


CLINICAL ARTICLE

Determinants of Complex Regional Pain Syndrome Type I among Radial Head Fracture Patients with Unilateral Arthroplasty

Ye Wang, MD^{1†}, Menglu Jiang, MD^{1,2†}, Xu Dai, MD¹, Qin Zhang, MD¹ 

¹Department of Anesthesiology, Wuxi No. 9 People's Hospital Affiliated to Soochow University, Wuxi and ²Soochow University, Soochow, China

Objective: This study aims to assess the proportions of complex regional pain syndrome type I (CRPS I) in radial head fracture patients undergoing unilateral arthroplasty and to explore associated factors.

Methods: This is a prospective observational study. From March 2016 to May 2019, a total of 221 adult patients with radial head fracture patients were included in consecutive studies and completed the 1-year follow-up. All patients were treated by unilateral arthroplasty. At each follow-up visit, the visual analogue scale was used to measure patients' pain level. Occurrence of CRPS I, which was diagnosed by Budapest criteria, was the main outcome collected at baseline and the 1-, 3-, 6-, and 9-month follow-ups. The baseline data were collected before surgery and included demographic and clinical data. Independent *t*-tests and χ^2 tests were used as univariate analyses to compare the baseline data of patients with and without CRPS I. Multivariate analysis (Backward-Wald) was used to identify factors independently associated with CRPS I.

Results: The proportion of CRPS I cases among radial head fracture patients undergoing unilateral arthroplasty was 11% ($n = 24$). A total of 19 (79%) patients were diagnosed with CRPS I within 1 month after surgery. Multivariable logistic regression analysis revealed that female gender (odds ratios [OR]: 1.537; 95% confidence interval [CI]: 1.138–2.072), age younger than 60 years (OR: 1.682; 95% CI: 1.246–2.267), moderate and severe Mayo Elbow Performance Score (MEPS) pain (OR: 3.229; 95% CI: 2.392–4.351) and anxiety (OR: 83.346; 95% CI: 61.752–112.320) were independently associated with CRPS I.

Conclusions: This exploratory study reported that the incidence of CRPS I developing after radial head arthroplasty was 11%. Female sex, younger age, moderate and severe MEPS pain and anxiety patients seems more likely to develop CRPS I.

Key words: Arthroplasty; Complex regional pain syndromes; Fractures; Logistic models; Radial heads

Introduction

Radial head fractures account for 1.7% to 5.4% of all fractures.¹ Radial head arthroplasty is a method commonly employed to restore the stability of the elbow joint, preserve the range of motion, and maintain the radial length.² However, chronic pain conditions after arthroplasty may occur, which is one of the reasons for patients' poor

functional outcomes and dissatisfaction. Clohisy *et al.*³ reported that hip pain is common among developmental dysplasia of the hip patients after arthroscopic. Most of the pain presents without an obvious cause. Complex regional pain syndrome type I (CRPS I) is one of the causes of some chronic pain syndromes and is most frequently induced by fracture.⁴

Address for correspondence Qin Zhang, MD, Department of Anesthesiology, Wuxi No.9 People's Hospital Affiliated to Soochow University, Wuxi, 214000 Jiangsu, China. Tel: +8615732189286; Fax: +8618032422946; Email: zhangqin@email.poe.edu.pl

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[†]Ye Wang and Menglu Jiang are co-first author.

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According to two population-based studies, the national incidence of CRPS I was 5.5 and 26.2 per 100,000 person-years in North America⁴ and Europe,⁵ respectively. CRPS I is a chronic neuropathic condition that includes continuing pain, hyperalgesia, temperature asymmetry, edema changes, and motor dysfunction.⁶ Varena *et al.*⁷ reported that trauma events were the most common triggering event CRPS I cases. According to Budapest criteria, the common symptoms of CRPS include abnormal sensation, hyperalgesia or allodynia, edema, sudomotor and vasomotor changes.⁸ The clinical signs include four categories: the evidence of sensory; vasomotor; edema and trophic. The diagnosis of CRPS I involves the presence of at least two clinical signs included in the four categories and at least three symptoms in its four categories.⁹ For the treatment of CRPS I, evidence has revealed that there may be greater potential gains from comprehensive approach, which includes physical therapy, educational interventions, and neurorehabilitation.⁹

Many studies reported that fracture was the most common trigger of CRPS I.^{10–12} Jellad *et al.*¹³ reported that CRPS I occurred in 32.2% of distal radius fracture patients. The injury mechanism of distal radius fractures was similar to radial head fractures. However, few studies have focused on the incidence of CRPS I secondary to radial head fractures.

