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Original Research Article

Prevalence and safety profile of commonly used drugs by pregnant women in primary care in Basrah City, Southern Iraq

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Abstract

Purpose: *To determine the prevalence of medication use, assess the safety profile of commonly used drugs, and examine their associations with sociodemographic characteristics among pregnant women attending primary care.*

Methods: *A cross-sectional study was conducted at two primary care centers in Basrah city from May 2018 to October 2019. Pregnant women attending two primary healthcare centers in Basrah, southern Iraq, completed a semi-structured questionnaire. Face-to-face interviews were used to collect the data required for the subsequent analysis. The questionnaire included items on sociodemographic characteristics, medication used during pregnancy, and reproductive characteristics.*

Results: *Among 1,525 pregnant women enrolled, 94 % reported taking at least one prescription drug, and 63 % used three to five drugs. Folic acid (75 %) was the most frequently used drug, followed by dydrogesterone for systemic use (43 %). Approximately 87 % of the drugs used were classified as safe, while 4 % were considered probably risky. Significant associations were observed between economic status and drug use, education level and drug use, and number of pregnancies and drug use.*

Conclusion*: This study concludes that drugs are widely used in pregnancy; most pregnant women took drugs regarded as safe, yet most were exposed to several drugs.*

Keywords*: Cross-sectional studies, Drugs, Pregnancy, Prevalence, Primary care, Safety profile*

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INTRODUCTION

Using medications during pregnancy can be difficult because pregnancy alters the pharmacokinetics of drugs and increases the risk of drugs crossing the placenta and harming the fetus [1]. However, medication treatment cannot always be avoided throughout pregnancy because some pregnant women may have chronic medical conditions that require continuous or periodic treatment (e.g., asthma, hypertension, and epilepsy). Therefore, taking medicine during pregnancy, whether prescription, over-the-counter, or herbal, is of major concern [2]. It is critical to assess and monitor the medications taken during pregnancy, as they may harm the fetus and result in low birth weight, deformities, and developmental abnormalities.

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It is estimated that up to 80 % of pregnant women use at least one prescription medication or over-the-counter (OTC) medication [3]. For instance, non-steroidal anti-inflammatory drugs (NSAIDs) are often taken during pregnancy to treat fever and inflammation. However, they may harm the developing fetus and newborn. Early prenatal NSAID exposure increases the risk of miscarriage and congenital disabilities. It also increases the risk of oligohydramnios and early closure of the fetal ductus arteriosus after 30 weeks' gestation [4].

Therefore, the United States Food and Drug Administration (FDA) categorizes drugs taken during pregnancy into five groups (A, B, C, D, and X). Category A is considered the safest, whereas category X is contraindicated during pregnancy [5].

Drug use during pregnancy has been the subject of studies in both developed [3] and developing countries [6].

A study conducted in Saudi Arabia found that the most frequently used medications were vitamins (13.2 %), paracetamol (13.2 %), herbal medicines (4.6 %), antibiotics (2.6 %), and medications for pregnancy-related nausea and vomiting (2.6 %), ranking next [7].

Studies to assess medication safety during pregnancy in Iraq are either scarce or describe the characteristics of pregnant women affected by drug use. This study aimed to assess medication safety, identify the drugs most often used by pregnant women, and examine links to sociodemographic characteristics.

EXPERIMENTAL

Study design

This cross-sectional study was conducted from May 2018 to October 2019, during which a semi-structured questionnaire was completed by 1,525 pregnant women attending two primary healthcare centers in Basrah, southern Iraq: Al Sadrain and Abo Sagheer.

Data collection, sampling, and recruitment

Pregnant women who were willing to participate in the study and provide information voluntarily were included. Questionnaires with incomplete or missing information were excluded. Those who were uncomfortable providing information were also excluded.

Face-to-face interviews were used to collect data, and the questionnaire was prepared in Arabic. Illiterate women received assistance from midwives to understand and complete the questionnaire.

The drugs were grouped according to FDA categories into safe (category A, B), probably risky (C, D, X) and unclassified (which did not belong to these categories).

Inclusion criteria were women aged 14 years and older in routine antenatal care who intended to answer all survey questions. Exclusion criteria were women with pregnancy complications such as gestational diabetes or hypertension. Others excluded were women with infectious diseases, risk of preterm labor, twin pregnancy, and women who used illicit drugs or herbal remedies. A total of one hundred pregnant women were excluded: 70 had chronic diseases, and the remaining 30 had incomplete information.

