Effects of reduction in shoulder pain on quality of life and community activities among people living long-term with SCI paraplegia: a randomized control trial

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Objective/background: People with spinal cord injury (SCI) paraplegia can develop shoulder problems over time, which may also cause pain. Shoulder pain may complicate or interfere with a person's daily activities, social events, and their overall quality of life (QOL). The purpose of this study was to examine changes in social interaction and QOL after an exercise treatment for shoulder pain in people with SCI paraplegia.
Design: Fifty-eight participants with SCI paraplegia who were also experiencing shoulder pain were selected and randomized to either an exercise treatment or a control group. Participants in the treatment group participated in a 12-week, at-home, exercise and movement optimization program designed to strengthen shoulder muscles and modify movements related to upper extremity weight bearing.
Methods: Participants filled out self-report measures at baseline, 12 weeks later at the end of treatment, and at a 4-week follow-up.
Outcome measures: The Wheelchair User's Shoulder Pain Index (WUSPI), the Social Interaction Inventory (SII), and the Subjective Quality of Life Scale.
Results: From the baseline to the end of treatment, repeated-measures analysis of variance revealed a significant interaction between WUSPI and SII scores, $P < 0.001$, and between WUSPI and QOL scores, $P < 0.001$.
Conclusion: Reductions in shoulder pain were related to significant increases in social participation and improvements in QOL. However, increases in social participation did not significantly affect improvements in QOL.

Keywords: Quality of Life, Interpersonal Relations, Shoulder Pain, Exercise Therapy, Spinal Cord Injuries, Activities of Daily Living, Paraplegia

Introduction

People who use a manual wheelchair as their primary or only source of locomotion are subject to shoulder problems after several years of usage. The length of time before the onset of shoulder problems can vary from 5 to 20 years, depending on factors such as the age of the individual, the level of injury, and the type of use. Moreover, people frequently adopt techniques for transfers, loading their wheelchairs, and miscellaneous upper extremity activities that are responsible for part of the shoulder problems experienced later.[1–3] This complication may compromise people's daily activities, cause them various degrees of pain, and in its most severe form may result in turning a person who was initially paraplegic into someone who is functionally tetraplegic.[4]

The structure of the human shoulder joint is not optimal for locomotion. Its purpose is primarily to position the hand, to be able to lift weights, and to counterbalance the walking motion. People with paraplegia due to spinal cord injury (SCI) are particularly at risk for developing shoulder problems and pain because their average age of onset is about 40 years of age and as a group they are now experiencing near-normal life expectancies[5] In one of our studies conducted by the rehabilitation research and training center on aging with SCI, it was discovered that approximately 40% of people

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developed such shoulder problems within 20 years following the onset of SCI.[6] These results are similar to those of Sie *et al.*[7] The high cost of additional care, possible surgeries, and interference with daily activities make this emerging problem one of great significance.

Shoulder pain and dysfunction can also have significant psychological consequences. Two of the most important impacts are on social participation and quality of life (QOL). Pain and dysfunction in the shoulders may reduce a person's ability and motivation to participate socially because of the difficulties getting around, using their normal means of transportation, and enduring pain while trying to participate with others. QOL itself can be impaired because of the distress of the pain, the limits it puts on enjoyable activities, and the anxiety created about future functioning. The world health organization has recognized the importance of both social participation and QOL as essential outcomes of all rehabilitation efforts.[8]

The purpose of the current study was to examine the interrelationships among changes in pain, changes in social interaction, and changes in QOL from baseline, to the end of treatment, and again 4 weeks later. This study is a companion to a study that examined primary outcomes, both physical and psychological from treating shoulder pain. The primary outcomes from that study are detailed in a separate article.[9] Stated briefly, the physical and psychological findings turned out to be highly significant. There was a significant difference on all physical measures in the treatment group. Participants in the treatment group were significantly better after 12 weeks on measures of pain and strength compared with a control group that received only education about the shoulder. When compared with the control group at the end of treatment, there was a significant difference on community activity levels. Likewise, there was a significant improvement on subjective QOL. However, that study did not examine the interactions among those variables in an attempt to discover potential causal linkages.