However, acutely injured patients often experience secondary injury, mostly caused by ongoing tissue trauma during surgical preparation, related inflammatory reaction, hypovolemia due to blood loss and other causes. In addition, surgical methods may have an impact on incidence of CRPS I.^{14–16} Jo *et al.*¹⁷ reported that the incidence of CRPS-I in distal radius fractures patients was higher after open reduction than after closed reduction. Therefore, we focused on the incidence of CRPS I after radial head arthroplasty.

Our hypothesis was that incidence and associated factors among patients after radial head arthroplasty would be different compared to other fracture types. The aim of this prospective observational study was to determine: (i) the incidence of CRPS I after radial head arthroplasty; and (ii) if

previously reported risk factors are actually associated with the development of CRPS I.

Methods

This prospective observational study was performed from March 2016 to May 2019 in two level II regional trauma centers. The sample size of this study was calculated based on the number of variables. The lower limit of the number of included individuals was at least 10 times the number of events per variable (EPV).¹⁸ In this study, 10 variables were eligible for multivariate logistic regression, and the lower limit of the number of included individuals was 100 individuals. Convenient sampling was used as a sampling method. Written informed consents were obtained before the trial began. The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Our research team explained the study to all participants. The study was registered with [Clinicaltrials.gov](https://www.clinicaltrials.gov); Trial registration number (ChiCTR2100050694).

The inclusion criteria were prespecified according to the PICO criteria: (i) types of participants—radial head fractures patients; (ii) types of interventions—patients undergoing unilateral arthroplasty were included; and (iii) types of outcomes—the primary outcomes were the occurrence of CRPS I, other observation index (independent variable) was shown in the section “Evaluations”.

The exclusion criteria were as follows: (i) patients who received conservative treatment or other operation methods; (ii) patients with multiple trauma; (iii) age \leq 18 years; (iv) associated neurovascular injury; (v) associated injuries that will impede postoperative rehabilitation training; (vi) previous diagnosis of CRPS I and other chronic pain conditions because it has been demonstrated that a history of CRPS is a risk factor for recurrence¹⁹; (vii) patients who developed complications, such as infection, heterotopic ossification, etc., because these complication may influence the

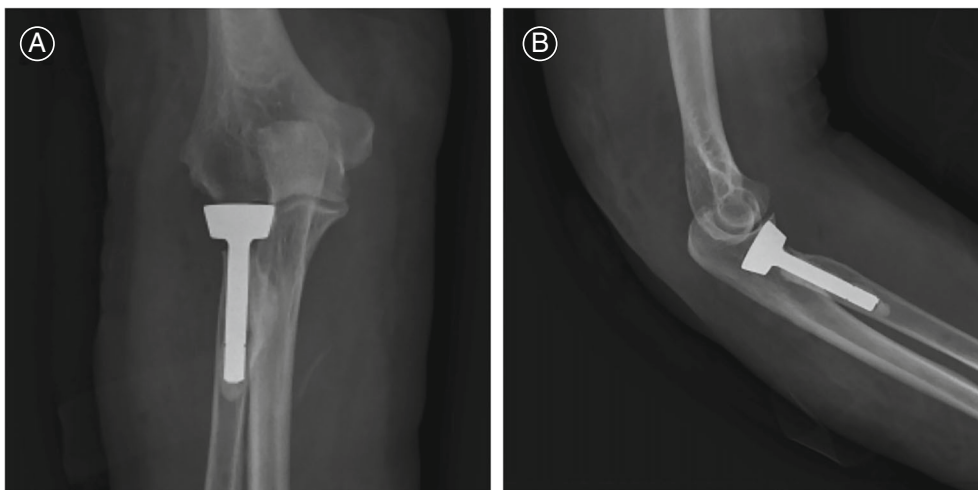


Fig. 1 Postoperative anteroposterior (A) and lateral (B) radiographs (radial head prosthesis; Wright Medical Technology, Memphis, TN, USA).

