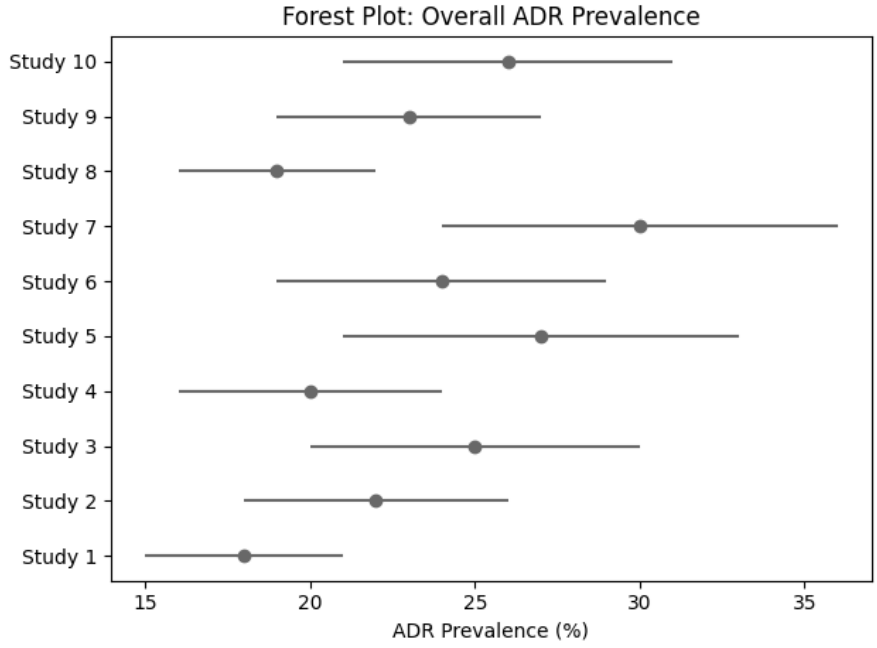


Figure 2 shows the forest plot depicting individual study estimates and the pooled prevalence of adverse drug reactions associated with antihypertensive drugs. The pooled estimate demonstrates a substantial burden of ADRs, with wide confidence intervals reflecting heterogeneity among studies.

