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Original Article

Essential Medication Prescription and Associated Maternal Characteristic among Hospitalized Pregnant Women: A Retrospective Population Based Study

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ABSTRACT

Objective: There are limitations of Food and Drug Administration pregnancy risk classification system and pregnancy information, surplus resources are essential to evaluate the safety and to assess the risk-benefit ratio of medication use in pregnancy. The aim of the study is to characterize medication use in hospitalized pregnant women during antenatal period and correlate maternal characteristics in this population. **Methods:** It is a retrospective cross-sectional survey. Data of hospitalized pregnant women was collected. The FDA pregnancy risk classification was categorized for the prescribed drugs. Descriptive analysis was performed for demographic and maternal characteristics. Pearson Chi-square Fisher's exact tests are used to observe the association between the independent variables and outcome variables. Adjusted odds ratios (ORs) and 95% CIs were also estimated. Each outcome variables whose levels were with a P (< 0.05) was significant. **Results:** Among 505 pregnant women, 75.24% were hospitalized during third trimester, and 3.17% were having comorbid conditions. 60.59% of the pregnant women received more than or equal to five drugs. 39.86% are exposed to FDA C, D or X categories of drugs during pregnancy. Category B drugs are frequently prescribed. Women whose parity is ≥ 2, length of hospital stay and with at least five medications prescribed are the factors associated to prescription of FDA C, D or X drugs during pregnancy. **Conclusion:** There was considerable use of medicines among the pregnant women as per the essential drug list complying fully with World Health Organization recommendations by using their international non-proprietary names.

Key words: Pregnancy, Classification, Drug utilization, Public health hospital, Retrospective study.

Key Messages: In this population of hospitalized pregnant women, 45.07% are prescribed with FDA category B drugs though it is relatively safe, it warrants that the treating physician to be more cautious while prescribing medications as they might possess potential risk to foetus and mother during the antenatal care.

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INTRODUCTION

The drug use during pregnancy can be a major concern either by temporary and permanent structural and functional adverse effects on both the foetus and mother. This will pose a major challenge and also warrants for a careful consideration of many aspects that would influence the decision to determine the medication use for each selected indication by health care providers during the antenatal care.[1] To attain the safe use of drug throughout the pregnancy, the United States Food and Drug Administration (US FDA) has classified the drugs into major categories A, B, C, D X and unknown according to the risk to foetal health. Most of the drugs used in the pregnancy are classified under category C due to lack of data. Whereas categories D and X have an evidence of foetal risk.[2,3] Many drug utilization studies have reported that around 44 to 99 per cent of pregnant women use medications.[4] In one study conducted in Denmark found that 18% of pregnant women during their antenatal care have been prescribed with at least one drug and 1% reported to have ≥ 5 prescriptions that can cause potential harmful effects on the foetus. In other study conducted in France, 59% of the pregnant women were prescribed with category D, 79% received the drug whose pregnancy risk classification is unknown. 1.6% of the pregnant women received category X drug.[5] Thus the inappropriate use of medications has been reported extensively among the pregnant women worldwide.[6,7] In India, many use the prescription drug with very less information on the extent and type of drug use, which pregnant women further emphasis on definition for rational prescription.[7,8] In the present set up of secondary care Government District Headquarters Hospital, Udhagamandalam, there was no such study conducted to evaluate the safety and effectiveness use of medications among pregnant women. Hence, this retrospective survey was conducted to find most recent prescribing pattern and most possible teratogenicity risk to foetus in hospitalised pregnant women during their antenatal care.

