Physical ability of people with rheumatoid arthritis and age-sex matched controls to use four commonly prescribed inhaler devices

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Abstract

Background: Respiratory disease is a common co-morbidity with rheumatoid arthritis (RA). RA commonly affects the hands, but there is little research investigating whether these patients are physically able to operate inhalers.

Aim: To compare the physical ability of people with and without RA to use four commonly prescribed inhaler devices (pressurised metered dose inhaler (pMDI), Easi-Breathe®, HandiHaler® and Turbohaler®).

Methods: Adults with RA and an equal number of age-sex matched controls were observed using placebo inhaler devices. Maximum inhalation flow rate was measured with an In-Check Dial device. Dichotomous data were compared (RA versus control) using Fisher's exact test.

Results: Thirty four participants were recruited for each group. For all inhalers, fewer participants with RA were able to complete all the steps necessary to operate the device: pMDI (50% vs. 91%), Easi-Breathe® (77% vs. 97%), HandiHaler® (15% vs. 94%) and Turbohaler® (85% vs. 100%). This difference was significant ($p<0.05$) for the pMDI, Easi-Breathe® and HandiHaler®. Significantly fewer people ($p<0.05$) with RA were able to depress the pMDI canister, or to complete three steps in the operation of the Handihaler® (open the dust cap, remove the capsule from its blister, pierce the capsule). Only one participant (RA group) was unable to achieve the minimum flow rates required to operate the Turbohaler® and HandiHaler® ($p=1.000$).

Conclusions: People with RA have varying physical abilities to use inhalers effectively. A person-centred approach is required to assess which inhaler device is appropriate for each individual patient.

KEYWORDS: Arthritis, Rheumatoid; Dry Powder Inhalers; Human Engineering; Metered Dose Inhalers; Nebulizers and Vaporizers

Introduction

Respiratory diseases are common in people with rheumatoid arthritis (RA), with up to 21% of people with RA having asthma and up to 8% having chronic obstructive pulmonary disease [1]. These people are likely to need to use inhalers.

Up to 70% of people with RA develop hand disability [2], and lung complications are a common extra-articular manifestation of RA [3]. Correct use of an inhaler requires both manipulation of the device and an appropriate inhalation manoeuvre, leading to anecdotal reports that people with RA have difficulty with these techniques [4-7]. However, to date only one study has investigated the usability of inhaler devices in people with RA [8]. This found significantly lower (though satisfactory) participant-reported ease-of-use of the Genuair® device for people with hand arthritis.

This study compared the physical ability of people with and without RA to use commonly prescribed inhaler devices [9]. Devices that are representative of larger classes of device were selected: pressurised metered dose inhaler (pMDI, QVAR® brand), breath-actuated pMDI (Easi-Breathe®), HandiHaler® (capsule dry powder inhaler) and Turbohaler® (multi-dose dry powder inhaler).

The pMDI and Easi-Breathe® are low resistance devices and require a slow inhalation, so have no minimum inhalation flow requirement [10]. However, the Turbohaler® and HandiHaler® are higher resistance devices and require a minimum inhalation rate for effective drug delivery: >30 $L.min^{-1}$ and >20 $L.min^{-1}$, respectively [10]. Therefore, the ability of participants to achieve these flow rates was also investigated.

Participants and Methods

An observational study was performed with age-sex matched pairs of participants with and without RA. Adults (>18 years) with physician-diagnosed RA were recruited at National Rheumatoid Arthritis Society support group meetings. Age (±2 years) and sex matched controls were recruited via the researchers' networks. Participants gave written informed consent before participation in an individual data collection session.

Participants with RA completed the Health Assessment Questionnaire Disability Index (HAQ-DI), a widely used and psychometrically validated tool which measures functional ability in daily life in people with RA [11]. HAQ-DI scores were calculated using the standard method, giving values between 0 (no disability) and 3 (very severe disability) [11]. All participants completed the first two scales of the Michigan Hand Outcomes Questionnaire (MHQ), a psychometrically validated tool which assesses hand function [12]. MHQ scores were calculated following the method described by Chung *et al.*, giving values between 0 (minimum hand function) and 100 (perfect hand function) [12].

Steps for the operation of each inhaler device were determined from the Patient Information Leaflet. Using placebo devices, a researcher demonstrated each step and then observed the participant's ability to perform the same manipulation.

Participants did not perform an inhalation via the placebo devices. Instead, an In-Check Dial 6 device (Clement Clarke International, Harlow, UK) set to Turbohaler® resistance was used to record participants' maximum inhalation flow rate [13]. Participants performed one practice inhalation, followed by three measurements of which the highest was recorded. The flow rate that each participant could have achieved via a HandiHaler® (a higher resistance device than the Turbohaler®) was calculated using the following relationship [14] and the resistances of the HandiHaler® and Turbohaler® (0.158 and 0.120 (cm $H_2O)^{0.5}$.L.min^{-1}, respectively) [15]

$$\sqrt{Pressure\ Drop\ Across\ Inhaler} = Inhaler\ Resistance \times Inhalation\ Flow\ Rate$$

The In-Check Dial 6 device has considerable handling differences compared with the four inhaler devices. However, these differences were not relevant, as the In-Check Dial 6 device was only used to measure respiratory function (maximum inhalation flow rate), not the physical ability to manipulate inhaler devices.

