Clinical evaluation of a single injection of high molecular weight sodium hyaluronate after arthrocentesis in patients with TMJ derangement: a pilot study

Avaliação clínica da injeção única de hialuronato de sódio de alto peso molecular após artrocentese em pacientes com desarranjo na ATM: estudo piloto

Evaluación clínica de una inyección única de hialuronato de sodio de alto peso molecular después de la artrocentesis en pacientes con trastorno de ATM: un estudio piloto

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ABSTRACT

Objective: To evaluate the efficacy of the technique and the longevity of the results obtained through the combination of minimally invasive surgical procedure of TMJ arthrocentesis combined with a single injection of high-molecular weight sodium hyaluronate (SH). **Methods**: A randomized clinical trial. The experimental unit was composed of 14 patients. The factor under study was time in five levels: Baseline, T1 (1 week), T2 (30 days), T3 (90 days), and T4 (6 months). The response variables were: pain, visual analogue scale (VAS) (0-10) (quantitative variable), joint noise (presence and absence) (nominal qualitative variable), and mouth opening (mm) (quantitative variable). **Results**: All pain values were significantly lower when compared with the baseline values, regardless of the evaluated side (p = 0.05). For mouth opening measurements (mm), there was no significant statistical difference in mean mouth opening over time (p = 0.28). There was no significant statistical difference (p = 0.05) for joint noise. **Conclusion**: A single injection of high-molecular weight SH after two-needle arthrocentesis seems to be an efficient treatment option for patients with no improvement after conservative treatment.

Keywords: Arthrocentesis, Temporomandibular joint disorders, Hyaluronic acid.

RESUMO

Objetivo: avaliar a eficácia da técnica e a longevidade dos resultados obtidos pela combinação do procedimento cirúrgico minimamente invasivo da artrocentese da, associado a uma injeção única de hialuronato de sódio (SH) de alto peso molecular. **Métodos:** ensaio clínico randomizado. A unidade experimental foi composta por 14 pacientes. O fator em estudo foi o tempo em cinco níveis: linha de base, T1 (1 semana), T2 (30 dias), T3 (90 dias) e T4 (6 meses). As variáveis de resposta foram: dor, escala analógica visual (EVA) (0-10) (variável quantitativa), ruído articular (presença e ausência) (variável qualitativa nominal) e abertura da boca (mm) (variável quantitativa. **Resultados**: Todos os valores de dor foram significativamente menores quando comparados aos valores basais, independentemente do lado avaliado (p = 0,05). Para as medidas de abertura bucal (mm), não houve diferença estatística significativa na abertura média da boca ao longo do tempo (p = 0,28). Não houve diferença estatística significante (p = 0,05) para o ruído articular. **Conclusão**: Uma injeção única de SH de alto peso molecular após artrocentese com duas agulhas parece ser uma opção de tratamento eficiente para pacientes sem melhora após tratamento conservador.

Palavras-Chave: Artrocentese, Transtornos da articulação temporomandibular, Ácido hialurônico.

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SUBMETIDO EM: 11/2019 | ACEITO EM: 12/2019 | PUBLICADO EM: 3/2020

RESUMEN

Objetivo: Evaluar la eficacia de la técnica y la longevidad de los resultados obtenidos mediante la combinación de un procedimiento quirúrgico mínimamente invasivo de la artrocentesis de ATM combinada con una inyección única de hialuronato de sodio (SH) de alto peso molecular. **Métodos:** ensayo clínico aleatorizado. La unidad experimental estaba compuesta por 14 pacientes. El factor en estudio fue el tiempo en cinco niveles: línea de base, T1 (1 semana), T2 (30 días), T3 (90 días) y T4 (6 meses). Las variables de respuesta fueron: dolor, escala analógica visual (EAV) (0-10) (variable cuantitativa), ruido articular (presencia y ausencia) (variable cualitativa nominal) y apertura de la boca mm) (variable cuantitativa). **Resultados**: Todos los valores de dolor fueron significativamente más bajos en comparación con los valores basales, independientemente del lado evaluado (p = 0.05). Para las mediciones de apertura de la boca (mm), no hubo diferencia estadística significativa en la apertura media de la boca con el tiempo (p = 0.28). No hubo diferencia estadística significativa (p = 0.05) para el ruido articular. **Conclusión**: una sola inyección de SH de alto peso molecular después de la artrocentesis con dos agujas parece ser una opción de tratamiento eficiente para pacientes sin mejoría después del tratamiento conservador.

