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Original Article

The effect of Tualang honey on the quality of life of patients with chronic obstructive pulmonary disease: A randomized controlled trial

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المخلص

أهداف البحث: يعد مرض الانسداد الرئوي المزمن مرضاً متعباً للعكس، واستخدام العسل كمكمل في العلاج لا يزال قيد البحث. تهدف هذه الدراسة إلى تقييم فعالية نظام ٦-أشهر من مكملات العسل في تحسين جودة الحياة لدى مرضى الانسداد الرئوي المزمن.

طرق البحث: أجريت دراسة عشوائية محكمة على ٣٤ مريضاً يعانون من مرض الانسداد الرئوي المزمن. تم تقسيم المشاركين إلى مجموعتين؛ العسل (عدد = ٢٢) ورعاية نموذجية (عدد = ١٢). تم استخدام استبانة سانت جورج التنفسية لتقييم جودة الحياة. وحللت مجموع نقاط جودة الحياة باستخدام مقياس انوفا المتكرر.

النتائج: لم يكن هناك فرق ذو دلالة إحصائية بين مجموعة العسل والرعاية النموذجية للمتغيرات الاجتماعية والديموغرافية وجودة الحياة. وأظهر التحليل في الوقت المناسب خطأ أساسياً ذا دلالة إحصائية واختلافات ما بعد ٢ و ٤ و ٦ أشهر لمجموع نقاط جودة الحياة في مجموعة العسل. من ناحية أخرى، تم الكشف عن فرق هامشي فقط بين الخط الأساسي وما بعد شهرين في مجموعة الرعاية النموذجية. المقارنة بين مجموع النقاط لجودة الحياة بين المجموعتين على أساس الوقت (بين وفي غضون) فضل مجموعة العسل. أظهرت مجموعة العسل معدل أقل بكثير لمجموع نقاط جودة الحياة بالمقارنة بمجموعة الرعاية النموذجية في ٤ أشهر و ٦ أشهر.

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الاستنتاجات: أظهرت مكملات العسل عند مرضى الانسداد الرئوي المزمن تغيرات متوسطة وطويلة الأجل أفضل في إجمالي جودة الحياة.

الكلمات المفتاحية: مرض الانسداد الرئوي المزمن؛ العسل؛ عسل توالانغ؛ جودة الحياة؛ دراسة عشوائية محكمة

Abstract

Objectives: This study aimed to assess the efficacy of a 6-months regime of honey supplementation in improving the quality of life (QoL) of patients with chronic obstructive pulmonary disease (COPD).

Methods: A single blind randomized controlled trial on 34 patients with COPD was conducted. The participants were divided into two groups, including honey (n = 22) and standard care (n = 12). St. George's Respiratory Questionnaire (SGRQ) was used to assess the QoL. The QoL total score was analysed using repeated measure ANOVA.

Result: There were no significant differences between the honey and standard care groups for socio-demographic and QoL variables. The within-time analysis showed statistically significant differences between baseline and post 2, 4 and 6-months in the total QoL score in the honey group. Otherwise, only marginally significant difference was detected between baseline and post 2-months in the standard care group. A comparison of total QoL score between the two groups, based on time (between

and within), favoured the honey group. The honey group demonstrated a significantly lower mean total QoL score compared with the standard group at 4-months (28.89; 95% CI: 21.19, 36.59 vs 42.38; 95% CI: 31.95, 52.81) and 6 months (22.91; 95% CI: 14.94, 30.87 vs 41.95; 95% CI: 31.17, 52.73).

Conclusion: Supplementation of honey in patients with COPD results in better intermediate and long-term changes in the overall QoL.

