



Original Article

Perceived risks of over-the-counter medication use among pregnant Saudi mothers: A cross-sectional study



Ashwaq Ayidh M. Alosaimi, MSN^a, Sahar M. Zamzam, Ph.D.^b,
Daniel Joseph E. Berdida, Ph.D.^{c,*} and Hazel N. Villagrancia, Ed.D.^d

^a General Administration of Health Programs and Chronic Diseases, Ministry of Health, Riyadh, KSA

^b Maternity and Gynecologic Nursing, Alexandria University, Alexandria, Egypt

^c College of Nursing, University of Santo Tomas, Manila, Philippines

^d Medical-Surgical Nursing Department, College of Nursing, University of Ha'il, Ha'il City, KSA

Received 3 August 2021; revised 16 February 2022; accepted 4 March 2022; Available online 20 March 2022

المخلص

أهداف البحث: يستخدم عدد كبير من السيدات الأدوية دون وصفة طبية، خاصة أثناء الحمل. لهذا، تهدف هذه الدراسة للتحقيق في إدراك المخاطر لاستخدام الأدوية بين الأمهات السعوديات الحوامل.

طرق البحث: تم اعتماد التصميم المقطعي وأخذ العينات الهادفة لهذه الدراسة، تم استخدام الـ 28 عنصراً لمقياس المعتقدات الصحية لتعاطي الأدوية لجمع العينات من الأمهات السعوديات الحوامل (العدد=366) من مستشفى متخصص من الدرجة الثالثة. تم تحليل البيانات باستخدام الإحصاء الوصفي والاستنتاجي. بعد الاختبارات الطبيعية، تم استخدام النسب المئوية، متوسط الدرجات، والانحراف المعياري لفحص البيانات الديموغرافية. تم استخدام اختبار انوفا الاتجاه الواحد لتحديد الاختلافات في المخاطر المتصورة على مقياس المعتقدات الصحية بما يخص متغيرات الملف الاجتماعي الديموغرافي. تم استخدام الاختبارات اللاحقة لتحديد الاختلافات بين المجموعات في المتغيرات المستقلة.

النتائج: عبر المجالات الخمسة لمقياس المعتقدات الصحية، حصل مجال الحساسية المدرك على أعلى مرتبة (0,36). كان هناك اختلاف كبير بين متوسط درجات إدراك الأمهات السعوديات الحوامل للقبالية للإصابة وفوائد استخدام الأدوية دون وصفة طبية، إدراك القابلية، والفوائد عند استخدام الأدوية دون وصفة طبية. ولكن، لم يكن هناك فرق كبير في درجة الشدة، والعوائق، والكفاءة الذاتية للأمهات عند استخدام الأدوية التي تصرف دون وصفة طبية.

الاستنتاجات: هناك اختلافات ملحوظة لإدراك السيدات الحوامل لمخاطر استخدام الأدوية دون وصفة طبية. نوصي بزيادة الوعي بمخاطر الأدوية دون وصفة طبية أثناء الحمل لضمان سلامة الأم وطفلها. ونحث على إجراء المزيد من الأبحاث حول مبادرات تدريس مخاطر استخدام الأدوية دون وصفة طبية أثناء الحمل.

الكلمات المفتاحية: الأدوية دون وصفة طبية؛ إدراك المخاطر؛ الأمهات الحوامل؛ المملكة العربية السعودية

Abstract

Objectives: Many women use over-the-counter (OTC) medicines, particularly during pregnancy. Therefore, this study investigated the perceived risks of using OTC medicines among pregnant Saudi mothers.

Methods: With a cross-sectional design and purposive sampling, the 28-item Drug Use Health Belief Scale was used to collect data from pregnant Saudi mothers (n = 366) in a general tertiary hospital. The data were analyzed with descriptive and inferential statistics. After normality testing, the percentages, mean scores, and standard deviations were used to examine the demographic data. One-way ANOVA was used to identify the relationships between perceived risks on the Health Belief Scale and the participants' sociodemographic profile variables. Post-hoc tests were used to identify differences in the independent variables among groups. The statistical significance threshold was set at $p \leq 0.05$.

Results: Across the five domains of the Health Belief Scale, the perceived susceptibility domain had the highest rank (0.36). Significant differences were observed between

* Corresponding address: College of Nursing, University of Santo Tomas, St. Martin de Porres Bldg., España Blvd., Manila, 1015, Philippines.

E-mails: deberdida@ust.edu.ph, djeberdidarn@gmail.com (D.J. E. Berdida)

Peer review under responsibility of Taibah University.



the mean scores of pregnant Saudi mothers' perceptions of susceptibility and the benefits of using OTC medications ($p = 0.05$), perceptions of susceptibility ($p < 0.001$), and benefits while using OTC medications ($p = 0.018$) than those who did not use OTC medications. However, no significant differences were observed in the degree of perceived severity, barriers, and self-efficacy in mothers using OTC medications ($p > 0.05$).

Conclusion: Notable differences were found in pregnant women's perceptions of the risks of using OTC medications. Greater awareness of the risks of OTC medication use during pregnancy is required. To ensure mothers' safety, a collaboration between prenatal multidisciplinary team of professionals (e.g., doctors, nurses, midwives) in community and hospital settings should be prioritized.

Keywords: Health belief; KSA; Over-the-counter (OTC) medications; Perceived risks; Pregnant mothers

© 2022 The Authors.

