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A placebo controlled double blind trial to evaluate the effectiveness of pulsed short wave therapy for osteoarthritic hip and knee pain

J.A. Klaber Moffett*[a], P.H. Richardson[b], H. Frost[c] and A. Osborn[c]

[a]*Centre for Health Economics, University of York, York, YO1 5DD (UK),* [b]*UMDS Division of Psychiatry and Psychology, St Thomas' Hospital, London (UK) and* [c]*Physiotherapy Research Unit, Nuffield Orthopaedic Centre, Oxford (UK)*

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Summary The aim of this study was to investigate the effectiveness of pulsed short wave (PSW) in the relief of pain in osteoarthritis of the hip and knee. Ninety-two patients, mean age 63 years, (34 men and 58 women) were randomly allocated to one of three groups: (1) Active PSW, using the dosage found in a pilot study to be non-significantly most effective, (2) Placebo PSW, (3) No treatment control group. Nine sessions of treatment were provided over a 3-week period, each application lasting for 15 min. The machine was modified by the manufacturers so that the therapist was able to administer the treatment and carry out assessments without being aware of the treatment allocation. Outcome measures included sensory and affective pain diary reports averaged over days and weeks, self-reported benefit and the General Health Questionnaire. Analysis of variance with repeated measures over time was used to find out if the active treatment had a specific effect, incremental to the placebo effect. There were no significant differences between the active and placebo groups over time. According to the pain diary reports, both active and placebo groups tended to improve slightly during treatment, but worsened after its withdrawal. Patients who were given the placebo application tended to report more benefit than those who had the active treatment, although this did not quite reach statistical significance ($P < 0.06$). Patients who were not on a waiting list for surgery did significantly better over time than those who were ($P < 0.03$). There were no significant differences between the groups over time for the other outcome variables. Any treatment effect on this patient population appears to have been largely placebo-mediated. No evidence was found therefore for the specific effectiveness of PSW for treatment of osteoarthritic hip or knee pain.

Key words: Pain relief; Osteoarthritic hips; Osteoarthritic knees; Pulsed short wave; Placebo; Randomised trial

Introduction

Short wave diathermy (SWD), which is radio-frequency electromagnetic energy of sufficient intensity to produce a biological thermal effect, has been used therapeutically since 1928 (Goats 1989). A more recent and popular variant is pulsed short wave (PSW). This consists of bursts of the same alternating high frequency current, interspersed with a cut-off phase, during which heat can be dissipated in the tissues. It is used for the treatment of soft tissue injuries and also for more chronic conditions including osteoarthritic hip pain (Green 1991). Various proposals have been made as to its likely mechanism of therapeutic action (Bentall 1976; Evans 1980; Collis and Segal 1988).

Clinical trials

Evidence for the therapeutic effects of PSW is inconclusive. Wilson (1974) claimed superior pain relief and reduction of swelling in patients with sprained ankles treated with PSW rather than short wave diathermy. There have been a number of reports of significant reduction in swelling and disability (Pasila et al. 1978), and also superior pain relief (Barclay et al. 1983; Binder et al. 1984). Bias in these studies was likely, however owing to a number of methodological shortcomings including poorly designed control conditions, lack of randomisation and the failure to ensure the therapist and assessor were blind to treatment allocation.

* *Corresponding author*: Dr J.A. Klaber Moffett, Centre for Health Economics, University of York, York, YO1 5DD, UK. Tel.: (44) 1904 433714; Fax: (44) 1904 633644.

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In contrast, Barker et al. (1985) found no significant post-treatment difference between patients with sprained ankles who had been randomly allocated to treatment and control groups. This study appears to be the only one to date that used a truly double blind design, where the assessor, therapist and patient were all blind to the treatment. Without such safeguards, bias, for example due to the therapist expectations, may influence the patient's response to treatment (Richardson 1993; Klaber Moffett and Richardson 1995).

Although it is a favoured method of treatment (Green 1991), there has been no randomised controlled trial to date on the use of PSW for the relief of pain in osteoarthritis of the hip.