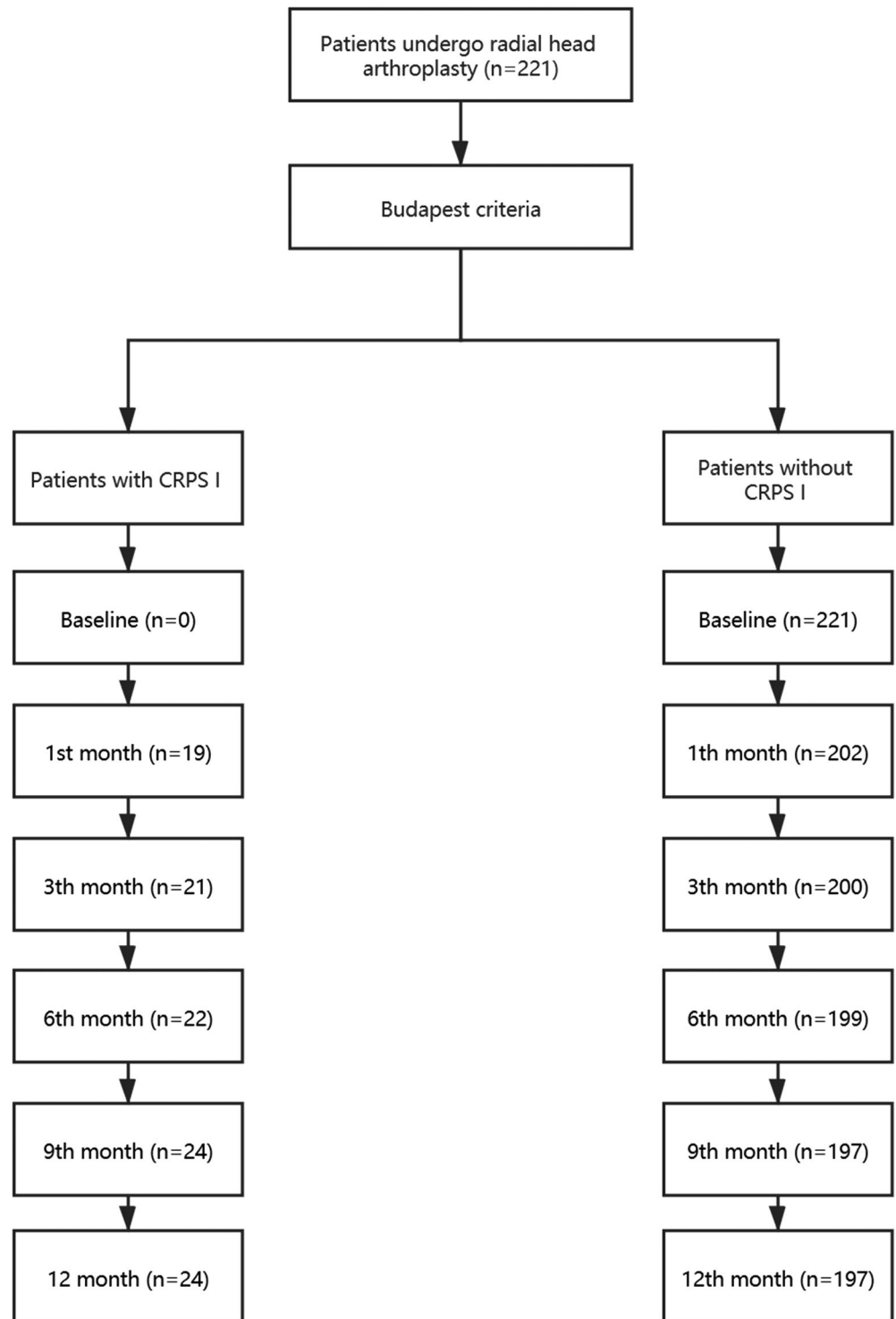


Fig. 2 Flow chart of patient inclusion in the present study: radial head fracture patients underwent prosthesis treatment and completed the 1-year follow-up.

accuracy of results; and (viii) patients who declined to participate in the study.

