An-Najah National University
Faculty of Graduate Studies

Assessing Appropriate Use of Inhaler Devices among Asthmatic Patients

By
Ola Adel Fawzi Salah

Supervisor
Prof. Waleed Sweileh
Co-supervisor
Dr. Samah Al-Jabi

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This thesis was defined successfully on 9/6/2013, and approved by

Defense Committee Members	Signature
1. Prof. Waleed Sweileh / Supervisor	
2. Dr. Samah Al-Jabi / Co-Supervisor	
3. Dr. Mahir Khdour / External Examiner	
4. Dr. Rowa Al-Ramahi / Internal Examiner	

Dedication

To my father's soul

To my generous lovely mom

To my brothers and sisters

To all whom I love

Acknowledgment

To my supportive supervisors professor Waleed Sweileh and Dr. Samah Al-Jabi for their endless support and advices.

To Dr. Nidal Kamal who hosted me in his own clinic for three months and his staff.

To all persons who taught me in this life either sciences or how to live.

To my family's support especially mom's.

To my friends' support.

To ALL of these many thanks are presented with flowers

الإقرار

أنا الموقعة أدناه، مقدمة الرسالة التي تحمل عنوان:

Assessing Appropriate Use of Inhaler Devices among Asthmatic Patients

تقييم مدى صحة استخدام أجهزة الاستنشاق (البخاخات) بين مرضى الربو

اقر بأن ما اشتملت عليه هذه الرسالة إنما هو نتاج جهدي الخاص، باستثناء ما تمت الإشارة إليه حيثما ورد، وأن هذه الرسالة كاملة، أو أي جزء منها لم يُقدم من قبل لنيل أي درجة أو لقب علمي أو بحثي لدى أي مؤسسة تعليمية أو بحثية أخرى.

Declaration

The work provided in this thesis, unless otherwise referenced, is the researcher's own work, and has not been submitted elsewhere for any other degree or qualification.

Student's Name: **اسم الطالبة:**

Signature: **التوقيع:**

Date: **التاريخ:**

Abbreviations

ATAQ	Asthma Therapy Assessment Questionnaire
DPI	Dry Powder Inhalers
GINA	Global Initiative for Asthma
GOAL	Gaining Optimal Asthma Control
ICS	Inhaled Corticosteroids
IRB	Institutional Review Board
LVS	Large Volume Spacer
MDI	Metered Dose Inhalers
MOH	Ministry of Health
SD	Standard Deviation
SPSS	Statistical Package of Social Sciences
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

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Assessing Appropriate Use of Inhaler Devices among Asthmatic Patients

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Abstract

Background: Appropriate use of inhaler devices such as metered-dose inhalers (MDIs) and dry-powder inhalers (DPIs) in clinical practice is not well studied in Palestine and few were carried out in the Arab world.

Objectives: The objectives of this study were to assess patients' administration technique of inhaler devices and its association with other variables.

Method: A cross sectional observational evaluation was conducted at a pulmonary clinic in Nablus, Palestine. Administration technique was evaluated based on a pre-defined checklist. Asthma control was assessed using Asthma Therapy Assessment Questionnaire (ATAQ) scale.

Results: MDIs (without spacer) and DPIs (turbuhalers and aerolizers) in patients with asthma disease were studied. The study included 149 patients with mean ± standard deviation (SD) age of 47.5 ± 18.5 years. Fifty five (36.9%) of the study patients had college education and higher. Forty two (28.2%) patients were using MDIs, 38 (25.5%) were using DPIs and 69 (46.3%) were using both devices. A total of 217 inhaler devices were evaluated: 111 (51.2%) for MDI and 106 (48.8%) for DPI. Mean scores ±

SD for correct inhaler technique were 61 ± 20.1, 71.4 ± 14.9 and 66.2 ± 15.7 for MDIs, turbuhalers and aerolizers respectively (p = 0.00). For MDI and DPI devices, step 3 “exhale to residual volume” was the least correctly done (22.5% and 13.2% respectively). There was a significant relationship between correct score of handling inhaler device and educational level (r = 0.187; p=0.006) where higher educated patients had higher correct scores. Among patients, ATAQ scale indicated that 22 (14.8%) patients had well controlled asthma, 56 (37.6%) patients were not well controlled and 71 (47.7%) patients were poorly controlled. There was significant difference in scores of correct inhaler device handling and asthma control category (p < 0.01) where patients had higher correct scores were with higher control for their asthma. Among patients using inhaled corticosteroids (ICS), there was a significant difference between adherence score and correct handling scores (p = 0.002) where patients with better adherence had higher correct scores.

Conclusion: Correct handling of inhaler devices was not common particularly among MDI devices. Regular checking of inhalation technique and proper practical teaching of patients is crucial for optimal use of most inhaler devices.

Chapter One

Introduction

Chapter One
Introduction

1.1 Background

Inhalation is the preferred route of delivery for drugs intended for asthma. The major advantage of inhaled therapy is that medications are delivered directly into the airways, which reduces risk of side effects and amount of medication required [1-3]. The mechanisms of action, effectiveness and the significance of inhaled corticosteroids (ICS) as well as short- and long-acting B2-agonists in the management of asthma and chronic obstructive pulmonary disease (COPD) are well-established. However, the importance of the mode of delivery of these agents, which is the inhaler device, is still disregarded [4]. The Gaining Optimal Asthma Control (GOAL) study showed that despite that current asthma treatments are effective and are able to achieve good asthma control in patients, asthma remains insufficiently controlled [5-6] . There are many reasons that might explain why asthma remains poorly controlled. Such reasons include: poor compliance with therapy, wrong inhaler choice by physician and improper inhalation technique [1, 3] .

Inhalation as a mode of therapy was developed within the last 50 years. However, this mode did not find widespread use until the introduction of the first propellant gas aerosols in the form of metered dose inhalers (MDI) in the middle of the 20th century. In the 1970s and 1980s, spacer devices were developed as an addition to MDIs. Further development in MDI technology came in the form of a breath-activated

MDI (Autohalers) launched in the United Kingdom (UK) in 1989 [1]. The development and introduction of breath-actuated devices, including dry powder inhalers (DPI) was an important progress in the history of inhalation therapy [7]. In 1969 the first DPI was available in the market. It was the Spinhalers (Fisons, UK), and then it was followed by the Rotahalers (GlaxoSmithKline, UK) in 1977 and the Diskhalers (GlaxoSmithKline, UK) in 1980. In 1988 the first multidose DPI, the Turbuhaler (AstraZeneca, UK), was introduced in the UK, followed by the Aerolizers (Novartis, Switzerland) and the Diskus/Accuhalers (GlaxoSmithKline, UK) and in 2001 the Novolizers (MEDA, Sweden) [1].

The most commonly used inhaler devices are either the MDIs or the DPIs, and the device selection should be based on the availability, cost of the device, patient and physician preference, and clinical setting. [8]. Metered dose inhalers have small size, portable, compact, convenient, relatively low cost, multi-dose capability, quick delivery, and the contents are protected from contamination by pathogens [9]. However, MDIs drug delivery is highly dependent on patient technique; misuse can result in a suboptimal (even zero) lung deposition. Most of the dose is deposited in the oropharynx causing high oropharyngeal impaction unless a holding chamber or spacer is used. Other disadvantages of MDI are failure to shake, have fixed drug concentration, and adverse reactions to propellants have occurred in some patients [9]. On the other hand, a primary advantage of DPIs is coordination of actuation with inspiration. However, they

depend on patient's inspiratory flow. A primary disadvantage of unit-dose DPIs is the time needed to load a dose for each use [9].

Because of these differences in the types of devices and their advantages and disadvantages there were many devices to be developed, a wide range of MDIs and DPIs are available nowadays trying to maximize drug delivery with low variability [10]. Inhalers also face many clinical challenges such as patient's age, clinical condition and inspiratory flow [8]. Also inhalers do not show the same performance and manufacturers are trying to present the best device design for the patients [10].

Good-quality outcomes in asthma hinge not just on the availability of medications but also on their appropriate use by patients. Both the efficacy of a medication and patient adherence to the therapeutic regimen influence the effectiveness of a treatment [11]. It has been recently demonstrated that inhaler misuse is associated with decreased asthma control in asthmatics treated with an ICS [7], where for ICS to be effective, good inhaler technique and adequate adherence are important. [12]. Large systematic reviews of bioequivalence have found that, when properly used, MDI and DPI devices are not different in delivering inhaled medications, and then patients will have the same asthma control [12-13].

In this study we want to provide baseline data about the ability of Palestinian patients to use their inhalers correctly.

1.2 Objectives

The objectives of the study were:

1. To assess the administration technique of inhaler devices among patients with asthma diseases.
2. To compare correct use of two different types of inhaler devices: [DPIs] versus [MDIs].
3. To determine the factors significantly associated with correct use of inhaler devices.
4. To determine the relationship between asthma control and correct use of inhaler devices.
5. To determine the extent of adherence to ICS and its relationship with correct use of inhalers.

1.3 Significance and Justification of the Study

This is the first study in Palestine and one of the few in the Arab world to assess appropriateness of drug administration technique among patients using inhaler devices. There is a lot of doubt that patients in Palestine might not get enough education from physicians, nurses and pharmacists about the proper use of inhaler device. Therefore, this study will provide baseline data about level of knowledge and actual practice of patients in this regard.

1.4 Expected Outcome of the Study

The results of this study should encourage the Ministry of Health (MOH) and health policy makers to invest more in pharmacists, particularly clinical pharmacists, to run patient education and counseling clinics for patients in general and for patients with inhaler devices in particular. Clinical pharmacists should take the lead in such topic by providing patient's education and counseling in asthma clinics. Teaching these patients will improve the therapeutic outcome, improve quality of life and have a positive economic impact.

Chapter Two

Literature Review

Chapter Two
Literature review

No previous studies have been carried out to assess administration technique of inhaler devices in Palestine. However, many studies were carried out worldwide and few in the Arab world. To the best of our knowledge, the following list briefly summarizes previous studies that are highly related to our study.

1. Khassawneh et al., 2008 (Jordan) [2]: a prospective observational study was held in three pulmonary clinics and included 300 patients (11-85 years old) with 525 inhaler devices, specific forms were filled; 193 MDIs, 83 aerolizers, 103 diskus and 146 turbuhalers. Results indicated that 74.6% of patients were using MDI's inappropriately, and 16.9%, 6.8% and 43.2% were the percentages for inappropriate use of aerolizers, diskus and turbuhalers respectively, he reported that diskus inhalers had the best technique and MDIs had the worst.

2. Osman et al., 2012 (Sudan) [14]: a study was carried out over 300 community pharmacists to show their ability in using the inhaler devices appropriately because they are the responsible persons in educating patients on how to use these devices. The study included 105 MDIs, 83 MDIs with spacers, 61 turbuhalers and 51 diskus inhalers with a checklist of 9 steps of inhaler device use. Only one pharmacist was able to demonstrate an optimal technique with no faults, and one third of pharmacists poorly demonstrated the technique.