An additional problem has been that there are no guidelines based on any systematic investigation to determine the most effective method of application. A small national informal survey of 'experts' and users was therefore carried out. The responses were varied, based on anecdotal evidence and were not considered specific enough to inform our decision as to which method of application should be used in a trial of PSW therapy for pain relief in osteoarthritic hip patients. The dosage was therefore determined from a pilot study of 45 patients with osteoarthritis of the hip.

The aim of the study was to investigate whether there are any differences between active and placebo PSW in their effectiveness in reducing pain and functional disability in patients with osteoarthritic hips and knees.

Method

Design

The design of the study was a double blind randomised controlled trial. Fig. 1 shows the overall plan of the investigation.

Population

Patients with osteoarthritis of the hip or knee referred from the outpatient clinics of the Nuffield Orthopaedic Centre (NOC), Oxford, were invited to take part in the study if they appeared to meet all the inclusion criteria. In addition, patients on a waiting list for total arthroplasty of the hip or the knee who met the criteria were eligible for inclusion, providing they were not expecting surgery within the next 6 months.

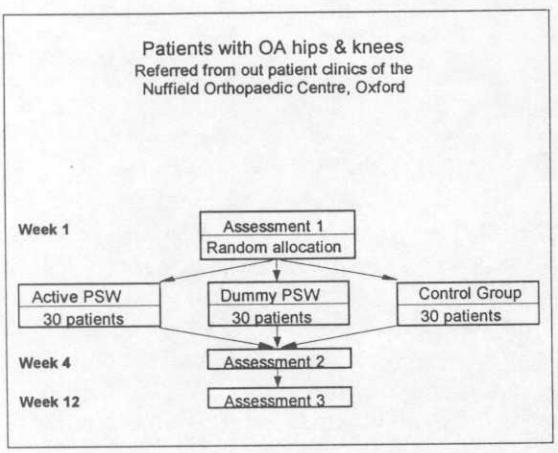

Fig. 1. Flow chart to show overall plan of investigation.

Inclusion criteria

(1) Radiological changes in the hip or knee reported as degenerative or osteoarthritic.
(2) Pain predominantly emanating from the one joint.
(3) Ability to walk 50 m.

Exclusion criteria

(1) Previous arthroplasty on joint to be treated.
(2) Surgery to this joint in past 6 months.
(3) Physiotherapy for this joint over the past 6 months.
(4) Documented contra-indications to PSW, e.g. pacemaker, pregnancy.
(5) Serious obesity as defined by Quetelet's Index (Khosla and Lowe 1967), which would make it difficult to position the applicator close to the hip joint.

Patients who met the criteria were given an explanation of the study, and if they consented to take part were included in the study.

Equipment

A pulsed short wave machine Ultramed 11S 601 with a drum applicator, called a 'Circuplode' containing a coil, provided the PEMF. It was placed almost in contact with the patient, directly over the centre of the joint being treated. To ensure therapist blindness, the machine was modified (by Central Medical Equipment in conjunction with Bosch) to enable a physiotherapist to apply the treatment without knowing whether it was in active or placebo mode. The modification provided the therapist with 10 different points on a dial, which were used in rotation. Patients were sequentially allocated to a number on this dial. Half the points on the dial provided active, and half provided placebo applications. The code for these points was in a sealed envelope and remained unknown to the researchers until all data had been collected.

Outcome measures

Pain diaries

Pain diaries were the main outcome measure used in this study. They allowed pain reports to be assessed over days and over weeks (Pearce and Richardson 1987; Main 1989). Patients were asked to complete them four times daily, at 'breakfast time', 'lunch time', 'tea time' and 'last thing at night', using a numerical rating scale (0–100). They were asked to record both pain intensity and pain related distress 1 week prior to treatment, during treatment, at the end of treatment, and at 3 months follow up providing a total of 7 week's pain data. Each pain diary contained a week's data and was collected at the appointment immediately following its completion.

One-off subjective pain reports

Patients were asked by the therapist at each assessment, to rate the intensity of hip or knee pain over the past few days, using the same numerical rating scale (0–100) as for the pain diaries. They were also asked to rate the level of any referred pain experienced in their low back, thigh, knee and below the knee, using the same scaling system and they were also asked whether the pain had been constant or intermittent. Further details of this outcome measure compared with the pain diary reports are provided elsewhere (Klaber Moffett 1994).

