

# Patients' Claims Regarding Drug Allergies

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## SUMMARY

**Introduction:** According to the World Health Organization (WHO) definition, drug allergies are defined as harmful, unintended, and undesirable reactions that occur when administered at doses used to prevent, diagnose, and treat disease.

**Aim:** The aim of study was to determine the rate of patients' claims to be allergic to a drug.

**Material and Methods:** This non-commercial study is a retrospective analysis of the work of one physician at the City Institute for Emergency Medical Services Belgrade for a total of 10711 patients during the period from 2014 to 2019. Medication allergy claims are entered in the appropriate fields in the access program.

**Results:** Based on the study inclusion and exclusion criteria 1721 patients were eligible for analysis. 1106 patients were female and 615 were male. Most patients claimed to be allergic to penicillin preparations (56.13%), followed by trimethoprim + sulfomethoxazole 12.02%, followed by ibuprofen 3.95%. In addition to one-drug allergy claims, 338 (19.64%) patients reported allergy to two or more drugs: two drugs 64.80%, three drugs 22.20%, four and more drugs 6.5% each.

**Conclusions:** In our study, the majority of reported allergic reactions indicated penicillin preparations, then trimethoprim + sulfomethoxazole followed by ibuprofen.

**Keywords:** drug allergy, emergency health care, penicillin, ibuprofen, trimethoprim sulfomethoxazole

## INTRODUCTION

According to the World Health Organization, adverse drug reactions occur in 10% of the world population and in 20% of hospitalized patients. Worldwide, in 20% of cases, drugs could be the cause of death resulting from an anaphylactic reaction [1]. According to a study by Pirmohamed et al. from 2004, adverse drug reactions led to a 6% increase in morbidity, mortality, hospitalizations, 2% mortality and costing the National Health System £ 466m annually [2].

Drug allergies, as defined by the

World Health Organization (WHO), are defined as adverse, unintended and undesirable reactions to drugs that occur when administered at those doses that are used to prevent, diagnose or treat the disease [1]. According to the 2003 World Organization for Allergy (WAO) definition, allergic reactions are defined as immune-mediated hypersensitivity reactions. The mechanism of allergic reactions may be mediated by IgE or non-IgE reactions [3]. Originally, two types of adverse drug reactions were described: type A is predictable and

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dose-dependent. On the other hand, type B, which is unpredictable and dose-independent, affects a small population of people, with individual factors of the human body playing a large role in their emergence [4,5]. Also, type C (chronic reaction), type D (delayed), type E (end-of-treatment) and most recently, type F (Unexpected failure of therapy) have been described [5,6]. Multiple drug hypersensitivity (MDH) is a syndrome that develops as a consequence of massive T-cell stimulations and is characterized by long-lasting drug hypersensitivity reactions (DHR) to various drugs [7]. Adverse drug reactions are common in clinical practice, affecting from 15-25% of patients, serious adverse reactions occur in 7-13% of patients [8,9]. According to Warrington et al. the incidence of allergic reactions is the highest following the administration of penicillin, cephalosporin, sulfonamide, topical and general anesthetics, acetylsalicylic acid, non-steroidal anti-inflammatory rheumatics (NSAIDs), radioactive contrasts, and therapeutic monoclonal antibodies [10]. According to a study by Hemstreet et al. Penicillin allergy is a big risk factor for developing a sulfonamide allergy. According to their results, penicillin allergy is a predictor for the subsequent development of a sulfonamide allergy, with a large number of patients reporting an allergy to several drugs, including penicillin [11].

In the work of Kusic et al. adverse reactions to penicillin preparations were reported by 86.4% of those tested for drug allergies [12]. Senst et al. have shown that adverse reactions to antibiotics occur in more than 3% of patients in hospital settings [13], leading to complications during treatment in 10-20% of cases [14,15]. Some patients report allergic reactions to many medicines, making it difficult for the physician to choose which medications to prescribe [16]. Multiple drug intolerance (MDI) or Multiple drug allergy syndrome (MDAS) is defined as intolerance to two or more structural or pharmacologically unrelated drugs taken in three different circumstances [17].

