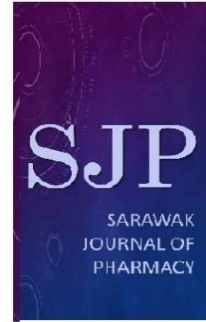


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Beliefs about Regular Inhaled Therapy among Chronic Obstructive Pulmonary Disease (COPD) Patients in Sibü Hospital

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Introduction: The primary treatment goal of managing stable Chronic Obstructive Pulmonary Disease (COPD) are a reduction of symptoms and future risk of exacerbation. Patients with Modified Medical Research Council (mMRC) dyspnea scale of <2 categorised as low symptoms of COPD while patients with exacerbation history of <2 times per year classified as a lower risk of exacerbation. The use of regular inhaled bronchodilators has shown to reduce symptoms and hospitalisation rate among patients with COPD. Patient's belief is one of the factors affecting their treatment adherence.

Objectives: This study aimed to investigate the belief of regular inhaled therapy in COPD patient and factors affecting such beliefs.

Methods: This was a cross-sectional study conducted from January 2019 to April 2019. We recruited stable COPD patients encountered in Outpatient pharmacy of Sibü Hospital for a face-to-face interview. We collected the respondent's demographic data, history of hospitalisation and mMRC dyspnea scaled. Belief about Medicines Questionnaire- Chronic Obstructive Pulmonary Disease (BMQ-COPD) scale adopted to measure the beliefs in term of concern or necessity towards regular inhaled therapy (*Cronbach alpha: Necessity score: 0.8. Concern score: 0.75*). Mean BMQ-COPD score for each parameter was analysed using independent *t*-test.

Results and Discussions: Fifty respondents participated in the study. The mean BMQ-COPD necessity score was significantly higher in the group with exacerbation < 2 times per year (16.89 vs 14.48, $P=0.03$) and in the group with mMRC <2 (18.6 vs 15.2, $P=0.013$). Patients using inhaler \geq five years have a higher concern score ($P=0.027$). Other factors such as ethnic, age and education level did not show significant association with patient's belief.

Conclusion: Prescribers and pharmacists should assess the patient's concern on regular inhaled therapy if they have used regularinhaled therapy for more than five years.

Keywords: Chronic obstructive pulmonary disease, regular inhaled therapy, concern, necessity, belief, Sibü

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a progressive respiratory disorder characterised by deterioration in lung function in the form of adverse changes to expiratory flow with considerable morbidity and mortality. COPD is not curable, but optimal management with the use of regular inhaled therapy provides symptom control, slows the progression of the disease, and may improve the quality of life (1,2).

Malaysia has an estimated prevalence of COPD of 4.7% (3). Despite being prescribed with regular inhaled therapy, quality of life of some COPD patients are still poor. A study conducted by Loh et al. in Seremban, Malaysia, showed that quality of life in the patient was generally low and about one-fifth of the patients had exacerbation more than 12 times a year (4). One of the reasons postulated is the patient's compliance. Since COPD is a progressive disease requiring long term use of inhaled therapy, the adherence to regular inhaled therapy in patients with COPD has been historically poor. According to James et al., COPD patient has low adherence to treatment than asthmatic patients (5). Several studies have reported that an average of 60% of patients with COPD does not adhere to prescribed therapy (6) and up to 85% of patients use their inhaler ineffectively. A study done by Ang et al. in northern peninsular Malaysia showed that more than half of the repeat prescriptions COPD inhalers showed undersupply, in which the patients may not be compliant nor using the inhaler correctly.

The reasons of non-compliance have been studied, in which one of them is the patient's belief towards the use of regular inhaled therapy. There are significant differences in health beliefs, experiences, and behaviours observed between COPD patients with different levels of adherence. George *et al.* have identified several beliefs, experiences, and health behaviours as strong predictors of low adherence to treatment in 276 patients with COPD (7). Generally, there are limited studies done in Malaysia regarding the belief of regular inhaled therapy in COPD patient. This study aimed to assess the patient's belief towards the use of regular inhaled therapy in the management of COPD; and to compare between patient's socio-demographic/ medication & disease characteristics with their belief towards the use of regular inhaled therapy in the management of COPD.

