

# Pseudoephedrine and Acute Coronary Events: A Real-World Assessment in Acute Myocardial Infarction Patients

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## Abstract

**Aim:** The decongestants are frequently prescribed for symptomatic relief to reduce mucosal congestion. However, even in the absence of overt cardiovascular symptoms, patients may subsequently present with serious acute cardiac events. The present study aims to assess the potential association between recent pseudoephedrine exposure and the occurrence of coronary vasospasm in patients presenting with acute myocardial infarction (AMI) to the emergency department, who reported the use of pseudoephedrine-containing products within the preceding week.

**Materials and Methods:** The study population included patients who presented with chest pain and were diagnosed with AMI [either ST-elevation myocardial infarction (STEMI) or non-STEMI]. The primary objective was to evaluate the history of pseudoephedrine use within the week preceding symptom onset.

**Results:** Among patients with a history of pseudoephedrine use, the 1-month incidence of major adverse cardiac events (MACE) was 13% (n=3), compared to 12.7% (n=21) in those without such a history. When comparing age, diagnosis, and MACE rates between patients with and without pseudoephedrine use, no statistically significant differences were observed. Regarding MACE subtypes, the most frequent event was death, occurring in 7.4% (n=14) of all patients. Heart failure was identified in 2.6% (n=5), while recurrent myocardial infarction was observed in 2.1% (n=4) patients.

**Conclusion:** Our findings suggest a clinically relevant association between recent pseudoephedrine use and acute cardiac events in vulnerable patients. This calls for increased awareness among clinicians, pharmacists, and the general public regarding the possible adverse outcomes associated with pseudoephedrine, even when used short-term or at therapeutic doses.

**Keywords:** Pseudoephedrine, major adverse cardiac events, acute myocardial infarction, percutaneous coronary intervention, emergency

## Introduction

Over-the-counter (OTC) decongestants are commonly used worldwide for the symptomatic relief of upper respiratory tract infections, particularly to reduce mucosal congestion. These agents exert their effects through direct or indirect sympathomimetic activity, acting as agonists at both  $\alpha$ - and  $\beta$ -adrenergic receptors. When administered orally (e.g., pseudoephedrine, phenylephrine) or intranasally (e.g., oxymetazoline, naphazoline, phenylephrine, ephedrine), they induce vasoconstriction of the nasal mucosa and

reduce mucosal edema (1). However, their pharmacologic actions are not confined to the respiratory tract; systemic cardiovascular effects may also occur.

Cardiovascular adverse events, such as hypertension, tachyarrhythmias, and coronary vasospasms, have been documented, particularly in individuals with underlying ischemic heart disease, prompting regulatory restrictions on their use in several countries (2). Among these agents, pseudoephedrine has been particularly associated with serious complications, including



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coronary vasospasm and cerebrovascular events, such as stroke (3-5). These effects are pharmacodynamically consistent with the sympathomimetic profile of the drug. Nevertheless, no clear consensus has not been established, and such adverse outcomes have been reported regardless of patient age, dosage, or vascular health status (4-7). It is also important to consider that pre-existing endothelial dysfunction may serve as a predisposing factor for these events.

In routine clinical practice, especially in outpatient settings, these decongestants are frequently prescribed for symptomatic relief. However, even in the absence of overt cardiovascular symptoms, patients may subsequently present with serious acute cardiac events. Given these risks, it is imperative to re-evaluate the safety profile of pseudoephedrine-containing decongestants, particularly in patients with potential cardiovascular vulnerability.

The present study aims to explore the relationship between pseudoephedrine exposure and reversible coronary artery constriction that may contribute to myocardial ischemia in patients presenting to the emergency department (ED) with acute myocardial infarction (AMI) who reported using pseudoephedrine-containing products within the preceding week.

## Materials and Methods

### Study Design and Ethical Approval

This observational study was conducted from January 1 to June 30, 2024, in the ED of a tertiary-care hospital. The study population included patients who presented with chest pain and were diagnosed with AMI [either ST-elevation myocardial infarction (STEMI) or non-STEMI (NSTEMI)]. The primary objective was to evaluate the history of pseudoephedrine use within the week preceding symptom onset. Approval was obtained from Manisa Celal Bayar University Ethics Committee prior to study initiation (approval number: E-20478486-050.04-756900, date: 03.04.2024). The study was conducted in accordance with the principles outlined in the Declaration of Helsinki.