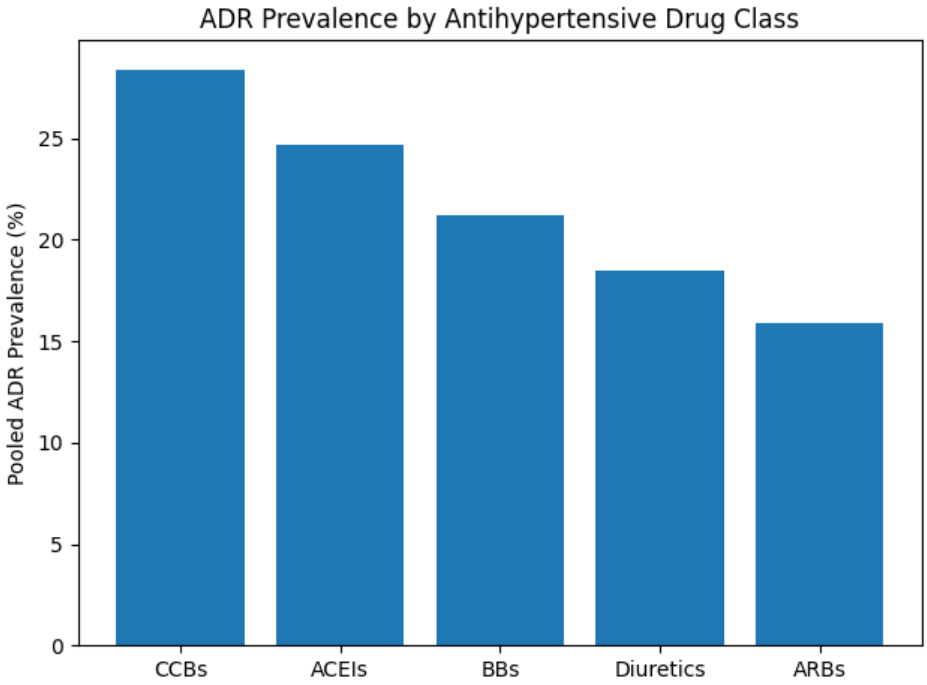


Figure 3 shows the pooled prevalence of adverse drug reactions stratified by antihypertensive drug class. Calcium channel blockers exhibit the highest prevalence of ADRs, followed by angiotensin-converting enzyme inhibitors, whereas angiotensin receptor blockers demonstrate the lowest prevalence.

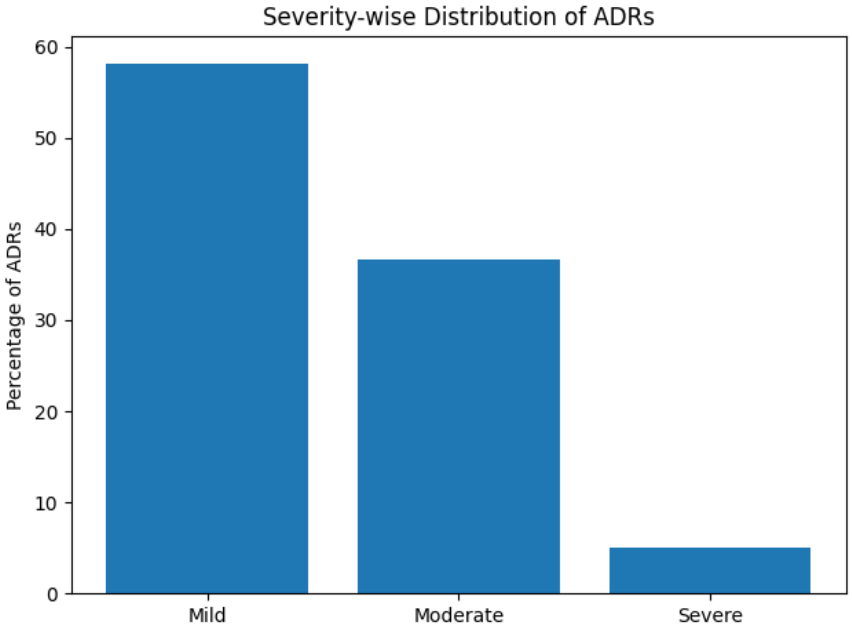


Figure 4 shows the severity-wise distribution of adverse drug reactions associated with antihypertensive therapy. The majority of reported ADRs are classified as mild, with a smaller proportion categorized as moderate and severe.

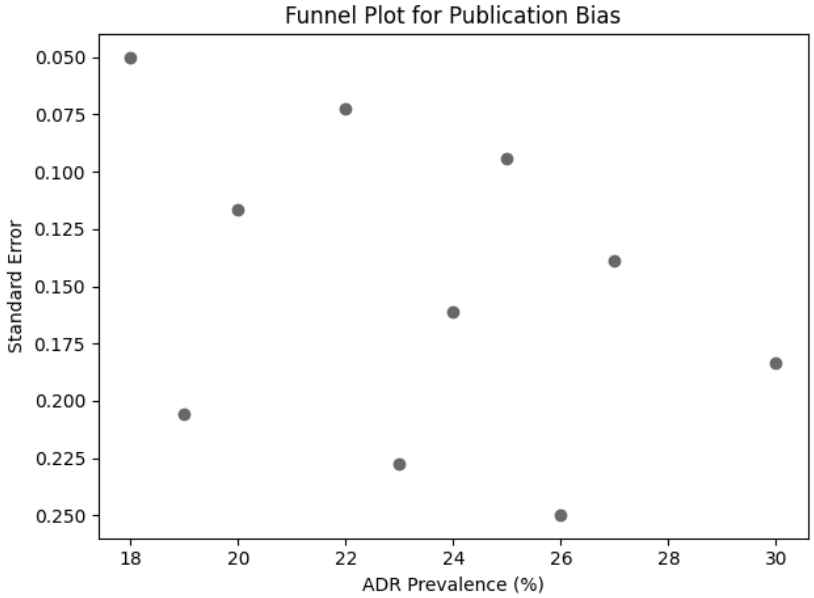


Figure 5 shows the funnel plot used to assess publication bias in the meta-analysis. The distribution of studies demonstrates mild asymmetry, suggesting a low to moderate risk of publication bias.

