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Original article

An evaluation of pulsed shortwave on knee osteoarthritis using radioleucoscintigraphy: a randomised, double blind, controlled trial

Michael J. Callaghan [a,*], Paula E. Whittaker [b], Stephen Grimes [c], Linda Smith [c]

[a] *Centre for Rehabilitation Science, Manchester Royal Infirmary, Oxford Road, Manchester M13 9WL, UK*
[b] *Department of Physiotherapy, Royal Liverpool University Hospital, Prescot Street, Liverpool L7 8XP, UK*
[c] *Department of Nuclear Medicine, Royal Liverpool University Hospital, Prescot Street, Liverpool L7 8XP, UK*

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Abstract

Objective. – To evaluate the effects of pulsed shortwave on osteoarthritis of the knee.

Methods. – A double blinded, randomised, controlled trial. Thirteen female and 14 male patients with radiographic evidence of knee osteoarthritis were randomly allocated to either low dose (10 W), or high dose (20 W) or placebo high frequency pulsed shortwave. Knee radioleucoscintigraphy was performed pre and post treatment as well as objective functional and subjective evaluations.

Results. – There were no significant differences between the groups in the pre and post treatment percentage change for radioleucoscintigraphy ($P > 0.05$). Functional and subjective measures also revealed no pre and post treatment differences between the groups ($P > 0.05$), except for improved knee range of motion in the placebo group ($P < 0.05$).

Conclusion. – Joint inflammation in knee osteoarthritis, measured using radioleucoscintigraphy, was not altered significantly by pulsed shortwave, therefore this therapeutic modality has little or no anti-inflammatory effect on conditions such as osteoarthritis of the knee.

Keywords: Radionuclide imaging; Shortwave therapy; Physiotherapy; Electrotherapy

1. Introduction

Osteoarthritis (OA) is a major health problem affecting over 60% of adults in the Western world over 65 years of age, with the knee being one of the most commonly affected joints, yet it receives scant resources for clinical research [1]. The use of pulsed shortwave therapy has increased significantly since 1980 and has gained popularity as a treatment modality [2]. The rationale for its use in OA is that the on–off effect of pulsing produces non-thermal effects that might promote tissue healing and relieve pain and inflammation (for a review see [3]). There have been only three controlled trials evaluating pulsed shortwave in the treatment of OA knee; these have produced contradictory results. In the first, Klaber-Moffet et al. [4] evaluated both hip and knee OA in 92 patients and found no differences in pain, general health and activities of daily living between the active and placebo treatment groups; measures of joint inflammation were not taken. In the second, Trock et al. [5] treated 86 patients with OA knee with active or placebo pulsed shortwave. Using measures of pain, pain on motion, joint tenderness and a non validated ADL score, they found statistically significant improvements *within* both the active and placebo groups in all measures at the end of treatment. However, *between* groups analyses revealed that the active group had borderline significant differences in three outcomes and no difference in pain on passive motion. This led them to conclude that active pulsed shortwave had therapeutic benefits in OA. Measures of joint inflammation were not used in this study either. In the third study, Sewell et al. [6] attempted the more technically advanced method of thermal imaging to assess knee joint swelling in 81 patients with sero-positive rheumatoid arthritis. They reported no differences between active and placebo treatments, but as their study was only published in abstract form, full analysis of the results was not possible.

One of the potential benefits of pulsed shortwave seems to be a decrease in joint inflammation, yet efforts to assess the

* Corresponding author. Tel./fax: +44-161-276-8078.
E-mail address: michael.callaghan@man.ac.uk (M.J. Callaghan).

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degree of inflammation in an arthritic joint are difficult and rely primarily on clinical estimations of swelling and warmth that are either subjective or prone to measurement error [7]. Methods are available in the field of nuclear medicine using ^{99}technetium hexamethylpropyleneamine oxime ($^{99}Tc^{m}$—HMPAO)—labelled white blood cells (WBC) to scan knee joints of patients with rheumatoid and osteoarthritis. This enables clinicians to have quantitative measurements of the inflammatory process and a sensitive index for monitoring disease activity, thus providing an objective assessment of joint inflammation and its response to treatment. Previous studies have described how this technique is extremely useful not only in assessing chronic knee pain in a variety of pathologies including OA [8], but in detecting even a low-grade inflammatory component in OA knee [9]. Furthermore, the technique can be used to assess anti-inflammatory therapy. The purpose of this study was to employ established radioleucoscintigraphy techniques to evaluate objectively the effect of pulsed shortwave on the inflammatory component of OA knees. To our knowledge this is the first study to use this technique to evaluate this form of electrotherapy.

