Infrared therapy for chronic low back pain: A randomized, controlled trial

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OBJECTIVE: The objective of the present study was to assess the degree of pain relief obtained by applying infrared (IR) energy to the low back in patients with chronic, intractable low back pain.
METHODS: Forty patients with chronic low back pain of over six years' duration were recruited from patients attending the Rothbart Pain Management Clinic, North York, Ontario. They came from the patient lists of three physicians at the clinic, and were randomly assigned to IR therapy or placebo treatment. One patient dropped out of the placebo group; as a result, 21 patients received IR therapy and 18 recieved placebo therapy. The IR therapy was provided by two small, portable units in a sturdy waistband powered by small, rechargeable batteries made by MSCT Infrared Wraps Inc (Canada). These units met safety standards for Food and Drug Administration portability, and are registered with the Food and Drug Administration as a therapeutic device. The unit converted electricity to IR energy at 800 nm to 1200 nm wavelength. The treated group received IR therapy. The placebo group had identical units, but the power was not connected to the circuit-board within the IR pad. Patients attended seven weekly sessions. One baseline and six weekly sets of values were recorded. The principle measure of outcome was pain rated on the numerical rating scale (NRS). The pain was assessed overall, then rotating and bending in different directions.
RESULTS: The mean NRS scores in the treatment group fell from 6.9 of 10 to 3 of 10 at the end of the study. The mean NRS in the placebo group fell from 7.4 of 10 to 6 of 10.
CONCLUSION: The IR therapy unit used was demonstrated to be effective in reducing chronic low back pain, and no adverse effects were observed.

Key Words: *Chronic back pain; Infrared therapy; Low back pain; Lumbar pain*

La thérapie à infrarouge pour les douleurs lombaires chroniques : Un essai aléatoire et contrôlé

OBJECTIF : La présente étude vise à évaluer le degré de soulagement dorsal apporté par l'application d'énergie infrarouge (IR) dans la région lombaire de patients atteints d'une douleur lombaire chronique réfractaire.
MÉTHODOLOGIE : Quarante patients atteints d'une douleur lombaire chronique depuis plus de six ans ont été recrutés parmi les patients de la *Rothbart Pain Management Clinic* de North York, en Ontario. Ils provenaient de la liste des patients de trois médecins de la clinique et ont été divisés de manière aléatoire entre la thérapie IR et un traitement placebo. Un patient a quitté le groupe placebo. Par conséquent, 21 patients ont reçu la thérapie IR et 18, le traitement placebo. La thérapie IR a été administrée à l'aide de deux petites unités portatives placées sur une robuste ceinture alimentée par de petites piles rechargeables fabriquées par MSCT Infrared Wraps Inc. (Canada). Ces unités respectaient les normes de sécurité de portabilité de la *Food and Drug Administration* (FDA) des États-Unis et sont enregistrées auprès de la FDA comme des dispositifs thérapeutiques. L'unité convertissait l'électricité en énergie IR selon une longueur d'ondes de 800 nm à 1 200 nm. Le groupe traité a reçu une thérapie IR. Le groupe placebo a reçu des unités identiques, mais l'alimentation n'était pas reliée au circuit imprimé du panneau IR. Les patients participaient à sept séances hebdomadaires. Une série de valeurs a été enregistrée au départ, suivie de six hebdomadaires. La principale mesure d'issue a été cotée selon la douleur sur l'échelle d'évaluation numérique (ÉÉN). La douleur a été évaluée dans l'ensemble, puis à la rotation et à la flexion dans différentes directions.
RÉSULTATS : Les indices moyens de l'ÉÉN du groupe traité ont chuté de 6,9 sur 10 à 3 sur 10 en fin d'étude. L'ÉÉN moyenne du groupe placebo est passée de 7,4 sur 10 à 6 sur 10.
CONCLUSION : On a démontré que l'unité de thérapie IR utilisée était efficace pour réduire les douleurs lombaires chroniques, et aucun effet indésirable n'a été constaté.

The use of electricity for healing dates from 2750 BC, when electric eels were used to provide electric shocks (1). Magnetism from lodestones was also used by ancient people. Attempts to use electricity and magnetism in the 18th century met with little success. In 1975, Melzack (2) developed transcutaneous electrical stimulation (TENS) for prolonged pain relief. This provided 50% pain relief in 50% of patients in one study (3) but was no better than the placebo in another (4). Electrical and magnetic fields have been used successfully to stimulate bone repair (5) and soft tissue healing (6).

Recently, infrared (IR) therapy has been developed, which has shown improved wound healing (7-9), relief of arthritic knee pain (10), increased endorphin levels (11) and bioactivation of neuromodulators (11-13).

Because low back pain is the most common cause of musculoskeletal disability, it was decided to determine the effect of IR on this condition using a new instrument developed by MSCT Infrared Wraps Inc (Canada).

THE IR UNIT

The IR unit developed by MSCT Infrared Wraps Inc is light, portable and designed to be worn on a belt. It is powered by a small, rechargeable battery and is claimed to be 99% efficient in converting electricity to IR energy.