General Health Questionnaire

The GHQ-30 was administered at all 3 assessment points as a measure of current psychological symptomatology. It has been validated as a screening device for a minor psychiatric disturbance and been shown to be reliable (Goldberg 1978).

Activities of daily living

Activities of daily living and range of motion were measured at all 3 assessment points and are reported elsewhere (Klaber Moffett 1994).

Procedure

Ethical approval to carry out this study was given by the Central Oxford Research Ethics Committee, prior to setting up the study.

Baseline stabilisation

At the initial contact with the patient, an attempt was made to stabilise patients on the same drugs up until the last assessment. The patient's gait was checked and, if appropriate, a walking aid was supplied and the patient was taught how to use it correctly. Weight and diet were also discussed where this was deemed important, using the Quetelet Index as a guide (Khosla and Lowe 1967). A simple exercise routine for both hip and knee patients was taught but no other advice or treatment was provided, apart from PSW therapy, until the trial was completed.

Randomisation

Patients were randomised to their treatment groups using the minimisation method (Pocock 1983).

Application of treatment

In a pilot study of patients with osteoarthritic hips ($n = 45$), the following three variations of application/dosage were compared, each providing a mean wattage of 23 watts which was considered to be subthermal for practical purposes:

'Dose A' = 200 pulses/sec × 3
'Dose B' = 110 pulses/sec × 5
'Dose C' = 82 pulses/sec × 7

There were no significant differences between these three applications in terms of pain reports, General Health Questionnaire scores, functional ability or range of motion, as assessed immediately before and after the 3-week course of treatment.

In the main study, 'Dose C' was chosen, as the pain reports averaged out from the daily diary data over the weeks showed an improvement from pre- to post-treatment of 23% compared with only 8% for 'Dose A' and 'Dose B'. PSW (82 pulses/sec × 7) was administered three times a week for 15 min, over a period of 3 weeks. For hip pain the patient was positioned comfortably supported with pillows in the supine position and the circuplode was positioned directly over the centre of the joint, not quite touching the skin. For knee pain it was applied in the semi-recumbent position with sufficient pillows placed under the knee joint to support it in mid flexion, with the patella not overlying the knee joint.

Analysis and results of the study

Ninety-two patients with pain predominantly in one joint due to OA, 46 with OA hip pain and 46 with OA knee pain were included in the study and largely complete data sets were available for analysis of all these patients on all baseline measurements. All patients in the placebo and active groups attended for their course of treatment, except one who only attended 6 sessions as her date for surgery was brought forward. The total number of drop-outs by the third assessment was 8, with 5 of these in the control group, 2 in the placebo group and 1 in the active treatment group. A further 9 patients had incomplete sets of pain diary data.

Baseline data

Of the 92 subjects included in the main study, 34 were male and 58 female with a mean age of 63 and ages ranging from 35 to 80 years old.

Results of *t*-tests showed that there were no statistically significant differences between the patients with hip or knee pain on any of the baseline data. Therefore, it was considered legitimate to analyse data from both sets of patients together.

The baseline data for the three treatment groups (active, placebo and control groups) are displayed in Table I. Analysis of variance indicated that there were no significant differences on the baseline data between these treatment groups.

Comparing treatment effects across three groups over time

Analysis of Variance with Repeated Measures over time was used to compare the mean scores of each of the three groups (active, placebo and control) at pre-treatment, and post-treatment at 1 month and 3 months follow up. Greenhouse Geisser adjusted probabilities are reported where there are several levels of repeated measures factors over time.