Production and hosting by Elsevier Ltd on behalf of Taibah University. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Introduction

Self-medication with over-the-counter (OTC) medicines is widely used by the general public, including pregnant women, to treat a variety of conditions. However, this practice may have harmful effects on maternal and fetal outcomes in pregnant women. The United States' Food and Drug Administration (FDA) created a system to classify the safety of medications for pregnant women and their effects on fetal development, in response to the increased prevalence of birth abnormalities caused by OTC medicines.¹ Category A denotes no risk to the fetus, category B denotes no indication of fetal harm in humans, and category C indicates that limited or no studies have been conducted on a drug's use during pregnancy in humans, but animal studies have indicated adverse fetal consequences.¹ In human investigations, category D has been shown to cause prenatal harm, but use of this class of drugs may be important for pregnant women despite the danger to the fetus.¹ Category X indicates evidence of fetal harm according to animal and human studies.¹ Thus, drugs in category X are not recommended, because the dangers outweigh any potential medical benefits.²

According to Parisi et al. (2011),³ the first trimester of pregnancy is a critical period in organogenesis (when vulnerable organs are formed). Drug exposure during other stages of pregnancy (second and third trimesters) has been associated with fetal congenital anomalies. A lack of information regarding the pharmacokinetics, pharmacodynamics, safety, and efficacy of drug use during pregnancy can lead to insufficient treatment and potential harm among pregnant women.³

Many studies have investigated the dangers, safety, and adverse effects of OTC drugs on pregnancy outcomes.^{3–7}

However, few studies have examined pregnant women's awareness of the risks and benefits of OTC medicine use.^{4,5} Regardless of their safety profiles, OTC drugs are commonly available in pharmacies^{4,5} and are used during 90% of all pregnancies worldwide. Furthermore, 10% of all birth abnormalities are associated with medication taken during pregnancy⁶ to treat pregnancy-related illnesses such as back discomfort, shortness of breath, heartburn, headache, nausea, and vomiting.⁷

A multinational survey in Europe by Lupattelli et al. (2014)⁸ has found that 80% of pregnant women use either prescribed or OTC medicine; moreover, because of hazards to the fetus, the use of OTC drugs during pregnancy poses a barrier to antenatal care. According to Khalaf et al. (2018),⁹ 36% of pregnant women use herbal remedies, and approximately 39% believe that a lack of understanding about pregnancy safety may be hazardous to both the mother and fetus. In another study, 20% of Hispanic women have been found to believe that herbs and vitamins are safer or better to use than prescription medication for treating medical problems.¹⁰

Most antenatal clinics do not provide information on drug use during pregnancy.¹¹ Consequently, nurses play crucial roles as health educators and counselors in promoting awareness of the hazards of OTC medications among pregnant women, to decrease medication errors and assess women's safety.^{11,12} Although most OTC drugs for pregnant women are regarded as safe, others have not yet been assessed for safety or are known to have unfavorable effects on unborn children. Certain drug safety profiles may differ according to the fetus's gestational age.¹³

In KSA, approximately 40% of the population uses OTC and herbal medicines to avoid the expense of healthcare consultations.¹⁴ Self-medication practices are frequently learned from family or neighbors, as well as from social media.¹⁵ Pregnant women often assume that OTC medications are safe because they are available without a prescription, and the adverse effects of these medications are rarely reported because doctors, specialists, and nurses do not promote their use.¹⁶ Therefore, health-care practitioners should be aware of pregnant women taking OTC medication when providing them with medication health education.¹⁴ Despite its cost-effectiveness, self-medication with OTC should be evaluated and supervised.¹⁷

Few published studies in KSA have examined the local and national prevalence of OTC medication use during pregnancy.^{14,18} Drug use, particularly that of OTC drugs, varies greatly according to patient demographics and geographical locations during pregnancy.¹⁶ Self-medication is common in KSA, which has the highest use of OTC medications compared with other Arabia peninsula countries.¹⁹ Because of poor perception of OTC medications use, self-medication is practiced among the general population in rural areas of the Kingdom.^{14,18,20} Pregnant mothers and their unborn children may be at elevated risk because of the use of OTC medications. Consequently, pregnant women's perceptions of the hazards of OTC medication use with respect to their health and that of their unborn children must be assessed.^{16,18}

For this reason, pregnancy risk ratings have been established to guide treatment decisions regarding pregnancy outcomes.²¹ An individual's feelings toward obstacles or impediments can influence the perceived cost-benefit analysis.²¹ This study investigated pregnant women's perceptions of barriers, including indicators such as being too busy to take recommended health actions concerning hospitalization, prenatal visits being too expensive or complex, knowledge assimilation of healthcare workers influencing their health education to pregnant women,²¹ and the lack of availability of healthcare specialists, including advanced practice nurses in KSA. The term self-efficacy refers to a belief in one's ability to engage in the behaviors necessary to result in a given outcome,²² and may refer to a belief in one's ability to successfully accomplish a particular behavioral attribute.^{21,22}

The perceptions of pregnant mothers regarding the use of OTC medications remains understudied from the Middle Eastern perspective. This study fills this research gap by investigating the relationships between the demographic characteristics of pregnant Saudi mothers and their perceived risks of using OTC medications. The findings of this study should serve as a primer for developing future holistic care for pregnant mothers.

Materials and Methods

Study design

The present study used a descriptive, cross-sectional design. Significant differences between the perceived risks of OTC medication use and pregnant mothers' sociodemographic characteristics were investigated.

Study setting

A 200-bed capacity general tertiary public hospital situated near Riyadh in KSA was the setting for this study. The hospital has multiple departments, including outpatient, emergency, medical-surgical, and maternal and childcare departments, as well as other specialized areas (e.g., operating rooms, an intensive care unit, and a hemodialysis unit). The study was conducted in the antenatal care unit, which offers public services and follow-up visits for pregnant mothers.

Sampling method

With a non-probability purposive sampling strategy, the study sample was chosen through non-random procedures with inclusion and exclusion criteria. This sampling approach is a widely used technique that was appropriate for the study design.²³ The study's eligibility criteria included being currently pregnant and between 20 and 45 years of age, regardless of parity; being registered for antenatal care; and being available at the time of study implementation. Any expecting mothers who did not meet any of the inclusion criteria were excluded.²³ Pregnant women with chronic diseases or those considered to have high-risk pregnancies were also excluded.²³ Polit and Beck (2018)²³ have emphasized that high-risk populations such as pregnant women, people with chronic diseases, very young and old

people, marginalized people, and tribal communities are particularly vulnerable to the risks in any study; thus, they must be treated ethically.