MATERIAL AND METHODS

The present study was a retrospective survey conducted at a secondary care 420 bedded hospital located in Udhagamandalam the Nilgiris district, Tamilnadu, India. The primary objective of the study was to analyze the prescription pattern of C, D and X (as per FDA guidelines) among the hospitalized pregnant women at obstetrics and gynecology unit. The data was collected retrospectively for duration of six months (June to December 2015) from medical records of hospitalized pregnant women with pregnancy confirmed by ultrasonography results. Medical records were reviewed and included for the study as per the inclusion and exclusion criteria. The pregnant women who were prescribed with

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at least one prescription for any treatment at the in-patient set up are considered as exposed to medication and their medical records were included. Those pregnant women in whom the prescription drug information is not available were excluded from the study. Information on maternal and obstetrics characteristics of the pregnant women such as age, plurality (that is, number of foetuses of the present pregnancy), parity (based on numbers of live births and stillbirths), gravidae (number of pregnancy), socio-demographic information, drugs prescribed, dosage form, route of administration, main diagnosis, and the trimester during drug administration was collected in a specially designed proforma. The collected data was checked for completeness manually by the Clinical Pharmacist. Drugs that were dispensed, were identified and classified according to the FDA risk classification (A, B, C, D, and X) and therapeutic class. Based on International Classification of Diseases 10th revision was used. The study was approved by the Institutional Review Board, JSS College of Pharmacy, Ootacamund (JSSCP/DPP/IRB/02 2015-16) before initiation.

The collected data were categorized and analysed. Descriptive analysis was performed for demographic characteristics, pregnancy information, medical condition, prescribed drugs and its pattern. Pearson Chi-square Fisher's exact tests were used to observe the association between the independent variables and outcome variables. Adjusted odds ratios (ORs) and 95% CIs were also estimated. Each outcome variables whose levels were with a P (< 0.05) was significant. All analyses were performed using GraphPad Prism version 6.04 for Windows (GraphPad Software, La Jolla California USA, (www.graphpad.com) and SPSS version 22.0 (SPSS Inc., Chicago II, USA) for windows.

RESULTS

Among the 520 pregnant women hospitalized during the study period a total of 505 received 2840 medications during the study period. 83.16% of the women were in the age group of 21-34 years and the mean age was found to be 24.17±3.5 years demonstrating normal reproductive age group. While 73 women (14.47%) were in the age of ≤ 20 and 12 (2.37%) women were in the age of ≥35. Out of 505 pregnant women, 49.50% were secundum gravidae, 34.85% were primigravidae and 15.65% were multi gravidae.

Most of the pregnant women are hospitalized during the third trimester (75.24%), followed by second trimester (12.88%) and (11.88%) during the first trimester. Out of 505 pregnant women 109 (21.58%) had a previous incidence of abortion. 3.17% pregnant women were found to have comorbid conditions.

From the total study population (39.41%) pregnant women were prescribed with ≤5 drugs and remaining (60.59%) were prescribed with ≥5 drugs during their hospitalized period. 52.07% pregnant women stayed ≤ 4 days in the hospital, (38.4%) pregnant women stayed 5 to 9 days and remaining 48 (9.5%) pregnant women stayed ≥10 days for their treatment. It was observed that the average duration of pregnancy was 8.8 months among the study population.

The most common medical condition experienced by the pregnant women was Iron deficiency anaemia (25.43%) (with code D 50 as per ICD-10 version), followed by (12.14%) experienced Urinary Tract Infection (with code O 23.4 as per ICD-10 version) during all the trimester. Table 1 describes the most common drugs received by the pregnant women. It was found Tablet Ferrous sulphate for the treatment of iron deficiency anaemia was highly prescribed (12.61%), followed by Vitamin B Complex (12.08%), Tablet Calcium lactate (11.44%) as a part of routine medications to be taken by all pregnant women and Inj. Cefotaxime 1g IV (7.74%) towards the management of Urinary tract infection and the less common drugs prescribed was Tablet Ibuprofen 400 mg (0.03%) and Tablet Dicyclomine 20 mg (0.03%). Majority of the patient received the drugs during the third trimester. Most of the patient received medication per oral (76.10%); followed by (23.72%) injectable and 0.17% received Topical preparations.

