Original Article

The use of medicines by pregnant women who receive care in the Brazilian Universal Healthcare System*

Uso de medicamentos por gestantes usuárias do Sistema Único de Saúde

Uso de medicamentos por gestantes del Sistema Único de Salud

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ABSTRACT

Objective: To identify the use of medicines by pregnant women who receive care at the Brazilian universal healthcare system, specifically in the municipal district of Bandeirantes, Paraná. **Methods**: A cross-sectional descriptive study was used. A sample of 205 women participated in the study. Data were collected from July 2006 to November 2007 using a structured questionnaire. **Results**: A great number of participants (83.4%) reported they had used at least one medicine during their pregnancy and 8.2% of them used over-the-counter medicines. The majority of the women (80.5%) received warnings about the use of medicines during pregnancy. There was significant statistical relationship between the last 3 months of pregnancy and the increase in medicines use. Although Ferrous sulfate (45.0%) and Paracetamol (43.4%) offer serious risks to the fetus, these two medicines were among those most used by the participants. **Conclusion**: Pregnant women have been exposed to a variety of medicines. There is a need to improve the quality of care to pregnant women in order to prevent potential risks to the fetus.

Keywords: Pregnancy; Drug utilization; Fetal development/drug effects

RESUMO

Objetivo: Identificar o uso de medicamentos por gestantes usuárias do Sistema Único de Saúde do município de Bandeirantes - Paraná. **Métodos**: Estudo analítico transversal. População: 245 gestantes e amostra de 205. O instrumento para coleta de dados foi um questionário estruturado. Estudo realizado de julho de 2006 a novembro de 2007. **Resultados**: 83,4% das gestantes entrevistadas declararam utilizar pelo menos um medicamento, destas 8,2% o fizeram sem prescrição médica e 80,5% receberam alerta sobre perigos de certos medicamentos. Os dados evidenciaram uma relação estatisticamente significante entre o 3º trimestre e o maior uso de medicamentos. Sulfato ferroso (45,0%) e paracetamol (43,4%) foram os mais utilizados, porém medicamentos considerados de risco para o feto também foram empregados. **Conclusão**: As gestantes estão sendo expostas a uma variedade de medicamentos, o que exige atenção criteriosa para evitar possíveis danos ao feto.

Descritores: Gravidez; Uso de medicamentos; Desenvolvimento fetal/efeitos de drogas

RESUMEN

Objetivo: Identificar el uso de medicamentos por gestantes del Sistema Único de Salud del municipio de Bandeirantes - Paraná. **Métodos**: Se trata de un estudio analítico transversal. La población estuvo constituida por 245 gestantes siendo la muestra de 205. El instrumento para la recolección de datos fue un cuestionario estructurado. El estudio fue realizado de julio del 2006 a noviembre del 2007. **Resultados**: el 83,4% de las gestantes entrevistadas declararon utilizar por lo menos un medicamento, de éstas el 8,2% lo hicieron sin prescripción médica y el 80,5% fueron alertadas sobre los peligros de ciertos medicamentos. Los datos evidenciaron una relación estadísticamente significativa entre el 3º trimestre y el mayor uso de medicamentos. El Sulfato ferroso (45,0%) y el paracetamol (43,4%) fueron los más utilizados, pero también los medicamentos considerados de riesgo para el feto. **Conclusión**: Las gestantes están siendo expuestas a una variedad de medicamentos, lo que exige una atención con criterio para evitar posibles daños al feto.

Descriptores: Embarazo; Utilización de medicamentos; Desarrollo fetal/efectos de drogas

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* *Study Performed at the Health Secretariat in Bandeirantes (PR), Brazil.*

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Received article **29/05/2008** and accepted **12/08/2008**

INTRODUCTION

In the daily medical practice, several medications are prescribed for different clinical conditions. These medications present, many times, a chance to interact with each other and to influence some physiological conditions of patients such as, for example, pregnancy[1].

The use of medications by pregnant women and its consequences to fetuses became a concern after facts that occurred in the end of the 1950's and beginning of the 1960's. According to the literature, about 10 thousand newborns in that period presented phocomelia due to the use of thalidomide[2-4].

A study conducted in France demonstrated that 99% of women received prescription for at least one medication during pregnancy and in a study conducted in Brazil the mean found was 4.2 medications per pregnant woman[5].

Studies conducted in Brazil pointed out that 83.8% to 97.6% of pregnant women are exposed to medication with or without medical prescription[6-8].

