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Efficacy of dextrose prolotherapy for the management of chronic temporomandibular disorders: Clinical trial study

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Abstract---Background and objective: Temporomandibular disorders defined as multiple orofacial conditions that cause pain at temporomandibular joint or associated muscles or both of them, limitation of mouth opening, problem of lateral movement of the jaw and functional joint sounds. Temporomandibular disorders can be treated with non invasive or invasive therapy according to the indication of each condition, non invasive therapy involve medication, physiotherapy, oral splints, injection therapy while invasive therapy include arthrocentesis, arthroscope or surgery. The present study designated to find out the effect of dextrose prolotherapy as a hypertonic material for treating common chronic temporomandibular disorders. Methods: 40 patients were divided into two groups randomly, prolotherapy group received dextrose injection, while medication group received myogestic and profen tab. The variables recorded are pain of the joint, masseter muscle, degree of mouth opening, clicking and hypermobility, follow up period was 1 week, 1 month, and 2 months. Results: The mean of joint pain score and masseter muscle pain score of the medication group were higher than those of the prolotherapy group, but the differences were not significant ($p = 0.253$, and $p = 0.102$ respectively). The mean mouth opening of the medication group (40 mm) was higher than that of the prolotherapy group (36.5 mm) ($p = 0.018$). 45%

of patients of medication group still had clicking compared to 15% of prolotherapy group. All the patients in both groups have no recurrence of the dislocation episodes. Conclusion: The dextrose is very effective material for treating common chronic temporomandibular disorders.

Keywords---dextrose, disorders, prolotherapy, temporomandibular joint.

Introduction

Temporomandibular (TM) disorder can be defined as multiple orofacial conditions that cause pain at the temporomandibular joint or associated muscles or both of them, limitation of mouth opening, problem of lateral movement of the jaw and functional joint sounds (Shehata, 2019). TM disorders can be caused by either physical factors like problems with occlusion which is considered the most common cause of TM disorders, bruxism, bad orthodontic treatment, trauma to the region, joint looseness. Or the psychosocial causes like depression, anxiety, tension and stress (Sharma, Gupta, Pal, & Jurel, 2011). TM disorders can be treated with conservative or non conservative therapy according to the indication of each condition, the conservative therapy involve medication, physiotherapy, oral splints, injection therapy and instruction about life style while non conservative therapy include arthrocentesis, arthroscope or surgery (Gil-Martínez, Paris-Alemany, López-de-Uralde-Villanueva, & La Touche, 2018). There are many types of injection therapy that has been used to treat the temporomandibular disorders like injection of steroid into the joint, injection of hyaluronic acid for osteoarthritis, injection of botulinum toxin into the muscles of mastication, and dextrose injection that can be used on both the joint and the surrounded muscles for elimination of pain and dysfunction, dextrose injection is called prolotherapy or called regenerative therapy (Sit et al., 2021).

The loosening of the tendons and ligaments of the TMJ is the main cause of musculoskeletal pain, dysfunction and clicking of the TMJ so the injection of dextrose will lead to mild inflammation in the region which will lead to proliferation of fibroblast that will enforce the joint and the associated tendons and ligaments (Younis, Shah, & Rashid, 2020). Hypertonic dextrose is the most commonly used solution because it is obtainable, cheap, water soluble, biocompatible and safe (Haggag, Al-Belasy, & Ahmed, 2022), but it still has some adverse effect that related to the injection procedure itself like discomfort, fullness of the tissue after injection, pain during 72 hours after injection also detected in about 10% of cases, light headache, nerve injury or infection (Rabago, Reeves, Doherty, & Fleck, 2019). The aim of this study is to find out the effect of dextrose prolotherapy as a hypertonic material for treating common temporomandibular disorders like pain

originating from TMJ or the associated muscles, clicking, limitation of mouth opening, TMJ hyper mobility (subluxation and dislocation).

Patients and Methods

This single blinded randomized control clinical trial study was performed on patients suffered from temporomandibular disorders; they all treated in Department of Maxillofacial Surgery at Rizgary Teaching Hospital in Erbil-Iraq, the period of the study extended from November 2021 to November 2022 including data collection & entering, analysis and finality. 40 patients were randomly and equally distributed into two groups, the first group received prolotherapy with dextrose solution and the second group received medication. The age of patients was 18 – 55 years, 18 male and 22 female. Inclusion criteria were patients with common chronic TM disorders that presented for more than 3 weeks. While exclusion criteria were patients with acute TM disorder (less than 3 weeks), patients with previous history of joint surgery, patients with any TMJ disease or tumor or other anomaly, patients with coagulative disorders.

