

THE USE OF PHARMACEUTICALS FOR DIALYSIS PATIENTS. HOW WELL DO WE KNOW OUR PATIENTS' ALLERGIES?

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Bhandari S., Armitage J., Chintu M., Chinnappa S., Kendrew P. (2008). The use of pharmaceuticals for dialysis patients. How well do we know our patients' allergies? *Journal of Renal Care* 34(4), 213-217.

SUMMARY

Medication allergies are potentially important but usually poorly documented in patient medical records. Allergy awareness by clinical staff may be low in the haemodialysis population despite their regular attendance for treatment sessions. A cross-sectional study of 25 patients in a satellite unit was performed. All known allergies were not documented in 36% of patients despite the patients being known to the renal service for more than five years. 81% of allergies were medication allergies. The rest were due to topical agents. 57% (affecting 8 patients) of the medication allergies related to antibiotics (especially penicillin). Four patients had multiple antibiotic allergies. The nature and severity of these allergies was not well documented. This study demonstrates that despite being under long-term care there remains incomplete information, which is vital for optimal safe practice. Without such information, the potential for adverse events and anaphylaxis is significant in a population that is exposed to numerous pharmaceutical agents and are frequently prescribed antibiotics. Medication histories should be comprehensively re-evaluated regularly and prescribing should not occur unless the allergy box is completed.

KEY WORDS Allergies • Dialysis • Documentation • Medication

INTRODUCTION

A recent study of hospital admissions in the United Kingdom found that 7% of people admitted to hospital had experienced

at least one adverse drug reaction (Lazarou 1998). Prescription errors are common in hospital in a wide variety of clinical settings (Raju *et al.* 1989; Mandal & Fraser 2005). Patients on renal replacement therapy (RRT) in the form of haemodialysis have to attend a dialysis facility regularly for outpatient dialysis treatment. However, effective documentation regarding allergies in this potentially captive population is unknown, at least in this institution. A search of the literature reveals few articles in relation to this topic of interest. One paper suggests that in medical admissions to the hospital acute medical admission unit up to 13% of patients did not have their allergies documented and 0.5% of cases had an incorrect history of allergy reported (Gray *et al.* 2007). Therefore a study was designed to evaluate how thorough the documents held in the renal unit were regarding potential drug allergies. The hypothesis was that RRT patients who attended regularly would be likely to have a comprehensive documentation of potential allergies. The definition of 'comprehensive' is taken in this study as a complete written record of all known allergies of each patient (medication or other not including food allergy).

METHOD

A cross-sectional study in a single satellite dialysis unit attached to Hull and East Yorkshire Hospitals NHS Trust was conducted. The Trust currently has three satellite units of various sizes.

BIODATA

Sunil Bhandari is a Consultant in Nephrology/Honorary Clinical Reader HYMS, Director of Clinical Studies for HYMS (Hull York Medical School).

Current research interests funded by the British Heart Foundation, Department of Health and HYMS consist of examining the energetics, mechanisms and signalling pathways and gene expression of insulin resistance in uraemic heart failure and the effects of exogenous erythropoietin. We are also investigating the expression and distribution of somatostatin and its receptors in human kidney and disease.



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All dialysis patients in the chosen unit ($n = 25$) were comprehensively evaluated. A questionnaire was used to record what allergies the patients considered they had; these were entered on a specific form, which had been designed for this study. These new records were then compared with:

1. The existing documentation in the dedicated allergy column in hospital case records (specific alert area on the front of the patient case records file)
2. All the documented case histories (medical clerking by junior medical staff of each previous admission to hospital for various complaints)
3. All the drug medications cards used during admission to hospital (each admission requires a new medication card for inpatient prescribing of regular and new medications (both continuous and intermittent) and has a specific allergies box which is completed).

Discrepancies between these data sets were noted and a final combined data set consisting of all the collected information was created to produce a comprehensive data set of all the possible allergies for each patient. The data were collected by two doctors and compared to assess the scale of any potential omissions. One doctor retrieved the information from the patient as given in the interviews while the other doctor scanned the documents as detailed above, to produce a list for each patient for comparison with his colleague's list at the end of the whole process. The completeness of the record of allergies was presumed to consist of those known allergies verbally volunteered by the patient collected during the interviews in conjunction with those documented in the each patient's hospital case medical records.

