Title Page

(a) Manuscript Title:

The Importance of an Early Positive Change in Pain and Function in Determining Overall Clinical Improvement Following Strengthening Treatment for Chronic Neck Pain

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This work has not been submitted for any other degree.

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Abstract

STUDY DESIGN: This prospective study tested the relationship between a change of 7 points or more on the Neck Disability Index (NDI) following 3 weeks of neck strengthening therapy for chronic neck pain and a change of 7 points or more on the NDI at discharge. **OBJECTIVES:** To determine the potential for identifying people with chronic neck pain who will show positive improvements in (NDI) scores at the end of a course of neck-strengthening using changes in NDI scores after 3 weeks as a predictor. **SUMMARY OF BACKGROUND DATA:** People with chronic neck pain respond variably to exercise therapy. No research exists regarding the predictive progress characteristics that may indicate a successful outcome at the end of a course of neck strengthening therapy for chronic neck pain. **METHODS:** Linear regression analysis was used to determine the correlation between the change in NDI scores at the completion of a course of neck strengthening therapy, and the change in NDI scores recorded 3 weeks into the neck strengthening program. An odds ratio was derived from the regression analysis to determine whether the probability of responding to the neck strengthening program was the same for the group that demonstrated a positive change in NDI at the end of the first 3 weeks compared with the group that demonstrated a negative change in NDI at the end of the first 3 weeks. **RESULTS:** Regression models revealed that an overall reduction in pain and disability could be predicted with high specificity and moderate sensitivity for patients with chronic neck pain. Odds ratio analysis suggests that a positive response on the NDI at the end of the first 3 weeks gives a participant a greater (25.15) odds of response to non-response compared to a negative response. **CONCLUSIONS:** The probability of responding to a course of neck strengthening treatment is greater in those that respond at the end of the first 3 weeks.

Key Words

Chronic neck pain, strengthening exercise, predicting response, Neck Disability Index

Mini Abstract

This study tested the relationship between change in NDI scores after 3 weeks of strengthening exercise and response to strengthening exercise at the final assessment. A change in the NDI of 7 points after 3 weeks correctly classified 93.2% of participants that would display a positive change at the final assessment.

INTRODUCTION

Cervical pain is common in the Australian community and is an important cause of morbidity. Gordon et al[1] conducted a random population-based study to determine the frequency, duration and prevalence of waking cervical spine pain and reported that 18% of the Australian population wake with cervical pain and 4% suffered from it all day. Cervical pain often originates as a result of muscular weakness or from fatigue resulting from sustained muscular contracture[2,3,4]. In addition, this region is frequently injured in motor vehicle, work place and sporting accidents[2,3].

Chronic pain has been described as pain that has been present for at least three months[5]. Chronic neck pain is associated with high costs and an unpredictable and variable prognosis. The Australian Acute Musculoskeletal Pain Guidelines Group in their evidence review, "Evidence-based Management of Acute Musculoskeletal Pain"[6] state that risk factors for chronicity following acute neck pain are older age at the time of injury, severity of initial symptoms, past history of headache and past history of head injury. Socio-demographic factors associated with a longer recovery from acute neck pain include older age, female sex, having dependents and not being employed full time, with each of these variables decreasing the rate of recovery by 14-16%[7].

Clinical reasoning would suggest that a chronic neck pain population would benefit from neck strengthening as there may be the presence of disuse atrophy. Indeed, studies [3,8,9] have suggested that patients with chronic neck pain have weak neck muscles. Silverman et al[8] compared anterior cervical muscle strength in supine, chin retracted, and neck flexed positions in 30 subjects with mechanical neck pain and in 30 asymptomatic control subjects.

Results demonstrated that patients with neck pain had significantly less strength in all three positions than controls.

Ylinen et al[9] evaluated neck flexion, extension and rotation strength in women with chronic neck pain compared with healthy controls. Results demonstrated that the group with neck pain had lower neck muscle strength in all the directions tested than the control group. Jordan et al[3] compared physical characteristics of the cervical musculature, including maximal isometric strength of the flexors and extensors, relative isometric endurance of the extensors and the active range of motion (ROM) in extension in a group of patients seeking treatment for chronic neck pain and a group of age-matched healthy people. The neck pain patients exhibited significant reductions in maximal isometric torque in both the flexors and extensors of the cervical spine, with the greatest reduction seen in the extensor muscle group. Most of this patient group also demonstrated a significant reduction in relative isometric endurance of the extensors.

