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Letters:

Effect of a pain diary use on recovery from acute whiplash injury: a cohort study

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Previously, it was shown that the use of a symptom diary for two weeks, even in generally healthy subjects, results in increased recall of daily symptoms and increased perception of symptom severity (Ferrari and Russell, 2010). In that study, generally healthy female subjects were asked to recall symptoms experienced in the previous two weeks, after keeping a symptom diary for two weeks, while a control group was asked to recall symptoms experienced in the previous two weeks without having kept a symptom diary. While both groups had initially similar recall of their symptoms prior to the study interventions, the diary group subsequently experienced symptom amplification. That is, after 14 d of symptom diary use, the diary group recalled having symptoms on average (2.6 ± 0.7) d in the last 14 d, with an average intensity of symptoms at 5.1±1.3 out of severity 10. This was nearly double their baseline measures. The control group experienced no statistically significant change in average number of days of recalled symptoms in the prior 14 d or in average recalled intensity of symptoms experienced in the last 14 d.

The ability to accurately assess the intensity, duration, and nature of a patient's pain has been considered an important activity for the clinician managing acute whiplash injury, and to evaluate new treatments. Pain and other symptom diary assessments, for example, serve to guide physicians in their choice of treatment strategies, and in the clinical trial setting, they are often used to determine whether therapeutic interventions are effective or not. Extensive literature has demonstrated, however, that patients' pain experiences are heavily affected by numerous factors, such as their current emotional state in addition to the underlying disease processes (Eich et al., 1985; Kahneman et al., 1993; Gendreau et al., 2003). The problems of recalling of pain experiences are in broad agreement with the literature on human recall in general. The process of encoding and subsequent retrieval of the details of daily life is often prone to error and systematic biases (Gorin and Stone, 2001; Hufford et al., 2001) in part because questions administered in clinical settings are often temporally distant from when the pain was originally experienced. In an attempt to avoid the problems associated with retroactive self-reports, researchers and clinicians have turned to diaries as a way of capturing data from patients closer in time to the events or experiences of interest (Roelofs et al., 2004; Aaron et al., 2005; Sadovsky and Dodick, 2005). In this study, it was hypothesized that four weeks of pain dairy use in acute whiplash-injured subjects would reduce the rate of recovery relative to a control group.

Three subjects in the diary group and one subject in the control group did not return for follow-up and were not included in the study. Thus, there were 27 subjects in the diary group and 29 in the control group. The characteristics of both groups at the outset are shown in Table 1. The groups were similar in mean age, gender distribution, and initial Whiplash Disability Questionnaire (WDQ) scores. Thus, randomization was effective. As well, based on self-report, there was no difference in the number of subjects in

each group who were complaint with the initial referral for active, exercise therapy.

Table 1 Descriptive statistics for the diary group (n=27) and control group (n=29)

Group	Age (year)	Male (%)	Mean WDQ score	Subjects complying with physiotherapy referral
Diary	37.1±12.4	41	68.0±25.5	19
Control	39.2±15.2	45	65.3±22.1	22

WDQ: Whiplash Disability Questionnaire score at presentation. All *P*-values in comparisons for this table were not statistically significant (*P*>0.05)

Two subjects in the control group, despite not being asked to do so, were later found to have kept a pain and symptom diary. Three subjects in the diary group failed to maintain a diary at all. Only 60% of the diary group subjects returned their diaries, but 80% (24 of 30) reported that they had completed at least the first two weeks of the diary entries. Of those who did return their diaries (18 of 30 subjects), 100% (18/18) had completed the first two weeks of entries, and 50% (9 of 18 subjects) had completed at least 75% of the four weeks of entries.

At three months post-injury, 59% (16/27) of the diary group reported recovery, while 86% (25/29) of the control group reported recovery, a difference which is statistically significant (P=0.023). None of the subjects responded "not sure" to the question of recovery (i.e., from the above figures of who responded "yes" to the recovery question, the remaining numbers responded "no" to the recovery question). If it is assumed that all subjects lost to follow-up in the diary group recovered, and all those lost to follow-up in the control group failed to recover (i.e., an assumption which would tend to reduce differences in recovery rates between the two groups), the P-value is 0.081 (not significant). It is noteworthy, however, that the two subjects in the control group who actually kept a symptom diary were among those in the sample who failed to recover at three months post-injury. Thus, if they are excluded from the analysis, as well as three subjects in the diary group who did not keep a diary (and who should be excluded because the intervention did not occur), the difference between the two groups is again significant.