The dropout criteria were as follows: participants who are unable to comply with this study, or who experience severe changes in this condition during treatment, were dropped from the study.

Treatments and Diagnosis

All patients underwent axillary brachial plexus block by one anesthesiologist (MJ). All treatments were performed by the same surgical team using the lateral approach. We used the same radial head prosthesis (Wright Medical Technology, Memphis, TN, USA) in this study

QuickDASH Score

Patient Name: _____

Patient MRN: _____

Date: _____

Dominant Hand: R L Both (Circle One)

Affected Arm: R L (Circle One)

	No Difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Unable
1. Open a tight or new jar.	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5
2. Do heavy household chores (e.g., wash walls, floors, etc.).	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5
3. Carry a shopping bag or briefcase.	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5
4. Wash your back.	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5
5. Use a knife to cut food.	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5
6. Recreational activities in which you take some force or impact through your arm, shoulder, or hand (e.g., golf, hammering, tennis, etc.).	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5

	Not At All	Slightly	Moderately	Quite A Bit	Extremely
7. During the past week, to what extent has your arm, shoulder, or hand problem interfered with your normal social activities with family, friends, neighbors, or groups?	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5

	Not Limited At All	Slightly Limited	Moderately Limited	Very Limited	Unable
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder, or hand problem?	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5

	None	Mild	Moderate	Severe	Extreme
9. In the last week, please rate the severity of arm, shoulder, or hand pain.	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5
10. In the last week, please rate the severity of tingling (pins and needles) in your arm, shoulder, or hand.	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5

	No Difficulty	Mild Difficulty	Moderate Difficulty	Severe Difficulty	Cannot Sleep
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder, or hand?	<input type="checkbox"/> +1	<input type="checkbox"/> +2	<input type="checkbox"/> +3	<input type="checkbox"/> +4	<input type="checkbox"/> +5

Number of Completed Responses ('n'): _____ Sum of 'n' Responses (55 points): _____

$$\text{QuickDASH Score} = \left(\frac{\lceil \lceil \text{sum of } n \text{ responses} \rceil \rceil}{n} - 1 \right) \times 25, \text{ where } n \text{ is the number of completed responses}$$

Fig. 3 Determinants of complex regional pain syndrome type I among radial head fracture patients with unilateral arthroplasty.

(Figure 1). All patients received the same postoperative rehabilitation.²⁰

At each follow-up visit, a pain specialist (YW) who was blind to baseline questionnaire scores measured the patient's pain level using the visual analogue scale (VAS). Previous studies found that few patients undergoing radial head arthroplasty reported greater pain (VAS > 50 points) 1 month after surgery. Therefore, we regard 50 points as the cut-off scores of the pain level.^{21,22} For patients who present disproportionate pain in the operated limb, we initially attempted to exclude other

potential causes. Second, we diagnosed CRPS I according to Budapest criteria,²³ which includes four categories (sensory, vasomotor, sudomotor/edema, motor/trophic). The specific process is shown in Figure 2.

Evaluations

General Data

Preoperatively, the injuries were classified into high energy (motor vehicle collision/fall from height >1 m), medium

TABLE 1 Demographic characteristics of study sample

Characteristics	Patients with CRPS I (n = 24)	Patients without CRPS I (n = 197)	T value/x value ²	p value
Age (year)	51.5 ± 14.2	58.7 ± 16.8	-2.013	0.045*
Gender, n (%)				
Male	2	54		
Female	22	143	4.116	0.042*
Dominant hand, n (%)				
Left	7	35		
Right	17	162	1.806	0.179
Injured side				
Dominant	20	141		
Non-dominant	4	56	1.496	0.221
Body mass index (kg/m ²)	21.3 ± 1.4	19.9 ± 3.8	1.787	0.075
Marital status, n (%)				
Married	17	138		
Single	1	0		
Divorced	2	43		
Widowed	4	16	11.849	0.008
Education, n (%)				
University	15	130		
Primary and middle	7	63		
Illiterate	2	4	3.224	0.200
Job status, n (%)				
Unemployed (%)	8	71		
Employed	16	126	0.068	0.794
Socioeconomic status, n (%)				
High	9	65		
Medium	10	87		
Low	5	45	0.198	0.906
Type of trauma				
High energy	2	57		
Medium	12	104		
Low energy	10	36	9.057	0.011*
Tobacco use, n (%)	5	39	0.014	0.904
Alcohol use, n (%)	1	24	1.370	0.242
Medical problems				
Hypertension, n (%)	9	51	1.458	0.227
Diabetes mellitus, n (%)	5	43	0.012	0.911

