AMERICAN JOURNAL OF PHARMTECH RESEARCH

Journal home page: http://www.ajptr.com/

Factors Associated with Pharmacotherapy Care of Pregnant Women with Epilepsy in Khartoum State, Sudan

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ABSTRACT

Epilepsy is a common and non-communicable disorder of the brain affecting people of all ages. While epilepsy may cause complications in women during pregnancy, women can still enjoy healthy pregnancy with proper medical care. This study was aimed at identifying factors associated with enhancing pharmacotherapy care of pregnant women with epilepsy in Khartoum State, Sudan. This research was conducted using survey method to gather cross-sectional data from 30 pregnant women who are using prescribed antiepileptic drugs (AEDs), 30 doctors and 30 pharmacists. Structured Interview Schedule was used to collect data from study subjects.Sixty percent of sampled pharmacists contain AEDs prescribed by physicians.In addition, only 23% of the women respondents were able to afford the prices of AEDs prescribed for them, and 63% of them purchased their prescribed AEDs from private pharmacies where prices are higher. Moreover, the difference in the level of effort by pregnant women to ensure compliance and safety in use of AEDs prescribed is not associated with differences in age, educational level and source of incomeof the women respondents, as well as availability and affordability of AEDs to the women.No association was found between the compliance and safety among respondents and age group, educational level and sources of income of the women respondents as well as availability and affordability of AEDS. Moreover, there is need for more on-the-job training for pharmacists in order to develop their knowledge and skills to ensure patient compliance and safety.

Keywords: Antiepileptic Drugs; Availability; Affordability; Compliance; Safety

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Received 29 May 2016, Accepted 07 June2016

Please cite this article as: Sara AI *et al.*, Factors Associated with Pharmacotherapy Care of Pregnant Women with Epilepsy in Khartoum State, Sudan. American Journal of PharmTech Research 2016.

INTRODUCTION

Epilepsy is a common and non-communicable disorder of the brain affecting people of all ages, and responsible for 0.5% of the world's disease burden[1]. A meta-analysis provided a global estimate of 70 million for cases of life-time epilepsy[2]. More than 80% of people with epilepsy live in resource-poor countries where the incidence of epilepsy is two to three times higher than in high-income countries[3]

Incidence of epilepsy is the highest among children and the elderly. Men are affected slightly more often than women. The difference arises not only because of the biological difference between women and men but also because of the difference in the social-role they play in life. As a result of these biological and social-role differences, women with epilepsy face special challenges especially in the area of reproductive health. Epilepsy is a major cause of indirect maternal deaths, which are not only due to direct obstetric causes, but also aggravated by physiological effects of pregnancy. Other causes of indirect deaths include diabetes, cardiac disease and hormone-dependent malignancies[4].

According to the 2008 Sudan Population and Housing Census, the population of Sudan is 30.9 million, of which 49.5% is female and 50.5% is male. A total of about 8.8 million (29%) of the total population are female between the ages of 15 – 44 years[5]. The population of Sudan is growing quickly (2.5% per year), reflecting the relatively high fertility rate and the large population in the reproductive age. The Sudan Household Health Survey 2010 states that the national Maternal Mortality Ratio (MMR) is 216 per 100,000 live births, but the rate varies widely across regions and is disproportionately higher among the poorest, the rural, and the nomads in the country[6].

This research aims to promote public awareness about the influence of availability and affordability of AEDs on the therapeutic outcomes. In this study we assessed the knowledge and counseling of pharmacists regarding the use of AEDs by pregnant women to determine whether an educational programs should be implemented. This research eventually will also contribute to knowledge and improve practice in community Pharmacy on understanding how compliance and safety in the use of prescribed AEDs for pregnant women with epilepsy can enhance pharmacotherapy for the women in Sudan. This research is also expected to influence government policy on enhancing pharmacotherapy for pregnant women with epilepsy towards reducing MMR in Sudan.

MATERIALS AND METHOD

Research Design

Descriptive research design was used to conduct this research project. The research approach involved use of survey method for gathering cross-sectional data from the following three categories of target groups:

Women who are currently pregnant and have condition of epilepsy and/or previously pregnant with condition of epilepsy. All the women must be taking prescribed AEDs for treating their epileptic condition.

- Prescribers of AEDs to pregnant women with epilepsy (Medical Doctors).
- Pharmacists who are dispensing AEDs.

Location of the Study

The research study was conducted in the following medical facilities and government pharmacies in Khartoum State, Sudan: Ibrahim Malik Teaching Hospital; Ibn Sina Teaching Hospital; Khartoum Teaching Hospital; Bashir Teaching Hospital; Haj Al Safi Teaching Hospital; and Soba Advance Teaching Hospital. Other locations of the study were private pharmacies in Khartoum.

