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ORIGINAL ARTICLE

Analysis of profitability in the diagnosis of allergy to beta-lactam antibiotics

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Abstract Drug allergy is the third most common reason for allergy consultations. There is a tendency to call any adverse drug reaction (ADR) allergic, even without confirmatory allergy study.

Objectives: (1) Evaluate time of resolution allergy to beta-lactam's study in a sample of 100 patients. (2) Analyse cost-effectiveness of current diagnostic study (skin tests, specific IgE and drug provocation test (DPT)). (3) Describe type and frequency of ADRs in adult/paediatric patients. (4) Compare cost of complete study with DPT. (5) Assess the need to restructure current study methodology according to results obtained.

The study is part of a strategic plan of the allergy department (2005–2010). Patients with suspected allergy to beta-lactams were included. Procedures performed: medical history, specific IgE, skin tests and DPT. Cost/patient analysis. Cost of protocol analysis for current diagnostic/direct DPT.

Results: 100 patients were studied, 52 females/48 males; 43 children/57 adults. Symptoms: 89 cutaneous, 4 anaphylaxis, 3 vasovagal reactions, 6 non-specific symptoms and 4 not recalled. Allergy was confirmed in six patients (only one child). Complete-study cost: 149.3 Euros/patient. DPT-study cost: 97.19 Euros/patient (34.9% less). Resolution time 9–13 months, absenteeism 28.04%.

Conclusions: In the series studied, diagnosis of allergy to beta-lactams was confirmed in 6% of patients (2.3% of paediatric patients). After analysing results and cost of the study we believe that we should propose a specific diagnostic algorithm in those paediatric patients without suspected IgE-mediated ADR, and for those patients direct DPT should be conducted. This will reduce cost/patient (−34.9%), time of resolution and absenteeism.

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Introduction

Suspected drug allergy is the third most common reason for first visits to allergy specialists. According to data from the Spanish ''Alergológica-2005'' observational epidemiological study (study on epidemiological, clinical and socioeconomic aspects of allergic diseases in Spain), drug allergy is the third leading reason for consultation after rhinoconjunctivitis and bronchial asthma.[1] Thus, in 2005, of all patients seen in allergy clinics in Spain, 14.7% were referred for study of drug allergy (the percentage was lower, 9.8%, in the case of paediatric patients).

In general terms, most adverse drug reactions are attributed to allergy (especially when skin symptoms predominate) with between 5 and 10% of cases confirmed as such.

The group of drugs known as beta-lactams consists of natural and semi-synthetic antibiotics, which inhibit the synthesis of bacterial cell wall. They act as haptens and their attachment to a carrier allows them to be recognised by the body's immune system, enabling the triggering of hypersensitivity reactions.

Beta-lactam antibiotics are classified according to their chemical structure: penicillins, cephalosporins, monobactam, carbapenems, oxacephems and clavams. They are formed by a common ring (beta-lactam ring) which identifies them as a group and, among the subgroups, there are other chemical structures (thiazolidine rings, side chains) that allow differentiation and are responsible for the presence or absence of cross-reactivity between antibiotics of the same group.

An adverse drug reaction (ADR) is defined as that noxious and unintended response that occurs upon administration of a suitable drug dose in order to obtain a therapeutic, prophylactic or diagnostic benefit.[2] ADRs are classified into predictable and unpredictable. Predictable reactions are the most common (over 80%), are dose-dependent and are explained by the pharmacological action itself. The unpredictable are unexpected, independent of the dose and do not form part of the pharmacological actions (hypersensitivity reactions included).

Type I hypersensitivity reactions manifest as urticaria, angio-oedema and/or anaphylaxis. The current beta-lactam allergy study protocol is based on clinical history, specific IgE measurement, immediate-reading and delayed-reading skin tests and challenge test. This protocol is valid for the study of reactions mediated by IgE antibodies and is not useful in diagnosing other delayed type reactions.[3]

Objective

The study of drug allergy involves a long and complex diagnosis (patient risk, economic cost) a fact that highlights the need for a specific cost/benefit analysis.

The objectives of this work are:

1. To assess the time of resolution for the study of allergy to beta-lactam type drugs (penicillin group).
2. To analyse the cost-effectiveness of diagnostic tests for allergy to penicillin (study results, economic cost) according to the current study algorithm.
3. To describe types and frequency of ADRs in patients according to age (younger and older than 14 years).
4. To compare the cost of the current complete study with conducting direct DPT (gold standard).
5. To assess the need to restructure the study methodology according to the results obtained.

Materials and methods

The study is part of the strategic plan of the allergy department of the Althaia Foundation in the period 2005–2010.[4]

This is a retrospective descriptive analysis of patients referred to the allergy department suspected of allergy to beta-lactam drugs, from January 2009 to May 2010.

Data on health care activity during the study were obtained from the centre's Management Control Service and the allergy department itself. The Department of Biological Diagnosis provided data on specific IgE measurements.

The economic study was based on data provided by the Management Control Service. Calculating the cost of the study took into account costs including health intervention and resources consumed by the patient (staff time spent and cost of diagnostic extracts used). This study does not include analysis of indirect costs, due to a lack of sufficient data because it is a retrospective study.

The patients studied were divided according to age (younger or older than 14 years) and type of reaction presented (immediate or delayed).

The methodology of the study was as follows:

1. Detailed clinical allergy study
   a. drug(s) involved
   b. dosage and means of administration
   c. reason for prescription
   d. symptoms, and time between drug intake and onset of symptoms (immediate/delayed reactions)
   e. prior drug tolerance
   f. subsequently tolerated drugs
   g. time interval between allergic reaction and allergy study
2. Inclusion/exclusion criteria (see Table 1).

Table 1 Inclusion and exclusion criteria for the study of allergic ADR.

Inclusion criteria	Exclusion criteria
Suspected allergy to beta-lactams. Informed consent signed (if under 16 it is signed by parents or legal guardians).	No clinical history suggestive of allergic ADR Concomitant treatment with antihistamines or immunosuppressive agents Treatment with beta-blockers Uncontrolled asthma Pathologies that contraindicate the use of epinephrine Informed consent not signed