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PRACTICAL CHRONIC PAIN ASSESSMENT TOOLS IN CLINICAL PRACTICE

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SUMMARY – The aim of the study was to show the role of tools in the evaluation of chronic pain (CP) in general practitioner (GP) everyday clinical practice. The study was done by analyzing electronic database of the first visits of 1090 CP patients referred to the Pain Clinic of the Karlovac General Hospital, Karlovac, Croatia, by their GPs. All patient records were analyzed according to the cause of CP, strongest pain a week before the examination, quality of sleep, and the Patients' Global Impression of Change scale. All statistical analyses were done using the IBM SPSS Statistics version 19.0.0.1 (www.spss.com). CP predominantly occurs in older age group. Patients with musculoskeletal pain accounted for the highest percentage (n=316; 29%), followed by those with neuropathic pain (n=253; 23.20%) and those with low back pain (n=225; 20.60%). The mean pain intensity rating scale score was 8.3±1.8 a week before the examination and the mean quality of sleep score was 6.8±1.9. Moderate and severe sleep quality disorder was significantly present in patients over 65 years of age (p=0.007), patients with musculoskeletal and neuropathic pain, back pain, and those having rated Patients' Global Impression of Change scale as worsening (p=0.001). The severity of pain and poor quality of sleep are the leading causes of deterioration of the Patients' Global Impression of Change scale in patients suffering from musculoskeletal and neuropathic pain. In order to treat CP comprehensively, it is important for GPs to evaluate the outcomes of clinical treatment using tools for CP assessment.

Key words: *Chronic Pain; Primary Care; Family Practice; Pain Measurement; Sleep*

Introduction

Chronic pain (CP) has a major impact on physical, emotional and cognitive function, on social and family life, and on the ability to work[1]. CP of moderate to severe intensity occurs in 19% of adult Europeans, seriously affecting the quality of their social and working lives[2-4]. Common chronic pain conditions affect a large percentage of the population in both developed and developing countries of the world[5]. Additionally, CP combined with increased mortality requires a deeper look at it as a public health problem[4].

The majority of patients with CP are treated by their general practitioner (GP). Only a small percentage is under the care of pain specialists[6]. Therefore, it is of extreme importance for GPs to be able to apply unique therapeutic guidelines and evaluate the effect of applied therapy in their patients. Numerous studies indicate the need of changes in the treatment of CP in family medicine[7-10].

Comprehensive evaluation of any chronic pain condition requires complete history of the pain, physical examination, specific diagnostic tests, and the application of chronic pain assessment tools[11,12]. Pain assessment is the basis of clinical research and

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effective treatment of pain. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials recommendations (IMMPACT) are primarily recommendations for improving the methodology of clinical trials. Having outcome measures that are practical enough to be applied to all patients is also important for everyday clinical practice. These measures should be comprehensive in order to be used in the evaluation of the patient's complaints and the physician's recommendations[11]. Pain intensity rating, quality of sleep, and patient ratings of improvement or worsening of the pain condition using the Patients' Global Impression of Change scale (PGIC) are all parts of the recommended tools to evaluate chronic pain. Despite the above, the fact is that these measures are very rarely used by GPs in their everyday clinical practice, but are mainly used as part of clinical trials. Not only do pain scales provide a recognized and validated method for tracking changes in pain intensity and the effectiveness of treatments, but they will also signal to the patient that the pain is taken seriously. The research by Breivik *et al.*[2] from 2006 showed that only 9% of respondents confirmed that their doctor used a pain scale.

Sleep disturbance is perhaps one of the most common complaints of patients with chronic pain conditions. Experimental studies of healthy persons and cross-sectional studies of clinical populations suggest the possibility that the interaction between sleep disturbances and pain is reciprocal, so that pain disrupts the continuity and quality of sleep, and poor sleep exacerbates the pain[13,14]. Various instruments are effective for measuring sleep disorders. Among the instruments used in clinical trials to examine sleep disturbances in patients with pain, the Pittsburgh Sleep Quality Index (PSQI) and the Medical Outcomes Study (MOS) sleep scale may be the best choice[15]. The sleep quality numerical rating scale can be used in everyday clinical practice. Assessment of the complete quality of sleep can be estimated by using this scale, and it is often employed to evaluate analgesic effects in patients with fibromyalgia[15].

The PGIC scale is recommended by IMMPACT for use in studies of chronic pain as a basic measure of global improvement in treatment. PGIC enables sensitive and easily-evaluated patient estimates in terms of the importance of deterioration and improvement. Respondents use this scale with seven possible answers (a seven-point rating scale): very significant improvement, significant improvement, minimal improvement, no change, minimal deterioration, significant deterioration, and very significant deterioration[12].