Palabras clave: Artrocentesis, Trastornos de la articulación temporomandibular, Ácido hialurónico.

INTRODUCTION

The temporomandibular joint (TMJ) is a synovial joint that allows the mandibular movements around a fixed bone, namely the temporal bone. The TMJ is a bilateral joint, connected from side to side by the mandibular bone; it is independent but simultaneous, and can be classified as a joint. Its differs from the other joints of the body because it has a fibrocartilage lining, has very discordant articular facets, includes a joint disc between the articular facets, has simultaneous rotation and translation movements, and the impulses are generated to the teeth and buccal structures (MADEIRA MC, 2006; DOLWICK MF, 1997).

TMJ arthrocentesis is a simple form of surgical therapy with the purpose of washing and removing the inflammatory mediators, releasing the disc and avoiding adhesion between the disc and the fossa. Lysis and lavage of the TMJ upper compartment are valuable in patients with anterior disc displacement without reduction because they increase the jaw range of motion and relieve TMJ pain.

As this arthroscopic intervention is beneficial, it does not include repositioning of the disc, and the surgical relocation of the disc is questioned when trying to overcome the TMJ dysfunction and pain (GONZALES-GARCIA R e RODRIGUEZ-CAMPO FJ, 2011; NITZAN DW, et al., 1991; NITZAN DW, et al., 1990; KOPP S, et al.,1993; BALAZS EA e DENLINGER JL.1993).

In this context, the hyaluronate (SH) is a polymer of the mucopolysaccharide family. It is an important constituent of the extracellular matrix, and can be found at higher levels in cartilage and synovial fluid regions. SH has anti-inflammatory effects. Its use has frequently increased in orthopaedic joint surgeries, arthrocenteses, and arthroscopies because of its antiadhesion characteristics (NITZAN DW, et al., 1990; BUTLER J, et al.,1970; KOPP S, et al.,1991). Intra-articular injection of SH is used in track horses for pathologies like traumatic arthritis, and has been used in humans in large joints such as the knee, shoulder, and hip (BUTLER J, et al.,1970).

Viscosupplementation of the TMJ is a minimally invasive technique by which the SH injection is performed. It aims to eliminate or reduce the patient's pain, promoting improvement of the synovial fluid. In performing the exchange of pathological fluid from the joint for exogenous SH, the molecular weight and synovial fluid concentration are returned to normal.

Studies on the efficacy of viscosupplementation with SH indicate that, after three applications, the intra-articular injection is effective in combating the pain of patients with TMJ disorders, and also considerably increases mandibular mobility. To compare the effectiveness of single-session viscossuplementation protocols (high- and medium-molecular weight) with multiple-session protocols, the multiple-session protocol was performed after arthrocentesis. In conclusion, the effectiveness of the multiple-session protocol proved to be

superior at 6 months, and there was no significant difference in the outcome between the single-session groups (KOPP S, et al.,1993; BALAZS EA e DENLINGER JL.1993; BONOTTO D, et al., 2018; GUARDA NI, et al.,2012; TRIANTAFFILIDOU K, et al., 2013; GUARDA NI, et al.,2015; OZDAMAR SM, et al., 2017).

The study compared the efficacy of intra-articular injections of three different agents with well-known anti-inflammatory properties in 100 patients diagnosed with TMJ disorder. Patients with symptoms of jaw pain, limited or painful jaw movement, and clicking or grading within the joint were evaluated with temporomandibular computed tomography for the presence of cartilage or capsule degeneration. The pain relieving effect of tenoxicam (TX) was found to decrease significantly between the 1st and the 6th week.

The authors found that the HA produced better pain relief scores when compared to the other anti-inflammatory agents studied. The main disadvantage of HA is its relatively higher cost (GENCER ZK, et al., 2014). The efficacy of serial SH injections after arthrocentesis to reduce symptoms of osteoarthritis and to maintain improvements over time (GUARDA NI, et al.,2007).

