# Establishing the prognosis for patients with chronic Complex Regional Pain Syndrome: the value of the CRPS-UK Registry.

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| Abstract: | Objective: The long term prognosis of patients with Complex Regional Pain Syndrome (CRPS) is unknown with no reported prospective studies from the UK longer than 18 months. The CRPS-UK Network aims to study this by use of a Registry. The aims of this paper are to outline the CRPS-UK Registry; assess the validity of the data; and to describe the characteristics of a sample of the UK CRPS population.<br>Methods: A Web-based CRPS-UK Registry was developed and made accessible to centres experienced in diagnosing and managing patients with CRPS. Pragmatic annual follow-up questions were agreed.<br>Results: As from July 2013, the Registry has recruited 240 patients. A blinded, randomly selected, validation study demonstrated 95.6% completion and 99.4% accuracy of a random sample of the recorded data. These patients have chronic disease (median duration 29 months); 72.5% were female (2.6:1), with a mean age at symptoms onset of 43 years, and were left-handed more than expected (21.8% versus 10% in the general population). Patients reported a delayed diagnosis, with the median time between symptom onset and diagnosis of 6 months. Thirty patients (12.5%) had multiple limb involvement and most of them (83.3%) had either a unilateral or contralateral spread of CRPS.<br>Conclusion: CRPS-UK Registry is a validated method for actively recruiting well-characterised patients with CRPS to provide further information on the long term outcome. |
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## Abstract

*Objective*: The long term prognosis of patients with Complex Regional Pain Syndrome (CRPS) is unknown with no reported prospective studies from the UK longer than 18 months. The CRPS-UK Network aims to study this by use of a Registry. The aims of this paper are to outline the CRPS-UK Registry; assess the validity of the data; and to describe the characteristics of a sample of the UK CRPS population.

*Methods*: A Web-based CRPS-UK Registry was developed and made accessible to centres experienced in diagnosing and managing patients with CRPS. Pragmatic annual follow-up questions were agreed.

*Results*: As from July 2013, the Registry has recruited 240 patients. A blinded, randomly selected, validation study demonstrated 95.6% completion and 99.4% accuracy of a random sample of the recorded data. These patients have chronic disease (median duration 29 months); 72.5% were female (2.6:1), with a mean age at symptoms onset of 43 years, and were left-handed more than expected (21.8% versus 10% in the general population). Patients reported a delayed diagnosis, with the median time between symptom onset and diagnosis of 6 months. Thirty patients (12.5%) had multiple limb involvement and most of them (83.3%) had either a unilateral or contralateral spread of CRPS.

*Conclusion:* CRPS-UK Registry is a validated method for actively recruiting well-characterised patients with CRPS to provide further information on the long term outcome.

## Introduction

Complex Regional Pain Syndrome (CRPS) is a disabling, usually post-traumatic condition, characterised by severe pain and changes in the appearance of a limb (see Diagnostic Criteria). Community studies have demonstrated an incidence of CRPS of between 5 (USA) and 20 (The Netherlands) per 100,000 population, with 70-80% having resolution of their symptoms within 1 year [1,2]. Approximately 25% of patients will have unrelenting pain for more than 1 year after the onset of symptoms with effects on employment, quality of life, activities of daily living and mood. In the UK therefore, up to 10,000 adults have experienced CRPS for longer than 1 year. What is their prognosis?

No UK prospective studies have followed patients with CRPS for more than 1 year after symptom onset despite the condition being significantly associated with a poor quality of life. In 2008, the CRPS-UK Network, a group of rheumatologists, anaesthetists, allied health professionals and researchers interested in this condition, established the CRPS-UK Registry. This 35-year project will complement other international Registries; provide prognostic information for a cohort of patients diagnosed with CRPS in the UK in the 21st Century; and provide a resource for further studying this condition. The aims of this paper are to outline the CRPS-UK Registry; assess the validity of the data; and to describe the characteristics of a sample of the UK CRPS population.

