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Drug adverse effects in medicine outpatient department An analysis in a tertiary care hospital of Bangladesh

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Abstract

Background: Adverse drug effects are common among patients receiving treatments in outpatient department due to lack of proper follow up of treatment. It causes decrease compliance to the treatment leading to treatment failure.

Aim: The present study was aimed to analyze the pattern, causality and severity of the adverse drug effects complained by the patients at internal medicine outpatient department.

Materials and Method: It was a cross-sectional study done at outpatient department for a period of four months. Patients presenting with sign symptoms of adverse drug effects were included for this study. Each patient underwent a detailed evaluation by a consultant once they were medically stable.

Results: A total of 86 adverse drug effect cases were reported. Most of them are females (65.1%). Older age group (>60 years) were more prone to the side effects (37.2%). NSAIDs (31.4%) and the Antipsychotics (16.3%) were the commonest drugs. Drugs administered orally (62.8%) and taken by self without proper consultation (41.9%) caused most of the side effect. Gastrointestinal symptoms were the commonest complaints (47.7%). More than half of the complaints were reported within weeks (64%). Most of the cases (87.2%) were managed in outpatient settings without fatal complications.

Conclusion: Detecting the adverse drug effects among patients at early stage will improve continuation and adherence to treatment.

Keywords: Adverse Drug Effects, Medicine Outpatient, Follow Up.

Introduction

A Harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product is called an adverse drug effect or reaction. Such reactions are currently reported by use of WHO's Adverse Reaction Terminology, which will eventually become a subset of the International Classification of Diseases. Adverse drug effects are classified into six types: non-dose-related, dose-related, both dose-related and time-related (Chronic), time-related, withdrawal, and therapy failure. Timing, the pattern of reaction, the investigations, and re challenge can help attribute causality to a suspected adverse drug reaction. Withdrawal of the drug if possible and specific treatment of its effects is considered to be the main management. Reporting should be done if any adverse drug effect suspected. Adequate surveillance can detect reactions and prove the correct associations.

Adverse drug effects are among the leading causes of death in many countries. A Canadian survey showed that 19.1% of the hospital admissions presented with at least one drug-related adverse effect (Canadian ADR Newsletter, 2000; Canadian ADR Newsletter, 2001) [15, 16]. A study conducted by Jha in the year 2007 on both inpatient and outpatient departments in hospitals of Nepal revealed that 0.64% of the admissions were related to drugs. Similarly, in another study which was conducted in Nepal also revealed the prevalence of 0.86% of adverse effects (Shrestha R *et. al* 2006) [14]. Drug related complications are often ignored in developing countries. People often put their lives at risk as they do not know the consequences of irrational drug use without proper patient counseling and expert advices. Previously limited number of studies regarding pattern and severity of drug adverse reactions had done in our hospitals. Therefore the present study was carried out to find out the pattern of the adverse drug reactions reported to the center as well as to carry out the causality, severity, and preventability of the reported adverse drug reactions.

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Materials and Method

Study design and data collection

This was a cross-sectional study conducted during four month period from July 2014 to October 2014. 1000 patients were selected randomly by non-probability or purposive sampling. Patients presented with complaints or sign symptoms of adverse effect of drugs to the medicine outpatient department of Chittagong Medical College Hospital (CMCH) during this time period entered the study. Data were collected by registered physicians through face to face interview with patients. Only patients who were fully alert and conscious entered the study after obtaining a written informed consent from them. Data regarding socio demographic profile, pattern of adverse reaction, route, timing and severity was collected and entered the questionnaires.

Statistical analysis

Survey data were analyzed using the SPSS statistical program (Version 16). Descriptive statistical analyses were performed and a P value <0.05 was considered statistically significant.

Ethical considerations

Institutional Review Board (IRB) approval was obtained from ethical committee of Chittagong Medical College and Hospital. Before administering the survey, investigators explained the purpose of the study to all patients. The voluntary nature of participation and the anonymous and confidential nature of the interview schedules were strongly emphasized. Verbal informed consent was obtained from all patients.

Results

A total 86 patients presented with sign symptoms of adverse drug reactions during the period of the study. Among them female was the predominant (65.1%, n=56). Older age groups were more vulnerable than others (58.1%, n=50). Patients above the age 60 showed significant adverse effects (37.2%, n=32). (Table 1)

Table 1: Age groups and gender effected by adverse drug reactions.