Panoramic radiograph was taken for every patient to exclude any disease or tumor or any other anomaly, The data were obtained by a direct interview with the patients themselves by using a case sheet that include information name, sex, age, and patient contact number, history of present illness, score of pain of the joint, pain of masseter muscle (recorded by visual analogue scale), the degree of mouth opening (recorded by ruler), present of clicking (with palpation and hearing) and dislocation, it also include questions about the improvement of the complain in each follow up visit. The follow up periods was one week, one month and two months from starting the treatment and it should be performed by another clinician.

Prolotherapy technique

The preauricular area was scraped with povidin iodine, a ruler and soft pen was used to determine the points of injections, an imaginary line between the tragus of the ear and the outer canthus of the eye was determined by the ruler, then we draw a point 10 mm from the tragus of the ear, the first point was 2 mm inferior to that point, then we draw another point which is 20 mm from the tragus of the ear, the second point was 10 mm inferior to that point(or we can feel the notch anterior to the condylar head), the third point was 1 cm from the origin of the masseter muscle, while the fourth one was at the insertion of the masseter muscle.

We mixed 1.5 ml of 5% dextrose with 1.5 ml of distilled water with 3 ml of lidocaine without adrenaline, this mixture diluted the dextrose to the wanted concentration which is 12.5%, each patient of the study group was given four injections, each injection of one ml and given at the drawing points consecutively, the first ml was given at the superior joint space (the needle directed superiorly, anteriorly and medially until touches the glenoid fossa, then directed into the superior joint space, it is inserted

about one inch, 2.5 cm), the second one was given at the point of insertion of lateral pterygoid muscle just anterior to condylar head (the needle directed anteriorly and medially about one inch depth, 2.5 cm), the third ml was injected one cm from the origin of the masseter muscle from the zygomatic arch (the needle inserted about 1 cm), and the fourth ml was injected at the insertion of masseter muscle (the needle inserted about 1 cm) Figure 1 (A,B,C,D). The medication group was given Myogesic tab 1*3 for two weeks, Profen tab 400 mg 1*3 also for two weeks.

