Clinics in Surgery

Research Article
Published: 23 Jul, 2024

Comparison of the Clinical Outcome of Hegab Splint, Arthrocentesis, and Arthroscopy in Treatment of TMJ Closed Lock: Randomized Controlled Clinical Trial

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Abstract

Background: Temporomandibular joint closed lock represents a clinical challenge that is mostly attributed to disc displacement without reduction.

Objective: This prospective, randomized control study aimed to compare the clinical outcome of Hegab splint, arthrocentesis, and arthroscopy in treatment of TMJ closed lock. The study sample was derived from the population of patients who presented for evaluation and treatment of TMJ disorders. The patients were randomly assigned to one of the following three groups:

Group I (Control): Patients treated by Hegab splint.

Group II: Patients treated by arthrocentesis with injection of HA/PRP mix plus Hegab splint.

Group III: Arthroscopy with injection of HA/PRP mix plus Hegab splint.

The primary outcome variable was the change in pain using a visual analog scale, and improvement of maximum voluntary mouth opening. The secondary outcome variable was the change in joint sound. The third category of variables (age and sex) was evaluated in relation to the outcomes.

Results: Group II and Group III exhibited significantly higher MVMOs than Groups I throughout the study period at 1, 3, 6, and 12 months (P=0.02). While statistical analysis between group II and III showed that Group III exhibited higher MVMO than Group II throughout the study periods (P=0.0002).

Conclusion: With the limitation of the current study, the current study suggests that the use of arthroscopy with injection of HA/PRP mix plus Hegab splint showed higher performance results with statistically significant difference in relation to other groups. The use of arthrocentesis with injection of HA/PRP mix plus Hegab splint showed comparable results to the use of arthroscopy and should be used as the first treatment modality in closed lock cases before using arthroscopy.

Keywords: Hegab splint; Arthrocentesis; Arthroscopy; HA/PRP mix; TMJ closed lock

OPEN ACCESS

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Received Date: *02 Jul 2024*
Accepted Date: *16 Jul 2024*
Published Date: *23 Jul 2024*

Citation:
Hegab AF, Abd Al Hameed HI, Ali Hasan AA. Comparison of the Clinical Outcome of Hegab Splint, Arthrocentesis, and Arthroscopy in Treatment of TMJ Closed Lock: Randomized Controlled Clinical Trial. Clin Surg. 2024; 9: 3720.

Introduction

Prior to the early 1970s, the surgical treatment of internal derangements of the Temporomandibular Joint (TMJ) involved either restoration of the intraarticular disc to its normal position or removal of the disc. However, the introduction of arthroscopic surgery for the management of internal derangements by Ohnishi in 1975 and the subsequent development of the technique represented a major advancement in the treatment TMJ closed lock [1-3].

The success reported with arthroscopic management of internal derangements ultimately led to the introduction of arthrocentesis for the treatment of closed lock in the TMJ by Nitzen et al. in 1991 [4,5]. This procedure involved lavage of the TMJ *via* 2 hypodermic needles introduced into the upper joint space and lysis of adhesions by lavage solution and by manual manipulation of the mandible [6-9].

However, because arthrocentesis does not involve visualization of the joint structures or the use of additional surgical manipulations, it raises the question of whether arthroscopy should be the preferred initial treatment for TMJ closed lock or no.

Recently, Hegab et al. introduced Hegab TMJ splint with 6 mm vertical thickness as an effective

treatment modality in treatment of closed lock jaw (DDNR with limited mouth opening) [10].

Hegab et al. [11] compared the efficacy of the combined use of HA+PRP as well as the independent effects of HA and PRP following arthrocentesis for the management of TMJ-OA. The study results showed that, intra-articular injection of a combination of PRP+HA was superior to intra-articular injection of HA or PRP independently in terms of increasing the MVMO, decreasing the VAS, and improving joint sound. PRP combined with HA has significant long-term clinical efficacy and clear advantages over HA and PRP.

The objective of this study was to evaluate the efficacy of Hegab splint alone, arthrocentesis with injection of HA/PRP mix plus Hegab splint, and arthroscopy with injection of HA/PRP mix plus Hegab splint for treatment of TMJ closed lock. The specific aim of the study was to compare the improvements in joint pain and function in terms of pain relief and increase in mouth opening between the study groups.

