

A Comparative Evaluation of the Efficacy of Normal Saline and Sodium hyaluronate in the Treatment of Temporomandibular Joint Diseases by Arthrocentesis – An In-Vivo Study

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Abstract

Aim: To evaluate and compare the efficacy of normal saline and sodium hyaluronate in treatment of temporomandibular joint diseases by arthrocentesis.

Materials and method: An In vivo randomized clinical trial was carried in Department of oral and maxillofacial surgery on 30 patients aged between of 18-60 years having Temporomandibular joint disorders. The patients were equally distributed for both arthrocentesis with NS and sodium hyaluronates.

Standardization of the measurements were done by marking the reference points on the face. Patient was evaluated and noted preoperatively for: pain evaluation with the help of visual analog scale and scores were assigned as per pain perception. Clicking sound of TMJ was also preoperatively evaluated. Lateral and protrusive movement were also measured preoperatively with the help of scale Deviation of mandible was also recorded. All this preoperative record were maintained for respective patient of both

group Patients were evaluated post-operatively at end of treatment and after 1 week, 1 month, 3 months and 6 months for all the above mentioned parameters.

Conclusion: Arthrocentesis by hyaluronic acid showed significant difference in treatment outcome of TMJ disorders when compared to arthrocentesis by normal saline in terms of pain, TMJ sound, interincisal opening, lateral excursions, protrusive movements.

Keywords- Arthrocentesis, Normal saline, Sodium hyaluronate, Lateral excursions, Protrusive movements

Introduction:

Temporomandibular joint disorder is a term that encompasses a number of overlapping condition. It occurs in approximately 10% of the population. TMJ pain and dysfunction can be caused by various etiologic factors like neuromuscular hyperactivity (Bruxism), malocclusion, trauma, disc dislocations and degenerative joint diseases, the presenting symptoms are often similar. [1] The ‘Temporomandibular Joint Internal Derangement’ describes an abnormal relationship of the articular disc to the mandibular condyle and the articular eminences. The internal derangement of the TMJ generally progresses from the first stage, where there is clicking accompanied by normal maximal mouth opening to a stage where the clicking gradually ceases concomitantly that is attributed to a non-reducible anteriorly displaced disc acting as an obstacle to the gliding condyle. The mainstay of these surgical options were based on the changing the morphology or position of the disc or removal of the disc with or without replacement. An important change in therapeutic approach occurred with the introduction of arthrocentesis. Arthrocentesis is a procedure in which the fluid in joint cavity is aspirated with needle and therapeutic substance is then injected. This procedure has been shown to achieve acceptable

results with minimal complication in treating internal derangement of TMJ. The procedure has been shown to achieve a relatively high success rate as well as its unique treatment manner as a borderline procedure between surgical and non-surgical intervention. This procedure neither changes the shape nor the position of the disc. Macroscopic analysis of aspirated blood obtained from the diseased joint confirms the diagnosis and concurrently eliminates the devastating harm caused pressure generated by the haemorrhage and its sequelae i.e. fibro adhesions. [2] It is a natural consequence to arthroscopic lysis and lavage. The physical action of this technique was thought to be responsible for its success. It has been proved to be simple and relatively less invasive alternative. Nitzan et al. were the first to describe arthrocentesis of TMJ as a treatment concept for severe closed lock symptoms. TMJ arthrocentesis is a non-arthroscopic lavage procedure often replaces surgical intervention in the TMJ when complemented by joint uploading and physiotherapy. It is highly efficient in resolving signs and symptoms associated with disorders caused by adhering forces or friction that is eliminated by lavage, such as intermittent clicking, anchored disc phenomenon, open lock, and is also efficient for releasing limited mouth opening and pain in approximately 70% of patients who have TMJ osteoarthritis. The outcomes are sufficiently effective to prevent further surgical intervention. [3] The arthrocentesis, which is a relatively less invasive, simple, inexpensive and highly efficient procedure that can be performed under local anaesthesia, has thus found an important place in the treatment of internal derangement of TMJ. A technique using a single needle for both fluid injection and ejection has been approach for washing the TMJ was based on the rationale that