Study population

Pregnant women who were registered for antenatal care at our general tertiary public hospital composed the study population. With a margin of error of 5% ($d = 0.05$) and a 95% confidence interval, the sample size was calculated with the single proportion method,²⁴ and the prevalence of perceived risk of self-medication was 59.7% ($p = 0.59$).²⁵ The final sample size was 366, because the total number of pregnant women receiving prenatal care at the hospital was less than 10,000 (approximately 7,400).

Instruments

We investigated participants' perceptions of the dangers associated with the use of OTC drugs by using a two-part survey questionnaire. Part 1 contained information on the pregnant Saudi mothers' sociodemographic profiles, such as age, marital status, educational level, occupation, monthly income, number of family members, and number of children with special needs. Part 2 examined their risk perceptions by using Erci and Çiçek's (2017)²¹ Drug Use Health Belief Scale, which has internal reliability and a Cronbach's alpha score of 0.80. This 28-item instrument is composed of five domains: susceptibility (six items), severity (six items), barriers (six items), benefits (four items), and self-efficacy (six items).²¹ The scale is scored on a five-point scale of strongly disagree (1), disagree (2), uncertain (3), agree (4), and strongly agree (5). The scores obtained for the five domains were summed to determine the total score on the scale. A score of 28 and 140 indicated the lowest and highest scores in health views regarding OTC medicines and prescription drug use, respectively.²¹

The structured survey questionnaire was tested with a pilot study and reviewed under the guidance of a panel of experts in obstetrics and gynecology. The resulting 28-item list regarding drug use health beliefs was used as the basis for determining the health beliefs associated with conscious and prescription drug use described in the present study. A test-retest reliability result of 0.87 and an overall internal coefficient of 0.91 were determined.

Ethical considerations

Relevant precautions were taken to protect the participants' rights: they were provided details about the study, and their consent was obtained before participation. Participants' anonymity and rights to confidentiality were maintained in this study. All participants were allowed to withdraw from the study at any point.

Data collection

After approval by the University's Ethics Review Committee and the Ministry of Health, data collection began. After pilot research was conducted, the validated questionnaire was administered to qualified individuals. The

questionnaire could be completed in less than 30 min. During the administration of the questionnaire, the participants were provided with adequate assistance to answer their questions about the study. The data were collected over a period of 2 months from December 2019 to February 2020. A total of 366 of 412 recruited participants completed the study, with a response rate of 88.8%.

Data analysis

SPSS version 24 for Windows was used to analyze the collected data. After normality testing, descriptive statistics was used to examine descriptive demographic data, according to percentages, mean scores, and standard deviation (SD). The perceived risks, according to the Health Beliefs Scale in terms of sociodemographic profile variables (age, educational attainment, marital and working status, and monthly income) were investigated with one-way ANOVA for inferential statistics. Because the independent variables comprised more than two groups, post-hoc tests were used to identify differences among them. Statistical significance was defined as a p-value ≤ 0.05 .

Results

Participants' sociodemographic characteristics

Table 1 displays the sociodemographic characteristics of pregnant mothers by age group, educational attainment, marital status, occupation, monthly income, and use of OTC medications. Pregnant mothers 30–39 years of age composed the majority (44.8%) of the study sample, whereas women

younger than 30 years composed two-fifths (39.9%). A total of 37.4% of the study participants had a secondary school diploma, and 35.0% had a bachelor's degree. Furthermore, most of the study participants (95.4%) were married; only 3.6% and 1% were widowed and divorced, respectively. Homemakers composed 41.3% of the participants, whereas 34.2% worked in the healthcare industry, and 24.6% worked in other fields. A total of 79.8% of the research participants had incomes above 10,000 Saudi Arabian riyals (SAR), whereas 12.6% had incomes between 5,000 and 10,000 SAR. During pregnancy, 73.8% of the women used OTC drugs, whereas only 26.2% did not.

Individual means and SDs of perceived risk scores in the use of OTC medications during pregnancy

Table 2 shows that the highest mean within the domain of perception of susceptibility was for "if I use OTC medication, my chance of drug allergy is likely to be high," with a mean score of 1.72 (0.66); the lowest was for "if I use OTC medication, the likelihood of harm is very high for me," with a mean score of 1.19 (0.66). The overall mean score of perception of susceptibility among women was 1.56 (0.36). "I am afraid of having an allergy due to OTC medication," with a mean score of 1.74 (0.53), had the highest mean in the category of severity perception, whereas "a drug allergy scares me," with a mean score of 1.23 (0.52), had the lowest mean. The overall mean score for the women's impressions of severity was 1.52 (0.29). The highest mean within the domain of the perception of benefits was for "using OTC medication will decrease or completely block drug poisoning," with a mean score 1.75 (0.56), and the lowest mean was for "using OTC medication will promote healing," with a mean score of 1.15 (0.40). The overall mean score of the perception of benefits among women was 1.39 (0.32). The highest mean score within perceived barriers to OTC use was for "no one will help me use OTC medication," with a mean score 1.66 (0.61), and the lowest was for "using OTC medication is difficult for me," with a mean score of 1.28 (0.52). The overall mean score of perception of barriers among women was 1.52 (0.34). Finally, the highest mean within the self-efficacy domain was for "I can get drug information and correctly use my drug," with a mean score 1.66 (0.53), and the lowest was for "I know the procedure for getting OTC medication," with a mean score of 1.14 (0.46). The total mean self-efficacy score was 1.45 (0.32).

Additionally, Table 2 shows the mean scores and SDs for each item for the perceptions of the risks of using OTC medication during pregnancy among pregnant Saudi mothers. The factors ranked from highest to lowest were as follows: 1) perceived susceptibility (1.56; 0.36), 2) perceived severity (1.52; 0.29) and barriers (1.52; 0.34), 3) self-efficacy (1.45; 0.32), and 4) perceived benefits (1.39; 0.32).