The aim of our study was to show the role of tools in the evaluation of chronic pain (PI-NRS, single-item Sleep Quality Numerical Rating Scale, PGIC) in everyday clinical practice of GPs, their influence on the assessment of therapeutic effect, and the possible need of change in therapeutic strategy. The secondary objective was to investigate the mutual effect of pain intensity and quality of sleep in the PGIC in certain groups of CP patients.

Patients and Methods

The study was done by analyzing the electronic database of the first examination of all patients treated at the Clinic for Pain and Palliative Medicine, Karlovac General Hospital in the period from September 24, 2008 to December 8, 2011. All patients were referred by their GPs due to chronic pain of malignant or benign origin. The research was given approval by the local ethics committee. Karlovac General Hospital is a county hospital in the Republic of Croatia with a catchment population of about 70,000. The proportion of people aged 65 and over in the total population of Karlovac County is 19.93% (15.62% in Croatia), and Karlovac County ranks among the counties with the oldest population in Croatia. Seventy-six teams of family physicians provide care for the given population.

The analysis included a total of 1090 patients. Data on the age, gender, and diagnosis of CP condition were collected and analyzed for each patient. Following the initial diagnoses by family physicians, patients were divided into five groups, as follows: musculoskeletal pain, headaches, neuropathic pain, low back pain, and malignant pain. In order to evaluate the effectiveness of previous therapy, the strongest pain a week prior to the examination was recorded at the initial examination, as well as the quality of sleep and PGIC. All analyzed data are required parts of the patient medical records collected by our outpatient clinic personnel.

The severity of chronic pain was measured using a numerical scale for pain on an 11-point numerical

pain intensity rating scale (PI-NRS), where 0 means no pain and 10 the worst possible pain. Taking into account the PI-NRS, patients were divided into four groups, as follows: no pain (0), mild pain (1-3), medium-severe pain (4-6), and very strong pain (7-10). A single-item scale was used to assess the overall quality of sleep. Patients reported the quality of their sleep on an 11-point numerical rating scale ranging from 0 (best possible sleep) to 10 (worst possible sleep). Given the quality of sleep, patients were divided into four groups, as follows: no sleep disturbances (0), mild sleep disturbance (1-3), mild to moderate sleep disturbance (4-6), and very strong sleep disturbance (7-10). The PGIC scale was recorded as the primary measure of global improvement of the applied treatment by the GP. This seven-answer scale (seven-point rating scale) is applied in everyday clinical practice in our surgery, but is divided into the following three categories: improvement, deterioration, and no change.

Data are shown in tables. Data distribution was analyzed using the Smirnov-Kolmogorov test and appropriate parametric tests, and descriptive statistics were used in succeeding analyses. Means and standard deviations were used to describe quantitative variables and frequencies, with overall percentage for categorical values. Between-group differences according to the quality of sleep were analyzed by the χ^2-test. Pearson correlation coefficients were calculated between PGIC scores and other clinical scores. All p values below 0.05 were considered significant. All statistical analyses were done using the IBM SPSS Statistics version 19.0.0.1 (www.spss.com).

Table 1. General descriptive statistics in study sample (N=1090)

Gender	Male: n (%)	376	34.50%
	Female: n (%)	714	65.50%
PGIC	Deterioration: n (%)	521	47.80%
	Without changes: n (%)	380	34.90%
	Improvement: n (%)	6	0.60%
	Missing: n (%)	183	16.80%
Diagnosis	Musculoskeletal pain: n (%)	316	29.00%
	Headaches: n (%)	138	12.70%
	Neuropathic pain: n (%)	253	23.20%
	Low back pain	225	20.60%
	Malignant pain	158	14.50%
PI-NRS	No pain: n (%)	0	0.00%
groups	Mild pain: n (%)	11	1.00%
	Secondary severe pain: n (%)	176	16.10%
	Very strong pain: n (%)	848	77.80%
	Missing: n (%)	55	5.00%
Quality of sleep	Without sleep disturbances: n (%)	0	0.00%
	A slight disorder: n (%)	68	6.20%
	Medium strong disorder: n (%)	244	22.40%
	Very strong disorder: n (%)	627	57.50%
	Missing: n (%)	151	13.90%
Age (yrs)	Mean ± SD	62.3	±15.3
PI-NRS	Mean ± SD	8.3	±1.8
Quality of sleep	Mean ± SD	6.8	±1.9

PGIC = Patients' Global Impression of Change; PI-NRS = numerical scale for pain on an 11-point numerical pain intensity rating scale; Quality of sleep on an 11-point numerical rating scale

Results

Table 1 shows general descriptive statistics of the sample of 1090 patients. In the examined sample, there were 714 (65.50%) women and 376 (34.50%) men, mean age 62.3±15.3 years. The most common reason for referral to a pain clinic by the GP was musculoskeletal pain in 316 (29.00%), neuropathic pain in 253 (23.20%), low back pain in 225 (20.60%), malignant pain in 158 (14.50%) and headache in 138 (12.70%) patients.

