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Evaluation of the long-term effectiveness of three instruction modes for inhaling medicines

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Abstract

Inhaled medication is important in the treatment of chronic obstructive pulmonary disease (COPD). In this paper a comparison of the long-term efficacy of three instruction-modes is presented. A total of 152 COPD-patients were randomized into one of four groups: Personal-, video-, group-instruction and a control group. Inhalation technique was assessed by means of checklists, on which essential inhalation manoeuvres were identified. Up to 9 months later, 148 patients returned for follow-up assessment. Prior to instruction 61% of patients in the control group had a perfect score on essential actions, compared to 62, 65 and 53% for those receiving group-, personal- and video-instruction respectively. At follow-up these percentages were 49, 97, 75 and 76%. For group-(35%) and video-instruction (24%) the increase from baseline was significant. Examining the different inhalers under investigation, it is striking, that only 24% of all patients with a Metered Dose Inhaler (MDI) performed all essential checklist items correctly, versus 96% for those using a Diskhaler. The fact that for the MDI this percentage improved to 90% post-instruction, shows that time spent on instruction, is time well spent. We conclude that group instruction seems superior to personal counselling, and equally effective or even better than video instruction. Personal instruction should not be dismissed and a combination with video instruction might prove to be effective as well.

Keywords: Patient education; Inhalation technique; Randomized controlled trial; Nebulizers and vaporizers

1. Introduction

Inhaled medication plays an important role in the treatment of asthma and chronic obstructive pulmonary disease (COPD). The active drug can be inhaled with a metered-dose inhaler (MDI) or a dry-powder inhaler. The percentage of patients inhaling their medication effectively varies from 10–100% depending upon the type of inhaler used and also the method of assessment [1–5]. A study in 152 COPD patients evaluating the

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effectiveness of four different inhalers, revealed that 40% of patients failed to use their inhaler effectively [6]. These results clearly demonstrate the need for checking and improving inhalation technique, because the efficacy of inhaled medication depends largely on this. Some patients have never received any form of instruction. Others have to rely on package inserts only [3,7,8], which is certainly not sufficient to assure efficient use of inhaled medication [3,4,9–12].

Previous research showed that verbal instruction or verbal instruction plus an automatic visual signal or a videotape with similar contents can accomplish a significant improvement in inhalation technique, both short-term (0–3 weeks) [6,13] and longer-term (2–3 months) [14]. A study comparing verbal and videotape instruction found both to be equally effective [15]. Both forms were superior to written instruction. Unfortunately follow-up was only 6 weeks and the number of patients was small ($n = 15$).

Our study is the first one to compare the long-term efficacy of three types of instruction in one trial. Patients either received a group instruction, personal counselling or were given a videotape with similar contents. A control group did not receive instruction. A unique feature was that patients in the video instruction group were allowed to take the videotape home and all patients in the three instruction groups were given a copy of their checklist home, on which their errors were marked. Our research question was wether the three types of instruction are equally effective.

This study has been initiated as part of a 4 year project to develop a self-management program for outpatient adult asthmatics.

2. Methods

2.1. Subjects

Approval for the study was acquired from the hospital's ethical committee, and informed consent was obtained from all COPD patients (aged 18–65 years) who attended the pulmonary outpatient department between February and June 1994. Those who had used inhaled medication for less than 1 month and those with a limited ability to understand and speak Dutch, were excluded. The inhalers investigated were either MDI's or the dry-powder inhalers Turbuhaler^R (TH), Diskhaler^R (DH) and Rotahaler^R (RH). Some patients were using more than one inhaler. In these cases the study was confined to one device only, and because the inhaler distribution was not uniform, a descending order of preference was established as follows: MDI, DH, TH and RH, to redress the balance.

2.2. Procedure

A total of 152 COPD patients were included in the study. They were randomized into one of four groups: Personal-, video-, group-instruction and a control group. Randomization was stratified by inhaler and the possession of a video recorder. Inhalation technique was assessed by well-trained pulmonary function technicians using purpose designed inhaler specific checklists (Table 1). Some checklist items like "exhale to residual volume" and "hold breath for five seconds" were common for all inhalers; others were device specific. For each inhaler items, essential for delivery of the active drug into the lungs, were identified. These essential manoeuvres were different for the four types of inhalers (Table 1). Details are described elsewhere [6].

