ABSTRACT

Background: Headache, or cephalalgia, is one of the 20 most disabling diseases in the world and affects a large portion of the world's population. People generally use over-the-counter medications to treat headaches and other minor symptoms. A pharmacist should help patients choose the most effective, safe, and convenient pharmacotherapeutic option.

Objective: To assess the counselling skills of community pharmacists for headache management by using the simulated patient approach.

Methods: A cross-sectional study was conducted from March 2010 to July 2010. Data were obtained from a convenience sample consisting of one pharmacist from each of the 24 participating community pharmacies. In order to evaluate the pharmacists' counselling skills, a simulated patient role played a standardized headache case requesting self-medication. The interactions of the simulated patient with the pharmacists were audiovisually recorded using a hidden micro camera, and these recordings were analysed using a validated questionnaire.

Results: Of the 24 evaluated pharmacists, 19 (79.1%) were women. Information was spontaneously provided by 15 (62.5%) pharmacists. At least one question was asked by the pharmacist to assess the signs and symptoms. Most pharmacists (n=17, 70.8%) recommended sodium dipyrone, either alone or in combination with other drugs. The most discussed items in the simulation visits were contraindications (n=17, 70.8%), indications (n=10, 41.6%), and drug administration times (n=8, 33.3%). None of the pharmacists recommended any non-pharmacological therapeutic alternatives. The overall impressions of the pharmacists' professional counselling skills ranged from poor to fair.

Conclusion: This study showed that the pharmacists' counselling skills and the guidance provided by the pharmacists to the simulated patient were insufficient for the satisfactory management of headache.

Keywords: Headache; Community Pharmacy Services; Professional Practice; Pharmacists; Patient Simulation; Brazil

EVALUACIÓN DE LAS HABILIDADES DE ASESORAMIENTO DE LOS FARMACÉUTICOS COMUNITARIOS SOBRE EL MANEJO DEL DOLOR DE CABEZA UTILIZANDO UN ABORDAJE DE PACIENTE SIMULADO: ESTUDIO PILOTO

RESUMEN

Antecedentes: El dolor de cabeza o cefalea es una de las 20 enfermedades más incapacitantes en el mundo y afecta a una gran parte de la población mundial. La gente utiliza generalmente medicamentos OTC para tratar los dolores de cabeza y otros síntomas menores. Un farmacéutico debería ayudar a los pacientes a elegir la opción farmacoterapéutica más efectiva, segura y conveniente.

Objetivo: Evaluar las habilidades de los farmacéuticos comunitarios para el manejo del dolor de cabeza utilizando un abordaje de paciente simulado.

Métodos: Se realizó un estudio transversal entre marzo 2010 y julio 2010. Se obtuvieron datos de una muestra de conveniencia consistente en un farmacéutico de cada 24 farmacias comunitarias participantes. Para evaluar las habilidades de asesoramiento de los farmacéuticos, un paciente simulado recreó un caso estandarizado de dolor de cabeza solicitando auto-medicación. Las interacciones del paciente simulado con el farmacéutico fueron audiovisualmente grabadas utilizando una micro-cámara oculta, y estas grabaciones fueron analizadas utilizando un cuestionario validado.

Resultados: De los 24 farmacéuticos evaluados, 19 (79,1%) eran mujeres. 15 farmacéuticos (62,5%) proporcionaron información espontáneamente. El...
INTRODUCTION

Headache, or cephalalgia, is one of the 20 most disabling diseases in the world; it poses challenges to health professionals and leads to huge economic losses. In the United States, migraine is responsible for an estimated loss of USD20 billion annually. The tension-type headache, a primary headache, is characterized by constrictive headache pain that is usually bilateral; this type of headache is of mild to moderate severity. This type of headache is also known as common headache, stress headache, psychogenic headache, or idiopathic headache. Tension-type headache can be further divided into 2 subtypes: episodic tension-type headache (which affects around 80% of the population) and chronic tension-type headache. The chronic subtype causes severe impairment of quality of life and a high level of disability, and in the majority of cases, patients opt for self-medication with over-the-counter (OTC) drugs.

OTC drugs provided by community pharmacies can satisfactorily treat minor symptoms, such as headaches, but pharmacists must be careful when recommending OTC drugs since even these drugs can cause health hazards if not properly used. Therefore, help from a pharmacist is required when choosing a pharmacotherapeutic option so that the selected medication is the most effective, safe, and convenient. Further, the pharmacist is responsible for identifying minor signs and symptoms and should refer the patient to another team member when situations that may harm the patient’s health are identified.

According to the World Health Organisation (WHO, 1988), it is the pharmacist’s duty to detect the predominant minor symptoms affecting the population and to develop strategies for self-medication and responsible self-care practices. The pharmacy professional must be duly qualified to undertake the management of headache and provide support to the patient. However, the lack of knowledge and the inability to provide appropriate counselling is an important barrier hindering the effective management of headache.

