An Assessment of Quality of Life in Libyan Patients with Bronchial asthma: a Clinical Benefit in using most Desirable Inhaler Techniques

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Abstract

Inhaled drug therapy remains the treatment option of choice for majority of patients with asthma. Asthma is a major chronic inflammatory disease of the respiratory tract. This study is designed to evaluate if the use of 2Tone helps patients maintain the correct inhalation technique after training and can improve their quality of life using AQLQ (Asthma quality of life questionnaire) and JMI (Jones morbidity index) questionnaires. AQLQ is a disease-specific health related quality of life tool which has good measurement properties and valid as an evaluative and a discriminative instrument. JMI is used as a simple and practical tool for asthma evaluation morbidity. 125 Libyan asthmatic patients from respiratory department outpatient of medical center (Tripoli) were included. Patients were divided into two groups; intervention and control. The intervention group was divided into those who were verbally trained about the MDI inhalation flow rate technique named verbal group (VT) and those called the 2Tone group (2T). Patients in the 2T group received the same verbal training as the VT group and were given 2Tone Trainer. The second visit for all patients was held six weeks later and each patient was assessed in the same manner as on the first visit. The patient was asked to fill in a self-administered AQLQ and answer questions from JMI. All patients in control group at both visits were inhaling at flow rate < 90 L/min with mean IFR of 66 L/min. Patients mean IFR in VT and 2T groups were less than 90 L/min at visit 2. Comparison of patient's total AQLQ scores between visits shows no patients in group control group recorded statistical difference. In contrast, 17 patients (48.6%) in VT group and 30 patients (83.3%) in the 2T group recorded significant difference in AQLQ score between visits. Comparisons in morbidity between groups at visits shown that about half of patients in 2T group and 20% of patients in VT group were reduced in the severity category after counselling whereas in control group. There was almost no statistical different between visits. No difference between the patient's perceptions of symptom control at visit 1 between the groups was observed but a significant difference at

visit 2 was noted. Comparison between visits within each group showed that in 2T group patients' perception of their asthma symptoms improved but did not change in the other two groups. A correlation was very strong between juniper questionnaire and JMI as studied by counselling group with significant association. This study shows that a high correlation between juniper questionnaire and JMI by counselling. This may be a reflection to use JMI as a quick tool to evaluate asthmatic patients to save time and increase patient compliance.

Keywords
Asthma, COPD, MDI, Lung drug delivery, 2 Tone trainer, Libya

Introduction

Asthma is a serious chronic inflammatory disease of the airways, estimated to affect some 300 million people worldwide in adults [1, 2]. Medical advances have led to comprehensive understanding of the pathophysiology of asthma. Despite this apparent progress, the cost in terms of quality of life for many patients and financial burden for global health care services remains high [3]. Several scientists explain this failure to effectively manage asthma symptoms by highlighting the inability of several patients to use their inhalers properly [4 - 6]. In spite of these observations, inhaled drug therapy remains the treatment option of choice for the majority of patients with bronchial asthma. The direct route of administration to the lungs allows lower doses to be administered, providing a rapid clinical response with reduced systemic side effects [7]. The key to effective use of inhalers by patients has to lay with the provision of appropriate training by healthcare professionals. Self and others [8] conducted a review of twenty different studies investigating the ability of healthcare professionals to correctly use inhalation devices including MDls and noted that a consistent lack of skill was evident among clinicians tested. It is unsurprising, therefore, that some patients struggle.

Laube and others [9] provides full instructions on how to use metered dose inhalers and stresses that this type of device should only be used in those patients with good inhaler technique. These recommendations were made by Newman et al. [10] who observed that slow deep inhalation followed by 10 second breath hold whilst using MDl resulted in optimal bronchodilation response. It shows that inhaler mishandling is common in patients with asthma [6] and the most common 'critical' errors made by patients involve the key points identified by Newman et al. [10], namely no exhalation before actuation, excessively forceful inhalation (not slow and steady) and either no or very short breath hold after inhalation [3, 6]. Therefore, many patients fail to achieve full therapeutic benefit because of poor MDI technique. This potentially may result in a sub-therapeutic response or prevent relief during acute exacerbation of the disease and wasted medicine and money. Even after MDI technique counselling and subsequent demonstration by the patient of perfect technique, 50% will use their MDI correctly 1 to 30 days later. It is crucial that patients receive repeated counselling. Healthcare professionals rely heavily on clinical outcome measures such as PEFR and spirometry to assess progress of asthma. It is difficult to determine the effect of asthma on the patient's day-to-day activities.

