Oral Glucosamine Hydrochloride Combined With Hyaluronate Sodium Intra-Articular Injection for Temporomandibular Joint Osteoarthritis: A Double-Blind Randomized Controlled Trial

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Purpose: Temporomandibular joint (TMJ) disorders occur in many people and osteoarthritis (OA) is a severe form of this disease. Glucosamine has been used to treat OA of the large joints for many years and has been proved effective. A double-blinded randomized controlled trial was designed to investigate the effectiveness and safety of oral glucosamine hydrochloride pills combined with hyaluronate sodium intra-articular injection in TMJ OA.

Patients and Methods: One hundred forty-four participants with TMJ OA were randomized to 4 hyaluronate sodium injections and oral glucosamine hydrochloride (1.44 g/day) for 3 months (group A) or 4 hyaluronate sodium injections and oral placebo for 3 months (group B). All participants were followed for 1 year. Eighteen participants were lost to follow-up.

Results: The intention-to-treat analysis showed that group A had similar maximal interincisal mouth opening and pain intensity during TMJ function at months 1 and 6 ($P > .05$). However, during long-term follow-up, group A had significantly greater maximal interincisal mouth opening compared with group B at month 12 (41.5 vs 37.9 mm; $P < .001$). For pain intensity, group A showed obviously lower visual analog scale scores than group B at month 6 (20.6 vs 29.2 mm; $P = .007$) and month 12 (17.4 vs 28.6 mm; $P = .001$). Twenty-four participants had gastrointestinal tract side effects, fatigue, and rash. Of these, 23 had slight side effects that were not correlated with glucosamine. There was no significant difference between the 2 groups ($P > .05$).

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Conclusion: The results of this study suggest that, compared with hyaluronate sodium injection alone, glucosamine hydrochloride pills added to hyaluronate sodium injection had no meaningful effect on TMJ OA in the short term but did relieve the pain caused by TMJ OA and improved TMJ functions in the long term. Q3

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Temporomandibular joint (TMJ) disorders (TMDs) refer to a group of clinical signs and symptoms caused by pathologic changes of the TMJ or masticatory muscles that lead to facial pain, muscle stiffness, clicking and crepitus of the TMJ, and mandibular movement restrictions.[1] Osteoarthritis (OA) might be one of the most severe TMDs. TMJ OA is an organic change of the chondral or osseous part of the condyle or glenoid fossa. It has a huge impact on quality of life and occurs in 10 to 76% of the population and people 20 to 40 years old have the highest prevalence.[2,3] The primary goals of treatment of TMJ OA are to ease pain, lessen dysfunctions, and relieve or even reverse bone destruction. Treatment can be conservative or operative. Conservative treatment, such as splints, anti-inflammatory drugs, physical therapy, or drug injection, is usually encouraged, but few of these treatments have been proved completely effective.[4,5]

Glucosamine is widely used in the treatment of OA of other large joints of the human body.[6] It promotes anti-inflammation through inhibiting the activity of interleukin-1 and the activation of nuclear factor-κB and metal matrix protenase.[7,8] It also can regulate the activity of collagenase to prevent damage to the articular cartilage.[9,10] Moreover, it can be a substrate to synthesize proteoglycan, the latter being an indispensable component of the cartilage matrix. Studies also have proved that it can promote the proliferation of cartilage cells.[11] Many clinical trials have proved its function in the treatment of OA of the knee joint, shoulder joint, and other large joints of the body and systematic reviews support this conclusion,[12] but the effect of glucosamine on TMDs is still uncertain.

The authors conducted a randomized controlled trial to investigate the effectiveness and safety of oral glucosamine hydrochloride pills when used in combination with hyaluronate intra-articular injection for TMJ OA.

Patients and Methods

This randomized control trial was conducted according to the Consolidated Standards of Reporting Trials (CONSORT) statement of 2010.

PATIENTS

Symptomatic patients 16 to 70 years old with OA were included. The diagnosis was based on the Research Diagnostic Criteria for Temporomandibular Disorders and the imaging results of cone-beam computed tomography (CBCT).[13,14] The specific CBCT criteria for the diagnosis of TMJ OA include bony changes, such as irregular and possibly thickened cortical outlines, erosions, osteophyte formation, and subchondral "cyst" formation, and other changes include narrowing of the joint space and other signs of osseous remodeling, such as flattening of the articular surfaces and subchondral sclerosis.[14] The diagnostic evaluation was performed jointly by radiologists and TMD surgeons. Screening before randomization was conducted to exclude patients with an incorrect diagnosis or without a need for therapy. Patients who were allergic to several drugs or had hypersensitivity disease; severe dysfunction of the heart, liver, kidney, or blood system; infection in the TMJ area; or previous jaw fracture, previous TMJ surgery, or other TMJ pathology were excluded. Additional eligibility criteria are summarized in the World Health Organization's (WHO) International Clinical Trial Registry Platform (ICTRP). The symptoms of TMJ OA mainly manifest as pain and dysfunction, and the severity of OA can vary greatly from slight to considerable in different patients. All patients were informed about the study design and the potential effectiveness and adverse reaction of the drug they might be administered. All provided written informed consent.

DESIGN

This double-blinded randomized controlled trial was conducted in the Temporomandibular Joint Disease Clinic of the Department of Oral and Maxillofacial Surgery at the West China Hospital of Stomatology of Sichuan University (Chengdu, China). Ethical approval was obtained from the medical ethics committee of the hospital (2009022). The trial was registered in the WHO ICTRP before patient enrollment (registration number ChiCTR-TRC-09000592; available at: http://apps.who.int/trialsearch/Trial.aspx?TrialID=ChiCTR-TRC-09000592).

For randomization and allocation, staff at the Chinese Cochrane Center used specialized software to generate the randomized sequence. The sequence was kept in the hospital pharmacy and the Good Clinical Procedure (GCP) Center, and the pharmacist

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