

Do pharmacists counsel customers about the effects of sedating antihistamines on driving skills? A survey of community pharmacies in Saudi Arabia

Journal of International Medical Research

2019, Vol. 47(5) 2018–2025

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DOI: 10.1177/0300060519838953

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Abstract

Objective: To investigate the level of counselling regarding the effects of sedating antihistamines on driving skills provided by private community pharmacies in Madinah, Saudi Arabia.

Methods: This study randomly selected private community pharmacies. Mystery shoppers following a similar scenario individually visited these pharmacies. These clients asked for a commonly used brand of sedating antihistamine and noted the counselling offered by the pharmacist. If spontaneous counselling was not offered, necessary information regarding the medication's use was requested. Finally, the content of counselling was documented.

Results: Of the 100 pharmacies selected, 12 were excluded for various reasons and 88 pharmacies were included in the study. Only 23 pharmacies offered spontaneous counselling. Although 73.9% of pharmacists (65 of 88), spontaneously or upon request, mentioned sedation as a side-effect, only one pharmacist warned the client against driving after taking the medication, and three other pharmacists warned against dealing with hazardous machinery. Other side-effects were almost ignored.

Conclusion: A life-threatening insufficiency in the quality of counselling at Saudi Arabian private community pharmacies exists. Traffic accidents, secondary to the side-effects of sedating antihistamines, may be avoided if proper counselling is offered. Saudi Arabian authorities should take appropriate actions to ensure optimal practice in community pharmacies.

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Keywords

Antihistamines, psychomotor, road traffic accidents, Saudi Arabia, patient counselling

Date received: 9 November 2018; accepted: 28 February 2019

Introduction

Antihistamines that block H₁ receptors represent a group of compounds that are commonly used for the treatment of various allergic and inflammatory conditions and cold symptoms, in addition to motion sickness.¹ These medications are conventionally classified into two distinct subgroups or generations. The first generation, or sedating antihistamines, includes compounds such as diphenhydramine and chlorpheniramine;² while examples of the second generation, or non-sedating antihistamines, are cetirizine and desloratadine.³ However, at high doses up to four-folds such as those used in the treatment of chronic urticaria, some of the non-sedating antihistamines were reported to cause sedation.⁴ Because the former generation possesses a significant sedative effect, some of its related compounds are also commonly used as over-the-counter sleep aids by adults who have difficulty falling asleep.⁵

On the other hand, sleepiness is a major cause of road traffic accidents.⁶ In Saudi Arabia, a country with a high rate of motor vehicle accidents and related casualties, sleep-related accidents accounted for 11.6% of total car accidents according to a study published in 2014.⁷ One of the reasons behind sleep-related accidents could be the intake of sedating antihistamines or possibly other sedative/hypnotic agents or medications that affect consciousness in general.^{8–12} Sedating antihistamines lower the level of perception and psychomotor skills needed for a variety of daily functions, including driving and dealing with

dangerous machinery.¹³ Moreover, this effect may extend to the next day.¹⁴

Since the commonly used first-generation antihistamines are available as over-the-counter medications, pharmacists should warn buyers against driving after taking these medications. However, the quality of patient counselling at private community pharmacies in Saudi Arabia is generally insufficient regarding prescription drugs, making the provision of education about nonprescription drugs questionable.^{15–17} Therefore, this study aimed to investigate the level of provision of customer education regarding the effects of sedating antihistamines on driving skills by Madinah private community pharmacies, as a model for other Saudi Arabian cities.

Materials and methods

Study design

Private community pharmacies were visited between 17:00 and 22:00 each day between 7 July 2018 and 13 July 2018. In order to avoid behavioural changes by pharmacists secondary to informing them that they were being investigated, and because the researcher is a faculty member in a college of pharmacy in the same city who may be recognized by some community pharmacists, four adults were hired and trained to play the role of simulated clients (i.e. mystery shoppers) in this survey. Each client was assigned 25 pharmacies and given a printed name of a commonly used, nonprescription brand of sedating antihistamine that is widely available over-the-counter in

Saudi Arabia. Two other alternative brands of sedating antihistamines were memorized by each client. A special form was also distributed to the clients, to be filled in immediately after leaving each pharmacy visit. The researcher followed up with the clients in the field to provide support accordingly. The study protocol was approved by the Research Ethics Committee of Taibah University, Madinah, Saudi Arabia (no. TUCDREC/20180510/Khojah2).

Selection of pharmacies

A list of private community pharmacies (353 pharmacies) and their locations in Madinah was obtained from the Directorate of Health Affairs in Madinah in March 2018. Each pharmacy was given a unique serial number. One-hundred pharmacies were randomly selected using MS Excel 2016 (Microsoft, Redmond, WA, USA). Pharmacies were excluded based on the following criteria: (i) the pharmacy was still closed after three visits on different days; (ii) the pharmacy was permanently closed; (iii) the pharmacy was not found in the given location; (iv) the requested anti-histamine or the other two alternatives were not available, and the pharmacist did not spontaneously mention the side-effects; or (iv) the pharmacist refused to sell medicines without a prescription.

