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Retrospective Descriptive Evaluation of Patients with Complex Regional Pain Syndrome Presenting To an Interdisciplinary Tertiary Chronic Pain Clinic

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Abstract

Background: Complex regional pain syndrome (CRPS) is a disabling condition seen in chronic pain clinics. Despite many studies addressing the management of CRPS, there is a lack of high-quality studies on the efficacy of therapies, and particularly on effectiveness of interdisciplinary programs, for CRPS in both controlled and real-world clinical settings.

Aims: To retrospectively assess the effectiveness of an interdisciplinary treatment program on pain and functional domains in patients with CRPS.

Methods: Patients with CRPS participating in this interdisciplinary clinic who completed self-reported survey data at baseline and follow-up for routine clinical purposes were identified through convenience sampling. This data was retrospectively extracted from the electronic medical record (EMR) for descriptive analysis as well as a pre-post analysis for pain and functional outcomes.

Results: 33 patients with CRPS were included in this study. Median (IQR) duration of CRPS was 1.3 (2.9) years. 20 patients had follow-up data a median (IQR) of 298 (361.5) days from baseline. A significant reduction in pain severity (Mean (SD) = 7.39(1.42)) to (Mean (SD) = 6.22(2.37)), p = 0.0045, but no significant reduction in pain disability index score (Mean (SD) = 51.90(10.55)) to Mean (SD) = 46.263(14.36)), p = 0.058 was found. Duration of CRPS had no significant association with magnitude of improvement.

Conclusion: Results are interpreted in context of retrospective pre-post design on EMR data but encourage improvements in data processes for future evaluation. More real-world evaluation of interdisciplinary programs for patients with CRPS is needed to ensure evidence-based therapies are effective in uncontrolled clinical environments.

Keywords: Complex regional pain syndrome; Chronic pain; Electronic medical record

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Abbreviations: CRPS: Regional Pain Syndrome; EMR: Electronic Medical Record; PCS: Pain Catastrophizing Scale; PDI: Pain Disability Index; PHQ: Patient Health Questionnaire; GAD: Generalized Anxiety Disorder.

Background and Rationale

Complex regional pain syndrome (CRPS) is a chronic pain condition of unclear pathophysiology classically involving the extremities, commonly occurring after injury or surgery, but may not have any clear preceding trauma at all [1,2]. Nonetheless, CRPS can be disabling for activities of daily living and quality of life and thus, is often prioritized for intake due to reports that CRPS becomes increasingly disabling without appropriate early intervention, making CRPS one of the few urgent conditions seen in a chronic pain practice [1-3]. Although there has been accumulating evidence for CRPS-specific therapies such as physiotherapy, and for some pharmacological therapies such as bisphosphonates and ketamine, there is still a "critical lack of high-quality evidence" for CRPS therapeutics in the literature [4,5]. Further, studies assessing CRPS evaluate specific treatments in specific contexts, such as ketamine infusions or physiotherapy, leaving little data assessing the efficacy of interdisciplinary treatment programs that aim to synthesize these individual therapeutic components into a comprehensive program, [5-8] and even less data on evaluation of real-world interdisciplinary care on CRPS outcomes, [9,10]. More real-world, practice-based evaluations of pain programs for CRPS are needed to assess the effective application of evidenced based therapies into practice. [11,12]. This is especially important since the reproducibility of pain trials has been called into question as well as documented specific example of discrepant outcomes using the same CRPS therapeutic program between a clinical trial versus a real world clinic [13,14].

At this tertiary interdisciplinary chronic pain clinic seeing 1500 patients a month, with an estimated 1.2% prevalence of CRPS in the chronic pain patient population, [15] there should be adequate volume of patients whose data are available for evaluation of effect of real-world interdisciplinary care that includes medical, interventional, occupational, physiotherapy, nurse practitioner, social worker, psychiatric, and group education sessions on CRPS patient outcomes. Importantly, for internal purposes, we have not yet systematically assessed the effect of our interdisciplinary program for patients with CRPS. Therefore, our aim is to conduct this descriptive pre-post study on retrospective clinical data of CRPS patients to describe demographic and pain patterns and to assess whether the interdisciplinary interventions provided in this chronic pain clinic benefit patients CRPS. We hope through this initial study, we may identify weaknesses in our current research process and motivate future higher-quality evaluations of real-world clinical effectiveness of our program.

Objective

The objective of this study is to retrospectively assess the effectiveness of interdisciplinary treatment program provided by the Pain Management Clinic in Surrey, BC on pain and functional domains in patients with CRPS.

Methodology

This study was deemed quality improvement and thus was exempt from review by the University of British Columbia Clinical Research Ethics Board as well as Fraser Health Research Ethics Board in accordance to the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans, Article 2.5.