Patients & Methods

The study followed all tenets of the Declaration of Helsinki for research involving human participants and was reviewed and approved by the Institutional Review Board of Al-Azhar University School of Dentistry. Written informed consent was obtained from all patients enrolled in the study.

Study design

The current study is a prospective clinical randomized controlled trial. The study sample was derived from the population of patients who presented to the Department of Oral and Maxillofacial Surgery and Hegab Academy for maxillofacial and TMD for evaluation and treatment of TMJ disorders between January 2021 and December 2022.

Inclusion & Exclusion criteria

To be included in the study, patients age >18 years with TMJ closed lock confirmed by Magnetic Resonance Imaging (MRI) who didn't response to conservative treatment modality (pharmacotherapy, physiotherapy, and anterior repositioning splint). Potential participants were screened through medical history, physical examination, and MRI. The MRI scans were reviewed for all participants and categorized according to the Hegab classification [12]. Patients who had undergone previous treatment for TMJ disorders (joint injection, and previous joint surgeries) were excluded from the study. Patients with systemic diseases (*e.g.*, rheumatoid arthritis, psoriatic arthritis, and juvenile arthritis), those receiving anticoagulant therapy, and those unwilling to participate in the study were excluded from the study.

Patients with Hegab stages 3A & 3B were included in this study:

Stage 3A: MRI shows DDNR associated with pathologic changes of the LPM+/joint effusion.

Stage 3B: MRI shows DDNR associated with pathologic changes of the disk+/Bone degenerative process of the condyle [12].

The primary predictor variables were the independent use of Hegab splint, arthrocentesis with HA/PRP mix injection plus Hegab splint, and arthroscopy with HA/PRP mix injection plus Hegab splint. The primary outcome variable was the change in pain using a Visual Analog Scale (VAS), with 0 indicating the absence of pain and 10 indicating the worst pain possible, and improvement of Maximum Voluntary (non-assisted) Mouth Opening (MVMO) in millimeters. The secondary outcome variable was the change in joint sound. The third category of variables (covariates): That described the sample (age and sex) was evaluated in relation to the outcomes.

Randomization procedures

Opaque randomization envelopes with the allocated treatment method were sequentially numbered by a person who was not clinically involved in the study. The patient selected one of the envelopes and was then administered the allocated group. The patients were randomly assigned to one of the following three groups:

Group I (Control): Patients treated by Hegab splint [10] for one year.

Group II: Patients treated by arthrocentesis with injection of HA/PRP mix plus Hegab splint for one year.

Group III: Arthroscopy with injection of HA/PRP mix plus Hegab splint for one year.

Hegab splint

Hegab TMJ Splint (HTS) is a hard full coverage maxillary occlusal splint with indentation. The splint was used by the patient all the time except during eating. The splint vertical thickness was 6-mm vertical splint thickness measured at the first molar tooth and used for one year of treatment.

Injection technique

The Holmlund-Hellsing line (tragus to external canthus) was drawn, and a point was marked 10 mm in front of the tragus and 2 mm inferior to the line. The mandible was opened, and a 19-gauge needle to distend the joint with 2 ml Ringer's solution. The second needle was inserted at the exit point with the joint distended. Arthrocentesis was performed using 200 ml Ringer's solution. Once arthrocentesis was completed, a mixture of 1 ml HA and 1 ml of PRP was injected into the TMJ.

In case of arthroscopy, the puncture is placed at maximum concavity of the glenoid fossa. to avoid iatrogenic damage to the cartilaginous surfaces during introduction of the trocar, 2 mL Ringer's solution was injected for joint inflation. Through the small skin incision 0.5 cm to 1.0 cm, the lateral capsule is punctured with a sharp trocar in an arthroscopic sheath inserted in the same direction as the previous injection needle. The sharp trocar is exchanged for a blunt one and the arthroscopic sheath is advanced further into the upper joint space. Another skin incision is made 0.5 cm from the first skin incision in anterolateral direction for outflow cannula to be inserted into the upper joint anterior recess. Before inserting the scope, the joint washed to remove all blood and synovial fluid. The scope can be inserted next. The image on the monitor will confirm correct entry into the joint space. During arthroscopy, a sweeping procedure between the disc and fossa release the adhesions and fibrillations increasing the mobility in the joint. Release of the adhesions and fibrillations of the superior surface of the disc and shaving the surface of articular fossa in the upper joint compartment are performed with the aid of a blunt obturator or hook and grasping forceps. At the end of the procedure, mandibular manipulation was performed followed by revaluation by the arthroscope for any adhesion. Closure of the incision with non-resorbable suture followed by blind joint injection to avoid leak of the injection material form the incisions.

