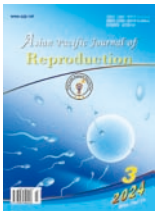

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A cross–sectional study to assess medication safety, knowledge, attitude, and practices regarding nutrition and medication among pregnant women

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ABSTRACT

Objective: To assess pregnant women's knowledge, attitude, and practice regarding nutrition and medication usage, analyse the prescribing pattern, and categorize them based on the Food and Drug Administration (FDA) guidelines.

Methods: A cross-sectional study was conducted with 264 pregnant women in the obstetrics and gynaecology department of a tertiary care hospital from October 2022 to August 2023. A knowledge, attitude, and practice (KAP) questionnaire was prepared in English language by the researchers and validated by an expert panel consisting of 12 members. The validated questionnaire was then translated into regional languages, Kannada and Malayalam. The reliability of the questionnaire was assessed with test-retest method with a representative sample population of 30 subjects (10 subjects for each language). The subjects' knowledge, attitude, and practice were evaluated using the validated KAP questionnaire. The safety of the medication was assessed using the FDA drug safety classification for pregnancy.

Results: The mean scores for nutritional and medication usage knowledge, attitude, and practice were 4.14±1.15, 4.50±1.09, and 3.00±1.47, respectively. Among 30 prescribed medications, 3 belong to category A (no risk in human studies), 8 belong to category B (no risk in animal studies), 18 belong to category C (risk cannot be ruled out) and 1 drug is not classified. A significant association was observed between medication knowledge and practice (r=0.159, P=0.010).

Conclusions: Most of the study population knows the need to maintain good dietary and medication practices during pregnancy. Counselling pregnant women regarding diet and medication usage is crucial in maternal care.

KEYWORDS: Pregnancy; Nutrition; Medication; Knowledge; Practice; Safe medication

1. Introduction

Pregnancy is a transformative and crucial phase in a woman's life. During pregnancy, the woman may experience physical and depressive symptoms[1]. The nutritional requirement in pregnancy increases to maintain the proper growth of the fetus and the mother's well-being. Likewise, the appropriate use of medications during pregnancy is essential for maintaining maternal health[2].

In 2017, global maternal deaths numbered around 295 000, reflecting a 35% decrease compared to the 451 000 reported in 2000. Among these fatalities, India accounted for approximately 12%, with an estimated 35 000 maternal deaths recorded. However, managing comorbidities in pregnant adolescents presents additional challenges[3]. Furthermore, limited research on the effects of drugs during pregnancy contributes to knowledge gaps, further complicating the promotion of maternal health.

Significance

Pregnancy is a crucial stage in a woman's life. In the present study, we assessed medication safety and pregnant women's knowledge, attitude, and practice regarding medication. Medication knowledge and practice were significantly correlated. Counseling pregnant women regarding their medication regimen and lifestyle is crucial for preventing complications associated with pregnancy.

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Malnutrition can lead to infections, pregnancy losses, preeclampsia, anemia, and increased infant mortality[4]. Malnutrition arises from factors such as poverty, gender inequality, substandard prenatal care, and low literacy rates[5]. Many women hold misconceptions about nutrition, often driven by fear of cesarean section and painful labor during pregnancy. Promoting accurate nutrition information, use and disposal of medicines and addressing misconceptions are essential for improving maternal health[6,7].

The government of India has implemented effective health and population policies. Accredited Social Health Activists (ASHAs) are instrumental in informing, educating, and supporting pregnancies, births, and deaths. They maintain accurate records and ensure timely registration, facilitating necessary healthcare services at the community level[8,9].

The use of medication during pregnancy should be approached with caution due to the potential teratogenic effects associated with the drug[10,11]. In 1979, the Food and Drug Administration (FDA) introduced a classification system to categorise the medications used in pregnancy, considering the potential teratogenic risk of drugs based on data from both animal and human studies. The FDA categorises drugs used during pregnancy into five categories: categories A, B, C, D, and X. Category A is considered safe, while category X is contraindicated in pregnancy[12,13]. Studies have shown that pregnant women have little knowledge about medications, which impacts their attitude and practice[14]. With this background, the current study was carried out to evaluate pregnant women's knowledge, attitudes, and practices (KAP) about nutrition and medication and also to assess the safety of medication based on FDA guidelines.

