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ANALYSIS OF PRESCRIPTION PATTERNS AND PREGNANCY CONTRAINDICATED MEDICATION AMONG PREGNANT WOMEN UNDERGOING FOLLOW-UP AT RAS DASTA GENERAL HOSPITAL MEDICAL CENTER

Takele Achalu Dengela*

Lecturer at Africa Medical Collage.

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Corresponding Author: Takele Achalu Dengela

Address: Lecturer at Africa Medical College.

Email ID: takeleachalu@gmail.com,

ABSTRACT

Background: Due to the potential risk to the mother and fetus, this could impair the reproductive system. It is challenging to explain pharmaceutical use during pregnancy and their respective contributions to birth abnormalities in the setting of the majority of developing nations, including Ethiopia, for a number of reasons. **Objective:** to assess the prescription drug usage trends and pharmacological contraindications for pregnancy among the pregnant patients at Ras Dasta General Hospital. **Methods:** An institutionally-based cross-sectional study technique was used to describe the pattern of medication use and drug contraindications among pregnant women seeking follow-up treatment at Ras dasta general hospital Hospital. Both the primary and secondary data's sources were cited. The primary sources of the data were pregnant women who visited the ANC clinic at JMC during the study period. The source of secondary data was a review of medical records, prescriptions, and the ANC follow-up registration book. A face-to-face interview and a simultaneous review of the patient's medical data were conducted. Medical records were reviewed for any relevant information on prescription and over-the-counter drugs, and pregnant women were interviewed. Result Except for vitamins and vaccinations, 79 (53.74%) and 68(46.26%) of the pregnant women reported using at least one POM and/or OTC medication during the current pregnancy, respectively. An average of 1.5 + 0.5 OTC and 1.6 + 0.5 POM medications were consumed per pregnant lady. Of the 79 prescription medications used, 25 (17%) (53.74%)

were purchased without a prescription. **Conclusion:** In this study, POM and OTC drug usage without a prescription was common, and use of potentially harmful pharmaceuticals (category-C) appeared to be increased throughout all trimesters. The findings of this research back up the recommendation of a few potentially harmful medications that could have been avoided while pregnant. In order to follow their doctor's prescription, pregnant women should undergo intensive medication usage counseling from healthcare specialists.

KEYWORDS: adverse reactions, dosage guidelines, and contraindications categories of pregnancy risk, prescription pharmaceuticals, over-the-counter medications, and pregnancy

1. Background

During pregnancy, a woman's body experiences a considerable physiological change. When treating sickness issues in pregnant patients, these specific changes make it more challenging for doctors to select the best treatments for their patients. Drug usage during pregnancy may increase the teratogenic potential of the fetus. However, it is impractical and may even be hazardous to advise women to refrain from all drugs while they are pregnant.[1, 2] Clinicians shouldn't let being pregnant get in the way of treating their patients' medical issues. Drug use is necessary for maintaining and regaining health. Therefore, it is a rare risk-benefit situation to prescribe medicine while pregnant.[3,4] Many pregnant women were exposed to medications, including those that might be hazardous to the fetus, according to a study conducted in Addis Abeba, Ethiopia. Additionally, pregnant women used modern medications or traditional botanicals as self-medication. Healthcare practitioners should therefore weigh both the drug's therapeutic benefits for the mother and any potential hazards to the fetus before prescribing a prescription. Furthermore, it's crucial to periodically inquire about women's usage of self-medication and to provide pregnant women with the appropriate advice.[5] Because the majority of teratogen hazards associated with medications are still unknown, it is essential to frequently monitor medication use among pregnant women. Studies on drug use reveal that, according to estimates ranging from 441 to 99%, the majority of pregnant women use drugs.[6] But because study designs differ, comparison is difficult. The drugs being studied, such as vitamins, iron, and analgesics, may or may not be available over-the-counter (OTC), and information on drug use may be acquired through interviews or prescription databases. Most studies have found a surge in drug use during pregnancy.[7]

In 1979, the Food and Drug Administration (FDA) developed a framework based on the level of risk the fetus faces based on the clinical data that was then available.[10] Only 55% of the

pharmaceuticals in the Danish prescription database could be categorized as FDA pregnancy-related drugs. Avoiding drugs while pregnant is not always possible. Women who have certain chronic medical conditions, such as epilepsy, diabetes, inflammatory bowel disease, or asthma, must take drugs, and the benefits to the mother and child may likely outweigh the drug's teratogen risk.[8, 9]

Medical attention could be needed for other chronic conditions, whether they are connected to the pregnancy or not.