The simulated client scenario

The client will enter the pharmacy, wait until called if the pharmacist is busy, greet the pharmacist, and then ask about the availability of the medication written on the paper. The client's response to the pharmacist's behaviour will be as follows: (i) if asked about the purpose of using the medication, the client will claim that a friend has recommended it for the treatment of a transient allergy of the skin and nose; (ii) if the medication is not available and the

pharmacist offers an alternative, the client will agree if it is from the memorized ones provided by the researcher; (iii) if the medication is available and the pharmacist mentions any side-effect, the client will decide not to buy it because of the side-effects; (iv) if the medication is available but the pharmacist offers a non-sedating alternative, the client will decide to buy the sedating one; (v) if the medication is available but the pharmacist does not spontaneously counsel the client, the client will ask for it; (vi) if the medication is not available and the pharmacist does not spontaneously warn the client about its side-effects, the pharmacy will be excluded as mentioned under exclusion criteria. Some pharmacies may be following a policy of not offering drug information to nonbuyers. Although this behaviour may be considered as an ethical issue, it is, however, not under the scope of this study; (vii) if the medication is not available but the pharmacist spontaneously warns the client about its effects, the pharmacy will not be excluded; (viii) if the medication is available and the pharmacist denies any side-effects, the client will claim that they forgot to bring their wallet; (ix) finally, the client will humbly thank the pharmacist and leave the pharmacy.

The survey form

A separate form for each pharmacy was immediately completed by each simulated client, away from the pharmacy. The form header contains the pharmacy serial number and name, date and time of the visit, and the client's name. However, the header was then folded and stapled by the clients. The body of the form contained all expected pharmacist responses (e.g. mentioning the sedative effect, warning against driving, and recommending a non-sedating product) listed as simple checkboxes in addition to an empty space for documenting additional unclassified

responses. Finally, all forms, with folded and stapled headers, were collected at once, shuffled to mix them up and handed over to the researcher.

Confidentiality

No personal information was collected from pharmacists. The names of pharmacies will not be declared except to the Saudi Arabian authorities upon request.

Statistical analyses

This study only used descriptive analysis (frequencies and ratios).

Results

From the 100 randomly selected private community pharmacies, two were found to have gone out of business (permanently closed), three were not found in the given location and three were still closed on the third visit. In four pharmacies, the medication was not available and the pharmacists did not offer spontaneous counselling. Therefore, only 88 pharmacies were

included in the survey. Table 1 shows the summary of all responses made by the pharmacists.

Spontaneous counselling was offered by only 23 pharmacies (26.1%) and in two of them, the sedating antihistamine was not available. Twenty-two of the spontaneous counsellors mentioned sedation as a side-effect, while one stated that the medication is safe without any side-effects. Of the 22 who mentioned sedation, 13 recommended using a non-sedating alternative, and one claimed that the medication is, however, safe.

In the remaining 65 pharmacies (73.9%), the pharmacists just provided the selected sedating antihistamine (or another sedating alternative) without offering any education to the clients, who had to ask for it. Although 43 of them mentioned sedation as a side-effect, only two of them recommended using a non-sedating alternative, only one warned against driving, three warned against using dangerous machinery or tools, and two advised the clients to take it at bedtime. Moreover, one pharmacist informed the client that the medication

Table 1. Summary of the responses given by pharmacists in a study that investigated the level of provision of customer education regarding the effects of sedating antihistamines on driving skills by private community pharmacies ($n = 88$) in Saudi Arabia.

Content of the counselling	Spontaneous counselling $n = 23$	Counselling upon request $n = 65$
Causes sedation, better to use a non-sedating alternative	13 (14.8)	2 (2.3)
Causes sedation, very safe	1 (1.1)	1 (1.1)
Causes sedation	8 (9.1)	32 (36.4)
Very safe, no side-effects	1 (1.1)	20 (22.7)
Causes sedation, avoid driving	–	1 (1.1)
Causes sedation, avoid using dangerous tools	–	3 (3.4)
Causes sedation, take at bedtime	–	2 (2.3)
Causes sedation, good as sleep aid, very safe	–	1 (1.1)
Causes sedation, may elevate blood pressure	–	1 (1.1)
Causes dry mouth	–	1 (1.1)
May cause addiction	–	1 (1.1)

Data presented as n of pharmacists (%).

may elevate blood pressure, and two claimed that it is totally safe (one of them recommended it as a sleep aid). Of those who did not mention sedation, 20 claimed that the medication has no side-effects and that it is totally safe, one stated that it causes dry mouth, and one stated that it may cause dependence.

Collectively, 65 of 88 pharmacists (73.9%) mentioned sedation as a side-effect. Fifteen of them (17.0% of the total) recommended using a non-sedating alternative, and two (2.3%) said that it is, however, safe. Twenty-one pharmacists (23.9% of the total) claimed that the medication has no side-effects and hence it is totally safe.

