Disability and pain after cortisone versus placebo injection for trapeziometacarpal arthrosis and de Quervain syndrome

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Abstract

Background This study tested the null hypothesis that type of injection (corticosteroid vs. placebo) is not a predictor of arm-specific disability as measured with the Disabilities of Arm, Shoulder and Hand questionnaire 1 to 3 months after injection of dexamethasone or placebo for treatment of trapeziometacarpal (TMC) arthrosis or de Quervain syndrome. Secondly, we tested if type of injection was a predictor of pain intensity.

Methods Thirty-six English-speaking adults with TMC arthrosis or de Quervain syndrome were randomized for a dexamethasone or a placebo injection. At time of the injection, patients completed a demographic data sheet and validated questionnaires assessing arm-specific disability, pain intensity, depressive symptoms, pain catastrophizing, and patient's health-related beliefs. At an average of 1.4 ± 0.42 months (range, 0.79–2.5 months) after the injection, patients completed questionnaires regarding arm-specific disability, pain, and treatment satisfaction. Grip and pinch strength measurements were measured at both time points. Bivariable and multivariable analyses assessed predictors of arm-specific disability and pain intensity at follow-up.

Results Type of injection was not a predictor of arm-specific disability or pain intensity 1 to 3 months after injection. The best model both for arm-specific disability and pain intensity at follow-up included pain catastrophizing and explained 18 % and 33 % of the variability, respectively.

Conclusions Catastrophic thinking was a better predictor of both of arm-specific disability and pain intensity than

diagnosis or type of injection (steroid vs. placebo) 1 to 3 months after an injection.

Keywords Arm-specific disability · Corticosteroid injection · De Quervain syndrome · Pain · Trapeziometacarpal arthrosis

Introduction

Disability associated with common upper extremity diseases correlates most strongly with mood and coping strategies [2, 3, 18]. It is unclear to what degree physical treatments can decrease disability, whether they are disease-modifying or palliative. Specific to this study, it is not clear whether a corticosteroid injection can decrease disability associated with either trapeziometacarpal arthrosis or de Quervain syndrome.

Data to date have not demonstrated a consistent advantage of intra-articular corticosteroid injections over placebo for trapeziometacarpal arthrosis [22]. The only randomized placebo-controlled trial comparing steroid and placebo injection for de Quervain syndrome that we are aware of demonstrated an advantage for steroid at 1 week and up to 1 year [14].

This study tested the null hypothesis that type of injection (corticosteroid vs. placebo) is not a predictor of arm-specific disability as measured with the Disabilities of Arm, Shoulder and Hand (DASH) questionnaire 1 to 3 months after injection of dexamethasone or placebo for treatment of TMC arthrosis or de Quervain syndrome. Our secondary null hypothesis was that type of injection is not a predictor of pain intensity 1 to 3 months after injection of dexamethasone or placebo for treatment of TMC arthrosis or de Quervain syndrome. Finally, we assessed if there were other predictors than type of injection for arm-specific disability as measured with the DASH questionnaire and pain intensity 1 to 3 months after injection

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of dexamethasone or placebo for treatment of TMC arthrosis or de Quervain syndrome.

Materials and Methods

A prospective, randomized, double blind study comparing injection with dexamethasone and lidocaine versus injection of placebo (lidocaine only) for lateral epicondylitis was approved by our human research committee. The study for lateral epicondylitis was initiated and completed with balanced 1:1 randomization, but patients did not like the idea of receiving a placebo. During the study, we requested and received permission to add patients diagnosed with TMC arthrosis and de Quervain syndrome to our study and to change to unbalanced randomization so that three out of four patients would receive dexamethasone instead of a placebo. This change did not improve enrollment as much as hoped and the trial was terminated. Given how difficult these data were to generate, we developed a new primary study question in an attempt to learn from it.