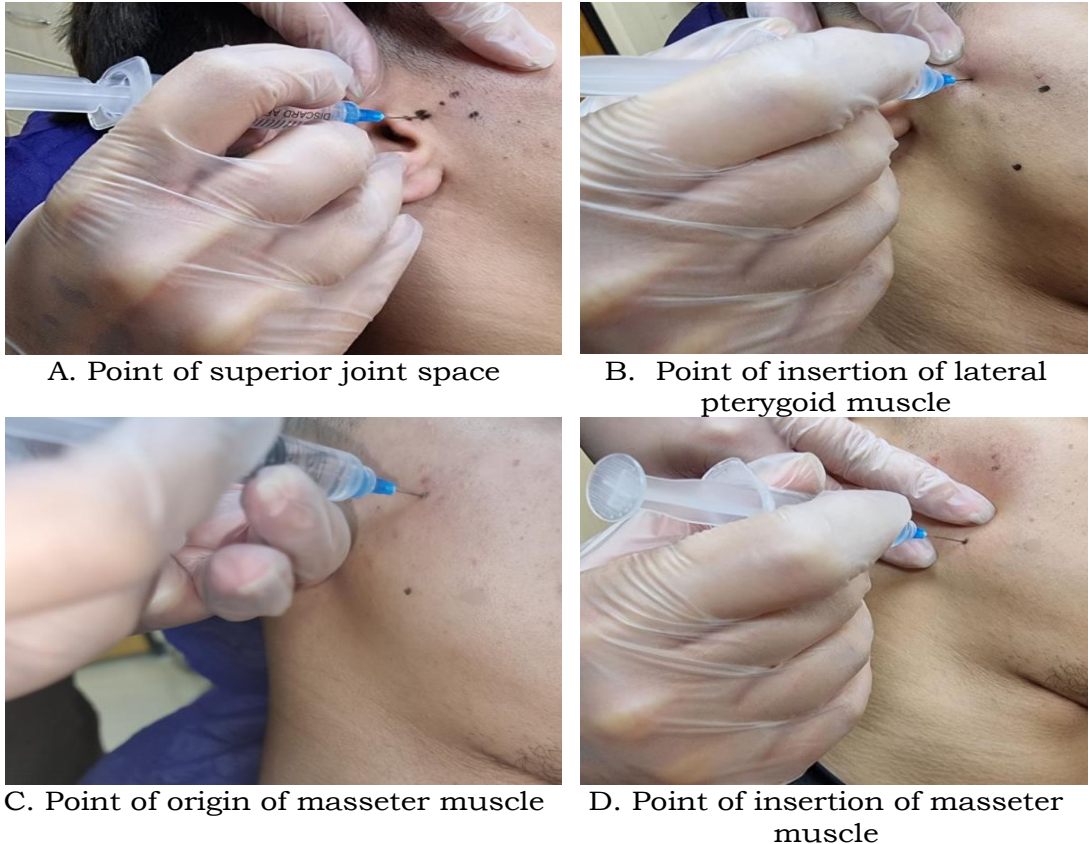


Figure 1. Anatomical areas of points of injections

Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences (SPSS, version 25). Shapiro-Wilk test was used to test the normality of data. Chi square test of association was used to compare proportions. Fisher's exact test was used when the expected frequency (value) was less than 5 or more than 20% of the cells of the table. McNemar test was used for the 2X2 table to compare a categorical variable of the same sample but at different time periods. Student's t test of two independent samples (unpaired t test) was used to compare means of two samples. Friedman test (non-parametric equivalent of repeated measures ANOVA) was used to compare the medians at different time periods (three or more time

periods), and after that Wilcoxon signed ranks test was used to compare the medians of each two time periods. Mann Whitney test (non-parametric equivalent of unpaired t test) was used to compare the mean ranks of two groups. A p value of ≤ 0.05 was considered as statistically significant.

Results

Forty patients participated in the study, 20 were managed by dextrose injection and 20 were managed with myogestic and profen tablets, the age range was 18 – 55 years, 18 male and 22 female. First of all the comparison of the variables within group was made, in the prolotherapy group all the differences between the time periods of temporomandibular joint pain were significant except for the difference between the first and second month parameters, while in the medication group only the differences between day 0 and the other periods until 2 months were significant (Table 1). For the pain of masseter muscle it is evident in (Table 2) that, in each of the two study groups, there was a significant decrease of the pain parameters from day 0 until 2 months after treatment. Regarding the mouth opening, in the prolotherapy group there was an increase in the mouth opening although it was not significant (Table 3). In the prolotherapy group, the rate of clicking decreased to 15% after two months, while in the medication group it decreased to 45% at the end of the study, the dislocation disappeared after one week in both groups (Table 4). For the medication group, as the patients take medication and they take it orally, so there are (20%) developed stomach upset (Figure 2).

Table 1
Pain parameters at temporomandibular joint (TMJ) at different time periods among patients of the two study groups.

Pain at TMJ (time)	Mean	SD	Median	Mean Rank	p (Friedman)	Comparisons	P*
Prolotherapy							
0	3.9	2.8	4.5	3.78	< 0.001	0 vs 1 WK.	< 0.001
1 Week	1.0	1.5	0.0	2.38		0 vs 1 M.	< 0.001
1 Month	0.5	0.9	0.0	1.88		0 vs 2 M.	< 0.001
2 Months	0.5	0.9	0.0	1.98		1 Wk. vs 1 M.	0.016
						1 Wk. vs 2 M.	0.047
						1 M. vs 2M.	0.564
Medication							
0	3.3	3.3	3.0	3.1	0.002	0 vs 1 WK.	0.003
1 Week	1.7	2.2	1.0	2.2		0 vs 1 M.	0.018
1 Month	1.6	2.5	0.0	2.3		0 vs 2 M.	0.027
2 Months	1.7	2.6	0.0	2.5		1 Wk. vs 1 M.	0.888
						1 Wk. vs 2 M.	0.756
						1 M. vs 2M.	0.317

*Wilcoxon Signed Ranks Test

Table 2
Pain parameters at masseter muscle at different time periods among patients of the two study groups.

