Development of a clinical prediction rule to identify patients with neck pain who are likely to benefit from home-based mechanical cervical traction

Congcong Cai · Guan Ming · Lih Yen Ng

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Abstract The objective of the study was to identify the population of patients with neck pain who improved with home-based mechanical cervical traction (HMCT). A prospective cohort study was conducted in a physical therapy clinic at a local hospital. Patients with neck pain referred to the clinic for physical therapy were included in the study. A HMCT program was given to participants for 2 weeks. The patient's demographic data, Numerical Pain Scale (NPS) score, Neck Disability Index (NDI) and Fear-Avoidance Beliefs Questionnaire score were collected, and standard physical examination of the cervical spine was conducted before intervention. The NPS score, NDI and a global rating of perceived improvement were collected after the intervention was completed. A total of 103 patients participated in the study and 47 had a positive response to HMCT. A clinical prediction rule with four variables (Fear-Avoidance Beliefs Work Subscale score < 13, pre-intervention pain intensity $\geq 7/10$, positive cervical distraction test and pain below shoulder) was identified. With satisfaction of at least three out of four variables (positive likelihood ratio = 4.77), the intervention's success rate increased from 45.6% to over 80%. It appears that patients with neck pain who are likely to respond to HMCT may be identified.

Keywords Neck pain · Cervical traction · Clinical prediction rule · Classification · Intervention success rate

Introduction

Neck pain is a frequently reported musculoskeletal condition, which is associated with high socio-economic burden [8]. Twenty-six to 71% of the adult population recall experiencing an episode of neck pain or stiffness in their lifetime [10, 30]. Patients with neck pain are frequently encountered in outpatient physical therapy practice. Over 50% of patients with neck pain seen by a general practitioner are referred for physical therapy [2].

Mechanical cervical traction is an intervention that is often recommended for the treatment of patients with neck pain [46]. Despite its common use in clinical practice, the evidence of the effectiveness of cervical traction is still limited or inconclusive [20, 41]. However, most studies have not studied a homogenous subgroup of patients though likely to benefit from the intervention [41]. The treatment protocols adopted in those studies regarding traction force, force application method (intermittent or continuous), application position (sitting or supine) and treatment frequency vary greatly.

Additionally, the emphasis on patient-centred health care triggered by the rise in health consumerism increasingly requires the provider to improve decision-making by matching treatment to the specific patient as well as to improve treatment cost-effectiveness. One retrospective study on home-based mechanical cervical traction (HMCT) reported excellent results [40]. HMCT harbours the potential to be a cost-effective cervical traction approach, if it is matched to a specific group of neck pain patients with a standardised application protocol. Therefore, the purpose of this study was to develop a clinical prediction rule (CPR) to identify patients with neck pain who would likely benefit from HMCT.

C. Cai (✉) · G. Ming · L. Y. Ng
Rehabilitation Department, Alexandra Hospital,
378 Alexandra Road, Singapore 159964, Singapore
e-mail: ccongcong@hotmail.com

Methods

The study was approved by the local hospital's bio-ethics committee.

Subjects

The 103 consecutive subjects in this study were referred from the orthopaedic outpatient clinic in the local hospital over 6 months. The sample size was based on the local estimated HMCT response rate of 40% and 10 responders to contribute 1 prediction variable in the final model. Therefore, our estimated sample size was between 100 and 120 patients.

All the subjects were enlisted while they were on the waiting list to consult a physical therapist and had a diagnosis of cervical spondylosis or cervical spine degenerative changes, and a chief complaint of pain and/or numbness in the cervical spine, with radicular pain and/or numbness in the upper extremity, and/or headache. All the subjects gave written consent allowing the release of test results for research purposes. The exclusion criteria were current pregnancy, signs of spinal cord injury, prior cervical spine surgery, history of osteoporosis or spinal fracture. Subjects were not included in the data analysis if the clinician had determined the subject's symptoms to be likely of non-spinal origin.

