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A pilot study to evaluate the role of stabilization splint therapy and self-management based instructions in the treatment of Temporomandibular disorders (TMD)

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Abstract

Background: There is conflicting evidence in the literature about the usefulness of a stabilization splint therapy in treating Temporomandibular disorders (TMD) in comparison to alternative treatments.

Aim: To evaluate the effects of stabilization splint therapy and self-management based instructions in the treatment of TMD.

Methodology: A total of 40 patients diagnosed with TMD according to Diagnostic criteria for TMD axis I and fulfilling the inclusion criteria were randomly allocated to two treatment groups using a random numbers table. The main inclusion criteria were the presence of pain or tenderness in Temporomandibular joint (TMJ) and/or muscles of mastication and reduced inter incisal opening of <40mm. First group of patients were treated by stabilization splints which were constructed by adapting polyethylene thermoplastic sheet of 2mm thickness to maxillary casts and occlusal surface of splints modified with auto polymerizing acrylic resin. Second group of patients were treated by pre-determined set of instructions in the self-management. Intensity of pain was measured by Visual analogue scale and maximum mouth opening was measured as inter incisal distance at pre-treatment, at 1 week, at 2 weeks, at 1 month, and 3 months. Intragroup comparison was done using the Wilcoxon signed-rank test and Paired samples t-test. Intergroup comparison was done using Mann-Whitney U test and independent t-test. The significance level was kept at 5%.

Results: The splint group patients reported significant pain reduction at 3 months in comparison to self-management group however there was no significant difference in the improvement of inter incisal opening between the two groups.

Conclusion: Based on the above findings we can conclude that stabilization splints are more effective in reducing pain in patients with temporomandibular

disorders for short-term in comparison to self-management alone.

Keywords: orofacial pain, self-management, stabilization splint, temporomandibular Joint Disorders

Introduction

Temporomandibular disorder(TMD) is a group of conditions that affect masticatory muscles, TMJ, and associated structures.[1] Most common symptoms include pain, limitation, or deviation in mandibular motion, and joint sounds.[1]It is often associated with poor sleep quality and depression.[2] TMD affects up to 15% of adults and 7% of adolescents.[3] Chronic pain is the most common reason for patients with TMD to seek treatment.[3] The etiology of TMD can be multifactorial and due to multiple causes including emotional, psychological, structural, and biomechanical factors.[4]

Management of TMD involves a multidisciplinary approach in which Dentists, physiotherapists, orthodontists, behavior therapists, psychologists work together. Non-invasive methods are preferred because of their reversible nature and low cost.

A Stabilization splint is one of the most widely used appliances in the oral cavity by a general dentist and dental specialists.[5] Many studies in the literature found that stabilization splint therapy improves symptoms of TMD over time.[6,7] However several studies in the literature reported that the effects of stabilization splint are not superior in comparison to other treatment modalities.[8-10] Counselling and self-management form an integral part of any treatment modality for TMD. Self-management may be the only treatment required for persons who are adaptive and self-motivated. Currently, educational and self-management therapies have been used as initial treatment of almost all types of TMD, especially when pain is present.[11] The literature regarding these therapies shows that reducing harmful behaviors, enforcing patient responsibilities, and the balance between physiological, social, and psychological factors are powerful tools for the control and relief of TMD signals and symptoms.[12,13]

This study was undertaken to find the effectiveness of stabilization splint and self-management in the treatment of TMD. The null hypothesis states that there are no significant differences in the effects obtained by stabilization splint and self-management on the intensity of pain and maximum mouth opening in the management of TMD.

Methodology

Study settings

The Sample includes participants who suffered from TMD, diagnosed by Diagnostic criteria for TMD(axis-I) at XXX Dental College & Hospital and XXX Dental College & Hospital of XXX India. Inclusion and exclusion criteria for the study are shown in Table 1.

Sample Size

Group sample sizes of 20 and 20 with total sample N=40 achieved 80% power to detect a difference of 0.13 between the null hypothesis that group A means change from baseline was 0.39 and the alternative hypothesis that the mean change from baseline of group B was 0.26 with group standard deviations of 0.202 and with a significance level (alpha) of 0.05 using a two-sided two-sample t-test.

