DOI: 10.21522/TIJPH.2013.12.02.Art009

Prevalence and Potential Risks Associated with Utilization of Medication During Pregnancy- A Cross-Sectional Study

Suhaila Abdalkarim Ali
Department of Community and Family Medicine, Faculty of Medicine, Jazan University,
Saudi Arabia

Abstract

Medication usage during pregnancy is increasing twofold, and it should be considered a public health issue due to increasing complications associated with medication. Data on prescribed and selfprescribed medication among Sudani females is limited. Hence, this study aims to assess the prevalence and associated risk factors of drug usage among Sudanese females, including prescribed medication and self-prescribed medication, who are registered in tertiary care facilities. A cross-sectional descriptive study was planned in the hospital setting at Omdurman Maternity Center, Sudan. Data were collected between January 2023 and February 2023 through semi-structured interviews. The sample comprised 878 pregnant females and was divided into two groups: 453 females on medication and 425 females not on medication. The data were analyzed using univariate and multivariate logistic regression, and statistical significance was set at 0.05. The result of this study shows that 51.1% of females were on medication, of which 14.1% were on self-medication. The maximum drugs taken were antibiotics, followed by diabetic and hypertensive medication. Data showed a statistically significant relationship between medicine usage and chronic medical conditions (p<0.001). However, no significant association was reported between medicine usage, body mass index, gravidity, maternal age, and education. The prevalence of medicine usage among Sudani women is high. These findings underscore the importance of enhancing the initiatives undertaken by healthcare professionals, particularly in the prenatal setting, to ensure the appropriate management of medication usage during pregnancy, thereby reducing the risk of potential complications for both the mother and the fetus.

Keywords: Medication, Pregnancy, Maternal Health, Self-Medication.

Introduction

Literature on maternal health reports that 80 to 90% of pregnant females take some form of medication. [1-4]. This high percentage is linked to the health and age of pregnant women [5]. Older females are more prone to medical conditions that require continuous treatment, which can help prevent adverse health effects on both the female and the fetus [5]. However, the major concern regarding medication utilization among pregnant females is the type of drug, as most of the drugs have the potential to cross the placenta barrier and can affect the fetus's health. [6].

Studies support the use of medication that is safe during pregnancy; however, there are several drugs that are associated with fetal health risks [7-9]. Moreover, the drugs that are contradicted and do not have many studies related to maternal and fetal health are considered risky drugs and should not be used during pregnancy [2].

Pregnant females require medication to control pregnancy-related symptoms or acute and chronic medical conditions. Some females acquire this information from health care professionals, while some take self-medication. Taking self-medication is mostly found in

 females from developing parts of the world, where proper clinics and knowledge are not provided. [10, 11] In a recent survey, it was demonstrated that around 50% of African females take self-medication during pregnancy [7, 8].

The United States Food and Drug Administration (US FDA) has classified pregnancy medication into A, B, C, D, and X, where the drugs under the A category are the safest, followed by B. The medication in the C category is considered to have potential risks to the fetus, and those in categories D and X have evidence of fetal risks [12, 13] It has been reported that around 8-9% of pregnant females received some pharmacological assistance due to medical problems, and around 7-20% of pregnant women take the US FDA D and X category of medication [12, 13].

Medication usage among pregnant females is considered a public health concern due to the lack of knowledge about the adverse effects of medication. Previous studies on pregnant females in Sudan have examined stillborn fetuses and associated factors [14, 15]. These studies have reported medication use but were limited to blood supplements and over-thecounter medicine [14, 15]. Additionally, they explored the knowledge of females and their partners on medication usage without analyzing prevalence and associated factors comprehensively [14, 15]. Studies have been published regarding the prevalence of drug usage in some countries. [1-4, 6]. However, there is a gap in knowledge regarding medication usage and the risk factors associated with medication among pregnant females in Sudan. Therefore, the main objective of the current study is to assess the prevalence and associated risk factors of drug usage among Sudanese females, including prescribed medication and self-prescribed medication, who are registered in tertiary care facilities.

