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A Retrospective Analysis of Adverse Drug Reaction Reports from the Cardiology Department (2020-2024)

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Abstract: To analyze the pharmaco-epidemiological characteristics of adverse drug reaction (ADR) reports related to the Department of Cardiology submitted by Nanjing First Hospital from 2020 to 2024, and to provide a reference for future clinical ADR prevention and management. ADR reports were collected through voluntary reporting by healthcare professionals, retrospective review, and case note screening based on a trigger tool. A total of 226 ADR reports from the Department of Cardiology, submitted between January 2020 and December 2024, were selected as the analysis data. Relevant epidemiological data were gathered, and the Naranjo Adverse Drug Reaction Probability Scale was used to assess the causality of the ADRs. Among the patients in the ADR reports, the mean age was 64.42 ± 12.86 years, comprising 116 males and 110 females; over 60% of the cases were aged over 60 years. Analysis of the administration routes showed that oral dosage forms accounted for 60.2%. Regarding the involved drug types, from 2020 to 2024, ADR reports for intravenous preparations decreased significantly, and reports for adjunctive medications also saw a substantial reduction, while reports for oral dosage forms gradually increased. This suggests that our hospital has achieved certain results in controlling the proportion of intravenous infusions in inpatients, indicating a trend towards more rational clinical drug use. During 2020–2024, contrast agents consistently ranked first in the number of ADR reports in our hospital. In the causality assessment of ADRs, 3 cases (1.3%) were deemed 'definite', 24 cases (10.6%) 'probable', 125 cases (55.3%) 'possible', and 74 cases (32.7%) 'doubtful'. Targeted analysis and preventive management of ADRs related to cardiovascular drugs help enhance the understanding of these medications, avoid the occurrence of ADRs, improve the management of cardiovascular drug therapy, and ensure patient medication safety.

1. Preface

With the aging population and the steady rise of metabolic risk factors, China's cardiovascular and cerebrovascular disease prevention and control face severe challenges. According to data from the 2024 "China Cardiovascular Health and Disease Report", cardiovascular diseases (cardiovascular disease, CVD) account for 48.98% and 47.35% of all deaths in rural and urban areas respectively. Two-fifths of deaths are attributed to cardiovascular diseases. It is estimated that approximately 330 million people in China are affected by cardiovascular diseases, with an estimated 435 million individuals with normal-to-high blood pressure. Consequently, cardiovascular medications have

consistently ranked among the top three categories of prescription drugs in China. Most cardiovascular diseases are chronic conditions requiring long-term medication control. Patients' underlying conditions, comorbidities, concurrent medications, and even daily dietary habits may affect drug efficacy and even potentially induce or exacerbate adverse reactions. Adverse drug reactions (ADR) frequently occur in modern medical practice, with their incidence and mortality rates continuously rising alongside increasing healthcare costs. Studies indicate that cardiovascular medications are one of the most common causes of adverse events in hospitalized patients. Since cardiovascular diseases predominantly affect elderly patients, this further increases the incidence of ADR. A systematic review involving global hospitalized elderly patients reported an ADR prevalence rate of 11.5-24% [2]. Another systematic review incorporating adverse reaction data from many countries including Europe and the United States showed that about 10% of global hospitalization was related to ADR [3].

Medication adherence is crucial for managing chronic conditions like hypertension and effectively controlling disease progression. A previous systematic review revealed that up to 40% of patients worldwide fail to adhere to antihypertensive regimens [4]. Poor medication adherence correlates with cardiovascular diseases including myocardial infarction and stroke, as well as impaired renal function and increased all-cause mortality [5]. Among factors affecting medication adherence, treatment-related elements such as adverse drug reactions (ADRs) are paramount. This study analyzes ADR occurrences and specific circumstances among hospitalized cardiovascular patients at our hospital from 2020 to 2024, aiming to elucidate complex interactions between patients, medications, and diseases. The findings will inform optimized cardiovascular drug management strategies, enhance clinical pharmacy support, improve patient education on medication use, prevent irrational combination therapies, and reduce ADR risks. The report is presented as follows:

2. Materials and methods

2.1 Data Source

The adverse reaction analysis group was composed of myself and two clinical pharmacists of cardiovascular medicine, focusing on the collection of cardiovascular diseases in our hospital

All adverse drug reactions reported by the Department of Internal Medicine during 2020-2024, including data such as:

1) Voluntary reporting by medical staff, involving active participation of clinicians, nurses and pharmacists, to collect and record any ADRs observed during the period of 2020-2024 in the department of cardiovascular medicine.

2) Medical records/drug review, using retrospective review, all cases of ADR were included in the study.

3) For trigger-based medical record review, we implement a two-phase approach: First, using predefined Adverse Drug Reaction (ADR) triggers in our hospital's Hospital Information System (HIS), we screen patient records for specific indicators such as laboratory values exceeding 5, antidote prescriptions, certain phrases, or drug events indicating potential ADRs. For example, patients receiving warfarin therapy with an International Normalized Ratio (INR) ≥5, statins users showing ALT levels ≥3× upper limit of normal value (ULN), diuretics patients with serum potassium <3.0 mmol/L, and iodinated contrast agents combined with topical corticosteroids or antihistamines like promethazine. Subsequently, our research team analyzes these patients' medical records, supplemented by clinical consultations and caregiver interviews when necessary, to determine whether medication use correlates with adverse events or confirm actual ADR occurrences.

2.2 Methodology

In accordance with the reporting requirements of the National Adverse Reaction Monitoring Center, all cardiovascular adverse reactions/events involving eligible patients from our hospital between January 2020 and December 2024 were selected. A cardiovascular ADR investigation team led by myself, comprising two clinical pharmacy trainees specializing in cardiology, conducted a systematic analysis of the causes, management, and prevention strategies for cardiovascular ADRs. All adverse reaction reports were collected, including patient demographics, involved medications, drug classifications, co-administration patterns, administration routes, affected tissues/organs, and primary clinical manifestations. Each evaluation was conducted by two team members using the Noy's Adverse Drug Reaction Assessment Scale [5]. In cases of disagreement, a third pharmacist member performed a re-evaluation. Specific scoring criteria are detailed in Table 1.

Table 1: Noy's adverse drug Reaction assessment scale

order number	related issues	Question score		
		yes	deny	unknown
1.	Have there been similar reports before?	0	0	0
2.	Did the ADR occur after use of the suspected drug?	2	-1	0
3.	Did ADRs subside after discontinuation or use of antagonists?	1	0	0
4.	Did ADRs recur after re-exposure to the suspected drug?	2	-1	0
5.	Are there other reasons that may have contributed to this ADR?	-1	2	0
6.	Whether the ADRs were repeated after the administration of placebo	-1	1	0
7.	Is the drug toxic in blood or other body fluids?	1	0	0
8.	Does an increase (or decrease) in ADRs occur with an increase (or decrease) in dose?	1	0	0
9.	Has the patient been exposed to this drug or similar drugs with similar reactions?	1	0	0
10.	Is there any objective evidence to confirm this reaction?	1	0	0

Note: A total score of ≥9 indicates that the association between the drug and ADR is "definite", a total score of 5-8 indicates that the association between the drug and ADR is "likely", a total score of 1-4 indicates that the association is "possible", and a total score of ≤0 indicates that the association is "suspicious".

2.3 Statistical analysis

Count data were expressed as frequency and percentage (%), and measurement data were expressed as mean (SD). Statistical analysis was carried out on the relevant data using Excel table.

3. Results

3.1 Case data

This study collected 226 cardiovascular drug Adverse Reaction (ADR) reports from our hospital between 2020 and 2024, involving 116 male and 110 female cases with an average age of 64.42 years (range: 12-86 years). The distribution was as follows: 40 cases in 2020,41 in 2021,40 in 2022,48 in 2023, and 57 in 2024. Basic data for these ADR reports in the Department of Cardiology are detailed in Tables 2-3.

