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A Preliminary Study on the Effectiveness of Pharmacists' Counselling on Inhaler Technique in Patients with Chronic Lung Disease

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ABSTRACT

Introduction: In managing patients with chronic lung diseases, the correct use of inhaler devices is crucial to ensure adequate drug delivery. This study aimed to examine the effectiveness of pharmacists' counselling on inhaler techniques among patients with chronic lung diseases in Sarawak, Malaysia.

Methods: This study involved patients with chronic lung diseases admitted into the general medical wards in Sarawak General Hospital. Those prescribed with any of the five types of inhaler devices, including metered-dose inhalers (MDI), MDI + spacer, Turbuhaler®, Accuhaler® and Handihaler®, were recruited. The inhaler technique for each inhaler device was assessed using a 6-step device-specific checklist adapted from a local protocol. Each step of the inhaler technique contributes one mark, with a total score ranging from zero to six. A total score less than four indicates the "Poor" technique; four to five indicates "Satisfactory"; and six indicates "Good". Assessments were performed on admission (*t1*), upon discharge (*t2*) and four to six weeks post-discharge (*t3*). Counselling by ward pharmacists was performed right after *t1*. The change in percentage of participants measured effectiveness rated "Satisfactory/Good" from *t1* to *t2* and from *t2* to *t3*, respectively, following per-protocol analysis.

Results: Two hundred participants were recruited, four of whom passed away before discharge, and a further 83 patients were lost to follow-up at *t3*. Hence, 196 and 113 responses were included in the outcome analyses upon *t2* and *t3*, respectively. Most participants (88%) were pre-existing inhaler devices users. Pharmacists' counselling resulted in statistically significant ($P < 0.05$) improvements in the percentage of participants with "Satisfactory/Good" inhaler technique for the MDI (from 63.6% to 100%), MDI + spacer (from 64.3% to 96.4%), and Turbuhaler® (from 50.0% to 100%) at *t2*, but not Accuhaler® (from 87.5% to 96.9%) and Handihaler® (from 80.0% to 100%). The improvements were sustained until *t3*. Notably, more of Accuhaler® and Handihaler® users had "Satisfactory/Good" inhaler technique upon admission than other inhaler devices.

Conclusion: This study provided preliminary evidence on the impact of pharmacists' counselling on the inhaler technique of inhaler devices.

Keywords: counselling, dry powder inhalers, Malaysia, metered-dose inhalers, pharmacists

INTRODUCTION

Chronic lung diseases such as chronic obstructive pulmonary disease (COPD) and bronchial asthma are illnesses that require long term medical management and good patient compliance. Despite the development of various efficacious drugs and established guidelines, COPD and bronchial asthma control in most patients were still suboptimal (1,2). In order to attain the potential benefits that prescribed medications promise, a good understanding of inhalation medication use and the proper technique required of it is vital. Several studies have shown that the proportion of patients who had demonstrated improper inhaler technique ranged from 41% to 71% (3). A systematic review also showed that despite decades of experience with inhaler devices and the invention of more advanced devices, the incorrect technique was still unacceptably frequent (4). The improper use of inhalers had been shown to lead to suboptimal drug delivery, low patient's adherence to medication, poorly-controlled disease, multiple emergency department visits, and unwanted extra financial burden to the patient and the healthcare system alike (3,5–7).

In order to ensure the correct use of inhaler devices, patients need to be assessed regularly (8). A Norwegian study showed that a structured pharmacist-led inhalation technique assessment service effectively improved patients' technique from baseline and remained improved after three months (9). To the best of our knowledge then, little was known about the effectiveness of pharmacists' counselling on inhaler technique following a local counselling protocol. Primarily, this study aimed to examine the effectiveness of pharmacists' counselling on inhaler technique. Secondarily, it also explored the most common mistakes of different inhaler devices.