Survey instruments/questionnaire

The questionnaire included items on sociodemographic characteristics (age, educational level, and economic status), medication used during pregnancy by medical prescription, and reproductive characteristics (parity, number of abortions, and anomalies). The questionnaires were validated by the Scientific Committee of the Department of Clinical Pharmacy at the College of Pharmacy, University of Basrah.

Ethical approval

The first page of the survey recorded each participant’s informed consent, and the study was approved by the College of Pharmacy’s Human Research Ethics Committee at the University of Basrah. All procedures followed the Declaration of Helsinki and its later amendments [8]. Because the study did not entail medical procedures, clinical trials, or any intervention that would typically require a formal ethical approval number, no such number was issued. Nonetheless, the research protocol, including the questionnaire design, consent process, and data handling procedures, was reviewed and approved by the University of Basra/ college of Pharmacy Ethics Committee in accordance with the institution’s guidelines for research involving human participants.

Statistical analysis

Results were expressed as numbers and frequencies, and associations between variables

were tested with SPSS version 23 (IBM Corp., Armonk, NY, USA) using the Pearson chi-square test. It was determined that a p-value below 0.05 was considered statistically significant.

RESULTS

During data collection, 1,525 pregnant women were included; all participants completed the entire form during their prenatal visit. Table 1 presents the clinical and sociodemographic information of the participants. Participants ranged from 14 to 42 years of age (mean 24.3 years), with most aged 20-29 years (51.5 %). Regarding economic status, most participants had a moderate economic status (70.8 %), 6.6 % had a good status, and 22.6 % had a poor economic status.

Regarding education, only 6.9 % of participants had completed college, while 46.6 % had completed only primary school, 22.6 % had completed secondary school, and 23.9 % had received no education. The number of pregnancies ranged from 1 to 11 (average of 2.98 pregnancies per woman). In total, 29 % of the pregnant women had a previous abortion and 4.9 % of women had a previous child with an anomaly.

Table 1: Sociodemographic and clinical data for the pregnant women

Variable	Category	N	%
Age (years)	< 20	425	29
	20–29	785	52
	30–39	275	18
	≥ 40	40	2.6
Economic status	Good	100	6.6
	Moderate	1080	71
	Bad	345	23
Educational level	Illiterate	365	24
	Primary	710	47
	Secondary	345	23
	College	105	6.9
No. of pregnancies	1–3	990	65
	4–6	450	30
	7–9	60	3.9
	10–11	25	1.6
Abortion history	Yes	435	28.5
	No	1090	72
Anomaly history	Yes	75	4.9
	No	1445	95

Frequency (%), Number of women (n = 1525)

Table 2 shows the medications most commonly used by pregnant women who participated in this study at the time of the interview. Medications for hematopoietic organs and blood were the most commonly prescribed drugs (folic acid 75.41 %, n = 1,150), followed by dydrogesterone for systemic use (43.28 %, n = 660) and multivitamins (39.34 %, n = 600).

Table 2: Most commonly used medications by pregnant women

Medication	n	%
Folic acid	1150	75.41
Dydrogesterone	660	43.28
Multivitamins	600	39.34
Meclizine	210	13.77
Amoxicillin	190	12.46
Methyldopa	150	9.84
Hyoscine butylbromide	140	9.18
Metoclopramide	115	7.54
Vitamin B6	110	7.21
Insulin	65	4.26
Cephalexin	50	3.28
Chlorpheniramine	40	2.62
Famotidine	25	1.64
Metronidazole	25	1.64
Lactulose	20	1.31
Dextromethorphan	15	0.98
Thyroxine	5	0.33
Erythromycin	5	0.33
Loperamide	5	0.33
Bromhexine	5	0.33
Loratadine	5	0.33
Aspirin	40	2.62
Gaviscon	30	1.97
Atenolol	30	1.97
Omeprazole	15	0.98
Domperidone	15	0.98
Streptomycin	10	0.66
Diazepam	5	0.33
Gentamicin	5	0.33
Danazol	5	0.33
Miconazole	5	0.33
Hydralazine	5	0.33
Salbutamol	100	6.56
Calcium	100	6.56
Vitamin D3	65	4.26
Prifinium bromide	30	1.97
Bisacodyl	35	2.3
Spiramycin	15	0.98
Omega-3	15	0.98

Frequency (%), Number of women (n)

In total, 94 % of pregnant women reported taking at least one medication, and approximately 63 % used 3-5 drugs (Table 3).