All patients underwent the arthrocentesis and arthroscopy under general anesthesia. To prevent the possibility of bias, the preoperative and postoperative outcome measures were recorded independently by another clinician who didn't know the type of treatment intervention.

Postoperative assessment

All outcome variables were assessed and compared among the three groups at baseline and at 1-, 3-, 6-, and 12-month intervals. The third category of variables included patients' age and sex, which were correlated with the outcome variables. The adjustment variables included baseline MVMO and pain scores. For all variables, repeated measures analyses of variance were performed to assess the existence of significant within-group and between-group treatment effects. Adjustments for age and sex were made to assess the influence of demographic data on treatment effectiveness.

Statistical analysis

Sample size calculation was performed using G*Power version 3.1.9.2. With a level of 0.05 (5%) and a sample size of 15 participants per group, the power was 0.97 (97%), indicating that the sample size was adequate. The numerical data were explored for normality by examining the distribution of data, calculating the mean and median, and using tests of normality. One-way analysis of variance and chi squared tests were used to compare the demographic and preoperative factors between the three groups. Repeated-measures ANOVA was used to compare changes in the primary outcomes. The significance level was set at P<0.05. The data were analyzed using InStat (GraphPad, La Jolla, CA, USA) statistical software.

Results

During the study period, 68 participants were screened for eligibility. Of these, 7 patients did not meet the inclusion criteria, and 11 were unwilling to participate in the study. In addition, 5 patients were lost to follow-up before the end of the follow-up period, and they were excluded from the present study.

The final sample comprised 45 participants divided into three equal groups (15 patients in each group). No statistically significant differences were found between the mean age and sex distribution among the three groups. Comparisons of demographic features and baseline values of the outcome variables between the study groups are provided in Table 1. The effects of treatment were not influenced by demographic data.

Statistical analyses to find the relationships of age, sex & Hegab stage with the outcomes of the study revealed that no significant difference observed. Table 2 showed the association between the study variables (age, sex & Hegab Stage) and the outcome variables (mouth opening, pain & joint sound) within the study groups at bassline.

Statistical analysis of the improvement of MVMO within the groups showed that all the groups exhibited highly statistical improvement of the MVMO at the end of the study in comparison to the baseline measurements.

Group II and Group III exhibited significantly higher MVMOs than Groups I throughout the study period at 1, 3, 6, and 12 months (P=0.02). While statistical analysis between group II and III showed that Group III exhibited higher MVMO than Group II throughout the study periods (P=0.0002).

Regarding the pain score, Group III exhibited significantly lower VAS scores than Groups I and II throughout the study periods (P=0.004). While statistical analysis between group II and III showed that Group III exhibited lower VAS scores than Group II throughout the study periods (P=0.02) (Table 3, 4).

Statistical analysis of joint sound changes within the group showed that no significant differences, while statistical analysis between the group showed that group III exhibited significant changes in the joint sound at the end of the study (P<0.0001) (Figure 1, 2).

Table 1: Association between the demographic characteristics and baseline values of the outcome variable between the study groups.

Study Variable	Group I	Group II	Group III	P Value
Sample size	15	15	15	
Gender				
Female	11	11	13	0.02
Male	4	4	2	
Age (yr.)	29.9 ± 4.46	31.9 ± 5.28	30.3 ± 5.97	0.6
MVMO (mm)	23.33 ± 1.543	23.33 ± 2.289	23.33 ± 1.88	0.4
Pain (0−10 on VAS)	7.80 ± 1.01	7.93 ± 0.96	7.87 ± 1.06	0.6
Joint sounds	0.067 ± 0.26	00 ± 00	00 ± 00	0.5
Hegab stage				
3A	7	6	5	0.12
3B	8	9	10	

MVMO: Maximum Voluntary Mouth Opening

Table 2: Association between the study variables (age, sex & Hegab Stage) and the outcome variables (mouth opening, pain & joint sound) within the study groups at bassline.