METHODS

Study Type and Design

We conducted a cross-sectional survey on medical clinic days (i.e. Monday and Wednesday) in outpatient pharmacy Sibu Hospital. Our target population was COPD patients using regular inhaled therapy. Ethical approval obtained for this study before the initiation of data collection (NMRR-18-2682-43408).

Data Collection

Data collection was carried out from January 2019 till April 2019 by investigators. According to data generated from Pharmacy Information system (PhIS) Sibu Hospital, the number of COPD patient using regular inhaled therapy estimated to be 844 per year while sample size required is 265 subjects according to Krejcie & Morgan 1970 sample size estimation (8). However, in this study, we recruited 50 subjects only due to manpower and time constraints.

We employed convenience sampling method in this study. Subjects selections based on inclusion/ exclusion criteria. Once the patient agreed to participate, the informed consent form was explained, signed and dated by both patient and investigator. Around 15 minutes face-to-face interview was conducted using a data collection form (containing questionnaire). At the end of the session, the investigator re-checked the questionnaire to ensure that the data collection form was complete.

There were two sections in the data collection form, namely, section A (demographics and disease characteristics) and section B (belief). Section A (part 1) consisted of questions about demographic characteristics such as age, gender, race, status, employment status, and educational level. Section A (part 2) consisted of questions regarding the patient's medication and disease characteristics which included: 1) Number of years on inhaled therapy; 2) mMRC (modified British Medical Research Council) score; 3) Number of exacerbation per year; 4) Number of other medications taken (i.e. the number of long term medications taken by patient excluding inhalers).

Section B consisted of COPD specific Belief about Medicines Questionnaire (BMQ-COPD), which was a validated questionnaire adapted from Horne *et al.* (9). This section consisted of twodomains, which were thenecessity scale (7 questions) and concerns scale (15 questions). Each domain used a 5-point Likert scale in which each item was given a score from 5 (strongly agree) to 1 (strongly disagree)and summed to obtain a total score. In the “necessity” domain, the total score ranged from 7 to 35 (Item no 7 was reversely scored) while in the “concern” domain, the total score ranged from 15 to 75 (Items no 8, 10 and 11 were reversely scored).

The “necessity” scale reflects the patient’sbeliefs about the necessity of regular inhaled therapyto control their illness.Patients with higher scores on the Necessity scale have stronger perceptions of the need for the drug to maintain their physical health. The “concerns” helps to evaluate their concerns about the potential adverse consequences of taking medication. Patients with higher Concerns scores means more substantial concerns about the regular use of the drug.

The original survey form of BMQ-COPD is available in the English version and used as Investigator-assisted administration. The data collectors had a group discussion to standardiseoral translation of keywords in the questionnaire.

Inclusion and Exclusion Criteria

We included all COPD patients attending medical specialist clinics during the study period.Our inclusion criteria included the adults diagnosed with COPD according to the Global initiative for Chronic Obstructive Lung Disease (GOLD) guideline and COPD patients prescribed with regular use of inhaled therapy as one of their treatment regimen. We excluded patients with language barrier/cognitive impairment and patients who were dependent on a caregiver for the administration of inhaled therapy in term of dose and frequency.

Data Analysis

The data collected was analysed using the SPSS® (Statistical Package for the Social Sciences) software program. The socio-demographic characteristics of the respondents were analysed using descriptive analysis. Categorical variables such as gender, race, age, status, educational level and

employment status were recorded and presented as frequency (%). For numerical variables such as age, number of years on the inhaler, number of other medications taken, numbers of exacerbation per year, and mMRC score were presented as mean and standard deviation (SD); or median and interquartile range (IQR) for the skewed data. Independent *t*-test used to compare mean “necessity” or “concern” score among the groups.

RESULTS

Socio-Demographic Characteristics

A total of 50 respondents with COPD participated in this study. Table 1 summarised the socio-demographic information of participants. Forty participants (80%) with mMRC (modified Medical Research Council) dyspnea score ≥ 2 , which means most subjects still have high COPD symptoms despite using regular inhaled therapy. However, the mean number of exacerbation was 1.32 per year, reflecting relatively low exacerbation risk. Most subjects were male (82%), Iban ethnic (82%) and married (96%).

