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A double-blind randomized controlled trial comparing arthrocentesis and nonsurgical approaches for managing temporomandibular joint closed lock and pain.

Dr. Tushar Saxena[1] Dr. Prasanna Kumar P.[2] Dr. Ankita Raj[3] Dr. Avinash Bhadhuria[4] Dr. Ankur Rathaur[5] Dr. Akash Tiwari[6]

Post Graduate Student, Department of Oral and Maxillofacial Surgery, Rama Dental College, Hospital and Research Center, Kanpur, Uttar Pradesh, India.
tusharsaxena132@gmail.com
9005000012
Professor and Head of Department of Oral and Maxillofacial Surgery, Rama Dental College, Hospital and Research Center, Kanpur, Uttar Pradesh, India.
prasannamaxface@gmail.com
9886122780
Professor, Department of Oral and Maxillofacial Surgery, Rama Dental College, Hospital and Research Center, Kanpur, Uttar Pradesh, India.
drankitaraj.rdc@ramauniversity.ac.in
88875777
Reader, Department of Oral and Maxillofacial Surgery, Rama Dental College, Hospital and Research Center, Kanpur, Uttar Pradesh, India.
avinash0411@gmail.com
8299127393
Senior Lecturer, Department of Oral and Maxillofacial Surgery, Rama Dental College, Hospital and Research Center, Kanpur, Uttar Pradesh, India.
ankurrathaur10@gmail.com
8802879982

Senior Lecturer, Department of Oral and Maxillofacial Surgery, Rama Dental College, Hospital and Research Center, Kanpur, Uttar Pradesh, India.
akash.tiwari5186@gmail.com
9696643192

ABSTRACT:

This double-blind randomized controlled trial aimed to evaluate the effectiveness of conservative treatments, arthrocentesis, and their combination in managing temporomandibular joint (TMJ) pain and improving mandibular opening. Sixty patients presenting with TMJ pain and limited mouth opening were randomly allocated into four groups: conservative treatment alone, conservative treatment with medication, arthrocentesis alone, and arthrocentesis combined with medication. The interventions were assessed based on improvements in maximum interincisal opening and pain reduction. The results demonstrated significant clinical improvements in all groups compared to baseline, with no statistically significant differences observed between the groups. These findings suggest that both conservative treatments and arthrocentesis are effective in reducing TMJ pain and enhancing mandibular opening, with neither approach showing clear superiority over the other after a six-month follow-up.

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INTRODUCTION:

Temporomandibular disorders (TMDs) are musculo- skeletal conditions characterized by facial pain and impaired temporomandibular joint (TMJ) function. Lim- ited mouth opening, joint and muscular pain, and noises during mandibular movements are some of the most common symptoms.[1] It has been reported that TMD rep- resents the second most frequent musculoskeletal condi- tion after low back pain, affecting between 10% and 30% of the world population. Furthermore, 80% of peo- ple with TMD have some degree of internal joint derangement (ID).[2] Broadly, TMDs can be divided in 2 large groups: IDs and masticatory muscle disorders. The present study focused on the management of IDs and not on masticatory muscle disorders.

Because of the multifactorial nature of IDs and the complexity and variability observed in the natural course of the condition, several treatment modalities have been implemented to obtain the same common result: decrease symptoms and improve function.[3] There are 2 major categories of treatment: conservative or nonsurgical and surgical. Conservative alternatives have long represented the first line of treatment for most TMDs.[4,5] Examples include reducing the masticatory load with a soft food diet, pharmacologic treatment with nonsteroidal anti- inflammatory drugs (NSAIDs),[6] physical therapy, and acrylic orthotic devices to equilibrate occlusal load and prevent parafunctional habits.[7]

When conservative attempts do not achieve adequate results, treatment evolves to surgical management, usually starting from the least to the most invasive options. Arthrocentesis is considered as a minimally invasive pro- cedure with rapid postoperative recovery, a low rate of complications, low cost, and capability of being per- formed with the patient under local anesthesia with seda- tion.[8,9] Initially described by Nitzan et al.[10] in 1991, arthrocentesis gained popularity for its beneficial effects on articular pain reduction; mandibular range of motion improvement; better patient compliance than with medi- cations and splints; and improvement in patient quality of life, especially after conservative measures have failed.[4,11]

Because of the inflammatory nature of joint pathol- ogy, arthrocentesis goals include washout of the articu- lation and decrease in the presence of proinflammatory products, mechanical lysis of adhesions, stimulation of the lubricating function of the synovial membrane, relief of joint pain, and improvement in mandibular mobility.[12] According to Dym and Israel,[13] NSAIDs should be prescribed for a minimum of 14-30 days, depending on how long the symptoms have been pres- ent. Arthrocentesis takes only a few minutes to per- form, and if it is able to resolve the symptoms as well as NSAIDs, it seems reasonable to try articular lavage as a first-line treatment for selected IDs.