Significant differences in the perceived risks per domain in the use of OTC medication according to pregnant mothers' sociodemographic characteristics

As shown in Table 3, the mean degree of susceptibility perceptions among mothers varied significantly by age

Table 1: Participants' sociodemographic characteristics (n = 366).

Profile variables	Frequency	Percentage
Age		
<30 years	146	39.9
30–39 years	164	44.8
>39 years	56	15.3
Educational attainment		
Intermediate	83	22.7
Secondary school	137	37.4
Diploma	18	4.9
Bachelor's degree	128	35.0
Marital status		
Married	349	95.4
Divorced	4	1.1
Widowed	13	3.6
Occupation		
Employee in the healthcare sector	125	34.2
Employee in other sectors	90	24.6
Homemaker	151	41.3
Monthly income		
<5,000 SAR	28	7.7
5,000–10,000 SAR	46	12.6
>10,000 SAR	292	79.8
Use of OTC medications		
Yes	270	73.8
No	96	26.2

Table 2: Individual mean scores and SDs of the perceived risks of use of OTC medications during pregnancy (n = 366).

Domain	Item	Mean	SD
Perceived susceptibility	If I use OTC medication, the likelihood of harm is very high for me.	1.19	0.41
	If I use OTC medication, my chance of drug allergy is likely to be high.	1.72	0.66
	If I use OTC medication, I might possibly die.	0.63	32.6
	If I use OTC medication, my body and organs may be damaged.	0.66	33.8
	Others suggest that the drugs will harm me.	0.68	31.4
	I do not suggest my drug to others for fear of causing damage.	0.65	31.6
	Total	1.56	0.36
Perceived severity	A drug allergy scares me.	1.23	0.52
	I am afraid of having an allergy due to OTC medication.	1.74	0.53
	When I think of damage/adverse effects of drugs on the body, I experience stress.	1.37	0.58
	I have problems concerning adverse effects/damage from OTC medication if I continue use for a very long time.	1.61	0.60
	If I use OTC medication, it can undermine my confidence in my relationships with other people.	1.62	0.60
	If I incorrectly use OTC medication, serious changes in my life may result (e.g., loss of vision)	1.55	0.62
	Total	1.52	0.29
Perceived benefits	Using OTC medication will promote healing.	1.15	0.40
	Using OTC medication will have benefits.	1.20	0.47
	Using OTC medication will decrease or completely block drug poisoning.	1.75	0.56
	Using OTC medication, I protect my legal rights.	1.48	0.64
	Total	1.39	0.32
Perceived barriers	Using OTC medication is difficult for me.	1.28	0.52
	No one will help me use OTC medication.	1.66	0.61
	Procedures for using OTC medication take a long time.	1.58	0.57
	I do not need to comply with tedious procedures to use OTC medication, because non-prescription drugs promote recovery.	1.61	0.59
	If a drug results in recovery, a prescription is not needed for this drug.	1.54	0.68
	I do not have time to get OTC medication.	1.45	0.64
	Total	1.52	0.34
Self-efficacy	I know the procedure for getting OTC medication.	1.14	0.46
	I can get drug information and correctly use my drug.	1.66	0.53
	I am able to use my drug correctly.	1.20	0.50
	I can achieve recovery by using my drug correctly.	1.65	0.59
	I can use the correct doses of my drug.	1.51	0.64
	I can use my drug at the recommended time intervals.	1.55	0.64
	Total	1.45	0.32

($p < 0.001$). Tukey's post-hoc test was used to demonstrate group differences. The test showed a difference in age between women younger than 30 and those older than 39 years, with older mothers outnumbering younger mothers. Susceptibility perceptions were higher in pregnant women with a high school diploma ($p < 0.001$). The mean degree of susceptibility among mothers differed significantly according to monthly income ($p = 0.017$). A significant difference in the degree of *severity perceptions* was observed between mothers younger than 30 and those older than 39 years ($p = 0.014$). Pregnant women with high school diplomas perceived greater severity ($p < 0.001$). A significant difference was also found in the level of severity for mothers with monthly incomes below 5,000 SAR ($p < 0.001$).

A significant difference was found in the mean scores of mothers' *perceptions of the benefits* according to age ($p < 0.001$): mothers older than 39 years had a higher level of perceived benefits. Additionally, a significant difference in the mean perceptions of the benefits was observed according

to educational attainment ($p < 0.001$). Moreover, there was a significant difference in the mean scores for *perceptions of barriers* regarding their age ($p = 0.031$) and monthly income below 5,000 SAR ($p < 0.001$). Likewise, significant differences were observed in the mean level of mothers' *self-efficacy* according to age ($p = 0.012$), educational attainment ($p < 0.001$), and monthly income below 5,000 SAR ($p < 0.001$).

Significant difference in perceived risks according to the use of OTC medications

Table 4 demonstrates a significant difference in mothers' perceptions of susceptibility to OTC medication use ($p < 0.001$). Those who did not use OTC medications had higher mean susceptibility scores. A significant difference in the perceived benefits of using OTC medications ($p < 0.018$) was also observed: those who did not use OTC medications reported greater mean scores for perceived benefits. However, no significant difference was observed in

Table 3: Perceived risks in the use of OTC medication according to pregnant mothers' socio-demographic characteristics (n = 366).

