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การบริการทางเภสัชกรรมในผู้ป่วยโรคไมเกรนที่มีความรุนแรงระดับมากของร้านยา

Pharmaceutical Services on Severe Migraine Headache in Community Pharmacies

องอาจ มณีใหม่[1]*, กนกวรรณ สมจิตร์[1], ณัชญากาญจน์ พานิชพิบูลย์[1], ธีรวัฒน์ จันทร์ไชย[1], วันทนีย์ วังวล[1]
Ong-art Maneemai[1]*, Kanokwan Somjit[1], Natchayakarn Panichpiboon[1], Teerawat Junchai[1], Wantanee Wungwol[1]

บทคัดย่อ

การกำเริบของโรคไมเกรนที่มีความรุนแรงระดับมากต้องได้รับการรักษาที่จำเพาะ การศึกษาเกี่ยวกับการบริการทางเภสัชกรรมในผู้ป่วยโรคไมเกรนของประเทศไทยมีอยู่อย่างจำกัด การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาการให้บริการทางเภสัชกรรมในผู้ป่วยโรคไมเกรนที่มีระดับความรุนแรงระดับมากในร้านยา การศึกษานี้เป็นการวิจัยเชิงพรรณา เก็บข้อมูลโดยใช้ผู้ป่วยจำลองโรคไมเกรนที่มีระดับความรุนแรงระดับมากในร้านยา จำนวน 57 ร้านในพื้นที่จังหวัดพะเยา ผลการศึกษา พบว่าผู้ป่วยจำลองได้รับบริการจากผู้ให้บริการที่เป็นเภสัชกรจำนวน 33 ร้าน (57.89%) และไม่ใช่เภสัชกร จำนวน 24 ร้าน (42.11%) ยาที่ถูกจ่ายมากที่สุดคือ ยาบรรเทาอาการปวด (n = 30, 52.63%) เช่น ยาต้านการอักเสบที่ไม่ใช่สเตียรอยด์ (n = 14, 24.56%), Ergotamine (n = 8, 14.04%) และ Paracetamol (n = 8, 14.04%) โดยพบการจ่ายยาร่วมกันระหว่างยาบรรเทาอาการปวดและยากลุ่มอื่นๆ จำนวน 13 ร้าน (22.81%) ยาบรรเทาอาการคลื่นไส้อาเจียนที่จ่ายมากที่สุดคือ Domperidone (n = 8, 14.04%) ร้านยาจ่ายยาป้องกันการกำเริบซ้ำ (n = 6, 10.53%) เช่น Flunarizine (n = 3, 5.26%), Cinnarizine (n = 2, 3.51%) และ Amitriptyline (n = 1, 1.75%) โดยสรุปพบว่า ร้านยาส่วนมากมีการซักประวัติและการจ่ายยาสำหรับผู้ป่วยโรคไมเกรนมีระดับความรุนแรงระดับมากไม่เหมาะสม ฉะนั้นหน่วยงานที่เกี่ยวข้องจะต้องจัดให้มีการส่งเสริมความรู้และทักษะในการจัดการผู้ป่วยไมเกรนในร้านยาเพิ่มเติม

คำสำคัญ: ไมเกรน, เภสัชกรรม, ร้านยา

* Corresponding author: E-mail: ongart.ma@up.ac.th, 0622387888
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[1] คณะเภสัชศาสตร์ มหาวิทยาลัยพะเยา 56000
[1] School of Pharmaceutical Sciences, University of Phayao, 56000, Thailand