Table 1. Socio-Demographic Characteristics of the Study Participants (n=50)

| Variable | n (%) | Mean (SD) | Median (IQR) |
|---|---------|-------------|----------------------|
| Age (years) | - | - | 66 (14) ^a |
| <65 | 23 (46) | - | - |
| ≥ 65 | 27 (54) | - | - |
| Number of years using inhalers (years) | - | - | 5 (8) ^b |
| <5 | 26 (52) | - | - |
| ≥ 5 | 24 (48) | - | - |
| Number of other medications taken | - | 7.22 (3.84) | - |
| <7 | 22 (44) | - | - |
| ≥ 7 | 28 (56) | - | - |
| mMRC score | - | 2.22 (0.86) | - |
| <2 | 10 (20) | - | - |
| ≥ 2 | 40 (80) | - | - |
| Number of exacerbation per year | - | 1.32 (1.11) | - |
| <2 | 29 (58) | - | - |
| ≥ 2 | 21 (42) | - | - |
| Gender | | | |
| Male | 41 (82) | - | - |
| Female | 9 (18) | - | - |

Table 1. Socio-Demographic Characteristics of the Study Participants (n=50) (*con't*)

| Variable | n (%) | Mean (SD) | Median (IQR) |
|-----------------------|--------------|------------------|---------------------|
| Ethnic | | | |
| Malay | 2 (4) | - | - |
| Chinese | 5 (10) | - | - |
| Iban | 41 (82) | - | - |
| Melanau | 2 (4) | - | - |
| Marital status | | | |
| Single | 2 (4) | - | - |
| Married | 58 (96) | - | - |
| Education | | | |
| No formal education | 15 (30) | - | - |
| Primary school | 16 (32) | - | - |
| Secondary school | 19 (38) | - | - |
| Working status | | | |
| Working | 7 (14) | - | - |
| Retired | 26 (52) | - | - |
| Not working | 17 (34) | - | - |

^aAge was negatively skewed (Skewed to the left)

^bNumber of years using inhalers was positively skewed (Skewed to the right)

Patient's Belief on the Necessity and Concern towards the Use of Regular Inhaled Therapy

Patient's belief reflected as "necessity" and "concern" on the use of regular inhaled therapy. BMQ-necessity scales (Figure 1) showed that most of the subjects agreed with the need for inhalers to maintain their health. More than half of the participants answered agree to 6 out of 7 the necessity scale (i.e. Item no. 1, 2, 4, 5, and 6). Among which, the highest agreement was 82% for both No. 2 "My life would be impossible without this inhaler" and No. 6 "This inhaler is the most important part of my treatment".