*p < 0.05.

energy (fall from <1 m), and low energy (ground-level fall) types based on the mechanism. Elbow range of motion and strength was assessed by one expert physician. We measured elbow range of motion using a goniometer (Longhua Medical Company, Shijiazhuang, China). We measured elbow flexion strength and grip strength of the hand using a dynamometer (Dongxing Medical Company, Wuxi, Jiangsu, China). The strength scores of the nondominant hand were increased by 5% to exclude the discrepancy between dominant and nondominant hand strength.^{24,25} Elbow pain was assessed using the 100-mm VAS.

Intraoperatively, we recorded incision length, operative time, and intraoperative blood loss. According to the soaked gauze weight and the aspirated fluids, the surgeon and the anesthesiologist measured the intraoperative blood loss at the end of the operation. In order to measure the skin incision, digital photography was used to image each wound daily with a ruler included for scale at the end of surgery.

Functional Evaluation

We assessed elbow function using the Mayo Elbow Performance Score (MEPS)²⁶ (<60, poor; 60–74, fair; 75–89; and 90–100, excellent). Elbow pain was also assessed using the MEPS (none = 45; mild = 30; moderate = 15; severe = 0)²⁷ We assess elbow disability in activities of daily living using the Patient-rated Elbow Evaluation (PREE) questionnaire^{28,29} (<70, poor; 70–80 fair, 80–90 is good and 90–100 excellent). The Shortened Disabilities of the Arm, Shoulder, and Hand Questionnaire (QuickDASH) was used to evaluate the patients' upper limb function. The scale scores had a minimum of 0 points (no disability) and a maximum of 100 points (most severe disability). The Chinese version of the Short-Form Health Survey (SF-12) was used to evaluate patients' quality of life,³⁰ The score standard had a maximum of 100 points (best possible outcome).

Mental Status Assessment

We evaluated the patient's psychological conditions using the Hospital Anxiety and Depression Scale (HADS).³¹ The

TABLE 2 Clinical characteristics of study sample

Characteristics	Patients with CRPS I (n = 24)	Patients without CRPS I (n = 197)	T value/x value ²	p value
Pain at rest (VAS) (out of 100)	18.7 ± 9.4	12.6 ± 3.2	-0.437	0.664
Pain at activity (VAS) (out of 100)	57.6 ± 21.5	48.3 ± 16.4	2.529	0.012*
Elbow strength (mm)	91 ± 19.5	96 ± 11.2	-1.875	0.062
Quick DASH	28.3 ± 8.2	30.9 ± 6.5	-1.795	0.074
Maximum displacement (mm)	2.1 ± 0.6	2.2 ± 0.3	-1.344	0.180
Number of free fragments	1.6 ± 0.2	1.5 ± 0.6	0.810	0.419
Elbow range of motion (°)				
Flexion	119 ± 23	123 ± 19	-0.951	0.343
Extension	18 ± 5	15 ± 8	1.793	0.074
Pronation	59 ± 10	64 ± 13	-1.818	0.070
Supination	61 ± 13	58 ± 16	0.883	0.378
SF-12 (points)				
Physical (0–100)	52 ± 6	56 ± 7	-2.681	0.008*
Mental (0–100)	52 ± 4	55 ± 2	-6.05	<0.001*
Strength (kg)				
Flexion	8.4 ± 2.1	8.9 ± 1.8	-1.261	0.209
Grip	33.6 ± 11.7	31.5 ± 13.6	0.724	0.470
MEPS (points)				
Pain (0–45)	28 ± 3	24 ± 5	3.831	<0.001*
Arc of motion (0–20)	15 ± 2	16 ± 3	-1.589	0.114
Stability (0–15)	7 ± 3	8 ± 3	-1.542	0.125
Daily function (0–20)	11 ± 5	10 ± 2	1.857	0.065
Total (out of 100)	61 ± 6	59 ± 4	2.174	0.031*
PREE (points)				
Pain (0–50)	31 ± 19	22 ± 8	4.267	<0.001*
Function (0–50)	22 ± 12	23 ± 7	-0.602	0.548
Total (0–100)	51 ± 21	49 ± 18	0.504	0.614
HADS				
Depression	7.4 ± 3.1	6.9 ± 2.5	0.900	0.369
Anxiety	7.1 ± 3.8	6.0 ± 2.2	2.104	0.037*