Table 2: Patient data of cardiovascular patients with ADR report in our hospital from 2020 to 2024 (n=226)

	2020	2021	2022	2023	2024	2020~2024
Average age (years)	64.23 (13.45)	67.27 (13.07)	63.08 (13.62)	63.35 (13.03)	64.98 (12.62)	64.42 (12.86)
Minimum age (years)	28	35	35	35	34	28
Maximum age (years)	93	89	89	93	85	94
Number of male patients (proportion , n%)	24 (58.54%)	29 (72.50%)	16 40.00%	28 58.33%	19 33.33%	116 51.33%
Number of female patients (proportion , n%)	17 41.46%	11 27.50%	24 60.00%	20 41.67%	38 66.67%	110 48.67%

Table 3: Age stratification of patients with ADR reports of cardiovascular drugs in our hospital from 2020 to 2024 (n=226)

	<40 years old	40-59 years	60-75 years	> 75 years old
2020	3	8	23	7
2021	1	11	16	12
2022	2	11	23	4
2023	1	13	28	6
2024	1	11	36	9

3.2 ADR mainly involves the route of administration

According to the analysis of 2020-2024 ADR report data, the ADR of cardiovascular drugs in our hospital mainly involved several drug administration routes including oral, subcutaneous injection, intravenous injection, etc. According to the three drug administration methods of oral, subcutaneous and intravenous administration, the results are shown in Table 4.

Table 4: Comparison of administration routes of patients with ADR reports of cardiovascular drugs in our hospital from 2020 to 2024 (n=226)

	2020	2021	2022	2023	2024
Oral (number of cases, %)	20(50.0%)	19(46.3%)	21(52.5%)	29(60.4%)	47(82.5%)
Under skin (no. of cases, %)	2(5.0%)	1(2.4%)	1(2.5%)	1(2.1%)	1(1.8%)
Venous (number of cases, %)	18(45.0%)	21(51.2%)	18(45.0%)	18(37.5%)	9(15.5%
Total (number of examples, %)	40(100.0%)	41(100.0%)	40(100.0%)	48(100.0%)	57(100.0%)

3.3 ADR mainly involves the use of combination drugs

Analysis of the 2020-2024 ADR reports shows that cardiovascular drug-related adverse events (ADRs) in our hospital were categorized into three scenarios based on combination therapy: monotherapy, dual-drug regimens, and triple or higher-drug combinations. Specifically, 10 cases (4.4%) involved dual-drug regimens, 70 cases (31.0%) used triple-drug regimens, and 146 cases (64.6%) employed quadruple or higher-drug regimens. The detailed findings are presented in Table 5.

Table 5: Comparison of combined medication status of patients with ADR reports of cardiovascular drugs in our hospital from 2020 to 2024 (n=226)

	2020 (example)	2021 (example)	2022 (example)	2023 (example)	2024 (example)
Two drug combinations and below	2	3	2	1	2
Triple drug use	15	17	14	10	14
Four or more drugs	23	21	25	37	41

3.4 Drug categories involved in ADR

This study investigated cardiovascular drug Adverse Reaction (ADR) cases occurring at our hospital between 2020 and 2024. The top five medications in 2020 included Danshenone IIA Sodium Injection, Shenmai Injection, Xueshuantong Injection, Amlodipine Tablets, and Benazepril Tablets. Notably, the list underwent significant changes in 2024, with new additions including Ticagrelor Tablets, Iohexol Injection, Aspirin Enteric-coated Tablets & Capsules, Atorvastatin Calcium Tablets, and Azelastine Dispersible Tablets. Detailed distribution data are presented in Table 6.