Therapists

Four physical therapists working in the physical therapy clinic of the local hospital participated in this research. A 2-h pre-study briefing regarding study measures, introduction, intervention and ethics issues was given to the therapists.

Measures

The basic demographic information of the subjects collected before the intervention is shown in Table 1.

Disability related to neck pain was measured by the Neck Disability Index (NDI) [42]. All participants were asked to complete the NDI before intervention and after 2-week intervention had been completed. In addition, each participant completed the Fear-Avoidance Beliefs Questionnaire (FABQ) [44] before intervention to assess their beliefs about the influence of work and activity on neck pain [17]. Both the FABQ and the NDI have been shown to be reliable and valid [7, 17].

Pain intensity was measured by Numerical Pain Scale (NPS; 0–10, 0 indicates no pain, 10 indicates maximum pain). All participants completed the NPS by indicating the average pain level experienced during the past 1 week

before intervention. The pain intensity was also assessed in the same manner after 2-week intervention had been completed.

A physical examination (PE) [13, 15, 26, 28, 29, 32, 45] was done by four physical therapists. The PE tests are listed in Table 1. The specific operational definitions for the cervical distraction test, upper limb tension test A and the criteria for defining a positive test are included in Table 2.

Intervention

All patients were given HMCT treatment for 2 weeks. The traction method was standardised, with written instructions about the use of a simplified over-the-door traction suspension and a standard adjustable cervical halter (Figs. 1, 2, CT-10 Cervical Traction System, Shi Wei Group, Singapore). The traction force was determined by 10–15% of the subject's body weight [1]. Patients were instructed to pull the pulley string (Fig. 1b) to generate traction force, until the determined traction force was reached. The traction force generator (Fig. 1a) is designed to generate 0.5 kg of traction force per pull from the patient, and to self-lock at the end of each pull. This design allows the patient to generate traction force independently, and the force to be sustained by the device itself. Patients were also instructed to use a mirror to read the force meter (Fig. 1c) in order to confirm that the determined traction force had been reached. In general, patients were instructed to generate traction force that should be “moderate to moderately strong” without increasing symptoms. The patients were told to have daily traction treatment for 20 min for 2 weeks, reinforced by a treatment diary, in which they recorded both the compliant sessions and missed sessions. Compliance to the treatment regimen was calculated as the percentage of compliant sessions over total sessions.

The safety instruction, including warning signs to termination of treatment and precaution of overloading, was given to all patients.

Determination of responders

We used flow charts (Figs. 3, 4, 5) to judge the patients' response to treatment. We set 50% improvement between pre- and post-treatment of NPS, NDI (scale range 0–50) or rated as ‘much better’ or ‘completely recovered’ in the seven-scale global rating scheme (much worse, worse, no change, slightly better, much better, completely recovered) as criteria to determine responders from all patients. With regard to the minimal clinically important changes (MCICs) of NDI and NPS, we set the criterion as 100% improvement between pre- and post-treatment for those patients with NDI = 5–10 or NPS = 2. Patients with

Table 1 Basic demographic information and results of physical examination of subjects

