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Evaluation of Pregnant Women Attitude Toward OTC Medications Use; A cross Sectional Study Conducted in Azawia Libya

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ABSTRACT

Objective: Safety is one of the most important characteristics of over the counter medications (OTCs); however, does this safety profile extend to women during pregnancy or not. this is questionable, as the safety of some medications may change according to the gestational age of the foetus. Around 10 % or more of birth defects result from maternal drug exposure, the U.S. Food and Drug Administration has assigned a risk category to each drug. Many drugs have not been evaluated in controlled trials and probably will not be, because of ethical considerations .

Aim: This study was designed to aware and assesses the use, knowledge and beliefs about OTCs among pregnant women in Azawia city in Libya, by using a cross sectional survey performed by using a self-administrated questionnaire .

Results and Conclusion: Majority of the pregnant women are used OTC medicines at least one time during their pregnancy, however most of the participants don't believe in the safety of these non-prescription drugs as well as herbal products (92%, 86% respectively). Vitamins and minerals were the most used medicines during pregnancy (83% for folic acids, 51% for Iron). Most of pregnant women in this study were aware about the use of analgesics (13% for paracetamol). These findings were an indicator to the low level of knowledge and information about the use of OTCs where the pharmacists should improve their counselling skills and their new roles regarding health promotion and pharmaceutical care.

Key words: OTCs, FDA, Self-medication, Drug safety, minor ailments, Pregnancy, Libya

INTRODUCTION

The use of drug during pregnancy still represents a challenge to the health care providers, since the majority of drugs cross the placental barrier with a potential to cause several congenital problems to the foetus, and most of them have not been clinically tested in pregnant patients, because of ethical considerations (1). Although most over the-counter drugs have an excellent safety profile, some have unproven safety or known to adversely affect the foetus. On the other hand, the safety profile of some medications may change according to the gestational age of the foetus. The medical community's approach to the use of mediations during pregnancy has changed dramatically since the early 1970s, largely because of the problems with thalidomide and diethylstilbestrol; consequently, extensive testing is required before a drug can be labelled for use during pregnancy (2). Non-prescription drugs account for about 60% of medications used in United States, and more than 80% of pregnant women take OTC or prescription drugs during Pregnancy to relief the symptoms of minor ailments (2). The most common minor conditions of pregnancy like nausea, vomiting, heartburn, constipation and headache required medications that should be selected carefully to avoid any adverse reactions either to the mother or foetus. Of the commonly used OTCs by pregnant women are the allergy medications, analgesics, cough preparations, laxatives and antidiarrheal and some dermatological products (3). Since 1975, the U.S. Food and Drug Administration (FDA) has assigned pregnancy risk factors to all drugs used in the United States (4). Unfortunately, many drugs have not been adequately researched during pregnancy and that is because of ethical considerations. FDA divides medications into five different pregnancy risk categories (Appendix1). Drugs are placed in these categories based on available studies in humans and animals (5).

In Azawia city as in all cities in Libya, there is a misuse of medicines by most of Libyan citizens either with or without prescription (6). This increase in misuse of medicines necessitates that pharmacists in community pharmacies and other health care providers have to up-date information and knowledge about OTCs and improve

their skills of counselling and solving drug related problems

METHOD:

A cross sectional descriptive survey was carried out at 5 different clinics and hospitals in a Zawia city over a period of two months (September and October 2019). One hundred and six pregnant women visit the clinic in this period were invited to the study. The questionnaire was formulated according to the work of Araujo et.al.(1) where some items were used from previous studies (7,8,9). This questionnaire was presented in both Arabic and English languages and divided into 5 sections with 20 questions as following:

Section1 contains personal information (Q1-Q6) in order to assess the socio- demographic data of the participants such as: age, nationality and educational level.

Level of knowledge was assessed in section2 (Q7-Q10) to evaluate the attitude of the participants toward OTC drugs and herbal safety. Past and current medication use was assessed in section3 (Q11-Q12) to determine whether the participant where using any OTC medications or vitamins and whether they had side effects. Current health status of the pregnant women and medical history was assessed in section4 (Q13-Q15) to establish whether the participant had any chronic disease or experience of any condition during pregnancy and information on previous children born. Assessment of self – medication by using OTC was part of section 5 (Q16-Q20), the aim of this section was to determine the overall knowledge of participants on OTC drugs and whether they intended to increase their knowledge of the OTC drugs they are used by reading the leaflet. The data needed for completing the survey were obtained exclusively through answers from participants. The processing and analysis of data was performed by using SSPS. Descriptive analysis was used to calculate the response proportion of each group of respondents for each item in the questionnaire. Public responses options to the survey questions related to education level, use of over-the-counter drugs, medical history, and over-the-counter drug and vitamin use were reduced to three categories: yes, no, and sometimes. This enabled more reader comprehensible confidence intervals for the relative proportions to be calculated.