RESULTS

A total of 25 dialysis patients (16 male and 9 female) completed the study (response rate 100%). The mean age of the patients was 70.6 ± 2.1 years (median 74 years, range 47–89 years). These patients were on dialysis for 2.91 ± 0.36 years (median 2.5 years, range 5–80 months) and known to the renal services for 6.19 ± 0.98 years (median 5.4 years, range 2–16 years). Of the 25 patients, 11 had allergies to various medications and nonmedications. The study showed that 36% of the patients (nine patients) did not have all of their allergies documented in their hospital medical case notes or current drug cards (dialysis medication charts) despite the patients being well known to the

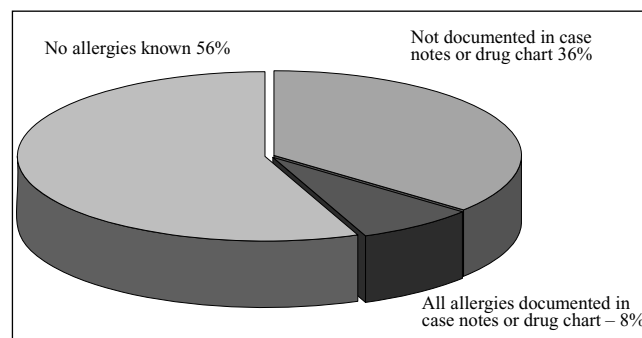


Figure 1: Percentage of patients whose allergy status was documented correctly. Twenty-five patients of which 11 had allergies (44%) and 9 (36% of whole group) did not have these documented.

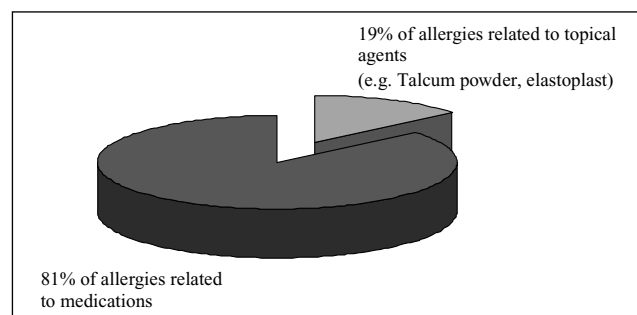


Figure 2: Details of type of allergy known: Percentage of allergies due to medication and nonmedication products.

renal service for more than five years (Figure 1). Only 2 of the 11 patients had all their allergies documented. In those cases where allergies were documented no incorrect allergy records were found. A total of 37 allergies were recorded in the 11 patients, with 8 of the 11 having multiple allergies. Of the allergies ascertained from the various sources, 81% were medication related allergies and the rest were due to topical agents like talcum powder, elastoplasts, mouthwash etc (Figure 2). 57% (17 allergies out of 30 affecting 8 patients) of the medication allergies were related to putative antibiotic allergies. One patient was also allergic to vancomycin, an antibiotic commonly prescribed in haemodialysis patients. Four patients had multiple antibiotic allergies of different chemical classes. The commonest drug allergy was to the antibiotic, penicillin (six patients); however, there was no mention in the majority of cases about the nature of the allergy and whether it was severe or even significant (Figure 3). In those patients with antibiotic allergy the majority of the information on penicillin allergy was obtained from historical data

