Comparison Between Betamethasone and Sodium Hyaluronate Combination with Betamethasone Alone After Arthrocentesis in the Treatment of Internal Derangement of TMJ—Using Single Puncture Technique: A Preliminary Study

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Received: 17 February 2014 / Accepted: 5 April 2014 / Published online: 7 May 2014
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Abstract

Purpose This study was designed to compare the intra-articular injection of betamethasone and sodium hyaluronate (combination) with betamethasone alone after arthrocentesis using single puncture technique into the upper joint space in the treatment of temporomandibular joint internal derangements.

Materials and Methods Fourteen patients with internal derangement were randomly selected and divided into 2 groups (7 in each group). Arthrocentesis with single puncture technique of the upper joint space was then performed using ringer lactate under local anesthesia, followed by injection of either betamethasone and sodium hyaluronate combination or betamethasone alone into the joint. Clinical data was collected in the form of pain (visual analog scale), maximum mouth opening, and clicking sound before and after treatment up to 6 months.

Results At the follow up of 6 months, there was statistically significant decrease in intensity of pain and increase in mouth opening was seen in betamethasone and sodium hyaluronate combination group compared to betamethasone alone group. Although there was statistically significant difference between the two groups when clicking was evaluated in the initial time interval (2nd post op day), on follow up of up to 6 months there was no statistically significant difference in clicking.

Conclusion Although patients benefitted from both techniques, arthrocentesis with intra-articular injection of betamethasone and sodium hyaluronate combination is

superior to arthrocentesis with betamethasone injection alone.

Keywords Temporomandibular joint arthrocentesis · Betamethasone and sodium · Hyaluronate · Internal derangement

Introduction

Since the description of arthrocentesis by Nitzan in 1991, the procedure has gained wide acceptance among maxillofacial surgeons in treating internal derangement of temporomandibular joint (TMJ), because it can be done on outpatient basis under local anesthesia and is easy to perform. The procedure increases the hydraulic pressure of upper chamber of the TMJ, which removes adhesions and increases the range of motion [1]. Arthrocentesis is a method of flushing out the TMJ by placing needles into the upper joint compartment using local anesthesia or sedation; it can also be used for diagnostic purposes [2, 3]. Arthrocentesis was considered as an intervening treatment modality between nonsurgical treatment and arthroscopic surgery. The major indications for arthrocentesis are acute and chronic limitation of motion due to disk displacement, adhesions and hypomobility due to restriction of condylar translation in the upper joint space [3].

The traditional procedure uses 2 needles inserted through 2 different puncture sites. One of the needles serves for the inflow of the lavage solution and second for the outflow. The insertion of the second (outflow) needle can sometimes be difficult [2, 4]. In our study we have used a dual needle device with single puncture technique which avoids the need for second puncture and difficulty associated with it. Rahal et al. demonstrated that single puncture

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arthrocentesis using the dual-needle is fast and easy to perform [4].

Intra-articular corticosteroid injection alone or after arthrocentesis provides long-term palliative effects on subjective symptoms and clinical signs of TMJ pain. Unfortunately, intra-articular corticosteroid injection has an unpredictable prognosis and also can cause local side effects on joint tissues [5, 6]. Recently, sodium hyaluronate (SH) has been proposed as an alternative therapeutic agent with similar therapeutic effects. This highly viscous, high-molecular substance plays an important role in joint lubrication and protection of the cartilage [5], which diminishes granulation tissue formation and diminished formation of adhesions. Intra-articular sodium hyaluronate might be the best alternative due to reduced risk for side effects. Several randomized comparisons of either intra-articular hyaluronic acid (sodium hyaluronate) or corticosteroid (betamethasone) TMJ injections have shown no significant difference between the two treatments. Both treatments resulted in sustained, significantly reduced TMJ symptoms and improved joint mobility for 1–2 years [7, 8]. Rovetta and Monteforte have evaluated the efficacy of a combination of SH and triamcinolone acetone injection plus physical exercises in the management of established idiopathic capsulitis of the shoulder [9].

In our previous study we utilized double puncture arthrocentesis technique followed by intra-articular injection of either sodium hyaluronate or betamethasone and found no statistically significant difference among the two groups [10]. In our present study we have evaluated whether the combination of betamethasone and SH after single puncture arthrocentesis could produce clinically better results compared to betamethasone alone in patients with internal derangement of TMJ.

