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Interobserver reliability of diagnosis in patients with complex regional pain syndrome

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Abstract

Complex regional pain syndrome type I (CRPS-I), formerly reflex sympathetic dystrophy (RSD), is a chronic pain syndrome of unknown aetiology. Its diagnosis is a clinical one, for which several criteria systems have been defined. Despite their widespread use, the reliability of these criteria has never been studied. In this interobserver study 25 chronic CRPS patients were interviewed and examined by six physicians. Through structured questionnaires signs, symptoms, and diagnosis were recorded, after which observer agreement for these was calculated with κ statistics. Physicians' agreement in assessment of signs and symptoms in CRPS patients varied greatly. More importantly, final diagnosis of CRPS showed poor observer agreement (κ: 0.20). The κ values were higher, had physicians applied IASP criteria, but still insufficient. The application of Bruehl's criteria results in a fair κ of 0.38, but then frequency of CRPS diagnosis in our study population decreased from 73% to 43% in comparison with physicians' own diagnosis. We conclude that, using current criteria systems, the diagnosis of CRPS is not reliable.

Keywords: Reflex sympathetic dystrophy; Criteria validation; Interobserver agreement; κ values; Physical examination; Clinical diagnosis

1. Introduction

Complex regional pain syndrome type I (CRPS-I), formerly reflex sympathetic dystrophy (RSD), is a chronic pain syndrome of unknown aetiology. It is usually characterised by pain, swelling, autonomic dysregulation and chronic functional impairment after a trauma of the affected limb. The diagnosis of CRPS is a clinical one. A gold standard in the form of an objective test is not available (Blumberg and Hoffmann, 1992; Casale and Elam, 1992; Glynn and Casale, 1993; Low et al., 1994; Kurvers et al., 1995; Lee and Weeks, 1995; Baron et al., 1996; Bruehl et al., 1996; Birklein et al., 1997; Gulevich et al., 1997; Masson et al., 1998; Sandroni et al., 1998). Although diagnostic criteria for CRPS have been formulated (Kozin et al., 1981; Amadio et al., 1990; Bonica, 1990), none is generally used. The International Association has developed the most official criteria system for the Study of Pain, IASP (Merskey and Bogduk, 1994). As far as we know three validation studies on these CRPS criteria have been published (Galer et al., 1998; Bruehl et al., 1999; Harden et al., 1999). These studies address the validity of IASP criteria as to their specificity in delineating CRPS from other neuropathic pain syndromes. However, the distinction between CRPS and other neuropathic pain syndromes, e.g., postherpetic neuralgia and diabetic polyneuropathy, is not a diagnostic problem in daily clinical practice. The main clinical problem is interphysician variability in CRPS diagnosis. This is due to the variability in observed signs, symptoms and the amount of signs, symptoms and credibility in patients needed to reach the diagnosis CRPS. Until now, interphysician agreement studies of diagnosis in CRPS

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patients have not been done. Herein we report a study with 6 physicians examining 25 patients, to assess interobserver variability in diagnosing CRPS.

2. Subject and methods

2.1. Subjects

Twenty-five patients who visited our outpatient clinic for pain management in the preceding four years participated in the study. They had been at random selected from a database with patients once diagnosed as CRPS or RSD. All patients were informed about this diagnosis and had received some treatment for it and remained to have pain and other symptoms despite CRPS treatment. All patients gave informed consent. The Institutional Review Board of the University Hospital Maastricht approved the study.

