ORIGINAL ARTICLE

Intra-hospital pharmacovigilance. Knowledge and practices

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ABSTRACT

Introduction: pharmacovigilance is the discipline that deals with the collection, follow-up, investigation, assessment and evaluation of information from health professionals and patients on adverse drug reactions; incomplete knowledge of this discipline is currently one of the greatest weaknesses of modern therapeutics.
Objective: to evaluate knowledge and practices of Pharmacovigilance in medical personnel working at the "Enrique Cabrera" Hospital in Havana about the most commonly used drugs in patients with cardiovascular diseases and the most frequent comorbidities.
Methods: a cross-sectional descriptive study was carried out, the universe consisted of 410 physicians and the sample consisted of 80 of them chosen at random. Data were collected through the application of an anonymous questionnaire.
Results: Specialists represented 81.25% and physicians without teaching category 70%. There was a predominance of respondents with inadequate knowledge about the concept of Pharmacovigilance (70%) and its importance (55%); there was an adequate level of knowledge about the drugs that are appropriately prescribed according to the most frequent diseases and there was an inadequate identification of the drugs causing rhythm disorders (70%).
Conclusion: a large percentage of the staff has a deficient knowledge of pharmacovigilance due to lack of knowledge of its generalities, but not in relation to adverse drug reactions. There is a deficiency in the knowledge of the drugs most used in daily medical practice and which cause rhythm disorders. Intervention measures are required to reverse this situation.
Key words: pharmacovigilance; adverse drug reactions; health knowledge, attitudes, practice

RESUMEN

Introducción: la Farmacovigilancia es la disciplina que trata la recolección, el seguimiento, la investigación, la valoración y la evaluación de la información procedente de los profesionales de la salud y de los pacientes sobre reacciones adversas a medicamentos; el conocimiento incompleto sobre esta disciplina es actualmente una de las mayores debilidades de la terapéutica moderna.

Objetivo: evaluar conocimientos y prácticas de Farmacovigilancia en el personal médico que labora en el Hospital "Enrique Cabrera" de La Habana acerca de los medicamentos más utilizados en pacientes con afecciones cardiovasculares y en las comorbilidades más frecuentes.
Métodos: se realizó un estudio descriptivo de corte transversal, el universo estuvo constituido por 410 médicos y la muestra por 80 de ellos elegidos al azar. Los datos fueron recogidos mediante la aplicación de un cuestionario anónimo.
Resultados: los Especialistas representaron el 81,25% y los médicos sin categoría docente el 70%. Hubo predominio de encuestados con conocimientos inadecuados acerca del concepto de Farmacovigilancia (70%) y de su importancia (55%); se observó un nivel de conocimiento adecuado sobre los fármacos que resultan prescripción adecuada acorde con las enfermedades más frecuentes y hubo una identificación inadecuada de los fármacos causantes de trastornos del ritmo (70%).
Conclusiones: un gran por ciento del personal tiene un conocimiento deficiente sobre Farmacovigilancia por desconocimiento de sus generalidades, no así en relación a las reacciones adversas de los medicamentos. Existe deficiencia en el conocimiento de los fármacos más utilizados en la práctica médica diaria y que son causantes del trastorno del ritmo. Se requieren medidas de intervención para revertir esta situación.
Palabras clave: farmacovigilancia; reacciones adversas a medicamentos; conocimientos, actitudes y práctica en salud