Material and Method

Study Design and Sample Population

A descriptive cross-sectional study was conducted in the hospital setting at Omdurman Maternity Center. Omdurman Maternity Hospital was founded in 1957 and is one of the largest tertiary centres that provides all tertiary childbirth and care services. The hospital has 65 beds, 70 family health strategic teams, and one reference hospital for childbirth. The data were collected from the pre-existing medical records of 1,580 women registered (medical data recording and analyzing software). Exclusion criteria were high-risk pregnancy, women on medication post-pregnancy, duplicate entries, and women who were not receiving antenatal care through Omdurman Maternity Centre, resulting in the inclusion of 878 pregnant women.

The study population was women above the age of 18 years who attended antenatal clinics for regular checkups. The size of the study sample was calculated based on pregnant women who registered and were able to participate in the study. The sample size was calculated based on a previous study by Sullivan et al., 2009 using OpenEpiinfo software, where the prevalence of drug use was 50% among pregnant women, with an estimating error of 5% and a confidence interval of 95%, with 20% of loss resulting in 878 pregnant women [16]. This was followed by a random stratified sampling model, distributing women into two groups, one with medication usage during pregnancy (n=453) two without medication (n=425), respectively.

The data were collected from January 2023 to February 2023 through semi-structured interviews conducted with patients while they visited the hospital. The instrument used to collect data was the Ministry of Health Sudan prenatal consultation script (Part one- clinical history) [15]. The dependent variable was the type of medication used in pregnancy. The

independent variables were age, visits to clinics, qualifications, marital status (single, divorcee, or with a partner), family income, chronic illness, abortion, and advice for drug usage. The medication usage level was classified according to the World Health Organization for the Anatomical therapeutic classification (ATC), and the risk factors associated with drug usage in the FDA five group risk factors were considered.

Data Analysis

The collected data were entered into the Microsoft Excel sheet (2021) and later subjected to statistical analysis using the Statistical Package for Social Sciences (SPSS) version 21. The variable of interest was dichromate with outcome variables of drug usage (Yes/No). Descriptive analysis was performed using frequencies in percentage format. Univariate analysis was performed to verify the association between the variables of outcome of interest. If the association was significant, a multivariate regression analysis was performed to confirm the findings. For all the analyses, the confidence interval was 95%, with a level of error of 0.05%. The statistical significance was considered with the pvalue<0.05.

Ethical Consideration

The participants agreed to participate and signed a consent form before taking part in the study, and all the regulations that involved human participants were followed. The research project was ethically approved by the Human Research Ethical Committee of the Omdurman Maternity Hospital (Registration number: 2022-07).

Result

The mean age of the 878 pregnant females included in this study was 20.0 to 28.0 years, where 62% were in the age group between 24 and 27 years. More than half of the females had completed their secondary education (71.3%), were married (70%), and worked (5.1%) (Table

1). In the index pregnancy, 453 women (51.6%) reported medication usage. Of these, 386 women (44.0%) had taken some antibiotics, 37 women (4.2%) used medications for diabetes mellitus, 11 women (1.3%) used antihypertensive drugs, and 22 women (2.5%) used other medications (e.g., for thyroid or epilepsy). Among them, 89 women (10.1%) used these drugs during the first trimester, and 124 women (14.1%) reported using self-administered drugs (Table 1).

The median gravidity within the included females was two, with an interquartile range (IQR) of 1–4, consistent across both groups. The overall cohort's median body mass index (BMI) was 26.4 kg/m² (IQR 24.1 to 29.6 kg/m²). Notably, individuals who utilized medications like metformin, commonly prescribed for conditions such as gestational diabetes mellitus and polycystic ovarian syndrome, exhibited a marginally higher median BMI of 26.6 kg/m² (IQR 24.0 to 30.4 kg/m²) compared to those who did not employ such medications, the latter presenting with a median BMI of 26.1 kg/m² (IQR 24.1 to 28.8 kg/m²) (Table 1).

Among the participants, a majority (72.2%) attended four or more antenatal care sessions, with comparable proportions observed between medication users (70.0%) and non-users (74.6%). In terms of educational qualification, 71.3% of women possessed at least a secondary education, with a higher prevalence noted among medication users (75.3%) compared to non-users (67.9%). Most women identified as homemakers (94.9%), and their employment status showed no significant divergence between the groups. Most participants had no history of cesarean section (81.7%), though slightly lower proportions were seen among medication users (79.5%) compared to nonusers (84.0%). Likewise, the majority had no history of abortion (86.4%), with similar rates across both groups. Concerning medical conditions, most women reported underlying illnesses (89.5%), yet a notably higher percentage of medication users

acknowledged having medical conditions (17.0%) compared to non-users (3.5%) (Table 1).

