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## **Authors**

Brodsky, Marc Spritzer, Karen Hays, Ron D et al.

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# Change in Health-Related Quality-of-Life at Group and Individual Levels Over Time in Patients Treated for Chronic Myofascial Neck Pain

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Marc Brodsky, MD<sup>1</sup>, Karen Spritzer, BS<sup>2</sup>, Ron D. Hays, PhD<sup>2</sup>, and Ka-Kit Hui, MD<sup>2</sup>

#### **Abstract**

Background. This study evaluated change in health-related quality of life at the group and individual levels in a consecutive series of patients with chronic myofascial neck pain. Methods. Fifty patients with chronic neck pain self-administered the Short Form-36 Version 2 (SF-36 v2) before treatment and 6 weeks later. Internal consistency reliability was estimated for the 8 scale scores and Mosier's formula was used to estimate reliability of the physical and mental health composite scores. Significance of group-level change was estimated using within-group t statistics. Significance of individual change was evaluated by reliable change index. Results. Statistically significant (P < .05) group mean improvement over time was found for all SF-36 scores. At the individual level, 20% of the possible changes were statistically significant (17% improvement, 3% decline). Conclusions. Estimating the significance of individual change in health-related quality of life adds important information in comparing different treatment modalities for chronic myofascial neck pain.

#### Keywords

health-related quality of life, myofascial neck pain

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Myofascial neck pain may be detrimental to health-related quality of life (HRQOL),<sup>1</sup> and chronic neck pain can cause disability.<sup>2</sup> Aside from chronic neck pain, myofascial pain of the head and neck may contribute to or be associated with other conditions such as whiplash symptoms,<sup>3</sup> migraine, and tension headaches in adults and children,<sup>4,5</sup> temporomandibular joint pain,<sup>6</sup> fibromyalgia,<sup>7</sup> and cancer-related pain.<sup>8,9</sup>

The UCLA Center for East-West Medicine served as a clinical site in a neck pain utility study. This article evaluates group-level and individual-level change in HRQOL in 50 consecutive patients from the UCLA study site.

## **Methods**

The UCLA Center for East-West Medicine is an organized unit within the Department of Medicine. The clinical staff consists of physicians and licensed practitioners trained in traditional Chinese healing methods with emphasis on health promotion, disease prevention, treatment, and rehabilitation.

The Center served as a site in a neck pain utility study sponsored by the Bone and Joint Decade 2000-2010 Task Force on Neck Pain located at the Division of Outcomes and Population Health, Toronto Western Research Institute. Participants recruited for the study were between the ages of 18 and 65 years and sought care from the Center for myofascial neck and shoulder girdle pain of at least 3 months duration.

Data were collected from patients with chronic myofascial neck pain who were referred by a primary care physician (26), neurologist (9), anesthesiologist (3), rheumatologist (1), orthopedic surgeon (1), and oral maxillofacial surgeon (1). Nine patients were self-referred. These patients had failed medical treatments including over-the-counter and prescription medications, physical therapy, and interventional procedures (eg, surgery).

Myofascial pain syndrome was diagnosed by history and physical exam findings that demonstrated major and minor criteria for myofascial trigger points per Centers for Medicare & Medicaid Services criteria (Table 1). <sup>10,11</sup> Trigger points, a diagnostic feature of myofascial pain syndrome, are most commonly identified in the upper trapezius muscle in chronic myofascial neck pain. Trigger points associated with chronic neck pain are less prevalent in the levator scapulae, sternocleidomastoid, and temporalis muscles. <sup>12</sup> Patients were excluded from the study with (1) neck pain due to fracture, dislocation, subluxation, neoplasm, infection, severe spondyloarthropathy, or other nonmechanical cause; (2) progressive neurological deficit,

## Corresponding Author:

Marc Brodsky, MD, 32 Strawberry Hill Court, Stamford, CT 06902, USA. Email: mbrodsky@stamhealth.org

<sup>&</sup>lt;sup>1</sup> Stamford Hospital, Stamford, CT, USA

<sup>&</sup>lt;sup>2</sup> University of California, Los Angeles, CA, USA

**Table 1.** Centers for Medicare & Medicaid Services Major and Minor Criteria for Myofascial Trigger Point.

Major Criteria (All 4 Required)	(At Least 1 of 4 Required)
I. Regional pain complaint	Reproduction of referred pain pattern by stimulating the trigger point
<ol><li>Pain complaint or altered sensation in the expected distribution of referred pain from a trigger point</li></ol>	Altered sensation by pressure on the tender spot
3. Taut band palpable in an accessible muscle with exquisite tenderness	3. Local response elicited by snapping palpation at the

4. Some degree of restricted range of motion, when measurable

at one point along the length of it

tender spot or by needle insertion into the tender spot

4. Pain alleviated by stretching

Minor Criteria

4. Pain alleviated by stretching or injecting the tender spot

myelopathy, or severe incapacitating pain; (3) a severe coexisting disease; (4) lack of ability to read English; (5) pain involving third-party liability or workers' compensation; or (6) mentally incapacitating condition or were unfit to provide informed consent or participate in an interview.

