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Prescribing Patterns of Antihypertensives in Pregnancy Induced Hypertension (PIH) in Relation with Food and Drug Administration (FDA) Categories and Essential Drug List in Two Tertiary Care Hospitals Gulbarga

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ABSTRACT

To describe the prescribing pattern of Antihypertensives in relation/respect with Food and Drug Administration categories and essential drug list used in pregnancy induced hypertension in two tertiary care hospitals. Study was carried out in Obstetrics and Gynecology Department of two tertiary care hospitals, Gulbarga from January 2010 to December 2010 by collecting the data from MRD Medical Record Department of Sangameshwar General Hospital and Government General Hospital, Gulbarga. A total of 200 prescription data was collected. In our study category A and X drugs were not at all used. More percentage of drugs used belonged to category 'C', comparatively, followed by B and D. Most of the Essential drugs used belong to Essential drug list June 2011. In our study majority prescriptions were belongs to category C, for which safety data on humans were not unknown. Therefore educational programmes are required for rational prescribing to treat pregnancy related illness.

Keywords: Prescribing patterns, Antihypertensives, Food and Drug Administration, Essential Drugs.

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INTRODUCTION

Hypertension in pregnancy involves a significant risk to both mother and baby. Although the incidence of eclampsia is falling, hypertension in pregnancy still results in some maternal deaths, and can cause miscarriages, preterm deliveries, and small for date babies due to placental problems. Mothers can be left with chronic hypertension and inherited lifelong cardiovascular risk. Chronic hypertension affects 1-5% of pregnancies. Pregnancy induced hypertension affects 5 to 10% of all pregnancies and is more common in first pregnancies (upto 25%). [1,2]

Though general instruction is to avoid unnecessary medication during pregnancy, nearly 35% of women reportedly take at least one drug during pregnancy [3]. Women with chronic illnesses already stabilized on treatment will at times require to take the drugs during pregnancy for a better maternal and fetal outcome. Appropriate dosing medications also play an important role during pregnancy which can be difficult, as physiological changes occur throughout pregnancy, that can cause deviation from the expected pharmacokinetic process in the pregnant patients and necessitate dose adjustments [3,4-7].

A fine balance needs to be maintained to avoid over dosing as well as inadequate treatment. Most drugs admitted to the pregnant mother cross the placenta and may affect the physical or mental development of the foetus or may have delayed effect on the neonate. Because of the potential risk of teratogenicity, FDA has categorized drugs into different categories.

FDA Categories for drugs and medications [8].

Category A	Human studies show no fetal risk e.g multivitamins or prenatal vitamins
Category B	No fetal risk in animal studies but there are no human studies.
Category C	No adequate studies in animals / human or there are adverse fetal affects in animal studies but no available human data.
Category D	Evidence of fetal risk but benefits are thought to out weigh these risks.
Category E	Proven teratogens.

During pregnancy the drug use may be required for

- Treatment of common minor ailments
- Treatment of pre existing or pregnancy aggravated medical illness like hypertension.

Drugs suitable for non urgent blood pressure are.

- Methyl Dopa,
- Adrenergic bloking agents, Eg., Atenolol, Acebutalol, Labetalol are widely used.
- Calcium channel antagonists Eg., Nifedipine, Diltiazem, and Nicardipine.

- Miscellaneous are prazosin, Hydralazine are used as second line drugs.

Drugs for hypertensives emergencies are

- Hydralazine
- Labetalol
- Nifedipine
- Nitropruside

On the other hand essential medicines are defined as those that satisfy the health care needs of the majority of a population [9]. The world health organization defined essential medicines based on the premise that a limited list of carefully selected medicines, will improve quality of health care, provide cost – effective health care and better management of medicines [9]. The first WHO model list of essential published in 1977, now the seventeenth WHO model EML published in March 2011, is proof that the concept is still valid after nearly 34 years and continues to have many advantages when it is used approximately in conjunction with standard treatment guidelines [10].

The National list of essential medicines of India (NLEMI 2011) was revised recently [11] by the ministry of health, family welfare (MOH & FW), government of India in June 2011, nearly eight years after the previous list, in the directions of the supreme court of India [12]

Objectives: To describe the prescribing patterns of antihypertensive in relation with FDA categories and essential drug list used in Pregnancy Induced Hypertension (PIH) in two tertiary care hospitals. [GULBARGA].

METHODOLOGY

Subjects and Methods

Study setting

Obstetric and gynecology dept of two tertiary care hospitals.

- Sangameswar General and Teaching Hospital Gulbarga.
- Govt. General Hospital Gulbarga.

Sample size

100 prescriptions each were collected from Medical Report Department (MRD) from both hospitals during the period Jan 2010 to Dec 2010.

Ethical Consideration

Study was carried out after the permission obtained from the institutional ethical committee. Permission was also obtained from HOD of Gynaec and Obstretics from both hospitals, to collect the data from Medical Record Department (MRD).

Procedure

Inpatient records were accessed from record section of both the hospitals. Relevant data was tabulated in the pre prepared proforma.

Informed Consent

Not applicable as the study involved only retrospective analysis of records.

Statistical analysis

Was done by using simple random sampling method.

