Original Article

The prevalence of adverse drug event-related admissions at a local hospital in Malaysia

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ABSTRACT

Aims: To determine the prevalence of adverse drug event (ADE)-related admissions and the related drugs.
Setting and Designs: This study was conducted prospectively in two medical wards in Malaysia.
Subjects and Methods: Information was collected from patients' medical and medication charts over a period of 24 weeks. All screened patients were assessed using a list of criteria and were classified into: Therapeutic failure (TF), adverse drug reaction (ADR), medication error (ME), and drug overdose (DO). Patients admitted due to ADEs and its subcategories were analyzed and presented in counts and percentages. The prevalence of ADE-related admissions and the drug associated with each category were identified and calculated.
Results: Out of 1,200 screened patients, 39% (n = 443) were ADE-related admissions. A total of 483 ADEs were identified; 79% (n = 351) were due to TF, 21% (n = 94) were due to ADR, 5% (n = 21) were due to DO, and 3% (n = 15) were due to ME. Cardiovascular drugs, antidiabetics, and antiasthmatics were most commonly associated with these admissions. The most common complaint by patients admitted due to a TF was chest pain, whilst hypoglycemia was the main cause of admission related to ADRs.
Conclusions: The prevalence of admissions related to ADEs is high in Malaysia and this was mainly contributed by admissions related to TF. Some useful strategies such as educational interventions on the main causes of ADEs, monitoring of patients prescribed with drugs most commonly associated with ADEs, and appropriate prescribing should be targeted at all healthcare professionals to prevent future occurrences. However, further investigation is needed to clarify the high proportion of patients admitted due to TF.

Key words: Adverse drug events, adverse drug reactions, prevalence, therapeutic failure

INTRODUCTION

According to the World Health Organization (WHO), an adverse drug event (ADE) is '*any undesirable experience associated with the use of a medical product in a patient, but which does not necessarily have a causal relationship with this treatment*'.[1]

Access this article online	
Quick Response Code:	Website: www.archivepp.com
	DOI: 10.4103/2045-080X.123224

The percentage of ADE-related patient admissions has been estimated to be between 2.5 and 30.4%.[2-6] It has also been reported that ADEs prolong hospital stay[7,8] and increase hospital costs.[2,3,8] The most common type of ADE reported in the literature is adverse drug reactions (ADRs),[9-12] which accounted for 53-90% of ADE related admissions; this is followed by therapeutic failure (TF).[4,6,13,14] However, all of the studies have investigated different types of ADEs, sites, and populations; making comparison between these studies difficult.

In Malaysia, data on the prevalence of ADE related admissions are limited. Malaysian ADR Advisory Committee (MADRAC) receives and evaluates

the spontaneous reporting of ADRs and this is the main source of data on the safety of drug use in the Malaysian population. Although the reporting rate was found to be low in 2003,[15] the number has been recently increasing and these reports are mainly submitted by pharmacists.[16] In parallel with MADRAC, the Ministry of Health (MOH) has created the Medication Error Reporting System (MERS) in an effort to encourage ME reporting by healthcare professionals and monitoring of the reports, thus enabling the identification of high-risk areas and the implementation of safety solutions.[17] The Malaysian MOH's commitment to patient safety led to the creation of the Patient Safety Council (PSC) in 2003 to ensure that its citizens receive safe healthcare.[18] This council closely follows the recommendations on patient safety strategies and programs made by the WHO's Alliance for Patient's Safety.[18]

The intention of the PSC in initiating programs and strategies to improve patient safety is a good start. However, without identifying the extent of the problem and areas that would most benefit from interventions, these programs may not be able to eradicate the root cause. The reports received by MADRAC and MERS are not sufficient or suitable to calculate the incidence or prevalence of ADRs or medication errors (MEs). This is due to incomplete numerators (number of ADEs occurring) and denominators (number of patients exposed to a drug). Additionally, they are not able to identify other types of ADEs which may also compromise patient safety, such as drug overdose (DO) and TF. A few small-scale studies have addressed the issue pertaining to drug-related admissions in Malaysia.[19,20] However, these studies did not include all types of ADEs and were conducted over short periods of time.

