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Ethno-epidemiological study of medicinal products and medicinal plants use among pregnant women

[Estudio etnoepidemiológico de medicamentos y uso de plantas medicinales en mujeres embarazadas]

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Abstract: The objective of this study was to examine the profile of pregnant women who visited the Unified Health System of the municipality of Umuarama/PR and to analyze their use of drugs categorized as D and X according to the United States Food and Drug Administration FDA and contraindicated medicinal plants for evaluating the potential gestational risks. A cross-sectional ethnoepidemiological study using a questionnaire was conducted among 500 pregnant women from January to May 2017. According to the pregnant women, during the prenatal period, 67.8% did not receive information on the use of medicinal plants and 26.6% used contraindicated plants. Among the drugs used, 12.2% belonged to category "D" (anticonvulsants), and 2.4% belonged to category "X" (hormonal contraceptives). This work highlights the need to expand health promotion activities to the basic units and implement protocols and technical guidance tools as well as training of pharmaceutical professionals to educate the population on the risk of these drugs during pregnancy.

Keywords: Phytotherapy; Maternal Health; Integral assistance to health; Pharmaceutical care; Infant mortality; Patients' safety.

Resumen: El objetivo de este estudio fue examinar el perfil de las mujeres embarazadas que visitaron el Sistema Único de Salud del municipio de Umuarama/PR y analizar el uso de medicamentos clasificados como D y X según la Administración de Alimentos y Medicamentos de los Estados Unidos (FDA) y plantas medicinales contraindicadas por posibles riesgos gestacionales. Se realizó un estudio etnoepidemiológico transversal a través de un cuestionario realizado entre 500 mujeres embarazadas en el período enero a mayo de 2017. Según las mujeres embarazadas, durante el período prenatal, el 67.8% no recibió información sobre el uso de plantas medicinales y el 26,6% respecto de plantas contraindicadas. Entre los medicamentos utilizados, el 12,2% pertenecía a la categoría "D" (anticonvulsivos), y el 2,4% pertenecía a la categoría "X" (anticonceptivos hormonales). Este trabajo destaca la necesidad de ampliar las actividades de promoción de la salud a las unidades básicas e implementar protocolos y herramientas de orientación técnica, así como la capacitación de profesionales farmacéuticos para educar a la población sobre el riesgo de estos medicamentos durante el embarazo.

Palabras clave: Fitoterapia; Salud maternal; Asistencia integral a la salud; Cuidado farmacéutico; Mortalidad infantil; Seguridad de los pacientes.

INTRODUCTION

Infant mortality rate is an important indicator of the health of a country as it reflects the quality and access to health services, the socio-economic conditions of public health practices, as well as women's health status (Rocha *et al.*, 2013). According to the Paranaense Institute of Economic and Social Development - IPARDES (2017), the infant mortality rate of Umuarama/PR is 13.60 per 1,000 live births. The prevention of obstetric complications and education of women in the pregnancy-puerperal cycle are essential (Silva *et al.*, 2015). As no medicine is free of toxicity to the mother or fetus, and there may be teratogenic risk including abortion, death or congenital malformations, the irrational use of medications during pregnancy should be considered a public health problem (Rocha *et al.*, 2013).

In Brazil, the potential fetal risks associated with different medications have been categorized as per the Food and Drug Administration (FDA) groupings as A, B, C, D, and X. According to Lacy *et al.* (2009), medications labeled by the FDA as "A" have the possibility of fetal harm appears remote; those labelled as "B" have no controlled studies in humans, but in animals showed no risks and for those labelled as "C" the risk/benefit ratio should be assessed since there is a potential for adverse effect on the fetus after its use. The FDA category "D" includes drugs for which there is positive evidence of fetal risk, but the benefits can be acceptable despite the risks; the category "X" drugs are considered contraindicated for use in pregnancy due to evidence of fetal risk from animal or human studies, or on the basis of human experience (Zomerdijsk *et al.*, 2015). According to RDC no. 60, from December 17th 2010 (ANVISA, 2010), categories A, B, C, D, and X medications include folic acid (vitamin supplement), paracetamol (analgesic), omeprazole (anti-ulcer), valproic acid (anticonvulsant), and ethinyl estradiol (hormonal contraceptive), respectively.