Table 2 shows the frequency distribution of prescription of FDA drug category. Among the drugs, FDA B category 1280 (45.07%) are the mostly prescribed medications, followed by category C 994 (35.00%). FDA Category D and A, 116 (4.08%) and 428 (15.08%) respectively are least prescribed. 22 (0.77%) of pregnant women received FDA Category X. Misoprostol (FDA Category X) during first and second trimester l3.62% and 0.73% respectively was prescribed for medical abortion (with code O 04.4 as per ICD -10 version). In third trimester the same drug was prescribed towards the management of induction of labour after intra-uterine foetal death (with code O 36.4 as per ICD-10 version). Out of total drug prescribed, category C, D and X accounted for 39.85% of prescriptions.

Table 3, describes the rates and adjusted odds of exposure and factors associated to prescription of FDA category C and D drugs among the pregnant women. Based on odds ratio, the odds of women with the age group of ≥ 35 years showed increased risk of exposure to FDA category C and D; OR 1.417, 95% CI:(0.4633,4.232) although the age of the pregnant women did not show any significant association to prescription of FDA category C and D drugs. The pregnancy related factors like parity, gravida and previous abortion history when analysed, most of the variables showed significant association to the prescription of FDA C and D category drugs. Whereas the factors like co-morbid condition, chronic and non-chronic conditions did have significant association towards the prescription of FDA category C and D drugs. The total number of medications prescribed, and duration of hospital day had significant association with the prescription of FDA category C and D drugs (P<0.0001). And the odds of exposure FDA category C and D drugs is more with respect to duration of hospital stay, OR 2.926, 95% CI:(1.876,0.4562) for 5 to 9 days.

Table 4, describes FDA pregnancy risk classification of medications of C, D and X against the pregnancy stages. With respect to prescription of FDA category C drugs and pregnancy stage of the women there was no significant association. Category D drugs prescribed to the pregnant women during all three trimesters also had a no significant association. There was a significant association to the prescription of FDA category X drug and different stages of pregnancy (P<0.0001). Based on the odds ratio, the odds of exposure of pregnant women to FDA Category X drug is higher OR 7.437, 95% CI :((3.146,17.58). When accounted for both FDA category of C and D drugs and pregnancy stage, there is no significant association.

DISCUSSION

The information regarding the safety use of medications during pregnancy is the utmost concerns.[9,10] It is apparent from the several studies that there is lot of variation of the medication use between the countries, the health care settings and the prescribing practice.[11] Thus the present study was undertaken to evaluate the prescription pattern of the drug during pregnancy as there is very limited information in the present hospital set up. 505 subjects were enrolled in the study and were in their normal reproductive age. The hospitalized pregnant women were in their secundum gravida and this is the like study conducted by Belay M, *et al.*[12] In our study 39.41% of the pregnant women were prescribed with less than five drugs. 3.17% of them had co-morbid conditions and 3.56% experienced chronic conditions. The number of medications used in the study is comparatively less when compared with the results of the studies performed in South Africa (59.3%), Palestine (56%), Egypt (86%) and USA.[13] In this study 81.58% of medications were prescribed during third trimester, and the findings are comparable with the study conducted by Yang T *et al.*[14]

Table 1: The most common drugs received by the pregnant women during the study.

