Pulmonary Pharmacology & Therapeutics 43 (2017) 46–54

Contents lists available at ScienceDirect

Pulmonary Pharmacology & Therapeutics

journal homepage: www.elsevier.com/locate/ypupt

Mastery of pMDI technique, asthma control and quality-of-life of children with asthma: A randomized controlled study comparing two inhaler technique training approaches

Wesam G. Ammari [a, *], Nussaibah Al-Hyari [a], Nathir Obeidat [b], Mona Khater [b], Amal Sabouba [c], Mark Sanders [d]

[a] Department of Clinical Pharmacy, Faculty of Pharmacy and Medical Sciences, Al-Ahliyya Amman University, Jordan
[b] Department of Respiratory Medicine, Jordan University Hospital, Jordan
[c] Department of Paediatric Respiratory Medicine, Al-Hussain Public Hospital, Jordan
[d] Clement Clarke International, Harlow, United Kingdom

ARTICLE INFO

Article history:
Received 21 August 2016
Received in revised form
14 November 2016
Accepted 12 February 2017
Available online 17 February 2017

Keywords:
pMDI technique
Verbal counselling
Trainhaler
Inhalation flow rate
Asthma control
Quality of life

ABSTRACT

Objective: Verbal counselling (VC) is the clinical standard for training patients on correct inhaler use. Patients fail to recall their VC with time. Ethical approval was obtained to compare the pressurized metered dose inhaler (pMDI) VC with Trainhaler (TH), a novel pMDI inhalation flow and technique training device, in children with asthma.

Methods: At visit 1, 7–17 year-old children with a pMDI hand-lung coordination problem including a fast peak inhalation flow (PIF) through pMDI >60 L/min were randomized into either VC group that received verbal pMDI training; or into TH group that were trained on- and given TH to practice at home. Whereas, children with correct pMDI use formed the control group (CT). Overall pMDI technique, PIF through inhaler, asthma control (AC) and quality of life (QoL) were evaluated. Participants were re-evaluated 6–8 weeks later (visit 2).

Results: Of 105 enrolled children; 76 completed the study (VC = 21, TH = 25 and CT = 30). VC decreased non-significantly ($p > 0.05$) the mean PIF from 104.0 L/min at visit 1 to 84.8 at visit 2. Whilst, the TH did significantly ($p < 0.05$) reduce the PIF from 113.5 to 71.4 L/min. The two approaches similarly and significantly ($p < 0.05$) improved the inhaler technique, AC and QoL scores.

Conclusions: The TH improved the inhalation flow through the pMDI close to the ideal needed for adequate lung deposition. Both methods equally enhanced the children's mastery of pMDI use. This was reflected on better AC and QoL. Accessibility to TH might help maintaining the good inhaler use and decreasing regular VC.

1. Introduction

The pressurized metered dose inhaler (pMDI) remains a key inhaler option in asthma management, [1,2]. Despite its wide global prescription, patients commonly use their pMDIs improperly, [3–5]. Although the correct pMDI technique (Fig. 1) seems simple to understand and follow, many patients do forget the inhaler verbal training they frequently receive; particularly coordinating the start of a slow and deep inhalation flow through the inhaler with actuating its canister to release the aerosol, [6,7]. A slow inhalation flow profile achieved by the patients through their pMDIs is critical for therapeutically adequate lung deposition; where a peak inhalation flow (PIF) in this profile should be slightly less than or around 30 L/min, [8,9]. However, a PIF up to 60 L/min through the pMDI is acceptable when patients cannot learn to modulate their inspiratory efforts to achieve the slower PIF through their pressurized inhalers, [10]. Nevertheless, it has been reported that most patients using pMDIs inhale at a much faster flow (>100 L/min), [6,7,11].