In most countries, herbal medicines are available without a prescription. Given this ease of access, the majority of women report that they make decisions regarding use of herbal medicines on their own or based on the recommendation of family and/or friends (Kennedy *et al.*, 2016). Medicinal plants play a significant role on the treatments associated with the women's health such as venereal disease, gynecological inflammation, promote fertility or avoid pregnancy; and according to Yasbek *et al.* (2016), the data of ethnopharmacology on medicinal plants used in women's health can

contribute to reduce the mortality rate, either through pharmacological studies to prove their efficacy or toxicological studies to assess their safety.

Regarding the use of herbal medicines, there are regional differences in the traditions (Kennedy *et al.*, 2016), and this is reflected in the differences across studies. Moreover, as pointed out by Smeriglio *et al.* (2014), the evidence from safety studies are often not conclusive. However, understanding the use of herbal medicines is important for both pregnant women and health professionals. Moreover, the Resolution 1,757, 18 February 2002, (Diário Oficial, 2012), reiterates the need to adopt strategies to improve the health of pregnant women.

Epidemiological studies are important for understating disease and behavior patterns as well as assisting public health professionals in the implementation of specific policies and programs to address population health challenges. According to Monteiro & Brandelli (2017), ethnobotanics studies demonstrate the relationship between plants and people, and enable the collection of relevant information about the use of medicinal plants. The objective of this work was to assess the profile of pregnant women seen by the Unified Health System (SUS) of Umuarama/PR including their socioeconomic status, gestational health, use of drugs during and after pregnancy, as well as examine the potential risks of pregnancy from the use of medications classified as "D" and "X" and medicinal plants contraindicated during pregnancy.

MATERIAL AND METHODS

Place of study and Sampling

A cross-sectional, ethno-epidemiological study was carried out among pregnant women of SUS between January and May 2017 at 24 points of care in the municipality of Umuarama/PR. To determine the sample size, Epi Info™ system was used, considering the estimated population of the municipality in 2017. According to the Brazilian Institute of Geography and Statistics (IBGE, 2020), there were 109,955 inhabitants and 2,000 pregnant women registered with the SIS-PRENATAL.

The sample consisted of 500 pregnant women, with a confidence interval of 95% for the purpose of standardization. It was determined that the number of samples per Unit of Health would be the total number of pregnant women enrolled in the establishment and we adopted a minimum target of 70% participation rate. The population of Umuarama/PR attend 24 health units (US) for prenatal care, and obstetric specialist care is delivered at

the medical support of the Maternal-infant Reference Center and Maternity Hall - Norospar.

The interviews were conducted at the US and the pregnant women who agreed to participate in the study signed the informed consent form. The USs are health care facilities that provide basic support and is the closest point of contact to most people's homes. Based on the risk stratification performed by the doctor and local nurse, the pregnant woman can

be referred to the Maternal-infant Reference Center and Maternity Hall – Norosparto see an obstetricians for specialized services.

In the basic health support of the US, the professionals prioritized by local management are doctors, nurses, dentists and community health agents. However, some units also have pharmacists for providing pharmaceutical care.

Figure No. 1
Municipality of Umuarama, Paraná, Brazil



Source: Wikipedia (2019)

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Research instrument

The data collection instrument was a questionnaire that collected socio-demographic data and information about general obstetric health. The questionnaire included questions regarding age, schooling, marital status, gestational week, risk rating, number of consultations, history of live births, miscarriages and/or stillbirths, as well as questions related to the use of medicinal products and medicinal plants. For the medicinal products and medicinal plants, participants reported their level of consumption, prior knowledge about contraindications, and preference for using medicinal plants and their derivatives over conventional therapy.

