

A Pilot Study of Low-Power Laser Therapy in the Management of Chronic Neck Pain

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ABSTRACT. Objective: This pilot study was undertaken to test techniques of application of laser therapy, appropriate outcome measures and to determine effect sizes in order to facilitate the performance of a larger, clinical trial of laser therapy in chronic neck pain.

Methods: We conducted a randomized double-blind, placebo-controlled study of low level laser therapy in 20 patients with chronic neck pain. The primary outcome measure was change in a 10 cm Visual Analogue Scale [VAS] for pain. Other measures used included a Self-Reported Improvement in pain [SRI], measured by a VAS, Short-Form 36 Quality-of-Life questionnaire [SF-36], Northwick Park Neck Pain Questionnaire [NPNPQ] and the McGill Pain Questionnaire [MPQ]. Measurements were taken at baseline, at the end of 7 weeks treatment and at 12 weeks from baseline.

Results: We found a positive, pain-relieving effect in the treated group compared with those given placebo using the VAS [$P < 0.039$], SRI [$P < 0.001$], NPNPQ [$P < 0.002$] and the MPQ [$P < 0.009$]. The results of the SF-36 did not differ significantly between the two groups. Patients in the treated group experienced an average pain score improvement of 66.7% compared with 16.6% in the placebo group.

Conclusion: Low-power laser therapy, at the parameters used in this pilot study, may provide a non-invasive, non-pharmaceutical therapy for chronic neck pain for patients in general practice. Further study of this technique in a large-scale trial would be justified on the basis of the findings of this pilot study. [Article copies available for a fee from The Haworth Document Delivery Service: 1-800-HAWORTH, E-mail address: <docdelivery@haworthpress.com> Website: <<http://www.HaworthPress.com>> © 2004 by The Haworth Press, Inc. All rights reserved.]

KEYWORDS. Chronic neck pain, gallium aluminum arsenide laser diode, 830 nanometre wavelength, low-power laser therapy

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INTRODUCTION

Chronic neck pain has a high prevalence in the community and is responsible for significant loss of workdays and a reduction in quality of life for individuals (1,2). Non-steroidal anti-inflammatory drugs are commonly used for this condition but have significant side-effects, and pain-modulating therapies, such as anti-epileptic medication, are often not well tolerated. Radiofrequency neurotomy has been shown to be effective for cervical zygapophyseal joint [CZJ] pain but requires specialised skills, hospital based facilities, needs repeating regularly and is restricted to those patients whose pain arises from the CZJ (3). There is a need for non-drug, non-invasive therapies for chronic neck pain which can be used as a first-line therapy in general practice (4). We have previously reported an audit of patients with chronic neck pain who were treated with 830 nm, 300 mW laser at a primary care practice between 1998 and 1999 (5). This study revealed a useful pain-relieving effect. However, there are few extant, randomized, controlled trials of laser therapy for neck pain. Moreover, these describe the use of different wavelengths (6,7) in the treatment of chronic pain or report findings in acute rather than chronic pain (8). In the only study in which an 830-nm wavelength was used, the application technique was different from our technique and a lower power output being used (9). There are some studies of laser therapy with positive outcomes in musculoskeletal conditions other than neck pain (10,11). However, formal available meta-analyses provide conflicting evidence of the efficacy of laser in musculoskeletal conditions (12,13).

The apparent efficacy of laser can only be definitively assessed through a prospective, methodologically-sound study. The present study was performed to appraise several key components of a proposed randomized, double-blind, controlled trial. Specifically, we aimed to determine the feasibility of treatment and blinding protocols, the most suitable outcome measures and the effect size [if any] of laser therapy to enable planning of a properly-powered trial in chronic neck pain.

SUBJECTS AND METHODS

Ethical Approval

The Sydney University Human Ethics Committee approved all aspects of the study. Informed consent was obtained from all participants.

Patient Recruitment and Selection

The first twenty patients who fulfilled the inclusion criteria, were recruited from those responding to advertisements displayed in the practice of the principal author, or published in a local newspaper and a newsletter to local general practitioners.

Patients were included if they were 18 years of age or over; had unilateral or bilateral chronic neck pain; were able to attend a full course of 14 treatments given twice a week; able to understand the nature of the trial and had not experienced previous treatment with low-level laser therapy [except laser acupuncture].