	Answers/recording	Data category
Demographic information		
Age	Years	Continuous
Gender	Male/female	Binary
Height	Meter	Continuous
Weight	Kilogram	Continuous
BMI	–	Continuous
Highest education level	Diploma or graduate above (yes/no)	Binary
Smoking situation	Smoker (yes/no)	Binary
Onset duration	Weeks	Continuous
Course of pain	Gradual (yes/no)	Binary
Prior history of pain episode	Yes/no	Binary
Increase in frequency of pain episode	Yes/no	Binary
Pain below shoulder	Yes/no	Binary
Job status	Deskbound work: yes/no	Binary
Presence of headache	Yes/no	Binary
Bilateral neck pain	Yes/no	Binary
Pain medication	Yes/no	Binary
Aggravating neck position	Flexion: yes/no	Binary
	Extension: yes/no	Binary
	Rotation: yes/no	Binary
	Neutral: yes/no	Binary
	Resting: yes/no	Binary
	All of the above: yes/no	Binary
Relieving neck position	Flexion: yes/no	Binary
	Extension: yes/no	Binary
	Rotation: yes/no	Binary
	Neutral: yes/no	Binary
	Resting: yes/no	Binary
	None of the above: yes/no	Binary
Physical examination		
Postural assessment (26)	Scapular protraction: yes/no	Binary
Neurological screen (15)	Neurological deficit involvement: yes/no	Binary
Neck condition centralisation test (32)	Symptom centralisation: yes/no	
Cervical range of motion measurements and symptoms response (28)	Hypomobility at one or more cervical levels with spring test: yes/no	Binary
The amount of motion and symptom response was recorded for both segmental mobility testing (15) of the cervical spine and spring test (29) of the cervical spine and thoracic spine (C2–T4)	Pain at one or more cervical levels with spring test: yes/no	Binary
	Hypomobility at one or more upper thoracic levels with spring test: yes/no	Binary
	Pain at one or more upper thoracic levels with spring test: yes/no	Binary
Cervical distraction test (45)	Positive: yes/no	Binary
Upper limb tension test A (13)	Positive: yes/no	Binary

pre-treatment NDI < 5 were not judged by the NDI criterion. Those with pre-treatment NPS < 2 were not judged by the NPS criterion. Patients who satisfied one of these three criteria, i.e. NPS, NDI and global rating of perceived improvement, were determined as ‘responders’.

Data analysis

Univariate analyses (using Chi-square tests and individual *t* tests) were conducted to determine which variables had a significant relationship with the responsiveness to

Table 2 Operational definitions of the special tests used in the study

Test	Performance	Criteria for positive test
Cervical distraction test	Patient lies supine and the neck comfortably positioned. The examiner securely grasps the patient's head under the occiput and chin and gradually applies an axial traction force up to approximately 12 kg	Reduction or elimination of symptoms
Upper limb tension test A	With the patient supine, the examiner sequentially introduces the following movements to the symptomatic upper extremity: (a) scapular depression, (b) shoulder abduction, (c) forearm supination, (d) wrist and finger extension, (e) shoulder external rotation, (f) elbow extension, (g) contralateral then ipsilateral cervical side bending	Reproduction of patient's symptoms

Fig. 1 The patient generates force on his/her own by pulling the pulley string: *a* traction force generator, *b* patient self-force generating pulley string, *c* force meter and *d* harness **Fig. 2** The patient is having the traction treatment: *a* traction force generator, *b* patient self-force generating pulley string, *c* force meter and *d* harness

HMCT. We performed this analysis to determine which variables would be entered into a subsequent binary logistic regression model. Chi-square analysis was done to determine which of the binary variables (shown in Table 1) were predictive of detecting a responder of HMCT. Continuous variables were analysed for their relationship with the responders of HMCT using independent *t* tests. Continuous variables included age, height, weight, body mass index (calculated), onset duration (weeks), pre-intervention pain, pre-intervention NDI and FABQ score.

The α level for all univariate analyses was set at 0.10. We chose a more liberal significance level to avoid excluding potential predictive variables. For continuous variables with a significant univariate association, sensitivity and specificity values were calculated for all possible cut-off points and then plotted as a receiver operator characteristic (ROC) curve. The point on the curve nearest

the upper left-hand corner represents the value with the best diagnostic accuracy, and this point was selected as the cut-off for defining a positive test.

Potential prediction variables were entered into a forward stepwise logistic regression equation to determine the most parsimonious set of variables. A *p* value of <0.05 was required to enter a variable into the model and a *p* value of >0.10 was required to remove it. The goodness-of-fit of the final regression model was tested with the Hosmer–Lemeshow statistic [21]. The proportion of variance explained by the final model was determined using the Nagelkerke *R* statistic [33]. Variables retained in the regression model were used to develop a multivariate CPR for classifying subjects as likely to benefit from HMCT. Predictive statistics were calculated for each level of the CPR.

