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ABSTRACT

This study evaluated the one-year effect of physical therapy on pain and mandibular dysfunction associated with anterior disc displacement without reduction of the temporomandibular joint (closed lock). Forty-nine individuals were randomly assigned to either a physical therapy group [$n = 23$, mean age (SD) 34.7 (14.0) yrs] or a control group [$n = 26$, mean age 38.5 (15.1) yrs]. At baseline and after 3, 6, 12, 26, and 52 wks, pain and mandibular function were evaluated. All patients received extensive information about avoiding parafunctions and oral habits on all evaluation days. The physical therapy group received, in a 6-week period, 9 sessions of physical therapy, including joint mobilization, exercises, and massage, and the information on avoiding parafunctions and oral habits was repeated each time. All pain variables decreased, and all function variables increased significantly over time for both groups. The interaction between time and treatment group was not significant. Hence, physical therapy had no significant additional effect in patients with anterior disc displacement, without reduction, of the temporomandibular joint (ClinicalTrials.gov number, CT01475630).

KEY WORDS: clinical trials/studies, comparative effectiveness research (CER), evidence-based dentistry/health care, temporomandibular disorders, rehabilitation medicine, joint disease.

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Randomized Controlled Trial on Physical Therapy for TMJ Closed Lock

INTRODUCTION

Temporomandibular disorders (TMD) may affect the temporomandibular joint (TMJ), the masticatory muscles, and associated structures (McNeill, 1993). The Research Diagnostic Criteria for TMD (RDC-TMD) (Dworkin and LeResche, 1992; Ohrbach *et al.*, 2010) classify TMDs by a dual-axis system. Axis I distinguishes between (I) patients with masticatory muscle pain with/without limitation of mouth opening, (II) patients with internal derangement of the TMJ, and (III) patients with arthralgia, osteoarthritis, and osteoarthritis. Axis II assesses TMD-related pain and parafunctional behaviors, psychological distress, and psychosocial dysfunction.

As a consequence of the multifactorial etiology of TMD (Oral *et al.*, 2009), the therapeutic approach must be interdisciplinary. In the literature, a multitude of treatment modalities has been applied. A recent Cochrane review concluded that evidence for the effect of physical therapy (PT) in TMD patients was scarce and equivocal (Craane *et al.*, 2006). The methodological quality of the included studies was low. Consequently, the aim of the present study was to investigate the effect of PT on pain and mandibular function in patients with anterior disc displacement without reduction (ADD-R) of the TMJ in a randomized controlled trial.

MATERIALS & METHODS

This randomized controlled trial was conducted at the University of Leuven, Belgium, from June 2003 to November 2009. The study was approved by the Medical Ethical Committee of the University Hospital (No.: ML2210). All patients were recruited from the Oral Pain and Dysfunction Clinic and strictly satisfied the RDC-TMD criteria for disc displacement without reduction, with (group IIb) or without (group IIc) limitation of mouth opening, based upon history and clinical examination. Additionally, pain experienced during the first examination had to be ≥ 35 mm on a visual analog scale (VAS) of 100 mm. Patients were excluded if their medical history mentioned orofacial trauma, systemic disorders, cervical disorders (operationalized as complaints, pain, or referral patterns of pain provoked during movements of the cervical spine), neurologic disorders, drug or alcohol abuse, and use of antidepressants or hormonal medication. Participants had not received therapy for symptoms of TMD within the preceding 2 mos. All participants were informed about the study orally and in writing. Participants also needed to agree to visit a physical therapist involved in the study, in case they were randomized into the PT

group. The sample size was calculated based on the study by Dao *et al.* (1991), where pain intensity was scored on a VAS. With α set at 0.05 and β at 0.2, a minimum number of 21 patients *per* group would be needed to test a significant difference between the treatment and control groups regarding a clinically relevant pain reduction of 45 to 60% from baseline to 6 wks (end of the treatment period) (Farrar *et al.*, 2000; Rowbotham, 2001). With potential dropouts taken into account, the total study sample was set at 50 patients.