Patients were excluded if they had a work-related or third party injury in which litigation or compensation was still current; had abnormal neurological signs in the upper limbs relating to nerve entrapment or impingement from the cervical spine; inability to discontinue temporarily any activity which exacerbated the pain; pregnancy; previous surgery to the cervical spine; other systemic rheumatological disease such as rheumatoid arthritis; neck pain which was part of a widespread pain syndrome involving other areas or previously demonstrated photosensitivity.

A total of 99 patients contacted the study team expressing interest in the trial. The first 20 consecutive patients who fulfilled the inclusion and exclusion criteria were recruited. Of the remainder, 28 patients did not meet criteria, 11 patients could not attend for the course of treatments and assessments, 2 declined to consent, 1 failed to attend, 10 patients could not be contacted, and 27 patients rang after enrolment was complete.

Randomization and Blinding

Patients were randomized to one of two identical lasers, labeled A or B by selecting

one of 20 sequentially numbered, sealed envelopes, prepared earlier by a third party. The contents stated which laser and treatment protocol [see below] were to be used. Both lasers were identical in appearance but only one emitted laser light. Before the machine was switched on, the patient and doctor donned protective glasses specific for 830 nm wavelength. The glasses protected the eyes and blinded both the patient and the doctor to which laser [active or sham] was being used. At the completion of the course of treatment, the patients were asked whether they thought they had received active or placebo treatment.

Laser Device and Parameters

Patients were treated with one of two Diolase devices [DioLase Corporation of Mountain View, California, USA], marked A or B, with a classification of Class III B in accordance with the Australian/New Zealand Standard, 4173: 1994. They were identical in all aspects of observable function but only one emitted a laser beam with a fusiform shape, 15 mm in length and 3 mm at its widest with a wavelength of 830 nm and power of 300 mW in continuous wavemode at a Power Density [PD] of 0.67 Watts/cm². The laser parameters selected were based pragmatically on that used in every day practice by the principal author [RC] as reported previously.

Calibration of the Laser

The lasers were calibrated for output at the Department of Laser Physics, Macquarie University, Sydney. The output remained stable in the active laser at 300 mW over the course of the study.

Treatment Protocols:

Fixed-Time and Flexible Time Protocols

Initially 20 patients were block-randomized to 4 equal groups. They were allocated to Laser A or Laser B, and then either a "fixed-time" or "flexible-time" protocol. The original intention was to first mark all palpated tender points and then to treat each one. The laser was to be applied for 30 s per point [fixed-time protocol] or until the area became less tender

[flexible-time protocol]. The marks would be removed at the end of treatment. Thirty minutes were allocated for each attendance. However, on the first day of the study it became apparent, that, in patients with multiple areas of tenderness, it was not possible to mark all tender points and complete either treatment protocol in the allotted time. Therefore, after the first 5 treatments, marking of tender points was abandoned and a fixed-time protocol, with 30 s treatment per tender point was used for all patients.

Application Technique

The laser hand piece was held perpendicular to the skin, centered over each tender point using contact pressure technique (14).

Tender Point Identification

Points for treatment were identified by systematic palpation with firm finger pressure. Palpation commenced at the midline at the external occipital protuberance, distally over each spinous process down to T8, the lowest insertion of the trapezius muscle aponeurosis, laterally along the nuchal line to the mastoid process on the affected side or sides. This was continued laterally over the articular pillars from C2 to C7 and para-vertebral areas of T1-T8, extending laterally over muscle bellies to the tip of the shoulder [including the acromioclavicular joint], the sternomastoid muscle bellies and insertion at the sternum and clavicle. The medial border of the scapulae and the insertion of muscles on the spines of the scapulae were also palpated. The number of points treated varied between patients and was dependent on the clinical condition of the patient on the day of treatment.

Medication Use

Patients continued to take whatever medication they had been prescribed when they presented for laser therapy. This included analgesics, anti-inflammatory and pain-modulating medication and drugs for other, unrelated medical conditions. Intake of analgesics in this patient group varied from those who took medication on an as-needed basis to those who

took regular pain medication. Over the course of treatment, patients were free to use whatever analgesic medication they felt was necessary to control the symptoms.

