Physical Medicine and Rehabilitation - International

Open Access

Austin Publishing Group

Special Article – Chronic Pain Management

Pain, Disability and Quality of Life in Chronic Nonspecific Neck Pain

Andrade-Ortega JA[1]*, Cerón-Fernández E[2], Ribeiro-González M[2], García-Llorent R[2], Almécija-Ruiz R[3] and Delgado-Martínez AD[4]

[1]Head of the Rehabilitation Service, Complejo Hospitalario de Jaén, Jaén, Spain

[2]Rehabilitation Service, Complejo Hospitalario de Jaén, Jaén, Spain

[3]Occupational Prevention, Fraternidad-Muprespa, Jaén, Spain

[4]Orthopedic Surgery Specialist, Associate Professor University of Jaén, Spain, Chief of Department of Orthopedic Surgery, Hospital "Reina Sofía", Córdoba, Spain

***Corresponding author:** Juan Alfonso Andrade Ortega, Complejo Hospitalario de Jaén, Av del Ejército Español, 10, 23007 Jaén, Spain

Received: July 22, 2016; **Accepted:** August 11, 2016; **Published:** August 16, 2016

Abstract

Introduction: In research on spine diseases, self-reported pain, disability and health-related quality of life (HRQoL) are usually primary evaluation tools. Our objective is to determine how pain, disability and (HRQoL) interact with each other over time in nonspecific chronic neck pain. Moreover, the minimum clinically important difference (MCID) is considered to help to understand the meaning of the changes.

Materials and Methods: 141 patients with nonspecific chronic neck pain who were treated in the Andalusian Public Health Care System (Spain). Outcome Measures: A) At baseline, after treatment and at six months: Pain (Visual Analogue Scale), Disability (Neck Disability Index) and HRQoL (SF-36: Physical Component Summary -PCS- and Bodily Pain -BP-); B) After treatment and at six months: Satisfaction.

Results: Correlation coefficients pain-disability were 0.54 (baseline), 0.80 (after treatment), and 0.71 (six months); pain-PCS: -0.36, -0.56, -0.54; pain-BP: 0.51, 0.62 and 0.51; disability-PCS: 0.75, 0.73 and 0.77. The satisfaction depended on the improvement in pain and disability, but not so clearly on PCS; it didn't depend on BP.

Conclusions: According to the MCID values, pain, disability and HRQoL don't go in the same direction in chronic nonspecific neck pain. The satisfaction doesn't depend on HRQoL.

Keywords: Neck pain; Disability evaluation; Quality of life; Patient satisfaction

Abbreviations

HRQoL: Health-related Quality of life; VAS: Visual Analogue Scale; MCID: Minimum Clinically Important Difference; SEM: Standard Error Mean; ROC: Receiver Operating Characteristic; NDI: Neck Disability Index; SF-36: Short Form Health Survey (SF-36); SF-36-PCS: SF-36-Physical Component; SF-36-BP: SF-36-Bodily Pain; FEDER: Fondo Europeo de Desarrollo Regional; FIBAO: Fundación de Investigación Biosanitaria de Andalucía Oriental.

Introduction

In the field of spine disorders, self-reports of pain, disability, and health-related quality of life (HRQoL) are usually the primary outcome measures. They are used in order to evaluate the patients' health and their response to treatment. Self-reported patient satisfaction is also a commonly used outcome measure [1]. Clinically relevant improvements in pain may lead to almost unnoticeable changes in disability or other related measures. For example [2], the strongest correlation between the pain visual analogue scale (VAS) and the Oswestry disability index occurs after spine surgery, but this correlation was still not considered strong (0.69). Varied correlations between pain, disability, and patient satisfaction in patients with chronic neck pain have been reported [3]: a moderate correlation was noted between disability and patient satisfaction and between disability and pain; a weak relationship was found between pain and patient satisfaction. These correlations tended to increase in the follow-up assessments. Therefore, all of these variables should be assessed separately when evaluating the effect of any form of treatment for back or neck pain [2-4].

Historically, clinical measures used to assess the effect of the treatment have primarily focused on reliability and validity. The issue of measures allowing us to detect change over time has not been widely studied. More recently, however, clinical relevance has received increasing emphasis in order to determine the practical (clinical) importance of a treatment, rather than just merely noting statistical significance [5,6]. Expressed as an average change for groups of patients, the response to treatment described in self-reports cannot adequately reflect the individual patient experience [7]. It's not only important to know whether results are statistically significant, but also whether they are relevant for patients or clinicians. Consequently, insight into clinically important differences or changes is needed [8].