Variables	Perceived susceptibility					Perceived severity				Perceived benefits				Perceived barriers				Self-efficacy			
	N	Mean	SD	F (df)	P value*	Mean	SD	F (df)	P value*	Mean	SD	F (df)	P value*	Mean	SD	F (df)	P value*	Mean	SD	F (df)	P value*
Age groups																					
<30 years	146	1.52	0.21	8.833	<0.001*	1.53	0.26	4.353	0.014*	1.31	0.19	12.395	<0.001*	1.48	0.29	3.507	0.031*	1.45	0.20	4.519	0.012*
30–39 years	164	1.53	0.31	(2.363)		1.48	0.27	(2.363)		1.41	0.34	(2.363)		1.53	0.34	(2.363)		1.42	0.30	(2.363)	
>39 years	56	1.74	0.63			1.61	0.39			1.55	0.45			1.62	0.43			1.57	0.54		
Educational attainment																					
Intermediate	83	1.71	0.58	7.954	<0.001*	1.63	0.45	6.166	<0.001*	1.55	0.53	9.090	<0.001*	1.59	0.50	2.526	0.057	1.58	0.52	7.797	<0.001*
Secondary	137	1.55	0.27	(3.362)		1.52	0.27	(3.362)		1.33	0.16	(3.362)		1.46	0.20	(3.362)		1.39	0.19	(3.362)	
Diploma	18	1.40	0.11			1.48	0.27			1.41	0.32			1.53	0.37			1.59	0.52		
Bachelor's degree or higher	128	1.49	0.22			1.46	0.12			1.36	0.23			1.53	0.32			1.42	0.17		
Marital status																					
Married	349	1.56	0.36	0.170	0.844	1.52	0.29	0.701	0.497	1.40	0.32	0.455	0.635	1.52	0.34	0.340	0.712	1.45	0.32	2.746	0.066
Divorced	4	1.66	0.19	(2.363)		1.58	0.09	(2.363)		1.25	0.28	(2.363)		1.50	0.00	(2.363)		1.33	0.38	(2.363)	
Widowed	13	1.57	0.22			1.61	0.35			1.42	0.21			1.60	0.25			1.65	0.28		
Working status																					
Healthcare sector	235	1.57	0.40	1.644	0.195	1.54	0.34	2.269	0.105	1.41	0.36	1.619	0.199	1.52	0.35	1.617	0.200	1.52	0.35	1.617	0.200
Other sectors	27	1.62	0.38	(2.363)		1.56	0.22	(2.363)		1.46	0.29	(2.363)		1.43	0.17	(2.363)		1.43	0.17	(2.363)	
Homemaker	104	1.51	0.23			1.47	0.16			1.35	0.20			1.56	0.34			1.56	0.34		
Monthly income																					
<5,000 SAR	28	1.75	0.36	4.093	0.017*	1.75	0.36	7.440	<0.001*	1.31	0.28	1.465	0.232	1.74	0.46	6.954	<0.001*	1.74	0.46	6.954	<0.001*
5,000–10,000 SAR	46	1.53	0.29	(2.363)		1.53	0.29	(2.363)		1.44	0.46	(2.363)		1.45	0.26	(2.363)		1.45	0.26	(2.363)	
>10,000 SAR	292	1.55	0.36			1.55	0.36			1.40	0.30			1.51	0.33			1.51	0.33		

*One way ANOVA; SAR, Saudi Arabian riyal.

Table 4: Perceived risks according to the use status of OTC medications (n = 366).

Domain/use		N	Mean	SD	t statistic	p value*
Perceived susceptibility	Used	101	1.46	0.22	-3.992	<0.001*
	Not used	265	1.60	0.39		
Perceived severity	Used	101	1.50	0.28	-0.641	0.522
	Not used	265	1.53	0.29		
Perceived benefits	Used	101	1.34	0.21	-2.377	0.018*
	Not used	265	1.41	0.35		
Perceived barriers	Used	101	1.48	0.27	-1.456	0.146
	Not used	265	1.54	0.36		
Perceived self-efficacy	Used	101	1.42	0.27	-1.196	0.233
	Not used	265	1.46	0.34		

*Independent sample t-tests.

the degree of severity, barriers, and self-efficacy of mothers using OTC medications ($p > 0.05$).

Discussion

Sociodemographic profile

Most pregnant mothers 30–39 years of age in the current study were married, had a secondary education and a bachelor's degree, and relatively high monthly income. During pregnancy, approximately 75% of the women used OTC medicines. Prior studies on mothers' perceived susceptibility, severity, benefits, barriers, and self-efficacy have indicated that the use of OTC medicines during pregnancy is controversial.^{14,18,26} Although healthcare providers in Saudi Arabian hospitals have a good understanding of, and favorable attitudes toward, the FDA's pregnancy category systems,²⁶ many pregnant mothers self-medicate.¹⁴ Therefore, appropriate educational initiatives to educate women in the dangers of using OTC medications during pregnancy may be required.

Previous research has indicated that raising public awareness of the risks and negative effects of OTC medications during pregnancy is necessary.^{27–29} The factors influencing OTC medication use and its relationships with sociodemographic characteristics have not received substantial attention in the literature. Self-medication with OTC drugs is common among patients. However, according to Abduelkarem and Mustafa (2017),³⁰ 24.3% of pregnant women have never heard of OTC medications, and participants who do not comprehend this term have poor comprehension of OTC medications. Zaki and Albarraq (2014)¹⁴ have provided insights into OTCs that may contribute to more negative beliefs regarding medications; however, the high prevalence of well-educated women participating in the current study (most of whom were homemakers) might have enabled the women to conduct internet searches and gain knowledge regarding drug use in pregnancy.

Professional health education in the use of OTC medications is critical. Navarro et al. (2018)³¹ have reported that illiteracy among younger people is associated with misunderstanding of medication use during pregnancy. The participants were homemakers or had been unemployed for a long time period, thus influencing their use of OTC

medications. Our study suggests that education and job type influence OTC medication use. For example, we identified a link between illiteracy and inadequate knowledge of medicine administration during pregnancy.³¹ Women in health-related occupations are more knowledgeable regarding the risks of untreated sickness during pregnancy than women in other occupations, and they believe that physicians should be consulted before using herbal therapies.¹⁸ This finding might be explained by women in health-related fields having greater medical knowledge and trust in physicians than women in other occupations.¹⁴ Being a homemaker or being unemployed for a long time period may influence the decision to use OTC drugs during pregnancy.³²