Statistical Analysis

The prevalence of use of medicinal products and medicinal plants was analyzed according to socio-

demographic characteristics and obstetric health status. The drugs were categorized according to the List II of Annex I of RDC No. 60 of December 17, 2010, and for medicinal plants, Resolution 1,757, 18 February 2002, Rio de Janeiro State was used as the reference.

The results obtained from the use of drugs and medicinal plants contraindicated in pregnancy were compared using Chi-squared test (χ^2) with Yates correction or Fisher's test and, when applicable, the *Odds Ratio* was calculated alongside 95% confidence interval using the IBM SPSS v 21.0 statistical software. In addition, in order to examine the association between categories, Multiple Correspondence Analysis (MCA) was performed using the Burt table, in which variables related to the number of pregnancies, abortion history, stillbirths and live births, gestational risk, use of medicines and medicinal plants, preference to use medicinal plants,

self-assessment of use, presence of contraindicated medicinal plants in pregnancy and use of FDA category "D" and "X" drugs were examined. The results were categorized into those with intense correlation (greater than 1.96 for $\alpha = 5\%$) or less intense correlation (greater than 1.60 for $\alpha = 10\%$).

Ethical Aspects

This project was approved by the Platform Brazil Committee on Ethics in Research Involving Humans under protocol CAAE no: 61132316.0.0000.0109 and also by the Department of Health of the municipality of Umuarama/PR.

RESULTS

In this study, 500 women aged 18-45 years were interviewed. The mean age was 26.84 ± 5.85 years. With the exception of units of New Jerusalem and Vila Nova Uniao, which did not have pregnant

women enrolled in this period, the interviews were carried out in the other 22 US. The US district of Vitória Régia had the highest number of pregnant women interviewed with 87 women being interviewed, while the US district of Roberto Silveira had the lowest number of interviews, with only one pregnant woman being enrolled.

The sample consisted predominantly of pregnant women with family incomes of up to two times the minimum wage (66.2%). Moreover, most had complete or incomplete secondary education (63.4%), were in a stable union (47.8%) or officially notarized (44.6%), interviewed in the 3rd quarter of pregnancy (46.2%), classified as being of normal gestational risk (46.6%), had held up to four pre-natal consultations (49.8%), had up to two pregnancies (71%), experienced live births in previous pregnancies (46%), 13.8 and 1.4 had abortions and stillbirths, respectively (Table No. 1).

Table No. 1
Characteristics of pregnant women interviewed in the municipality of Umuarama, Paraná, Brazil from January to May 2017

VARIABLES	N	%
Income		
Up to 2 minimum wages	331	66.2
Up to 4 minimum wages	152	30.4
More than 4 minimum wages	17	3.4
Educational Level		
Elementary school	92	18.4
High School	317	63.4
Higher Education	91	18.2
Marital Status		
Single	27	5.4
Common law marriage	239	47.8
Marriage	223	44.6
Divorced/separated	10	2
Widow	1	0.2
Gestational age		
1-12th week	76	15.2
13- 24th week	193	38.6
25- 40th week	231	46.2
Number of Consultations Pre-Natal		
Up to 4	249	49.8
5 to 7	138	27.6
More than 8 consultations	113	22.6
Risk classification		
Unknown	34	6.8
Usual	233	46.6
Intermediate	90	18.
High	143	28.6
Number of pregnancies		
Up to 2	355	71

From 3 to 4	127	25.4
More than 5	18	3.6
Presence of live births		
None	219	43.8
All of them	230	46
Partial	51	10.2
Presence of stillbirths		
None	493	98.6
All of them	2	0.4
Partial	5	1.0
Presence of Abortions		
None	431	86.2
All of them	22	4.4
Partial	47	9.4
TOTAL	500	100

Source: Elaborated by the author

With respect to the use of medicinal products and medicinal plants in pregnancy, the majority (78.4%) used only medication during pregnancy, and there was a single case of a pregnant woman who only used medicinal plants but was marked as an exception and excluded from the multivariate analysis. Moreover, 67.8% of pregnant women replied that they had not informed and/or have not been questioned by health professionals during the pre-natal period with respect to the use of medicinal

plants, although, the use of medicinal plants contraindicated in pregnancy was observed in 26.6% of the sample, and 26.2% were unaware that they were using drugs and medicinal plants contraindicated during the gestational period. In a self-assessment, 66.6% of pregnant women said they do not use medicinal plants and 68.8% had no preference to use phytotherapy over traditional medicines (Table No. 2).