METHODS

This was a single-arm, pre-and post-interventional study. The recruitment period was open from June 2015 to June 2016. Our study population was in Sarawak, the largest state in Malaysia. Sarawak General Hospital, located in the capital city of Sarawak, was chosen as the study site as it is the largest tertiary public hospital in Sarawak. Participants were recruited conveniently from all three general medical wards in the hospital. The G*Power sample size calculation software calculated the minimum sample size. Assuming that alpha equals 0.05, power equals 0.8, and the probability of discordant pairs to be 0.5, the minimum sample size required for the two-tailed McNemar test was 398 (10). All patients admitted during the recruitment period with underlying

or newly diagnosed chronic lung diseases and who had been on or newly started on inhaler devices were invited to participate in the study. Informed consent was obtained prior to recruitment. Patients were allowed to recover from their acute attack before being enrolled into the study. Patients who were medically unstable or unfit for counselling throughout the entire admission or did not provide consent were excluded from the study.

Nevertheless, we ensured that all patients had received the same level of standard pharmaceutical care in the ward. This research was approved by the Medical Research & Ethics Committee, Ministry of Health Malaysia (KKM/NIHSEC/P14-569) on 05 August 2014. It was also registered with the National Medical Research Register bearing the registration ID NMRR-14-481-20030.

Participants were assessed at baseline on admission (*t1*) and were subsequently given counselling sessions during the admission. Pre-existing inhaler device users were counselled one-to-one, using verbal instructions and hands-on demonstration based on a targeted approach, explicitly tackling errors made during the initial assessment. New inhaler device users were also counselled similarly, going through all steps required to use the respective inhaler device correctly. All counselling sessions were conducted by pharmacists on duty in the medical wards. All study pharmacists were trained on the study protocol and assessment checklist. The counselling and assessment were based on a modified 6-step checklist adapted from the Malaysian Ministry of Health Respiratory Medication Therapy Adherence Clinic protocol--Appendix 6b (11), which was unique for individual inhaler devices (refer Suppl. Table 1). Participants were required to feedback their understanding by demonstrating their inhaler technique during the same session. The goal was to ensure that patients could use inhalers consistently without critical errors and achieve "Satisfactory/Good" technique upon discharge. The inhaled corticosteroid-containing device was preferentially assessed for those using more than one of the same inhaler devices with different active ingredients. Counselling sessions and assessments were primarily performed using our national language, Malay. However, Sarawak is a multi-cultural state with people from various ethnic backgrounds. Since not all were well versed in the Malay language, some sessions had to be tailored according to the participant's native language or dialect.

During the assessments, each step of the inhaler technique was marked as either being performed correctly (1 mark) or incorrectly (0 mark), with a maximum total score of 6. "Poor technique" was defined by a total score of less than 4, "Satisfactory" by a total score of 4-5, and "Good" by a perfect total score of 6. Critical steps were identified and highlighted in the inhaler technique checklist (refer Suppl. Table 1). Failure to perform any critical step correctly automatically scores the patient with a "Poor" technique.

After the initial assessment at *t1*, patients were counselled on the correct use of their inhaler device, as many times as were required, by the same assessor (ward pharmacist). Patients who repeatedly demonstrated a "Poor" technique on MDI alone were provided with a spacer (Aerochamber®) prior to discharge, along with counselling on its use and maintenance. Patients who demonstrated a "Satisfactory/Good" technique did not require the addition of a spacer and hence were not supplied with one.

Upon discharge (*t2*), patients were assessed again in the ward. Further counselling was provided if the technique was found to be "Poor" without repeating the *t2* assessment. A follow-up visit 4-6 weeks after discharge (*t3*) was arranged, and inhaler technique assessments were performed once again to assess the sustainability of the inhaler technique upon discharge (*t2*). The pharmacist in charge of *t1* assessment and subsequent counselling sessions were the respective medical ward pharmacists. Pharmacists-in-charge for *t1*, *t2* and *t3* assessments were independent to minimize bias.

