

Original Research

Are Sudanese community pharmacists capable to prescribe and demonstrate asthma inhaler devices to patrons? A mystery patient study

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ABSTRACT*

Although community pharmacists have become more involved in the care of asthma patients, several studies have assessed pharmacists' ability to illustrate appropriately inhalation technique of different asthma devices. Many studies addressed inappropriate use of asthma devices by patients and pharmacists, in addition to its clinical, humanistic and economic burden.

Objective: To evaluate community pharmacists' practical knowledge and skills of demonstrating proper inhalation technique of asthma inhaler devices available in Sudan.

Method: Three hundred community pharmacies located around the three major hospitals in the capital city (Khartoum) and four other provinces were approached, and four asthma devices were assessed: Metered-dose inhaler (MDI) (n=105), MDI with Spacer (n=83), Turbuhaler (n=61), and Diskus (n=51). Investigator (a pharmacist) acted as a mystery patient. He selected one device and asked the serving pharmacist to demonstrate how to use the device. Investigator completed a checklist of 9 steps of inhaler device use immediately after leaving the pharmacy. Essential steps derived from published literature were pre-specified for each device. Five evaluation categories were accordingly formulated as follows: optimal technique, adequate technique, poor technique, totally unfamiliar with the device, and does not know.

Results: More than half of the pharmacists approached with metered dose inhaler did not know how to use optimal technique (ie all steps correct) all through. A third poorly demonstrated the technique, and only one pharmacist was categorized as being able to demonstrate an "optimal technique". The majority of pharmacists approached with spacing chamber and dry powder inhalers (Turbuhaler and Diskus) either did not know proper technique or were totally unfamiliar with the devices.

Conclusion: The majority of community pharmacists, who were expected to educate asthma patients on their dispensed inhalers, lack the basic

knowledge of proper use of commonly dispensed asthma inhaler devices.

Keywords: Nebulizers and Vaporizers. Asthma. Community Pharmacy Services. Pharmacists. Patient Simulation. Sudan.

SON CAPACES LOS FARMACÉUTICOS COMUNITARIOS SUDANESES DE PRESCRIBIR Y DEMOSTRAR LOS INHALADORES DE ASMA LOS CLIENTES? UN ESTUDIO CON PACIENTE SIMULADO

RESUMEN

Aunque los farmacéuticos comunitarios se han involucrado en el cuidado de los pacientes con asma, varios estudios han evaluado las capacidades de los farmacéuticos para ilustrar apropiadamente la técnica de inhalación de los diferentes dispositivos. Muchos estudios encararon el uso inapropiado de los inhaladores por pacientes y farmacéuticos, además de su daño clínico, humanístico y económico.

Objetivo: Evaluar en los farmacéuticos comunitarios el conocimiento práctico y las habilidades para demostrar la técnica de inhalación apropiada de los dispositivos para asma disponibles en Sudan.

Métodos: Se abordó a 300 farmacéuticos comunitarios situados alrededor de 3 hospitales principales de la ciudad de Kartum y de otras 4 provincias, y se evaluaron 4 dispositivos para el asma: Inhaladores dosificadores (MDI) (n=105), MDI con cámara espaciadora (n=83), Turbuhaler (n=61), y Diskus (n=51). Un investigador (farmacéutico) actuó como un paciente simulado. Seleccionaba un dispositivo y pedía al farmacéutico que le demostrase como utilizarlo. El investigador rellenaba un *check-list* de 9 pasos sobre el uso del inhalador inmediatamente después de abandonar la farmacia. Los pasos esenciales extraídos de la literatura fueron previamente especificados para cada dispositivo. Se crearon 5 categorías de evaluación: técnica óptima; técnica adecuada; técnica pobre; dispositivo totalmente extraño; y no sabía.

