Original Research Article

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A demographic study on gender related differences in adverse drug reactions of a tertiary care teaching hospital

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ABSTRACT

Background: As a part of pharmacovigilance program of India (PvPI) adverse drug reactions (ADRs) are cause of mortality and morbidity in patients unnoticed, which is a part of WHO program for International Drug Safety Monitoring across world. ADRs are considered to be among top 10 causes for mortality. The reason for sex difference in medication response is multi factorial with wide range of aspects like steroid hormones, organ physiology to psychology and socio-cultural factors. The aim was to study on gender related differences in adverse drug reactions in patients attending tertiary care teaching hospital at Nandyal.

Methods: ADR cases were collected from multicenter health care units from tertiary care teaching hospital. ADRs were reported in ADR notification forms or yellow form, CDSCO forms are used to report ADR to Regional pharmacovigilance center. Causality assessment of the ADRs was done based on WHO-UMC causality assessment scale using modified Hartwig and Seigel scale.

Results: In the 30 ADR reports collected 21 reports (70%) are of female patients and 9 reports (30%) are of male patients. According to WHO-UMC scale 20 (70%) of Adverse drug reactions were falling into PROBABLE, while 10 (30%) ADR's are CERTAIN. In 21 females, ADR reports were due to 15(76.43%) Antibiotics, 2 (9.52%) NSAID's, 2 (9.52%) proton pump inhibitors, 2 (9.52%) anti-convulsants. In 9 males, ADR reports were due to 5 (55.5%) Antibiotics, 2 (22.22%) NSAID's, 2 (22.22%) anti-convulsants.

Conclusions: ADRs are the common occurrences but ADR monitoring helps in prevention of morbidity and mortality in patients. The most commonly affected gender is among female patients, as they are more exposed to drugs starting their journey right from the childhood, pregnancy till their adult menopausal stage.

Keywords: ADR, CDSCO, Pharmacovigilance center, WHO-UMC

INTRODUCTION

According to WHO an adverse drug reaction is defined as any response of a drug which is noxious, unintended and which occurs at normal doses used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. In recent years there has been growing interest and increasing

recognition that gender may play a significant role in a person's response to medication in relation to ADRs, as a result of desired effects of drug due to pharmacokinetics and pharmacodynamics occurring in patients.¹

The reasons for sex difference in medication response are clearly multi factorial, encompassing a wide range of aspects of sex steroid hormones and organ physiology to psychology and socio-cultural factors.³ Sex or gender

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may be significant risk factors for the development of adverse drug reactions, side effects and complications of medication are more prevalent in woman than men. Multiple drug use may be more common in women, leading to an increased propensity for unwanted drug reaction. The present study conducted was to know for the incidence of ADRs among genders, as one of the factors predispose to ADRs along with age, immunity, polypharmacy and in relation to pharmacogenomics. Therefore study on assessment of ADRs would help in safer drug therapy and which can be prevented in controlling mortality and morbidity in female patients compared to men.⁵

METHODS

It is a prospective observational study done for a period of 6 months from Nov 2016- Apr 2017; where ADR cases were collected from various health care centers in and around Nandyal village.

Inclusion criteria

Among all suspected ADRs who got admitted were reported and were getting treated in emergency care units and also from all peripheral centers.

Exclusion criteria

- i. Physicians who refused to report ADRs or under reported were excluded. 12
- ii. Using of alternative system of medicines like Ayurveda, Homeopathy, Unani were not considered.
- iii. Incomplete data related to drugs causing ADRs were excluded.
- iv. Comatose patients unable to respond to verbal questions were also excluded from the study.

ADRs were reported taking ADR notification forms, CDSCO forms are used to report adverse drug reaction. Causality assessment of the ADR's was done based on WHO-UMC causality assessment scale. Severity assessment of adverse drug reaction was done based on the modified HARTWIG AND SEIGEL scale. 4.8

After Collection of data, and were tabulated. Statistics applied for data in the study is Chi Square Test run by SPSS-24 and results were obtained. The statistical association between the parameters was observed. The results were compared to the p<0.05 for significant association between sex, type of classified ADRs and systems involved with drug interactions as outcome of the study accepting null hypothesis and where p>0.05 was accepting alternative hypothesis.

RESULTS

A total of 30 ADR reports are collected, in that majority of Adverse drug reaction reports are from female

patients. In the 30 ADR reports collected 21 reports (70%) are of female patients and 9 reports (30%) are of male patients. According to WHO-UMC scale 20 (70%) of Adverse drug reactions were falling into probable, while 10 (30%) ADR's are certain. In female patients out of 21 ADR reports 11 (52.38%) were related to cutaneous system, 8 (38.09%) were related to GI system, 2 (9.52%) related to respiratory system. In males of the 9 ADR reported 7 (77.7%) were related to cutaneous system, 2 (22.2%) were related to GI system. In 21females, ADR reports were due to 15 (76.43%) Antibiotics, 2 (9.52%) NSAID's, 2 (9.52%) proton pump inhibitors, 2 (9.52%) anti-convulsants. In 9 males, ADR reports were due to 5 (55.5%) Antibiotics, 2 (22.22%) NSAID's, 2 (22.22%) anti-convulsants.

Table 1: Distribution of sex.

Sex	Frequency	Percent
Male	9	30.0
Female	21	70.0
Total	30	100.0

Table 2: Classification of ADRs as per WHO-UMC scale.

Classification of ADRs	Frequency	Percent
Certain	10	33.3
Probable	20	66.7
Total	30	100.0

Table 3: Distribution of ADRs according to systems involved.