Various classification schemes assign drugs to risk categories based on their known or unknowable effects on the fetus, despite the difficulties in identifying potential risks to the unborn child and pregnant woman. The Swedish Classification System, which employs risk categories for drugs used during pregnancy and breastfeeding, requires that all pharmaceutical products that have been approved be categorized into one of four risk groups.[11] The classification method makes no attempt to assess potential long-term impacts. As a result, the goal of this study was to evaluate the drug prescribing patterns and pregnancy-related contraindications among pregnant women who visited the obstetrics and gynecology department at JUMC. The results of this study will give information regarding the manner in which medications are prescribed and whether they are harmful to expectant mothers. The results will also help to reduce the morbidity experienced by expectant moms and the fetus by enhancing accurate and practical knowledge. Additionally, it will give medical professionals a foundational understanding of risky medications for pregnant patients. Additionally, it will provide as a benchmark for other scholars working on the same and similar fields.

2. METHODS AND MATERIALS

2.1. Study Area and period

The research was carried out at Ras dasta general hospital, which is situated in Ras dasta general hospital. Ras dasta hospital more than 800 beds, 32 acute care units, and 1600 staff members, the hospital can accommodate 15 million patients. In order to service their soldiers, Italian invaders erected JUMC, one of the nation's earliest hospitals, in 1930 E.C. These services are offered in addition to the 160,000 outpatient attendants, 11,000 emergency cases, 4,500 deliveries annually, and 15,000 inpatient attendants.

2.2. Study Design

An institutional-based cross-sectional study design was used to describe the drug usage and contraindications among pregnant patients receiving follow-up care at Ras dasta general hospitalHospital during the study period.

2.3. Population

2.3.1. Source population

All Pregnant women attending in Ras dasta general hospital hospital ras dasta general hospital hospital.

2.3.2. Study population

Pregnant women who met the inclusion criteria and attended the prenatal clinic during the study period made up the study population (age 18 years and above; new Women who came for ANC and those who were already enrolled in routine ANC program). The ANC clinic serves roughly 2595 patients a year and employs one nursing staff member (with a diploma) along with a small number of medical interns and residents. It is estimated that 216 pregnant women visited during the time of the study.

2.4. Sample size & Sampling Technique

2.4.1. Sample Size Determination

There are several approaches to determining the sample size. These include using a census for small populations, imitating a sample size of similar studies, and applying formulas to calculate a sample size. This study wasemployed aYamane (1967:886) simplified formula to calculate the required sample sizes as:

$$n = \frac{N}{1 + N(e2)}$$

Where**'n'** is the required sample size, **N** is the source population (N = 216), and **'e'** is the level of precision (e = 0.05).Usingthis formula,

$$n = \frac{216}{1+216(0.05^2)} = 140$$

Considering a 10% non-response rate, the final sample size was 154.Therefore, **154** respondents**w**asincluded in the study.

2.4.2. Sampling Technique

Convenience random sampling was employed to select the targeted study participants.Therefore, 154 pregnant women wasinvolvedas sample size.

2.5. Inclusion & Exclusion Criteria

2.5.1. Inclusion Criteria

- ✓ 18 years and above
- ✓ enrolled in routine ANC program

2.5.2. Exclusion Criteria

- ✓ Women not volunteer

2.6. Source of Data

Both primary and secondary data was used with their respective source. The sources for Primary data were pregnant women attending ANC clinic of JMC during the study period. The source for secondary data was reviewed of medical charts, prescriptions and ANC follow-up registration book.

2.7. Data Collection procedures

A semi-structured questionnaire was developed and contextualized to the situation based on past investigations. It contained basic demographic data, the number of prescription and over-the-counter medications listed on each order sheet, supplements, relevant medical history, co-morbidities, and common illnesses, educational level, pre-conception and current substance use status, and other information pertaining to the use of medications and supplements during pregnancy. A face-to-face interview and a simultaneous review of the patient's medical data were conducted. Medical records were reviewed for any relevant information on prescription and over-the-counter drugs, and pregnant women were interviewed.