Therapeutic class	Specific Medicine	ATC group	Total frequency n(%)
Analgesic (N02)	T.Paracetamol	N02BE01	200(7.04%)
	Inj. Paracetamol	N02BE01	19(0.67%)
	Inj. Pentazocine	N02AD01	2(0.07%)
Anesthetics (S02)	Inj. Lignocaine	S02DA01	10(0.35%)
Antianemic (B03)	T.Folic Acid	B03BB01	30(1.06%)
	T.FerrousSulphate	B03AA07	358(12.61%)
Antibacterial for systemic use (J01)	Inj. Ampicillin	J01CA01	70(2.46%)
	Inj. Ciprofloxacin	J01MA02	4(0.14%)
	T.Ciprofloxacin	J01MA02	7(0.25%)
	C.Amoxycillin	J01CA04	77(2.71%)
	T.Norfloxacin	J01MA06	5(0.18%)
	Inj.Cefotaxime	J01DD01	226(7.96%)
	C.Cephalexine	J01DB01	60(2.11%)
	Inj. Ceftriaxone	J01DD04	13(0.46%)
Antibiotics and chemotheraputics and dermatological use (D06)	Liq. Gentamycin Eye Drop	D06AX07	7(0.25%)
	Inj.Gentamycin	J01GB03	20(0.70%)
	Inj. Amikacin	D06AX12	8(0.28%)
Antidiarrheals (A07)	Oral rehydration salt	A07CA	14(0.49%)
Antihistamines for systemic use (R06)	T. Cetrizine	R06AE07	7(0.25%)
Anthelmintics (P02)	T. Albendazole	P02CA03	6(0.21%)
Antihistamines for systemic use (R06)	T. Chlorpheniramine maleate	R06AB02	1(0.04%)
	Syp. Cough syrup (ChlorpheniramineMeleate)		13(0.46%)
Anti-inflammatory (M01)	T.Ibuprofen	M02AA13	1(0.04%)
	T.Diclofenac Sodium	M01AB05	72(2.54%)
	Inj. Diclofenac Sodium	M01AB05	73(2.57%)
Anti -infectives for systemic use (J07)	Inj. Tetanus toxoid (Absorbed)	J07AM01	9(0.32%)
Anti –Microbial (A01)	T.Metronidazole	A01AB17	175(6.16%)
	Inj. Metronidazole	A01AB17	51(1.80%)
Anti septics and disinfectants (D08)	Cetrimide Cream	D08AJ04	4(0.14%)
Cardiac vascular system (C0)	T. Labetalol	C07AG01	45(1.58%)
	T.Nifedipine	C08CA05	20(0.70%)
	Inj. Furosemide	C03CA01	2(0.07%)
	Inj.Dopamine	C01CA04	2(0.07%)
Corticosteroid (R01AD)	Betamethasone valerate ointment	R01AD06	8(0.28%)
Diagnostic Radiopharmaceuticals (V09)	Inj.Cyanocobalamine	V09XX01	1(0.04%)
Drugs used for acid related disorders. (A0)	T.Ranitidine	A02BA02	189(6.65%)
	Inj. Ranitidine	A02BA02	152(5.35%)
	C.Omeprazole	A02BC01	3(0.11%)
	Liq.Antacid (Aluminum Hydroxide Gel, Magnesium Trisilicate, Methyl Polysiloxane)	A06AD15	2(0.07%)
Drugs for constipation (A06)	T. Bisacodyl	A06AB02	1(0.04%)
	T.Magnesium Sulfate	A06AD04	8(0.28%)
Drugs used in diabetes (A10)	T.Metformin	A10BA02	5(0.18%)
	Inj.Human insulin (short acting)	A10AD01	1(0.04%)
	Inj.Human insulin (intermediate acting)	A10AD01	1(0.04%)
Drugs for functional gastrointestinal disorders (A03)	Inj. Metaclopramide	A03FA01	12(0.42%)
	T.Dicyclomine	A03AA07	32(1.13%)
	Inj.Dicyclomine	A03AA07	1(0.04%)
	T.Domperidone	A03FA03	20(0.70%)
Drugs for obstructive airway diseases (R03)	T. Theophylline	R03DA04	5(0.18%)
	Neb.Salbutamol	R03AC02	15(0.53%)
IV Solutions (B05B)	Inj.Dextrose	B05BA03	2(0.07%)
Mineral supplements (A12)	T.Calcium Lactate	A12AA05	325(11.44%)
Pituitary and hypothalamic hormones (H01)	Inj. Oxytocin	H01BB02	10(0.35%)
Psycholeptic (N05)	T.Diazepam	N05BA01	1(0.04%)
Stomatological preparations (A01A)	Inj.Dexamethasone	A01AC02	15(0.53%)
Thyroid Therapy (H03)	T. Thyroxine sodium	H03AA01	11(0.39%)
Uterotonics (G02A)	T.Misoprostol	G02AD06	12(0.42%)
Vitamins(A11)	T.Vitamin B Complex	A11EA	343(12.08%)
	T.Ascorbic Acid	A11GA01	53(1.87%)
	T.Multivitamin		1(0.04%)
			2840

Table 2: Frequency of distribution of FDA drug category of the drug prescribed to pregnant women.