Study Setting and Description of Interdisciplinary Treatment Program

This study took place at the Pain Management Clinic located at the Jim Pattison Outpatient Care and Surgery Centre in Surrey, BC. This interdisciplinary clinic consists of Pain Specialists (six anesthesiologists, one orthopedic surgeon and one physiatrist), a nurse practitioner, psychologist, nurses, physiotherapists, occupational therapists, social workers, pharmacists and patient care coordinators. Patients begin the intake process with an orientation session on pain education and self-management strategies, and then complete a package of intake questionnaires which become part of the medical record and served as baseline data for this study. Patients then proceed into the interdisciplinary program and are treated according to their needs which may include education classes, physiotherapy, injection interventions, and/or social and psychological support. Follow-up questionnaires are administered to monitor clinical progress and served as follow-up data for this study.

Participants

Identified through convenience sampling from physiotherapy records, patients with confirmed CRPS who were seen at the Pain Management Clinic between

June 2016 to June 2019 for routine clinical care were included in the analysis. Inclusion criteria were diagnosis of CRPS 1 or 2 made by clinician in accordance to the Budapest Criteria [16] who were receiving outpatient care at the Pain Management Clinic. Exclusion criteria included patients with cancer related pain and patients with comorbid CRPS but referred and treated for another complaint.

Study Design

Descriptive retrospective chart review with pre-post analysis

Data Collection

All data were retrospective and extracted from the Fraser Health electronic medical record (EMR) system, Meditech, by means of chart review, and stored in Research Electronic Data Capture (REDcap).

Measures

Measures collected in the intake included demographics (age, gender, occupation), pain characteristics (duration of CRPS, type of injury, area of pain, and pain-related comorbidities) and pain instruments in accordance to IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials) [17].

The pain instruments included a pain severity scale, a 1 item, 11-point patient self-reported numerical rating scale where 10 is the worst pain and 0 is no pain, on average, in the last week; The Pain Disability Index (PDI); [18] 7-item patient self-reported scale assessing the impact of pain on 7 life domains. The Pain Catastrophizing Scale (PCS); [19,20] 13 item self-report measurement tool to help quantify a patient's pain experience. The Patient Health Questionnaire-9 (PHQ-9);9-item patient self-reported screening tool for depression. The Generalized Anxiety Disorder (GAD-7); 7-item questionnaire designed to assess generalized anxiety disorder [21-23].

Due to limitations in retrospective data available for follow-up comparisons, only the pain severity scale and the Pain Disability Index were available for the pre-post analysis.

Data Analysis

Data from all sources were extracted and tabulated to calculate distribution of patient characteristics. In addition, paired t-tests were conducted to compare outcomes between intake and follow-up. Pearson correlation assessed the relationship between time since CRPS diagnosis and magnitude of pain and functional improvement.

Results

A total of 37 records were identified, and of these 33 had confirmed CRPS. These 33 patients were seen in the clinic sometime between September 2014 to April 2019. 20 patients had follow-up data available where the median (IQR) time to follow up was 298 (361.5) days.

Demographics and pain characteristics

Patient demographics and pain characteristics are shown in Table 1. The age range of patients was 16 - 75. CRPS duration between onset and intake (n = 33) ranged between 3 months to 38 years, with a median (IQR) of 1.3 (2.9) years and was localized mainly to the hand (43.8%) and foot/ankle (31.3%). Patients (n = 32) were chiefly diagnosed with CRPS as the result of either a fall (25%) or following surgery (25%) (Table 1). In terms of pain-related comorbidities, out of 33 patients, most (45%) had none, followed by depression (36.4%), migraine (18%), and previously resolved CRPS (12%).

Variables (total number of patients, n = 33)	%
Sex (n = 33); Females	75.8
Age (n = 33) Mean (SD)	44.7 (10.7)
Duration of pain (n = 33)	
0 – 6 months	18.2*
6 – 12 months	18.2
1 – 5 years	51.5
>5 years	12.1
Suspected type of inciting injury to CRPS (n = 33)	
Fall	25
Surgery	25