2.8. Data quality control

It was pretested in order to assess the questionnaire's clarity, sensitivity, response, interview time, research instrument, and logistical supplies. In light of their comments, an adjustment will be made. The questionnaire underwent pre-testing on 5% of expectant mothers to verify its validity and make any necessary adjustments. Pregnant women who took part in the pre-test procedure were not allowed to participate in the trial to avoid data contamination.

2.9. Study Variables

2.9.1. Dependent Variable

- ✓ Medication prescribing pattern
- ✓ Medicines contraindicated pregnant women
- ✓ Prescription and over the counter medications

2.9.2. Independent Variable

- **Sociodemographic variables** (Age, Occupation, Educational Status, Pre-conception, Current substance use)
- **Clinical variables (**Gestational age**,** Trimester**,** Diseases)
- **Medications and related variables** [Regimen (Name, dose, duration), Number of medication]

2.10. Data Presentation and Analysis

The Statistical Package for Social Sciences (SPSS) for Windows version 20 was used to edit, clean, and analyze the acquired data after it had been clearly classified and entered into the computer. It was done using descriptive statistics, which included frequency and percentage. To determine the relationship between the independent factors and each outcome variable, chi-square statistical tests were employed. 95% confidence intervals (CI) were generated, and a P value of 0.05 was used to indicate statistical significance.

2.11. Ethical consideration

Before commencing data collection, letter for ethical clearance was obtained from responsible body. After explaining the objectives of the study in detail, written consent was made known by all study participants. Confidentiality of the information collected was assured and information was collected keeping the privacy of the respondents and anonymity.

3. RESULT

The study aimed to gather information from 154 pregnant women who attended the antenatal clinic at Ras dasta general hospital Hospital during the study period and met the inclusion criteria (age 18 years and above; new women who came for ANC and those who were already enrolled in routine ANC program), but the researcher was only able to gather 147 questionnaires. This represents a 95.45% response rate, which is excellent for analysis. A response rate of 60% is considered good, and one of 93.02 percent is considered extremely good, according to Babbie (2004).

3.1. Socio-demographic characteristics Pregnant Women

There were 147 respondents in all that participated in the survey. 100 of them (68.02%) were primarily found to be between the ages of 21 and 40. Regarding respondents' marital status, the majority of 83 (56.46%) of the women were married, followed by 28 (19.05%) of those who secondary school, followed by 33 respondents (22.45%) who were enrolled in primary school, and 24 respondents (14.29%) who were in other educational levels, such as certificate and higher education levels. Regarding the study population's occupation, the majority of them—42 (28.57%)—were merchants, followed by 38 (25.85%) housewives and 28 (19.05%) farmers. Regarding respondents ethnicity larger proportion 62 (42.18%) were Oromo, 31 (21.09%) those were Amara and the least group 8 (5.44%) were found in other categories. The monthly income of the study population showed that the larger proportion 51 (34.69 %) of them were earned 1000-1500 birr per month followed by 39 (26.53%) those have been earned birr >1500 and the least group 21 (14.29%) were earned unknown amount. Most of 89 (60.54%) of the respondents were reside in urban the remaining 58 (39.46%) were came from the rural (Table 1).

Table 1: Socio-demographic description of the pregnant women (n=147) Ras dasta general hospital hospital Ras dasta general hospital hospital Specialized, Ethiopia July - August 2021.

Variables		Frequency	percentage
Age group (in years)	15-20	39	26.53
	21-30	47	31.97
	31.40	53	36.05
	41-50	8	5.44
Marital Status	Married	83	56.46
	Single	28	19.05
	Widowed	19	12.93
	Divorced	17	11.56
Educational Status	Illiterate	24	16.33
	Literate	23	15.65
	Primary School level	33	22.45
	Secondary school	46	31.29
	Others	21	14.29
Occupational status	Farmer	28	19.05
	Merchant	42	28.57
	Gov't employee	23	15.65
	Housewife	38	25.85
	Laborer	9	6.12
	Others	7	4.76
Income per month in birr	<1000	36	24.49
	1000-1500	51	34.69

	>1500 Unknown	39 21	26.53 14.29
Place of residence	Urban Rural	89 58	60.54 39.46

Source: Own Survey, 2021

3.2. Pregnancy Related Information

The majority of respondents, 64 (43.54%), were found to be pregnant during their second trimester, followed by 49 (33.33%) of those who were found to be pregnant during their third. Regarding the women's parity, 44 (29.93%) of them had more than three children, followed by 67 (45.58%) of those who had 1-3 children. The majority of the 82 women's pregnancies (55.78%) were planned, whereas unplanned pregnancies occurred in 65 (44.22%) of the women. 53 (36.05%) of the respondents indicated that they had previously used Depo-Provera for family planning purposes, followed by 34 (23.13%) who had used tablets and 32 (21.77%) who had used condoms.The majority of 98 (66.67%) and 93 (63.27%) were respectively non-smokers of cigarettes and non-drinkers of alcohol.Considerable proportion 35 (23.81%) of the women were had adverse pregnancy history (See table 2).