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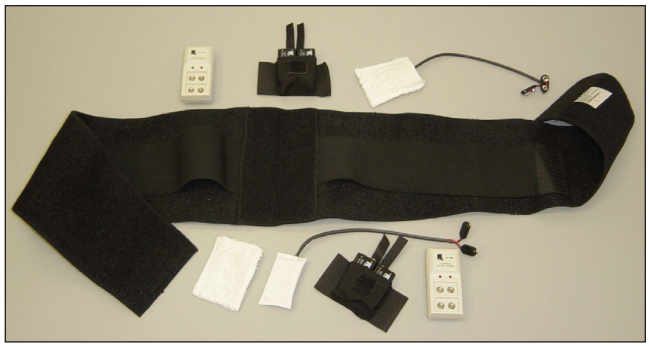

Figure 1) *Infrared lower back pain wrap (MSCT Infrared Wraps Inc, Canada)*

It contains an IR-emitting element in a unique design with an IR grid and buzz bars down each side to deliver the electricity, converting it to IR energy at a wavelength of 800 nm to 1200 nm.

This instrument has met safety standards for portability and was registered with the Food and Drug Administration as a therapeutic device in 2003. The unit used in the present study (Figure 1) contained two IR units and two batteries housed in a sturdy lumbar belt. The batteries require recharging every 24 h and were then functional for 8 h to 10 h per day. The IR output was reliable at 800 nm to 1200 nm of wavelength, and there was an automatic shut-off if the temperature rose to 42°C. This feature was lacking in IR laser units, which therefore could cause thermal injury.

THE POTENTIAL FOR ADVERSE EFFECTS

The continued use of heating devices in the past, some as simple as a hot water bottle, have caused the development of skin changes known as erythema ab igne. Very thin individuals and those with bony spurs have the potential to develop thermal injury, but no injuries have been found during extensive testing of the MSCT unit on horses and human volunteers (S Wolfe, personal communication).

METHOD

It was decided to conduct a double-blind, placebo-controlled trial of IR using the IR wrap in patients suffering from musculoskeletal low back pain attending the Rothbart Pain Management Clinic (RPMC), North York, Ontario.

The protocol was submitted to the Ethics Committee of the RPMC and approval was obtained. The committee was comprised of three internal members of the RPMC and two external physicians.

Safety features of the IR wrap were considered to be satisfactory because the wrap meets the safety standards of the Food and Drug Administration for portability and registration. Moreover, the emitted IR at 800 nm to 1200 nm is considered to be a form of energy that is not harmful to tissues and even protects from the effects of ultraviolet light because of IR's antioxidant effect. The only theoretical harmful IR effect discussed in the literature is overheating, but this is unlikely to occur with the MSCT unit because it has an automatic shut-off at 42°C.

The waist wraps given to both groups were identical. In the placebo group, the power was not connected to the circuit board within the IR pad. Patients were informed which group they were in at the end of the study; those in the placebo group could try the IR wrap. Care was taken to ensure that both treated and control subjects continued to use the treatment throughout the investigation period. All subjects were correctly advised that heat may not always be felt because with prolonged use, the response of the tissues may change. Of the 40 subjects enrolled, there was only one dropout (a 60-year-old man assigned to the placebo group), resulting in 39 study participants in total.

Patient recruitment took place by means of a notice posted in the patient waiting room of the clinic. The average duration of low back pain was 6.5 years. Subjects ranged in age from 26 to 80 years. There were 20 women and 19 men. The investigations carried out included x-rays, computed tomography and magnetic resonance imaging. All patients were already on other forms of therapy for chronic pain at the direction of the treating doctor. The patients continued their medications and nerve blocks during IR or placebo treatment. Medications included antidepressants, anti-inflammatories and opioids (21 of 39 participants were on opioids). Nerve blocks included paravertebral nerve blocks and occasional caudal epidural blocks. Those in the placebo group were advised that they would be able to try the active IR wrap after the study.

Experimental design

This was a randomized, double-blind, placebo-controlled trial. Data were collected using an 11-point numerical rating scale at commencement and then at weekly intervals for seven variables for each subject: overall pain (standing still), pain bending forward, pain bending backward, pain rotating right, pain rotating left, pain bending right and pain bending left.

All subjects suffered from low back pain, but initial pain levels differed. Twenty-one subjects received the IR wrap and 18 were assigned to the placebo device.

Statistical summary

The average pain for each subject was calculated for each of the seven weekly observations; a summary was then produced for each time interval using Procedure Means (PROC MEAN), a feature of the SAS statistical software program (SAS Institute Inc, USA).

RESULTS

The IR therapy group showed a progressive decline in pain levels of approximately 50%, which was greater toward the end of the seven-week study period (Table 1 and Figure 2). This was highly significant both by within-group comparison ($P<0.0001$) and compared with the placebo group ($P<0.0001$). There was also a small decrease in pain levels in the control group (Table 2).

DISCUSSION

Back pain is the most common cause of disability in North America, and it accounts for 64% of new consultations at this pain clinic (RPMC); many of these patients have had failed back surgery.

