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ORIGINAL ARTICLES

Drug allergies interpretation based on patient's history alone may have therapeutic consequences in hospital setting

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Abstract: Background and aim. Adverse drug reactions (ADRs) are common events in medical practice, representing a matter of concern for both outpatient and in hospital care. Understanding and management of ADRs depend on their mechanism and clinical picture, which are complex and highly heterogeneous. Drug hypersensitivity reactions (DHRs) are immunologically-mediated ADRs, which are considered allergies after demonstrating evidence of either drug-specific antibodies or T-cells. The correct diagnosis of a drug allergy in hospital setting is essential for the outcome of treated disease and for the patient future in terms of therapeutic needs. Patients may be labeled as being drug allergic, based on their history and vague symptoms that do not correspond to a true allergic reaction. The aim of our study was to evaluate consequences of drug allergy labelling of female patients hospitalized in the department of obstetrics and gynecology from a university hospital during one year, in terms of medical attitude and therapeutic approach.

Method and Results. We found that 159 out of 2395 patients hospitalized in the obstetrics-gynecology department declared a history of drug allergy on admission, but only 3 patients had medical documents and adequate recommendations from the allergist. Hospital medical attitude was significantly influenced in all declared allergic patients, mainly in terms of antimicrobial and anti-inflammatory therapy.

Conclusion. We concluded that overestimation of drug allergies in hospital care has important consequences in terms of current and future recommended therapy that should be based on standardized allergist evaluation.

Keywords: drug allergies, hospital setting, patient's history, therapeutic errors

INTRODUCTION

Adverse drug reactions (ADRs) are common events in medical practice, representing a matter of concern for both outpatient and in hospital care. The ADRs definition accepted by the World Health Organization is any noxious and unintended response to a medication that occurs at normal doses used for prophylaxis, diagnosis and/or treatment [1]. ADRs severity range from minor common side effects to potentially life-threatening medical conditions. The reported incidence of ADRs in general population varies between countries and may account for 2-3 % of all hospital admissions in some regions, as reported from Australia [2].

No reliable data about incidence of ADRs in Romania could be found. Understanding and management of ADRs depend on their mechanism and clinical picture, which are complex and highly heterogeneous [3].

The pharmacological classification of ADRs includes two major subtypes: type A which are dose-dependent and predictable reactions, with non-immunological mechanism,

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commonly termed intolerance and type B, which are unpredictable, not dose-dependent and have immunologic mechanism [4]. Drug hypersensitivity reactions (DHRs) are immunologically-mediated ADRs, considered allergies after demonstrating evidence of either drug-specific antibodies or T-cells [5]. Therefore it is recommended to use the term allergy only to describe reactions for which an immunological mechanism has been demonstrated. The majority of ADRs (>85%) are type A, while drug allergies comprise up to 15 % of ADRs [4]. It is considered that drug allergies affect more than 7 % of the general population [6]. The correct classification of an adverse drug reaction, by medical professionals, as allergy (due to immunological mechanism) or intolerance (non-immunological mechanism) has important medical implications [3]. Both underdiagnosis, due to underreporting and overdiagnosis, due to an overuse of the term „allergy“ are common. There are still many controversies in drug allergy and recognized need for standardized and improved approaches of patients who report prior drug allergy [7]. Mislabeling of a drug allergy in patients records may result in unnecessary avoidance of an effective drug and medical recommendation of a second-line therapy, possibly less effective or more expensive. This situation is more frequent in case of antimicrobial drugs and may be also responsible for increased bacterial resistance to frequently used antimicrobials. Despite lack of reliable evidence, if an allergy label is noted into a patient medical record, it will remain for the rest of his life in most of the cases [8]. Maintaining the diagnosis of a drug allergy in hospital setting is essential for the outcome of treated disease and for the patient future in terms of therapeutic needs.

The aim of our study was to evaluate medical recording and consequences of drug allergy labeling of female patients hospitalized in the department of Obstetrics and Gynecology from a university hospital during one year, mainly in terms of current medical attitude, clinical outcome and therapeutic approach.

MATERIAL AND METHOD

We performed a retrospective analysis of hospital data over

one-year period and we recorded diagnosis of drug allergies based on patient's history, as well as medical events considered as drug allergy and medical therapeutic attitude during hospitalization.

A total number of 2,395 female patients have been hospitalized during twelve months between January-December 2016 in the Obstetrics-Gynecology department of Nicolae Malaxa Clinical Hospital from Bucharest, with 1,817 patients hospitalized for childbirth and 578 patients hospitalized for gynecological diseases.