During the last decade, some teaching-learning methodologies have been developed to evaluate and improve the knowledge, communication skills, and attitudes of pharmacists. One such method is the simulated patient approach. This approach involves training a patient-individual who impersonates a character and simulates specific circumstances. The aim of this pilot study was to evaluate the counselling skills of community pharmacists in terms of headache management by using the simulated patient approach.

METHODS

An exploratory cross-sectional study in the State of Sergipe was conducted from March 2010 to July 2010. The Federal University of Sergipe’s Human Research Ethics Committee approved this study.

Study Sample

The state of Sergipe has four pharmacy chains. The Laboratory of Teaching and Research in Social Pharmacy (LEPFS) in Sergipe, Brazil was selected, for convenience, all the pharmacies from the two largest pharmacy chains.

The sample consisted of 24 pharmacists (1 in each selected pharmacy). The participating pharmacies were informed about the methodology and the aim of the pilot study. All pharmacists were eligible and were included consecutively.

Before the study, all pharmacists were informed that a simulated patient would visit their pharmacy and ask for the pharmacists’ advice on a case of self-medication. They were also informed about the goals of the study and the confidentiality of the collected data. However, no details were provided regarding the study design, drugs involved, or timing of the study. Further, the pharmacists and pharmacy staff were unaware of the simulated patient’s identity. Pharmacists who could compromise the anonymity of the simulated patient were excluded from the study.

Simulated Patient and Scenario

A simulated patient who played the role of a patient with a headache visited the pharmacy and obtained an audiovisual recording of the pharmacist’s counselling. To meet the educational needs of the simulated patient, specific training through a theoretical/practical workshop and instructions on how to act during the simulations were provided. In addition, several situations were simulated to standardize the role-playing of everyday situations.

Along with the training, the simulated patient received a manual containing details on how simulations should be performed, the clinical case to be simulated, and instructions for using the micro camera to record the simulations.

The simulated case was that of a female patient aged 20 years with a history of insomnia and poor sleep. She complained of recurrent headaches daily for the past 3 months, characterized by mild to moderate pain that was usually bilateral; this type of headache is of mild to moderate severity. This type of headache is also known as common headache, stress headache, psychogenic headache, or idiopathic headache. The tension-type headache can be further divided into 2 subtypes: episodic tension-type headache (which affects around 80% of the population) and chronic tension-type headache. The chronic subtype causes severe impairment of quality of life and a high level of disability, and in the majority of cases, patients opt for self-medication with over-the-counter (OTC) drugs.

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diet. The simulated patient complained that she experienced headaches about twice weekly, for which she consumed acetaminophen. However, the patient felt the need for a more-effective treatment and therefore visited the pharmacy.

In the standard script, the simulated patient had a passive role, only answering questions when asked and not providing information spontaneously.

**Documentation of the Counselling Process and Data Analysis**

During each visit, the simulated patient audiovisually recorded her interaction with the pharmacist by using a hidden micro camera. The recorded interactions were then analysed by 3 investigators according to the instrument proposed by Berger et al. (2005) and translated into Portuguese and validated by Mesquita et al. (2010). The questionnaire contains questions related to the information provided by the pharmacist, self-diagnosis, the medicine selection process, directions for use of the drug, non-pharmacological recommendations by the pharmacist, and so on.

The data were descriptively analysed using Statistical Package for the Social Sciences® (SPSS) v. 17 for Windows.

**RESULTS**

One pharmacy was excluded from the study because both the pharmacists at the pharmacy knew the simulated patient personally; that could have jeopardized her anonymity. Of the 24 evaluated pharmacists, 19 (79.1%) were women. In the simulation, 15 (62.5%) pharmacists spontaneously provided information, whereas 9 (37.5%) enquired about who required the medication.

The most common question asked during simulation visits was on the type of signs/symptoms shown by the patient (asked by 12 [50%] of the pharmacists). The second-most-common question (n=11, 45.8%) concerned the type of medication previously used. In 20 (83.3%) of simulation visits, the pharmacist asked about the presence of specific conditions that could affect diagnosis or recommended treatment. Two (8.3%) pharmacists asked the simulated patient whether she was currently taking any other medications. Questions regarding the presence of allergies were more common (n=17, 70.8%).

In this study, the most commonly recommended drug for headache was sodium dipyrone (or sodium dipyrone in combination with other medications; n=17, 70.8% of visits), and a prescription drug was recommended by 2 pharmacists. Only 2 pharmacists suggested that the patient consult a doctor to identify the cause of the headache. In 13 (54.16%) simulation visits, the patient was involved in the medication-selection process.

The most-discussed items were ‘contraindications’ (n=17, 70.8%), ‘indications’ (n=10, 41.6%), and ‘drug administration times’ (n=8, 33.3%). None of the pharmacists advised the patient on possible drug interactions, adverse drug reactions, what should be done if the patient forgets to take the medicine, or how to store the drug. Moreover, none of the pharmacists asked the patient whether she needed additional information, and no non-pharmacological alternatives were recommended for treating headache (Table 1).