Data were analysed using SPSS Statistics 22 (IBM Corp., Armonk, NY, USA). Dichotomous data were compared (RA versus control) using Fisher's exact test. MHQ scores were compared using the Mann-Whitney U-test. In all cases, a significance level of 5% was used. To have 90% power to detect a difference

between 100% of controls and 75% of people with RA being able to use an inhaler, each group required 32 participants.

The study was approved by the University of Bath Ethical Implications of Research Activity process.

Results and Discussion

Results and participants' demographic details are summarised in Table 1.

Table 1: demographic details and physical ability to use inhaler devices of participants with and without rheumatoid arthritis.

	Rheumatoid arthritis group (n=34)	**Control group (n=34)**	**P-value**
Percentage of females (n)	76% (26)	76% (26)	
Age range (years)	31 – 86	31 – 85	
Mean age (years ± SD)	60.8 ± 13.0	60.8 ± 13.2	
Percentage with respiratory co-morbidity (n)	38% (13)	12% (4)	0.023
HAQ-DI score range	0.125 – 3.0	-	
Mean HAQ-DI score ± SD	1.58 ± 0.68	-	
Median MHQ score (range)	54.9 (6.8 – 96.0)	100.0 (57.5 – 100.0)	<0.001
Pressurised metered dose inhaler – percentage (n) of participants who…			
…had previously used device	44% (15)	18% (6)	0.034
…could complete all steps	50% (17)	91% (31)	<0.001
…could remove cap	100% (34)	100% (34)	-
...could shake device	97% (33)	100% (34)	1.000
...could depress canister	53% (18)	91% (31)	<0.001
...could replace cap	100% (34)	100% (34)	-
Easi-Breathe® inhaler – percentage (n) of participants who…			
…had previously used device	18% (6)	6% (2)	0.259
…could complete all steps	77% (26)	97% (33)	0.027
...could shake device	100% (34)	100% (34)	-
...could fold down cap	91% (31)	97% (33)	0.239
...could close cap	85% (29)	100% (34)	0.197
HandiHaler® – percentage (n) of participants who…			
…had previously used device	18% (6)	3% (1)	0.105
…could complete all steps	15% (5)	94% (32)	<0.001
... could open dust cap	79% (27)	100% (34)	0.011
... could open mouthpiece	85% (29)	100% (34)	0.053
... could remove capsule from blister	65% (22)	94% (32)	0.006
... could close mouthpiece	100% (34)	100% (34)	-
... could pierce capsule	21% (7)	94% (32)	<0.001
... could remove capsule	91% (31)	100% (34)	0.239
... could close mouthpiece and dust cap	100% (34)	100% (34)	-

Turbohaler® – percentage (n) of participants who…			
…had previously used device	6% (2)	0% (0)	0.493
… could complete all steps	85% (29)	100% (34)	0.053
... could unscrew cap	97% (33)	100% (34)	1.000
... could twist grip to activate	88% (30)	100% (34)	0.114
.. could replace cap	100% (34)	100% (34)	-

Percentage (n) of participants with inhalation flow rate…			
…>30 L.min^{-1} (measured) with Turbohaler® resistance (%)	97% (33)	100% (34)	1.000
…>20 L.min^{-1} (calculated) with HandiHaler® resistance (%)	97% (33)	100% (34)	1.000

The HAQ-DI scores obtained from the RA group indicated mild through to very severe disability [11]. The MHQ scores of the RA group were significantly lower than the control group, demonstrating poorer hand function in people with RA [12]. These results suggest that representative participants were recruited.

For all inhalers, a smaller proportion of the RA group was able to complete all the necessary steps. This difference was statistically significant for the pMDI, Easi-Breathe® and HandiHaler®, despite significantly more of the RA group having previous experience of pMDI use.

The pMDI step which caused the most difficulty was depressing the canister. This applied to both groups, although the RA group were significantly less likely to complete this step. Similar results to the control group have been reported before for older people without RA [16]. This may be as a result of the force required to depress a pMDI canister [4].

For the HandiHaler® three steps caused significantly more difficulty for the RA group: opening the dust cap, removing the capsule from its blister, and piercing the capsule. The latter two steps are similar in other capsule inhaler designs, suggesting this whole class of devices might be unsuitable for people with RA.

Only one participant (RA group) was unable to achieve the minimum inhalation rates required to operate the Turbohaler® and HandiHaler®, and this participant was also unable to perform all the necessary manipulations to use either of these devices. Despite a significantly greater proportion of the RA group having a respiratory co-morbidity, there was no significant difference between the number of participants in

each group able to achieve the minimum inhalation rates. This suggests that lung manifestations of RA are not important in determining whether people are able to use an inhaler appropriately.

With time, people with RA might develop strategies to enable them to use an inhaler. However, these results were obtained despite more participants in the RA group having prior experience with each inhaler device (significantly more for the pMDI), suggesting that these findings can be extrapolated to long-term use in people with RA and respiratory disease. In addition, the participants enrolled in this study were directly representative of people with RA beginning to use a new type of inhaler. These results are therefore especially applicable to the initiation of adherence to an inhaled medicine, which is known to be poor in many patients [17].

Limitations

A large number of inhaler devices are available, so the small range used in this study is a limitation. However, the devices studied are commonly prescribed [9] and representative of larger classes. Lack of observation validation is another limitation, however the ability to perform every inhaler step could be determined objectively.

Conclusions

This is the first study comparing the physical ability of people to RA to use different inhaler devices. It demonstrates the varying physical abilities of people with RA to use inhalers effectively. Therefore, a person-centred approach is required to assess which inhaler device is appropriate for each individual patient [18, 19].

Declarations

Conflicts of interest

None.

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