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Diclofenac Sodium Iontophoresis Enhances Quality of Sleep in People with Knee Osteoarthritis

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Research Article

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Abstract

Background and Objectives: Osteoarthritis (OA) is a common cause of physical and psychosocial disabilities in people characterised by pain and joint dysfunctions which hinder their daily and social activities as well as quality of sleep. Iontophoresis, involving the transference of drugs transdermally, is one of the novel therapeutic modalities for managing OA .The objective of this study was to determine the effect of diclofenac sodium iontophoresis on quality of sleep in people with knee osteoarthritis.

Method: Twenty (20) participants (5 males, 15 females; mean age 55 years) with knee OA were recruited for this study. The participants were randomly assigned into two groups. Group A was treated with diclofenac sodium iontophoresis in addition to exercises. Group B, the control group, received only exercises. Each group was treated for duration of 4 weeks, comprising 2 treatment sessions per week. The Medical Outcome Study (MOS) Sleep Scale was used to assess quality of sleep, respectively.

Result: Significant improvement occurred in both groups post-treatment (experimental group p= 0.004 respectively. Control group: p= 0.001). However, ION group had more improvement (p= 0.02) in quality of sleep when compared to CTRL group.

Conclusion: This study revealed that there is a significant improvement in quality of sleep in people with osteoarthritis when treated with diclofenac sodium iontophoresis.

Keywords: Knee Osteoarthritis; Iontophoresis; Diclofenac Sodium; Quality of Sleep

Abbreviations: OA: Osteoarthritis; MOS: Medical Outcome Study; FITT: frequency intensity time and type; MOS: Medical Outcome System; SPSS: Statistical Package for Social Sciences; BMI: body mass index; SMN: sleep scores for somnolence; SLA: sleep adequacy; SN: snoring; SLD: sleep disturbance; ASBH: awaken by shortness of breath and headache.

Introduction

Knee osteoarthritis (OA) is an inflammatory and degenerative disease of the knee joint characterised by destruction of the articular cartilage and formation of new bone at joint surfaces and margins [1,2]. As a most common form of OA, It has been reported to negatively impact various aspects of the life of a person [2,3]. Clinical signs and symptoms associated with knee OA include pain, crepitation, articular stiffness, joint deformities, reduced range of motion, muscle weakness, and limitations in activities of daily living [4,5]. Knee OA is also the common cause of physical and psychosocial disabilities in patients due to the pain and joint dysfunctions which hinder their daily and social activities as well as quality of sleep [6,7]. The multifaceted, hyperalgesic nature of OA creates potentially debilitating physical and psychological burdens, making individuals particularly susceptible to comorbid disorders that may exacerbate OA-associated symptoms. Sleep disturbance is one such comorbidity. Among persons with knee OA, up to 31% report significant disturbances initiating sleep, 81% have difficulties maintaining night-time sleep, and up to 77% report any sleep problem [8-10].

Physiotherapy plays a major role in the management of people with knee OA, and one of the novel therapeutic interventions used is transdermal drug delivery or iontophoresis. Although iontophoresis with various drugs has been seen to be effective in the reduction of pain in knee osteoarthritis, its efficacy has not been investigated on quality of sleep. The purpose of this study therefore was to examine the effect of diclofenac sodium iontophoresis on quality of sleep in people with knee osteoarthritis.

Materials and Methods

Subject Selection

Twenty (20) participants comprising 5males and 15 females whose ages ranged between 51 and 60 years with a mean age of 55 years were recruited for the study. They had previously been diagnosed of knee OA and referred by an orthopaedic surgeon and rheumatologist for physiotherapy. People with knee OA excluded from the study were individuals that had neurological conditions, cognitive impairments, knee arthroplasty, and fracture of any of the lower limb bones in the last 6 months. Other people with knee OA who had a history of allergies to topical application of sodium diclofenac or recently had dermatological problems, or had open wounds around the knee region were also excluded.

Prior to the intervention, each participant underwent subjective and objective assessments. Subjective assessment included obtaining detailed history relating to: age, sex, address, onset and duration of knee pain, social and family information, past medical and medication history. Objective assessment involved physical examinations of weight, height, pain, range of motion, muscle power, muscle bulk, quality and duration of sleep by using the various outcome measures as displayed on Table 1.