The arthrocentesis plus platelet-rich plasma (PRP) injections are not superior to arthrocentesis plus a single SH injection. Thus, PRP injection should not be considered as first-line treatment. Arthrocentesis plus SH injection would appear to be more acceptable for patients.[21] Serial SH injections were performed after arthrocentesis for the treatment of TMJ osteoarthritis and for maintenance of improvements over a 6-month follow-up period (MANFREDINI D. 2012).

Single-puncture arthrocentesis is clinically as effective as standard double-needle arthrocentesis. A well designed randomised control trial with standard arthrocentesis protocol comparing different single-puncture techniques with standard double-needle technique for the treatment of TMJ disorders is warranted (NAGORI SA, et al., 2018).

The aim of this study is to evaluate the efficacy of a single injection of high-molecular weight SH into the TMJ in reducing pain and improving the mouth opening range and joint noises. The effects were evaluated through a subjective questionnaire and clinical examination.

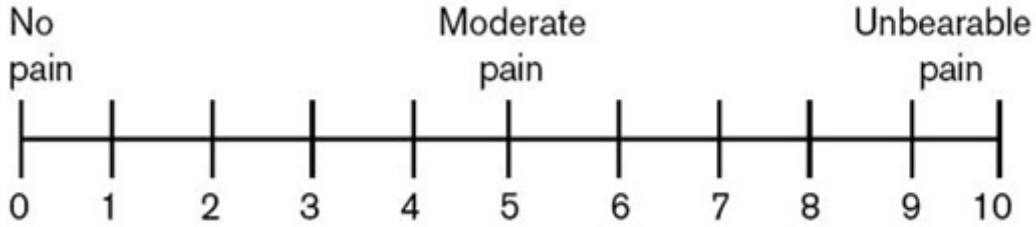
METHODS

This research was carried out in intra-articular TMJ disorder patients attending the FOUNIP Dental Clinic, after approval by the Ethics and Research Committee of FOUNIP number: CEP 040391/2017. Patients received detailed information about the therapeutic protocol for TMJ disorder treatment and comprehensive instructions on the benefits that the treatment could bring. Participants signed an informed consent form.

The study was carried out in an outpatient setting and the procedures were performed after thorough anamnesis followed by clinical examination. After the injection of high-molecular weight SH (OPUS JOINT^{DMC}) into the TMJ, the patients returned and answered the questionnaires regarding their pathology and the evolution of the symptoms prior to the application and from the application.

A Analogic visual scale (VAS) was applied to assess pain (this scale is measured with a ruler or a similar straight line divided in millimeters and is scored from zero to ten, with zero being no pain at all, one to three being mild pain, four to six being moderate pain, seven to nine being strong pain, and ten being the worst pain ever experienced) (**Figure 1**).

Figure 1 - Analogic visual scale vas.



Source: Mello GFS, et al., 2016.

The presence or absence of intra-articular noise was diagnosed with a stethoscope. The level of the patient's interocclusal mouth opening, which should be between 30 and 40 millimeters between the incisal edges of maxillary and mandibular incisor teeth, was evaluated with a millimeter ruler. In patients with absence of some of the anterior elements, the use of homologous teeth is recommended; in the case of a totally edentulous patient, the measurement is performed on the alveolar ridges.

The patient assessment procedures of before and after the surgical procedure were performed in the following intervals: 7 days postoperatively, 30 days postoperatively, 90 days postoperatively, 6 months postoperatively.

These periodic post-intervention patient assessments were performed in an outpatient setting at the FOUNIP clinic, where the patients underwent clinical and physical examination including palpation and auscultation of the joint with a stethoscope. Patients also completed the self-assessment questionnaire, which evaluated the improvement or not of the symptoms of the disorder after the procedures. The answers were sent for statistical analysis.

Patients aged between 17 to 70 years of age, of both sexes, who had painful symptoms, with or without presence of joint noise, and had unilateral or bilateral internal derangement of the TMJ proven by clinical examination, with no improvement after conservative treatment, were included in the study.