2. Methods

The study design was approved by the Ethics Committee and the Administration of Radioactive Substances Advisory Committee (ARSAC) of the institution where the study took place. Fig. 1 outlines the study.

Thirty two patients with primary generalised OA and a diagnosis of OA knee consented to enter the study from the Department of Orthopaedic Surgery. Radiographs were used as a benchmark for diagnosis due to the problems of predicting OA by using clinical variables alone [10]. Radiographs were assessed by the same orthopaedic surgeon throughout the entire study who classified them into graded categories of OA according to Kellgren and Lawrence [11]. Exclusion criteria were grades 0 (none) and 1 (doubtful) and 2 (minimal) radiographic categories, a diagnosis of inflammatory joint disease (confirmed by blood tests), or an intraarticular corticosteroid injection in any joint 8 weeks prior to the first scan that may suppress the classic features of inflammation [12]. Those patients with grades 3 (moderate) and 4 (severe) were included in order to make radiographic classification easier and to enable pulsed shortwave to have as large a treatment effect as possible. Informed consent was obtained from each patient.

Patients were asked to maintain their normal activity level 1 week prior to the first scan and to remain on their normal medication for the duration of the study. All patients from the placebo group were offered active treatment at the end of the study.

2.1. Sample size calculations

Calculations were performed in order to ascertain the number of patients needed to see statistically significant differences between the three groups. As there were no previous published data for radioleucoscintigraphy, data were taken for the subsidiary analyses from a previous study on patients with OA knee [13]. Based on the pain outcome with a visual analog scale VAS, with an alpha level at 0.05 and 95% power, 10 patients would be needed in each group.

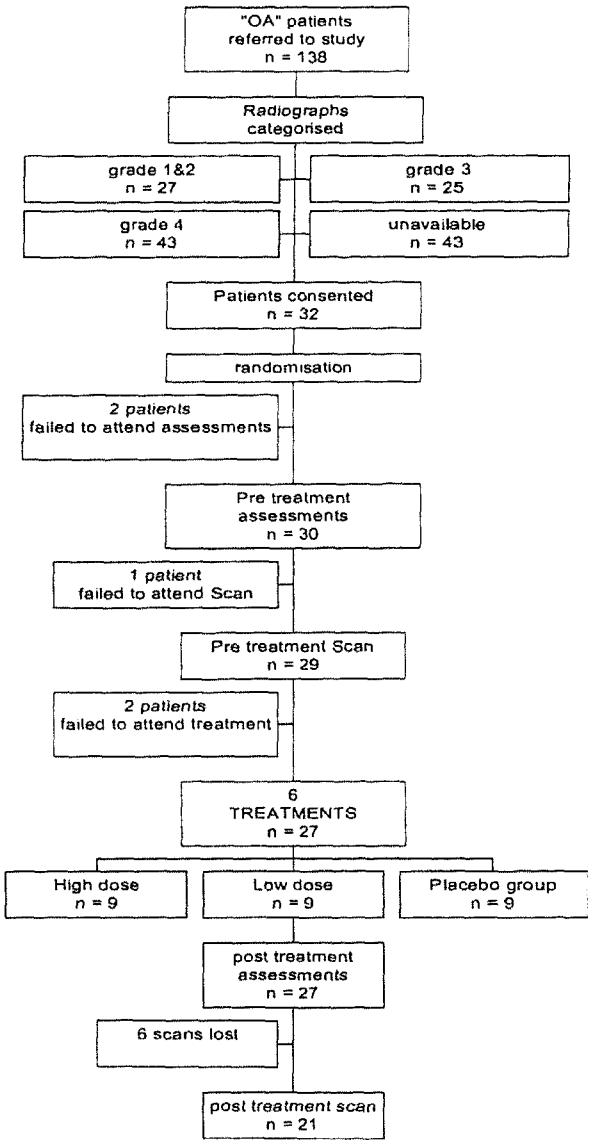

Fig. 1. CONSORT diagram.