Abstract

Severe migraine attacks often required treatment with specific drugs. The study of pharmaceutical services on the patients with migraine headache has still been limited in Thailand. This study aimed to investigate the pharmaceutical services offered for a severe migraine patient in the community pharmacies. The study was descriptive research and collected data by using a simulated patient with a severe migraine headache. The fifty-seven community pharmacies, in Phayao province, Thailand, were assessed for the pharmaceutical services. The results demonstrated that the simulated patients received the services from 33 pharmacist-pharmacies (57.89%) and 24 non-pharmacist pharmacies (42.11%). The most frequent dispensed medication was the single drug of pain relievers (n = 30, 52.63%). Non-steroidal anti-inflammatory drug (n = 14, 24.56%), ergotamine (n = 8, 14.04%), and paracetamol (n = 8, 14.04%) were top three most dispensed pain relievers, respectively. Combination therapy between analgesics and other medications was found in 13 pharmacies (22.81%). Domperidone was used as an antinausea drug (n = 8, 14.04%). Prophylactic drugs (n = 6, 10.53%) were flunarizine (n = 35.26%), cinnarizine (n = 2, 3.51%), and amitriptyline (n=1, 1.75%). In conclusion, most pharmacy personnel performed inappropriate practice on taking the necessary information from the patient and drug dispensing for severe migraine. Educational interventions should be developed and trained to improve knowledge and practice in the migraine management.

Keywords: Migraine, Pharmacy, Community pharmacy

Introduction

Pharmacists are one of the important parts of the healthcare system. Their primary role is providing drug and medications and other services in patient care. Thus, their knowledge and skills are vital in achieving the patient's outcomes. In Thailand, the community pharmacies were allowed to diagnose illnesses, dispense medications, and give recommendations to the patients. However, the prior studies showed that community pharmacies provided the inappropriate pharmaceutical services such as patient's history taking, medication counselling, and medication label writing [1–3].

Evidence in this area suggests that migraine is not well manage in community pharmacies across the world. Health care providers performed misdiagnose, and many patients who are correctly diagnosis receive sub-optimal treatment[2, 4, 5]. Furthermore, patients with migraine about 67% avoided and delayed the use of antimigraine drugs due to various reasons[6]. On the contrary, some patients overuse such drug, leading to the transformation of migraine to medication-overuse headache[7].

The study of pharmaceutical services on the patients with migraine headache was limited in Thailand. The previous study was conducted in mild and moderate migraine patients among pharmacy personnel in southern of Thailand. The results showed that most pharmacists and non-pharmacists had inadequate knowledge and inappropriate practice regarding management of mild and moderate migraine[2]. Severe migraine attacks often required treatment with specific drugs. However, a significant number of patients with migraine headache may not receive appropriate medications[8].

Lack of knowledge and the inability to provide appropriate pharmaceutical care is an important barrier hindering the effective management of severe migraine headache. The simulated patient approach has been developed to evaluate the community pharmacists' competency. This approach involves training a patient – individual who impersonates a character and simulates specific circumstance[9, 10]. This study applied simulated patient approach to investigate the pharmaceutical services to a severe migraine patient in community pharmacies, focusing on taking patient's history and dispensed medications.

Methods

Design and population

This descriptive study was conducted in Phayao province, located in northern Thailand. The study population was 62 community pharmacy units. Taro Yamane's formula was used for sample size calculation. The minimum sample size was 54. The minimum number of needed samples was added to ensure that the study has an adequate sample size. In the fieldwork, data was collected from 57 community pharmacies. List of all community pharmacies obtained from the provincial public health office of Phayao.

Data collection

The data was collected by two female simulated patients (the fifth-year pharmacy students, 21-year-old). Couples collected data in every community pharmacy. The first simulated patient played role as a migraine patient that had a terrible headache and asked for the treatment at a drugstore. The other one observed and memorized the details of interaction during their conversation. The simulated patients memorized the provider behaviors and relevant information during the encounter. After leaving the drugstore, all information including questions, necessary information, dispensing medication, and advice provided by the pharmacy personnel were filled in the data collection form. All visits took place between 1 to 8 pm because many pharmacists worked in the pharmacies part time, so that they were most likely to be on duty during that time frame and simulated patients visit the providers when there were no or only a few customers in the pharmacy. During the encounters, they could interact with the providers as long as needed.

The data collection form was developed using relevant information from literature

reviews. The instrument was then reviewed and assessed by 4 experts; two were clinical instructors in the department of pharmacy practice and experience in teaching and practicing in community pharmacies and two were community pharmacists. Thirty items of question asking, each answered "Do" = 1 or "Don't" = 0. The appropriate dispensing was defined as a triptan (without NSAIDs, ergotamine, and prophylactic medication). Drug dispensing practice was reported as frequencies.

