



Prescription pattern of drugs during pregnancy in a tertiary care centre: A retrospective study

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Abstract:

Despite the absence of adequate studies on the safety and effectiveness of prescribing drugs during pregnancy evidence available shows that physicians prescribe and pregnant women self medicate surprisingly large number of drugs. This study is designed to evaluate the current drug utilization pattern during Pregnancy. The retrospective study involved data collected from 150 pregnant women who have delivered in the tertiary care hospital. Information regarding the gravida, number of ANC visits per pregnant woman, disease status and the drugs prescribed during pregnancy was collected. The data were analysed using SPSS and descriptive statistics was used. Around 90% of pregnant women attended more than 3 ANC visits and among diseases suffered pre-eclampsia was the most frequent (45.33%) followed by gastrointestinal disturbances (32%). Nutritional supplements including iron and folic acid supplements were the most commonly prescribed in more than 93% which is followed by tetanus toxoid(92%). Cephalosporin was the most commonly prescribed antimicrobials for systemic infections. Most of the Drugs consumed belong to category A, B & C of FDA categorisation while only 2 drugs i.e. Diazepam & Atenolol belonged to Category D. Majority of the pregnant women attended Antenatal Clinic as per the WHO guidelines. The drug utilization pattern was found to be rational in this study as almost all the drugs prescribed were compatible with the FDA categorisation. The most frequently observed medical condition was Pre-eclampsia.

Key words: Drug prescription, Pregnancy, Antenatal Care

Introduction:

Pregnancy is a time of profound physiological changes in a woman's body. These unique changes during pregnancy challenge the clinicians in managing disease states in the selection of medications best suited to treat them. Maternal drug use during pregnancy may pose a teratogenicity risk to the foetus. However, avoiding all drugs during early pregnancy is unrealistic and may be dangerous to the health of the mother and indirectly to that of the foetus too. Pregnancy should not deter clinicians from providing their patients with appropriate management of their medical conditions; hence, prescribing in pregnancy is an unusual risk benefit situation.¹ Since 1980, less than 10% of medications approved by

U.S. Food and Drug Administration (FDA) have enough information to determine the teratogenic risks.²

Information on use of drugs during pregnancy is scarce and rather anecdotal.¹ Despite the absence of adequate studies on the safety and effectiveness of prescribing drugs for pregnant women, evidence available shows that physicians prescribe and pregnant women take (often self medicated) a surprisingly large number of drugs.^{1,3} However it has been documented that congenital anomalies caused by drugs account for less than 1% of total congenital anomalies.³

The primary objective of the study was to evaluate the current drug utilization pattern during pregnancy. The secondary objectives were to find the disease seeking medical attention pattern during antenatal

period and categorization of drugs prescribed according to FDA classification.

Materials & Methods:

This study was conducted at Sree Siddhartha Medical College, a tertiary care centre located in Tumakuru, Karnataka a southern part of India. A prior permission from the hospital authorities and ethics committee approval has been obtained. Data was collected from the medical records department of the hospital wherein case sheets of 150 pregnant women who have delivered were randomly retrieved. Information regarding the gravida, number of ANC visits per pregnant woman, disease status and the drugs prescribed during pregnancy was collected.

After getting the complete list of drugs they were classified into categories based on classification for drug use during pregnancy, introduced by the US Food and Drug Administration (FDA) in 1979. Category A drugs show no foetal risk, Category B drugs are also quite compatible as there is not much evidence (both animal and human studies have failed to prove any substantial risk), Category C drugs are harmless at lower doses, Category D drugs have proved teratogenic potential but has been deemed to be essential to administer only in case maternal life is threatened by some diseased state. Category X drugs are "contraindicated in women who are or may be pregnant".^{4,5} The data were analysed using SPSS and descriptive statistics was used.

Results:

Among the 150 case of pregnant women, 64 (42.67%) were primigravidae while the remaining 86 (57.33%) were multigravidae. Pregnant women attending more than 3 ANC visits during their period of pregnancy was 90%. Among diseases

suffered during pregnancy for which medical attention was received, pre-eclampsia was the most frequent (45.33%) followed by gastrointestinal disturbances (32%), systemic infection like UTI & RTI (21.33%) and others. (Table I)

Nutritional supplements were the most commonly prescribed drugs, which is followed by tetanus toxoid. Antimicrobials accounting for 46.67%, wherein the most commonly prescribed were cephalosporin for systemic infections, fluoroquinolones and anti-amoebic drug combination was given for bacterial gastroenteritis and amoebiasis. Antihypertensive prescribed for pregnancy induced hypertension form the next major group (45.33%) followed by drugs acting on gastrointestinal tract (24%), anticonvulsants and analgesics 10%. Aspirin was used as antiplatelet drug in pre-eclampsia and as a prophylactic agent for patients with bad obstetric history. Betamethasone and pheniramine maleate was given as pre transfusion medicine in case of blood transfusion (Table II). Most of the Drugs consumed belong to category A, B & C of FDA categorisation while only 2 drugs i.e. Diazepam & Atenolol belonged to Category D (Table III).