The use of medications during pregnancy deserves special attention due to the potential risks to the developing fetuses, and, at first, they should be avoided[9]. According to some authors despite the risks, currently there is a picture of medicalization "resulting from the market logic and practices of medication producers and to the hegemony of the "mechanistic", biomedical and Cartesian view of the health-disease process"[4].

Medications are classified according to the risk associated with their use during pregnancy. The classification adopted by the Food and Drug Administration (1980) puts medication into five categories which are: Risk Category **A** – considered as no risk. Risk category **B** – animal studies have not revealed risks, however, there are no studies in pregnant women, Category **C** – animal studies have shown adverse effects to the fetus and there are no studies in pregnant women, Category **D**– evidence of fetal risk, however, the benefit to pregnant women may justify the use, Category **X** – studies have demonstrated positive evidence of fetal abnormalities or risks; the use is contraindicated during pregnancy, and no classification (**NC**), when it was not possible to find information about the medication[1,7-11].

The use of medications during pregnancy should be cautiously seen and a careful assessment of the risk/benefit must be conducted due to the implications to the fetus' health. Taking this into account, studies identifying the use of medications by pregnant women are important. Thus, the objective of the present survey was to identify the use of medications by pregnant women using the Single Health System (SUS) at the town of Bandeirantes – Paraná.

METHODS

Place of study

Cross-sectional analytic study developed in Bandeirantes. This town is located in the North of the State of Paraná; and it is approximately 270 miles away from the capital – Curitiba. It has around 447,617 km2 and the population was estimated at 33,370 inhabitants in 2005.

Health services in the municipality

There is a Maternal and Child Care Center (AMI) for outpatient care of women and children, a care center for general practice and four Basic Health Units, all of them have teams from the Family Health Program (PSF). Prenatal care is performed at AMI and in two units from the PSF.

Study Population

The study population was formed by 245 pregnant women users of the Single Health System (SUS), enrolled at the Service of Information on prenatal from July 2006 to November 2007 and that received prenatal care at AMI.

Two-hundred and five pregnant women approached in the waiting room at AMI before prenatal consultation took part in this study. Women were interviewed regardless of their gestational age. The remaining pregnant women enrolled (40) were classified as loses because delivery had already occurred.

Pregnant women were asked to give their written consent and confidentiality was ensured according to the Resolution # 196/96 of the National Health Council that regulates research with human beings. The research project was approved by the Ethical Research Committee of the Universidade Estadual do Norte do Paraná (State University of the North of Parana)- *campus* Bandeirantes.

Instrument for data collection

The instrument used for data collection was a structured questionnaire with open and closed questions with variables like: age, marital status, schooling, gestational age, family income, as well as the use of medication, prescription and awareness on the hazards of medications during pregnancy.

Data analysis

Results have been presented in tables and a picture. The program 7.1 and the Statistical Analysis System (SAS – 9.1) were used for tabulation. In the statistical analysis, we have calculated the frequency of defined variables using Chi-Square test and Fisher's exact test when necessary. In all analysis a 5% significance level has been adopted.

RESULTS

Mean age of the population was 23.7 years (± 6.04,

Table 1 - Number and % of the use of medications per pregnant women cared for at SUS according to sociodemographic variables and gestation period, Bandeirantes -PR, 2007

Variables	Use of medications				P
	Yes	%	No	%	
Marital Status					
Single	30	14.6	2	1.0	
Married	78	38.1	17	8.3	0.2193
Living with partner	63	30.7	15	7.3	
Schooling					
Incomplete Elementary School	56	27.3	14	6.8	
Complete Elementary School	19	9.3	3	1.5	
Incomplete High School	38	18.5	8	3.9	
Complete High School	45	22.0	7	3.4	0.9548
Incomplete University	5	2.4	1	0.5	
Complete University	8	3.9	1	0.5	
Family Income					
Up to 1 MW	24	11.7	5	2.5	
1 to 2 MW	108	52.7	20	9.7	
3 to 4 MW	35	17.1	9	4.4	0.8283
Over 5 MW	4	1.9	0	0.0	
Gestation period at the time of interview					
1st Quarter	32	15.6	15	7.3	
2nd Quarter	69	33.5	9	4.5	0.0055
3rd Quarter	70	34.3	10	4.8	

Table 2 – Frequency and percentage of medications used by pregnant women seen at SUS in the town of Bandeirantes, Pr, 2007