Table 1. Demographic Characteristics of the Study Samples

Variables		Total (N=878)	Women who used medications N=453 (51.6%)	Women who did not use medication N=425 (48.5%)			
The median (interquartile range) of							
Maternal age, years		24.0 (20–29)	24.0(20.0–28.0)	20.0 (20.0–29.0)			
Gravidity		2 (1–4)	2 (1–4)	2 (1–4)			
Body mass index, kg/m2		26.4(24.1-29.6)	26.6(24.0-30.4)	26.1 (24.1–28.8)			
Number (percentage) of							
Antenatal care	≥4 visit	634 (72.2%)	317 (70.0%)	317 (74.6%)			
	<4 visit	244 (27.8%)	136 (30.0%)	108 (25.4%)			
Maternal education status	≥secondary	418 (71.3%)	204 (75.3%)	214 (67.9%)			
	<secondary< th=""><th>168 (28.7%)</th><th>67 (24.7%)</th><th>101 (32.1%)</th></secondary<>	168 (28.7%)	67 (24.7%)	101 (32.1%)			
Maternal employment status	Employed	45(5.1%)	23(5.1%)	22(5.2%)			
	Housewife	833(94.9%)	430 (94.9%)	403 (94.8%)			
History of caesarean section	No	717 (81.7%)	360 (79.5%)	357 (84.0%)			
	Yes	161 (18.3%)	93 (20.5%)	68 (16.0%)			
History of abortion	No	759 (86.4%)	390 (86.1%)	369 (86.8%)			
	Yes	119 (13.6%)	63 (13.9%)	56 (13.2%)			
Medical diseases	No	786 (89.5%)	376(83.0%)	410 (96.5%)			
	Yes	92 (10.5%)	77 (17.0%)	15 (3.5%)			

Table 2 displays the outcomes of a multivariate analysis investigating the relationship between various factors and medication utilization among expectant

mothers. Odds ratios (OR) with corresponding 95% confidence intervals (CI) are presented alongside p-values to ascertain the statistical significance of these relationships. Maternal

age exhibited no significant association with medication usage (OR=0.98, 95% CI 0.96-1.01, p=0.329). Similarly, gravidity and body mass index (BMI) were not significantly linked to medication use (OR=0.99, 95% CI 0.94-1.05, p=0.894; OR=1.01, 95% CI 0.99-1.02, p=0.489, respectively). Antenatal care visit frequency, when compared to four or more visits, did not show a significant association with medication use (OR=1.52, 95% CI 0.93-1.69, p=0.128). Likewise, maternal education below the secondary level did not significantly correlate with medication use (OR=1.29, 95% CI 0.94-

1.76, p=0.107), nor did maternal employment status (OR=0.98, 95% CI 0.53-1.78, p=0.947) (Table 2). Although a borderline significant association was noted between a history of cesarean section and medication use (OR=1.53, 95% CI 0.96-1.91, p=0.084), no significant association was observed for a history of abortion (OR=1.06, 95% CI 0.72-1.56, p=0.752). However, the presence of medical conditions significantly increased the likelihood of medication use during pregnancy (OR=5.59, 95% CI 3.16-9.90, p<0.001).

Table 2. Multivariate Logistic Regression Analysis of Factors Associated with Medication

Variables	Odds ratio (95% confidence interval)	P-value	
Maternal age, years	0.98 (0.96–1.01)	0.329	
Gravidity	0.99 (0.94–1.05)	0.894	
Body mass index, kg/m ²		1.01 (0.99–1.02)	0.489
Antenatal care	≥4 visit	Reference	
	<4 visit	1.52 (0.93–1.69)	0.128
Maternal education status	≥secondary	Reference	
	<secondary< td=""><td>1.29 (0.94–1.76)</td><td>0.107</td></secondary<>	1.29 (0.94–1.76)	0.107
Maternal employment	Employed	Reference	
status	Housewife	0.98 (0.53–1. 78)	0.947
History of caesarean section	No	Reference	
section	Yes	1.53 (0.96–1.91)	0.084
History of abortion	No	Reference	
	Yes	1.06(0.72–1.56)	0.752
Medical diseases	No	Reference	
	Yes	5.59 (3.16–9.90)	<0.001*

