



ISSN: 2277- 7695
TPI 2015; 4(10): 97-100
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www.thepharmajournal.com
Received: 22-10-2015
Accepted: 25-11-2015

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Hypoglycemic complications with diabetes mellitus management: the predominant adverse drug reaction presenting to the accident and emergency patient of Birdem hospital Dhaka, Bangladesh

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Abstract

To find out maximum benefits of drug therapy adverse drug reactions (ADRs) evaluation is important. This study was done to assess the types of ADRs presenting to the Accident and Emergency department (A&E) of the Birdem Hospital of the Bangladesh. About 19 weeks were needed for this study and the patients logbooks were the main source for collecting information. This study mainly focused on the patient logbook, medical report, doctor's information and the collecting data from the hospital. To confirm the occurrence of ADRs and the suspected drug of the 11500 admissions to A&E. About 35(0.3%) were found who were related to ADRs and most of them were females consisting mean age (\pm standard error) was 52.5 (\pm 5) years medical records of patients with suspected. ADRs evaluated by an Emergency Medicine Consultant of A&E after data collection. Drug initiated hypoglycemia which counted for 21 (47%) cases of ADRs and covered mainly patients on insulin, with or without a sulphonylurea therapy. Allergic reactions accounted for 10 (21%) of the ADR, cardiovascular drugs (14.28%), analgesic/anti-inflammatory medications (17.14%), drugs acting on the central nervous system (11.42%) and anti-infective (11.42%). It is concluded that drug-initiated hypoglycemia is the major ADR presenting to the A&E of the Birdem Hospital of the Bangladesh; it is a preventable ADR and therefore further investigation should evaluate possible factors attributed to the occurrences.

Keywords: Adverse drug reactions, diabetes mellitus, drug-induced hypoglycemia

1. Introduction

Drugs have helped to bring improved health and longer life to human beings, but they are not without risks, as there is always the potential for adverse drug reactions. An adverse drug reaction (ADR), as defined by the World Health Organization (World Health Organization 2002) [1], such as, A drug which is noxious and its response used for the prophylaxis and determining of diseases of physiological functions. Adverse drug reactions may be previously described or appear with use of the drug in the general market. They are a frequent cause of mortality and morbidity of patients worldwide. (Lazarou J, Pomeranz *et al.*, 1982, Ramesh *et al.*, 2003, Patel H *et al.*, 2007) [2, 3, 4]. Accounting for 2-7% of hospital admissions and being the fourth to sixth leading cause of death. (Lazarou J, Pomeranz *et al.*, 1982, Pirmohamed M *et al.*, 1998) [2, 5]. Additionally, the majority is related to the pharmacological action of the drug (Type A) and some actions are not stated by the pharmacology of the drug (Type B). As an example allergic response and irritation of organs may be determined. Therefore, for the assessment of risk versus benefits of drugs observation of ADRs is important, especially clinical trials must be needed for drugs before use in children and pre-market, the elderly, as well as the impact of long term use, comorbidities and drug interactions. While some assessment has been made of the cases of drug-related angio-edema presenting to the Birdem Hospital of the Bangladesh (Williams-Johnson JA *et al.*, 2007) [6], there is little available data on other types of ADRs. The present study aimed to examine the prevalence and trends of ADRs presenting to the Accident and Emergency department of the Birdem Hospital of the Bangladesh.

2. Subjects and Methods

The study was approved by the Faculty of Pharmacy, Manarat International University, and Birdem Hospital of the Bangladesh Ethics Committee.

It was a prospective, observational study conducted on patients seen at the Accident and Emergency department (A&E) of the Birdem Hospital from October 2014 to February 2015 for 19 weeks.

Here mainly followed patients logbook, patients medical records, collected data and advised from an Emergency Medicine Consultant of A & E for arranging every step for admission.

An assessment of whether the ADR was type A, that is, associated with the pharmacological action of the drug or type B, that is, not related to pharmacological action (eg. allergic) (Meyboom R *et al.*, 1997) [7] was also done. According to the Information which taken from patient medical records and included details of drugs implicated (daily dose and route), description of the ADR, length of ADR event, abnormal laboratory test results, age and gender. Other relevant history, such as co-administered drugs and other pre-existing medical conditions were also collected. The frequency and distribution of the most common ADRs and drugs associated with ADRs were analyzed. ADRs were classified using the scale of "certain, probable, possible, unlikely, unclassified and unclassifiable" as standardized by the World Health Organization (Edwards IR *et al.*, 1994) [8].