In an earlier study, we found a significant correlation of -0.35 between shoulder pain as measured in this study and QOL.[1] This finding led us to hypothesize that changes in pain may relate to changes in QOL as well. Certainly, pain is one of those distressing experiences that can diminish enjoyment, productivity, and interpersonal relations enough to impact one's QOL. Such relationships between pain and QOL measures have been observed by others. Latimer *et al.* [10] found a significant relationship between bodily pain and a measure of depression, which was reduced when the pain was treated. However, to our knowledge no previous studies exist about specifically treating shoulder pain in people with SCI and assessing their QOL before and after. Similarly, it is well known that among people with an SCI there is a strong correlation of about 0.45 between social interaction and QOL.[11,12] This finding suggest the necessity of testing whether any improvement in QOL that results from decreases in shoulder pain occurs directly through the mechanism of increased social participation following the reduction of shoulder pain.

This study tested the following hypotheses: (1) decreases in shoulder pain will be associated with increases in social participation, (2) decreases in shoulder pain in people with SCI paraplegia will be associated with improvements in QOL, and (3) increases in social participation will be associated with increases in QOL.

Method

Participants

This study was approved by the institutional review boards of the University of Southern California, Los Angeles, CA and Rancho Los Amigos National Rehabilitation Center (RLANRC), Downey, CA. Recruitment for participants occurred at RLANRC between March 2004 and December 2005. A total of 127 individuals were screened for eligibility.

Participant ages ranged from 22 to 72 years ($M = 45.0$, SD = 11.2). All participants had an SCI for a duration of at least 5 years ($M = 20.1$, SD = 10.5) with an average duration of shoulder pain of approximately 5 years ($M = 5.5$, SD = 6.7). Pain was measured by use of the Wheelchair User's Shoulder Pain Index (WUSPI).

Participants were screened and selected if they met the following criteria: (1) interference of at least one functional task (e.g. body transfers, wheelchair propulsion) due to unilateral or bilateral shoulder pain, (2) between 19 and 75 years of age, (3) onset of paraplegia at age 14 or older, (4) at least 5 years duration with SCI, and (5) ability to understand consent.

Participants were excluded from the study if any of the following conditions were present: (1) hospitalization within the last month, (2) cortisone injection to the shoulder within the last 4 months, (3) fracture within the last year, (4) shoulder surgery to the painful side within the last year, (5) diagnosis of complete rotator cuff tear, rheumatoid arthritis, adhesive capsulitis at the shoulder, or complex regional pain syndrome (formally known as reflex sympathetic dystrophy), (6) any serious medical conditions, (7) major depression, (8) alcohol abuse, or (9) unlikely to complete the 12-week treatment.

Of the initial 127 screened, 80 participants were eligible for participation. The remainder were excluded

because they either did not meet inclusion criteria or they met exclusion criteria. Once participants met eligibility requirements, they signed informed consent forms and were randomized by a computer-generated list to either a treatment or alternative treatment group. Participants were informed that they would be in one of the two treatment groups. Participants received $50 at baseline and $50 post-intervention as incentive for participation.

All participants were initially screened, assigned to groups, and begun on their program at a large, urban rehabilitation center. The outcome measures described in this study were all taken by a physical therapist who was blinded to group assignment of the participants. Of the 80 participants who were randomized, 22 of the individuals withdrew before receiving instruction in the intervention (14 in the exercise/movement optimization group and 8 in the attention control group.) An additional six participants in the control group were lost to follow-up after the immediate post-intervention assessment but before the 4-week follow-up evaluation (see later section). Adverse events were reported according to the Safety Monitoring Board protocol. No adverse effects were reported by any of the participants. Participants carried out their programs at home but returned to the center for re-evaluation over the 12 weeks of treatment and follow-up.

Measures

The first measure for this study was the WUSPI.[13] The WUSPI provides an aggregate index of the intensity of shoulder pain during 15 different activities including transfers, activities of daily living, and mobility performed from a wheelchair.[13] The questionnaire utilizes a series of visual analogue scales consisting of 10-cm lines anchored by 'no pain' and 'worst pain ever experienced' with a maximum total score of 150. The WUSPI has been shown to be both reliable and valid for people with SCI.[14]

The second measure was the Social Interaction Inventory (SII) (formerly called the Community Activities Checklist[15]). This 16-item questionnaire asks people to indicate how many times during the previous 7 days they engaged in a range of specified social activities. Extensive item analysis, normative, reliability, and validity studies have been carried out with the SII. Its test–retest reliability is 0.87 over a 3-week interval and it has proven to be a valid outcome for interventions designed to improve functioning among people with a disability, including those with an SCI.[15] The possible range of scores is from 0 to 84; it is easy to understand and takes approximately 5 minutes to complete. The SII has three subscales: community activities (six items), social activities (six items), and preparatory activities (four items).

