

**Asthma Inhalers Sale without Medical Prescription in Riyadh, Saudi Arabia: A Cross Sectional Study**

Azizah M. AL-Mutairi¹, Dalia H. AL-Enezi¹, Areej Algeer¹, Mustafa M Altannir², Mohammed Al-Sadoon², Mohammad Chaballout², Ahmed S Qannita², Amin Almardini², Mohamad A Al-Tannir^{3*}

¹College of Pharmacy, Princess Noura University, Riyadh, Saudi Arabia

²Faculty of Medicine, Alfaisal University, Riyadh, Saudi Arabia

³Research and Scientific Publication Center, King Fahad Medical City, Riyadh, Saudi Arabia

***Corresponding author e-mail:** maltannir@kfmc.med.sa

ABSTRACT

This study aims to quantify the sale of inhalers without a prescription, describe the degree of difficulty for obtaining these inhalers without a prescription and assess if pharmacists educate patients about the correct use of the inhaler. A cross-sectional study of a quasi-random sample of 252 pharmacies stratified by the five regions of Riyadh. Each pharmacy was visited once by two investigators who used simulated patient methodology with governance of good research principles who simulated having a relative with difficulty of breathing due to airborne dust. Asthma inhalers were dispensed without prescription from 181 pharmacies (72%). Of these, 12% prescribed the inhaler after trying the level 1 of demand and 68% after the third level. Only 31 pharmacists (17%) explained how to use the inhalers. Asthma inhaler could be obtained in Riyadh without a medical prescription or an evidence-based indication with disobedience of pharmacists to educate on the appropriate use of inhalers.

Keywords: Prescription, regulations, over the counter, inhaler, asthma, pharmacy.

INTRODUCTION

Asthma is a common chronic disorder of the airways, characterized by variable reversible and recurring symptoms related to airflow obstruction, bronchial hyper-responsiveness, and underlying inflammation (1). Asthma is one of the most common chronic diseases worldwide; it is not surprising that the prevalence of asthma is increasing rapidly (2). In Saudi Arabia, asthma affects more than 2 million Saudis (3,4). Airway-narrowing can cause shortness of breath, coughing, congestion and wheezing, the narrowing can be caused by swelling in the airway, muscle spasms and a build-up of mucus (5). Asthma inhalers are prescribed as a way to help open the airways of an asthma sufferer (5). While most modern industrialized countries strictly limit availability of inhalers to the general public (6), Saudi Arabia and many less developed countries do

not have or enforce such policies (7). Unregulated dispensing of asthma inhalers by unqualified personnel is of particular concern (7). This unauthorized dispensing might be worrying when not inquiring about pre-existing medical conditions which could complicate diagnosis and treatment (8). Yet in this region it is a common practice that pharmacies often circumvent official regulations and sell drugs to patients who seek medical care for their expressed symptoms (8). In Saudi Arabia, dispensing all types of drugs without prescriptions is prohibited by law, excluding over-the-counter remedies (9-11). In addition, Dispensing inhalers without prescription would lead to inappropriate use that result in poor drug delivery, decreased disease control and increased inhaler use [12]. In Saudi community pharmacy, the majority of pharmacists are violating the pharmacy law without recognizing the potential harm they are imposing the community (13). Also,

many pharmacists lack the skills essential to demonstrate the correct use of metered dose inhalers (14).

Thus, we conducted this study to quantify sale of metered dose inhalers without a medical prescription, to describe the degree of difficulty for obtaining these inhalers without a prescription and to assess if pharmacists educate patients about the correct use of an inhaler.

METHODS

This a cross sectional study of a quasi-random sample of 252 pharmacies was conducted in Riyadh, the capital of Saudi Arabia with about 5 million habitants, in August 2013. The sample was intended to be representative of all Riyadh pharmacies. The sample was stratified by the five regions of Riyadh (Eastern, Western, Northern, Southern, Central) regardless of the pharmacy's size, deprivation level of the area. A convenience sample of streets was chosen from each region and a complete enumeration of all pharmacies in each street was considered. Each pharmacy was visited once by two investigators (total of 2 female pharm D students and 4 male medical students participated) who simulated having a relative with a specific clinical illness (difficulty of breathing due to airborne dust via terrestrial sources) according to simulated-client method pharmacy surveys (15, 16). The investigators concealed their identity and the study objective of their visits from the approached pharmacists who were identified by their licenses and pictures on the front wall of the pharmacy.