Table 2: Pregnancy Related Information of Pregnant Women among pregnant women attending ANC during the study period (n=147) Ras dasta general hospital hospital Ras dasta general hospital hospital Specialized, Ethiopia July - August 2021.

	Pregnancy information	Frequency	Percentage (%)
Pregnancy stage	First trimester	34	23.13
	Second trimester	64	43.54
	Third trimester	49	33.33
Parity	Nuli-para	36	24.49
	1-3 children	67	45.58
	More than 3 children	44	29.93
Current pregnancy planning status	Planned	82	55.78
	Unplanned	65	44.22
Family planning methods Used	Condom	32	21.77
	Pills	34	23.13
	Depo-Provera	53	36.05
	Implants	21	14.29
	Others	7	4.76
Cigarette smoking status during pregnancy	Yes	49	33.33
	No	98	66.67
Alcohol drink status during Pregnancy	Yes	54	36.73
	No	93	63.27
History of adversepregnancy Outcome	Yes	35	23.81
	No	112	76.19

Source: Own Survey, 2021

Out of the total 35 women those had adverse pregnancy history larger proportion 9.52% of the adverse pregnancy outcome was cleft palate, followed by 5.44% cardiac defect, 4.76% Down syndrome and 4.08% had more than one adverse pregnancy outcome (Figure 1).

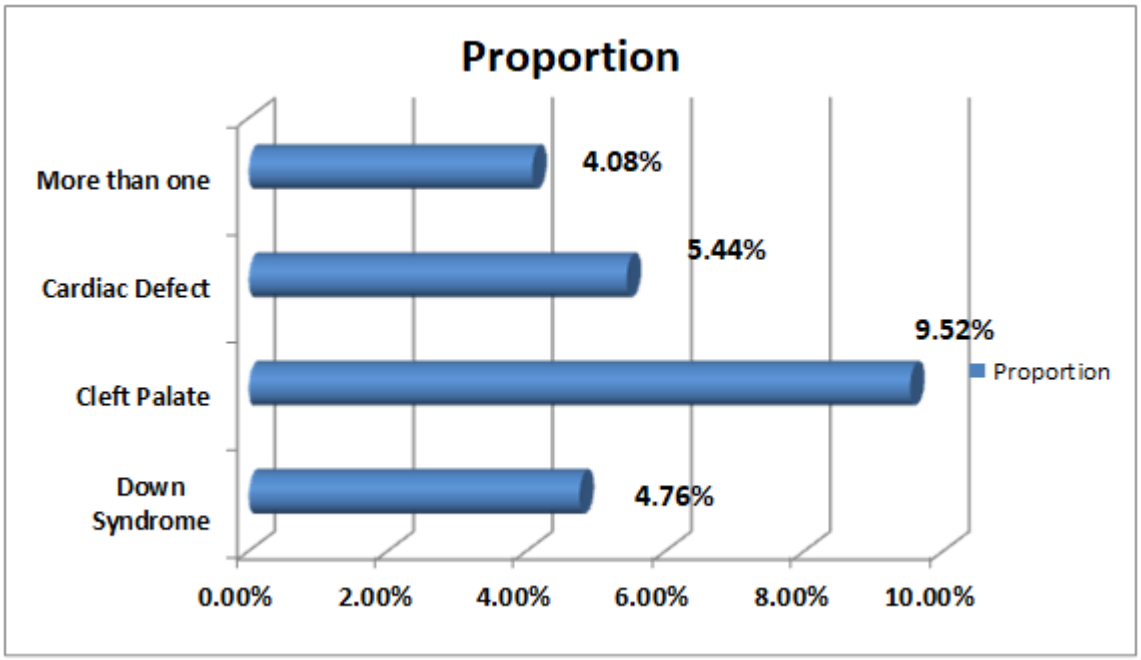

Figure 1: Types of adverse pregnancy outcome among pregnant women attending ANC during the study period (n=147) Ras dasta general hospital hospital Ras dasta general hospital hospital Specialized, Ethiopia July - August 2021.