An electronic randomization plan generator using the method of randomly permuted blocks with two possible groups generated the allocation sequence (www.randomization.com). The randomization list was kept in an envelope. One examiner (ADL) conducted the enrollment procedure. If patients satisfying the inclusion criteria were willing to participate in the study, a consent form was signed. Then, the patients were informed and instructed, as described under 'treatment'. Only thereafter was the allocation list consulted and the patient assigned to the PT group or the control group.

Afterward, examiner BC, blinded to treatment assignment, performed all evaluations at baseline and at 3, 6, 12, 26, and 52 wks (T0 to T5). Patients were instructed not to discuss treatment allocation with the examiner.

At all evaluation days, all patients were extensively informed about normal jaw function and that overuse, misuse, or para-function could enhance or provoke their complaints. They received instructions to keep the jaw muscles relaxed, and to avoid non-functional tooth contacts and excessive mouth opening. The instructions were given orally by one investigator (ADL) in a standard way. In addition, all the patients received a brochure to reinforce and re-study these instructions at home.

Patients assigned to the PT group had 9 PT sessions over a 6-week period (twice weekly for 3 wks and once weekly for the last 3 wks) with one of four physical therapists who had special training in the management of TMD, and working in different regions of the country. The applied treatment was standardized according to a detailed manual (see Appendix). At all evaluations, patients were seated in a conventional dental chair and first completed the McGill Pain Questionnaire (MPQ) (Dutch Language Version, Vanderiet *et al.*, 1987), also featuring a 100-mm VAS (Van der Kloot *et al.* 1989) with the ends defined as 'no pain' and 'worst pain imaginable', to score current pain intensity. The average pain intensity level was obtained from the intensity ratings for each adjective in the MPQ and expressed in the 'total pain rating index' (PRI_{total}). The 'total number of words chosen' (NWC_{total}) resulted from summing the total number of chosen adjectives in the MPQ. The Mandibular Function Impairment Questionnaire (MFIQ) (Stegenga *et al.*, 1993) assesses the TMD-related impairment of 17 daily activities and functions of the masticatory system using a 5-point Likert scale (0 = not at all, 4 = very much). Maximal active mouth opening (MMO_{active}) was measured by means of a plastic ruler, as the interincisal distance (mm) adjusted to the vertical overlap of the upper and lower incisor teeth. Maximal passive mouth opening (MMO_{passive}) was obtained when, upon active maximal opening, the investigator gently increased the interincisal distance by pushing on the upper and lower teeth with thumb and index finger.

MMO_{active} was measured as the last of 3 maximal opening and closing movements. MMO_{passive} was measured immediately after the active opening measurement.

Then, the patient was put into a supine position to record the pressure pain threshold (PPT) by means of a Somedic algometer Type II (Somedic production AB, Solentuna, Sweden). The tip size of the algometer was 1 cm². For all PPT measurements, the pressure increase was standardized at 40 kPa/s. PPTs were taken bilaterally. Registration points were determined as the most bulky part of the superficial masseter (PPT_{mass}) and temporalis (PPT_{temp}) muscles while patients were clenching their teeth (Isselée *et al.*, 1997). Before the measurement began, the procedure was explained in detail to the patients. With an interval of a few seconds between the sites, the measurements were taken in the following sequence: right masseter, right temporalis, left masseter, and left temporalis. After a rest period of approximately 1 min, the entire procedure was repeated. The PPT was defined as "the point at which a sensation of pressure becomes painful". The mean of the 2 PPT measurements of the affected side was calculated and used for further analysis. To ensure that patients would not confuse the PPT with the pain tolerance, the measurement procedure and the definition of PPT were repeated at the beginning of each evaluation. To reproduce the measuring sites for the PPTs during the different evaluations, we marked the sites on the skin during the first session (T0). These spots were then copied onto a deformable plastic template, together with some facial reference points (vertical nose line, eyebrows, eye, and corner of the mouth). Prior to the present study, the examiner familiarized and practiced the PPT measurements in a non-patient population until a high reproducibility of the PPT measurements was obtained. PPT values of the affected side were compared between groups.