3. Mehmood Khan, 2012 (Sudai Arabia) [15]: This study was held in Saudi Arabia, Al Ahsa area, to test the community pharmacists' ability to use the inhaler devices appropriately, specifically MDIs. The study included 71 community pharmacists; most were Egyptians (70 pharmacist), and using a nine-step checklist. The most step done appropriately was inserting the mouthpiece into mouth between closed lips, while the least two were waiting for 20–30 seconds before starting the second puff and holding breath for 5–10 s respectively. Pharmacists were found to have a poor MDI technique with mean (±SD) score of 4.2± 2.08 for the nine steps.

4. Hassan, 2009 (Saudi Arabia) [16]: A study in Saudi Arabia, Riyadh city investigated the use of MDIs among 100 COPD patients over one month and a half using a nine step checklist. Results showed that no patient got a complete technique to his/her MDI device and only 20% get over 50% of the total score of 9, and the mean (±SD) score was 3.2±1.7 out of 9. Highly educated patients had significantly better technique than others ($p = 0.005$).

5. Roy, 2011 (United States of America, USA) [12]: The study included 270 participants over 18 years old with mean (±SD) age of 48.2 ± 13.3 years. The study was held over 33 months, 163 (60%) of participants were using DPIs and 107 (40%) were using MDIs. The study showed no significant difference in the inappropriate use of DPIs and MDIs ($p=0.46$). In addition, among DPI users, the steps least often completed

were exhalation to residual volume prior to putting the inhaler in the mouth (32%) and holding the breath for 5 seconds after removal of the inhaler (47%). Patients who were using DPIs were more likely to be adherent to their medications ($p = 0.001$), also patients who were using DPIs had more emergency department visits ($p = 0.04$) and were more likely to require oral steroids ($p = 0.002$) in the previous year, while the type of inhaler device was not associated with any of the co-morbid conditions assessed in the survey ($p > 0.10$).

6. Muller et al., 2011 (Hungary) [17]: One hundred and eleven patients were studied, 53 were using MDIs and 58 using DPIs. The study showed that asthma control was achieved by 45.9% of patients. However, 38.7% were partially controlled and 15.3% were uncontrolled, also control in patients using MDIs was better than that in patient using DPIs.

7. Hardwell et al., 2011 (UK) [18]: 1291 patients with mean (±SD) age of 52 ± 21 years were included in this study, the study showed that 85.6% of patients using MDIs failed to use their devices appropriately, and even 78.4% had inappropriate use after inhaler technique education.

8. Heidarnazhad, 2009 (Iran) [19]: 123 patients were interviewed, 41.9% hadn’t used their inhalers regularly. In addition, most mentioned that they were feeling no need to use medications during symptom-free intervals, while 30.5% only were using their inhaler devices appropriately.

9. Adeyeye, 2008 (Nigeria) [20]: 106 patients between 13 - 64 years old were included in the study, with 72 (67.9%) of them were using MDIs, 32 (30.2%) were using diskus and 10 (10.6%) were using nebulisers. The study found that 47.2% were using the inhalers with good rating and 52.8% were using them with poor rating, and 34 patients had done all steps correctly. In addition, 94.3% of the patients were not adherent with their inhaler devices.

10. Desalu et al., 2012 (Nigeria) [21]: Another study in Nigeria was carried out on 124 asthma patients to show their asthma control using Global Initiative for *Asthma* (GINA) guidelines and the predictors associated with uncontrolled asthma. The study showed that most patients (69.3%) had uncontrolled asthma, 22.6% had partly controlled asthma and 8.1% had controlled asthma. One of the predictors that was significantly and strongly associated with uncontrolled asthma was the incorrect use of inhaler devices ($p < 0.05$). Other predictors were the lack of adherence to ICS, presence of other diseases and asthma severity, while the duration of asthma wasn't associated with the degree of asthma control.

11. Hilton, 1990 (Britain) [22]: the study included 422 patients, of these 262 (63 %) were using MDIs, 62 (15 %) were using rotahalers, 36 (9 %) were using MDIs with spacer devices, 23 (5%) were using turbohalers, 26 (6%) were using diskhalers and 12 patients were using other devices. The study showed that 25% of patients had inadequate technique and that administration technique among patients with MDIs was worse than

those with other devices (45%) while the turbuhaler had the best technique (78%) among inhaler devices.

12. Molimard et al., 2003 (France) [7]: an observational study on 3811 patients was carried out. In this study, 769 aerolizers, 728 autohalers, 894 diskus, 552 MDIs, and 868 turbuhalers were used among patients. The study showed that 76% of patients using MDIs made an error during their use while the percentage of error in using other devices was 49 - 55%. The two most common errors were failure to exhale before actuation (28.9%) and failure to hold breath after inhalation (28.3%), also it reported that turbuhaler had the best technique (24%) and MDIs had the worst (6%)

13. Melani et al., 2004 (Italy) [23]: A multicenter study which examined inhalation technique and variables associated with misuse of MDIs and DPIs in clinical practice over 1404 outpatients (15 - 88 years old) were examined, 47% of them were suffering from asthma and 39% were suffering from chronic obstructive pulmonary disease. This study found that there was no significant difference in technique between MDIs and DPIs, and that 24%, 3%, 17%, 23%, and 24% of patients had poor use of MDI alone, MDI with an add-on l*arge volume spacer* (LVS), aerolizer, turbuhaler, and diskus respectively. Results of this study suggested that other factors besides technique should be investigated to examine advantages and disadvantages with different inhalation device use as treatment for asthma.

14. Chapman et al., 2000 (Canada/ Torinto) [24]: this study concluded that physicians should consider many factors when selecting a device for a patient, including personal preference, patient preference, frequency of administration, patient age, cost, convenience, likelihood of proper use and adherence.

15. Morice et al., 2002 (UK) [25]: this study had examined patient preference for asthma delivery devices. It analyzed 339 patients including adult and pediatric patients with asthma and their acceptability of MDIs and DPIs using a questionnaire. The study found that after 12 weeks of use, more patients found DPI easier to use (67%) compared to MDI (22%) with a significant difference ($p < 0.01$), patients also found the DPI dose counter to be useful and significantly more patients preferred DPI (63%) to MDI (28%; $p < 0.01$).

16. Sheth, 2003 (India) [26]: this study evaluated patient preference as well as correctness of technique in DPIs compared to MDI using a randomized open-label crossover study design. In this study 59% of patients found DPIs easier to use with 60% preferring DPIs compared with MDI ($p < 0.025$).

17. Van Beerendonk et al., 1998, (Netherlands) [3]: this study was using the same checklist we had used in our study to assess the inhalation technique in asthma patients, 316 patients were included in the study, only 35 patients (11.1%) had no mistakes in using their inhaler devices, where at least 281 (88.9%) of patients made at least one mistake, and

most of them (200 patients, 63.2%) had skill mistakes. Also patients who were using MDIs had better inhalation technique than those who were using DPIs. Another factor that was studied and showed a significant difference ($p < 0.011$) in the inhalation technique among patients was the age, showing that older patients made more mistakes in the inhalation technique than younger patients.

18. Price et al., 2013 (UK) [27]: this is a review article which stated that many patients have problems adopting the correct inhaler technique for both MDIs and DPIs, and this leads to poor asthma control, often, it is the very young and the elderly who had more mistakes using inhaler devices. Also this review stated that it is important to train patients how to use their inhaler devices by health care professional, the problem was that only 15.69% of healthcare professionals can use inhaler devices correctly, in addition to that patients who initially learn how to use their inhalers properly, do not maintain this correct technique over time.

19. Lavorini et al., 2008 (Italy) [28]: This study indicated that the first most frequent error made by patients using all types of inhaler devices in many studies was losing the exhalation step before using their devices.

20. Cain et al., 2001 (USA) [29]: This study indicated that the mean ± SD of the correct use scores of MDI, turbuhaler and diskus devices among pharmacists were 72.2% ± 12.8, 61.2% ± 13.4 and 49.8% ± 18.6, respectively. After giving instructions to the pharmacists about the proper use of these inhalers, improvements in their scores were noticed to get 89.3% ± 12.8, 83.8% ± 15.8 and 88.3% ± 12.4, respectively.

Chapter Three

Methodology

Chapter Three
Methodology

3.1 Study design

This was a cross-sectional observational study conducted at a private pulmonary clinic in Nablus, north West-Bank, Palestine. Nablus is a major city in northern West-Bank of Palestine with approximately more than 200,000 inhabitants.

3.2 Study Sample

Sample size was calculated using Raosoft sample size calculator (http://www.raosoft.com/samplesize.html) assuming a margin of error of 5%, a total population of patients with asthma attending the clinic during the study period of 300 and a response rate of 50%. The estimated sample size will be 168 patients. Convenience sampling method was used by the researchers who visited the clinic on a daily basis from 10 am – 2 pm. Data for this study were collected between June and August, 2012. Patients who used inhaler devices were screened, and those who had used inhaler devices for at least 3 months were included in the study. New patients and those who had received education on inhaler use during the preceding three months and patients whose age was less than 18 years old were excluded from the study, patients using devices for any disease other than asthma were excluded.

3.3 Study tool

Two types of inhaler devices were included in the study: MDI and DPI. Since spacer was not routinely used among our patient population and the study aim was to evaluate actual practice, the effect of adding spacer to MDI was not evaluated. The outcome of interest in this study was inhalation technique administration. Inhalation technique was assessed by asking participants to demonstrate how they use their inhalers with a placebo device. All participants were asked to demonstrate use of a MDI device or a DPI device or both depending on what they are currently using as an inhalation device. Inhalation technique scores were assessed using instruments adapted from validated standardized checklists specific to each device (Appendix 1) [3, 12, 30-31]. For MDI and DPI devices, the technique was scored on an 8-points and 7-points scale, respectively, with higher scores indicating better technique and vice versa.

The scoring procedure was as follow: for each step in the checklist of MDI or DPI, a score of 0 was given if the step was done incorrectly and a score of 1 was given if the step was done correctly. To make the numbers easier to be understood, the total score of correct and incorrect steps was summed and converted to percentage with a total score of 100 means that all steps were done correctly while a total score of zero means that all steps were done incorrectly. For MDI and DPI, certain steps were considered essential and any mistake in any of these steps was considered a critical error in handling the device. These steps were derived from the medication leaflet and from previous studies [2, 7, 32]. For MDI, these steps were:

“Shake the inhaler and remove protective cap” and “Inhale slowly and simultaneously active the canister”. While those for DPI were: “Prepare the inhaler before usage” and “Inhale forcefully and deeply”.

3.4 Data Collection

A clinical pharmacist who was well acquainted with inhaler devices and their proper handling performed the evaluation procedure. The training of the clinical pharmacist on the proper technique was based on video teaching materials as well as by the specialist at the pulmonary clinic and the principal investigators. The clinical pharmacist observed each step of the inhalation technique with a placebo device. To ensure subjective scoring, a pilot study was carried out and 2 clinical pharmacists were separately asked to assess and score the inhalation technique of a sample of patients attending the clinic over two weeks of study. At the end of the pilot study, the scores obtained by the 2 clinical pharmacists were compared. Significant and strong positive correlation was obtained suggesting appropriate and subjective scoring with minimum inter- rater variations. Patients included in the pilot study were not included in the final study sample.