The percentage of participants rated as "Satisfactory/Good" was calculated at *t1*, *t2* and *t3*, respectively. The effectiveness was represented by the change in the percentage of participants rated as "Satisfactory/Good" from *t1* to *t2* and from *t2* to *t3*, respectively. Missing data due to drop-out were not included in our per-protocol analysis. Statistical analyses were conducted paired, according to the type of device used. A single patient using multiple devices would have resulted in separate analyses for each device used. The McNemar test was used to evaluate the statistical significance of the changes in percentage at different time points. The level of statistical significance was set at 0.05 with a 95% confidence interval. Statistical Package for the Social Sciences version 17.0 was used for statistical analyses. As the minimum sample size was not

achieved, post hoc computations of statistical power for the findings with statistical significance were carried out using the G*Power 3.1. These were presented as a footnote in Table 2.

RESULTS

A total of 200 participants were recruited. At *t2*, four participants (2%) dropped out of the study as they succumbed to illness. A further 83 of 196 (42.3%) dropped out at *t3* due to loss to follow-up. The final number of participants included in the analyses upon *t2* and *t3* was 196 and 113, respectively.

Table 1: Participants' Demographics (n = 200)

Demographics	Number of participants (n)	Percentage (%)
Age (years) - Median (IQR)	55 (26.5)	
≤ 20	12	6.0
21 – 40	44	22.0
41 – 60	79	39.5
>60	65	32.5
Gender		
Male	105	52.5
Female	95	47.5
Highest education level		
No formal education	39	19.5
Primary	54	27.0
Secondary	95	47.5
Tertiary	12	6.0
Duration on inhalers (years)		
New user	24	12.0
<1	26	13.0
1-3	37	18.5
>3	113	56.5
Previously taught by HCP*		
Yes	150	85.2
No	26	14.8
NA (new user)	24	-

*HCP: Healthcare professionals

Table 1 shows participants' demographics. Participants had a median age of 55 (Interquartile range = 26.5), with just over half being male (52.5%). Over half of our patients (56.5%, n=113) were chronic users (>3 years) of inhaler devices. Surprisingly, 14.5% (n=26) of pre-existing users reported never being taught how to use their inhaler devices by any healthcare professional.

Table 2: Change of Inhaler Technique upon Discharge

Type of Devices (n)	**Proportion of subjects attaining "Satisfactory/Good" technique, n (%)**		***P* value[a]**
	On Admission (*t1*)	**Upon discharge (*t2*)**	
All devices (186)	127 (69.3)	184 (98.9)	**<0.001**
Metered Dose Inhaler (MDI) (99)	63 (63.6)	99 (100)	**<0.001[b]**
MDI + spacer (28)	18 (64.3)	27 (96.4)	**0.004[c]**
Turbuhaler® (12)	6 (50.0)	12 (100)	**0.031[d]**
Accuhaler® (32)	28 (87.5)	31 (96.9)	0.25
Handihaler® (15)	12 (80.0)	15 (100)	0.25

[a] McNemat test.

[b] The post hoc computation of power using G*Power 3.1 showed that this finding has the power of 0.26.

[c] The post hoc computation of power using G*Power 3.1 showed that this finding has the power of 0.04.

[d] The post hoc computation of power using G*Power 3.1 showed that this finding has the power of 0.05.

At *t2*, pharmacists' counselling resulted in a statistically significant improvement in the percentage of participants achieving a "Satisfactory/Good" technique for all devices (n=186), from 68.3% to 98.9%, $P < 0.001$. Subgroup analyses also showed significant improvements in the MDI (from 63.6% to 100%, $P < 0.001$; post hoc statistical power = 0.26), MDI + spacer (from 64.3% to 96.4%, $P = 0.004$; post hoc statistical power = 0.04), and Turbuhaler® (from 50.0% to 100%, $P = 0.031$; post hoc statistical power = 0.05) groups (Table 2). However, no improvements in the percentage achieving "Satisfactory/Good" technique were observed among users of the Accuhaler® (from 87.5% to 96.9%, $P = 0.25$) and Handihaler® (from 80.0% to 100%, $P = 0.25$) (Table 2).