The SPSS software version 13.0 for Windows (SPSS Inc, Chicago, IL) was used for data analysis.

Fig. 3 Flow chart for judging responders by Numerical Pain Scale

Fig. 4 Flow chart for judging responders by global rating of perceived improvement

Fig. 5 Flow chart for judging responders by Neck Disability Index

Results

All 103 participants completed the treatment with overall high compliance to the treatment program. The mean compliance rate was 91.0% (85.7–100%). The cause of the unusually high compliance rate was determined as ‘courtesy answer’ from the interviews with participants. Therefore, the compliance rate was not entered into statistical analysis for this reason.

The descriptive statistics data of the 103 subjects are listed in Table 3. According to the criteria of responders, there were 47 patients (45.6%) shown in the category, and 56 (54.4%) were non-responders.

The univariate analysis of all variables provided 10 potential predicting factors (Table 3), including answering yes to pain below shoulder ($p = 0.002$), use of pain medication ($p = 0.066$), all positions aggravate pain ($p = 0.062$), neck flexion ranked as best position ($p = 0.089$), no position relieves pain ($p = 0.044$), rotation neck movement limited by pain ($p = 0.094$), upper limb tension test A positive ($p = 0.021$), cervical distraction test positive ($p = 0.020$), pain intensity ($p = 0.031$) and FABQW subscale sore ($p = 0.082$). The cut-off points were found from ROC curve for pain intensity = 7/10 (Area Under Curve = 0.598, $p = 0.041$) and FABQW = 13 (Area Under Curve = 0.583, $p = 0.049$).

Table 3 Comparison of demographic data, pain, physical examination, disability and fear-avoidance beliefs between the non-responder and responder groups

Variable	All subjects (<i>N</i> = 103)	Non-responders (<i>N</i> = 56)	Responders (<i>N</i> = 47)	<i>p</i> value
Female gender (%)	37.9	39.2	36.2	0.745
Age (years)	48.8 (11.7)	47.2 (12.4)	50.7 (10.7)	0.139
Weight (kg)	65.4 (11.9)	65.2 (12.2)	65.5 (11.6)	0.887
Height (m)	1.65 (0.1)	1.66 (0.09)	1.65	0.715
Smoking status (%)				
Smoker	16.5	16.1	17.0	0.819
Highest education level (%)	45.6	48.2	42.6	0.566
Duration (weeks)	30.6 (42.8)	31.4 (34.9)	29.7 (51.1)	0.849
Gradual onset	69.9	73.2	66.0	0.424
Pain below shoulder (%)	60.2	46.4	76.6	0.002*
Bilateral neck pain (%)	41.7	42.9	40.4	0.803
Prior history of neck pain (%)	57.3	60.7	53.2	0.442
Episodes of neck pain becoming frequent	39.8	41.0	38.3	0.775
Deskbound work (%)	51.5	55.4	46.8	0.387
Use of pain medication (%)	47.6	39.3	57.4	0.066*
Presence of headache (%)	34.0	28.6	40.4	0.206
Neck flexion ranked as worse position (%)	17.4	14.3	21.3	0.352
Neck extension ranked as worse position (%)	38.8	34.0	44.7	0.256
Neck rotation ranked as worse position (%)	23.3	25.0	21.3	0.656
All positions aggravate pain (%)	3.9	7.1	0	0.062*
Neck flexion ranked as best position (%)	18.4	12.5	25.5	0.089*
Neck extension ranked as best position (%)	11.7	7.1	17.0	0.120
Neck rotation ranked as best position (%)	16.5	19.6	12.8	0.349
No position relieves pain (%)	36.0	44.6	25.5	0.044*
Neck movement limited by pain (%)				
Flexion	14.6	16.1	12.8	0.636
Extension	47.6	48.2	46.8	0.887
Rotation	17.5	23.2	10.6	0.094*
No movement limited	15.5	19.6	10.6	0.209
Upper limb tension test A positive (%)	29.1	19.6	40.5	0.021*
Cervical distraction test positive (%)	58.3	44.6	74.5	0.020*
Hypomobility at one or more cervical levels with spring testing (%)	94.2	94.6	93.6	0.825
Pain at one or more cervical levels with spring testing (%)	82.5	85.7	78.7	0.352
No symptom centralisation (%)	86.4	91.1	80.9	0.132
Hypomobility at one or more upper thoracic levels with spring testing (%)	86.4	83.9	89.4	0.423
Pain at one or more upper thoracic levels with spring testing (%)	65.0	62.5	68.1	0.554
Neurological deficit involvement (%)	25.2	26.8	23.4	0.694
Scapular protraction (%)	53.4	51.8	55.3	0.720
Pain intensity (numeric rating scale)	5.4 (1.8)	5.1 (1.8)	5.8 (1.8)	0.031*
Fear-Avoidance Belief Questionnaire				
Work Subscale	16.7 (9.9)	18.3 (8.8)	14.8 (11.0)	0.082*
Physical Activity Subscale	13.0 (6.4)	13.5 (6.4)	12.5 (6.4)	0.415
Neck Disability Index	26.8 (12.9)	25.3 (12.7)	28.7 (13.0)	0.182