The subjective quality-of-life (QOL) scale is a single-item scale that asks people to rate their own overall QOL. The scale is a 7-point Likert-type scale anchored at the low or negative end with the statement 'life is very distressing. It's hard to imagine how it could get much worse'. It is anchored at the high positive end with the statement 'Life is great. It's hard to imagine how it could get much better'. The midpoint is described as 'Life is so-so, neither good nor bad'. This scale has a test–retest reliability over 2 weeks of 0.84.[16] It has been used successfully as an outcome measure in other studies.[1,16] It is easy to comprehend and takes approximately 3 minutes to administer.

Procedure

A full description of the physical therapy treatment protocol and the control conditions educational program are detailed in the primary outcome study of this trial.[9] For the purposes of this psychologically oriented article, the treatment protocol can be described as a 12-week, at-home, exercise and movement technique program that emphasized strengthening of selected muscles and instruction to modify movement technique for activities related to upper extremity weight bearing (transfers, propulsion, lifting, etc.). The 12-week duration for treatment was considered by the leading therapists in the study to be sufficient to reasonably improve shoulder pain and function. The attention control education group viewed a general information video and received written information about the shoulder joint and how to maintain its function. Outcome measures for both groups were taken by a blinded physical therapist before and after the 12-week intervention period, and 4 weeks later, making a total of three measurements over approximately 16 weeks. After enrollment into the study, participants were randomized to receive one of two interventions: a combination of shoulder exercises and instruction to optimize performance techniques or an attention-control educational program. Before the start of the procedures, each participant took the relevant baseline measures (in this study the WUSPI, SII, and QOL). Participants in the comparison group received a video program and written materials about shoulder function that were general in nature and not designed to change behavior. Participants randomized to the treatment group were instructed in a home exercise program of three stretching exercises and four strengthening exercises using elastic bands and hand weights for resistance. Participants were instructed to perform the exercises

while sitting in their wheelchair three times per week for 12 weeks. In addition, individuals in the exercise group were given a list of recommendations of how to perform various activities involving upper extremity weight bearing with less stress placed on the shoulder joints. A physical therapist evaluated those activities that specifically provoked shoulder pain for the individual and gave specific recommendations to improve the movement technique. Participants in the exercise group returned at 4 weeks following the initial instruction to review progress in the exercises and to increase the level of resistance. All participants were reassessed on the outcome measures at the end of the 12-week intervention period and again 4 weeks later.

Results

A total of 22 people were missing at least one score during the study due to errors, incompleteness, or failure to take the measure. Fourteen of these were in the treatment group and eight were in the comparison group. None of the participants were missing baseline scores. All data were missing on six participants in the attention control group for the 4-week follow-up and an additional two participants did not complete the SII measure, although they completed all other measures. These missing data were replaced with the score from the 12-week, end of treatment score as that is the best and most conservative estimate of what the score would be. No data were missing from the treatment group.

A one-way repeated-measures analysis of variance (ANOVA) was conducted and found that there were no significant changes on WUSPI scores, $F(2, 62) = 0.55$, ns; SII scores, $F(2, 62) = 0.27$, ns; or QOL scores, $F(2, 62) = 0.05$, ns, for the control group. Therefore, the following results will be limited to the treatment group. In the experimental group, there significant changes were found for WUSPI scores, $F(2, 50) = 29.80$, $P < 0.001$; SII scores, $F(2, 50) = 3.77$, $P = 0.03$; and QOL scores, $F(2, 50) = 7.82$, $P = 0.001$. Owing to the lack of change found in the control group, the following results are confined to the experimental group.

Hypothesis 1: Decreases in shoulder pain will be associated with increases in social participation.