Age group	Male	Percentage	Female	Percentage
<15	2	2.3	7	8.1
15-30	3	3.5	8	9.3
30-45	10	11.6	6	7.0
45-60	4	4.7	14	16.3
>60	11	12.8	21	24.4
Total	30	34.9	56	65.1

Our study revealed that the NSAIDs were the commonest drug causing side effects (31.4%). Due to irrational use of NSAIDs as an over the counter drug (OTC) made this drug commonest. Antipsychotic drugs prescribed at medicine outpatient department without consulting the expert psychiatrist also showed significant side effects among patients (16.3%). Steroids, antibiotics, antiepileptics, antidiabetics and anti hypertensives also showed side effects in a number of patients. (Table 2).

Table 2: Common drugs causing adverse effects in medicine outpatient department.

Drug category	Number	Percentage
NSAIDs	27	31.4
Antipsychotics	14	16.3
Steroids	11	12.8
Antibiotics	9	10.5
Anti-epileptics	9	10.5
Anti hypertensives	5	5.7
Anti-diabetics	3	3.5
Hormonal preparations	2	2.3
Others	6	7

Which route of administration causing most of the side effects was also investigated in this study. Drugs given by oral route showed most of the side effects (62.8%, n=54). It may be due to most of the patients in the outpatient setting are managed with oral medication. Intravenous drugs showed side effects in 13 patients (15.1%). A few number of patients showed adverse effects on topical (10.5%), intramuscular (4.7%) and inhalation (2.3%) route. (Figure 1)

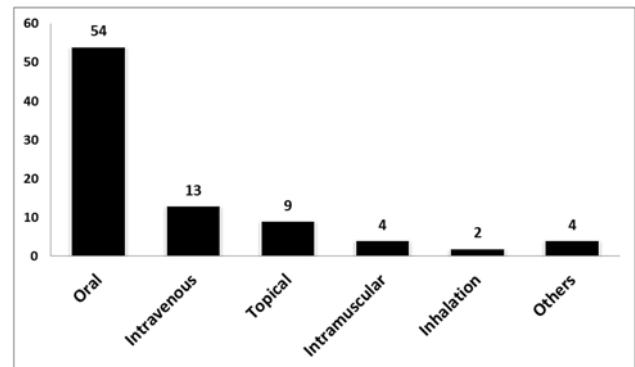


Fig 1: Common route of drug adverse effects.

This study also showed that, self-administered drugs showed most of the side effects (41.9%, n=36). It is may be due to wrong dosage and frequency of drugs. 21 patients (38.4%) complained of side effects of drugs prescribed by the registered practitioner. 5 cases found accidental administration (5.8%). (Figure 2)

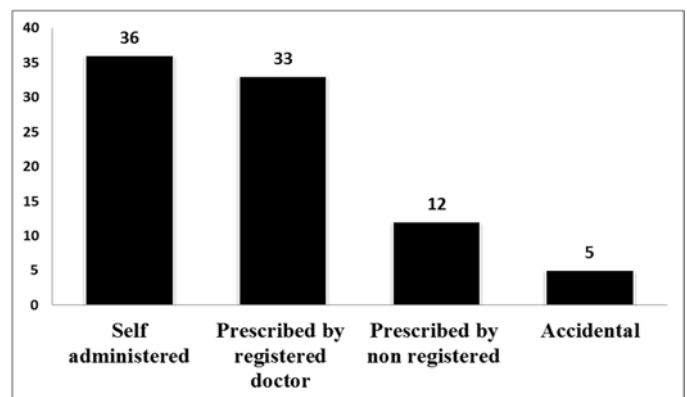


Fig 2: Reason of drug administration.

Gastrointestinal system was the most common system affected by the drugs adverse effects (41.7%). Nausea, vomiting, diarrhea and abdominal pain were the main gastrointestinal complaints reported. Dermatological reactions also showed significant drug reactions (26.7%) by itching, rash and blister formation. Other systems commonly

involved are central nervous system, immune, genitourinary and hematological system. One case was found complaining cardiac and respiratory problem. (Table 3)

Table 3: Systems effected by drug adverse effects.

