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Management of acute whiplash: A randomized controlled trial of multidisciplinary stratified treatments

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ABSTRACT

Acute whiplash is a heterogeneous disorder that becomes persistent in 40% to 60% of cases. Estimates of recovery have not changed in recent decades. This randomized, single-blind, controlled trial tested whether multidisciplinary individualized treatments for patients with acute whiplash (<4 weeks postinjury) could reduce the incidence of chronicity at 6 mo by 50% compared to usual care. Participants (n = 101) were recruited from accident and emergency centres and the community. It was hypothesized that better recovery rates were achievable if the heterogeneity was recognised and patients received individualised interventions. Patients randomized to pragmatic intervention (n = 49) could receive pharmaceutical management (ranging from simple medications to opioid analgesia), multimodal physiotherapy and psychology for post-traumatic stress according to their presentations. The treatment period was 10 wks with follow-up at 11 weeks and 6 and 12-months. The primary outcome was neck pain and disability (Neck Disability Index (NDI)). Analysis revealed no significant differences in frequency of recovery (NDI $\leqslant$8%) between pragmatic and usual care groups at 6 months (OR 95%, CI = 0.55, 0.23–1.29), P = 0.163) or 12 mo (OR 95%, CI = 0.65, 0.28–1.47, P = 0.297). There was no improvement in current non-recovery rates at 6 mo (63.6%, pragmatic care; 48.8%, usual care), indicating no advantage of the early multiprofessional intervention. Baseline levels of pain and disability had a significant bearing on recovery both at 6 and 12 mo in both groups, suggesting that future research focus on finding early effective pain management, particularly for the subgroup of patients with initial high levels of pain and disability, towards improving recovery rates.

1. Introduction

Challenges persist in the management of patients with whiplash-associated disorders (WAD). There is concordance in the international literature that acute whiplash transitions into a persistent disorder in 40% to 60% of cases [8,29,35,46]. There appears to be no substantive change in recovery status after the first 3 to 6 months after whiplash and no evidence that these estimates have changed in recent times despite a growing body of research into WAD [8,24,29,47]. Because various approaches to treatment in the chronic stage have met with limited success [21,51,58], effective management in the early stage of WAD would seem to offer the best possibility of reducing chronicity.

Whiplash is a heterogeneous disorder even within the Quebec Task Force's classification of WAD II [40]. In the acute stage, patients present with varying pain levels. Initial high intensities of neck pain and of neck pain and disability have proven to be the most consistent predictors of poor recovery [24,34,60]. The most recent meta-analysis [60] determined that a pain score of 5.5/10 and a score of >29% on the Neck Disability Index (NDI) [59] were strong predictors of poor recovery. Pain may or may not be associated with widespread mechanical and cold hyperalgesia, the latter suggestive of augmented central pain processing or possibly neuropathic pain [11,25,44,52]. Elevated cold pain thresholds show promise as a predictor of poor recovery [15]. Pain may be associated with sensations of dizziness and unsteadiness which are often accompanied by disturbances in cervical sensorimotor function [10,32,55]. Range of cervical movement is variously impaired [4,12]. There are changes in cervical motor function [18]. Patients may present with various psychological features, such as elevated general distress, fear of movement, anxiety and, notably, symp-

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toms of post-traumatic stress which show promise as a predictor of poor recovery [6,7,42]. Despite this knowledge of the array of potential reactions, early treatments trialled to date have focused mainly on physical therapies and/or education [54] and have treated patients with acute whiplash as a homogenous group, without regard to differing pain and disability levels or to the presence or absence of and the nature of any sensory changes or psychological reactions presenting in individual participants.

We proposed that better recovery rates could be achieved. First, if acute whiplash were recognised as a heterogeneous disorder and, second, if patients received individualised interventions which addressed their particular presenting features across sensory, physical and psychological domains. The aim was to offer management within a multidisciplinary context based on the individual patient's clinical presentation. Such management could include medication, physiotherapy and psychological approaches. We hypothesised that treatment of patients with WAD II delivered pragmatically, as determined by their individual presentations, would be more efficacious than current usual care and would reduce by 50% the current incidence of chronicity at 6 months after whiplash.

2. Methods

2.1. Study design

The study was a randomised controlled clinical trial with unblinded treatment but blinded outcome assessment of patients with acute whiplash disorders classified as WAD II [40]. The effectiveness of individualised multiprofessional management (medical, physiotherapeutic, psychological) was tested against usual care. Within the randomisation process, subjects were stratified on the basis of 3 factors suggestive of poor prognosis: high levels of pain and disability; symptoms of moderate post-traumatic stress reaction; and abnormal sensory responses. The period of intervention and the number of medical, physiotherapy and psychological consultations were variable and as required by the individual participant, but they continued for a maximum of 10 wk. Outcomes were tested after the 10-wk intervention period (wk 11), regardless of the duration of treatment, and at 6 and 12 mo after the whiplash event. Ethical clearance for the trial was obtained from the institutional and hospital medical ethics committees, and all participants provided informed consent. The trial was registered with the Australian Clinical Trials Registry (ACTRN12605000109606).