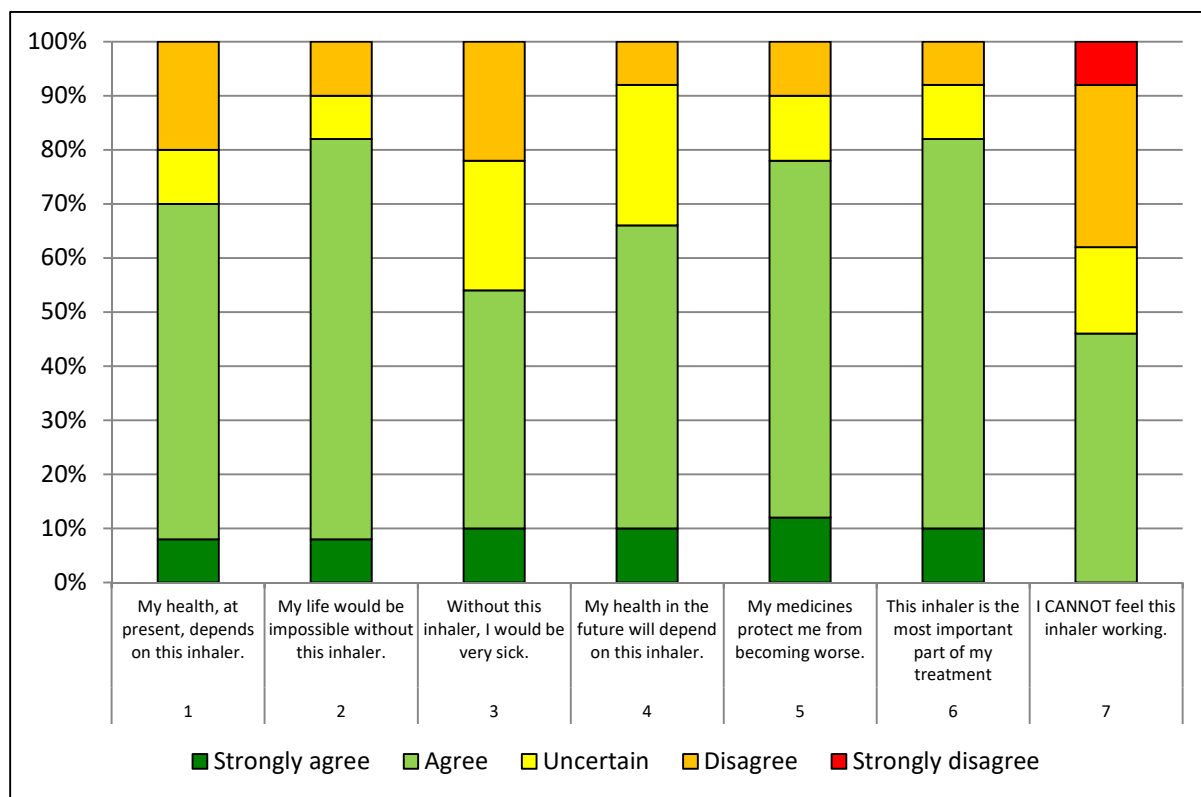


Figure 1. Overall BMQ-Necessity Scale

In the BMQ-Concern Scale (Figure 2), 58% of subjects agreed to Item no. 5 (I sometimes worry about becoming too dependent on this inhaler). More than half of the subjects showed less concern as they disagreed to item no.1 (having this inhaler worries me), no.4 (This inhaler disrupts my life), no.6 (this inhaler does more harm than good), no.7 (People who take this inhaler should stop their treatment for a while every now and again) and no.11 to no.14. Most patients (80%) disagreed that inhalers give unpleasant side effect (no.12). There were 48% of

subjects who disagreed that sufficient information provided regarding their treatment. Besides, other statements had relatively even distribution between agree/ disagree.

