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RESEARCH

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Uso seguro de anticoncepcionais hormonais injetáveis segundo critérios médicos de elegibilidade

Safe use of injectable hormonal contraceptives according to medical eligibility criteria

El uso seguro de anticonceptivos inyectables hormonales segundo criterio de elegibilidad médica

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ABSTRACT

Objective: To classify users of injectable hormonal contraceptives (AHI) in accordance with the safe use according to medical eligibility criteria of the World Health Organization (WHO) and assess the association between type of injection and use of time with safe use. **Methods:** Cross-sectional, descriptive and exploratory study. The population was composed by 52 users of AHI. Data were collected through interviews, which followed form developed by the authors, and identified factors that contraindicate or indicate the use of the method, classifying them into categories from 1 to 4. The project was approved by the Ethics Committee of the University Federal do Ceará, CAAE: 36668314.3.0000.5054. **Results:** Were identified 44 (84.7%) women in safe use and 8 (15.3%) in unsafe use. Users with over a year of use had a higher frequency of unsafe use (p=0.001). **Conclusion:** Following WHO recommendations should be routine in nursing consultation to the protection and safety of women.

Descriptors: Contraceptive agents; Evaluation; Medical eligibility criteria.

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RESUMO

Objetivo: Classificar usuárias de anticoncepcionais hormonais injetáveis (AHI) quanto ao uso seguro segundo critérios médicos de elegibilidade da Organização Mundial da Saúde (OMS) e verificar associação entre tipo de injetável e tempo de uso com o uso seguro. **Métodos:** Estudo transversal, descritivo e exploratório. A população foi composta pelas 52 usuárias de AHI. Os dados foram coletados por meio de entrevista, que seguiu formulário elaborado pelas autoras, sendo identificado fatores que contraindicassem ou indicassem o uso do método, classificando-as em categorias de 1 a 4. O Projeto foi aprovado pelo Comitê de Ética em Pesquisa da Universidade Federal do Ceará, CAAE: 36668314.3.0000.5054. **Resultados:** Foram identificadas 44 (84,7%) mulheres em uso seguro e 8 (15,3%) inseguro. Usuárias há mais de um ano tiveram uma frequência maior de uso inseguro (p=0,001). **Conclusão:** Seguir as recomendações da OMS deve ser rotina nas consultas de enfermagem visando à proteção e segurança da mulher.

Descritores: Anticoncepcionais; Avaliação; Critérios Médicos de Elegibilidade.

RESUMEN

Objetivo: Clasificar las usuarias de anticonceptivos hormonales inyectables (AHI) segundo criterio de elegibilidad médica de la Organización Mundial de la Salud (OMS) y evaluar la asociación entre el tipo de inyección y el uso del tiempo con uso seguro. **Métodos:** Estudio transversal, descriptivo y exploratorio. La población fue compuesta por 52 usuarias de AHI. Los datos fueron colectados a través de entrevistas desarrollada por las autoras, e identificó los factores que contraindican o indiquen el uso del método, clasificándolos en categorías 1 a 4. El proyecto fue aprobado por el Comité de Ética de Investigación de la Universidad Federal do Ceará, CAAE: 36668314.3.0000.5054. **Resultados:** Se identificaron 44 (84,7%) mujeres en el uso seguro y 8 (15,3%) no seguro. Las usuarias más de un año habían una mayor frecuencia de uso inseguro (p=0,001). **Conclusión:** El uso de las recomendaciones de la OMS debe ser rutinario en la consulta de enfermería.

Descriptores: Anticonceptivos, Evaluación, Criterios médicos de elegibilidad.

INTRODUCTION

Injectable Hormonal Contraceptives (AHI) are the most effective methods among reversible contraceptives, with a high number of users in Brazil and in other countries of the world.

A study carried out in Brazil, with 343 women, found that the participants used a variety of contraceptive methods, with hormonal prevalence (105 - 30.6%), with AHI being used by 8.2% of women.[1]

AHI are the most used methods in regions such as Ethiopia, where their use rose from 3.0% in 2000 to 21.0% in 2011, being used by 14.0% of women of childbearing age residing in that country; And Sub-Saharan Africa, with 9 million users, making up 43.0% of total contraceptive use.[2]

In Brazil, AHI offered by the Unified Health System (SUS) is found in two presentations, being the monthly (combined) and the quarterly (exclusive of progestogen). The monthly HIAs contain an ester of a natural estrogen, estradiol, and a synthetic progestogen. The trimesters have 150 mg Medroxyprogesterone Acetate Deposit (AMP-D).[3] The use of AMP-D is highlighted in situations where there is contraindication of the estrogen hormone, such as in the presence of cardiovascular diseases, smoking associated with age above 35 years, exclusive breastfeeding and obesity.[4]