Outcome Measures

Several validated outcome measures were selected. A horizontal 10cm VAS for pain was marked by the patient at baseline, immediately before each treatment, at completion of the course of treatment and 1 month later. A derived score based on the difference between the initial VAS and the final VAS, expressed as a percentage of the initial VAS, was used as the primary outcome measure. The SF-36, the NPNPQ and the MPQ, all validated outcome measures of pain, were self-administered at baseline, at the end of the course of treatment and 1 month later [approximately 12 weeks after baseline]. The SF-36 questionnaire consists of 11 questions about general health and can be divided into physical [PCS] and mental health scores [MCS]. The NPNPQ consists of nine questions, each with a possible score ranging from 0 to 4, describing neck pain symptoms. The final score is expressed as a ratio of the sum of the scores for each question over a maximum score of 36. A tenth question provides a global estimate of change in symptoms and covers the spectrum of responses from 'much worse' to 'much better.' The MPQ provides a total score as well as sensory and affective components of pain as separate scores. In addition, it gives a qualitative measure of the intensity of pain and a VAS measure of the previous week's pain.

The VAS for self-assessed improvement, which rates global improvement, included a negative arm to indicate worsening of symptoms. This was completed at the end of treatment and 1 month later. A pain diagram was completed at baseline, at the end of the course of treatment and 1 month later, as well as at each treatment, to indicate the extent of pain on the day of treatment.

Patients were also given a treatment diary to fill in daily for the duration of the study. The treatment diary consisted of a VAS to be filled in daily at 20:00 h, a drug diary, a list of symptoms that might be experienced as side-effects of treatment and the option to indicate any other symptoms that might have occurred that day.

At the initial examination of the patients, it was apparent that the extent and severity of tenderness varied widely. A proportion of patients had a single, unilateral, localised area of pain which required moderate palpation to elicit tenderness, whereas other patients had widespread areas of tenderness over the neck, bilaterally, which extended over both scapulae, shoulders, all muscle bellies and attachments and were tender to light palpation. To provide some quantitative estimate of this variation in severity of tenderness, a clinically-based score was devised to provide an additional measure of the patient's condition. This was referred to as the 'severity score' as a measure of the clinical severity of the patients' condition. Two measures were used and were later compared. One was the multiple of the number of sections tender to palpation (1-6) times the degree of overall degree of tenderness to palpation [graded 1 to 3]. Grade 1 is a verbal expression that palpation causes pain, Grade 2 is grimacing and verbal expression of pain, and Grade 3 is expression of pain and reflex withdrawal from the painful stimulus. This method is based on that used in a study of cephalic muscle tenderness in a general population (15). A maximum score of 18 was possible. This score was referred to as the severity score by multiplication [SSM]. The second measure was simple addition of the scores for each section, with a maximum possible score of 18. This was referred to as [the severity score by addition [SSA].

Statistical Methods

We computed differences in all outcome measures and compared across groups at baseline and between baseline and 12 weeks later using the Two-Sample t-test. The Chi-square test was used to compare gender across groups. All tests were performed at a 5% level of significance. The program, Statistical Package for the Social Sciences [SPSS] Version 10, was used for analysis.

RESULTS

Characteristics of the Study Group

Sixteen women and 4 men were enrolled. The mean age was 57.7 years [SD: 10.9 years].

There was no statistically significant difference in age between the treated and placebo groups [$P = 0.75$]. Mean duration of pain was similar between the treated and control groups [13.5 years vs. 13.1 years, $P = 0.91$] [see Table 1].

Treatment Procedure

Ideally patients were seen for seven consecutive weeks, with treatment administered twice a week. One patient in the placebo group withdrew from the study after five treatments as she wanted to pursue other treatment options. Seven patients in the placebo group completed the full course of 14 treatments, with two completing 13 treatments. Eight patients in the active group completed 14 treatments, with two completing 13.

Outcome Measures

Difference between scores at baseline and 12 weeks later were compared. At baseline there was no significant difference between the mean VAS scores of the two groups [$P = 0.316$] [see Table 2]. At 12 weeks after baseline, there was a significantly greater improvement percentage VAS change in the active group compared with placebo [$P < 0.039$]. The raw mean VAS did not show statistical significance between baseline and 12 weeks as the study was under-powered for the observed effect size.