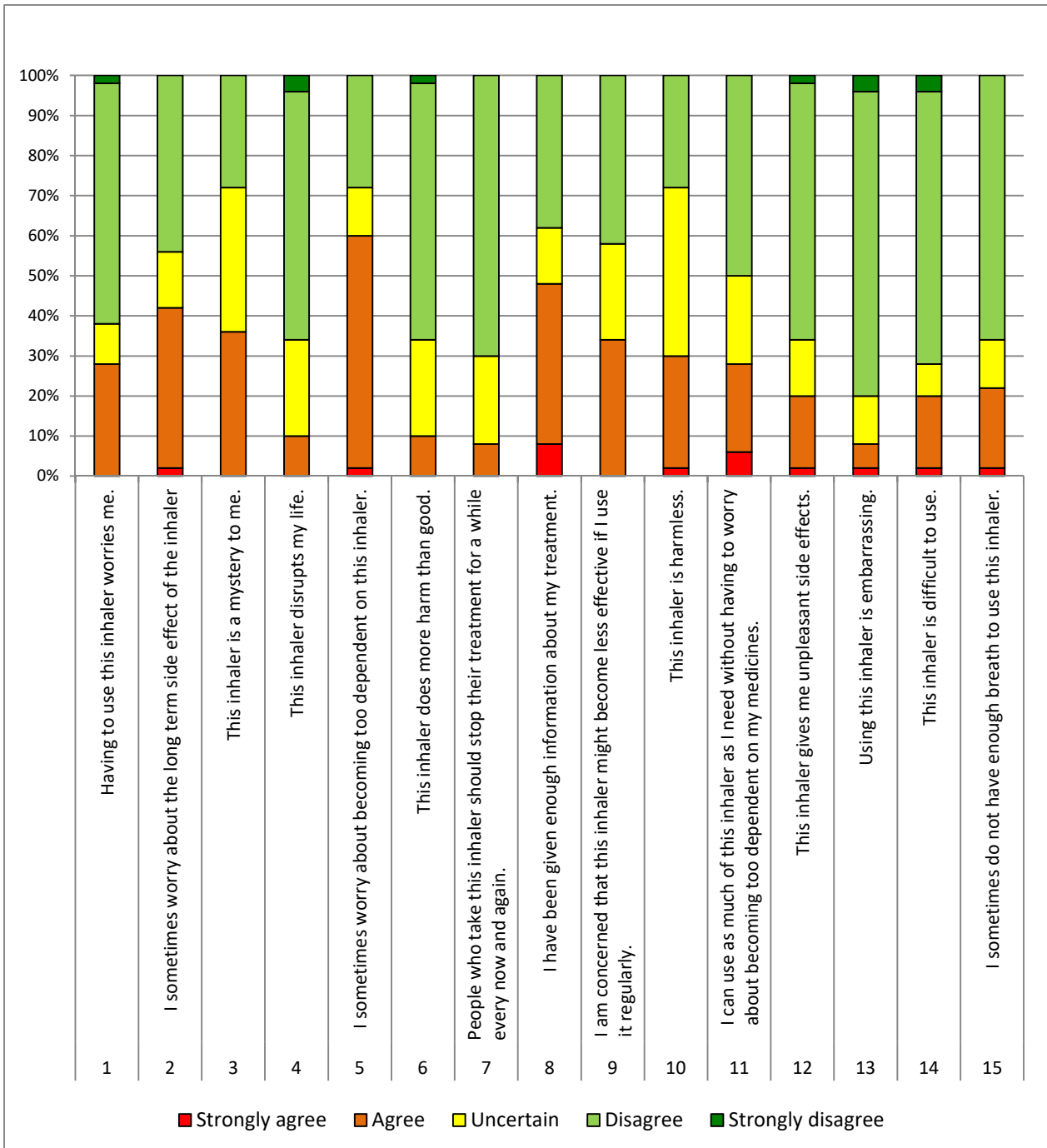


Figure 2. Overall BMQ-Concerns Scale

Comparing the Necessity Scale with Different Socio-Demographic Parameters

Table 2. Comparing Socio-Demographic with Necessity Score on the Use of an Inhaler

| Variable | n | Necessity score, Mean (SD) | t- statistics (df) | P-value |
|---|----|-------------------------------|------------------------|--------------------|
| Number of years using inhalers (years) | | | | |
| < 5 | 26 | 15 (5.50) ^a | -0.128 ^a | 0.898 ^a |
| ≥ 5 | 24 | 16 (2.75) ^a | | |
| Number of other medications | | | | |
| <7 | 22 | 16.07 (0.79) | -0.385 (48) | 0.702 |
| ≥7 | | | | |
| mMRC score | | | | |
| <2 | 10 | 18.60 (3.50) | 2.580 (48) | 0.013 |
| ≥2 | 40 | 15.20 (3.78) | | |
| Number of exacerbation per year | | | | |
| <2 | 29 | 16.89 (3.49) | 2.231 (48) | 0.030 |
| ≥2 | 21 | 14.48 (4.17) | | |
| Age (years) | | | | |
| <65 | 23 | 16.69 (3.77) | 1.364 (48) | 0.179 |
| ≥65 | 27 | 15.19 (4.01) | | |
| Gender | | | | |
| Male | 41 | 16.29 (3.77) | 1.608 (48) | 0.114 |
| Female | 9 | 14.00 (4.36) | | |
| Ethnic | | | | |
| Iban | 41 | 16.05 (3.97) | 0.643 (48) | 0.523 |
| Non-iban | 9 | 15.11 (3.89) | | |
| Education | | | | |
| No formal education | 15 | 16.00 (4.00) ^b | 1.984 (2) ^d | 0.371 |
| Primary school | 16 | 15.00 (3.75) ^b | | |
| Secondary school | 19 | 15.00 (5.00) ^b | | |

Note:

^a Mann Whitney test is used due to Levene's test not satisfied. Result presented as median (IQR) with Z statistics.