Statistics

A linear mixed-model analysis was performed (MLwin 2.22) (Twisk, 2003). The effect of time on outcome variables was checked for linearity by means of plots. On the basis of plots, the outcomes were assumed to change linearly with time, and time was entered as an interval variable. In the analysis, the predictor's time, therapy, RDC IIB, RDC IIC, time-therapy interactions, and RDC group – time interaction were entered stepwise as fixed effects. Predictors remained in the regression equation analysis if the model fit increased significantly or if β were significant (Wald test). Thereafter, random effects were explored for intercept (patients) and slope (time and patients) for all predictors. If random effects did not change the model fit significantly, a fixed effect was assumed. The residuals followed a normal distribution, so we used mixed linear models with normal errors. The results were analyzed according to the intention-to-treat principle.

RESULTS

From 6,883 patients seeking treatment for orofacial pain over a 6-year period, several hundred presented with closed lock of the TMJ, but in the given time period, only 49 patients met all inclusion

Figure. Flow diagram of patient recruitment and dropouts during the study: T0 - T5.

criteria and were willing to participate in the study. In the therapy group [$n = 23$, mean age (SD) 34.7 (14.0) yrs], 12 patients had a RDC IIb diagnosis and 11 patients RDC IIc; nine patients had a closed lock on the left and 14 on the right TMJ. In the control group [$n = 26$, mean age 38.5 (15.1) yrs], 13 patients were IIb and 13 patients were IIc; 10 of them had a left-sided and 16 a right-sided

closed lock. The average time between symptom onset and start of treatment varied between several wks to several yrs. In the PT group, one patient missed evaluations T3, T4, and T5 because of illness, one patient was excluded after T3 because of arthrocentesis treatment, and one missed T4 and T5 because of moving to a foreign country. In the control group, two patients decided not to participate in the study after T1, and two patients decided to end their participation after T3 for time-related reasons (Fig.). All available data of the 49 patients were used for a multi-level analysis. Comparison of the two groups at baseline showed no significant differences (Table 1). Scores of the outcome variables at different evaluation times are summarized in Table 2. The results of the linear mixed-model analyses are summarized in Table 3. Therapy and time-therapy interactions did not contribute significantly to the model fit, and the regression coefficients (β) were not significant. For all outcomes, the interaction of time and treatment group had a $p > 0.144$. For all outcome variables, there was a significant improvement over time, independent of the therapy given. Differences between RDC-TMD groups IIb and IIc were significant for MMObactive, MMOpasive, and PPTmasseter.

DISCUSSION

The present study illustrated that an additional PT program did not increase the effects of information and instructions. To improve the methodological quality, the current research trial focused on a specific subgroup of TMDs in an RCT design. We used very strict inclusion and exclusion criteria to optimize homogeneity of the

groups. Additionally, to allow for assessment of clinically relevant improvement, one of the inclusion criteria was a minimum pain score of 35 mm on a VAS scale. To optimize the standardization of the therapy, only four physical therapists were selected, and potential participants often refrained from entering the study because of travel distances. As a result, it took 6 yrs to recruit 49