Patients with TMJ disorders who improved with clinical treatment, which makes the SH injection procedure contraindicated, were excluded from the study. Patients with muscular TMJ disorder without the presence of internal derangement and patients with systemic problems that prevented the procedure from being performed were also excluded.

The technique of outpatient injection of high-molecular weight SH consists of: Facial disinfection in ear region and preauricular region (biosafety); Positioning of surgical drapes; Injection of local anaesthetic (xylocaine with epinephrine 1: 200,000); Injection of local anaesthetic in the preauricular region (auricular-temporal region); Skin and intra-auricular injection of local anaesthetic; Marking of the adjacent anatomical sites, the zygomatic arch, and the articular eminence with a demographic pen for insertion of the needle in the first portal, located 10 mm anterior to the tragus, and infusion of saline solution and application of the second 40X12 needle in the anterior recess 10 mm anterior to and 7 mm below the first portal. Infusion of 100 mL of intra-articular saline solution.

Opening and closing of the mouth simultaneously with the infusion and removal of second 40/12 needle from the anterior recess; Application of 1 mL of high-molecular weight SH (OppusJointDMC®) through the first needle already located inside the joint in the posterior recess of the TMJ, dressings, removal of surgical drapes; Follow up of the patient after the single application of SH, evaluating the evolution of the signs and symptoms of the pathology.

RESULTS

Thirty-eight patients were initially evaluated. Of these, 24 patients, with complaints of muscular TMJ disorder, were excluded from the study and referred for conservative clinical treatment (i.e., use of medication and interocclusal devices). Patients with the diagnosis of intra-articular TMJ disorder were entered into the protocol.

The experimental unit was composed of patients (n = 14) with clinical and imaging diagnosis of intra-articular TMJ disorder, submitted to the proposed procedures. Of these 14 patients, 12 had leukoderma (85%) and two had melanoderma (15%). There were 13 women (92.8%) and one man (0.8%), and the mean age was 37 years. As partial results of this study, we evaluated that this parameter measures the intensity of pain using a VAS and we were able to evaluate according to the graphs the following notes:

The analyzed factors were described: Factor 1 - Side of the condyle in two levels - left and right, factor 2- Time in five levels - Baseline, T1 (1 week), T2 (30 days), T3 (90 days), and T4 (6 months). The response variables were: Pain - VAS (0-10) (quantitative variable); Noise - presence and absence (nominal qualitative variable); Mouth opening (mm) - (quantitative variable).

To verify the normality and homoscedasticity of the data, which are requirements to meet the assumptions of the analysis of variance, making possible its use, Shapiro-Wilks's and Levene's tests were used, respectively. To verify the required assumptions, the analysis of variance (1-factor ANOVA) in split-plot scheme was used for the quantitative variable - pain. In case of lack of normality of errors, the non-parametric Friedman test was used for the comparison over time, and the Wilcoxon test was used for the comparison between the sides of the condyles.

For the mouth opening variable, the required assumptions regarding the normal distribution of errors and the homoscedasticity of the data were verified. After the verification, the analysis of variance was used in a repeated measures scheme. For the noise variable, the Cochran's Q test for related samples was used. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) 2.1 software and Bioestat® software. An α=0.05 was adopted.

Due to the lack of normal distribution for the pain variable, non-parametric Wilcoxon and Friedman tests were used. For the mouth opening variable, the analysis of variance of repeated measures was used. For the noise variable, Cochran's Q test was used.

Regarding pain, the results after 30 days onwards indicated that pain values, measured by VAS, were statistically similar in the left and right condyles. All pain values were significantly lower when compared with baseline values, regardless of the evaluated side, as shown in **Table 1**.

Table 1 - Median (min-max-standard) pain (VAS) according to the side of the condyle (n = 14).

Side of the condyle	*Baseline*	1 week	30 days	90 days	6 months
Left	2.5 (0-10) Ba	0 (0-7) Bb	0 (0-5) Ab	0 (0-6) Ab	0 (0-5) Ab
Right	5.5 (0-9) Aa	2.5 (0-8) Ab	0 (0-6) Ab	1 (0-6) Ab	0 (0-6) Ab

Source: Silva TW, 2019.