In order to solve this situation, we use the minimum clinically important difference (MCID), which has been defined as the smallest change that is important to patients and proposed as a minimum threshold of improvement. Some authors prefer to use the term "minimal clinically important change" for the change in health status in patients and the term "minimal clinically important difference" to indicate differences between patients [8]. Four methods have been described to calculate the MCID [6]: consensus, anchor-based,

Citation: Andrade-Ortega JA, Cerón-Fernández E, Ribeiro-González M, García-Llorent R, Almécija-Ruiz R and Delgado-Martínez AD. Pain, Disability and Quality of Life in Chronic Nonspecific Neck Pain. Phys Med Rehabil Int. 2016; 3(4): 1094.

distribution-based, or a combination of anchor and distribution-based methods. In the anchor-based method, the pain (or any other related measures) scores are compared with an external, independent, face valid criterion, named "anchor", to determine a MCID. The anchor is usually a questionnaire with well-proven high reliability and validity in which patients report their level of improvement. The anchor can be used to create a receiver operating characteristic (ROC) curve, whose cutoff is the value for which the sum of percentages of false positives and false negatives is the smallest. Distribution-based methods measure the variability of a variable and determine which degree of change in that variable is generally of clinical importance. One distribution-based approach uses the standard error mean (SEM): due to the SEM value reflecting the imprecision of a measurement, a MCID value below the SEM would not reflect a true change.

Although this concept is not exempt from criticism [7], the assessment of clinically meaningful differences in patients' self-reported outcomes has become increasingly important when interpreting the results of clinical studies in patients with neck pain [5,7-13]. The minimal clinically important changes for pain severity have been explored in several publications. In patients with non-specific neck pain, improvements less than or equal to 15 points on the VAS scale could be seen as irrelevant [10]. In patients with chronic non-specific neck pain who were treated with cupping therapy [9] the MCID value was 8. After cervical spine fusion, this cut-off point was 25 [11]. The MCID values have also been explored for the Neck Disability Index (NDI); these varied from 3/50 in patients with chronic non-specific neck pain treated with cupping therapy [9] to 10/50 in patients with cervical radiculopathy [12]. This value was 7.5/50 in patients with mechanical neck disorders [10] and patients who underwent cervical spine fusion [11]. Cleland et al [13] reported a MCID of 7.0 using an anchor-based method for NDI in patients who underwent physical therapy for cervical radiculopathy. Pool et al [8] reported a value of 10.5/50 using an anchor-based method and a value of 3.5 using ROC analysis in patients with non-specific neck pain undergoing physiotherapy or continued care from a general practitioner. Regarding the HRQoL, the 36-item short form health survey (SF-36) is generally used. For the SF-36-physical component summary (SF-36-PCS) the calculated MCID varied from 2.6 to 4.1 [9,11]. For SF-36-bodily pain (SF-36-BP) the estimated value of MCID was 10 [9].

We have recently published a double-blind randomized controlled trial in which it was concluded that microwave diathermy does not provide additional benefit to a treatment regimen for chronic neck pain that already involves other treatment approaches [14]. Our main objective in the present paper is to determine how pain, disability and HRQoL interact with each other over time in the patients recruited for this trial regardless of which treatment arm each patient was assigned. A secondary objective is to consider this interaction by taking into account the MCID that have been measured in the above mentioned settings [8-13] in order to improve understanding the changes in pain, disability and HRQoL. Another secondary objective is to explore the differences between these changes according to the patients' satisfaction with the treatment.

Materials and Methods

149 patients with non-specific chronic neck pain participated in the abovementioned trial. In the current work, the patients participated regardless of the treatment arm each patient was assigned. Because of the failure of the treatment prescribed by the general practitioner, the patients were referred to the Department of Rehabilitation in a hospital of the Andalusian Public Health Care System in Jaén, Spain. Most people in Jaén, a rural area in southern Spain, are covered by the public health care system. The study was approved by the ethics committee of the hospital.

After signing the informed consent, every patient underwent 15 therapy sessions (5 per week, 3 weeks). Each session included, in this order: range of motion and isometric exercises, transcutaneous electrical nerve stimulation, and microwave diathermy. All patients were instructed to perform indefinitely the learned exercises at home. The details of the treatment are described elsewhere [14].