Table 1. Comparison of the Two Groups at Baseline

Variable	Physical Therapy (n = 23)	Control (n = 26)	Difference (95%CI)	p value
Age, yrs, mean (SD)	34.7 (14.0)	38.5 (15.1)	-3.8 (-12.2 to 4.6)	NS ¹
Gender, male/female	0/23	2/26		NS ²
IIb/IIc	12/11	13/13		NS ²
VAS med (25 th -75 th perc)	50 (38.0; 60.0)	54.5 (39.5; 65.0)		NS ³
MMOa [mean (SD)]	35.8 (7.4)	36.2 (7.1)	-0.4 (-4.4 to 3.8)	NS ¹
MMOp [mean (SD)]	38.3 (7.1)	39.3 (7.0)	-1.0 (-5.0 to 3.1)	NS ¹
PPTm affected side	176.1 (48.5)	165.3 (57.4)	10.8 (-20.0 to 41.5)	NS ¹
PPTt affected side	268.0 (91.6)	253.5 (93.0)	14.5 (-38.7 to 67.6)	NS ¹
PRIt (med 25 th -75 th perc)	15 (7; 19)	14 (11.8; 20.3)		NS ³
NWCt [mean (SD)]	8.9 (3.7)	8.5 (3.2)	0.5 (-1.5 to 2.4)	NS ¹
MFIQ [mean (SD)]	31.0 (8.9)	31.6 (8.5)	-0.6 (-5.6 to 4.4)	NS ¹

Baseline demographics: SD (standard deviation), CI (confidence interval), IIb/IIc [subgroup regarding RD/TMD (research diagnostic criteria/temporomandibular disorders)], VAS (visual analog scale - 0 to 100 in mm), PPTm (pain pressure threshold, masseter muscle in kPa), PPTt (pain pressure threshold, temporalis muscle in kPa), med (median; 25th and 75th percentiles), PRIt (total pain rating index - maximal score = 63; higher score is more pain), NWCt (total number of words chosen - maximal score = 20; higher score is more pain), MMOa (maximal active mouth opening in mm), MMOp (maximal passive mouth opening in mm), MFIQ (mandibular function impairment questionnaire - maximal score 68; higher score is more impairment), NS (p values > 0.05), ¹(Independent *t* test), ²(Fisher exact), ³(Mann-Whitney U-test).

Table 2. Scores of the Outcome Variables at Different Evaluation Times

		Baseline (T0)	3 Wks (T1)	6 Wks (T2)	12 Wks (T3)	26 Wks (T4)	52 Wks (T5)	T0 - T5
		nt = 23; nc = 26	nt = 23; nc = 26	nt = 23; nc = 24	nt = 21; nc = 24	nt = 20; nc = 22	nt = 20; nc = 22	nt = 20; nc = 22
		mean (SD)	mean (SD)	mean (SD)	mean (SD)	mean (SD)	mean (SD)	mean (SD)
MMOa	PT	35.8 (7.4)	35.4 (6.3)	37.4 (5.6)	39.4 (6.3)	41.3 (6)	42.7 (5.7)	7.8 (6.2)
	control	36.2 (7.1)	38 (6.8)	39.6 (6.8)	42.5 (6.9)	45.4 (6.5)	46.5 (7.1)	10.1 (8.2)
MMOp	PT	38.3 (7.1)	38.6 (6.3)	40.2 (5.5)	42 (6.4)	44 (6.2)	45.4 (5.6)	7.9 (6.3)
	control	39.3 (7.0)	40.8 (6.3)	42.4 (6.7)	45.2 (6.6)	47.9 (6.4)	49 (7)	9.4 (8.3)
PPTm	PT	176.1 (48.5)	170.8 (46.4)	185.3 (40.2)	197.6 (43.7)	202 (55.1)	202.8 (49.8)	33.7 (50.6)
	control	165.4 (57.4)	172.8 (60.7)	169 (56.9)	191.1 (69.9)	201.3 (82)	207.4 (74)	55.8 (69)
PPTt	PT	268.0 (91.6)	269.9 (85.8)	276 (70.4)	294.3 (63)	317.6 (83.7)	320.8 (89.1)	60.5 (92.3)
	control	253.5 (93)	248.3 (98.9)	267.8 (88.6)	289.3 (100.5)	296.8 (124.1)	326.1 (136.8)	92.7 (119)
MFIQ	PT	31.0 (8.9)	30 (9.6)	25.2 (8.3)	22.6 (12.3)	18.5 (10.9)	12.9 (12.6)	18.5 (13.1)
	control	31.6 (8.5)	29.9 (8.6)	25 (10)	18.4 (11.1)	13.3 (8.9)	12.5 (9)	19.1 (12.9)
NWCtotal	PT	8.9 (3.7)	8.9 (3.7)	7.8 (3.9)	7.4 (4.7)	6.8 (4.7)	3.7 (4.6)	5.6 (6.1)
	control	8.5 (3.2)	8.3 (3.8)	7.9 (3.7)	5.6 (3.2)	4 (3.4)	4.1 (3.9)	4.1 (3.9)
		Median (25th-75th perc)	Median (25th-75th perc)	Median (25th-75th perc)	Median (25th-75th perc)	Median (25th-75th perc)	Median (25th-75th perc)	Median (25th-75th perc)
VAS	PT	50.0 (38 - 60)	36 (30 - 51)	24 (12.5 - 39)	23 (6.5 - 33.5)	17.5 (0.5 - 30)	2 (0 - 16)	39.5 (33 - 56.3)
	control	54.5 (40 - 65)	41 (20 - 56)	30 (11 - 43)	18.5 (1 - 30)	6 (0 - 20)	2.5 (0 - 13)	46.5 (38.2 - 59.3)
PRItotal	PT	15 (7 - 19)	13.5 (8 - 20)	11 (7 - 15.5)	9 (7.5 - 15)	7.5 (4 - 11)	3.5 (0 - 7)	11.5 (3.8 - 15)
	control	14 (11 - 20)	11.5 (8 - 17)	9.5 (7 - 14)	8 (4 - 9)	4 (1 - 7)	3.5 (1 - 9)	9.5 (6 - 13.5)