A 2×2 repeated-measures ANOVA was conducted comparing WUSPI scores and SII scores from those in the exercise group between baseline and the end of treatment. The results of this analysis showed a main effect for WUSPI scores, $F(1, 25) = 7.82$, $P = 0.01$, a main effect for SII scores, $F(1, 25) = 16.31$, $P < 0.001$, and a significant interaction between changes in WUSPI and changes in SII scores, $F(1, 25) = 28.78$, $P < 0.001$. WUSPI scores decreased from an average of 52.4 before treatment to an average of 14.9 at the end of treatment. Social interaction scores increased from an average of 45.7 to an average of 53.3 at the end of treatment (see Fig. 1). Although the difference in SII scores was relatively small, it was highly significant.

We conducted another 2×2 repeated-measures ANOVA using WUSPI and SII scores comparing the end of treatment with 4-week follow-up for those in the exercise group to see if these changes were sustained. The results of this analysis indicated a significant main effect for WUSPI scores, $F(1, 25) = 51.50$, $P < 0.001$, but no significant effect for SII scores, $F(1, 25) = 1.42$, ns, nor their interaction, $F(1, 25) = 0.273$, ns.

To determine the strength of relationship between changes of the measures, correlation coefficients were calculated between the measures at baseline, the end of treatment, and at 4-week follow-up. These correlations can be seen as Table 1. The relationship between WUSPI scores and SII scores at baseline, the end of treatment, and 4-week follow-up was found to be small at all three time points.

When analyzed on an individual basis, among all people who decreased on their WUSPI scores between baseline and the end of treatment ($N = 23$), 13 (57%) increased on social interaction. There were 16 people who further decreased their WUSPI scores between the end of treatment and 4-week follow-up, of these 16 who continuously decreased their WUSPI throughout the study, six (38%) increased their SII score from the beginning of the study to 4-week follow-up.

Hypothesis 2: Decreases in shoulder pain in people with SCI paraplegia will be associated with improvements in QOL.

A 2×2 repeated-measures ANOVA was again conducted comparing WUSPI scores and QOL scores from those in the exercise group between baseline and the end of treatment. The results of this analysis showed a significant main effect for WUSPI scores,

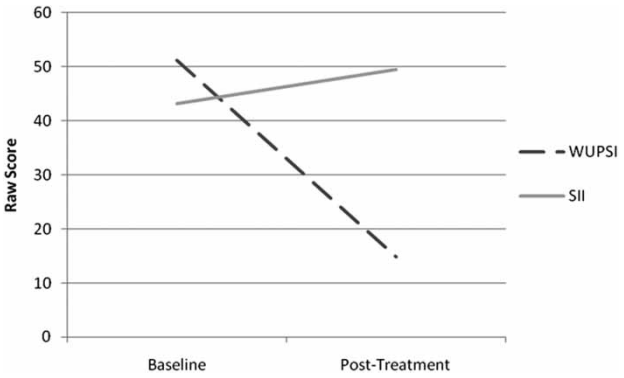

Figure 1 Interaction of WUSPI scores and SII scores between baseline and the end of treatment.

Table 1 Means, standard deviations, and correlations of exercise optimization group

	1	2	3	4	5	6	7	8	9
1. WUSPI baseline	–	0.07	0.28	0.25	0.25	−0.08	−0.20	−0.18	−0.01
2. WUSPI end of treatment		–	0.84**	0.24	−0.10	−0.02	0.03	0.10	−0.19
3. WUSPI 4-week follow-up			–	−0.18	0.05	−0.04	−0.06	0.10	−0.01
4. SII baseline				–	0.53*	0.04	−0.02	−0.01	0.46*
5. SII end of treatment					–	0.44*	−0.01	0.01	0.21
6. SII 4-week follow-up						–	0.13	0.42*	0.23
7. QOL baseline							–	0.83**	0.62**
8. QOL end of treatment								–	0.55**
9. QOL 4-week follow-up									–
Mean	52.39	14.91	13.75	45.70	53.31	46.73	4.77	5.19	5.42
Standard deviation	33.17	14.03	15.31	24.22	30.58	20.69	1.31	1.02	1.03

Notes: *$P < 0.05$, **$P < 0.01$.