Sample size= $2 * (Z\alpha/2 + Z1 - \beta) \wedge 2/(m1 - m2/\sigma) \wedge 2$

Where $Z\alpha/2$=1.96

Z1- β =0.84

m1= mean change from baseline of group 1=-0.39

m2= mean change from baseline of group 2 =0.26

σ = standard deviation=0.202

Ethics committee approval

The procedure followed in the study were in accordance with the Helsinki Declaration of 1975, as revised in 2008.

Presentation of research protocol was done in front of the Institutional ethics committee and approval was received.

Study design

A total of 87 patients who attended the OPD of XXX Dental College and Hospital and XXX Dental College and Hospital were diagnosed with TMD by DC/TMD(axis I). 34 patients were excluded from the research based on exclusion criteria. Patients who fulfilled inclusion criteria were invited to take part in the research. 13 patients declined to take part in the study. All the participants of the research signed the informed written consent form.

Randomization

A Statistician had allocated patients(N=40) in two different groups with the use of a random number table, written the allocation sequence on the card and sealed the cards in opaque envelopes, and kept in a locker till the start of treatment for all patients.

Intervention

Before starting the intervention proper history and clinical examination were done and important findings like a type of dysfunction, characteristics of pain like duration, nature, severity, aggravating, and relieving factors were recorded.

Group A(N=20) patients received stabilization splint therapy in which Poly-ethylene sheets of 2 mm thickness were adapted on the maxillary casts of patients after taking alginate impression. This poly-ethylene sheets were modified on the occlusal surface with auto polymerizing acrylic resin to include the uniform contact of opposing teeth during centric closure.(Fig:- 1) Modification is also done to include proper incisal guidance and canine guidance. Verification of splint was done in patients' mouth before final delivery of splint. All the patients were advised to wear the splint at night for a minimum of 12 hours. Patients were recalled for adjustments and follow up after 24 hours, after 1 week, after 2 weeks, after 1 month, and after 3 months.

Group B (N=20) received Instruction for self-management Patients were educated regarding identification, monitoring, and avoidance of any parafunctional behavior that can exacerbate the pain and were made conscious to avoid daytime clenching, clicking, or grinding of teeth. Patients were advised to avoid unilateral chewing, excessive talking, and chewing gum, to take proper rest and sleep, to do deep breathing exercises. Patients had been advised a Pain-free diet for a period of 2 weeks followed by a review to check the tolerance to firmer consistency food. Patients were instructed to apply moist heat to the area of discomfort for 10 minutes each time for 2-4 times/day. Patients were educated regarding the diagnosis and generally favorable prognosis of TMD when appropriate which includes reassurance that TMD is a typically benign condition and self-limiting in the vast majority of cases.[14]

Outcome measurement

The Intensity of pain was measured on a visual analogue scale(VAS) and maximum mouth opening was measured as inter incisal opening (twice and averaged) before the start of treatment, after 1 week, after 2 weeks, after 1 month, and after 3 months.

Statistical analysis

Data for pain on VAS for intragroup comparison was analyzed using the Wilcoxon Signed-rank test and for comparison between groups by Mann Whitney U test.

Data for maximum mouth opening for intragroup comparison was analyzed using paired-sample t-test and for intergroup comparison by independent samples test. Level of Significance was kept at 5%.

Results

Table 2 describes the age and gender-wise distribution of patients in both groups. Table 3 describes subgroups of

TMD according to DC/TMD which shows that the maximum number of patients were of myofascial pain followed by disc displacement with reduction. Table 4 and Table 5 describes pain on VAS and maximum mouth opening at different time interval in comparison to pre-treatment levels for group A and group B. Table 6 and 7 describe intergroup comparison for pain on VAS and maximum mouth opening respectively.

Discussion

The present study aimed to determine and compare the effects of stabilization splint therapy with self-management in the treatment of TMD. Pain decreased and mouth opening increased for both the groups in comparison to pre-treatment, however comparison between the groups revealed that there was a statistically significant reduction in pain for the splint group as compared to the self-management group but there was no statistically significant difference in the improvement of mouth opening between both groups. Hence the null hypothesis is partially rejected.