Duration of the study

The study was conducted from October 2015 to December 2015.

Sample Size

Non-probability sampling involving purposive sampling method was used to select a total of 30 women, 30 doctors, and 30 pharmacists who meet the selection criteria set in the research design. Purposive sampling was used as it was difficult to obtain the population sizes of the three categories of target groups for this study.

Data Collection

Data was collected using structured interview schedule for collecting data from sampled women as some of them would need to be assisted in understanding the questions in the instrument. Questionnaires were administered by the sampled medical doctors and pharmacists.The research instruments, contained in Appendices 2–4, were subjected to face validity to ensure that the contents in them make sense for data collection for achieving objective of this study. An Introduction Letter, from the University, for data collection from the target groups is at Appendix 1.

The measurement scale on efforts on compliance and safety of respondents with prescribed AEDs, used in Appendix 2, was adapted from the ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling[7].

Statistical Analysis

Data analysis for this study was conducted using the Statistical Package for the Social Scientists (SPSS) Version 21 released in 2012. Descriptive statistical analysis of Mode was conducted on collected data, and the obtained results were presented as Frequency Distribution Tables and Bar Charts. Inferential statistical analysis was conducted using Chi Square Test, which is a nonparametric statistical test. Data from non-randomised sampling (like Purposive Sampling) cannot be assumed to have Normal Distribution; hence, a nonparametric test is appropriate for analysing such data[8].

RESULTS AND DISCUSSION

Personal Characteristics of the Sampled Women

Age Groups of Women Respondents:

Table 1 shows that the modal group of the respondents is adult women who comprise 70%, while youths comprise 30% of the respondents.

Table 1: Frequency Distribution of Age Groups of Women Respondents

Age Group	Frequency	Per cent (%)
24 years and below (Youth)	9	30.0
Above 24 years (Adult)	21	70.0
Total	**30**	**100.0**

Educational Levels of Women Respondents:

Table 2 shows that a total of 77% of the respondents had formal education with secondary school level by 33%, tertiary level by 27%, and primary level by 17%. Only 23% of the respondents do not have formal education.

Table 2: Frequency Distribution of Educational Levels of Women Respondents

Educational Levels	Frequency	Per cent (%)
No attendance of a formal school	7	23.0
Primary school education	5	17.0
Secondary school education	10	33.0
Tertiary education	8	27.0
Total	**30**	**100.0**

Sources of Income of Women Respondents:

Table 3 shows that majority of the respondents (63%) obtain their income from family assistance

while 37% obtain their income from employment or their private business.

Table 3: Frequency Distribution of Sources of Income of Women Respondents

Age Group	Frequency	Per cent (%)
Income obtained from family	19	63.0
Personal income from employment or business	11	37.0
Total	**30**	**100.0**

Methods used for Purchase of Prescribed AEDs by Women Respondents:

Table 4 shows that majority of the respondents, 67%, purchase their prescribed AEDs by cash while 33% use health insurance for their purchase.

Table 4: Frequency Distribution of Methods used for Purchase of Prescribed AEDs

Method of Purchase	Frequency	Per cent (%)
By use of cash	20	67.0
By use of Health Insurance	10	33.0
Total	**30**	**100.0**

Places where Women Respondents Purchase Prescribed AEDs:

Table 5 shows that majority of the respondents, 63%, purchase AEDs prescribed for them from pharmacies outside of government hospitals (Private Pharmacy) while 37% of them make their purchase from pharmacies within government hospitals (Government Pharmacy).

Table 5: Frequency Distribution of Places where Women Respondents Purchased AEDs

Place of Purchase of AEDs	Frequency	Per cent (%)
From pharmacy outside of government hospital	19	63.0
From pharmacy inside of government hospital	11	37.0
Total	**30**	**100.0**

AEDs Prescribed by Sampled Medical Doctors and Stocked by Sampled Pharmacies.

Table 6 shows the list of AEDs prescribed by sampled medical doctors, and same list of AEDs with one more type of AED stocked by the sampled pharmacies. The list of trade names of the stocked AEDs is presented in Appendix 5.

Table 6: List of Prescribed and Stocked AEDs in Khartoum State Sudan

AEDs Prescribed by Medical Doctors	AEDs Stocked in Pharmacies
Phenytoin	Phenytoin
Sodium Valproate	Sodium Valproate
Phenobarbital	Phenobarbital
Carbamazine	Carbamazine
Oxycabarmazine	Oxycabarmazine
Lamotrigine	Lamotrigine
Benzodiazapine	Benzodiazapine
Felbamate	Felbamate
	Topiramate

Levels of efforts by Women Respondents and Pharmacists to ensure Compliance on use of Prescribed AEDs.