Variables	MVMO (mm)	Pain (0-10 on VAS)	Joint sounds
	P-Value	P-Value	P-Value
Age			
Group I	0.2	0.4	0.6
Group II	0.5	0.5	NA
Group III	0.6	0.8	NA
Gender			
Group I	0.2	0.6	0.6
Group II	0.9	0.4	NA
Group III	0.08	0.1	NA
Hegab stage			
Group I	0.13	0.7	0.4
Group II	0.8	0.35	NA
Group III	0.53	0.22	NA

MVMO: Maximum Voluntary Mouth Opening; Statistically significant (P-Value <0.05); NA: Not Applicable

Discussion

This study aimed to compare the efficacy of Hegab splint alone, arthrocentesis with injection of HA/PRP mix plus Hegab splint, and arthroscopy with injection of HA/PRP mix plus Hegab splint for treatment of TMJ closed lock. The specific aims were to evaluate changes in the pain scores and MVMO.

In our study, we used the Hegab classification because it is the most recent classification and is a reasonable, reliable, and feasible system, including detailed descriptions of all the pathologic changes of the joint [12].

Table 3: Association between the primary predictor (type of treatment: Splint, arthrocentesis, arthroscopy) and the outcome variables (MVMO, pain -VAS score, and joint sound) throughout the study periods.

Variable	Preoperative	1 month postoperative	3 months postoperative	6 months postoperative	12 months postoperative	P Value Within groups	P Value between groups
MVMO							
Group I	23.33 ± 1.543	30.13 ± 1.46	36.20 ± 1.66	39.33 ± 1.49	39.60 ± 1.45	<0.0001	0.02*
Group II	23.33 ± 2.29	35.47 ± 1.41	39.00 ± 1.36	40.20 ± 1.47	40.20 ± 1.47	<0.0001	
Group III	23.33 ± 1.88	35.47 ± 1.96	40.80 ± 1.32	40.87 ± 1.25	40.87 ± 1.25	<0.0001	
VAS							
Group I	7.8 ± 1.01	3.67 ± 1.05	1.6 ± 0.98	0.0 ± 0.0	0.0 ± 0.0	<0.0001	0.004**
Group II	7.93 ± 0.96	2.53 ± 0.64	0.73 ± 0.8	0.27 ± 0.46	0.0 ± 0.0	<0.0001	
Group III	7.87 ± 1.060	2.07 ± 0.88	0.47 ± 0.74	0.0 ± 0.0	0.0 ± 0.0	<0.0001	
Joint Sound							
Group I	0.067 ± 0.26	0.067 ± 0.26	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.4	<0.0001***
Group II	0.0 ± 0.0	0.0 ± 0.0	0.067 ± 0.26	0.067 ± 0.26	0.067 ± 0.26	0.4	
Group III	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.13 ± 0.35	0.13 ± 0.35	0.08	

MVMO: Maximum Voluntary Mouth Opening (mm); * Statistically significant (P-Value <0.05)

Table 4: Statistical analysis of the improvement of mouth voluntary mouth opening, pain (VAS), and joint sound between Group II and Group III.

Variables	MVMO (mm)		P-Value	Pain (0-10 on VAS)		P-Value	Joint sounds		P-Value
	Group II	Group III		Group II	Group III		Group II	Group III	
1 Month	35.47 ± 1.41	35.47 ± 1.96	0.0002	2.53 ± 0.64	2.07 ± 0.88	0.02	0.0 ± 0.0	0.0 ± 0.0	<0.0001
3 months	39.00 ± 1.36	40.80 ± 1.32		0.73 ± 0.8	0.47 ± 0.74		0.067 ± 0.26	0.0 ± 0.0	
6 months	40.20 ± 1.47	40.87 ± 1.25		0.27 ± 0.46	0.0 ± 0.0		0.067 ± 0.26	0.13 ± 0.35	
12 months	40.20 ± 1.47	40.87 ± 1.25		0.0 ± 0.0	0.0 ± 0.0		0.067 ± 0.26	0.13 ± 0.35	

MVMO: Maximum Voluntary Mouth Opening (mm); * Statistically significant (P-Value <0.05)