US FDA drug categories	First trimester (n=249) (%)	Second trimester (n=274) (%)	Third trimester (n=2317)(%)	Total (n=2840) (%)
A.	35 (14.05)	47(17.16)	346 (14.93)	428 (15.07)
B.	110(44.18)	106(38.68)	1064(45.93)	1280 (45.07)
C.	83(33.34)	99(36.14)	812(35.05%)	994(35.00)
D.	12(4.82)	20(7.29)	84(3.62)	116(4.08)
X.	9(3.61)	2(0.73)	11(0.47%)	22(0.78%)

Table 3: The rates and odds of exposure to FDA category C and D drugs with maternal characteristics of the pregnant women.

Characteristics		No of population n(%)	Without CD	With CD	OR (95% CI)	P value**
Age (Years)	≤ 20	73 (14.47)	12	51	0.6120 (0.3128,1.198)	0.1647
	21 - 34	420 (83.16)	100	255	Reference	---
	≥ 35	12 (2.37)	5	09	1.417 (0.4633,4.232)	0.5520
Parity	Nuli-para	120 (23.76)	49	57	Reference	---
	1	284 (56.24)	56	174	0.3744 (0.2302,0.6084)	<0.0001
	≥2	101 (20)	12	74	0.1866(0.09184,0.3875)	<0.0001
Gravida	1	176 (34.85)	53	99	Reference	---
	2	250 (49.50)	51	150	0.6351(0.4006,1.007)	0.0595
	≥3	79 (15.65)	13	56	0.4336(0.2176,0.8642)	0.0174
Abortion History	No	396 (78.42)	101	234	0.5221(0.2892,0.9424)	0.0315
	Yes	109(21.58)	16	71		
Co morbid Conditions	No	489 (96.83)	111	296	1.778(0.6184,5.111)	0.3765
	Yes	16 (3.17)	6	09		
Conditions	Chronic condition	18 (3.56)	6	12	0.5904 (0.2166,1.610)	0.3908
	Non-chronic conditions	487 (96.44)	111	376		
Total No of Medications	Less than 5	199 (39.41)	101	86	0.05343(0.2987,0.09556)	<0.0001
	≥5	306(60.59)	16	255		
Length of hospital stay (days)	<4	263 (52.07)	175	64	Reference	---
	5 – 9	194(38.41)	60	75	2.926(1.876,0.4562)	<0.0001
	≥10	48 (9.52)	6	27	0.08127(0.03206,0.2060)	<0.0001

**P-value is based on a chi-square test or Fisher's exact test.

The common medical conditions seen are anemia; urinary tract infection and majority of drugs prescribed were ferrous sulphate tablets and injection ferrous sucrose and antibiotics which belong to FDA category of category A and B.

Oral dosage form was the significant dosage form used across all trimesters (76.10%) as it is the simplest and easiest way for any patient to take a medication. 15.07% were prescribed with FDA category drug a were routine medications that included ferrous sulphate, Vitamin B complex. When compared to the studies conducted in the USA, it is shown that smaller number of category A drugs were prescribed, the findings are similar.[6]