Score of the outcome variables at T0 (baseline), T1 (3 wks), T2 (6 wks), T3 (12 wks), T4 (26 wks), and T5 (52 wks); PT (physical therapy); MMOa (maximal active mouth opening); MMOp (maximal passive mouth opening); PPTm (pain pressure threshold, masseter muscle); PPTt (pain pressure threshold, temporalis muscle); MFIQ (mandibular function impairment questionnaire); NWCtotal (total number of words chosen); VAS (visual analog scale); PRItotal (total pain rating index); SD (standard deviation); nt (number of patients in PT group); nc (number of patients in control group); perc (percentiles).

Table 3. Summary of the Results of Linear Mixed-model Analyses

Outcome Variable	Constant β (SE)	Time in Wks β (SE)	Physical Therapy β (SE) #	RDC IIc β (SE)	RDC IIc* Wks β (SE)
VAS pain	36.2 (2.2) _p	-0.6 (0.04) _t	1.1 (2.8)	NS	NS
Mouth opening active (RDC IIb control group)	33.4 (0.8) _p	0.2 (0.02) _p	-1.5 (0.9)	9.8 (0.9) _f	-0.09 (0.03) _f
Mouth opening passive (RDC IIb control group)	36.3 (0.7) _p	0.2 (0.02) _p	-1.4 (0.9)	9.7 (0.9) _f	-0.09 (0.04) _f
MFIQ	28.1 (1.4) _p	-0.4 (0.03) _f	1.1 (2.1)	NS	NS
PPT masseter (RDC IIb control group)	160.0 (10.7) _p	0.8 (0.2) _p	9.5 (12.7)	26.3 (12.7) _f	NS
PPT temporalis	258.6 (15.2) _p	1.3 (0.3) _p	15.8 (22.0)	NS	NS
PRI total	11.5 (1.7) _p	-0.2 (0.02) _{p,t}	1.8 (1.4)	NS	NS
NWC total	7.9 (0.6) _p	-0.1 (0.01) _p	0.9 (0.8)	NS	NS