At baseline the following variables were recorded: age, sex, body mass index, and intensity of work activity ("light" for non physically demanding jobs, and "heavy" for physically demanding jobs). Housekeeping, highly represented in our sample, was included in the "heavy" category. The outcomes measures were neck pain intensity, disability due to neck pain, HRQoL and satisfaction with the treatment. Results concerning pain, disability and HRQoL were obtained at session 1, session 15, and at 6 months. Pain intensity was measured using VAS, the use of which is widespread [15]. Disability was measured according to the NDI; the Spanish version of the NDI has been validated [16,17]. The HRQoL was measured according to the SF-36 health survey; only PCS and BP values were considered. The Spanish version of the SF-36 has been validated [18]. At session 15 and at 6 months, patients' satisfaction with the treatment was also assessed according to a 5-point scale (very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, and very dissatisfied). The latter scale is one of the items of the NDI-based satisfaction questionnaire [19]. Given that no patient said to be dissatisfied or very dissatisfied, only two groups were considered for convenience in order to be analyzed: a) satisfied or very satisfied, and b) neither satisfied nor dissatisfied. The measurements taken at the beginning and on completion of treatment were collected at the hospital, whereas those taken at 6 months were collected by telephone or mail.

Statistical analysis was performed using R-Commander software (R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL: http://www.R-project.org/.). All quantitative variables were transformed to normal distribution (Kolmogorov-Smirnov test). The Pearson's r correlation test was used when linear correlation for paired numeric data was necessary. The Student's t-test was used for quantitative data to compare means. Statistical significance was set at the 5% level (two tailed).

Results and Discussion

Table 1 shows the main epidemiological features of our sample. Table 2 shows the values of pain (VAS), disability (NDI) and HRQoL (SF-36-PCS and SF-36-BP) at baseline, after treatment and at six months.

The correlation coefficients between pain and disability were r= 0.54 at baseline, r= 0.80 after the treatment and r= 0.71 at six months ($p<0.01$). The correlation coefficients between pain intensity and

Table 1: Baseline Values.

Baseline values	
n	149
Age, y*	44.2 SD 10.1
Males, n (%)	36 (24.1)
Females, n (%)	113 (75.9)
BMI†, kg/m²	24.9 SD 3.0
LA‡, n (%)	93 (62.4)
HA§, n (%)	56 (37.6)

*: years; †: Body Mass Index; ‡: Light activity; §: Hard Activity.

Table 2: Pain, Disability and Health-related Quality of Life during the study.

Pain, Disability and Health-related Quality of Life during the study			
	At baseline n = 149	After treatment n = 145	At 6 months n = 141
VAS*	53.5 SD 15.8	37.2 SD 21.5	37.3 SD 21.1
NDI†	34.4 SD 12.1	25.8 SD 14.5	23.3 SD 14.2
SF-36-PCS‡	49.8 SD 19.0	59 SD 21.7	58.9 SD 21.9
SF-36-BP§	42.1 SD 20.8	53.8 SD 23.6	51.9 SD 24.9

*VAS: Visual Analogue Scale; †: Neck Disability Index; ‡: Short Form-36-Physical Component Summary; §: Short Form-36-Bodily Pain.

HRQoL (PCS) were -0.36, -0.56, and -0.54, respectively ($p<0.01$). Even when only the correlation coefficients between pain intensity and the BP dimension were considered, the obtained values were rather low: -0.51, -0.62 and -0.51 respectively ($p<0.01$). The correlation coefficients between disability and HRQoL (PCS) were -0.75, -0.73 and -0.77 respectively ($p<0.01$). 121 patients (83.5%) were satisfied or very satisfied after treatment and 117 (83%) were satisfied or very satisfied at 6 months respectively.

Table 3 shows how the satisfaction with the treatment and the main outcome measures interact with each other.

Correlations between pain, disability and HRQoL were uneven. This issue has not often been addressed by researchers. Despite the bibliography occasionally showing a strong relationship between the HRQoL and disability in patients with neck pain [20], a less strong correlation is found elsewhere, e.g. in a systematic review about outcomes after spine surgery [2]. In this review, we can also find a poor correlation between the change in HRQoL and the change in pain outcome measures. Our data is in line with these correlations.

