Patient-Centered Outcome Criteria for Successful Treatment of Facial Pain and Fibromyalgia

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Aims: *To define treatment success from the facial pain and fibromyalgia pain patient perspective across four domains (pain, fatigue, emotional distress, interference with daily activities) through the use of the Patient-Centered Outcomes (PCO) Questionnaire.* ***Methods:*** *Participants included 53 facial pain (46 women, seven men) and 52 fibromyalgia (49 women, three men) patients who completed the PCO Questionnaire. The PCO assesses four relevant domains of chronic pain: pain, fatigue, distress, and interference in daily activities. Participants rated their usual levels, expected levels, levels they considered successful improvements, and how important improvements were in each of the four domains following treatment. Repeated-measures analyses of variance were performed to determine whether differences existed across domains and across pain groups.* ***Results:*** *Both groups of participants defined treatment success as a substantial decrease in their pain, fatigue, distress, and interference ratings (all approximately 60%). Fibromyalgia participants reported high levels of pain (mean = 7.08, SD = 2.04), fatigue (mean = 7.82, SD = 1.71), distress (mean = 6.35, SD = 2.46), and interference (mean = 7.35, SD = 2.21). Facial pain participants' ratings of these domains were significantly lower for pain (mean = 5.62, SD = 2.38), fatigue (mean = 5.28, SD = 2.64), distress (mean = 4.34, SD = 2.78), and interference (mean = 4.10, SD = 3.06).* ***Conclusion:*** *These results demonstrate the high expectations of individuals with facial pain and fibromyalgia regarding treatment of their symptoms. Health care providers should incorporate these expectations into their treatment plans and discuss realistic treatment goals with their pain patients.* J OROFAC PAIN 2009;23:47–53

Key words: facial pain, fibromyalgia, patient-centered care, treatment outcome, pain/psychology

Chronic pain is one of the most frequent, costly, and disabling medical conditions in the United States, with estimates suggesting that 15% of adults experience some form of chronic pain.[1] Specifically, a significant number of these adults are affected by facial pain (FP) or fibromyalgia (FM). Whereas FP is a local pain syndrome, FM is defined by chronic widespread pain and tenderness. However, there is substantial overlap between both pain syndromes, and they seem to share relevant pain mechanisms.[2] Although FP is a heterogeneous syndrome that includes dental disorders, headaches, and neuropathic pain, most patients in this group have temporomandibular disorders. Recent estimates suggest that from 5% to 10% of adults and 30% to

Table 1 Demographic Characteristics of Samples

	FP sample	FM sample
Sex	46 women 7 men	49 women 3 men
Race	All Caucasian	43 Caucasian 3 African American 1 Hispanic 1 Pacific Islander
Mean age (SD)	47.3 (15.2)	46.5 (10.8)
Pain duration (SD), mo	93.4 (111.6)	110.3 (57.5)

* No significant differences were found between groups for any variable.

50% of the elderly population are living with chronic and severe uncontrolled FP or FM.[2–4] In fact, it has been estimated that more than 40% of individuals with FP or FM have experienced severe pain for over 5 years without finding effective means of achieving pain relief.[3] These clinical groups are difficult to treat because many individuals with chronic pain present with pain of an unknown etiology. Moreover, these populations are frequently misdiagnosed and given unsuccessful treatments, leading to patient frustration and multiple transitions between medical providers in an attempt to effectively control their pain.[3,5]

Traditionally, determinations regarding successful treatment for chronic pain have been made predominantly by health care providers. However, this "medical model" of treatment does not allow for the incorporation of patient perspectives of successful outcomes for any particular course of treatment. In contrast, adopting patient-centered models of treatment allows for health care providers and patients to work together to determine success criteria.[6] Researchers have recently begun investigating the patient-centered model of treatment outcomes and there is a large body of evidence showing the importance of a collaborative relationship between health care providers and their patients.[7,8] In fact, Alamo et al concluded that a patient-centered approach for the treatment of pain was more effective than a provider-centered approach. The former strategy led to improvements in most of the outcome measures during the 1-year study period.[9] Although often reflecting high expectations, patient criteria of therapeutic success are variable throughout treatment.[10] Through interactions with their providers, chronic back and neck pain patients became less stringent in their success criteria during the course of treatment, and used these lenient criteria in making judgments about treatment success.[10]

Due to the complex nature of chronic pain, many individuals report frustration with their health care providers related to multiple failed treatment attempts. Thus, individual expectations in the treatment of chronic pain appear to be extremely relevant for successful outcomes.[11,12] Despite burgeoning interest, little is currently known regarding the specific factors that individuals with FP and FM consider important for successful treatment. Thus the present study examined the treatment expectations in a sample of FP and FM patients.