^b Kruskal-Wallis test is used due to non-normal distribution in all three groups. Result presented as median (IQR) with X^2 statistics and *df*.

The study compared the necessity scale among different socio-demographic groups (Table 2). All numerical variables were parametric except years on the inhaler and education. Education parameter analysed using Kruskal-Wallis test due to non-normal distribution in all three groups.

Results showed that patients with mMRC <2 has higher necessity score (mean=18.60) compared to mMRC \geq 2 (mean=15.20), $P=0.013$. Similarly, patients with exacerbation per year of <2 also have a higher necessity score (mean=16.89) compared to \geq 2 (mean=14.48), $P=0.03$. There was no significant difference in the necessity score for other variables.

Comparing Concern Scale with Different Socio-Demographic Parameters

The current study compared the concern scale among different socio-demographics (Table 3) using Independent *t*-test (for parametric variables) or Mann-Whitney test (for non-parametric variables). Results showed that the patients using inhaler \geq five years have a higher concern score (mean=50.63) compared to < five years (mean=47.35), $P=0.027$. This finding suggests that patients using inhalers < five years has a lower concern about the potential adverse consequences of the inhalers. Mann-Whitney test also showed that female had higher concern score (mean=52.00) compared to male (mean=49.00), $P=0.033$. There was no significant difference in the concern score for other variables.

Table 3. Comparing Socio-Demographic with Concern on the Use of an Inhaler

| Variable | n | Concern score, Mean (SD) | <i>t</i> - statistics (df) | <i>P</i> -value |
|---|----|-----------------------------|-------------------------------|-----------------|
| Number of years using inhalers (years) | 26 | 47.35 (5.47) | -2.283 (48) | 0.027 |
| < 5 | 24 | 50.63 (4.60) | | |
| \geq 5 | | | | |
| Number of other medications | | | | |
| <7 | 28 | 49.68 (4.77) | 0.901 (48) | 0.372 |
| \geq 7 | 22 | 48.32 (5.67) | | |
| mMRC | | | | |
| <2 | 10 | 47.70 (4.92) | -0.813 (48) | 0.420 |
| \geq 2 | 40 | 49.23 (5.39) | | |

Table 3. Comparing Socio-Demographic with Concern on the Use of an Inhaler (*con't*)

| Variable | n | Concern score, Mean (SD) | t- statistics (df) | P-value |
|--|----|-----------------------------|------------------------|---------|
| Number of exacerbation per year | | | | |
| <2 | 29 | 48.59 (4.99) | -0.521 (48) | 0.605 |
| ≥2 | 21 | 49.38 (5.77) | | |
| Age (years) | | | | |
| <65 | 23 | 48.69 (5.13) | -0.274 (48) | 0.785 |
| ≥65 | 27 | 49.11 (5.51) | | |
| Gender | | | | |
| Male | 41 | 48.00 (7.00) ^b | -1.129 ^b | 0.033 |
| Female | 9 | 52.00 (6.50) ^b | | |
| Ethnic | | | | |
| Iban | 41 | 49.00 (7.00) ^c | -0.330 ^c | 0.742 |
| Non-Iban | 9 | 48.00 (8.00) ^c | | |
| Education | | | | |
| No formal education | 15 | 48.00 (7.00) ^d | 3.236 (2) ^d | 0.198 |
| Primary school | 16 | 51.50 (6.25) ^d | | |
| Secondary school | 19 | 47.00 (7.00) ^d | | |

Note:^a Mann-Whitney test is used due to Levene's test not satisfied. Result presented as **median (IQR)** with **Z statistics**.

^b Mann-Whitney test is used due to negatively skewed histogram distribution in the female group. Result presented as **median (IQR)** with **Z statistics**.