The overall percentage of patients with a "Satisfactory/Good" technique significantly reduced from 100% at *t2* to 95.5% at *t3* ($P = 0.008$), as shown in Table 3, indicating non-sustainability. However,

individual devices indicated sustainability at 4-6 weeks from the day of discharge, whereby McNemar's did not show any statistically significant differences between *t3* and *t2*.

Table 3: Change of Inhaler Technique 4 To 6 Weeks After Discharge

Type of Devices (n)	**Proportion of subjects attaining "Satisfactory/Good" technique, n (%)**		***P* value[a]**
	Upon discharge (*t*2)	**4-6 weeks after discharge (*t*3)**	
All devices (179)	179 (100)	171 (95.5)	**0.008**
Metered Dose Inhaler (MDI) (65)	65 (100)	62 (95.4)	0.25
MDI + spacer (40)	40 (100)	39 (97.5)	1.00
Turbuhaler® (17)	17 (100)	16 (94.1)	1.00
Accuhaler® (43)	43 (100)	41 (95.3)	0.50
Handihaler® (14)	14 (100)	13 (92.9)	1.00

[a] McNemar test

The most common mistakes made by MDI users were poor hand-breath coordination, while dry powder inhaler (DPI) users either committed errors in device handling or did not hold their breath long enough (Table 4).

Table 4: Most common mistakes detected upon admission (*t*1)

Type of Devices (n)	**Most common mistake at *t*1**	**n (%)**
MDI (138)	Poor hand-breath coordination	70 (50.7)
MDI + spacer (29)	Took less than five breaths *and/or* face mask not tightly fitted	10 (34.5)
Turbuhaler® (14)	Inhaler not held upright *and/or* dial not turned correctly	5 (35.7)
Accuhaler® (34)	Did not remove the device from the mouth *and/or* did not hold breath long enough	8 (23.5)
Handihaler® (18)	Did not press actuator correctly *and/or* pressed more than once	5 (27.8)

DISCUSSION

This study was designed to evaluate the effectiveness of a patient's inhaler technique after pharmacists' counselling among in-patients. It was found that pharmacists' counselling in the ward significantly improved patients' inhaler technique, particularly for the MDI, MDI + spacer, and Turbuhaler®, consistent with the findings from several studies where pharmacist-led interventions had led to significant improvements in patient's inhaler technique (9,12). Nevertheless, non-significant improvements were also observed for the Accuhaler® and Handihaler®. It is worth noting that a more significant percentage of participants using these inhaler devices had a "Satisfactory/Good" technique at baseline (*t1*), both of which were at least 80%, as shown in Table 2. Although a larger sample size could have picked up statistically significant differences, it was reassuring that most of these participants were handling the Accuhaler® and Handihaler® relatively well prior to admission. Chrystyn et al., in their systematic review and meta-analyses, had also reported that patients generally had higher error rates with MDIs versus DPIs (13).

The DPIs (Accuhaler® and Handihaler®) had higher proportions of a "Satisfactory/Good" technique at baseline, suggesting that our participants possibly handled these DPIs better than the other inhaler devices. A recent real-life study (14) conducted in nearly 3000 patients reported fewer critical errors with the Diskus® (also known as Accuhaler® in Malaysia) and Handihaler® compared to MDI and Turbuhaler®; which was in line with our findings. On the other hand, other studies reported somewhat inconsistent findings, whereby error rates were generally higher with the MDIs than DPIs (13). Nevertheless, comparisons between the results of our study with the literature were challenging as study designs, counselling methods, and inhaler technique assessment checklists used in various trials were dissimilar. Furthermore, patient demographics, education background, socioeconomic background, devices' experience, and previous instruction by qualified healthcare professionals were potentially important confounders (15).