Chiu et al [3] conducted a longitudinal cohort study with a 6-month follow-up in 218 subjects. The correlation among these measurements was uneven: moderate correlation was noted between improvement in disability and patient satisfaction (r range: 0.50-0.65), and between disability and pain (r range: 0.55-0.63). A fair relationship was found between pain relief and patient satisfaction (r range: 0.43-0.48). The correlations tended to increase in the follow-up assessments. Our data only partly coincides with these findings. As described above, our patients greatly improved regarding disability and HRQoL-PCS, but not as clearly concerning pain and HRQoL-BP (Table 2).

Our results suggest that the effectiveness of therapeutic interventions should be interpreted depending on which outcome measure is considered. Pain relief in our patients could be considered

Table 3: Changes in outcome measures depending on the satisfaction with the treatment.

Changes in outcome measures depending on the satisfaction with the treatment				
	Global n= 145	Satisfied or very satisfied n= 121	Neither satisfied or dissatisfied n= 24	p*
Change in VAS after treatment	-16.3 (SD 19.1)	-19 (SD 19)	-0.8 (SD 10.9)	<0.001
Change in VAS at 6 months	-16.2 (SD 18.4)	-18.1 (SD 18.4)	-2 SD (11.4)	<0.001
Change in NDI after treatment	-8.6 (SD 11.8)	-10.6 (SD 11.1)	2.8 (SD 8)	<0.001
Change in NDI at 6 months	-11.1 (SD 11.4)	-12.8 (SD 10.3)	1 (SD 9.6)	<0.001
Change in SF-36-PCS after treatment	8.80 (SD 14.8)	9.9 (SD 15)	3.2 (SD 12.9)	0.042
Change in SF-36-PCS at 6 months	8.2 (SD 14.5)	9.3 (SD 14.7)	3 (SD 12.8)	0.052
Change in SF-36-BP after treatment	11.2 (SD 23)	11.3 (SD 23.9)	10.9 (SD 18.2)	0.946
Change in SF-36-BP at 6 months	9.1 (SD 23.3)	9.1 (SD 24)	8.9 (SD 20.3)	0.961

SD: Standard Deviation; *: Student's t.

as irrelevant if we keep in mind the published data about the MCID in non-specific neck pain [10]. However, disability improvement was unequivocal in terms of MCID, particularly after six months [8,10]. Nevertheless, the improvement was greater in HRQoL when MCID was considered [9,11]. In short, it seems that our patients achieved the best results in terms of HRQoL, while achieving good results in disability and average results in pain. Consequently, pain, disability and HRQoL measures may not always go in the same direction. However, satisfaction depends clearly on the improvement in pain and disability, and not as much on the change in SF-36-PCS (Table 3). Interestingly, the SF-36-BP values do not seem to be related to the patient's satisfaction. Unlike in Chiu's work, our correlations increased after treatment, but did not tend to increase in the follow-up assessments.

Our work presents some weaknesses. Firstly, in a chronic disorder, a longer follow-up would have yielded better results. Secondly, we have used MCID values obtained elsewhere to interpret our results. Ideally, we should have calculated these values for our own patients.

Conclusion

Correlations between pain, disability and HRQoL were uneven, mainly because of the poor correlation between the change in pain and the change in HRQoL outcome measures. This occurred even when only the bodily pain dimension was analyzed.

On the basis of MCID values, our patients achieved the best results in terms of HRQoL, while achieving good results in disability and average results in pain.

The patients' satisfaction with the treatment depended clearly on the improvement in pain intensity and disability. However, there was a very poor relationship between HRQoL and satisfaction.

Further studies are needed to clarify the relationship between pain, disability and other related measures, as well as to determine the role MCID and other related concepts may play.

Acknowledgement

The author would like to thank the members of FIBAO for their methodological and statistical advice.