The paucity of information regarding the epidemiology of all types of ADEs in Malaysia means that there is the potential to identify areas in which to implement preventive measures that have not been realized. Therefore, this study was the first to investigate admissions of all categories of ADEs in Malaysia. This study aimed to determine the prevalence of admissions related to ADEs and the drugs associated with those ADEs.

SUBJECTS AND METHODS

This study was conducted in two medical wards at a government hospital in Malaysia. It is an 800-bed hospital with 20 clinical disciplines. Patients admitted to the medical wards are hospitalized for various medical conditions such as cardiovascular diseases, diabetes mellitus, respiratory diseases, renal diseases, hematological conditions, and liver diseases. Ethical approval was obtained from the Malaysian Research Ethical Committee (MREC), MOH. Permission was also obtained from the hospital director and ward sisters.

A pilot study on 136 admissions was conducted and a prevalence of admissions was found to be 38%. Based on this, sample size was calculated using a sample size calculator designed by Naing *et al*.[21] The required sample size was estimated to be 1,141 at a 95% confidence level and with 2% precision. However, it was decided that 1,200 patients will be reviewed.

Medication charts and medical records of all patients in two medical wards were reviewed, after 24 h of admission, from November 2009 to April 2010. Each ward was visited by a researcher on alternate weeks. Data collected included demographic data, presenting complaints, vital signs and investigations on admission, medication on admission, past medical and medication history, initial and confirmed diagnoses, laboratory results, and other medical findings.

Classifying the ADE

All screened cases were then assessed by the researcher (n = 1,200). Following the assessment, some admissions were excluded from further review (n = 572): Patient admissions without past medication history, elective admissions, and those due to poisoning with non-medicinal products. The remaining admissions (n = 628) were assessed using ADE assessment criteria [Figure 1]. Based on the literature [22-27] and discussion with the research team, this assessment criteria was developed after a pilot study.

All ADE cases were then classified into four different types of ADEs:

- Therapeutic failure - defined as an inadequate therapeutic response to a drug as evidenced by the presence of symptoms of a diagnosed disease state or condition[6]
- Adverse drug reaction - defined as a response to a drug that is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological functions[1]
- Drug overdose - defined as an exposure of an individual, by ingestion or inhalation, to an amount of substance associated with the significant potential to cause harm[28]

Assess whether patient's complaints and symptoms are related to past medication indicating side effects of a drug, prescribing errors (inadequate dose, wrong choice of drug, dose or frequency), drug-drug interactions, or overdose of a drug.

Assess whether patient's complaints and symptoms are related to past medical conditions indicating exacerbation of a past medical condition, drug-disease interaction, or drug contraindicated for a past condition or age.

Review medication changes on admission whether there was an addition of a new drug, substitution of a different drug, abrupt cessation of a drug, reduction or increment of a drug dose or prescription of an antidote.

Review whether there are any abnormalities or improvements in laboratory tests and other findings or changes in the subjective complaints (improved or worsened).

Review whether the diagnoses are related to the side effects of the patient's medication, insufficient dose of the patient's medication, prescribing error (wrong choice of patient's medication, dose or frequency), interactions of the patient's medication, overdose of the patient's medication, or drug contraindication/drug-disease interactions.

If three or more criteria were met, then it was considered as an adverse drug event (ADE) case (criteria one and/or criteria two must be fulfilled by all cases).

If less than three criteria were met then it was considered as a non-ADE case.

Figure 1: List of criteria used to assess all screened cases

- Medication error - defined as any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer.[29]

As a process of checking the reliability of the criteria used to identify and classify ADE cases, and to ensure that the identification and classification of ADE and non-ADE cases were appropriate, 10% of ADE cases (n = 46) and non-ADE cases (n = 19) were assessed by a hospital physician, a hospital pharmacist and an academic pharmacist using the ADE assessment criteria. These cases were generated randomly using Statistical package for the social sciences (SPSS) version 17.0. All remaining cases were assessed by a single researcher who is an academic clinical pharmacist. In addition, all suspected ADR cases were sent to MADRAC for causality assessments.