Using a spacer device with a pMDI improves drug delivery to lungs and decreases the risk of side effects, [12]. International

* Corresponding author. Faculty of Pharmacy and Medical Sciences, Al-Ahliyya Amman University, Zip Code 19328 Amman, Jordan.
E-mail addresses: wammari@ammanu.edu.jo, w_ammari@hotmail.com (W.G. Ammari).

http://dx.doi.org/10.1016/j.pupt.2017.02.002
1094-5539/

The most desirable MDI technique
1) Remove the cap from the mouthpiece.
2) Shake the inhaler.
3) Breathe out slowly, as far as comfortable to empty your lungs.
4) Place the mouthpiece of the inhaler between your lips.
5) Close your lips around the mouthpiece creating a seal.
6) Start to breathe in slowly, through your mouth and immediately press the aerosol canister to release a dose (puff).
7) Breathe in slowly until your lungs are full of air (as far as you can), the breath in step should take you about 5 seconds.
8) Remove the inhaler from your mouth and seal your lips.
9) Hold your breath for 10 seconds.
10) Breathe out slowly.
11) Repeat steps 1 to 10 after 30 seconds if another dose is necessary.

Fig. 1. The most desirable pMDI technique.

Asthma Management Guidelines recommend using suitable spacers with pMDIs in all young children ≤5 years. In older patients, spacers can be used provided that the patients' pMDI adherence and compliance are not jeopardized. Poor adherence, which leads to poor asthma control, might arise from many factors such as therapy cost, multiple inhalers and poor understanding of inhaler use, cultural or social stigmatization, [12]. The latter can be a serious issue in school-aged children (>6 years) and adolescents, and probably is the reason why asthmatic children are prescribed and trained, when they are psychologically and physically fit, to start using their pMDIs alone without the bulky spacers, [13,14].

Patients prescribed pMDIs for the first time are normally verbally counselled (VC), with or without placebo inhaler demonstration, on the correct inhaler technique by their healthcare providers, [15]. However, only half of the trained patients managed to remember and maintain the good inhaler use within 30 days after the VC session [5], and only 60% maintained their correct pMDI use even with a spacer attachment, [16]. Therefore, routine clinic-based check and reinforcement of the patients' mastery of correct inhaler technique is performed; a practice that can be a time, effort and cost burden in busy healthcare settings.

The Aerosol Drug Management Improvement Team (ADMIT) in Europe have stated in their report that inhaler training tools designed with feedback mechanisms of good inhalation flow and technique can help patients improving and maintaining their inhaler use, [17]. Trainhaler™ (TH) is a recent pMDI training device developed by Clement Clarke International, United Kingdom. The TH (Fig. 2) has been designed to enhance the patient's Hand-Lung co-ordination along with a slow and deep inhalation flow through their pMDIs. When the patient inhales through the TH, they will hear a whistle sound as an audible feedback of the correct, slow inhalation flow (30–60 L/min). Once the whistling sound starts, this is the signal for the patient to immediately press the TH's canister which will produce a "Whoosh" noise feedback mimicking that of a real puff released from an actuated pMDI. The patient is instructed to change their inspiratory effort to keep the whistling sound going over at least 5 s. They will need, then, to simulate this manoeuvre when they use their real pMDI therapy. The current work aimed to compare the pMDI VC with the novel TH tool in 7–17 year-old children with asthma attending respiratory outpatient clinics. Clinical implications in asthma control and quality of life were also evaluated.

2. Methods

The approvals of the Research Ethics Committees at the Jordan University Hospital (Ref: IRB/2014/122) and at the Jordanian Ministry of Health (Ref: MOH/REC/150041) were obtained for this study which was conducted at the paediatric respiratory outpatient clinics of the involved hospitals according to Helsinki Declaration and Good Clinical Practice (ICH/GCP) Guidelines. Seven to 17 year-old children with asthma, male or female, who were originally prescribed and using pMDI therapy (without a spacer device) including a corticosteroid inhaler for at least 3 months prior to enrolment in this research were eligible for participation. Children were excluded from participation if they had experienced an acute exacerbation of asthma or had received oral prednisolone one month prior to recruitment, had other diseases adversely affecting

Fig. 2. The Trainhaler pMDI training device.