2.2. Study design

Six physicians (three anaesthesiologists, two surgeons and one neurologist) with known experience on CRPS participated in the study. They were instructed to take a semi-structured interview and perform a physical examination of the patient scoring absence or presence of signs and symptoms by yes/no (Suylekom et al., 1999). The observers were free to ask additional questions to obtain adequate information. Finally they estimated the patient's pain and filled in a diagnosis according to their own clinical view. No instructions were given about CRPS diagnostic criteria. Physicians were not allowed to discuss any aspect of the study with each other. The items for interview and physical examination had been selected by collecting symptoms and signs from published RSD criteria (Kozin et al., 1981; Amadio et al., 1990; Bonica, 1990; Veldman et al., 1993), the IASP classification of pain (Merskey and Bogduk, 1994) and the Neuropathic Pain Scale (Galer and Jensen, 1997) (list available upon request). After interview and examination physicians were asked to give their diagnosis. They were instructed to select one of the following: CRPS 1,CRPS 2, CRPS 3 (pain and sensory, motor and/or tissue abnormalities not otherwise specified), (diabetic) polyneuropathy, radiculopathy, myofascial pain, nerve entrapment, (Boas, 1996), somatoform pain disorder, (idiopathic) pain not otherwise specified. The questionnaire contained 35 CRPS symptoms and 27 CRPS signs (see Tables 1 and 2). The study was set up in three sessions with six patients and one session with seven patients. To limit the fluctuation in time of signs between successive physical examination, the six observers successively saw all patients within approximately 2 h, but examination varied from 10 to 20 min per patient. Because some patients had more than one affected extremity, physicians were asked to focus on the most affected limb. Test results like EMG, laser Doppler flow-metry, and three-phase bone scanning were not provided. Temperature difference of the skin of both extremities was measured manually.

Diagnostic criteria for CRPS type I are identical to CRPS type II in which nerve damage is proven. Therefore we consider CRPS patients in this report as patients with either CRPS type I or type II. Preliminary data suggest that CRPS type I patients do not differ from CRPS type II patients in signs, symptoms and therapy results (Alexeyev et al., 1999; Bruehl et al., 1999). We compared expert-based diagnosis with diagnosis using criteria systems (the official IASP criteria and the most recently proposed CRPS criteria of Bruehl et al. (Merskey and Bogduk, 1994; Bruehl et al., 1999).

2.3. Statistical analysis

Data were analysed in the following steps:

1. Analyses of interobserver agreement on signs and symptoms by group κ and percentage of agreement, measured by a generalised κ statistics for more than two raters (group κ) (Schouten, 1986). In the group κ coefficient, the average observed agreement is compared to the average chance agreement, with the average taken over all pairs of expert-physicians and over all patients. κ values range from -1 to 1. Positive values show certain agreement beyond chance agreement. κ values were classified as slight ($\kappa = 0.00$–0.20), fair ($\kappa = 0.21$–0.40), moderate ($\kappa = 0.41$–0.60), substantial ($\kappa = 0.61$–0.80) and almost perfect agreement ($\kappa = 0.81$–1.0) (Landis and Koch, 1977).
2. Analysis of interobserver agreement in expert-based diagnosis (group κ).
3. By applying the official IASP criteria (Merskey and Bogduk, 1994) and the CRPS criteria of Bruehl et al. (Bruehl et al., 1999) on our data sets we compared criteria-based diagnosing with expert-based diagnosing (see Appendices A and B for criteria sets). IASP and Bruehl diagnostic criteria were applied in the 150 datasets (Merskey and Bogduk, 1994; Bruehl et al., 1999). This resulted in new interobserver agreement values for criteria-based diagnosing and CRPS prevalences. These were compared with κ value for interobserver agreement in expert-based CRPS diagnosis (Cohen, 1960).
4. IASP and Bruehl diagnostic criteria were applied to the 150 datasets containing signs and symptoms(Bruehl et al., 1999). This resulted in new frequencies of CRPS diagnoses. These were compared with expert-based CRPS frequencies.
5. The value of patient's symptoms in CRPS diagnosis is unknown. We analysed the effect on the frequency of CRPS diagnosis, when reported symptoms instead of objective signs were applied in criteria systems.

Table 1
Group κ, interobserver agreement for CRPS symptoms and frequency of symptoms in experts' diagnosis (%)