Although there appear to be strength differences between neck pain patients and age-matched controls, neck strengthening treatment for chronic neck pain has highlighted that there appear to be a sub-group of patients that respond well to exercise therapy. However, there are a comparable number of patients that do not respond to exercise therapy.

Ylinen et al[10] compared intensive isometric neck strength training and lighter endurance training of neck muscles on pain and disability in women with chronic neck pain. The authors concluded that both strength and endurance training for were effective methods for decreasing pain and disability. In addition, stretching and aerobic exercising alone proved to be a much less effective form of training than strength training for women experiencing chronic neck pain.

Bronfort et al[11] compared neck exercise and spinal manipulation for patients with chronic neck pain. Patients were given either manipulation with low technology strengthening exercises, MedX strengthening exercise, or manipulation alone. MedX machines (MedX Corp., Ocala. FL) are able to perform isolated testing and specific exercise for the cervical extensors and rotators. The manipulation with low technology strengthening exercise group showed greater gains in all measures of strength, endurance, and range of motion than the manipulation group alone. The MedX strengthening exercise group demonstrated more strength gains in extension and greater flexion-extension ROM than the manipulation and low technology strengthening exercise group. However, the group differences in the Neck Disability Index and Short Form (SF-36) after 11 weeks of treatment were not statistically significant. During the follow up year, both exercise groups showed very similar improvement for all outcomes other than the manipulation and low technology strengthening exercise group who reported greater satisfaction with care. In the two year follow up to this study, Evans et al[12] demonstrated a difference in patient-rated pain in favour of the two exercise groups. There was also a group difference in satisfaction with care with spinal manipulation combined with low-tech rehabilitative exercise superior to MedX rehabilitative exercise and spinal manipulation alone. However, there were no significant group differences for the Neck Disability Index. Even so, the authors suggest that treatments including supervised rehabilitative exercise should be considered for chronic neck pain sufferers.

Korthals-de Bos et al[13] compared spinal mobilisation, exercise or general practitioner care for people with two or more weeks of neck pain. The authors demonstrated that spinal mobilisation showed a faster improvement than the exercise group and the general practitioner care group up to 26 weeks. However, there were minimal differences by follow up at 52 weeks. In addition, results showed that spinal mobilisation was more cost-effective than exercise or general practitioner care.

Verhagen et al[14] conducted a systematic review of conservative treatments for whiplash and concluded that there was limited evidence that both passive and active interventions were more effective than no treatment. Hoving et al[15] conducted a systematic review of articles on the effectiveness of conservative treatment for neck pain and concluded that there is inconclusive evidence for the use of traction and manipulation and there was no agreement regarding the effectiveness of other conservative interventions. Aker et al[16] also conducted a review of the conservative management of mechanical neck pain and concluded that there was little information available from clinical trials to support many of the treatments for mechanical neck pain. The authors suggest that conservative interventions have not been studied in enough detail to adequately assess effectiveness.

Despite these reviews, clinicians often encounter patients with chronic neck pain that achieve significant functional improvements in response to neck strengthening programs. The challenge is in determining likely patient response or non-response to neck strengthening before time and money is invested in this therapy.

The question arises as to whether or not there are any identifiable patient and pain characteristics at the initial assessment that indicate a better outcome from a course of neck strengthening. Keating et al[17] analysed patient response to an individually tailored exercise program for chronic neck pain to identify presenting characteristics that may predict the likelihood of response to exercise therapy for individual patients. Results indicated that scoring 15 or more points on the initial NDI increases the odds of response (OR 5.56) to non-response compared to scoring less than 15 points in the initial NDI. Furthermore, when the NDI was divided into the 10 individual categories of functional ability, higher scores on lifting, reading, concentration, work, driving, sleeping and recreation increased the probability of response to therapy, indicating that those with higher functional incapacities in these seven tasks had more potential for significant improvements between the start and end of therapy. Age, sex, duration of symptoms and compensation status (whether or not the patient is in the process of receiving money as payment for injury[18]) were also tested as predictors of a positive response to strengthening exercise for chronic neck pain but no significant predictive value was acknowledged.