Table 6: Distribution of drug varieties reported by ADR in the Department of Cardiovascular Medicine from 2020 to 2024

sort	2020		2021		2022		2023		2024	
	breed	example	breed	example	breed	example	breed	example	breed	example
1	Iodixanol injection	7	Iodixanol injection	9	Iodixanol injection	10	Iodixanol injection	6	Tegrelo	7
2	Teglitinil tablets	4	Teglitinil tablets	5	Aspirin enteric-coated tablets	5	Enoxaparin Sodium	4	Iodixanol injection	5
3	Nicotine injection	3	Nicodil injection	4	Tegrelo	3	Tegrelo	4	Aspirin enteric-coated tablets	4
4	Cysteine dihydrogen phosphate injection	2	aspirin	3	warfarin	3	Omesartan hydrochlorothiazide	3	atorvastatin calcium	3
5	Libalosban Tablets	2	Amiodarone tablets	2	Nicodil injection	2	Pulse Kang Capsule	2	Acesomis dispersible tablets	3

3.5 Analysis of tissues and organs involved in ADR

The cases of cardiovascular drug ADR occurred in our hospital from 2020 to 2024 mainly involved the following systems: allergic reaction, cardiovascular system, nervous system, respiratory system, digestive system, systemic injury and other types of reactions. The specific cumulative tissue, organ

and clinical manifestations of related adverse reactions are shown in Table 7.

Table 7: Cumulative types of tissues, organs and clinical manifestations of ADR cases related to cardiovascular medicine in our hospital from 2020 to 2024

Classification of organs and tissues	Clinical Manifestation	Number of examples
anaphylactoid reaction	Chills, shivering, shock, etc	3
mental symptom	Hallucinations, hallucinations, aphasia, mental confusion, mania, aggressive behavior, etc	4
cutaneous reaction	Skin stinging, itching, skin inflammation, urticaria and so on	61
Cardiovascular system response	Palpitations, chest pain, arrhythmia, phlebitis, etc	36
Neurological response	Dizziness, headache, convulsions and stiffness of limbs, restlessness, confusion, etc	3
Respiratory response	Breathing difficulties, dry cough, cough, etc	6
Digestive system response	Stomach discomfort, nausea, vomiting, diarrhea, abdominal pain, liver function abnormalities, etc	46
Blood system response	Affect hematopoietic or coagulation system various functions	32
Systemic injuries	Fevers, weakness, weak hands and feet	18
other	Transient carotid pulse can not be felt, stiff, numb and so on	17
amount to		226

3.6 Population distribution and correlation evaluation of ADR reports

The cardiovascular department of our hospital reported 61 Adverse Drug Reactions (ADRs) from 2020 to 2024. Physicians documented 61 cases (27.0%), nurses reported 13 cases (5.8%), and pharmacists recorded 37 cases (67.2%). In the analysis of ADR correlation reports, 3 cases (1.3%) were confirmed, 24 cases (10.6%) were likely, 125 cases (55.3%) were probable, and 74 cases (32.7%) were suspected.

4. Analysis and discussion

According to the 2024 National Adverse Drug Reaction Monitoring Report, cardiovascular medications rank third in usage frequency. By dosage form, injectable and oral formulations account for 62.7% and 39.1% respectively, second only to anti-infective drugs and oncology medications, making them the primary component of drug-induced diseases. As a cardiovascular hospital in Nanjing City, our institution treats over 7,000 patients annually, representing a relatively high patient volume. Many cardiovascular drugs in our cardiology department exhibit narrow therapeutic windows (e.g., digoxin), significant individual variations, and susceptibility to various factors affecting efficacy (e.g., warfarin, clopidogrel), along with numerous high-risk emergency medications. Therefore, conducting statistical analysis and prevention strategies for adverse drug reactions (ADRs) in cardiovascular medications is crucial. This approach enhances understanding of cardiovascular drug management, prevents ADRs, optimizes treatment protocols, and ensures patient

medication safety.