Non-dominant hand values increased by 5%; MEPS, Mayo Elbow Performance Score; PREE, Patient-rated Elbow Evaluation; Quick DASH, Quick Disabilities of the Arm, Shoulder, and Hand; VAS, 100-mm visual analogue scale.; * $p < 0.05$.

TABLE 3 Logistic regression for variables predictive factors of occurrence of CRPS I

Variable	β	Odds ratio	95% CI	p value
Gender (female)	0.430	1.537	1.138–2.072	0.043*
Age (younger than 60 years)	0.520	1.682	1.246–2.267	0.018*
MEPS (moderate and severe pain)	1.172	3.229	2.392–4.351	0.022*
Anxious personality	4.423	83.346	61.752–112.320	0.011*

Multivariable logistic analysis was used.; MEPS, Mayo Elbow Performance Score.; * $p < 0.05$.

scale included the anxiety subscale and depression subscale, with each scale including seven questions. The cut-off scores of depression and anxiety were eight points. The patients were divided into present cases (depressed or anxious) and absent cases (nondepressed/nonanxious) according to the responses of the questions^{32,33} (Figure 3).

Statistical Analyses

The statistical analyses were performed using Statistical Package for the Social Sciences (SPSS, version 25, Chicago, IL, USA). The mean and standard deviation results are

presented for symmetric distribution variables. Independent t -tests and χ^2 tests were used as univariate analyses to compare the baseline data of patients with and without CRPS I. Multivariate analysis (Backward-Wald) was used to identify factors independently associated with CRPS I, including two types of predictors. The first type included predictors with statistically significant results ($p < 0.1$) in univariate analysis, and the second type included clinically relevant variables reported in previous studies. The Pearson correlation coefficient statistic, the -2 log-likelihood ratio test and Hosmer–Lemeshow goodness-of-fit chi-square test were used

to assess the multicollinearity, overall significance and fit of the model. This model also used the estimated values and Pearson and deviation residuals to explore the outliers and detect the influential observations.³⁴ The results of logistic regression are expressed as ORs and 95% confidence intervals (CIs). All reported *p*-values were two-tailed. Differences were considered statistically significant at *p* < 0.05.

Results

A total of 461 patients visited our trauma center. In total, 255 patients were recruited in this study. The sample size of this study met the standard of 10 EPV. The reason for non-participation were as follows: 121 patients have received conservative treatment or other operation methods; 37 patients were diagnosed with multiple trauma; five patients were younger than 18 years old; 31 patients had CRPS I or other chronic pain conditions; and 12 patients declined to participate in this study. 221 patients completed the 1-year follow-up. At the end of the follow-up period, the dropout rate was 13.3% (34 patients: 21 refuse to follow in the study and 13 were unreachable). The demographic characteristics are summarized in Table 1.

General Results

There were 56 male and 165 female patients. The mean time interval from injury to radial head arthroplasty was 5 days (range, 3–10 days). A total of 24 (11%) patients were diagnosed with CRPS I during the first year after surgery. The average time from operation to onset of CRPS I was 2.7 ± 1.8 weeks. In our series, 19 (79%) patients were diagnosed with CRPS I within 1 month after surgery. There was no significant difference for intraoperative results in all patients, which includes the incision length, operation time and blood loss (*p* > 0.05). The mean incision length was 8.07 ± 1.02 versus 7.91 ± 1.15 cm (*t* = 0.651, *p* = 0.516). The mean operation time was 79.3 ± 17.9 versus 77.6 ± 18.5 min (*t* = 0.426, *p* = 0.670), and intraoperative blood loss was 72.5 ± 14.3 versus 74.2 ± 16.9 mL (*t* = -0.472, *p* = 0.637). Significant differences in old age, younger than 60 years, high energy trauma. We present clinical characteristics of the patients in Table 2.