Simulated patients

The scenario was used to evaluate performances of health-care providers on taking necessary information from the patient, and dispensing appropriate medication. The simulated patients visited the community pharmacies to buy analgesic drugs. The additional information was given if asked: the simulated patients would say that she had had throbbing head pain for 8 hours (pain score 8/10). In addition, her unilateral headache had persisted after took 400 mg ibuprofen 2 tablets and other symptoms were nausea and vomiting. Moreover, the symptom disrupts her daily life and did not seem to be better. Furthermore, a headache occurred about quarterly: she had no eyes pain, no fever, no cough, and no runny nose; as well as no pregnant. Besides, she had no underlying disease and her family members did not have underlying disease as migraine as well. Finally, she had no history of drug and food allergy and did not drink alcohol and smoke. Including, she had not had a prejudicial head.

Statistical analysis

Data analysis was performed in statical program. Patient's necessary information practice and medication dispensed for the simulated patient with severe migraine were expressed in frequency and percentage. The differences of question asking between pharmacist and non-pharmacist community pharmacies by using Wilcoxon rank sum test and sets a level of statistical significance to 0.05 ($p = 0.05$).

Ethical consideration

The research protocol and ethical issue were obtained and approved by the Human Research Ethics Committees, University of Phayao (Ref. No. 2/003/58) The permission and invitation letters with full research proposal were sent to each community pharmacy. Before the initial data collection, the eligible pharmacies were asked to sign an informed consent. The simulated patients randomly visited the community pharmacies for gathering the service assessment after one month of the informed consent was perform.

Results

Taking the necessary information from the patient

The assessment of pharmaceutical services of 57 community pharmacies showed that the simulated patient received the services from 33 pharmacist-pharmacies (57.89%) and 24 non-pharmacist pharmacies (42.11%). Table 1 showed the results of taking the necessary patient's information. For the questions that the pharmacists statistically

significant asked the patient more than the others were patient's identification (p = 0.030), inquiring for headache differential diagnosis (p = 0.005), patient's underlying diseases (p = 0.020), prior medications used for headache (p = 0.050), drug allergy history (p <0.001), and making a summary of patient's disease and symptoms to the patient (p <0.001).

Table 1 Patient's necessary information that were asked and taken in the pharmacies: n (%)

	Overall (n =57)	Pharmacists (n = 33)	Non-Pharmacists (n = 24)
Accuracy of patient's identification	32 (56.14)	23 (69.70)*	9 (37.50)
Patient's age	1 (1.75)	1 (3.03)	0 (0.00)
Chief complaint	55 (96.49)	33 (100.00)	22 (91.67)
Inquiring for different diagnosis	38 (66.67)	27 (81.82)*	11 (45.83)
Alarm signs and symptoms for referring	3 (5.26)	3 (9.09)	0 (0.00)
Duration of headache attack	17 (29.82)	16 (48.48)**	1 (4.17)
Severity of headache	6 (10.52)	5 (15.15)	1 (4.17)
Patient's underlying diseases	10 (17.54)	9 (27.27)*	1 (4.17)
Prior medications used for headache	18 (31.57)	14 (42.42)*	4 (16.67)
Drug allergy history	31 (54.39)	26 (78.79)**	5 (20.83)
Pregnancy and breastfeeding history	1 (1.75)	1 (3.03)	0 (0.00)
Factors associated with headache	6 (10.52)	5 (15.15)	1 (4.17)
Making a summary for patient	31 (54.39)	25 (75.76)**	6 (25.00)

Note: *p-value <0.05, **p-value <0.001

Medication dispensed for patient's headache

Table 2 showed the medications were dispensed to the simulated patient with severe migraine headache. The most frequently dispensed was monotherapy of pain relievers (n = 30, 52.63%). Pain relievers frequently dispensed by both pharmacists and non-pharmacists were non-steroidal anti-inflammatory drug (NSIADs) (n = 14, 24.56%), ergotamine (n = 8, 14.04%) and paracetamol (n = 8, 14.04%). The dispensed NSAIDs were ibuprofen (n = 18, 54.55%), mefenamic acid (n = 9, 27.27%), naproxen (n = 3, 9.09%) and diclofenac (n = 3, 3.03%). Double therapies of analgesics were dispensed (n = 11, 19.30%). Ergotamine and NSAIDs combination (n = 8; 14.04%) were frequently offered for the patient. Triple therapy of analgesics was found in two pharmacies.