	ION GRP	CTRL GRP	t-value	U-value	p-value
	X+S	X+S			
AGE(years)	59.22 ± 9.03	52.44 ± 9.70	0.87		0.43
VAS	6.11 ±1.37	6.22 ± 1.39		0.86	0.47
BMI (kg/m²)	31.19 ± 5.06	30.66 ± 5.36	0.89		0.44
SLPB	34.80 ± 13.03	15.98 ± 13.75	0.07		0.01*
SLD	20.86 ±18.78	18.75 ± 18.72	0.99		0.49
SMN	18.52 ± 10.94	42.67 ± 11.60	0.03		2.11
SLA	71.11 ± 16.15	78.89 ± 23.68	0.46		0.15
SN	17.78 ± 33.83	26.67 ± 34.68	0.95		0.47
ASBH	11.11 ± 19.43	26.67 ± 17.63	0.26		0.03*

Table 1: Baseline characteristics of the participants.
*: significant at p< 0.05.
Keys: ION: Iontophoresis group; CTRL: Control group; SD: Standard Deviation; SLPB: Sleep problem; SLD: Sleep disturbance; SMN: Somnolence; SLA: sleep adequacy; SN: Snoring; VAS: Visual Analogue Scale; ASBH: Awaken by shortness of breath or headache.

Ethical Approval

Approval was obtained from the Health Research and Ethics Committee of Lagos University Teaching Hospital (LUTH) Idi-Araba, Lagos, Nigeria and Health Research and Ethics Committee of National Orthopaedic Hospital, Igbobi, Lagos, Nigeria. Informed consent was also obtained from each participant.

Instrumentation

The following instruments were used to carry out the research in order to obtain a credible outcome from the study.

Direct Current Machine: This is a white cased direct current machine made by F.W. Read and Sons, England and was used for iontophoresis.

Diclofenac Sodium: It is a non-steroidal anti-inflammatory drug taken or applied to reduce inflammation and pain. It was made to form a solution of 5% diclofenac sodium which was passed via the electrodes into the skin.

Metallic Electrodes: These are 2 pairs of square-shaped aluminium electrodes which were used to pass the diclofenac sodium solution into the skin.

A Firm Plinth: This is a treatment couch upon which the participants laid to receive treatment. It was 76.5cm high, 181.5cm long and 59cm wide.

Skin Sensation Test Pick: This is a short, pointed piece of wood. It was used to carry out skin sensation tests for each participant.

Simple Goniometer: This is a calibrated device reading up to 360 degrees having both stationary and movable arms mounted on a fulcrum. It was used to measure the knee joint range of motion pre- and post- intervention.

Stopwatch: It was a digital stopwatch calibrated in seconds and manufactured in Beijing China by Casio Ltd. This was used to measure treatment durations.

Measuring Cylinder: This is a tapering cylindrical glassware. It was calibrated in ml and was used in preparing 2% of diclofenac sodium.

Non-Absorbent Weighing Paper: This is a practical weighing paper. It was used to conserve 1gram of diclofenac sodium after measurement prior to its use.

Tape Measure: This is an inelastic fabric which is calibrated to measure linear displacement in centimeters (0-150) and inches (0-60). It was used to measure the thigh muscle bulk of participants. It was manufactured by Ashprint Ltd, London, United Kingdom.

Bicycle Ergometer: This is a stationary bicycle with accessories for regulating or adjusting workload when a person exercises on it.

Research Procedure

The research was an experimental research with the randomized controlled trial design. Participants were randomly assigned into two groups using flip of paper drawn from a bowl.

In the ION group which was the experimental group, participants were treated with diclofenac sodium iontophoresis in addition to conventional physiotherapy treatment (free active exercises and home programme in the right prescriptions using the frequency, intensity, time and type (FITT) principle). In CRTL group, participants only received conventional physiotherapy treatment (free-active exercises and home programme in the right prescriptions using the FITT principle).

The participants were instructed to come to the clinic after being fully rested without consuming caffeine or food containing caffeine 4 hours preceding intervention so as not to alter their response to the intervention. They were also instructed not to engage in any strenuous physical activity within 24 hours preceding intervention so as not to alter their metabolic response and interaction with the intervention drug. The intervention went for 4 weeks during which 2 treatment sessions per week were administered.