	Group κ	Observer agreement	Frequency in subjects
Continuous (spontaneous) pain	–	0.97	0.94
Dysesthesia	–	0.93	0.96
Functional impairment	–	0.94	0.96
Cold or warm sensation in affected limb	–	0.94	0.97
Pain aggravated with cold and/or heat	–	0.92	0.94
Decreased range of motion	–	0.91	0.96
Start after phys.l trauma or relevant disease	–	0.90	0.95
Pain outside original affected area	–	0.90	0.95
Loss of strength	–	0.97	0.99
Aggravation of pain with stress	0.86	0.94	0.36
Anhydrosis/hyperhidrosis	0.80	0.91	0.67
Changed nailgrowth	0.79	0.90	0.65
Superficial pain	0.73	0.88	0.67
Burning pain	0.71	0.86	0.60
Sympathetic block diminished complains	0.69	0.90	0.21
Pain upon soft touch (mechanical allodynia)	0.67	0.85	0.65
Throbbing pain	0.66	0.86	0.70
(Spontaneous pain) in one extremity	0.65	0.87	0.75
Changed hair growth	0.59	0.82	0.31
Spontaneous sensations (paresthesias)	0.58	0.80	0.60
Colour changes	0.57	0.86	0.79
Deep pain	0.55!	0.90	0.88
Hypersensibility to touch (hyperesthesia)	0.51	0.81	0.73
Sharp pain	0.50	0.80	0.72
Cold pain	0.47	0.75	0.63
Swelling (edema)	0.40	0.75	0.72
Tremor	0.37	0.72	0.32
Start after immobilization	0.35	0.72	0.31
Skin temperature asymmetry	0.33!	0.81	0.83
Concentrate to move (motor neglect)	0.30	0.70	0.69
Guarding' of affected extremity	0.29!	0.83	0.87
Provoked pain last longer (hyperpathia)	0.28!	0.85	0.89
Hypesthesia	0.25!	0.77	0.81
Limb movements are painful (acute)	0.25!	0.82	0.86
The use of limb aggravates pain (delayed)	0.21!	0.81	0.86

Dash (–) indicates κ cannot be calculated (frequency of <10% or >90 of patients). Exclamation point (!) indicates frequency of 10–20% or 80–90% (see Section 2).

3. Results

Twenty-five patients with a mean age of 42.3 years (23–65 years) participated of whom 18 had upper extremity involvement and seven lower extremity involvement. Twenty-three patients were women. Duration of symptoms had a median of 39 months (range 5–168 months). Therefore some of these patients will be considered by some as late stage CRPS, although it is unclear how to differentiate between acute stage and late stage CRPS. All patients would consider themselves as having CRPS, because at least once a physician considered them as having CRPS and treated him/her as such.

All patients were diagnosed as CRPS-I by at least one observer. CRPS type I was diagnosed in 99 (67%) assessments, CRPS II in 11 (7%), CRPS III in 15 (10%), somatoform disorder in 17 (11%), and myofascial pain or idiopathic pain not otherwise specified in eight cases.

3.1. Observer agreement in signs and symptoms

κ values, observer agreements and frequencies of potential diagnostic criteria are shown in Table 1 (interview) and Table 2 (physical examination). κ values of signs and symptoms ranged from fair to moderate. κ value has not been calculated in those instances with a prevalence of findings being less than 10% or more than 90%. These κ values would have been affected by the extreme prevalences. In these cases, only percentages of agreement uncorrected for chance agreement are given (van Triet et al., 1990).

3.2. Interobserver agreement in CRPS diagnosis

We expected κ values would increase if experts had applied criteria systems. To evaluate the validity of these criteria systems, we applied physicians' findings in the interview and examination to diagnose according to

Table 2
Group κ, interobserver agreement for CRPS signs and frequency (%) of signs in experts diagnosis

	Group κ	Observer agreement	Frequency in subjects
Functional impairment	–	0.96	0.95
Decreased range of motion	–	0.94	0.93
No dermatome related symptoms	–	0.93	0.96
Changed reflexes	–	0.88	0.08
Cervical, or in case of legpain lumbar, ipsilateral pressure pain paravertebrally	0.58	0. 79	0.53
Changed hair growth	0.54!	0.88	0.16
Tremor	0.53!	0.91	0.11
Pain after with movement (passive/active)	0.51!	0.90	0.89
Pain upon soft touch (mechanical allodynia)	0.50	0.77	0.64
Edema	0.41	0.73	0.35
Changed nailgrowth	0.37	0.70	0.39
Hypersensibility	0.34	0.67	0.58
Colour changes	0.33	0.67	0.54
Sympathetic disregulation	0.28	0.67	0.65
Dysesthesia	0.27	0.71	0.73
Thoracal paravertebral pressure pain	0.25!	0.81	0.14
Anhydrosis/hyperhidrosis	0.23	0.65	0.33
Skin temperature asymmetry	0.23	0.62	0.59
Dystrophy or atrophy cutis/subcutis/muscles	0.22	0.61	0.47
Guarding of affected extremity	0.20	0.67	0.73
Dystonia	0.15	0.63	0.30
Pain aggravates with cold and/or heat	0.11	0.68	0.80
Sensory deficit	0.11	0.66	0.75
Hperpathia	0.10	0.66	0.77
Hyesthesia	0.08	0.54	0.57
Loss of strength	0.02!	0.77	0.87
Neurological disorder in affected extremity	0.02	0.47	0.49
Credibility of patients' complaints	0.22	0.71	0.76
Pain behavior	0.12	0.56	0.40
Diagnosis	0.20	0.57	0.73

Dash (–) indicates κ cannot be calculated (frequency of <10% or >90 of patients). Exclamation point (!) indicates frequency of 10–20% or 80–90% (see Section 2).

