

Evaluation of the Effects of Polidocanol Injection in the Treatment of Temporomandibular Joint Hypermobility - A Prospective Study

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Abstract

Introduction: Sclerosing agents have been used for temporomandibular joint (TMJ) hypermobility since decades, some of which are ethanolamine oleate, and OK-432, sodium psylliate (syalnasol), but there are no studies on the usage of polidocanol – a well-known sclerosing agent which does not have much side effects and is inexpensive. Hence, this study evaluates the effect of polidocanol injection in the treatment of TMJ hypermobility. **Methodology:** This was a prospective observational study in which patients with chronic TMJ hypermobility were included. Out of the 44 patients who had symptoms of clicking and pain of the TMJ, 28 were diagnosed as internal derangement of the TMJ. The final analysis included 15 patients in whom multiple injections of polidocanol were given on the basis of post-operative parameters. The sample size was calculated based on a significance level of 0.05 and a power of 80%. **Results:** Overall, a success rate of 86.6% (13/15) was encountered at the end of three months, with seven patients not reporting any further episodes of dislocation after one injection and six patients not reporting any episode of dislocation after two injections. **Discussion:** Polidocanol sclerotherapy can be used as a treatment modality for chronic recurrent dislocation of the TMJ, rather than opting for more invasive procedures for the same.

Keywords: Hypermobility, polidocanol, sclerotherapy, temporomandibular joint, temporomandibular joint disorders

INTRODUCTION

Temporomandibular joint (TMJ) hypermobility is a pathophysiologic joint condition that involves dislocation and subluxation. Dislocation is rare and is a non-reducing displacement of the condyle with subsequent inability to close the mouth.^[1,2] Subluxation is when the condyle moves anteriorly and results in a momentary inability to close the mouth from a maximally open position.^[3,4] When patients experience multiple repeated episodes of dislocations due to normal day-to-day activities, it is referred to as ‘chronic recurrent dislocation’.^[5] The injection of sclerosing agent for this purpose has been reported with varying success rates. There are some sclerosing agents that have been used for TMJ hypermobility, some of which are ethanolamine oleate,^[6] and OK-432,^[7] sodium psylliate (syalnasol),^[8] but there are hardly any studies on the usage of polidocanol – a well-known sclerosing agent which does not have much side effects and is inexpensive.

METHODOLOGY

The Institutional Ethical Committee approval (IEC/PGTh/July19/43) and the Institutional Research Committee approval (IRC/2020/PGTh/July19/43) were taken on June 9, 2020.

The sample size was calculated based on a significance level of 0.05 and a power of 80%. All procedures performed in the study were conducted in accordance with the ethics

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standards given in the 1964 Declaration of Helsinki, as revised in 2013.

The inclusion criteria – patients with chronic recurrent TMJ dislocation, subluxation of TMJ, greater than or equal to two episodes of dislocation within a period of six months, unilateral or bilateral involvement and confirmatory radiographic diagnosis of dislocation with TMJ radiographs/Orthopantomogram (OPG) were included in the study.

The American Society of Anesthesiologists (ASA) grading III/IV patients, patients with internal derangement of TMJ, previous TMJ surgery, joint fractures/trauma, drug-induced hypermobility, osseous abnormality of joint confirmed by magnetic resonance imaging, inflammatory connective tissue disorders, neurological issues, parafunctional habits, malignant disease and decreased compliance were excluded from the study.

Informed written consent was obtained from all patients who were included in our study. The diagnosis of subluxation or chronic dislocation was made based on history and clinical and radiological examination. Seven parameters were assessed