### Study Population and Variables

During the study period, patients presenting to the ED with chest pain were triaged, monitored, and evaluated by electrocardiography (ECG). Necessary diagnostic tests and initial treatments were administered, and patients with suspected acute coronary syndrome were referred to the cardiology department. Among these, 189 patients were diagnosed with STEMI or NSTEMI and subsequently evaluated for a self-reported history of pseudoephedrine use within the previous seven days. Only

patients aged 18 years or older who were conscious, cooperative, oriented, and willing to provide informed consent were included. Patients with myocardial injury secondary to conditions such as hemorrhagic shock or sepsis were excluded from the study.

Demographic data (age, sex, comorbidities), presenting complaints, ECG findings, vital signs at admission, history of pseudoephedrine use, emergency outcomes, cardiology department interventions, and the occurrence of major adverse cardiac events (MACE) within one month among pseudoephedrine-exposed individuals were systematically recorded using a standardized data collection form. MACE was defined as recurrent myocardial infarction, heart failure, ischemic stroke, or death.

### Statistical Analysis

All statistical analyses were conducted using the Statistical Package for the Social Sciences, version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were employed to summarize the data, including frequencies and percentages for categorical variables and the mean, standard deviation (SD), median, and range (minimum-maximum) for continuous variables. The Kolmogorov-Smirnov test was used to assess the normality of continuous variables. For univariate analysis, normally distributed continuous variables were expressed as mean  $\pm$  SD and compared using the independent samples t-test. Categorical variables were analyzed using the Pearson's chi-square test. A p value of less than 0.05 was considered indicative of statistical significance.

## Results

A total of 189 patients diagnosed with AMI who presented to the ED with chest pain between January and June 2024 were included in the data analysis. The demographic characteristics, comorbidities, clinical presentations, and outcomes of all patients are summarized in Table 1.

The mean age of the study population was  $60.88 \pm 13.82$  years; the majority of participants were male ( $n=143$ , 75.7%). Among these patients, 57.1% ( $n=108$ ) were diagnosed with NSTEMI. When patients' comorbidities were evaluated, the most common comorbidity was hypertension (53.4%), followed by ischemic heart disease (38.1%) and diabetes mellitus (34.9%). On admission, non-specific ECG changes were the most frequent finding, observed in 45% of cases. Of the 189 patients, 23 (12.2%) reported a history of pseudoephedrine use within the week preceding the onset of AMI symptoms. Among these 23 patients, 8 (34.8%) had a history of ischemic heart disease, 7 (30.4%) hypertension, and 7 (30.4%) diabetes mellitus (7).

Regarding ED outcomes, 87.8% of patients were admitted to the coronary intensive care unit for further monitoring and treatment. One patient died in the ED, while two patients refused further treatment and were discharged against medical advice.

<b>Age, years, mean ± SD</b>	60.88±13.82	
<b>Gender</b>	Male	143 (75.7)
	Female	46 (24.3)
<b>Comorbidities</b>	Hypertension	101 (53.4)
	Ischemic heart disease	72 (38.1)
	Diabetes mellitus	66 (34.9)
	Heart failure	20 (10.6)
	COPD	14 (7.4)
	CKF	11 (5.8)
	Stroke	3 (1.6)
	Obesity	45 (23.8)
<b>Major complaint</b>	Chest pain	147 (77.8)
	Shortness of breath	15 (7.9)
	Epigastric pain	10 (5.3)
	Nausea-vomiting	5 (2.6)
	Palpitations	3 (1.6)
	Sweating	3 (1.6)
	Back pain	2 (1.1)
	Numbness in arms	2 (1.1)
	Weakness-malaise	1 (0.5)
	Syncope	1 (0.5)
<b>Diagnosis</b>	STEMI	81 (42.9)
	NSTEMI	108 (57.1)
<b>Electrocardiography findings</b>	ST segment elevation	80 (42.3)
	ST segment depression	14 (7.4)
	T wave inversion	10 (5.3)
	Non-specific	85 (45)
<b>History of pseudoephedrine use</b>	Yes	23 (12.2)
	No	166 (87.8)
<b>Percutaneous coronary intervention</b>	Yes	171 (90.5)
	No	17 (9)
<b>Intervention type</b>	Balloon-stent	110 (58.2)
	Medical follow-up	37 (19.6)
	By-pass	24 (12.7)
<b>One-month MACE</b>	Yes	24 (12.7)
	No	165 (87.3)

