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Original Research Article

Evaluation of Adverse Drug Reactions of Drugs Used in Gynaecology Department for Different Complications at a Tertiary Care Teaching Hospital

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ABSTRACT

Purpose: To monitor the adverse drug reactions of the drugs used in the Gynaecology Department with the objectives to evaluate the side effect and ADRs experienced by out-patients and in-patients in the Gynaecology Department and also to study the pattern of ADRs and side effects by spontaneous reporting.
Methods: A prospective observational study was carried out in the department of gynaecology and the patients who qualified the inclusion criteria were enrolled in the study. The data were analyzed with the help of SPSS Statistics ver. 20.
Results*:* During the course of the study, 51 patients developed adverse drug reactions from the agents used in the gynaecology department. Majority of the reactions occurred in the age group 21-30 years (64.7%) followed by the 31-40 year age group (21.6%) developed ADRs. Most common reaction or problem was abdominal pain+headache; occurred in 8(15.7%) patients. Tab. Folvate Inj. Iron sucrose, Tab. Rantac, Tab. Canfree, Tab. Levobact, Tab. Doxycycline caused the majority of reactions and problems in 3 (5.9%) patients individually. All the ADRs were caused by the drug administered via peroral route. According to the Naranjo probability scale, causality assessment was probable in 28(74.1%) patients. The offending drug was discontinued in all the 51 patients. No serious reaction occurred at the time of the study.
Conclusion: This study helped us to investigate the pattern of the ADRs in the Gynaecology Department. Creating awareness among the health care professionals and promoting ADR reporting is necessary for the optimization of the drug therapy. Overall, drug therapy used in the Department of Gynaecology is usually safe and the drugs are given with care, but there are still some chances that certain drugs could possibly cause some potential ADRs to occur.
Keywords: Adverse drug reaction, Gynaecology, Pharmacovigilance, Antibacterial drugs.

INTRODUCTION

The increasing development and availability of new medicines during the dawn of the 20th century resulted in the emergence of adverse drug reactions and other drug-related problems. Adverse drug reaction has been creating headlines over the last 40 years typified by the thalidomide tragedy of the early where pregnant women exposed to the drug for morning sickness gave birth to phocomelic babies. International attention to patient safety has been growing significantly since the publication of the US Institute of Medicine report "To err is human: building a safer health system. [1] Earlier there were no standard definition of adverse drug reaction, therefore, earlier studies used their own definitions, which were indistinct and could be interpreted to include intentional and unintentional overdose, as well as some administrative errors. [2-3]

Pharmacovigilance is the tracking of adverse drug reaction is now mandated by regulatory agencies. In order to identify and prevent adverse drug reactions, methods that

can accurately predict those most at risk for an adverse drug reaction must be developed. Concurrent with this, to ensure that the method developed to identify this sub-population are efficient, practical, and less expensive than current methods. [4] Adverse drug reactions may also result in diminished quality of life, increased physician visits, hospitalizations and even death. In addition, they result in increased health care costs. The numerous medications, multiple chronic medical problems and frequent acute illnesses experienced by the patients put them at increased risk for ADRs and makes detection more difficult. The fundamental role of the Healthcare professional is to identify potential and actual drug-related problems resolved problems and prevent potential drug-related problems. This should lead to a heightened awareness of ADRs, increased reporting of ADRs and Increased opportunities to review drug selection and prescribing practices affecting patient outcome. [5]

Epidemiological data support the presence of certain factors that escalate the risk of ADRs, such as old-aged patients, hospitalized patients and the female gender of the patients. [6-9] Female patients have 1.5- to 1.7 times more risk of emerging an ADR, including adverse reactions of the skin, compared to male patients. The reasons for the occurrence of the adverse reactions at a higher rate in females are not understood completely but are believed to be gender-related differences in pharmacokinetics, pharmacodynamics, immunological and hormonal aspects as well as modifications in the consumption of medications by females when compared to males. It is important to recognize the risks for ADRs, henceforth the common drugs known to cause ADRs, their therapeutic class, demographic data of patients suffered from ADRs and concomitant medications used should be in knowledge. Not only this, ADR specific data such as the probable causes, type of reaction, and the system affected will be of great importance to reduce the chances of the ADRs. Thus, the present study was aimed to identify and characterize the pattern of ADRs due to commonly used drugs in the Gynaecology department in a tertiary care teaching hospital and analyze them on the basis of various parameters. This information would be useful in identifying and minimizing preventable ADRs, at the same time it may help clinicians to tackle with ADRs more efficiently.

