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Original article

Effect of jaw-opening exercise on prevention of temporomandibular disorders pain associated with oral appliance therapy in obstructive sleep apnea patients: A randomized, double-blind, placebo-controlled trial[☆]

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ABSTRACT

Purpose: There are no studies on the prevention of temporomandibular joint and/or masticatory muscle pain (TMD pain) associated with oral appliance (OA) therapy in patients with obstructive sleep apnea (OSA). The aim of this study was to determine the effect of jaw-opening exercise on TMD pain associated with OA therapy in OSA patients.

Methods: Twenty-five OSA patients without pain-related TMD were consecutively enrolled into a two-arm, randomized, double-blind, placebo-controlled trial. One group performed jaw-opening exercise (JE, n=13), and the other group performed placebo exercise (PE, n=12) for 1-month, and had started 2-weeks prior to insertion of an adjustable OA. TMD sign using the Research Diagnostic Criteria for Temporomandibular Disorders and TMD pain intensity

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using a visual analog scale (VAS) in the morning and daytime were evaluated at baseline (pre-exercise) and at 2-weeks, 1-month, and 3-months after OA insertion.

Results: Pain-related TMD was not observed in the JE-group at all evaluation periods, although one subject in the PE-group was diagnosed with arthralgia at the 1-month evaluation. The JE-group showed lower morning and daytime VAS scores than the those of the PE-group at all evaluation periods, and significant group differences were found in terms of chewing pain and jaw-opening pain in the morning at the 1-month evaluation, and of jaw-opening pain during daytime at the 3-month evaluation ($P < 0.05$).

Conclusions: Within the limitations of the study, jaw-opening exercise prior to OA therapy reduced the risk of TMD pain associated with OA use. Therefore, jaw-opening exercise may contribute to the prevention of TMD pain.

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1. Introduction

Oral appliance (OA) therapy is a treatment option for obstructive sleep apnea (OSA). An OA dilates the upper-airway by positioning the mandible forward; this prevents upper-airway obstruction during sleep [1–3]. However, OA therapy has short-term side effects, such as excessive salivation, dry mouth, and occlusal discomfort [4,5]. In addition, it sometimes causes pain in the temporomandibular joint (TMJ) and/or masticatory muscles, which is diagnosed as temporomandibular disorders (TMD) [5–8], as OA holds the mandible in an unnatural anterior position. Pain in the TMJ and masticatory muscles associated with OA use may decrease compliance and result in treatment failure. In fact, the main reasons for dropout from OA therapy are a perceived lack of improvement and side effects [9–11]. Therefore, prevention of TMD and ensuring the oral comfort with an OA is necessary for its long-term use and successful treatment results.

TMD is commonly a self-limited disease [12]. In general, conservative treatments with noninvasive and reversible modalities are the first choice for TMD [13]. Therapeutic exercise, involving stretching of the muscle and joint, is intended to relieve pain and decrease functional impairment during the chronic phase of TMD [14]. In musculoskeletal disorders, such as bone fractures, lower back pain, and knee pain, therapeutic exercise is applied not only for treatment, but also for prevention of these diseases [15,16]. In OSA patients with TMD that includes symptomatic pain, jaw-opening exercises have been effective in reducing pain and increasing OA compliance [17]. However, it is not known whether jaw-opening exercises in OSA patients without TMD are effective for preventing TMJ and/or masticatory muscle pain (TMD pain) associated with OA use. The purpose of this study was to determine the effect of jaw-opening exercises on TMD pain associated with OA use, and OA compliance in OSA patients without pain-related TMD. The null hypothesis tested in this study was that occurrence of pain-related TMD, TMD pain intensity, OA compliance at the 3-month follow-up in patients with OSA who performed jaw-opening exercises prior to OA insertion would be no different to those in patients who performed placebo neck exercises.

2. Materials and methods

2.1. Subjects

Patients with OSA, diagnosed using polysomnography (PSG) according to the American Academy of Sleep Medicine guidelines in 2007 [18], were consecutively recruited from the Dental Clinic for Sleep Disorders (Apnea and Snoring) of Tokyo Medical and Dental University Dental Hospital for OA therapy. Eligibility for the study is presented in Table 1. All subjects were provided verbal and written information about the study and signed informed consent forms. The study protocol was approved by the Tokyo Medical and Dental University Dental Hospital ethics committee (No. 1037).

2.2. Study design

This study employed a two-arm, randomized, double-blind, placebo-controlled trial. The subjects were randomly allocated into a jaw-opening exercise (JE) or placebo exercise (PE) group, and performed exercises for 2-weeks before and 2-weeks after OA insertion (1-month in total). OA compliance, TMD signs, TMD pain intensity, and therapeutic outcomes were evaluated prior to starting exercise (baseline), and at 2-weeks, 1-month, and 3-months after OA insertion (Fig. 1).

Degree of TMD pain has been observed to vary with sex differences [19]. Thus, we used a block size of four, and random allocation was stratified for gender using an envelope method, which was performed by an independent study operator. A therapist (H.I) instructed the subjects in the allocated exercise. A specialist (S.I) who conducted OA treatment and a TMD examiner (A.N) were blinded to information on group allocation. Patients were told at the time of enrollment that either exercise was effective for prevention of masticatory muscle and TMJ pain; thus, they were blinded to the actual type of exercise assigned.

TMD pain with OA therapy occurs in 10–70% of cases [4–8], and the variation is large. Using the results of previous studies, we estimated the requirement of a sample size of 90 participants, with an effect size of 0.6, alpha of 0.05, power of 0.80, and allocation ratio of 1:1 between arms.

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