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ORIGINAL ARTICLE

Do psychological factors and general health influence the short-term efficacy of resilient appliance therapy in patients with temporomandibular disorder pain?

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Abstract

Objectives. To study how sense of coherence (SOC), grade of depression and non-specific physical symptoms and general health influence the efficacy of intraoral appliance therapy in patients with temporomandibular disorder (TMD) pain. A second objective was to study the association between SOC, grade of depression, grade of non-specific physical symptoms and general health. ***Material and methods.*** A total of 73 TMD pain patients participated; 36 were treated with a resilient appliance and 37 with a non-occluding control appliance in a randomized controlled trial for a period of 10 weeks. All patients had at least one pain diagnosis according to the research diagnostic criteria for TMD, including both the Symptom Checklist-90-Revised (Axis II) measuring grade of depression and non-specific physical symptoms, and general health (physical characteristics). Patients also filled in the 29-item SOC questionnaire. ***Results.*** A low grade of SOC was found in eight of the patients in the treatment group and in 17 of the control group at baseline, with a statistically significant difference between the groups. Logistic regression analyses revealed that, after correcting for the background variables, the resilient appliance did not differ from the non-occluding control appliance in terms of treatment outcome. No statistically significant differences were found when correlating mean SOC with grade of depression, grade of non-specific physical symptoms and general health. ***Conclusions.*** These findings indicate that none of the studied background variables (age, gender, SOC, depression, non-specific physical symptoms or general health) seemed to influence the short-term efficacy of intraoral appliances. No association was found between SOC and depression, non-specific physical symptoms or general health in TMD pain patients.

Key Words: *Orofacial pain, resilient appliance, sense of coherence, treatment outcome*

Introduction

Pain and dysfunction relating to temporomandibular disorders (TMDs) have been treated for many years with different designs of intraoral appliance. A review by Clark [1] concluded that treatment response to occlusal appliance therapy varied between 70% and 90%. Most studied appliances have been fabricated from hard acrylic. Another frequently used appliance has been a resilient one, which has not been so extensively evaluated and studied as the hard-acrylic stabilization appliance. In a recent randomized controlled trial (RCT) a resilient appliance was estimated to have a positive treatment outcome in about 63% of patients with TMD pain, without any statistically significant difference between the treatment group and the control group, who were treated with a control appliance [2]. In order to predict treatment outcome with an intraoral appliance and to evaluate the prognosis in patients with pain associated with TMD, it is important to investigate factors influencing the treatment response.

The theoretical model of sense of coherence (SOC) was presented by Antonovsky [3]. It is based on a salutogenic way of looking at health and disease in life. SOC mainly measures the capacity of individuals to respond to stressors in daily life by a variety of coping and other strategies [4]. The higher the SOC score measured (stronger SOC), the better the ability to cope with stressors such as pain. Over the years, a 29-item questionnaire has been used to measure SOC in patients suffering from different pain conditions

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[5–9]. In a study by Schumacher et al. [10] the SOC scale was tested in a large community sample of the German population. The authors concluded that SOC depended on age and gender, with women and older people estimating a lower SOC. On the other hand, Eriksson and Lindström [11] stated in a review article in 2006 that SOC tends to increase with age, and that it is a cross-culturally applicable instrument measuring how people manage stressful situations and stay well. In a study by Söderberg et al. [8], women suffering from fibromyalgia with a stronger SOC perceived greater well-being than those with a weaker SOC. In a descriptive study examining the relationship between self-assessed health, health status and SOC in a random sample of African American women, the authors showed that women who perceived their health as being toward the 'best possible health' had a stronger SOC than those who viewed their health as being toward the opposite end of the scale. They concluded that a low SOC may indicate an inability to handle pain [12]. In a recently published study by Sipilä et al. [13], SOC was investigated among 4859 subjects aged 30–64 years by a 12-item version of the original 13-item short version of the SOC scale and by a clinical examination. They found that low SOC was associated with myogenous TMD findings and they concluded that SOC as a psychosocial aspect has a role to play in the background of TMD.