Resultados: Más de la mitad de los farmacéuticos abordados con el dispositivo no conocían la técnica óptima de uso (i.e. todos los pasos correctos). Un tercio demostraba pobremente la técnica y solo un farmacéutico fue calificado como capaz de demostrar la "técnica óptima". La mayoría de los farmacéuticos abordados con cámara espaciadora o con inhaladores de polvo seco (Turbuhaler y

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Diskus) o no sabían la técnica apropiada o desconocían totalmente los dispositivos.

Conclusión: La mayoría de los farmacéuticos comunitarios, de los que se esperaba que educasen a los pacientes con asma sobre los inhaladores dispensados, carecían de conocimientos básicos sobre el uso apropiado de los inhaladores para asma comúnmente dispensados.

Palabras clave: Nebulizadores y Vaporizadores. Asma. Servicios de Farmacia Comunitaria. Farmacéuticos. Simulación de Paciente. Sudán.

INTRODUCTION

Asthma is a chronic disease that is characterized by inflammation, increased responsiveness to a variety of stimuli, and airways obstruction. Effective treatment reverses the symptoms.¹ It is estimated that 300 million people of all ages, and various ethnic backgrounds, suffer from asthma. The burden of this disease to governments, patients and their families is increasing worldwide. There may be an additional 100 million persons with asthma by 2025.²

In many parts of the world, patients with asthma do not have access to basic asthma medications or medical care.³ Such limited access to health care and increasing prevalence of asthma increase the public need for more active role of community pharmacists in its care. Pharmacists may provide general asthma counseling, particularly with regard to inhaler-device handling technique, and importance and differences of the various asthma inhaled medications.

Inhaled medications are preferred in the management of bronchial asthma, because of their greater efficacy and fewer adverse effects when compared with available oral medications. One of the major asthma device-related problems is the failure of asthma patient to adequately handle prescribed inhalers. Poor inhaler technique is associated with delivery of sub-therapeutic doses of medications, and subsequently poorer asthma control.⁴⁻⁶ By virtue of their unique position, accessibility, frequent contact with patients on prescription refilling and proficiency on medications, community pharmacists shoulder the responsibility of assisting patients with asthma attain better control of their disease state and thereby improve their quality of life.

Many studies have substantiated that the pharmacists' care of asthma patient, in different setting, has a positive impact on clinical and humanistic asthma outcomes in the long term.⁷⁻¹⁰ Additionally, some studies have shown that health professionals' knowledge of the proper use of aerosol inhalers is generally as poor as that of the patients.^{7,11,12} Community pharmacists have also been inefficient in counseling asthma patients about effective usage of their inhaler devices.¹³

Few studies in developing countries have investigated expanding clinical services provided in community pharmacy for asthma patients. There

has not been any study in Sudan to assess the pharmacists' knowledge and skills regarding appropriate technique of asthma inhaler devices.

There is no recent electronic or archival data uncovering the prevalence of asthma in Sudan. Annual Health Statistical Report of Federal Ministry of Health (Jun, 2005) might provide some insight regarding asthma burden. Asthma is rated as the 5th most common disease in the top 10 leading causes of hospital admission; the 1st in the top 5 non-infectious diseases treated by hospital admission; the 8th in the ten leading diseases necessitating hospital admission for children aged 0-5 year, and the 3rd in the ten leading diseases treated in an out-patients setting.

Mystery patient is a method used for evaluation of guideline compliance, clinical communication skills in community pharmacy, counseling process associated with prescribed or over the counter medications, and assessing the impact of continuing professional training program.¹⁴ Also described as simulated or surrogate shopper or client, pseudo patient, covert patient, and standardized client. Mystery patient is an individual who has been trained to make a concealed visit to a community pharmacy in order to present a scenario that will check a specific behavior of a member of pharmacy staff, without the staff member being informed of the mystery patient's identity or that they were being tested.

Mystery patient technique is quite widely used in community pharmacy setting to explore the real day-to-day dispensing practice and recommendations of pharmacists. The basic rationale for using mystery patients is that the pharmacist's performance varies when the existence of a test is known. We utilize this method to achieve our aim.