There are no studies examining whether patient or pain characteristics at the initial assessment predict *non*-response following neck strengthening for chronic neck pain. If an individual patient possesses many of the positive predictor characteristics to neck strengthening identified by Keating et al[17] at the initial assessment, but do not seem to be responding in the early stages of intervention, a predictive model for positive response after trialling the treatment for a 3 week period would be of benefit in making a clinical decision to cease or continue treatment. Currently however, there is no data investigating the importance of an early positive change in NDI scores on the likelihood of overall positive response. In the absence of a detailed predictive equation for response and non-response at the initial assessment, the ability to recognise likelihood of overall positive response based instead on the amount of early change in NDI scores may assist in making the most therapeutic and cost effective clinical decision for each individual patient.

Aim of project

To determine the potential for identifying people who will show positive improvements in NDI scores at the end of a course of neck strengthening therapy using changes in NDI scores after 3 weeks. The proposed project will examine the likelihood of responding favourably to strengthening therapy in a chronic neck pain population based on the amount of positive early change in pain and function.

Hypothesis

The probability of responding to a course of neck strengthening treatment is greater in those who respond in the first 3 weeks.

MATERIALS AND METHODS

The Victoria University Human Ethics Committee approved the study design (HRETH.FHD.088/03). Approval documents are included in Appendix I.

Participants

Between 1998 and 2003, two hundred and thirteen patients were referred to a physiotherapy Clinic in Melbourne, Australia for the treatment of chronic neck pain. These patients included both males and females and ranged in age from 18-65 years. The physiotherapy clinic provided retrospective de-identified data from this patient group to the researchers. This study involved the statistical analysis of this de-identified data.

Initial assessment

The initial assessment involved the patient history, Vertebro-Basilar Insufficiency (VBI) screening, and completion of the Neck Disability Index[19]. The Neck Disability Index (NDI) was developed by Vernon and Mior[19] to assess disability associated with cervical spine complaints. An electromechanical device called the BTE Multi-Cervical Unit (MCU)* was used to measure range of motion (ROM) of cervical flexion, extension, lateral flexion and rotation. Isometric strength of cervical flexion, extension and lateral flexion were also assessed. The BTE Multi-Cervical Unit has been tested for inter- and intra-observer reliability for measuring strength and range of movement[20]. The results of the study revealed that all test-retest data were highly correlated (average 0.79).

Participants unable to initiate 3lbs (1.36 kgs) of force for all isometric testing or unable to initiate inner head brace movement during ROM testing were excluded from exercise therapy.

* The BTE Multi-Cervical Unit manufactured by BTE Technologies Inc.

Participants that experienced a flare-up post assessment for longer than 36 hours or experienced a significant exacerbation of peripheral symptoms following the initial assessment were also excluded from the program[21]. The exclusion criteria were derived from a treatment protocol[21] developed over time through observation and treatment by experienced physiotherapists at the clinic. The exclusion criteria are used as a guide for other clinicians to determine a patient's suitability for strengthening treatment on the BTE Multi-Cervical Unit. An extract of these recommendations is included in Appendix II.

Participants were included for neck strengthening therapy if they demonstrated less than desirable strength values. These values were compared to normal strength measurements taken from a study produced by Jordan et al[22] using isometric strength values of 100 healthy volunteers. ROM values were compared to the values published by the American Medical Association[23]. However, participants were neither included nor excluded from therapy based on ROM values.

Outcome Measures

The minimum clinically important difference (MCID) for the NDI is 7/50 points (14/100 percentage points)[24]. The MCID is a useful measure for the clinician and researcher as it can be used as a guide to determine whether a change in score on the questionnaire might be clinically important. For example, if the NDI detects a change of 5 points but the patient is still unable to perform the same activity of daily living as before then this 5-point change is clinically irrelevant. Consequently, participants were classified as having a 'positive change' if their NDI scores had changed by 7 points or more, or as having a 'negative change' if their NDI changed by less than 7 points.