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Even though arthrocentesis has demonstrated favor- able results in reducing joint function and pain, there is no solid evidence to support major effectiveness of articular lavage compared with conservative options as a first-line treatment.[5,14]

The aim of this double-blind randomized controlled trial (RCT) was to assess the effectiveness of arthrocentesis, either alone or combined with NSAIDs, in alleviating joint pain and enhancing mandibular opening.

MATERIALS AND METHODS

The double-blind randomized controlled trial (RCT) was conducted between December 2023 and July 2024, involving patients that reported to the Oral and Maxillofacial Department of Rama Dental College Hospital and Research Centre, Kanpur. These patients presented with temporomandibular disorders (TMDs), including arthralgia, joint noise, and degenerative disease.

Ethical approval for the study was obtained from the Ethical Committee of Rama Dental College Hospital and Research Centre before initiating the research.

The clinical examination followed the Diagnostic Criteria for Temporomandibular Disorders, assessing mandibular movement limitations, the primary cause and location of pain, joint noises such as popping, clicking, or crepitation, and the presence of parafunctional habits like bruxism. Additionally, magnetic resonance imaging (MRI) was performed on all patients to identify potential internal derangements.

The inclusion criteria required participants to be between 18 and 70 years old, report a minimum joint pain score of 4 on a 10-cm visual analog scale (VAS), have a mandibular opening of at least 35 mm, and have a history of joint noise and locking.

Exclusion criteria included a history of TMJ surgery, absolute indications for surgical treatment (e.g., ankylosis), systemic joint diseases, gastric or other conditions preventing NSAID use, muscular pain as the primary symptom source, cognitive impairment, and Wilkes classification IV and V cases. The decision to exclude Wilkes IV and V cases aimed to create a more homogeneous sample, focusing on patients typically managed with conservative or minimally invasive treatments.

Sample size calculation was based on a previous study by Baker et al., using a significance level of 0.05, a power of 80%, and a mean pain score of 3.3 with a standard deviation of 3.6 on the VAS. Power analysis determined that each group required 13 patients. Participants were randomly allocated into four groups of 15 patients each using a computer-aided block randomization method. An independent examiner, uninvolved in the treatments, assigned patients by distributing opaque, sealed, and numbered envelopes indicating their treatment type. The envelopes were sequentially given to the surgeon responsible solely for performing the procedure. To maintain blinding, patients were unaware of their assigned treatment groups. Table I provides an overview of the treatment distribution across groups.

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PROCEDURE DESCRIPTION

Oral sedation was administered using 10-15 mg of midazolam, followed by local anesthesia with approximately 4 mL of 2% lidocaine containing 1:100,000 epinephrine. This included around 3 mL for skin anesthesia and 1 mL for the joint. Once an adequate level of sedation and anesthesia was achieved, synovial fluid aspiration was performed on all patients using a standardized technique. The Holmlund-Hellsing line, extending from the tragus to the external canthus, was marked, and a reference point was identified 10 mm anterior to the tragus and 2 mm below the line. With the patient's mandible open, a 21-gauge needle (0.8 × 30 mm) attached to a 10-mL syringe containing 1-2 mL of saline was inserted at the designated point and advanced into the superior joint space. After injecting saline, the fluid was allowed to return to the syringe, after which the syringe was disconnected.

For patients undergoing arthrocentesis (groups C and D), a second needle was inserted 10 mm anterior to the first point and 5-10 mm below the Holmlund-Hellsing line to facilitate drainage. The joint was irrigated with 100-200 mL of saline while the mandible was mobilized. Patients in groups A and B, who did not receive joint lavage, had the syringe and needle removed after synovial fluid aspiration. Instead, external irrigation of the auricular region was performed while mobilizing the mandible to mimic the arthrocentesis procedure. This protocol ensured immediate pain relief and maintained the double-blind nature of the study. Additionally, approximately 2 mL of synovial fluid was collected as part of a separate ongoing study examining the molecular aspects of internal derangement (ID).

Each patient received three boxes of medications. Box 1 contained three tenoxicam 20-mg tablets, while Box 3 held 30 pantoprazole 20-mg tablets. For groups A (control) and C (arthrocentesis), Box 2 contained 27 placebo tablets. In groups B (medication) and D (arthrocentesis + medication), Box 2 included 27 tenoxicam 20-mg tablets. All medications were compounded to have identical appearance, with no logos or distinguishing features to prevent identification. Patients were instructed to take one tablet from Box 1 and one from Box 3 daily after the procedure. Starting from the fourth day, they continued with one tablet from Box 2 and one from Box 3 daily until the pills were finished.