INTRODUCTION

While all the advantages offered by drugs are well known, it should also be known that their undesirable effects are as old as medicine itself. There is growing evidence that adverse drug reactions (ADRs) are a frequent, but often preventable, cause of illness, disability and even death.[1]
The World Health Organization (WHO) in 2002 defined an ADR as "any adverse drug reaction (ADR) as "any adverse reaction to a drug that is not a serious adverse effect.
The World Health Organization (WHO) in 2002 defined an ADR as "any unintended harmful reaction occurring at doses normally used in humans for prophylaxis, diagnosis or treatment or for modification of a physiological function"[2] and states that ADRs are one of the top 10 causes of death worldwide.[3]
In 1937, the first serious warning about the risks of drugs occurred due to the death of 107 people in the United States (mostly children) caused by a sulfonamide elixir. The Food and Drug Administration (FDA) was created, the first drug regulatory agency to appear in the world with laws that made it mandatory to supervise the safety of drugs before they were marketed. However, it was not until 1968, following the epidemic of phocomelia in newborns caused by thalidomide in Europe, that the WHO, in the framework of the International Drug Monitoring Program, proposed the creation of a Center for International Pharmacovigilance, currently established in Uppsala, Sweden.[4]
Since then, Pharmacovigilance has emerged as the discipline that deals with the collection, follow-up, investigation, assessment and evaluation of information from health professionals and patients on adverse reactions to drugs, biological products, medicinal plants and traditional medicines with the aim of identifying new adverse reactions to drugs and preventing harm to patients.[5]

Cuba is linked to the International Pharmacovigilance Program through the National Pharmacovigilance System (SCFv, Sistema Nacional de Farmacovigilancia), which emerged in 1999, as a key element for the effectiveness of pharmaceutical regulatory systems, clinical practice and public health programs.[3]

Hospital pharmacovigilance has great utility and high value because it can lead to actions with an impact on patient safety and help prevent risks associated with drugs; for its implementation, the importance of its knowledge and application should be promoted and disseminated among health personnel in order to achieve its ultimate goal, which is to achieve the rational and safe use of drugs.

In clinical practice, there are several factors that can hinder the detection of ADRs and, as a consequence, contribute to their underreporting, but one of the most important is the lack of knowledge about pharmacovigilance actions. Different studies have shown that 41% of patients treated with drugs and up to 46% of hospitalized patients present some ADR.[6]

Incomplete knowledge of the frequency and severity of adverse drug effects is currently one of the major weaknesses of modern therapeutics. To ensure that actions for the identification, evaluation and prevention of drug-related risks are effective, knowledge, training and dissemination of the system are necessary, and healthcare professionals must play an active role in these actions.[7]

No drug is completely harmless; any substance that is capable of producing a therapeutic effect is also capable of producing an ADR even if it has been administered correctly. Drugs used in cardiovascular conditions and in the main diseases that accompany them do not escape from this; an example is the percentage of patients (23.7%) admitted to the Coronary Care Unit of the "Enrique Cabrera" Hospital with rhythm disorders of pharmacological etiology in addition to other adverse reactions observed in consultations secondary to drugs commonly used in the daily practice of Cardiology Specialists and correlated specialties. This research was carried out with the objective of evaluating knowledge and practices of Pharmacovigilance in the medical staff working at the "Enrique Cabrera" Hospital about the most commonly used drugs in patients with cardiovascular conditions and in the most frequent comorbidities

METHODS

Design and population

A descriptive cross-sectional study was carried out. The universe was constituted by 410 physicians belonging to the "Enrique Cabrera" General Teaching Hospital of Havana who were working between April 2021 and April 2022. The sample consisted of 80 physicians chosen at random. Physicians who did not agree to participate were excluded from the study.

Study variables

The following variables were studied: academic level, teaching category, knowledge of general Pharmacovigilance and adverse drug reaction (ADR), which was evaluated in the case of Pharmacovigilance based on its concept

and importance and, in the case of ADR, its concept, the notification model and how to report ADR.
To evaluate medical practice, the variables used were knowledge of prescribing in chronic diseases (bronchial asthma, gout, chronic kidney disease, arterial hypertension and ischemic heart disease) and the identification of drugs causing rhythm disorders.
The following were considered correct knowledge:
Concept of Pharmacovigilance: chose that it is a discipline in charge of assessing safety in the field of drugs.
Importance of Pharmacovigilance: pointed out that it allows the timely detection of an adverse drug reaction.
Concept of ADR: he identified that they occur in therapeutic doses regardless of the time of exposure.
AMR reporting model: he was familiar with it.
AMR report: identified the authorized personnel for its notification and receipt.
The following were considered good practices:
Adequate knowledge of the medical prescription: pointed out safe medication in correspondence with the disease: persistent bronchial asthma, sodium cromoglycate; gout, allopurinol; chronic kidney disease with glomerular filtration rate less than 30ml/min, furosemide; arterial hypertension, methyldopa and ischemic heart disease: clopidogrel.
Drugs that produce rhythm disorders: checked the option All of the above including the drugs: carbamazepine, ciprofloxacin, timolol, digoxin, azithromycin and atenolol.
The definition of appropriate prescription was taken from the action protocols of the different services of the Hospital and from the National Formulary of Medications.[9]