RESULTS

A total of 252 antihypertensive drugs were used in Sangameshwar Hospital and 192 drugs in Govt. General Hospital, Gulbarga (Table 1). In our study the drugs belonging to category A were not at all used (Table 2 and 3). Five out of 252 category B drugs (1.98 %) were used in Sangameshwar Hospital compared to 11 out of 192 (5.72%) in Govt. General Hospital. Category C drugs in total used were 244 (96.82%) in Sangameshwar Hospital, 181 (94.7%) in Govt. General Hospital. Total number of category D prescribed were 3 (1.19 %) in Sangameshwar Hospital. But in government hospital category D drugs were not prescribed. Percentages of different categories of drugs were mentioned in table 3.

Out of 11 antihypertensives used in our study, 10 drugs were used from Essential drug list. Essential drugs used in our study were as follows:

1. Tab Myogard (Nifedipine)
2. Inj Lasix (Furosemide)
3. Tab Stambo (Amlolipine)
4. Tab Depin (Nifedipine)
5. Tab Methyl Dopa (Methyldopa)
6. Tab Nicardia Retard (Nifedipine)
7. Tab Aten (Atenolol)
8. Tab Amlong (Amlodipine)
9. Tab Aldactone (Spicanolactone)
10. Tab Alphasopa (Methyl dopa)

Tab Ditide (Benzthiazide+Triamterene) prescribed was not included in essential drug list

Table 1: Total number of drugs used in both the hospitals.

Name of Drug	Sangameshwar Hospital	Govt. General Hospital
Tab. Myogard	89	82
Tab Ditide	74	38
Inj. Lasix	41	34
Tab. Stamblo	28	07
Tab. Depin	07	17
Tab Methyl Dopa	04	09
Tab Nicardia	01	-
Tab Aten	03	-
Tab Amlong	02	03
Tab Aldactone	02	-
Tab Alphadopa	01	02
Total	252	192

Total number of drugs used in Sangameshwar Hospital – 252.

Total number of drugs used in Govt. General Hospital – 192.

Table 2: Name of Antihypertensives used according to FDA Categories

Name of Drugs	Sangameshwar Hospital	Govt. General Hospital	Category of Drugs
Tab Myogard	89	82	C
Tab Ditide (Benzathiazide + Tromterene)	74	38	C
Inj Lasix (furosemide)	41	34	C
Tab Stamblo (Amlodipine)	28	07	C
Tab Depom (Nifedipine)	07	17	C
Tab Methyl Dopa	04	09	B
Tab Nicardia Retard (Nifedipine)	01	-	C
Tab Aten (Atenolol)	03	-	D
Tab Amlong (Amlodipine)	02	03	C

Tab Aldartone Spineanalactone	02	-	C
Tab Methyldopa	01	02	B
TOTAL	252	192	

Table 3: Percentage of Different Category of Drugs used during Pregnancy

Category of Drugs	Sangameshwar Hospital	%	Govt. General Hospital	%
A	--	--	--	--
B	05 [252]	1.99	11 [192]	5.72
C	244 [252]	97.2	181 [192]	94.7
D	03 [252]	1.19	--	--

- Category A – No drugs were used.
- Category B – Tab Methyldopa.
- Category C – Tab Myogard, Tab Ditide, Tab Lasix, Tab Stamblo, Tab Depin
Tab Nicardia Tetard, Tab Amlong, Tab Aldactome
- Category D – Tab Aten.

DISCUSSION

Rational drug use in pregnancy requires the balancing of benefits and potential risks. The benefits of rational drug use during pregnancy are not only restricted to the recovery of maternal health, but also helpful in the development of the fetus. By appropriate treatment of conditions like Diabetes mellitus and infectious diseases of genital organs, embryopathies, preterm birth and abortions could be prevented [13,14].

In our study, category A drugs were not at all used, but when compared with the study done by Dr. Rashmi, majority of the drugs used were from category A [15]

In the present study category B drugs used in Sangameshwar Hospital was 1.98% and Govt. General Hospital was 5.72% but comparatively less with Dr. Rashmi, et al., study.

Category C drugs prescribed in our study were 96.82 % in Sangameshwar Hospital and 94.27% in Govt. General Hospital in contrast to 2.9 % prescribed in study done by Dr. Rashmi et al.

Category D drugs used in Sangameshwar Hospital was 1.19% which is similar to reports from other developed and under developed countries of the world [16-19].

In a retrospective, register based cohort study in Finland it was found that 20.4% of women purchased at least one drug classified as potentially harmful during pregnancy and 3.4% purchased at least one drug classified as clearly harmful [20].

In a study from Bratislava and Nitra it was reported that vast majority of prescribed drugs during pregnancy belong to Category C [21].

Regarding Essential drugs 90-95% of drugs used belonged to Essential drug list in both of the hospitals.

CONCLUSION

In our study drugs grouped in category C were used more commonly, for which safety data in human were not available. Therefore health care professional make efforts to improve the prescribing patterns to deliver better health care service. This can be improved by continued CME, seminars, integrated teaching, group discussions. Similar studies are required in primary and secondary care hospitals, thereby therapeutic guidelines could be revised accordingly, to give rational care to the community.

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