NDI scores were collected after 9 sessions (3 weeks) and the value for each patient was subtracted from their initial NDI score to obtain a "3 week NDI change" score. NDI scores were then collected at the final assessment and the value was subtracted from the patient's initial NDI scores to obtain a "final NDI change" score. The time period between the initial and final assessment varied between individual patients and depended on how quickly a patient responded to therapy. Final assessments were taken at 18 sessions, 27 sessions or 36 sessions. The average number of sessions for the group at the final assessment was 18.03 (± 9.001).

Treatment

The aim of the rehabilitation program was to target weak movements identified at the initial assessment[21]. Strength target ranges were set relative to normal ranges achieved during isometric strength testing of 100 healthy subjects.[22] In addition, the rehabilitation program aimed to correct imbalances between the left and right sides as well as aiming to achieve a desired flexion/extension ratio of 1:1.7 as suggested by Jordan et al [22]. The resistance for each of the neck strengthening exercises were set at 25-40% of the maximum isometric score achieved at the initial assessment. Participants attended 3 times per week and at each session performed 3 sets of 10 repetitions for each of 6-8 exercises. After each 9 sessions (3 weeks), isometric strength, range of movement and NDI scores were re-assessed. Treatment outcomes were collected at discharge from the treatment centre.

Analysis of Data:

Linear regression analysis was used to determine, for predictive purposes, the degree of correlation between the "final NDI change" scores and the "3 week NDI change" scores.

Linear regression is a tool for fitting a line to a set of data and is used when wanting to predict the value of a dependent variable (y) by knowing the value of an independent variable (x).

An odds ratio was used in the interpretation of the results of the regression analysis and was computed from a 2x2 classification table shown in Figure 1. Odds ratios (OR) were used to compare whether the probability of responding to the neck strengthening program was the same for the group that demonstrated a positive change in NDI in the first 3 weeks compared with the group that demonstrated a negative change in NDI in the first 3 weeks. To achieve this, NDI 3 week change scores were dichotomized into positive improvement ($\geq$7 point change on the NDI) and negative improvement (<7 point change on the NDI). For the group that showed positive improvement at 3 weeks, final NDI change scores were then dichotomized again into positive improvement at final ($\geq$7 point change on the NDI) and negative improvement at final (<7 point change on the NDI). For the group that showed negative improvement at 3 weeks, the data was also dichotomized according to the same scale (example format shown in Figure 1).

The odds ratio (OR) is calculated using the formula $OR = \frac{a \times d}{c \times b}$

The odds ratio however, cannot be negative and therefore has a positive skew distribution. By calculating the log odds ratio can receive both positive and negative values and has an approximately normal distribution[25]. The standard error for the log odds ratio gives the confidence band. The standard error of the log odds ratio is estimated by the square root of the sum of the reciprocals of the four frequencies taken from the contingency table.

$$SE(\log OR) = \sqrt{\frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d}}$$

A 95% confidence interval for the log odds ratio is obtained as 1.96 standard errors on either side of the estimate[25] using the formula 95% CI log OR = log $OR \pm 1.96 \times SE(\log OR)$

Antilogging these values give the upper and lower ends of the confidence band for the odds ratio itself[25].

RESULTS

Raw data is included in Appendix III.

Demographic Data

Patient characteristics are summarised in Table 1.

Data was collected from 213 patients. There were 6 patients that did not meet the criteria for an analysis of a chronic pain population because they had less than a 3 month duration of symptoms[5]. The remaining 207 patients (n= 67 males; n = 140 females) were of an average age of 40.7 years and had a median duration of symptoms of 60 months (5 years). These participants attended for a median of 18 neck strengthening sessions. Medians were considered more appropriate to describe the discrete data such as number of treatment sessions and weeks of treatment. Medians were also used to describe duration of symptoms because of the number of positive and negative shifts caused by outliers.