preoperatively. The number of episodes of dislocation and regional tenderness was assessed subjectively, joint sounds were assessed via auscultation, pain was assessed by the Visual Analogue Scale (VAS) with scores from 0 to 5 (0 for ‘no pain at all’ to 5 for ‘severe pain’), masticatory efficiency was assessed with a subjective scale of 0-5 (0 for ‘no difficulty in chewing’ to 5 for ‘unable to chew at all’) and maximal interincisal opening was measured via Vernier calipers. TMJ radiographs or OPGs were taken for assessment of position of condyle and articular eminence. Post-operative follow-up was done at two weeks, four weeks, three months and six months. Initially, a test dose of 0.5 ml of polidocanol was administered intradermally in the forearm region three days before the procedure to rule out any allergic reactions. After painting, positioning and draping, auriculotemporal nerve blocks using 2 ml of 2% lignocaine (1:200,000 adrenaline) were given in the pre-auricular region bilaterally. The superior joint space (SJS), inferior joint space (IJS) and posterior disc attachment were marked as points A, B and C, respectively, on the left side first. SJS was marked at a point 10 mm anterior to tragus on the Holmlund–Helsing line and IJS was marked 2 mm below point A. Point C was marked just in front of the tragus [Figure 1]. Three 30-gauge needles were inserted into the marked site [Figure 2]. 2 ml of 3% polidocanol was diluted to 1% using 4 ml of sterile water. Using a three-way stopcock and two 10 ml syringes, the foam was created. Within 60 s, the foam was injected into the marked areas A, B and C, with the depth of insertion being 25 mm and the quantity being 1 ml into each of the three markings [Figure 3]. After bilateral injection of polidocanol into the joint, Barton’s bandage was applied for immobilisation for a week [Figure 4]. Postoperatively, the patients were advised a soft diet and restricted mouth opening. Muscle relaxants and analgesics were prescribed. Patients were recalled at two weeks, four weeks, three months



Figure 1: Marking of canthal-tragal line and points A,B,C corresponding to superior joint space, posterior disk attachment and inferior joint space respectively



Figure 2: Insertion of needles into marked points



Figure 3: Making of polidocanol foam and injection of foam into marked areas

and six months, thereafter telephonic conversations were also done to follow up with the patients. On subsequent follow-ups, assessment for hypermobility of the joints in the form of recurrence of dislocations was done. The other parameters already described were assessed. Reinjection up to a maximum of three times was given in the follow-ups if required. The first injection was given at the time of visit, and if required, the injections were repeated at the 2nd week, 4th week, 3rd month and 6th month, respectively. Results were tabulated and derived.

Statistical analysis

The statistical analysis was done using SPSS for Windows version 20 software (SPSS Inc., Chicago, IL, USA). All continuous variables will be expressed as mean/median along with standard deviation interquartile range depending upon the normalcy of the data. Categorical variables such as regional tenderness, joint sounds and radiological investigations have been expressed as frequency and percentages. Repeated measures analysis of variance was applied for the scale variables such as VAS scores, mouth opening and masticatory efficiency scores. McNemar test was applied for comparisons between categorical groups such as pre- and post-regional tenderness, pre- and post-joint sounds and pre- and post-radiological findings. *P* < 0.05 was considered statistically significant.

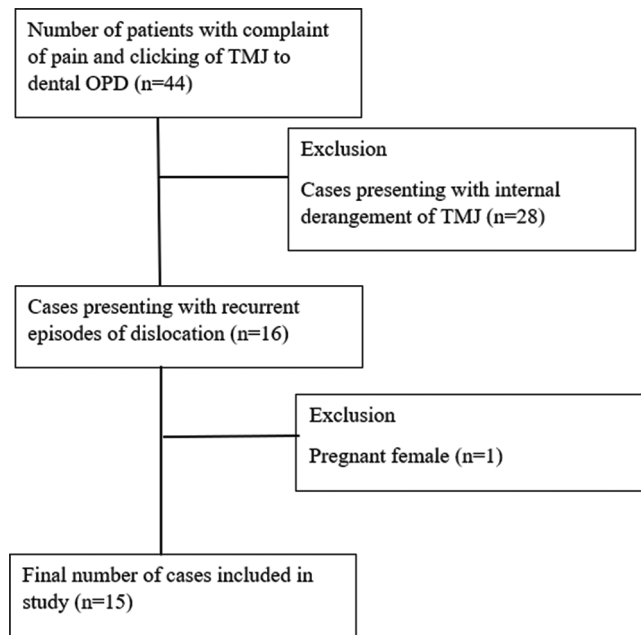
RESULTS

Fifteen patients were included in the final analysis [Flowchart 1]. They had a mean age of 45.93 ± 12.77 years (range: 19-67 years). 46.6% were male, and 53.3% were female. Twelve (80%) patients belonged to ASA I category whereas three (20%) patients fell into the ASA II category [Table 1]. All the 15 patients were diagnosed with recurrent dislocation of the TMJ. The frequency of dislocation ranged between one and five. The average maximum mouth opening (MMO) was 40.1 ± 2.93 [Table 1]. On palpation, regional tenderness

was present in seven patients (46.7%) and absent in eight patients (53.3%). On orthopantomogram/TMJ radiograph, the condyle was located anterior to articular eminence in nine out of 15 cases (60%) and was located just below the tip of the eminence in 6/15 cases (40%) preoperatively.