MVA	18.8
Work	15.6
Other (sports, overuse)	12.5
None	6.3
Main pain area (of greatest severity, n = 33)	
Hand	43.8
Shoulder	9.4
Foot/ankle	31.3
Other (arm, leg, thoracic)	15.5
Pain Severity Index - baseline (n = 30)	
Mean (SD)	6.97 (1.75)
0 – 3 (Mild)	3.3
4 – 6 (Moderate)	30
7 – 10 (Severe)	66.7
Pain Disability Index – baseline (n = 31)	
Mean (SD)	50.9 (10.45)
0 – 20	0
21 – 40	19.4
41 – 60	61.3
61 – 70	19.4
Patient Health Questionnaire (PHQ9) n = 31	
Median (IQR)	12 (13)
0 – 9 (none/mild)	45.2
10 – 19 (moderate)	29
20 – 27 (severe)	25.8
Generalized Anxiety Disorder 7 – baseline (n = 29)	
Mean (SD)	11.4 (5.5)
0 – 9 (minimal/mild)	44.8
10 – 14 (moderate)	24.1
15 – 21 (severe)	31
Pain Catastrophizing Scale - baseline (n = 29)	
Mean (SD)	27.3 (12.2)
0 – 20 (< 50 percentile)	34.5
21 – 50 (> 50 percentile)**	65.5

Table 1: Patient demographics and pain-related characteristics from initial questionnaire.
*Minimum duration was 3 months.
**Based on a sample of 851 workers compensation patients with soft tissue injuries [20].

Pre-post analysis

18 patients reported their pain severity at follow-up. Results from the paired t-test indicated there was a statistically significant reduction in pain severity from baseline (Mean (SD) = 7.39(1.42)) to follow-up (Mean (SD) = 6.22(2.37)), p = 0.0045 (Figure 1). It was found that 4 patients or 22% had clinically significant improvement of pain severity where the cut off was 2.3 points on the NRS scale [24]. 8 patients had non-clinically significant reduction, 5 patients had unchanged, and 1 patient had worsened pain severity from baseline to follow-up. Nineteen patients reported their PDI scores at follow-up. Results from the paired t-test indicated no significant difference between baseline (Mean (SD) = 51.90(10.55)) and follow-up (Mean (SD) = 46.263(14.36)), p = 0.058, (Figure 2). It was found that 3 patients or 18% had clinically significant improvement in scores based on cut-offs from a study of patient important PDI change scores [25]. 2 of 3 of these patients were the same as those experiencing clinically significant reduction in pain severity. Eleven patients had non-clinically significant reduction, 1 patient had unchanged, and 4 patients had worsened PDI from baseline to follow-up. Results of the spearman correlation indicated no significant association between duration of CRPS and the

magnitude of pain severity change (r = -0.113, p = 0.330), and no significant association between duration of CRPS and the magnitude of PDI score change (r = 0.297, p = 0.108).

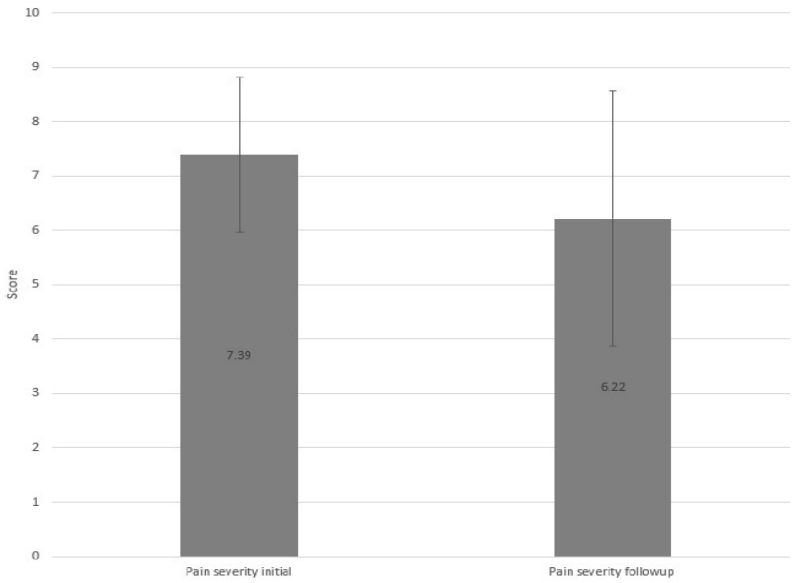

Figure 1: Change in pain severity from baseline to follow-up, error bars represent standard deviation. n = 18, p = 0.0045.