^c Mann-Whitney test is used due to negatively skewed histogram distribution in the non-iban group. Result presented as **median (IQR)** with **Z statistics**.

^d Kruskal-Wallis test is used due to non-normal distribution in all three groups. Result presented as **median (IQR)** with **X² statistics** and *df*.

DISCUSSION

Patient's Belief on Necessity towards the Use of Regular Inhaled Therapy

Under the necessity domain, findings were overall positive, which suggests that most COPD patients feel the use of regular inhaled therapy is necessary for COPD. There were 82% of subjects agreed for both item no.2 "My life would be impossible without this inhaler" and no.6 "This inhaler is the most important part of my treatment".

Our study also showed patients with fewer symptoms ($mMRC < 2$) and less exacerbation (< 2 per year) had a higher necessity score that results from better adherence towards the use of regular inhaled therapy among patients with higher necessity belief, which in turn improves symptoms and reduce exacerbation. A study done by Duarte-de-Araujo et al. and foot et al. showed that adherent patients have higher mean BMQ Necessity score (11, 12). According to Bourbeau et al., adherence is affected by patients' perception of their disease, type of treatment or medication, the quality of communication provided to the patient and the social environment (10). They stated that patients are more likely to adhere to treatment when they believe it will improve disease management or control, or anticipate serious consequences related to non-adherence (10).

Hence, for COPD patients with more symptoms ($mMRC \geq 2$) and frequent exacerbation (≥ 2 per year), it is essential to assess the patient's compliance and technique before escalating the treatment.

Patient's Belief on Concern towards the Use of Regular Inhaled Therapy

Concern domain has also shown a relatively positive result in which most subjects disagreed to concern statements (negative belief). The main concern was item no.5 Q5 (I sometimes worry about becoming too dependent on this inhaler) in which 58% of subjects agreed. This finding is consistent with a previous study carried out by Chan & DeBruyne in 2000 (13). According to Chan, this misconception may be due to modern-day inhalational drug abuse. Intensive campaigns that bombard people with visions of inhaled drugs and drug addicts may lead to this misconception (13).

This study also showed patients using inhaler \geq five years have a higher concern score (mean=50.63) compared to $<$ five years (mean=47.35), $P=0.027$. Although statistically significant, the magnitude of the difference is only 3.28, which may not reflect clinically. Nevertheless, a previous study done by Jahedi et al. in 2017 showed patients on long term use of inhaler believed that they are at risk of becoming dependent on their inhaler medications (14).

Therefore, we would like to suggest pharmacists or prescribers to always ask for any concern of becoming dependent on the inhaler, especially if the patient has been using inhalers for more

than five years. If the patient identified as having such problem, it is essential to address and reassure patient that the use of inhalers is to control symptoms and reduce exacerbation risk, which does not cause dependence.

LIMITATION

One of the limitations of our study is the small sample size. We had only recruited 50 subjects instead of 265 subjects. Convenience sampling used instead of random sampling method, therefore the subjects may not represent the population. Nevertheless, this study can serve as preliminary data for further studies.

Besides, the survey questionnaire used was adapted from a previous study which initially designed to be self-administered by the patient. However, due to concern of limited literacy among target population (elderly) and possible language barrier (the questionnaire was only available in the English version), we decided to switch to interviewer-administered. Nevertheless, we have carried out a group discussion to standardise and translate keywords in the questionnaire to reduce the discrepancy.

Future multi-centred studies with adequate sample size are required for generalisation of results to other populations. Researcher may include patient's compliance assessment in the future study.

CONCLUSION

About 80% of COPD patients still have high COPD symptoms (with mMRC score ≥ 2) despite on regular inhaled therapy mMRC (modified Medical Research Council). COPD patients in Sibul Hospital seemed to have relatively positive necessity belief and less concern towards the use of regular inhaled therapy. Patients with higher necessity belief seem to have better control of symptoms and less exacerbation. COPD patients may have concern regarding being dependent on inhalers, particularly if it has been used for more than five years. Hence, prescribers and pharmacists should assess the patient's concern on regular inhaled therapy if they have used regular inhaled therapy for more than five years.

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