Results of sensory and affective pain diary reports

Data from the pain diaries were analysed separately for the sensory and affective reports. The four daily pain reports were averaged across each of the 7 weeks for each patient. This included: (i) 1 week of baseline pain reports, (ii) 4 weeks of pain diary data spanning the period between the first and second assessment points and including the 3 weeks of treatment and (iii) 2 weeks of pain diary data collected prior to the follow-up assessment point, 3 months after the first assessment

TABLE I
MEANS AND STANDARD DEVIATIONS OF BASELINE DATA FOR CONTROL, PLACEBO AND ACTIVE GROUPS COMBINING HIP AND KNEE PATIENTS

Variable	Control		Placebo		Active	
	Mean	SD	Mean	SD	Mean	SD
Age (years)	64.42	10.32	63.48	10.53	62.67	8.69
Duration of history (months)	111.23	151.30	103.07	107.37	62.00	102.89
Pain diary reports — sensory	34.69	22.01	28.40	18.60	28.18	18.18
Pain diary reports — affective	33.10	21.83	26.86	18.91	26.34	18.36
GHQ (scores 0–90)	28.24	10.75	25.72	9.38	29.34	12.78

TABLE II
MEANS AND STANDARD DEVIATIONS OF PAIN REPORTS (SENSORY AND AFFECTIVE, 0–100) AVERAGED ACROSS THE WEEKS COMBINING PATIENTS WITH OA HIP AND KNEE PROBLEMS

	Time	Control ($n = 27$)	Placebo ($n = 22$)	Active ($n = 26$)
Sensory				
Pre-treatment	Baseline	34.69 (22.01)	28.40 (18.60)	28.18 (18.75)
During treatment	Wk 1	35.79 (23.19)	24.97 (16.76)	26.25 (17.84)
	Wk 2	36.19 (24.41)	23.10 (16.74)	24.13 (18.26)
	Wk 3	36.00 (23.58)	22.49 (15.97)	24.34 (18.44)
End of treatment	Wk 4	34.56 (23.20)	24.04 (18.56)	23.52 (18.90)
Follow-up	Wk 11	39.27 (27.52)	30.40 (24.33)	32.02 (24.83)
	Wk 12	39.87 (27.36)	30.87 (24.68)	31.14 (25.22)
Affective				
Pre-treatment	Baseline	33.10 (21.83)	26.86 (18.91)	26.34 (18.36)
During treatment	Wk 1	34.04 (22.60)	23.36 (17.20)	24.42 (17.29)
	Wk 2	34.61 (24.14)	21.25 (16.55)	22.46 (17.63)
	Wk 3	34.25 (23.35)	20.94 (15.71)	22.80 (18.26)
End of treatment	Wk 4	32.73 (22.96)	22.58 (18.39)	22.15 (18.56)
Follow-up	Wk 11	37.95 (27.76)	29.32 (24.41)	30.85 (24.79)
	Wk 12	38.65 (27.56)	29.80 (24.99)	30.11 (25.17)

Values are means with SD in parentheses.

point (Table II). The sensory and affective reports followed a very similar pattern; both the placebo and the active treatment groups improved slightly during treatment but returned to baseline levels by the time of the follow-up assessment period. The pain scores of the control group appear to be higher at every assessment point. However, one-way analyses of variance carried out at baseline, immediately following treatment, and at follow-up on both the sensory and affective components of pain showed that none of the differences between the treatment groups approached statistical significance. The repeated measures analysis of variance showed significant variations over time for both the sensory ($F = 9.76$, $P < 0.0001$), and affective component ($F = 11.05$, $P < 0.0001$). However, no significant differences emerged between the three treatment groups (main effect), or the groups over time (interaction effect).

Comparison of the three groups on GHQ scores and self-reported benefit

Mean GHQ score for the three assessment points (pre-treatment, post-treatment and follow-up) along

TABLE III
MEANS AND STANDARD DEVIATIONS OF REPORTED BENEFIT AND GHQ SCORES COMPARING CONTROL, PLACEBO AND ACTIVE GROUPS PRE-, POST-TREATMENT AND AT FOLLOW-UP COMBINING HIP AND KNEE PATIENTS

Variable	Time points	Control	Placebo	Active
Reported benefit (NRS 0–100)	1	—	—	—
	2	—	50.45 (31.01)	40.12 (24.95)
	3	—	53.86 (29.36)	35.92 (32.84)
GHQ (scores 0–90)	1	28.24 (10.75)	25.72 (9.38)	29.34 (12.78)
	2	28.10 (12.13)	22.31 (11.97)	27.93 (14.20)
	3	32.00 (14.18)	26.79 (13.58)	30.27 (15.80)

Values are means with SD in parentheses.

with self-reported benefit of treatment assessed of course only for the treatment groups at post-treatment and follow-up are displayed in Table III.