The primary aim of this study was to define treatment success from the FP and FM pain patient perspective across four domains (pain, fatigue, emotional distress, interference with daily activities) through the use of a Patient-Centered Outcomes (PCO) Questionnaire.

Materials and Methods

Chronic Pain Participants

This study used a sample of 53 individuals who were consecutively referred to an orofacial pain clinic at the University of Florida (Table 1). The sample consisted of individuals who were heterogeneous with regard to orofacial pain complaint. Specifically, 42.6% of patients had jaw pain, 29.6% had FP localized to one side of the face, 13.0% had headaches, and 11.1% had pain related to teeth/gums. The diagnosis was verified by a board-certified dentist (HG) following physical examination. FP participants who met criteria for FM (detailed below) were excluded. The average duration of pain was 93.4 months (*SD* = 111.6).

The sample of FM participants was comprised of 52 individuals (Table 1). They were randomly selected from a pool of participants recruited from the rheumatology clinic of one of the authors (RS) at the University of Florida or affiliated pain clinics. Chronic pain was reported on average for 110.3 months (SD = 57.5). All FM participants fulfilled the 1990 American College of Rheumatology

MANY PEOPLE EXPERIENCE PAIN, FATIGUE (I.E., FEELING TIRED), EMOTIONAL DISTRESS (E.G., WORRIES, FEELING SAD), AND INTERFERENCE WITH DAILY ACTIVITIES (E.G., NOT BEING ABLE TO WORK OR DO HOUSEHOLD CHORES) AS A RESULT OF THEIR MEDICAL CONDITION. WE WOULD LIKE TO UNDERSTAND HOW YOU HAVE BEEN IMPACTED IN EACH OF THESE AREAS. WE WOULD ALSO LIKE TO LEARN MORE ABOUT WHAT YOU WANT YOUR TREATMENT TO DO FOR YOU.

FIRST, WE WOULD LIKE TO KNOW YOUR **USUAL** LEVELS OF PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE.
On a scale of ***0 (none) to 10 (worst imaginable)***, please indicate your usual level (during the past week) of …
- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

NOW, WE WOULD LIKE TO LEARN ABOUT YOUR **DESIRED** LEVELS OF PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE. IN OTHER WORDS, WE WOULD LIKE TO UNDERSTAND WHAT YOUR IDEAL TREATMENT OUTCOME WOULD BE.
On a scale of ***0 (none) to 10 (worst imaginable)***, please indicate your desired level of …
- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

PATIENTS UNDERSTANDABLY WANT THEIR TREATMENT TO RESULT IN DESIRED OR IDEAL OUTCOMES LIKE YOU INDICATED ABOVE. UNFORTUNATELY, AVAILABLE TREATMENTS DO NOT ALWAYS PRODUCE DESIRED OUTCOMES. THEREFORE, IT IS IMPORTANT FOR US TO UNDERSTAND WHAT TREATMENT OUTCOMES YOU WOULD CONSIDER **SUCCESSFUL**.
On a scale of ***0 (none) to 10 (worst imaginable)***, please indicate the level each of these areas would have to be at for you to consider treatment successful.
- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

NOW, WE WOULD LIKE TO KNOW WHAT YOU **EXPECT** YOUR TREATMENT TO DO FOR YOU.
On a scale of ***0 (none) to 10 (worst imaginable)***, please indicate the levels you expect following treatment.
- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

FINALLY, WE WOULD LIKE TO UNDERSTAND HOW **IMPORTANT** IT IS FOR YOU TO SEE IMPROVEMENT IN YOUR PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE FOLLOWING TREATMENT.
On a scale of ***0 (not at all important) to 10 (most important)***, please indicate how important it is for you to see improvement in your…
- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

Fig 1 Patient-Centered Outcomes Questionnaire.