References

1. Vavken P, Ganal-Antonio AK, Quidde J, Shen FH, Chapman JR, Samartzis D. Fundamentals of Clinical Outcomes Assessment for Spinal Disorders: Clinical Outcome Instruments and Applications. Global Spine J. 2015; 5: 329-338.
2. DeVine J, Norvell DC, Ecker E, Fourney DR, Vaccaro A, Wang J, et al. Evaluating the correlation and responsiveness of patient-reported pain with function and quality-of-life outcomes after spine surgery. Spine (Phila Pa 1976). 2011; 36: S69-74.
3. Chiu TT, Lam T, Hedley AJ. Correlation among physical impairments, pain, disability, and patient satisfaction in patients with chronic neck pain. Arch Phys Med Rehabil. 2005; 86: 534-540.
4. Kovacs FM, Abraira V, Zamora J, et al. Correlation between pain, disability, and quality of life in patients with common low back pain. Spine (Phila Pa 1976). 2004; 29: 206-210.
5. Gatchel RJ, Lurie JD, Mayer TG. Minimal Clinically Important Difference. Spine. 2010; 35: 1739-1743.
6. Katz NP, Paillard FC, Ekman E. Determining the clinical importance of treatment benefits for interventions for painful orthopedic conditions. Journal of Orthopaedic Surgery and Research. 2015; 10: 24.
7. Copay AG. Commentary: The proliferation of minimum clinically important differences. Spine J. 2012; 12: 1129-1131.
8. Pool JJ, Ostelo RW, Hoving JL, Bouter LM, de Vet HCW. Minimal clinically important change of the Neck Disability Index and the numerical rating scale for patients with neck pain. Spine (Phila Pa 1976). 2007; 32: 3047-3051.
9. Lauche R, Langhorst J, Dobos GJ, Cramer H. Clinically meaningful differences in pain, disability and quality of life for chronic nonspecific neck pain - a reanalysis of 4 randomized controlled trials of cupping therapy. Complement Ther Med. 2013; 21: 342-347.
10. Kovacs FM, Abraira V, Royuela A, Corcoll J, Alegre L, Tomás M, et al. Minimum detectable and minimal clinically important changes for pain in patients with non-specific neck pain. BMC Musculoskelet Disord. 2008; 10: 43.
11. Carreon L, Glassman S, Campbell M, Anderson PA. Neck Disability Index, short form-36 physical component summary, and pain scales for neck and arm pain: the minimum clinically important difference and substantial clinical benefit after cervical spine fusion. Spine J. 2010; 10: 469-474.
12. MacDermid JC, Walton DM, Avery S, Blanchard A, Etruw E, Mcalpine C, et al. Measurement properties of the neck disability index: a systematic review. J Orthop Sports Phys Ther. 2009; 39: 400-417.
13. Cleland JA, Fritz JM, Whitman JM, Palmer JA. The reliability and construct validity of the Neck Disability Index and patient specific functional scale in patients with cervical radiculopathy. Spine (Phila Pa 1976). 2006; 31: 598-602.
14. Andrade-Ortega JA, Cerón-Fernández E, García-Llorent R, Ribeiro-González M, Delgado-Martínez AD. Microwave diathermy for treating nonspecific chronic neck pain: a randomized controlled trial. Spine J. 2014; 14: 1712-1721.
15. Huskisson EC. Measurement of pain. Lancet. 1974; 2: 1127-1131.
16. Andrade-Ortega JA, Delgado-Martínez AD, Almécija-Ruiz R. Validation of a Spanish version of the Neck Disability Index. Med Clin (Barc). 2008; 130: 85-89.
17. Andrade-Ortega JA, Delgado-Martínez AD, Almécija-Ruiz R. Validation of the Spanish version of the Neck Disability Index. Spine. 2010; 15; 35: E114-118.
18. Alonso J, Prieto L, Antó JM. The Spanish version of the SF-36 Health Survey (the SF-36 health questionnaire): an instrument for measuring clinical results. Med Clin (Barc). 1995; 104: 771-776.
19. Hessler C, Boysen K, Regelsberger J, Vettorazzi E, Winkler D, Westphal M. Patient satisfaction after anterior cervical discectomy and fusion is primarily driven by relieving pain. Clin J Pain. 2012; 28: 398-403.
20. Carreon LY, Bratcher KR, Das N, Nienhuis J, Glassman SD. Estimating EQ-5D values from the Neck Disability Index and numeric rating scales for neck and arm pain. J Neurosurg Spine. 2014; 6: 1-6.

Phys Med Rehabil Int - Volume 3 Issue 4 - 2016
ISSN : 2471-0377 | www.austinpublishinggroup.com

Citation: Andrade-Ortega JA, Cerón-Fernández E, Ribeiro-González M, García-Llorent R, Almécija-Ruiz R and Delgado-Martínez AD. Pain, Disability and Quality of Life in Chronic Nonspecific Neck Pain. Phys Med Rehabil Int. 2016; 3(4): 1094.