The aim of the study was to evaluate the community pharmacists' practical knowledge and skills to demonstrate correctly different steps of asthma inhaler devices marketed in Sudan using the mystery patient technique.

METHODS

Design and sample

This was a cross-sectional observational study. Data were collected in the period between January 2008 and March of 2008. Based on population of approximately 1200 community pharmacies in the 5 areas, confidence level of 95% and margin of error of 5, a convenience sample of 300 community pharmacies were selected during a two-month period in the capital city (Khartoum) and 4 other provinces (Madani, Sinnar, Managil and Damazeen). All pharmacies around the 3 major hospitals in capital city were approached. All hand-held asthma devices available in Sudan were included: Metered Dose Inhaler of short acting beta₂ agonist (brand name: Vental®), add-on spacing chamber (brand name: Aero-chamber®) and two dry powder delivery systems; Turbuhaler (brand name: Symbicort®) and Diskus (brand name:

Seretide®). Asthma devices that are not available in market place were excluded. Label fixed to aero-chamber tube and inserted leaflets of other devices were removed. Approval for the study was granted by the ethics committee of the University of Medical Science and Technology.

Scenario

Investigator posed as a "mystery patient", entered the pharmacy carrying one device pre-selected before approaching the pharmacy, and spoke to the pharmacist in Arabic words "my doctor has just prescribed this device for me but he did not tell me how to use it and I forgot to ask. Can you please show me how I can use it?" Investigator then observed carefully the pharmacist's demonstration. He completed immediately after leaving the pharmacy, a post-visit report using a validated checklist of 9 steps. The most clinically important steps which were required to ensure proper technique was specified for each device.¹⁵⁻¹⁸ Failing to perform one or more of these steps could substantially reduce the delivery and drug deposition in the lungs. Hence, the effectiveness and therapeutic outcomes of inhaled medications

will be negatively affected. Such steps are specified as "critical steps" and are highlighted in italic bold (Table 1).

Data evaluation

Based on "critical steps", the following five evaluation categories were formulated: "optimal technique"- a label that is awarded to pharmacists completing successfully the 9 steps, "adequate technique"- a label that is awarded to those who completed the "critical steps" but not all the 9 steps, "poor technique"- a label that is awarded to pharmacists who failed to complete the "critical steps", "does not know"- a label that is awarded for pharmacists who either did not demonstrate any of the "critical steps" or gave a response of "I don't know", "totally unfamiliar"- a label that is awarded to pharmacists who were unfamiliar with the device. Data were analyzed descriptively using Statistical Package for the Social Sciences version 15.0.

RESULTS

Out of 300 pharmacists participated, 50% (n=150) were male and another half were females. Majority