RESULTS:

A total of 106 questionnaires were distributed over study period of 2 months, where the response rate was 94%.

SOCIO-DEMOGRAPHIC DATA:

Among the 100 pregnant female who participated in this survey, the majority where Libyan 85% and 48% were between 26-35 years of age. 78% of participants held a university degree and only 16% work at health care unites. The age of participants is shown in figure 1A and educational level is shown in figure 1B, where all details about participants and personal information are shown in table 1

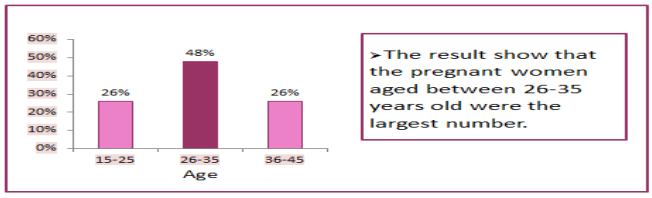

Figure1A. Age of participants as one of socio-demographic data.

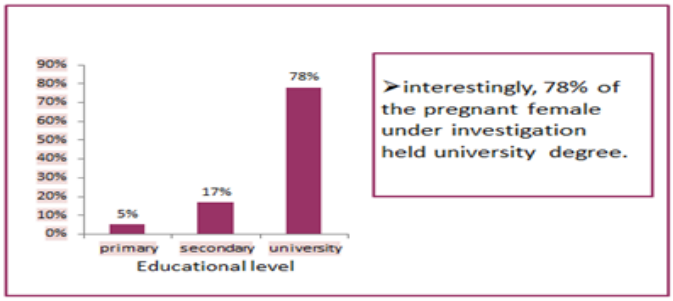

Figure1B. Educational level of participants

Table1. Socio-demographic characteristic of participants

Characteristic		Frequency (%)
Nationality	Libyan	85%
	Other Arabic nationality	15%
Age (years)	15-25	26%
	26-35	48%
	36-45	26%
Educational level	Primary school	5%
	Secondary school	17%
	University	78%
Occupation	Student	14%
	Housewife	48%
	Health care provider	16%
	Others	22%
Previous children	None	18%
	One	17%
	Two	12%
	More than two	53%
Pregnancy stage	First trimester	22%
	Second trimester	29%
	Third trimester	49%

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KNOWLEDGE AND PRACTICE OF OTCS USE, THEIR SIDE EFFECTS DURING PREGNANCY AND MEDICAL HISTORY OF THE PARTICIPANTS:

The knowledge about safety of OTCs and herbal products is shown in figure3, where the majority of the participants (92%) agreed with that OTCs were not safe to be used during pregnancy, and also more than third quarter (86%) of the participants disagreed about safety of herbal products. Figure 3 and table 2 shows all answers about knowledge of OTCs and medical history. while Table3 summarize vitamins, minerals and OTC analgesics used by pregnant women

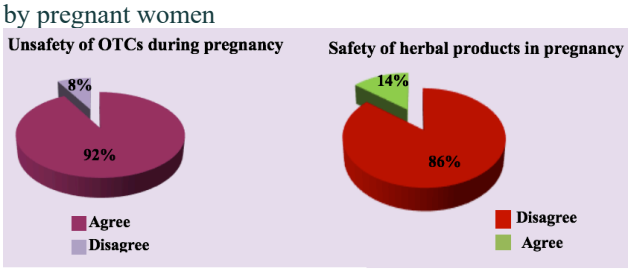

Figure3. Knowledge about safety of OTCs and herbal products

Table2. Knowledge about OTCs and medical history

Survey items		Percentage (%)
Do you know what is meant by over-the counter drugs?		43%
Do you think that all over the counter drugs are safe to be taken during pregnancy?		8%
Do you think that all herbal medications are safe during pregnancy?		14%
Have you ever used an over the counter drug before pregnancy?		47%
Do you read/check the accompanying leaflet?		64%
Have you ever used an over the counter drug or vitamin in your current pregnancy?		31%
OTC side effects	Constipation	5%
	Headache	8%
chronic diseases	Diabetes	5%
	Hypertension	5%
child with special need	Hereditary disease	0%
	No family history	3%
	Due to drug use	0%
critical time for the use of the over-counter-drugs during pregnancy	First trimester	82%
	Second trimester	6%
	Third trimester	12%

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Table3. Summary of vitamins, minerals and OTC analgesics used during pregnancy