According to the data of Khan et al. a combination of acetylsalicylic acid (ASA) and nonsteroidal anti-inflammatory drugs (NSAIDs) can cause allergic and pseudo-allergic reactions, including respiratory disease exacerbation, angioedema, urticaria, and anaphylactic reactions. "Within minutes of ingestion of therapeutic doses of ASA or NSAIDs,

patients with Aspirin-exacerbated respiratory disease (AERD) typically have both rhinoconjunctivitis and bronchospasm. The bronchospasm induced can be severe and result in respiratory failure with a need for intubation and mechanical ventilation "[18].

It is highly suspected that all side effects when using a drug are indeed allergic reactions. In a study by Natasa Kusic et al. it is said that out of the total number of patients who were clinically tested for a reported allergy to penicillin preparations in vitro, none had a positive result and only 2.5% of those tested positive in vivo [12]. The study by Vicentijevic states that in 23% of patients, allergies were further examined and confirmed by analysis [19]. Notwithstanding this suspicion, the patient's statement that they are allergic to a drug entails great caution when prescribing.

City Institute for Emergency Medical Services Belgrade (*Srb. Gradski zavod za hitnu medicinsku pomoć Beograd*) is a primary health care institution and has an outpatient clinic that operates 24/7 without interruption, in shifts of 12 hours each.

## AIM

The aim of our study was to establish incidence of patients' claims that they are allergic to some drug.

## MATERIAL AND METHODS

This is a non-commercial cross-sectional study, as a result of the work of a medical doctor from City Institute for Emergency Medical Services Belgrade, in the period of 5 years, starting from 16 April 2014 to 14 April 2019 on 10711 patients. Information regarding medication allergy is taken as part of the medical history when a patient arrives at the outpatient ambulance. The patient's allergy to a drug was confirmed by a doctor after an adverse event in the past, and the patient was informed that he was allergic to the drug and should no longer use it. Patient's answers are entered into the corresponding field in the access program. The data was exported to excel where the data was searched and sorted. The search identified patients who appeared two or more times. Their allegations of drug allergies were compared. The criteria for inclusion in the study were patients' claims that they should not take one or more drugs because of an allergic re-

action. Exclusion criteria: If a patient repeatedly reported allergies to the same medication during the visits, then one entry was left and the others were deleted. Also, if patients made different allegations of drug allergies at different visits, then all patient records were deleted. 1721 patients remained for analysis, accounting for 16.067% of the total number of patients examined. Patients claim to be allergic to bactrim, which is synonymous with all combina-

tions of sulfamethoxazole and trimethoprim, or ibuprofen preparations, or claim that they should not receive any of the penicillin preparations because their doctor explained it to them. Patients sometimes claim to be allergic to the acetylsalicylic acid preparations produced by only one manufacturer and may use parallels from other manufacturers. Descriptive statistics methods have been applied for the primary processing of statistical data, and

