

Allergic reactions during coronary angiography or PCI in Poland: Occurrence, trends, and long-term perspective based on the Polish ORPKI registry

Karol Kaziród-Wolski¹, Michał Zabojszcz¹, Paulina Jaskulska¹, Natalia Dardzińska¹, Ewa Strzelczyk¹, Krzysztof P Malinowski^{2,3}, Janusz Sielski¹, Zbigniew Siudak¹

¹Institute of Medical Sciences, *Collegium Medicum*, Jan Kochanowski University, Kielce, Poland

²Center for Digital Medicine and Robotics, Jagiellonian University Medical College, Kraków, Poland

³Department of Bioinformatics and Telemedicine, Faculty of Medicine, Jagiellonian University Medical College, Kraków, Poland

Correspondence to:

Karol Kaziród-Wolski, MD, PhD,
Institute of Medical Sciences,
Collegium Medicum,
Jan Kochanowski University,
IX Wieków Kielc 19A, 25–317
Kielce, Poland,
phone: +48 41 349 69 11,
e-mail: karol.kazirod-wolski@
ujk.edu.pl

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A B S T R A C T

Background: Allergic reactions during coronary angiography and percutaneous coronary intervention (PCI) in patients with acute coronary syndromes can affect their outcomes.

Aims: We aimed to investigate the incidence of allergic reactions and predictors of their occurrence in the catheterization laboratory.

Material and methods: The study included 1 812 994 treatment cases available in the ORPKI Polish National Registry, of which 659 372 were for women and 1 144 689 for men. Data were collected from 161 interventional cardiology centers in Poland between 2014 and 2022 and included in the retrospective analysis. An allergic reaction was defined as any hypersensitive response of the immune system manifesting as bronchospasm, asthma exacerbation, conjunctivitis, urticaria, eczema, angioedema, or anaphylactic shock.

Results: There was a decreasing incidence of allergic reactions overall, in both sexes and all age subgroups. The incidence of allergic reactions each year oscillated between 0.02% and 0.11% ($P < 0.001$), and the most recent one was 0.02% in 2022. The incidence of allergic reaction was associated with low-molecular-weight heparin (LMWH) (OR, 23.5 [95% CI, 18.92–29.19]), glycoprotein IIb/IIIa inhibitors (GPIIb/IIIa) (OR, 2.31 [95% CI, 1.92–2.78]), previous PCI (OR, 1.55 [95% CI, 1.34–1.8]), radiation dose (OR, 1.25 per 1000 mGy [95% CI, 1.19–1.31]), and contrast dose (OR, 1.17 per 100 ml [95% CI, 1.08–1.28]).

Conclusions: The overall incidence of acute allergic reactions in the cath lab is low and decreased significantly between 2014 and 2022. The decrease in frequency did not depend on age or sex. Independent predictors of allergic reaction incidence were the use of GPIIb/IIIa, LMWH, and dose of contrast agent and radiation.

Key words: allergic reaction, anaphylaxis, coronary angiography, iodinated contrast media, myocardial infarction, percutaneous coronary intervention

INTRODUCTION

Despite variable reports, the overall number of revascularization procedures has been increasing in recent years, the clinical profile of the patient has been changing, and higher risk procedures (left main coronary artery revascularization, rotablation and chronic total occlusion revascularization) are being performed more frequently [1–4].

Patients undergoing revascularization procedures are increasingly older and have more risk factors for atherosclerosis [2, 5]. Assessing the frailty of elderly patients remains crucial in selecting an appropriate revascularization strategy [6]. Despite these changes in patient profile, peri-procedural mortality in percutaneous coronary intervention (PCI) remains steady [3–5]. The rate of PCI complications,

WHAT'S NEW?

We present a retrospective study based on ORPKI (National Registry of Invasive Cardiology Procedures), which is the latest report on acute allergic reactions during coronary angiography and percutaneous coronary interventions. The overall incidence of acute allergic reactions in the cath lab is low and decreased significantly between 2014 and 2022. Recent data from other studies suggest that their incidence is higher. The decrease in frequency did not depend on age or sex. Independent factors that significantly increased the risk of allergic reaction were the use of glycoprotein IIb/IIIa inhibitors, low-molecular-weight heparin, contrast agents, and radiation.