Pain at masseter (time)	Mean	SD	Median	Mean Rank	p (Friedman)	Comparisons	P*
Prolotherapy							
0	4.1	2.7	4.5	3.68	< 0.001	0 vs 1 WK.	0.001
1 Week	1.7	2.4	0.0	2.45		0 vs 1 M.	< 0.001
1 Month	1.1	2.1	0.0	1.95		0 vs 2 M.	< 0.001
2 Months	1.0	2.0	0.0	1.93		1 Wk. vs 1 M.	0.016
						1 Wk. vs 2 M.	0.024
						1 M. vs 2M.	0.414
Medication							
0	6.0	2.3	6.0	3.63	< 0.001	0 vs 1 WK.	< 0.001
1 Week	3.1	2.6	3.0	2.38		0 vs 1 M.	0.001
1 Month	2.0	2.4	1.0	1.98		0 vs 2 M.	0.001
2 Months	2.0	2.7	1.0	2.03		1 Wk. vs 1 M.	0.020
						1 Wk. vs 2 M.	0.067
						1 M. vs 2M.	1.000

* Wilcoxon Signed Ranks Test

Table 3
Parameters of mouth opening at different time periods among patients of the two study groups.

Mouth opening mm (time)	Mean	SD	Median	Mean Rank	p (Friedman)	Comparisons	P*
Prolotherapy							
0	34.5	5.8	35.0	2.23	0.112	0 vs 1 WK.	0.482
1 Week	35.0	4.9	34.5	2.28		0 vs 1 M.	0.085
1 Month	36.6	4.0	37.5	2.73		0 vs 2 M.	0.126
2 Months	36.5	5.0	38.0	2.78			
Medication							
0	38.9	1.6	40.0	2.13	0.023	0 vs 1 WK.	0.257
1 Week	39.5	2.1	40.0	2.38		0 vs 1 M.	0.019
1 Month	40.1	2.0	40.0	2.83		0 vs 2 M.	0.048
2 Months	40.0	2.2	40.0	2.68			

* Wilcoxon Signed Ranks Test

Table 4
Rates of clicking and dislocation on presentation compared with rates at different periods after intervention.

	Day 0	1 week	P*	1 month	P*	2 months	P*
Prolotherapy							
Clicking	14 (70.0)	10	0.125	5 (25.0)	0.004	3 (15.0)	0.001

Dislocation	5 (25.0)	(50.0)	NA	0 (0.0)	NA	0 (0.0)	NA
Medication							
Clicking	13 (65.0)	10 (50.0)	0.250	9 (45.0)	0.125	9 (45.0)	0.125
Dislocation	3 (15.0)	0 (0.0)	NA	0 (0.0)	NA	0 (0.0)	NA

*All the comparisons (1 week, 1 month, and 2 months) were made with day 0 using the McNemar test.

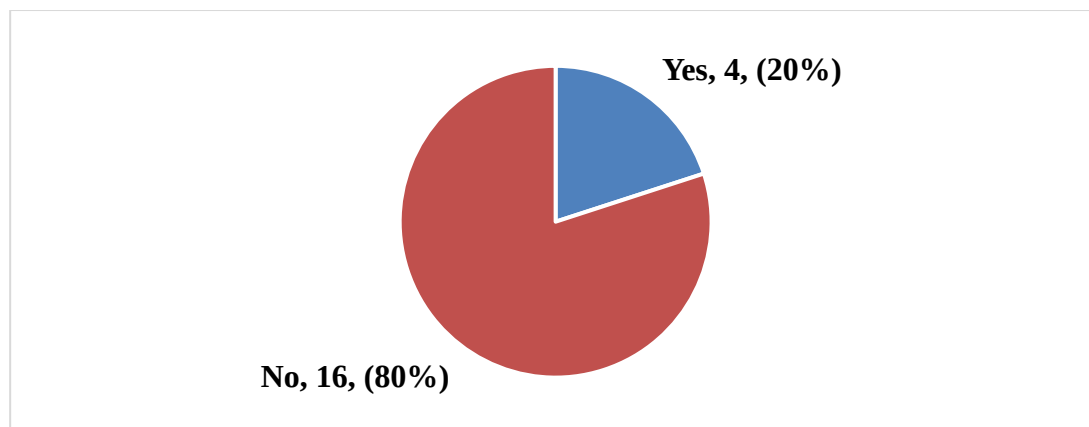


Figure 2. Complications of Medication on stomach.