Source: Own Survey, 2021

3.3. Prescription and over the counter medications used by pregnant women

A total of 79 (53.74%) and 68(46.26%) of the pregnant women had used at least one POM and/or OTC drug during the current pregnancy, respectively, excluding supplements and vaccination. Per pregnant woman, an average of 1.5 + 0.5 OTC and 1.6 + 0.5 POM drugs were taken. 25 (17%) of the 79 prescription drugs utilized (53.74%) were acquired without a prescription.

104 (70.75%) had a higher percentage of periods than 79 (53.74%) did when pregnant. From 15 (18.99%) in the first trimester to 22 (27.85%) in the second, and 42 (53.16%) in the third, there was an increase in POM use over the trimesters. 95 pregnant women had used over-the-counter (OTC) drugs in the 2-4 weeks prior to becoming pregnant, and nearly half of them (46.26%) had done so while they were pregnant. The third trimester of pregnancy had the highest rate of 40 (58.82%) OTC medicine use during pregnancy compared to the other

trimesters. The majority of the women, 105 (71.43%), were unaware of the dangers of self-medication. Pregnancy stage did not significantly correlate with the usage of prescription or over-the-counter drugs since p> 0.05. (Table 3).

Table 3: Prescription and over the counter medications used by pregnant women (n=140) Ras dasta general hospitalhospital Ras dasta general hospitalhospital Specialized, Ethiopia July - August 2021.

Medications and herbs used	2-4 weeks pre pregnancy	Pregnancy stages			X^2	P-value
		First trimester	Second trimester	Third trimester		
POM (79)	104 (70.75%)	15 (18.99%)	22 (27.85%)	42 (53.16%)	0.5092	0.775
OTC (68)	95 (64.63%)	12 (17.65%)	16 (23.53%)	40 (58.82%)		

Source: Own Survey, 2021

The distribution of medicines prescribed to these pregnant women involved in this study is as shown in figure 2. Minerals were the most frequently prescribed medicines 54.3 % which followed by 42.2% GI drugs, 26.63% antibiotics, and 16.10% anti-pains. Folic acid was the most frequently prescribed drug in the Ras dasta general hospitalhospital. Other minerals and vitamins prescribed included ferrous Sulphate, vitamin C and calcium lactate. Omeprazole the most prescribed GI-drugs followed by anti-acid suspension/peptic gel. Paracetamol was the most frequently prescribed analgesic; other analgesics included methamizole, acetylsalicylic acid, piroxicam, pentazocin. (Figure 2).

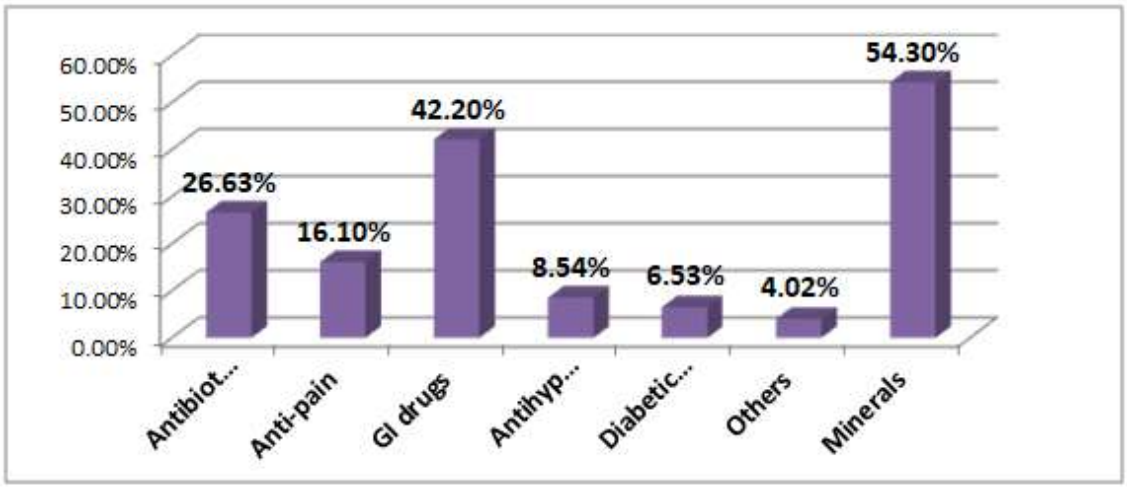

Figure 2: Types of the group of medicine prescribed among pregnant women attending ANC during the study period (n=147) Ras dasta general hospitalhospital Ras dasta general hospitalHospital Specialized, Ethiopia July - August 2021