Discussion:

Drugs are prescribed in pregnancy in spite of paucity of data on its safety. Thus constant monitoring on drug prescription has to be done to prevent any threat for future generation and hence many studies have been carried out all over the world irrespective of the developmental status of the nation. The present study was conducted at a tertiary care hospital to find out the drug utilization pattern in pregnancy and simultaneously the other parameters like frequency of ANC visits, disease status during pregnancy and categorization of these prescribed drugs as per the FDA guidelines.⁴

Table I: Diseases for which medical treatment received in tertiary care hospital

Sl. No	Medical Conditions	No	Percentage
1.	Pre-Eclampsia (Pregnancy Induced Hypertension)	68	45.33%
2.	Loose Stool/Dyspepsia /vomiting	48	32.00%
3.	Urinary Tract /Respiratory Tract Infection	32	21.33%
4.	Eclampsia	10	6.67%
5.	Pre-Term Labour	7	4.67%
6.	Anaemia	5	3.33%
7.	Per-Vaginal Bleeding/ Spotting	5	3.33%
8.	Suspected case of Pre-eclampsia (because of previous Bad Obstetric History)/IUGR	5	3.33%
9.	Oligo-hydramnios	4	2.67%
10.	Symptoms of Abdominal Pain	15	10.00%

In the present study it was found that most of the pregnant admitted were multigravidae and 90% of them had ANC visits more than 4 times which is as per the WHO guidelines for developing Countries.^{6,7} However 5 women did not have even a single ANC visit. The reason for more ANC visits may be due to the pregnant awareness or to prevent any

complications that have occurred in previous pregnancy.

Looking at the reasons for admission, more than 100 out of 150 were admitted to manage their pregnancy related illness like pre-eclampsia, suspected pre-eclampsia, eclampsia, growth retardation, anaemia etc than other systemic illness like infections, loose stools etc. Patients may be preferring tertiary care centre for managing such pregnancy related illness.

Similar studies were conducted by Uchenna IE in Nigeria in 2007 and Rohra DK in Pakistan in 2008.^{1,8}

With reference to the drugs utilized in pregnancy, it was found that nutritional supplements like folic acid, iron, calcium, and protein supplements were the most commonly prescribed drugs this result being same as that observed in Western Nepal.⁽⁹⁾ Most of the women had taken 2 doses of tetanus toxoid (90%) in the 2nd trimester as per the schedule.^{10,11} Urinary tract and respiratory tract infections were the common infections encountered for which antimicrobials, especially cephalosporins were administered (46.67%) and for enteritis, fluoroquinolones and anti-amoebic drugs like ornidazole or tinidazole was given. Pre-eclampsia was reported very high in this group for which antihypertensive like methyldopa, labetalol, nifedipine, amlodipine and atenolol were prescribed. Gastrointestinal drugs like ondansetron, ranitidine and metoclopramide were prescribed for nausea, vomiting and dyspepsia. Paracetamol was the sole analgesic which was prescribed for pain as and when required. Aspirin was used as antiplatelet drug was used in Pre-eclampsia and IUGR and as a prophylactic for patients with bad obstetric history. Betamethasone and pheniramine maleate was given to all patients of anaemia who went for blood transfusion. Isoxsuprine was the preferred drug given in cases of pre-term labour.

After obtaining the complete list of drugs they were categorized based on the FDA

Table II: Drugs prescribed during antenatal period

Sl.No	Name of Drugs Prescribed	Number of pregnant	Percentage
1.	Nutritional Supplements:	150	
	Folic Acid	145	96.67%
	Iron	140	93.33%
	Calcium	138	92%
	Protein Supplements	142	94.67%
	Vitamin E	5	3.33%
2.	Tetanus Toxoid	135	90%
3.	Antimicrobials:	70	46.67%
	Cefixime	8	
	Ceftriaxone	12	
	Ceftizidime	10	
	Cefotaxime	22	
	Ofloxacin + Ornidazole	8	
	Norfloxacin + Tinidazole	10	
4.	Antihypertensives:	68	45.33%
	Labetalol	28	
	Methyldopa	25	
	Nifedipine	10	
	Amlodipine	3	
	Atenolol	2	
	Gastrointestinal Drugs:	36	24%
	Metoclopramide	12	
	Ondansetron	10	
	Ranitidine	14	
6.	Anticonvulsants:	15	10%
	Magnesium Sulphate	10	
	Diazepam	5	
7.	Analgesics: Paracetamol	15	10%
8.	Antiplatelet and antithrombotics:	13	8.67%
	Aspirin	9	
	Low molecular Heparin(enoxaparin)	4	
9.	Corticosteroids: Betamethasone	12	8%
10.	Sympathomimetic: Isoxpurine	7	4.67%
11.	Antihistamine: Pheniramine maleate	5	3.33%

Sl. No.	FDA Categories	Drugs Prescribed
1.	A	Folic Acid, Iron Tablets, Calcium Tablets, Protein Supplements, Vitamin E.
2.	B	Magnesium Sulphate, Methyl dopa, Cefixime, Ceftriaxone, Ceftizidime, Cefotaxime, Metoclopramide, Ondansetron, Ranitidine, Paracetamol
3.	C	Aspirin, Betamethasone, Isoxpurine, Phenyramine Malate, Furosemide, Norfloxacin, Ofloxacin, Amlodipine, Nifedipine, Tetanus Toxoid.
4.	D	Diazepam, Atenolol.
5.	X	--

Table III: Categorization of Drugs [According to the FDA Categories]

category.⁴ Majority of the drugs belonged to schedule A, B and C. There are some drugs which are not completely safe but were administered as the benefits outweighed the risks.

Limitations: Complete data on the drugs usage, adherence to treatment and over the counter drugs used could not be evaluated because it was a retrospective study. Such study if done prospectively with large number of subjects will give more information.

Conclusions:

The drug utilization pattern was found to be rational in this study as almost all the drugs prescribed were compatible with the FDA categorisation. The most frequently observed medical condition was pre-eclampsia. Drugs most commonly prescribed were nutritional supplements. Majority of them attended Antenatal Clinic as per the WHO guidelines.

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