Table 3 provides insights into the prevalence of medication usage among pregnant women. Of the included participants, 386 individuals (44.0%) reported using antibiotics, while 37 (4.2%) used medications for diabetes mellitus. Additionally, 11 participants (1.3%) reported the use of antihypertensive drugs, and 22 (2.5%) used other medications, including those for

conditions such as thyroid disorders and epilepsy, either individually or in combination with other drugs. Among these medication users, 89 women (10.1%) reported drug usage during the first trimester of pregnancy, and 124 individuals (14.1%) reported self-administration of medications.

Table 3. Medication Prescribed or Self-Prescribed During Pregnancy

Drugs taken during pregnancy		%
1.Antibiotics (Amoxycillin, cloxacillin, amoxicillin-clavulanate, cephalosporins)		44.0%
2. Gestational diabetic drugs (Metformin and Glyburide)		4.2%
3.Gestational Hypertensive drugs (Nefidipine and ketanserin)	11	1.3%
4.Dermatological medications	10	0.9%
5. Thyroid medication	10	0.9%
6. Epilepsy medication	2	0.02%
7. Self- medication	144	14.1%
Total	453	51.6%

Discussion

The primary objective of this descriptive cross-sectional research was to analyze the prevalence of medication utilization among pregnant women and to evaluate the associated risks and consequences. This study aimed to offer insights into medication usage trends point potential during pregnancy, out contributing factors, and assess their influence on maternal and fetal well-being. By examining these elements, the study endeavors to enhance comprehension of medication utilization during pregnancy and provide relevant data to healthcare practitioners and policymakers, facilitating the optimization of maternal and

fetal healthcare services. The result of this study suggests the significant association of drug usage among young pregnant females with chronic medical illness.

Regarding demographics, the pregnant women included in the study were young, with an average age of 24 years. This aligns with findings from prior research examining medication utilization among pregnant women attending primary care prenatal services, where mean ages of 23.4 and 25.75 were reported, respectively [6, 17, 18]. In this study, it was found that 51.6% of women utilized medications during their index pregnancy. Among these, 44.0% reported using antibiotics,

while 4.2% used medications for diabetes mellitus, 1.3% used antihypertensive drugs, and 2.5% utilized other medications combinations (e.g., for thyroid or epilepsy). Additionally, 10.1% of women reported medication usage during the first trimester, and 14.1% self-administered these medications. Conversely, in the study of Brazilian females' medication usage, the maximum number of females (70.1%) used medication multivitamins, folic acids, and antipyretic drugs, which are recommended as safe drugs by the FDA [3]. However, in this research, no participants have reported taking such drugs. This difference could be attributed to the pregnancy safety-related information available in different countries.

Multinational research conducted in 2019 examined the prevalence and determinants of medication usage during pregnancy, revealing that approximately 83.6% of pregnant women take at least one medication, whether prescribed or self-administered, throughout their pregnancy [19]. Among the most utilized medications were those addressing pain, heartburn, and upper respiratory issues. Studies have reported variations in medication utilization, with higher rates reported in Northern Europe, North America, and Australia, particularly for chronic or long-term conditions compared to Western Europe [1,10,18]. Additionally, factors such as age, educational levels, and lifestyle characteristics were found to be associated with medication usage during pregnancy [6, 11]. A cross-sectional study conducted in Iran identified a prevalence of 2.6% for self-reported substance abuse among pregnant women [20]. This finding reports the importance of understanding and addressing substance abuse issues during pregnancy. The prevalence and implications of substance abuse in pregnancy, providing valuable context for understanding this complex issue [21, 22].