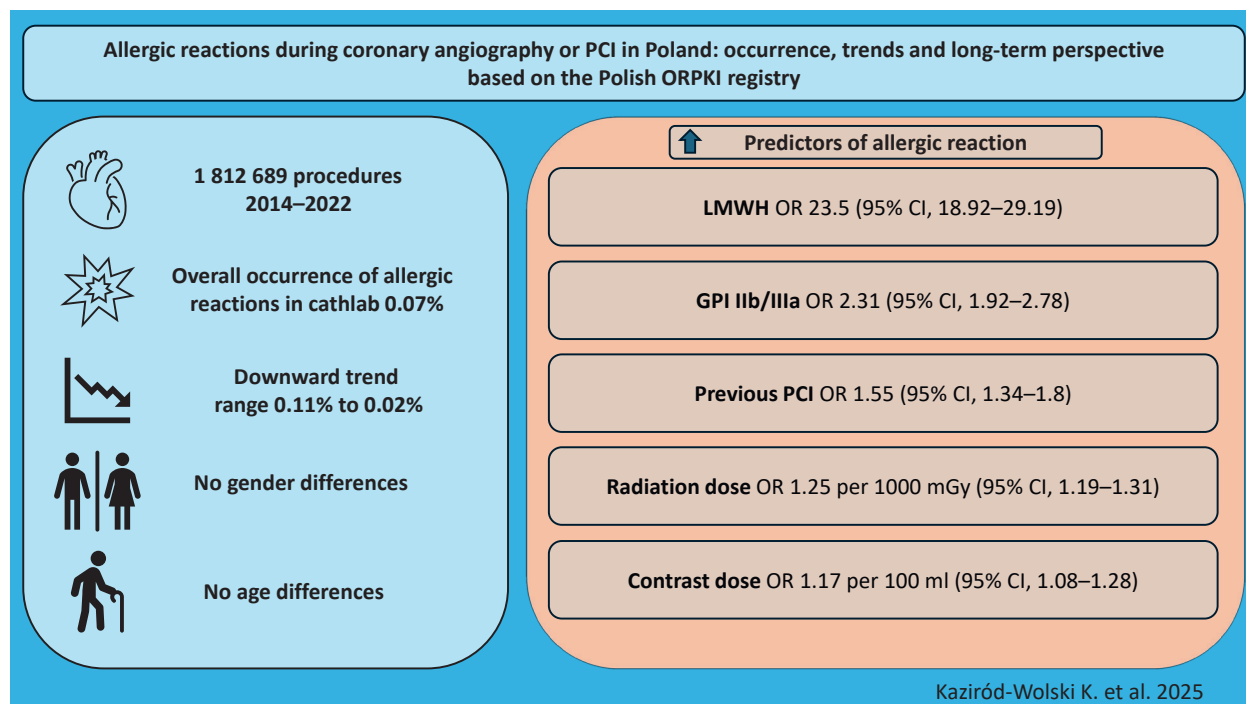
such as coronary artery perforation and major vascular access complications, remains constant [7, 8]. Other complications, such as allergic reactions, are less studied. Based on available data, the incidence of allergic reactions during PCI is estimated to be 0.08% in patients without psoriasis and 0.4% in patients with psoriasis [9]. Allergic reactions during PCI can be caused by antiplatelet and anticoagulant drugs, as well as drug-eluting stents and contrast alone [10–12]. The incidence of contrast reactions, regardless of study type and mechanism of the allergic reaction, varies between 1% and 3% [13].

The purpose of this study is to accurately analyze the incidence of allergic reactions during coronary angiography and/or PCI, to select the most sensitive groups, and to identify predictors of such reactions.

MATERIAL AND METHODS

The National Registry of Invasive Cardiology Procedures (ORPKI) was launched in 2004 by the Association of Cardiovascular Interventions of the Polish Cardiac Society.