Postoperatively, all patients followed a soft diet for one month. Warm compresses were recommended for the first two weeks, with a gradual return to normal chewing function. Physical therapy began in the second week, consisting of five-minute sessions of mouth opening, lateral, and protrusive movements, repeated four times daily. Cognitive behavioral therapy was also introduced, starting with an educational session on how parafunctional habits and excessive chewing can impact the TMJ. Patients maintained a daily journal to track their adherence to dietary modifications and avoidance of parafunctional habits.

Clinical assessments were conducted at baseline (T0) and postoperatively at 2 weeks (T1), 1 month (T2), 3 months (T3), and 6 months (T4). A single blinded examiner recorded all evaluations, including maximum interincisal opening (MIO), joint pain at rest, and pain during maximum mouth opening, measured using a 10-cm visual analog scale (VAS). Joint noises were also documented. Treatment success was defined as an increase in mouth opening and a reduction in pain scores to below 4 on the VAS, combined with an MIO exceeding 35 mm.

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Patients who still exhibited pain and limited mouth opening were offered additional treatments, including arthrocentesis (for groups A and B), arthroscopy, or open joint surgery.

STATISTICAL ANALYSIS

Statistical analysis was conducted using SPSS Statistics 17.0 software (SPSS, Chicago, IL). The Kolmogorov-Smirnov test was employed to evaluate the normality of continuous variables, which were found to have a non-normal distribution. To compare assessment values across different groups, the Kruskal-Wallis test was utilized. Within-group differences were analyzed using the Friedman test, while the Wilcoxon test, with two-sample comparisons adjusted by the unilateral Bonferroni correction, was applied to assess variations over time within each group. Categorical variables were examined using the chi-square test. A significance threshold of $P < .05$ was established for all analyses.

RESULTS

A total of 305 individuals presenting with internal derangement (ID) symptoms were assessed. After applying the inclusion and exclusion criteria, 60 patients (52 women and 8 men) were selected and randomly divided into four groups, each consisting of 15 participants. One patient from the arthrocentesis group was removed due to noncompliance during follow-up.

The average age of the participants was 34.17 ± 13.1 years. Among them, 33 patients experienced pain on the left temporomandibular joint (TMJ), while 26 had pain on the right side. MRI findings revealed that 72.9% had some form of ID; 54.2% reported joint noises, 55.9% experienced episodes of closed lock, 32.2% had missing teeth, 16.9% exhibited malocclusion, and 11.9% used dental prostheses. The patient distribution across groups showed no significant differences, as presented in Table II.

Within-group analysis indicated that all groups experienced significant improvements in maximum interincisal opening (MIO) and pain levels when comparing baseline measurements (T0) with subsequent time points (T1, T2, T3, and T4), as detailed in Tables III and IV. However, intergroup analysis found no significant differences, indicating that no specific treatment was superior to the others. Mean values for each measured variable over the follow-up period are illustrated in Figures 1 and 2.

MRI assessments of the 60 patients revealed that 43 (72.9%) had ID. Among them, 25 cases (58.13%) were diagnosed with anterior disc displacement without reduction, 13 cases (30.23%) had anterior disc displacement with reduction, and 5 cases (11.62%) exhibited other pathological conditions such as synovitis and edema. The distribution of these characteristics among the groups showed no significant differences ($P = .478$).

After six months of follow-up, all 59 remaining patients showed improvements in MIO and pain levels. However, nine cases did not meet the success criteria of achieving an MIO greater than 35 mm and a pain level below 4 on the visual analog scale (VAS). Among these, seven patients had articular disc disorders, one had joint effusion detected on MRI, and one did not show ID on MRI (Table V).

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TABLE: 1

Group	Procedure
(A) Control	Local anesthetic injection, soft diet, physiotherapy, cognitive behavioral therapy
(B) Medication	Local anesthetic injection, medication for 30 days, soft diet, physiotherapy, cognitive behavioral therapy
(C) Articular lavage	Arthrocentesis, soft diet, physiotherapy, cognitive behavioral therapy
(D) Articular lavage + medication	Arthrocentesis, medication for 30 days, soft diet, physiotherapy, cognitive behavioral therapy