VAS (Visual analogue scale), RDC IIb: Research diagnostic criteria group IIb (see text for explanation group IIb), RDC IIc* wks: interaction between time and Research diagnostic criteria group IIc, (see text for explanation group IIc), MFIQ (Mandibular function impairment questionnaire), PPT (Pain pressure threshold), PRI total (Total pain rating index), NWC total (total number of words chosen), β (Beta), SE (standard error of beta), subscript p (random effects for patient), subscript t (random effects for time), subscript f (fixed effect), NS (not significant), # The betas for physical therapy were all non-significant.

patients. Consequently, the present sample is not representative of the general TMD population. The diagnosis of closed lock of the TMJ was made on the basis of the patient's history and clinical examination. Following standard protocol and to avoid extra costs, confirming MRI imaging was performed only in case of doubt (six patients out of 49).

Allocation bias was minimized because only after the providing of information, motivation, and instruction at the first visit was the allocation list consulted. Observer bias was reduced because that individual was kept blind for the group allocation.

Sample size and power analysis were performed adequately. Data were analyzed according to the intention-to-treat principle. The statistical analysis also allowed for the inclusion of seven patients with missing data.

The VAS is a reliable and valid instrument for quantitative assessment of pain and for the detection of clinically important changes in such pain (Scott and Huskisson, 1976; Gallagher *et al.*, 2002; Taddio *et al.*, 2009). Excellent reliability has previously been found for vertical range of motion measures (Dworkin *et al.*, 1990). Also, the MFIQ is a reliable instrument (Kropmans *et al.*, 1999). PPTs have been used as a reliable, reproducible, and valid tool for quantification and follow-up of experimental and clinical jaw muscle pain in longitudinal studies (Svensson *et al.*, 1995; Isselée *et al.*, 1997; Kinser *et al.*, 2009). However, important inter-individual differences of PPT values were observed in the present study, confirming previous results (Isselée *et al.*, 1998). We did not include RDC-TMD Axis II outcome variables, since, at the start of this study, these data were not commonly collected at the consultation. The present findings are in line with previous studies that compared a variety of treatment modalities for arthrogenous TMD: Significant improvement, but no between-group differences, were found over time (Minakuchi *et al.*, 2004; Schiffman *et al.*, 2007). In patients with masticatory muscle pain, Carlson *et al.* (2001) did not find an additional effect of PT, similar to observations in other musculoskeletal pain conditions (Bronfort *et al.*, 2004; Furlan *et al.*, 2008).

The patient sample in the present study included patients with TMJ closed lock, both with (IIb) and without (IIc) limitation of mouth opening. Separate statistical analysis of these groups did not reveal differences except for active and passive mouth opening, which (evidently) improved significantly more in the IIb group than in the IIc group.

In spite of its strict design, the present study has several limitations. The diagnosis of anterior disc displacement without reduction was based upon anamnestic and clinical examination, and no MRIs were taken to confirm the diagnosis in a systematic way. Patients were selected on the basis of the TMJ closed lock, but concomitant muscle pain was not an exclusion criterion. Since PPT measurements were taken at muscle sites and not the TMJ capsule, this might have had an influence on our results, *e.g.*, the significant difference regarding PPT between groups IIb and IIc at the end.

Since no exact data were recorded regarding the time of symptom onset relative to the start of treatment, it was impossible to examine this variable separately regarding the (non-) response to treatment. Over the length of the study, there was no specific measurement of the compliance of the patients regarding home exercises.

The principal symptoms for ADD-R (closed lock) are pain and limited mouth opening. In this study, these variables were assessed by objective and subjective pain measures and by active and passive maximal mouth opening. Recently, there has been increased focus on health outcomes based on the patient's personal appreciation of his/her illness (Bruce and Fries, 2003). In line with this development, the impact of TMD on mandibular function in daily life was assessed by use of the MFIQ.

This study demonstrated a significant positive effect of informing and instructing patients with ADD-R. Physical therapy did not have an additional effect. The results confirmed that, in most patients, the natural course of TMJ closed lock is benign and self-limiting, probably because of the adaptive capacity of the structures involved. A conservative approach of providing information and instruction, therefore, is warranted.

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