Patients with pain in the radial styloid region that could be reproduced with (1) palpation over the first dorsal compartment of the wrist, and (2) active or passive ulnar deviation with a fist around the thumb (Finkelstein maneuver), were considered for enrollment into the de Quervain syndrome group. Patients with pain at the base of the thumb that could be reproduced along with crepitation by pushing and moving the thumb metacarpal against the trapezium (the grind test) were considered for enrollment into the TMC arthrosis group. After enrollment and informed consent, the diagnosis was confirmed when the majority of symptoms and signs were relieved after injection of lidocaine (with or without dexamethasone) into the origin of the first dorsal wrist compartment (for de Quervain syndrome) or the TMC joint (for TMC arthrosis). Radiological assessment was not considered necessary for diagnosis. More diffuse pain and tenderness were not considered a reason for exclusion if all of the above criteria were met. Informed consent was obtained from all patients.

Forty-two English-speaking adult patients (18 years or older) that presented to one of two hand surgeons at an outpatient clinic of a tertiary care hospital with complaints and physical findings consistent with the diagnosis of TMC arthrosis or de Quervain syndrome that existed for less than 6 months were enrolled in this randomized controlled trial between November 2004 and February 2008. Patients with the following criteria were excluded from this study: (1) other problems or complaints concerning the involved arm, (2) systemic inflammatory disease, (3) pregnant women, (4) prior treatment with corticosteroids (either an

injection or iontophoresis), (5) prior surgery for the condition, (6) abnormal neurologic examination, and (7) history of adverse reaction to lidocaine or corticosteroids.

After informed consent was obtained, patients were randomized to either a single injection with 1 mL dexamethasone (4 mg dexamethasone sodium phosphate per milliliter saline; American Region Laboratories Inc., Shirley, NY) mixed with 1 mL 1 % lidocaine (10 mg lidocaine hydrochloric acid per milliliter saline; Abbott Labs, N. Chicago, IL) without epinephrine or a single placebo injection of 2 mL 1 % lidocaine. All injections were prepared by a trained research assistant and administered by the treating hand surgeon. Both the patient and the surgeon were blinded from the assigned treatment for the duration of the study. Patients were randomized 3:1 in the dexamethasone and the placebo cohort, respectively.

Before the injection was administered, patients completed a demographic data sheet and the following questionnaires: 10 cm Visual Analogue Scale (VAS) to measure pain intensity, the DASH [5] questionnaire to determine arm-specific disability, the Center for Epidemiologic Studies-Depression Scale (CES-D) [15, 21] to measure symptoms of depression, the Pain Catastrophizing Scale (PCS) [17] to evaluate pain catastrophizing, and the general Multidimensional Health Locus of Control (MHLC) [20] scale to assess patients' health-related beliefs. The MHLC subscales evaluate patients' belief if the forces determining one's health are (1) primarily internal, (2) under the control of powerful others, and (3) a matter of chance. Patients who score high on the "Internal Health Locus of Control" (IHLC) subscale find themselves personally responsible for their health. Those who score high on the "Powerful Others Health Locus of Control" (PHLC) subscale rely on important others for control on their health (e.g. their doctor), and patients with a high score on the "Chance of Health Locus of Control" (CHLC) subscale believe that their health status is a matter of chance. Patient's grip and pinch strength were measured by an independent research assistant as the average of three attempts. The Jamar dynamometer (Asimov Engineering, Los Angeles, California) was used to measure grip strength and a pinch gauge (B&L Engineering, Santa Ana, California) was used to measure pinch strength. Grip and pinch strength were expressed as the percentage of strength of the involved side compared to the noninvolved side (involved/noninvolved side). At time of follow-up, patients completed the DASH, the VAS for pain, and the VAS for treatment satisfaction. Grip and pinch strength measurements were repeated.

The primary outcome was arm-specific disability as measured with the DASH 1 to 3 months after enrollment. The secondary outcome measure was the VAS for pain intensity 1 to 3 months after enrollment.