Criteria.[13] They reported chronic widespread musculoskeletal pain for more than 3 months and had at least 11 out of 18 tender points. None of the FM participants complained of facial pain during their office visits, although 88% reported the presence of frequent headaches. All participants recruited had to be 18 years of age or older, have the ability to read and write English, and have the ability to consent to participate.

Procedures

Participants were asked to complete a brief demographics questionnaire and a questionnaire about patient outcomes before their medical appointments. The PCO Questionnaire assessed four domains (pain, fatigue, emotional distress, and interference with daily activities) relevant to chronic pain populations on a numerical rating scale ranging from 0 to 10 (Fig 1). For each domain, the PCO Questionnaire asked participants to provide the following ratings: their usual levels of symptoms, the levels considered to be a successful treatment outcome, the levels they desire, the levels they expect following treatment, and how important improvement is for them in each of the four domains. The PCO Questionnaire has been shown to have acceptable test-retest reliability (r = .84 to r = .90, P < .001, for usual levels across domains) and concurrent validity with standardized measures of pain, mood, and disability.[14]

Statistical Analyses

Descriptive statistics were generated for each domain and normality assumptions were tested for

Table 2 Descriptive Data from the PCO Questionnaire

	FP Sample		FM Sample	
	Mean	SD	Mean	SD
Usual levels				
Pain	5.62	2.38	7.08	2.04
Fatigue	5.28	2.64	7.82	1.71
Distress	4.34	2.78	6.35	2.46
Interference	4.10	3.06	7.35	2.21
Desired levels				
Pain	0.81	1.34	1.35	1.99
Fatigue	0.93	1.33	1.14	1.95
Distress	0.85	1.20	1.15	1.65
Interference	0.52	1.17	1.02	1.90
Expected levels				
Pain	2.01	1.89	3.48	2.32
Fatigue	1.94	1.81	3.50	2.34
Distress	1.79	1.79	2.85	2.29
Interference	1.38	1.60	3.21	2.35
Successful levels				
Pain	2.19	1.42	3.13	1.50
Fatigue	2.16	1.54	3.00	1.64
Distress	1.92	1.33	2.62	1.71
Interference	1.56	1.45	2.69	1.62
Importance levels				
Pain	8.90	2.49	9.17	1.32
Fatigue	7.87	2.94	8.87	1.31
Distress	7.08	3.67	7.54	1.88
Interference	7.69	3.54	8.54	1.54
Amount of Change Needed (Usual – Success)				
Pain	3.43	2.03	3.94	1.67
% reduction	61.7		55.8	
Fatigue	3.13	2.10	4.82	1.90
% reduction	59.3		61.6	
Distress	2.42	2.20	3.73	2.35
% reduction	56.0		58.7	
Interference	2.55	2.38	4.65	2.05
% reduction	61.6		63.4	

each measure. The relationship between the demographic variables and the dependent variables was also examined to assess whether further covariate analyses should be conducted. Repeated-measures analyses of variance (ANOVAs) were performed to determine whether differences existed across domains in the amount of change necessary for treatment to be deemed successful for FP participants. Subsequently, paired *t* tests were conducted to examine the specific differences in the amount of change necessary for treatment across domains. Repeated-measures ANOVAs were performed using participants' PCO ratings for the amount of change (usual minus success) needed to meet success criterion for each of the four domains during treatment compared across the two pain groups.

Results

Descriptive FP and FM PCO Data

Descriptive information about participants' ratings for usual levels, desired levels, expected levels, levels considered to be successful, and importance ratings for each of the four PCO domains (pain, fatigue, emotional distress, and interference with daily activities) are provided in Table 2. Participants' success criteria for each domain were subtracted from their ratings for usual levels of each domain to determine the amount of change that was needed for treatment to be perceived as successful. Overall, for treatments to be considered successful, FP participants required a pain level of

2.19 (61.7% reduction), a fatigue level of 2.16 (59.3% reduction), a distress level of 1.92 (56% reduction), and an interference level of 1.56 (61.6% reduction). On the other hand, FM participants required a pain level of 3.13 (55.8% reduction), a fatigue level of 3.00 (61.6% reduction), a distress level of 2.62 (58.7% reduction), and an interference level of 2.69 (63.4% reduction). Before conducting covariate analyses, the assumption was tested that the covariates (sex, race, age, and pain duration) were related to the dependent variables. The only significant relationship was between sex and usual pain ratings, with women showing slightly higher values than men. However, the small sample of men compared to women (10/105) in this study precludes a full understanding of this small relationship. Nonetheless, the analyses were repeated without the men and the results did not change. Moreover, a chi-square analysis to assess for significant differences of men in each group found that sex was equally distributed across the groups.