Data analysis

SPSS version 17.0 was used for statistical analysis. Inter-reviewer reliability in case classifications was evaluated using Cohen's kappa. Poor agreement is indicated by a kappa value of less than 0, followed by slight agreement (0.01-0.20), fair agreement (0.21-0.40), moderate agreement (0.41-0.60), substantial agreement (0.61-0.80), and perfect agreement (0.81-1.00).[30] Chi-squared tests were used where appropriate. The results are presented as frequencies and percentages. A $P < 0.05$ was regarded as being statistically significant.

RESULTS

A total of 1,200 patient charts were screened on the two medical wards over a 24-week period. Of these, 76 (6%) patients were excluded due to incomplete past medication history (information was not in the charts). Therefore, a total of 1,124 patients were assessed for ADEs. Table 1 shows the characteristics of those patients. Of the 1,124 patients, 50% were male and 49% were from the Malay ethnic group. The mean age (±SD) of the patients was 49.7 ± 17.7 years and the mean age of patients with admissions related to ADE was 54.6 ± 15.8 years.

Of the 1,124 assessed patients, 362 (32%) had no past medication history, 121 (10%) were electively admitted, and 13 (1%) were admitted due to an overdose of non-medicinal products [Figure 2]. After accounting for all of these cases, a total of 628 (56%) patients were suspected as being admitted due to an ADE and they were evaluated using the ADE assessment criteria.

A total of 443 admissions met three or more criteria and were therefore classified as ADE-related admissions, giving a prevalence of 39%. There were a total of 483 ADEs identified in 443 patient admissions; patients could be assessed as having more than one ADE. Almost three-quarters of ADE-related admissions were classified as resulting from TF (n = 351, 79%), giving a prevalence of

31%. In addition 21% of 443 admissions (n = 94) were classified as being related to an ADR (a prevalence of 8.4%) [Table 2]. This was followed by DO (n = 21, 4%) and MEs (n = 15, 3%), with a prevalence of 4.7 and 3.4%, respectively. The most common causes of TF-related admissions were chest pain, high blood pressure, exacerbation of asthma, and hyperglycemia, while hypoglycemia was the main cause of ADR-related admissions.

The most common drug groups causing more than 80% of the admissions related to an ADE were cardiovascular drugs (n = 222, 50%), antidiabetics (n = 96, 22%), and antiasthmatics (n = 65, 15%). Despite being prescribed with one or more antiplatelets, antianginals, and/or statins prior to admission, 23% (n = 81) of patients experienced chest pain resulting in their admission [Table 3]. This makes the aforementioned drugs the most common drug groups contributing to TF in this study. This was followed by corticosteroid inhalers, which were implicated in 17% of the TF-related admissions. Of the 94 ADR cases sent to MADRAC for causality assessment, one was classified as 'certain', and the rest as 'possible'. Hypoglycemia was found to be the most common cause of admissions related to ADR and the drugs implicated were glibenclamide and metformin [Table 4]. All but one patient had

Table 1: Demographic characteristics of patients admitted with and without an adverse drug event

	Number (%) of patients			*P* value*
	ADE-related admission *n*=443	Not ADE-related admission *n*=681	Total *n*=1124	
Age (year) (*n*=1124)				*P*<0.00
<15	-	16 (2.3)	16 (1.4)	
15-39	74 (16.7)	242 (35.5)	316 (28.1)	
40-64	252 (56.9)	300 (44.1)	552 (49.1)	
≥65	117 (26.4)	123 (18.1)	240 (21.4)	
Gender (*n*=1124)				*P*=0.02
Male	204 (46.0)	361 (53.0)	565 (50.3)	
Female	239 (54.0)	320 (47.0)	559 (49.7)	
Ethnic group (*n*=1059[a])				*P*=0.12
Malay	187 (43.3)	328 (52.3)	515 (48.6)	
Indian	181 (41.9)	222 (35.4)	403 (38.1)	
Chinese	64 (14.8)	77 (12.3)	141 (13.3)	