Table 1 Overview of cohorts at baseline, $n=36$

	Dexamethasone injection			Placebo injection				
	<i>n</i> =27			<i>n</i> =9				
Parameter	Mean	SD	Range	Mean	SD	Range	Correlation	<i>p</i> value
Age (years)	48	12	26–68	55	12	28–69	NS	0.13
Education (years)	16	2.8	12–24	14	3.5	8.0–18	NS	0.18
Onset of symptoms (<i>n</i> =32)	32	84	3.0–416	64	79	4.0–208	NS	0.70
DASH	31	18	1.7–69	31	11	17–53	NS	0.91
Pain	5.0	2.2	0.60–9.0	4.9	2.9	1.2–9.5	NS	0.96
IHLC	23	5.5	6.0–34	23	2.0	19–25	NS	0.53
CHLC	15	5.4	6.0–26	16	4.8	8.0–21	NS	0.52
PHLC	17	6.0	6.0–30	17	5.3	9.0–26	NS	0.99
CES-D	9.9	13	0.0–52	9.1	8.3	2.0–27	NS	0.36
PCS	21	8.8	13–39	20	6.2	13–30	NS	0.91
Parameter	Number		%	Number		%		
Gender							NS	0.67
Male	8		29.6	2		22.2		
Female	19		70.4	7		77.8		
Race							NS	0.17
White	24		88.9	7		77.8		
Black	1		3.7	2		22.2		
Asian/Pacific Islander	2		7.4	0		0.0		
Diagnosis							NS	0.71
TMC arthrosis	10		37.0	4		44.4		
De Quervain’s syndrome	17		63.0	5		55.6		
Marital status							NS	0.23
Single	7		25.9	0		0.0		
Married/living with partner	16		59.3	7		77.8		
Separated/widowed	4		14.8	2		22.2		
Work status								0.034
Working, full time or part time	22		81.5	4		44.4		
Homemaker	1		3.7	2		22.2		
Retired	1		3.7	0		0.0		
Unemployed	2		7.4	0		0.0		
Other/unknown	1		3.7	3		33.3		
Degree of education							NS	0.18
No diploma or high school diploma	5		18.5	4		44.4		
Post-secondary education degree	22		81.5	5		55.6		
Dominant hand involved							NS	0.70
No	14		51.9	6		66.7		
Yes	13		48.1	3		33.3		
Any previous treatment (<i>n</i> =31)							NS	0.99
No	6		27.3	2		22.2		
Yes	16		72.7	7		77.8		

N number, *SD* standard deviation, *NS* not significant, *DASH* Disabilities of the Arm, Shoulder and Hand, *IHLC* Internal Health Locus of Control scale, *CHLC* Chance Health Locus of Control scale, *PHLC* Powerful others Health Locus of Control scale, *CES-D* Center of Epidemiologic Studies-Depression scale, *PCS* Pain Catastrophizing Scale

The numbers in *Italics* indicate significant *p* values ($p<0.05$)

Statistical Analysis

A post hoc power analysis demonstrated that 36 patients provided 79 % power to detect three predictors with an *R*-squared that would explain 25 % of the variability in DASH scores using a multivariable linear regression analysis at a significance level of 0.05.

Missing or invalid measurements were imputed with the mean of the specific study cohort. Based on the small sample size, nonparametric tests were used to analyze the relationships between variables. In bivariable analysis, the Mann–Whitney *U* test was used to evaluate a dichotomous and a continuous variable, and the effect size (*r*) was calculated by dividing the *z* value by the square root of the total number of cases. The Kruskal–Wallis test was conducted to compare categorical variables with more than two categories and a continuous variable. The Pearson Chi-square test was performed to assess the relationship between two categorical variables. Whenever the expected cell frequency was less than five, the Fisher's exact test was used. Spearman correlations were performed to determine the relationship between two continuous variables.

Variables with a significance level of $p < 0.10$ met the criterion to be entered into a multivariable linear regression analysis using the stepwise backward method. Categorical variables with more than two categories were entered as dummy-coded variables.

Results

Of the 42 patients enrolled in this study, one patient was excluded because enrollment data were misplaced and five patients were lost to follow-up. Thirty-six patients (88 %) completed the study an average of 1.4 ± 0.42 months (range 0.79–2.5 months) after enrollment: 27 patients (75 %) in the dexamethasone injection cohort (10 patients with TMC arthrosis and 17 patients with de Quervain syndrome) and 9 patients (25 %) in the placebo injection cohort (four patients with TMC arthrosis and five patients with de Quervain syndrome). The 36 patients that completed the study had, on average, a higher IHLC score than the five patients who were lost to follow-up ($p = 0.014$).

Baseline characteristics of the cohorts are reported in Table 1. The only significant difference between the two cohorts was in work status ($p = 0.034$).