Complete data sets were required for analysis and were defined as NDI scores at all three intervals – initial, 3 weeks and final. There were a total of 174 (84.1%) complete data sets. There were 59 patients who only completed a 3 week program and were therefore unable to be included in an odds analysis. The reasons for not continuing treatment after three weeks were varied. Of the fifty-nine patients that only completed a 3 week course of neck strengthening therapy, twelve showed a positive change and twenty-seven showed a negative change as determined by the 7 point MCID. Fourteen patients did not continue due to personal reasons. One patient was advised against the program by a doctor or third party. Five patients did not continue for unknown reasons. The final number of data sets available for analysis was 115.

Linear Regression Analysis

The results of the linear regression analysis are summarised using an analysis of variance table (Table 2). This table indicates that the regression is significant because of the large F statistic ($F = 97.364$) and the small p value ($p = 0.000$).

Table 3 contains the coefficient of determination (R^2) which is the effect size of the intervention. The R^2 statistic is the proportion of the observed data explained by the regression and is calculated by dividing the regression sum of squares by the total sum of squares. This statistic indicates that a positive change in the 3 week NDI score explains 47% of the variance in the final NDI positive change ($R^2 = .47$).

Table 4 demonstrates that the constant (intercept) has a value of 3.908 (s.e. 0.516) and the slope of X1 is 0.696 (s.e. 0.071). From the *t* statistics for both the constant and the slope there is evidence that they are significantly different from 0. This suggests that there is a relationship between change in 3 week NDI scores and change in final NDI scores. The standardised coefficient (0.685) is the same as the correlation coefficient $r = 0.685$ (Table 3). This means that change in NDI scores at the 3 week assessment is an important determinant of change in NDI scores at the final assessment with a strong positive effect.

A scatter plot of the data with the regression line is seen in Figure 2. The line in the graph can be described as $y = b_0 + b_1x$ where y is the dependent variable (also plotted on the y axis of the graph), x is the independent variable (plotted on the x axis of the graph). The parameters that are estimated are b_0 (3.908) and b_1 (0.696).

Odds Ratio Analysis

Odds ratios (OR) were used to compare whether the probability of responding to the neck strengthening program was the same for the group that demonstrated a positive change in NDI in the first 3 weeks compared with the group that demonstrated a negative change in NDI in the first 3 weeks. Table 5 demonstrates the classification table used to calculate the odds ratio. Table 4 demonstrates the *a, b, c,* and *d* values as determined by dichotomizing NDI change scores at 3 weeks and final.

The odds ratio (OR) is calculated using the equation $OR = \frac{a \times d}{c \times b}$

Table 6 provides a summary of the odds ratio and 95% confidence intervals. The first column contains the predictor variable, which is the positive change at 3 weeks. The results suggest that a positive response on the NDI in the first 3 weeks gives a participant a greater (25.15) odds of response to non-response compared to a negative response.

A summary of positive and negative predictive values calculated from the classification table (Table 5) is presented in Table 7. The results show that a positive change at 3 weeks (greater than or equal to 7 points) on the NDI correctly classified 93.2% of participants who would display a positive change at the final assessment. It also shows that a change of fewer than 7 points in the NDI score at 3 weeks correctly classified 64.8% of people who did not show a positive clinical outcome at the final assessment.

The sensitivity and specificity associated with this test is 0.62 (95% CI 0.50 – 0.73) and 0.94 (95% CI 0.83 to 0.98) respectively. Sensitivity relates to how well an improvement of greater than or equal to 7 points on the NDI at 3 weeks is at picking up those that will respond overall. Specificity relates to how good an improvement of greater than or equal to 7 points on the NDI at 3 weeks is at correctly excluding those that will not respond overall.

DISCUSSION

This is the first study that has tested the importance of a positive early change in pain and function in predicting an overall positive response to a neck strengthening rehabilitation program. The results indicate that the probability of responding to this particular course of neck strengthening treatment is greater in those that respond in the first 3 weeks.

