

Original Research Article

Oral Diclofenac Sodium, Quadriceps Strengthening Exercises and Infrared Radiation Therapy in the Treatment of Osteoarthritis of the Knee in a South-Eastern Nigerian Population

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ABSTRACT

Background: Non-steroidal anti-inflammatory drugs (NSAIDs) and quadriceps strengthening exercises (QSE) with infrared radiation therapy (IRT) are usually used in the treatment of knee osteoarthritis (KOA). Hardly is there any scientific study comparing the efficacy of these modalities of treatment.

Purpose: The present study was designed to compare the efficacy of Non-steroidal anti-inflammatory drugs (NSAIDs) and quadriceps strengthening exercises (QSE) with infrared radiation therapy (IRT) in the treatment of patients with symptomatic KOA in a Nigerian population.

Materials and Methods: This was a randomized control trial involving 70 individuals (31.43% males; mean age=53.07±6.01 years) with symptomatic KOA consecutively recruited from physiotherapy clinic in a tertiary hospital in Nigeria. The participants were randomly allocated into two groups: ODS group and QSE with IRT group. Participants' quadriceps strength, walking time and knee pain intensity were estimated using Oxford Grading Scale, stop watch and Box Numerical Pain Scale respectively. Participants in the ODS group received a tablet of 50mg of ODS twice daily while participants in the second group received QSE with IRT three times a week for a total duration of seven weeks.

Results: There were significant improvement in pain intensity and walking time in both groups ($p < 0.05$). Quadriceps strength significantly improved only in the QSE with IRT group ($t = -12.30$; $p < 0.001$). However, the improvement in pain intensity, walking time and quadriceps strength were all significantly more in the QSE with IRT group than in the ODS group ($p < 0.05$).

Conclusion: In as much as both oral diclofenac and QSE with IRT can improve pain intensity and walking time among patients with symptomatic, the latter is more efficacious than the former.

Keywords: Diclofenac sodium, quadriceps strengthening exercises, infrared radiation therapy, Osteoarthritis of the knee, pain

INTRODUCTION

Osteoarthritis (OA) is the commonest rheumatic disease that primarily affects the articular cartilage and subchondral bone of a synovial joint, finally leading to joint failure. [1] Knee osteoarthritis (KOA) is the commonest degenerative joint disease amongst elderly men and women in most populations and one of the leading causes of pain and long term disability. [2] It is the disease that is most responsible for disability in walking, stair climbing and housekeeping. [3] It is characterized by knee pain, knee stiffness (noticed particularly in the morning or after prolonged inactivity), loss of mobility and difficulty in daily functional activities. [1, 4] Joint pain may originate not only from synovitis, but also from stretching of the joint capsule and ligaments, periosteal irritation due to osteophyte formation, interosseous hypertension and muscle spasm. [5] The pain may be aggravated by weather changes and increased activity. [4] In more advanced stages of the disease, the pain becomes constant. As joint degeneration progresses, patients may notice weakness of the quadriceps muscles, reduced ambulation speed, locking, catching and grinding sensations in the joint. [6,7] Major joint trauma, repetitive stress, joint overload, obesity, congenital defects, genetic factors, prior inflammatory joint disease, female gender and race are risk factors for KOA and all are important in its pathogenesis. [8]

Diclofenac sodium is a non steroidal anti-inflammatory drug (NSAID) which has pronounced antirheumatic, anti-inflammatory, analgesic and antipyretic properties used therapeutically in the treatment of KOA. [9] Prevention of the synthesis of prostaglandins at both the peripheral and central levels by inhibiting Cyclooxygenase 1 and 2 (COX-1 and COX-2) enzymes non-selectively is important for its mechanism of action. [10] Prostaglandins play an essential role in the development of inflammation, pain and fever; and administration of diclofenac sodium

decreases inflammation, pain and stiffness while improving function. [11] Despite these beneficial effects, oral diclofenac sodium administration can cause some adverse effects such as gastritis, haematemesis, gastro-intestinal tract (GIT) ulcers and bleeding, destabilization of blood pressure, impairment of renal function and increased risk of cardiovascular adverse events [12-14] Vitamin B complex is a group of substances which are essential for the activation of enzymes in the body. Although not chemically related, are generally found together in the same foods. These substances have not been documented in the literature to alleviate the symptoms of KOA.