pumping saline injection into the superior joint compartment with the patient in an open mouth position provides enough pressure to release joint adhesences and to allow fluid outflow when the patient closes their mouth [4] Sodium hyaluronate is largely responsible for the viscosity of normal synovial joint. Its capacity to function as a molecular sieve is thought to be important both in regulating the nutrition of articular cartilage and in physical interactions with the macromolecules of the articular surfaces. Hyaluronic acid is a linear polysaccharides consisting of polydisaccharide units of glucuronic acid and N-acetyl glucosamine linked by B1-3 & B1-4, glycosidic bonds. [5]

Hence the rationale of the study was to evaluate the efficacy of normal saline and sodium hyaluronate in treatment of temporomandibular joint diseases by Arthrocentesis.

Materials and method: The In-vivo randomized clinical trial was conducted in Department of oral and maxillofacial surgery. Trial design was approved by the institutional review board. Photographs of all participants were taken in a standard anatomical position by a digital camera and standardization of the measurements were done by marking the reference points on the face. The informed consent was obtained from the participants. A total of 30 patients aged between 18-60 years were included having the chief complaint of pain in the TMJ.

- Group I= 15 Patients (arthrocentesis with NS)
- Group II= 15 Patients (arthrocentesis with sodium hyaluronate)

The selection criteria was-

1. Minimum age more than 18 years
2. Wilkes stage 2 disease for at least 2 months
3. TMJ pain > 3 in visual analog scale
4. Patient who did not get any relief from

physiotherapy

Patient who were on muscle relaxants for at least 2 months, Patients with infection of the affected joint, Patient with previous surgery of the affected joint, Patient who have undergone same procedure previously, Any history of drug allergy, Pregnant and lactating patients, Medically compromised patient were excluded from the study. Patients were randomly divided into two groups regardless of severity of disease.

Procedure

The same protocol of asepsis were followed for all patients. The surgical field were scrubbed with savlon and painted with 10% povidone iodine (Betadine) and covered with sterile drape. Anaesthesia was induced by blocking the auriculotemporal nerve with 2 % lignocaine hydrochloride containing 1:80,000 adrenaline. The anaesthetic solution was infiltrated into the joint cavity, skin surface, and soft tissues over the joint.

2. Double needle technique were followed for normal saline group

a. Two points were marked: the first at 10 mm anterior and 2 mm inferior and the second at 20 mm anterior and 10 mm inferior to the tragus on the line between the canthus and the tragus. b. Two 20-gauge needles were placed to the entry and exit points for washing. The arthrocentesis was performed with Normal saline 100mL to eliminate the catabolites present in the synovial fluid. For both groups Post-operative medication were given that consist of antibiotic coverage with analgesics for 1 week. For both groups Post-operative medication were given that consist of antibiotic coverage with analgesics for 1 week. Single Needle technique were followed for hyaluronic acid group 4.

Following procedure was performed

a. First, a line was drawn from the external canthus to the tragus (Holmlund– Helsing line).

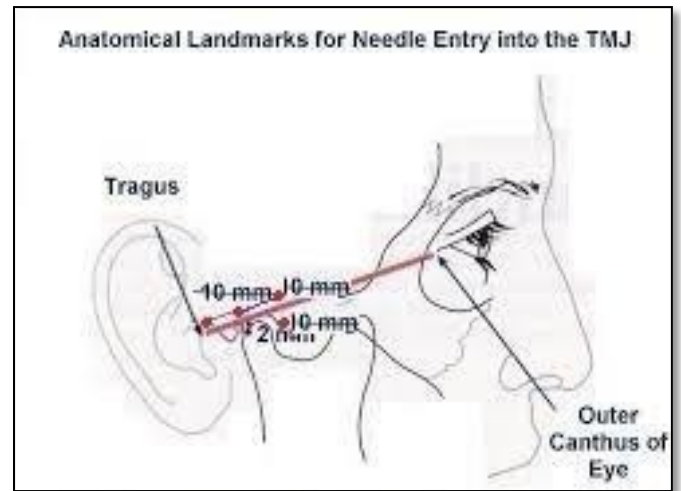
b. Then in open mouth position, the contour of the inferior border of the glenoid fossa was marked.