The findings reported by Sharma et al. (2006)³² contradict our findings. They have observed that among Indian women, self-medication is associated with higher education and socioeconomic status. Pregnant women's education and socioeconomic status are major characteristics of OTC medicine use. However, the evidence is mixed: 10% of all birth abnormalities are associated with OTC medicine use during pregnancy.⁶ Many existing drugs are safe and effective for use during pregnancy, but studies have been limited because of ethical concerns regarding exposing the developing fetus to potential dangers.^{3,4} Furthermore, drugs, whether prescribed or OTC, can be teratogenic, thus posing substantial risks to not only pregnant mothers but also unborn children.²

Significant difference in perceived risks according to the use of OTC medications

In this study, participants' perceptions of the risks OTC medications were low to moderate, as seen in various domains, such as perceived severity, benefits, barriers, and self-efficacy. One previous study has indicated that self-medication use is best predicted by participants' perceived severity and susceptibility.³³ According to our findings, lower levels of these perceptions were associated with higher levels of self-medication, thus explaining the lower mean scores and higher prevalence of OTC drug use. However, we observed substantial differences in the perceptions of susceptibility, severity, and self-efficacy according to the mothers' age, educational achievement, and monthly income. Similarly, the perceived barriers or benefits differed by the mothers' age.

Our findings indicated that, during pregnancy, nearly 31% of the pregnant women took no prescription drugs at any stage, whereas 69% were prescribed at least one drug, with a mean of 2.87 medications per woman. The most commonly prescribed drugs were folic acid, iron preparations, anti-infective agents, systemic antibiotics, and drugs for endocrine disorders. Additionally, the rate of prescribed drug use was highest during the third trimester (58%), and lower in the second (26%) and first (16%) trimesters. The observed patterns in the prescription of drugs in the three trimesters were consistent with those in previous studies.^{10,13,17} Furthermore, the study indicated well-considered and cautious drug prescription during pregnancy by the obstetricians in the hospital setting. Because the potential fetal risks of drug use during pregnancy have been established for only several drugs,^{1–3} the present study emphasizes the need for clear guidelines for physicians regarding the use of drugs during pregnancy.

Pregnant women are increasingly using OTC drugs.³⁴ Slightly less than three-quarters of pregnant women used OTC medications in this single-center study, and the prevalence is rising in KSA^{14,18–20} and Ethiopia.^{27–29} Egyptian¹¹ and Brazilian³⁴ surveys have indicated a slightly lower prevalence.

The main reasons for using OTC medicines are cost, time savings, and a lack of access to doctors. Mild pregnancy-related complaints are another reason why women use OTC drugs.²⁸ OTC drug use has been associated with past experience and time savings in one study.²⁹ Respondents also have stated that their primary sources of knowledge were friends and/or pharmacists.^{28,29} Although most OTC medicines are safe during pregnancy, others have not been tested and may harm the developing fetus.^{9,11,13}

The number of drug-induced birth abnormalities is increasing in KSA. Because most OTC medications are associated with birth abnormalities and poor pregnancy outcomes,³⁵ using OTC medications is a public health concern. Studies have shown that one-fifth of Saudi women are unaware that some medicines can harm the fetus.³⁶ Most pregnant women do not believe that OTC medications are the cause of birth defects.¹⁴

Lutz et al. (2020)³⁴ have found that women with three or more health issues during pregnancy use more drugs, including OTC medications. Lower income groups, smokers, and multiparous women have higher rates of OTC usage. However, one study has found no correlation between education and OTC drug use.²⁷ This finding may explain why women without health insurance and a history of poor pregnancy outcomes are more likely to take over-the-counter drugs.

Significant differences in perceived risks per domain in the use of OTC medication according to pregnant mothers' sociodemographic characteristics

Increasing research on medication perceptions and beliefs is increasingly being conducted with the health belief model.^{21,22,37} However, few studies have examined pregnant women's self-medication habits.^{14,33} Moreover, few related studies are available in the Middle East, particularly in KSA.^{14,18} Our study focused on pregnant women's perceptions of susceptibility, severity, benefits, barriers, and self-efficacy with respect to OTC medication use.

Only two Saudi studies have examined women's attitudes toward OTC medication use during pregnancy.^{14,18} The findings have indicated that most women have positive opinions about drugs in general but believe that pregnant women should be cautious about drug use. The medicines that participants indicated should be avoided in previous studies roughly match the FDA system classifications.¹⁴ Aljoher et al. (2018)¹⁸ have found that more than one-quarter of women forgo prescriptions, nearly two-thirds forgo OTC medications, and one-third forgo natural products. The most avoided drugs are paracetamol and herbal medications, both because of fetal consequences.

Aljoher et al. (2018)¹⁸ have reported that medicines and herbs should be avoided during the first trimester. These beliefs are associated with the sociodemographic characteristics of the participants. Additionally, strong links have been observed between participants' education or occupation, and pharmaceutical beliefs.¹⁴ Well-educated women and women in the health field have been found to have suitable opinions about OTC and prescription drugs. Women in health-related professions, including nurses and doctors, also tend to be more aware of the life-saving effects of medications on unborn children. Thus, the use of medication during pregnancy has been investigated in several societies, and women have shown diverse perceptions, knowledge, and attitudes toward OTC medication.^{13–16,38}

Overall, better understanding of the underlying perceptions and patterns of OTC medication use in pregnant women is needed to enable important educational strategies to be developed while minimizing the negative effects on pregnancy outcomes. Nurses value decisions about when and how to provide appropriate health education according to patients' unmet needs.

Studies are increasingly examining the use of OTC medications among pregnant women. However, their behavior patterns, as well as their thoughts and beliefs, must be studied holistically. Additional research is needed to identify the factors influencing OTC medicine use among pregnant women, particularly among high-risk groups. Specifically, consistent differences in age, educational level, and monthly income were found to significantly alter mothers' perceived hazards of using OTC drugs.

The greatest dangers revealed were perceived susceptibility and benefits, because the mothers were already aware of the effects of OTC medications during their pregnancy yet continued to use them. Therefore, a primer on holistic care produced by a team of experts in maternity and child nursing is needed to achieve positive health outcomes and prevent negative effects on the fetus and mother during and after pregnancy.