Currently, the registry is coordinated by the Jagiellonian University College of Medicine in Krakow [14]. The data used in the statistical analysis in our study were accessed on January 10, 2024. All consecutive patients who underwent coronary angiography or coronary angiography with immediate PCI at 161 interventional cardiology centers in Poland between 2014 and 2022 were included in this retrospective analysis. The total number of patients referred to all assessed patients in consecutive years of the registry. Patients with incomplete data on baseline characteristics were excluded. No methods were used to impute missing data. An allergic reaction was defined as any hypersensitive response of the immune system manifesting as bronchospasm, asthma exacerbation, conjunctivitis, urticaria, eczema, angioedema, or anaphylactic shock. All of these symptoms had to be detected during the patient's stay in the catheterization laboratory and had not been present before admission to the hospital. Other complications or adverse events were diagnosed at the operator's discretion according to the current European Society of Cardiology



Graphical abstract

Abbreviations: CI, confidence interval; GPI, glycoprotein inhibitor; LMWH, low-molecular-weight heparin; OR, odds ratio; PCI, percutaneous coronary intervention

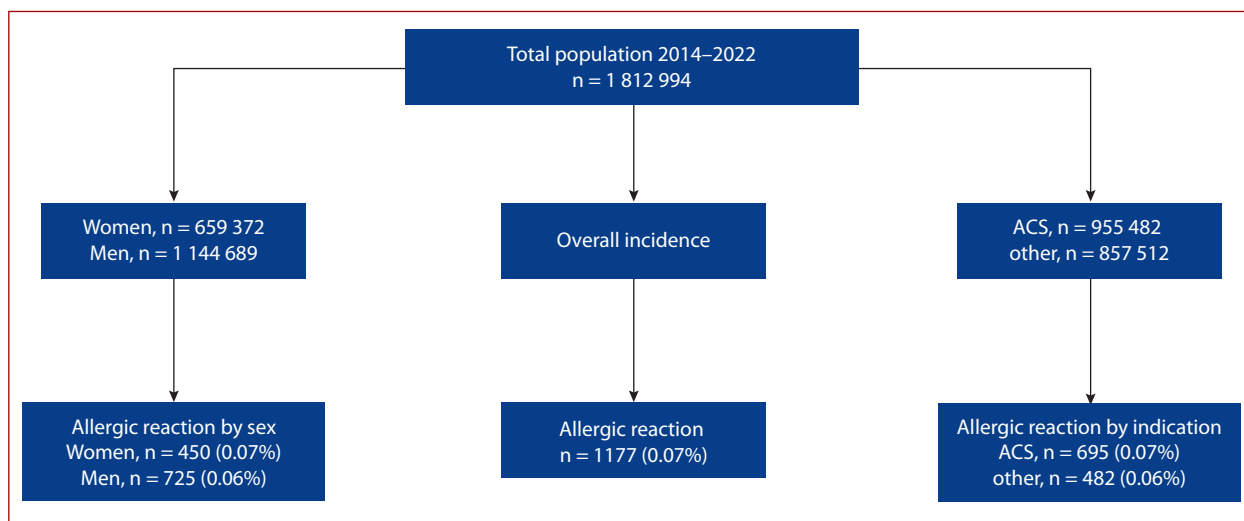


Figure 1. Incidence of allergic reactions in study population

Abbreviations: ACS, acute coronary syndrome

definitions. No further evaluation or follow-up of patients was performed. ORPKI is a national PCI registry in which all PCI patients from various hospitals are enrolled. The signed informed consent for PCI hospitalization contains consent for data transfer to the ORPKI registry. Since this is a mandatory and central national registry, ethics committee approval was waived. The study complied with the ethical principles of clinical research based on the Declaration of Helsinki, as amended. We had access to information that could identify individual participants during or after data collection, and this information was used only for long-term observation, which does not apply to the current study. No external funding was used to support this registry.

Clinical variables such as arterial hypertension, diabetes mellitus, chronic obstructive pulmonary disease, active smoking status, kidney disease, and history of stroke or myocardial infarction were defined as positive if confirmed by the patient during clinical history taking or based on documentation. Kidney disease was defined by a reduced estimated glomerular filtration rate of <60 ml/min/1.73 m². The use of unfractionated heparin (UFH), therapeutic doses of low-molecular-weight heparin (LMWH), glycoprotein IIb/IIIa inhibitor (GPI IIb/IIIa), and thrombolysis during angiography or PCI was determined by documentation. Cardiac arrest at baseline referred to cases where this event occurred before the procedures were performed. Using the Killip–Kimball classification, the severity of heart failure was determined (I — no clinical evidence of left ventricular failure, II — mild-to-moderate failure, III — severe failure, pulmonary edema, IV — cardiogenic shock) [15]. Variable “angiography” referred to cases in which only coronary angiography was performed, and variable “PCI” referred to all types of revascularization procedures. Variable “stent” indicated implantation of a specific type of stent (drug-eluting stent, bare metal stent, bioabsorbable stent). Variable “drug-eluting balloon” concerned the use of antimitotic drug-releasing balloons. Variable “chronic total occlusion”