Assessment of pre- and post-operative parameters

- The condyle was posterior to the eminence postoperatively in all the cases except the two cases in which they were anterior to the eminence [Figure 5 and Graph 1].
- Pain and masticatory efficiency scores were found to decrease significantly at the end of two weeks, four weeks and three months (*P* < 0.05) [Table 1 and Graph 2].



Flowchart 1: Flowchart depicting study methodology

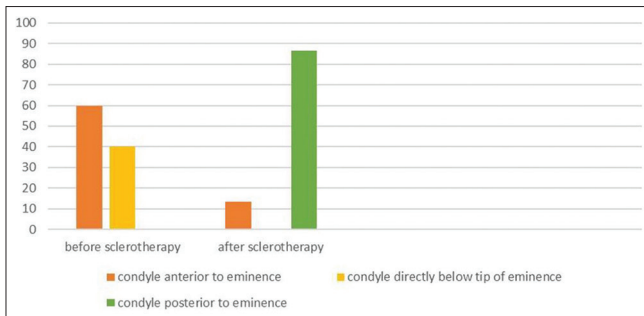
Table 1: Comparison of pre- and post-operative parameters

	Number of episodes of dislocation (mean - 2.53±0.9), n (%)	Joint sounds, n (%)	Pain (mean VAS scores)	Masticatory muscle efficiency	Mouth opening	Number of patients who received single injection	Number of patients who received two injections	Number of patients who received three injections
Pre-operative	5 episodes=1 (6.7) 4 episodes=1 (6.7) 3 episodes=4 (26.7) 2 episodes=8 (53.3) 1 episode=1 (6.7)	10 (66.6)	1.20±0.94	0.87±0.74	40.1±2.93			
Post-operative								
2 weeks	0	8 (53.3)	1.07±0.70	0.47±0.51	38.6±2.95	15		
4 weeks	2 episodes=1 (13.3) 1 episode=6 (40) 0 episodes=7 (46.6)	6 (40)	0.67±0.61	0.20±0.41	36.8±2.67	7	8	
3 months	1 episode=2 (13.3)	2 (13.3)	0.47±0.51	0.0	36.43±2.8	7	6*	1 [#]
6 months						-	-	-
<i>P</i>		0.008	0.016	0.001	0.001			

*1 patient did not comply for the third injection due to recurrence after the second injection, [#]Loss to follow-up after the third injection. VAS=Visual Analogue Scale



Figure 4: Post-operative dressing with Barton's bandage



Graph 1: Graph depicting the relationship of condyle to articular eminence before and after sclerotherapy

- There was a statistically significant decrease in the pre-operative mouth opening at the end of three months ($P < 0.05$) [Table 1 and Graph 2].

At the end of four weeks, a success rate of 46.6% (7/15) was seen. Overall, a success rate of 86.6% (13/15) was encountered at the end of three months, with seven patients not reporting any further episodes of dislocation after one injection and six patients not reporting any episode of dislocation after two injections. Symptomatic relief in terms of pain, masticatory efficiency, joint sounds, regional tenderness and mouth opening was seen in 100% of patients (15/15) [Table 1].

Hence, the success rate of polidocanol injection for TMJ hypermobility at the end of this study was 86.6% (13/15).

DISCUSSION

Injectable agents should always be the first choice of treatment in chronic recurrent dislocation before opting for more invasive methods.^[9] Sclerosing agents have been used for the treatment of venous vascular malformations of the head-and-neck region since long.^[10,11] In TMJ hypermobility, they are proposed to strengthen lax ligaments, by causing trauma to the ligaments of the TMJ, along with subsequent inflammation and fibrosis of the same. Various sclerosing agents have been used in the past.^[7,8,12,13] Polidocanol is one such sclerosant which has proven efficacy towards varicose veins as well as head-and-neck venous malformations but has never been used for TMJ hypermobility *per se*.