Many researchers have reported that quadriceps strengthening exercises [15-17] with infrared radiation therapy [18,19] are beneficial in the management of KOA. These benefits include; improved knee range of motion, improved knee function, reduced joint pain and reduced joint stiffness. There are also reported studies on the use of oral NSAIDS and physical therapy in the management of KOA [20-22] but the researchers could not find scientific studies comparing the efficacy of oral diclofenac sodium and quadriceps strengthening exercises with infrared radiation therapy in the treatment of patients with symptomatic KOA in the literature. The purpose of this study was to compare the efficacy of oral diclofenac sodium and quadriceps strengthening exercises with infrared radiation therapy in the treatment of patients with symptomatic KOA at Nnewi, south eastern Nigeria using reduction in knee joint pain intensity, increase in quadriceps muscle strength and reduction in walk-time as outcome measures.

MATERIALS AND METHODS

Sample population and Study design

The research population comprised subjects diagnosed of KOA according to the criteria established by the American College of Rheumatology (ACR Classification). [23] Ethical approval was obtained from the Ethical Committee of Nnamdi Azikiwe

University Teaching Hospital, Nnewi, and all patients gave written informed consent for participation after the purpose and procedure of the study had been clearly explained to them. The participants were recruited from the outpatient Orthopaedic clinic of the Nnamdi Azikiwe University Teaching Hospital at Nnewi using the consecutive sampling technique. The calculated estimated sample size was approximately 266 participants [24] using a prevalence of 19.6% for KOA in Nigeria [25] but the researchers were able to recruit seventy participants who met the inclusion criteria for the study. The participants were randomly allocated into two groups; oral diclofenac sodium group (32 participants) and quadriceps strengthening with infrared radiation therapy group (38 participants).

Tablets of diclofenac sodium each containing 50mg of active substance (manufactured by Merckle GmbH, Blaubeuren-Weiler, Germany for Mepha LLC, Aesch-Basel, Switzerland) were used for oral diclofenac sodium treatment while tablets of vitamin B complex (Manufactured by Emzor Pharmaceutical Industries Isolo-Lagos, Nigeria) each containing 1mg of vitamin B1, 1mg of vitamin B2 and 15mg of Nicotinamide were used as the oral placebo drug. A stadiometer (SECA model) was used to measure the weights (in kilograms) and heights (in metres) of the participants while Infrared Lamp (Infraphil, Philips model, 150watts) was used for infrared radiation therapy. Stop watch (Nokia model, 8850) and an inelastic measuring tape (Bouncing Rabbit, made in China) were used to record the 30.4metres walk time in seconds and the 30.4metres walk distance in metres respectively. The quadriceps muscle strength of the affected lower limbs was obtained using the Oxford grading scale [26] and sand bags of different weights were used to increase resistance during quadriceps strengthening exercises. Knee joint pain intensity score was determined using the Box Numerical Pain Scale (BNPS) of 1-10. [27] The sex, age, occupation, duration of knee pain, family history, social

history and x-ray reports of the affected knee(s) of the participants were documented. Baseline knee joint pain intensity score, quadriceps muscle strength and 30.4m walk-time were recorded at beginning of study for each participant.

Each participant in the diclofenac sodium group received one tablet containing 50mg of diclofenac Sodium and one tablet of vitamin B complex twice daily (morning and evening), taken before a meal without chewing with a glass of water for seven consecutive weeks. The participants in the quadriceps strengthening with infra-red radiation therapy group received one tablet of vitamin B complex twice daily taken before a meal without chewing with a glass of water and in addition performed supervised Quadriceps muscle strengthening exercises (isometric and isotonic) three times a week and also received Infrared radiation therapy for 15 minutes during each exercise session for seven consecutive weeks. [28] The participants in the diclofenac sodium group did not perform supervised quadriceps strengthening exercises and did not also receive infrared radiation therapy. During the study period, all the participants were not allowed to have additional therapies such as topical NSAIDS, intra-articular injections or any other analgesic. All the 70 participants who were recruited completed the study and were all included in the analysis. None was lost to follow-up or discontinued the intervention. There was no incidence of adverse drug reaction. The study lasted for a period of one year. The knee joint pain intensity score, quadriceps muscle strength and 30.4m walk-time were measured and recorded at the end of seven weeks of intervention for each participant.