Procedures/data collection and handling

Data were collected through the application of an anonymous questionnaire designed to explore knowledge and practices on pharmacovigilance. The structure of the questionnaire and its content, dimensions and logistics of data collection were shaped. Item composition, number and arrangement were organized. The questionnaire represents several dimensions due to the complexity of the phenomenon. It is structured in two blocks, the first one of general data of the subjects and the second one of the questions that give output to the explored variables. A short and simple questionnaire was chosen as the best way to characterize the knowledge and practices of pharmacovigilance, with easy application and comfortable possibilities of response by the subject. The structure and formulation of the questions in the questionnaire were subjected to a process of content validation by expert criteria, which was used to evaluate the correspondence of the items in relation to the operational definition and the proposed categories and to evaluate the questionnaire according to the five basic properties formulated by Moriyama. The response of the experts and their evaluation of the aforementioned properties was recorded on an ordinal scale that included: adequate and inadequate. The selection of the expert judges was made taking into consideration their professional and research experience and was carried out by a group of seven experts. The characterization of the expert judges

was: physicians and pharmacoepidemiologists with more than five years of experience in the subject and linked to the pharmacoepidemiology network.

Statistical analysis

SPSS version 20.0 for Windows was used to perform the statistical analysis.
for Windows was used to perform the statistical analysis. Descriptive statistics, frequency distribution and percent of the variables used were used. The Chi-squared test or Fisher's exact test were used to test the association between the categorical variables. The level of statistical significance used was $p<0.05$ with a 95% confidence interval. The results were expressed in hundreds in the form of tables and graphs.

Ethical considerations

Informed consent was requested in writing from each respondent and approval was obtained from the Medical Ethics Committee and the Scientific Council of the institution. The research was conducted in accordance with the principles and recommendations for physicians in biomedical research on human subjects adopted in the Declaration of Helsinki.

RESULTS

In the population studied, taking into account the academic level, there was a predominance of specialist physicians (81.25%); and as for the teaching category, physicians without teaching category predominated (70%).
Table 1 shows a predominance of respondents with inadequate knowledge about the concept of Pharmacovigilance (70%) and its importance (55%) and of physicians with correct knowledge about the spontaneous reporting model (90%), the concept of ADR (85%) and how to report ADR (80%).

Table 1. Distribution of the population according to knowledge of Pharmacovigilance and adverse drug reaction (ADR)

Knowledge	Appropriate		Inappropriate	
	No.	%	No.	%
Concept of Pharmacovigilance	24	30.0	56	70.0
Importance of Pharmacovigilance	36	45.0	44	55.0
Concept of AMR	68	85.0	12	15.0
Spontaneous reporting model	72	90.0	8	10.0
How to report AMR	64	80.0	16	20.0

Regarding the knowledge of the drugs that result in an appropriate prescription according to the most frequent diseases, there was a predominance of an appropriate level of knowledge in all (more than 80%), with no significant differences among them (p=0.389).
Table 2 shows a predominance of an inadequate identification of the drugs causing rhythm disorders (70%); the highest percentage of appropriate responses corresponds to Specialists (27.5%) and physicians with teaching category (18.75%).

Table 2. Distribution of the study population according to the identification of drugs causing rhythm disorders in relation to academic level and teaching category

Academic level and teaching category		Identification of drugs that cause rhythm disorders				Total	
		Appropriate		Inappropriate			
		No.	%	No.	%	No.	%
Physician	Resident	2	2.5	13	16.3	15	18.8
	Specialist	22	27.5	43	53.8	65	81.3
Total		**24**	30.0	**56**	**70.0**	**80**	**100.0**
Teaching category	Yes	15	18.8	9	11.3	24	30.0
	No	9	11.3	47	58.8	56	70.0
Total		**24**	30.0	**56**	**70.0**	**80**	**100.0**

n=80

The predominance of inappropriate identification of drugs causing rhythm disorders is shown in Table 3. Carbamazepine (81.25%), ciprofloxacin (75%), azithromycin (72.5%) and timolol (52.5%) reached the highest percentages; those adequately identified were atenolol (81.25%) and digoxin (65%). Only 30% of the respondents adequately identified all the drugs.