Materials and Methods

A randomized clinical study was conducted on patients visiting the Department of Oral and Maxillofacial Surgery, Government Dental College and Research Institute, Bangalore. Fourteen patients, with unilateral internal derangement of TMJ, 7 females and 7 males aged 22–49 years, were selected for this study. Patients with TMJ internal derangement were included in the study, this was diagnosed on the basis of pain around TMJ, limited mouth opening, clicking sounds and deviation of the mandible on opening. Exclusion criteria included patients with previous TMJ surgery, TMJ arthritis and bony changes over glenoid fossa, articular eminence and condyle. Medically compromised patients were also excluded. Orthopantomogram and transpharyngeal imaging of TMJ were used to help diagnosis.

Patients were randomly divided into 2 groups after performing single puncture arthrocentesis. First group included patients who were administered 0.5 ml of betamethasone and 0.5 ml of sodium hyaluronate (combination) intra-articularly, and the second group included patients who were intra-articularly injected 1 ml of betamethasone only. Both groups contained patients either with disc displacement with reduction or with closed lock. Patients were informed about the procedure, its possible complications, and about the materials used. Patient consent was obtained before the procedure. Injection site was prepared with antiseptic solutions and was isolated with sterile drapes. Local anesthesia was injected in and around the joint. The dual needle was prepared by soldering two 20 gauge 38 mm long needles and bent towards the bevel (Fig. 1) The technique of dual needle arthrocentesis (single puncture technique) is similar to double needle technique except that the second needle insertion is not required [4]. Dual needle insertion is made 1 cm anterior to the midpoint of tragus along cantho-tragal line and 2 mm inferior to the line [11]. After the puncture, the dual-needle device is directed anteriorly and superiorly until contact is made with the zygomatic arch. Keeping close contact with the bone in this area, needle is inserted into the joint space, which is further aided by the patient moving the jaw to open position and to opposite side. About 100–200 mL ringer lactate solution is injected into the joint space from one needle which comes out from the other needle on its own. During this procedure the needle was manipulated in order to optimize the flow. Patient was also asked to move the jaw during the procedure. At the end of the procedure, either combination of 0.5 ml of betamethasone and 0.5 ml of sodium hyaluronate or 1 ml of betamethasone alone was injected into one needle after occluding the outer end of the other needle. Once the dual needle device was removed, the patient's lower jaw was gently manipulated in vertical, protrusive and lateral excursions to facilitate lyses of adhesions. The procedure usually lasted for around 30 min following which the patient was advised soft diet, NSAIDs and muscle relaxants for 7–10 days and continuous physiotherapy for 1–2 months (Fig. 2).

Clinical evaluation of the patients was done before the procedure, immediately after the procedure, on postoperative day 2, and at 1, 2 weeks, 1, 2 and 6 months postoperatively.

Fig. 1 Dual-needle device

Fig. 2 Holmlund line and reference points

Fig. 3 Dual needle device in the joint cavity

Maximal mouth opening was measured and recorded at each appointment. The maximum mouth opening was measured as the distance in millimeters between the incisal edges of the central incisors. Pain was assessed using visual analog scale (VAS) 0–10, 0 reading of VAS was taken as absence of pain and 10 as the maximum pain. Clicking (opening click and closing click sounds) in internal derangement of TMJ was decided on the basis of the proportion of improvement at the end of the treatment by noting either their presence or absence (Fig. 3).

Results

All results were calculated using the mean value and standard deviation for each of the parameters considered and checked for statistical significance using both t test and Chi square test. Among the study population, combination drug group patients were with age ranges from 22 to 35 years with mean age being 29.71 years and

Table 1 Demographic data of the study samples in both the groups

Group	Age Mean $\pm$ SD	Gender	
		Male	Female
Betamethasone	31.14 $\pm$ 8.971	4	3
Betamethasone and sodium hyaluronate	29.71 $\pm$ 4.751	4	3

betamethasone group patients were with age ranges from 22 to 49 years with mean age being 31.14 years (Table 1).