2. Subjects and methods

2.1. Study design

A cross-sectional study was conducted from October 2022 to August 2023 in the Department of Obstetrics and Gynecology of a tertiary care hospital.

2.2. Data collection tool

2.2.1. Development validation and reliability testing of KAP questionnaire

The researchers prepared a KAP questionnaire in English language and validated with an expert panel consisting of 12 members. The expert panel consists of one general physician, one gynecologist, three registered nurses, two dieticians, three academic pharmacists and two clinical pharmacists. Corrections were made to the questions as per the expert's suggestions. The questionnaire consists of three sections: knowledge, attitude, and practice, with six questions in each section. One mark is assigned to each correct answer (Supplementary File 1). Professional translators translated the validated English version of the KAP questionnaire into the regional languages (Kannada and Malayalam). To ensure consistency of information, the translated versions of the questionnaire were back-translated. The test retest method was used to assess the reliability of the questionnaire in a representative population with 10 patients in each English, Kannada and Malayalam versions of the questionnaire. For the English, Kannada, and Malayalam versions, the Intraclass Correlation coefficient (ICC) values were 0.98, 0.98, and 0.95, respectively, while Cronbach's alpha coefficients were 0.95, 0.95, and 0.92, respectively.

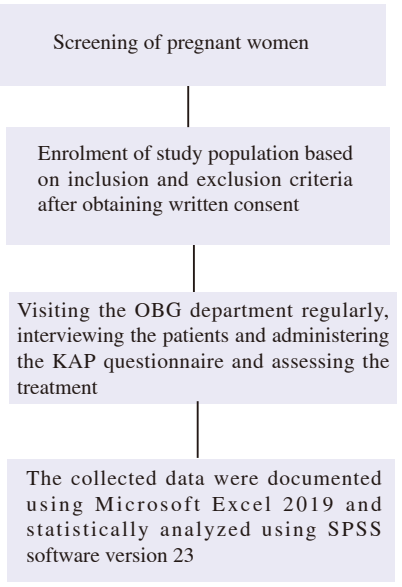

Figure 1. Methodology of the research study. OBG: obstetrics and gynaecology; KAP: knowledge, attitude, and practice.

2.2.2. Data collection

The research team regularly visited the outpatient department of obstetrics and gynecology, interviewed the study subjects, and administered the KAP questionnaire after obtaining written consent. The prescribed medications were assessed as per the FDA safety category. The collected data were documented using Microsoft Excel 2019 and statistically analysed using SPSS version 23 (Figure 1).

2.3. Sampling

The sample size for the study, determined using the population proportion formula, with a *P*-value of 0.45 (proportion of nutrition knowledge of pregnant adolescents), a precision of 6%, and α=1.96,

was found to be 264; the formula used to calculate the sample size is shown as below:

$$n = \frac{Z_{\frac{\alpha}{2}}^2 p\, q}{d^2}$$

Where, 'n' is the sample size, 'Z' is the confidence level at 95% (standard value: 1.96), 'p' is the expected proportion, 'q' is (1-p), and 'd' is the absolute precision.

2.4. Selection criteria

Pregnant women aged 20 years and above at their first, second, and third trimesters and who are willing to participate were included in the study. Psychiatric patients were excluded from the study. The enrolment of the study subjects was carried out after obtaining their consent. The patient enrolment was carried out using the convenience sampling method.

2.5. Study parameters

The study parameters assessed included pregnant women's knowledge, attitude, and practices related to their medication and dietary habits, as well as the safety of the prescribed drugs.

2.6. Statistical analysis

Data analysis was performed using SPSS 23.0 at a 95% confidence level. Categorical variables were presented as frequency and percentage. Continuous variables were presented as mean±standard deviation (mean±SD). An unpaired *t*-test was used to analyse the difference in the mean scores of knowledge, attitude, and practice. Karl Pearson's coefficient of correlation was used to perform the correlation between knowledge, attitude, and practice. Multiple linear regression analysis was used to analyse the factors influencing learning, attitude, and approach. In addition to this, the instrument of KAP was tested for reliability. A Cronbach's alpha coefficient greater than 0.70 will be considered acceptable. A P value < 0.05 was regarded as statistically significant.

2.7. Ethical statement

Ethical approval was obtained from the Institutional Ethical Committee before initiating the study (Ref No: NGSMIPS/IEC/028/2022).