COPD: Chronic obstructive pulmonary disease, CKF: Chronic kidney disease, STEMI: ST-segment elevation myocardial infarction, NSTEMI: Non-ST-segment elevation myocardial infarction, MACE: Major adverse cardiovascular events, Data were presented as n (%) except age

Following diagnosis, 90.5% of patients (n=171) underwent percutaneous coronary intervention, and 58.2% (n=110) received balloon angioplasty and/or stent placement.

Among patients with a history of pseudoephedrine use, the one-month incidence of MACE was 13% (n=3), compared with 12.7% (n=21) among those without such a history. No statistically significant differences in age, diagnoses, and MACE rates were observed between patients with and without pseudoephedrine use (Table 2).

Regarding MACE subtypes, the most frequent event was death, occurring in 7.4% (n=14) of all patients. Heart failure was identified in 2.6% (n=5) of patients, while recurrent myocardial infarction was observed in 2.1% (n=4) of patients.

## Discussion

This study provides valuable insights into the potential cardiovascular risks of pseudoephedrine use, especially in populations with underlying vulnerabilities. Pseudoephedrine, a sympathomimetic agent commonly included in OTC cold and allergy medications, is frequently perceived as benign due to its widespread availability and symptomatic efficacy. However, our findings highlight that a non-negligible proportion (12.2%) of patients presenting with AMI had used pseudoephedrine within the preceding week, underscoring the importance of reevaluating the cardiovascular safety of pseudoephedrine in susceptible individuals.

Although no statistically significant association was identified between pseudoephedrine use and the incidence of coronary vasospasm in AMI patients, this observation must be interpreted with caution due to the limited sample size. Importantly, a considerable proportion of patients exposed to pseudoephedrine had pre-existing cardiovascular comorbidities: 34.8% had ischemic heart disease, 30.4% had hypertension, and 30.4% had diabetes mellitus. These conditions are well-known contributors to endothelial dysfunction, which plays a critical role in the pathogenesis of vasospasm and thrombosis, particularly in the presence of vasoconstrictive agents such as pseudoephedrine (8,9). Although definitive causality cannot be determined from

History of pseudoephedrine use	Yes (n=23)	No (n=166)	p value
<b>Age, years, mean ± SD</b>	58.52±18.04	61.20±13.17	0.384
<b>Diagnosis (n, %)</b>			0.404
STEMI	8 (34.8)	73 (44)	
NSTEMI	15 (65.2)	93 (56)	
<b>1-month MACE, n (%)</b>			0.958
Positive	3 (13)	21 (12.7%)	
Negative	20 (87)	145 (87.3%)	

SD: Standard deviation STEMI: ST-segment elevation myocardial infarction, NSTEMI: Non-ST-segment elevation myocardial infarction, MACE: Major adverse cardiovascular events

our cross-sectional design, the data suggest that pseudoephedrine may precipitate ischemic events in predisposed individuals.

One of the most compelling aspects of our findings is the continued use of pseudoephedrine despite advanced age and significant cardiovascular comorbidities patient profiles for which regulatory bodies such as the Food and Drug Administration and European Medicines Agency have issued cautionary guidelines (10). This points to a concerning gap in clinical awareness and risk stratification regarding the systemic effects of pseudoephedrine, particularly in emergency and primary care settings where comprehensive medication histories may not always be obtained. Easy access to pseudoephedrine-containing products exacerbates this risk, particularly among individuals who self-medicate without consulting healthcare professionals.