The mean strongest pain a week prior to the examination (PI-NRS) was 8.3±1.8. Eight hundred and forty-eight (77.80%) patients graded it as very strong pain, 176 (16.10%) as medium-severe pain and 11 (1.00%) as mild pain. Data on the severity of pain were missing for 55 (5.00%) patients.

The mean quality of sleep on the 11-point numerical rating scale was 6.8±1.9. Very strong quality of sleep disorder was present in 627 (57.50%), medium to mild in 244 (22.40%), and mild in 68 (20.6%) patients. None of the patients was free from sleep quality disruption. The overall improvement over therapy previously administered by their family doctor (PGIC) was rated as improved by 0.60%, no change by 34.90% and deteriorated by 47.80% of patients. Data were missing for 16.80% of patients.

Table 2 shows comparison of the values measured in groups with sleep quality disorder and categorical values (χ^2-test with Yates correction). It is clear that medium-strong and strong sleep quality disorders were not significantly more present in females (p=0.069), but had a higher incidence in the >65 age group (p=0.007). Patients who rated their PGIC as

Table 2. Comparison of measured values according to groups with sleep quality disorders (χ^2-test)

		Quality of sleep group						p
		Mild disorder		Medium-strong disorder		Very strong disorder		
		N=68		N=244		N=627		
		n	%	n	%	n	%	
Gender	Male	32	47.10	78	32.00	218	34.80	0.069
	Female	36	52.90	166	68.00	409	65.20	
Age: groups	<45	14	20.60	31	12.70	89	14.20	0.007
	45-55	22	32.40	48	19.70	102	16.30	
	55-65	11	16.20	46	18.90	145	23.10	
	>65	21	30.90	119	48.80	291	46.40	
PGIC1*	Deterioration	28	45.90	129	60.60	340	58.90	0.001
	Without changes	31	50.80	80	37.60	237	41.10	
	Improvement	2	3.30%	4	1.90	0	0.00	
Diagnosis	Musculoskeletal pain	19	27.90	73	29.90	186	29.70	0.008
	Headaches	19	27.90	25	10.20	68	10.80	
	Neuropathic pain	12	17.60	64	26.20	152	24.20	
	Low back pain	8	11.80	52	21.30	136	21.70	
	Malignant pain	10	14.70	30	12.30	85	13.60	
PI-NRS	No pain	0	0.00	0	0.00	0	0.00	0.140
	Mild pain	2	2.90	2	0.80	6	1.00	
	Medium severe pain	5	7.40	42	17.30	111	17.70	
	Very strong pain	61	89.70	199	81.90	509	81.30	

*Missing data on 183 patients; PGIC = Patients' Global Impression of Change; PI-NRS = numerical scale for pain on an 11-point numerical pain intensity rating scale; Quality of sleep on an 11-point numeric rating scale

aggravated had a significantly worse sleep quality (p=0.001) compared to those whose PGIC was rated as an improvement or no change. Medium-strong and severe sleep disturbance was more common in patients with musculoskeletal pain, neuropathic pain and back pain, whereas patients with headache had mild sleep disorder. The severity of pain did not affect the severity of sleep quality disorders. All patients with severe pain complained equally of all categories of sleep quality disorders.

Table 3 shows correlation of strongest measured pain scores and sleep with PGIC compared to diagnosis by Pearson correlation coefficient. There was a significant negative correlation between the strongest measured pain (r=-0431, p<0.001) and sleep scores (r=-0230, p<0.001) with PGIC in musculoskeletal pain. A significant negative correlation between the strongest measured pain (r=-0336, p<0.001) and sleep score (r=-0230, p<0.001) with PGIC was found in neuropathic pain. A significant negative correlation between the intensity of pain and PGIC was found for low back pain (r=-0390, p<0.001) and malignant pain (r=-0445, p<0.001), whereas there was no significant correlation with the quality of sleep and PGIC for these diagnoses. There was no correlation between headaches and PI-NRS and quality of sleep with PGIC.