Table No. 2
Characterization of pregnant women interviewed in health units of the municipality of Umuarama, Paraná, Brazil from January to May, 2017

VARIABLES	n	%
Use of products during pregnancy		
Yes, medications and medicinal plants	63	12.6
Yes, only medications	392	78.4
Yes, only medicinal plants	1	0.2
No, none of them.	44	8.8
Information and/or questioning of the health care professional regarding the use of the products		
No, none of them.	59	11.8
Yes, medications and medicinal plants	102	20.4
Yes, only medications	339	67.8
Presence of use of drugs of FDA Category "D" during pregnancy		
Yes	61	12.2
No	439	87.8
Presence of use of drugs of FDA Category "X" during pregnancy		
Yes	12	2.4
No	488	97.6
Presence of the use of medicinal plants contraindicated in pregnancy		

Yes	133	26.6
No	367	73.4
Presence of knowledge about the contra-indication of medicinal plants and medicines in pregnancy		
Yes	369	73.8
No	131	26.2
Preference to use medicinal plants and derived rather than the traditional medicines		
Yes	156	31.2
No	344	68.8
Self-evaluation of the use of medicinal plants		
Do not use	333	66.6
Rarely	49	9.8
Hardly ever	82	16.4
Regular	36	7.2
Reference in case of doubts of medicinal plants and medicines		
Family members and friends	104	20.8
Health Professionals	138	27.6
Health Institutes	142	28.4
Internet and others	116	23.2
TOTAL	500	100

Source: Elaborated by the author

Table No. 3

Analysis of the association between the use of contraindicated medicinal plants in pregnancy and previous knowledge of contraindications of pregnant women interviewed in the Health Units of the municipality of Umuarama, Paraná during the period from January to May, 2017

Value	Prior knowledge of contra-indications		Odds ratio	95% confidence interval	
	No	Yes			
Presence of medicinal plants contraindicated	No	111	2,450	1,449	4,142
	Yes	20			

Source: Elaborated by the author

The use of FDA category "D" and "X" drugs was observed in 12.2% and 2.4% of pregnant women, respectively, with a slight preference for seeking drug information from some type of health establishments (28,4%), followed by directly seeking information from health professionals (27,6%). Among the women interviewed, the average number of medications used during pregnancy was 4.1 and the average number of medicinal plants used was 0.5.

From the analysis, women without prior knowledge of contraindicated medicinal and herbal products in pregnancy had twice higher odds of using these products compared to those with prior knowledge, as shown (Table No. 3).

The MCA demonstrated an intense correlation between pregnant women of intermediate and high risk in relation to a history of the presence of abortions and/or partial births, the preference of alternative medicine to conventional medicine among those who regularly use medicinal plants and the use of "D" and "X" drugs with the use of medicinal plants contraindicated in pregnancy. Moreover, there was a less intense but present correlation among pregnant women with regular self-evaluation of medical plants with high risk classification, as well as high risk classification among those who were using medicinal plants and medications at the time of the interview.

Table No 4
Report of use of medicinal plants contraindicated use in pregnancy by pregnant women in Umuarama during the gestational period for the period January to May, 2017

Popular name	Scientific Name	Number
Camomila	<i>Chamomillarecutita</i> (L.) Rauschert	69
Erva-doce	<i>Foeniculumvulgare</i> L.	44
CapimCidreira	<i>Cymbopogoncitratus</i> (DC.) Stapf	18
Boldo da Terra	<i>Plectranthusbarbatus</i> Andrews	03
Poejo	<i>Cunilafasciculata</i> Benth.	03
Canela	<i>Cinnamomumverum</i> J. Presl	02
Alecrim	<i>Rosmarinusofficinalis</i> L.	01
Figatil	<i>Vernoniacondensata</i> Baker	01
Mastruz	<i>Chenopodiumambrosioides</i> L	01