Keywords: Chronic obstructive pulmonary disease; Honey; Quality of life; Randomized controlled trial; Tualang honey

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Introduction

Chronic obstructive pulmonary disease (COPD) is a common public health illness with a high prevalence, morbidity and mortality.¹ It is the third leading cause of death in the world,² and the death rate from COPD is increasing rapidly, especially among the elderly.³ COPD is characterized by a progressive, partially reversible airflow obstruction and lung hyperinflation with significant extra pulmonary manifestation that leads to a comorbid condition.⁴ The airway limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases. Patients with COPD usually present with a chronic cough and copious sputum production for many years.

COPD has no cure and is an irreversible disease.⁵ The patients not only suffer physically and mentally, they also have a poor quality of life. A study by E.A. Regan et al. noted that the quality of life (QoL) in her COPD patients worsened in a five year time period and was associated with increased dyspnea and a reduced walking distance.⁶ An impaired quality of life was significantly linked to increased medical costs for COPD patients.⁷ Thus, a positive perception of health and preserving the quality of life should be the goal in caring for these patients apart from the usual clinical treatment.⁸

There are minimal published clinical studies evaluating at the effects of Tualang honey on COPD patients. Based on animal studies, honey has antimicrobial properties and significantly reduces macrophage recruitment in the airway following inflammatory response due to cigarette smoke inhalation.⁹ It is hypothesized that honey might have a beneficial effect on COPD patients by improving airway relief, symptoms, nutritional status and, subsequently, quality of life.

Therefore, this study aimed to assess the efficacy of Tualang honey in COPD patients in terms of nutritional status, pulmonary function and quality of life. In addition, a further assessment on the safety of honey provides additional scientific information on the usefulness of honey, specifically in COPD patients.

Materials and Methods

Study population

Outpatients from two chest clinics, namely, the Hospital Universiti Sains Malaysia and the Hospital Raja Perempuan Zainab II, Kelantan, Malaysia, with follow ups between December 2010 and December 2011 were enrolled. The patients were required to fulfil the COPD diagnostic criteria as defined by the America Thoracic Society, such as history of exposure to risk factors with present of symptoms, such as chronic cough, sputum production or dyspnoea.

Spirometry was done with post-bronchodilator forced expiratory volume in one second, with a forced vital capacity (FEV1/FVC) ratio of <0.7. The diagnosis should be confirmed by spirometry. A post-bronchodilator FEV1/FVC ratio of less than 0.7 confirms the presence of an airflow limitation that is not fully reversible and is currently widely accepted as a diagnostic of COPD.⁴ The other inclusion criteria included age within 40–80 years, a smoking history of at least 20 pack-years and a history of exposure to risk factors for the disease with symptoms of chronic cough, sputum production or dyspnoea. Patients with a history of asthma or atopy, left ventricular failure, and clinical evidence of pneumonia and who received at least one month oral steroids were excluded from the study.

The sample for recruitment was 30 for intervention and 30 for the controls with an 80% power and an alpha error of 0.05 and after considering a 10% loss to follow up. The calculation was based on the variable QoL score reported by Abolhassan et al., with a standard deviation of 16.14 and a clinically meaningful difference of 10 score.⁵ The ratio of the intervention to control was set at 1:1.

Operational definition

The intervention group consisted of COPD outpatients who consumed Tualang honey as a supplementary therapy apart from their usual COPD treatment. Meanwhile, the control group was comprised of COPD outpatients who received the usual COPD standard care treatment. The standard care for the present COPD patients included medications, such as seretide/simbicort, salbutamol and tiotropium bromide (Spiriva) and advise for a healthy lifestyle.

The efficacy of honey refers to the therapeutic effect of Tualang honey on the COAD patients' QoL, pulmonary function and nutritional status. The safety of honey refers to deteriorating clinical investigations in the COPD patients who received Tualang honey. The clinical safety parameters included blood pressure, renal function, liver function and blood glucose.

Method of data collection

The COPD patients who came to the chest clinic for a follow up and met the inclusion criteria and not the exclusion criteria were sequentially assigned to either the intervention or control group based on a prepared randomized coding in opaque, sealed envelopes. The simple randomization was

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