3.4.1 Data collection form

An appropriate form, which included demographics and a checklist of the essential steps, was completed for each device. Potential associated factors for correct handling, including age, sex, primary diagnosis, and level of education of the patient, were noted (Appendix 2). The study was

explained to the patients and an informed consent was obtained. All aspects of the study protocol, including access to and use of the patient clinical information, were authorized by the institutional review board (IRB) and the faculty of graduate studies before initiation of this study (Appendix 3,4).

3.4.2 Asthma Therapy Assessment Questionnaire

The scale used to assess asthma control is Asthma Therapy Assessment Questionnaire (ATAQ): The scale contains two questions, the first is divided into three parts (1st: in the past 3 weeks did you: A. miss any work school or normal daily activity because of your asthma? B. wake up at night because of asthma? C. believe that your asthma was well controlled?) , each is answered by yes, no or unsure; and the second question (2nd A: do you use an inhaler for quick relief from asthma symptoms?) is answered as yes, no or unsure also and if the answer is yes another question is answered according to the number of puffs used by the patient (2nd B: in the past 4 weeks what was the highest number of puffs in one day you took off the inhaler). The score is calculated by giving 0 to (no) answer in the first two parts of question one and to (yes) answer in the third part; and giving 1 to (yes or unsure) answer in the first two parts of question one and 1 to (no or unsure) answer in the third part; while giving 0 to (no or unsure) answer in the second question, or if the puffs are less than 4, and giving 1 if the highest number of puffs used during the previous month are higher than 5 (Appendix 5). [33]

3.4.3 Morisky adherence scale

The scale used to assess adherence to medication was Morisky adherence scale [34-35]. The scale was used to assess adherence to DPI and not MDI since all the MDIs used in the current study were short acting bronchodilators. Morisky scale was used to calculate the adherence of the asthmatic participants to their inhaler devices, it consists of 8 questions with scoring 1 to (no) answer and 0 to (yes) answer except in the 5th question it is 0 to (no) answer and 1 to (yes), and for the 8^{th} question it is calculated by dividing the value by 4. Morisky score will show us the following results for adherence: if score < 6 (low adherence); if score 6 - <8 (medium adherence); and if score = 8 (high adherence) (Appendix 6).

3.5 Statistical analysis

Descriptive analysis was conducted on the demographics and patient characteristics. Mean ± standard deviation (SD) was used for continuous variables and frequency and percentage were used for categorical variables. Correct handling among different inhaler devices was compared with One Way ANOVA and Tuky post hoc test for multiple comparisons. Relationship between correct scores and other factors was analyzed using Pearson correlation for continuous or ordinal variables while Mann Whitney U test was used for non categorical factors. Analysis was performed with Statistical Package for Social Sciences program software (SPSS version 20, SPSS, Chicago, Illinois).

Chapter Four

Results

Chapter Four
Results

4.1 Socio-demographic characteristics

A total of 149 asthmatic patients were included in the study and were tested for their administration technique of their inhaler devices. Table 1 shows the demographic and clinical characteristics of the participants. The majority of the study sample was female (94; 63.1%), while male patients were 55 (36.9%). Mean ± SD of patients' age was 47.5 ± 18.5 years (median: 47; inter-quartile range Q1 – Q3: 31 – 62; range: 18 – 90 years). Fifty five patients (55; 36.9%) had college education or higher while 30 (20.1%) were illiterate. In addition, the mean reported duration of asthma was 11.96 ± 10.6 (median: 10; Q1 – Q3: 3 – 18) years. Most of the patients (128; 85.9%) reported being taught how to use their inhaler devices, mostly by physicians (106; 71.1%) or family members or other healthcare providers such as pharmacists or nurses. Moreover, inhalers used by the patients were salbutamol, ipratropium bromide, formoterol, budesonide/ formoterol, and budesonide alone. The most commonly used inhaler was budesonide/ formoterol inhaler. Twenty four (24; 16.1%) reported being current smokers. Sixty nine (69; 46.3%) of the patients reported using different types of herbs as a complementary therapy for their asthma.

4.2 Correct handling of inhaler devices

Forty two patients (28.2%) were using MDI, 38 (25.5%) patients were using DPI and 69 (46.3%) patients were using both DPI and MDI

devices (Figure 1). At the end of the study period, 217 inhaler-device-specific forms had been completed: 111 (51.2%) for MDI and 106 (48.8%) for DPI (Figure 2). The DPI devices used were as follows: 76 (71.7%) for turbuhalers and 30 (28.3%) for aerolizers (Figure 3). Test-retest reliability which assesses the degree to which test scores are consistent from one test administration to the next of MDI and DPI devices was acceptable with Spearman rank correlation r values of 0.9 and 0.7 respectively.

For MDI devices, 4 patients (3.6%) had a complete score of 100% while among DPI users, 7 (6.6%) patients had a complete score of 100%. A total of 50 (45%) MDI users scored ≤ 50% while a total of 10 (9.4%) DPI users scored ≤ 50% (Figure 4).

Regarding MDI devices, the percentage of correct handling committed in each step was calculated and shown in Figure 5. Among the 8 steps in MDI administration procedure: step 3 (**Exhale to residual volume**) was the least correctly done (22.5%) followed by step 6 **(Continue slow and deep inhalation)** 42.3%, while step 4 (**Place mouthpiece between lips and teeth**) and step 2 (**Hold inhaler upright**) were the most correctly performed (98.2% and 90.1% respectively). Regarding the correct handling of DPI devices, Figure 6 shows the percentage of correct handling committed in each step among DPI users: step 3 (**Exhale to residual volume**) was the least correctly done (13.2%) followed by step 7 (**Hold breath for 5 seconds**) 47.2%, while step 6 (**Take**

the inhaler out of the mouth) and step 4 (**Keep inhaler horizontal**) were the most correctly performed (100% and 98.1% respectively).

Total scores of correct handling were not normally distributed with a Kolmogrove-Smironv test value of ($p = 0.00$). Therefore, non-parametric tests were used. Figure 7 is a bar chart comparison of the total scores of correct handling of MDI, turbuhaler and Aerolizer. The difference was significant (Kruskal Wallis analysis: Chi-square = 7.04; $p = 0.03$) with MDI devices significantly have lower total scores of correct handling than turbuhaler ($p < 0.01$) and aerolizer ($p = 0.008$). The mean rank; medians (Q1-Q3) for total correct scores were (mean rank: 56; median: 62.5; Q1 – Q3: 50 - 75) for MDI devices, (mean rank: 38.5; median: 71.4; Q1 – Q3: 57.1 – 85.7) for turbuhaler and (mean rank: 15.5; median: 71.4; Q1 – Q3: 57.1 – 71.4) for aerolizer.

Regarding the 2 critical steps in handling MDI devices, **"shaking the inhaler and removing the protective cap"** was the most frequently committed critical error in handling the MDI. In handling DPI, **"failure to inhale forcefully and deeply"** was the most frequently committed critical error (Table 2). The two critical steps of MDI devices were both incorrectly handled by 69/111 (62.2%) while the two critical steps of DPI devices were both incorrectly handled by 35/106 (33%); the turbuhaler by 21/76 (27.6%), and the aerolizer by 14/30 (46.7%) users. Committing critical errors was compared between MDI and each DPI device. MDI use was associated with a higher frequency of critical errors, when compared with

turbuhaler and aerolizer devices: 62.2% versus 27.6% and 46.7% respectively ($p < 0.001$). No significant difference in committing critical errors between turbuhaler and aerolizer was found ($p = 0.08$).

4.3 Factors associated with correct use of inhaler devices

Evaluation of total scores of correct handling of inhaler devices was carried out to determine if nominal variables such as gender, herbal use, current smoking cigarettes, ICS uses and number of inhaler devices used simultaneously have significant association with correct use. The results are summarized as the following (table 3):

1. There was no significant difference in total scores of correct handling of inhaler devices based on gender [(male: 64.8 ± 22.9; 71.4 (50 – 85.7) versus female: 65.6 ± 16.7; 71.4 (50 – 75); $p = 0.76$)], smoking [smokers: 65.4 ± 19.8; 67 (50 – 85.7) versus non-smokers: 65.4 ± 18.1; 71.4 (50 – 75), ($p = 0.992$)] or herbal use [user: 62.6 ± 16; 71.4 (57.1 – 71.4) versus non-user: 66.5 ± 20; 71.4 (50 – 85.7), ($p = 0.169$)].

2. ICS users had higher scores of correct handling of inhaler devices compared to non users with a significant difference [ICS users: 67.4 ± 16.2; 71.4 (57.1 – 75) versus non-ICS users: 60.5 ± 23.8; 62.5 (37.5 – 85.7); ($p = 0.014$)].

3. Handling of inhaler devices was not significantly influenced by the number of inhaler devices used by the patient [(one device: 63 ± 20.7; 67 (42.9 – 72.3); two devices: 66.7 ± 18.6; 71.4 (50 – 85.7); three devices: 64.1 ± 13.5; 59.8 (57.1 – 75); $p = 0.402$)].

Furthermore, the evaluation of the relationship between other variables like age, duration of asthma and educational level was carried out to gain further understanding of their relationship with scores of correct handling of inhaler devices. Results showed the followings:

1. There was significant relationship between total scores of correct use and educational level ($r = 0.187$, $p = 0.006$); where patients with higher educational level record higher scores of correct handling for the inhaler devices.

2. Although patients with more asthma years get higher scores of correct handling of their devices than those with fewer asthma years, there was no significant difference between total scores of correct use and duration of asthma, where ($r = 0.085$; $p= 0.211$).

3. There was no significant relationship between age and total scores of correct handling of inhaler devices ($r = -0.061$, $p = 0.372$)

4.4 Association between asthma control and scores of correct use of inhaler devices

Using ATAQ, 22 (14.8%) of patients were well controlled, 56 (37.6%) were not well controlled and 71 (47.7%) were poorly controlled. Analysis showed that there was a significant difference in the means of scores of correct handling of inhaler device in MDIs and turbuhalers ($p = 0.01$. $p = 0.031$ respectively) among the three categories of asthma control, while there was no significant difference in the mean score of correct

handling of inhaler devices in aerolizers (p = 0.8) among the three categories of asthma control. In generl patients who were well controlled showed the highest scores (median (Q1-Q3)) of correct handling while those who were poorly controlled showed the lowest score of correct handling: [scores for well controlled patients: 74.3 (67.9 – 90.9); scores for not well controlled patients: 67 (56 – 75.8); scores for very poorly controlled patients: 61.6 (46.8 – 74.9)]. Figure 7 shows box plot of correct handling stratified by asthma control category.

4.5 Determination the extent of adherence to ICS and its relationship with appropriate use of inhaler devices

There were 97 (65.1%) patients who were using ICS. The medean (Q1-Q3) of Morisky score was 5.75 (4.75-7). There were 47 (31.5%) patients, 35 (23.5%) patients and 15 (10.1%) patients with low, intermediate and high adherence respectively. There was a negative correlation between adherence score and correct handling scores (r = 0.205). However there was a significant difference between adherence score and correct handling scores (p = 0.002) where patients with high adherence get higher scores of correct use of inhaler devices than those with intermediate and low adherence patients.