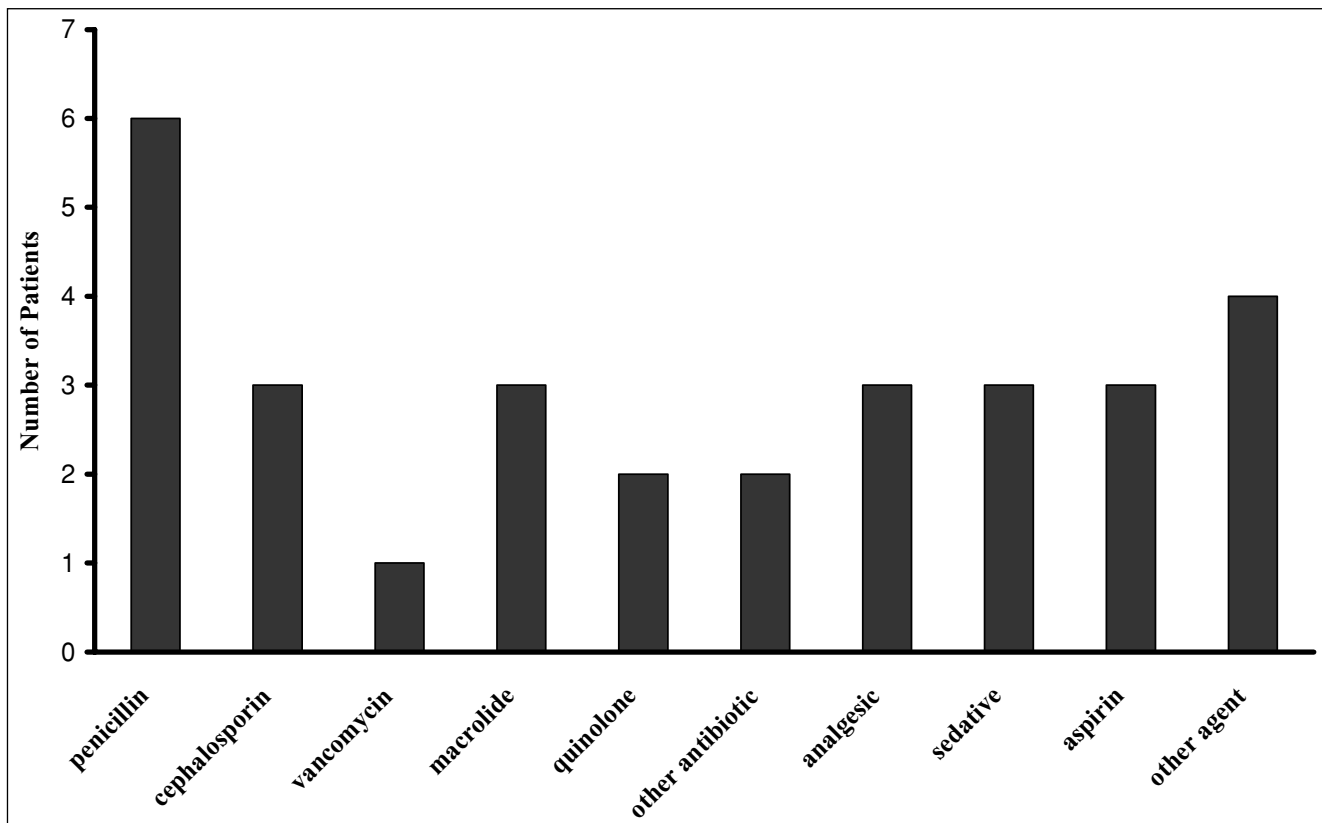


Figure 3: Breakdown of antibiotic and nonantibiotic medication allergies. (Patients may have more than one allergy).

in the hospital medical records and the allergies were simply documented as a rash or itchiness. Five patients did not have all their antibiotic allergies documented. There was no documentation of anaphylaxis in the majority of cases. Intravenous iron is a commonly used treatment in haemodialysis patients (Moniem & Bhandari 2007) and known to lead to possible anaphylactic or anaphylactoid reactions (Fletes *et al.* 2001; Chertow *et al.* 2004). Fortunately, during the study there was no known allergic reaction to iron; however, when looking back retrospectively over six months there was one documented case of a patient who had a significant adverse reaction (Venofer 100 mg) requiring cessation of the medication and supportive clinical measures with oxygen and fluid. The time period (six months), however, may be too short to evaluate this accurately.

DISCUSSION

Currently, the most common triggers of drug allergy include analgesics such as codeine and morphine and antibiotics such

as penicillin. However, there is a wide range of symptoms from a mild rash to anaphylactic immune reactions. In the United Kingdom, around 15% of patients hospitalised report adverse reactions to medications but less than 5% are true allergic reactions and most are harmless with less than 1% being fatal (Morris 1999). In dialysis patients anaphylactic and anaphylactoid reactions related to haemodialysis have been previously described historically. The majority of these cases were related to the historical use of ethylene oxide sterilizer for dialysis membranes and the non bio-compatible complement-activating cellulose and polyacrylonitrile AN69 high flux membranes, which are no longer used and are no longer available in Europe (Marschall *et al.* 1985; D'Ambrosio *et al.* 1997). More recently iron, used to optimise the use of erythropoietin stimulating agents (Bhandari 1998a, 1998b) appears to be another important cause of potentially severe haemodialysis-related anaphylactoid reactions (Fletes *et al.* 2001; Chertow *et al.* 2004; Moniem & Bhandari 2007). Currently, the newer iron dextran

preparations that are of lower molecular weight (Cosmofer; Vitaline, Buckinghamshire, UK) appear safer with a low incidence of anaphylactic reactions in comparison to the historical iron preparations. A recent editorial from Auerbach *et al.* concludes that intravenous iron therapy is safe and effective and total dose infusions can be administered (Auerbach & Talib 2008).