This study reveals that use of a daily pain dairy for four weeks after whiplash injury is associated with a lower rate of recovery at three months post-collision. Diaries are commonly used in clinical practice, and by a wide range of therapists when encountering acute whiplash injured subjects. Often patients are asked to keep more than a pain diary, and they are often asked to do so by more than one person. For example, two subjects in the control group were advised by others to start a symptom diary, which tracked more than pain. While diaries may serve a useful purpose to facilitate practitioner-patient communication about symptoms and to track the course of symptoms, the benefits have not been demonstrated. Moreover, maintaining a pain diary appears to impact recovery. Symptom diaries may increase the perception and recall of a greater frequency and intensity of symptoms.

It is worth mentioning that the diary group did show a gradual diminishment in pain level over the course of four weeks, but there were too few diaries returned to comment further on this data. That diary entries suggested that pain improves over time is encouraging. The problem may be, however, that recovery is determined in part by how much one notices symptoms. Pain diaries do not readily permit a subject to *not* notice symptoms. In fact, even by three months post-injury, it may be that the pain levels in the two groups were very similar, but the diary group was simply more aware of pain. Because pain is subjective, the feeling of recovery is partly based on perceptions. Diary use may alter these perceptions significantly. The duration of four weeks of diary use was chosen to increase the likelihood of compliance with the diary record, knowing that a two-week period of diary use has the effect of symptom amplification in healthy subjects (Ferrari and Russell, 2010). There was no attempt to enforce or encourage the diary use further. Despite the possibility of significant non-compliance with the intervention, the mere initiation of diary use may be sufficient to induce symptom amplification and affect recovery in these cohorts. In fact, the intervention in this study is not so much, but the pain diary itself in essence is simply having a clinician provide instructions to a whiplash patient to track their pain. The mere act of this instruction to a whiplash patient, even when they do not track their pain completely or for very long, has an apparent impact on their outcome. It would in fact be of interest to know if the results would have been even more divergent had the diary group been asked to keep a pain diary for a full three months, or to provide the results of their diary every week to encourage further amplification. It would also be of interest to know, via future studies, if diary use affected perceptions of disability.

There are limitations to this study. First, although the subjects did not have contact with the researcher in the interval between being assigned a diary and evaluation three months later, it is possible that the family physician or treating therapist discovered that some subjects were keeping track of their pain. This possibility was not formally evaluated. On the one hand, if the practitioners were aware of diary use and advised patients against its use, the effect could only be to reduce the differences noted in this study, and this merely reinforces the powerful effect of diary use (i.e., an effect was noted even if there were actions taken by others that would diminish this effect). On the other hand, if knowledge of dairy use affected how the patients were treated by the practitioners, and this in turn led to a worse outcome, that is exactly the point of this study: diary use is not helpful and may even influence treatment.

The first author has tracked and reported outcomes from cohorts in this same setting (data unpublished), and has the expectation of the recovery rate at three months exceeding 80%, as was achieved in the control group. This high recovery rate has been partly related to legislative changes which have increasingly and dramatically altered outcomes in this jurisdiction (Russell and Ferrari, 2008), but also because the practice circumstances are unique: a family physician, a specialist with extensive knowledge of whiplash injury, and a single physiotherapist, all with similar approaches and philosophies, co-manage these patients with an insistence on education, exercise, and avoidance of passive treatment approaches.

In any case, the two groups (diary vs. control) differed in the proportion recovered, even in these optimal circumstances, suggesting that diary use is likely not only *not* helpful, but harmful.

In conclusion, until we have further data confirming that symptom diaries have an overall health benefit to their use, this study raises concerns about the potential for a detrimental effect of diary use in acute whiplash injury in particular, where recovery may subsequently be adversely affected.

Subjects and methods

Design

This was a parallel, randomized, controlled, nonconcealed allocation study. Subjects were randomly assigned to either a diary (intervention) group or control group.

The Research Ethics Board of the College of Physicians and Surgeons of Alberta (Canada) approved the study.

Setting and participants

Subjects were recruited from a sample of consecutive whiplash-injured patients presenting within 7 d of their collision to a single primary care centre. Patients with a motor vehicle collision and suspected whiplash-associated disorder (WAD) were routinely referred from general practitioners at the clinic directly to one of the researchers (RF), who was acting as a specialist consultant within that clinic. In this study, one general practitioner provided all the referrals. Data were gathered on subjects referred over a four-month period (June to September 2010), the measurements being conducted at the initial consultation as part of usual assessment. Prospective subjects were further assessed for inclusion and exclusion criteria at the time of initial interview. WAD grade 1 or 2 patients were included if they were seated within the interior of a car, truck, sports/utility vehicle, or van in a collision (any of rear, frontal or side impact), had no loss of consciousness, were 18 years of age or over, and presented within 7 d of their collision. Patients were excluded if they were told that they had a fracture or neurological injury (i.e., grade 3 or 4 WAD), had objective neurologic signs on examination (loss of reflexes, sensory loss), previous whiplash injury or a recollection of prior spinal pain requiring treatment, no fixed address or current contact information, were unable to communicate in English, had non-traumatic pain, were injured in a non-motor vehicle event, or were admitted to hospital. All subjects were, at the time of the study, in a system of new legislation that places a cap on compensation for whiplash grades 1 and 2, of 4000 USD. A standardized diagnostic treatment protocol applied to each subject. This system has been described elsewhere (Russell and Ferrari, 2008). All subjects had filed a claim with an insurance company to receive treatment

benefits (Ferrari and Louw, 2011).