Despite the benefits offered by AHI to their users, these methods can cause some side effects and complications such as menstrual changes (irregular menstrual cycle, increased or decreased flow, and even amenorrhea), mastalgia, headache, dizziness, nausea, increase Weight loss, fluid retention, acne, thromboembolic complications, myocardial infarction, arterial hypertension, and stroke. The development of these events depends mainly on the type of hormone used, its dosage and the presence of associated diseases.[5]

It is essential that the health professional is able to perform the clinical follow-up of the user, guiding the selection and correct use of AHI, its side effects and complications.

In order to assist the health professional in the management of contraceptive methods (indication of the method or not), the World Health Organization (WHO) Eligibility Criteria for Use of Contraceptive Methods (CME) is available.[6]

The CMEs endorsed by WHO are defined as the set of characteristics presented by the candidate to use a particular method, which indicates whether or not it can use it. They are arranged in four categories: Category 1 - the method can be used without restrictions; Category 2 - the method can be used with restrictions, which are situations in which the advantages of using it usually outweigh the proven or theoretical risks that its use could entail, that is, the method is not the first choice and, if used, More careful monitoring is necessary; Category 3 - the proven and theoretical risks arising from the use of the method generally outweigh the benefits - when there is Category 3 condition for a method, it should be the last choice and, if chosen, it is necessary to follow the user strictly ; Category 4 - the method should not be used as it poses an unacceptable risk.[6]

The correct and consistent use of AHI depends on factors related to the woman, the method and the health professional. The application of CMEs will favor an adequate clinical practice by the health professional, which will consequently result in greater safety for the user. The safe use of a contraceptive method implies a lesser exposure of the user to the risks of complications.[6]

Considering the importance of the CMEs as a support for the health professional to carry out the evaluation of the candidate for the use of AHI, the following research questions were elaborated: In which WHO category, AHI users accompanied in a family planning service would be classified? Is there an association between type of AHI and time of use with WHO categories attributed to users, according to the CME?

The objective of the study was to classify AHI users for WHO categories and to verify the association between

the type of injectable and the time of use with the WHO categories attributed to the users.

METHOD

This is a cross-sectional, descriptive and exploratory research, carried out in a unit belonging to the Hospital Complex of the Federal University of Ceará (UFC), located in the outskirts of the Municipality of Fortaleza, Ceará. The unit is used as a field of practice for students of several courses in the health area, to highlight the Nursing Undergraduate Course.

At the site, Nursing students offer family planning services, with Nursing consultations and health education activities. These activities are carried out under the supervision of professors and students of the postgraduate course in Nursing of the UFC (Masters and Doctorate).

The research population consisted of 52 AHI users followed in the referred service, constituting the sample of the research where all participated. The data were collected through an interview, following a structured form, which was elaborated by the authors. The form was composed of open and closed questions, addressing the socioeconomic data, type of AHI in use and time of use; and a screening system developed on the basis of the WHO CME, allowing to register the clinical conditions of the participants. After the clinical analysis of AHI users, women were classified in the categories proposed by the WHO: category 1, the method is indicated in any circumstances; Category 2, the method can generally be used; Category 3, the method is generally not recommended unless other more appropriate methods are not available or are not acceptable; Category 4, the method should not be used. The WHO also proposes for the circumstances in which there are limited resources for clinical judgment to join categories 1 and 2, using the indicated method, and junctions of categories 3 and 4 being the use of contraindicated method. In these terms, the results related to this theme were discussed according to this parameter of joining the categories, considering the characteristics of the service searched.

The interviews were conducted in a private setting, previously selected for this purpose. They had an average duration of 20 minutes and occurred between the months of November/2014 and April/2015.

The data were organized in Excel for Windows and analyzed in the Statistical Package for Social Science (SPSS), version 20.0, license number: 10101131007. A descriptive statistical analysis of the results was carried out and Fisher's Exact Test was applied to verify the associations between type of AHI and time of use with WHO categories attributed to AHI users, where significance was set at a value of $p < 0.05$.

The Research Project was approved by the Research Ethics Committee of the Federal University of Ceará, according to CAAE protocol: 36668314.3.0000.5054, opinion no. 851,453.

RESULTS

Participants ranged in age from 16 to 41 years, with a predominance of 20 to 34 years old, corresponding to 32 (61.5%) of the total interviewees. The other 20 (38.4%) women were at the reproductive ends.