* $p < 0.1$

According to the above cut-off points, these two variables were dichotomised into positive or negative test results before being entered into logistic regression analysis. The

positive test results were pain intensity $\geq 7/10$ and FABQW < 13 . The sensitivity, specificity and positive likelihood ratio (LR+) of each individual variable

Table 4 Accuracy statistics (95% CI) of individual variables in predicting success

Variables associated with success	95% CI		Positive likelihood ratio
	Sensitivity	Specificity	
Pain below shoulder level	0.77 (0.62–0.87)	0.54 (0.40–0.67)	1.65 (1.19–2.28)
Use of pain medication	0.57 (0.42–0.71)	0.61 (0.47–0.73)	1.46 (0.97–2.20)
All positions aggravate pain	0.01 (0–0.11)	0.92 (0.81–0.97)	0.13 (0.01–2.39)
Neck flexion ranked as best position	0.26 (0.14–0.41)	0.88 (0.75–0.94)	2.04 (0.88–4.77)
No position relieves pain	0.26 (0.14–0.41)	0.55 (0.42–0.68)	0.57 (0.32–1.01)
Neck rotation limited by pain	0.89 (0.76–0.96)	0.23 (0.13–0.37)	1.16 (0.98–1.39)
Cervical distraction test positive	0.74 (0.59–0.86)	0.55 (0.42–0.68)	1.67 (1.19–2.33)
Upper limb tension test positive	0.40 (0.27–0.56)	0.80 (0.67–0.89)	2.06 (1.09–3.88)
Pain intensity (numeric rating scale $\geq 7/10$)	0.38 (0.25–0.54)	0.84 (0.71–0.92)	2.38 (1.18–4.80)
Fear-Avoidance Belief Questionnaire Work Subscale < 13	0.51 (0.36–0.66)	0.80 (0.67–0.89)	2.60 (1.43–4.73)

Table 5 Predictors for the responder to home-based cervical mechanical traction (forward stepwise logistic regression)

Predictor	Coefficient	Odds ratio	95% CI	<i>p</i> value
Pain intensity (numeric rating scale $\geq 7/10$)	1.380	3.974	1.337–11.812	0.013
Fear-Avoidance Belief Questionnaire Work Subscale < 13	1.554	4.731	1.727–12.957	0.003
Manual traction produces relief	1.265	3.544	1.333–9.423	0.011
Pain below shoulder level	1.294	3.647	1.367–9.733	0.010

Table 6 Number of subjects in the success and non-success groups at each level of the clinical prediction rule

No. of predictor variables present	No. of subjects in the home-based mechanical cervical traction success group	No. of subjects in the home-based mechanical cervical traction non-success group
4	3	0
3	24	6
2	40	19
1	46	46
0	1	10

associated with responsiveness were calculated with 95% confidence interval (CI) (Table 4).