While establishing a causal link between pseudoephedrine use and AMI through long-term prospective studies is methodologically complex, the real-world data presented here provide a compelling signal. In particular, our findings align with prior literature and case reports suggesting that pseudoephedrine can induce coronary vasospasm, arrhythmias, and cerebrovascular events via sympathomimetic mechanisms (11,12). In our study, pseudoephedrine users frequently exhibited non-specific electrocardiographic changes, such as ST-segment alterations, which may reflect transient myocardial ischemia or vasospastic phenomena. Although we did not evaluate QT intervals or utilize ambulatory electrocardiographic monitoring, this absence underscores a broader gap in the assessment of the cardiovascular effects of OTC medications in clinical practice and highlights the need for more comprehensive monitoring in future studies.

Furthermore, the 1-month rate of MACE was comparable between pseudoephedrine users (13%) and non-users (12.7%). However, the presence of serious outcomes including death among recently exposed individuals is clinically significant and warrants attention. These findings support the hypothesis that pseudoephedrine may not act as a direct etiological factor but rather as a physiological stressor capable of triggering cardiovascular events in patients with preexisting endothelial vulnerability or atherosclerotic disease.

In addition to cardiovascular concerns, pseudoephedrine's potential neurotoxicity must be considered. Although our study primarily focused on cardiac outcomes, it is worth noting that the mean age of the cohort was 60 years. Elderly individuals are particularly vulnerable to the systemic effects of sympathomimetics. Pseudoephedrine has been associated with central nervous system depression, seizures, and even fatal outcomes, especially in patients with pre-existing neurological

conditions (7,13). A notable case report describes an 83-year-old woman who developed prolonged seizures after ingesting 120 mg of pseudoephedrine; her symptoms persisted for three months (14). These findings underscore the need for heightened vigilance when prescribing or recommending OTC medications in geriatric populations.

### Study Limitations

Our study has several limitations, most notably its single-center design and relatively small sample size, which may limit generalizability. In addition, the absence of data on patients' baseline vital signs, vascular health, renal and hepatic function, as well as detailed information on pseudoephedrine dosage, frequency, and route of administration introduces further uncertainty. Furthermore, the relatively small number of patients reporting pseudoephedrine use and the absence of detailed dosage information limit the strength of the conclusions. Additionally, given the lack of statistically significant differences, the findings should be interpreted with caution and not be considered evidence of a causal relationship.

### Conclusion

Pseudoephedrine remains a widely used agent for symptomatic relief in conditions such as the common cold and allergic rhinitis. However, its systemic sympathomimetic effects particularly in elderly individuals and those with cardiovascular or neurological comorbidities carry potential risks that are frequently underrecognized. Although not statistically significant, our findings suggest a clinically relevant association between recent pseudoephedrine use and acute cardiac events among vulnerable patients. This calls for increased awareness among clinicians, pharmacists, and the general public of the possible adverse outcomes associated with pseudoephedrine, even when used in the short term or at therapeutic doses. Patient education, enhanced pharmacovigilance, and more stringent regulatory oversight may be warranted to mitigate these risks. Particularly in high-risk populations, medication histories should be carefully evaluated before initiating even seemingly benign symptomatic therapies.

### Ethics

**Ethics Committee Approval:** Approval was obtained from Manisa Celal Bayar University Ethics Committee prior to study initiation (approval number: E-20478486-050.04-756900, date: 03.04.2024). The study was conducted in accordance with the principles outlined in the Declaration of Helsinki.

**Informed Consent:** Only patients aged 18 years or older who were conscious, cooperative, oriented, and willing to provide informed consent were included.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: C.Y., M.İ.Ş., Concept: C.Y., M.İ.Ş., A.A., Design: M.İ.Ş., M.U., Data Collection or Processing: C.Y., Analysis or Interpretation: C.Y., M.İ.Ş., Ö.B., A.A., Literature Search: C.Y., Ö.B., A.A., Writing: C.Y., M.İ.Ş., M.U.

**Conflict of Interest:** No conflict of interest was declared by the authors.

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### Data Availability Statement

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request

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