Table (1): Demographic characteristics of the study sample

Variable	Statistics N = 149
Age (years)	Mean ± SD: 47.5 ± 18.5 Median: 47; Q1 – Q3: 31 – 62 Range: 18 – 90 years
Gender Male Female	 55 (36.9%) 94 (63.1%)
Level of Education ≤ High school ≥ College	 94 (63.1%) 55 (36.9%)
Prior device-handling education by a healthcare provider Yes No	 128 (85.9%) 21 (14.1%)
Smoking Yes No	 24 (16.1%) 125 (83.9%)
Do you use herbals **Yes** **No**	 69 (46.3%) 80 (53.7%)
Duration of asthma disease (years)	Mean: 11.96 ± 10.6 Median: 10; Q1 – Q3: 3 – 18
Percentage of patients using each type of inhaler device MDI DPI MDI + DPI	 42 (28.2%) 38 (25.5%) 69 (46.3%)
Types of inhaler devices used (N = 217) **DPI** (N = 106) Turbuhaler Aeroliozer **MDI** (N = 111)	N = 217 N = 106/217 (48.8%) 76/106 (71.7%) 30/106 (28.3%) N = 111/217 (51.2%)
Adherence in patients using DPI for chronic use (N = 97) Low adherence Medium adherence High adherence	 47 (48.5%) 35 (36.1%) 15 (15.4%)
Asthma Control (N = 149) Well controlled Not well controlled Poorly controlled	 22 (14.8%) 56 (37.6%) 71 (47.7%)

Abbreviations: DPI: dry powder inhaler, Q1 – Q3: interquartile range, MDI: metered dose inhaler, SD: standard deviation,

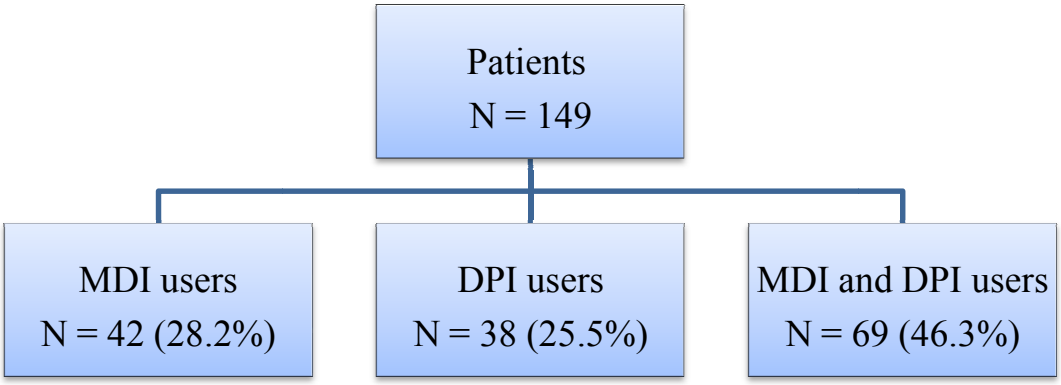

Figure (1): Distribution of participants stratified by type of inhaler device.

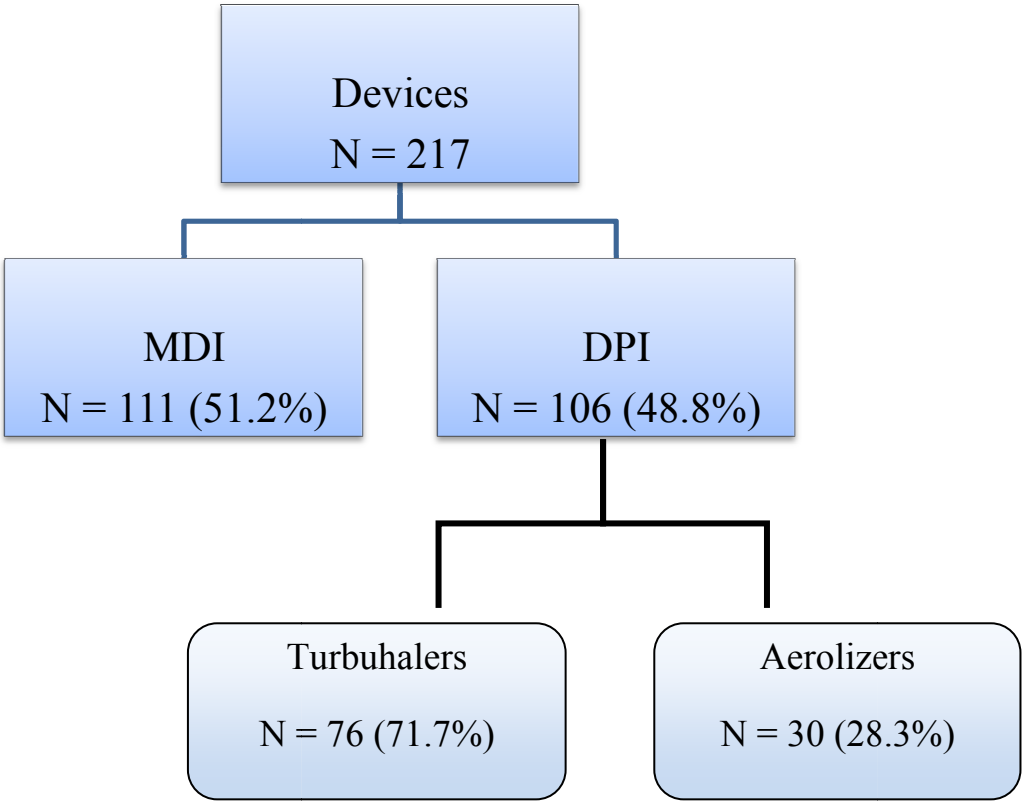

Figure (2): Total number of inhaler devices tested for correct use stratified by their type: metered dose inhaler (MDI) and dry powder inhaler (DPI); Turbuhalers and Aerolizers.

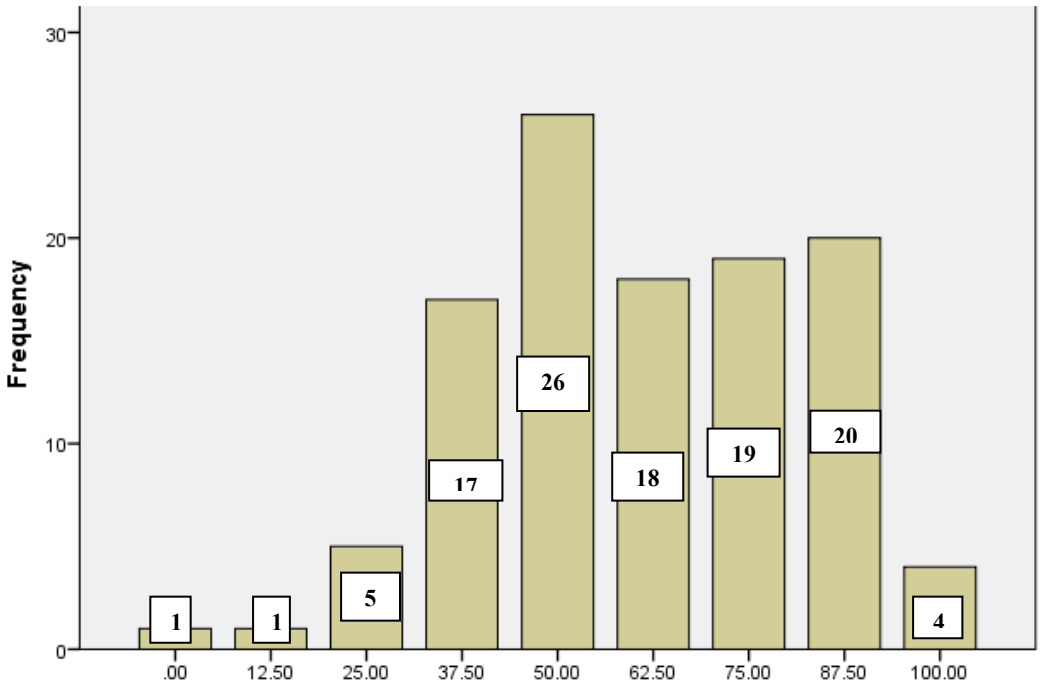

Figure (3-A): comparison of the total scores of correct handling of metered dose inhaler (MDI)