The potential predicting factors identified from the univariate analysis were entered into the forward stepwise logistic regression analysis. There were four variables retained in the final model (Table 5): FABQW score < 13 , pain intensity $\geq 7/10$, cervical distraction test positive and pain below shoulder (model $\chi^2 = 34.76$, $df = 4$, $p < 0.000$, Nagelkerke R^2 value = 0.383). These four variables were used to form the CPR. The final models fit the data (Hosmer–Lemeshow $\chi^2 = 4.114$, $p = 0.767$).

Three out of 47 patients responded to HMCT (responders) had all 4 predictors present. None of 56 patients who did not respond to HMCT (non-responders)

had all 4 predictors present. Twenty-four of the 47 responders had 3 or more predictors present, and 6 of 56 the non-responders had 3 or more predictors present. Forty of the 47 responders had 2 or more predictors present, and 19 of the 56 non-responders had 2 or more predictors present. Forty-six had 1 or more predictors presented in both responder and non-responder category. There was 1 responder and 10 non-responders who did not match any predictor (Table 6).

According to the pre-prediction probability obtained from those patients who were classified as responders to HMCT in the study (45.6%), the LR+ and the post-prediction probability were calculated for each level of the prediction model [18]. The accuracy statistics including sensitivity, specificity, LR+ and post-probability of successful HMCT for each level of the model are listed in Table 7.

Discussion

The purpose of our study was to identify neck pain patients who would demonstrate a short-term improvement to the HMCT approach. In order to distinguish the responders from the non-responders, we used three different outcome criteria which were considered clinically important: reduction of pain intensity, global rating of perceived improvement and improvement of NDI. Reduction of pain

Table 7 Accuracy statistics (with 95% confidence interval) for each level of the prediction model

Number of predictors present	Sensitivity	Specificity	Positive likelihood ratio	Probability of successful traction (%)
≥1	0.98 (0.87–1.00)	0.18 (0.09–0.31)	1.19 (1.05–1.36)	50.0
≥2	0.85 (0.71–0.93)	0.66 (0.52–0.78)	2.51 (1.71–3.68)	67.8
≥3	0.51 (0.36–0.66)	0.89 (0.77–0.96)	4.77 (2.13–10.67)	80.0
All 4	0.07 (0.02–0.20)	0.99 (0.91–1.00)	8.31 (0.44–156.96)	87.4

In the calculation of sensitivity, specificity and positive likelihood ratio for all four predictors present, each cell adds 0.5 to the original number due to “0” being present in the cell of “negative test result and condition absent”

intensity and perceived improvement have been widely accepted as cardinal outcome measures for treating spinal disorders [3, 4, 6, 14, 25, 27, 35, 38, 39, 43]. Based on a review article of the prognostic factors for neck pain, Borghouts et al. [3] found that the decrease in pain intensity from clinical intervention ranged from 22 to 79%, with a median of 46%. Therefore, we set the cut-off point at 50% or more in pain reduction to classify the patients into the responder group in this study. The MCIC on NPS of neck pain patients was reported as 2.5 [36] as the optimal cut-off point. Therefore, we only selected patients with $NPS \geq 2$ as candidates judged by this particular criterion. We only classified those with $NPS = 2$ as ‘responders’ when their improvement was 100%. To avoid small improvement resulting from a placebo effect, we classified those who rated ‘much improved’ or ‘completely recovered’ in the global rating of perceived improvement into the ‘responder’ group. Perceived improvement reflects the improvement of all symptoms that occurred after a treatment [5, 22]. Since different patients exhibit different symptoms about which they may have different concerns, they will only consider a treatment as successful if their individual concerns are addressed and improved by the treatment. In other words, perceived improvement could be a sensitive indicator that reflects one of the dimensions of the treatment outcome [22]. The NDI is a questionnaire that is commonly used in clinical trials to measure the functional status of patients with neck pain [22, 47]. It has been shown to be valid [23, 42] and reliable [42]. The MCIC on NDI of neck pain patients was reported as 3.5 to 5 [36, 37] for optimal cut-off point (scale range 0–50). Therefore, we only selected patients with $NDI \geq 10$ as candidates judged by this particular criterion. We only classified those with $NDI = 5$ –10 as responders when their improvement was 100%. This judgment criteria seem more stringent than $MCIC = 3.5$. However, NDI carries a wide range (0–50; therefore, we feel that setting a more parsimonious criterion in an explorative study is necessary to minimise the possibility of false positive.