Inclusion and exclusion criteria

The subjects who were recruited were those who fulfilled the criteria established by the American College of Rheumatology (ACR), living in Nnewi and had at least grade 2 tibio-femoral KOA on the Kellgren /Lawrence grading system (K/L 2-4) [29] Participants who had any form

of inflammatory arthropathy, recent injury in the knee, history of peptic ulcer, congestive heart disease, pregnant or lactating were excluded from the study.

Statistical analysis

The Statistical Package for Social Sciences version 20 (SPSS 20) software was used for the data entry and analysis. Descriptive statistics of mean and standard deviation were calculated for measurements taken. Paired t-test was used to compare baseline and end of study test score changes for each parameter (knee joint pain intensity score, quadriceps muscle strength and 30.4m walk-time) in each treatment group. Analysis of covariance was used to test for significant differences in knee joint pain

intensity score, quadriceps muscle strength and 30.4m walk-time between the two groups at the end of the experiment. Alpha level for all statistics employed was set at $p < 0.05$.

RESULTS

Seventy participants (31.43% males) with age range and mean age of 45-69 years and 53.07 ± 6.01 years respectively participated in the present study. The mean weight, height, body mass index (BMI) and duration of KOA among the participants were 86.89 ± 7.41 kg, 1.73 ± 0.03 m, 29.11 ± 2.34 Kg/m² and 2.91 ± 1.21 years respectively. The participants' weight and BMI, unlike their disease duration, age and height significantly differed between the groups ($p < 0.05$) (table 1).

Table 1: Baseline characteristics of the participants

Characteristics	Treatment Groups			f- value	p- value
	Diclofenac sodium	Quadriceps strengthening With infra-red radiation	General		
Number of participants	32	38	70		
Male/Female	10/22	12/26	22/48		
Mean duration of condition (years)	3.03 ± 1.28	2.82 ± 1.16	2.91 ± 1.21	-.738	.463
Mean age (years)	53.22 ± 5.87	52.95 ± 6.20	53.07 ± 6.01	-.187	0.852
Mean height (m)	1.73 ± 0.03	1.72 ± 0.04	1.73 ± 0.03	-1.520	.133
Mean weight (Kg)	83.69 ± 7.96	89.58 ± 5.75	86.89 ± 7.41	3.488	0.001*
Mean BMI (Kg/m ²)	27.79 ± 2.18	30.21 ± 1.87	29.10 ± 2.34	5.009	0.000*

*significant at $p < 0.05$.

There was significant reduction in the knee joint pain intensity score at the end of seven weeks of intervention in both diclofenac ($t=3.75$; $p=0.001$) and quadriceps strengthening and infra-red ($t=6.73$; $p=0.045$) groups. At the end of seven weeks, there was significant increase in quadriceps strength in the quadriceps strengthening and infra-red group ($t=-12.30$; $p < 0.001$) but not in the diclofenac group ($t=-1.982$; $p=0.056$). After the intervention, there was significant reduction in working time in both groups ($p < 0.05$) (table 2).

Table 2: Paired t-test showing the effects of oral diclofenac sodium and quadriceps strengthening exercises with infrared radiation therapy on pain intensity, quadriceps strength and walking time of the participants

Treatment group	Baseline	Post-intervention	t-value	p-value
Pain intensity score				
Diclofenac sodium	7.03 ± 1.43	5.59 ± 2.34	3.749	0.001*
Quadriceps strengthening with infra-red radiation	7.74 ± 1.46	4.84 ± 2.64	6.73	0.045*
Quadriceps strength				
Diclofenac sodium	3.41 ± 0.50	3.59 ± 0.50	-1.982	0.056
Quadriceps strengthening with infra-red radiation	3.13 ± 0.34	3.95 ± 0.23	-12.30	0.000*
Walking time				
Diclofenac sodium	42.02 ± 7.52	37.76 ± 5.56	2.70	0.011*
Quadriceps strengthening with infra-red radiation	41.92 ± 6.22	37.00 ± 5.64	5.47	0.000*

*significant at $p < 0.05$.

After controlling for baseline measurements and BMI, participants in the quadriceps strengthening with infra-red

group had significantly higher quadriceps strength ($F=8.81$; $p < 0.01$) and lower pain intensity ($F=3.42$; $p=0.02$) and walking time

($F=4.29$; $p=0.01$) values than the diclofenac group (table 3).