3. Results

3.1. Socio–demographic status of the study population

Total 264 pregnant women were included in the study. The age-wise distribution among the subjects was found to be predominantly in the 21-30 years of age group, comprising 191 participants (72.3% of the total), while the lowest was observed in the age group of 41-45 years, with only 2 participants (0.8%). A breakdown of the participants' residential areas indicated that the majority of participants, 151 (57.2%), were from rural areas, while 113 (42.8%) were from urban areas. Most subjects had a pre-university level of education, which was 109 (41.3%). Majority of the study subjects were homemakers, with 204 (77.3%). Among the total study subjects, 179 (67.8%) subjects were in their third trimester of pregnancy. A smaller proportion of participants, 56(21.2%) individuals, were in their second trimesters, while only 29(11.0%) individuals were in their first trimesters (Table 1).

3.2. Distribution of drugs based on FDA pregnancy category

Among 30 prescribed medications, 3 belong to category A, 8 belong to category B, 18 belong to category C, and 1 is not classified (Figure 2) (Supplementary File 2).

Table 1. Socio-demographic status of the study population.

Characteristic	*n* (%)
Age group, years	
≤20	8 (3.0)
21-30	191 (72.3)
31-40	63 (23.9)
41-45	2 (0.8)
Domiciliary status	
Urban	113 (42.8)
Rural	151 (57.2)
Education status (self)	
Primary	40 (15.2)
High school	78 (29.5)
Pre-university course	109 (41.3)
Graduates	31 (11.7)
Postgraduates	6 (2.3)
Education status (partner)	
Primary	56 (21.2)
High school	131 (49.6)
Pre-university course	60 (22.7)
Graduates	15 (5.7)
Postgraduates	2 (0.8)
Occupation	
Housewife	204 (77.3)
Working	60 (22.7)
Trimesters	
First trimester	29 (11.0)
Second trimester	56 (21.2)
Third trimester	179 (67.8)
Abortion history	
No abortion	214 (81.0)
One abortion	37 (14.0)
More than one abortions	13 (5.0)
Vomiting symptom	
Yes	49 (18.6)
No	215 (81.4)
ASHA's assistance	
Yes	239 (90.5)
No	25 (9.5)

ASHA: Accredited Social Health Activists.

Table 2. Correlation between nutritional and medication usage with medication knowledge and practice.

Domains	*r* value	*P* value
Nutritional knowledge and attitude	0.118	0.056
Nutritional knowledge and practice	0.095	0.124
Nutritional attitude and practice	0.108	0.080
Medication knowledge and attitude	0.041	0.505
Medication knowledge and practice	0.159	0.010
Medication attitude and practice	0.065	0.296

Karl Pearson's correlation is used.

3.3. KAP of the study population regarding nutrition and medication usage

The mean scores for nutritional and medication usage KAP were 4.14±1.15, 4.50±1.09, and 3.00±1.47, respectively. A significant correlation was obtained between medication knowledge and practice (r=0.159, P=0.010) (Table 2).

3.4. Impact of medication knowledge and practice on nutritional practice

From the current study, it was understood that medication knowledge has no impact on nutritional practice (r=0.003, P=0.96), but medication practice significantly impacts nutritional practice (r=0.186, P=0.02) (Table 3).

4. Discussion

Among 264 patients, a significant difference was observed between the educational qualification of the participant's partners and the nutritional and medication practices of pregnant women. The findings were similar to that of the study by Daba *et al*, where the husband's educational level had a significant impact on nutrition knowledge during pregnancy[15]. A significant difference was observed between abortion history and nutritional practice among pregnant women. Similar findings were observed in a study conducted by Diddana *et al*, where the women with a history of abortion had poor dietary patterns[16].

In the present study, we observed that the ASHA intervention was found to have a significant impact on medication and nutrition practices among pregnant women. These findings were similar to the study by Blanchard *et al*[17]. Medication knowledge showed a significant correlation with medication practice. This aligns with the survey conducted by Navero *et al*, where a significant correlation was observed between knowledge and ritual among pregnant women[18].