For more than a decade the research diagnostic criteria for TMD (RDC/TMD) have been used worldwide to describe and diagnose signs and symptoms of TMD [14]. This diagnostic system includes a questionnaire estimating grade of depression and grade of non-specific physical symptoms according to the validated Symptom Checklist-90-Revised (SCL-90-R) scale [15]. Dworkin et al. [16] have shown a significant association between number of pain conditions reported and high levels of non-specific physical symptoms and depression as measured by the SCL-90-R. They also concluded that the number of pain conditions reported was a good predictor of major depression.

Associations between general health and TMD symptoms have been investigated in a number of studies [17–20]. It seems that TMD symptoms have a negative impact on oral health-related quality of life and general health [21]. Johansson et al. [18] reported that variables related to general health were more common in a group of 50-year-old subjects with self-reported TMD problems. In another study by the same group, impaired general health was found to be the strongest risk factor for reported TMD symptoms [17].

One aim of this study was to investigate whether the lack of difference in treatment outcome between patients provided with either a resilient appliance or a non-occluding control appliance was due to the treatment or whether other factors were of importance to the treatment outcome. Another aim was to study the associations between SOC and grade of depression, grade of non-specific physical symptoms and general health in patients with TMD pain.

One hypothesis was that factors other than treatment with an intraoral appliance influenced the treatment outcome. Another hypothesis was that a severe grade of depression and/or a severe grade of non-specific physical symptoms and poor general health are associated with a low SOC.

Material and methods

Subjects

The patients in this study participated in an RCT investigating the treatment outcome of a resilient appliance. The selection process took place between April 2000 and April 2003. The study subjects consisted of the 1584 patients referred for TMD treatment to the Department of Stomatognathic Physiology, Faculty of Odontology, Malmö University. On the basis of the information in the referrals, 532 patients were clinically screened according to the inclusion and exclusion criteria. Eighty patients fulfilled the inclusion criteria and were randomized to the study. Of these, seven moved away from the area or declined to participate before the start of the study, and so 73 patients with TMD pain participated. After 10 weeks of treatment, 68 patients were evaluated and five had moved away from the area or refused to continue to participate in the RCT. Inclusion and exclusion criteria, and a detailed power analysis describing the determination of sample size, have previously been presented [2].

All the patients were informed about the study and gave their written consent to participate. The study was presented and approved by the Ethics Committee of Lund University, Lund, Sweden (ref. nos. LU 327-00 and LU 505-00), which follows the guidelines of the Declaration of Helsinki.

Experimental methods

In the RCT [2], patients were randomly allocated to one of two groups: treatment with a resilient appliance (treatment group) or treatment with a palatal hard non-occluding appliance (control group). Two dental assistants randomized the patients in blocks of 10 to one of the two groups. Each block included five concealed sheets with the text 'resilient appliance' and five with the text 'control appliance'. This procedure for randomization was repeated until 80 patients were included.

Before treatment, two examiners (E. E. and H. N.) performed the screening, history-taking and clinical

examination and informed the patients about their diagnoses. The same examiners evaluated the patients after 10 weeks of treatment. Both examiners were blinded to the group assignment. One examiner (E. E.) was a TMD specialist calibrated according to the RDC/TMD. The other (H. N.) was an experienced general practitioner undergoing TMD specialist training, who had been educated theoretically and clinically trained in the RDC/TMD. Another TMD specialist who was not involved in the evaluation delivered and adjusted the appliances.

Two different intraoral appliances were used as treatment alternatives: a 4-mm thick resilient appliance and a hard non-occluding palatal appliance used as a control. A specialist delivered the appliances after adjustments and informed the patients about how to use them. Patients were instructed to use the appliances at night for 10 weeks. Both appliances were designed to be placed in the maxilla. All patients were informed in the same way and made the same number of visits. No additional treatment was recommended for TMD pain during the 10-week follow-up period. Treatment outcome at 10 weeks was judged positive when the visual analog scale (VAS)-reported worst TMD pain experienced was at least 30% lower than at baseline [22]. The two intraoral appliances were equivalent in terms of treatment outcome from a short-term perspective. Registered worst TMD pain at baseline (mean VAS score = 75 mm in the treatment group and 69 mm in the control group) and at 10 weeks (mean VAS score = 43 mm in the treatment group and 44 mm in the control group) showed no statistically significant differences between groups. More than 90% of the patients had used their appliances every night or most nights per week (91% in the treatment group and 94% in the control group) at the 10-week follow-up [2].