*Chi-square test comparing ADE with non-ADE-related admissions. A *P*<0.05 was regarded as being statistically significant. [a]this group does not total 1,124 due to the exclusion of the 'other' ethnic group (*n*=65), ADE=Adverse drug event

Table 2: Types of adverse drug events

	Number of patients	% of patients among total ADE-related admissions*	Prevalence
Therapeutic failure	351	79.2	31.2
Adverse drug reaction	94	21.2	8.4
Drug overdose	21	4.7	1.9
Medication error	15	3.4	1.3

*In some cases, more than one ADE was found, ADE=Adverse drug event

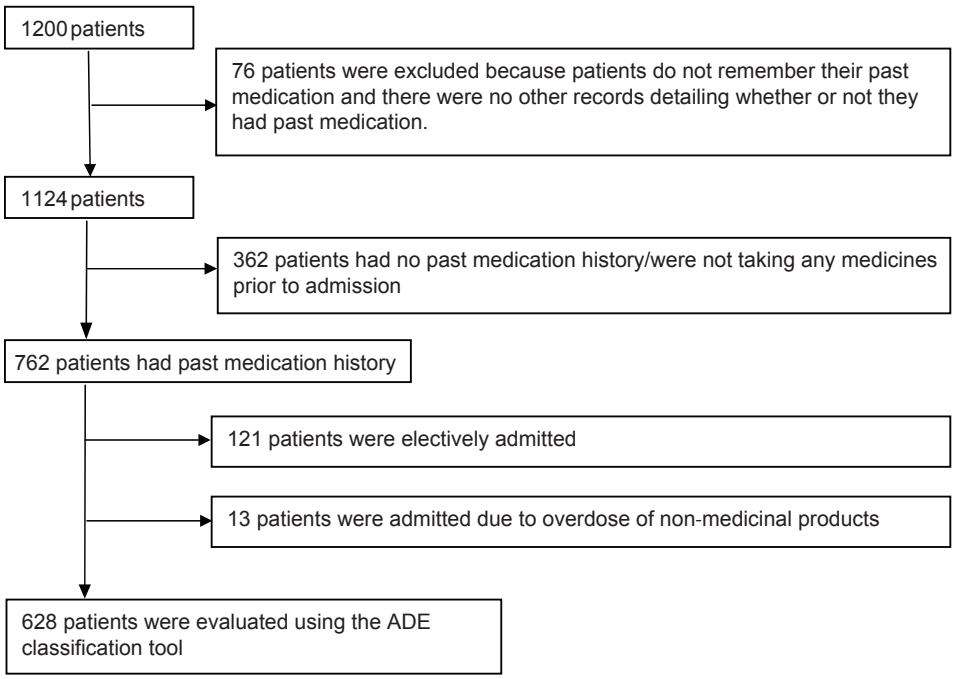

Figure 2: Flow chart of case assessment

Table 3: The most common drug groups associated with therapeutic failure-related admissions