Each subject completed two 70-minute interviews between May 2005 and November 2005. The survey instruments in the interview included the self-administered paper-and-pencil version of the Short Form-36 Version 2 (SF-36 v2) health survey at baseline and at the end of therapy approximately 6 weeks later.

The SF-36 v2 is composed of multi-item scales designed to evaluate physical and mental health: physical functioning (10 items), role limitations caused by physical health problems (4 items), pain (2 items), general health perceptions (5 items), energy/fatigue (4 items), social functioning (2 items), role limitations caused by emotional health problems (3 items), and emotional well-being (5 items). Furthermore, the SF-36 has physical component summary (PCS) and mental component summary (MCS) scores that are weighted combinations of the 8 scale scores. The 8 scale scores and 2 summary scores are scored on a *T*-score metric, where the mean is fixed at 50 and the standard deviation is 10 in the US general population.<sup>13</sup>

Each participant in the Task Force on Neck Pain study was scheduled for 6 weekly follow-up visits and received usual evidence-based comprehensive care at the Center for chronic myofascial neck pain. Together with their physician, patients explored how they might incorporate positive lifestyle changes related to diet, exercise, <sup>14</sup> social support, stress and anger management, sleep hygiene, and other self-care strategies to restore resiliency. The treatment plan for all patients in the study started with trigger point injections with lidocaine <sup>15,16</sup> and acupuncture <sup>17-19</sup> performed by the physician. Repeat trigger point injections were performed for persistent pain. Evidence of partial improvements to the range of motion in any muscle area after an injection justified a repeat injection.

If the patient's condition did not improve within 3 visits, the patient was seen by the physician and another practitioner on each subsequent visit and received massage<sup>21</sup> in addition to trigger point injections and acupuncture. Ten of the subjects received massage therapy.

## **Analytic Methods**

Internal consistency reliability was estimated for the 8 SF-36 scales using a 2-way mixed (fixed item effect) effects model by

subtracting mean square error (interaction between respondents and items) from the mean square between, and dividing by the mean square between.<sup>22</sup> Reliabilities were estimated for the SF-36 PCS and MCS using Mosier's formula.<sup>23</sup>

We computed Student's (W. S. Gossett) t test to assess the significance of change for the sample. The within-group or dependent t test was computed as the average difference divided by the standard error of the difference. We estimated the significance of individual change using the reliable change index.  $^{24,25}$ 

#### Results

Of the 56 patients who were recruited for the neck pain utility study, 50 completed it and 6 were lost to follow up. Average age was 47 years, with a range of 23 to 63 years; 79% were women; and 70% were white, 10% were Hispanic, 10% were African American, and 10% were Asian.

Internal consistency reliabilities for the SF-36 v2 scales in this sample ranged from 0.76 (general health perceptions) to 0.95 (role limitations due to physical health problems). The estimated reliabilities of the PCS and MCS were 0.93 and 0.91, respectively (Table 2). Table 2 also shows SF-36 v2 scale scores at baseline and follow-up for the sample. Group change in the sample of patients with chronic myofascial neck pain was an increase of 2.6 on the PCS and 3.3 on the MCS. Mean changes in SF-36 v2 scores for the sample ranged from 2.0 (general health perceptions) to 3.7 (role limitations due to physical health problems). Statistically significant (P < .05) group mean improvement over time was found for each of the SF-36 v2 scales and 2 summary scores. The magnitude of the significant changes ranged from 0.19 (general health perceptions) to 0.43 (bodily pain) of a standard deviation. Individual statistically significant change occurred in 16% on the PCS (16% improvement, 0\% decline) and in 34\% on the MCS (26\% improvement, 8% decline) (Table 3).

#### **Discussion**

The analysis presented in this article describes the change in HRQOL of a series of patients with chronic myofascial neck pain. In this small sample, statistically significant improvement was demonstrated at the group level for all SF-36 v2 scores at 6 weeks after treatment began relative to baseline. At the individual level, of the possible changes on the SF-36 v2 scores, 17% represented significant improvement and 3% significant worsening (Table 3). Limitations of the study include small sample size, lack of a control group, only 2 data points for HRQOL, and lack of long-term follow-up.