MATERIALS AND METHODS

We conducted a Prospective Observational Study for a period of 6 months in the Department of Gynaecology of Guru Gobind Singh Medical College and Hospital, Faridkot and S.D Thapar Hospital, Moga. All the patients having ADRs in the gynaecology department were enrolled in the study by considering the inclusion and the exclusion criteria. A total of 51 cases were taken over the period of time. All the Inpatients or outpatients diagnosed with ADRs in accordance with the WHO's definition in the gynaeology department were included in the study and the patients who reported ADRs due to Accidental and intentional poisonings and improper administration of the medicines were excluded from the study. The study was approved by the Institutional Ethics Committee of Indo-Soviet Friendship College of pharmacy.

For the collection of data, case reports of inpatients and medical cards of the outpatients were used. ADRs were also collected at the time of ward round participation and through spontaneous reporting by the healthcare professionals. Medical history taken from the medication chart played an important role during ADRs collection. Moreover, a set of questions about the dose and the administration of the drug were asked from the patients and their attendants. The ADR reporting and documentation form containing Naranjo's scale for causality assessment and the Central drug standard control organization (CDSCO) form for reporting and

documentation of the suspected ADRs were employed in the study conducted.

Data analyses

Descriptive statistics were employed on various parameters taken in the study and were statistically analyzed with the help of SPSS Statistics version 20. Causality Assessment of the ADRs was done by using the Naranjo's scale of probability.

RESULTS

The findings of the study showed that the majority of the patients who had ADR were falling under the age group between 21-30 years that is 33(64.7%) patients. Second most of the patients who reported ADRs were from the age the group of 31-40 years that is 11(21.6%) patients. The mean age of the patients that were recruited in the study was found to be 22.48±7.50.

Total 30 drugs were reported to cause adverse drug reaction over the period of a study conducted. Tab. Folvate Inj. Iron sucrose, Tab. Rantac, Tab. Canfree, Tab. Levobact, Tab. Doxycycline caused the majority of reactions and problems in 3 (5.9%) patients individually. The descriptive analysis of the various drugs used in the Department of Gynaecology is depicted in Table-1.

On the evaluation of the dose of the drug given, the majority of ADRs reported was of dose 100 mg, 150mg, 200mg. Dose 100mg was generally used for Tab. Doxycycline, 150mg was the strength of Tab. Canfree and 200mg was the dose used for Tab. Iron Sucrose. On the evaluation of route of administration of the drug, most of the patients that is 43(84.3%) patients had adverse drug reactions after taking the drug by per oral route as depicted in the Table 2 and the majority of the patients that is 30(58.8%) patients took the medication with twice a day (BD) frequency.

Table 1: Drugs wise distribution of ADRs in patients

Brand or generic name of the drug	No. of patients (n=51)	Percentage (%)
Tab. Nilser	2	3.9%
Tab. Folvate	3	5.9%
Tab. Doxycycline	3	5.9%
Tab. Novelon	1	2%
Tab. Buscopan	1	2%
Inj. Serglow	2	3.9%
Inj.Iron sucrose	3	5.9%
Cap.HerNMP	1	2%
Tab. Doxinate	2	3.9%
Tab. Rantac	3	5.9%
Tab. Tranexa	2	3.9%
Tab.Canfree	3	5.9%
Tab. Livogen	1	2%
Tab. Rubired	2	3.9%
Tab.Cal.shelcal	1	2%
Tab.Drospirenone+ethinyl estradiol	1	2%
Tab.Irex	1	2%
Tab.Corium D3	1	2%
Cap. Lupigest	1	2%
Tab. Rablet	2	3.9%
Tab. Zoncin	2	3.9%
Tab. Labetalol	1	2%
Tab. Regestrone	1	2%
Tab. Misoprostol	1	2%
Pes.VH3 Kit	1	2%
Inj. Tazar	1	2%
Tab.Iron	1	2%
Tab. Levobact	3	5.9%
Tab. Metrogyl	2	3.9%
Tab.Lyser d	2	3.9%
Total	51	100

Table 2: Route administration of the Drug

Route of the drug	No. of patients (n=51)	Percentage (%)
Peroral	43	84.3%
Intravenous	6	11.8%
Sublingual	1	2%
Vaginal	1	2%
Total	51	100%

The majority of the reactions caused by the drugs were abdominal pain and headache. Abdominal pain and headache were reported in 8(15.7%) patients and the second most common reactions found were the shivering and the fever reported in 6(11.8%) patients as shown in Table 3.

On the evaluation of indication of the therapy used, total 23 types of indication of therapy were reported, out of 51 patients, the majority of patients that is 11(21.6%) patients were on antibacterial drugs and for the causality assessment, Naranjo's probability scale was employed. The causality assessment of the majority of the patients was "probable" that is in 28 (54.9%) patients as represented in table 4. The causality assessment was done based on the scoring for the Naranjo's algorithm: >9=

definite ADR; 5-8= probable ARD; 1-4= possible ADR; 0=doubtful ADR.