referred to procedures during which chronic total occlusion of at least one vessel was found. Variable “TIMI” (Thrombolysis in Myocardial Infarction) refers to perfusion in the culprit vessel: 0 — no perfusion, 1 — penetration without perfusion, 2 — partial perfusion, 3 — complete perfusion) [16].

Statistical analysis

In this study, nominal variables were represented as percentages along with their respective counts. The temporal variation in the proportion of allergic reactions was analyzed using the Cochran–Armitage test for trend. The logistic regression model was employed to identify the predictors of periprocedural allergic reactions. All potential demographic, baseline, and procedural characteristics were incorporated into a multivariable model if the *P*-value in a univariable model was less than 0.2 or if they were considered to have clinical significance. The final model was derived by minimizing the Akaike information criterion. The robustness of the model was validated using bootstrap resampling. To evaluate the presence of multicollinearity, variance inflation factors were analyzed. The results were expressed as odds ratios with 2-sided 95% confidence intervals. The entire statistical analysis was conducted using R software (version 4.3.1)

RESULTS

The study included 1 812 994 coronary and PCI procedures available in the ORPKI registry, of which 659 372 were for women and 1 144 689 for men (Figure 1). We found a declining incidence of allergic reactions overall, as well as in subgroups of men and women, between 2014 and 2022. The overall incidence of allergic reactions oscillated between 0.02% and 0.11% (*p*<0.001), and the most recent one, noted in 2022, was 0.02% (Table 1). When assessing the incidence of allergic reactions according to the indications for coronary/PCI, there was a decrease in the frequency of allergic reactions regardless of acute

Table 1. Incidence of allergic reaction in general and according to gender and indication

| Variable | Year | 2014, n (%) | 2015, n (%) | 2016, n (%) | 2017, n (%) | 2018, n (%) | 2019, n (%) | 2020, n (%) | 2021, n (%) | 2022, n (%) | Total | P-value |
|------------|-------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-----------|---------|
| Total | Yes | 221 | 244 | 231 | 200 | 148 | 34 | 30 | 31 | 38 | 1177 | <0.001 |
| | Total | 227 971 | 224 642 | 230 324 | 226 484 | 210 836 | 199 230 | 150 924 | 166 096 | 176 487 | 1 812 994 | |
| Gender | Year | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | Total | |
| | Women | 93 | 93 | 84 | 68 | 54 | 15 | 13 | 12 | 18 | 18 | 450 |
| Men | Yes | 85 266 | 83 102 | 84 790 | 83 411 | 77 154 | 72 139 | 52 945 | 58 288 | 62 277 | 659 372 | |
| | Total | 128 | 150 | 147 | 132 | 94 | 19 | 17 | 19 | 19 | 725 | <0.001 |
| Indication | Year | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | Total | |
| | ACS | 162 | 153 | 119 | 112 | 85 | 12 | 18 | 16 | 18 | 18 | 695 |
| Other | Yes | 135 410 | 129 203 | 124 830 | 120 862 | 105 443 | 97 686 | 78 689 | 81 909 | 81 450 | 955 482 | |
| | Total | 59 | 91 | 112 | 88 | 63 | 22 | 12 | 15 | 20 | 482 | <0.001 |
| | Total | 92 561 | 95 439 | 105 494 | 105 622 | 105 393 | 101 544 | 72 235 | 84 187 | 95 037 | 857 512 | |