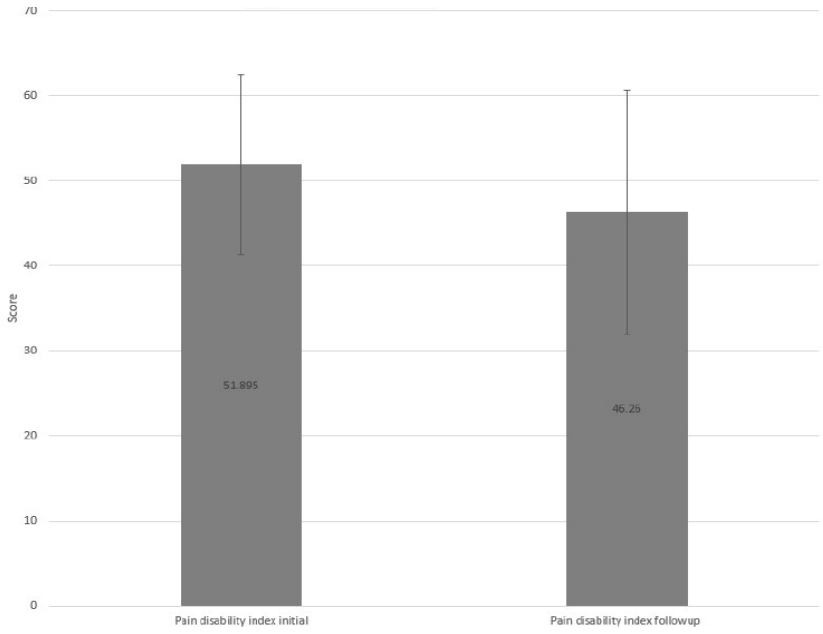

Figure 2: Change in pain disability index score from baseline to follow-up, error bars represent standard deviation. n = 19, p = 0.0575.

Discussion

Through this initial evaluation of retrospective EMR data of our interdisciplinary program, we were able to observe improvement in a sample of patients with CRPS while identifying limitations to overcome for future evaluation. In the pre-post analysis, there was a statistically significant reduction in pain severity from intake to follow-up, which could be attributed in part to our interdisciplinary pain program. Based on data available however, no causality can be inferred. However, physiotherapy (graded motor imagery and graded activity and desensitization) which was tried by 94% of our patients, has fair evidence of efficacy for CRPS, and it could likely have a large contribution to the benefits observed [5,26].

On the other hand, the lack of benefit in pain-related disability and a general lack of clinically significant benefit in pain and function in this small sample may be a product of the high level of initial disability in treatment resistant, longstanding CRPS, data quality, and/or ineffectiveness. First, descriptive data show a high level of pain disability in our patients, similar to that previously shown in other chronic pain clinics with general pain populations described in Canada [27,28]. What's more, the majority, 64%, had CRPS for more than a year, 81% more than 6 months, thus having chronic CRPS (greater than 6 months from onset). In general, most patients with CRPS see resolution of most or all symptoms within the first year of onset, [29] but it is estimated from a retrospective cohort study of 102 patients with CRPS that 15% of patients with CRPS will have persistent symptoms and significant refractory disability 2 years from onset, [30] and most likely our clinic receives those patients as reflected in our baseline data, thus limiting potential improvement.

Secondly, as this is a study on retrospective EMR data, significant limitations exist. Importantly, this study had no control and could not access health usage data to control for confounding variables introducing bias that impacts data quality and limits the ability to make outcome conclusions. Using clinical EMR data not collected for research purposes posed challenges as well, such that diagnostic labels were not reportable, follow-up time-points were not standardized, and the data inputs had uncertain accuracy, common issues encountered using EMR data [31]. For example, there was no system in place to identify and extract patients with a diagnosis of CRPS and thus we had to rely on convenience sampling from physiotherapy patient lists, which significantly limited data quantity and patient representation introducing a selection bias. Follow-up time-points ranged between 3 months to 4.5 years which grouped patients who potentially had very little therapy with those potentially with a lot in the same evaluation, which likely introduces bias and questionable validity into change scores. Furthermore, there was 53% loss to follow-up due to inconsistent questionnaire completion, further limiting data quantity.

Despite the limitations, we believe this study serves to highlight the importance for programs to evaluate their own clinical populations to determine whether the evidenced-based therapies implemented provide the benefit seen in controlled studies. For example, a randomized control trial (RCT) of 51 patients with CRPS and phantom limb pain undergoing 6 weeks of graded motor imagery (GMI) vs traditional physiotherapy found a significantly greater improvement in pain and function for the GMI group, [32] which is in contrast to a prospective audit of 2 CRPS inpatient programs using the same graded imagery program [14]. In this prospective audit, out of 32 patients, pain severity did not significantly decrease and function was only improved in 1 of the 2 programs. The reason for these discordant findings were not certain, but as often occurs in real-world treatment settings, deviations from the treatment protocol for pragmatic or logistical reasons occurred in this prospective audit and may have contributed to the different outcome seen [14].

In conclusion, more data is needed from real-world interdisciplinary programs for patients with CRPS on the effect their evidence-based therapies have on their patient outcomes through practice-based research, both to monitor actual effectiveness and disseminate findings with a higher degree of external validity [11,12]. In this study, we set out to evaluate the effectiveness of our interdisciplinary program for patients with CRPS and have some sense of the clinical trajectory. Further improvements to the data collection and quality are needed for future evaluations to accurately reflect our interdisciplinary program effectiveness.

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