Table 3: Number of medications used during pregnancy and their frequencies

No. of medications	n	%
1-2	485	34
3-5	900	63
>5	45	3
Total	1430	94

Frequency (%), Number of women (n)

Regarding the FDA risk classification, 87.24 % of the medications are considered safe in pregnancy, 4 % are probably risky, and 8.75 % were unclassified or unidentified by the FDA at the time of data extraction (Table 4).

Table 4: Distribution of drugs by United States Food and Drug Administration (FDA) risk classification

FDA risk classification	N	%
Safe medications	3590	87.24
Probably risky drugs	165	4.01
Unclassified drugs	360	8.75

Number of medications used (n = 4115), Frequency (%)

The result of the chi-square analysis showed that age was not significantly associated with drug use during pregnancy ($\chi^2 = 2.68$, df = 3, p = 0.444; Table 5). There was a statistically significant association between economic status and drug use during pregnancy; in this sample, women with higher economic status used more medications ($\chi^2 = 7.44$, df = 2, $p = 0.024$). When education level was assessed against medication use, the data showed a significant decrease in drug use with higher education ($\chi^2 = 11.34$, df = 3, p = 0.010).

A significant association was also found between the number of pregnancies and drug use, with decreased drug use as the number of pregnancies increased ($\chi^2 = 25.76$, df = 3, $p < 0.001$).

No association was found between previous abortion ($\chi^2 = 1.66$, df = 1, p = 0.198) or child anomalies ($\chi^2 = 0.069$, df = 1, p = 0.793) that women experienced previously and medication use in the current pregnancy

Table 5: Pearson chi-square test of associations between participants' characteristics and their drug use during pregnancy

Variable	χ^2	Df	Asymptotic significance
Age of pregnant women	2.68	3	0.444
Economic status	7.44	2	0.024
Level of education	11.34	3	0.010
Number of pregnancies	25.76	3	< 0.001
Previous abortion	1.66	1	0.198
Previous child anomalies	0.069	1	0.793

DISCUSSION

Research has shown that over the last 30 years, medication use among pregnant women has increased by about 60 % [8]. Because such work informs interventions to limit indiscriminate drug use, it is important to identify patterns of drug consumption in pregnant women. Pregnant women also need higher-quality care, especially regarding medication use, to reduce potential harmful effects on the fetus. The study protocol, including the inclusion of pregnant adolescents aged ≥14 years, was reviewed and fully approved by the Ethics Committee of University of Basra, College of pharmacy.

The committee approved the inclusion of the 14-year-and-older age group because teenage pregnancy is a high-risk group and a significant public health issue in the study region, and excluding them would bias the results. In accordance with the Declaration of Helsinki and local regulations in Iraq, where judicial marriage is permitted from 15 years and pregnant adolescents are considered as "emancipated minors" for reproductive health decisions. For every participant under 18 years, written informed consent was obtained from her legal guardian (parent or husband, as she is married). In addition, written informed assent was obtained from the adolescent herself, after explaining the study aims, risks, and benefits in simple, non-coercive language. She was informed that participation is voluntary and refusal would not affect her medical care.

Studies have shown that prescribed medication use during pregnancy in developing countries is widespread [6]. However, there is no confirmed percentage (to our knowledge) because of limited reporting of drug utilization; this gap encouraged this study, which focused on the prevalence of medication use during pregnancy in a defined area.

The present study also examined associations between drug use by pregnant women and socio-economic factors to clarify possible drivers of this drug use. Regarding education level, approximately 69.2 % of participants had 6 - 12 years of education. The current study concluded that higher education level and lower economic status are associated with a lower percentage of drug use. Olesen *et al* [9] also found that overall prescription medication use was highest among women with basic schooling and lowest among women with the highest education.

Economic status is another important factor contributing to drug use in general, as a low economic level tends to reduce unnecessary drug consumption. The same association was found regarding the number of previous pregnancies. The more pregnancies a woman had, the fewer drugs she used. These findings may reflect that women in their first pregnancy are often more concerned and attend more medical visits, with more drugs prescribed. With greater experience, women often reduce prenatal care visits and drug use; multiparous women

may also feel more confident. Similar results were reported by Odalovic *et al* [10] regarding predictors of maternal medication use; they stated that prescription medication use during pregnancy was reduced when parity was greater than 1. Since the present study collected data from two primary healthcare centres, most drugs prescribed (87 %) are considered safe for use during pregnancy. Nevertheless, a relatively large proportion of drugs are unclassified or probably risky, which remains a concern. The current study identified folic acid, an antianemic drug, as the most commonly used drug. Folic acid is recommended for all pregnant women for its antianemic effect and protection against neural tube defects and possibly other congenital malformations, especially if given in the periconceptional period. Several studies have reported this high prescription rate of folic acid among pregnant women; Albader *et al*. reported that 87.7 % of women in their study used folic acid during pregnancy [11].