In relation to schooling, 34 (65.3%) had 10 to 12 years of schooling, demonstrating that these women had at least high school education. Just over half of the women had a fixed partner, corresponding to 27 (52%).

There was a predominance of participants who declared themselves to be at home, that is, 36 (69.3%), followed by 16 (30.7%) who stated that they had paid work and/or were studying.

Of the 52 participants, 35 (67.3%) were users of Combined Injectable Contraceptive (ICA) and 17 (32.7%) of Exclusive Progestogen Injectable Contraceptive (AIEP). In Table 1, AHI were presented by type and according to the time of use.

Table 1 - Distribution of the number of users of injectable hormonal contraceptives according to time of use. Fortaleza/CE, November 2014 - April 2015

Type of hormonal	Usage time (month)									
	1-12		13-24		25-36		37-48		120 -156	
	n	%	N	%	n	%	n	%	n	%
*AIC (n=35)	19	54.2	9	25.7	2	5.8	3	8.5	2	5.8
**AIEP (n=17)	13	76.4	3	17.7	---	---	---	---	1	5.9

Subtitle: *AIC - Combined injectable contraceptive; **AIEP - Progestin-only injectable contraceptive

A total of 33 (63.4%) AHI users were identified, accompanied by the family planning service, in Category 1, that is, the method can be used without restrictions; 11 (21.1%) women were evaluated in Category 2, which indicates, in general, the use of the method; 3 (5.8%) women were classified in Category 3, ie the method is not recommended, unless other more appropriate methods are not available or are not acceptable; and 5 (9.7%) users were classified in Category 4, that is, the method should not be used because it presents an unacceptable risk.

Among the three AHI users classified as Category 3, 1 (1.9%) users of AIC were classified as reporting migraine without aura and being younger than 35 years as CME. The 2 (3.8%) AIEP users who were also in Category 3, one was due to migraine with aura and the other due to having diastolic blood pressure equal to 100 mmHg.

The five AHI users classified in Category 4 reported with migraine CME with focal neurological signs and aura, which contraindicates the use of the method at any age.

The association between the AHI and the time of use with the categories of the CME attributed to the users is found in Table 2.

Table 2 - Association between type of AHI and time of use with categories of CME/WHO attributed to the users. Fortaleza, CE, Brazil, November 2014 – abril 2015

Variables (n=52)	Categories 1 e 2		Categories 3 e 4		Valor de p
	N	%	n	%	
****Type of AHI**					*1.000
***AIC	29	82.9	6	17.1	
****AIEP	15	88.2	2	11.8	
Time of use					*0.011
Up to 1 year	37	92.5	3	7.5	
More than 1 year	7	58.3	5	41.7	

Legend: * Fisher's Exact Test; ** Injectable hormonal contraceptive (HIA); *** Combined injectable contraceptive (AIC); **** Progestin-only injectable contraceptive (AIEP).

DISCUSSION

The AHI use time ranged from 1 to 156 months. The majority of users focused on the use time of up to 24 months, corresponding to 28 (79.9%) of ICA users and 16 (94.1%) of ICU users, that is, the majority of users Of AHI continued the use of the method until that period, when, from then on, the percentage of users reduced sharply, with 8 (18.6%) using the method a considerable length of time (more than 24 months). Therefore, it can be observed that with the increase of the time of AHI use, the percentage of users tends to decrease.

The aforementioned finding is corroborated in the analysis of 60 Demographic and Health Surveys (DHS) that occurred in the years 1990 to 2009. This review concluded that the probability of interrupting the use of AHI at 12 months was 41.0 %. In 24 months it was 65%; and in 36 months it was 74%. The reasons for discontinuation were related to the type of AHI, side effects and health problems.[7] Thus, the increase in AHI use time seems to influence the interruption of the method.

Another aspect observed is that the percentage of AIEP users was higher than the percentage of AIC users in the first year, a relation that is reversed in the second year, when the percentage of AIC users is higher than the AIEP users. Research conducted in Nigeria found that there is a high rate of continuation of AIEP and that many users were using the method for 12 months.[8]

In Honduras, authors found that women who had used a MAC for less than 12 months or discontinued use compared to women who had used a method for more than one year were significantly more likely to change and stop the method used.[9]

The emergence of side effects, especially those related to changes in the menstrual flow, is the main reason for the discontinuation of the use of AHI, of the type Acetate of medroxyprogesterone deposition (AMP-D) and *Cyclofem®*.[10] Therefore, adequate guidance to the HIA user about side effects and their management is essential in order to avoid discontinuation of the method.