2.2. Functional measurements

Before commencing the study each patient was assessed by an assessor (MJC) blinded to the treatment group allocation. Post treatment assessment was performed within 5 days of completing the study.

2.2.1. Range of motion

Knee joint range of motion (ROM) was measured by a universal goniometer aligned from the greater trochanter to the lateral malleolus through the lateral joint line.

2.2.2. Pain

Pain at the time of presentation for measurement was assessed using a 10 cm visual analogue scale, where 0 cm represented no pain and 10 cm represented the worst pain ever. Further subjective evaluation was measured by using the pain, mobility and physical activity subscales of the Arthritis Impact Measurement Scale (AIMS) [14].

2.2.3. Muscle strength

The quadriceps isokinetic concentric peak torque of the affected leg of each patient was assessed using the KinCom 500H isokinetic dynamometer (Chattanooga Inc.). This device has been tested for reliability for knee extension [15]. The positioning of the patient on the chair, use of restraining straps, joint alignment and gravity correction were carried out in accordance with the manufacturer's instructions and recommendations and recorded in order to replicate positioning for the post study assessment. Patients were instructed on the use of the dynamometer and were supervised while warming up at submaximal level until they were competent at the test. Once this was completed and after 2 min rest period, each patient performed three maximum voluntary isokinetic contractions from 90° flexion (or the fullest available flexion) to the fullest available extension at an angular velocity of 90°/s. The single peak torque was recorded.

2.2.4. Timed walk

In order to measure the level of disability the patients were asked to walk along a straight 13 m walkway. The time taken to complete the full 13 m was recorded [16].

2.3. Radioleucoscintigraphy

This was performed in the Department of Nuclear Medicine by assessors who were blinded to outcome measures and treatment group allocation. Each patient had his or her knees positioned at 25° flexion on a specially designed plastic mould. The patient's own WBC's were labelled using $^{99}Tc^{m}$ HMPAO prepared according to the manufacturer's instructions. The acquisition and processing protocol was similar to that validated in previous work performed in the department on OA knees [9].

With the subject in a fixed position, 20 min anterior and posterior static images of both knees were acquired using a GE 400AT gamma camera. The camera was set at a fixed radius and manually rotated round the subject for the anterior to the posterior projections. A similar set of images were obtained of a 100 ml plastic bottle, position centrally on the plastic mould, containing a known percentage of the injected patient dose as a standard. The first scan took place one day prior to the first pulsed shortwave treatment session at 4 h post injection. The second scan was performed using the same geometrical arrangement within 5 days of the final pulsed shortwave treatment. The two sets of patient data were analysed simultaneously. Regions of interests were drawn on both sets of the right and left anterior images and in a similar manner on both sets of posterior images. Regions of interests were also defined anterior and posterior on the standard images. The anterior and posterior counts were combined geometrically for each knee on each occasion and compared to the geometric mean standard count. With knowledge of the injected dose and the standard dose the uptake in each knee as a percentage of the injected dose was calculated. Background subtraction was not performed due to the difficulty in isolating a common area on each limb to act as a standard background. It was assumed that the background activity in the knee area was common on both occasions.

3. Treatments

After baseline measurements, patients were allocated by a stratified randomisation technique to three treatment groups by an independent assessor who was blinded to the outcome measures and the coding for the treatment group allocation. Treatment was applied each time by the same physiotherapist (PW) who remained blinded to the pre-test outcome measures. The active treatment was delivered by an EMS Megapulse unit (EMS Ltd., UK). The placebo machine was altered by the manufacturer to retain all features of a working device without any output to the patient.

Group A (n = 10) received active high frequency (27 MHz) pulsed shortwave for 20 min to the affected knee joint using a dose of 200 μs and 400 pulses per second with an output of 10 W.