The assessment of the patients' inhaler technique was followed by the assigned form of instruction, save for patients in the control group. Patients who were allocated to the personal instruction group, received instructions from the pulmonary function technician. Errors were corrected by verbal instructions and visual demonstrations and patients had to demonstrate their inhalation technique, until no errors were made anymore. With patients who were to receive a group instruction, an appointment was made, preferably in the same or next week. Every group consisted of five to seven patients and the educator was a specialized registered nurse. In these groups, up to four different inhalers were used and all patients had to demonstrate their inhalation technique in front of the group. An

Table 1
Inhaler-specific checklists with item and inhaler scores

	Baseline ($n = 25$) Item-score†	Follow-up ($n = 20$)* Item-score
MDI-checklist		
1: Shake the inhaler‡	60%	100%
2: Hold inhaler upright	100%	100%
3: Exhale to residual volume	40%	75%
4: Keep head upright	92%	95%
5: Mouthpiece between teeth and lips	68%	100%
6: Inhale slowly and press canister‡	48%	95%
7: Continue slow and deep inhalation‡	68%	95%
8: Hold breath for 5 seconds	44%	80%
Total score	65%	93%
Total score on essential checklist-items only	59%	97%
% of patients with a perfect score on essential items	24%	90%
Diskhaler checklist	Baseline ($n = 26$) Item-score	Follow-up ($n = 22$) Item-score
1: Perforate blister‡	96%	100%
2: Exhale to residual volume	58%	91%
3: Exhale away from mouthpiece	77%	91%
4: Mouthpiece between teeth and lips	96%	86%
5: Inhale forcefully and deeply‡	100%	100%
6: Hold breath for 5 seconds	65%	91%
7: Exhale away from mouthpiece	89%	100%
8: Rotate disc	85%	100%
Total score	83%	95%
Total score on essential checklist-items only	98%	100%
% of patients with a perfect score on essential items	96%	100%
Rotahaler checklist	Baseline ($n = 66$) Item-score	Follow-up ($n = 51$) Item-score
1: Keep rotahaler upright‡	65%	80%
2: Insert rotacap correctly	96%	100%
3: Keep rotahaler horizontal	85%	90%
4: Rotate both ends to open capsule‡	100%	100%
5: Exhale to residual volume	35%	76%
6: Exhale away from mouthpiece	58%	92%
7: Mouthpiece between teeth and lips	79%	96%
8: Inhale forcefully and deeply‡	89%	94%
9: Hold breath for 5 seconds	46%	84%
10 Exhale away from mouthpiece	80%	94%
Total score	73%	91%
Total score on essential checklist-items only	85%	92%
% of patients with a perfect score on essential items	59%	75%
Turbuhaler checklist	Baseline ($n = 32$) Item-score	Follow-up ($n = 22$) Item-score
1: Keep inhaler upright‡	68%	86%
2: Rotate grip until 'Click'‡	100%	100%
3: Exhale to residual volume	32%	73%
4: Exhale away from mouthpiece	48%	91%
5: Mouthpiece between teeth and lips	71%	95%
6: Inhale forcefully and deeply‡	94%	86%
7: Hold breath for 5 seconds	58%	68%
8: Exhale away from mouthpiece	84%	91%
Total score	69%	86%
Total score on essential checklist-items only	87%	91%
% of patients with a perfect score on essential items	61%	77%

*, Scores at follow-up are calculated for instructed patients only.
†, Percentage of patients performing the checklist-items correctly.
‡, Essential checklist-items.

average session lasted 45 min. Worth of note is that patients in the video group took the videotape and a copy of their inhaler checklist home, instead of watching it at the outpatient clinic. The videotapes were not especially designed for our study, but were readily available from the various pharmaceutical companies.

Up to 9 months later, depending upon the next scheduled visit to the chest physician, the patient's inhalation technique was checked again, using the same inhaler specific checklist. In order to avoid observer bias none of the patients were assessed by the same pulmonary function technician twice.