Drug	Number of subjects	%
Penicillin	966	56,13
Trimethoprim-sulfometoksazol (Bactrim® Galenika AD Beograd and other)	207	12,02
NSAID	151	8,82
<i>Ibuprofen (Brufer® Farmar A.V.E. Anthoussa Plant and other)</i>	68	4,00
<i>Diclofenac (Diklofen DUO® Galenika AD Beograd and other)</i>	67	3,90
<i>Nimulid/nimesulide (Nimulid® Panacea Biotec LTD)</i>	11	0,63
<i>Movalis/meloxicam (Movalis® Bioheringer Ingelheim Pharma GMBH &amp; CO.KG)</i>	5	0,29
Paracetamol + propifenazone + kofein (Caffetin sc® Alkaloid AD Skopje)	54	3,13
Cephalosporines	47	2,73
<i>Cephalexin (Palitrex® Galenika AD Beograd, Cefaleksin® Hemofarm)</i>	22	1,27
<i>Cefaclor (Alfacet® Galenika AD Beograd)</i>	12	0,70
<i>Others</i>	13	0,76
Acetylsalicylic acid	59	3,43
<i>Acetylsalicylic acid (Ando® Pliva Hrvatska)</i>	47	2,73
<i>Acetylsalicylic acid (Aspirin® Bayer Bitterfeld GMBH)</i>	12	0,70
Iodine/povidone (Visipaque® GE HEALTHCARE IRLEAND LIMITED)	39	2,26
Metamizole	43	2,5
<i>Metamizole-Na (Novalgetol® Galenika AD Beograd, Baralgin M® Jugoremedija)</i>	26	1,51
<i>Metamizole-Na, pitophenone, fempiverinium bromide (Baralgetas® Union-medica D.O.O. Novi Sad)</i>	17	0,99
Dovicin/doxycycline (Dovicin® Galenika AD Beograd)	27	1,57
Erythromycin (Eritromicin HF®, Hemofarm AD Vršac)	24	1,40
Sulfonamides	22	1,28
Gentamicin (Gentamicin® Galenika AD Beograd et others)	14	0,81
Ciprocin/ciprofloxacin (Ciprocin® Zdravlje AD Leskovac)	11	0,63
Nifelat/nifedipine (Nifelat® Zdravlje AD Leskovac)	8	0,46
Paracetamol/paracetamol (Paracetamol® Galenika AD Beograd)	8	0,46
Klometol/metoclopramide (Klometol® Galenika AD Beograd)	8	0,46
Buscopan/hyoscine butylbromide (Buscopan® Bioheringer Ingelheim Espana S.A.)	8	0,46
Dexason/dexamethasone (Dexason® Galenika AD Beograd)	5	0,29
Orvagil/metronidazole (Orvagil® Galenika AD Beograd)	4	0,23
Palin/pipemidine acid (Palin® Lek farmacevtska družba d.d.)	4	0,23
Klacid/clarithromycin (Klacid® ABBVIE S.R.L.)	3	0,17
Other	9	0,52
Total	1721	100,00

**Table 1.** Medicines claimed by patients to have caused adverse effects and therefore they should not use them

Comparing the first seven drugs by frequency Chi square = 3346.43992  $p < 0.01$ , we found a statistical significance between the frequency of allergic reactions to different drugs, i.e. penicillin is significantly the most commonly reported drug.

the statistical significance test applied is the Chi-square test.

## RESULTS

The study included 1721 subjects, 1106 (64.27%) female and 615 (35.73%) male, Chi-square = 160.4556331  $p < 0.01$ .

At the time of data collection, the average age of our subjects was  $50 \pm 16.5$  years, range from 17 - 95. Most respondents claimed to be allergic to penicillin (all penicillin preparations) (56.13%), trimethoprim + sulfamethoxazole (Baktrim®, Galenika and other generics) was second (12.02%), followed by ibuprofen (Brufen® Farmar A.V.E. Anthoussa Plant and other generics) in the third place (3.95%) (Table 1). In addition to allegations of allergy to one drug, 338 (19.64%) respondents claimed to be allergic to two drugs (64.80%), three drugs (22.20%), four drugs (6.50%) and more than four drugs (6.50%). Penicillin was reported in more than 65% of allegations of allergic reactions to multiple drugs (combination with two, three, four or more than four drugs). The most common combinations of medicines that patients claimed to be allergic to were: penicillin + other antibiotics (125, 7.26% of patients, most in combination with trimethoprim-sulfamethoxazole 49 i.e. 2.85% of patients, followed by cephalosporins 31 patients or 1.80%, and 45 patients (2.61%) reported allergy claims to other, various antibiotics, followed by a combination of penicillin and analgesics (92 patients), with penicillin and NSAIDs being the most prevalent (56 patients), penicillin + salicylates (19 patients) and penicillin + pyrazolones (17 patients). Allergy claims to analgesics from various

pharmacological groups were reported in 19 patients, 16 patients claimed to be allergic to combinations of analgesics and antibiotics, 7 patients claimed to be allergic to the combination of penicillin and iodine as a contrast agent for diagnostics. Seven patients claimed allergies to combinations of antibiotics from different pharmacological groups (Table 2).