In the study of pain in betamethasone alone group (Table 2), the reduction in pain from 2nd day to 1 week and 2 weeks to 1 month was found to be statistically significant. In the study of pain in corticosteroid and sodium hyaluronate combination group (Table 3), the reduction in pain from 2nd day to 1 week, 1 to 2 weeks, 2 weeks to 1 month was statistically significant. In the study of comparison between the two groups it was found that (Table 4) from pre-op day to 6 months follow-up, there was statistically significant reduction in pain in the combination group compared to betamethasone alone group (Fig. 4).

In the study of mouth opening in betamethasone alone group (Table 2) it was found that the increase in mouth opening, from 2nd day to 1 week and 1 to 2 weeks, was statistically significant. In the study of mouth opening in corticosteroid and sodium hyaluronate combination group (Table 3) it was found that the increase in mouth opening, from 2nd day to 1 week and 1 to 2 weeks, was statistically significant. In the comparison between two groups (Table 4) it was found that higher mean mouth opening was recorded in combination group compared to the betamethasone alone group at all time intervals. The difference in the mouth opening between the two groups from 2 to 6 months time interval was statistically significant ($P < .05$) (Fig. 5).

The effect of the treatment for clicking was decided on the basis of the proportion of improvement at the end of the treatment by noting either their presence or absence. On comparing both the groups, at 2nd day, in combination group significant reduction in clicking was recorded compared to betamethasone alone group. On follow up of up to 6 months there was no statistically significant difference in reduction of clicking on comparing both the groups (Table 5).

Discussion

Arthrocentesis is becoming mainstay in the treatment of internal derangements of the TMJ as the procedure can be performed on outpatient basis under local anesthesia, and

Table 2 Evaluation of pain and mouth opening in betamethasone alone group at different time intervals

Time interval	Pain			Mouth opening		
	Mean $\pm$ SD	T value	P value	Mean $\pm$ SD	T value	P value
Pre2op	4.43 $\pm$.534	2.121	.078	35.43 $\pm$ 6.503	-.660	.534
2nd day	4.00 $\pm$.577			36.29 $\pm$ 3.904		
2nd day	4.00 $\pm$.577	4.382	.005*	36.29 $\pm$ 3.904	-3.873	.008*
1 week	2.86 $\pm$.690			38.43 $\pm$ 3.359		
1 week	2.86 $\pm$.690	1.000	.356	38.43 $\pm$ 3.359	-3.618	.011*
2 week	2.57 $\pm$.535			40.14 $\pm$ 2.734		
2 week	2.57 $\pm$.535	6.000	.001*	40.14 $\pm$ 2.734	-1.528	.177
1 month	1.71 $\pm$.488			41.14 $\pm$ 2.545		
1 month	1.71 $\pm$.488	1.000	.356	41.14 $\pm$ 2.545	-.548	.604
2 month	1.57 $\pm$.535			41.43 $\pm$ 1.902		
2 month	1.57 $\pm$.535	1.000	.356	41.43 $\pm$ 1.902	1.000	.356
6 month	1.43 $\pm$.787			41.14 $\pm$ 1.902		

* indicates the statistically significant values

Table 3 Evaluation of pain and mouth opening in betamethasone and sodium hyaluronate combination group at different time intervals

Time interval	Pain			Mouth opening		
	Mean $\pm$ SD	T value	P value	Mean $\pm$ SD	T value	P value
Pre2op	3.29 $\pm$ 1.113	1.922	.103	37.86 $\pm$ 3.934	-.603	.569
2nd day	2.71 $\pm$.951			38.43 $\pm$ 3.552		
2nd day	2.71 $\pm$.951	3.240	.018*	38.43 $\pm$ 3.552	-2.610	.040*
1 week	1.71 $\pm$.756			41.14 $\pm$ 2.545		
1 week	1.71 $\pm$.756	2.828	.030*	41.14 $\pm$ 2.545	-5.461	.002*
2 week	1.14 $\pm$.690			43.00 $\pm$ 2.380		
2 week	1.14 $\pm$.690	4.583	.004*	43.00 $\pm$ 2.380	-1.549	.172
1 month	.14 $\pm$.378			43.57 $\pm$ 1.618		
1 month	.14 $\pm$.378	1.000	.356	43.57 $\pm$ 1.618	-1.922	.103
2 month	.00 $\pm$.000			44.71 $\pm$.951		
2 month	.00 $\pm$.000	-	-	44.71 $\pm$ 951	-1.000	.356
6 month	.00 $\pm$.000			44.86 $\pm$.900		