Drug-related event (number of patients)	Drug group*	Number of patients (%) (*n*=351)	Individual drug (number of patients)
Chest pain (*n*=81[a])	Antiplatelet	70 (19.9)	Aspirin (50), clopidogrel (18), Ticlopidine (18)
	Antianginal	64 (18.2)	Trimetazidime (35), Glyceryl trinitrate (31), Isosorbide dinitrate (29), Isosorbide mononitrate (1)
	Statin	61 (17.4)	Simvastatin (28), lovastatin (24), Atorvastatin (8), rosuvastatin (1)
Hypertension (*n*=80[a])	Calcium channel blocker	47 (13.4)	Amlodipine (33), nifedipine (10), Felodipine (4)
	Angiotension converting enzyme inhibitor	39 (11.1)	Perindopril (25), captopril (12), Enalapril (2)
	Beta-adrenoceptor blocker	35 (10.0)	Metoprolol (21), atenolol (10), Bisoprolol (3), propranolol (1)
Exacerbation of asthma (*n*=65[a])	Corticosteroid inhaler	59 (16.8)	Beclomethasone (25), budesonide (21)
	Beta-agonist inhaler	50 (14.2)	Salbutamol (49), formoterol (1)
	Inhaler with combination of beta agonist+antimuscarinic bronchodilator	25 (7.1)	Ipratropium bromide+albuterol (24), Ipratropium bromide+fenoterol (1)
	Inhaler with combination of corticosteroid+beta-agonist	18 (5.1)	Budesonide+formoterol (16), Fluticasone+salmeterol (2),
Hyperglycemia (*n*=55[a])	Biguanide	28 (8.0)	Metformin (28)
	Sulphonylurea	24 (6.8)	Glibenclamide (15), gliclazide (9)
	Insulin	20 (5.7)	Intermediate to long acting insulin (29), short acting insulin (7)

[a]More than one drug group can be associated with an admission, *only the most frequent drug groups are listed in this table

intentionally ingested an overdose of a drug. Paracetamol (*n* = 12), either alone or in combination with other drugs, was the most common analgesic associated with overdoses. In addition, three out of 15 patients who were admitted due to ME were prescribed aspirin without a prophylactic drug despite having a history of gastritis or peptic ulcer disease.

Of the 10% of cases reviewed by the assessors, the overall agreement for "presence of an ADE in a patient" ranged from 'slight agreement' to 'moderate agreement'. The agreement between all four assessors regarding classification of ADE types ranged from 'fair agreement' to 'substantial agreement'.

Table 4: The most common drug groups associated with adverse drug reaction-related admissions

Drug group*	Number of patients (%) (*n*=94[a])	Individual drug (number of patients)
Antidiabetic	36 (38.3)	Metformin (21), glibenclamide (14), Gliclazide (13), insulin (13), acarbose (1)
Antiplatelet	10 (10.6)	Aspirin (9), ticlopidine (1)
Thiazide diuretic	10 (10.6)	Chlorothiazide (10)
Angiotensin converting enzyme inhibitor	10 (10.6)	Perindopril (7), captopril (2), enalapril (1)
Calcium channel blocker	10 (10.6)	Amlodipine (4), nifedipine (4), felodipine (2)

[a]More than one drug group can be associated with an admission, *only the most frequent drug groups are listed in this table

DISCUSSION

Two-fifths (39% of 1,124) of admissions to two medical wards in a government hospital in Malaysia were considered to be related to ADEs. This prevalence is higher than those reported by previous studies, which ranged from 0.5 to 30.4%,[10-13,31-34] and is attributed to the high proportion of admissions related to TF (31% of 1124 admissions to two medical wards), which was similar to other studies.[4,6,14] This was followed by ADRs, which accounted for 8.4% of 1,124 admissions. In other words, of the 628 patients who were on medication prior to admission, 70.5% of admissions were related to an ADE.

The high prevalence in the current study could be explained by a number of reasons: (1) The comprehensive assessment method using a classification tool may have increased the likelihood that all drug-related admissions were identified; (2) a single assessor assessed all of the cases and the results relied on individual interpretation, thus may

have overestimated the number of admissions caused by ADEs; and (3) the types of ADEs investigated in the present study was comprehensive, whilst other studies only investigated particular types of ADEs such as ADR and TF,[26] ADR, and overdose[31,33,34] or ADR, TF, and overdose.[10,12,14]

The highest proportion of TF-related admissions was most frequently related to cardiovascular drugs, antidiabetics, and antiasthmatics, which is in common with previous studies of drug-related admissions.[4,5,12-14,35-38] In 2006, the Malaysian National Health and Morbidity Survey III reported that hypertension, diabetes mellitus, asthma, and heart disease were the most prevalent conditions among the Malaysian population,[39] and thus, it is not surprising that TF in this study was frequently related to these medical conditions. The prevalence of these medical conditions is reported to be increasing in Malaysia,[40-43] with the main reasons being cited as poor dietary control and sedentary lifestyle.[42] In addition, these studies reported that more than 70% of patients who were on drug therapy had poor control of their medical conditions.[40,43] This indicates that poor control of chronic medical conditions is a serious problem in Malaysia which may in part account for the higher prevalence of TF found in this study.