| Table 1: Recommended Checklist of asthma devices | |
|--|---|
| Metered-Dose Inhaler (MDI) ¹⁵ | |
| step | Instructions |
| 1 | <i>Remove the cap</i> |
| 2 | <i>Shake the inhaler several times</i> |
| 3 | Stand and hold head up straight, holding the inhaler in a mouth-piece down position |
| 4 | Exhale all the way until you can breathe out no more |
| 5 | Place the mouth piece between your teeth and close your lips, don't block the opening with your mouth |
| 6 | <i>While breathing in deeply and slowly depress the top of the metal canister to release a dose</i> |
| 7 | Continue to breathe in slowly over 4-5 second |
| 8 | Hold your breath for 10 second |
| 9 | Breathe out slowly |
| Turbuhaler ¹⁶ | |
| step | Instructions |
| 1 | <i>Unscrew and lift off the cover</i> |
| 2 | <i>Keep the inhaler upright</i> |
| 3 | <i>Rotate the grip as far as it will go and then back until it clicks</i> |
| 4 | Exhale to residual volume |
| 5 | Exhale away from mouth piece |
| 6 | Place the mouth piece between your teeth and close your lips |
| 7 | <i>Inhale forcefully and deeply</i> |
| 8 | Hold breath for 5 seconds |
| 9 | Exhale away from mouth piece |
| Diskus ¹⁷ | |
| step | Instruction |
| 1 | <i>Place thumb on groove and open by pushing the groove to the right until it clicks</i> |
| 2 | <i>Slide lever to the right until it clicks</i> |
| 3 | Holding the discus horizontally |
| 4 | Breathe out away from the mouth piece of diskus |
| 5 | Place the discus in mouth between teeth and close lips |
| 6 | <i>Breathe in steadily and deeply</i> |
| 7 | Remove the discus from mouth and hold breath in full-inspiration for 5-10 seconds |
| 8 | Breathe out slowly |
| 9 | Put thumb on groove and slide the thumb back towards you as far as it will go to click it shut |
| MDI + spacer ¹⁸ | |
| step | Instructions |
| 1 | <i>Remove the mouth piece cover of MDI actuator</i> |
| 2 | Check the mouth piece of the inhaler and spacer thoroughly to see that is clean |
| 3 | Insert the MDI mouth piece firmly to the end of the spacer |
| 4 | <i>Hold your spacer and MDI together and shake well, at least 4 or 5 times</i> |
| 5 | Place the mouth piece of the spacer in your mouth and put your lips around it and then exhale |
| 6 | <i>Spray one puff of medicine into spacer and immediately begin to inhale slowly, taking a full deep breath</i> |
| 7 | Remove the spacer from your mouth, hold breath for 8 to 10 seconds |
| 8 | Breathe out slowly |
| 9 | Release one more puff if more is required, wait at least one minute between each puff |

of the pharmacies located in Khartoum (n=251, 83.7%), 28 (9.3%) in Madani, 10 (3.3%) in Sinnar, 7 (2.3%) in Managil, and 4 (1.3%) in Damazeen. One hundred and five community pharmacists were approached with metered dose inhaler, 83 with metered dose inhaler with spacer, 61 with Turbuhaler and 51 pharmacists with Diskus. The results indicated that 59% (62/105) of pharmacists that were approached with a metered-dose inhaler did not know how to use it properly, 36.2% (38/105) had poor technique, 3.8% (4/105) demonstrated "adequate technique", one pharmacist only was labeled with "optimal technique" (0.9%) and none were "totally unfamiliar" with the inhaler. For metered dose inhaler plus spacer, 41% (34/83) were "totally unfamiliar" with the device, 42.2% (35/83) did not know how to use it correctly, 9.6% (8/83) showed "poor technique", 7.2% (6/83) demonstrated "adequate technique", and no pharmacist was awarded "optimal technique". Among pharmacists who were approached with Turbuhaler, 65.6% (40/61) did not know the correct inhalation technique, 21.3% (13/61) had "poor technique", 8.2% (5/61) were totally unfamiliar with the device, 4.9% (3/61) showed "adequate technique", and none achieved optimal technique. Finally, 64% (33/51) of pharmacists approached with Diskus did not know how to use it properly, 11.8% (6/51) were totally unfamiliar, 8% (4/51) showed "poor technique", 15.7% (8/51) demonstrated "adequate technique", and none was awarded "optimal technique".

Overall, only one pharmacist (0.3%; 1/300) was categorized with "optimal technique" while on average more than half of the pharmacists did not know how to use the devices.

Some pharmacist asked the mystery patient to refer to prescribing physician for demonstration. Few recommended going back to pharmacist who firstly dispensed the device. A number of pharmacists started intuitively explained different steps (mainly pharmacist who approached with metered dose inhaler). Some pharmacists referred to package inserted leaflet. They asked mystery patient to wait, they read and translate to Arabic language. Finally, they were classified as "poor technique".