From the study, we also observed that medication practice significantly impacted the nutritional approach. During pregnancy, due to nausea and vomiting, it is difficult to eat regular meals, and pain can make it challenging to prepare healthy meals. Also, some medications can interact with certain foods, which can make it dangerous to eat certain foods, such as some blood thinners can interact with grapefruit, which can increase the risk of bleeding. According to a study by Diddana *et al*, pregnant women who took medication for nausea and vomiting were more likely to report skipping meals and eating unhealthy snacks[16].

The FDA pregnancy risk category was used to classify the safety of medications. The majority of prescribed drugs were in category C, followed by categories B and A. This can be compared with the study of Patel *et al* and Alani *et al*, where category A drugs were the most commonly prescribed, followed by category C, B, and D. No medications from category X were prescribed[14,19]. Overall, the

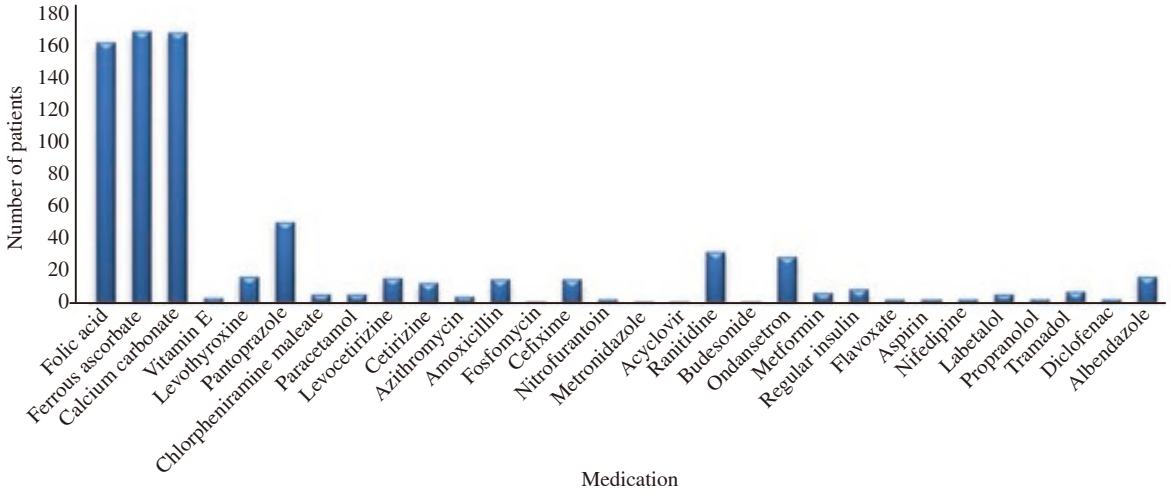

Figure 2. Medication prescribing pattern in the study population.

Table 3. Impact of medication knowledge and practice on nutrition and medication usage practice.

Model	Unstandardized coefficients		Standardized coefficients	*t*	*P* value
	B	Std. Error	Beta		
(Constant)	1.889	0.267		7.077	<0.001
Medication knowledge	-0.067	0.150	-0.028	-0.447	0.655
Medication practice	0.253	0.082	0.191	3.095	0.002

Multiple regression analysis with dependent variable: Nutritional practice.

drug utilization pattern during pregnancy appeared to be safe in the study populations, although further research is needed to gain more insights into the prescribing practices.

The current study has certain limitations that should be considered. The present study was a single-centred study with a smaller sample size for a shorter duration of time. The long-term impact of nutritional and medication practices on postpartum outcomes was not examined in this study. A long-term study evaluating the impact of educational interventions on pre and post-delivery outcomes can be possible in this area.

In conclusion, the majority of the prescribed drugs were in category B, but caution is advised with category C drugs for their use in pregnancy. Most of the study population knew the need to maintain good dietary and medication practices during pregnancy. From our study, we understood that the assistance of ASHA workers was crucial in improving pregnant women's knowledge and practice.

Conflict of interest statement

The authors have no conflict of interest to declare.

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Authors' contributions

Gauthami R, Bipin Shaji, Juno Jerold Joel and Krishnapriya Radhakrishnan provided the concept of the research study. Gauthami R collected the data. Reshma Kolar analysed the data. Bipin Shaji and Twinkle MJS interpreted the data. Gauthami R, Bipin Shaji and Twinkle MJS prepared the manuscript. Juno Jerold Joel and Krishnapriya Radhakrishnan reviewed the manuscript. All authors approved the final manuscript.

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