c. Next, the puncture was outlined on the depression formed between the inferior border of the glenoid fossa and the lateral pole of the condyle.

d. Then in other group of patient the arthrocentesis was performed by initial wash of Normal saline and then Hyaluronic acid was injected into joint cavity by using only one needle.

e. After injecting 1ml of hyaluronic acid solution in the superior joint space: the patient was asked to protrude and lateralize the mandible in the highest range that they could.

f. Then the patient was asked to try to close his/her mouth at that time. Once the administration of the medication is completed, the syringe was moved. Patient was evaluated and noted preoperatively for: pain evaluation with the help of visual analog scale and following scores were assigned as per pain perception 2. Clicking sound of TMJ was also preoperatively evaluated 3. Lateral and protrusive movement were also measured preoperatively with the help of scale 4. Deviation of mandible was also recorded All this preoperative record were maintained for respective patient of both group 5. Patients were evaluated post-operatively at end of treatment and after 1 week, 1month, 3 months and 6 months for all the above mentioned parameters. Data was entered in Microsoft excel and was descriptively and statistically analysed.



Anatomical Landmarks for Two Needle Technique for Normal Saline group

Fig.1: Holmlund–Hellsingline (Reference line)



Fig.2: NS Lavage of Joint Capsule

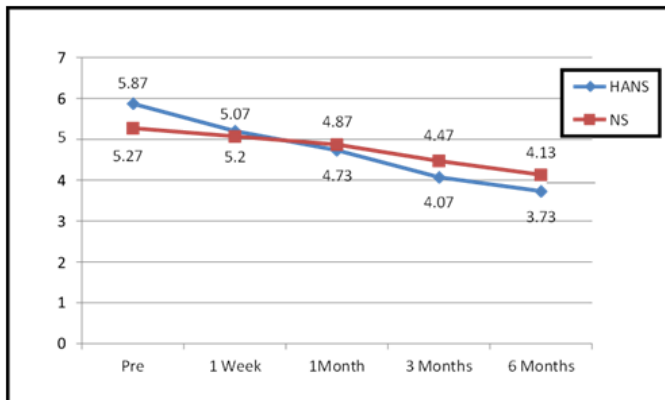


Fig.3: Hans Administration In Joint Capsule



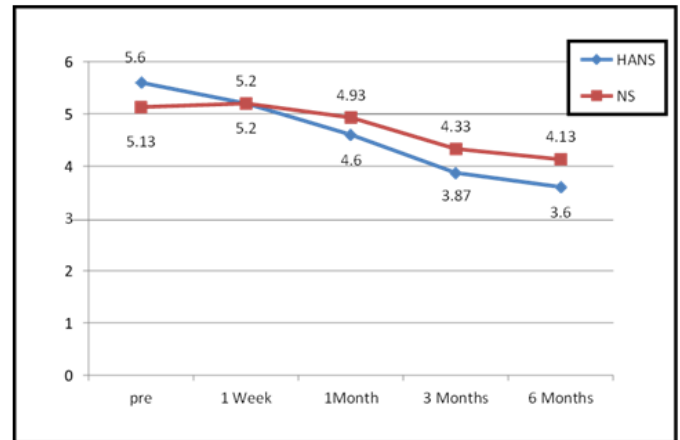
Results: Pre Pain score in HANS group patients was 5.87 ± 0.50 while that in NS group it was 5.27 ± 1.03 . There was statistically no significant ($p > 0.05$) difference in mean pre pain score in between HANS and NS group.