The comparison of the variables between the two groups regarding the clicking, the patients of the prolotherapy group had better response to treatment than those of the medication group (Figure 3). Regarding the dislocation there is no joint dislocation to compare at the three times periods of follow up, the response happened from the first week after treatment in the two groups. At the end of the study, the mean and mean rank of TMJ pain score and masseter muscle pain score of the medication group were higher than those of the prolotherapy group, but the differences were not significant. The mean mouth opening of the medication group was higher than that of the prolotherapy group and the difference was significant (Table 5). No significant differences were detected between the two groups regarding the improvement of mouth opening after one week, one month and two months (Table 6).

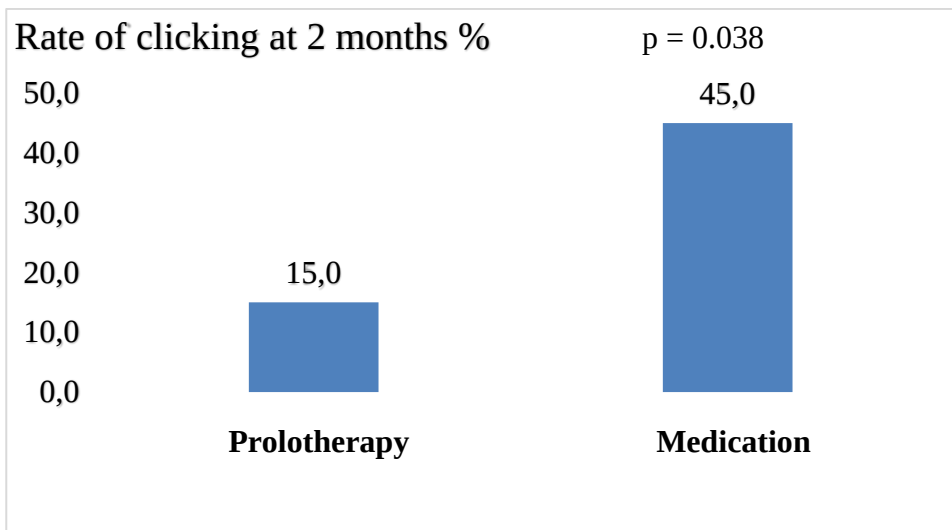


Figure 3. Complications of Medication on stomach.

Table 5
Comparing the outcomes (between the two study groups) at the end of the study

	Prolotherapy			Medication			P*
	Mean	(SD)	Mean Rank	Mean	(SD)	Mean Rank	
Pain TMJ 2 Months	0.50	(0.95)	18.35	1.70	(2.60)	22.65	0.253
Pain Masseter 2 Months	0.95	(2.04)	17.45	2.00	(2.71)	23.55	0.102
Mouth opening (mm) 2 Months	36.50	(4.97)	16.18	40.00	(2.18)	24.83	0.018

*By Mann Whitney test.

Table 6
Means of improvements of mouth openings at different time periods by type of management.

	Prolotherapy			Medication			P*
	Mean	(SD)	Mean Rank	Mean	(SD)	Mean Rank	
Improvement in mouth opening (mm)							
1 W - 0	0.55	(3.28)	20.68	0.55	(2.26)	20.33	0.925
1 M - 0	2.15	(5.20)	20.43	1.15	(2.43)	20.58	0.968
2 M - 0	2.05	(5.96)	20.60	1.10	(2.49)	20.40	0.968

*By Mann Whitney test, W: week, M: month

Discussion

In this study prolotherapy was used as a first line treatment for common temporomandibular disorders, there are several materials that can be used in prolotherapy; however, this study used dextrose solution as it is effective, cheap and safe material. It is important to use dextrose concentration of more than 10%, as a hypertonic material which induces inflammation (Hakala & Ledermann, 2010). Multiple concentrations have been used in different studies, including 12.5, 15 and 25% or even more, the exact concentration is not so critical as they all will produce mild inflammation as long as it is more than 10% (Shehata, 2019). Nevertheless, in this study 12.5% of dextrose has been used.