Items used by pregnant women	Survey item	Yes (%)
Vitamins	Folic acid	83%
	Calcium	38%
	Iron	51%
	Other	16%
	Multivitamins	75%
Medications	Paracetamol	13%
	Ibuprofen	2%
	Other	2%

DISCUSSION:

Pregnancy is a special state where intake of medication is a challenge and a major concern as it may harm the fetus as these drugs may cross the placenta (10) but practice of Self-medication is common among these women due to pregnancy related problems. (11,12). As the whole world, people in Libya tend to go for self-medication, for many reasons, which include the high cost of medical consultations, lack of time, long hours of waiting at physician's clinic, and lack of trust in the physician's medical knowledge. Furthermore, previous experience with a medical condition and its drug management and the lack or the unavailability of nearby health facilities where identified as reason for seeking OTC medications.

To our knowledge, it is the first study on this subject in Azawia-Libya, where according to our findings 85% of the participants were Libyan women and 48% of them were between 26 to 35 years of age. Although 78% of the participants were with high educational degree, 57% of them have no idea about OTC medicines and only 26% have a good knowledge about the safety of the non-prescription medicines. These findings were correlated with study of Bohio R et.al. (13) Regarding the safety of OTC use during pregnancy, it was found that the majority of the participants 98% reported that OTCs are not safe, where 86% reported that herbal products are not safe to be used during pregnancy where in UAE 42.9% agree with herbal products safety. (14) In other study 83.1% recognized the potential risk of using non-prescribed medications during pregnancy and the need to receive a medical advice. (15) Almost all participants reported "Yes" to the survey question "have you ever use OTC drug or vitamin in your current pregnancy?" where the majority of participant 90% did not experience any side effects from the drug they used during their pregnancy, 10% reported some side effects.

Constipation 6% and headache 8% were the most common side effects reported by the participants. However, 64% of the pregnant females in the study reported "Yes" to survey statement "read the accompanying leaflet content before using the OTC drugs". This result is similar to the study of Abduelmula R. et.al. (14). This may indicate to one of the reasons behind reading the OTC medication leaflet before taking the OTC was either a lack of knowledge on how to take the drug or fear of side effects of medication.

Responses were recorded for the survey question "Do you know the critical time for the use of the over-counter-drugs during pregnancy?" More than third quarter 82% indicated the first trimester, the rest decided on the second trimester 6% and third trimester 12%, we noticed that the majority of participants are aware to that the first trimester is critical period of pregnancy; more care should be taken because it is period of organogenesis, and drug intake during this period has profound effect on the foetus, this awareness is better than awareness of pregnant women in that study performed in UAE were 55.7% indicated the first trimester (14).

Commonly used OTC medications are analgesics, antipyretics, anti-emetics, and nutritional supplements. Even though, all the drugs are not associated with medical complications to the foetus and mother. High doses of acetylsalicylic acid result in increased prenatal mortality neonatal haemorrhage, low birth weight, prolonged

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gestation/labour, and possible birth defects. The use of folic acid is essential in the first trimester of pregnancy to prevent neural tube defect (16). In this study, the most commonly used supplements were folic acid 83%, followed by iron 51% and then calcium 38%. These drugs are commonly recommended by doctors and recommended for use during pregnancy. These findings are similar to those of Inamdar et. Al (17) and Hanafy et al. (18)

In this study, analgesic drug use is low, 13% of the pregnant women using paracetamol. This finding is similar to study conducted in Saudi Arabia 13.2% (19) and far from other studies in Pakistan 43.6% (13), Ethiopia 37.5% (20) and UAE 55.1% (14). This low percentage of usage of analgesics by pregnant women in Azawia Libya and in Saudi Arabia could be due to low level of knowledge about OTC medicines compared to other countries. Finally it was noticed that the usage of OTC drugs among pregnant women in Azawia Libya is limited during pregnancy, and majority of them didn't know "what meant by Over-the-counter drugs", this may be due to low level of knowledge and it is obviously that this marked low level of knowledge about OTC in our country is may be due to poor counselling by the pharmacists who don't play their new roles in health promotion and pharmaceutical care and insufficient information regarding drugs in pregnancy from the clinical practitioners.

CONCLUSION:

The results clearly shows the low level of familiarity and information of the participants about the use of OTCs where the pharmacists should improve their counselling skills and their new roles regarding health promotion and pharmaceutical care, The role of the pharmacist in this particular field is great toward enhances the knowledge of the community and has to be improved via the either the individual practices of the pharmacists and community pharmacies or by the governmental program through the Ministry Of Health in the direction of growing the counselling skills up.

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