Regarding mouth opening, patients were initially evaluated after 1 week, 30 days, 90 days and and after six months. During this period, despite a clinical improvement. There was no statistically difference when the times were compared. Regarding mouth opening (mm), no significant statistical difference was observed in the mean mouth opening over time, as shown in **Table 2**.

Table 2 - Mean and standard deviation of mouth opening (mm) over time.

Time	Mouth opening (mm)	Standard deviation
Baseline	38.21A	10.35
1 week	38.93A	10.95
30 days	40.07A	9.98
90 days	40.64A	11.91
6 months	41.08A	11.43

Source: Silva TW, 2019.

Regarding noise, patients were evaluated initially and after 1 week, 30 days, 90 days, after six months. During this period, despite a clinical improvement. There was no statistical difference when the times were compared. Regarding joint noise, there was no significant statistical difference, as shown in **Table 3**.

Table 3 - Frequency and percentage of noise according to the side of the condyle (n=14).

Side of the condyle	Time	Without noise		With noise	
		n	%	n	%
Left	baseline	5	35.71	9	64.29
	1 week	7	50	7	50
	30 days	9	64.29	5	35.71
	90 days	7	50	7	50
	6 months	6	42.86	7	50
Right	baseline	3	21.43	11	78.57
	1 week	8	57.14	6	42.86
	30 days	8	57.14	6	42.86
	90 days	7	50	7	50
	6 months	5	35.71	8	57.14

Source: Silva TW, 2019.

DISCUSSION

TMJ arthrocentesis is a form of surgical therapy with the purpose of washing and removing the inflammatory mediators, leading to disc release and removing the adhesion between the disc and the fossa. (NITZAN DW, et al., 1991) It is a non-invasive, simple, and effective method for certain cases and should be considered before more invasive surgical procedures. (LYRIO MC, et al., 2010) In our study, all patients underwent two-needle arthrocentesis prior to the application of SH.

Arthrocentesis was performed using the single-puncture technique, using 1 mL of medium-molecular weight SH (Sinovial IBSA Farmaceutici Lodi Italy®) in one of the groups. In the other group, 1 mL of low-molecular weight SH (Hyalgan Fidia Abano Terme Italy®) was used.

At the end of the follow-up, it was observed that there was no statistical difference in the clinical results of the influence of the molecular weight of the SH applied.[11] However, in another study a joint lavage was performed, and high-molecular weight SH (Durolane SJ®) was injected in group A and medium-molecular weight SH (Sinovial®) was injected in group B. In group C, five weekly lavages were performed, and medium-molecular weight SH was injected.

The five-arthrocentesis session group showed a better response to pain and wider mouth opening compared with the single-intervention groups after 6 months. However, in another study, patients underwent a cycle of five arthrocentesis with weekly injections of 1 mL SH (Hyalgan Fidia Abano Terme Italy®) with patient assessments at 1-week, 1-month, 3-month, 6-month, and 1-year follow-up. There was a significant reduction in the symptoms of osteoarthritis throughout the follow-up time. (GUARDA-NARDINI I et al., 2007)

A study was carried out comparing the effectiveness of operative arthroscopy and lysis and lavage arthroscopy, and the patients' pain scale and mouth opening were evaluated. There was an average gain of 13mm in mouth opening and a considerable decrease in pain in both procedures, and the improvement was proven. Both in operative arthroscopy and in lysis and lavage arthroscopy, patients in WILKES IV stage had a great reduction in pain and better opening, with WILKES stage IV patients being the most favorable to the TMJ arthroscopy procedure. (GONZALES e RODRIGUES, 2011).

In another study, patients were divided into four groups: 1) control, 2) single SH injection, 3) double high-molecular weight SH injection, and 4) stabilization splint therapy. The SH injection groups indicated superior improvement for pain and mouth opening compared with the stabilization splint group and the control group. Pain scores in the single-injection group were more satisfactory than in the double-injection group (KORKMAZ YT, et al., 2016).

The SH used in the present study (Opus Joint®) has high-molecular weight and behaves more elastically when at high frequency (representing the joint in motion), and more viscously when at low frequencies (representing the joint at rest).