One of the most frequently prescribed drugs is the progestin hormone dydrogesterone. An optimal progesterone level is essential for maintaining pregnancy and supporting a good outcome. Progesterone deficiency is commonly linked to miscarriage and is usually treated with a synthetic progestin that mimics endogenous progesterone. Although it shares structural similarities with progesterone, the common synthetic progestin dydrogesterone has a higher bioavailability and is more selective for the progesterone receptor, dydrogesterone is approved as effective for the treatment of threatened and recurrent miscarriage [12].

In the present study, dydrogesterone was prescribed to about 43 % of pregnant women who visited the care unit during data collection. This considerably high prescribing rate of dydrogesterone is questionable because no specific confirmation of need for this medication was documented. This result is consistent with a retrospective, observational, multicenter study in India that found participants were given dydrogesterone (46.9 %) for threatened abortion and repeated pregnancy loss (27.3 %) [13].

Clinical studies have shown that dydrogesterone can increase pregnancy rates, support luteal-phase defect management, and improve reproductive outcomes, which helps explain its high use alongside threatened and recurrent miscarriage [14]. Additionally, dydrogesterone lowers the risk of preterm labor and helps create a more favorable environment for maintaining pregnancy [15].

It is currently especially useful in the *in vitro* fertilization (IVF) and intrauterine insemination (IUI) cycles, with better patient adherence and fewer adverse effects. Dydrogesterone stabilizes the endometrial environment in recurrent pregnancy loss (RPL), supporting implantation and early embryonic development [16]. These indications of dydrogesterone may partly explain this increased rate of use. Furthermore, gynecologists in Basrah city prescribed dydrogesterone to some pregnant women, even without clear indications, in an attempt to sustain pregnancy [17]. Because it is easy to give orally, has comparable or better efficacy and tolerability than micronized progesterone, requires a lower dose due to its high bioavailability, and improves outcomes in infertility, threatened abortion, and recurrent pregnancy loss, dydrogesterone has become a preferred option for progesterone-deficient obstetric and gynecological conditions [12].

The third most commonly prescribed product is multivitamins. It is well established that pregnant women's need for multivitamins is about 1.5 times that of non-pregnant individuals, which can be explained by increased metabolic demands [18]. Therefore, medical practitioners advise taking a multivitamin to help meet these additional needs. It is important to note that taking vitamins within the normal daily requirement is classified as category A, whereas excess multivitamin doses may be classified as category C. Excessive dietary vitamin A intake is considered teratogenic [19].

It is recommended from this study that records of medications used by pregnant women be reviewed to confirm their safe use. One limitation of this study is its cross-sectional design, which cannot establish cause-and-effect relationships among variables. Other limitations include sample bias, limited representativeness, and difficulties calculating response rates. Further studies focused on drug safety by trimester are needed.

CONCLUSION

This study has reported that medication use in pregnancy is often unavoidable and that most participants used multiple medications. Antianemic drugs, dydrogesterone, and multivitamins were the most widely used medication classes. Data from this research and related studies confirm the importance of improving health knowledge among pregnant women and increasing awareness of, and access to, prescribing guidelines among prescribers and pregnant women.

DECLARATIONS

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Ethical approval

It is stated in the methods.

Use of Artificial intelligence/Large language models

The authors confirm that AI-based tools were used solely for language editing and manuscript polishing purposes (e.g., grammar, phrasing, and clarity). No AI tools were used to generate content, interpret data, or influence study design, results, or conclusions. All intellectual contributions, study analyses, and interpretations reported in the manuscript are the original work of the authors.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of interest

No conflict of interest is associated with this work.

Contribution of authors

We declare that this work was done by the author(s) named in this article, and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. Zainab Najim Abdul-nabi**:** Conceptualization, Methodology, Writing – Original Draft. Shaema Mohammed Ali Mohammed: Analysis, Writing – Review & Editing. Kasim Fawzi Abdulkarem: Visualization, Supervision. Wafaa Yusuf Khalaf: Funding Acquisition, Resources, Data Collection.

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