Numbers Analyzed

Mean imputation was used for one missing DASH questionnaire, one missing VAS for pain, one missing IHLC subscale, one missing CES-D questionnaire, eight missing

grip strength measurements, and three missing pinch strength measurements at enrollment. At time of follow-up, one missing DASH questionnaire, one missing grip strength measurement, and one missing pinch strength measurement were imputed with the mean of the specific cohort.

Follow-up Comparisons

There was no significant difference in arm-specific disability ($p = 0.81$) or pain intensity ($p = 0.80$) 1 to 3 months after enrollment between patients who received a dexamethasone or a placebo injection (Tables 2 and 3)

Predictors of Arm-Specific Disability at Follow-up

Variables with a significant relationship with arm-specific disability at follow-up in bivariable analysis were any previous treatment ($p = 0.029$), the PCS ($p = 0.0071$), and the CES-D ($p = 0.0083$), but not placebo or dexamethasone injection. The best multiple linear regression model for greater arm-specific disability included greater catastrophic thinking and explained 18 % of the variability (adjusted *R*-squared = 0.18, $p < 0.001$) (Table 2). Any previous treatment was not entered into this model because this would affect the number of patients taken into account. A multivariable analysis with PCS, CES-D, and any previous treatment resulted in a best model which included greater catastrophic thinking and explained 17 % of the variability (adjusted *R*-squared = 0.17, $p = 0.013$).

Predictors of Pain Intensity at Follow-up

Variables with a significant relationship with pain at follow-up in bivariable analysis were degree of education ($p = 0.036$), PHLC subscale ($p = 0.035$), the PCS ($p < 0.001$), and the CES-D ($p = 0.0020$), but not placebo or dexamethasone injection. The best multiple linear regression model for greater pain intensity included greater catastrophic thinking alone and explained 33 % of the variability (adjusted *R*-squared = 0.33; $p < 0.001$) (Table 3).

Discussion

We were not able to reject our null hypothesis: there was no difference in arm-specific disability as measured with the DASH 1 to 3 months after injection of dexamethasone or placebo for treatment of TMC arthrosis or de Quervain syndrome. Furthermore, there was no difference in pain intensity 1 to 3 months after injection of dexamethasone or placebo for treatment of TMC arthrosis or de Quervain syndrome. Pain catastrophizing was the strongest predictor of arm-specific disability and pain intensity.

Table 2 Bivariable and multivariable analysis—follow-up DASH, $n=36$

Bivariable analysis	Correlation	<i>p</i> value
Mann–Whitney <i>U</i> test		
Cohort (dexamethasone vs. placebo)	NS	0.81
Diagnosis	NS	0.40
Sex	NS	0.45
Degree	NS	0.24
Dominant hand affected	NS	0.75
Any previous treatment ($n=31$) ^a	0.36	0.029
Kruskal–Wallis test		
Race	NS	0.12
Marital status	NS	0.45
Work status	NS	0.21
Spearman correlation		
Baseline		
Age (years)	NS	0.21
Education (years)	NS	0.97
Onset of symptoms ($n=32$)	NS	0.56
IHLC	NS	0.16
CHLC	NS	0.33
PHLC	NS	0.76
PCS	0.44	0.0071
CES-D ^b	0.43	0.0083
Follow-up		
Follow-up time (weeks)	NS	0.18
Multivariable analysis		
PCS	Adjusted R^2	<i>p</i> value
	0.18	0.0062
Bivariable analysis with response variables ^c		
Spearman correlation		
Baseline		
Pain	0.43	0.0098
Grip strength (%)	NS	0.85
Pinch strength (%)	−0.34	0.041
Follow-up		
Pain	0.64	<0.001
Grip strength (%)	NS	0.76
Pinch strength (%)	NS	0.66

DASH Disabilities of the Arm, Shoulder and Hand, *N* number, *NS* not significant, *IHLC* Internal Health Locus of Control scale, *CHLC* Chance Health Locus of Control scale, *PHLC* Powerful others Health Locus of Control scale, *CES-D* Center of Epidemiologic Studies–Depression scale, *PCS* Pain Catastrophizing Scale

^a Variable not entered in the multivariable analysis because this would decrease the sample size of the model

^b Variable entered in the multivariable analysis but not included in the strongest model