Systems involved in ADRs	Frequency	Percent
Cutaneous ADRs	18	60.0
Gastro intestinal ADRs	10	33.3
Respiratory ADRs	2	6.7
Total	30	100.0

Table 4: Distribution of ADRs according to relation with drugs.

Drugs associated with ADRs	Frequency	Percent
Antibiotics	20	66.7
NSAIDs	4	13.3
Anticonvulsants	4	13.3
Proton pump inhibitors	2	6.7
Total	30	100.0

Table 5: Sex* Classification of ADRs.

	Certain	Probable	Total
Male	4	5	9
Female	6	15	21
Total	10	20	30

*P-value is 0.398, more than 0.05 which is accepting Alternate hypothesis.

Table 6: Sex* Systems involved in ADRs.

	Cutaneous	Gastro Intestinal	Respiratory	Total
Male	7	2	0	9
Female	11	8	2	21
Total	18	10	2	30

^{*}P value is 0.366, more than 0.05 which is accepting alternate hypothesis.

Table 7: Sex*drugs related to ADRs.

	Antibiotics	NSAIDs	Anticonvulsants	Proton Pump Inhibitors	Total
Male	5	2	2	0	9
Female	15	2	2	2	21
Total	20	4	4	2	30

^{*}P value is 0.454, more than 0.05 which is accepting alternate Hypothesis.

Table 8: Classification of ADRs* Drugs related to ADRs.

	Antibiotics	NSAIDs	Anticonvulsants	Proton Pump Inhibitors	Total
Certain	4	0	4	2	10
Probable	16	4	0	0	20
Total	20	4	4	2	30

^{*}P value is 0.001, less than 0.05 which is accepting alternate hypothesis.

Table 9: Systems involved in ADRs * drugs related to ADRs.

	Antibiotics	Nsaids	Anticonvulsants	Proton pump inhibitors	Total
Cutaneous ADRs	11	3	2	2	18
Gastro intestinal ADRs	7	1	2	0	10
Respiratory ADRs	2	0	0	0	2
Total	20	4	4	2	30

^{*}P value is 0.817, more than 0.05 which is accepting alternate hypothesis.

Table 10: Classification of ADRs * drugs related to ADRs.

	Antibiotics	NSAIDs	Anticonvulsants	Proton pump inhibitors	Total
Certain	4	0	4	2	10
Probable	16	4	0	0	20
Total	20	4	4	2	30

^{*}P value is 0.001, less than 0.05 which is accepting alternate hypothesis.

Table 11: Sex * systems involved in ADRs.

	Cutaneous ADRs	Gastro Intestinal ADRs	Respiratory ADRs	Total
Male	7	2	0	9
Female	11	8	2	21
Total	18	10	2	30

^{*}P value is 0.366, more than 0.05 which is accepting alternate hypothesis.

DISCUSSION

In nature males and females have many biological differences which affect pharmacokinetics (Pk) and pharmacodynamics (Pd) action of drugs. Women when compared to men have lower body weight, small organ size, more fat distribution and with low glomerular filtration which alters absorption, distribution, metabolism and elimination of drugs. Therefore the

common gender getting affected in the study was showing females compared to males, the reactions related to drugs were due to dose and pharmacological action of the drug.² Lucca et al, in their study concluded that female patients had more ADRs compared to men who were put on antipsychotics.⁵

In the present study, drugs involved in causing ADRs were more from antibiotics followed by NSAIDs and

anticonvulsants. The same cause of ADRs were concluded by Rehan et al, due to infections where antibiotics reported to be the most common which were prescribed irrationally, followed by analgesics and anticonvulsants. The systems involved in ADRs due to drugs were mostly cutaneous lesions followed by gastro intestinal effects and respiratory effects which was similar to the study done by Ramesh.

The study had limitations, shows that the number of cases reported is few due to unrecognized ADRs, under reporting of ADRs followed by phobia by the treating doctors not to report as it may cause bad reputation. Most of the ADRs were Probable based followed by Certain in our study which was similar to study done by Jovic et al.¹¹

CONCLUSION

ADRs are the common occurrences but ADR monitoring helps in prevention of morbidity and mortality in patients. The most commonly affected gender is among female patients, as they are more exposed to drugs starting their journey right from the childhood, pregnancy till their adult menopausal stage. Therefore results from data suggest and confirm that ADRs represent an important problem especially in female population, should be considered as serious issue. Therefore everyone should strive for better evidence based medicine approach and should follow rational usage of medicines in order to improve quality of life for women who are responsible for bearing future generations to come into this world.

Recommendations

- Majority of the adverse drug reactions reported are in females. So caution should be taken while prescribing drugs to females.
- Majority of the ADR's been due to the use of Antibiotics so they should be given carefully and stop unnecessary usage of Antibiotics.
- Every health care professional should be aware of possible adverse drug reactions and should work to minimize them.
- Most of the Drug Trial studies conducted showed less of female participation, therefore there is a need for more number of studies.
- As ADRs are under reported, need for more awareness for ADR reporting's by Medical Officers, clinicians, nursing staff and patients.
- There is a need for more of Pharmaco-genomic studies which help clinicians to conclude and confirm the cause for ADRs.
- Need for training in reporting of ADRs by Medical Officers at Primary Health Centers to improve quality of life in rural population by avoiding irrational usage of drugs in the community.
- To adopt rational use of drugs by PHC medical officers for safe usage of drugs in the community.

• To educate the rural population regarding early reporting of Adverse Drug Reactions to prevent mortality in the community.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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