3. Results

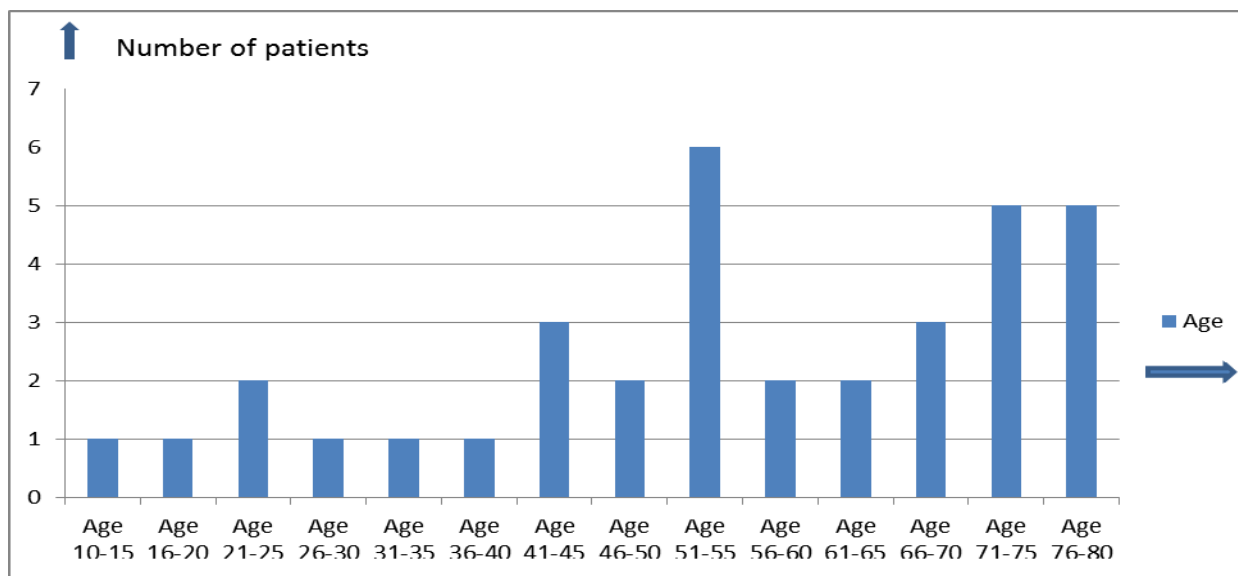
During the 10 weeks of the study, 11500 patients presented to the A&E department and 35 were found to be associated with ADRs, giving a prevalence of 0.3%. There was a greater

representation of females (20, 57.14% of the total ADRs) than males (15, 42.85% of ADRs, odds ratio = 1.2). The majority of the cases were associated with elderly adults (Table 1) with 15 of the cases being over the age of 60 years (mean ± standard error = 52.5 (± 5) yrs)

Table 1: Frequency of patients according to age range

Age range	Frequency
10-15	1
16-20	1
21-25	2
26-30	1
31-35	1
36-40	1
41-45	3
46-50	2
51-55	6
56-60	2
61-65	2
66-70	3
71-75	5
76-80	5

This results are shown in a graph which is given below to make it easy for understanding. In the graph has shown the Frequency of patients according to age range. There is also shown a another graph in below the table 2 according to the table 2 as like as table 1.

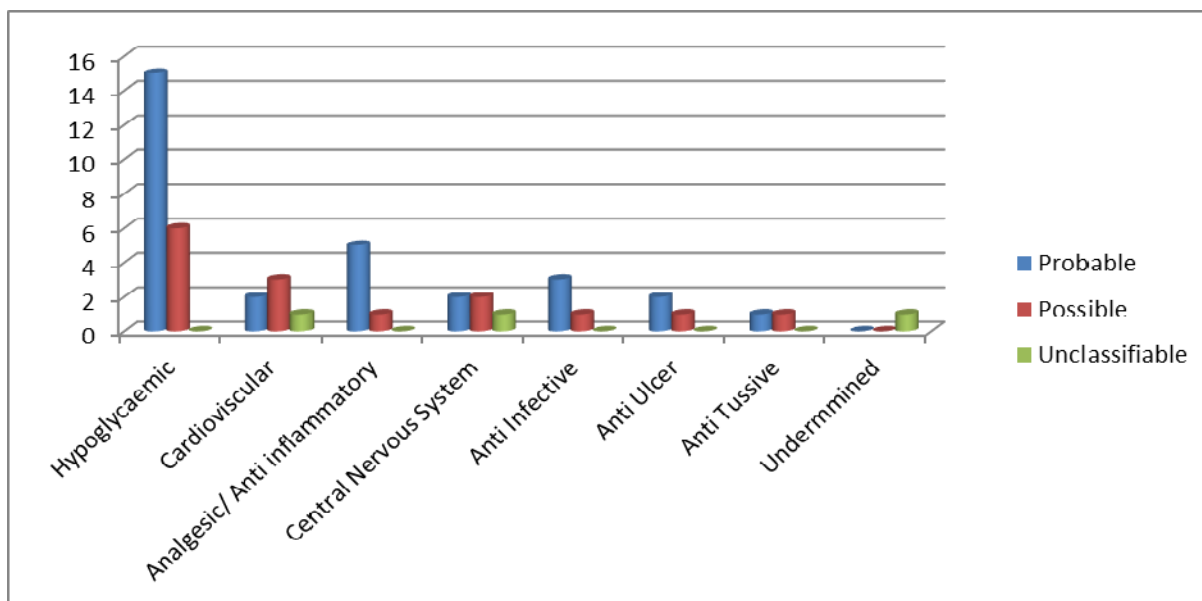


Distribution of the age of the patients shows adverse drug reaction in the BIRDEM Hospital in Bangladesh. According to the classification of World Health Organization, the ADRs were classified as "certain", due to the outcome of

re-challenge was not assessed. Thirty of the cases were classified as probable, 15 as possible and 3 were unclassifiable (Table 2).