The principal cause of admissions and death in Malaysian public hospitals is cardiovascular diseases.[44] Poor control of these medical conditions could worsen the situation. Thus, it is important to recognize patients at high risk or with established cardiovascular disease to prevent recurrence. Patients should be educated regarding the importance of adherence, and the impact and risk of an uncontrolled medical condition. Public hospitals in Malaysia are always crowded and it is not possible for physicians to provide one-to-one care for patients, let alone a counseling service.[45-48] This provides an opportunity for pharmacists to be involved in educating and monitoring patients. The implementation of Medication Therapy Adherence Clinic (MTAC) services in certain public hospitals in Malaysia is one of the services provided by pharmacists to improve patient's medication adherence behavior. This service has been reported to increase the medication adherence and result in better disease control in patients.[48] More MTAC services should be encouraged in all hospitals and at a community level. To ensure the quality of the services provided in the clinic, it is important to have a protocol or guideline to ensure minimum standards of all hospitals.

In this study, the most common ADRs (hypoglycemic reactions) were predictable as it is the known pharmacology of the drugs, and therefore, were likely to be preventable. The drugs most commonly resulting in ADR-related admissions were antidiabetics. Although the prevalence of ADR-related admissions of 8.4% was similar to other studies,[12,26,49] gastrointestinal events due to nonsteroidal anti-inflammatory drugs (NSAIDs) and aspirin were reported as the most common ADR in these studies. Government statistics have shown that metformin and glibenclamide are the most utilized drugs in Malaysia.[39,50] Furthermore, diabetes mellitus is one of the most prevalent medical conditions in Malaysia.[42] In light of this, the higher prevalence of hypoglycemia in this study could reflect the high utilization of these drugs. The early detection of hypoglycemia and determination of the underlying cause is necessary so that appropriate steps can be taken to prevent future events. As hypoglycemia is a prominent problem in diabetic patients, practitioners should be vigilant when prescribing antidiabetics, and should ensure that patients have adequate knowledge about their medicines. It is important that primary care practitioners provide information about side effects of drugs, their contraindications, and how to handle ADRs, as well as where to obtain high quality drug information.

Limitations

One of the limitations of this study is that it investigated patients admitted to two medical wards in a public hospital and may not reflect the ADE occurrences of other wards or private hospitals. Similarly, patients were missed when patient charts were not available for screening, for example when patients were attending procedures such as scans and X-rays.

Recommendations

Due to a high prevalence of ADE-related admissions in two wards, it is recommended that a larger study involving more than one hospital with different types of admissions is conducted in the future. The causes or risk factors of ADEs should also be investigated to provide further insight into the problem and highlight areas for intervention.

CONCLUSIONS

The prevalence of ADE-related admission is high in Malaysia. TF is the major contributor to these admissions, whilst hypoglycemia is the main cause of ADR-related admissions. As ADE remain an important cause of patient injury and hospital

admissions, preventive strategies, such as patient monitoring and providing continuous and up-to-date education to healthcare professionals could prevent future occurrences.

ACKNOWLEDGMENT

Dr. Khor Boon Pin (consultant physician and gastroenterologist), Mdm Aziah (clinical pharmacist) and MADRAC for assessing the cases.

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How to cite this article: Karuppannan M, Nee TK, Ali SM, Thong WK, Boardman H. The prevalence of adverse drug event-related admissions at a local hospital in Malaysia. Arch Pharma Pract 2013;4:160-7.

Source of Support: Nil. **Conflict of Interest:** None declared.