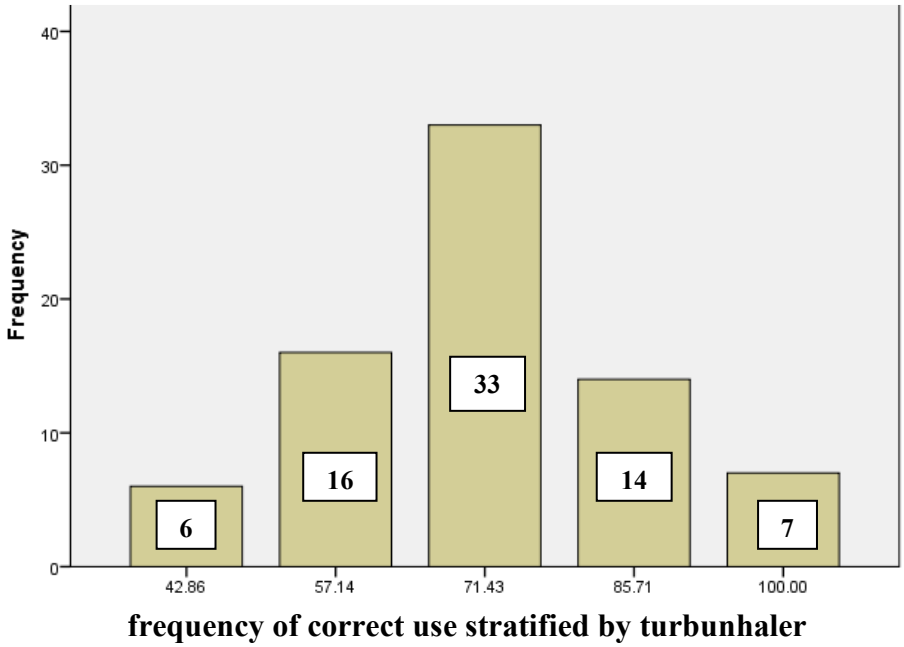

Figure (3-B): comparison of the total scores of correct handling of turbunhaler

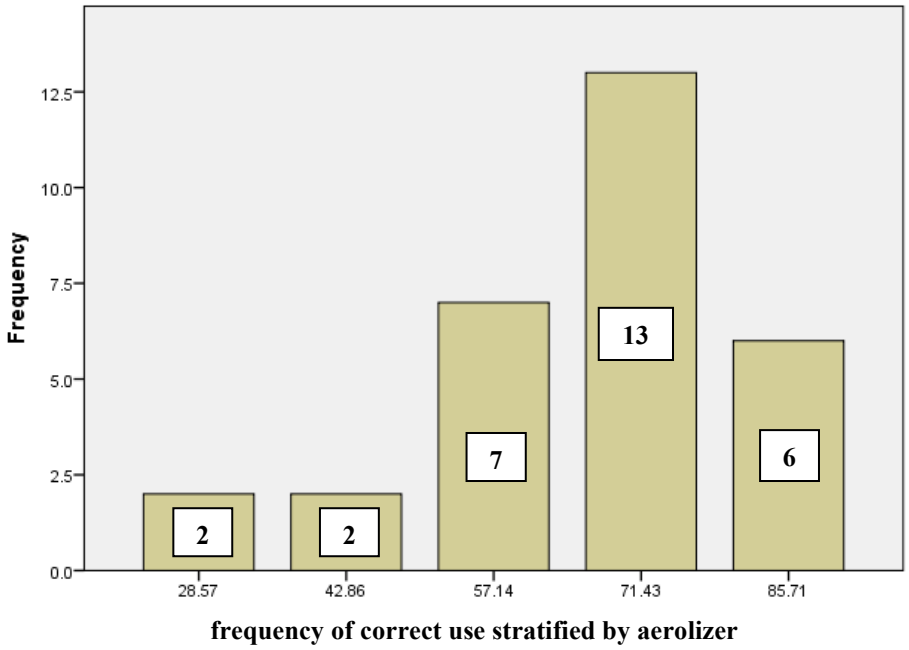

Figure (3-C): comparison of the total scores of correct handling of aerolizer

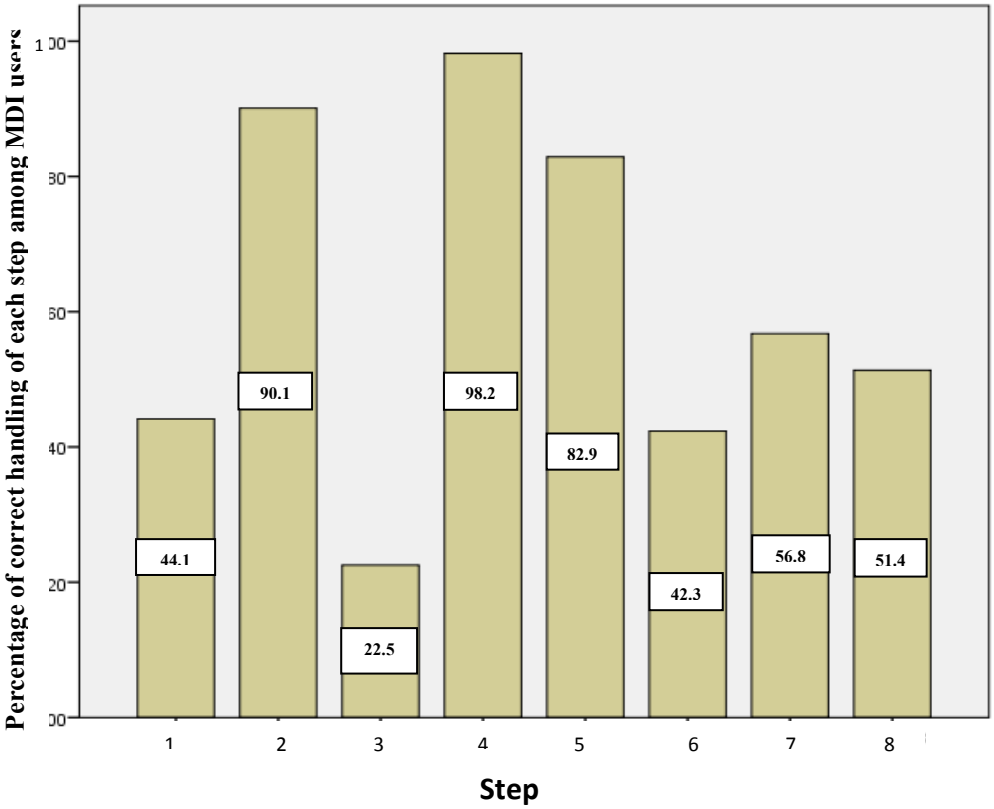

Figure (4): The percentage of correct handling committed in each step among metered dose inhaler users.

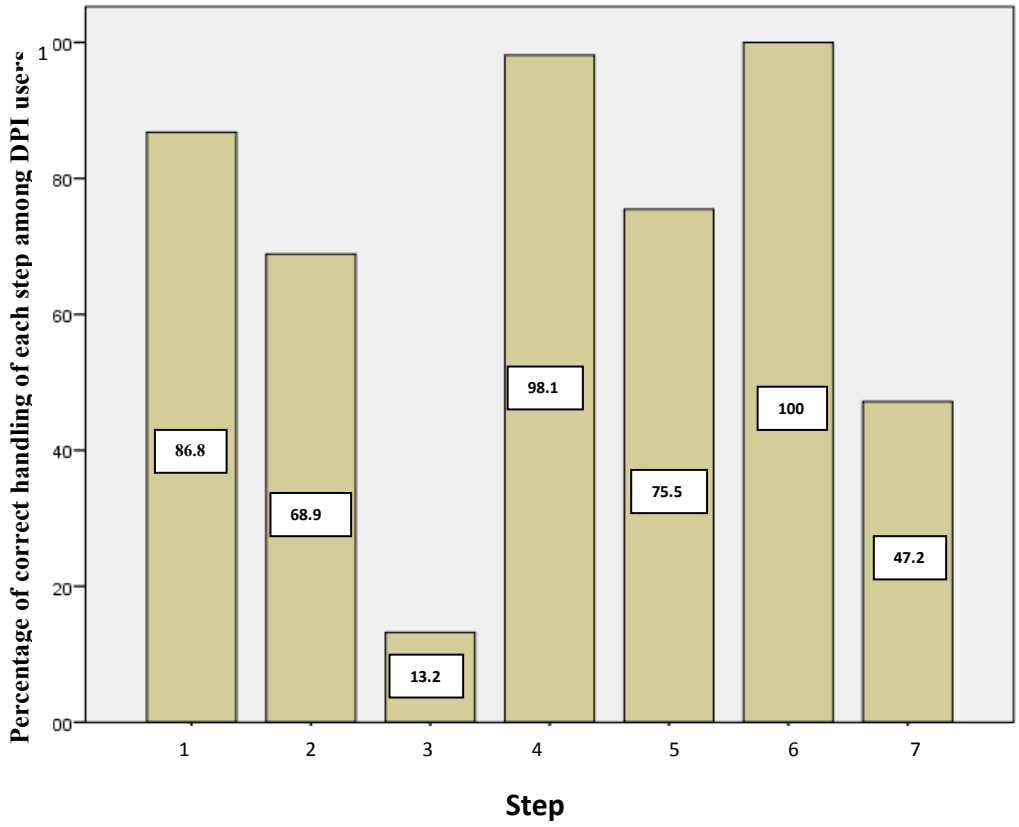

Figure (5): The percentage of correct handling committed in each step among dry powder inhaler users

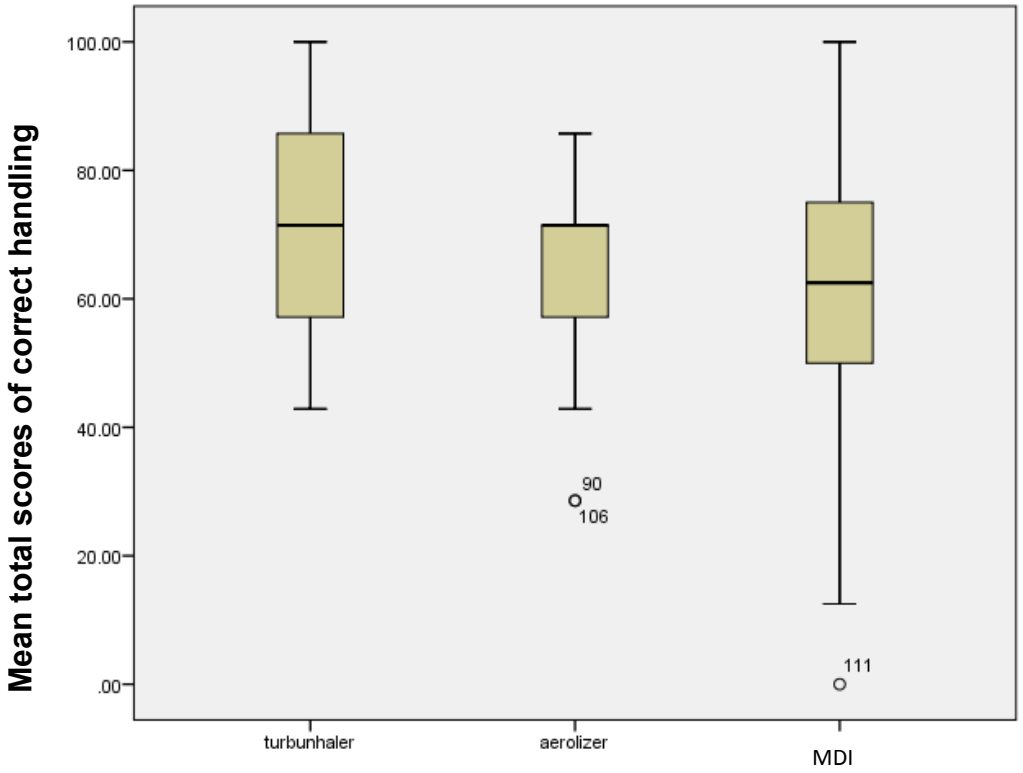

Figure (6): Comparison of correct handling among types of inhaler devices

Table (2): Percentage of incorrect handling committed in critical steps in handling metered dose inhaler (MDI) and dry powder inhaler (DPI) devices.

Device	Critical step	N (%)
MDI	Shake the inhaler and remove protective cap	**62 (55.9%)**
	Inhale slowly and simultaneously active the canister	**19 (17.1%)**
DPI	Prepare the inhaler before usage	**14 (13.2%)**
	Inhale forcefully and deeply	**26 (24.5%)**

Abbreviations: DPI: dry powder inhaler, MDI: metered dose inhaler

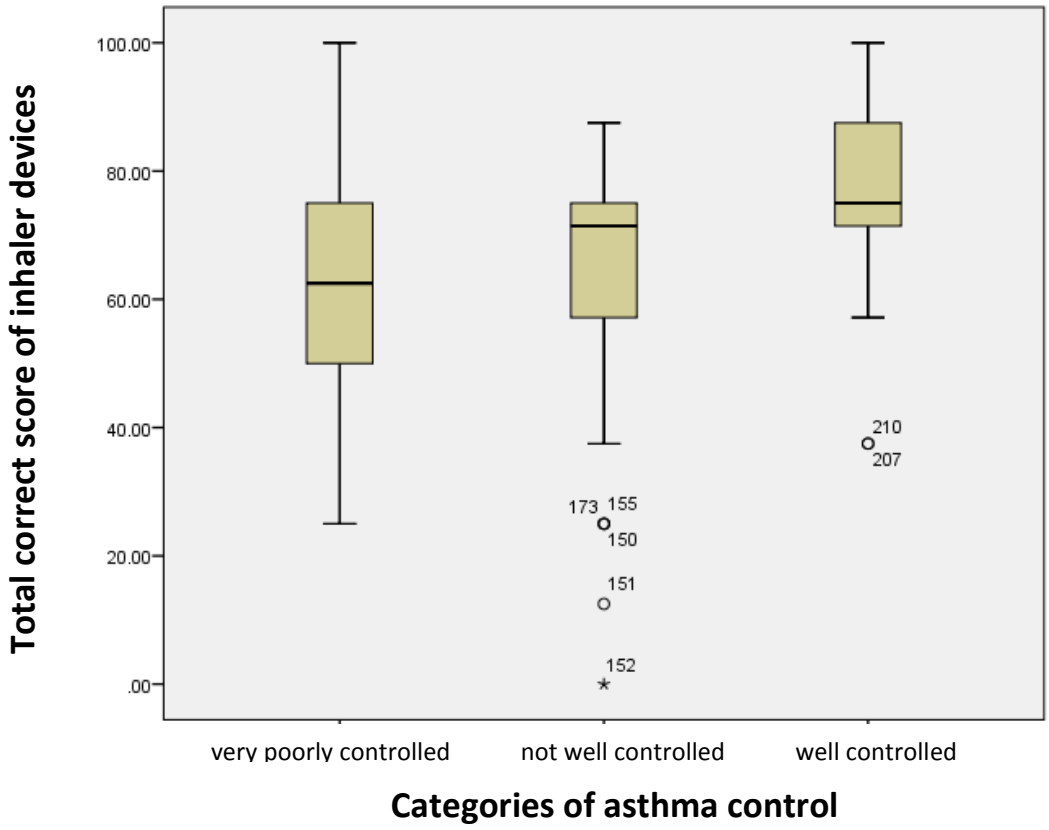

Figure (7): Total correct score of inhaler device handling stratified by level of asthma control.