TABLE: 2

Variable		Groups		
	Control	Medication	AL	AL + medication
Female sex, n (%)	13 (86.7%)	15 (100%)	12 (80%)	12 (80%)
Left side, n (%)	8 (53.3%)	7 (46.7%)	11 (73.3%)	7 (46.7%)
Locking, n (%)	8 (53.3%)	8 (53.3%)	6 (40%)	11 (73.3%)
Absent teeth, n (%)	6 (40%)	7 (46.7%)	3 (20%)	3 (20%)
Dental prosthesis, n (%)	4 (26.7%)	2 (13.3%)	1 (6.6%)	0 (0.0%)
Articular noise, n (%)	6 (40%)	9 (60%)	8 (53.3%)	9 (60%)
Malocclusion, n (%) Internal derangement, n (%)	2 (13.3%) 12 (80%)	2 (13.3%) 12 (80%)	3 (20%) 8 (53.3%)	3 (20%) 11 (73.3%)
Wilkes class II	7 (46.7%)	9 (60%)	8 (53.3%)	8 (53.3%)
Wilkes class III	8 (53.3%)	6 (40%)	7 (46.7%)	7 (46.7%)

TABLE: 3 Maximum interincisal opening according to group and timing

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Groups	T0-T1	MIO P value	T0-T3	T0-T4			Mean values		
		T0-T2			T0	T1	T2	T3	T4
Control	.015	.00	.00	.00	26.67	32.27	34.13	38.40	37.53
Medication	.008	.00	.00	.00	25.60	32.93	38.14	41.13	42.53
AL	.058	.00	.00	.00	25.00	28.43	36.36	40.07	40.50
AL + medication	.052	.002	.00	.00	29.33	32.43	36.14	42.29	42.21

	Pain on opening P value				Mean Value				
GROUP	T0-T1	T0-T2	T0-T3	T0-T4	T0	T1	T2	T3	T4
Control	.015	.00	.00	.00	7.39	3.72	3.66	2.58	1.98
Medication	.008	.00	.00	.00	7.42	3.43	3.05	1.04	1.00
AL	.058	.00	.00	.00	6.58	4.80	3.71	2.87	1.52
AL + medication	.052	.00	.00	.00	6.19	4.78	4.26	1.86	1.49

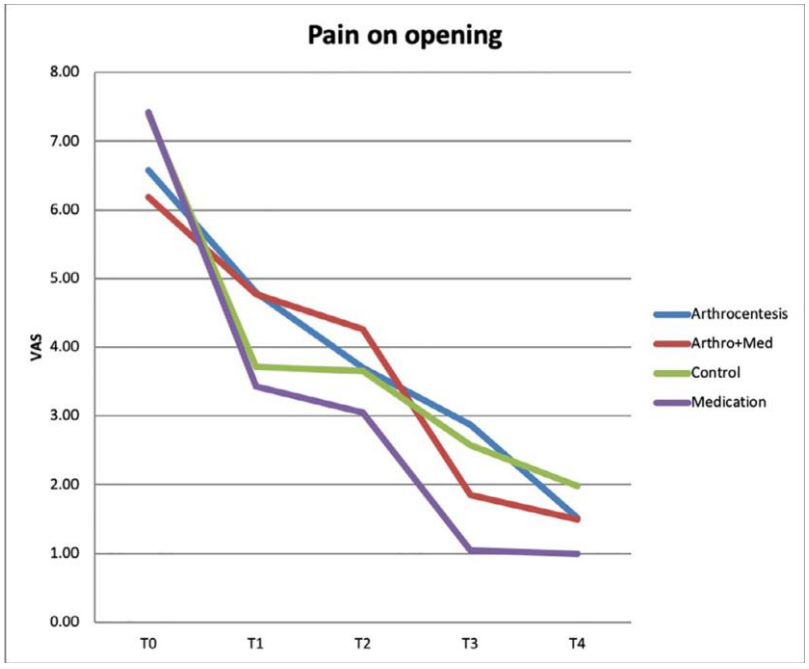

Fig. 1. Mean value of the 10-cm visual analog scale to evaluate pain at each time point.