At baseline, patients filled in the Swedish version of the RDC/TMD history questionnaire and the SOC 29-item questionnaire in Swedish, according to Antonovsky [23]. The total score ranges from 29 to 203, with higher scores reflecting stronger SOC. From Antonovsky's definition of SOC, it can be divided into three components corresponding to comprehensibility, manageability and meaningfulness of one's life when stimuli from the internal or external environment strike the individual. Of the 29 items, 11 contribute to comprehensibility, 10 to manageability and eight to meaningfulness. Antonovsky proposed that a 'strong' SOC facilitates psychological adjustment and somatic health, which is why it has been suggested that it should be used as a whole rather than divided into the three domains when used in the clinical research situation. SOC was graded as weak (≤136), moderate (137–148) or strong (≥149) according to Langius [24]. In a systematic review by Eriksson and Lindström [25], it was concluded that the SOC scale seems to be a reliable and valid instrument.

Axis II in the RDC/TMD was used to assess the psychological status of the participating patients [14]. Psychological status was assessed with the depression score and the score for non-specific physical symptoms from subscales of the SCL-90-R [15]. General health-expressing physical characteristics in RDC/TMD were assessed by a five-grade scale: 1 = poor, 2 = fair, 3 = good, 4 = very good and 5 = excellent. Studies performed on the RDC/TMD instrument have shown good validity and reliability [26,27].

Six variables possibly influencing the treatment outcome were selected from the RDC/TMD and the SOC questionnaire registered at baseline. Table I shows the distribution of the six variables in the two treatment groups.

Statistical analysis

Logistic regression models with likelihood ratio tests were used when analyzing data. The effect of the treatment was tested in two regression models. In the first model the treatment outcome was tested, whereas in the second model, the treatment outcome was tested after correcting for six possible background variables. One-way ANOVA was used when testing the association between SOC and grades of depression, non-specific physical symptoms and general health. A significance level of $\alpha = 5\%$ was used in all the tests.

Statistical analyses were carried out with the Statistical Package for the Social Sciences 13.0 for Windows (SPSS Inc., Chicago, IL).

Results

The mean value for SOC was 142 for the women and 150 for the men; 22 of the women (37%) and three of the men (23%) had a low grade of SOC. Patients between 20 and 40 years of age had a mean SOC of 145, while the corresponding figure for older patients was 141. Mean SOC was 147 in the treatment group ($n = 36$) and 139 in the control group ($n = 37$) (Table I).

In the treatment group, 20 patients had a moderate or severe self-reported grade of depression according to the SCL-90-R, and in the control group the corresponding figure was 25. Self-reported non-specific physical symptoms were moderate or severe in 24 patients in the treatment group and in 27 in the control group. Good-to-excellent perceived general health was reported by 32 patients in the treatment group and by 30 in the control group (Table I).

A logistic regression analysis was carried out to test whether there were differences among the

Table I. Distribution of background variables possibly affecting treatment outcome in the TMD pain patients.

Variable	Treatment (*n*=36); *n* (%)	Control (*n*=37); *n* (%)	Total (*n*=73); *n* (%)
Age (years)			
<20	8 (22)	7 (19)	15 (21)
20–40	18 (50)	19 (51)	37 (50)
41–60	6 (17)	9 (24)	15 (21)
>60	4(11)	2 (6)	6 (8)
Gender			
Male	8 (22)	5 (14)	13 (18)
Female	28 (78)	32 (86)	60 (82)
SOC grade			
Low (≤ 136)	8 (22)	17 (46)	25 (34)
Moderate (137–148)	9 (25)	4 (12)	13 (18)
High (≥ 149)	19 (53)	16 (42)	35 (48)
Depression[a]			
Normal	15 (43)	11 (31)	26 (37)
Moderate	7 (20)	12 (33)	19 (26)
Severe	13 (37)	13 (36)	26 (37)
Non-specific physical symptoms[a]			
Normal	11 (31)	9 (25)	20 (28)
Moderate	10 (29)	10 (28)	20 (28)
Severe	14 (40)	17 (47)	31 (44)
General health			
Excellent	7 (20)	1 (3)	8 (11)
Very good	13 (36)	11 (30)	24 (33)
Good	12 (33)	18 (49)	30 (41)
Fair	3 (8)	6 (15)	9 (12)
Poor	1 (3)	1 (3)	2 (3)

[a]Two patients, one from each group, had not filled in the SCL-90-R.