2.3. Statistical analysis

Three analyses will be presented: The first analysis concerns all checklist items (1), the second involves a subgroup of selected "essential" checklist items only (2), while the third analysis is based on the percentage of patients completing *all* essential items correctly (3).

The total score for each inhaler was calculated by dividing the number of items correctly completed by the total number of items on the checklist. The result was expressed as a percentage (1). A score for the "essential" checklist items was similarly arrived at for each patient (2), together with the percentage of patients completing *all* essential items on the list correctly (3).

Differences in scores among the four study groups were tested with the non-parametric Kruskall-Wallis test or with Analysis Of Variance (ANOVA). Comparisons between the groups were performed by the Student-Newman-Keuls test (SNK-test) to adjust for multiple testing. Within-patient changes in continuous variables were analysed using the paired T-test and 95% confidence intervals (95% CI) are presented. Differences in percentages of patients with a perfect score on essential items within treatment groups were compared with McNemar's test.

Differences between groups regarding discrete variables such as age categories, gender and educational achievement were tested using chi-squared analyses. Relationships between continuous variables and checklist scores were assessed using Spearman's correlations. The limit of statistical significance was set at $P = 0.05$ (two sided). Analyses were performed using the statistical package SPSS [16].

3. Results

Out of 152 patients with COPD, whose baseline inhalation technique was assessed, 148 returned for follow-up after on average 21.9 weeks (range 8–39). There were no apparent differences between baseline checklist scores and demographic characteristics obtained from these 148 patients and the four patients who did not appear for their follow-up assessment.

The percentage of patients correctly completing each item on the checklist was calculated for each of the inhalers, for both baseline assessment and at follow-up (Table 1).

Of the 148 COPD patients, (mean age 55.2 years; SD 8.7 years), characteristics are summarized in Table 2. No differences between the four groups were observed, except for time to follow-up, which was longer for the control group (25 weeks) and patients who had received a group instruction (26 weeks), compared to personal- and video-instruction (both 19 weeks). The correlations between time to follow-up on the one hand and checklist scores, both for all items ($r = -0.09$) and essential checklist items only ($r < -0.01$), on the other hand were not significant. When looking at the four groups separately, no significant correlations were found (all $P < 0.291$).

Patients who took the videotape home, watched it a median of 3 times (range 1–50) and they rated the quality of the video instruction high (8.4 on a scale of 1 to 10).

3.1. All checklist items (1)

Scores based on all checklist items, are reproduced in Table 3. The mean percentage of all checklist items performed correctly was 73% (SD 19, range 13–100%) pre-instruction and

Table 2
Patient characteristics*

	Control group	Group instr.	Personal instr.	Video instr.	Total
N	33 (22)	37 (25)	40 (27)	38 (26)	148
Age (yrs, $P = 0.867$)	56 (8)	54 (9)	55 (9)	56 (9)	55 (9)
History of COPD (yrs, $P = 0.217$)	15 (14)	12 (13)	19 (17)	15 (16)	15 (15)
Experience with inhaler (yrs, $P = 0.432$)	5 (6)	4 (4)	6 (6)	5 (6)	5 (6)
Time to follow-up (wks, $P < 0.001$)	25 (7)	26 (9)	19 (7)	19 (7)	22 (8)
Gender ($P = 0.911$)					
Men	20 (61)	24 (65)	25 (62)	26 (68)	95 (64)
Women	13 (39)	13 (35)	15 (38)	12 (32)	53 (36)
Educational level ($P = 0.365$)					
Low	26 (79)	31 (86)	35 (87)	28 (74)	120 (82)
High	7 (21)	5 (14)	5 (13)	10 (26)	27 (18)
Type of health care insurance ($P = 0.890$)					
Private	7 (21)	7 (19)	6 (15)	8 (21)	28 (19)
Public	26 (79)	30 (81)	34 (85)	30 (79)	120 (81)
Marital status ($P = 0.985$)					
Partner	26 (79)	30 (81)	31 (77)	30 (79)	117 (79)
No partner	7 (21)	7 (19)	9 (23)	8 (21)	31 (21)
Previous instruction ($P = 0.636$)					
Yes	24 (73)	29 (78)	33 (82)	32 (84)	118 (80)
No	9 (27)	8 (22)	7 (18)	6 (16)	30 (20)