The clinical scenarios were presented as follow; one investigator talked to the pharmacist while the other observed the discussion and memorized the responses. Immediately after leaving the pharmacy, both investigators completed a standardized data form that included information about the location of the pharmacy, asthma inhalers dispensing practice, pharmacists' inquiries about associated symptoms (e.g. shortness of breath/chest pain/coughing / wheezing), allergy history, pregnancy status , type of asthma inhalers; and information about drug interactions if inquired by the pharmacist. Two sessions of standardization took place in the presence of all actors. Each group rehearsed simulating the clinical scenario to the senior investigator using the same complaints (terminology and statements). Rehearsal was repeated to ensure reliability of the simulated scenario. The investigators used lay language and refrained from using any jargon.

Only the following clinical information was presented to the pharmacist. Any additional information was only provided if the pharmacist inquired about it. The specific scenario was difficulty of breathing due to airborne dust via terrestrial sources. Three different age categories were used with the simulated clinical scenarios: (6-12 years), (13 to 55 years) and above 55 years old in both genders.

Three levels of demand were used sequentially until an asthma inhaler was dispensed or denied:

- 1- Can I have something to relieve my shortness of breathing? (Level I)
- 2- Can I have something stronger? (Level II)
- 3- I would like to have a metered dose inhaler. (Level III)

Data are presented as percentage of the pharmacists' responses toward the simulated clinical scenario. The study was approved by the Institutional Review Board at King Fahd Medical City. Deception and incomplete disclosure to study subjects (pharmacists) were considered ethically acceptable because this was a minimal risk study and it could not have been performed with complete disclosure of investigator entity. Data were kept anonymous.

RESULTS

Two hundred fifty two pharmacies were visited from all five regions of Riyadh (Eastern, Western, Northern, Southern, Central). The distribution of the percentage of pharmacies that dispensed metered inhalers without prescription for the simulated scenario with different levels of demand and age categories is summarized in Table 1. Asthma inhalers were dispensed without medical prescription from 181 pharmacies (72%) of 252 with different levels of demand where level 1 scores the least (12%) and the third level ranks the highest with 68%. The clinical scenario was simulated in 125 males (49.6%) and 127 females (50.4%) with three different age groups as follow: 76 (30%) among the youngest age group from 6 to 12 years old, 127 cases (51%) in the middle age group from 13 to 55 years old and 49 cases (19%) in the oldest group from 55 years and above. The instructions and recommendations of pharmacists that dispensed metered inhalers without prescription are summarized in Table 2. Only 11/252 (4%) of the visited pharmacists asked about history of drug allergy whereas none of the pharmacists asked the 127 female simulated scenarios about pregnancy. On the other hand, 31/181 (17%) explained how to use the metered inhalers when dispensing for any of the simulated clinical scenarios.

DISCUSSION

In this representative sample of community pharmacies in Riyadh we observed that asthma inhalers could be easily obtained without a medical prescription or an evidence-based indication with different levels of demand and a poor compliance of demonstrating how to use these metered inhalers. This study used simulated patient methodology with governance of good research principles. This is an internationally applicable tool for deriving outcome measures in pharmacy practice research (16). The high observed rate of inhalers sales without a prescription in Riyadh highlights the problem of self-medication in Saudi Arabia; this could be explained by several factors: lack of enforcement of the national regulations, suboptimal compliance to the code of ethics and professionalism among community pharmacists, and financial interests of community pharmacists (9). A study conducted by Giraud et Roche showed that the misuse of pressurized metered-dose inhalers is frequent and associated with poorer asthma control in inhaled corticosteroid-treated asthmatics (17). In accordance with previous Saudi surveys (13), this survey showed that the majority of pharmacists (72%) were not recognizing the potential harm they are imposing the community by dispensing drugs without prescription, this would lead to inappropriate use which may result in poor drug delivery, decreased disease control and increased inhaler use (12). Thus, the current practice

of pharmacists needs to be changed to provide a safer pharmaceutical service to the public. Pharmacists are the one responsible to educate the patients about how to use adequately the metered inhaler because poor treatment outcomes for the asthmatic patients are extensively reliant on the incorrect use of inhalers (7). In our study, this disobedience was potentialized by the fact that only 17% of pharmacists gave instructions on how to use the inhalers. Although this study has been conducted in Riyadh, it serves as a good reference for the remaining cities in the kingdom. This is not the first study that explores pharmacist behavior towards dispensing drugs without prescription; regrettably results are still in harmony with those conducted for the last three decades. In conclusion, In a representative sample of community pharmacies in Riyadh, we observed that an asthma inhaler could be obtained in Riyadh without a medical prescription or an evidence-based indication with disobedience of pharmacists to educate on the appropriate use of inhalers. Strict implementation of the regulations governing the sale of drugs and the specification of drugs to be sold over the counter on registration are warranted.