Source: Elaborated by the author

With respect to medicinal plants, the botanical identification of species cited was not performed, and some species used were acquired in vacant lots. Camomila, and Erva-doce were consumed more commonly in markets, Cinnamon was used as an emmenagogue and Mastruz was used to improve immunity. Canela caused backaches and cramps and Mastruz was continued even after interruption request by the health team. The influence of cultural factors could be observed since the user reported that she learnt the use of the medicinal plant from the mother and she indicated that she did not to use gynecological or antibiotic ointments during pregnancy.

DISCUSSION

In this study, the average number of medicines consumed during pregnancy was 4.1 the same as that reported by Brum *et al.* (2011) and similar to the 4.6 and 4.2 reported by Araújo *et al.* (2013) and Lunardi-Maia *et al.* (2014), respectively. Costa *et al.* (2017) found that in the municipality of Santo Antônio de Jesus/BA which has a population and number of US similar to Umuarama/PR, among 924 pregnant women, the average number of medicines used was 2.41, being 1.7 lower than our results. This suggests medicalization during the nine months of pregnancy is common as a woman may use vitamin supplements, analgesics, anti-emetic, anti-infectives and other medications as a result of signs and symptoms caused by hormonal changes, nutritional and/or pathological findings.

In this study, 13.8% of women had experienced abortion in previous pregnancies compared to 20.5% and 14.2% reported by Araújo *et al.* (2013) and Lunardi-Maia *et al.* (2014),

respectively. Moreover, among the women in this study 26.2% of the interviewees were unaware of any risk due to medicinal products, which is higher than the 11.5% observed by Araújo *et al.* (2013). Thus, continuous health education is important to minimize unnecessary self-medication and ensure the safety of pregnant women.

The use of FDA category "X" medications was not observed in the studies by Araújo *et al.* (2013) and Guerra *et al.* (2008). However, in a study by Mengue *et al.* (2001), the prevalence of use of FDA category "X" medications were 0.6%. Moreover, 9.3%, 0.3%, and 3.0% of participants in the studies by Araújo *et al.* (2013), Guerra *et al.*, (2008), and Mengue *et al.*, (2001) were using FDA category "D" drugs, respectively. In this study, 12.2% and 2.4% of pregnant women were using FDA Category "D" and "X" drugs. When a drug is used during pregnancy, the benefits and risks to the mother and fetus should be assessed. The drug of choice should be the one that does not cause teratogenic effect or functional alteration (Brum *et al.*, 2011). The category "D" medications include antiepileptics. The use of phenytoin, carbamazepine, valproate, lamotrigine, and phenobarbital has been associated with an increased risk for the development of major malformations or morphological abnormalities (Hirama *et al.*, 2008). In the study by Guerra *et al.* (2008), of the four pregnant women who used medications included in risk category D, two had been suffering from epilepsy, one was using phenobarbital alone, and the other, together with carbamazepine, both prescribed throughout the pregnancy period. Women with epilepsy of childbearing age should receive information before conception towards minimizing the risk of

complications and maternal-fetal malformations (Hirama *et al.*, 2008).

The majority of category "X" medicines in Umuarama/PR were sex hormones. A positive association was observed between the use of sexual hormones and congenital anomalies in a study by Pizzol *et al.* (2008). Moreover, most unplanned pregnancies are caused by failure of contraceptive method probably due to incorrect use of oral contraceptives (Lunardi-Maia *et al.*, 2014). Thus, family planning is essential to avoid potential risks of an unplanned pregnancy, as well as ensuring the safety of the mother and the fetus. Regardless, this raises questions about the theme leads us to question the effectiveness of contraceptives, as well as the correct use of these drugs.

Regarding information for pregnant women, 19.5% of the interviewees by Melo *et al.* (2009) and 37.8% in Guerra *et al.* (2008) reported that they had not received guidance regarding the risks of certain medications during pregnancy. As indicated by Rodrigues *et al.* (2011), health professionals need to inform women about the risk of the use of medicinal plants and herbal medicines during pregnancy, and if the use of these are required, the duration of use should be the shortest possible time.