Group B (n = 10) received active high frequency (27 MHz) pulsed shortwave for 20 min at a dose of 400 μs and 400 pulses per second, with an output of 20 W.

Group C (n = 10) received sham treatment for 20 min and acted as the placebo control group.

The active settings and treatment programme were recommended after personal communication with the manufacturers that also reflected clinical practice. After six treatment sessions, which took place over a period of 2 weeks, all patients were re-measured by the same independent, blinded assessor (MJC).

4. Statistical analysis

Data were analysed using SPSS (v9) for windows. To ascertain homogeneity between the three groups, in the first instance a Kruskal–Wallis analysis of the pre test data was performed. Although data were normally distributed (Kolmogorov–Smirnov test—$P > 0.05$) thus indicating parametric analysis, it was decided to use non parametric equivalents due to the calculation of percentage change between pre and

Table 1
Descriptive statistics of 27 patients who completed treatment. NSS between groups ($P > 0.05$)

Group	Gender (male/female)	Age (mean ± S.D.)	BMI (means ± S.D.)	Test side (left/right)	Current severity VAS for randomisation (mean)	X-ray category (moderate/severe)
Placebo	5/4	63.5 ± 7.9	27.2 ± 4.5	6/3	4.1	6/3
High dose	4/5	58.3 ± 7.3	26.8 ± 3.9	3/6	3.9	6/3
Low dose	5/4	59.5 ± 6.7	29.9 ± 4.3	5/4	3.6	9/0

VAS = visual analogue scale.

post assessments and also the smaller than expected sample sizes. Data are tabulated as both means (S.D.) and medians and inter-quartile ranges (IQR) and are graphically represented as medians (IQR).

4.1. Between groups analysis

A Kruskal–Wallis test was used to compare the percentage change between the three groups for the scan result and functional outcomes.

4.2. Within groups analysis

Wilcoxon signed ranked tests were used to find differences within the groups for pre and post test outcomes.

4.3. Correlations

To ascertain any correlations between the inflammation count, radiographic category and pain, a correlation matrix was constructed using Spearman's rho.

The hypothesis was that the primary outcome measure (radioleucoscintigraphy) and the secondary measures for function and subjective assessment would be favourably influenced by the treatment intervention of pulsed shortwave. The null hypothesis was that there was no change in any of the main or subsidiary outcome measures between the three groups. The significance level was set at $P < 0.05$.

5. Results

Twenty seven patients completed treatment and had full pre and post physiotherapy assessments However, scans for six patients were lost due to technical problems or scanning errors, leaving 21 patients with pre and post treatment scans (see Fig. 1). The three groups were balanced for age, sex and BMI ($P > 0.05$) (see Table 1).

Table 2 shows the means (S.D.) and the medians (IQR) for pre and post treatment results for all outcome measures. The Kruskal–Wallis signed ranks test revealed no significant between group differences except for improvement of knee ROM. Further analysis using a Mann–Whitney U-test established that this change was in the placebo group ($P < 0.05$).

A Wilcoxon signed ranks test revealed some within group changes with improvements of ROM in the placebo group ($P = 0.014$); for the walking test in the low dose group ($P = 0.02$) and for quadriceps muscle strength in the high dose group ($P = 0.042$).

A Spearmans' rho test revealed no significant correlations between the continuous data of pain and inflammation count ($P = 0.392$) and a Mann–Whitney U-test for the dichotomous data of radiograph category and inflammation count.

Fig. 2 shows the medians (IQR) of the percentage changes for the scan results. It indicates that high dose, low dose and placebo groups showed a slight increase in the inflammatory count, with the horizontal line at zero representing no change between pre and post assessments.

6. Discussion

This study was the first to assess the effect of pulsed shortwave on the inflammatory component of OA knee using sophisticated radionuclide methods. It may improve the unacceptably small knowledge base noted by researchers in the treatment of OA [17] and on pulsed electromagnetic energy therapy [3].

