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Clinical Study Protocol

Autologous Blood Injection for the Treatment of Recurrent Temporomandibular Joint Dislocation

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Temporomandibular joint (TMJ) dislocation can occur during daily activities and negatively affect a patient's quality of life. Although both nonsurgical and surgical techniques have been used to treat recurrent TMJ dislocation, the former is not always successful and the latter, although having a high success rate, is invasive and requires hospitalization. Recently, autologous blood injection has been used to treat recurrent TMJ dislocation. However, this technique is not yet widely used in clinical practice. We designed this study to obtain further information as to efficacy, safety and stability of autologous blood injection for recurrent TMJ dislocation.

Key words: autologous blood injection, recurrent temporomandibular joint dislocation

Temporomandibular joint (TMJ) dislocation can occur during simple activities such as laughing and yawning, and it may occur after excessive mouth opening during dental treatment, tracheal intubation or episodes of vomiting. There is a higher frequency of TMJ dislocation in patients with Parkinson's disease or cerebrovascular disorders, which is attributed to masticatory muscle incoordination [1]. A person with TMJ dislocation is unable to close his mouth, which remains locked open until a mechanical reduction is performed. Frequent dislocation episodes characterize a condition referred to as recurrent TMJ dislocation. Thus, patients with this problem risk TMJ dislocation simply by carrying out their daily activities; the disorder can be especially dangerous when self-reduction of the TMJ dislocation is difficult or impossible.

Methods of treating recurrent TMJ dislocation range from conservative treatment [2, 3] to surgical interventions [4–7]. Conservative treatments such as restricting mandibular motion with a chin cap, an elastic facial bandage or maxillomandibular fixation often fail to manage the condition. Whereas surgical treatment through eminectomy is considered the gold standard in the treatment of recurrent TMJ dislocation with success rates greater than 85% [5, 8]. Surgical intervention may have a high success rate, but it is an invasive procedure requiring general anesthesia, a hospital stay and a skin incision, in addition to increased risk of facial nerve injury.

Schulz [9] first described autologous blood injection for treating recurrent TMJ dislocation in 1973. In Japan, Takahashi *et al.* [10] first reported the efficacy of autologous blood injection in a compromised patient who was unable to receive surgery in 2003.

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The reported overall success rate of autologous blood injection is approximately 80% [8, 11, 12]. The action mechanism of TMJ autologous blood injection is not fully understood. However, the pathophysiological reaction to blood injected into the superior joint space and the pericapsular tissue of the TMJ would be scarring and fibrous tissue formation [13]. Therefore, the concept behind autologous blood injection is promotion of fibrosis within the capsular tissue and consequently restraining the motion of mandibular excursion. Autologous blood injection could be a promising alternative to surgery for recurrent TMJ dislocation, particularly in patients who are not eligible for surgical procedures. However, the procedure is not yet widely used.

Endpoints

This study is intended to evaluate the efficacy, safety and stability of TMJ autologous blood injection for the treatment of recurrent TMJ dislocation in an effort to standardize the procedure. The primary outcome is to have no condylar dislocation episodes for 6 months following the procedure. A secondary outcome is improving quality of life with a decreased frequency of condylar dislocation.

Eligibility Criteria

All patients who meet the main inclusion criteria without excluding factors will be included in this study. The target sample size will be 5 patients per year. Table 1 lists the main inclusion and exclusion criteria [14]. An investigator must obtain written informed consent from the patient or the legally authorized representative before the procedure. This study follows the Declaration of Helsinki on medical protocol and ethics. The Ethics Committee of Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences and Okayama University Hospital approved this study's protocol (Approval No.1108). UMIN registration number: 000022197.

Treatment Methods

This protocol is designed as a single-arm, prospective, non-randomized, non-comparative open-label study.

The procedure is performed under local anesthesia. The skin overlying the TMJ is scrubbed with 10% povidone iodine and local anesthesia is induced with 1% lidocaine containing 1/80000 epinephrine injected in the auricular fossa to block the auriculo-temporal nerve and the preauricular area. The auricular fossa is located at a point 10 mm anterior to the tragus of