Discussion

Our study showed that chronic pain usually occurred in older age groups. The mean age of our patients was 62.3±15.3 years, which was somewhat higher than the age analyzed in other studies available[2,5,16]. The reason for this is probably the older age structure in our county. Likewise, CP was more common in women (65.50%), which is comparable with the literature[2,5]. Considering the causes of CP, in our patients the most common one was musculoskeletal pain (29.00%), followed by neuropathic pain (23.20%) and low back pain (20.60%). These results are consistent with the research by Sjøgren *et al.*[17], which showed the musculoskeletal pain (66.8%) to be the most common cause of CP conditions. However, Tsang *et al.*[5] concluded that common pain conditions affected a large percentage of people in both developed and de-

Table 3. Correlations of the strongest measured pain and quality of sleep with PGIC compared with diagnosis (Pearson correlation coefficients)

Diagnosis			PI-NRS	Quality of sleep
Musculoskeletal pain	PGIC	Pearson correlation	-0.431	-0.23
		p	<0.001	<0.001
		n	260	244
Headaches	PGIC	Pearson correlation	-0.116	-0.092
		p	0.235	0.365
		n	107	99
Neuropathic pain	PGIC	Pearson correlation	-0.366	-0.198
		p	<0.001	0.004
		n	221	210
Low back pain	PGIC	Pearson correlation	-0.390	-0.016
		p	<0.001	0.826
		n	199	187
Malignant pain	PGIC	Pearson correlation	-0.445	-0.140
		p	<0.001	0.145
		n	116	110

PGIC = Patients' Global Impression of Change; PI-NRS = numerical scale for pain on an 11-point numerical pain intensity rating scale; Quality of sleep on an 11-point numeric rating scale

veloping countries, and back pain and headache were most common, with a higher incidence of CP conditions in women and older age groups. The mean strongest pain a week before the examination (PI-NRS) in our patients was 8.3±1.8. Very strong pain after the treatment administered by the GP was described by 77.80% of patients. Breivik *et al.*[2] report on one of five adult Europeans on average to suffer from CP, which is moderate in two-thirds and severe in one-third of cases. This suggests substantial underestimation in the treatment of CP in family medicine, poor therapeutic approach, and the need of education in the use of treatment guidelines and tools to evaluate CP.

Many studies indicate a connection between CP and sleep quality[13,18,19]. Among the many symptoms associated with pain, significant sleep disorder is one of the most common. It occurs in at least 50% of CP patients. Sleep disorder involves a combination of problems in initiating sleep, as well as maintenance or benefit of sleep. There is considerable evidence that inadequate sleep contributes to pain and *vice versa*. The fact is that the treatment of pain in clinical trials is combined with reduction of insomnia, daytime sleepiness, and suffering[15]. Sleep disorder has a bidirectional relationship with other features of CP. Previous clinical studies suggest that sleep and rest are frequently disturbed in patients with CP. Up to 88.9% of patients had at least one problem with sleep. Disruption of sleep correlates with stronger pain, depression, disability, and physical symptoms[19,20].

In order to evaluate the complete quality of sleep, we used a single-item sleep quality numerical rating scale in our study. Easy applicability makes it a suitable tool to evaluate the quality of sleep in everyday clinical practice. All our subjects had a sleep quality disorder. The mean quality of their sleep on an 11-point numerical rating scale was 6.8±1.9. Very strong disorder in the quality of sleep was present in 627 (57.50%), medium-strong in 244 (22.40%), and mild in 68 (20.6%) patients. Disruption of sleep quality was significantly present in patients aged over 65 (p=0.007), those with musculoskeletal pain, neuropathic pain, back pain, and those who had their PGIC evaluated as deteriorating (p=0.001). These data indicate the need of strategies in the treatment of CP, which should include evaluation and treatment of sleep quality correlated with age, gender, and the cause of CP. Goral *et al.*[14] have shown that chronic pain itself, or as a comorbidity with depressive and anxiety disorders, is associated with increased likelihood of sleep problems. Patients with CP have a two- to three-fold greater likelihood of sleep problems than those who do not suffer from CP or psychiatric disorders. The strong association of pain, depression, anxiety symptoms and sleep disorders suggests that some patients with pain require a comprehensive strategy with the aim of treating all three problems. Available clinical trials indicate that a significant number of patients who suffer from CP are not pleased with their examination, diagnosis, or treatment methods offered[2,17]. The PGIC is recommended by IMMPACT for use in the research on chronic pain as a basic measure of global improvements in treatment, or as the main outcome measure of global improvement in therapy[12]. Even using this tool to evaluate CP, 47.80% of our respondents estimated PGIC on 'previously conducted therapy with your GP' as aggravation.