Figure 1 shows that 26 out of the 30 of women respondents (87%) received guidance on use of prescribed AEDs when they request such from pharmacists, while four of the respondents (13%) reported that pharmacists themselves always provide to them guidance on use of prescribed AEDs.

Figure 1: Level of Compliance and Safety Efforts by Women Respondents on use of Prescribed AEDs

Figure 2 shows that 60% of sampled pharmacists always offer and provide guidance to customers (patients) on use of prescribed AEDs purchased, while 40% of the pharmacists provide such guidance when requested by customers.

Figure 2: Level of Compliance and Safety Efforts by Pharmacist use of Prescribed AEDs by Customers

Availability of AEDs to Pregnant Women in the Sampled Pharmacies.

Table 7 shows that 60% of the sampled pharmacies reported that they always have stock of AEDs while 40% of the pharmacies reported that they make order for AEDs whenever requested by customers with prescriptions.

Table 7: Availability of AEDs to Pregnant Women in Sampled Pharmacies

Availability of AEDs	Frequency	Percent (%)
Pharmacy always have stock of AEDs	18	60.0
Pharmacy makes order for AEDs whenever requested by customers	12	40.0
Total	**30**	**100.0**

Affordability of Prescribed AEDs for Women Respondents.

Table 8 shows that only 23% of the respondents are able to afford the prices of AEDs prescribed for them. Whereas, 57% of the respondents cannot afford the price of the prescribed AEDs, while 20% of the respondents had to borrow money sometimes in order to make their purchase.

Table 8: Affordability of AEDs to Women Respondents

Affordability of AEDs	Frequency	Per cent (%)
Sometimes cannot afford the price of the drug	17	57.0
Sometime had to borrow money to buy the drug	6	20.0
Price of the drug is affordable	7	23.0
Total	**30**	**100.0**

Sources where Sampled Pharmacists Acquire Knowledge and Skills on Counselling and Educating of Customers (Patients) for ensuring Compliance and Safety in use of AEDs.

Table 9 presents results of multiple responses by 30 cases (Pharmacists). The results showed that only 13% of the 30 sampled pharmacists reported that they never received training on counseling and educating of customers. However, 73% of the sampled pharmacists reported that they were taught on the subject matter in their pharmacy courses at the university; 47% of them reported they had self training on the job; 43% had on-the-job training as pharmacists; while 23% attended training courses on the subject matter after their graduation from the university.

Table 9: Sources where Sampled Pharmacists Acquire Knowledge and Skills on Counselling and Educating of Customers (Patients)

Sources of Knowledge and Skills	Frequency	Per cent (%)
Through University Course in Pharmacy	22	73.0
Through Self-training on the job as a Pharmacist	14	47.0
Through on-the-job training as a Pharmacist	13	43.0
Through attending of courses	7	23.0
No training received on Counselling and Educating of customers	4	13.0

Results of Inferential Statistical Data Analysis

The inferential statistical analysis was done using Chi Square Test towards accepting or rejecting the null hypotheses set in Chapter One of this research project. The level of significance set for the test is 0.05 level ($\alpha = 0.05$). A null hypothesis is accepted (no significant association between two variables) if the observed significance level is higher than the set significance level of 0.05. Whereas, a null hypothesis is reject (significant association exist between two variables) if the observed significance level is equal to or lower than the set significance level of 0.05.

Table 10 shows that none of the five associated factors in the null hypotheses of this study has significant association with the variable on compliance and safety of women respondents with Prescribed AEDs, as the observed significance level of each of the independent variables is higher than the set significant level of 0.05 for the Chi Square Test.

Table 10: Results of Chi Square Tests

Associated Factors	Dependent Variable	Set Significance Level (α)	Observed Significance Level
Age Groups of Women Respondents	**Compliance and Safety** of Women Respondents with Prescribed AEDs	0.05	1.00
Educational Levels of Women Respondents	**Compliance and Safety** of Women Respondents with Prescribed AEDs	0.05	0.18
Sources of Income of Women Respondents	**Compliance and Safety** of Women Respondents with Prescribed AEDs	0.05	0.13
Availability of Prescribed AEDs to Women Respondents	**Compliance and Safety** of Women Respondents with Prescribed AEDs	0.05	0.28
Affordability of Prescribed AEDs for Women Respondents	**Compliance and Safety** of Women Respondents with Prescribed AEDs	0.05	0.17

DISCUSSION

The modal group of the respondents was adult women who comprised 70%, while 30% were women of youth age group. This is considered as good result for the study as the respondents were expected to have good experience on the incidence of epilepsy and issues concerning use of prescribed AEDs among pregnant women.

A very high proportion of women respondents, a total of 77%, had formal education between primary – tertiary level of education. The result also indicates a possible high understanding among the women respondents of issues concerning use of prescribed AEDs among pregnant

women.