The major risk factor leading to allergic events relates to prescription errors or a lack of information of previous known allergies. Prescription errors (defined as either an error in writing the prescription, or an error in the prescribing decisions, which may delay the timeliness of treatment administration or have the potential for harming the patient and includes allergies (Dean *et al.* 2000), remain the commonest potentially avoidable risk in clinical medicine. Prescribing errors are a universal problem occurring in both in-patient and outpatient settings (Raju *et al.* 1989; Bates *et al.* 1995; Smith 1999; Mandal & Fraser 2005). Without such information the potential for adverse events is significant in a population that receives polypharmacy and which is frequently prescribed antibiotic therapy. In addition to the potential harm there is the possible financial costs to the NHS which may result from an error or from unnecessary prescribing (Audit Commission 2001; Fry *et al.* 2007).

The current study demonstrates that, in haemodialysis patients, who are under the long-term care of a renal service, there remains incomplete medication related information, which is essential for optimal and safe clinical practice. Drug allergies were not documented in 36% of patients. These omissions are therefore potentially serious.

Adverse reactions (any side effect) to medications are common. The prevalence rate of allergic reactions in the general population is around 9–16%. Of this, 1% is due to food allergies, 3.3% insect stings and approximately 1% due to latex allergy. Other allergies such as animal dander and cosmetics that provoke an immunoglobulin (IgE) mediated response are uncommon. According to the National Institute of Allergy and Infectious Diseases, allergic drug reactions account for 5–10% of all adverse reactions to medications (NIAID 2008). However, 'true' drug allergies occur in only 5–10% of these cases. A 'true' allergic reaction is defined as an IgE mediated response to the allergen (usually a protein). It is, however, important to identify these true allergic reactions, because of the risk of

life-threatening anaphylaxis, which is potentially fatal. Some drugs may cause urticarial reactions without an IgE response and may therefore not be classified as an immunological reaction. The incidence of a 'true' allergy may also be overestimated. For example food allergies that have not been discussed in this paper (were not investigated during the study) may be confused with food intolerance where the immune system is not involved. This confusion can lead to a four-fold overestimation of food allergy (Woods *et al.* 2001; Venter *et al.* 2006).

In what ways is it possible to reduce the potential adverse effects of allergic reaction as a result of prescription or documentation errors? To reduce clinical risk, medication histories should be re-evaluated regularly and comprehensively to include an updated history of allergies. This will undoubtedly lead to reduced morbidity, patient admissions and health care costs by the careful documentation of allergies such that these are not given inadvertently (error in planning actions) (Ferner & Aronson 2006).

Electronic prescribing represents another way of reducing transcription and dosage errors (e.g. illegible handwriting). It would allow the creation of a unique, permanent, shared record of allergies and therefore would be supposedly more robust than regularly checking that the information has been copied from one handwritten record to another. However, this method of prescribing may not be so effective at policing the completeness of the documentation of allergies as it removes the human element. (Teich 2005). Indeed, electronic documentation will make very little difference if it is not done regularly, it can eliminate mistakes on dosage hand writing errors, but cannot itself make changes to the drug prescriptions nor write in allergies. The main issue remains around the correct and frequent updating of records regarding allergies. It is only this rigorous intervention from the health care team that will make the clinical difference. Currently, studies are few and give variable results in relation to patient outcomes in using electronic records.

CHANGES IN PRACTICE FOLLOWING THE STUDY

All health care workers have a duty to minimize medication errors and use all available methods to optimise good practice. The Hospital Trust policy dictates that all allergies should appear in the medical case records and on any medication cards used for prescribing while the patient is under

the care of the Trust. Following completion of this study a 'Zero Tolerance' rule has been implemented whereby the pharmacy will not process and nurses will not administer medication unless the allergy box on the medication chart has been accurately completed. This has led to an improvement in documentation of allergies. In addition to this, renal

patients have access to a handheld patient medication record card that allows allergy status and current medication to be documented. This record is written on a special medication card and retained by the dialysis unit and patients after being completed jointly by the patient and staff and is updated regularly.

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