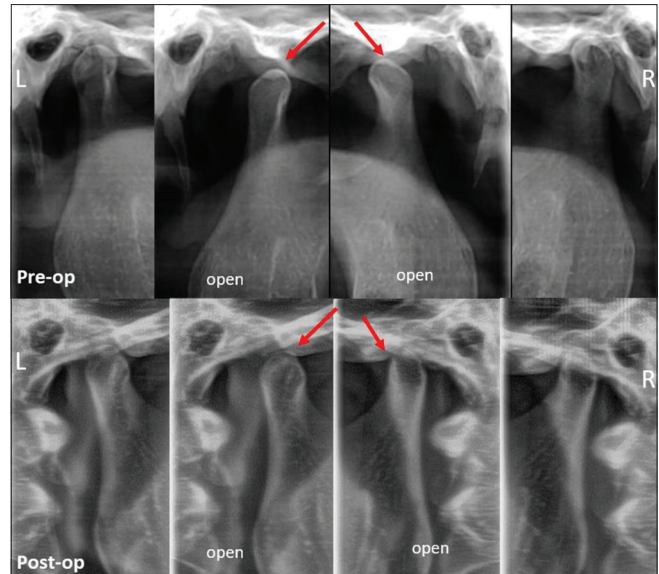
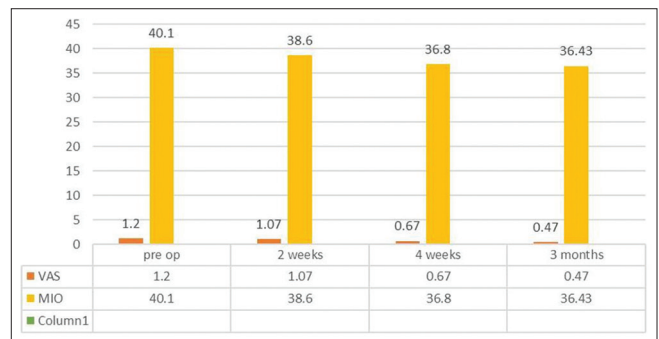


Figure 5: OPG depicting pre-operative and post-operative images



Graph 2: VAS scores and Maximal Interincisal Opening (MIO) before and after sclerotherapy over a time period of 3 months

Sclerotherapy or ‘proltherapy’ has been postulated to strengthen lax ligaments by the use of sclerosing agents.^[14,15] The transient low-grade inflammatory response when initiated propagates the migration of macrophages and tissue repair. These proliferants can be classified as irritants, osmotics and chemotactics.^[16]

Numerous studies have reported the effects of various sclerosing agents and several potential ‘proliferants’ have been identified. 5% ethanolamine oleate injection in the pericapsular area of TMJ has shown angiogenesis, new bone formation and cartilaginous hyaline tissue.^[17] Many of the studies on proltherapy have used dextrose in a concentration of 10-30%.^[18] Arthrocentesis can be done before injecting 30% dextrose solution, thereby decreasing the number of injections.^[19] Prospective trials have been carried out using autologous blood injections (ABIs).^[12,20] ABI has been reported superior to dextrose in a study.^[21] Sodium psylliate was used as a sclerosant for TMJ hypermobility by Becker in 100 patients with satisfactory results.^[8] The usage of OK-432 Picibanil was suggested by Matsushita *et al.*^[7] IMF has also been implicated either alone or in combination with other sclerosants.^[22] Yoshida used botulinum toxin A in the lateral pterygoid muscle in patients

with TMJ hypermobility.^[23] Studies by Majumdar *et al.* and Yoshida *et al.* evaluate the effect of 25% dextrose and ABI, respectively.^[24,25]

Polidocanol is a sclerosing agent that has been used widely in the treatment of varicose veins as well as low-flow venous malformations of the oral cavity.^[26,27] It is an alkyl polyglycol ether of lauryl alcohol and was initially developed as a local anaesthetic in 1931.^[28] Mild urticaria is the most general complication reported. The French Polidocanol Study on Long-Term Side Effects of Polidocanol supported it as a safe sclerosing agent.^[27,29] The only study where polidocanol has been used in the TMJ is a comparative study between polidocanol and sodium tetradecyl sulphate. 0.25% polidocanol was used in joints of the shoulders, hips, knees and the TMJs.^[30] In the present study, we used 1% polidocanol compared to the 3% polidocanol used in venous malformations. The commercially available 3% was diluted to 1% by using sterile water.^[31] Polidocanol foam was made prior to injection using the 'Tessari's' method of foam preparation. This method involves mixing the liquid sclerosant and the gas between two syringes via a three-way stopcock. Foam that is created by pumping back and forth the liquid and the gas has an advantage of increased potency, cohesion and the ability to not mix with the blood, which means it can stay at the target site for a longer time.^[27] The mechanism of action of polidocanol in TMJ hypermobility is to decrease joint mobility as a whole by causing inflammation of the ligaments, and their subsequent fibrosis, thus tightening them.