Functional Evaluation

According to the MEPS, we measured the patients' pain level at rest and activity. During the resting state, the VAS scores were 18.7 ± 9.4 in patients with CRPS I to 12.6 ± 3.2 in patients without CRPS I (*t* = -0.437, *p* = 0.664). During the activity state, the VAS scores were 57.6 ± 21.5 in patients with CRPS I to 48.3 ± 16.4 in patients without CRPS I (*t* = 2.529, *p* < 0.05). Significant difference was observed in the total scores and pain aspect of the MEPS score system (61 ± 6 vs. 59 ± 4 , *t* = 2.174, *p* < 0.05; 28 ± 3 vs. 24 ± 5 , *t* = 3.831, *p* < 0.001) There was no significant difference between the total scores of PREE between the two groups (*t* = 0.504, *p* > 0.05). However, significant difference was observed in the pain aspect of the PREE score system ($31 \pm$

19 vs. 22 ± 8 , *t* = 4.267, *p* < 0.01). The mean points of two groups were 28.3 and 30.9. No significant difference was observed in QuickDASH Scores (*t* = -1.795, *P* > 0.05).

Mental Status Assessment

The depression scores were 7.4 ± 3.1 and 6.9 ± 2.5 respectively in the two group patients (*t* = 0.900, *p* = 0.369), and the anxiety scores were 7.1 ± 3.8 and 6.0 ± 2.2 (*t* = 2.104, *p* < 0.05), respectively. A significant difference was observed in anxiety scores between the two groups.

Independently Associated Factors

Significant differences in higher scores of pain at activity, high SF-12 physical and mental points, higher MEPS pain and total points, and higher PREE pain points were noted between the patients with CRPS I (*n* = 24) and without CRPS I (*n* = 197). The parameters with significant differences were regarded as dependent variables and included in multivariable logistic analysis to identify the independently associated factors of developing CRPS I after radial head fractures, which included female sex (OR: 1.537; 95% CI: 1.138–2.072), age younger than 60 years (OR: 1.682; 95% CI: 1.246–2.267), moderate and severe MEPS pain (OR: 3.229; 95% CI: 2.392–4.351) and anxiety (OR: 83.346; 95% CI: 61.752–112.320) (Table 3).

Discussion

This study reported that the incidence of CRPS I after radial head arthroplasty was 11%. According to the multivariable logistic analysis, the independently associated factors were female sex, age younger than 60 years, moderate and severe MEPS pain and anxiety.

The Incidence of CRPS I after Radial Head Arthroplasty

Jellad *et al.*¹³ reported that, the incidence of CRPS I was 32.2% for distal radius fracture patients, which is higher than our study. The disparity of fracture types and could well explain this difference. Our studies included radial head fracture patients. Compared to the distal radius fracture, radial head fracture may even have more effect on functional recovery after fracture. Another possible explanation of this lower incidence is the difference in therapeutic schedule. The patients included in their study got conservative treatment and our study focused on the patients undergoing unilateral arthroplasty. We also found that the majority of patients met the criteria of CRPS I within 1 month after surgery. Field *et al.*³⁵ showed that CRPS I often occurs within 2 weeks in patients who suffered distal radius fractures. In general, elbow pain, swelling, and reduced movement are considered normal features within 7 days after surgery. If the pain persists for a long time and shows no evidence of decreasing or reappears after relief, doctors should consider the possibility of CRPS I.