The overall impression of the pharmacists’ professional counselling skills was evaluated using a 5-point Likert scale (1=very poor, 2=poor, 3=fair, 4=good, and 5=excellent), and the average value for pharmacists was 2.29 (SD=1.04), which is between poor and fair.

**DISCUSSION**

Self-medication using OTC drugs is the most prevalent form of care worldwide. Self-medication is a widespread practice for treatment of headache, and the majority of individuals with headache undertake it without the supervision of a health-care professional. However, self-medication is a serious problem, because it may mask or worsen diseases in addition to increasing costs for the health-care system. According to the literature, pharmacists are responsible for providing information to help patients choose the most suitable, effective, safe, and convenient medicine.

Most pharmacists in our study provided information spontaneously, and 50% of the pharmacists enquired about the patient’s signs and symptoms. Considering the report by Smiley (2005) and the fact that the cause of headache is not clear in a few cases, a thorough assessment to identify the cause of headache is required. Thus, to choose an appropriate therapeutic agent, the pharmacist should seek information concerning the patient’s history and pain characteristics (starting time, duration, location, and magnitude of the pain) in addition to information on conditions that increase or mitigate pain and other associated symptoms.

In Brazil, medicines are classified as prescription or non-prescription. Pharmacists can only suggest non-prescription medicines; furthermore, the sale of medicines that require a prescription without the presentation of the medical prescription would constitute a violation of the law. However, two
pharmacists in the present study indicated prescription drugs.\textsuperscript{18}

Regarding the medication indicated, the first-line pharmacotherapeutic options for headache are analgesics (e.g., non-steroidal anti-inflammatory drugs (NSAIDs): acetaminophen, naproxen, ibuprofen, and dipyrone). Sodium dipyrone was the most recommended medication in this study. However, it is not recommended by some research and is banned in countries such as the United States and the United Kingdom because of its alleged bone-marrow depression effects (i.e. aplastic anaemia and agranulocytosis).\textsuperscript{19} However, according to the International Agranulocytosis and Aplastic Anaemia Study (Boston Study; 1986), the use of sodium dipyrone is not directly associated with these conditions.\textsuperscript{20} Accordingly, the National Agency of Sanitary Surveillance (ANVISA) considers dipyrone as a safe and effective medicine and imposes no restrictions on the sale of sodium dipyrone as an OTC drug in Brazil.\textsuperscript{19}

During the simulation visits, no non-pharmacological therapeutic alternatives were recommended. The literature recommends changes to habits in order to improve patients’ health.\textsuperscript{8} Non-pharmacological treatments for headache include patient education regarding the health problem and lifestyle changes that help prevent pain, such as improving sleep, regular meals, physical exercise, and avoidance of stress.\textsuperscript{8,21}

The results showed that the information provided during the simulation visits was incomplete; this may be related to the graduation of pharmacists in Brazil. Brazil’s National Guidelines for Undergraduate Education in Pharmacy (2002) include formal training in counselling and communication skills as an integral part of the pharmacy curriculum. However, most Faculty of Pharmacy courses in Brazil have yet to implement communication skills in their curricula.\textsuperscript{22} This fact is corroborated by data showing that across the country, despite the fact that 70\% of services provided by pharmacists are related to dispensation, the material in the Faculty of Pharmacy course concerns mostly industry, food, and laboratory analysis. Of the 64 disciplines offered by the pharmacy course, only 6 are part of the core in Social Pharmacy. The lack of a school of pharmacy in 20\% of the educational institutions surveyed is one of the factors that hinder academic professionalism, since this environment is of paramount importance in the development of techniques related to counselling skills.\textsuperscript{23}

In this sense, effective methods of continuing education and training of pharmacists can enhance pharmacists’ skills in counselling patients, making an important public-health contribution through potential improvements in health outcomes. Several studies have demonstrated the effects of continuing education (as training programs and workshops that improve counselling skills).\textsuperscript{24,25} Furthermore, the pharmacy literature provides evidence that simulated patient methods, when used as an educational tool, provide immediate information on performance and corrective feedback and can equip pharmacists with effective counselling skills.

In addition, the provision of written materials for pharmacists—such as guidelines—with information on the disease, treatment, therapeutic alternatives, and expected results could facilitate patient counselling. Finally, as a means of patient empowerment, patient counselling and selection of medication should be made in collaboration with the patient, so that the patient bears joint responsibility for the chosen treatment and for his/her well-being.\textsuperscript{16}

The present study has some limitations. The study was conducted on pharmacies in only one state in Brazil; therefore, it is not generalizable. Furthermore, only one clinical condition was simulated; this precludes the evaluation of the pharmacists’ counselling skills regarding other minor symptoms encountered at pharmacies.

CONCLUSIONS

Our results show that the counselling skills of the evaluated pharmacists and the guidance provided were insufficient for the satisfactory management of headache. Further studies are needed to understand the main reasons for these shortcomings and to propose measures to improve the skills of pharmacists at community pharmacies.

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CONFLICT OF INTEREST

The authors of this manuscript do not have any kind of conflicts of interest.

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