Three prospective studies have examined long term outcomes of patients with CRPS. Vaneker *et al* followed 45 patients with upper limb CRPS diagnosed using the

Veldman criteria for 8 years using the validated Impairment Level Sumscore (ISS) [3]. Temperature and range of movement scores had improved whereas the global ISS had no significant change. In the randomised controlled trial by Kemler *et al*, 64 patients with CRPS reported pain scores of 4-6/10, five years after recruitment [4]. Zyluk published a single-centre follow-up of 27/30 patients with reflex sympathetic dystrophy in Poland followed for 13 months on average [5]. Pain and swelling resolved but some patients were still functionally weak. Four retrospective reviews have noted the outcomes of patients with CRPS. Geertzen *et al* studied 65 patients finding that 62% of patients were still limited in their activities of daily living 5 years after diagnosis [6]. Galer *et al* surveyed 31 patients with a mean duration of symptoms of 3.3 years [7]. Pain levels ranged between 3.9-7.3/10 with an average of 5.9. Field *et al* published a cohort of 100 Colles fracture patients with 55 having had a follow-up at 10 years [8]. 6 patients were identified to have finger stiffness 12 weeks after fracture. All 6 continued to have evidence of CRPS (algodystrophy) at 10 years. Finally, de Mos *et al* identified 102 CRPS patients from the Dutch general practitioners database who had had symptoms for an average of 5.8 years [9]. 16% reported the CRPS as still progressive and 31% were incapable of working.

Taken together, these studies suggest a poor outcome for patients with CRPS existing more than one year. Poor follow-up, small numbers and inexact diagnostic criteria undermine these results. Research and diagnostic criteria have recently been published allowing more uniformity of study patients and thus comparison across data sets [10]. Patients' prognoses may have improved as newer therapies including innovative rehabilitation strategies and pharmacotherapies become available. Furthermore, increased clinician awareness following the publication of the CRPS-

UK Guidelines and earlier intervention may have improved the long term outcome for patients with CRPS [11]. A larger and more contemporary study is needed.

## Methods

The CRPS-UK registry is based on EDGE, a Secure Socket Layer encrypted web-based research management resource developed by the Cancer Research UK Clinical Centre, Clinical Informatics Research Unit, University of Southampton. Patients are fully consented to provide personal contact details to be uploaded to the registry by a clinician who has confirmed the clinical diagnosis. The CRPS-UK Registry is fully approved by NRES (REC No: 08/H0306/38) and sponsored by Cambridge University Hospitals NHS Foundation Trust.

The diagnosis is confirmed by the application of the IASP (Budapest) diagnostic criteria (Harden) by a clinician experienced in the diagnosis and management of patients with CRPS.

**Diagnostic criteria for CRPS**

A history of symptoms or the presence of signs are assessed the following categories:

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| *Sensory:* | Hypersensitivity to sensations such as light touch; temperature; deep pressure; or pinprick. Allodynia or hyperalgesia. |
| *Vasomotor* | Temperature asymmetry; skin colour changes; skin colour asymmetry |
| *Sudomotor* | Oedema; sweating changes; sweating asymmetry |

*Motor/trophic* Decreased range of motion; motor dysfunction (weakness, tremor, dystonia); trophic changes (hair, nail, skin)

Diagnostic criteria for CRPS are met when symptoms in 3 domains are reported and signs in 2 domains are witnessed.

Research criteria are met when symptoms in 4 domains are reported in the presence of signs in at least 2 domains.

Patients with CRPS type 1 (no major nerve damage) and type 2 (major nerve damage) are recruited. Children under the age of 18 years require the consent of the responsible guardian or parent. It is recorded whether the patient meets diagnostic or research criteria on the Budapest definitions. This recruitment strategy ensures a reliably homogenous study population, although does not reflect the entirety of the population who develop CRPS. Patients with self-limiting CRPS or non-specific limb pain in the absence of vasomotor, trophic, motor and sudomotor changes are likely to be under-represented in this Registry as they will be less likely to be referred to the centres who are actively recruiting.