Skeletal muscle atrophy and the resultant reduction in neck strength may be a contributing factor in many cases of chronic neck pain. The participants of the present study were chosen for neck strengthening therapy because they demonstrated less than desirable strength values compared to isometric strength measurements of 100 healthy subjects[22]. The resistance exercise training was designed to induce hypertrophy via the optimal activation of myogenic mechanisms to increase muscle fibre size. Conley et al[26] has previously examined responses in neck muscle size and strength following similar resistance training. Subjects were assigned to one of three groups - RESX (head extension exercise and other resistance exercises), RES (resistance exercises without specific neck exercise), or CON (no training). RESX showed an increase in total neck muscle cross-sectional area (CSA) after training but RES and CON groups did not. This hypertrophy for RESX was due mainly to increases in the CSA for the splenius capitis, and semispinalis capitis and semispinalis cervicis muscles.

However, the results have shown that there is a sub-group of patients (38.3%) who respond favourably in the first 3 weeks of therapy, which suggests a neural adaptation to exercise as the expected hypertrophy benefits do not dominate until after 3 weeks in a strengthening rehabilitation program [27,28,29,30,31,32]. Moritani & deVries[30] examined the time course of strength gain with respect to the contributions of neural factors and hypertrophy. The results indicated that neural factors accounted for the larger proportion of the initial strength increment and thereafter both neural factors and hypertrophy took part in the further increase in strength, with hypertrophy becoming the dominant factor after the first 3 to 5 weeks[30]. This information in conjunction with the results of the present study suggest that initially neck strength training is probably a motor skill development activity where the central nervous system is harnessing existing resources to perform the strength activities more efficiently.

The assumption in this case is that this increase in muscle performance translates into decreased levels of self-perceived disability. Indeed, if a muscle is functioning better, regardless of whether the change is neural, myogenic or otherwise, then the functional capabilities of the patient are also likely to improve. The results prove the exercise program has improved the participants' self-perceived disability but the exact mechanism of effect is unknown and further research is required.

Neural adaptations can only be accurately measured via the use of electromyography (EMG). By measuring both EMG and maximal voluntary contraction (MVC), it is possible to divide strength changes into neural and muscular factors. If an increase in strength has occurred due to neural factors alone, it will manifest as an increased force, which is directly proportional to an increased activity on the EMG. If an increase in strength has occurred due to muscle hypertrophy alone, this will manifest as an increased force with no increase in EMG activity[33]. Finally, if strength increase is due to a combination of neural and muscular factors, the relative proportion of each can be calculated from the experimental method displayed in Box 1.

For this reason EMG analysis may be useful in future studies to determine the relative contribution of neural and muscular factors to strength increase. It is possible the sub-group of patients that experienced functional improvements after only 3 weeks of the neck strengthening treatment were experiencing hypertrophy of the cervical muscles earlier than the norm. This further highlights the need for more detailed assessment techniques if the objective is to determine the reasons why these patients are achieving significant functional benefits so early in the rehabilitation program.

While current research has suggested initial adaptations to the course of neck strengthening are unlikely due to an increase in muscle fibre size, the expected hypertrophy benefits experienced after 3-5 weeks of training may have a protective or maintenance effect in this group of early responders. A six month follow up comparison between the group that responded in the first 3 weeks and were discharged from further strengthening and the group that responded in the first 3 weeks and then continued a further course of neck strengthening would be interesting to examine the long term effects of strengthening for chronic neck pain. This may identify another sub-group of patients that require neck strengthening for the neural benefits only and a sub-group of patients that require neck strengthening for both neural and myogenic benefits.

The results also highlighted that an improvement of greater than or equal to 7 points on the NDI at 3 weeks is moderately sensitive at picking up those that will respond overall. This means that there is still a sub-group of patients that will respond by more than 7 points at the final assessment, but not necessarily demonstrate this improvement in the first 3 weeks. Given the possibility that some patients need strengthening therapy primarily for neural benefits and some patients require strengthening therapy primarily for hypertrophy benefits, a 7 point change on the NDI at 3 weeks should not be expected to predict all those who will respond at the final assessment. This would suggest that response after 3 weeks is the only predictor of overall response and if this were the case, patients would not be recommended to continue strengthening therapy after 3 weeks. In contrast, the sensitivity of the test should be considered in conjunction with other socio-demographic factors that have been associated with a longer recovery such as age, gender and employment status[7] and overall higher scores on the NDI and higher scores in seven of the ten individual categories on the NDI[17].