Combination therapy between analgesics and other medications was found in 13 pharmacies: 8 (14.04%) with antinausea drugs, and 5 (8.77%) with migraine prophylactic medications. Antinausea drug dispensed to the simulated patient were domperidone

(n = 8, 100.00%). The pharmacy personnel dispensed flunarizine (n = 3, 50.00%), cinnarizine (n = 2, 33.33%) and amitriptyline (n = 1, 16.67%) for migraine prophylaxis.

Table 2 Medication dispensed for the simulated patient with migraine: n (%)

Dispensed Medication	Overall (n = 57)	Pharmacists (n = 33)	Non-Pharmacist (n = 24)
NSAIDs	14 (24.56)	4 (12.12)	10 (41.67)
Ergotamine	8 (14.04)	6 (18.18)	2 (8.33)
Paracetamol	8 (14.04)	0 (0.00)	8 (33.33)
Ergotamine and NSAIDs	8 (14.04)	5 (15.15)	3 (12.50)
Ergotamine and Paracetamol	2 (3.51)	1 (3.03)	1 (4.17)
NSAIDs and Paracetamol	1 (1.75)	1 (3.03)	0 (0.00)
NSAIDs, Ergotamine and Paracetamol	2 (3.51)	2 (6.06)	0 (0.00)
NSAIDs and Domperidone	3 (5.26)	2 (6.06)	1 (4.17)
Ergotamine and Domperidone	3 (5.26)	3 (9.09)	0 (0.00)
Paracetamol and Domperidone	1 (1.75)	1 (3.03)	0 (0.00)
NSAIDs, Ergotamine and Domperidone	1 (1.75)	1 (3.03)	0 (0.00)
NSAIDs and Prophylactic medications	1 (1.75)	1 (3.03)	0 (0.00)
Ergotamine and Prophylactic medications	1 (1.75)	1 (3.03)	0 (0.00)
NSAIDs, Ergotamine and Prophylactic medications	3 (5.26)	3 (9.09)	0 (0.00)
Prophylactic medications	1 (1.75)	1 (3.00)	0 (0.00)

Note: NSAIDs = Non-steroidal anti-inflammatory drugs

Discussion

This study aimed to investigate community pharmacy practice on severe migraine headache. The results of this study expressed that most pharmacy personnel in community pharmacies had inappropriate practice regarding the management of severe migraine.

Most pharmacy personnel inadequately missed some crucial questions for migraine diagnosis especially in severity of headache. A previous study in southern of Thailand[2] showed the main results of pharmacy practice in mild and moderate migraine patients similar to our study. The findings from prior studies on various diseases such as diarrhea[3], common cold(1) and upper respiratory tract infection(9) were consistent to our study.

Key to the management of migraine is accurate diagnosis. While thirty-eight pharmacies (66.7%) of participants in this study asked questions for differential diagnosis, only six pharmacies (10.53%) asked for a severity of pain. This may be misclassification

of severity of migraine, resulting in choosing inappropriate medication dispensing performance. A question about pregnancy or breastfeeding was rarely asked (only once in 57 pharmacies), similar to previous studies[1,2]. Thus, providers may dispense medicines that are harmful to the patients. For example, ergotamine is contraindicated in pregnant women. A drug – disease interaction should be concern. Few of pharmacy personnel inquired to determine underlying disease. Incomplete patient information obtained from history taking makes it difficult to appropriately recommend the treatment. A study in UK[11] demonstrated that pharmacists insufficiently asked questions among headache patients; however, the most frequent questions were asked were duration of headache (79%), character of pain (57%), other related symptoms (57%), and prior medication (57%). On the contrary, in the current study was performed by less than 50%, excepted for character of pain. A study in Ethiopia[12] demonstrated 73.3 % of them asked for duration of headache and others issues were less than 25%.