Dangers and risks, including electrolytic burns, were non-existent during the research due to the engagement of proper safety procedures.

Participant Preparation: The aims and objectives of the study, as contained in the informed consent form, were carefully explained to all the participants including the details of the research procedures. Participants were given adequate information as to how the procedures would be carried out.

Demographic Data: Demographic data such as gender, height, weight, religion and occupation were obtained.

Intervention Procedure: The participants went through a series of treatment regimen depending on the group. ION group and CTRL group received different intervention protocols as follows:

Ion Group: participants were positioned supine on a plinth with the knee supported on a pillow at approximately 15° from full knee extension. The participants' skins were cleaned with methylated spirit prior commencement of the iontophoresis. The procedure was explained to the participants together with the anticipated response.

Diclofenac Sodium Iontophoreis: Two pairs of aluminium electrodes 4cm by 3cm placed on 4 lint pads each consisting of 8 folds (each 6cm by 5cm) was plugged into the direct current machine. The lint pads were initially soaked in warm water in order to improve electrical conductivity and then placed over the knee joints. The diclofenac sodium drug was then placed on the pad containing the negative electrode. The parameters for treatment were set thus: duration, 10 minutes; and intensity, 4-12Ma. The machine was then turned on slowly until the patient felt a tolerable tingling sensation.

Bicycle Ergometer: The bicycle ergometer was ridden by each of the participants for 20 minutes at their own speed.

Squatting Exercise: The procedure was explained to the participants in the first treatment session. The participants were instructed to place their backs against the wall, with the head, buttocks and the heels of their feet touching the wall, the participants then bent the knees to about 45º. They were in that position for 10 seconds and they relaxed afterwards, taking in deep breaths intermittently. This was repeated five times.

CTRL Group: The participants in the CTRL Group were engaged in the following kinematic exercises (which the participants of other groups participated in):

Bicycle Ergometer: The bicycle ergometer was ridden by each of the participants for 20 minutes at their own speed.

Squatting Exercise: The procedure was explained to the participants in the first treatment session. The participants were instructed to place their backs against the wall, with the heads, buttocks and the heels of their feet touching the wall, the participants then bent the knees to about 45º. They were in that position for 10 seconds and they relaxed afterwards, taking in deep breaths intermittently. This was repeated five times.

Outcome Measure and Variable

The Medical Outcome System (MOS) sleep scale [11] was used to take assessment of sleep at the beginning and end of the study.

Statistical Analysis

Data analysis was done using Statistical Package for Social Sciences (SPSS), version 17. Descriptive statistics of mean, standard deviation and percentage were calculated for the variable; quality of sleep. t-test statistics was used to measure pre-goniometric and post-goniometric values. The level of significance was set at $p \leq 0.05$.

Results

The baseline characteristics of participants are given in Table 1, There were no significant differences in baseline characteristics between the groups with respect to age, body mass index (BMI), VAS scores and sleep scores for somnolence (SMN), sleep adequacy (SLA), snoring (SN), sleep disturbance (SLD) but there was a significant difference with respect to sleep scores for sleep problem (SLPB) and awaken by shortness of breath and headache (ASBH) with p-value of 0.0005, and 0.003 respectively.

Analysis of treatment outcome of participants in the two groups pre- and post-intervention, according to Table 2 shows statistically significant differences regarding improvement changes in outcome measures (SLEEP SCALES) were found in ION and the control group (p= 0.04 respectively in the ION group and p= 0.001 respectively in the CTRL group).