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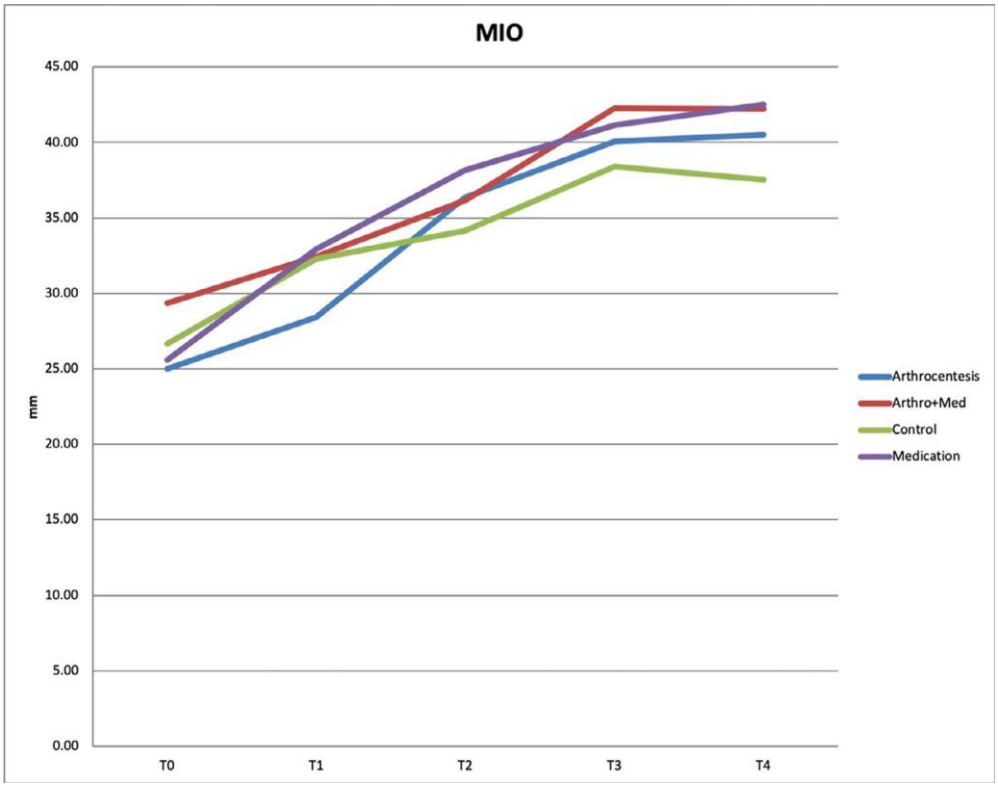

Fig. 2. Mean maximum interincisal opening at each time point.

DISCUSSION

Bouchard et al.[5] conducted a meta-analysis comparing arthrocentesis and conservative treatments, highlighting methodological inconsistencies and bias, recommending TMJ lavage with caution. This double-blind RCT found similar outcomes for both treatments as first-line options.

Sahlstrom et al.[17] and Baker et al.[16] reported no significant differences in 45 patients receiving anesthetic infiltration alone (A) or with lavage (AL), with similar clinical improvements at 3 months[17] and 3 years[16] despite increasing group asymmetry. Unlike their study, ours ensured balanced groups and standardized conservative treatment, including diet, physical therapy, cognitive behavioral therapy, thermal therapy, and anti-inflammatory medication in group B.

Vos et al.[18] found similar long-term effectiveness but noted arthrocentesis relieved pain and improved function faster (3–12 weeks). Their study lacked clear blinding, and conservative treatment was progressive, unlike our consistent approach. Diracoğlu et al.[19] found superior results with arthrocentesis in disc displacement without reduction but lacked proper randomization and blinding, increasing bias.

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Machon et al.[20] and Tatli et al.[21] observed that arthrocentesis combined with conservative treatment outperformed splints alone. Alpaslan et al.[22] and Ghanem[23] found muscle disorders hindered joint symptom improvements, with bruxism patients experiencing worsening symptoms post-arthrocentesis. Consequently, we excluded patients with parafunctional habits and predominant muscle pain.

Our findings—higher rates of crepitus (54.2%), locking (55.9%), and ID (72.9%)—align with Al-Moraissi[24] but differ from Nitzan et al.[11]. The study population was mostly female (88.1%), consistent with previous research.[25–27] Andrabi et al.[28] noted younger patients with inflammatory components benefited more from arthrocentesis.

Among nine treatment failures, severe ID was the most common factor. Strict inclusion criteria ensured a homogeneous sample but limited generalizability. Conducting blinded RCTs for surgical vs. nonsurgical treatments is challenging; we standardized interventions to minimize bias but acknowledged small sample size limitations.

Conservative treatment for arthralgia includes pain management, load reduction, mobility exercises, stress control, and habit management.[6,7,21,30–32] Strengths of this study include MRI-based diagnostics, randomized groups, and participant blinding. Most trials compare arthrocentesis with partial conservative approaches, modified techniques (e.g., HA, PRP), or surgical interventions.[21–24,33–36]

CONCLUSION

In conclusion, both arthrocentesis and conservative treatment effectively enhanced mandibular opening and reduced pain in ID patients. Thus, arthrocentesis can be considered a second-line option when conservative methods fail to improve jaw mobility and pain management.

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