Table (3): Factors associated with correct use of inhaler devices

Variable		Percentage n = 149	p-value	MDI (%) n = 217	p-value	Turbuhaler (%) n = 217	p-value	Aerolizer (%) n = 217	p-value
Gender	Male	36.9	0.756	35.1	0.323	31.6	0.640	33.3	0.201
	Female	63.1		64.9		68.4		66.7	
Age (years)	12-35	32.2	0.372	26.1	0.514	28.9	0.706	16.7	0.922
	36-55	34.2		36.9		40.8		36.6	
	> 56	33.6		36.9		30.3		46.6	
Educational level	≥ college	36.9	0.006*	33.3	0.008*	40.8	0.182	20	0.272
	< college	63.1		66.7		59.2		80	
Smoking	Yes	16.1	0.992	16.2	0.656	14.5	0.370	16.7	0.456
	No	83.9		83.8		85.5		83.4	
Duration of asthma	< 10 years	49	0.211	25.2	0.461	27.6	0.627	30	0.088
	≥ 10 years	51		74.8		72.4		70	
Number of inhaler devices	One	47	0.402	28.8	0.844	31.6	0.162	33.3	0.217
	Two	48.3		64.9		63.2		50	
	Three	4.7		6.3		5.3		16.7	
Herbal use	Yes	46.3	0.169	18	0.119	43.4	0.046*	33.3	0.420
	No	53.7		82		56.6		66.7	
ICS use	Yes	65.1	0.014*	53.2	0.221	100	–	63.3	0.303
	No	34.9		46.8		0		36.7	
Asthma control	Well	14.7	0.000*	11.7	0.010*	22.4	0.031*	0	0.805
	Not well	37.6		34.2		38.2		30	
	Poor	47.7		54.1		39.5		70	

Abbreviations: MDI: metered dose inhalers, ICS: inhaler corticosteroids

*** p-value is significant.**

Chapter Five

Discussion

Chapter five
Discussion

The main objective of this study was to assess administration technique of inhaler devices by patients attending a private pulmonary clinic in northern Palestine, we screened asthma patients to be more specific in airway diseases, also patients under 18 years were excluded because we used the ATAQ of adults (over 18 years) to measure asthma control, since our study cares about how the patient will use the device after a period since the first time he took an education about how to use it, and this is what was done in many previous studies worldwide [2, 11], we tend to exclude those patients who had learned how to use their devices in the previous three months.

The results of this study indicated that correct handling of inhaler devices is uncommon among the study patients. Furthermore, MDI devices had significantly lower scores of correct handling compared to DPI devices. Correct handling of inhaler device was significantly related with educational level and ICS use.

Low scores of correct handling of inhaler devices reported in this study are consistent with results published previously [7, 36]. A potential explanation of these low scores of correct handling of inhaler devices is the possibility that treating physicians may not spend enough time with their patients to teach them the proper use of the inhaler device. Furthermore, it is possible that the education techniques demonstrated by the healthcare providers are done without an actual inhaler or demonstration device.

Unfortunately, published reports indicated that health care providers themselves might not be acquainted with proper device handling [37-39]. In a study of medical interns, only 5% were found to be able to correctly use an MDI device [40].The same study showed that a substantial increase in correct use occurred after one training session [40]. In a systematic review of educational programs for self-management of asthma in children and adolescents, education was associated with improved lung function, reduced school absenteeism, decreased numbers of days with restricted activities and fewer visits to emergency departments [41]. Other potential reasons for inhaler errors include the device itself, patients' beliefs and adherence. Patients who believe using their inhaler is an important part of their asthma management demonstrate higher levels of correct inhaler use [42]. Another important factor to consider is patient preference for inhalers. Evidence indicates that patients do express preference for particular inhaler devices and that this is associated with increased ease of teaching the patient how to use the inhaler as well as increased likelihood of correct use [32, 43]. The low scores of correct handling of inhaler devices might indicate that patients are not getting the maximal therapeutic benefit from inhaler therapy. It has been reported that inadequate inhaler instruction and poor inhaler technique are major causes of poor disease control [2, 44-47].

Previous studies examining type of device and inhaler technique in real-life settings have had mixed results [2, 7, 22-23, 48]. Some previous studies have shown no difference in technique between various device types [23, 48]. However, some other studies showed that MDI users had

worse techniques than users of other delivery devices [2, 7, 22]. In a review of 21 studies looking at misuse of metered dose inhalers, poor technique was estimated to be prevalent in 14 - 90% (with an average of 50%) of cases [36].

Although the majority of the patients in our study claimed that they have been taught the proper use of the inhaler device, either by physicians, health care professionals, parents and family members or others, yet the prevalence of correct handling was low in many steps of either MDI or DPIs. Actually, most of the patients have been taught the proper use of inhaler device through demonstration which seems an ineffective procedure compared to practical and training methods. A study by Madueno Caro *et al*. (2000) showed that practical experience concerning inhalation systems is much better than theoretical knowledge [49]. Another study showed that patients who learned the use of inhalers by demonstration had a lower mean score of correct inhaler technique compared by those who learn how to use inhalers by leaflets [16].

The majority of patients in this study claimed that they were taught by physicians (71.1%) while just about 12% claimed that they were taught how to use the inhaler by dispensing pharmacists. Pharmacists should get more involved in patient counseling. Pharmacists can play a significant role in patient education and counseling of inhaler devices if they are well trained to do that. A study has demonstrated that a single instructional session can dramatically improve a community pharmacist's ability to

demonstrate the correct method of actuation [29]. Primary care physicians may rely on the community pharmacist to educate patients in the proper use of medications. This includes the correct actuation sequence for inhaler devices.

The MDI is still the most frequently prescribed inhaler device worldwide despite the fact that most patients cannot use it correctly [32]. This is because MDIs require good coordination of patient inspiration and inhaler activation to ensure correct inhalation and deposition of drug in the lung. Patients frequently fail to continuously inhale slowly after activation of the inhaler and exhale fully before the inhalation [50]. In addition, patients often activate the inhaler before inhalation or at the end of inhalation and conclude inhaler activation while breath-holding [50]. A study of MDI use in a group of 115 asthmatics showed that 72% of patients who received no instruction were unable to use their MDI correctly compared with 48% after physician training. Another study carried out in 207 patients revealed that almost half of these patients (47%) used their MDI inadequately, women more frequently than men [51].

This study indicated that correct handling of inhaler devices was significantly lower with MDI compared to DPI. Several reasons could explain this finding. MDI device is inherently more difficult to use and needs proper coordination, regardless of the quality of the inhaler technique education the patient has received [7]. In the current study the most frequent critical error in handling the MDI was the inability to

simultaneously trigger the device and inhale slowly and deeply. Adding a spacer to the MDI helps to eliminate poor hand-lung coordination [52]. However the effect of a spacer was not evaluated in this study because the spacer was not commonly used among our patients.

Educational level was significantly correlated with scores of correct handling. This finding is in agreement with those reported by a study published in Saudi Arabia [16]. Results shows also that age and duration of asthma disease were not significantly correlated with scores of correct handling. This might suggest that patients from all age groups are trying to be careful to use the device in the correct way. Furthermore, this finding might suggest that the severity of the illness rather than the duration is the detrimental factor for correct use of the device. This finding is in agreement with Saudi study which did not find significant differences in the mean correct score between various age categories [16]. Our results contradict that of Allen, 2002 who showed that elderly patients are unable to use MDI simply because of cognitive impairment [53]. Regarding smoking, we found no significant difference in correct handling of the device between smokers and non-smokers. This result is different than that reported by other studies.

Simultaneous use of various inhaler devices was not significantly associated with the score of correct handling. It appears that using more than one device simultaneously makes it confusing and more difficult to handle each device correctly as Hassan et al reported that patients who were using more devices get lower scores of correct handling, his finding is

in disagreement with ours while Khasawaneh reported results similar to what we find [2, 16].

Some studies showed that DPI devices were better handled than MDI devices among patients, and there were differences in the handling of the various DPI devices [7]. These results were different from those reported in other controlled trials [48]. Some of these recent studies suggest that when salbutamol is given via the Turbuhaler, only half the dose is required compared with drug given by the MDI [54]. Although more recent studies showed no differences between the doses in the two devices [48]. With the conventional MDI, inefficient inhaler use is a common problem with many patients unable to co-ordinate actuation of the device with inhalation. Surveys suggest that MDI are badly used by 14–90% of patients [7] . This in turn, can result in poor drug delivery, decreased disease control and increased inhaler use. This problem obviously has cost implications, both in terms of medication, visits to the specialist, and hospital admissions [7, 32].

Limitations

Our study has some limitations that need to be mentioned.

1. The relatively small sample size which also limited the type of inhaler devices studied.

2. Furthermore, the study was carried out at one clinic and therefore the study does not represent patients from Palestine although it represents patients from a major district in Palestine

Conclusions and Recommendations

1. In actual pulmonary clinical practice the majority of patients were unable to use MDI correctly, whereas correct handling of DPI devices was acceptable.

2. Regular checking of inhalation technique and proper teaching by health care providers are crucial for optimum use of most inhaler devices.

3. Most of the patients in this study get their education about how to use their inhalers from the physician, and low scores of correct use were got, it is recommended to increase the role of the pharmacist as the medication expert in educating the patients how to use their inhalers.

3. Further and larger studies that correlate proper handling of inhalers in real practice with clinical efficacy and disease control are needed.