Table 2. Incidence of allergic reaction according to age decades

| Age, decades | Count | Row % | 2014, n (%) | 2015, n (%) | 2016, n (%) | 2017, n (%) | 2018, n (%) | 2019, n (%) | 2020, n (%) | 2021, n (%) | 2022, n (%) | Total | P-value | |
|--------------|-------|--------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------|---------|--------|
| 10-19 | Yes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | NA | |
| | Total | 82 | 77 | 73 | 47 | 59 | 45 | 16 | 18 | 21 | 438 | | | |
| 20-29 | Yes | 0 | 0 | 1 | 0.33 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0.28 | |
| | Total | 348 | 326 | 304 | 309 | 287 | 233 | 175 | 232 | 201 | 2415 | | | |
| 30-39 | Yes | 2 | 0.1 | 1 | 0.05 | 2 | 0.1 | 3 | 0.15 | 0 | 0 | 9 | 0.047 | |
| | Total | 1969 | 1996 | 2010 | 1967 | 1950 | 1911 | 1427 | 1520 | 1600 | 16350 | | | |
| 40-49 | Yes | 9 | 0.08 | 18 | 0.18 | 7 | 0.07 | 10 | 0.1 | 2 | 0.02 | 1 | 0.01 | <0.001 |
| | Total | 10 661 | 10 242 | 10 491 | 10 063 | 9417 | 9231 | 7169 | 8067 | 8203 | 83 544 | | | |
| 50-59 | Yes | 52 | 0.11 | 65 | 0.15 | 43 | 0.11 | 40 | 0.1 | 21 | 0.06 | 4 | 0.01 | <0.001 |
| | Total | 46 806 | 43 427 | 40 776 | 38 340 | 33 590 | 30 667 | 22 658 | 23 938 | 24 417 | 304 619 | | | |
| 60-69 | Yes | 81 | 0.1 | 72 | 0.09 | 84 | 0.1 | 76 | 0.09 | 49 | 0.06 | 13 | 0.02 | <0.001 |
| | Total | 81 549 | 83 160 | 86 718 | 85 850 | 79 457 | 73 732 | 55 467 | 59 426 | 61 482 | 666 841 | | | |
| 70-79 | Yes | 51 | 0.09 | 49 | 0.08 | 66 | 0.11 | 40 | 0.07 | 39 | 0.07 | 9 | 0.02 | <0.001 |
| | Total | 59 620 | 57 671 | 60 470 | 61 071 | 59 189 | 57 780 | 45 323 | 52 654 | 59 290 | 513 068 | | | |
| 80-89 | Yes | 26 | 0.1 | 38 | 0.15 | 26 | 0.09 | 30 | 0.11 | 24 | 0.1 | 6 | 0.03 | <0.001 |
| | Total | 25 388 | 26 117 | 27 478 | 27 007 | 24 980 | 23 646 | 17 220 | 18 719 | 19 450 | 210 005 | | | |
| 90-99 | Yes | 0 | 0 | 1 | 0.07 | 2 | 0.12 | 2 | 0.12 | 2 | 0 | 0 | 0 | 0.18 |
| | Total | 1363 | 1467 | 1661 | 1689 | 1667 | 1652 | 1273 | 1374 | 1477 | 13 623 | | | |
| 100-109 | Yes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | NA | |
| | Total | 27 | 18 | 32 | 28 | 22 | 19 | 19 | 26 | 18 | 209 | | | |
| 110-119 | Yes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | NA | |
| | Total | 5 | 4 | 9 | 10 | 3 | 7 | 6 | 10 | 8 | 62 | | | |

coronary syndromes (ACS) (Table 1). In the analysis of age subgroups by decades, a significant decrease in the incidence of allergic reactions was found in the age range of 30-90 years; in other groups, the number of recorded allergic reactions was very low, which influenced the lack of significance of the difference in years (Table 2). Among clinical and pharmacological factors, the risk of allergic reactions was increased by a history of myocardial infarction, a history of coronary artery by-pass grafting, a diagnosis of ST-segment elevation myocardial infarction (STEMI), a diagnosis of ACS, the use of IIb/IIIa glycoprotein inhibitor (GPI IIb/IIIa), low molecular weight heparin (LMWH), and earlier PCI. The risk of allergic reaction was reduced by active smoking, renal disease, chronic obstructive pulmonary disease, UFH, and performing coronary angiography only (Table 3).