It is the effectiveness of therapy, as well as the satisfaction of patients, which are considered essential outcomes of CP treatment. Correlation coefficients have shown that the PGIC is under strong negative impact of pain intensity in patients with musculoskeletal pain, neuropathic pain, low back pain, and malignant pain. That is, the absence of pain is one of the leading causes of PGIC worsening and, with headaches, there is no link between the PI-NRS and quality of sleep with PGIC. This supports the concept that the level of pain is the leading component of the global response of patients that integrates the effect of therapy (treatment), side effects, and patient expectations.

This concept was also proven by Farrar and Young[21]. Data collected from 2724 patients from 10 placebo-controlled clinical trials of pregabalin in diabetic polyneuropathy, post-herpetic neuralgia, low back pain, fibromyalgia, and osteoarthritis showed close correlation between changes in PI-NRS and the PGIC. These serve as an information that facilitates comparison of results between studies, but also helps determine the value of a given therapy in clinical practice. Equally so, by using Pearson correlation coefficient in our results, we showed the PGIC as a global outcome measure of improvements in therapy to be under strong negative impact of poor quality of sleep in patients with musculoskeletal and neuro-

pathic pain. There are only a small number of clinical trials showing that the experience of pain and other comorbid symptoms affects PGIC[21,22]. In a study investigating the interaction between changes in pain, depressive mood, physical function, vitality, sleep disorders, cognitive complaints, and PGIC in 1260 participants with fibromyalgia who had completed one of two clinical trials of safety and efficacy of milnacipran, Geisser *et al*.[22] demonstrated a very strong correlation between changes in clinical status and PGIC in many of these relationships. Therefore, it is likely that changes in other symptoms, along with pain perception, contribute to global improvement because of the intervention. The authors' findings suggest that the perception of improved clinical status is largely made up of a set of clinical parameters out of which pain is the most important.

Conclusion

Chronic pain is a disorder commonly encountered by the GPs, and the aging of the population will result in an increased prevalence of this diagnosis. For a comprehensive approach to treating CP by GPs, together with the application of clinical guidelines, it is important that clinicians evaluate clinical outcomes of treatment in a standardized framework. Tools to evaluate CP in daily clinical practice must be practical enough to evaluate everything the patients report and to provide clinicians with a comprehensive therapeutic approach. Subsequent studies should evaluate those most applicable for the treatment of CP in family medicine.

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Sažetak

PRIKLADNI ALATI ZA PROCJENU KRONIČNE BOLI U KLINIČKOJ PRAKSI

M. Lončarić-Katušin, M. Milošević, A. Žilić, P. Mišković, V. Majerić-Kogler i *J. Žunić*

Cilj istraživanja bio je pokazati ulogu alata za procjenu kronične boli u svakodnevnoj kliničkoj praksi obiteljskog liječnika. Istraživanje je provedeno analizom elektroničke baze podataka prvog pregleda 1090 bolesnika s kroničnom boli upućenih od obiteljskog liječnika u Ambulantu za bol Opće bolnice Karlovac, Karlovac, Hrvatska. Za sve bolesnike analizirani su uzrok kronične boli, najjača bol tjedan dana prije pregleda, kvaliteta sna i ljestvica općeg dojma bolesnika o promjeni. Statistička analiza je učinjena pomoću programa IBM SPSS Statistics ver. 19.0.0.1 (www.spss.com). Kronična bol se pretežito javlja u starijoj dobnoj skupini. Najzastupljeniji su bili bolesnici s mišićno-koštanom boli (n=316; 29%), potom oni s neuropatskom boli (n=253; 23,20%) i oni s bolnim leđima (n=225; 20,60%). Srednja najjača bol (*Pain Intensity Rating Scale*, PI-NRS) tjedan dana prije pregleda bila je 8,3±1,8, a kvaliteta sna 6,8±1,9. Srednje jaki i jaki poremećaj kvalitete sna značajnije je prisutan kod bolesnika iznad 65 godina starosti (p=0,007), bolesnika s mišićno-koštanom, neuropatskom boli i bolnim leđima te onih koji su prema ljestvici općeg dojma bolesnika o promjeni ocijenili kao pogoršanje (p=0,001). Jačina boli i loša kvaliteta sna bili su vodeći uzrok pogoršanja prema ljestvici općeg dojma bolesnika o promjeni za bolesnike koji boluju od mišićno-koštane i neuropatske boli. Radi sveobuhvatnog liječenja važno je da obiteljski liječnici procijene ishode kliničkog liječenja alatima za procjenu kronične boli.

Ključne riječi: *Kronična bol; Obiteljska medicina; Bol, mjerenje; San*