* indicates the statistically significant values

does not require elaborate and expensive equipment. Elsewhere its benefits have been described [1, 2, and 3]. Several surgeons have proposed the use of single puncture technique and claim good results and also several drugs have been used after arthrocentesis to further aid in controlling the symptoms of the TMJ including steroids, morphine, fentanyl, sodium hyaluronate etc [7, 8, 12]. Intra-articular corticosteroid injections have potent anti-inflammatory effect on synovial tissue and are known to reduce effusion, decrease pain and bring about an increase in range of motion of synovial joints. But these drugs have some side effects on joint tissues, such as progression of an existing joint disease and condylar resorption [6–8]. Sodium hyaluronate which is a highly viscous, high-molecular substance plays an important role in joint lubrication and protection of the cartilage [5].

Rovetta and Monteforte [9] have evaluated the efficacy of a combination of SH and triamcinolone acetonide

injection plus physical exercises in the management of established idiopathic capsulitis of the shoulder and found improvement of pain and joint motion after 6 months in all patients, especially in the patients treated with sodium hyaluronate and steroid group, as against the group which received steroid alone. No such study using combination of these drugs has been carried out in TMJ patients. However in a previous study by Giraddi et al. though there was no statistical significant difference between the betamethasone and SH after arthrocentesis, patients who received betamethasone had better relief of the symptoms in the initial period of 2nd post op day to 2 weeks while patients who received SH had better pain relief at later stages at 1–6 months follow up period [10]. We wanted to evaluate whether the combination of betamethasone and SH after single puncture arthrocentesis could produce clinically better results both initially and during later periods.

Table 4 Comparison of pain and mouth opening between the two groups at different time intervals

Time interval	Group	Pain			Mouth opening		
		Mean difference	T value	P Value	Mean difference	T value	P value
Pre Op	Betamethasone	1.143	2.449	.031*	−2.429	−.845	.414
	Betamethasone and sodium hyaluronate						
2nd day	Betamethasone	1.286	3.057	.012*	−2.143	−1.074	.304
	Betamethasone and sodium hyaluronate						
1 Week	Betamethasone	1.143	2.954	.012*	−2.714	−1.704	.114
	Betamethasone and sodium hyaluronate						
2 Weeks	Betamethasone	1.429	4.330	.001*	−2.857	−2.085	.059
	Betamethasone and sodium hyaluronate						
1 Month	Betamethasone	1.571	6.736	.00*	−2.429	−2.131	.55
	Betamethasone and sodium hyaluronate						
2 Months	Betamethasone	1.571	7.778	.000*	−3.286	−4.087	.002*
	Betamethasone and sodium hyaluronate						
6 Months	Betamethasone	1.429	4.804	.000*	−3.714	−4.572	.001*
	Betamethasone and sodium hyaluronate						

* indicates the statistically significant values

Fig. 4 Dual-needle device in place

In our prospective study on 14 patients with TMJ internal derangement, arthrocentesis was performed using single puncture technique and either betamethasone alone or combination of betamethasone and sodium hyaluronate was injected at the end of the arthrocentesis. This technique avoids the need for second puncture and difficulty associated with it. Advantages of this technique include less time consumption, more patient tolerance and also only single puncture is required which prevents the leakage and reduction in hydraulic pressure during procedure [4]. As leakage is less, post-operative drugs injected will remain in the joint space only and effect of drug will be more compared to classic arthrocentesis (double puncture arthrocentesis). There was statistically significant decrease in intensity of pain in betamethasone and sodium

Fig. 5 Injecting the drug from one end while irrigation fluid can be seen flowing out occluding the other end of dual needle

hyaluronate combination group compared to betamethasone alone group. Mouth opening improved and was statistically significant at 2 and 6 months follow up in the combination drug group compared to betamethasone alone group. Although there was statistically significant difference between the two groups when clicking was evaluated in the initial time interval (2nd post op day), on follow up of up to 6 months there was no statistically significant difference.