Among perioperative factors, the use of drug-eluting balloons decreased the risk of allergic reaction, and the amount of contrast and radiation increased the risk of allergic reaction (Table 4). Based on multivariable regression analysis of selected variables, we found that independently the risk of allergic reaction was increased by LMWH (25-fold increase in risk), GPI IIb/IIIa (2-fold increase in risk), previous PCI (1.5-fold increase in risk), each 1000 mGy of radiation (29% increase in risk) and each 100 ml of contrast (20% increase in risk) and. Independently, the risk of allergic reaction was reduced by factors such as active smoking, diabetes (21% decrease in risk), and UFH (50% decrease in risk) (Figure 1). The distribution of the variables used in the regression analysis is shown in Supplementary material, Table S1.

DISCUSSION

Our study showed a declining incidence of allergic reactions during invasive ACS treatment. The incidence of allergic reactions was 0.02% during the 176 487 coronary angiography and PCI procedures performed in 2022. This study did not include a breakdown of the etiology of these reactions, therefore, the reported frequency refers to reactions to contrast agents and drugs together. Our multivariable logistic regression analysis showed that GPI IIb/IIIa, LMWH, previous PCI, contrast dose, and x-ray dose were independent predictors of allergic reaction occurrence. According to recent data, the incidence of immediate allergic reactions to non-ionic iodine contrast agents is 0.02%–1%, and late reactions are 1%–3% [17–19]. In patients with a history of radiocontrast allergy, the risk of recurrence is 16%–35% [20]. Contrast reactions in most cases (29%) are rash-like skin reactions, while anaphylaxis occurs in about 8.6% of patients [21]. Confirmed methods for managing patients with a history of allergic reactions to contrast are to routinely check for a history of such reactions, use skin tests, avoid triggers, and premedicate [22]. Recommended protocols for managing patients with a history of allergic reaction to contrast help prevent complications in predisposed individuals [23].

Table 3. Clinical and periprocedural factors affecting incidence allergic reaction

| Variables | Univariable | |
|--------------------------------|---------------------|---------|
| | OR (95% CI) | P-value |
| Male sex | 0.93 (0.83–1.04) | 0.21 |
| Age, years | 1 (0.99–1) | 0.24 |
| Weight, kg | 1 (1–1) | 0.49 |
| Diabetes | 0.87 (0.75–1) | 0.06 |
| Previous stroke | 1.14 (0.83–1.57) | 0.42 |
| Previous myocardial infarction | 1.27 (1.12–1.44) | <0.001 |
| Previous PCI | 1.37 (1.22–1.55) | <0.001 |
| Previous CABG | 0.89 (0.68–1.16) | 0.37 |
| Smoking status (active) | 0.8 (0.68–0.94) | 0.01 |
| Arterial hypertension | 0.96 (0.85–1.09) | 0.56 |
| Kidney disease | 0.68 (0.5–0.92) | 0.01 |
| COPD | 0.46 (0.27–0.78) | 0.003 |
| ACS (yes/no) | 1.29 (1.15–1.45) | <0.001 |
| UFH during angiogram | 0.67 (0.52–0.87) | 0.003 |
| LMWH during angiogram | 0.53 (0.2–1.41) | 0.21 |
| Cardiac arrest at baseline | 1.24 (0.62–2.48) | 0.55 |
| Direct transport to cathlab | 0.64 (0.41–0.99) | 0.045 |
| UFH | 0.34 (0.3–0.39) | <0.001 |
| LMWH | 49.18 (43.85–55.15) | <0.001 |
| GPI IIb/IIIa | 4.46 (3.79–5.24) | <0.001 |
| Killip IV vs. Killip I | 1.09 (0.57–2.11) | 0.79 |
| Thrombolysis during angiogram | 11.67 (1.63–83.46) | 0.01 |
| Angiography | 0.33 (0.29–0.37) | <0.001 |
| PCI | 2.74 (2.4–3.12) | <0.001 |
| CTO | 0.94 (0.7–1.25) | 0.67 |
| Bifurcation lesion | 1.18 (0.96–1.45) | 0.12 |
| DES | 1.18 (0.97–1.44) | 0.11 |
| BVS | 1.25 (0.56–2.8) | 0.58 |
| BMS | 0.73 (0.44–1.19) | 0.21 |
| Implanted stent (any) | 1.15 (0.92–1.42) | 0.22 |
| DEB | 0.43 (0.2–0.9) | 0.03 |
| TIMI 0-1 PRE | 0.93 (0.8–1.07) | 0.31 |
| TIMI 3 POST | 0.89 (0.68–1.16) | 0.38 |
| Contrast per 100 ml | 1.53 (1.46–1.6) | <0.001 |
| Radiation per 1000 mGy | 1.5 (1.46–1.55) | <0.001 |

