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

*Ana Patricia SANTOS. Laboratory of Teaching and Research in Social Pharmacy (LEPFS), Faculty of Pharmacy, Federal University of Sergipe. São Cristóvão (Brazil).

Alessandra R. MESQUITA. Laboratory of Teaching and Research in Social Pharmacy (LEPFS), Faculty of Pharmacy, Federal University of Sergipe. São Cristóvão (Brazil).

Karolline Sales OLIVEIRA. Laboratory of Teaching and Research in Social Pharmacy (LEPFS), Faculty of Pharmacy, Federal University of Sergipe. São Cristóvão (Brazil).

Divaldo P. LYRA Jr. Adjunct Professor. Laboratory of Teaching and Research in Social Pharmacy (LEPFS), Faculty of Pharmacy, Federal University of Sergipe. São Cristóvão (Brazil).
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 head 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
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

---

**Table 1. Frequencies of pharmacotherapeutic recommendations provided by pharmacists during interactions with the simulated patient (Aracaju-SE, 2010).**

| Items                        | n   | %   |
|------------------------------|-----|-----|
| Indication                   | 10  | 41.6% |
| Pharmaceutical forms         | 3   | 12.5% |
| Dosage                       | 0   | 0%   |
| Methods for drug administration | 1  | 4.1% |
| Drug administration times    | 8   | 33.3% |
| Contraindications            | 17  | 70.8% |
| Drug interactions            | 0   | 0%   |
| Adverse drug reactions       | 0   | 0%   |
| Adherence to treatment       | 0   | 0%   |
| What must be done if the patient forgets to take the medicine | 0 | 0% |
| Safe storage of medicine     | 0   | 0%   |
| Therapeutic alternatives     | 0   | 0%   |
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.

ACKNOWLEDGMENTS
The authors are grateful to Dr. Luciana F. R. P. Lyra for her contribution in training the simulated patient.

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

This study was supported by grants from the Brazilian National Council for Technological and Scientific Development (CNPq; National Council for Technological and Scientific Development).
Santos AP, Mesquita AR, Oliveira KS, Lyra DP Jr. Assessment of community pharmacists’ counselling skills on headache management by using the simulated patient approach: a pilot study. Pharmacy Practice 2013 Jan-Mar;11(1):3-7.

5. Alonzo HGA, Cristiana L, Corrêa CL, Zambrone FAD. [Analgesics, antipyretics and non-steroidal anti-inflammatory drugs: epidemiological data on six intoxication control centers in Brazil.] Rev Bras Toxicol. 2001;14:49-54.

6. WHO. The role of the pharmacist in self-care and self-medication. The Hague: Report of a WHO Consultive. 26-28 August 1998.

7. Porteous T, Ryan M, Bond CM, Hannaford P. Preferences for self-care or professional advice for minor illness: a discrete choice experiment. Br J Gen Pract. 2006;56(533):911-7.

8. Smiley T. The role of the pharmacist in identification, referral, and management of migraine headache. CE Compliance Centre National Continuing Education Program 2005.

9. Berger K, Eickhoff C, Schultz M. Counselling quality in community pharmacies: implementation of the pseudo customer methodology in Germany. J Clin Pharm Ther. 2005;30(1):45-57.

10. Benrimoj SI, Werner JB, Raffaele C, Roberts AS, Costa FA. Monitoring quality standards in the provision of non-prescription medicines from Australian Community Pharmacies: results of a national programme. Qual Saf Health Care. 2007;16(5):354-8.

11. McDonough P, Bennett MS. Improving communication skills of pharmacy students through effective precepting. Am J Pharm Educ. 2006;70(3):58.

12. Boal A. [Theatre of the oppressed and others poetics policies.] 8th ed. Rio de Janeiro: Civilização Brasileira, 2008.

13. Boal A. [Games for actors and non-actors.] 12th ed. Rio de Janeiro: Civilização Brasileira, 2008.

14. Mesquita AR, Santos EA, Porto JG, Barros IM, Lyra Jr DP. Translation in Brazilian Portuguese and content validation of the questionnaire “Avaliação do Processo de Atendimento Farmacêutico”. Acta Farmacêutica Bonaerense 2012;31:1422-9.

15. Wertheimer AI, Serradell J. A discussion paper on self-care and its implications for pharmacists. Pharm World Sci. 2008;30(4):309-15. doi: 10.1007/s11096-007-9187-y

16. Yusef AM, Al-Bakri AG, Bustanji Y, Wazaify M. Self-medication patterns in Amman, Jordan. Pharm World Sci. 2008;30(1):24-30.

17. Sanvito WL, Monzillo PH. [Primary headaches: clinical and therapeutic aspects.] Medicina, Ribeirão Preto. 1997;30:437-48.

18. Brazil. Law nº 6.437, of August 20, 1977. [Sets violations of federal health legislation, establishes the respective sanctions, and other arrangements]. Brasília, DF, 24 Aug. 1977.

19. Knappmann AL, Melo EB. [Quality of over the counter drugs: a study of dipyrone brands marketed in a drugstore on Cascavel (PR, Brazil).] Cienc Saude Coletiva. 2010;15(3):3467-3476. doi: 10.1590/S1413-81232010000900021

20. Toklu HZ, Dülger GA, Hidiroglu S, Akici A, Yetim A, Gannemoglu HM, Güns H. Knowledge and attitudes of the pharmacists, prescribers and patients towards generic drug use in Istanbul – Turkey. Pharm Pract. 2012;10(4):199-206.

21. National Council of Education. [National guidance for the undergraduate teaching of Pharmacy], Brazil 2002. Oficial Gazette: Brasília. 2002;1:9.

22. Fernandes ZC, Bermond MD, de Oliveira Filho NCF, Camargo EES, Cecy C. [The challenges of pharmaceutical education in Brazil]. Brasília: Federal Council of Pharmacy, 2008.

23. Aslani P, Benrimoj SI, Krass I. Development and evaluation of a training program to foster the use of written drug information in community pharmacies: part 1—development. Pharm Educ . 2006;6(1):41-52.

24. de Almeida Neto AC, Benrimoj SI, Kavanagh DJ, Boakes RA. Novel educational training program for community pharmacists. Am J Pharm Educ. 2000;64:302-7.