With respect to the use of alternative therapies, 31.0% of pregnant women in Brum *et al.* (2011) and 30.9% in Araújo *et al.* (2016) reported the use of medicinal plants, whereas in our study this was 26.6% resulting in an average of 0.5 medicinal plants being used by the pregnant women. In a study by Mengue *et al.* (2001), phytotherapies were used in 55 cases (0.6%), products composed of raw materials of vegetable origin associated with the substances isolated were used in 91 cases (1.0%) and homemade teas were used in 116 cases (1.2%). The main guideline for pregnant women is not to use any medication, be it of plant origin or not without the prior knowledge of their doctor, because of the possible embryo toxic, abortive and teratogenic effects (Rodrigues *et al.*, 2011).

In 2015, the municipality of Umuarama/PR received financial support from the Ministry of Health for inclusion of the project of phytotherapy in SUS according to a Decree no. 1.835 from November 13th 2015 (Diario Oficial, 2015), and in accordance with the national policy and program of medicinal and herbal medicines, expanding therapeutic options to users, ensuring access to medicinal plants, herbal medicines and services related to herbal medicine, with safety, efficacy and quality (Diario Oficial,

2006). The State of Rio de Janeiro also considers the role of phytotherapy within its health system and to better guide prescribers, it established the SES/RJ Resolution no. 1.757, dated from February 18th 2012 (Diario Oficial, 2012), which prohibits the use of medicinal plants reported to have abortive or emmenagogue effects in the scientific literature in the state of Rio de Janeiro.

Care protocols guarantee safety for both patients and health professionals, and it will be important for the municipality of Umuarama/PR to adopt such strategies as implemented in the state of Rio de Janeiro. According to Maeda & Secoli (2008), protocols and guidelines regarding the use of drugs are not sufficient to ensure a risk-free practice, and that systematic actions of guidance and education in health, such as mandatory strategies are necessary in the promotion and prevention of diseases. The need for pharmacists in the primary health care units in order to ensure the rational use of medicines during pregnancy have been emphasized, with consequent decrease in problems due to inappropriate use of medicines (Araújo *et al.*, 2013). In the municipality of Umuarama, the adequacy of local pharmaceutical assistance is necessary.

For the majority of medicinal plants, there are no data regarding the safety of their use during pregnancy or even if available, are usually scarce and often contradictory (Rodrigues *et al.*, 2011). Chamomile (*Matricaria arcutita* L.) has pharmacological, anti-inflammatory, and antispasmodic activities and reports of allergic reactions to Chamomile are common (Rangel & Bragança, 2009). The estrogenic activity of fennel (*Foeniculum vulgare* L.) has been proven by Malini *et al.* (1985) since the acetonic extract of the fruits caused an increase in the weight of the mammary glands and oviducts, endometrium, myometrium, cervix and vagina in rats. In this study, there was a medical request for interruption in the use of fennel tea following an increase in breast size after use of the product and this resolved after interruption in use. Moreover, there was report of allergy in the lower limb after use of chamomile tea with fennel. Medicinal plants contra-indicated in pregnancy and that are part of the project of insertion of phytotherapy in the municipality of Umuarama/PR include *carqueja*, mint, horsetail and chaguinha (Gorriil *et al.*, 2016).

CONCLUSIONS

This work reiterates the need to expand health

promotion activities in basic units, implement protocols, technical guidelines as well as improve availability of pharmaceutical professionals to enhance education among the population. About 30% of the pregnant women used medicinal plants during the gestational period with some contraindication and that, during antenatal consultations, no indication or information on the subject was obtained. Based on the information in this paper, we will undertake community projects, such as information leaflets and request the passage of municipal law, as done in the

State of Rio de Janeiro, to strengthen the incentive and safe use of medicinal and phytotherapeutic plants and to ensure compliance with the guidelines of the National Policy.

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