In the prolotherapy group, the pain of the TMJ decreased gradually from the first week up to the second month and the difference was significant ($p < 0.05$). The mean value of pain score decreased from 3.9 at baseline to 0.5 at two months, these findings agreed with the results of (Zhou, Xue, & Liu, 2021), in their study after two weeks follow up period the pain of the TMJ of 37 patient was recovered, and at six months follow up period 39 patients have no pain. Also agreed with (Ungor et al., 2013) they used arthrocentesis first and then used prolotherapy with dextrose solution, the mean of pain score decreased from 1.9 preoperatively to 0.9 at three months follow up period. (Elwerfelli, Kalil, & Abdullah, 2019) also used arthrocentesis first and then used prolotherapy with dextrose solution, the percentage of reduction in pain score was 93%, their finding obviates the need for arthrocentesis before prolotherapy. These findings also come in agreement with a study performed by (Louw, Reeves, Lam, Cheng, & Rabago, 2019), the difference of VAS for pain after 3 months follow up period was 4.3 points. Findings of this study didn't come in accordance with that of (Hauser, Hauser, & Blakemore, 2007), about 57% of patients got pain relived to about 75% while 93% said that the pain relived to about 50% at the last follow up period. This difference of results may be because of the long follow up period which is 18 months which lead to recurrence of pain.

In the prolotherapy group of the present study, the dextrose injection was given at the origin and insertion of masseter muscle, the mean value of pain decreased from 4.1 at baseline to 1.0 at 2 months follow up period, these findings agreed with (Shehata, 2019) who used dextrose prolotherapy injection into the most tender point at the origin of masseter muscle. His follow up period was 24 months; the mean of pain preoperatively was 1.78 and postoperatively was 0.48. In spite of the longer follow-up period of his study, the comparable results might be explained by the use of a second injection at the insertion of the masseter muscle. The results also agreed with that of (Dasukil, Shetty, Arora, & Degala, 2021), dextrose injection was given the most tender point of masseter muscle, the sessions repeated three times with two weeks intervals, the mean value of pain of masseter muscle preoperatively was 7.04 while postoperatively at 3 months follow up period was 3.16, in spite of the larger number of sessions of dextrose prolotherapy of his study, the

comparable results might be explained by the use of a second injection at the insertion of the masseter muscle.

The mean value of mouth opening of the present study for the prolotherapy group was 34.5 mm preoperatively and become 36.5 mm at 2 months, so the degree of improvement of mouth opening was 2.05 mm after 2 months, these results come in agreement with that of (Younis et al., 2020), the degree of mouth opening was 33.2 mm preoperatively and 33.8 mm at 2 months follow up periods, which mean that the improvement of mouth opening was only 0.6 mm. The results also agreed with that of (Shehata, 2019), the mean of degree of mouth opening preoperatively was 33.7 mm and postoperatively was 36.5 mm, there is barely a significant difference ($p = 0.05$).

The number of patients with clicking in prolotherapy group decreased from 14 to 3 after two months of treatment, this come in consistence with the study of (Elwerfelli et al., 2019), 14% of patients still have clicking after six weeks follow up period. The results disagree with that of (Ungor et al., 2013), the clicking sounds disappeared only in 50% of patients in the last follow up period which is 3 months, the results also disagree with that of (Younis et al., 2020), 20 patients received dextrose injection into the superior joint space, only 3 patients show improvement of clicking. The reason for this difference from their results is because in the present study injection has been given into the area of insertion of lateral pterygoid muscle to the disc (in addition to the other points) this leads to harmonization and returning of the disc to normal position.

In the prolotherapy group the cases of luxation or dislocation decreased to zero from the first week and there is no recurrence during the follow up periods, the results agreed with that of (Kiliç & Güngörmüş, 2016), they use 3 sessions of dextrose injection of 1 month intervals, no recurrence of luxation during the follow up periods was seen. So may be no need to perform more than one session of prolotherapy. The results also agreed with that of (Mustafa, Güngörmüş, & Mollaoglu, 2018) no recurrence of luxations or dislocation was seen. These results come in accordance with a study of (Saadat, Khedr, Saad, & Naguib, 2018), dextrose prolotherapy was used into the superior joint space to treat recurrent dislocation. 75% of patients have no recurrence of the dislocation during the whole follow up period, only 3 patients have other episodes after treatment, this may be due to injecting the dextrose only in one point as compared 4 points in the present study. The most important points to control the dislocation are the superior joint space and the insertion of lateral pterygoid muscle on the condyle.

Conclusion

At the end of the study it is concluded that there is very good effect of dextrose injection on the pain of TMJ, masseter muscle, degree of mouth opening, clicking and hypermobility (subluxation and dislocation). So the dextrose prolotherapy can be used as a first line treatment to treat

common chronic TM disorders as it is easy technique, safe and cheap material with very little complications and did not has any effect on stomach like the medication. In this study an injection on the insertion of masseter muscle has been used and according to the results it is an effective step for the treatment.

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