Pain reduction, perceived improvement and NDI are three outcomes that are not mutually exclusive. In fact,

these three terms could mean the very same thing to some patients. However, using only one outcome may not address all the concerns in different patients and combining all three of them together can be too restricted or partial. We had already set a high standard for each criterion; therefore, we believed that meeting one of the three criteria would be sufficient to define treatment success for this study.

Our study identified four possible predictors, namely, FABQW score < 13 [odds ratio (OR) 3.97, 95% CI 1.34–11.81], pre-intervention $NPS \geq 7/10$ (OR 4.73, 95% CI 1.73–12.96), pain below shoulder presented (OR 3.54, 95% CI 1.33–9.42) and cervical distraction test positive (OR 3.65, 95% CI 1.37–9.73).

Of the four predictors mentioned above, two of them (cervical distraction test positive and pain below shoulder) appear to be related to cervical nerve root compression. Pain below shoulder may indicate some mechanical compression on neural tissue, and cervical distraction producing relief may demonstrate relief of neural compression or tension. This supports the notion that patients presenting with signs of nerve root compression may represent the subgroup of patients who are most likely to benefit from cervical traction. It is well known that fear-motivated behaviours have the potential to adversely impact treatment outcomes for patients with musculoskeletal pain [16]. In a previous comparison study, no significant difference in fear-avoidance beliefs was noted between patients with cervical spine pain and lumbar spine pain [17]. Our study results suggest that patients with high levels of fear-avoidance beliefs about work are likely to require an alternative treatment approach as also suggested by a previous study [11]. Pain was reported to be the primary stressor by the patients and the reduction of pain is the most important goal of treatment [34]. It was observed that the functioning of daily task performance of patients with neck pain was significantly related to pain intensity [34]. However, due to the design of our study, the reduction in neck pain could not be clearly differentiated between the natural history of neck pain and the effect of traction intervention in a short period of 2 weeks. The cut-off point for NPS in

the regression model was 7/10, which is considered high. The patient with a high level of pain is more likely to have greater reduction in pain in the short term. Therefore, sufficient attention needs to be paid to this particular pain reduction predictor in clinical practice before the validation study is done.

It was surprising that almost all the tests included in the PE did not show a significant relationship with the responsiveness of HMCT, except in the cervical distraction test and upper limb tension test A. The upper limb tension test A has shown low sensitivity (0.4, 95% CI 0.27–0.56) in accuracy statistics. It was not retained in the final logistic regression model. The above findings may indirectly reflect the poor reliability and validity of those tests included in the PE. However, those tests are still used often in clinical practice, despite arguments of their poor reliability and validity. Therefore, we suggest reconsidering the usage of those tests in clinical practice.