Source: Own Survey, 2021

The distribution of medicines self-prescribed (OTC) to these pregnant women involved in this study is as shown in figure 3. Antibiotics were the most frequently self-used medicines 45 % which followed by 33.5 % anti-pains, 26.80% GI drugs, and 12.80 % Minerals.

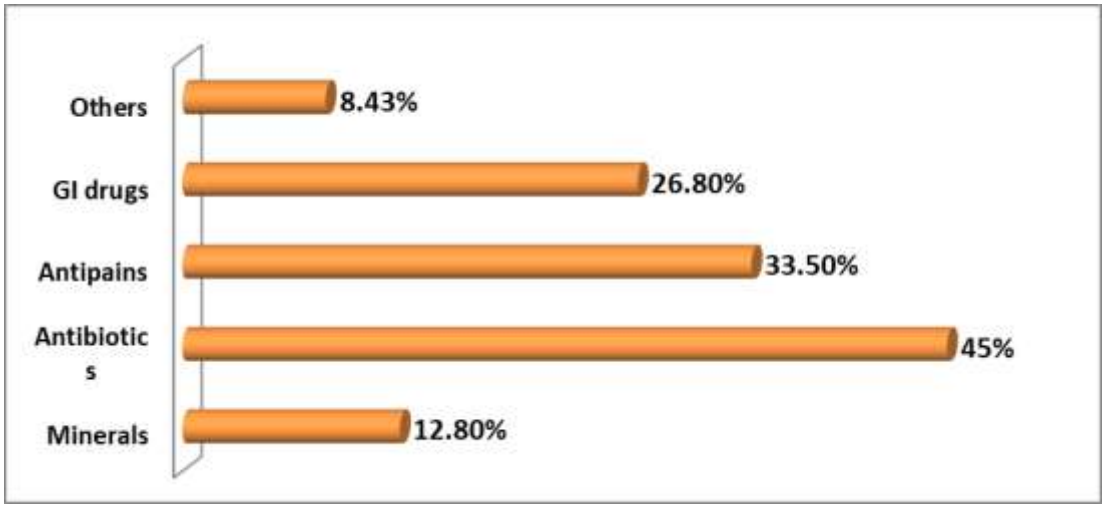

Figure 3: Types of the group of medicine Self prescribed (OTC) among pregnant women attending ANC during the study period (n=147) Ras dasta general hospitalhospital Ras dasta general hospitalhospital Specialized, Ethiopia July - August 2021

Source: Own Survey, 2021

Majority 80 (40.20 %) of medications used were fromcategory-C followed by category-B 69 (34.67%) and category-A 50 (25.13%). The chi-square test showed that there was no significant association between women pregnancy trimester and drug category since p-value>0.05 (Table 4).

Table 4: US-FDA pregnancy risk class of medications vs. pregnancy stage of the women.

Pregnancy stage	FDA Category						Total	X^2	P-value
	A		B		C				
	N	%	N	%	N	%			
1st Trimester	5	2.50	11	5.53	12	6.03	28	1.6714	0.796
2nd Trimester	10	5.03	17	8.54	19	9.55	46		
3rd Trimester	35	17.59	41	20.60	49	24.62	125		
Total	50	25.13	69	34.67	80	40.20	199		

Source: Own Survey, 2021

A classification of medicines according to risk to the fetus indicated that of all the medicines prescribed, 50 (25.13 %) were in category A, 69 (34.67 %) category B, and 80 (40.20%) category C.