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Appendices

Appendix (1) [12]: Checklists Used to Assess Inhaler Technique

Checklists Used to Assess Inhaler Technique	
Metered Dose Inhaler	**Dry Powder Inhaler**
1. Shake the inhaler and remove protective cap	**1. Prepare the inhaler before usage**
2. Hold inhaler upright	**2. Keep inhaler horizontal**
3. Exhale to residual volume	**3. Exhale to residual volume**
4. Place mouthpiece between lips and teeth	**4. Place mouthpiece between lips and teeth**
5. Inhale slowly and simultaneously active the canister	**5. Inhale forcefully and deeply**
6. Continue slow and deep inhalation	**6. Take the inhaler out of the mouth**
7. Hold breath for 5-10 seconds	**7. Hold breath for 5 seconds**
8. Take inhaler out of mouth and hold breath for 5-10 seconds	

Appendix (2): Data collection form

بسم الله الرحمن الرحيم

إستبيان خاص

"تقييم مدى صحة استخدام أجهزة الاستنشاق (البخاخات) بين مرضى الربو"

لأغراض البحث العلمي كمتطلب لرسالة الماجستير في الصيدلة السريرية – جامعة النجاح الوطنية – نابلس – فلسطين

الطالبة علا عادل صلاح

*** المعلومات الشخصية**

1- الجنس : _____ 2- العمر : _____

3- مستوى التعليم: _____

4- مكان السكن الدائم: _____

5- هل انت مدخن أ. نعم ب. لا ج. مدخن سابق

اذا كان الاجابة نعم، كم عدد السجائر اليوميه؟ _____

6- هل تدخن الأرجيلة أ. نعم ب. لا ج. سابقاً

7- عدد سنوات الاصابة بالربو : _____

8- اسماء أدوية الربو المستخدمة:

_____

9- عدد أجهزة الاستنشاق (البخاخات) المستخدمة وأنواعها:

_____

10- هل تعلمت سابقاً على كيفية استخدام جهاز الاستنشاق الخاص بك؟ _____

اذا كانت الاجابة نعم، من الذي قام بتعليمك؟ _____

11- هل تعاني من امراض مزمنة اخرى؟ ماهي وماعدد سنوات الاصابة بها؟

_____

*** تقييم استخدام اجهزة الاستنشاق**

قائمة التدقيق المستخدمة لتقييم استخدام اجهزة الاستنشاق			
بخاخات البودرة الجافة (DPIs)		بخاخات الجرعات المقاسة (MDIs)	
تحضير البخاخ قبل الاستعمال		هز البخاخ وازالة الغطاء	
ابقاء البخاخ افقيا		امساك البخاخ عموديا	
الزفير الكامل		الزفير الكامل	
وضع قطعة الفم بين الاسنان والشفتين		وضع قطعة الفم بين الاسنان والشفتين	
الاستنشاق بقوة وعمق		الاستنشاق ببطئ وبنفس الوقت تشغيل العلبة	
ازالة البخاخ من الفم		الاستمرار بالاستنشاق البطئ والعميق	
حبس النفس ل 5 ثواني		حبس النفس من 5-10 ثواني	
نوع ال DPIالمستخدم:		ازالة البخاخ من الفم وحبس النفس من 5-10 ثواني	

*** تقييم مدى السيطرة على مرض الربو عند المريض (باستخدام مقياس ATAQ)**

1. خلال الاربعة اسابيع الماضيه هل:

a. تغيبت عن عملك/ مدرستك/ او اي نشاط يومي بسبب مرضك (الربو)؟

نعم لا غير متأكد/ة

b. استيقظت ليلا بسبب مرضك (الربو)؟

نعم لا غير متأكد/ة

c. تعتقد ان مرضك (الربو) كان مسيطر عليه بشكل جيد؟

نعم لا غير متأكد/ة

2. هل تستخدم جهاز الاستنشاق للاغاثة السريعة من اعراض الربو؟

نعم لا غير متأكد/ة

إذا كانت الاجابة نعم:

في الاربع اسابيع الماضية' ما هو أكبر عدد من البخات المستخدمة من جهاز الاستنشاق خلال يوم واحد؟

أ. 0 ب. 1-4 ج. 5-8

د. 9-12 ه. اكثر من 12

*** تقييم مدى التزام المريض باستخدام ادوية الربو الخاصة به:**

1. عندما تشعر بأن مرض الربو لديك تحت السيطرة، هل تلجأ أحيانا الى التوقف عن إستعمال الدواء؟

2.تناول العلاج بشكل يومي قد لا يروق لبعض الناس. هل تشعر بعدم رضا أو إمتعاض أو تشويش بسبب التزامك اليومي بالدواء؟

3.كم من الأحيان تواجه صعوبة في تذكر تناول جميع أدويتك؟ (يرجى وضع دائرة حول الرقم الصحيح)

أبدا / نادرا	0	من حين الى حين	1	أحيانا	2
عادة	3	دائما	4		

4.هل تنسى أحيانا أن تتناول دواءك الخاص بمرض الربو ؟

5.لا يتناول الناس احيانا الأدوية الخاصة بهم لأسباب أخرى غير النسيان. هل كان هناك أية أيام على مدى الأسبوعين الماضيين لم تتناول فيها دواءك الخاص بمرض الربو؟

6.هل سبق لك أن خفضت أو توقفت عن تناول دواء الربو دون أن تخبر طبيبك وذلك لأنك شعرت بأن حالتك الصحية أصبحت أسوأ عندما تناولت الدواء؟

7.عندما تسافر أو تغادر المنزل ، هل تنسى أحيانا إصطحاب دواء الربو الخاص بك؟

8.هل تناولت دواء الربو بالأمس؟

*** تقييم استخدام الاعشاب من قبل مرضى الربو:**

هل تستخدم اعشابا بهدف علاج مرض الربو لديك او التخفيف من حدته؟ _____

اذا كانت الإجابة نعم، الرجاء ذكر هذه الأعشاب:

_____

Appendix (3): informed consent form

جامعة النجاح الوطنية

كلية الدراسات العليا

نموذج موافقة على المشاركة في بحث

- ✓ الباحثة: علا عادل صلاح الطالبة في كلية الدراسات العليا قسم الصيدلة السريرية، جامعة النجاح الوطنية
- ✓ المشرف: البروفيسور وليد صوليح أستاذ في كلية الصيدلة جامعة النجاح الوطنية و الدكتورة سماح الجابي استاذ في كلية الصيدلة جامعة النجاح الوطنية.
- ✓ الجهة المشرفة: جامعة النجاح الوطنية كلية الدراسات العليا قسم الصيدلة السريرية
- ✓ عنوان البحث: تقييم مدى صحة استخدام أجهزة الاستنشاق (البخاخات) بين مرضى الربو

Assessing appropriate use of inhaler devices among asthmatic patients

يحتوي هذا الملف على :

1. معلومات وتفاصيل البحث
2. شهادة الموافقة على المشاركة في البحث

(سيقدم لكل مشارك نسخة كاملة عن ورقة الموافقة على المشاركة في البحث)

معلومات وتفاصيل البحث

مقدمة

أخي/ أختي المشارك/ة:

انا الصيدلانية علا عادل صلاح طالبة ماجستير صيدلة سريرية في جامعة النجاح الوطنية يسرني ان ادعوك الى المشاركة في بحثي المتعلق بتقييم مدى صحة استخدام أجهزة الاستنشاق (البخاخات) بين مرضى الربو.

لك كامل الحرية والارادة في المشاركة في هذا البحث ولك الحق في اخذ الوقت الكافي للتفكير في المشاركة من عدمها وسؤال الباحثة عما تراه مناسبا والتحدث لاي شخص او جهة عن هذا البحث.

كما يمكنك الاستفسار عن اي جزء يتعلق في البحث الان او فيما بعد واذا كانت هناك كلمات او اجزاء غير مفهومة بامكانك سؤال الباحثة وستجد/ين الوقت والاجابة الكافيتين.

يضمن البحث سرية المعلومات المتعلقة بالمشارك/ة.

الهدف من البحث

يهف هذا البحث لتقييم مدى صحة استخدامك لاجهزة الاستنشاق الخاصة بعلاج مرض الربو لديك والمقارنة بين نوعين مختلفين من اجهزة الاستنشاق المستخدمة لعلاج الربو في بلادنا من حيث صحة استخدامهم، كما تهدف لتقييم مدى السيطرة على مرض الربو لديك والنظر في مسببات السيطرة على مرضك، كما ان مشاركتك ودعمك لهذا البحث سيساهمان في تطوير وتعزيز الواقع الصحي في فلسطين.

طبيعة المشاركة في البحث

بعد الموافقة على المشاركة في البحث سنطلب من المشارك ان يرينا كيفية استخدامه لجهاز الاستنشاق الخاص به، تليها مقابلة شفوية لاخذ معلومات تتعلق بالعوامل الاجتماعية والديموغرافية، ثم اربعة اسئلة للاستفسار عن وضع المريض الصحي لتحديد مدى السيطره على مرضه.

اختيار المشاركين

سيتم اختيار المشاركين من المرضى الذين يستخدمون اجهزة الاستنشاق الخاصة بمرض الربو لفترة لا تقل عن ثلاثة شهور ماضية والمراجعين في عيادة الدكتور نضال شوكت– نابلس بشكل ملائم لاغراض البحث.

المشاركة طوعية واختيارية وبامكان المشارك الانسحاب من البحث في اي وقت ودون الحاجة لابداء الاسباب وبدون اي تبعات.

المدة المتوقعة لانهاء اجراءات البحث

عشرة دقائق لكل مشارك.

شهادة الموافقة على المشاركة في البحث

اقرار من المشاركة في البحث:

قمت بقراءة المعلومات الواردة في ورقة معلومات البحث واتيحت لي الفرصة ان اسال اي سؤال وقد تمت الاجابة على كافة اسئلتي بشكل كاف، وبناءا على ذلك اوقع طوعيا على المشاركة في هذا البحث.

اسم المشارك.....

توقيع المشارك.....

التاريخ.....\.....\.....

اقرار من الباحثة:

قمت بقراءة المعلومات الواردة في ورقة معلومات البحث بطريقة صحيحة وواضحة، وبذلت جهدي ان يعي المشارك ان البحث سيتضمن:

1. مقابلة المشارك في البحث في عيادة الدكتور نضال شوكت والتحدث اليه شفويا لاخذ المعلومات المتعلقة بالعوامل الاجتماعية والديموغرافية، ثم الاجابة عن اربعة اسئلة للاستفسار عن وضع المريض الصحي لتحديد مدى السيطره على مرضه.
2. الطلب من المشارك ان يرينا كيفية استخدامه لجهاز الاستنشاق الخاص به.

اؤكد على ان المشارك اخذ الفرصة الكافية للاجابة على اسفساراته بشكل واضح وصحيح وبذلت ما بوسعي لتحقيق ذلك.

اؤكد ان المشارك لم يجبر على التوقيع على الورقة وان مشاركته كانت بمحض ارادته وكامل اختياره.

