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The effects of Momordica charantia (bitter melon) supplementation in patients with primary knee osteoarthritis: A single-blinded, randomized controlled trial

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ABSTRACT

Background: Osteoarthritis is a common problem affecting the joints in the elderly, caused disability and consequently decrease the quality of life. The conservative treatment includes the usage of analgesia, but the use of herbal medicine is growing. Momordica charantia or bitter melon has been widely described to have anti-diabetic and anti-inflammatory effects. However, its effect on reducing pain in primary knee osteoarthritis is not well studied. We aim to determine the effects of Momordica charantia in reducing pain among primary knee osteoarthritis patients.

Materials and methods: Thirty-eight and thirty-seven primary knee osteoarthritis patients underwent 3 months of Momordica charantia and placebo supplementation respectively. Three 500 mg per capsule of Momordica charantia were taken thrice daily. Rescue analgesia was allowed as needed. Pain and symptoms throughout the Momordica charantia supplementation period were assessed using Knee Injury and Osteoarthritis Outcome Score and EQ-5D-3L Health questionnaire, while rescue analgesia intake throughout the period of supplementation was measured using analgesic score.

Results: After 3 months supplementation period, body weight, body mass index, and fasting blood glucose reduced significantly in the Momordica charantia group. There were also significant improvements in Knee Injury and Osteoarthritis Outcome Score subscales and EQ-5D-3L dimension score, and reduction in analgesic score. The placebo group had also shown significant improvements in certain Knee Injury and Osteoarthritis Outcome Score subscales and EQ-5D-3L dimension score, but with increased of the analgesic score.

Conclusion: Momordica charantia supplementation offers a safe alternative to reducing pain and improving symptoms among the primary knee osteoarthritis patients while reducing the need for analgesia consumption. These beneficial effects can be seen as early as 3 months of supplementation.

1. Introduction

Osteoarthritis (OA) is the major cause of chronic disability at older ages, notably when the knee and hip joints are involved. The prevalence of knee OA increases rapidly with advancing age. In the European Union only, there are approximately 100 million people who are suffering from knee OA. It has been estimated that, with regards the incidence of knee OA among persons between 60 and 79 years of age in western European countries, there will be an increase from 18% to 25% and from 24% to 40% in men and women respectively [1]. In Malaysia, the prevalence of knee OA among the population aged more than 65 years old is estimated to be at 30%. About 9.3% of Malaysian adults have experienced knee pain, and there was a trend that showed a rise in pain rate, whereby it had increased to 23% for population aged more than 55 years old, and to 39% in population more than 65 years old [2].

Knee OA patients seek treatment for joint pain and daily life activity limitations, especially walking, kneeling or squatting, and climbing upstairs. The main goal of treatment is the improvement of function and quality of life. OA is one of the major health problems in which patients prefer to use alternative methods of treatment [3], particularly after

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experiencing the side effects of painkillers; or failure of conventional medication to improve the symptoms. Alternative treatments that are used for OA include herbs, supplements, acupuncture, and electromagnets. Globally, the use of traditional/herbal medicine has been garnering growing attention as it offers better accessibility and affordability in the face of the rising cost of health care services [4].

Momordica charantia (MC), a type of tropical plant of the Cucurbitaceae family, is widely planted in Asia, East Africa, and South America. MC is locally referred to as bitter melon, karela, balsam pear or bitter gourd [5,6]. Famously recognized for its bitter taste, it is commonly used in cooking and traditional medicine. Previous studies have reported the healing properties of MC such as antidiabetic, antioxidative, antiviral, anti-inflammatory, antioxidative, antimutagenic and cholesterol-lowering effects [6–8]. In traditional practice, almost all parts of MC such as fruits, stems, leaves, and roots are used in the treatment of various human diseases like hyperlipidemia, digestive disorders, microbial infection and menstrual problems [9].

Most studies done on the effects of MC pertain to diabetes mellitus in humans. There were also studies performed among adult participants where metabolic syndrome incidence rate was decreased with MC supplementation [10]. The potential analgesic effect of MC has been demonstrated in mice and rats models [11–13], but none of such studies have been carried out in the human population. Therefore, this study was designed to determine the effectiveness of MC supplement in pain reduction, improvement of symptoms and the quality of life in patients with primary knee OA as well as to determine the change of frequency of analgesia intake with MC supplementation. In this study, we hypothesize that MC supplementation may reduce the pain, improve the symptoms and the quality of life as well as reduce the analgesic intake in patients with primary OA.