Health-related quality of life questionnaires are used to assess the functional effects of an

illness and its consequent therapy upon a patient as perceived by the patient [11]. Asthma Quality of Life Questionnaire (AQLQ) is a disease-specific 32-item instrument designed specifically for use in clinical trials. Patients rate the impairments they experienced during the previous 14. AQLQ has good measurement properties and is valid as an evaluative and a discriminative instrument. Jones Morbidity Index (JMI) is very simple and subjective evaluative tool to determine the morbidity of an asthmatic. It is a useful method which allows patients who require more urgent assistance and to evaluate the success of such assistance. A common property of MDIs is the dependence of the resulting lung dose on the inhalation flow rate used. The most desirable inhalation flow rate is 30 L/min and that a flow rate of approximately 100 L/min and above is too fast. It shows when patients used MDIs the mean peak inspiratory flow rate was greater than 100 L/min. A training aid; the 2Tone Trainer (Canday Medical Ltd) was introduced to help patients obtain the most desirable inhalation rate when using a MDI. The patient information leaflet provided with 2Tone encourages patients to practice using the device in the same way that they would use their MDI. During this use the training device provides them with audible feedback according to the inhalation rate they have used. It makes a two-tone sound when inhaling faster than 60 L/min, one tone between 30 - 60 L/min and no sound at < 30 L/min. Patients are advised to obtain the one tone sound and thus become customized with the degree of inspiratory effort they need to use to achieve this rate through a MDI. Continued use of the 2Tone Trainer, at home, after a training session may be a solution to the problem of using a slow inhalation rate and repeated inhalation technique training. A clinical benefit of optimal inhaler technique has not yet been demonstrated. Thus, this study is designed to use AQLQ and JMI to determine whether there is a clinical benefit in using most desirable inhaler technique.

Materials and Methods

This study was designed to be a parallel clinical study to assess the effect of inhaler technique on the quality of life of Libyan patients with bronchial asthma. Asthmatic patients were obtained from Tripoli Medical Center (TMC), Respiratory department outpatients in the beginning 2017. This study was of two groups; intervention and control. Allocation of patients to either the control or intervention groups was according to their inhaler technique regarding their IFR, measured using an In-Check dial™ (Clement Clarke International, UK). Those with correct IFR values of less than 90 L/min formed the control group and those identified with poor IFR values of more than 90 L/min were the intervention group. The intervention group was divided into those who were verbally trained about the MDI inhalation flow rate technique, called the verbal group (VT) and those called the 2Tone group (2T). Patients in the 2T group received the same verbal training as the VT group and were given a 2Tone Trainer (Candy Medical Ltd, UK). Approval for the study was obtained from the Ethical committee of the TMC to carry out this study. All patients giving signed informed consent were asked to agree and sign. For more details about study patient and design, see our previous study [12]. Their inhalation flow rate through an MDI was measured using an In-Check Dial. Patients were classified to poor and good inhalation technique according to their IFR. Those with good IFR of < 90 L/min were the control group, whilst those with a poor IFR of > 90 L/min were the intervention group. Patients in the intervention group were randomly allocated into the verbal

training group (VT) or the verbal training plus 2 Tone group (2T). The control group were not told what the correct flow was nor directed on how to use their inhalers. VT patients were trained on the most desirable IFR. Patients in the 2T group received the same verbal training as VT group. Patients in 2T group were trained how to use the 2Tone Trainer according to its patient information leaflet (PIL) and practiced inhaling through this training aid to familiarize themselves with the different sounds according to the inhalation rates. The second clinic visit for all patients was held six weeks later and each patient was assessed in the same manner as on the first visit. Patients were asked to demonstrate their inhaler technique with a placebo pMDI device. The inhalation technique was marked for 1 to 13 steps, according to the most desirable inhalation technique and a score out of 13 was given for each patient. The same person carried out the tests on each occasion to provide consistency in the measurements.