Majority of the women respondents (63%) obtained their incomes for purchase of prescribed AEDs through financial assistance from their family members. This finding supports the report that poverty is deep and widespread in Sudan[30].Majority (67%) of the respondents purchased their prescribed AEDs by cash payment. Private pharmacy was the major source of purchase of prescribed AEDs by 63% of the women respondents.

The brands of AEDs prescribed by the sampled medical doctors were stocked in 60% of the sampled pharmacies. This indicates that AEDs prescribed by physicians were available in the sampled pharmacies. Similarly, other studies showed that AEDs available for pregnant women with epilepsy in Sudan are of different brands and good quality [14, 15, 16, 21, 29].

The result on ready availability of the stocked brands of AEDs in 60% of the sampled pharmacies did not agree with the year 2010 finding that, on the average, availability of selected essential medicines at the public (government) pharmacy, medicine stores, and private pharmacies is between 80% - 93.0% in Sudan, and with the conclusion that generally availability and stock out duration of essential medicines in the Sudan were acceptable[28]. The current inflation in the country could be a reason for the lower level of availability of AEDs, as most of the drugs are imported into the country. However, more researches need to be conducted to determine the actual factors responsible for the current availability of AEDs in Sudan.

Result from this study showed that affordability of the drugs is a problem, as only 23% of the women respondents were able to afford the prices of AEDs prescribed for them. This result is not unexpected as findings in this study showed that 63% of the women respondents depended on their family for income, and 67% of them made purchase of their prescribed AEDs by cash payment. These results from this study support the report that affordability of drugs is a critical factor for a country like Sudan, where poverty is deep and widespread[30].

The problem of affordability of AEDs for pregnant women is further shown by the source of their purchase of the drugs, as 63% of them purchased their prescribed AEDs from private pharmacies. While, in Sudan, a pricing mechanism has been built into the Drug Registration System as a route of administrative exercise from the very beginning of medicine registration that is controlled by the National Medicine, and Poisons Board (NMPB)[30]. However, price is a component of affordability of medicines, and the private sector had slightly higher prices[31].

All the pharmacists sampled reported that they were providing guidance on use of prescribed AEDs to customers, but customers (sampled women) rated level of guidance provided by pharmacists lower than the rating the sampled pharmacists provided for themselves. Hence, while

87% of the sampled women reported that they received the guidance only when they made request for guidance to pharmacists, 60% of sampled pharmacists reported that they always offer and provide guidance on use of prescribed AEDs. The difference in the results above is critical regarding ensuring compliance and safety of patients in use of prescribed drugs like AEDs. A pharmacist is required to strongly support patient counseling requirements in order to positively influence patient compliance with pharmacotherapy and to ensure patient safety[24]. An effective counseling session between patient and pharmacist ensures that the patient receives essential educational information related to the medication and provides an opportunity for the patient to ask questions. It is not only that patient counseling is the right thing to do, it is mandated by law in a developed country like United States of America. It is vital to document this care provision to validate compliance[26].

Results showed that majority (87%) of the sampled pharmacists had some knowledge and skills on counseling and educating of customers (patients) for ensuring compliance and safety in use of prescribed AEDs. University was the main source of training on the subject matter, as reported by 73% of the sampled pharmacists, while lesser number (43% of the sampled pharmacists) reported training on-the-job. This implies that patient counseling skill of pharmacist needs to be strengthened by proper on-the-job training. This finding is also supported by another study that showed patient counseling provided by pharmacists is an acquired skill[25].

The results of the Chi Square Test to identify the factors that are associated with compliance and safety of women respondents with prescribed AEDs did not show significant association with the selected factors: age group of the women respondents, their educational level and their sources of income as well as the availability and the affordability of prescribed AEDs for women respondents. The results showed that the differences in age, educational level, and sources of income of pregnant women with epilepsy did not bring about differences in the level of compliance and safety efforts in use of prescribed AEDs among the women. The results also showed that the differences in availability and affordability of prescribed AEDs among pregnant women with epilepsy did not bring about differences in the level of compliance and safety efforts in use of prescribed AEDs among the women.

CONCLUSION

This study showed that the differences in the level of efforts by the women respondents towards ensuring compliance and safety in use of AEDs do occur without significant association with the differences in the level of the following factors among the women respondents: age, educational

level, source of income, availability of AEDs and affordability of AEDs.This research also indicates inadequate effectiveness in guidance provided by pharmacists for ensuring compliance and safety in use of prescribed AEDs. Thus, there is a need for more on-the-job trainingfor developing knowledge and skills of pharmacists to in order to enhance their positive influence in patient's compliance with pharmacotherapy.

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