Graph 1: Comparison of Pain score in between HANS and NS



TMJ sound score in patients within HANS group of 5.6 ± 0.51 while NS group had score of 5.13 ± 0.74 . There was statistically no significant ($p > 0.05$) difference in mean pre TMJ sound score in between HANS and NS group.

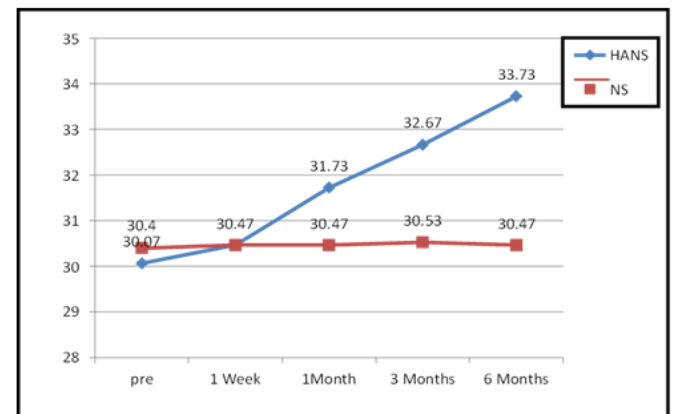
Graph 2: Comparison of TMJ sound in between HANS and NS



At 1 month HANS group patients had Inter-Incisal opening of 31.73 ± 2.12 while the NS group was 30.47 ± 3.11 . There was statistically highly significant ($p < 0.01$) difference of Inter-Incisal opening in between HANS and NS group at 1 month. 3 months At HANS group patients had Inter-Incisal opening of 32.67 ± 1.63 while the NS group Inter-Incisal opening was 30.53 ± 3.22 . There was statistically significant ($p < 0.05$) difference of Inter-Incisal opening in between HANS and NS group at 3 month.

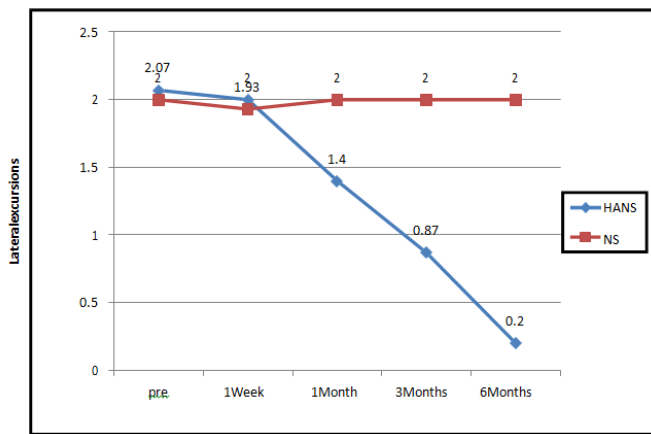
At 6 months HANS group patients there was statistically highly significant ($p < 0.01$) difference of Inter-Incisal opening in between HANS and NS group at 6 month.

Graph 3: Comparison of Inter incisal opening in between HANS and NS



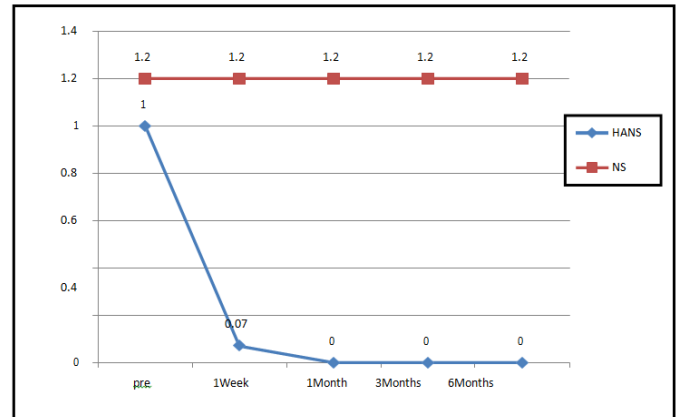
Pre lateral excursion in patients within HANS group was 2.07 ± 0.25 while NS group had lateral excursion of 2.00 ± 0.65 . There was statistically no significant ($p > 0.05$) difference in mean pre lateral excursion in between HANS and NS group. At 6 months HANS group patients had lateral excursion of 0.20 ± 0.41 while the NS group was 2.00 ± 0.65 . There was statistically very highly significant ($p < 0.001$) difference of lateral excursion in between HANS and NS group at 6 month.