Statistical analysis: Data were entered and analysed by SPSS 18 database package and by MINITAB. Comparison made pre and post counselling by using mean and standard deviation. Paired t test was used for the comparison of the responses for each group pre and post counselling (visit 1 vs 2) for inhalation flow rate and peak flow measurement. Independent t test was used for responses between groups (2Tone vs verbal, 2Tone vs control and verbal vs control). Data compared between visit 1 and 2 using the Wilcoxon test and between individual grouped by Mann-Whitney U test.

Results

Full descriptive of the study patient's data involved was previously given in Tarsin et al. [10]. Thus, at visit one: 38, 44 and 43 patients were registered into three different groups: C, VT and 2T, respectively. At the second visit, the number of patients were found to be 36, 35 and 36 in C, VT and 2T groups, respectively. The mean (SD) age of patients was 57.16 (15.1) years. The youngest patient was 22 and the oldest patient was 87 years old. The normality test has revealed that IFR is not normally distributed but for AQLQ and lung function tests (FEV_1 and PEFR) showed normal distribution. Seventy-one patients (66.4 %) inhaled at rate greater than 90L/min and thus formed the intervention group. 11 patients (15.5%) in the intervention group (VT and 2T) returned for the follow-up (visit 2) at flow rate greater than 90 L/min after counselling. 10 patients (28.6%) were from VT group and one patient (2.8%) from 2T group. All patients in C group at visits 1 and 2 were inhaling at flow rate < 90 L/min with mean IFR of 66 L/min. Patients mean IFR in VT and 2T groups were less than 90 L/min at visit 2.

Asthma Quality of Life Questionnaire (AQLQ)

The means (SD) of total AQLQ scores for all the groups at visits 1 and 2 are summarized in table 1. Values split into the four domains (symptoms, environmental stimuli, emotional function and activity limitation). The change between visits 1 and 2 for AQLQ and its domains for all the groups are summarized in table 2. Comparison of patient's total AQLQ scores between visits 1 and 2 is shown in figure 1. It shows that no patients in group C recorded statistical significant difference. In contrast, 17 patients in VT group (48.6%) and 30 patients

in the 2T group (83.3%) recorded a significant difference in their AQLQ scores between visits 1 and 2 (Table 3).

Comparison using a paired t-test with mean difference (95% confidence interval) of the total AQLQ and each domain for all groups between visits 1 and 2 is shown in table 4. Thus, no significant difference between visits 1 and 2 in AQLQ domains for patient in C group was found. On the other hand, VT group showed a significant difference in total AQLQ and each AQLQ domains except for environment domain between visits 1 and 2. In addition, the 2T group showed a significant difference in all the AQLQ domains between visits 1 and 2.

Analysis of data by ANOVA (one-way) followed by Bonferroni correction test, between the groups are shown in table 5. Thus, there was no significant difference in AQLQ domains between all the groups at visit 1. Also, AQLQ emotional and activity limitation domains at visit 2 showed no significant difference between the groups. However, comparisons between groups for AQLQ (total, symptom and environment) domains have showed a statistical significant difference at visit 2. An analysis of the overall change, from visits 1 and 2, between the groups is described in table 6. This shows that the change in the total AQLQ in the 2T group was highly significantly ($p < 0.001$) higher than the VT and C groups. Furthermore, the change for the VT group was also very highly significantly ($p < 0.001$) more than the control group.

Table 1: AQLQ domains at visit 1 and 2 for all groups

Control group		**VT group**		**2T group**	
Visit 1	Visit 2	Visit 1	Visit 2	Visit 1	Visit 2
3.69 (1.1)	3.73 (1.12)	3.9 (1.04)	4.23 (1.03)	3.82 (1.09)	4.56 (1.03)
3.43 (1.03)	3.47 (1.01)	3.51 (1.18)	3.99 (1.14)	3.62 (1.3)	4.69 (1.12)
3.32 (1.61)	3.27 (1.5)	4.17 (1.5)	4.06 (1.54)	3.5 (1.34)	4.18 (1.36)
3.81 (1.61)	3.91 (1.57)	3.79 (1.53)	4.2 (1.58)	3.56 (1.43)	4.17 (1.57)
4.21 (1.51)	4.28 (1.51)	4.26 (1.35)	4.69 (1.24)	4.5 (1.5)	4.97 (1.38)