Limitations

Although disparities in participants' perceptions and opinions are expected, other explanations may limit the study's findings. First, the study's small sample size might have influenced the results. Second, the study sample included pregnant mothers who were registered for prenatal check-ups in only one tertiary hospital. Third, although the sample size was deemed appropriate, the results may not be generalizable to mothers seeking prenatal check-ups in other Saudi Arabian hospitals or similar healthcare settings. Fourth, because we used a self-reported questionnaire to

collect data, the participants might have underestimated or overestimated their levels of risk perception of OTC medications and their relevant attributes. Finally, our use of a correlational descriptive strategy allowed for only correlations, but not causal links, to be established.

Conclusion

The outcomes of this study and the results of prior research indicate that developing a holistic approach to care for pregnant women could help decrease self-medication. The dangers of using over-the-counter medications must crucially be emphasized to ensure that mothers consistently follow antenatal and postnatal programs. As a next step in improving mother and fetal outcomes, behavioral modification programs are also considered helpful.

Recommendations

This study examined one public hospital and excluded private hospitals. Future research should include pregnant women treated in other private sectors to better understand the relevant phenomena. More studies are needed with alternative measures of perceived risks of OTC medication use to encompass a wider range of pregnant mothers' experiences. In addition, further multilevel modeling and multi-site research are required to discover key attributes related to OTC medication risk perceptions.

Source of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflict of interest

The authors have no conflicts of interest to declare.

Ethical approval

The Ethical Review Committee of King Saud University (reference No. 4/67/149251) and the Ministry of Health (reference No. 26-12-2019-04-1441) approved the study.

Authors contributions

AAMA and SMZ conceived and designed the study, conducted research, provided research materials, and collected and organized data. SMZ analyzed and interpreted data. HNV and DJEB wrote the initial and final drafts of the article and provided logistic support. DJEB corresponded with the journal. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

Acknowledgment

The authors thank the Dean of Scientific Research and RSSU at King Saud University for technical support.

References

1. Brucker MC, King TL. The 2015 US Food and drug administration pregnancy and lactation labeling rule. *J Midwifery Wom Health* 2017; 62(3): 308–316. <https://doi.org/10.1111/jmwh.12611>.
2. Wilmer E, Chai S, Kroumpouzou G. Drug safety: pregnancy rating classifications and controversies. *Clin Dermatol* 2016; 34(3): 401–409. <https://doi.org/10.1016/j.clindermatol.2016.02.013>.
3. Parisi MA, Spong CY, Zajicek A, Guttmacher AE. We don't know what we don't study: the case for research on medication effects in pregnancy. *Am J Med Genet C Semin Med Genet* 2011; 157C(3): 247–250. <https://doi.org/10.1002/ajmg.c.30309>.
4. Fontoura A, Ayres LR, Nagai MM, Dewulf NL, dos Santos V, Martinez EZ, Pereira R. Prevalence of medications use among low-risk pregnant women: a medications utilization study. *Afr J Pharmacy Pharmacol* 2014; 8(36): 883–892.
5. Mohammed MA, Ahmed JH, Bushra AW, Aljadhey HS. Medications use among pregnant women in Ethiopia: a cross sectional study. *J Appl Pharm Sci* 2013; 3(4): 116–123.
6. Stanley AY, Durham CO, Sterrett JJ, Wallace JB. Safety of over-the-counter medications in pregnancy. *MCN Am J Matern Child Nurs* 2019; 44(4): 196–205. <https://doi.org/10.1097/NMC.0000000000000537>.
7. Benotsch EG, Koester S, Martin AM, Cejka A, Luckman D, Jeffers AJ. Intentional misuse of over-the-counter medications, mental health, and polysubstance use in young adults. *J Community Health* 2014; 39(4): 688–695. <https://doi.org/10.1007/s10900-013-9811-9>.
8. Lupattelli A, Spigset O, Twigg MJ, Zagorodnikova K, Mårdby AC, Moretti ME, et al. Medication use in pregnancy: a cross-sectional, multinational web-based study. *BMJ Open* 2014; 4(2):e004365. <https://doi.org/10.1136/bmjopen-2013-004365>.
9. Khalaf SA, Aly SE, Ahmed AA. Prevalence and attitude regarding non prescribed medications among pregnant women attending maternal and child health care centers in Assiut City. *J Nurs Health Sci (IOSR-JNHS)* 2018; 7(5): 1–11.
10. Bercaw J, Maheshwari B, Sangi-Haghpeykar H. The use during pregnancy of prescription, over-the-counter, and alternative medications among Hispanic women. *Birth (Berkeley, Calif.)* 2010; 37(3): 211–218. <https://doi.org/10.1111/j.1523-536X.2010.00408.x>.
11. Hanafy SA, Sallam SA, Kharboush IF, Wahdan IH. Medications utilization pattern during pregnancy in Alexandria, Egypt. *Eur J Pharm Med Res* 2016; 3(2): 19–29.
12. Kassada DS, Miasso AI, Waidman MA, Marcon SS. Prevalence and factors associated with medications use in pregnant women assisted in primary care. *Texto Contexto-Enferm* 2015; 24(3): 713–721. <https://doi.org/10.1590/0104-07072015002770013>.
13. AlQasimi MS, Mohamed ME. Medications without prescription at Saudi community: extent and perception. *British J Med Health Res* 2016; 3(4): 83–91.
14. Zaki NM, Albarraq AA. Use, attitudes and knowledge of medications among pregnant women: a Saudi study. *Saudi Pharm J* 2014; 22(5): 419–428. <https://doi.org/10.1016/j.jsps.2013.09.001>.
15. Shah AP, Parmar SA, Kumkishan A, Mehta AA. Knowledge, Attitude and Practice (KAP) survey regarding the safe use of medicines in rural area of Gujarat. *Adv Trop Med Pub Health* 2011; 1(2): 66–70.
16. Kline KL, Westberg SM. Over-the-counter medication use, perceived safety, and decision-making behaviors in pregnant women. *Innov Pharm* 2011; 2: 1.
17. Al-Mohamadi A, Badr A, Mahfouz LB, Samargandi D, Al Ahdal A. Dispensing medications without prescription at Saudi