Abbreviations: ACS, acute coronary syndrome; BMS, bare metal stent; BVS, bioresorbable vascular scaffold; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; CTO, chronic total occlusion; DEB, drug-eluting balloon; DES, drug-eluting stent; GPI IIb/IIIa, IIb/IIIa glycoprotein inhibitor; LMWH, low molecular weight heparin; PCI, percutaneous coronary intervention; UFH, unfractionated heparin; TIMI, thrombolysis in myocardial infarction

Dery et al. [24], in a study involving 1342 patients, showed that re-administration of abciximab was associated with a very low incidence of allergic reaction (5 patients) and did not require interruption of the drug infusion. In contrast, Masood et al. [23], in a study involving 37 patients receiving eptifibatid, reported allergic reactions in 3 patients (10.75%). These reactions can be characterized as anaphylaxis and require urgent interventions [26, 27]. The incidence of allergic reactions during the use of tirofiban is very rare, but anaphylactic reactions and rash can occur even during the first exposure (similar to apixaban) [28].

In our study, the strongest predictor of allergic reaction was the use of LMWH. In the available literature, cutaneous allergic reactions as adverse reactions to this group of drugs occur with a frequency of 7.5% to 39.5% [29–31].

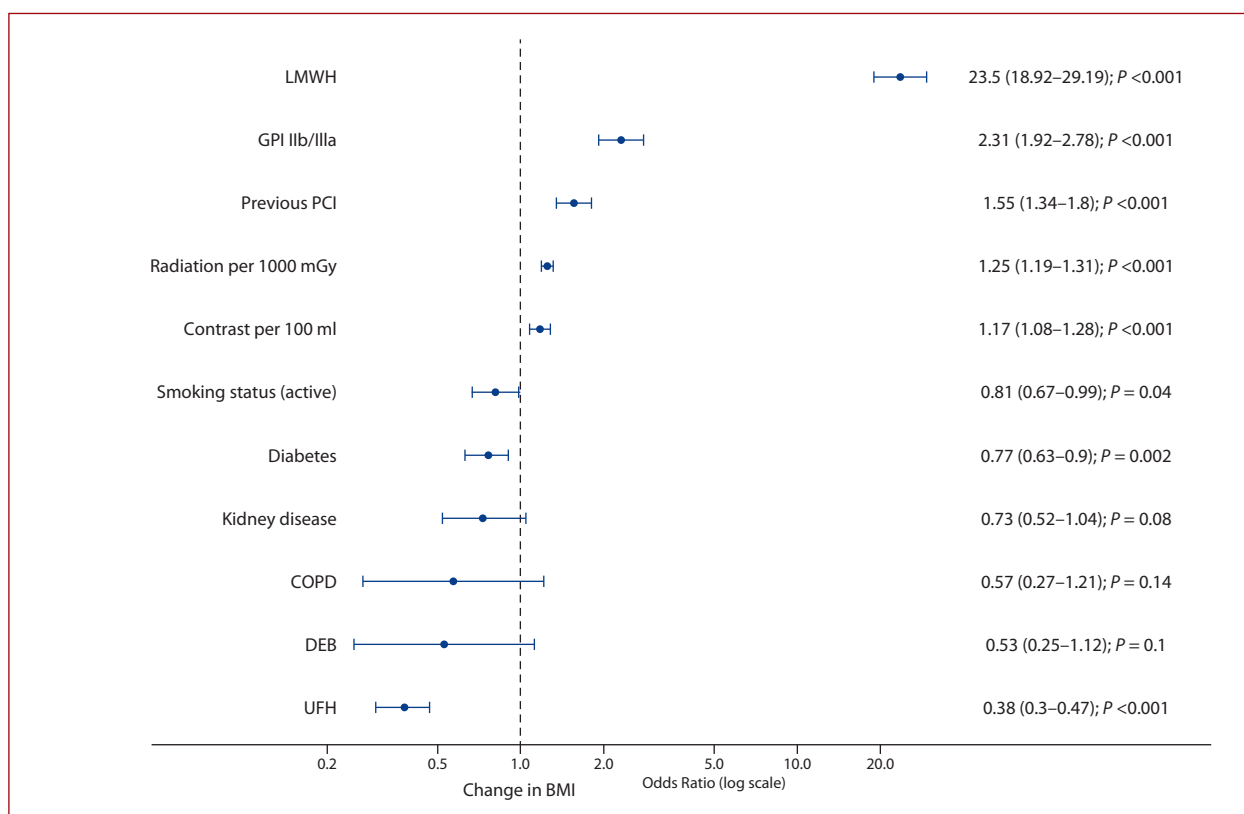


Figure 2. Independent predictors of allergic reactions during procedure adjusted to consecutive years

Abbreviations: COPD, chronic obstructive pulmonary disease; DEB, drug-eluting balloon; GPI IIb/IIIa, IIb/IIIa glycoprotein inhibitor; LMWH, low molecular weight heparin; UFH, unfractionated heparin

These reactions are most often delayed-type hypersensitivity reactions [30, 32] but can also appear immediately [33]. In addition, clinically, these reactions can manifest as pustulosis, urticaria, bullous eruptions, necrosis, and heparin-induced thrombocytopenia [34]. Of all LMWHs, nadroparin has the highest risk of late cutaneous reactions [35]. The association of the occurrence of allergic reaction with LMWH use may be due to the subcutaneous route of administration of the drug. So far, it has been established that the heparin molecule itself is not immunogenic, while it may be a hapten that gains immunogenicity when combined with previously unrecognized proteins after intradermal or subcutaneous administration [36].