The Associated Factors of CRPS I

Similarly, some previous studies reported the same results as this study, in which female sex, young age, moderate and severe MEPS pain were the independent risk factors for the development of CRPS I.^{4,36,37} Women seem to exhibit an increased prevalence of radial head fractures compared with men (1.3:1).³⁷ Another possible cause of this phenomenon is vitamin D deficiency. Women are considered at-risk populations with a high prevalence of vitamin D deficiency. Previous studies³⁸ have verified that vitamin D deficiency is the potential reason for neuropathic pain. Yoon *et al.*³⁹ reported that younger age was associated with worse postoperative outcomes and more complications, which may partly explain the increased incidence of CRPS I. However, Hastie *et al.*⁴⁰ reported that basal pain sensitivity and modulation vary widely in different patients. Many studies have reported that perioperative pain is one of the risk factors for CRPS I, which may be ascribed to sensitization of the nervous system.^{41,42} Therefore, orthopedists should pay more attention to perioperative pain.

In our study, there is no significant difference in the depression scores between the patients with and without CRPS I, which was different from those observed in a previous study.⁴³ In that study, depression may contribute to the development of CRPS. Reverse causation may serve as a potential limitation of the study. Causality cannot be determined from the logistic regression model. On the same hand, it is difficult to explain the changes and abnormalities in the tissues by psychiatric factors only. However, anxiety was also a risk factor for the development of CRPS I. A prospective study performed in the United States verified that high preoperative anxiety levels predict the development of CRPS I in patients undergoing total knee arthroplasty.⁴⁴ The increased catecholamine activity could account for the relationship between anxiety and CRPS I. Harden *et al.*⁴⁵ verified that catecholamine levels in the injured limb were significantly increased compared with normal control levels. Additionally, catecholamine levels are associated with the patient's anxiety status.⁴⁵

There is no significant difference of the post-operation elbow function in 9-month of follow-up between two groups of patients. This phenomenon may be attributed to the characteristics of CRPS I, because the regional pain of CRPS I is disproportionate in time or severity to the trauma events.⁹ However, a previous study by Reimer *et al.* drew different conclusions, which reported that motor dysfunction, sensory symptoms and mild pain persisted in CRPS-I.⁴⁶ The factors responsible for the seemingly conflicting results of these prior studies are unclear but may be related to the small sample size of their study ($n = 19$) resulting in larger variance around outcome estimates. Further investigation into the effects of CRPS-I on post-operation elbow function is needed to draw a more precise conclusion.

Our study only included patients undergoing radial head arthroplasty. Given the lack of a control conservative treatment group, we cannot determine whether radial head arthroplasty exerts an influence on the progression of CRPS I. In 2021, Jacques *et al.*⁴⁷ verified that the incidence of CRPS I after total knee arthroplasty was 13%. Therefore, they suggested that doctors should closely monitor CRPS I and provide appropriate interventions as early as possible in patients undergoing arthroplasties. For radial head fracture patients, a vigilance medical care could lead to greater potential gain, which includes careful medical history taking, optimal postoperative pain management, and prompt intervention providing. Medical history taking should more focus on patients' biological, psychological, and social condition, which may identify associated risk factors. For suspected CRPS I cases, postoperative pain management should be provided by a multidisciplinary team, including physical therapy, prompt intervention providing, and psychological counseling.

Limitations

The limitations of this study were as follows. First, our study is based on patients who underwent radial head arthroplasty, and the results may not be universally applicable to patients who undergo other treatments. Second, the findings of this study are limited to the small sample size, which limits the generalizability of our results. Third, some factors, such as radiological parameters of fractures and the cost of surgery, were not included in this study. The strength of this study was the use of a multivariate analysis regression model and the availability of demographic and clinical data to CRPS I in radial head fracture patients undergoing unilateral arthroplasty. As far as know, this is the first study to explore the incidence of CRPS I in radial head fracture patients undergoing unilateral arthroplasty. Another important point of this study was the identification of associations between baseline data, clinical data and CRPS I in radial head fracture patients undergoing unilateral arthroplasty.

Conclusion

In this prospective observational study, the proportion of CRPS I in radial head fracture patients undergoing unilateral arthroplasty was 11% and to explore associated factors. The risk factors for developing CRPS I after radial head arthroplasty include female sex, younger age, moderate and severe MEPS pain and anxiety. Future research needs to base upon more large survey sample to assess the actual prevalence of CRPS I in radial head fracture patients with different surgical methods.

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