We have compared this present study with our previous study, [10] (Table 6) from which we conclude that out of the four groups in these studies, there was highest percentage of reduction of pain in the combination group of betamethasone and sodium hyaluronate after single puncture arthrocentesis (100 %), which was followed by the sodium hyaluronate alone group with double puncture arthrocentesis (85.18 %), the

Table 5 Presence of clicking in the groups at different time intervals

Time interval	Group	Present		Absent		Total	χ^2	P-Value
		N	%	n	%			
Pre Op	Betamethasone	5	71.4	2	28.6	7	4.571	.033*
	Betamethasone and sodium hyaluronate	6	85.7	1	14.3	7		
2nd Day	Betamethasone	5	71.4	2	28.6	7	4.571	.033*
	Betamethasone and sodium hyaluronate	6	85.7	1	14.3	7		
1 Week	Betamethasone	4	57.1	3	42.9	7	.286	.593
	Betamethasone and sodium hyaluronate	4	57.1	3	42.9	7		
2 Weeks	Betamethasone	4	57.1	3	42.9	7	1.143	.285
	Betamethasone and sodium hyaluronate	1	14.3	6	85.7	7		
1 Month	Betamethasone	4	57.1	3	42.9	7	1.143	.285
	Betamethasone and sodium hyaluronate	1	14.3	6	85.7	7		
2 Months	Betamethasone	4	57.1	3	42.9	7	1.143	.285
	Betamethasone and sodium hyaluronate	1	14.3	6	85.7	7		
6 Months	Betamethasone	4	57.1	3	42.9	7	.286	.593
	Betamethasone and sodium hyaluronate	2	28.6	5	71.4	7		

* indicates the statistically significant values

Table 6 Comparison of results of our present study of single puncture arthrocentesis followed by either betamethasone and sodium hyaluronate combination group or betamethasone alone group with our previous study [10] of double puncture arthrocentesis followed by either sodium hyaluronate alone group or betamethasone alone group

	Time interval	Mean pain	Average reduction in pain	Reduction of pain in percentage (%)	Mean mouth opening (mm)	Increase in mouth opening (mm)	Mean clicking (%)	Reduction of clicking in percentage (%)
<i>Double puncture arthrocentesis</i>								
Betamethasone alone group	Pre-op	6.13	5.00	81.56	35.25	6.25	88	75
	At 6 month	1.13			41.50		13	
Hyaluronate alone group	Pre-op	6.75	5.75	85.18	37.25	6.50	88	75
	At 6 month	1.25			43.75		13	
<i>Single puncture arthrocentesis</i>								
Betamethasone alone group	Pre-op	4.43	3.00	67.72	35.43	5.71	71.4	14.3
	At 6 month	1.43			41.14		57.1	
Betamethasone and sodium hyaluronate combination group	Pre-op	3.29	3.29	100	37.86	7.00	85.7	57.1
	At 6 month	00			44.86		28.6	

betamethasone alone group with double puncture arthrocentesis (81.56 %) and the lowest percentage of reduction of pain was in the betamethasone alone group with single puncture arthrocentesis (67.72 %). Similarly on comparing the mouth opening, there was highest increase in the average mouth opening in the betamethasone and sodium hyaluronate combination group with single puncture arthrocentesis (7 mm), followed by sodium hyaluronate alone group with double puncture arthrocentesis (6.5 mm), and betamethasone alone group with double puncture arthrocentesis (6.25 mm) and the

lowest was in the betamethasone alone group after single puncture arthrocentesis (5.71 mm). Reduction in clicking (opening and closing clicking sounds) was observed in all the four groups of our studies.

Conclusion

It is concluded that combination (corticosteroid and sodium hyaluronate) has a faster and longer effect on pain relief,

mouth opening and clicking. Our results are encouraging and have been promising, showing a significant improvement in TMJ symptoms after single puncture arthrocentesis followed by betamethasone and sodium hyaluronate combination injection into the joint. Arthrocentesis with corticosteroid and sodium hyaluronate injection combination is superior to the arthrocentesis with corticosteroid alone. Further studies with a larger sample size and a longer follow up period are required to determine the efficacy of betamethasone and sodium hyaluronate combination after single puncture arthrocentesis in the treatment of internal derangement of TMJ.

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