DISCUSSION

Many studies have focused on the assessment of patient's mishandling of asthma inhaler devices and its clinical consequence in term of disease control or unscheduled hospital admissions.¹⁵ The present study revealed that community pharmacists were much closer to traditional product-focused practice, whereby they lacked the basic knowledge and essential skills of demonstrating inhalation technique that is essential for effective asthma patients counseling. Failure of pharmacists to properly handle asthma devices seems to be compatible with studies that documented that physicians, house staff and nurses are similarly were often unable to demonstrate aerosol inhalers techniques adequately.¹¹ Our findings confirmed the results of few studies that evaluated the pharmacists' ability to appropriately use asthma

inhaled medications. Frew and MacFarlane¹⁹ found that only 3 of 18 hospital pharmacists were able to use metered dose inhalers correctly. Ketsen *et al.*²⁰ used a check list of 11 essential steps of metered dose inhalers graded by a trained observer. The percentage of pharmacists performing greater than 6, 8, and 10 steps correctly was 96 percent, 87 percent, and 62 percent respectively. Mickle *et al.*²¹ evaluated the pharmacist's practice in patient education when dispensing metered dose inhaler to an investigator posing as a patient. Of those pharmacists providing education, only 29 percent were able to describe greater than 50 percent of the steps correctly. Only 1 of the 52 pharmacists demonstrated proper inhalation technique of metered dose inhaler and this was in response to a request. Hounkpati *et al.*²² evaluated pharmacist knowledge about how to use metered dose inhaler, they found that 27.4% of pharmacist poorly understand correct inhalation technique. Ketsen *et al.*²⁰ found that almost half of pharmacists using metered-dose inhaler with spacing chamber, and a third of pharmacists using Turbuhaler had failed to complete the 11 essential steps specified for each devices.

These previous studies¹⁹⁻²² had evaluated the pharmacists based on the number of performed and non-performed steps without specifying the most clinically important or relevant steps. This might result in an overestimation of pharmacists' performance. In the present study, we considered the clinical consequences of fulfilling or missing each step by specifying "critical steps" for each device and evaluating the pharmacists accordingly.

Total unfamiliarity with spacing chamber and dry powder inhalers critically undermines the quality of clinical services provided in community pharmacies for asthma patients. Spacing chamber had the highest rate of total unfamiliarity despite its long duration in the market place. The pharmacist's knowledge of the device does not seem to be affected by the length of time the device has been available in the market. Suboptimal prescribing of this device might be the main cause. Valve spacer is recommended for use in patients receiving inhaled corticosteroids via metered dose inhaler, even those with a perfect metered dose inhaler technique and obviously in those with poor coordination of firing-inhalation steps.

Few studies had evaluated the pharmacists' ability to demonstrate adequate technique of Diskus inhaler. Basheti *et al.*²³ assessed the most problematic steps, forty-two community pharmacists in Jordan and thirty-one in Australia were asked to demonstrate the use of Diskus. Almost all the pharmacist in both countries performed correctly critical steps specified for each device. Conversely to our finding, where the majority of participating pharmacists either did not adequately use Diskus or were totally unfamiliar with the device.

An interventional study performed by Basheti *et al.*²⁴ to evaluate the effectiveness of a single educational intervention on pharmacists' retention of their own inhalation technique. Thirty-one pharmacists participated in the study. At the initial assessment,

few pharmacists demonstrated correct technique of Turbuhaler and Diskus, 13% and 6%, respectively.

The present findings might offer some explanation of poor usage of inhaler device by patients, and sporadic pattern of ineffective counseling by community pharmacists. Some pharmacists in this study had the perception that they are not responsible for educating and training patients with asthma on inhalation technique. They frequently asked the mystery patient to return back to the physician who prescribed the device for training on device use. Some pharmacists, who were approached with metered dose inhaler, remarked to mystery patient "it is so simple; just open your mouth and puff". Some of them asked him to return back to the pharmacy from where he bought the device.