Medication	N	%
Ferrous sulfate	92	45.0
Paracetamol	89	43.4
Folic Acid	28	13.6
Dimenhydrinate	21	10.2
Dipyrone	15	7.3
Metoclopramide	13	6.3
Cephalexin	10	4.9
Scopolamine Butyl Bromide	10	4.9
Piperidolate hydrochloride	9	4.4
B Complex	8	3.9
Amoxicillin	5	2.4
Multi vitamins	4	1.9
Diclofenac	4	1.9
Orphenadrine Citrate	2	1.0
Bisacodyl	2	1.0
Aluminum Hydroxide	2	1.0
Acetylsalicylic Acid	2	1.0
Dimeticone	2	1.0
Insulin	2	1.0
Ethinylestradiol+levonorgestrel	1	0.5
Benzyl Benzoate	1	0.5
Diazepam	1	0.5
Aminophyllin	1	0.5
Albuterol	1	0.5
Methyldopa	1	0.5
Fenoterol hydrobromide	1	0.5

Obs: Values do not total 100% because there is more than one answer per interviewee.

median and moda 23.0 years). Among women, 80 (40%) were in the 20 to 25 years old age group.

As for schooling, 70-34.1% had not finished Elementary School. When the level of education was compared with the use of medication during pregnancy, there was no statistically significant difference (p=0.9548) (Table 1).

Among interviewees, 95 (46.4%) were married, 78 (38.0%) lived with partners, and 32 (15.6%) were single (Table 1).

Regarding monthly family income, 29 pregnant women (14.1%) lived with less than 1 minimum wage, 128 (62.4%) earned 1 to 2 minimum wages, 44 (21.5%) earned 3 to 4 minimum wage and only 4 (2.0%) earned more than 4 minimum wages (Table 1).

Regarding the variable "occupation" 127 interviewees (62%) were not employed, they were "housewives" or "students".

Of the 205 pregnant women, 171 (83.4%) said they have used at least one medication during pregnancy.

When gestational age was compared with the use of medications, the relationship was statistically significant

Picture 1 – Classification, according to risk category, of the medications used by pregnant women seen at SUS in the town of Bandeirantes, Pr, 2007

Medications	Risk category*
Acetylsalicylic Acid	C
Folic Acid	A
Aminophyllin	C
Amoxicillin	B
Benzyl Benzoate	NC
Fenoterol hydrobromide	D
Scopolamine Butyl Bromide	C
Cephalexin	B
B Complex	B
Piperidolate hydrochloride	B
Diazepam	D
Diclofenac	C
Dipyrone	C
Orphenadrine Citrate	C
Dimenhydrinate	B
Aluminum Hydroxide	C
Insulin	C
Bisacodyl	B
Dimeticone	C
Multi Vitamins	A
Methyldopa	B
Ethinylestradiol+levonorgestrel	X
Paracetamol	B
Metoclopramide	B
Salbutamol/Albuterol	B
Ferrous sulfate	A

*A – Control studies in women have not shown risk to the fetus.
B – Studies with animals have not shown fetal risk, however, there are no controlled studies in pregnant women.
C – Studies with animals have demonstrated adverse effects in the fetus and there are no controlled studies in women.
D – There are evidences of risk for human fetus; however the benefits of use in pregnant women may outweigh the risk.
X – Contraindicated drug for women who are pregnant or willing to get pregnant.
NC – It was not possible to obtain information on the referred drug

(p=0.0055). Women that were in the third quarter reported more often having taken or being taking some kind of medication, and the medications more commonly taken were ferrous sulfate (92– 45.0%) and paracetamol (89 – 43.4%) (Table 2).

Of the 26 medications used by pregnant women, 9 were category **C**, 2 were category **D** and 1 category **X**, which are those considered as riskier for the fetus (Picture 1).

Fourteen pregnant women (8.2%) used medication without medical prescription. Among them, those that could harm the fetus, because they were in risk category C, were scopolamine butyl bromide and diclofenac.

When they were asked if they had been informed about the harms of some medications during pregnancy, 165 of them (80.5%) said they had, and most of them mentioned that physicians had given them this information (35.6%), followed by relatives (30.7%)

DISCUSSION

Data from this study showed a young population (mean age 23.7 years), as observed by other studies such as the one performed with pregnant women using a prenatal primary care center and with mothers of live birth infants where mean age was 23.4 and 25.75 years, respectively[4,11].

In a study conducted in 2007 with pregnant women seen in a municipal hospital, 44.4% of these women had completed Elementary School, these data are higher than those found in the present study (34,1%)[9]. The literature mentions that education gives access to work (in the present study most interviewees were housewives), and to different levels of income (most families' incomes were 1 to 2 minimum wages), as well as to facilitate the access to different behaviors regarding health, therefore, schooling can be seen as a cause or consequence of income level[6].