	SLPB	SLD	SMN	SLA	ASBH x±s	SN
	x±s	x±s	x±s	x±s		x±s
ION GRP						
Pre- Rx	19.21±	20.86±	25.19±	71.11±	15.56±	17.78±
	18.78	13.04	14.82	16.16	19.44	33.83
Post- Rx	14.19±	6.44±	16.30±	56.67±	4.44±	4.45±
	10.04	7.02	8.24	7.53	8.82	8.82

t-value	0.72	2.37	1.38	1.03	1.8	1.03
p-value	0.25	0.04*	0.21	0.33	0.19	0.33
CTRL GRP						
Pre-Rx	15.99±	18.75±	22.96±	87.78±	11.11±	26.67±
	13.76	18.73	11.6	13.02	17.64	34.64
Post-Rx	9.13±	11.11±	16.30±	16.30±	6.67±	20.00±
	6.14	6.34	8.24	8.24	10	22.36
t-value	1.14	0.96	1.85	14.27	0.61	0.38
p-value	0.15	0.36	0.1	5.66	0.56	0.72

Table 2: Analysis of treatment outcome of patients in the two groups, pre- and post-intervention.
*: significant at p< 0.05 within the treatment group.
Keys: Rx: Treatment; x±s: Mean ± Standard Deviation; ION: Iontophoresis group; CTRL: Control group; SD: Standard Deviation; SLPB: Sleep problem; SLD: Sleep disturbance; SMN: Somnolence; SLA: sleep adequacy; SN: Snoring; ASBH: Awaken by shortness of breath or headache.

A post-hoc analysis of least significant difference was carried out to find out where significant differences existed between the two groups. According to Table 3 statistically significant differences regarding improvement changes in outcome measures (SLA subscale of MOS SLEEP SCALE) were found between ION and the control group (p= 0.02).

	ION	**Control Group**	**p-value**
	Mean ±SD	**x±s**	
SLEEP scores			
SLPB	9.13±1.56	14.20±1.49	0.18
SLD	6.94±0.82	11.11±2.01	0.26
SMN	26.67±2.53	16.30±2.12	0.12
SLA	87.78±8.82	56.67±6.52	0.02*
ASBH	6.67±0.80	4.44±0.68	0.71
SN	4.44±0.68	20.00±2.32	0.08

Table 3: Post-hoc analysis of changes in clinical outcomes measures between ION Group and Control Group.
*: significant at p< 0.05 within the treatment group.
Keys: Rx: Treatment; x±s: Mean ± Standard Deviation; ION: Iontophoresis group; CTRL: Control group; SD: Standard Deviation; SLPB: Sleep problem; SLD: Sleep disturbance; SMN: Somnolence; SLA: sleep adequacy; SN: Snoring; ASBH: Awaken by shortness of breath or headache.

Discussion

In this study, improvements in quality of sleep adequacy were obtained in the ION group, indicating the importance of this variable as a determinant of treatment efficacy in people with knee OA. The improvement in the use of iontophoresis is probably due to the depositor effect of iontophoresis described in earlier studies by Aiyejusunle, et al. [12] and Akinbo, et al. [13] this depositor effect has the ability to make the iontophoretic drug stay in the tissue for a while and gradually diffuse to the target structure where its therapeutic impact is felt. This will likely allow the patient to experience the benefit of a therapy long after its termination.

The finding of this study also corroborates earlier reports by Allen, et al. [14]. These authors found that sleep problem highly correlated with symptomatic hip and knee OA and opined that patients with OA should therefore be regularly screened for sleep disturbance as part of routine care. The findings from the study also agree with another study by Wilcox, et al. [6] that sought to describe the types and frequencies of sleep complaints and the biopsychosocial factors associated with sleep disturbance. The study also concluded that sleep disturbance is common in older adults experiencing knee pain or knee pain with radiographic evidence of OA therefore, interventions that take into account the multi determined nature of sleep disturbance in knee pain or knee OA are most likely to be successful.

Ability to get enough sleep is likely to improve the psychological and physical symptoms of people with knee osteoarthritis thereby leading to improvement in functional activities of daily living and ultimately their total wellbeing. There is, however, paucity of literature on the effect of iontophoresis on the quality of sleep in people with knee osteoarthritis. Hence, there is need for more studies to be carried out in this regard.

Conclusion

In conclusion, the results of this study provide evidence that patients with knee OA who have difficulty in having adequate sleep can achieve significant benefits from using diclofenac sodium iontophoresis in their rehabilitation. This study concluded that diclofenac sodium iontophoresis had significant effect on quality of sleep adequacy in people with knee osteoarthritis. .

Recommendation

It is therefore advised that clinicians should pay more attention to the assessment, treatment and monitoring of quality of sleep in people with knee osteoarthritis in order to optimise functioning for them.

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