A significant reduction in the pharmacists' counselling effect was found at *t3* compared to *t2* when analyzed as a whole. However, subgroup analyses showed that the percentage of patients who had a "Satisfactory/Good" technique was sustained for at least 4-6 weeks after discharge for individual devices, as supported by the results that no significant difference was observed at *t3* compared to *t2*. The conflicting findings were mainly attributable to the high drop-out rate, which reduced our

statistical power to detect any difference. A study conducted in Vietnam found that the mean technique scores for MDI and Turbuhaler® significantly improved after 1-3-monthly assessments and counselling; however, a significant drop in mean scores was reported when the period between assessments was six months (16). Nevertheless, we believe that there is a need to assess patients' inhaler techniques (17) regularly and that the assumption of good technique should not be made even among experienced inhaler users. This recommendation was in agreement with the Malaysian Clinical Practice Guidelines: Management of COPD (8).

In addition, it was found that the inhaler technique for the MDI, MDI + spacer and Turbuhaler® were poorer at baseline (*t1*) than the Accuhaler® and Handihaler®. This finding could have suggested poorer sustainability of inhaler technique overtime for the MDI, MDI + spacer and Turbuhaler® compared to the Accuhaler® and Handihaler®. No study known to date had compared the sustainability of inhaler technique between these devices. However, a meta-analysis of 9 studies did suggest that critical error rates were significantly lower in the Accuhaler® versus Turbuhaler® with an odds ratio (OR): 2.90 [95% CI 1.41–5.96], though heterogeneity was very high (93.9% I-squared statistic) (13).

On another note, the most common error detected was poor hand-breath coordination in 50.7% (n=70) of MDI users. This figure was extremely high compared to reports from other studies, ranging from 10-24.9% (6,18), but consistent with the figure reported by Molimard et al. (14). As reported in a recent systematic review, differences in error rates and types were typically thought to be influenced by various factors, including but not limited to education level, age, gender, and previous instruction by a healthcare professional (15). As for the MDI + spacer cohort, many patients had problems ensuring that the face mask fits tightly around the face. The Turbuhaler® group was consistent with Price et al. in reporting twist errors as the most common (18). Handihaler®, on the other hand, showed that more patients committed piercing/loading errors than other errors, which was in agreement with the findings from Wieshammer et al. (19). In general, the DPI users mostly had device-dependent errors, while hand-breath coordination was a significant problem among MDI users, as was found by Molimard et al. (14).

Several limitations in our study were identified. First, although measures were taken to allow patients to recover from their acute attack during their in-patient stay, it could have been more reflective of a patient's actual baseline inhaler technique if patients were recruited from an out-patient setting. Second, there was a high drop-out rate during follow up. Despite efforts being made to trace and remind patients, a 41.5% drop-out rate significantly impacted the power of our analyses. We attributed this to logistic issues among our patients in Sarawak, especially those living in the suburbs. Lastly, this study was likely underpowered to detect changes in the proportion of patients with a "Satisfactory/Good" technique. Although we recruited 200 participants, data analyses were performed on a per-device basis, resulting in a constricted sample size for individual inhaler devices. The sheer scarcity of participants prescribed with certain DPIs proved to be challenging.

Furthermore, only paired data were analyzed per protocol, resulting in the loss of *t1-t2* data for inhaler devices newly started during the admission and *t2-t3* data for participants lost to follow up. As a result of insufficient sample size, the findings of this study suffered from low statistical power and thus high probabilities of type II errors. Future studies employing a stratified sampling technique by inhaler device can ensure adequate study power for comparisons between inhaler devices, which may be achievable through a multicenter study design.