Up to 2013, recruitment to the registry was from 4 centres throughout the UK: Department of Rheumatology, Royal National Hospital for Rheumatic Diseases, Bath; Department of Pain Medicine, Walton Centre NHS Foundation Trust, Liverpool; Department of Rheumatology, Addenbrooke's Hospital, Cambridge; Pain Clinic, Department of Anaesthetics, Derriford Hospital, Plymouth. All centres have local R&D committee approval to contribute to the Registry.

*Data validation*

To determine the validity of the Registry data, a random sample of 20 patients (10 each from 2 centres) was selected in 2011. This was performed by obtaining the previous 10 records that were available from each of the 2 centres. Accuracy and completeness of all recorded variables were compared with the 'gold standard' medical records. Completeness was defined as the proportion of the data entered, and accuracy was defined as the percentage of the total data that correctly matched data from the medical record. In the CRPS-UK Registry, each patient has 37 variables recorded, thus giving at total of 740 data points to be analysed.

*Statistical analysis*

Descriptive statistics were calculated for the demographic and baseline data of the cohort. Means, standard deviations and ranges were calculated for the continuous variable age; while medians, interquartile ranges (IQR) and ranges were calculated for the other variables since they exhibited a skewed distribution. Frequencies and percentages were calculated for the categorical variables. A binomial test was used to test against the null hypothesis that the percentage right handed in the CRPS registry is the same as that in the general population; and separately to test if the percentage of patients with diagonal collateral spread was significantly different from the percentage expected (33%). A Fisher's Exact test was used to investigate any association between hand dominance and the first limb affected with CRPS. Statistical significance was concluded if $p<0.05$.

## Results

In July 2013, 240 patients with CRPS had been recruited. All fulfilled the diagnostic Budapest criteria for CRPS and 58 (24.2%) met the tighter research criteria. The demographic and disease related results are displayed in Table 1 and the patient symptoms and signs at the time of recruitment are displayed in Table 2.

With respect to data validation, the completeness of the database was 95.6%, with an accuracy of 99.4%. This compares favourably with other published registries [12,13].

The CRPS UK Registry is predominantly a female cohort (72.5%, 2.6:1) with the average age of symptom onset at 43 years (SD 12.7) and recruitment into the registry at 46 years (SD 12.3). Patients had had symptoms for an average of 29 months (IQR 39.7) before being recruited into the Registry. The median self-reported time from onset of symptoms to diagnosis was 6 months (IQR 13.4).

It is clear that this group of patients have ongoing symptoms despite having more than 2 years of symptoms on average. More than 88% of the patients included in the database reported ongoing allodynia. A reduced range of movement and weakness were also very prevalent in this cohort with more than 89% of all patients reporting these symptoms and more than 83% of the cohort having these documented on examination. Dystonia was reported to be the least common motor symptom (27%), but when this was present only one patient reported a resolution. Vasomotor symptoms were again very common with more than 74% of patients reporting

oedema, skin colour and temperature asymmetry and this being witnessed in about 60% of patients. Sweating was the least reported and witnessed sudomotor feature. Around one-third of patients reported trophic changes in each of the categories and around 30% of patients were seen to have these changes in each of the trophic categories upon recruitment.

Of the 160 patients in whom original hand dominance was recorded, 133 (83.1%)were right handed. This is significantly lower than the average general population of 90% ($p<0.01$) [14]. CRPS affected 50.2% of the cohort's right side first and 48.1% had their arm affected first rather than their leg. In the 133 right hand dominant patients, 26 (19.5%) had their left arm affected; 44 (33.1%) right arm; 35 (26.3%) left leg; and 28 (21.1%) right leg. In the 27 left hand dominant patients, 9 (33.3%) had their left arm affected; 5 (18.5%) right arm; 8 (29.6%) left leg; and 5 (18.5%) right leg. Hence it can be seen that there was no laterality preference, nor limb preference, dependent upon whether a patient was right or left hand dominant. This was confirmed by a Fisher's Exact test investigating if there was any association between hand dominance and first area affected ($p=0.302$).