Table 3
κ value in CRPS diagnosis

	κ	C.I. (95%)	Observ.
Expert-based diagnosis	0.20	0.06–0.33	0.57
IASP sign-based criteria	0.29	0.03–0.55	0.74
Bruehl sign-based criteria	0.35	0.15–0.55	0.68
Bruehl sign and symptom based	0.38	0.18–0.58	0.74

C.I. is confidence interval; (Observ. = observer agreement).

IASP and Bruehl's diagnostic criteria. Table 3 shows that κ values for diagnosing CRPS and idiopathic, CRPS-like, pain syndromes between the different pairs of observers resulted in a group κ of 0.20 (CI: 0.06–0.33) in expert-based diagnosis, but if IASP was applied, κ value rose to 0.29 (CI: 0.03–0.55). If Bruehl's diagnostic criteria were applied κ value rose to 0.38 (CI: 0.18–0.58) (see Table 3). Interphysician agreement on diagnosis varied from 0.07 to 0.30 (Table 4).

3.3. Frequency of CRPS diagnosis

Since signs in CRPS can fluctuate in time, physicians, in general, use both reported symptoms and physical examination for diagnosis. We analysed the validity of the use of subjective reported symptoms (symptom-based) in diagnosing. Bruehl's diagnostic criteria consist of two parts: symptoms and sign-based criteria. We applied these Bruehl's criteria, but we both calculated CRPS frequency when the signs and symptom criteria were synchronously applied, when only reported symptoms were applied and when only the sign-based criteria were applied (Table 5). Symptom-based IASP criteria resulted in a CRPS frequency of 98%. Frequency of CRPS diagnosis with Bruehl's criteria did not change much, if besides sign-based criteria also the symptom-based criteria were applied. When Bruehl's criteria were applied on our 150 datasets, 65 times CRPS-I/II would

Table 4
κ values between physicians in diagnosing patients suspected for having CRPS

	Physician 2 (surg.)	Physician 3 (surg.)	Physician 4 (anesth.)	Physician 5 (anesth.)	Physician 6 (neur.)
Physician 1 (anest.)	0.27	0.12	0.15	0.29	0.30
Physician 2 (surg.)		0.30	0.07	0.05	0.15
Physician 3 (surg.)			0.13	0.26	0.17
Physician 4 (anesth.)				0.18	0.25
Physician 5 (anesth.)					0.23

Anesth. is anesthesiologist; Surg. is surgeon; Neur. is neurologist.

Table 5
Frequency of CRPS diagnosis in 150 datasets

Expert-based diagnosis[a]	110/150	CRPSI/II (73%)
IASP-symptom based	147/150	CRPS I/II (98%)
IASP-sign based	114/150	CRPS I/II (76%)
Bruehl-symptom based	130/150	CRPS I/II (87%)
Bruehl-sign based	67/150	CRPS I/II (45%)
Bruehl complete	65/150	CRPS I/II (43%)

[a] Expert (view) based diagnosis is an experience-based diagnosis without any application of criteria systems.

be diagnosed, but symptoms were essential in only 2 out of 150 patient assessments (1.3%) to meet the Bruehl's diagnostic criteria for CRPS (see Table 5).

4. Discussion

CRPS is a clinical diagnosis for which criteria have been formulated. Until now interphysician agreement of the diagnostic process had not been studied. In this study we tried to assess the reliability and validity of CRPS diagnostic criteria. To this end we asked six different experienced physicians to interview and examine 25 possible CRPS patients. We felt that this set-up most closely resembles daily practice, although certain biases cannot be ruled out. One possible bias is caused by patient selection: all patients were chronic CRPS patients. According to earlier studies only minority of CRPS patients remains chronic. Also in chronic cases the symptom-based criteria may overwhelm sign-based criteria. Another bias may be caused by repetitive examination of the affected limb by different observers. We do not think that they seriously affected our conclusions, as the last examination in each session did not differ significantly form the first ones (data not shown).