Radioleucoscintigraphy is considered a complex and protracted process, but it is able to detect and quantify inflam-

Table 2
Means ± S.D. (in normal type) and medians with IQR (*in italics*) for pre (1) and post (2) treatment results

	ROM1 (degrees)	ROM2 (degrees)	PTorque1 (Nm)	PTorque2 (Nm)	Walk1 (s)	Walk2 (s)	AIMS1	AIMS2	SCAN1 (MBq)	SCAN2 (MBq)	Pain 1 VAS	Pain 2 VAS
Placebo	92.2 ± 27.5	102.2 ± 24.6	51.4 ± 38.2	49.4 ± 27.5	14.7 ± 3.7	13.9 ± 3.6	5.3 ± 1.4	5.1 ± 1.7	0.147 ± 0.051	0.164 ± 0.068	5.8 ± 1.7	6.3 ± 1.9
	90 (72–115)	*110 (85–122)*	*39 (20–92)*	*45 (23–72)*	*14 (12–16)*	*13 (11–16)*	*5 (4–6.6)*	*4.5 (4–6.4)*	*0.132 (0.11–0.19)*	*0.149 (0.11–0.19)*	*5 (5–6)*	*5 (5–8)*
Low dose	98 ± 25.4	89.0 ± 38.8	59.1 ± 38.9	61.3 ± 38.6	19.1 ± 14.3	14.7 ± 6.8	5.2 ± 2.8	5.5 ± 3	0.176 ± 0.091	0.147 ± 0.045	5.2 ± 3.3	5 ± 3.2
	88 (84–126)	*98 (50–130)*	*43 (33–94)*	*54 (32–86)*	*15 (9–26)*	*12 (9–20)*	*5.5 (2–8)*	*5.5 (2–8)*	*0.137 (0.14–0.28)*	*0.140 (0.12–0.16)*	*5 (2–8)*	*5 (1–8)*
High dose	112.5 ± 12.2	110 ± 14.9	53.7 ± 38.9	65.9 ± 37.5	14.1 ± 4.3	13.3 ± 2.8	5.1 ± 2.1	5.1 ± 2.3	0.177 ± 0.095	0.186 ± 0.122	6.5 ± 2.1	5.5 ± 2.7
	110 (105–120)	*113 (98–124)*	*54 (25–74)*	*68 (32.3–93)*	*13 (11–18)*	*13 (11–16)*	*4.8 (4–7)*	*5 (3–6)*	*0.144 (0.11–0.22)*	*0.160 (0.13–0.18)*	*6 (5–9)*	*5 (4–8)*

ROM, range of motion. Ptorque, peak torque. AIMS, Arthritis Impact Measurement Scale. MBq, megabequals.

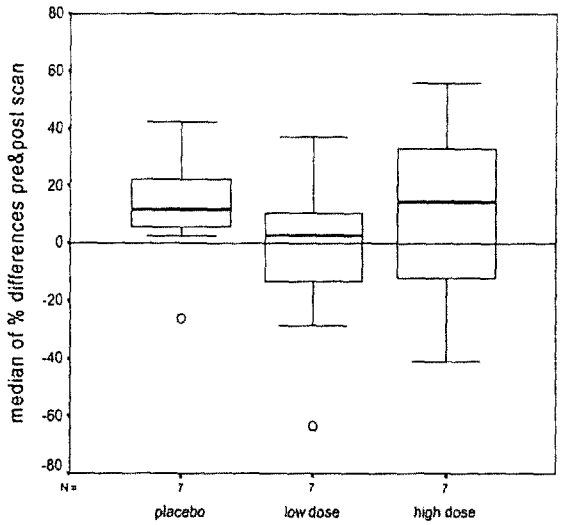

Fig. 2. Median (IQR) of the percentage differences pre and post radioleucoscintigraphy scan O = outliers. Horizontal line at zero = no change between pre and post assessments.

matory processes in joints and measure the effects of anti-inflammatory therapy [9]. Its use in this study has not only produced objective pre and post test measures, but has also provided insights into the inflammatory component in OA of the knee that are worth noting. For example, colleagues in nuclear medicine commented on the minimal inflammation counts in virtually all patients despite their level of symptomology, or their radiological status. A typical example of this is in Fig. 3 that shows minimal inflammatory count in both knees and no change between pre and post treatment. Formal analysis revealed poor correlations between the radiographic