^c Response variables not considered for the multivariable analysis

The numbers in Italics indicate significant *p* values ($p<0.05$)

Table 3 Bivariable and multivariable analysis—follow-up pain, $n=36$

Bivariable analysis	Correlation	<i>p</i> value
Mann–Whitney <i>U</i> test		
Cohort (dexamethasone vs. placebo)	NS	0.80
Diagnosis	NS	0.72
Sex	NS	0.94
Degree ^a	0.35	0.036
Dominant hand affected	NS	0.41
Any previous treatment ($n=31$)	NS	0.28
Kruskal–Wallis test		
Race	NS	0.22
Marital status	NS	0.48
Work status	NS	0.21
Spearman correlation		
Baseline		
Age (years)	NS	0.20
Education (years)	NS	0.12
Onset of symptoms ($n=32$)	NS	0.28
IHLC	NS	0.91
CHLC	NS	0.87
PHLC ^a	0.35	0.035
PCS	0.55	<0.001
CES-D ^a	0.50	0.0020
Follow-up		
Follow-up time (weeks)	NS	0.44
Multivariable analysis		
PCS	Adjusted R^2	<i>p</i> value
	0.33	<0.001
Bivariable analysis with response variables ^b		
Spearman correlation		
Baseline		
DASH	0.37	0.028
Grip strength (%)	NS	0.29
Pinch strength (%)	NS	0.50
Follow-up		
DASH	0.64	<0.001
Grip strength (%)	NS	0.57
Pinch strength (%)	NS	0.37

DASH Disabilities of the Arm, Shoulder and Hand, *N* number, *NS* not significant, *IHLC* Internal Health Locus of Control scale, *CHLC* Chance Health Locus of Control scale, *PHLC* Powerful Others Health Locus of Control scale, *CES-D* Center of Epidemiologic Studies–Depression scale, *PCS* Pain Catastrophizing Scale

^a Variables entered in the multivariable analysis but not included in the strongest model

^b Response variables not considered for the multivariable analysis

The numbers in Italics indicate significant *p* values ($p<0.05$)

The strengths of this study are the prospective randomized placebo-controlled data collection and the fact that the research assistant was not involved in patient care. Limitations include low power (79 %) in part due to the uneven allocation ratio, discontinuation of the original trial before reaching the target enrollment number because of the slow enrollment rate (patients preferred to receive the active treatment instead of a placebo) with subsequent alteration of the primary study question, and the loss of five patients (12 %).

Our findings should be put into perspective with other studies. Among the few randomized placebo injection controlled trials to date, none has demonstrated a benefit of corticosteroid injection over placebo for trapeziometacarpal arthrosis [4, 12]. Several prospective cohort studies of corticosteroid injection and an open-label trial of corticosteroid and hyaluronate injections documented improvements in both groups but did not compare to placebo injection [1, 7, 8, 10].

A randomized placebo-controlled trial of corticosteroid injection for de Quervain syndrome by Peters-Veluthamaningal and colleagues [14] followed patients a mere week after injection and found a benefit of steroids for pain relief, but not function. Retrospective and prospective cohort studies report improvements in most patients, but often over long time periods [6, 11, 16].

Regarding the surgical treatment options for these conditions, it is difficult to know the optimal rate of surgery for a problem that is self-limiting (de Quervain syndrome) and a problem that everyone eventually gets and most people adapt to (TMC arthrosis).

The findings of this study are in agreement with extensive study of musculoskeletal pain conditions that consistently finds that symptoms of depression and ineffective coping strategies such as catastrophic thinking (or low self-efficacy) explain more of the variation in pain intensity and disability than pathophysiology or biomedical treatments [9, 13, 19].

This study supports our belief that the effectiveness of corticosteroid injections for treatment of TMC arthrosis and de Quervain syndrome seems limited and uncertain, but that there is valuable opportunity to reduce suffering by helping patients to develop adaptation, resiliency, and optimism.

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Conflict of Interest All named authors hereby declare that they have no conflicts of interest to disclose related to this study.

Ethical Statement All authors adhere to the ethical standards described by the Committee on Publication Ethics and the International Committee of Medical Journal Editors. The study was completed under an IRB-approved protocol.

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