The score for self-assessed improvement of pain was significantly different between the active and placebo groups [66.7% versus 16.6%, $P < 0.001$] [see Figure 1].

With regard to the SF-36 quality of life questionnaire there was no significant differ-

ence between treated and placebo groups in the physical [PCS] and mental [MCS] scores for quality of life at any point in the study.

There was also no difference in the baseline NPNPQ scores between the two groups; however, a significant difference [$P < 0.023$] emerged 12 weeks later. The responses to question 10 of the NPNPQ, relating to the "global" effects of the treatment, were significantly different at 12 weeks after baseline [$P < 0.002$], indicating a "global" benefit of laser therapy in the treated group. Moreover, no patient reported worsening of his or her symptoms using this question.

Out of step with other measures, the MPQ showed a statistically significant difference between the treated group and the placebo group at baseline in the total score [$P < 0.009$], the sensory [$P < 0.023$], and affective component of the scores [$P < 0.002$], suggesting more severe symptoms in the active group.

Twelve weeks after baseline, i.e., one month after completion of treatment, the difference from the baseline total MPQ scores was statistically significant [$P < 0.000$], as were the individual sensory [$P < 0.001$] and affective components of the scores [$P < 0.004$], the direction of change showing improvement over and above the initial scores.

There was a significant difference between the baseline severity scores by the multiplication method between the treated and the placebo group [$P < 0.005$], the treated group having more severe pain at baseline. The baseline difference in SSA between the two groups approached, but did not reach significance [$P < 0.052$].

Daily Diary

All patients attempted to keep the diary but only 11 out of the 19 who completed the course of treatment filled in the diary in full. In the diaries, unusual tiredness was cited more frequently [$P < 0.01$], as a side-effect, by the treated group. No other symptoms occurred at a statistically significant frequency.

Patients were asked to record their drug intake in their diary on a daily basis. The drugs taken for pain included paracetamol [seven patients], rofecoxib [five patients], paracetamol 500 mg and codeine 8 mg [three patients],

TABLE 1. Baseline Characteristics of Patients in Laser and Placebo Groups Enrolled in the Pilot Study of Laser Therapy of Chronic Neck Pain

	Laser A [placebo]	Laser B [active]	P values
Age	58.50 [SE = 4.29]	56.90 [SE = 2.57]	$P = 0.75$
Sex	F	7	$P = 0.29$
	M	3	
Duration of pain	13.50 [SE = 2.42]	13.10 [SE = 2.54]	$P = 0.91$
Baseline VAS	3.2 [SE = 0.5]	3.9 [SE = 0.6]	$P = 0.32$

VAS = Visual Analogue Scale

TABLE 2. Differences Between Active and Placebo Groups in Outcome Measures Used in the Pilot Study to Assess the Efficacy of 300 mW, 830 nm Laser in the Management of Chronic Neck Pain, at Baseline and Between Baseline and 12 Weeks Later

Measurement tool	Baseline value		P value	Differences from baseline to 12 weeks		P value	
	Laser Mean [SE]	Placebo Mean [SE]		Laser Mean [SE]	Placebo Mean [SE]		
VAS (0-10)	3.9 [0.6]	3.2 [0.5]	P = 0.32	2.1 [0.9]	0.7 [0.5]	P = 0.210	
% VAS Improvement				65.9 [11.02]	29.82 [10.49]	P < 0.039*	
SF-36	PCS	39.0 [3.6]	41.6 [3.0]	P = 0.6	4.00 [2.6]	1.22 [2.0]	P = 0.4
	MCS	50.9 [3.4]	50.1 [2.5]	P = 0.9	1.71 [1.20]	0.00 [1.9]	P = 0.5
NPNPQ	0.37 [0.09]	0.30 [0.11]	P = 0.12	-0.12 [0.036]	-0.007 [0.025]	P < 0.023*	
MPS	total	17.4 [2.7]	7.5 [2.0]	P < 0.009*	-11.44 [2.24]	1.1 [1.52]	P < 0.00*
	sensory	12.9 [2.2]	6.2 [1.6]	P < 0.023*	-8.22 [1.56]	0.53 [1.35]	P < 0.001*
	affective	4.6 [1.0]	0.9 [0.3]	P < 0.002*	-3.22 [1.01]	1.0 [0.77]	P < 0.004*
SRI				66.7% [9.4]	16.6% [7.7]	P < 0.001*	