Patients were aged between 18-67 years, with a mean age of 33 years and about 80% lived in urban area. We recorded medical history documented in the patient file, including any type of reported drug allergies, written information regarding diagnosis confirmation and tolerated medication, concomitant diseases, other personal or familial allergies, current illness and medication, outcome and status at hospital discharge, particular recommendations regarding drug allergies. In cases who had medical events considered drug allergies during hospitalization, we noted type of reaction, severity, the possible culprit drug, relevant laboratory tests, therapeutic attitude and outcome.

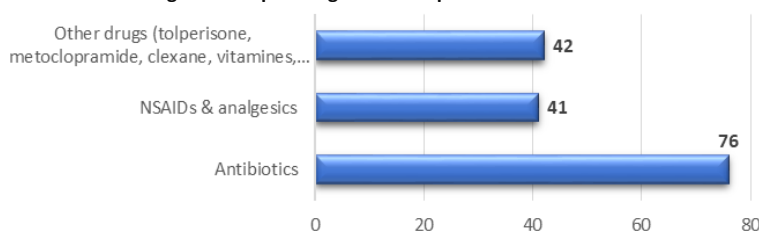
RESULTS

We found that 159 out of 2395 patients, meaning 6.63% of female patients hospitalized in the Obstetrics-Gynecology department declared a history of drug allergy on admission. From this group, 116 were pregnant patients hospitalized for childbirth and 43 patients were hospitalized for gynecologic diseases.

We noticed that 26 patients out of 159 (16.35%) were current smokers. The possible culprit drugs based on patient's declaration were: antibiotics in 76 patients (47.79%), non-steroidal anti-inflammatory drugs (NSAIDs) and analgesics in 41 patients (25.78%) and other drug allergies in 42 patients (26.41%) (Figure 1).

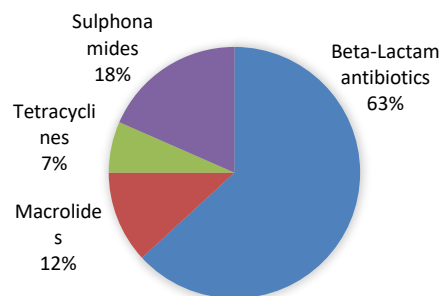
Only three patients out of 159 (1.88%) could show medical documents with diagnosis confirmation of drug allergy and clear recommendations to follow in case of future events.

Figure 1. Culprit drugs based on patient's declaration



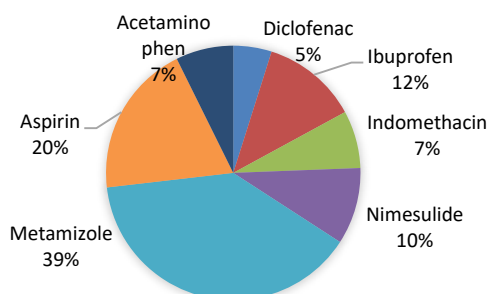
Clinical episodes considered drug allergies were recorded during hospitalization in another 9 patients from the total 2395 hospitalized group (0.37%), who have not declare any drug allergy on hospital admission. Eight patients had acute urticaria and one patient had respiratory symptoms. All these events have been successfully treated with antihistamines and systemic corticosteroids, based on allergist recommendation and resolved within short time. In all cases who declared history of drug allergy, the possible culprit drug was not administered and medication from another pharmacological class was considered. No allergological work-up could be performed during hospitalization, but this was recommended after hospital discharge. From the 76 cases who declared allergies to antibiotics, the incriminated classes were: beta-lactam antibiotics in 48 cases, macrolides in 9 cases, tetracyclines in 5, sulphonamides in 14 cases (Figure 2). The recommended antimicrobial therapy during hospitalization was quinolone in all cases (ciprofloxacin and levofloxacin).

Figure 2. Antimicrobials reported as culprit drugs



From the 41 cases who reported allergies to non-steroidal anti-inflammatory drugs (NSAIDs) and analgesics, the incriminated substances were: metamizole in 16 cases, aspirin in 8, acetaminophen in 3, diclofenac in 2, ibuprofen in 5, indomethacin in 3, nimesulide in 4 cases. (Figure 3)

Figure 3. NSAIDs and analgesics reported as culprit drugs



Other possible culprit drugs reported by patients who considered themselves to have drug allergies were: tolperisone, metoclopramide, clexane, vitamins,

ergometrine, drotaverine.