Table II. Association between SOC and three different variables: non-specific physical symptoms, depression and general health. Variance analysis showed no statistically significant differences between the mean SOC values for the different grades of each of the variables.

	SOC			
	Mean	SD	95% CI	*P*
Non-specific physical symptoms (SCL-90R)				
Normal	144	28	130–157	0.521
Moderate	148	22	137–159	
Severe	140	23	131–149	
Depression (SCL-90R)				
Normal	148	25	137–157	0.174
Moderate	148	21	137–158	
Severe	136	25	126–146	
General health				
Excellent	150	26	128–172	0.424
Very good	145	26	133–155	
Good	143	22	135–151	
Fairly good	129	30	105–153	
Bad	154	8	77–230	

background variables in relation to treatment outcome. No statistically significant difference in efficacy between the resilient appliance and the non-occluding control appliance was found (P = 0.344). When testing for six possible background variables (gender, age, SOC, non-specific physical symptoms, depression and general health) one by one, no statistically significant differences were found in relation to treatment outcome.

A severe grade of depression and a low grade of SOC (mean 136) were found in 26 patients (37%). Thirty-one of the studied patients (44%) had registered a severe grade of non-specific physical symptoms with a moderate grade of SOC (mean 140). Fairly good health and a low grade of SOC (mean 129) were found in nine patients (12%). Two patients with bad general health had a high grade of SOC (mean 154). In a variance analysis there were no statistically significant associations found between mean SOC and grades of depression, non-specific physical symptoms or general health (Table II).

Discussion

Previously, we found that 63% of patients treated with a resilient appliance and 52% of patients treated with a non-occluding control appliance had a 30% reduction in worst TMD pain at 10 weeks, without any statistically significant difference between the groups [2]. In the present investigation, when correcting for possible background variables, the logistic regression analyses did not reveal that any of the six tested variables were of significant importance to the treatment outcome in this group of patients with TMD pain, thus rejecting the first hypothesis of this study. This strengthens the result that the capabilities of the resilient appliance and the non-occluding control appliance to reduce symptoms in TMD pain patients are similar in the short term. Therefore, occlusion on a resilient material seems not to be an explanation behind the treatment effect of the resilient appliance. The results of our studies are in line with those of an RCT of Truelove et al. [28] studying the efficacy of a soft vinyl splint from both a short- and a long-term perspective; they found no differences in treatment outcome among their three groups of soft splint, hard splint and usual treatment. The patients in our study will be followed to test whether the resilient appliance is still equivalent to the non-occluding control

appliance and to evaluate the durability of the resilient appliance over a longer perspective.

The second hypothesis was also rejected since no statistically significant differences were found regarding the associations between grade of depression or non-specific physical symptoms and SOC. In a study by Büchi et al. [5] in patients with rheumatoid arthritis (RA), it was found that a low SOC was associated with an increased prevalence of depression. Their study measured self-reported depression according to the Hospital Anxiety and Depression scale, which is a reliable measure of depression in patients with physical illness. In another study by Frenz et al. [29], SOC has been shown to be associated with current depression measured by the Beck Depression Inventory scale. The results of these studies are thus not in line with our current findings in TMD pain patients. One explanation could be differences in the conditions of the study subjects, as Büchi et al. studied patients with RA and Frenz et al. studied both non-patients and patients with a psychiatric disorder. This differs from our study of patients with TMD pain. Another explanation could be that we used different instruments for measuring depression.