Table 2

Suspected drug group	Probable	Possible	Unclassifiable
Hypoglycaemia	15	6	0
Cardiovascular	2	3	1
Analgesic/Anti-inflammatory	5	1	0
Central nervous system	2	2	1
Anti-infection	3	1	0
Anti-ulcer	2	1	0
Anti-tussive	1	1	0
Not Determined	0	0	1



Of the cases presented, 21 cases of hypoglycemia, 2 case each of bradycardia, 5 cases of extrapyramidal effects, dizziness and elevated blood pressure (failure of therapy) were involved into type A reactions which accounted as 75%. Twelve ADRs (25%) were type B reactions, involving 2 cases of gastrointestinal irritation, 10 cases of allergic responses, most being skin related allergies and one anaphylaxis, resulting in death.

4. Discussion

This is the first study to evaluate the prevalence of ADRs presenting to the A&E department in Birder Hospital of Bangladesh. The report showed that 2 out of every 100 patients presenting to A&E were likely to be experiencing complications to normal drug therapeutic doses. The study also found that the patient presenting to A&E with an ADR was more likely to be elderly; a finding system, analgesics/anti-inflammatory drugs and anti-infectives accounted for 11.42%. % each of the total ADRs. Anti-ulcer and antitussive drugs were counted for 8.57% individually among of the total ADRs while there was another 8.57% in which the drug associated with the ADRs was undetermined because of the involvement of more than one drug and the nature of the ADR. Of the 45 patients consisting these other groups, excellent willingness with therapy was confirmed for 16 cases, that is consistent with advance age being an established risk factor for the occurrence of ADRs (Von Euler M *et al.*, 2006, Mjorndal T *et al.*, 2002, Routledge PA *et al.*, 2004) [9, 10, 11]. This study also found that the majority of the hypoglycemic episodes involved insulin therapy. This is consistent with other studies out of the United States of America and Hong Kong, showing a higher risk of hypoglycemia in insulin users (Ginde AA *et al.*, 2008, Ginde AA *et al.*, 1997, Chan TY *et al.*, 1998, Leese GP *et al.*, 2003) [12, 14, 15]. Drug induced hypoglycemia is characterized as a type A adverse drug reaction and therefore is preventable. It is well established that along with advancing age, co-morbidities and multi-drug use increase the risk of hypoglycemia. For example, concomitant administration of non-selective beta blockers or angiotensin converting enzyme inhibitors can increase the risk of hypoglycemia in patients with diabetes mellitus and coadministration of anti-diabetic drugs may require dose adjustments (Chelliah A *et al.*, 2004) [16]. Therefore, assessment of preventability becomes important

in order to determine what adjustments could be made to obviate re-occurrence.

The evaluation of preventability of ADRs according to the methods described by Schumock (Schumock GT *et al.*, 1992) [17] and Winterstein (Winterstein AG *et al.*, 2002) [18] depends on an evaluation of appropriateness of drug dose and route, in relation to patient factors (age, weight, disease state and compliance to therapy). It also requires evaluating whether there is need for therapeutic dose monitoring, information of previous problems with drug exposure and possible involvement of medication error. Some of these factors, such as blood concentration of drugs, patient history of previous ADRs and severity of co-morbid states could not be determined from patient case-notes and therefore no assessment was made of the preventability of the ADRs. In conclusion, the role of an emergency room should not only be to manage emergency cases effectively, but also to assess trends and practices associated with occurrences. There may be a need to design specific protocols for the collection and management of ADRs. The different types of cases of drug may initiate hypoglycemia and implications so the A&E department should be conscious about this. Consideration should be given to the design of specific protocols to accommodate adequate data collection that will facilitate causality assessment and reduce the risk of occurrences.

5. Acknowledgement

We gratefully acknowledge to Dr. Md. Azharul Islam, A.F.M Abdul Kalam for helping us to gather more information about diabetes and delivering a lots of data. We are knowing thanks to Dr. Abdur Razzak, Dr. Mehedi Hasan, Dr. GM. Jonayed Nayem and Dr. Wahida Islam for helping us. We also thank to Mrs. Halima Khatun, senior nurse, Birdem Hospital. We also gratefully knowledge to the Authority for using their web site and collecting information from Birdem Hospital.

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