Domain Analyses

The repeated-measures ANOVA yielded a significant effect for domain (F ([3,156]) = 5.15, $P < .05$, partial $\eta^2 = .09$). Paired samples t tests revealed that FP participants would like a significantly greater reduction in pain compared to emotional distress, (t [(52)] = 3.20, $P = .002$), in pain compared to interference (t [(52)] = 2.46, $P = .017$), and in fatigue compared to emotional distress (t [(52)] = 2.42, $P = .019$).

Pain Group Comparisons of PCO Data: Pain

For pain expressed by the pain groups, success was defined by significant decreases in their usual pain ratings (F [(1, 103)] = 411.64, $P < .01$, partial $\eta^2 = .80$). There was a significant difference between the pain groups (F [(1, 103)] = 14.25, $P < .01$, partial $\eta^2 = .12$). Specifically, FP participants had lower pain ratings than FM participants ($P < .05$). There was not a significant interaction between pain group and pain level (usual vs success), suggesting that the pain groups defined success approximately equal for the pain domain.

Pain Group Comparison of PCO Data: Fatigue

In the case of fatigue in the pain groups, success was defined by significant decreases in their usual fatigue ratings (F [(1, 103)] = 414.79, $P < .01$, partial $\eta^2 = .80$). There was a significant difference between the pain groups (F [(1, 103)] = 27.31, $P < .01$, partial $\eta^2 = .21$). Specifically, FP participants had lower fatigue ratings than FM participants ($P < .05$). There was a significant interaction between pain group and fatigue level (usual vs success) (F [(1, 103)] = 19.06, $P < .01$, partial $\eta^2 = .16$). FP participants required (for success) significantly less improvement in fatigue compared to FM participants ($P < .05$).

Pain Group Comparison of PCO Data: Emotional Distress

For emotional distress in the pain groups, success was defined by significant decreases in their usual distress ratings (F [(1, 103)] = 191.48, $P < .01$, partial $\eta^2 = .65$). There was a significant difference between the pain groups (F [(1, 103)] = 14.50, $P < .01$, partial $\eta^2 = .12$). Specifically, FP participants had lower distress ratings than FM participants ($P < .05$). There was a significant interaction between pain group and distress level (usual vs success) (F [(1, 103)] = 8.62, $P < .05$, partial $\eta^2 = .08$). FP participants required significantly less improvement in distress compared to FM participants ($P < .05$).

Pain Group Comparison of PCO Data: Interference

In the case of interference, success was defined by significant decreases in the usual interference ratings of the pain groups (F [(1, 103)] = 275.20, $P < .01$, partial $\eta^2 = .73$). There was a significant difference between the pain groups, (F [(1, 103)] = 35.68, $P < .01$, partial $\eta^2 = .26$). Specifically, FP participants had lower interference ratings than FM participants ($P < .05$). There was a significant interaction between pain group and interference level (usual vs success) (F [(1, 103)] = 23.55, $P < .01$, partial $\eta^2 = .19$). FP participants also required significantly less improvement in interference compared to FM participants ($P < .05$).

Discussion

FP and FM individuals require approximately 60% reductions in pain, fatigue, emotional distress, and interference with daily activities in order for treatment to be deemed successful. The present study also found that FP and FM individuals desired significantly greater reductions in pain compared to distress and interference and

significantly greater reductions in fatigue compared to distress. In addition, these results indicate that chronic pain populations also highly value improvements in their emotional and behavioral well-being.

For all study participants, success was defined by large improvements in their usual pain, fatigue, emotional distress, and interference with daily activities. These endpoints are also consistent with the multidimensional features of pain and supported by prior research.[15] Interestingly, participants did not expect total pain elimination for treatments to be successful. This finding suggests that participants accept the more realistic scenario that they may experience some level of pain regardless of the treatment, even though their desired levels are lower (ie, all pain groups had an average desired level of pain of less than 2 on an 11-point scale). Similarly, participants from both groups rated the importance levels for improvement in each domain an average of 7 or greater. These findings all suggest that patient-centered outcomes are a critical consideration for all health care providers.