Specificity relates to how good an improvement of greater than or equal to 7 points on the NDI at 3 weeks is at correctly excluding those that will not respond overall. Results demonstrated that a change of more than 7 points on the NDI is a highly specific test. This means that if patients were to respond by greater than or equal to 7 points on the NDI in the first 3 weeks, there is only a very small chance that they will not respond overall. This is important information for the patient, the clinician and the insurance company.

We were unable to examine the relationship between early positive change and overall positive change in those patients that did not complete more than a 3 week program (n = 59). As a result, a large proportion of participants were not studied and hence an opportunity to further understand another component to patient response to exercise therapy was lost. In those cases, administration of the NDI at earlier and more frequent time points in the course of therapy may have allowed examination of the relationship between the dependent and the modified predictor variable (in this case defined as initial change being *earlier* than 3 weeks).

Further analysis may consider verification on an independent sample for validity of the prediction model. Dichotomizing NDI data at several intervals may also be considered for further analysis to determine the odds of responding at each cut point to provide more defined predictive information. Similarly, examining the relationship between patients who change by, for example, 5 points or more on the NDI and overall positive outcome of a 7 point NDI change would further define the predictive model. In the present format, if a patient has already improved by more than 7 points on the NDI at 3 weeks then the analysis is more a measure of the odds of maintaining the MCID gain.

Further research may also examine whether improvements in strength at 3 weeks correlate with a positive improvement in NDI at the final assessment. Investigation of the sub-group of patients who show a positive response on the NDI in the first 3 weeks of a course of neck strengthening therapy may or may not elicit a corresponding increase in strength above a pre-determined cut-off point for the same time period. If there does appear to be a relationship between these two variables, further analysis could also determine whether this change is direction specific.

The results from this study highlight that predictors of overall positive clinical response such as amount of early positive change may be applied to provide both therapeutic and cost effective benefits. The cost of rehabilitation is of great importance to organisations, public or private, such as insurance companies that pay the health care expenses for beneficiaries at the time at which they are patients, otherwise known as third party payers[18]. Therefore the ability to provide likelihood of overall response based on initial progress is a valuable tool in gaining further funding for treatment. In addition, there is a significant psychological benefit to the patient when presented with a prediction equation stating that they are extremely likely to experience a positive outcome at the end of treatment if they have already demonstrated a positive change at 3 weeks. This psychological benefit is a clinically observable phenomenon that has not yet been objectively tested. Further research into other predictor variables is needed so we can incorporate them into more sophisticated predictive models.

Conclusion

This study presents data demonstrating that the probability of responding to a course of neck strengthening treatment using the BTE Multi-Cervical Unit is greater in those that respond in the first 3 weeks. Further research is needed to develop additional predictors of overall response to neck strengthening for the chronic neck pain population. In addition, the exact mechanism for these early functional improvements needs to be defined, as it appears neck strengthening may not involve hypertrophy adaptations alone.

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Figure 1. Example of the 2x2 Contingency Table Used To Calculate Odds Ratio.

	Improved at Final	Not Improved at Final
Improved at 3 weeks	a	b
Not Improved at 3 weeks	c	d

Table 1. Demographic Data

n	213
Number that met the inclusion criteria	207
Age in years (x, SD)	40.7 years (±12.3)
Duration of symptoms (months) *	60 months (24-132)
Number of treatment sessions*	6 weeks (3-12)
Weeks of treatment*	18 sessions (9-36)
Number of patients completing > 3 week program	148

*median and inter-quartile range

Table 2. Analysis of Variance (ANOVA)(b)

	Sum of Squares (SS)	df	Mean Square	F	Sig.(p)
Regression	1498.643	1	1498.643	97.364	.000(a)
Residual	1693.134	110	15.392		
Total	3191.777	111			

a Predictors: (Constant), Change Between Initial NDI and 3 Week NDI
b Dependent Variable: Change Between Initial and Final NDI

Table 3: Summary of the Regression Analysis (b)