These properties meet the immediate needs of the joints both in motion and at rest. In our study, a single injection of high-molecular weight SH was applied, and we obtained a statistically significant clinical improvement in pain. The results, using the VAS, were statistically similar in the left and right condyle. All pain values were significantly lower when compared with baseline values, regardless of the evaluated side.

The high-molecular weight SH used, in theory, takes longer to be dissolved, consequently leading to a response with longer time of action. However, comparing with studies where several intra-articular infusion protocols and other types of SH with other molecular weights were used, the results are not statistically significant; what was different was the amount of infusion (GUARDA NI, et al., 2012; KORKMAZ YT, et al., 2016; GUARDA NI, et al., 2007; MANFREDINI D, et al., 2012.

A systematic review was carried out to investigate the current evidence to assess the effectiveness of single puncture arthrocentesis versus standard double needle arthrocentesis in the treatment of temporomandibular joint (TMJ) disorders.

An electronic search of the PubMed, Scopus, Cochrane CENTRAL and Google Scholar databases was performed to identify studies published in English until October 2017. All 5 studies reported no difference in reducing pain intensity and improving maximum mouth opening between a single puncture technique and a standard double needle technique. (NAGORI SA, 2018)

In the articles used there was no statistical difference in the clinical performance of the protocols used. Regardless of the technique, all studies had statistically insignificant results in the difference between the applied protocols (LYRIO MC, et al., 2010; GUARDA NI et al., 2012; GUARDA NI, et. al., 2015; GUARDA-NARDINI I, et. al., 2017; MANFREDINI D, et al., 2012; MANFREDINI D, et al., 2014; MANFREDINI D, 2018).

One study worked with a sample consisting of 49 osteoarthritic joints in 31 consecutive patients. Patients were randomly divided into two groups according to the treatment technique applied: patients in the platelet-rich plasma (PRP) group underwent initial arthrocentesis plus PRP injection and four consecutive PRP injections; the patients in the HS group underwent a session of arthrocentesis and injection of HS. Outcome variables were recorded preoperatively and at 12 months postoperatively.

No statistically significant differences were observed between groups for any of the changes in VAS parameters. Both treatment techniques resulted in significant clinical improvements in all VAS. These findings suggest that arthrocentesis plus PRP injections are not superior to arthrocentesis and a single injection of HS. Therefore, PRP injection should not be considered a first-line treatment. Arthrocentesis plus HS injection seems to be more acceptable for patients (KILIÇ SC e GUNGORMUS M, 2016).

Single-puncture arthrocentesis is clinically as effective as standard double-needle arthrocentesis. A well-designed randomised control trial with standard arthrocentesis protocol comparing different single-puncture techniques with standard double-needle technique for the treatment of TMJ disorders is warranted (NAGORI SA, et al., 2018).

However, another study concluded that arthrocentesis plus PRP injections is not superior to arthrocentesis plus a single SH injection (KILIÇ SC e GUNGORMUS M, 2016). In our study, only the high-molecular weight SH improved pain parameters; however, there was no significant statistical difference in the mean values of mouth opening and noise over time.

SH was more effective than all other protocols, but in the first few weeks the TX results were better. Therefore, SH is the gold standard for viscosupplementation, but in its absence, TX and betamethasone are good options (MANFREDINI D, 2012). However, another study (KILIÇ SC e GUNGORMUS M, 2016).

Compared low-molecular weight SH with PRP, concluding that arthrocentesis with PRP injection is not superior to arthrocentesis with HS. The authors concluded, as we did in our study, that SH is a good option for pain control and for a slight increase in mouth opening range.

CONCLUSION

The single injection of high-molecular weight SH (Oppus Joint®) after two-needle arthrocentesis protocol was effective in improving the signs and symptoms of intra-articular TMJ disorder. It is an effective option to control the pain and the limitations that the disorder can cause, significantly improving the pain. Clinically, there were significant improvements in mouth opening range and joint noise. Therefore, this therapeutic approach seems to be an effective option to control the signs and symptoms of TMJ disorders, restoring the patient's comfort and improving their quality of life.

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