For the splint group, there was a significant reduction in pain and significant improvement in mouth opening in comparison to pre-treatment. These findings are in accordance with these previous studies.[7,15-17]

For the stabilization splint group, there was a significant reduction in pain in comparison to the self-management group however mouth opening improvement was not significant in comparison to the self-management group these findings are in line with the previous study which reported a significant reduction in pain and no significant improvement in mouth opening with the occlusal appliance in comparison to relaxation and brief information groups.[18] However, these findings are different from some previous studies according to which there are no significant differences between the effects of stabilization splint and other control groups treatments.[8-10,19]

Probable reasons for this type of findings can be variation in sample size, variation in the type of treatment selected for the control group, the different method used for the construction of splint, and the difference in the duration of various studies. So there is a strong need for further research using a larger sample size, longer duration of the study, and standardized method for fabrication of stabilization splint.

For the self-management group, there was a significant reduction in pain in comparison to pre-treatment at all-time intervals but improvement in mouth opening in comparison to pre-treatment was significant only after 1 month and 3 months. These findings are in accordance with the study by Craane B et al according to whom pain decreased and maximum mouth opening increased for counselling group with time.[20]

Intergroup comparison revealed that there was a significant reduction in pain for the splint group in comparison to the counseling group however, there was no significant difference in maximum mouth opening between groups. These findings are not in accordance with these previous studies according to whom there are no significant differences between self-management, education, and other active treatment.[21-23]

Single dentist has provided all the treatment and measured all the outcomes to avoid inter-examiner error. Homogeneity was increased by excluding the diseases and conditions which might have an effect on the outcome of the research. Because of the considerable overlap of symptoms, distinct subgroups were not taken into account during grouping which can be the limitation of the research.

Table1: Inclusion and exclusion criteria of the research

Inclusion Criteria	Exclusion criteria
➢ Pain in Temporomandibular joint, muscles of mastication, or both ➢ Reduced mouth opening including the vertical overlap of < 40mm ➢ Sign and Symptoms present for >4 weeks ➢ Age >20years	➢ Absence of maxillary and/or mandibular central incisors ➢ Presence of Oral submucous fibrosis ➢ Patients under treatment of Analgesics, NSAIDS, Muscle relaxants or Antidepressants ➢ History of fracture or surgery of jaw or TMJ

Table 2: The age and gender wise distribution of patients in group A and B

Groups	Age (in years)	Gender	
		Male n (%)	Female n (%)
Group A (n=20)	40.27. ± 9.65	10 (25)	10 (25)
Group B (n=20)	38.45 ± 8.25	8 (20)	12 (30)
Total (N=40)	39.46 ± 8.95	18 (45)	22 (55)

Table 3 Distribution of patients according to subgroups of TMD

TMD subgroups		Groups		Total N=40 (n %)
		Group A n=20 n (%)	Group B n=20 n (%)	
Local Myalgia		2(5)	1(2.5)	3(7.5)
Myofascial Pain		5(12.5)	5(12.5)	10(25)
Myofascial Pain with referral		2(5)	2(5)	4(10)
Arthralgia		2(5)	3(7.5)	5(12.5)
Headache		0(0)	0(0)	0(0)
Disc displacement with reduction	Right	3(7.5)	2(5)	6(15)
	Left	2(5)	2(5)	
Disk displacement with reduction with intermittent locking	Right	1(2.5)	2(5)	4(10)
	Left	1(2.5)	1(2.5)	
Disk displacement without reduction with limited opening	Right	2 (5)	1(2.5)	4(10)
	Left	1(2.5)	1(2.5)	
Disk displacement without reduction without limited opening		00	00	00
Degenerative joint disease		1(2.5)	1 (2.5)	2(5)
Subluxation		0	2(5)	2(5)

Table 4: Pain on VAS at different time interval in comparison to pre-treatment for Group A and Group B

Time interval	Group	Rank	N	Mean Rank	Sum of Ranks	P Value
After 1 week – Pre-treatment	Group A	Negative Ranks	5	3.00	15.00	0.0384
		Ties	15			
	Group B	Negative Ranks	7	4.00	28.00	0.0114
		Ties	13			
After 2 weeks –Pre-treatment	Group A	Negative Ranks	16	8.50	136.00	0.0004
		Ties	3			
	Group B	Negative Ranks	10	5.50	55.00	0.0030
		Ties	9			
After 1 month – Pre-treatment	Group A	Negative Ranks	18	9.50	171.00	0.0002
		Ties	1			
	Group B	Negative Ranks	14	7.50	105.00	0.0007
		Ties	3			
After 3 months- pre-treatment	Group A	Negative Ranks	19	10.00	190.00	0.0001
		Ties	0			
	Group B	Negative Ranks	15	8.00	120.00	0.0004
		Ties	2			