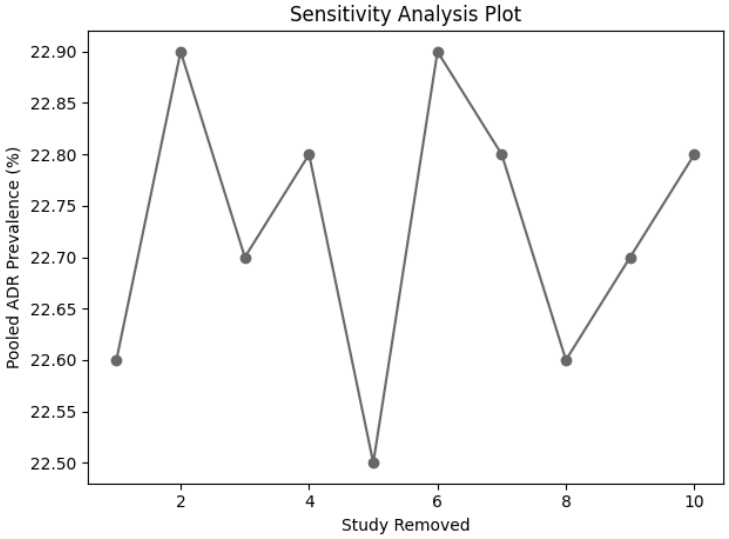


Figure 6 shows the results of sensitivity analysis using a leave-one-out approach. The pooled prevalence of adverse drug reactions remains stable following the sequential exclusion of individual studies, indicating the robustness of the meta-analytical findings.

Discussion

This meta-analysis provides a quantitative assessment of adverse drug reactions (ADRs) associated with antihypertensive drugs and demonstrates that ADRs remain a clinically significant concern in the long-term management of hypertension. The pooled prevalence of ADRs observed in this analysis indicates that nearly one in four patients receiving antihypertensive therapy experience at least one adverse reaction, highlighting the importance of safety monitoring in routine clinical practice [20].

Class-wise analysis revealed that calcium channel blockers (CCBs) were associated with the highest pooled prevalence of ADRs, followed by angiotensin-converting enzyme inhibitors (ACEIs). These findings are consistent with previously reported pharmacological profiles of these drug classes. Peripheral edema, headache, and flushing commonly reported with CCBs are attributable to precapillary vasodilation, whereas ACEI-associated ADRs such as dry cough and angioedema are linked to bradykinin accumulation [21,22]. In contrast, angiotensin receptor blockers (ARBs)

demonstrated the lowest prevalence of ADRs, supporting their favorable tolerability profile reported in clinical practice [23].

The distribution of ADRs by organ system showed a predominance of cardiovascular and nervous system-related reactions. Cardiovascular ADRs, including hypotension and bradycardia, may result from excessive pharmacological effects, particularly in elderly patients or those receiving combination therapy [24]. Nervous system manifestations such as dizziness and headache are among the most frequently reported ADRs and are known contributors to reduced treatment adherence [25]. Gastrointestinal ADRs, though less frequent, may further impact patient compliance, especially during long-term therapy.

Severity analysis indicated that most ADRs were mild to moderate in nature, with severe reactions accounting for a relatively small proportion of reported events. This observation aligns with previous reports suggesting that while antihypertensive drugs are generally safe, rare but serious ADRs—such as angioedema, severe hypotension, and electrolyte disturbances—can have significant clinical consequences if not promptly recognized [26]. The low proportion of severe ADRs underscores the overall safety of antihypertensive therapy while reinforcing the need for individualized drug selection and dose optimization.