ACKNOWLEDGEMENTS

The authors acknowledge the efforts of Ms. Amani Abu-Shaheen and Mr. Samer Kobrosly for their assistance in preparing this manuscript.

Table1. Percentage of Pharmacies Willing to Sell Inhaler without Medical Prescription by Different levels of Patient Demand and Age Groups.

	Age (years)			All
	(6-12) n=76	(13-55) n=127	(≥55) n=49	N=252
Dispensing inhalers without prescription				
Yes	50(66)	92(72%)	39(80%)	181(72%)
No	26(34)	35(28%)	10(20%)	71(28%)
Level I	7(14%)	13(14%)	1(3%)	21 (12%)
Level II	12(24%)	17(19%)	7(20%)	36 (20%)
Level III	31(62%)	62(67%)	31(77%)	124(68%)

Data presented as numbers (%).

Table 2. Pharmacists' Instructions and Recommendations upon dispensing the inhaler (n=181).

	N (%)
Explained how often to take asthma inhalers	30(16.6)
Explained how to use inhalers	31(17.1)
Explained how long the inhaler should be taken	21(11.6)
Recommend that patient see a physician if there is no improvement	34(18.8)
Showed how to check if your inhaler is empty or nearly empty	1(0.55)
Discussed any unwanted effects from medication	17(9.3)
Explained how to clean the inhaler and spacer	17(9.3)

Data presented as numbers (%).

REFERENCES

- 1- National Health Interview Survey. <http://www.cdc.gov/nchs/nhis.htm>
- 2- Asthma fact sheet No207. <http://www.who.int/chp/knowledge/publications/adherence>.
- 3- Al Frayh AR, Shakoor Z, Gad El Rab MO, Hasnain SM. Ann Allergy Asthma Immunol, 2001;86:292-6.
- 4- Al-Moamary M, Al-Hajjaj M, Idrees M, Zeitouni M, Alanezi M, Al-Jahdali H, Al Dabbagh M. Ann Thorac Med, 2009;4(4):216-33
- 5- Harmful Side Effects of Asthma Inhalers. http://www.ehow.com/about_5075045_harmful-side-effects-asthma-inhalers.html
- 6- Skaer T., Wilson C. J. Int Med Res, 1996;24(4):369-375
- 7- Khan TM, Azhar S. Saudi Pharmaceutical Journal, 2013; 21: 153-7.
- 8- Amidi S, Ajamee G, Sadeghi HR, Yourshalmi P, Gharehjah AM.. Am J Public Health 1978;68(5):495-7
- 9- Bawazir SA: International Pharmacy Journal, 1992;6(5):222-4.
- 10-.Al-Ghamdi M. Saudi Med J. 2001; 22(12):1105-8.
- 11- Bin Abdulhak AA, Altannir MA, Almansor MA, Almohaya MS, Onazi AS, Marei MA, Aldossary OF, Obeidat SA, Obeidat MA, Riaz MS, Tleyjeh IM. BMC Public Health, 2011; 11: 538.
- 12- Melani AS, Bonavia M, Cilenti V, Cinti C, Lodi M, Martucci P, Serra M, Scichilone N, Sestini P, Aliani M, Neri M; Gruppo Educazionale Associazione Italiana Pneumologi Ospedalieri. RespirMed. 2011;105(6):930-8.
- 13- Al-Mohamadi A, Badr A, Bin Mahfouz L, Samargandi D, Al Ahdal A. Saudi Pharm J, 2013 Jan;21(1):13-8.
- 14- Casset A, Rebotier P, Lieutier-Colas F, Glasser N, Heitz C, Saigne J, Pauli G, de Blay F. Rev Mal Respir, 2004; 21:925-33.
- 15- Madden JM, Quick JD, Ross-Degnan D, Kafle KK. Soc Sci Med, 1997;45:1465-82.
- 16- Watson M, Norris P, Granas A. IJPP, 2006;14:283-93.
- 17- Giraud V, Roche N. Eur Respir J. 2002; 19 (2):246-51.