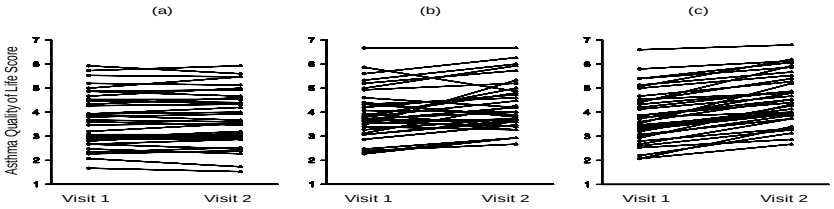
Data shown are Mean (SD).

Table 2: Mean AQLQ domains change for all groups between visits 1 and 2

AQLQ domains	**Δ C Mean (SD)**	**Δ VT Mean (SD)**	**Δ 2T Mean (SD)**
AQLQ total	0.04 (0.2)	0.33 (0.58)	0.74 (0.36)
Symptom	0.04 (0.34)	0.47 (0.74)	1.07 (0.64)
Environment Stimuli	- 0.06 (0.42)	- 0.11 (0.59)	0.68 (0.66)
Emotional function	0.1 (0.63)	0.41 (0.91)	0.6 (1.08)
Activity limitation	0.07 (0.4)	0.43 (0.7)	0.47 (0.58)

Δ-denotes the overall change between visit 1 and 2.

Figure 1: Comparison of patients AQLQ scores between visits 1 and 2



(a) for C group, (b) for VT group and (c) for 2T group

(b)

Table 3: Patients showing a change in AQLQ scores between visits 1 and 2

Group	AQLQ changes	AQLQ total n (%)	Symptom n (%)	Environment n (%)	Emotional n (%)	Activity n (%)
2 Tone n = 36	**<0.5 – -0.5<**	6 (16.7)	5 (13.9)	12 (33.3)	13 (36.1)	18 (50)
	1 – 0.5	22 (61.1)	16 (44.4)	17 (47.2)	10 (27.8)	13 (36.1)
	> 1	8 (22.2)	15 (41.7)	6 (16.7)	8 (22.2)	4 (11.1)
	- 0.5>	0	0	1 (2.8)	5 (13.9)	1 (2.8)
Verbal n = 35	**< 0.5 – -0.5<**	15 (42.9)	9 (25.7)	21 (60)	14 (40)	18 (51.4)
	1 – 0.5	14 (40)	14 (40)	5 (14.3)	9 (25.7)	11 (31.4)
	> 1	3 (8.6)	7 (20)	0	6 (17.1)	4 (11.4)
	-0.5>	3 (8.6)	5 (14.3)	9 (25.7)	6 (17.1)	2 (5.7)
Control n = 36	**<0.5 – -0.5<**	36 (100)	34 (94.4)	30 (83.3)	25 (69.4)	31 (86.1)
	1 – 0.5	0	1 (2.8)	3 (8.3)	4 (11.1)	3 (8.3)
	> 1	0	0	0	3 (8.3)	1 (2.8)
	-0.5>	0	1 (2.8)	3 (8.3)	4 (11.1)	1 (2.8)

Table 4: Mean differences of AQLQ between visits 1 and 2

AQLQ	C	VT	2T
AQLQ total	-0.04 (-0.11, 0.03)	-0.33 (-0.53, -0.13)**	-0.74 (-0.86, -0.61)***
Symptom	-0.04 (-0.16, 0.07)	-0.47 (-0.73, -0.22)**	-1.1 (-1.29, -0.85)***
Environment	0.06 (-0.09, 0.2)	0.11 (-0.88, 0.32)	-0.68 (-0.9, -0.45)***
Emotional	-0.1 (-0.31, 0.11)	-0.41 (-0.72, -0.1)**	-0.6 (-0.97, -0.24)**
Activity	-0.07 (-0.21, 0.07)	-0.43 (-0.67, -0.19)**	-0.46 (-0.66, -0.27)***

Significantly by * $P < 0.05$, ** $P < 0.01$ and *** $P < 0.001$.