## DISCUSSION

Out of the total number of patients, 16.6%, mostly female, claimed to be allergic to some drug and should not use it. Most often, patients have been reported to be allergic to penicillin preparations, followed by trimethoprim-sulfamethoxazole preparations, then to ibuprofen and diclofenac and caffetin. Of the total number of patients who claimed to be allergic to a drug, one fifth claimed to be allergic to more than one drug. The allegation of allergy to two drugs was given by 64.8%, three medicines 22.2%, to four and more medicines in 13%. The most common are combinations of penicillin with other antibiotics: trimethoprim + sulfamethoxazole and cephalosporins.

The average age of our subjects at the time of taking medical history was  $50 \pm 16.5$  years, which is less than in the Velickovic et al [12] study and Hemstreet BA [11], or more than in the Gambo study [20]. The study by Velickovic et al. in 2015 reported that gender representation in allergic drug reactions is approximately similar to our data [21]. Zhou et al. in their study [22] found a higher representation of female gender, slightly lower than in our study. Mertes et al also showed that allergic reactions to drugs are more common in female subjects [23].

**Table 2.** Common combinations of drugs claimed by patients to cause adverse allergic reactions

The most frequent combinations of drugs	Total number of subjects	%
Penicillin+NSAID	56	3,26
Penicillin+ trimethoprim and sulfometoksazol	49	2,85
Penicillin+ some other antibiotic	45	2,61
Penicillin+ cephalosporins	31	1,8
Penicillin+ salicylates	19	1,1
Analgesic+analgesic	19	1,1
Penicillin+ pyrazolones	17	0,99
Analgesic+antibiotic	16	0,93
Penicillin+iodine as a contrast agent	7	0,41
Antibiotic+antibiotic	7	0,41
Other	72	4,18
Total	338	19,64

Drug allergy reports vary across studies. In the research Vicentijevic-Radosavljevic S. 17.3%, patients claimed to be allergic to some drug, most commonly to penicillin, cephalosporins, and NSAIDs [19]. The study by Velickovic et al. record claims of surgical patients that they are drug-allergic in 38.5% of cases, mostly antibiotics most commonly penicillin, NSAIDs and iodine preparations [21]. According to a Zhou study published in 2016, 35.5% of patients report drug allergies. The most common adverse reactions were reported after administration of penicillin, sulfonamide antibiotics, opioids as the most common codeine, followed by NSAIDs, including ibuprofen 0.7% and macrolides [22]. Hemstreet B et al. reported that almost half of the patients reported an allergic reaction to trimethoprim-sulfamethoxazole [11]. Vicentijevic-Radosavljevic S reported that 23% of drug allergy claims were confirmed by testing [19].

Multiple drug allergies reported by patients are relatively common. In a study by Blumenthal KG et al. multiple drug intolerance (MDI) occurs in 6.4% of patients, and the incidence and prevalence of drugs varies from study to study. Multiple Drug Intolerance Syndrome (MDIS) in 1.2% of patients. "MDIS patients have intolerance or side effect reactions to three or more drug classes; Multiple Drug Allergic Syndrome (MDAS) patients had reactions to two or more drug classes with a possible immunologic mechanism". Most common multiple drug intolerance are those to penicillin, opioids, sulfonamides, NSAIDs, and macrolides, sulfonamide, cephalosporins, opioids, and NSAIDs [24]. In the study by Macy YE published in 2012, multiple drug intolerance syndrome was reported in 2.1% of penicillins, sulfonamides, and macrolides, with NSAID in 12<sup>th</sup> place [17]. Omer et al. stated that 4.9% of patients had allergic reactions to three or more drugs, and that the incidence of MDIS is similar in patients with and without penicillin intolerance. There is a wide range of medicines that contain antibiotics, including cephalosporin glycopeptides, macrolides penicillin, etc. and nonantibiotics, were paracetamol, lipid regulators, ace inhibitors, antihistamines and NSAIDs, aspirin, etc [25]. Sullivan et al study, 13% of patients who were allergic to penicillin developed allergic reactions to other "non-penicillin" antibiotics, such as sulfonamides (to which trimethoprim-