2. Materials and methods

2.1. Study design

This is a single-blinded, placebo-controlled randomized controlled study conducted in Hospital Universiti Sains Malaysia from October 2015 until October 2016. Study protocols had been approved by the Universiti Sains Malaysia (USM) Research Ethics Committee (Human) and were conducted according to the principles of the Declaration of Helsinki. All patients were required to sign an informed consent form before participating in the trial. Each patient was included in the trial for 3 months.

2.2. Sample size estimation

Based on the study by Giordano et al. [14], a sample size of 36 patients in each arm was required for a detectable difference (δ) of 9.3 (SD 13.9) in total pain score using KOOS score between MC and placebo groups with a two-sided 5% significance level and a power of 80%. Forty patients were enrolled per group to allow for 10% dropouts; therefore, total sample size calculated was 80.

2.3. Participants criteria and randomization

Eighty primary knee osteoarthritis (OA) patients who attended our orthopedic clinic and who fulfilled the inclusion criteria were recruited. To be eligible, the patients had to be confirmed as primary unilateral or bilateral knee osteoarthritis patients with the diagnosis made according to the clinical and radiological criteria of the American College of Rheumatology [15]; and OA grade between I and III, determined based on knee radiograph with the Kellgren-Lawrence classification [16]. Patients with debilitating medical conditions such as severe hematologic disorders or renal and liver disease, patients having grade IV knee OA, secondary knee OA, or who have been planned for surgical intervention were not included in this study. Following the simple randomization procedure, patients were randomized 1:1 into two groups: MC or placebo, with 40 patients in each arm by using an online randomization list generator. Patients had no knowledge of which arm of the trial they were allocated to.

2.4. Supplementation materials

Commercially available MC capsules were obtained from a local manufacturer (CCM Duopharma Sdn Bhd). Similar-looking capsules of placebo containing inactive excipients were also prepared accordingly by a local manufacturer (Skinfix Technologies Sdn Bhd). Both manufacturers are GMP-certified, and except for supplying MC and placebo capsules, they were not involved in any part of this study. Both manufacturers also did not make any therapeutic claims of their products based on the findings of this study. The MC capsules are products registered with the Malaysian National Pharmaceutical Regulatory Agency. Both the MC and placebo were 500 mg per capsule, with 60 capsules in each unlabeled identical bottle. The patient had no way of determining whether they were on MC supplement or placebo.

Three 500 mg capsules of MC or placebo were taken thrice daily post-meal for a 3-month supplementation period, resulting in a total of 4500 mg consumption of MC or placebo per day. The supplementation dosage of 4500 mg per day was chosen based on a clinical study among adults that found the effectiveness of MC supplementation in improving metabolic syndrome without serious side effects [10]. Current medications were continued, as usual, patients were allowed to take rescue analgesia as required; but consumption of analgesia was to be recorded in an analgesia diary. Within the supplementation period, all patients were asked to avoid intake of any MC-related foodstuff, corticosteroids and hyaluronic acid injections, and procedures such as arthroscopic surgery. Patients found to have violated the protocol was excluded.

2.5. Study procedures

On the first visit, social demographic data, medical history, current medications and knee OA history were recorded for each participant. Baseline body weight, height, and body mass index (BMI) were measured while blood was drawn for total cholesterol (TC), triglyceride (TG) and fasting blood glucose (FBG) measurements. The severity of knee pain and symptoms for each patient was quantified using the Knee Injury and Osteoarthritis Outcome Score (KOOS) and EQ-5D-3L Health questionnaires. Patients were then supplied with either MC or placebo capsules based on a randomization list and advised to follow the study procedure accordingly. During the second visit (one week after initiation), patients were assessed to evaluate compliance and safety of supplementation. Symptoms like nausea, vomiting, diarrhea, discomfort or other side effects experienced by patients after taking the trial medications were recorded and further actions such as prescribing rescue analgesia were taken accordingly. For rescue analgesia, patients were prescribed tablet acetaminophen 1 g stat for mild to moderate pain; and capsule celecoxib 200 mg stat for severe pain (or tablet tramadol 50 mg if unable to tolerate celecoxib). In addition, patients were provided with a medication diary to record the number and frequency of analgesia they had consumed. Change to another form of analgesia was not allowed except if they had informed the investigators beforehand. All patients were reassessed at first, second and the third month of the supplementation period. Side effects of the supplementation and compliance were evaluated, and the medication diary collected. Compliance was measured based on the return of unused capsules by patients using this formula: Compliance = (no. of capsules taken during the period/no. of capsules should have been taken) x 100, and any patients taking less than 80% of capsules are considered non-compliant. Evaluation of pain, symptoms, the quality of life and other related parameters was also performed using KOOS and EQ-5D-3L questionnaires while measurements of body weight, BMI, TC, TG, and FBG were repeated after the 3-month supplementation period.