Dizdar *et al.*² evaluated general knowledge and perception on asthma management of 174 Turkey pharmacists. Between 20 and 40% of the community pharmacists did not find that they were satisfactorily qualified in the handling of different asthma inhalers and in inhalation technique. Almost 75% of them favored to refer asthma patients to a physician rather than counsel them directly.

Raynor *et al.*²⁵ recruited twenty three people with asthma in the north of England to comment on leaflets of reliever and preventer inhalers. They found that patients preferred face to face information giving, since information could be individualized to their needs and abilities. And patients often threw away information leaflets as they looked unimportant and there was too much to read with boring appearance and small type. Most of patients thought that inhaler technique was not best learnt by reading about it.

These previous misconceptions ("not my responsibility", "it is so simple" and "someone else will teach the patients") might explain, to some extent, the lack of knowledge and poor inhaler device training skills of community pharmacists. Such misconceptions might discourage the pharmacists from gaining proper inhalation training. We thought a separate study is needed to address pharmacist's attitudes and beliefs about assessing and educating asthma patients regarding asthma inhaler technique.

Pharmacists who showed "poor technique" or were labeled with "does not know" did not initially admit such a state. They tried to demonstrate an improper technique to avoid saying "I don't know". This response might result in a vicious cycle, perpetuating patient mishandling of inhaler devices and depriving asthma patients from gaining training on proper inhalation method.

Some pharmacists who were approached with metered dose inhaler explained verbally different steps without using the device for practical demonstration. This might indicate that the pharmacists were not confident due to poor knowledge. Kritikos *et al.*²⁶ investigated community pharmacist's perception of their role in asthma care. Most pharmacists perceived time and patient-related factors to be the most important barriers to

optimal asthma care, pharmacist's lack of confidence and skills in different aspects of asthma care less important barriers. The finding from this study may point to lack of knowledge and confidence to be the main barriers.

Pharmacists who showed "optimal" or "adequate" technique did not ask mystery patient to re-demonstrate the use of the device to observe, revalidate and detect incorrect steps. International pharmacy practice guidelines recommended that the pharmacist should demonstrate the correct method of inhalation, and observe the patients using the devices initially and again on repeat visits to the community pharmacy.²⁷

Some pharmacists who were approached with the Turbuhaler and Discus picked the patient information leaflet from the device package they had in their pharmacy. They asked mystery patient to wait while they read it. Still they were not able to adequately demonstrate correctly the different steps written in the leaflet. Often, they were awarded "poor technique". It was concluded that the manufacturer's instruction leaflet, and written instructions, alone is ineffective in teaching patient correct technique.²⁸ We believe that further study is needed to investigate capability of community pharmacists to read, understand, and practically translate written information of inhaler technique into effective educational intervention.

In summary, lack of knowledge and practical skills must be considered as the most important barrier that should be overcome if responsible provision of asthma care is to become a reality in community pharmacists practice. The findings presented here have confirmed that there is a clear need for specific training and continuing educational programs directed specific on asthma management. Pharmaceutical companies can participate efficiently in such training by providing placebo asthma devices and face-to-face training session with community pharmacists. Essential remodeling of undergraduate pharmacy curriculum is needed to adopt and implement clinical pharmacy courses and pharmaceutical care philosophy, where patient-oriented practice is the main focus of pharmaceutical services. Legislations to make continuing training and assessment on asthma inhalers and care as compulsory activity for community pharmacists are clearly needed.

The present study has some limitations. Firstly, the findings may be biased by criteria that are used to evaluate pharmacists' performance. Secondly, the relatively small sample size for each device may limit generalizability. And finally, single investigator's judgment may lead to "subjective bias".

CONCLUSIONS

Many participating community pharmacists lack the basic knowledge and practical skills that are required to demonstrate the correct inhalation technique of the available bronchial asthma inhaler delivery systems. This will and is clearly going to have a serious negative impact on patient education

and training on one hand and the global push for better asthma care.

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CONFLICT OF INTEREST

Nothing to declare.

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