Table 3: Reaction or problem wise distribution of ADRs patients

Describedreaction of the patient	No. of Patient	Percentage (%)
Dry mouth+Dizziness	4	7.8
Indigestion+Breathlessness	1	2
Abdominal pain+Headache	8	15.7
Irregular heartbeat	2	3.9
Shivering+Fever	6	11.8
Diarrhea+Dizziness	2	3.9
Sleeping disturbances	1	2
Rashes+Dizziness	2	3.9
Constipation+Loss of appetite	5	9.8
Weight gain	2	3.9
Nausea +Constipation	2	3.9
Nausea+Vomiting	5	9.8
Stomach upset+ Irritation	1	2
Decreased urine output +Drowsiness	1	2
Dry mouth +Abdominal pain	1	2
Shivering	1	2
Rashes+Itching	2	3.9
Cramps+Fever	1	2
BP fluctuations +Nausea	1	2
Indigestion+Abdominal Pain	3	5.7
Total	51	100

Table 4:Causality assessment as per Naranjo's scale

Causality assessment	No. of Patients	Percentage (%)
Probable	28	54.9%
Possible	23	41.1%
Total	51	100%

After the occurrence of the ADR, the action taken by the physician was the withdrawal of the drug. The offending drug was discontinued in all the 51 patients as represented in Table 5.

Table:5 Action taken by the physician after ADR

Action taken	No. of patient (n =51)	Percentage (%)
Drug withdrawn	51	100%
Dose reduced	0	0%
Dose not changed	0	0%
Total	51	100%

Upon evaluation of the drug regimen given by the physician, it was reported that 40 patients were recovered from the adverse effect of the reaction, whereas, the remaining 11 patients were still in the phase of recovering at the time of the study.

DISCUSSION

A Study conducted in the past revealed that about 5% of all hospital admissions are associated with the adverse drug reactions and 10-20% of patients admitted to the hospital are known to report some sort of ADRs. [10] Our study indicates the uniform distribution of Adverse drug reaction amongst the female at the Gynaecology Department. Majority of the ADRs were presented by 21-30 year age group. It is likely that the population of this age group is more frequently engaged with the healthcare organizations and this is the major age group getting the treatment. The reason behind may be due to the hormonal imbalance, dependence on oral contraceptives or pregnancy yet results in the frequent occurrence of ADRs at the Gynaecology Department. Our finding suggests that the majority of reactions and problems caused by drug were an abdominal pain with Headache. They were reported in 8(15.7%) patients and the second highest mean of reactions were shivering with fever found in 6(11.8%) patients. Total 30 drugs were reported for causing adverse drug reactions during the study period. The highest number of reactions and problems were caused by the drug Tab. Folvate, Inj. Iron sucrose, Tab. Rantac, Tab. Canfree, Tab. Levobact and Tab. Doxycycline in about 3(5.9%) patients individually and was seen that mostly the ADRs occurred after taking the drug through oral route which comprises to 43(84.3%) ADRs affected patients. Since the most common route of administration of the drugs was the peroral route, it is believed that the common site for the development of the ADRs was the gastrointestinal system. [11] Out of 51patients, 30 (58.8%) patients took the medication with BD frequency. Antibiotics show a high incidence of ADRs. Data revealed that total 23 types of indications of therapy were used. Out of 51 patients, the majority of patients (21.6%) were on antibacterial drugs. There is a need to educate and train doctors to prescribe rationally by emphasizing this aspect in clinical practice teaching. Our study revealed the high exposure of the gastrointestinal system to the antibiotics, which may result in high gastric acidity. Such a pattern of the study was reported by

Dhar et al, [12] who revealed that dermatologic and gastrointestinal system were the most commonly affected organ system next to the genitourinary system. In order to find out the legitimacy of the ADRs occurred, we employed the use of Naranjo's probability scale for the casuality assessment of individual drug. [13] Out of 51 patients, the majority of patient's causality assessment was "probable" that is in 28 (54.9%) patients and "possible" constituted to 23 (45.1%) patients. The offending drugs which caused the ADRs were discontinued in all the 51 patients. 40 patients recovered from the ADRs, while the remaining 11 patients were still recovering.

The findings of our study provide information about the ADRs which could possibly occur due to the drugs used in the Gynaecology Department. The data in the present study will help the physicians make rational use of drugs in the Gynaecology Department.

CONCLUSION

All in all, drugs used in the Department of Gynaecology are generally safe and are administered with caution, but there is still a probability that they could cause some potential ADRs. This study helped us to investigate the pattern of the ADRs in the Gynaecology Department. Creating awareness among the healthcare professionals and promoting ADR reporting is necessary for the optimization of the drug therapy. Organizing regular workshops and continuous health education will progress the alertness of healthcare professionals regarding the Pharmacovigilance program and other systematic approaches have to be established for facilitating the ADR reporting culture in India.

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