Table 5: Mean differences of AQLQ domains score at visits 1 and 2

Groups	2T v' s VT	VT v' s C	2T v' s C
AQLQ (1)	-0.08 (-0.7, 0.54)	0.21 (-0.41, 0.83)	0.13 (-0.49, 0.75)
AQLQ (2)	0.33 (-0.29, 0.94)	0.5 (-0.11, 1.11)	0.82 (0.21, 1.43)**
Symptom (1)	0.11 (-0.57, 0.79)	0.09 (-0.59, 0.76)	0.19 (-0.48, 0.87)
Symptom (2)	0.71 (0.08, 1.34)*	0.52 (-0.11, 1.15)	1.22 (0.6, 1.85)***
Environment (1)	-0.67 (-1.53, 0.19)	0.85 (-0.13, 1.71)	0.18 (-0.68, 1.03)
Environment (2)	0.12 (-0.73, 0.97)	0.79 (-0.06, 1.64)	0.91 (0.07, 1.75)*
Emotional (1)	-0.23 (-1.11, 0.66)	-0.16 (-0.9, 0.87)	-0.24 (-1.12, 0.63)
Emotional (2)	-0.03 (-0.94, 0.88)	0.29 (-0.62, 1.2)	0.26 (-0.64, 1.16)
Activity (1)	0.24 (-0.6, 1.09)	0.05 (-0.79, 0.89)	0.29 (-0.54, 1.13)
Activity (2)	0.28 (-0.54, 1.08)	0.41 (-0.39, 1.21)	0.69 (-0.1, 1.48)

Significantly by * P < 0.05, ** P < 0.01 and *** P < 0.001.

Table 6: Mean differences of AQLQ domains score change between all groups

Groups	2T v' s VT	VT v' s C	2T v' s C
Δ Total AQLQ	0.41 (0.17, 0.64)***	0.29 (0.05, 0.53)*	0.69 (0.46, 0.93)***
Δ Symptom	0.6 (0.25, 0.91)***	0.43 (0.09, 0.77)**	1.03 (0.69, 1.37)***
Δ Environment	0.79 (0.46, 1.12)***	-0.06 (-0.39, 0.27)	0.73 (0.41, 1.06)***
Δ Emotional	0.19 (-0.32, 0.71)	0.31 (-0.21, 0.82)	0.5 (-0.13, 1.01)
Δ Activity	0.037 (-0.3, 0.37)	0.36 (0.03, 0.69)*	0.4 (0.07, 0.73)*

Δ-denotes overall change between visit 1 and 2. Significantly by * P < 0.05, ** P < 0.01 and *** P < 0.001.

Jones Morbidity Index

Morbidity according to JMI for all the groups at visits 1 and 2 is summarised in Table 7. Comparisons in morbidity between the groups at visits 1 and 2 indicating that about half of patients in 2T group and 20% of the patients in VT group were reduced in the severity category after counselling whereas in the C group there was almost no difference between visits 1 and 2. Using chi-square test to compare the morbidity between visits 1 and 2, no significant difference in the morbidity for patients in C and VT groups was found. This analysis revealed that morbidity improved from visit 1 to visit 2 in 2T group. A comparison between the groups showed a significant difference between all the groups. Comparison of the morbidity for visits 1 and 2 between groups revealed also a significant improvement in morbidity in VT ($p < 0.05$) and 2T ($p < 0.05$) groups but not in C group. Using Spearman's correlation, JMI has shown a highly significant strong negative correlation ($p < 0.001$, $r = - 0.51$) with AQLQ. Descriptions of correlation with all AQLQ domains are described in table 8. JMI, on the other hand, showed

significant ($p < 0.05$ and $p < 0.001$) positive correlation ($r = 0.24$ and $r = 0.34$) with the number of prednisolone and antibiotic courses, respectively. Also, it showed a significant positive correlation ($p < 0.05$, $r = 0.23$) with number of puffs used from the rescue inhaler.