sulfamethoxazole belongs), tetracyclines, erythromycin, vancomycin, and aminoglycosides [26], slightly less than our data show. According to ALIMIS, there is no cross-reaction between penicillin and salicylate, that is, between penicillin and pyrazolone (Novalgetol®), whereas in the study by Pinho et al one patient developed drug reaction with eosinophilia and systemic symptoms (DRESS) while administering metamizole and amoxicillin as evidenced by a positive patch test, which is similar to our study [27]. Zhou et al in their study also proved that there is a cause-and-effect relationship between developing allergic drug reactions. According to the Campagna MD et al study, a cross-allergic reaction between penicillin and first-generation cephalosporins is 1%, while the use of third- and fourth-generation cephalosporins carries a negligible risk of cross-allergic reaction with penicillin [18]. According to the study by Hemstreet et al penicillin intolerance is a significant risk factor for developing a sulfonamide intolerance. According to their results, penicillin allergy is a predictor for the subsequent development of sulfonamide allergy, with a large number of patients reporting an allergy to several drugs, including penicillin [11]. Some of our patients claimed that they are allergic to penicillin and a contrast agent, although according to The Agency for Medicines and Medical Devices of Serbia (ALIMIS) there were no reports that a contrast agent containing iodine (eg Optiray®) interacted with penicillin and caused adverse allergic reactions. The study by Velickovic et al record claims by surgical patients that they are drug-allergic, most notably antibiotics, most commonly penicillin, NSAIDs and iodine preparations [21]. Although a study by N. Kusic et al stated that none of the patients who were clinically tested for a reported allergy to penicillin preparations were positive in vitro, and only 2.5% of those tested were positive in vivo [12], Vicentijevic Radosavljevic S found that 23% of reported allergic reactions were confirmed by testing [19].

A limitation of our study is that no allergy was tested during the study, neither in vitro nor in skin tests to prove that the allergies did exist.

## CONCLUSION

Out of the total, 10711 patients examined, 1721 (16.067%) claimed to be allergic to one



or more drugs. The most reported allergic reactions were to penicillin and to a combination of penicillin and trimethoprim-sulfamethoxazole followed by ibuprofen.

## CONFLICT OF INTEREST

All authors declare no conflict of interest.

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## Tvrđnje pacijenata o alergijama na lekove

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### KRATAK SADRŽAJ

**Uvod:** Prema definiciji Svetske zdravstvene organizacije (WHO) alergije na lekove se definišu kao štetne, nenamerne, i neželjene reakcije koje se dešavaju prilikom primene lekova u dozama koje služe za prevenciju, dijagnozu i lečenje bolesti.

**Cilj:** Cilj našeg istraživanja bio je utvrđivanje učestalosti tvrdnji pacijenatama da su alergični na neki lek.

**Materijal i metode:** Studija je nekomercijalna, retrospektivna analiza rada jednog lekara u Gradskom zavodu za hitnu medicinsku pomoć (GZZHMP) ukupno na 10711 pacijenata tokom perioda od 2014. do 2019. godine. Tvrđnje o alergijama na lekove su upisivani u odgovarajuća polja u program access.

**Rezultati:** Na osnovu kriterijuma za uključivanje i isključivanje iz studije, za analizu je preostalo 1721 pacijent. 1106 pacijenata su osobe ženskog, a 615 osoba su muškog pola. Najviše pacijenata je tvrdilo da je alergično na penicilinske preparate (56,13%), zatim trimetoprim + sulfametoksazol (Bactrim®) 12,02%, a na trećem mestu je Brufen® (ibuprofen) 3,95%. Pored tvrdnji o alergiji na jedan lek, 338 (19,64%) pacijenata je prijavilo alergiju na dva i više lekova, na dva leka 64,80%, na tri leka 22,20%, na četiri leka i na više od četiri leka po 6,5%.

**Zaključak:** U našem istraživanju najviše je prijavljenih alergijskih reakcija na penicilinske preparate i trimetoprim + sulfametoksazol, potom na ibuprofen.

**Ključne reči:** alergija na lekove, hitna medicinska pomoć, penicilin, ibuprofen, sulfametoksazol trimetoprim

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