Wilcoxon signed ranks Test P<0.05 is significant

Table 5 Maximum mouth opening at different time interval in comparison to pre-treatment for Group A and Group B

Group	Time interval	Mean	N	Std. Deviation	Std. Error Mean	Mean difference	P value
Group A	At Pre-treatment	36.35	20	2.461	.550	-.050	0.163
	After 1 week	36.40	20	2.458	.550		
Group B	At Pre-treatment	35.30	20	2.953	.660	-.050	0.163
	After 1 week	35.35	20	3.014	.674		
Group A	At Pre-treatment	36.37	19	2.527	.580	-.237	0.025
	After 2 weeks	36.61	19	2.558	.587		
Group B	At Pre-treatment	35.21	19	3.006	.690	-.053	0.163
	After 2 weeks	35.26	19	3.070	.704		
Group A	At Pre-treatment	36.37	19	2.527	.580	-.684	0.001
	After 1 month	37.05	19	2.374	.545		
Group B	At Pre-treatment	35.12	17	3.155	.765	-.118	0.041
	After 1 month	35.24	17	3.255	.790		
Group A	At Pre-treatment	36.37	19	2.527	.580	-1.368	<0.001

	After 3 months	37.74	19	2.605	.598		
Group B	At Pre-treatment	35.12	17	3.155	.765	-.441	0.005
	After 3 months	35.56	17	3.097	.751		

Paired sample statistics Test where P<0.05 is significant

Table 6: Intergroup comparison of pain on VAS at different time interval for Group A and B

Time Interval	Group	N	Mean Rank	Sum of Rank	P value
At pre-treatment	Group A	20	22.15	443.00	0.3588
	Group B	20	18.85	377.00	
After 1 week	Group A	20	21.80	436.00	0.4659
	Group B	20	19.20	384.00	
After 2 weeks	Group A	19	17.66	335.50	0.2965
	Group B	19	21.34	405.50	
After 1 month	Group A	19	13.39	254.50	0.0017
	Group B	17	24.21	411.50	
After 3 months	Group A	19	13.16	250.00	0.0011
	Group B	17	24.27	416.00	

Mann Whitney U Test where P<0.05 is significant

Table 7: Intergroup comparison of maximum mouth opening at different time Interval for Group A and B

Time Interval	Group	N	Mean	Standard deviation	Standard Error	Mean Difference	P Value
At Pre-treatment	A	20	36.35	2.461	.550	1.050	0.229
	B	20	35.30	2.953	.660		
After 1 Week	A	20	36.40	2.458	.550	1.050	0.235
	B	20	35.35	3.014	.674		
After 2 Weeks	A	19	36.61	2.558	.587	1.342	0.152
	B	19	35.26	3.070	.704		
After 1 Month	A	19	37.05	2.374	.545	1.817	0.062
	B	17	35.24	3.255	.790		
After 3 Months	A	19	36.74	4.347	.997	1.178	0.361
	B	17	35.56	3.097	.751		

Independent samples test where P<0.05 is significant

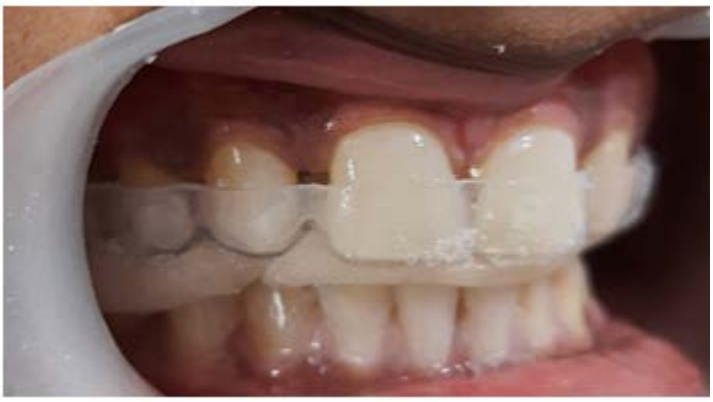

Figure 1: Stabilization Splint in the mouth during centric closure

Conclusion

Within the limitation of the research, we can conclude that stabilization splint therapy is effective in reducing the pain of Temporomandibular disorder in comparison to self-management alone however its effects on mouth opening are similar to self-management based therapy.

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