Table 7: Morbidity according to JMI

Group	Visit	Mild N (%)	Moderate N (%)	Severe N (%)	Total
2Tone n = 36**	**1**	7 (19.4)	12 (33.3)	17 (47.2)	36 (100)
	2	14 (38.9)	17 (47.2)	5 (13.9)	
Verbal n = 35	**1**	4 (11.4)	11 (31.4)	20 (57.1)	35 (100)
	2	6 (17.1)	16 (45.7)	13 (37.1)	
Control n = 36	**1**	5 (13.9)	18 (50.0)	13 (36.1)	36 (100)
	2	5 (13.9)	17 (47.2)	14 (38.9)	

Significantly by ** $P < 0.01$ between visit 1 and 2 (Chi-Square test)

Table 8: Correlations between percent predicted FEV1 and PEFR with AQLQ domains

Parameter	AQLQ total	AQLQ symptom	AQLQ emotion	AQLQ environment	AQLQ activity
JMI	- 0.51***	- 0.6***	- 0.29*	- 0.32*	- 0.38***

Significantly by * $P < 0.05$ and *** $P < 0.001$

Additional questions

Table 9 shows the number and percentage of patients that used prednisolone, antibiotic, and cough mixtures course in the last six months. Bivariate correlation using Spearman's showed a significant positive relationship ($r = 0.37$, $p < 0.001$) between prednisolone and antibiotic courses. Prednisolone and antibiotic courses showed also a significant positive relationship with JMI [($r = 0.24$, $p < 0.05$) and ($r = 0.34$, $p < 0.001$), respectively]. Prednisolone course had shown significant ($p < 0.01$) negative correlation ($r = -0.26$ and -0.25) with the AQLQ total and symptom scores, respectively. Also, it showed that antibiotic course has significant ($p < 0.05$) negative correlation ($r = -0.2$, -0.2 and -0.24) with the AQLQ total, symptom and activity scores, respectively. A summary of the patient's perception of their asthma symptoms are shown in table 10. Furthermore, comparison between patient's descriptions of asthma symptoms controlled is shown in figure 2.

An analysis of data by chi-square test has revealed no difference between the patient's perceptions of symptom control at visit 1 between the groups but there was a difference ($p < 0.001$) at visit 2. Further comparison between visits 1 and 2 within each group showed that in 2T group patients' perception of their asthma symptoms improved ($p = 0.02$) but did not change in the other two groups. Spearman's correlation showed a significant ($p < 0.01$) positive correlation with AQLQ total, symptom and emotional ($r = 0.278$, 0.282 and 0.294, respectively). Low significant positive correlation ($p < 0.05$, $r = 0.199$) was revealed with the activity limitation of the AQLQ. Patients were asked about the number of puffs from the rescue

inhaler, if they used one, pre and post training (Table 11). Also, they have been asked of the number of times per day used the rescue inhaler (Table 12). Statistical analysis (chi-square test) revealed no difference between reliever usage from visits 1 and 2 between and within the three groups.

Table 9: Patients using prednisolone, antibiotic and cough mixture in last 6 months

Groups	Number of courses	Antibiotic n (%)	Prednisolone n (%)	Cough mixture n (%)
2 Tone n = 36	0	16 (44.5)	16 (44.4)	28 (77.8)
	1	8 (22.2)	11 (30.5)	3 (8.3)
	2	4 (11.1)	4 (11.1)	4 (11.1)
	3	4 (11.1)	2 (5.6)	0
	>4	4 (11.1)	3 (8.4)	1 (2.8)
Verbal n = 35	0	12 (34.3)	18 (51.4)	27 (77.1)
	1	7 (20)	9 (25.7)	4 (11.4)
	2	4 (11.4)	4 (11.4)	2 (5.7)
	3	4 (11.4)	3 (8.6)	1 (2.9)
	>4	8 (77.1)	1 (2.9)	1 (2.9)
Control n = 36	0	17 (47.2)	14 (38.9)	28 (77.7)
	1	3 (8.3)	9 (25)	6 (16.7)
	2	8 (22.2)	7 (19.4)	0
	3	2 (5.6)	4 (11.1)	0
	>4	6 (16.7)	2 (5.6)	2 (5.6)