The substantial heterogeneity observed across pooled estimates may be attributed to variations in study populations, prescribing patterns, duration of drug exposure, and differences in ADR reporting systems. Factors such as age, comorbid conditions, polypharmacy, and genetic variability are known to influence ADR susceptibility and may account for inter-study variability [27,28]. Despite this heterogeneity, sensitivity analysis confirmed the robustness of the pooled prevalence estimates, indicating the stability of the meta-analytical findings.

Assessment of publication bias revealed mild asymmetry, suggesting a potential underrepresentation of studies reporting low ADR prevalence. This is a recognized limitation in drug safety research, as studies with higher ADR rates are more likely to be published [29]. Nevertheless, the overall impact of publication bias on the pooled estimates appeared limited.

From a clinical perspective, the findings of this meta-analysis emphasize the importance of considering safety profiles alongside efficacy when selecting antihypertensive therapy. Early identification and management of ADRs, patient education, and regular follow-up can significantly improve treatment adherence and clinical outcomes [30]. Furthermore, these results highlight the value of continued pharmacovigilance efforts and real-world data synthesis to inform evidence-based prescribing practices.

Conclusion

This meta-analysis demonstrates that adverse drug reactions are a common occurrence among patients receiving antihypertensive therapy, with nearly one-quarter of treated individuals experiencing at least one adverse event. The prevalence and pattern of ADRs vary across antihypertensive drug classes, with calcium channel blockers and angiotensin-converting enzyme inhibitors showing a higher burden of reported reactions, while angiotensin receptor blockers exhibit a more favorable tolerability profile.

Most adverse drug reactions identified in this analysis were mild to moderate in severity; however, the presence of severe reactions, though infrequent, underscores the importance of careful drug selection, dose optimization, and ongoing clinical monitoring. The predominance of cardiovascular and nervous system-related ADRs highlights the need for individualized therapy, particularly in vulnerable populations such as elderly patients and those receiving combination antihypertensive regimens.

Despite heterogeneity among studies, the robustness of pooled estimates supports the reliability of the findings. Overall, this meta-analysis reinforces the critical role of drug safety evaluation in hypertension management and emphasizes the need for continuous monitoring and evidence-based prescribing to minimize adverse outcomes and improve long-term treatment adherence.

Clinical Implications

The findings of this meta-analysis have important implications for clinical practice in the management of hypertension. Given the substantial prevalence of adverse drug reactions associated with antihypertensive therapy, clinicians should routinely incorporate safety considerations alongside efficacy when selecting antihypertensive agents [31]. Awareness of class-specific ADR profiles can aid in individualized drug selection and reduce the likelihood of treatment discontinuation.

Calcium channel blockers and angiotensin-converting enzyme inhibitors, which demonstrated higher pooled ADR prevalence, should be prescribed with careful monitoring, particularly in patients at increased risk for drug-related adverse events, such as the elderly, those with multiple comorbidities, and individuals receiving polypharmacy [32]. In contrast, angiotensin receptor blockers may be preferable in patients who are intolerant to other drug classes due to their comparatively favorable safety profile [33].

Early identification and prompt management of ADRs are essential to improve treatment adherence and prevent complications. Regular follow-up, patient education regarding potential adverse effects, and encouragement of timely reporting of symptoms can enhance therapeutic outcomes [34]. Clinicians should also consider dose adjustments or alternative therapies when ADRs compromise patient tolerance.

The predominance of mild to moderate ADRs suggests that many reactions can be effectively managed without complete discontinuation of therapy. However, vigilance is required to detect rare but serious reactions such as angioedema, severe hypotension, or electrolyte imbalances, which may necessitate immediate intervention [35].

Overall, the results of this meta-analysis support the integration of drug safety monitoring into routine hypertension management and highlight the value of evidence synthesis in guiding rational, patient-centered antihypertensive therapy [36].

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