* Statistical significance P < 0.05

VAS = Visual Analogue Scale

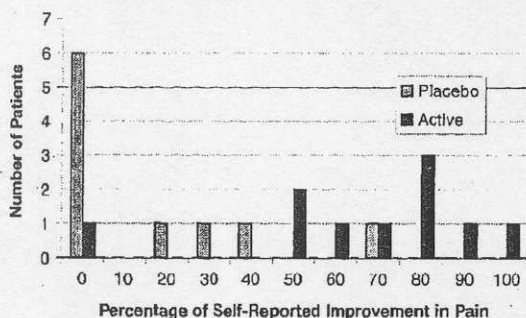
SF-36 = Short Form 36, quality of life questionnaire [PCS = Physical score, MCS = Mental score]

NPNPQ = Northwick Park Neck Pain Questionnaire

MPS = McGill Pain Score

SRI = Self-Reported Improvement in neck pain

FIGURE 1. Self-reported improvement in chronic neck pain, 12 weeks after baseline, expressed as percent improvement, in two groups of 10 patients, active and placebo, treated with 830 nm, 300 mW laser therapy. X axis: Number of patients; Y axis: Percent improvement in pain.



celecoxib [two patients], paracetamol 500 mg and codeine 30 mg [one patient], ibuprofen [one patient] and dextropropoxyphene and paracetamol [one patient]. Five patients took no medication at all during the 7 weeks of treatment.

Placebo Awareness

At the completion of treatment five of the ten patients treated with the placebo laser said that they did not know whether they had re-

ceived active treatment whereas five said they believed that they had not had active treatment.

In the treated group, seven patients stated that they believed they had been given active treatment, citing improvement in their symptoms as the reason. One patient believed that she was not having active treatment, and two patients did not know.

DISCUSSION

This study has demonstrated the feasibility of performing a double-blind, randomized, controlled trial of laser therapy in neck pain. Despite the small numbers, it also revealed a statistically significant and clinically useful effect. In addition, it provided an opportunity to consider, in some detail, several measures of neck pain and assess the limits and benefits of these measures. In considering these results, it is appropriate to review whether any methodological issues affected the internal and external validity of the study.

Patients

The selected inclusion and exclusion criteria were used with the intention of providing a

homogeneous sample. However, these criteria are not based on the different possible pathologies underlying neck pain, with the consequence that the study may "lump" patients together who may have quite different bases for their pain. Furthermore the selected criteria did not include any assessment of the extent and severity of tenderness of the soft tissues of the neck in any individual patient. Some patients displayed very localized areas of unilateral tenderness limited to an area overlying one or two segments while others had extensive areas of tenderness from the occiput to the inferior pole of the scapula, bilaterally. These tender areas in the neck may lie within muscle bellies, tendons, entheses and zygapophyseal joints. Specifically we did not attempt to identify and treat "trigger" points, which are said to be tender points, palpation of which elicit particular responses, including a "twitch" and a clearly defined pain referral pathway (16). There are reports in the literature in which "trigger points" are treated with laser (17), and a reduction in local tenderness occurs though significant controversy exists as to the nature and even the existence of trigger points in the neck (18).

Quantification of clinical tenderness has been attempted by several authors (15,19) using algometry (20-23) and, more recently, using a "palpometer" (24). However, we attempted to quantify this ourselves by deriving a "Severity Score" [SS] based on severity and extent of tenderness on clinical examination. The SSM showed concordance with McGill pain scores but not other measures. The usefulness of this score remains to be evaluated but may reflect another dimension to the clinical assessment of patients with neck pain.

Another patient factor relevant to laser therapy is the individual's responsiveness to light delivered in this way. Currently there is no method of assessment of a patient's "photo-responsiveness." Some patients appear to respond rapidly and others appear to be non-responsive no matter how long the laser is applied. This variation in sensitivity has also been alluded to by another author (25). A large enough sample of patients should provide a study population with a normal distribution of responsiveness to light.