The present study demonstrated significantly greater pain relief in the IR-treated group than in the placebo group. Both groups continued with their prestudy treatment such as antidepressants, opioids and palliative nerve blocks, and this may account for the small decrease of pain in the control group. Alternatively, actually wearing the lumbar belt without the IR may have been beneficial. There was only one dropout from the placebo group. The reduction in pain in the treated group

TABLE 1
The change in mean pain scores in treatment and placebo groups over seven weeks

Group	Pain scores		
	Assessment interval	n	Mean ± SD
Treatment, n=21	Week 1	21	6.94±1.63
	Week 2	17	6.28±2.18
	Week 3	18	6.46±1.91
	Week 4	19	5.89±2.04
	Week 5	16	5.42±2.31
	Week 6	16	4.54±2.63
	Week 7	21	3.05±1.57
Placebo, n=18	Week 1	18	7.48±1.64
	Week 2	16	7.31±1.85
	Week 3	17	6.60±1.03
	Week 4	18	7.34±1.80
	Week 5	17	6.23±1.37
	Week 6	17	7.48±3.27
	Week 7	17	6.02±1.46

Note: Each subject's reported pain scores are dependent over the seven weeks

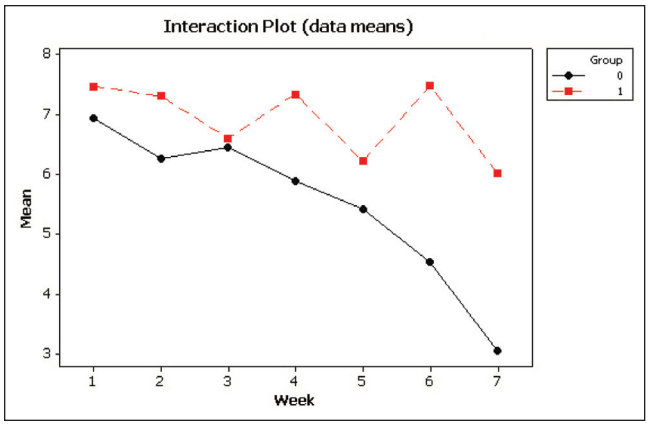

Figure 2) *Mean pain scores for each group at seven weekly observations. The above plot clearly shows the statistically significant differences in reported pain levels between the infrared wrap treatment group (group 0) and the placebo group (group 1)*

TABLE 2
Repeated measures analysis

Effect	P	Conclusion
Time × group interaction	<0.0001	The interaction effect was significant. On average, each subject's reported pain decreased over time, but the decrease in reported pain was much higher for the IR wraps treatment group than it was for the placebo group.
Time (among individual subjects)	<0.0001	There was a time effect. On average, each subject's reported pain decreased over time.
Groups (among subjects in a group)	0.0021	There was a group effect. When averaged over time, subjects in the IR wraps treatment group reported less pain than subjects in the placebo group.

IR Infrared

was progressive over seven weeks, with a 50% pain reduction in the entire group (Figure 2), while the control group achieved an approximately 15% reduction in pain.

Electrical stimulation with the TENS has been shown to provide a 50% pain reduction in only 50% of patients in one study (3), and was found to be no better than placebo in another (4). It is therefore probable that IR is more effective than TENS.

Pain relief with IR has been shown for arthritis of the knee (10). Other beneficial effects documented are increased wound healing (7-9), blood flow (14,15), endorphin levels (11) and bioactivation of neuromodulators (11-13).

Because IR warms the tissues, it may be prudent to avoid its use in cases with documented malignant hyperthermia and also scleroderma, because some forms of that condition deteriorate in sunlight, which has a wavelength close to IR. Also, many forms of prolonged heat therapy have produced a skin condition known as erythema ab igne; this is a potential theoretical risk, even though it has never been reported with IR. Another hazard is thermal injury in very thin individuals or those with bony prominences, even though the device will automatically shut off if the skin temperature in contact with the IR unit reaches 42°C. No adverse effects of any sort were found in the present study, as was the case with the extensive use of the MSCT IR unit in animals, principally horses (S Wolfe, personal communication).

The MSCT IR unit can conveniently provide prolonged therapy because it is light and portable, and when charged, the batteries provide IR therapy for 10 h while the wearer remains active during the day or resting at night.

One weakness of the blinding procedure in the present study was that IR energy could have caused heating, but the inactivated placebo unit did not. We may have overcome this problem by explaining to the subjects that warming is not always felt because of a variable response of the tissues, thus leaving open the issue of whether warming occurred or not. In any future study, the IR unit will be compared with a heat unit.

CONCLUSION

In a double-blind, placebo-controlled trial, the IR wrap has clearly demonstrated that it is easy to use, safe and effective, and reduced chronic back pain by 50% over six weeks. Contraindications are rare (possibly malignant hyperthermia and scleroderma), and the risks of thermal injury are low and are minimized by the use of an automatic shut-off when the unit in contact with the skin rises to a temperature of 42°C. Other units such as lasers may not have such a safety device.

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