Graph 4: Comparison of Lateral excursions in between HANS and NS



Mean Pre Protrusive movement in patients with in HANS group was 1 ± 0.66 while NS group had mean protrusive movement of 1.20 ± 0.41 . There was statistically no significant ($p > 0.05$) difference in mean pre mean protrusive movement in between HANS and NS group. There was statistically very highly significant ($p < 0.01$) difference of mean protrusive movement in between HANS and NS group at 1 month, 3 months and 6 months.

Graph 5: Comparison of Protrusive movement in between HANS and NS group



When pain at rest and at function was compared with baseline, study group was found to be more clinically significant in all-time intervals than control group. Although there was statistically insignificant difference within these groups when compared for pain. Thus, arthrocentesis with normal saline followed by injecting sodium hyaluronate into the joint cavity had a faster and longer effect of pain relief than arthrocentesis with normal saline alone. This effect can be explained by long term lubricating effect of injection sodium hyaluronate, which prevents the onset of inflammatory mediators that are responsible for pain which is in the correlation with the study done by **Gokhan H Alpaslan and Cansu Alpaslan (2001)**.⁴

Inter-Incisal Opening showed statistically significant difference after 1 month of intervention in patients with arthrocentesis with normal saline followed by injection sodium hyaluronate than in patients with arthrocentesis with normal saline alone. This result is in contrast with the study of **Dolwick and Nitzan(1991), Dimitroulis et al (2000)**.⁵

When parameters such as lateral excursions, protrusive movements, joint noises in both groups were compared with each other the difference found was statistically

significant. This is in contrast with the result of the study done by Gokhan H Alpaslan and Cansu Alpaslan (2001).

Thus, in our study when two intra-articular injections of sodium hyaluronate 1 week apart were given after arthrocentesis, a significant improvement at 1 month and 6 months was detected when compared with baseline for all outcome measures including maximal inter-incisal opening, lateral excursions (right and left side), protrusive movement, joint pain, TMJ pain (at rest, at function). Probable reason could be explained on the basis of findings reported by **Zardeneta et al.** (2000)⁶, when they compared arthrocentesis alone and arthrocentesis with sodium hyaluronate. In both the groups all patients had symptomatic improvement in their pain but when checked for biomarkers, those patients who received injection sodium hyaluronate, had considerable decrease was found in these biomarkers. This may provide indirect evidence supporting the anti-inflammatory properties of sodium hyaluronate.

Discussion

Temporomandibular disorder may present with cluster of joint and muscle disorders characterized primarily by pain, joint sounds and irregular or deviating jaw function. There is clinical evidence supporting the existence of disc displacement in TMJ internal derangement. An internal derangement occurs when there is a disturbance in the normal anatomic relationship between the articular disc and condyle that interferes with the smooth movement of the joint and causes momentary catching, clicking, popping or locking. Internal derangement is defined as any interference with smooth joint movement. Although the term Internal derangement includes all types of intracapsular interferences that impede smooth functional joint movements, with regard to the temporomandibular joint (TMJ) the term is usually used