CRPS was diagnosed in more than one limb for 30/240 (12.5%) of patients in this cohort. Only 5/30 (16.7%) of patients had diagonal contralateral spread (e.g. right arm and left leg), half of what was expected (33%, $p=0.054$). 25/30 (83.3%) of patients with two limbs involved had had either a unilateral or contralateral spread of CRPS.

The commonest trigger for CRPS was soft tissue injury (29.2%) followed by fracture (28.0%) and then surgery (23.7%). There was a high reported 'spontaneous' onset of CRPS (15.7%).

## Discussion

The inception of the CRPS-UK Registry following full ethical approval has been successful and this Registry intends to continue to recruit patients with chronic disease who are being managed in centres experienced in this condition. As from mid-2013, the Registry has recruited 240 patients. These patients, with a mean age at symptoms onset of 43 years, had chronic disease (median duration 29 months); tended to be female (2.6:1), and were left-handed more than expected (21.8% versus 10% in the general population). Patients in the Registry often reported a delayed diagnosis, with the median time between symptom onset and diagnosis of 6 months. Thirty patients (12.5%) had multiple limb involvement and the spread affected the contralateral diagonal limb less frequently than expected, although not significantly so. Most patients reported ongoing pain and signs and symptoms consistent with their diagnosis despite the average symptom duration of nearly two and a half years.

In the Netherlands, de Mos *et* al reported that the average age of their cohort of 238 patients was 52.7 (range 7-90 years old) with 77.3% female. Of this total, 74% were identified to be in secondary care and this group were slightly younger than those patients who remained in primary care (mean age 51.3 compared to 56.6 years). CRPS type II (underlying neural involvement) accounted for 2.9% of the cohort with the ratio of arm:leg involvement being 1.5:1. Fractures accounted for 44% of triggers. In 10.1% of the cohort, no obvious cause could be found to explain the onset of

CRPS. In the US, Sandroni *et al* reported the average age of their cohort of 74 patients with CRPS type I was 46.9 years (range 15-86 years) with 81.1% of the cohort female (4:1). 4.1% of the cohort had CRPS diagnosed at multiple sites and the ratio of arm:leg involvement was 2:1. A further 11 patients with CRPS type II were identified (12.9%). Fractures as the initial trigger accounted for 46%. No spontaneous onset cases were reported. In both studies, the peak incidence was between the ages of 50-70 years old.

When comparing the CRPS UK Registry to these two community-based studies, it is important to remember that these studies were designed to detect incident cases whereas the average duration of symptoms in the CRPS UK Registry population was nearly 3 years. Any potential differences between the community studies and the CRPS UK Registry population may therefore relate to poor prognostic factors. There are several notable differences. The CRPS UK Registry has a younger population with more male representation and more patients with multiple limb involvement. The CRPS-UK Registry also contains more patients with a spontaneous onset of their symptoms and a smaller proportion of patients with a fracture as a trigger. Finally, the CRPS-UK Registry has a greater proportion of patients with leg involvement (ratio of arm:leg 1:1). As expected, the Registry therefore differs from the community-based studies and suggests that risk factors for poor prognosis may include males; younger age of onset; spontaneous onset; leg; and multiple limb involvement.

In the published literature, 28 prognostic factors, both physical and psychological, identified from 12 studies are known to be associated with the outcome of patients with CRPS [15]. These include age less than 40 years; an initial presentation with a

cold limb; the affected limb being a leg; more than 1 limb affected [16]; depression [17]; perceived lack of social support [17]; and the use of anger as an emotional regulator [18].