Analysis of adverse drug reactions (ADRs) for cardiovascular medications at our hospital from 2020 to 2024 reveals distinct demographic patterns. The majority of ADRs occur in individuals over 60 years old, attributable to two primary factors: First, cardiovascular diseases such as coronary heart disease, hypertension, and heart failure show a clear age-related progression, particularly with chronic conditions. Second, elderly patients experience significant declines in drug metabolism and excretion functions. Delayed gastric emptying, reduced gastric acid secretion, and diminished gastric motility/tension make them prone to drug-induced gastrointestinal side effects [7]. Concurrently, weakened renal and hepatic functions in older adults—particularly impaired drug elimination due to insufficient renal perfusion—can lead to drug accumulation and increased adverse reactions. Moreover, the prevalence of comorbidities among elderly patients often necessitates combination therapies, which may trigger drug interactions and subsequent adverse outcomes [8]. Notably, balanced gender distribution and wide age ranges indicate cardiovascular diseases as chronic conditions requiring long-term management, significantly elevating adverse reaction risks compared to other medications.

On the other hand, from 2020 to 2024, ADRs (Adverse Drug Reactions) primarily involved significant differences in administration routes. In 2020, intravenous medications dominated, while oral medications became predominant by 2024. Both the total number of ADR cases and severe cases showed marked decreases compared to 2020, aligning with WHO and national guidelines advocating "oral over injection, injectable over IV infusion" [6]. The production of IV products may introduce contaminants like particles, which can trigger vascular reactions and allergic responses—key contributors to drug-induced diseases. Moving forward, clinical education should continue emphasizing reduced IV dosage and frequency.

Analysis of cardiovascular drug Adverse Drug Reactions (ADRs) in our hospital from 2020 to 2024 revealed that three injectable adjuvant medications were primarily involved in 2020, indicating suboptimal medication distribution. To address this, we implemented a comprehensive approach combining prescription review, medication guidance, and specialized review protocols. Pre-treatment guidance provided clinicians with clear instructions for rational drug use, while pharmacists conducted real-time prescription reviews to assess treatment plans and promptly address any issues. Post-treatment evaluations ensured thorough oversight, significantly improving clinical medication standardization through this multi-pronged strategy. By 2024, none of the top five ADR-inducing medications remained adjuvant drugs, demonstrating improved medication rationality. Other high-risk categories included antiplatelet/anticoagulant agents, antihypertensive drugs, lipid-lowering medications, and antiarrhythmic drugs, requiring intensified pharmaceutical monitoring by physicians and pharmacists. Specifically, anticoagulants and antiplatelet drugs carry bleeding risks; antihypertensive medications may cause neurogenic edema, ankle swelling, or dry cough; lipid-lowering drugs often lead to elevated liver and muscle enzymes. Clinical pharmacists should meticulously document patients' medication histories and allergy profiles during treatment management, implement rigorous pharmaceutical monitoring, and promptly identify adverse reactions to advise clinicians to reconsider treatment plans.

In the analysis of combination medication patterns among cardiovascular drug Adverse Reaction (ADR) cases from 2020 to 2024, it was observed that the proportion of combined drug use significantly increased in reported ADR cases, particularly among patients receiving multiple medications involving four or more drugs [1]. This suggests that reducing combination therapy may help decrease adverse drug reactions. For patients, combination therapy should follow the principle of "reducing toxicity while enhancing efficacy". If combination therapy increases the incidence of ADRs, clinicians must carefully evaluate the risks and benefits, and develop reasonable individualized treatment plans.

For adverse drug reactions (ADRs), prevention is better than cure. Personalized genetic monitoring or blood drug concentration tracking of certain medications can help prevent and identify adverse effects. For instance, the SLCO1B1 gene may influence statin efficacy and side effects, while genetic testing for high-risk patients using clopidogrel and warfarin aids in implementing personalized treatment plans that enhance therapeutic outcomes and reduce adverse reactions. As clinical pharmacists, actively exploring research on individualized medication regimens also contributes to promoting rational drug use in clinical practice.

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