*, Data are number of patients in each subgroup (%) or means (SD)

Table 3
Mean checklist-scores, based on all checklist-items

	Pre-instruction	Post-instruction	Difference (SD)	95% CI
Control group	69%	74%	5% (18)	−1; 12
Group instruction	74%	93%	18% (17)‡	13; 24
Personal Instruction	76%	90%	14% (19)‡	8; 20
Video instruction	72%	91%	19% (20)‡	13; 26
	$P = 0.541$*	$P < 0.001$*	$P = 0.007$†	

*, Kruskall-Wallis test.
†, Anova.
‡, Significantly different from controlgroup, Student-Newman-Keuls test.

increased significantly to 87% (SD 15, range 25–100%) post-instruction. The post-instruction score of the control group was significantly lower than for the three instructed groups (all $P < 0.001$; Wilcoxon rank sum tests).

For patients in the control group the increase was 5%. In patients receiving either a group-, personal- or videotape-instruction the increase was 18%, 14% and 19% respectively. All differences between the control group on the one hand and the three instruction groups on the other hand, were significant (SNK-test), while the

three instruction modes appeared to be equally effective (SNK-test).

3.2. Essential checklist items only (2)

Scores based on essential checklist items, are reproduced in Table 4. The mean percentage of essential checklist items performed correctly was 83% (SD 23, range 0–100%) pre-instruction and this was increased by 7% after instruction (95% CI 2; 11). In the control group a nonsignificant decline of 8% in the checklist score was observed, while in the combined instruction groups, a significant increase of 11% was found. Post-instruction scores for the control group were significantly lower than for the other three groups (all $P < 0.01$). The post-instruction score following group instruction was significantly higher then for personal- or video-instruction (both $P < 0.008$).

For both group- and video-instruction the observed increase from baseline was significant with 14% and 13% respectively.

Again, all differences between the control group and the three instruction groups were significant, and no statistically significant difference between the three instruction modes was found.

3.3. All essential items correct (3)

Scores based on the percentage of patients with a perfect score on essential checklist items, are reproduced in Table 5. Prior to instruction 60% of all patients had a perfect score on essential actions, with no significant differences between the four groups. At follow-up 49% of patients in the control group had a perfect score, versus 83% of instructed patients ($P < 0.001$). At follow-up 97% of patients who received a group instruction made no errors, compared to 75% and 76% for personal- and video-instruction respectively (both $P <= 0.014$). Only for group- and video-instruction the increase from baseline was statistically significant, with 35% and 24% respectively.

Pre-instruction, the percentages of patients who made no errors regarding essential checklist

Table 4
Mean checklist-scores, based on essential checklist-items only

	Pre-instruction	Post-instruction	Difference (SD)	95% CI
Control group	83%	76%	−8% (27)	−17; 2
Group instruction	86%	99%	14% (22)‡	6; 21
Personal Instruction	85%	91%	6% (28)‡	−3; 15
Video instruction	79%	92%	13% (30)‡	3; 23
	$P = 0.675$*	$P < 0.001$*	$P = 0.004$†	

*, Kruskall-Wallis test.
†, Anova.
‡, Significantly different from controlgroup, Student-Newman-Keuls test.

Table 5
Percentage of patients with a 100% score on essential checklist-items

	Pre-instruction	Post-instruction	Difference†	(*P*-value)
All patients	60%	75%	15%	0.005
Control group	61%	49%	−12%	0.344
Group instruction	62%	97%	35%	0.001
Personal instruction	65%	75%	10%	0.455
Video instruction	53%	76%	24%	0.035
	$P = 0.716$*	$P < 0.001$*		

*, Chi-squared test.
†, McNemars test.

items, were 24, 96, 59 and 61% for MDI, DH, RH and TH respectively (Table 1). Post instruction, and for instructed patients only, the corresponding numbers were 90, 100, 75, and 77%.