$F(1, 25) = 58.34$, $P < 0.001$, a significant main effect for QOL scores, $F(1, 25) = 27.67$, $P < 0.001$, as well as a significant interaction between changes in WUSPI scores and changes in QOL scores, $F(1, 25) = 29.07$, $P < 0.001$.

Another 2×2 repeated-measures ANOVA was conducted using WUSPI and QOL scores comparing the end of treatment to 4-week follow-up for those in the exercise group. The results of this analysis indicated a significant main effect for WUSPI scores, $F(1, 25) = 10.94$, $P = 0.003$, but no significant main effect for QOL scores, $F(1, 25) = 0.278$, ns, nor their interaction, $F(1, 25) = 0.558$, ns.

WUSPI scores decreased from an average of 52.4 at baseline to an average of 14.9 at end of treatment and continued to decrease from an average of 14.9 at end of treatment to 13.8 at the 4-week follow-up. QOL scores increased from an average of 4.8 at baseline to an average of 5.2 at end of treatment and continued to increase from an average of 5.2 at end of treatment to 5.4 at the 4-week follow-up. The relationship between WUSPI scores and QOL scores at baseline was found to be small. The relationship between the measures at end of treatment was found to have a moderate negative relationship. However, at 4-week follow-up this relationship did not maintain its strength (Table 1).

Of the 23 people who decreased on shoulder WUSPI between baseline and end of treatment, 10 (43%) increased their scores on QOL. There were 16 people who further decreased their WUSPI scores between the end of treatment and 4-week follow-up, of these 16 who continuously decreased their WUSPI throughout the study, nine (56%) increased their QOL from the beginning of the study to 4-week follow-up.

Hypothesis 3: Increases in social participation will be associated with increases in QOL.

A 2×2 repeated-measures ANOVA was conducted comparing the SII scores and QOL scores for those in the exercise group between baseline and the end of treatment. The results of this analysis showed a significant main effect for SII scores, $F(1, 25) = 116.12$, $P < 0.001$, but no significant main effect for QOL scores, $F(1, 25) = 3.62$, $P = 0.07$, nor a significant interaction between changes in SII scores and changes in QOL scores, $F(1, 25) = 2.62$, ns.

A final 2×2 repeated-measures ANOVA was conducted using changes in SII scores and QOL scores comparing the end of treatment with 4-week follow-up for those in the exercise group. The results of this analysis indicated a significant main effect for SII scores, $F(1, 25) = 137.46$, $P < 0.001$, but no significant main effect for QOL scores, $F(1, 25) = 0.764$, ns, nor their interaction, $F(1, 25) = 0.935$, ns. It should be noted that the SII scores decreased significantly from the end of treatment to 4-week follow-up, the mean score from the end of treatment was 53.3 and the mean score from the 4-week follow-up was 46.7.

The strength of the relationship between SII scores and QOL scores was found to be small throughout each of the data collection times (Table 1). As the ANOVA results showed that there was no significant relationship between changes in SII scores and changes QOL scores, we did not run further analysis between baseline and 4-week follow-up.

Discussion

In this study, the results showed that there were significant changes over time in the group that received the physical therapy treatment, but there were no changes over time on any of the dependent measures in the control group. Therefore, the discussion that follows will primarily deal with the findings in the experimental group. The major thrust of the intervention (i.e. to reduce shoulder pain) was overwhelmingly positive. The intensity of pain experienced was dramatically reduced and the number of people showing major

improvement was very high. This finding in itself is very useful for clinicians and individuals with SCI alike.

Association between changes in shoulder pain and social participation

Changes in pain between baseline and the end of treatment were significantly associated with changes in SII scores as indicated by the significant interaction effect (Fig. 1). The size of the effect was moderately large, with an η of 0.54. This effect did not increase further between the end of treatment (time 2) and the 4-week follow-up (time 3). In summary, decreases in pain were associated with increases in social participation.

Association between changes in shoulder pain and QOL

Between baseline and the end of treatment, changes in pain scores were associated with changes in QOL scores as indicated by the significant interaction effect. Once again however, this effect did not increase between the end of treatment and the 4-week follow-up. In summary, reductions in pain were associated with increases in QOL.