Table 1 Patient eligibility

Inclusion criteria
Aged 16 years or older
Diagnosed as having recurrent TMJ dislocation based on the clinical criteria of Nitzan [14].
Episodes of condylar dislocation for several times.
The conservative methods including restriction of the mandibular motions with chin cap, facial bandage, maxillomandibular fixation, or mouth opening training based on the self-reduce TMJ dislocation were ineffective.
Written informed consent
Exclusion criteria
Inflammatory diseases of temporomandibular joint, such as rheumatoid arthritis, tuberculous arthritis
Evidence of tumor or tumor like lesion in the TMJ
Temporomandibular disorders caused by metabolic diseases, including crystal deposition diseases such as gout, pseudogout, or crystal arthritis
Intercurrent facial palsy
Serious concomitant systemic disorder, including malignant hypertension, history of severe cardiovascular diseases or cerebrovascular disorders within 6 months, hemorrhagic gastric ulcers, uncontrolled diabetes, apparent bleeding tendency
Under anticoagulant therapy
Suspicion for active infection
History of serious psychiatric illness or psychiatry illness under medical treatment
Others diagnosed as inapplicable cases by an investigator

the ear and 2 mm inferior to the tragal-canthal line. At this location, a 21-gauge needle is inserted into the superior joint space with the patient's mouth open. The resistance to needle progression will decrease when the needle tip enters the superior joint space. After confirming correct needle placement, the joint space is flushed with 5 ml of saline via a T-shaped stopcock. The 21-gauge needle remains in position while 5 ml of blood is collected into a syringe from the patient's antecubital fossa. After connecting the blood syringe to the previously inserted needle, 3 ml of blood is injected into the superior joint space; the needle is pulled outward 1 cm, and an additional 1 ml of blood is injected into the pericapsular region (Fig. 1A). For bilateral, recurrent TMJ dislocation, the same procedure is performed on the opposite side. After the injections, the patient must eat only soft foods for 7 days and reduce mouth opening with an elastic facial bandage (Fig. 1B). If there is a relapse of TMJ dislocation, autologous blood injection can be repeated.

Statistical Consideration

Postoperative consultations will occur at 1 week, 2 weeks, 4 weeks, 3 months and 6 months post-operatively up to the last appointment before data collection. The follow-up parameters include clinical examination, measuring the maximal incisal opening, assessment possible complications such as pain, facial nerve paralysis, frequency of condylar dislocation, recurrence rates and evaluation of the TMJ region by panoramic TMJ projection. Visual analogue scale will be reported by patients to evaluate pain intensity. For the assessment of facial nerve paralysis, Yanagihara facial nerve grading system will be used. The collected data will be analyzed to assess the efficacy and safety of autologous blood injection for management of recurrent TMJ dislocation by multivariate analysis and χ^2 test.

Discussion

This study focuses on the efficacy, safety and stability of autologous blood injection for recurrent TMJ dislocation. Autologous blood injection is a simple, outpatient procedure that is less time consuming than surgery, minimally invasive and presents a low possibility of risks. We hope this procedure will prove to be a feasible alternative treatment for patients prior to any surgical intervention.

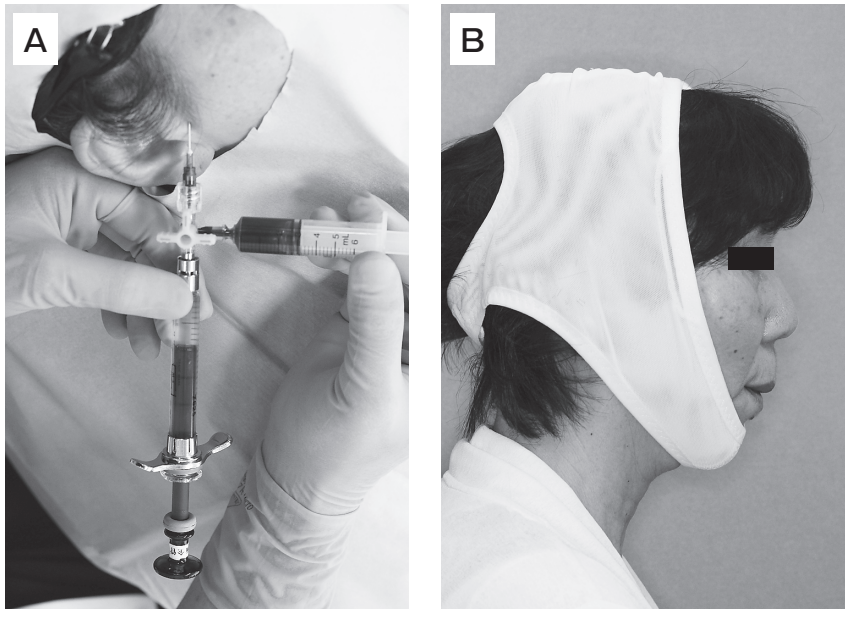

Fig. 1 TMJ autologous blood injection and postoperative care. **A**, Injection of 3 ml of autologous blood into the superior joint space and 1 ml into the pericapsular region; **B**, Elastic facial bandage applied to reduce mouth opening.

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