4. Discussion

Prior to instruction 40% of patients did not succeed in performing àll essential inhalation manoeuvres correctly. If one or more errors regarding these key actions are made, significant amounts of medication may fail to reach the lungs. As a result, loss of drug-efficacy may be expected. Two studies [5,17] found a significant loss of bronchodilatation in patients who made inhalation errors with an MDI. These patient errors were registered by well trained technicians. In the present study inhalation technique was also evaluated subjectively by well trained lung function technicians, using inhaler specific checklists. Appel [5] has shown that a trained bystander can achieve a 98% success rate in predicting a significant bronchodilator response from the subject's inhalation technique. This supports the validity of our study.

There is evidently a need for improving inhalation technique and therefore some type of patient instruction must be provided. Three studies have compared written information and personal instruction [12,15,17]. In all cases, the latter was superior. Unfortunately, follow-up was short, ranging from minutes after the instruction to (on average) 6 weeks.

One excellent study [8] compared verbal instruction with verbal instruction plus an automatic visual signal and found both to be equally effective. Only two studies compared personal instruction with a videotape instruction [15,17]. Again, follow-up was short (2–6 weeks). There was no difference in the results from the videotape instruction (shown in the clinic) and the personal instruction.

Our study is the first one to compare three types of instruction in one trial. Patients either received a group instruction, personal counselling or were given a videotape with similar contents. A control group did not receive instruction. A unique feature was that patients in the video instruction group were allowed to take the videotape home. All patients in the three instruction groups were given a copy of their checklist home, on which their errors were marked. Although it is not clear what the effect of this might have been, it can not explain the differences we found. Group instruction has shown to be effective, and has been widely used in self-management programs all over the world [18–23]. Its efficacy in improving inhalation technique compared to personal- and videotape-instruction has not been established yet.

From our results it seems that small-group instruction is superior to personal counselling, and equally effective or even better than video instruction. One explanation of the observed differences could be, that patients receiving groupwise instruction observed several demonstrations, and, by observing errors made by others, learned more effectively. In behavioural sciences this process is called modelling. Moreover, all the members of the group had to demonstrate his or her own inhalation technique in front of the group. This may have been a stimulus to pay attention very carefully. The fact that in these groups, up to four different inhalers were used, does not seem to be a problem. Quite a few manoeuvres are identical for all inhalers, e.g. holding your breath after inhaling. Finally, for the group instruction, patients had to come back to the outpatient clinic on a separate occasion, which could be beneficial to their overall state of mind. One drawback of group sessions is that not all patients will be keen to participate.

The efficacy of video instruction probably lies in the number of times patients were able to watch the video. Furthermore, the copy of their checklist, which indicated the errors in inhalation technique, will have helped to focus their attention as well. From the nonsignificant positive trends in checklist score with increasing time to follow-up, it is tentative to say, that patients who were provided a videotape, do not forget correct inhalation technique, but rather improve, by repeatedly watching the video in the course of time. This needs further careful investigation. In

the Netherlands the percentage of households with a video recorder is high (>75%). Clearly, in countries where this is not the case, video instruction will be of limited use.

Personal instruction was given by well trained lung function technicians, and all instructions were done according to a well-practised protocol, which was similar in contents to the other two instruction modes. The relative lack of efficacy of personal instruction might in part be explained by the fact that the patients' inhalation technique was assessed immediately prior to or after a visit to their chest physician. This might have been deleterious to their attention span. Furthermore, they only received one instruction, as opposed to multiple instructions in time (video) or different examples (group).

Looking at the different inhalers under investigation, it is striking, that only 24% of all patients with an MDI performed all essential checklist items correctly. The fact that checklist scores improved dramatically post-instruction, shows that time spent on instruction, is time well spent.

We conclude that there is a long term benefit from inhalation instruction. Group instruction gave the best results, but it is not easy to do for untrained persons. A video instruction is also effective if the videotape is taken home and a copy of the checklist is provided. Given the relatively poor results after personal instruction by well trained, highly motivated, patient lung-function technicians, it is doubtful that the average, overworked physician could do much better. Therefore, careful planning of instruction in inhalation technique of inhaled medicines is of utmost importance. If video instruction is not possible, and a group instruction is hard to arrange, personal instruction should not be dismissed, as it is still superior to doing nothing. A reasonable alternative could be the combination of a personal instruction together with the provision of a videotape.

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