A multinational online survey discovered that 81.2% of pregnant women utilized some form of medication, either through prescription

or over-the-counter channels, with a notable majority (over 65%) resorting to medication with over-the-counter products [10]. This study, underscores the widespread use of medication among pregnant populations across different regions [2]. Similarly, research conducted in Southern Tigray, Ethiopia, involving 647 pregnant women, revealed that a significant proportion (87.5%)received prescriptions for at least one medication during pregnancy [23]. Likewise, a cross-sectional study in Bahir Dar city administration, Northwest Ethiopia, which included 510 pregnant women, found that 88.4% were prescribed at least one medication during their pregnancy [24]. Notably, an interesting finding from this study was the statistically significant association between the low educational level of antenatal care providers and the prescribing of medications. This insight, identified by Admasie et al. in 2014, highlights the importance of considering healthcare provider characteristics in understanding medication prescribing practices during pregnancy [23]. A systematic review and meta-analysis conducted in Ethiopia yielded a pooled prevalence of prescription drug utilization among pregnant women at 17.6% across various trimesters [25]. Concurrently, a study in Brazil highlighted that 44.5% of pregnant women practiced selfmedication, with analgesics, antacids, and antibiotics emerging as the most used medications [20].

Table 1 outlines key findings suggesting no significant disparities in maternal age and gravidity between pregnant women who utilized medications and those who did not. Most participants attended four or more antenatal care visits, with no notable discrepancy in visit frequency observed among medication use groups. Concerning education, a higher proportion of medication-using women possessed secondary or higher education compared to non-users, contrasting findings from a study in Malaysia which revealed significant associations between

sociodemographic characteristics and medication use during pregnancy [26]. Employment status was similar across both groups, with the majority being homemakers. While most women had no history of cesarean section or abortion, a notably higher percentage of medication-using women reported having medical conditions compared to non-users.

The multivariate analysis of medication usage among pregnant women unveiled several noteworthy insights. Maternal age, gravidity, and body mass index (BMI) demonstrated no significant association with medication use. Similarly, neither the frequency of antenatal care visits nor maternal educational attainment exhibited significant correlations medication usage. Maternal employment status, whether employed or as a homemaker, also failed to reveal any significant association. Although a borderline significant association was noted between the history of cesarean section and medication use, no such association was found regarding the history of abortion. In contrast, the presence of medical conditions emerged as a significant factor influencing medication usage during pregnancy. Women afflicted with medical ailments exhibited markedly higher odds of medication utilization compared to those without such conditions [27]. These findings underscore the pivotal role of medical illnesses in shaping medication decisions during pregnancy. Conversely, maternal age, gravidity, BMI, antenatal care visits, maternal educational status, employment status, and obstetric history did not exert a significant influence on medication usage patterns among the pregnant women scrutinized in this study.

Moreover, it is worth acknowledging the potential limitations associated with the data collection methodology employed in this study, particularly the utilization of interviews. There exists a risk of measurement bias stemming from factors such as memory lapses, confusion, or reluctance among pregnant women to disclose medication usage. Moreover, the

study's inability to differentiate between specific types of medications utilized further obscures the understanding of medication patterns during pregnancy. Additionally, the findings may lack generalizability to other populations or regions due to the study's specific sample characteristics. Furthermore, the absence of exploration into potential confounding factors limits the comprehensive understanding of the associations observed. Lastly, the study's cross-sectional design restricts the ability to establish causality or ascertain the long-term effects of medication during pregnancy. Despite these usage limitations, this study offers valuable insights into medication utilization trends among pregnant women. It underscores the importance of further research in this domain to elucidate the complexities surrounding medication use during pregnancy and its implications for maternal and fetal health.

Conclusion

This study revealed a significant prevalence of medication usage among pregnant women, with the most reported medications being analgesics and antibiotics. Most of these medications are recognized as safe for use during pregnancy. Factors associated with medication usage during pregnancy included being in the first and third trimester, absence of chronic illness, presence of mental illness, and receiving guidance from healthcare professionals regarding medication usage.

These findings underscore the importance of enhancing the initiatives undertaken by healthcare professionals, particularly in the prenatal setting, to ensure the appropriate management of medication usage during pregnancy, thereby reducing the risk of potential complications for both the mother and the fetus. Given the complexity of this issue, it is evident that healthcare providers must possess comprehensive knowledge regarding the medications utilized by pregnant women and their potential adverse effects across

different stages of pregnancy. This knowledge can serve as a foundation for developing and implementing educational interventions aimed at pregnant women, empowering them with informed decisions regarding the rational utilization of medications during pregnancy.

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Acknowledgment

None.

Conflict of Interest

None.

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