Table 3: Analysis of covariance showing the comparative effect of diclofenac and quadriceps strengthening with infra-red radiation on pain intensity, quadriceps strength and walking time of the participants

Variable	Group means		F	p
	Diclofenac	Quadriceps		
Pain intensity	5.59±2.34	4.84±2.64	3.42	0.02*
Quadriceps strength	3.59±0.50	3.95±0.23	8.81	<0.01*
Walking time	37.79±5.44	37.00±5.64	4.29	0.01*

*significant at $p<0.05$.

DISCUSSION

The results of the study showed that oral diclofenac sodium and quadriceps strengthening exercises with infrared radiation therapy significantly reduced knee joint pain intensity. The pain relieving effect of diclofenac sodium has long been documented in the literature making it one of the most commonly used drugs for treating symptomatic KOA. [30] Infrared radiation therapy has also been reported by many researchers to relieve pain in symptomatic KOA [18,19,28] consistent with the findings in this study. Quadriceps strengthening exercises also contributed to pain reduction in the quadriceps strengthening with infrared radiation group consistent with the findings of Roddy et al, [15] Bennell et al [16] and Imoto et al [17] who reported that quadriceps weakness was common in patients with KOA and correlated with pain and that quadriceps strengthening exercises were effective in improving pain, function and quality of life in these patients. Quadriceps strengthening exercises and infrared radiation therapy had also been reported to increase tissue metabolism and blood flow, cause muscle relaxation and improve stability around the knee joint. These beneficial effects may also contribute significantly to the reduction of pain in this group. However, participants in the oral diclofenac sodium group showed lesser reduction in pain when compared with participants in the quadriceps strengthening with infrared radiation therapy group.

Participants in the quadriceps strengthening with infra-red radiation

therapy group demonstrated a significant increase in quadriceps muscle strength when compared with the subjects in the oral diclofenac sodium group which did not show any significant increase in quadriceps muscle strength. The stability and functional capacity of the knee joints are largely dependent on the quadriceps muscle strength. [31] Thus the quadriceps muscles of participants in the quadriceps strengthening with infra-red radiation therapy group increased in strength after a regimen of strengthening exercises. This is consistent with the findings of Roddy et al., [15] and Bennell et al. [16,32] who reported that judicious quadriceps strengthening exercises to an osteoarthritic knee improved the quadriceps muscle strength contributing in alleviating clinical symptoms. Participants in the diclofenac sodium group did not demonstrate significant increase in quadriceps muscle strength probably because diclofenac sodium had no significant effect in improving quadriceps muscle strength.

There was significant reduction in the 30.4m walk-time in both the oral diclofenac sodium and the quadriceps strengthening with infra-red radiation therapy groups. However the results also revealed that the participants in the quadriceps strengthening with infra-red radiation therapy group showed superior reduction in walk-time when compared with the participants in the oral diclofenac group. This may be because of the combined effect of reduction in knee joint pain intensity and significantly increased muscle strength which improved function and performance of the affected joints. This is also consistent with previous studies by Shekelle et al [33] and Stiskal et al [34] who reported that exercises improved functional capacities of patients being managed for KOA. Quadriceps strengthening exercises increase dynamic stability as reported by Hicks et al [35] further enhancing joint function. The reduction in walk-time in the oral diclofenac group may be attributed to the reduction in pain and is consistent with findings in

previous studies by Walker-Bone et al, [36] and Moore et al. [37]

CONCLUSION

In this study quadriceps strengthening exercises with infrared radiation therapy was superior to oral diclofenac sodium in improving knee joint pain, quadriceps muscle strength and walk-time in patients with symptomatic KOA.. Oral diclofenac sodium and quadriceps strengthening exercises with infra-red therapy are efficacious in the management of symptomatic KOA as shown by the results of the study hence both modalities of treatment can be used independently. This is of particular importance in patients with co-morbid conditions which contraindicate oral diclofenac sodium or in patients who may be at risk of the side effects of diclofenac sodium treatment. In this group of patients, the researchers recommend quadriceps strengthening exercises with infra-red radiation therapy.

Author's Contributions

This work was carried out in collaboration between all the authors. Chima Collins Ihegihu and Ebere Yvonne Ihegihu designed the study, wrote the protocol and the first draft of the manuscript. Emmanuel Chiebuka Okoye and Ifeoma Adaigwe Okeke performed the statistical analysis and the literature searches. All the authors were involved in data collection and interpretation of data. All authors read and approved the final manuscript.

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