Systems involved	Number	Percentage
Gastrointestinal	41	47.7
Dermatological	23	26.6
CNS	10	11.5
Immune	5	5.7
Genitourinary	3	3.8
Hematological	2	2.3
Cardiac	1	1.2
Respiratory	1	1.2

Most of the drugs showed adverse reaction within weeks (64%). Chronic drug effect was found in 31 patients. Only 3 patients showed immediate drug reaction which happened with twenty four hours. 9 patients showed chronic adverse effects, which was mild to moderate in severity and caused them delayed consultation. (Table 4)

Table 4: Starting time of drug adverse effect.

Timing	Number	Percentage
Immediately	6	7.0
Within weeks	55	64.0
Within months	16	18.6
Chronic (>6 months)	9	10.4

This study also investigated for the fatality of the drug reactions. Most of the patients were managed in the outpatient department without any hospitalization (87.2%, n= 75). Only 9 patients needed hospital admission. 2 patients needed emergency management and considered as fatal. There was no mortality reported. (Figure 3)

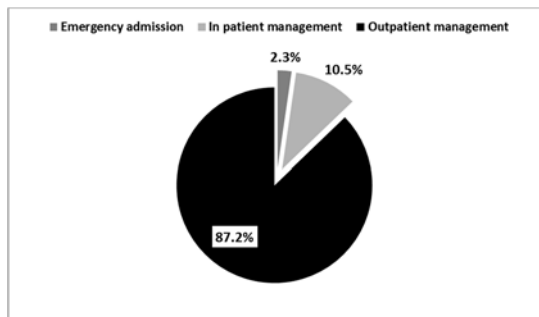


Fig 3: Fatality of drug adverse effects.

Discussion

Adverse drug effects are common during treatment. It can be mild, moderate or severe. Patients taking the treatment from outpatient department are prone to adverse drug reaction. Due to lack of proper follow up in outpatient department of hospitals in developing countries it's a big challenge to diagnose the adverse reaction at its early stage. From July 2014 to October 2014 a total 38250 patients attended in internal medicine outpatient department of Chittagong Medical College Hospital. Out of them 1000 patients were randomly selected where 86 adverse drug reaction cases found. Other studies also showed incidence and prevalence of adverse drug effects in similar percentages (Pirmohamed *et al.*, 2004; Giovanni *et al.*, 2006; Gor and Desai, 2008) [6, 3, 2]. In this study, female and older age groups were more prone to adverse effect of drugs which is similar to the study done

in India (Ramesh *et al.*, 2003) [10]. NSIADs were the commonest drug causing adverse effects was found in this study. Studies done in various regions of the world had shown dissimilar result with our study where antibiotics caused most of the adverse reactions (Moore *et al.*, 1998; Suh *et al.*, 2000; Nahar *et al.*, 2006; Rao *et al.*, 2006; Chowdhury *et al.*, 2008) [4, 12, 5, 9, 1]. Oral route of administration caused most of the drug effects which is also dissimilar to the study done in India (Rao *et al.*, 2006) [9] where intravenous route showed most of the adverse effects. Gastrointestinal system was the commonest system affected by adverse effects; this finding is consistent with the report of other studies (Pouyanne *et al.*, 2000; Ramesh *et al.*, 2003; Pirmohamed *et al.*, 2004;; Rao *et al.*, 2006) [8, 10, 6, 9]. Most of the adverse reactions were managed in the outpatient department without any severe complications. This report was similar to the studies done by various studies in India (Ramesh *et al.*, 2003; Rao *et al.*, 2006; Nahar *et al.*, 2006) [10, 9, 5]. Even though the adverse drug effects are of unpredictable type, their occurrence can be minimized by good history taking, follow up and patient counseling. In a developing country like Bangladesh where even strong NSAIDs and antibiotics are available very freely as an over the counter (OTC) drug, intensive monitoring of adverse drug effects requires a tremendous demand. There has to be regular training programs conducted for the health care professionals for making them aware about adverse drug effects. And reduce the occurrence of adverse drug effects.

Conclusion

Good management of diseases includes the initiation and the completion of therapy with minimal complications. Patients with adverse drug effects were more susceptible to develop unfavorable results diseases in the outpatient settings. Considering the prevalence of adverse drug reactions, continuous monitoring and regular follow up of patients is considered as important steps in their outpatient treatment process.

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