interchangeably with disc displacement.² The recent concept suggests that a change in position of disc is not a primary factor in dysfunction and pain of the TMJ. Alterations in joint pressure, a variety of biochemical substances and constitutions of the fluid may lead to clicking and derangement of the TMJ. Pain associated with TMJ disorder may be because of vasodilation. The release of nitric oxide and thiobarbituric acid reactive substance levels in the synovial fluid may result from mechanical stress and high pressure directed to the upper compartment during clenching and jaw movement. Arthrocentesis is an easy, minimally invasive, and highly efficient procedure to decrease joint pain and increase the range of mouth opening with TMJ disorder. Murakami et al (1987) was first to offer a systematic description of TMJ arthrocentesis and found excellent results in releasing closed lock by arthrocentesis lavage and lysis.¹⁰ Arthrocentesis as described by Nitzan et al is another simpler modification of arthroscopic lavage and lysis. Parafunctional habits such as clenching associated with high TMJ impact loading that convert shearing stresses to compressive stresses. Intra and extra articular overloading which exerts effects on synovial joint (eg. interruption of blood supply) is a major reason for the collapse of lubrication system. When joint is overloaded, the hypoxia reperfusion cycle evokes non enzymatic release of radical oxygen species (ROS) such as superoxide and hydroxyl anions. The highly reactive radical oxygen species (ROS) degrade hyaluronic acid, causing marked decrease in synovial fluid viscosity. Thus, the degraded form of hyaluronic acid indirectly affects the joint lubrication. In the absence of lubricant, there is increased adhesiveness, friction, shear and rupture of articular surfaces.¹¹ Lavage of upper compartment through TMJ arthrocentesis causes separation of the flexible disc from fossa, washes away

the degraded particles and inflammatory components (Radical Oxygen Species (ROS), interleukin, substance P, tumor necrosis factor, Bradykinin, Prostaglandin E2) and decreases the intraarticular pressure whenever the joint is inflamed. Inflammatory response is not only a significant source of pain, but also it may lead to the development of synovitis, capsulitis and ultimately fibrous adhesions and pseudowalls. Internal derangement may develop secondary to this, or it may be the inciting event. The relation between inflammatory changes and internal derangement is not well defined. The development of arthrocentesis as a therapeutic procedure has also allowed routine synovial fluid sampling. The success of arthrocentesis in many patients with nonspecific arthralgia, internal derangement, and osteoarthritis may be the result of decreasing inflammation, eliminating adhesions, or re-establishing a normal disc fossa relation. Moses and Poker (1989) reported that arthrocentesis treat both mechanical and inflammatory aspects of TMJ internal derangement. Sato et.al (2001) reported that improvement in maximal inter-incisal opening was significantly better when extensive techniques involving anterior release of the disc and lateral capsular release were used, than when only conventional Arthrocentesis Lysis and Lavage (ALL) was used.¹² Kopp et.al (1985) first published the intra-articular hyaluronic acid injections as a new approach in treatment of TMJ disorders.¹³ In various studies Kopp et. al, Bertolami et al (1993) found the significant improvement in subjective symptoms after sodium hyaluronate injection. Hyaluronic acid is a linear polysaccharides consisting of repeating disaccharide units of glucuronic acid and N acetyl glucosamine linked by B1-3 & B1-4 glycosidic bonds. It is available in the extracellular matrix of various mammalian tissues including skin, cartilage, umbilical cord, & synovial

fluid. Sodium hyaluronate is largely responsible for viscosity and rheological properties of synovial fluid. Its capacity to function as molecular sieve is thought to be important both in regulating the nutrition of articular cartilage and in physical interactions with macromolecules of articular surfaces. The precise mechanism of injection sodium hyaluronate is unknown. It provides lubrication for the articular surfaces and is largely responsible for synovial fluid viscosity.¹⁴ Arthrocentesis was considered as an intervening treatment modality between non-surgical treatment and arthroscopic surgery on the basis of its short term outcome. Success rate for arthrocentesis has been reported to increase up to 95% at about 3 year follow up in patients with TMJ closed lock and 91% long term success rate in patient with reduction. So it has clearly shown that arthrocentesis is highly successful for pain, dysfunction relief and achievement of normal range of mandibular movements both in closed lock and disc displacement with reduction. According to our study average age of patients of internal derangement who attended the clinic ranges from 25 to 45 years. In our study higher incidence of female patients were diagnosed with internal derangement of Temporomandibular joint. This finding is in accordance with the finding of Dolwick & Nitzan (1991) & Kit et. al (2006).¹⁴ When pain at rest and at function was compared with baseline, study group was found to be more clinically significant in all-time intervals than control group. Although there was statistically insignificant difference within these groups when compared for pain. Thus, arthrocentesis with normal saline followed by injecting sodium hyaluronate into the joint cavity had a faster and longer effect of pain relief than arthrocentesis with normal saline alone. This effect can be explained by long term lubricating effect of