Table 10: Patients description of asthma symptom control pre- and post-counselling

Groups	2Tone n (%)		Verbal n (%)		Control n (%)	
Visit	1	2	1	2	1	2
Poor	4 (11.1)	0	4 (11.4)	0	5 (13.9)	5 (13.9)
Fair	15 (41.7)	6 (16.7)	11 (31.4)	14 (40)	12 (33.3)	11 (30.6)
Good	10 (27.8)	17 (47.2)	10 (28.6)	11 (31.4)	15 (41.7)	19 (52.8)
Very good	6 (16.7)	12 (33.3)	7 (20)	6 (17.1)	4 (11.1)	1 (2.8)
Excellent	1 (2.8)	1 (2.8)	3 (8.6)	4 (11.4)	0	0

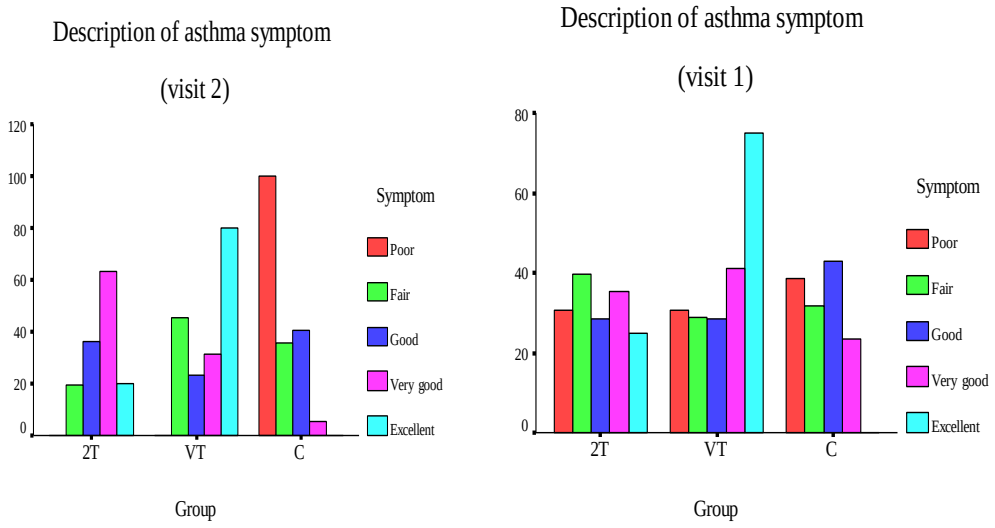
Table 11: Number of puffs used from reliever inhaler at visits 1 and 2

Groups	2T n = 36		VT n = 35		C n = 36	
Visit, n (%)	**1**	**2**	**1**	**2**	**1**	**2**
None	10 (27.8)	10 (27.8)	6 (17.1)	6 (17.1)	6 (16.7)	6 (16.7)
1 puff	1 (2.8)	4 (11.1)	1 (2.9)	2 (5.7)	3 (8.3)	4 (11.1)
2 puffs	25 (69.4)	22 (61.1)	28 (80)	27 (77.1)	27 (75)	26 (72.2)

Table 12: Number of time patients used reliever inhaler at visits 1 and 2

Parameter	2T, n = 36		VT, n = 35		C, n = 36	
Visit N (%)	**1**	**2**	**1**	**2**	**1**	**2**
None	10 (27.8)	10 (27.8)	6 (17.1)	6 (17.1)	6 (16.7)	6 (16.7)
1 or more/day	21 (58.3)	14 (38.9)	20 (57.1)	21 (60)	24 (66.7)	22 (61.1)
Every other day	3 (8.3)	7 (19.4)	6 (17.1)	1 (2.9)	4 (11.1)	6 (16.7)
1 - 2 times/week	2 (5.6)	5 (13.9)	3 (8.6)	7 (20)	2 (5.6)	2 (5.6)