- community pharmacy: extent and perception. **Saudi Pharm J** 2013; 21(1): 13–18. <https://doi.org/10.1016/j.jsps.2011.11.003>.
18. Aljoher AM, Alsaeed MA, AlKhlifan MA, Almethen AW, Almukhaitah MA, Zareen H, et al. Pregnant women risk perception of medications and natural products use during pregnancy in Alahsa, Saudi Arabia. Egypt. **J Hosp Med** 2018; 70(1): 13–20.
 19. Al-Rukban MO, Khalil MA. Adherence to OTC directory—the perception of community pharmacists in Saudi Arabia. **J Ayub Medl Coll** 2012; 24(3–4): 43–46.
 20. Makeen HA, Albarraq AA, Banji OJ, Taymour S, Meraya A, Alqhatani S, et al. Knowledge, attitudes, and practices toward self-medication in a rural population in South-Western Saudi Arabia. **Saudi J Health Sci** 2019; 8: 54–59.
 21. Erci B, Çiçek Z. Reliability and validity of drugs use health belief scale in adult women. **Int Arch Nurs Health Care** 2017; 3: 1–7.
 22. LaMorte WW. *The health belief model*; 2019. Retrieved October 5, 2020 from, <https://sphweb.bumc.bu.edu/otlt/mph-modules/sb/behavioralchangetheories/behavioralchangetheories2.html>.
 23. Polit D. *Essentials of nursing research*. 6th ed. Philadelphia: PA Wolters Kluwer; 2018.
 24. Daniel WW, Cross CL. *Biostatistics A foundation for analysis in the health sciences*. 11th ed. New York: John Wiley & Sons; 2018. pp. 141–142.
 25. Aljadhey H, Assiri GA, Mahmoud MA, Al-Aqeel S, Murray M. Self-medication in Central Saudi Arabia: community pharmacy consumers' perspectives. **Saudi Med J** 2015; 36(3): 328–334. <https://doi.org/10.15537/smj.2015.3.10523>.
 26. Alshammari TM, Alrwisan AA, Aljeraisly MI, Taher KW, Alissa FM, Mahmoud MA, et al. Knowledge and attitude of healthcare professionals toward medication pregnancy category systems in Saudi hospitals. **Saudi Med J** 2014; 35(7): 704–711.
 27. Ebrahimi H, Atashsokhan G, Amanpour F, Hamidzadeh A. Self-medication and its risk factors among women before and during pregnancy. **Pan Afric Med J** 2017; 27: 183. <https://doi.org/10.11604/pamj.2017.27.183.10030>.
 28. Ayalew MB. Self-medication practice in Ethiopia: a systematic review. **Patient Prefer Adherence** 2017; 11: 401–413. <https://doi.org/10.2147/PPA.S131496>.
 29. Jambo A, Mengistu G, Sisay M, Amare F, Edessa D. Self-medication and contributing factors among pregnant women attending antenatal care at public hospitals of harar town, Ethiopia. **Front Pharmacol** 2018; 9: 1063. <https://doi.org/10.3389/fphar.2018.01063>.
 30. Abduekarem AR, Mustafa H. Use of over-the-counter medication among pregnant women in sharjah, United Arab Emirates. **J Pregnancy** 2017; 2017: 4503793. <https://doi.org/10.1155/2017/4503793>.
 31. Navaro M, Vezzosi L, Santagati G, Angelillo IF, Collaborative Working Group. Knowledge, attitudes, and practice regarding medication use in pregnant women in Southern Italy. **PLoS One** 2018; 13(6):e0198618. <https://doi.org/10.1371/journal.pone.0198618>.
 32. Sharma R, Kapoor B, Verma U. Drug utilization pattern during pregnancy in North India. **Indian J Med Sci** 2006; 60(7): 277–287. <https://doi.org/10.4103/0019-5359.26602>.
 33. Karami-Matin B, Hosseini SN, Mahboubi M, Aghaei A, Fattahi M, Etesamifard T. Predicting factors related to self-medication among pregnant women referred to health centers in Kermanshah County. **Int J Trop Med** 2016; 11(2): 33–37.
 34. Lutz BH, Miranda V, Silveira M, Dal Pizzol T, Mengue SS, da Silveira MF, et al. Medication use among pregnant women from the 2015 pelotas (Brazil) birth cohort study. **Int J Environ Res Public Health** 2020; 17(3): 989. <https://doi.org/10.3390/ijerph17030989>.
 35. Abu-Elmagd M, Assidi M, Schulten HJ, Dallol A, Pushparaj P, Ahmed F, et al. Individualized medicine enabled by genomics in Saudi Arabia. **BMC Med Genomics** 2015; 8(Suppl 1): S3. <https://doi.org/10.1186/1755-8794-8-S1-S3>.
 36. Younis NS, Al-Harbi NY. Public understanding and awareness of isotretinoin use and safety in Al ahsa, eastern Saudi Arabia. **Ther Innov Regul Sci** 2019; 53(5): 618–622. <https://doi.org/10.1177/2168479018807677>.
 37. Alatawi YM, Kavookjian J, Ekong G, Alrayees MM. The association between health beliefs and medication adherence among patients with type 2 diabetes. **Res Soc Adm Pharm** 2016; 12(6): 914–925. <https://doi.org/10.1016/j.sapharm.2015.11.006>.
 38. Nordeng H, Ystrom E, Einarson A. Perception of risk regarding the use of medications and other exposures during pregnancy. **Eur J Clin Pharmacol** 2010; 66: 207–214.

How to cite this article: Alosaimi AAM, Zamzam SM, Berdida DJE, Villagrancia HN. Perceived risks of over-the-counter medication use among pregnant Saudi mothers: A cross-sectional study. *J Taibah Univ Med Sc* 2022;17(5):755–764.