Comparison of the Efficacy of Single and Double Puncture Arthrocentesis in Treatment of Temporomandibular Joint Disc Displacement Without Reduction

Date: 20/03/2020

This document contains study design and statistical analysis plan of the study entitled "Comparison of the Efficacy of Single and Double Puncture Arthrocentesis in Treatment of Temporomandibular Joint Disc Displacement Without Reduction".

Study Design:

This is a two-armed, randomized, parallel interventional clinical study enrolling 36 patients with temporomandibular joint disc displacement without reduction (DDwoR).

Eligibility:

Inclusion Criteria:

- Clinical diagnosis of Temporomandibular joint (TMJ) disc displacement without reduction.
- Restricted mouth opening

Exclusion criteria:

- History of systemic disease effecting TMJ.
- History of previous TMJ surgery

Patients were grouped according to the treatment they received: Single Puncture Arthrocentesis as group SPA, Double Puncture Arthrocentesis as DPA.

Double puncture arthrocentesis technique:

Posterior puncture method was used as described by Alkan and Etoz for DPA. A straight line was drawn with a marker pen along the skin from the middle portion of the auricular tragus to the lateral chantus. The first puncture point was marked 10 mm anterior and 2 mm inferior to the tragus and the second 7 mm anterior and 2 mm inferior to the tragus. After local anesthesia, upper joint cavity was irrigated with 200 mL of Lactated Ringer's (RL) solution by inserting two 21- gauge needle. At the end of the procedure, after withdrawn of one of the needles, 1 mL of sodium hyaluronate (SH) was injected into the upper TMJ compartment through the other needle.

Single Puncture Arthrocentesis Technique:

SPA was performed with one needle (SPA Type-1 according to Senturk and Cambazoglu). The first reference point in DPA was used as the needle entry point fort he SPA. With this technique, the inflow and outflow of solution were provided through the same cannula and lumen of one 21-gauge needle as described by Guarda-Nardini et al. The joint was irrigated with 200 mL of RL solution under high pressure. At the end of the procedure1 mL of SH was injected through

the needle

Outcome measures:

1. The Rate of Pain on Function (PoF) assessed by Numerical pain Scale (NRS)

Patients rated their pain on function (pain during chewing or speaking etc.) on a Numeric Rating Scale (NRS) (0−10 where 0 is no pain and 10 is the worst pain imaginable).

Patients were evaluated at preoperatively and postoperatively 1st week, 1st month, 3rd month, 6th month.

2. The measurement of pain-free maximum mouth opening (MMO) in millimeters:

Pain-free MMO was measured as the distance between the incisal edges of the upper and lower incisors by a caliper while patient′s mouth is open as possible without any assistance and without pain in massater muscle. Three measurements were performed, and their average is recorded. Patients were evaluated at preoperatively and postoperatively 1st week, 1st month, 3rd month, 6th month.

3. The rate of pain at rest (PaR) assesed by Numerical pain Scale (NRS)

Patients rated their pain level at rest on a Numerical pain Scale (NRS)(0−10 where 0 is no pain and 10 is the worst pain imaginable). Patients were evaluated at preoperatively and postoperatively 1st week, 1st month, 3rd month, 6th month.

4. Measurement of Duration of the Procedure in Minutes.

Total time for arthrocentesis was noted at the end of the procedure.

Patients were evaluated at the end of the procedure

5. Measurement of the easiness of the procedure to the operator by using Visual Analog Scale (VAS):

The operator rated the degree of easiness of the procedure on a VAS as 0-very easy 10-very difficult to perform at the end of the procedure

6. The rate of treatment tolerability assesed by 5-point Likert-type scale:

The degree to which overt adverse effects and post operative complications (pain, feeling of pressure in TMJ area and disturbing sound) can be tolerated by the patient. Patients were asked to rate the tolerability on a 5 point scale as 0- lowest, 4-highest at operation day, 1st week, end of follow up period (6th month)

7. The rate of chewing efficiency by using Visual Analog Scale (VAS):

Patients rated the chewing efficiency on a VAS as 0-can only eat semi-liquid foods, 10-eat any solid-food. Patients were evaluated at preoperatively and postoperatively 1st week, 1st month, 3rd month, 6th month.

8. Rate of perceived effectiveness of the treatment by using 5-point Likert-type scale:

Patients rated the subjective treatment effectiveness on a 5-point scale as 0- lowest, 4 highest values at the end of the follow up period (6th month).

9. Measurement of Lateral Movement of the mandible towards the affected Temporomandibular joint (TMJ) in millimeters

Lateral Movement of the mandible towards the affected Temporomandibular joint (LT) was measured as the distance between the midlines of the upper and lower incisors by a caliper while patient′s mandible was shifted towards the affected TMJ. Three measurements were performed, and their average is recorded. Patients were evaluated at preoperatively and postoperatively 1st week, 1st month, 3rd month, 6th month.

10. Measurement of Lateral Movement of the mandible away from the affected Temporomandibular joint (TMJ) in millimeters

Lateral Movement of the mandible away from the affected Temporomandibular joint (LA) was measured as the distance between the midlines of the upper and lower incisors by a caliper while patient′s mandible was shifted away from the affected TMJ. Three measurements were performed, and their average is recorded. Patients were evaluated at preoperatively and postoperatively 1st week, 1st month, 3rd month, 6th month.

11. Measurement of protrusive movement of the mandible in millimeters:

Protrusive movement of the mandible was measured as the distance in horizontal direction between the incisal edges of upper and lower incisors by a caliper when mandible moves forward. Patients were evaluated at preoperatively and postoperatively 1st week, 1st month, 3rd month, 6th month.

Statistical Analysis:

IBM SPSS 22 was used to analyze the data (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). Descriptive statistics of the variables were presented as mean ± standard deviation in statistical analysis. Normality of distribution for continuous variables was evaluated using the Kolmogorov-Simirnov test. Depending on whether the statistical hypotheses were fulfilled, either the Student's t-test or the Mann–Whitney U test was used to compare the independent continuous variables between the two groups, Wilcoxon signed rank test was used for intra-group evaluation of variables according to baseline such as PoF ve MMO. Statistical significance level was accepted as $p < 0.05$.