An initiative to create a set of standards for conducting research on neck pain may help us better understand the factors that influence the onset, natural history, and clinical course of chronic neck pain. Prognosis for patients with chronic myofascial neck pain may also depend on strategies to cope with chronic pain by understanding disposing, triggering, maintaining, and health-promoting factors.

A task force convened by the National Institutes of Health to create research standards for chronic low back pain Brodsky et al

Table 2. Reliability Estimates and Baseline and Follow-up Short Form-36 Version 2 Scores in 50 Patients<sup>a</sup>.

	Reliability	Time I, M (SD)	Time 2, M (SD)	Change	t Test	Probability
Physical functioning	0.94	43.9 (11.7)	46.3 (9.9)	2.4	2.59	.0125
Role limitations due to physical health problems	0.95	40.6 (12.1)	44.3 (10.8)	3.7	3.78	.0004
Bodily pain	0.83	39.5 (7.7) <sup>^</sup>	42.7 (7.9) <sup>^</sup>	3.3	4.37	.0001
General health perceptions	0.76	43.3 (10.4)	45.3 (9.7)	2.0	2.69	.0096
Energy/fatigue	0.84	42.9 (11.0)	46.3 (12.1)	3.4	3.45	.0012
Social functioning	18.0	39.6 (10.8)	43.0 (10.6)	3.4	2.61	.0118
Role limitations due to emotional problems	0.90	39.2 (12.9)	42.6 (12.5)	3.3	2.16	.0361
Emotional well-being	0.80	42.5 (9.8)	45.5 (10.6)	3.0	2.77	.0078
Physical component summary (PCS)	0.93	42.7 (9.9)	45.3 (9.1)	2.6	3.67	.0006
Mental component summary (MCS)	0.91	40.9 (11.0)	44.2 (12.0)	3.3	2.67	.0103

alnternal consistency reliability was estimated for the 8 scale scores and Mosier's formula was used to estimate reliability of the PCS and MCS. Total sample is 50 cases.

**Table 3.** Number of People in Sample Significantly Declining or Improving on Short Form-36 Scale<sup>a</sup>.

	Declined	Improved
Physical functioning	1	6
Role-physical	3	П
Bodily	1	10
General	0	0
Energy	1	7
Social functioning	0	7
Role-emotional	4	14
Emotional well-being	1	7
PCS	0	8
MCS	4	13
$\sum /n*10$	15/500 = .03	83/500 = .17

Abbreviations: PCS, physical component summary; MCS, mental component summary.

recommended that the proportion of subjects achieving certain thresholds should be reported. 26 Neck pain—related thresholds may include prespecified percent improvement in pain or function, a certain number of points as the relevant change, or reaching some function or pain level. In addition, composite outcomes may include those with improvement in all parameters of pain, function, and global assessment. Investigators could report the proportion of subjects with these degrees of improvement in pain, function, and/or global assessment.

Using status at the follow-up to describe change in HRQOL at the group or individual level beyond statistical significance alone may be useful. For instance, guidelines published for the RAND-36 Health Status Inventory classified significant positive change as either (1) positive, but insufficient; (2) favorable; (3) very favorable; or (4) optimal.<sup>27</sup> In addition, we can learn more about the outcomes that are most important to patients with neck pain to help define clinically significant change that may vary in different subgroups.

In clinical settings, the lag between assessments of HRQOL to capture significant change varies among patients. A better idea of the optimal data collection points may emerge by measuring changes in HRQOL over different intervals in a large sample of patients who receive treatments for neck pain.<sup>28</sup>

#### **Conclusion**

HRQOL at the group level improved in a small series of patients with myofascial neck pain who received 6 weeks of treatment with a patient-centered, scientifically informed approach to improve pain and function. Significant change at the individual level was observed in a minority of study participants.

#### **Author Contributions**

MB: Conception and design of the work, acquisition of data for the work, drafting the work and revising it critically for important intellectual content, final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

KS: Design of the work, analysis and interpretation of data for the work, drafting the work and revising it critically for important intellectual content, final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

KKH: Conception of the work, acquisition of data for the work, revising the work critically for important intellectual content, final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

RDH: Conception and design of the work, analysis and interpretation of data for the work, drafting the work or revising it critically for important intellectual content, final approval of the version to be published, and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

#### **Declaration of Conflicting Interests**

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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<sup>&</sup>lt;sup>a</sup>Significant decline and improvement was based on the reliable change index. Total sample is 50 cases.

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## **Ethical Approval**

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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