Levels of distress as measured by the GHQ-30 scores appeared to improve slightly in both the placebo and the active treatment over time but reverted to baseline levels by the third assessment. Repeated measures analysis of variance with repeated measures over time showed that although there was a significant overall variation in GHQ scores over time ($F = 6.6$, $df = 2,168$, $P < 0.002$) but there were no significant differences between the groups in their pattern of change in GHQ scores.

Contrary to expectation, patients in the placebo group tended to report a greater benefit than the active group (Table III) and the results of analysis of variance demonstrated a marginally significant difference between the groups ($F = 3.9$, $df = 1,45$, $P < 0.06$).

Comparison of patients on waiting list for joint replacement surgery with those not on waiting list — sensory and affective pain reports

The pain scores of patients in the active and placebo groups who were waiting for joint replacement surgery were compared with their counterparts who were not on a surgical waiting list. Group membership (active or placebo application) was not statistically significant ($F < 1$, $df = 1,44$, NS), and did not have any effect on the patterns of change over time. But the variables, waiting list and time did yield statistically significant F-values (respectively $F = 9.29$, $df = 1,44$, $P < 0.004$ and $F = 4.37$, $df = 6,264$, $P < 0.01$). The interaction effect of waiting list and time was also significant ($F = 3.30$, $df = 6,264$, $P < 0.03$). Fig. 2 graphically displays the differential effect of time on the waiting list versus non-waiting list patients' pain scores. It shows that pain scores of patients on the waiting list hardly changed at all during treatment, regardless of whether they were in the active or placebo groups and when it was withdrawn, tended to get worse. In contrast, *non-waiting list* patients improved by about 50%, whilst receiving placebo or active treatment and reverted slightly when it was withdrawn.

The same analysis was carried out with similar results for affective pain reports. The main effect of treatment group was not significant ($F < 1$, $df = 1,44$, NS), but again waiting list and time yielded highly statistically significant F-values (respectively $F = 8.75$, $df = 1,44$, $P < 0.01$ and $F = 5.14$, $df = 6,264$, $P < 0.004$). The interaction effect of waiting list and time was again significant ($F = 3.90$, $df = 6,264$, $P < 0.02$).

Patients on the waiting list reported significantly more benefit in the placebo group compared with the active group ($F = 5.8$, $df = 1,22$, $P < 0.03$).

Discussion

The results of this study showed no differences in effect between active or placebo treatment on the levels of pain reported. The small sample size and modest statistical power of this study limit the general significance of its findings. Nevertheless, the fact that all trends in the results favoured the placebo application