2.2. Participants

Participants of both sexes were recruited from the accident and emergency departments of 2 metropolitan hospitals through referrals from general practitioners or other health professionals and through advertising in the popular press. Volunteers were eligible if they were between 18 and 65 yrs of age and had had acute neck pain that was classifiable as WAD II for <4 weeks and was the result of a motor vehicle crash. Volunteers were ineligible if their neck pain was not related to a motor vehicle crash or was classifiable as WAD I, III or IV; if there was a previous history of whiplash or other neck pain for which treatment had been sought; if they lacked fluency in spoken and written English for independent questionnaire completion; or if they were unwilling to receive either pragmatic treatment or usual care.

The calculation of sample size was based on the primary outcome of the proportion of subjects reporting recovery at 6 mo based on an NDI score $\leqslant$8% [59]. The power calculation accommodated the various incidences of recovery reported in the literature (range, 40% to 60% at 6 mo) [8,35,46]. Our aim was to reduce the risk for developing chronic symptoms by 50% following the multidisciplinary pragmatic management. At the higher estimates of nonrecovery (60%), the reduction would be to 30% and for the lower estimates of nonrecovery (40%), to 20%. We considered that such a difference would have to occur so as to demonstrate a clinically relevant impact of early and concerted multiprofessional management. Thus, based on 90% power at 0.05, 56 subjects were required in each group to achieve a reduction to 30% of nonrecovered individuals. We allowed for a 10% loss to follow-up, which required 62 subjects per group (total 124 subjects).

2.3. Measurements

A series of assessments was performed in a university trial centre. They were used for the various purposes: as baseline and outcome measures, as measures for stratification purposes prior to randomisation; and/or as measures to direct prescription of individualised management in the pragmatic intervention group (Table 1). A questionnaire was used to obtain baseline data concerning patient demographics; accident history; compensation status; current symptoms, including pain intensity (visual analogue scale; VAS); and any treatment received to date (eg, by means of a general practitioner, medications or physiotherapy). The primary outcome measure was the Neck Disability Index (NDI) [59], a validated, self-report neck pain and disability questionnaire that was also used to calculate the proportion of subjects reporting recovery at 6 and 12 mo (NDI score $\leqslant$8%). Other measures included psychological, physical and psychophysical tests. Psychological questionnaires included the Impact of Events Scale (IES) to indicate symptoms of post-traumatic stress [16]; the Pictorial Fear of Activity Scale-Cervical (PFActS-C), a measure of fear of movement in patients with cervical pain [57]; and the General Health Questionnaire (GHQ 28), a standard measure of emotional distress in a medical setting [14]. Measures of physical impairment included range of cervical motion (3-dimensional external measurement device; 3-Space Fastrak; Polhemus, Colchester, VT) [12]; the craniocervical flexion test (electromyography analysis of cervical flexor function) [18,23]; measurement of balance (force platform and wavelet analysis) [56]; and cervical proprioception (joint position error) (Fastrak) [55]. The psychophysical pain tests included pressure-pain thresholds (PPTs) (pressure algometer; Somedic, Hörby, Sweden) over the cervical region and over a remote site, the tibialis anterior [49,50]; temperature-pain thresholds over the cervical region using a thermode (hot pain threshold [HPT] and cold pain threshold [CPT]) (Thermotest System, Somedic) [38]; and sympathetic vasoconstrictor response (a measure of sympathetic nervous system (SNS) function) [37,44]. The types and dosages of all medications taken by participants were documented at baseline, during the 10-wk period of the trial, as well as for the 2-wk period prior to follow-up points through the use of medication diaries.

2.4. Stratification and randomisation procedure

Randomisation was conducted independently by the Queensland Clinical Trials Centre. Subjects were stratified according to psychophysical measures suggestive of poor prognoses (values derived from confidence intervals of control subjects, except for the NDI and IES scores, where standard values of at least moderate dysfunction were used) [16,44,45,48,59]. Initial NDI was the first factor (F1); probable clinically significant post-traumatic stress symptoms (IES) was the second factor (F2); and abnormal sensory responses was the third factor (F3). At least 2 of the following factors were required: elevated cold-pain thresholds over the cervical region, lowered pressure pain thresholds over the tibialis anterior