injection sodium hyaluronate, which prevents the onset of inflammatory mediators that are responsible for pain which is in the correlation with the study done by Gokhan H Alpaslan and Cansu Alpaslan (2001).¹⁵ Inter-Incisal Opening showed statistically significant difference after 1month of intervention in patients with arthrocentesis with normal saline followed by injection sodium hyaluronate than in patients with arthrocentesis with normal saline alone. This result is in contrast with the study of Dolwick and Nitzan (1991), Dimitroulis et. al (2000). When parameters such as lateral excursions, protrusive movements, joint noises in both groups were compared with each other the difference found was statistically significant. This is in contrast with the result of the study done by Gokhan H Alpaslan and Cansu Alpaslan (2001). Thus, in our study when two intra-articular injections of sodium hyaluronate 1 week apart were given after arthrocentesis, a significant improvement at 1 month and 6 months was detected when compared with baseline for all outcome measures including maximal inter-incisal opening, lateral excursions (right and left side), protrusive movement, joint pain, TMJ pain (at rest, at function). Probable reason could be explained on the basis of findings reported by Zardeneta et. al. (2000), when they compared arthrocentesis alone and arthrocentesis with sodium hyaluronate. In both the groups all patients had symptomatic improvement in their pain but when checked for biomarkers, those patients who received injection sodium hyaluronate,had considerable decrease was found in these biomarkers. This may provide indirect evidence supporting the anti-inflammatory properties of sodium hyaluronate.

Conclusion: The rationale of the study was to evaluate the efficacy of normal saline and sodium hyaluronate in treatment of patients suffering from TMDs by

arthrocentesis. In the present study 30 patients suffering from same type of TMDs were included. Patients were divided into 2 groups. Group-1 consists of 15 patients who undergone arthrocentesis by normal saline and group-2 consists of 15 patients who undergone arthrocentesis by hyaluronic acid. All the cases were subjected to clinical evaluation for severity of TMJ disorder. In all the cases degree of pain, TMJ sound, Inter incisal opening, lateral excursions and protrusive movements were evaluated preoperatively, 1week, 1month, 3months, 6months respectively in both the groups. Arthrocentesis was performed as described by Nitzan DW et al. In all the cases extreme care was taken to minimize procedural complications. Within the limitation of the study following conclusion can be drawn, arthrocentesis by hyaluronic acid showed significant difference in treatment outcome of TMJ disorders when compared to arthrocentesis by normal saline in terms of pain, TMJ sound, interincisal opening, lateral excursions, protrusive movements. Hyaluronic acid has following advantages over normal saline

- It provides better lubrication for the articular surfaces.
- It acts as chief constituent which is responsible for viscosity of synovial fluid.
- It causes significant reduction in inflammatory biomarkers in joint capsules.

There are following certain drawbacks of the present study:

- Further research and studies are required to assess the efficacy of the hyaluronic acid and normal saline in treatment of TMJ disorders by arthrocentesis.
- Procedural complications like fibrosis of joint capsule may result because of multiple pricking at the preauricular region.

- Arthrocentesis is an extremely technique sensitive procedure, it is difficult for new learner to master the technique. Thus arthrocentesis by hyaluronic acid, which is a relatively less invasive, inexpensive and highly efficient procedure that can be performed under local anaesthesia, has thus found an important role in the treatment of internal derangement of TMJ

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