Radiation does not cause allergic reactions but leads to direct damage to the skin [37]. Skin lesions can appear immediately after exposure and pathophysiologically are usually dermatitis with a rash or blistering eruptions [38]. An earlier study [9] and our results confirmed the effect of rentgen radiation on the occurrence of allergic reactions; however, the mechanism of this phenomenon has not been clarified. A possible reason is the dependence of the radiation dose on the duration of the procedure and, thus, the increased likelihood of revascularization with the drugs used during the procedure. Although Killip–Kimball class IV did not affect the onset of allergic reaction, it remains one of the strongest predictors of poor short- and long-term prognosis [39]. As Cazzola et

al. [40] pointed out, the presence of a history of bronchial asthma may affect cardiovascular mortality; however, the registry presented here does not provide information on the prevalence of this disease or other allergic diseases in those undergoing coronary angiography and PCI. Currently, patients undergoing interventional cardiology procedures with a history of allergic reactions receive prophylactic antihistamines and corticosteroids, which significantly reduce the risk of recurrence of such reactions [41]. The above procedure, as well as the widespread use of low osmolality contrast agents, has significantly reduced the incidence of allergic reactions during contrast procedures [42]. If, despite adequate prophylaxis, a severe anaphylactic allergic reaction leading to shock develops, it is advisable to administer epinephrine by the intramuscular or even intravenous route in patients with severe hypotension [43].

Each predictor directly or indirectly influences the occurrence of allergic reactions. The results of this study can be used in direct clinical practice when performing invasive cardiac procedures. However, the study has some limitations. This is a multi-center national registry. Observation for allergic reaction included the duration of the patient's stay in the hemodynamics laboratory. The registry does not provide accurate information on the symptoms of an allergic reaction, type of allergic reaction, severity of the course, number of deaths due to an allergic reaction

or treatment of allergic reactions, as well as the type of LMWH or GPIIb/IIIa that were used during the treatments.

CONCLUSIONS

The overall incidence of acute allergic reactions in the cath lab is low and decreased significantly between 2014 and 2022. The decrease in frequency did not depend on age or sex. Independent strong predictors of allergic reaction were the use of GPIIb/IIIa, LMWH, high dose of contrast agent, and radiation. To reduce the risk of allergic reaction, one should consider avoiding these treatments if possible and minimizing contrast and radiation doses.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/polish_heart_journal.

Article information

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