A number of studies have used OPG as the screening aid for TMJ disorders.^[4,24,32] Hence, we took either OPG or TMJ radiograph as a diagnostic aid in our study. In six of our cases, the condyle was located directly below the tip of the eminence (type I Akinbami classification). In nine out of 15 cases, the condyle was located anterior to the tip of the eminence (type II Akinbami classification).^[33]

Our study took three easy landmark points for injection – SJS, IJS and the posterior disc attachment based on a literature review.^[6,16,18,34] Our hypothesis is that SJS and IJS being hollow cavities would allow for the solution to reach the surrounding collateral and TMJ ligaments uniformly, thereby decreasing the chances of technician error and the number of injection sites.

Nagori *et al.* in their meta-analysis and systematic review of studies comparing dextrose over placebo for TMJ hypermobility revealed a statistically significant reduction in MMO with the use of dextrose.^[35] This was in accordance with our study, where we report a statistically significant decrease in MMO over a 3-month period – 36.43 ± 2.80 using polidocanol.

Certain studies have used clicking sounds as a parameter pre- and postoperatively.^[34,36] In the present study, post-intervention, clicking sounds were found to be significantly lower at the end of 3 months ($P = 0.008$).

In our study, the frequency of dislocations ranged from 1 to 5, two episodes being the most common within a period of 6 months ($n = 8$). In comparison, other studies have not reported the number of dislocations before the initiation of treatment.

A statistically significant decrease in pain was seen in studies conducted by Cömert Kiliç and Güngörmüş, Refai *et al.* and Mustafa *et al.*^[16,18,34] This again was in accordance with our study where we report a statistically significant reduction of pain scores ($P = 0.016$).

Rodrigues suggested that in temporomandibular disorders (TMDs), the masticatory system adapts itself to the neuromuscular changes that occur and could therefore lead to a greater efficacy of the system.^[37] Postoperatively, the masticatory efficiency was found to improve at the end of 3 months and this was statistically significant. An additional parameter – 'regional tenderness' – was taken in our study which was elicited by palpation of the condyle bilaterally. Khamis *et al.* had also considered the same in their study.^[6]

Literature on the treatment of TMJ disorders using sclerotherapy is limited. A study comparing ABI and ethanolamine oleate suggested that the mean mouth opening by using sclerosing solutions was more or less the same as the decrease in mean mouth opening achieved by invasive procedures.^[6] A 100% success rate was reported with ethanolamine oleate as compared to our success rate of 86.6% using polidocanol. Both Khamis *et al.* and Arafat and Elbaz reported a greater decrease in mouth opening scores with ABI, when compared to ethanolamine oleate or dextrose groups.^[6,21] A maximum of three injections were required in our study. One injection was sufficient in seven out of 15 patients, and two injections were required in eight patients for the desired result. There is only one study that has used 0.25% polidocanol in TMJ hypermobility versus 0.11% tetradecyl sulphate in the Ehlers–Danlos population. This study was a comparison study between the two agents and did not report the effect of the individual agents.^[30] Therefore, we wanted to assess the effect of 1% polidocanol on isolated TMJ dislocation cases, rather than comparing it to other agents. One study reported successful treatment of hypermobility of TMJ by injecting sclerosing solution into the oblique protuberance and simultaneously cauterising the posterior attachment tissues lateral to the protuberance.^[38] Studies with 10% dextrose and 25% dextrose have shown a significant reduction in variables such as pain, joint sounds, number of dislocations as well as the masticatory efficiency.^[16,24,34,39] Overall, favourable results have been seen over the years with sclerotherapy.^[8,25] The same applied to our study as well. Except one patient who did not report due to recurrence after the second injection and another patient who was lost to follow-up after the third injection, all the other patients reported relief of symptoms, more importantly, the absence of locking episodes.

Some side effects have been reported with the sclerosing agents used in the literature – sloughing, ulceration, necrosis, pain, dysphagia, difficulty in chewing and speech with a nasal twang. In contrast, a high safety profile has been reported with polidocanol injections, especially to the foam form of this agent, which carries even lesser toxicity than the liquid

form. Our study reported no adverse effects by the use of this agent, except transient oedema of the surrounding cheek and eyelid areas in two patients who received only a single injection of polidocanol. This resolved in 2448 h after a stat intravenous injection of 8 mg dexamethasone after the procedure.

CONCLUSION

Polidocanol sclerotherapy can be used as a treatment modality for chronic recurrent dislocation of the TMJ, rather than opting for more invasive procedures for the same. Multicentric randomised controlled trials with a larger sample size are required for comparing the efficacy of polidocanol with other sclerosing agents.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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