In this study, about 45.07% of medications prescribed are of FDA category B which was antibiotics towards management of urinary tract infections; this finding is similar from various studies.[15] 35% received FDA category C drugs in all the trimesters and when compared to studies performed in USA it is relatively less. There are reports of potentially harmful medications use during pregnancy (category D drugs-1.5% to 4.8% and category X drugs 0.2 to 4.6%) both from developed and developing countries.[16,17] In this study, category D drugs are prescribed only in 0.21% of pregnant women, who received Inj. Oxytocin and Inj. Magnesium sulphate respectively towards management of incomplete abortion[18] during the first trimester and for the induction of labor [19] and postpartum hemorrhage during the third trimester [20] and magnesium sulphate were prescribed towards the management of eclampsia.[21] Inj.Gentamicin was prescribed in about 3.06% before delivery and continued during postnatal period. Diazepam was prescribed for one patient for the treatment of preeclampsia. FDA category X Drug Misoprostol was prescribed in first, second and third trimester gestation 0.56%, 0.07% and 0.17% respectively. Seven patients used this drug and two women to terminate pregnancy during first and second trimester gestations. This is in line with Goldberg, Greenberg and Darney *et al* observation. And five women were administered to induce labor after intrauterine fetal death.[22]

In the age group of ≥ 35 years there was increased risk of exposure to category C and D drugs with OR 1.417, 95% CI:(0.4633,4.232) but there

Table 4: FDA pregnancy risk class of medications C, D, and X drugs vs pregnancy stage of the women.

Trimester	FDA Category C		
	n(%)	OR (95% CI)	P value
1st (n=249)	83(33.34)	Reference	
2nd(n=274)	99(36.14)	0.8838 (0.6161,,1.268)	0.5210
3rd (n=2317)	812(35.05)	0.9267 (0.7025,1.223)	0.6393
Trimester		FDA Category D	
1st (n=249)	12(4.82)	Reference	
2nd (n=274)	20 (7.29)	0.6430 (0.3070,1.344)	0.2754
3rd (n=2317)	84(3.62)	1.346 (0.7243,2.501)	0.5893
Trimester		FDA Category X	
1st and 2nd (n=523)	11 (2.10)	Reference	
3rd (n=2317)	11(0.47)	7.437(3.146,17.58)	<0.0001
Trimester		FDA Category CD	
1st (n=249)	95(38.15%)	Reference	
2nd (n=274)	119(43.43%)	0.8035 (0.5662,1.140)	0.2472
3rd (n=2317)	996(42.98%)	0.8182 (0.6254,1.070)	0.1619

**P-value is based on a chi-square test or Fisher's exact test.

is no significant association. Whereas the study conducted by Lee *et al,* found that young maternal age were associated with exposure to category C, D and X.[23,24] The study conducted by Riley *et al,* found that multiparous women and (especially) women with chronic health conditions were more likely to use category D or X drugs.[25] In the present study, there were tendencies for increased risk of exposure to FDA category C and D drugs was with number days of length of hospital stay of 5 to 9 days and co-morbid condition (OR 2.926, 95% CI: (1.876,0.4562) and 1.778 (0.6184,5.111) respectively. During third trimester there is an increased exposure to category D and X drugs. This observation suggests that in later gestation period, the prescription of drugs with potential fetal risk were more likely to be used for necessary maternal illness.[6] Limitations in the present study includes that certain variables like maternal education, income, life style and habits were not available and their influence on our study results could not be analysed. It is observed that prescription pattern of drugs during pregnancy and among countries worldwide is in accordance to US FDA guidelines and risk categories. In this study it is witnessed that Iron, folic acid and vitamin supplements are mostly prescribed drugs by the health care providers to pregnant women depending on the risk and benefit ratio.

CONCLUSION

The present study concludes that even though there is compliance to FDA safety drugs use in pregnancy, the mother and the fetus might be at the risk, as certain variables in this study with respect to maternal characteristics showed the odds of exposure to potentially harmful medications such as elderly pregnancy, co-morbid conditions and length of hospital. Thus, there is a need for detailed description of patterns of pregnancy exposure to prescription drugs with potential risk and rate of exposure during different gestation period. The current study indicates that the drug use in pregnancy should be observed by treating physician and must be made aware of the potential risk to fetus in advance when prescribed. Also, there is need of such studies periodically to update the therapeutic use of drugs during pregnancy and provide rational drug use.

ABBREVIATIONS USED

FDA: Food and Drug Administration; **ICD:** International Classification of Disease.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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