The possible offending drug was avoided in all cases who reported drug allergies. No medical events attributable to anesthetics have been recorded.

In case of patients who declared allergy to NSAIDs, no drug from this class was administered, but also analgesics and antipyretics were avoided. No data referring to influence of drug allergy on duration of hospital stay could be found.

DISCUSSION

Our study showed that drug allergy is overestimated in hospital setting, based on patient's history alone and most of the patients have no evaluation or diagnosis confirmation from allergist. Hospital data referring to possible allergy were limited and some laboratory tests that might support atopy or certain symptoms of allergy, such as total serum IgE and blood eosinophilia were missing [9]. The main consequence for hospitalized patients who declare having drug allergy is change of the antimicrobial medication with a different class and refrain from any anti-inflammatory and painkiller medication. The situation might be more complicated and has to be more seriously considered for patients who declare multiple drug allergies to various and unrelated molecules.

The term „allergy” is frequently used and one study showed that more than 50% of reported allergies to antimicrobials have no immunologic pattern [10]. Generally, patients tend to overestimate adverse drug reactions and to interpret erroneously new symptoms or signs that occur during treating their disease.

Data from the literature showed that up to 25% of patient's self-report having drug allergies, most commonly induced by antimicrobials, mainly penicillins, followed by sulfonamides, macrolides and cephalosporines [11]. Beta-lactam allergy, recorded in up to 15 % hospitalized population and leading to increased use of broad-spectrum antibiotic use, is confirmed in only 5 % of patients [12].

Having a label of drug allergy or intolerance in the medical record may lead to withholding of first line therapy or even avoidance. It was proved that about 30% of patients having the label of drug allergy to at least one antimicrobial drug received another drug that did not reflect the standard of care [13]. Alternative antibiotic therapy may be less effective or may have less favorable safety profile, leading to treatment failure and increased risk of antibiotic resistance. Trends in antibiotic prescription rates show an increase use of broad-spectrum antibiotics, such as azithromycin and quinolones [14]. It was also proved that total hospital costs

with medication were increased for patients carrying the label of a drug allergy, with 63% higher antibiotic costs for patients with beta-lactam allergy [15]. Despite the potential deleterious consequences of selecting an alternate medication and the lack of validity of most allergy labels, many clinicians do not take time to complete a comprehensive drug allergy history before prescribing an antimicrobial. It was found that only 4% of patients who declared being allergic to antimicrobial medication on hospital admission had documentation detailing the specific reaction [16]. This finding may be due to the erroneous perception that therapeutic decisions based on an allergy label will not influence the patients' clinical outcome. The ability of health professionals to discriminate between allergy and intolerance, to evaluate the severity of an ADR and the degree of contraindication depends on their level of knowledge in the field of allergic diseases and was evaluated in recent studies and publications [17]. A published survey of physicians practice and knowledge in the field of drug allergies at a university medical center showed that those with any internal medicine training performed significantly better [18].

A recent study evaluating drug allergies in primary care practice in Romania concluded that the medical attitude and competence of family doctors in the field of drug allergies, as well as their collaboration with allergists are not standardized and updated according to guidelines and experts' recommendations [19]. Since primary care physicians play a key role in evaluating patients with possible drug allergies, there is a clear need for pre-and postgraduate allergy educational programs and training [20].

LIMITATIONS OF THE STUDY

Despite being the only study on drug allergy labeling

performed in Romania, our study has some limitations. The main limitation is the retrospective analysis of medical records, with relative few and variable information about drug allergies, depending on the level of knowledge of doctors in training, students or nurses who filled in the patient's files. We had no way to verify the proportion of patients from our study with true versus false drug allergy label, based on standardized diagnosis criteria. No follow-up of the patients who experienced allergic reactions during hospitalization was performed.

CONCLUSIONS

We concluded that the impact of drug allergy label is underestimated in hospitalized patients and diagnosis is generally based on patient's history.

The allergy label is overused, most of the patients who self-report drug allergies have no confirmation from specialist and no medical documentation. The main consequences are switch of antimicrobial medication to another class, generally quinolones and avoidance of anti-inflammatory or analgesic medication.

We consider that information referring to drug allergy should be taken by medical staff with minimal training in this field and recorded more detailed in patient's files on hospital admission. Improved collaboration between specialists, including allergists and primary care physicians is needed.

Conflict of interest

The authors declare no conflict of interest in relation with this study and manuscript.

Disclosure statement

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