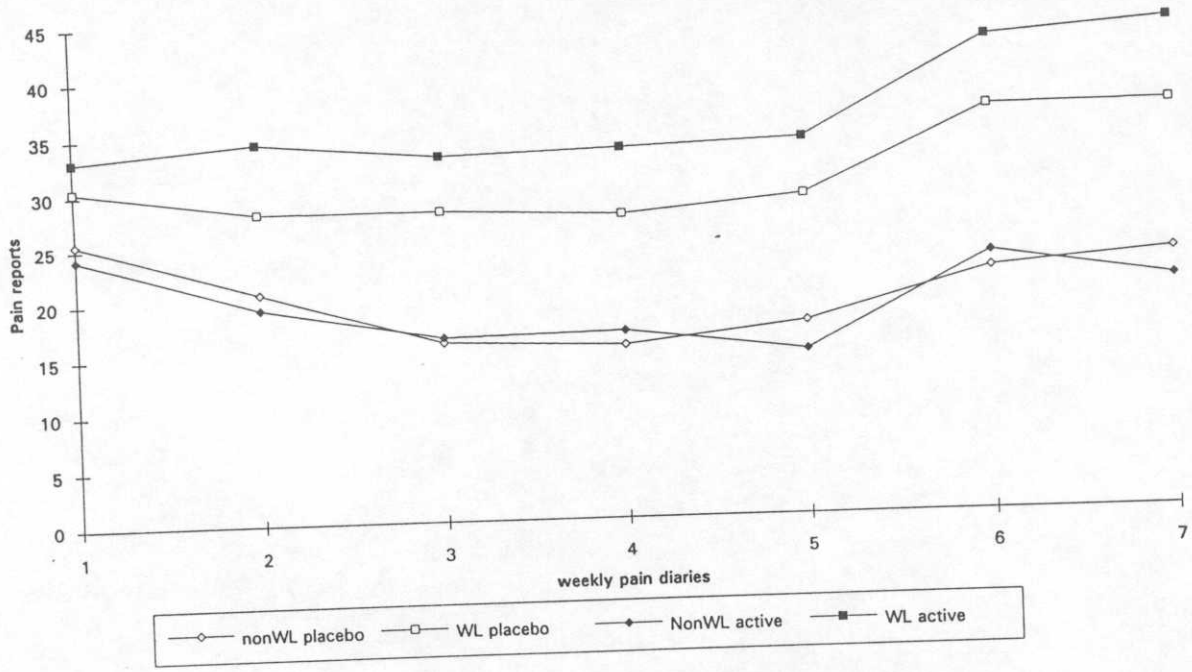

Fig. 2. Pain diary reports (sensory) comparing waiting list (WL) with non-WL patients in active and placebo groups.

mitigates against the likelihood that with greater subject numbers an active treatment effect would have emerged. In fact patients in the placebo group reported more benefit from treatment than those in the active treatment group, at a marginally significant level. It appears that the active PSW as administered in this study (with a circuplode at a dosage of 82 pulses per second at an intensity of 7) was not specifically beneficial for this patient population.

Patients who showed some response to treatment, that is patients who were not on the waiting list for surgery, improved while they had treatment (either active or placebo) by about 50% on average according to the pain level reported to the therapist. This provides strong evidence of the powerful placebo effect of this method of treatment. This has been previously demonstrated to be the case with ultrasound, in a series of studies on post-operative treatment of dental extraction (Hashish et al. 1986, 1988; Ho et al. 1988). These researchers concluded that the machine producing the ultrasound had a powerful placebo effect and that the therapist applying the treatment was also an important factor.

Although the levels of pain reports of patients in the waiting list and non-waiting groups (excluding the control group) were similar at the outset and also both groups showed slight improvement during treatment, there was a notable difference over the follow-up period. Three months after the first assessment, the patients who were on the waiting list had raised levels of pain reports whereas the non-waiting list patients had reverted to baseline levels. One interpretation is that the patients on a surgical waiting list differ fundamentally from patients who are not on a surgical waiting list and belong to a different population. However, since their pain reports at the outset were similar other interpretations of the different responses to treatment should also be considered. It is possible that patients who had been offered surgery did not find any credibility in the likely efficacy of PSW, since their joint was considered bad enough to require surgical replacement. Alternatively, a fear of being taken off the waiting list for surgery (or being put to the bottom of the list), if they continued to report less pain may have influenced the level of their pain reports. There is some evidence to suggest that expectations of pain relief to be gained from surgery may influence pain reports (Ignelzi et al. 1980). The present findings do not enable us to distinguish between these alternative interpretations.

The findings of this study can only be considered strictly relevant to PSW as applied in this study for pain relief in patients with OA hip or knee pain. Even with this group of patients it is possible that a different method of application, using different machine settings, would yield different results. Nevertheless, the method of application employed here was that which was found to be most effective in the pilot study where three popular applications were compared. It is also possible that if more acute conditions, such as early OA of the hip, the knee and other joints, were treated with PSW the effects might be found to be more positive.

In summary then:

- No evidence was found for a specific beneficial effect of PSW for patients with OA hip or knee pain.
- Patients who attended the hospital for PSW, that is both the active and placebo group tended to report less pain than patients who were in the no-treatment control group and did not attend hospital.
- Regardless of whether active or placebo PSW was administered, evidence was found of a significantly different pattern of pain response depending on whether or not patients were on a surgical waiting list. Those on the waiting list reported a worsening of symptoms by the time of the follow-up assessment unlike those who were not awaiting surgery.

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