The results showed that pain continued to improve after the end of treatment in some participants. This is probably due to people continuing to practice their treatment protocols on their own because they found it beneficial. However, SII scores and QOL scores did not continue to improve after the end of treatment. In fact, SII scores decreased from the end of treatment to the 4-week follow-up. This decrease may be due to the sharp increase in SII scores from baseline to the end of treatment, rather than a true decrease in SII. There may have been something about the treatment or the way the participants interpreted the instructions that encouraged them to participate more in the community thus increasing the score on the SII.

Association between changes in participation and QOL

This hypothesis was not supported by the data. Increases in social interaction between baseline and the end of treatment were not associated with increases in QOL. Similarly, there was no significant effect of social interaction scores on QOL scores when tested between the end of treatment and the 4-week follow-up. In summary, changes in social interaction were not associated with changes in QOL.

The common denominator between the findings of these three hypotheses is that reductions in pain served as a direct effect on both increasing social interaction and QOL. The improvements in QOL were not mediated through changes in social interaction.

The changes that occurred in social interaction between baseline and the end of treatment occurred primarily on two of the three subscales of the SII. These two were the community activities subscale and the preparatory subscale. The socialization subscale showed little change between baseline and the end of treatment. The reduction in pain itself and the treatment protocol which asked people to try out new techniques for doing tasks involving the shoulder may have led them to increase these kinds of activities. Thus, at the end of treatment (time 2) there was an increase in overall scores on the SII. At the same time, reductions in pain probably directly reduced the distress of carrying out daily tasks involving the shoulder and therefore increased the pleasure, enjoyment, and sense of self-efficacy in accomplishing these tasks. This would lead to an increase in QOL. The fact that there was no relationship between changes in SII scores and changes in QOL scores is somewhat surprising since these two variables when measured statically are usually correlated around 0.37–0.45. In fact, in the current study at all of the three different time points the static correlations between SII and QOL were all in this range (see Table 1). This was true even at 4-week follow-up when average SII scores actually decreased compared to the end of treatment. Even at that point the correlation between QOL and SII was a significant 0.34. Therefore, there is something different about measuring changes on these variables versus measuring their association statically. There are three possible explanations for this. First, because changes on the SII did not show an increase on the socialization component, it may have limited the degree of change that was measurable. Second, changes in SII scores at the end of treatment may not have been related to QOL scores at 4-week follow-up because the time between these two points was not long enough to pick up a 'lag' effect seen in some other studies relating SII to measures of well-being.[15] Finally, this lack of relationship between SII and changes on QOL may be a statistical artifact due to both the SII and the QOL scores having a very narrow range of change in this study. The activities that produced the increase in QOL may not have been reflected in the activities measured by SII.

Overall, two of the three hypotheses were supported in this study. Changes in pain led to changes in both SII and QOL, although changes in SII themselves did not lead to changes in QOL. The important variable seems to be pain itself and its effect on the number and kind of activities in which people engage and the amount of enjoyment and success they derive from

their activities versus the amount of distress and difficulty they have with the pain.

Conclusion

This study lends strong support to the proposition that shoulder pain among people with SCI paraplegia can be effectively treated over a relatively short period of time. Further, given success in treating shoulder pain, it can lead to improvements in both social interaction and community activities as well as improvements in subjective QOL.

Limitations of this study

This study is limited in its generalizations in several ways. First, this study used a convenience volunteer group from southern California, which may or may not be representative of people with SCI throughout the country. Differences in physical environments, weather conditions, and daily activities may vary depending on the part of the country. Second, this study had a relatively short follow-up period after the end of treatment. In retrospect, it might have been better to have a 12-week follow-up design that would allow participants more time to work out what patterns of activities would be best for them and to further monitor their pain for a longer period. Third, this study was limited to people with SCI. However, people with other diagnosis also use manual wheelchairs for their primary source of locomotion and the sample could be expanded to include some of these other groups such as people with post-polio, cerebral palsy, or amputations. A final limitation of this study was that the treatment group had one more face-to-face interaction with the therapists than did the control group. It is difficult to estimate the effect this may have had on the outcomes of the study. However, it is hard to imagine that such a limited contact could have had a substantial effect. For the purposes of this article, we focused mainly on pain, social interaction, and QOL. However, more physical measures were assessed and have been reported on. Those seeking information about the broader physical outcomes of this study are referred to that article.[9]

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