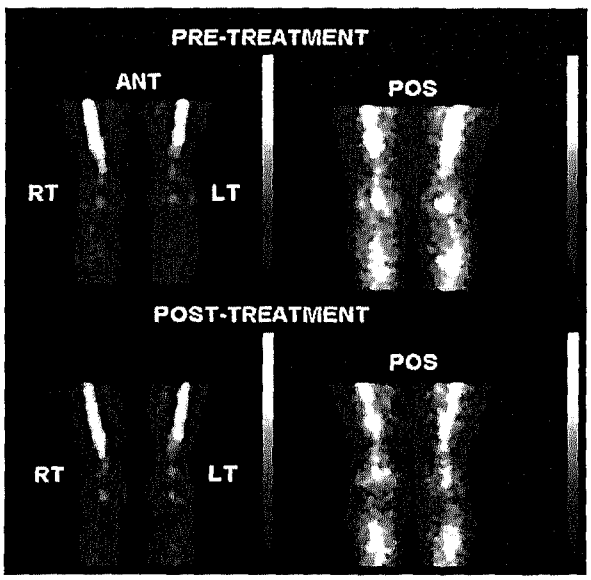

Fig. 3. Scan of a patient in the study with minimal inflammation and pre and post treatment counts. ANT, anterior view; POS, posterior view; RT, right knee; LT, left knee.

category, the inflammation counts and the patient's pain, thus concurring with earlier work by Al-Janabi et al. [9] who also found similarly poor correlations between WBC uptake and VAS scores in OA patients and offered several reasons for this. This illustrates the difficulty in the clinical environment of assessing the degree of arthritis and inflammation by asking patients their VAS score. For example, two patients had exactly the same low inflammatory cell count (1.4 MBq), but whereas one patient had a radiographic category of 'moderate' and a VAS of 2, the other was in the 'severe' category and had a VAS of 10. Several explanations for this may be, firstly, that patients' pain perceptions and thresholds are variable and a VAS is a relatively crude measure of this [9]. Secondly, that the inflammatory component of primary OA is quite small and that alterations in knee joint biomechanics causing stress on the joint capsule could have contributed to the symptomology rather than the inflammation per se. Thirdly, all patients had been diagnosed with OA for several years and their OA was chronic in nature possibly with a low inflammatory component. The implication is that the scan of a patient with a much more recent diagnosis may have had a higher inflammatory count resulting from a more obvious inflammatory component.

Our study concurs with previous randomised controlled trials that showed a lack of statistically significant differences between active and placebo pulsed shortwave in knee OA [4,6]. Furthermore, we employed high and low dose pulsed shortwave to counter any argument that the inflammation may be treated more effectively by high or low energy regimes. Once again the lack of statistical differences between the two active groups indicated that neither was effective for treating OA of the knee. However, our study disagrees with the other randomised controlled trial [5] whose patients receiving active treatment reached borderline significance in three of the four outcomes over a placebo group. The reasons why this study contradicted other studies with robust methodology similar to ours have been subject to recent debate [18].

6.1. Limitations

The authors concede that this study may be subject to a type II statistical error, i.e. incorrectly retaining the null hypothesis. Based on functional outcomes, the power of the study was calculated at 95% with an alpha level of 0.05 and a sample size of 10 in each group. Sample size calculations could not be performed for our primary outcome measure as there was no previous data available. A slower than predicted throughput of patients who fulfilled the inclusion and exclusion criteria and a sudden retraction of funding by one of the sources prevented the target sample size being completed. Nevertheless, we believe that the randomised, double blinded, controlled methodology together with its unique outcome measure of radioleucoscintigraphy still makes this a robust study that can contribute to the relatively small amount of literature on the efficacy of electrotherapy treatment of OA knee.

7. Conclusion

This study is the first to use radioleucoscintigraphy to assess the effects of pulsed shortwave on joint inflammation in OA. It has revealed that patients with OA knee have surprisingly little evidence of inflammation. Even so, this was not altered significantly by pulsed shortwave. It is concluded that this method of treatment has little or no anti-inflammatory effect on this condition.

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