Figure 3: Comparison of patient's asthma symptom descriptions for visits 1 and 2



Discussion

Aerosol inhalation as a route of drug delivery to the respiratory tract has well established in the treatment of asthma and other respiratory diseases. The efficiency of lung deposition from inhalation therapy is not high and about 10% of the inhaled dose reaches the lungs [10]. A very fast inhalation, bad co-ordination between the start of an inhalation and dose actuation are the most common errors that asthmatic patient made during the use of their MDIs. About 75% of the patients inhale too fast and do not use a slow inhalation when they used their pMDI [13, 14]. For this reason, this study was designed to us the 2 Tone device to train the patients to adjust their inhalation rate through the MDI which is very important factor for the drug to reach its site of action in adequate amount and to evaluate their quality of life after treatment. It is possible to increase the fraction of dose deposited in the lungs by training the patients in the correct inhalation techniques [15]. However, several studies have shown that patients forget their trained technique within one month [16]. In a previous study, it was reported that 50% or more of adult patients had a difficulty in using conventional MDIs efficiently even after careful training [17, 18] and this is another benefit of the use 2 Tone device [12]. Failure to use a slow inhalation was more common than good co-ordination between dose actuation and co-

ordination [17, 18]. It is estimated that around 50% of patients do not obtain sufficient therapy from their inhalers due to poor inhalation technique [20]. The results of this study show that the patients in the 2 Tone group managed to slow their IFR and obtain the optimum IFR needed for the MDI when they used the 2 Tone device compared with the two other groups. Patient inhalation technique including the proper IFR was considered to be an important factor for drug delivery to the lung and accordingly the clinical effect and the improvement in the lung function [12].

The results of this study investigated the relation between this factor and the AQOL and the JMI. Thus, it shows that the correlation coefficient (r) within the counselling and counselling with two-tone groups and demonstrates the effect of environmental stimuli on patients with bronchial asthma was very strong within the counselling with two-tone group. Also, it found a significant differences in visit 2 compared to visit 1 in the "influence of bronchial asthma on emotional function", however in the parameter "fell concerned about the need to take medication for your asthma" only the counselling group gives a significant difference and this may be due to biological differences between the patients in the two groups. Is also showed a very high percentage of change with "feel concerned about having asthma" which was more than a 100% for the counselling with two-tone group in comparison with 12% for the control group. There was no significant differences between the visits in the parameters that evaluate avoiding behavior of patients with bronchial asthma, on the other hand there was a significant difference in all the parameters that titled under "the response of patients with bronchial asthma" in the two-tone group when compared with the verbal counselling group and this may relate to the ability of the 2-tone device to adjust the inhalation flow rate, which gives good chance to the medication that present in the MDI to reach its site of action. These explain the importance of presence a device like two-tone to help the patient in correcting a vital step in the administration of medication through MDI, giving verbal advices in the counselling group is more difficult to understand and easier to forget. A significant difference from the first visit for both groups counselling and counselling with two-tone group, in the field "fell the need to clear your throat". Also, the correlation coefficient (r) within the counselling and counselling with two-tone groups and demonstrates the changes in symptoms of asthmatic patients was strong. This shows the importance for the patient to use MDI properly to obtain maximum effect and to decrease side effects of some medication supplied by inhalation route. The results of this study from the JMI shows a significant different between counselling with two-tone group and the control group. On the other hand, no significant difference was found between the control group and the verbal counselling group. This may be due to the improvement in the patient health condition as result of a correct inhalation technique when they used the two-tone device. This can be confirmed by highly significant differences in the measurement of PIFR using the In-Check Dial for both counselling and counselling with two-tone group pre and post counselling in the first visit, which mean that patients learned well how to adjust their inhalation flow rate using the 2-tone device. Two different parameters were used to evaluate the improvement in the health condition of the patients after using their medication; juniper questionnaire and JMI. The results of this study show that the correlation was very strong between juniper questionnaire [21] and JMI as studied by counselling group with statistically

significant association, this may be a reflection to use JMI as quick tool to evaluate asthmatic patients to save time and increase patient compliance.

Author Contributions: WT: original idea, reviewed literature and manuscript writing. NH: designing and collecting data. IE: collecting clinical patient's data and follow up, HC: original idea and manuscript editing. FS: writing, editing of manuscript and proofreading.

Conflict of interest statement: No conflict of interest to this study and the authors do not have commercial interest at all that represents a conflict of interest in connection with the manuscript submitted.

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