We found that interobserver agreement is reasonable for symptoms, but low for signs in our population with possible CRPS patients. Assessments of edema, hair growth and mechanical allodynia showed moderate agreement. κ values for signs should preferably be more than 0.40 (moderate agreement), when dealing with criteria for a diagnosis (Bogduk, 1997). κ value for edema in our population was comparable with κ value (0.47) for edema in juvenile rheumatoid arthritis (Guzmán et al., 1995). Perhaps κ values would have been higher in a population of recent CRPS patients, although Oerlemans et al. were not able to find agreement in subjective reports of skin temperature and objective measurements in patients with more acute CRPS (Oerlemans et al., 1999, 2000).

Reaching a final diagnosis of CRPS, according to the experts, reached a κ value of only 0.20 (Table 3). These κ values between pairs of physician varied from 0.07 to 0.30. These variations did not correlate with their specialty, i.e., agreement among surgeons was not better than that among anesthesiologists (Table 4). Diagnosing CRPS in our study was thus as reliable as diagnosing pneumonia with stethoscope and percussion, but without X-ray (Wipf et al., 1999). This poor observer agreement is less than other difficult clinical diagnoses as medical fitness for a job ($\kappa = 0.37$) and shoulder disorders ($\kappa = 0.45$)(de Kort et al., 1992; de Winter et al., 1999). The application of standardized instruments to measure for example edema, skin temperature or sensory abnormalities might improve diagnostic reliability further, but until now these results have been disappointing (Oerlemans et al., 1999, 2000).

Since the application of criteria systems often improves observer agreement in diagnosis, we calculated κ's for diagnosis when IASP and newly proposed criteria of Bruehl were applied to the data (Table 3). Agreement did indeed rise to almost moderate level if IASP or Bruehl's criteria were applied. Bruehl's criteria resulted in a fair κ value of 0.38 and the specificity of CRPS diagnosis increased too. CRPS frequency decreased to 43% in comparison to frequency of CRPS (73%) in experts' diagnosis (Table 4). Therefore, the option to increase specificity might be beneficial for research goals, but the concordant decrease in sensitivity probably limits the clinical value of Bruehl's criteria. In an effort to identify signs and symptoms with a major impact on the CRPS diagnostic process, we performed a logistic regression analysis on our dataset (data not shown). We were not able to find any signs or symptoms crucial for the diagnosis of CRPS. This accords with Veldman who found that sympathic signs and symptoms (like hyperhidrosis, hypertrichosis, and changed nail growth) as single entities do not contribute significantly to the diagnosis of CRPS (Veldman et al., 1993).

The remaining question is whether, with our current knowledge, valid CRPS criteria for clinical practice can be developed at all. Further studies are needed to develop other methods to diagnose CRPS.

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Appendix A. Diagnostic criteria in CRPS

Diagnostic criteria in CRPS type I (Stanton Hicks et al., 1995)

1. The presence of an initiating noxious event, or a cause of immobilization.
2. Continuing pain, allodynia, or hyperalgesia with which the pain is disproportionate to any inciting event.
3. Evidence at some time of edema, changes in skin blood flow, or abnormal sudomotor activity in the region of the pain.
4. This diagnosis is excluded by the existence of conditions that would otherwise account for the degree of pain and dysfunction.

Note. Criteria 2–4 must be satisfied (Merskey and Bogduk, 1994).

Appendix B. Criteria of Bruehl: research diagnostic criteria for CRPS

1. Continuing pain which is disproportionate to any inciting event.
2. At least one symptom in each of the following categories:
   Sensory: reports of hyperesthesia.
   Vasomotor: reports of temperature asymmetry and/or skin colour changes and/or skin colour asymmetry.
   Sudomotor/oedema: reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin).
3. At least one sign in two or more of the following categories:
   Sensory: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch).
   Vasomotor: evidence of temperature asymmetry and/or skin colour changes and/or asymmetry.
   Sudomotor/oedema: *evidence* of oedema and/or sweating changes and/or sweating asymmetry.
   Motor/trophic: evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin).

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