The amount of women that reported not having taken medications during pregnancy in the present study was much higher (16.6%) than that of similar studies. The recall can be a possible bias. Studies whose data collection refers to past events, in a way, do not correspond to the reality. We believe that the data from the present study may have been underestimated and, certainly, some medications taken during pregnancy were not reported.

In a study conducted in a teaching hospital, only 5.4% of the patients had not taken drugs during pregnancy, and this result is close enough to the 6% value found in the Brazilian sample included in the intercontinental study performed by *Collaborative Group on Drug use in Pregnancy*[10]. In another study, only 2.4% of the interviewed women reported having not taken medications during pregnancy[6].

According to the data obtained, the most commonly taken medication was ferrous sulfate (45%). Some authors consider the use of this medication as routine procedure[7].The World Health Organization is also in favor of the prescription of ferrous sulfate highlighting the need for it due to the high rates of anemia in third world countries, where there is great prevalence of malnutrition[4].

The rate of ferrous sulfate use was higher than 50% in a study conducted with pregnant women in a municipal hospital in Mato Grosso[9], the remaining studies, similar to that one, presented a use of about 30%[4, 7,10].

Another medication commonly mentioned by pregnant women was paracetamol (43.4%), many times in "benign self-limited conditions and, in many cases, unnecessarily", however, this medication, according to studies does not present evidence of risks[7, 9-10].

Two medications taken for analgesia by some pregnant women were dipyrone and acetylsalicylic acid. These medications belong to category C, that is, a category where risks cannot be excluded, but the benefits outweigh the potential risks. Dipyrone has the potential to produce agranulocytoses and the use of acetylsalicylic acid in high dosages has been associated with low birth weight, and it can also lead to hemorrhage before and after delivery. Therefore, for analgesia, paracetamol should be recommended because it is in category B[3,10].

The use of diazepam, which is category D, should be avoided, because a few studies ensure the use of this category during pregnancy. There are reports stating that its use during the first quarter is controversial. The first studies suggest that children exposed to intrauterine diazepam presented increased risk of cleft lips and cleft palate; later, other works concluded that it is impossible to establish a causal relationship[12-14]. In the present study, the pregnant woman took the medication in the sixth month, avoiding a greater risk.

The pregnant woman that took ethinylestradiol+ levonorgestrel, a medication in category X, reported having taken it because she did not know she was pregnant since her period was regular.

Women that were in the third quarter of pregnancy were those reporting more often the use of medication, and this value was statistically significant (p=0.0055). We may assume that since prenatal consultations had already started for a longer period, the physician had prescribed all necessary medications, however, in the articles referred, it was not possible to find parameters to infer on these values.

Regarding self-medication, the figure found in this study is probably below what was expected (8.2%), since in a country where public health does not receive the necessary budget and whose organizational structure represented by SUS is not efficient enough, it is expected that people in the social level that depend on this health system would be more prone to self medication. Comparatively, a study performed in Colombia showed that 45.4%

of the interviewees had taken at least one medication without medical prescription[10].

In the present study, 40 pregnant women (19.5%) reported they had never received guidance on the risks of certain medications during pregnancy. Some authors found a much higher percentage of pregnant women (44.4%) who said they had not been warned. The same researchers wonder if educational programs are being developed to solve this problem in primary care centers and to decrease this gap[9].

CONCLUSION

The outcomes found in this study show a young population with mean age of 23.7 years, incomplete elementary school (34.1%), married (46.4%), with family income of one to two minimum wages (62.4%), and unemployed (62%). Most of them (83.4%) took at least one medication during pregnancy. Ferrous sulfate and paracetamol were the most frequently taken medications. Among the other medications referred by interviewees are dipyrone and acetylsalicylic acid, which are in risk category C. As for self medication, it was below what was expected (8.2%) in the present study. Although all interviewed pregnant women were being followed-up during prenatal, 19.5% reported they had not received guidance regarding the risks of certain medications represented to the fetus.

It is impossible to protect pregnant women from the risks of drug therapy unless the total use of drugs is suspended, which would be unsuitable and irrational, since pregnant women, just like the rest of the population, are subject to events that need drug intervention. Indeed there is a way to spare them from the exposure to unnecessary risks offered by drugs that have been little studied, contraindicated, poorly prescribed and excessively used. To stop this practice, we propose that health professionals get responsibly involved so that intervention measures are taken, promoting the rational use of medications.

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