Several factors interfere in the continuation and, consequently, in the time of contraceptive use, such as side effects, difficulty of access, lack of knowledge on how to deal with the method, among others. In the service researched, access to the method is facilitated by the application of the injection in the Nursing consultation itself, where also the ample information is valued to the client, both in the sense of understanding the use and operation of the injectable and in the sense of dealing with the side effects. Thus, it is important to investigate the reasons that are leading the group to discontinue the use of AIEP in the second year.

Despite the presentation of the four categories of WHO, with their respective indications for contraceptive use, including AHI, the WHO itself recommends for the regions and/or services with limited clinical follow-up, the junction of category 1 and 2, defining Such as "Yes, use method"; and category 3 to 4, setting it to "No, do not use method".[6]

Therefore, among the AHI users surveyed, 44 (84.7%) were classified in categories 1 or 2, in which AHI can be used. This reflects the adequate Nursing follow-up offered in the family planning service of the service researched, where the Nursing consultation covers the physical examination of the users, the interview based on the CME, listening for the most common complaints and guidelines for users to exercise co-responsibility By the safe use of the AHI.

On the other hand, 8 (15.3%) users were classified in categories 3 or 4, which contraindicated the use of AHI.

Observing the CMEs identified in those users (a case of migraine without aura with age less than 35 years, one case of diastolic blood pressure equal to 100 mmHg and six cases of migraine with focal neurological signs with aura), it was verified that they could preexisting to the use of AHI, but could also have been developed in the course of its use, an aspect that does not legitimize the finding of the poor quality of the service. However, these results reinforce the importance of careful assessment of these users in the first time (to start the method) and in the return visits, always based on CME.

A study conducted in Fortaleza-CE with women with diabetes mellitus found very similar results, when 92 (88.4%) participants used MAC in WHO Category 1 or 2 and 12 (11.6%) used MAC in Categories 3 or 4.[11]

In a study conducted with 264 women, also in Fortaleza-CE, addressing the safe use of combined low-dose oral contraceptives based on CME, 91 (35.0%) users were identified in Categories 3 or 4, a much higher percentage of than the one found in the present research and research cited above. The CMEs responsible for these results were: smoking (less than 15 cigarettes per day) associated with age> 35 years (4), blood pressure (systolic 140-159, diastolic 90-99 mmHg), cardiovascular disease, personal history of thrombosis Deep vein thrombosis (DVT) and complicated valvular heart disease (11), headache with migraine and age <35 years (47),

liver disease (2), migraine headache and age> 35 years (14), headache with aura 12) and past breast cancer (1) woman.[12]

A study conducted in the United Kingdom found that with the use of WHO-endorsed WHO, there was a decrease in combined hormonal contraceptive prescriptions for women who were in Categories 3 and 4 for MAC use, however, the method was still prescribed for women who possessed Risk of developing cardiovascular disease.[13] Often, the small range of contraceptive methods in health services justifies this reality, as well as the client's resistance to changing methods.

Nurses and/or nursing students under supervision should remain vigilant during Family Planning Nursing consultations, as a clinical reevaluation of the IHI user is required, as well as the guidelines that should be sought with the users to encourage safe use Of the AHI.

Being in Categories 1 and 2 or WHO Categories 3 and 4 as an AHI user had no association with type of AHI and duration of use of the injectable (values of p = 1,000 and 0.011, respectively). However, the percentage of AHI users in Categories 1 and 2 was predominant in the first year of use, while the percentage of users in Categories 3 and 4 was predominantly pronounced in the second year of use.

The main contribution of this study is the demonstration of the relevance of the use of CME in Nursing consultations in family planning.

It is important to emphasize, as a limitation of the study, the reduced size of the sample, which was due to the fact that it represents the group served in a service only.

CONCLUSION

Among the AHI users surveyed, 44 (84.7%) were classified in categories 1 or 2, from WHO; And 8 (15.3%) users were classified in categories 3 or 4. Being in Categories 1 and 2 or WHO Categories 3 and 4 as an AHI user had no association with type of AHI and duration of use of the injectable (Values of p> 0.05). However, as the percentage of AHI users in Categories 1 and 2 was predominant in the first year of use, while the percentage of users in Categories 3 and 4 was predominantly accentuated in the second year of use, it is important to maintain vigilance to the health of the user as the time of use of the AHI increases.

Thus, nurses and Nursing students under supervision, who carry out family planning Nursing consultations, should maintain the use of CME in the approach of AHI users, in order to promote the safe use of the method.

It is suggested to carry out new researches that contemplate the evaluation of users of other hormonal methods and the classification according to the CME.

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