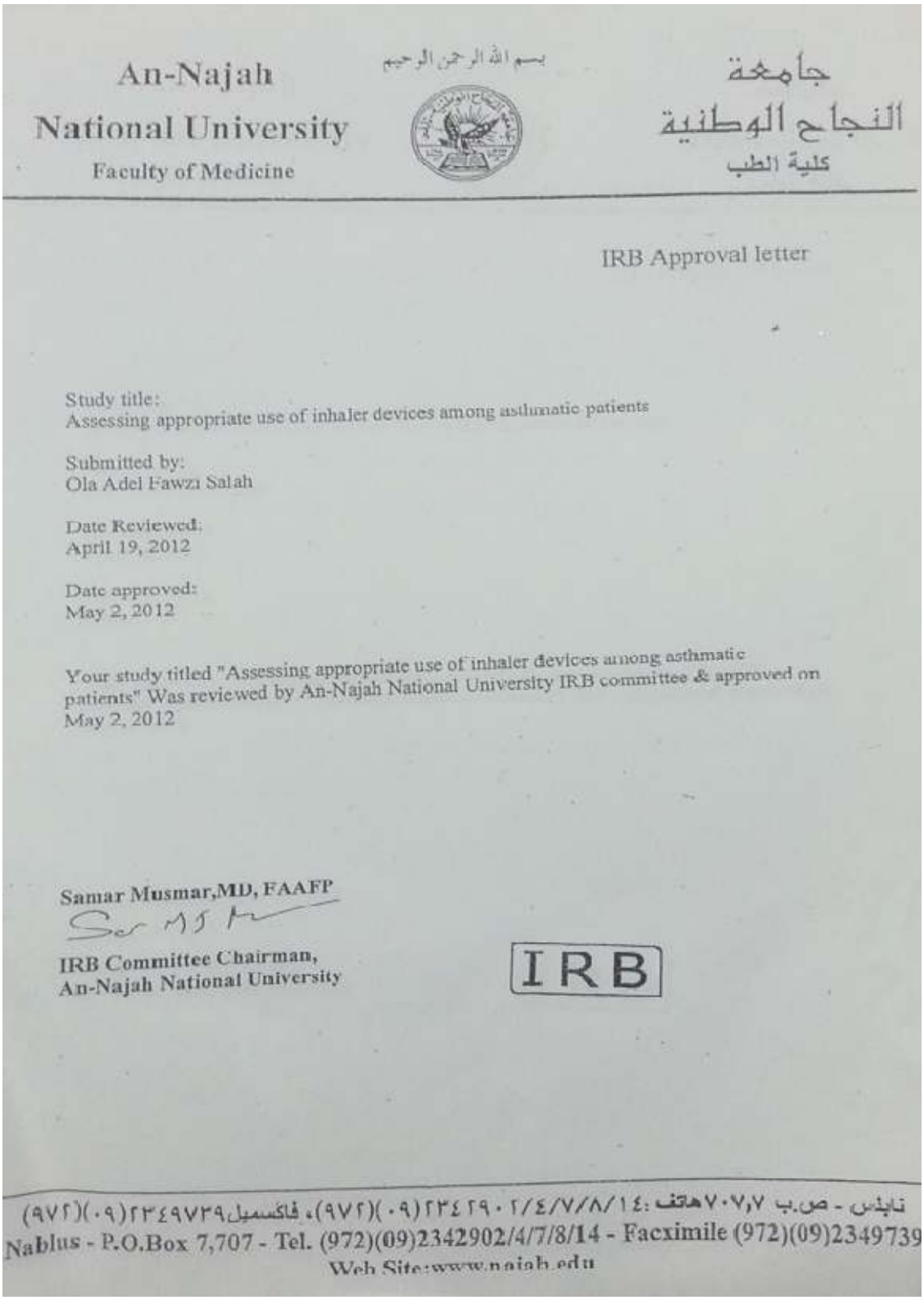
الباحثة علا عادل صلاح

توقيع الباحث.....

التاريخ.....\.....\.....

(يتم عمل نسختين من هذه الشهادة واحدة للباحثة واخرى للمشارك/ة ان رغب/ت بذلك)

Appendix (4): IRB approval



An-Najah
National University
Faculty of Medicine

بسم الله الرحمن الرحيم

جامعة
النجاح الوطنية
كلية الطب

IRB Approval letter

Study title:
Assessing appropriate use of inhaler devices among asthmatic patients

Submitted by:
Ola Adel Fawzi Salah

Date Reviewed:
April 19, 2012

Date approved:
May 2, 2012

Your study titled "Assessing appropriate use of inhaler devices among asthmatic patients" Was reviewed by An-Najah National University IRB committee & approved on May 2, 2012

Samar Musmar,MD, FAAFP
IRB Committee Chairman,
An-Najah National University

IRB

نابلس - ص.ب ٧٠٧,٧ هاتف: ١٤/٨/٧/٤/٢٠٩٠٢٣٤٢ (٠٩)(٩٧٢)، فاكسميل ٢٣٤٩٧٣٩ (٠٩)(٩٧٢)
Nablus - P.O.Box 7,707 - Tel. (972)(09)2342902/4/7/8/14 - Facsimile (972)(09)2349739
Web Site:www.naiah.edu

Appendix (5): Asthma therapy assessment questionnaire [33]

A. The tool questions and how the score is calculated are as follows:

1. In the past 4 weeks, did you:

a. Miss any work, school, or normal daily activity because of your asthma?

Yes (1) No (0) Unsure (1)

b. Wake up at night because of asthma?

Yes (1) No (0) Unsure (1)

c. Believe that your asthma was well controlled?

Yes (0) No (1) Unsure (1)

2. Do you use an inhaler for quick relief from asthma symptoms?

Yes No Unsure

If yes, in the past 4 weeks, what was the highest number of puffs in 1 day you took of the inhaler?

0 (0) 1 to 4 puffs (0) 5 to 8 puffs (1)

9 to 12 puffs (1) More than 12 puffs (1)

The score for this scale was calculated both manually and using the electronic calculator on the web site

http://www.asthmacontrolcheck.com/asthma_control/asthmacontrolcheck/consumer/index.jsp.

B. The results of the scale will be as shown in table 2.

Extent of asthma control	Well Controlled	Not Well Controlled	Very Poorly Controlled
ATAQ score	0	1 - 2	3 - 4

Appendix (6): Morisky scale [35]

1. **هل تنسى أحيانا أن تتناول الدواء (الخاص بمشكلتك الصحية) ؟**
2. **لا يتناول الناس احيانا الأدوية الخاصة بهم لأسباب أخرى غير النسيان. هل كان هناك أية أيام على مدى الأسبوعين الماضيين لم تتناول فيها الدواء (الخاص بمشكلتك الصحية)؟**
3. **هل سبق لك أن خفضت أو توقفت عن تناول الدواء (الخاص بمشكلتك الصحية) دون أن تخبر طبيبك وذلك لأنك شعرت بأن حالتك الصحية أصبحت أسوأ عندما تناولت الدواء؟**
4. **عندما تسافر أو تغادر المنزل ، هل تنسى أحيانا إصطحاب الدواء (الخاص بمشكلتك الصحية)؟**
5. **هل تناولت الدواء (الخاص بمشكلتك الصحية) بالأمس؟**
6. **عندما تشعر بأن (المشكلة الصحية لديك) تحت السيطرة، هل تلجأ أحيانا الى التوقف عن إستعمال الدواء؟**
7. **تناول العلاج بشكل يومي قد لا يروق لبعض الناس. هل تشعر بعدم رضا أو إمتعاض أو تشويش بسبب التزامك اليومي بالدواء؟**
8. **كم من الأحيان تواجه صعوبة في تذكر تناول جميع أدويتك؟ (يرجى وضع دائرة حول الرقم الصحيح)**

أبدا / نادرا	**0**
من حين الى حين	**1**
أحيانا	**2**
عادة	**3**
دائما	**4**

جامعة النجاح الوطنية
كلية الدراسات العليا

تقييم مدى صحة استخدام أجهزة الاستنشاق (البخاخات) بين مرضى الربو

اعداد
علا عادل فوزي صلاح

اشراف
أ. د. وليد صوليح
د. سماح الجابي

قدمت هذه الأطروحة استكمالاً لمتطلبات الحصول على درجة الماجستير في الصيدلة السريرية في كلية الدراسات العليا في جامعة النجاح الوطنية في نابلس، فلسطين.

2013م

تقييم مدى صحة استخدام أجهزة الاستنشاق (البخاخات)
بين مرضى الربو

اعداد

علا عادل فوزي صلاح

اشراف

أ. د. وليد صوليح

د. سماح الجابي

الملخص

المقدمة وهدف الدراسة: الاستخدام الصحيح لأجهزة الاستنشاق الخاصة بمرض الربو؛ كأجهزة الاستنشاق ذات الجرعات المقننة MDIs وأجهزة الاستنشاق بالمساحيق الجافةDPIs ؛ لم تدرس جيدا بعد في دولة فلسطين والدول العربية الاخرى. أهداف الدراسة تشمل تقييم الاستخدام الصحيح لأجهزة الاستنشاق لدى المرضى وتقييم مدى التحكم بالمرض لديهم ومن ثم الربط بين الاستخدام الصحيح لأجهزة الاستنشاق ومدى التحكم بالمرض.

المنهجية: دراسة تقييم استطلاعية مستقبلية أجريت في عيادة أمراض صدرية خاصة في مدينة نابلس، فلسطين. تمت دراسة أجهزة استنشاق ذات جرعات مقننة MDIs (بدون استخدام العبوات الفارغة المستعملة لإيجاد مسافة بين جهاز الاستنشاق والمريض) وأجهزة استنشاق بالمساحيق الجافة DPIs (aerolizers and turbuhalers). الاستخدام الخاطئ لاجهزة الاستنشاق عرف بناء على تقنية موحدة لتحديد التقنيةغير المناسبة لاستخدام اجهزة الاستنشاق. التحكم بمرض الربو لدى المرضى قيمت باستخدام مقياس ATAQ.

النتائج: تضمنت الدراسة 149 مريضا بمعدل عمر 47.5 ± 18.5، خمس وخمسون (36.9%) منهم يحملون شهادات جامعية، من هؤلاء المرضى وجد أن 42 (28.2%) يستخدمون MDIs، 38 (25.5%) يستخدمون DPIs و 69 (46.3%) يستخدمون كلا الجهازين، في النهاية حصلنا على 217 استبيان مملوء خاص بأجهزة الاستنشاق: 111 (51.2%) منهم يختصون بال MDIs و 106 (48.8%) منهم يختصون بال DPIs. اكثر الخطوات انجزت

بطريقة خاطئة كانت الخطوة الثالثة (الزفير لاخر نفس) في كلا أجهزة الاستنشاق 22.5% و 13.2% من المرضى المستخدمين لل MDIs وال DPIs على التوالي، وكانت متوسطات علامات المرضى للاستخدام الخاطئ لل MDIs, turbuhalers و aerolizers هي 61 ± 20.1، 71.4 ± 14.9 و 66.2 ± 15.7على التوالي. باستخدام مقياس ATAQ وجدت الدراسة أن 22 (14.8%) من المرضى لديهم تحكما جيدا بمرض الربو، 56 (37.6%) من المرضى يمتلكون تحكما غير جيد بمرضهم وأن 71 (47.7%) منهم يمتلكون تحكما ضعيفا بمرضهم. مستوى التعليم لدى المرضى كان له أثر هام بعلامات المرضى في استخدام اجهزة الاستنشاق (p = 0.006).

الخلاصة: في العيادة الرئيسية للأمراض الصدرية في شمال فلسطين وجد أن معظم المرضى يستخدمون أجهزة الاستنشاق الخاصة بهم بطريقة غير مناسبة، بدون أي فارق ذو أهمية بالنتائج بين ال MDI و ال DPI. ووجد أن معظم المرضى لديهم تحكما ضعيفا بمرض الربو.