According to necessary information retrieving process, the pharmacist providers asked more questions than non-pharmacist providers. Statistically significant differences were presented in patient's identification ($p < 0.05$), differential diagnosis ($p < 0.05$), duration of migraine attack ($p < 0.001$), underlying diseases ($p < 0.05$), prior migraine treatment ($p < 0.05$), history of drug allergy ($p < 0.001$), and disease summarization ($p < 0.001$). A previous study[1] showed statistically significant in asking about associated signs and symptoms ($p = 0.002$), underlying diseases ($p = 0.007$), and drug allergy ($p = 0.001$). There is a need to improve relevant question asking to confirm and clarify the illness for appropriate decision making in migraine management.

The American Academy of Neurology (AAN), the American Headache Society (AHS) and five other organizations formed the US Headache Consortium and released the first guideline for acute migraine treatment and prevention in 2000[13]. The protocol were updated in 2015[14]. Triptans, serotonin1B/1D receptor agonists e.g., sumatriptan, naratriptan, etc., was recommended as the first-line antimigraine agents for moderate-to-severe pain since 2000. Ergot alkaloids and derivatives such as dihydroergotamine, ergotamine, were considered as alternative choices for selected patients with moderate-to-severe migraine. NSAIDs was preferred in mild-to-moderate migraine[13, 14]. Our finding showed that severe migraine patients received single medicine (52.63%). NSAIDs were the most frequent dispensed (n = 33, 57.89%), the second was ergotamine tartrate plus caffeine combination tablets (n = 25, 43.86%). Most important, no pharmacy staff treated migraine with triptans. Patterns of specific antimigraine drug use in Netherlands above 95% of patients were prescribed with a drug in triptans group and 4.6% were received ergotamine[15]. Triptans account for almost 80% of antimigraine

analgesic prescribed in the US[16]. Findings from South Africa showed that migraine patients were prescribed with rizatriptan (28.0%) and ergotamine (26.0%)[17]. In Thailand, triptans were more expensive than ergotamine, this may be the reason why ergotamine was often dispensed in community pharmacies.

It was found that around 10.53% pharmacy personnel dispensed prophylactic therapy although the simulated patient in this study had no history that required prophylactic therapy. AHS recommended the migraine patients should be considered for preventive medications in any of the following situation: (1) attacks significantly interfere with daily life activity; (2) frequent attacks (>4 monthly headache days); (3) contraindication to, failure, or overuse of treatment of acute treatment; (4) adverse events of acute treatment; and (5) patient preference [18]. The earlier studies demonstrated that neurologists in US[5] and Taiwan[4] revealed that 45% and 69.9% prescribed prophylactic medications in cases not recommended by the guidelines. The preventive medications dispensed in this study were flunarizine, cinnarizine and amitriptyline. Amitriptyline was recommend in the US Headache Consortium guidelines[13]. Flunarizine and cinnarizine were recommend in various countries in Europe[19]. The most commonly prophylactic drug prescribes in Taiwan were flunarizine (87.0%) and tricyclic antidepressants (80.5%)[4]. This suggests the important of a continuing pharmacy education training to achieve the appropriate migraine management.

The present study had several limitations. First, this study was conducted on community pharmacies in only one province in Thailand. Generalization of this study findings to other regions and population should be done with caution. Second, the simulated patients were only female. Pharmacy personnel may provide services differently for male patients. Patient gender has been reported to affect practice patterns of physicians in migraine therapy[20]. Third, variations among simulated patients during pharmacy visited may occurred, although simulated patients had been trained intensively and showed high accuracy of simulated performance and data form completion. Finally, because only a specific case scenario was employed, it may not comprehensively assess the professionals' competency towards migraine management.

Conclusion

Most pharmacy personnel performed inappropriate practice on patient's history taking and drug dispensing for severe migraine. No pharmacy staff treated severe migraine headache with triptans. About 43.9% of pharmacy personnel treated severe migraine with ergotamine. Additionally, many pharmacy personnel irrationally dispensed prophylactic therapy. Further educational interventions should be developed and implemented to improve knowledge and practice in the migraine management.

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