Recruitment and outcome measures

A total of 71 prospective subjects were assessed over the course of the study and after evaluation for inclusion and exclusion criteria, and each subject was provided with instruction if eligible for the study. During the course of recruitment, 11 were excluded (8 due to previous history, 2 due to loss of consciousness, 1 due to language barrier). Thus, 60 subjects formed the sample for study, and all agreed to participate. During the course of recruitment, subjects were randomly assigned to keep a pain diary (diary group) or not (control group). Those assigned to the Diary group were given written instructions to examine their daily pain experience at the end of each day. They were asked to assess the overall pain experience (taking into account all their pains) and to consider on average how severe their pain was on that day. They were asked to record a number from 1-10 in a calendar provided or on a paper with dates recorded. They were instructed that 1 meant minimal or no pain, and 10 meant severe and barely tolerable pain. They were asked to leave their pain diaries at the clinic after four weeks. A diary was considered "achieved" if at least 75% of the days had a rating (i.e., at least 21 of 28 d), or at least the first two weeks were complete.

Randomization procedure

These subjects represented primary care patients routinely referred by a single general practitioner to one of the authors (RF). The author had been routinely using questionnaire-based measures in acute whiplash injury, but had not previously been using instructions to maintain a pain diary. To determine if the addition of formal instructions to maintain a pain diary had any effect on patient outcomes (beyond usual care), the author (RF) had the opportunity to randomly administer one of two sets of packages to subjects: one set containing a WDQ, and second package including the WDQ, as well as instructions on completing the pain diary, as stated above.

A third party created 30 sets, each of two sealed envelope packages to ensure blinding to the package contents. The author (RF) informed the patient that the author was studying the value of using questionnaires to monitor symptoms and outcomes including various means by which to track pain. The subjects

provided verbal informed consent to open the packages, follow the instructions, complete a questionnaire, and then be prepared for follow-up in three months with the author. The envelope packages were labeled with either an "A" (contained only the WDQ) or a "B" (contained the aforementioned and instructions to maintain a pain diary for four weeks). The contents corresponding to this lettered assignment were not known to the researchers. Each item within the package had a number from 1 to 60 to allow the responses to be collated for each subject. All subjects completed the component requiring the initial completion of the WDQ.

Outcomes

Subjects were asked to return for a three-month assessment even if improved or recovered, and were contacted by phone if necessary to increase compliance with the three-month assessment. The researchers were blind to the pain diary results at the time of re-assessment. Recovery was assessed with the question: "Do you feel you have recovered from your injuries?" with responses of "yes", "no", or "not sure". This question has been shown to correlate with WDQ scores (Ferrari et al., 2006). Subjects were also asked if they had complied with an initial referral for active exercise therapy, delivered by a physiotherapist. This was a standard prescription for all subjects, involving an initial physiotherapy assessment and either home exercises or a supervised exercise program as deemed necessary by the physiotherapist. The same physiotherapist was referred to in all cases, as it was known that the physiotherapist did not include diaries as a part of the physiotherapist's whiplash management recommendations.

Statistical analysis

Descriptive statistics were calculated for age, sex, and initial WDQ score in order to compare groups for similar baseline characteristics, as they are known prognostic factors (Carroll *et al.*, 2009). The proportion of subjects responding with "yes", "no", or "not sure" to the question of recovery at three months was recorded and compared at three-month follow-up. Significance was set at *P*<0.05. These variables were compared between groups using either Student *t*-test or Chi-squared for proportions, as appropriate.

Sample size calculation

No prior studies are available for comparison of sample size. Based on the study demonstrating an observable effect of symptom amplification and symptom recall in two groups of 20 subjects each (Ferrari and Russell, 2010), the study aimed to recruit at least this number, assuming a drop-out rate of perhaps 25%. Thus, the study was terminated when 30 subjects could be recruited in each group. This was to ensure at least 20 subjects per group.

Compliance with ethics guidelines

Robert FERRARI and Deon LOUW declare that they have no conflict of interest.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000(5). Informed consent was obtained from all patients for being included in the study.

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