Table 3. Distribution of the study population according to the identification of drugs causing rhythm disorders

Drugs	Identification of drugs that cause rhythm disorders			
	Appropriate		Inappropriate	
	No.	%	No.	%
Carbamazepine	15	18.8	65	81.3
Ciprofloxacin	20	25.0	60	75.0
Timolol	38	47.5	42	52.5
Digoxin	52	65.0	28	35.0
Azithromycin	22	27.5	58	72.5
Atenolol	65	81.3	15	18.8
All of the above	24	30.0	56	70.0

DISCUSSION

Despite its 40 years of history, pharmacovigilance is an essential scientific and clinical discipline for dealing with the problems posed by a drug arsenal that is growing in variety and potency because every drug has an inevitable and sometimes unpredictable potential for harm, thus guaranteeing the safe use of drugs.

In this study, an inadequate level of knowledge about the generalities of Pharmacovigilance was observed, data that coincides with those of a study[9] in which a deficient knowledge was found in more than 50% of resident physicians and 43% in general practitioners and in which it was noted that a great part of the lack of this knowledge was about where to go for the adverse reaction report and the lack of knowledge of the formats to do it in 69.6%, which differs from the results of the previous study, 6%, which differs from what was found in the present investigation because the great majority of the respondents had an adequate command of these aspects.

The observed results may be related to the preparation in Pharmacovigilance of the medical personnel during their training; the teaching program dedicated

to the subject should be evaluated, according to the experience in undergraduate and postgraduate teaching, which would contribute to improve the performance of the medical personnel in the rational use of drugs and as part of the corresponding responsibility, in favor of the quality and safety of the patient's health at the time of drug administration.

It is worth highlighting the adequate level of knowledge about the drugs that result in an adequate prescription according to the most frequent chronic diseases without significant differences between them (p=0.389).

The authors' attention is drawn to the deficient level of knowledge that exists (in more than 50% of the population studied) about drugs that cause rhythm disorders in spite of being one of the most frequent conditions in the environment, which coincides with the result of another research related to drugs that affect the cardiovascular system[10] in which 58.9% of the respondents answered inadequately.

The highest percentage of adequate answers corresponded to Specialists and physicians with teaching category despite having a low level of respondents with this last condition, a result expected by the authors. This result does not coincide with that of a study on Pharmacovigilance knowledge and practices in Stomatology personnel, which showed no difference in terms of correct answers regarding knowledge in those who did not have any teaching category.[11]

CONCLUSIONS

Pharmacovigilance has an immediate and high value utility, even with its simple methods, which can lead to actions with an impact on patient safety; a large percentage of the personnel have a deficient knowledge of Pharmacovigilance due to a lack of knowledge of its generalities, but not in relation to adverse drug reactions. It is concluded that there is a deficiency in the knowledge of the drugs most used in daily medical practice and which cause rhythm disorders. Strategies should be thought of to improve this situation and thus help prevent risks associated with the use of drugs.

BIBLIOGRAPHIC REFERENCES

1. Mata Maldonado J, Ortiz Reynoso M, Islas Flores H, Díaz Flores M, De León Camacho V, Tenorio Vieyra LE. Impacto de una intervención educativa en los conocimientos en farmacovigilancia y en el reporte de reacciones adversas a los medicamentos de profesionales de la salud en un hospital público de segundo nivel de atención en el Estado de México, México. Rev Mex Cienc Farm [Internet]. 2017 [cited 16/02/2021];48(4):78-89. Available at: https://www.redalyc.org/pdf/579/57956617009.pdf
2. Organización Mundial de la Salud. Promoción del uso racional de medicamentos: componentes centrales [Internet]. Ginebra: OMS; 2002 [cited 16/02/2021]. Available at: https://apps.who.int/iris/bitstream/handle/10665/67532/WHO_EDM_2002.3_spa.pdf
3. Tarragó Portelles SS, Gravier Hernández R, Gil del Valle L. La Farmacovigilancia en Cuba y la Infranotificaciones de Reacciones Adversas a los Medicamentos. Horiz Sanitario [Internet]. 2019 [cited 16/02/2021];18(1):7-15. Available at:

https://www.scielo.org.mx/scielo.php?script=sci_arttext&pid=S2007-74592019000100007. https://doi.org/10.19136/hs.a18n1.2514
4. Rodríguez Betancourt L, García Vigil JL, Giral Barnés C, Hernández Santillán D, Jasso Gutiérrez L. Farmacovigilancia I. El inicio. Rev Med IMSS [Internet]. 2004 [cited 16/02/2021];42(4):327-329. Available at: https://www.medigraphic.com/pdfs/imss/im-2004/im044h.pdf
5. Furones Mourelle J, Péperz Peña J. Necesidad de la Farmacoepidemiología. En: Furones Mourelle J, Bastanzuri Lara C, Calvo Barbado DM, Jimenez López G, Péperz Peña J, Cruz Barrios DA. Farmacoepidemiología. Uso racional de medicamentos. La Habana: Editorial Academia; 2010. p. 1-14.
6. Rodríguez Duque R, Gómez Leyva B, Rodríguez Moldón Y, Díaz Armas MT. Las reacciones adversas como causa de hospitalización. CCM [Internet]. 2019 [cited 16/02/2021];23(1):168-188. Available at: https://revcocmed.sld.cu/index.php/cocmed/article/view/2913/1366
7. Alfonso Orta I, Hevia Pumariega R, Jiménez López G, Ramón Fabregas L, Hernández Mullings AO, Barbán Lores D, et al. Curso Básico de Farmacovigilancia orientado a la industria, desde el ámbito regulador. La Habana: Cecmed; 2017 [cited 16/02/2021]. Available at: https://www.cecmed.cu/file/2608/download?token=VM7_rhLK
8. Centro para el desarrollo de la farmacoepidemiología. Formulario Nacional de Medicamentos. 4ta ed. La Habana: ECIMED; 2014 [cited 16/02/2021]. Available at: http://www.ecimed.sld.cu/2014/10/08/1943/
9. Castillo Torres ML. Conocimiento de farmacovigilancia y reporte de reacciones adversas institucional [thesis]. Poza Rica, Veracruz: Universidad Veracruzana; 2014 [cited 16/02/2021]. Available at: https://www.uv.mx/blogs/favem2014/files/2014/06/Tesis-Monse.pdf
10. Suazo Jarquín CA, Sobalvarro Coronado AC, Guevara Altamirano CA. Conocimientos acerca del uso racional de fármacos de interés odontológico por estudiantes de 4to año, de la Facultad de Odontología UNAN-LEÓN, primer semestre, 2017 [thesis]. León: Universidad Nacional Autónoma de Nicaragua [cited 16/02/2021]. Available at: https://repositoriosiidca.csuca.org/Record/RepoUNANL6908
11. Ruiz Hernández A, Cruz Barrios MA, Furones Mourelle JA, Palenzuela Rodríguez I. Conocimientos sobre farmacovigilancia del personal de estomatología en municipios seleccionados. Medimay [Internet]. 2015 [cited 16/02/2021];21(3):575-584. Available at: https://revcmhabana.sld.cu/index.php/rcmh/article/view/863/1287

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

AUTHORS' CONTRIBUTION

YCR: conceptualization, analysis of collected data, research, methodology, project supervision and management, writing the original draft, writing (reviewing and editing).
TPR: conceptualization, analysis of collected data, research, methodology, writing the original draft, writing (reviewing and editing).
AJGM: conceptualization, methodology, formal analysis, writing the original draft, writing (reviewing and editing).

LGCS, AMCV: conceptualization, visualization, writing the original draft, writing (review and editing).
GMG: formal analysis, drafting (review and editing).