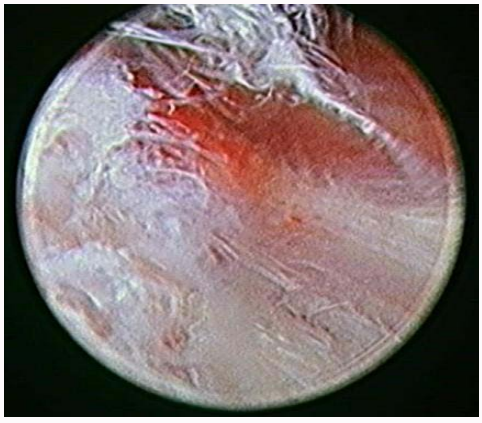

Figure 1: Chronic synovitis with fibrous adhesion and fibrous band of the left TMJ.

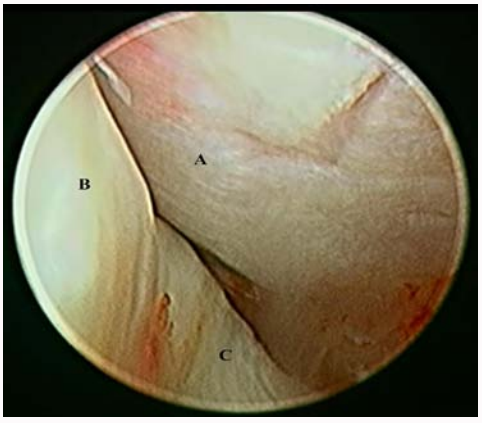

Figure 2: The left TMJ after arthroscopic removal of the fibrous adhesion. A) Articular eminence, B) Articular disk, C) Retrodiscal tissue

TMJ arthrocentesis has been widely accepted as a minimally invasive surgical procedure for TMDs not response to other conservative treatment to. TMJ arthrocentesis proves a very effective treatment for TMJ closed lock [1,2].

The results of the current study provide evidence that Hegab Splint (6 mm vertical thickness), arthrocentesis and arthroscopy are reliable methods for management of the closed lock jaw. However, both of arthrocentesis and the arthroscopic surgery exhibited better performance. The results supported that, the arthroscopic lysis with HA/PRP injection followed by Hegab splint demonstrated highly significant improvement in terms of Improvement of MVMO and pain score.

However, studies comparing the results of arthrocentesis and arthroscopic lysis and lavage showed that there is no statistical difference was noted [13-17]. However, these results are in contrary to the results of our study, which can be explained by TMJ arthroscopy has the benefit of allowing the surgeon to have a look into the joint and directly treat any pathology that could be exists.

Arthrocentesis is less invasiveness procedure without need for special instruments, less postoperative morbidity, lower cost, and fewer complications. While arthroscopic surgery has several complications such as arteriovenous fistula, facial, trigeminal, auditory nerve injury, infection, broken instruments, and perforation of tympanic membrane and deafness [18]. In the current study, we

didn't report any complication with arthroscopic surgery.

The successful management of patients with close lock using arthrocentesis or arthroscopy, involves the improvement of joint function rather than the disk recapture. Thus, the active manual manipulation of the joint during the procedure is so important which better to be done under general anesthesia [19].

In the current study, additional injection of HA/PRP mix had a positive effect on the treatment outcomes in terms of reduction in joint pain and increase in the range of movements. The results of this study support the long-term efficacy of PRP+HA after arthroscopy in reducing pain and improving the range of movements in patients with TMJ closed lock.

Another factor in the long-term success of TMJ arthroscopy for internal derangements is management of the underlying cause. The role of Hegab splint postoperatively is very important to unload the joint and prevent parafunction activity like clenching and bruxism.

One of the limitations of the current study is small sample size. Larger study with longer term follow-up might be useful in evaluating the treatment outcome.

Conclusion

With the limitation of the current study, the current study suggests that the use of arthroscopy with injection of HA/PRP mix plus Hegab splint showed higher performance results with statistically significant difference in relation to other groups. The use of arthrocentesis with injection of HA/PRP mix plus Hegab splint showed comparable results to the use of arthroscopy and should be used as the first treatment modality in closed lock cases before using arthroscopy.

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