The usefulness of a CPR in identifying a patient who would respond to HMCT is best represented by the likelihood ratio statistics. As the objective of our study was to identify responders of HMCT, the statistic of interest should be LR+. In our study, the LR+ of identifying responders of HMCT was 2.51 with the presence of 2 out of 4 positive variables. It increased from 2.51 to 4.77 with the presence of 3 out of 4 positive variables. The LR+ = 4.77 has nearly moderate accuracy [24]. In our study, the LR+ increased to 8.31 with the presence of all 4 positive variables, which is considered close to substantiate accuracy [24]. However there were only 3 participants who fulfilled the criteria. In view of the low sensitivity (0.07, 95% CI 0.02–0.20) and possibility of false negatives, we suggest not to use the CPR with the presence of all 4 positive variables. Instead, the threshold of 3 out of 4 positive variables met in the CPR should be used. The pre-prediction possibility of a successful treatment in our study was 45.6%, and the post-prediction possibility with 3 or more positive variables met was 80% according to the calculation stated by Go (1998) [18]. Cervical traction is usually considered as an adjunctive modality; thus 80% of treatment response rate should be considered clinically worthwhile. However, the CPR in our study represents a level IV CPR and requires validation in a separate sample before it can be implemented on a broad-scale basis [31]. Twenty-four patients who fulfilled the 3 out of 4 positive variables achieved successful treatment results. They formed 23.3% of the total population in our study. This could mean that only less than a quarter of patients with neck pain may eventually respond to HMCT in clinical practice.

There are several potential limitations of our study. First, there was no control group in this study. The responsive patients in the study could respond to any other

treatment other than cervical traction. Therefore, a validation study with a well-designed randomised control approach is necessary before the CPR can be applied to clinical practice.

Second, our sample was heterogeneous, with patients' reported experience of pain episodes (i.e. episode duration) spread over a long duration (1–208 weeks). The wide range of episode duration did not allow us to differentiate between acute and chronic conditions. The natural history of neck pain usually favours the acute condition regarding outcome measurement. Although the episode duration was not retained in the logistic regression model, the predictive value of chronicity should not be overlooked in clinical practice.

Third, the lack of clarity in the diagnoses could cause a potential problem in determining the patients who are likely to be responsive to HMCT. The predictive contribution from differentiating non-specific neck pain and pain of a cervical radicular nature could be masked in the study. The diagnostic-related classification still needs to be sufficiently addressed in future studies.

Fourth, the compliance rate was not entered into the statistical analysis as a predictive variable due to the unusually high compliance, which could be caused by participants giving a 'courtesy answer'. We could not exclude the possible predictive value of compliance rate from the current study.

Fifth, although 38.3% of the variance of prediction was accounted for in this study, more than 60% of the variance still remains unknown. Therefore, future studies should be designed to explore more variance, in order to have a more accountable prediction model.

Sixth, the traction regimen in this study lasted only 2 weeks. Therefore, the usability of CPR cannot be easily extrapolated to other long treatment regimens.

Seventh, the traction force in the study regimen was 10–15% of the patient's body weight. There is still a lack of agreement in the traction force that should be used in clinical practice. Forces as little as 5 lbs/2.27 kg [9, 12] and as much as 40 lbs/18.14 kg [19] have been utilised with varying results.

Finally, the small sample size (103 subjects) makes the validation study essential, before the CPR is applied to clinical practice. The influence of a small sample size could lead to insufficient number of patients (only 3 out of 103) fulfilling all 4 positive variables, which eventually caused the prediction rule with all 4 positive variables to have low sensitivity and a wide 95% CI range for LR+.

Due to the use of a single intervention study design, we also suggest that the results of our study should not be simply used in a multi-modality treatment regimen. The CPR for the use of traction in combination with other physical therapy interventions will require an independent

prediction study. It is clinically worthwhile to conduct a study of CPR, which may well be predictive of a subgroup of patients who will improve regardless of any form of physical therapy treatment given.

Conclusion

Four predictors have been identified for predicting responders to short-term HMCT. Based on the prediction model in this study, possession of 3 out of 4 predictors suggested increased probability of successful treatment. This CPR may significantly enhance the efficacy of clinical decision-making when considering HMCT as an appropriate intervention for patients with neck pain. Due to the study's limitations, future validation studies are necessary before the CPR can be implemented on broad-scale clinical practice.

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Conflict of interest None.

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