Discussion

The current study focused on the quality of patient counselling offered by private community pharmacies in Madinah, Saudi Arabia, for only one group of over-the-counter medications (i.e. sedating antihistamines). However, the unsatisfactory results can be generalized to the entire country for two reasons. First, they are consistent with the results of other studies on the quality of counselling at private pharmacies conducted in different major cities of Saudi Arabia.¹⁵⁻¹⁹ Secondly, about half of the pharmacies included in this study belong to chains that are spread throughout the country, and hence, they are expected to follow a similar pattern of practice.

This current study could be the first to investigate the provision of proper patient counselling and education about the effects of sedating antihistamines, particularly on driving. Unfortunately, only one pharmacist out of 88 warned the buyer against driving after taking such medications, and this counselling was only provided after the client asked for necessary information about the use of such medications as the pharmacist did not say anything while selling it, except mentioning the price.

In addition, only three other pharmacists warned the clients against dealing with hazardous machinery or tools after taking the medication. Again, these pharmacists did not spontaneously offer the counselling. This observed practice (i.e. offering counselling upon request, especially for medications with life-threatening side-effects) indicates a drastic insufficiency in providing the necessary patient education at private community pharmacies in Saudi Arabia.

Although 73.9% (65 of 88) of pharmacists, spontaneously or upon request, mentioned sedation as a side-effect, the client's perceptions about sedation may not include the negative effect of these medications on the psychomotor skills required for safe driving. Therefore, a life-threatening insufficiency in the counselling process seems to exist and the authorities in Saudi Arabia are strongly advised to take appropriate actions in this regard. There are several prescription and nonprescription drugs that affect perception and intellectual function, and they may be involved in the high incidence of vehicular accidents in the country.^{6,7} Whether the intake of sedating antihistamines should be included in the penalty of driving under the influence in Saudi Arabia requires multidisciplinary action because of the variability in the application of this law worldwide.^{20,21} However, strict measures must be taken to ensure the compliance of these pharmacies with higher standards in providing patient education. Such measures may include, but are not limited to, obtaining information from customers about the condition they will use the medication for, and asking customers whether they drive or deal with dangerous tools or machinery or work in professions responsible for the safety of others and hence require alertness and high intellectual capability. Pharmacists must be examined for their counselling skills and knowledge as part of the licensing examination because

the insufficient counselling offered by them may be due to the poor training they have received during their undergraduate course. In addition, pharmacists as well as physicians must always offer non-sedating antihistamines to such customers and patients because they are reported to be safer than the sedating ones regarding the effect on cognitive and psychomotor functions.^{22,23}

With regard to the other side-effects of the first-generation antihistamines, only one pharmacist mentioned a dry mouth, while there are other common side-effects that customers should be made aware of, such as blurry vision, headache, fatigue and psychomotor impairment.¹ Moreover, although sedation was the major content of the counselling offered, only 17.0% (15 of 88) of the pharmacists recommended a non-sedating alternative. On the other hand, almost a quarter of the pharmacists (21 of 88) claimed that the medication has no side-effects and hence is very safe. One pharmacist gave an exaggerated warning that the medication may raise blood pressure without asking if the client was suffering from a cardiac disease, and another pharmacist gave wrong information that the medication may cause addiction. None of the pharmacists asked if the customer was taking another medication (to check for possible interactions such as the synergistic effect with other central nervous system depressants) or had another health condition in which the medication might be contraindicated or must be taken with caution.

The current study has two major limitations. First, the random selection of pharmacies was performed by the researcher, who was not blinded to the list of pharmacies or the selected ones. However, the researcher was blinded as to pharmacy names during the analysis of the survey forms. Secondly, the study focused on

only one class of medication that may interfere with safe driving. This is because they are usually available as over-the-counter medications and are widely used, and because most other sedatives require special prescriptions, which are not possible to obtain.

In conclusion, this study demonstrated that the quality of customer counselling for over-the-counter medications at private community pharmacies in Saudi Arabia is generally poor. Pharmacists mostly offer counselling upon request from the customer rather than providing it spontaneously. Some life-threatening consequences, such as road traffic accidents, secondary to the side-effects of certain medications (e.g. sedating antihistamines) may be avoided if proper counselling is offered. The authorities in Saudi Arabia should take appropriate actions to ensure optimal practice in community pharmacies. Finally, further studies that focus on the provision of optimal counselling about the effects of other centrally acting medications on driving skills and investigate the quality of undergraduate pharmacy training are highly recommended.

Acknowledgment

The author would like to thank Mr Bassam Khoshhal, Mr Abdulrahman Almalki, Ms Razan Mofti and Ms Reham Alharbi for the role they played of mystery shoppers in this study.

Declaration of conflicting interest

The author declares that there are no conflicts of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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