The self-reported delay between the symptom onset and diagnosis is long on average and highly variable in the CRPS-UK Registry. This did not vary significantly between centres, so that local factors are not suspected. This does support the accepted view that a delay in diagnosis predisposes a patient to enter secondary and tertiary care for the management of their CRPS. This is an area that is worthy of further study. Given that community-based studies report that the symptoms of CRPS appear to self-limit in 70-80% of patients within the first year of onset, it would be important to make the correct diagnosis within 12 months to allow effective treatments and self-management to occur. Expert consensus states that early treatment is likely to improve long term outcomes although there is a paucity of data regarding this [19]. With the publication of the CRPS-UK Guidelines in 2011 (Royal College of Physicians), awareness and earlier diagnosis may be improved. It would be interesting to see whether the delay to diagnosis changes over time in the CRPS-UK Registry over the next five years.

Patients with spontaneous onset of CRPS are recognised. This has previously been reported at the level of 5-10% [20]. Our data has a slightly higher prevalence of this group (15.7%). Perhaps this could be explained due to the chronic nature of this cohort of patients, suggesting a more severe phenotype. This is preliminary data and will need to be confirmed but perhaps suggests a different phenotype in this group of patients. This is supported by de Mos' data, suggesting that patients with fracture have a better outcome than patients who have CRPS unrelated to a fracture [9].

The aetiology of CRPS has remained elusive. Neurological hypotheses have been proposed [21]. In the propagation of CRPS to multiple limbs, contralateral diagonal spread would be expected to occur less commonly. This was suggested by the CRPS-UK Registry cohort and has previously been reported in a separate cohort [22]. Our data would therefore support a role for neural transmission in the spread of CRPS.

The CRPS-UK Registry is only one a number of international registries. In the Netherlands, the TREND initiative has developed a network of interested clinicians and researchers with an active database of more than a thousand patients (www.trendconsortium.nl). In Switzerland, a specific CRPS registry has been established to capture patients who develop CRPS following trauma or orthopaedic procedures [23]. In the USA, the Reflex Sympathetic Dystrophy Syndrome Association sponsors a self-registry web portal for patients with CRPS to register with the intention of following them up for 20-years. The CRPS-UK Registry will contribute to these differing approaches to recruiting patients with CRPS and will provide novel data as well as allow the testing of hypotheses by recruiting patients into further studies. It is important to recognise the different patient populations that each Registry represents and this must be borne in mind when comparisons between data sets are made.

Despite the good recruitment into the CRPS-UK Registry there will be concerns over the future validity of the data generated and its generalisability. Patients enrolled into the CRPS-UK Registry have had the condition for nearly three years and are younger than expected. This is therefore a chronic cohort and not representative of all patients

who are diagnosed with CRPS, as the majority improve within the first year of symptom onset. Recruitment will need to be sustained over more than a decade to provide meaningful results.

In conclusion, the CRPS-UK Registry is actively recruiting well-characterised patients with CRPS to provide further information on the long term outcome. The cohort demonstrates that most continue to have ongoing symptoms and signs of the condition. Analysis demonstrates a well-validated cohort of patients who are willing to engage in being followed up. We hope that this will stimulate further research efforts in the UK for advancing the understanding and management of this challenging condition, and for the Registry to be available for comparisons with other international registries in due course.



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## Key Messages

- Patients with Complex Regional Pain Syndrome can be recruited to the CRPS-UK Registry
- CRPS that lasts for more than one year continues with pain and associated signs
- Chronic CRPS appears to occur more frequently in left-handed individuals

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**Table 1 Demographics and Baseline data of cohort**