Treatment

The selection of the appropriate wavelength and dose of laser for a particular condition is another area in which there is a paucity of clinical trials from which to derive treatment protocols. Many factors are involved in the selection of a particular dose or wavelength for a particular condition but, as yet, there are no clearly defined protocols for painful conditions and, in particular, neck pain. Historical factors, anecdote and varying modes of laser therapy, including the use of laser acupuncture, have all added to the confusion (26). One of the initial aims of this study was to compare two treatment protocols, defined as the "flexible-time" and the "fixed-time" protocols. It became apparent early in the trial that no protocol could be completed in the time allocated, and all patients were subsequently treated using the "fixed-time" protocol with 30 s per point.

On formal assessment of blinding, nobody in the placebo group felt they had received active treatment, but 7 out of 10 in the active group correctly identified that they had received active treatment at the end of the study. This may be due to either a positive treatment effect or a compromise of blinding, which may be from a placebo effect from patients being inadvertently unblinded. Since we have noted a delay in the onset of a treatment effect, testing blinding early in the course of treatment should permit these possibilities to be differentiated.

Measurement Tools

Several tools were used to measure the response to treatment, namely, VAS, self-reported improvement of pain, SF36, MPQ and NPNPQ. There was no difference in baseline scores between the 2 groups apart from the McGill pain questionnaire in which the active group had a higher score in all 3 components. Over the course of the study measures showed a significant improvement in the active group except for the SF-36.

The primary measure of response to laser therapy used in this study was the percentage change of VAS. It has generally been regarded as a linear scale, however, it is clear that a fall

of, say, 2 points, has very different clinical implications if the starting point is "8" rather than "4," the former being a drop of 25% and the latter being 50%. It could be argued that "severe" pain at "8" would be disabling to the patient and may require more powerful medication. Pain with a VAS of "4" would be milder and less intrusive to the patient, requiring minimal analgesia. In order to accommodate for this we also asked patients to record their perceived improvement of their pain as a VAS score, allowing them to indicate a worsening, as well as an improvement, in symptoms.

The self-reported improvement in pain in the active group was clinically significant with an average of 66.7% improvement reported one month after completion of treatment. This is consistent with other studies of laser therapy in other painful conditions which have previously reported improvement between 70-80% (27,28). In this study, one patient achieved complete relief of pain, which had been present for 7 years. Such a result is unusual and may have biased scores in this small group of patients.

All measures selected showed a positive response in the treated group except for the SF-36 which did not show any difference between the two groups at any point in the study. It may be thought that patients with long standing neck pain would have a poorer quality of life than patients without chronic pain and that improvement of chronic pain would result in improvement in quality of life. The discordance between the SF-36 and other measuring tools may be due to small numbers [type 2 error] or it may reflect the "insensitivity" of the SF-36 as an instrument in the measurement of quality of life in patients with pain in this setting. Patients may have already been optimising their function despite their pain or they may have concurrent problems eg back pain, depression, which may have kept the SF-36 stable.

In contrast to the SF-36, the NPNPQ contains questions specific to neck pain and associated symptoms. Therefore it may be expected to provide more data on the effects of neck pain on patients' functioning. In this study, the baseline NPNPQ scores between the two groups were not significantly different. Following treatment, scores in the active group were improved. This supports the need for a symptom-specific

questionnaire, rather than a general, quality-of-life questionnaire instrument. The responses to question 10, which is a question asking the patients to indicate a spectrum of response to treatment from "much better" to "much worse," demonstrated an overall benefit of treatment, concordant with other measures. No one in the sample was worse at the end of treatment.

Unlike the SF-36, the MPQ demonstrated differences between both groups, at all points measured. The baseline scores of all the components of MPQ were higher in the active than placebo group. However all the MPQ scores in the treated group fell over the course of treatment, indicating less pain, consistent with the other pain scores.

This small pilot study demonstrates the need for several different measures to be used in the assessment of chronic pain, as each measure has specific limitations. The use of several different outcome measures provides a more complete picture of responses and also provides a means of assessing internal validity.

Analgesic intake has been used to assess response of pain to treatment. In this study drug use for pain relief was minimal, even though many of the patients reported experiencing moderate to severe pain. In addition, many patients found the task of filling in a daily diary onerous. Because of the low intake of medication overall, the diary added little to the pain assessment and would not be used in a large-scale trial.