CONCLUSION

This study provided preliminary evidence on the effectiveness of pharmacists' counselling in improving patients' inhaler techniques. However, continuous reassessments at regular intervals are still recommended to ensure consistent and correct inhaler techniques over time. Future studies may include the assessment of medication adherence and disease control, which will further add value to correlate adherence, technique and the disease outcome.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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SUPPLEMENTARY TABLE 1: INHALER TECHNIQUE ASSESMENT

Indicate YES (1) or NO (0) if steps was performed in proper sequence

ID :				**MEDICATION :**																**DATE:**	**t1**	**t2**	**t3**			
				INHALER TYPE:□ MDI □ MDI + Spacer □ MDI + Mini Spacer □ Turbuhaler □Handihaler □Accuhaler																						
MDI	**t1**	**t2**	**t3**	**MDI+SPACER**	**t1**	**t2**	**t3**	**MDI+MINI SPACER**	**t1**	**t2**	**t3**	**TURBUHALER**	**t1**	**t2**	**t3**	**ACCUHALER**	**t1**	**t2**	**t3**	**HANDIHALER**	**t1**	**t2**	**t3**			
1.Shake the inhaler & remove the cap				1.Shake the inhaler and remove the cap				1.Shake the inhaler and remove the cap				1.Unscrew & lift off the cover				1. Open the device by pushing the thumb grip back until a 'CLICK' sound is heard.				1.Open the lid & lift open the mouthpiece						
2.Breathe out completely & comfortably				2.Connect inhaler to the Spacer				2.Connect inhaler to the mini spacer				2. **Hold the inhaler upright. Turn the grip as far it will go in one direction & turn it back again until a 'CLICK' sound is heard***				2. **Hold horizontally. Slide the lever away as far as it will go until another 'CLICK' sound is heard***				2. Remove a Spiriva capsule from the blister & place it into the capsule chamber. Close the mouthpiece until 'CLICK' sound is heard						
3.Place mouthpiece into mouth				3.Breathe out completely & comfortably				3.Breathe out completely & comfortably				3.Breathe out completely, away from the mouthpiece				3.Breathe out completely, away from the mouthpiece				3.**Hold the Handihaler with themouthpiece facing upwards and press the green piercing button once & release***						
4**. Actuate the canister ONCE while inhaling slowly and deeply (no aerosol mist seen)***				4.Apply mask to the faceand actuate the canister ONCE				4.Place the mouthpiece of the mini spacer between the teeth & seal the lips.				4. **Place the mouthpiece horizontally between teeth & seal the lips. Breathe in forcefully and deeply through the mouthpiece***				4.**Seal lips to the mouthpiece and inhale steadily & deeply***				4.Breathe out completely, away from the mouthpiece						
5.Hold breath for 4-10 seconds				5.**Inhale slowly and deeply and hold breath for 4-10 seconds OR 5-10 normal breath while remain on mask***				5. **Actuate the canister ONCE while OR before inhaling slowly and deeply** *				5.Remove the inhaler from the mouth before breathing out again				5.Remove the Accuhaler from the mouth and hold breath for at least 4-10 seconds, then breathe out slowly				5. **Place the Handihaler horizontally into the mouth and seal lips around the mouthpiece. Breathe in slowly and deeply at a rate sufficient to hear the capsule vibrating***						
6.Wait 30 seconds before next puff				6.Wait 30 seconds before next puff				6.Wait 30 seconds before next puff				6. Repeat step 2-5 if more than one dose is required. Replace the cover				6.Slide the thumb grip back to its original position until a 'CLICK' sound is heard				6.Repeat step 5 if needed to empty the capsule completely and dispose off the empty capsule						
TOTAL				TOTAL				TOTAL				TOTAL				TOTAL				TOTAL						
Rating (G/S/P)				Rating (G/S/P)				Rating (G/S/P)				Rating (G/S/P)				Rating (G/S/P)				Rating (G/S/P)						

Technique score rating: 6 (Good), 4-5 (Satisfactory), <4 (Poor)

*crucial steps failing which to perform automatically marks technique as "Poor"