The amount of pain reduction considered successful by FP participants is similar with those reported in our previous study of chronic pain patients. The current study showed that individuals with FP want pain to be reduced by an average of 3.43 points (61.7% reduction), a finding similar to that of the previous study[13] which found that individuals with chronic back pain want pain to be reduced by an average of 3.4 points (56% reduction). These studies are in disagreement with a recent meta-analysis which found that individuals with pain consider a decrease in pain by 2.0 points (30% reduction) as clinically meaningful.[16] An important caveat to note, however, is that the results of this meta-analysis were based on a different measure of treatment success, namely "patient global impression of change."

This study also demonstrated that FP participants had overall lower pain, fatigue, distress, and interference ratings than FM participants and that they required significantly less improvement in fatigue and distress than FM participants. Since demographic variables do not seem to be a contributor to the difference, an alternative explanation could be the difference in perceived severity of the different disorders. For example, individuals with FM often experience significant global impairments in physical functioning and emotional distress.[17] Moreover, FM is defined by the person reporting widespread pain (involving all four limbs and the trunk) and tenderness to digital palpation in at least 11 of 18 predetermined body areas called tender points.[13] However, individuals with FP typically have pain localized to one part of their body. Perhaps having a more localized pain condition results in a decreased need for as much of a symptom reduction in multiple domains compared to individuals with widespread pain conditions.[18] It is also important to note that individuals with FP had overall lower values than individuals with FM; therefore, the smaller need for improvement could also be a function of lower initial values.

Furthermore, chronic pain populations have been shown to be heterogeneous such that there are individuals who place a higher importance on certain domains.[19] In fact, Robinson and colleagues[14] performed a cluster analysis on a chronic pain population and found three subgroups: the Pain-Focused group, which placed greater importance on pain reduction; the Multifocused-High group, which rated improvement in all domains as extremely important; and the Multifocused-Moderate group, which reported moderate importance ratings across domains. These results suggest that treatment should be tailored to meet patients' expectations but should also aim for multidimensional treatment success. [20] Therefore, the PCO Questionnaire can provide important clinical information and may be used to determine types and focus of treatments for the different pain groups. Future studies will be necessary to further investigate the nature of these differences.

Several limitations of the study should be considered. The sample of the current study consisted predominantly of Caucasian individuals and may have limited the generalizability of findings to a more diverse population. Moreover, since most participants in the present study had experienced pain for a long duration, the results are not generalizable to individuals with shorter durations of pain. The FP sample consisted of heterogeneous FP problems; therefore, there could be individual differences between subsets of the FP population (eg, individuals with migraines versus individuals with temporomandibular joint pain). However, all chronic pain samples have heterogeneity on a number of dimensions. Further, there is no a priori reason to believe that heterogeneity would lead to differences in patient-outcome assessment. In addition, detailed information about prior treatments regarding the patients in this study was not collected. Although beyond the scope of this study, such treatment may have affected PCO ratings and therefore, there may be differences between participants who received

prior treatment for their pain condition and those who did not. However, the long duration of their illness (more than 7 years) makes it very unlikely that the majority of FM and FP participants had not received any pain treatments in the past. Furthermore, the PCO Questionnaire was completed by participants prior to any defined treatment endpoint, although most patients and health care providers would not consider a complete resolution of symptoms (cure) impossible. Thus it was impossible to determine whether participants adjusted their ratings in response to treatment modalities and strategies. A longitudinal design in future studies would help elucidate the effect of treatment strategies on PCO ratings.

In conclusion, FM and FP individuals expect more symptom relief from their health care providers than previously known. Reductions of approximately 60% for pain, fatigue, distress, and interference with daily activities are necessary to satisfy their success criteria. Importantly, for FM and FP individuals alike, reductions in pain and fatigue may rank higher than improved distress or function. Careful assessments of these important outcome measures are needed to tailor the comprehensive care that most individuals with chronic pain will require. Future research should examine the clinical relevance of differences in pain-related ratings across chronic pain groups, predictors of change, and the presence of further subgroups.

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