R	R Square	Adjusted R Square	Std. Error of the Estimate
.685(a)	.470	.465	3.923

a Predictor: Change Between Initial NDI and 3 Week NDI
b Dependent Variable: Change Between Initial and Final NDI

Table 4: Coefficients(a)

	Unstandardised Coefficients		Standardised Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant) (intercept)	3.908	.516		7.569	.000
Change B/W in NDI at 3 weeks (slope of x1)	.696	.071	.685	9.867	.000

a Dependent Variable: Change Between Initial and Final NDI

Figure 2. Relationship between Change in NDI at 3 Weeks and Change in NDI at Final

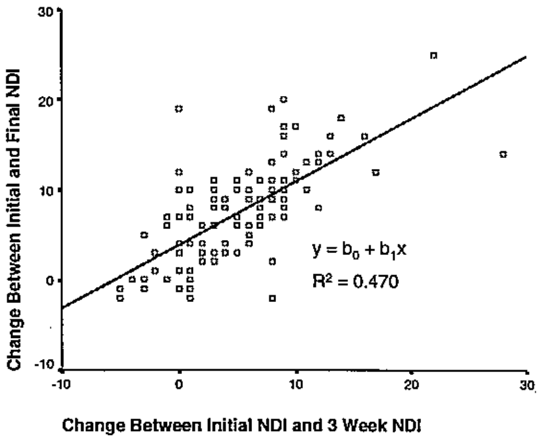


Table 5. Contingency Table - Odds Ratio

	Improved at Final	Not Improved at Final	Total
Improved at 3 weeks	$a = 41$ (35.7%)	$b = 3$ (2.6%)	44 (38.3%)
Not Improved at 3 weeks	$c = 25$ (21.7%)	$d = 46$ (40.0%)	71 (61.7%)
Total	66 (57.4%)	49 (42.6%)	115 (100%)

Table 6. Odds ratio analysis summary

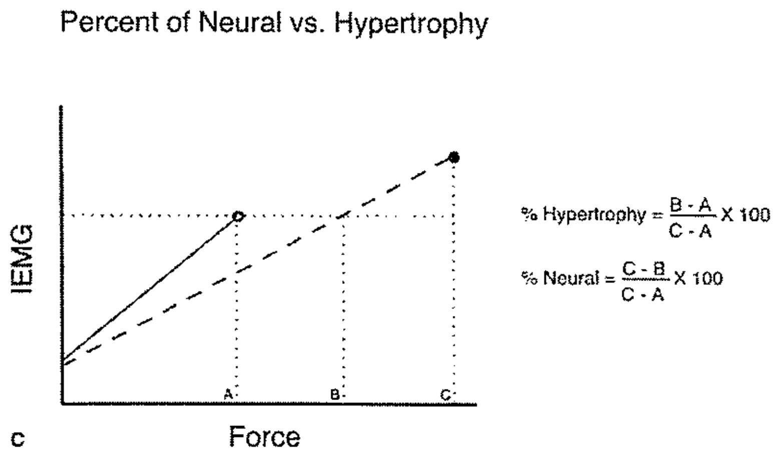
Predictor Variable	OR	95% CI
Improvement at 3 weeks	25.15	7.07 – 89.49

Table 7. Positive and negative predictive values for the regression model

Model	+ve predictive values(%)	-ve predictive values(%)
NDI change at 3 weeks predicts Overall NDI change	93.2	64.8

Box 1. Theoretical Presentation Of An Experimental Method For Determination Of Neural And Muscular Factors Responsible For Strength Increase[33].

(Adapted from: Lieber RL. Skeletal Muscle Structure, Function and Plasticity: The Physiological Basis of Rehabilitation. 2nd ed. Lippincott Williams & Wilkins 2002: Ch 4 p 217.)



(A) Situation in which all strength increase is due to neural factors since strength increase is directly proportional to EMG increase. **(B)** Situation in which all strength increase is due to muscular factors since strength increase occurs with no change in EMG. **(C)** Situation in which both neural and muscular factors are involved in strength increase along with method for calculation of the relative component of each.

Appendices