Low-power laser therapy is reported as being side effect free and studies rarely report any systematic recording of side-effects. Kert and Rose (29) are the only authors who have described in detail several possible patterns of increased pain as a reaction to treatment. In the author's [RC's] clinical experience side effects of laser do occur and we sought to record these symptoms in a systematic manner using a daily diary. Anecdotally, unusual tiredness, nausea and exacerbation of pain for hours to days after treatment have been described. They do not occur in all patients and are usually limited to the first few treatments. In this pilot study, unusual tiredness was the only symptom which occurred significantly more frequently in the treated group.

The mechanisms underlying an analgesic effect of laser in chronic pain remain to be

fully elucidated although a number have been postulated. While the underlying mechanism is unknown, it has been demonstrated in animal studies that laser therapy results in a selective reduction of A δ and C fibre activity (30). Analgesia may also occur due to the release of endogenous opioids following laser stimulation (31). Anti-inflammatory effects have been demonstrated both in-vitro (32) and in-vivo (33,34) and a direct effect on motoricity of lymph vessels (35,36), reducing interstitial fluid at the site of inflammation, has been described. Increased fibroblast activity and laying down of collagen in damaged ligaments may also contribute to long-term pain relief associated with laser therapy (37,38).

RESEARCH DIRECTIONS

Three research directions emerge from this study. Firstly, and unexpectedly, this small, pilot study showed a significant improvement in pain between the active and placebo groups. This type of would only be expected to show differences where treatment effect sizes are reasonably large, or may simply reflect the play of chance. This adds further weight to the imperative to perform a properly designed, methodologically-sound study which can help establish the efficacy or otherwise of this potentially attractive therapy. The second research direction emerging from this work is that which was originally planned, that is to plan and perform a more robust trial of laser therapy for neck pain. This pilot study gave us the valuable opportunity to test treatment protocols, recruiting strategies, inclusion and exclusion criteria, blinding effectiveness, outcome measures and other practical issues in the performance of such a study. This is of specific interest to other groups that may be interested in performing clinical trials of laser therapy. In consideration of our own proposed study, several substantial changes were made on the basis of the pilot findings.

In particular, we found that a fixed-time treatment protocol was the only practical option to use given the time restrictions. We also found that the effectiveness of blinding should be tested immediately after the first treatment,

rather than at the end of treatment to avoid a positive treatment effect "unblinding" the patients.

The primary outcome measure used in the pilot study [percentage change in the VAS] appeared sensitive to change, was simple to administer and calculate and moved consistently with other measures used. Secondary outcome measures such as the Short-Form-36 Quality of life questionnaire, a specific neck pain related questionnaire such as the Northwick Park Neck Pain questionnaire and a pain questionnaire such as the McGill Pain Score each seem to add distinct information and the simultaneous measurement of pain using these instruments adds, if nothing else, a means of checking the internal validity of a patient's response. The time of assessment of response to treatment remains arbitrary, but it seems clinically sensible to determine acute responses, and for a chronic condition the long-term effects of a therapy are axiomatically important. Therefore, we believe it is useful to assess outcomes at baseline, the end of treatment, and then at 6 and 12 months. An alternative approach would be to determine the duration of an arbitrary degree of relief and then describe the treatment effect in terms of time. This has been used in other studies of neck pain [39]. Ideally a blinded outcome assessor would administer the questionnaires.

Using the response rates and variances in principal outcome measures [percentage change in VAS] from the pilot study we have used established techniques to calculate sample sizes for future work. Selecting an α value [probability of a false positive—type I error] of 0.05, β [probability of a false negative, i.e., type II error] of 0.2 [i.e., a power of 0.8] and δ [detectable difference in VAS] of 2, and assuming that data are analysed by a Two-Sample T-test, 36 patients are required in each arm of the trial. This does not allow for drop-outs, contamination or other adverse contingencies.

Finally the apparent benefit of laser therapy for pain management needs to be better understood. This requires that basic research considers how laser might influence nociception at peripheral and central sites.

CONCLUSION

This pilot study has provided us with important data from which to plan and institute a methodologically-sound prospective, double-blind, randomized, placebo-controlled trial into the effects of low level laser on chronic neck pain.

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