Our study could not find any association between general health and mean SOC. Studies on chronic musculoskeletal pain conditions have reported contrary results when studying general health and SOC [6,8,9,12]. Söderberg et al. [8], in a study of women with fibromyalgia, found that patients with a stronger SOC perceived a greater well-being than those with a weaker SOC. They concluded that women with a weaker SOC may need extra support when experiencing poor health. In a study of a random sample of 48 African American women it was stated that a strong SOC was negatively related to general health status, and the author concluded that this may indicate an inability to handle pain in women with a weak SOC [12]. The results of these studies differ from those of our intervention study, where the majority of patients reported good general health. In an epidemiologic study by Johansson et al. [17] in which questionnaires were sent to 8888 persons and completed by 71% of 50-year-old subjects in two Swedish counties, the authors concluded that impaired general health was significantly associated with TMD symptoms. In our study, however, only 15% of the participating TMD pain patients reported poor general health at baseline. The difference in the results may be a reflection of the fact that our RCT used a selected sample of patients with a mean age of 34 years compared to their population-based sample of 50-year-old subjects. However, a single question about general health used in both the studies may not be optimal for measuring a condition dependent on many factors.

In a review article by Flensborg-Madsen et al. [30] it was concluded that the SOC scale can be used as a predictor for health measured from psychological aspects, while the scale is incapable of explaining physical health measured only by means of physical terms. The patients in our study were diagnosed according to the RDC/TMD (Axis I), thus they had a physical condition as one explanation for their perceived TMD pain, which could explain why we could not predict treatment outcome. The primary aim when treating patients with intraoral appliances is to reduce physical signs and symptoms of TMD to enhance orofacial health and sense of well-being.

In our study of TMD pain patients we found no statistically significant difference between the genders regarding mean SOC, which is in line with a study by Nilsson et al. [31]. They studied gender and psychosocial differences in a population of patients and asymptomatic subjects in northern Sweden. However, they found a statistically significant difference in SOC with age, showing a higher SOC for the older age group. This is not in line with our results showing no difference in SOC between younger and older patients. This could be explained by the different mean ages in the different studies. Our study included only patients with TMD pain, whereas their study included both healthy subjects and patients, which could be another explanation for the differing results.

The only statistically significant difference between the studied groups was a higher number of patients with low-grade SOC in the control group at baseline. Despite this fact, the regression analysis showed no statistically significant difference in treatment outcome between the two groups studied. Initial low SOC, therefore, did not appear to predict a negative treatment outcome when treating TMD pain patients with a resilient appliance or a palatal, non-occluding appliance.

In a study by Lee et al. [32], 87 TMD patients were referred for treatment at a specialist clinic in Hong Kong. The patients were diagnosed according to the RDC/TMD, and Axis II assessment revealed moderate-to-severe depression scores in 43%, and moderate-to-severe somatization scores in 60% of the patients. This result is not in line with our study showing higher scores for depression (63%) and non-specific physical symptoms (72%). The difference could be explained by different inclusion criteria; all the participants in our study were TMD pain patients and 18% of their patients had no TMD pain. Yap et al. [33] investigated physical diagnoses, psychologic distress and psychosocial dysfunction in 191 Asian TMD patients and compared the findings with Swedish and American TMD patients. They concluded that Asian patients were generally similar to their Swedish and American counterparts, and that a substantial proportion of TMD patients were depressed (40%) and experienced a moderate-to-severe grade of somatization (48%). The results of the two Asian studies differed from ours because the patients in our study also participated in an RCT of a

resilient appliance therapy [2]. The lower number of patients in our study is reflected in the power calculation performed for an intervention study and not an epidemiological study. Another study investigating the differences in prevalence of depression and somatization scores in 54 TMD patients examined according to the RDC/TMD confirmed our results [34]. The authors concluded that psychological factors play an important role in the etiopathogenesis of TMD as demonstrated by an increase in levels of depression and somatization.

To the authors' knowledge this is the first study of a 29-item SOC in patients treated for TMD pain. We have tested SOC in an intervention study, which could be a shortcoming. Sipilä et al. [13] have investigated the association of a 12-item version of SOC and clinical findings of TMD in an epidemiological survey, which gives a more realistic view of SOC in TMD patients compared to an intervention study. In the future, studies of SOC and subdiagnoses of TMD according to the RDC/TMD would be of interest.

Within the limitations of this study, a conclusion that can be drawn is that none of the studied background variables (age, gender, SOC, depression, non-specific physical symptoms and general health) seemed to be of importance for the short-term treatment outcome in patients treated with resilient or non-occluding intraoral appliances. No association was found between SOC and depression, non-specific physical symptoms and general health in TMD pain patients.

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