4. DISCUSSION

here are concerns about the potential negative effects of any pregnancy-related medicine use despite the fact that numerous studies have demonstrated that pregnant women commonly take pharmaceuticals.[17] For this reason, medical practitioners have long been concerned about the safety of drug use during pregnancy. According to a number of studies on the use of medications during pregnancy[13], there are differences in the medication use, methodologies (prescription collection, interview, chart review), and prescribing practices between developed and developing countries. Additionally, the drugs that were utilized in the majority of research were examined using a variety of risk classification methodologies. These variations complicate the comparison of our findings with those of other investigations. This study's average maternal age was comparable to that of a study of a same nature conducted in Nepal.[7] The majority of women visiting prenatal clinics were women in their first trimester of pregnancy. The pattern of medical disorders found in this study was different from that found in the Nepal study[7], where problem drug use was primarily brought on by gastrointestinal tract issues (vomiting, nausea, and dyspepsia), as well as vaginal spotting and bleeding.

Our research revealed that, out of 147 pregnant women overall, 53.74 percent and 43.74 percent, respectively, had used at least one POM and/or OTC drug during pregnancy, with the average being 1.6+0.5 POM and 1.5+0.5 OTC meds. Most of the women who received these medications—56%—were pregnant and in the third trimester. The current study's prevalence and average number of medications used are comparable to those of studies conducted in South Africa (59.3%), Pakistan, Palestine (56%) and Egypt (86%) as well as the United States.[42] This study showed that the number of women taking POM grew across the trimesters, leading to an increased tendency of POM use throughout trimesters, from the first trimester's 18.9% (n = 15) to the second trimester's 27.85% (n = 22), and the third trimester's 53.16% (n = 42), respectively.Similarly, an increased in OTC medications use across trimester was observed from 17.65% (n=12), to 23.53 % (n=16) and 58.82 % (n=42) in the second and third trimesters of pregnancy. The fact that more than half and one-fourth of respondents in our survey were in their third and second trimesters of pregnancy, respectively, may be the cause of the increasing usage of POM and OTC throughout trimesters. Studies conducted in Ethiopia and Pakistan also indicated an increase in the trend of medication use throughout pregnancy.[20]

In this study, minerals, GI medications, antibiotics, and analgesics were the most often recommended medications for pregnant women. There is no harm to the fetus at any trimester, according to adequate clinical studies: Vitamin B complex, vitamin C, and folic acid.[13] There are insufficient clinical research and no evidence from animal studies that the following medications harm the fetus: paracetamol, amoxicillin, ampicillin/cloxacillin, metronidazole, erythromycin, and cotrimoxazole.[37] A very low incidence of drugs was contraindicated. For effective prescribing to occur, such contraindications must not exist, yet in some cases, the use of such medications may be authorized if the benefits outweigh the dangers. 20 According to the FDA's classification of drugs based on fetal risk, the majority of the given pharmaceuticals came into category A, followed by category B. However, C also purchased medications. It's possible that this took place when the benefits outweighed the risks.

5. CONCLUSION

Based on the study's results, the researcher was able to make the following definitive claims. Both the perinatal and prenatal phases of this investigation revealed high rates of medication use overall. In this study, POM and OTC drug usage without a prescription was common, and use of potentially harmful pharmaceuticals (category-C) appeared to be increased throughout all trimesters. The results of this study support the advice to avoid using a few potentially dangerous drugs while pregnant. Most of the ladies were not aware of the potential risks associated with picking their own medications during pregnancy. Healthcare practitioners must be up-to-date on the potential advantages and disadvantages associated with the use of medicines during pregnancy in order to recommend or prescribe any medications only after carefully balancing the evidence supporting their usage during pregnancy. More research must be done in order to more clearly explain drug safety. The study's participants were exposed to one or more high-risk drugs, and there is currently little knowledge about the possible negative effects on fetal or neonatal development for a substantial number of pharmaceuticals taken during pregnancy and lactation. The researcher was able to provide the following recommendations as potential remedies for the study's discovered gaps based on the study's findings and concluding comments. The perception that OTC drugs can be used during pregnancy without medical supervision like at other times due to a lack of competent medication advice by healthcare professionals. Healthcare professionals would do better to provide pregnant women with intensive counseling regarding medication use in order to ensure that they follow their doctor's prescription for medication use. It was unknown

whether the vast majority of the drugs were safe for the unborn child and pregnant woman. The need for ongoing monitoring of the health and development of affected children is emphasized by the most current study on the long-term effects of prenatal exposure. According to the survey, many pregnant women preferred taking over-the-counter medications. Therefore, healthcare professionals should inform patients about safe medications to use while expecting and stress the importance of following a doctor's prescription.

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