| | **No. of recruited pts (%)** |
|---|---|
| **Gender** [N=240] | |
| Male | 66 (27.5) |
| Female | 174 (72.5) |
| **Age at onset of symptoms** (years) [N=239] | Mean 43 years (range 12-78, SD 12.7) |
| **Duration of symptoms at recruitment** (months) [N=237] | Median 29 months (range 0-297, IQR 39.7) |
| **Delay between onset and diagnosis** (months) [N=209] | Median 6 months (range 0-129, IQR 13.4) |
| **Trigger** [N=236] | |
| Fracture | 66 (28.0) |
| Soft tissue injury | 69 (29.2) |
| Surgery | 56 (23.7) |
| Spontaneous | 37 (15.7) |
| Nerve injury | 5 (2.1) |
| Electric injury | 1 (0.4) |
| Other | 2 (0.8) |
| **First limb affected** [N=239] | |
| Right arm | 65 (27.2) |
| Left arm | 50 (20.9) |
| Right leg | 55 (23.0) |
| Left leg | 69 (28.9) |
| **Hand dominance (original)** [N=160] | |
| Right | 133 (83.1) |

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|---|---|
| Left | 27 (16.9) |
| **Hand dominance (current)** [N=124] | |
| Right | 97 (78.2) |
| Left | 27 (21.8) |
| **Second area (if any) affected** [N=30] | |
| Right arm | 3 (10.0) |
| Left arm | 6 (20.0) |
| Right leg | 10 (33.3) |
| Left leg | 10 (33.3) |
| Right eye and neck | 1 (3.3) |
| **Time between onset of symptoms in first limb and second area** (months) [N=26] | Median 15 months (range 0-130, IQR 29.5) |

**Table 2 Symptoms and signs at recruitment to the CRPS UK Registry**

| | Symptoms (%) | | | | Signs (%) | | | |
|---|---|---|---|---|---|---|---|---|
| | N | Now | Previous | Never | N | Now | Absent | Not tested |
| **Sensory** | | | | | | | | |
| Allodynia | 232 | 206 (88.8) | 19 (8.2) | 7 (3.0) | 237 | 205 (86.5) | 28 (11.8) | 4 (1.7) |
| **Vasomotor** | | | | | | | | |
| Temperature asymmetry | 232 | 204 (87.9) | 18 (7.8) | 10 (4.3) | 238 | 147 (61.8) | 76 (31.9) | 15 (6.3) |
| Skin colour asymmetry | 233 | 204 (87.6) | 18 (7.7) | 11 (4.7) | 239 | 160 (66.9) | 73 (31.6) | 6 (2.5) |
| Oedema | 230 | 172 (74.8) | 49 (21.3) | 9 (3.9) | 234 | 137 (58.5) | 93 (39.8) | 4 (1.7) |
| Sweating asymmetry | 232 | 118 (50.9) | 55 (23.7) | 59 (25.4) | 236 | 88 (37.3) | 130 (55.1) | 18 (7.6) |
| **Motor** | | | | | | | | |
| | N | Now | Previous | Never | N | Now | Absent | Not tested |
| Reduced ROM | 230 | 206 (89.5) | 16 (7.0) | 8 (3.5) | 239 | 208 (87.0) | 27 (11.3) | 4 (1.7) |
| Weakness | 228 | 205 (89.9) | 13 (5.7) | 10 (4.4) | 238 | 198 (83.2) | 29 (12.2) | 11 (4.6) |
| Tremor | 229 | 83 (36.3) | 57 (24.9) | 89 (38.8) | 237 | 67 (28.3) | 147 (62.0) | 23 (9.7) |
| Dystonia | 227 | 62 (27.3) | 57 (25.1) | 108 (47.6) | 236 | 60 (25.4) | 150 (63.6) | 26 (11.0) |
| **Trophic** | | | | | | | | |
| | N | Now | Previous | Never | N | Now | Absent | Not tested |
| Hair changes | 231 | 71 (30.7) | 73 (31.6) | 87 (37.7) | 235 | 66 (28.1) | 148 (63.0) | 21 (8.9) |
| Nail changes | 233 | 94 (40.3) | 61 (26.2) | 78 (33.5) | 237 | 72 (30.4) | 143 (61.3) | 22 (9.3) |
| Skin changes | 230 | 101 (43.9) | 54 (23.5) | 75 (32.6) | 238 | 91 (38.2) | 128 (53.8) | 19 (8.0) |
| | | | | | | | | |

ROM – range of movement