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EFFECT OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION THERAPY ON PAIN AND FUNCTIONAL DISABILITY LEVEL AMONG PATIENTS WITH ROTATOR CUFF DISEASE- A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Shoulder pain is one of the leading causes of musculoskeletal pain and disability with rotator cuff disease was a common condition. The study aimed to assess the effect of TENS therapy on pain and functional disability level with rotator cuff disease patients.

Methods: A parallel-group randomized controlled with 1:1 allocation, open-label, the trial is done at Orthopaedics and Physical Medicine and Rehabilitation Out Patient Departments, AIIMS, Rishikesh, Uttarakhand, India. After applying inclusion and exclusion criteria total of 76 patients (42 males, 34 females) of rotator cuff disease were selected through total enumerative sampling, and block randomization with a block size of two is used to allocate treatments. The intervention was TENS therapy (high frequency (100Hz) with a pulse duration 120µs and low intensity (30- 40mA) for 20 minutes.) for consecutive five days plus standard treatment for the experimental group and standard treatment (Shoulder ROM, twice a day) as followed at AIIMS, Rishikesh to control group and Followed after completion of the treatment session. (after five days). SPADI scale is used for pain and functional disability level measurement.

Results: A total of 70 patients (38 males and 32 females) were analyzed. The experimental and control group were homogenous in terms of total SPADI, disability and pain score ($p>0.05$). Median post-intervention total SPADI, disability and pain scores of the intervention group were significantly less as compared to the control group ($p=0.000$). No side- effects of treatment in any group.

Conclusion: TENS therapy is an efficient therapy for patients experiencing rotator cuff disease

Trial registration- CTRI/2018/09/015659

Keywords: Rotator cuff disease, shoulder pain, TENS, electrotherapy modalities, physiotherapy.

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INTRODUCTION

Musculoskeletal health plays a very vital role in every individual's life. Dexterity of the upper limb helps an individual to carry out various psychomotor functions skillfully in their day to day life. In the present scenario, the global concern is arising related to compromised musculoskeletal health, manifested by an increasing rate of mortality and morbidity [1].

Globally, disabilities related to musculoskeletal disease were the second most common cause of ill health. These disabilities are not only associated with old age but often affect an individual throughout his/her life span. It is documented that one out of five people is concerned with one or more musculoskeletal problems, which leads to significant distress and disability among the sufferers. Musculoskeletal problems account for more than one half of the multimorbidity presentation and it also impacts a person's psychological state as well as leads to depression [2].

Shoulder pain is the leading cause of disability and distress among various musculoskeletal problems. Shoulder pain had the third position among musculoskeletal illness after back and neck pain [3]. Prevalence documented by different studies differs from 6.9- 26% with a lifespan prevalence of 6.7- 66.7% and incidence outlined between 0.9- 2.5%. A systemic review concluded that shoulder pain prevalence differs according to demographic conditions [4]. Studies showed that the prevalence of shoulder pain among adults in Northern India is 22.9%. The prevalence was high at the age of 40 to 50 years.

Results also concluded that shoulder pain was significantly related to obesity, left-hand dominance and diabetes [5].

Rotator cuff disease is a broad name that involves disorders of the rotator cuff and it is the leading cause of pain in the shoulder. A group of conditions that are grouped under these disorders is impingement syndrome, tendinitis, tears, etc. People of rotator cuff conditions often report pain in hands, which is aggravated by various maneuvers like overhead activity and the pain usually increases at night when a person is lying down on the affected side. A study reported that the burden of functional disabilities due to rotator cuff disorder is increasing continuously with age, and among persons involved in occupational activities (e.g., pushing, pulling, heavy lifting) or sports like swimming, tennis, that need repeated use of the hands [6].

Rotator cuff disease involves degenerative changes, but the exact cause is still unknown. Two hypotheses were assumed related to the pathophysiology behind these diseases. As per the extrinsic hypothesis: deformity in the rotator cuff is a result of repeated wear and tear of shoulder muscles tendon due to friction with various parts of the shoulder joint. In this theory, three different types of impingement syndromes occur. However, as per the intrinsic hypothesis, disability is linked to age-related deterioration of the tendon [7].

A study reported that a painful arc test is the best test

done to diagnose rotator cuff disorders. It is positive when pain occurs during active abduction of the affected arm between 60°- 120° [6]. Another researcher documented the effectiveness of the Hawkins Kennedy and Neer test for clinical detection of the disease by primary practitioners [8].

It has always been a question for the treatment of rotator cuff disease among health care workers because of many etiological factors [9]. The electrotherapies are used for decreasing pain and better functioning by increasing the energy field in the body. Energy can be given by various methods like electrical, sound, light, or thermal [6]. TENS therapy is one such technique that involves electrical energy. It is a common modality that has been used by various physiotherapists to manage pain related to muscles and bones [9]. TENS therapy is a simple, non-invasive technique with no habituating symptoms, used for reducing pain. Melzack and Wall published the gate-control theory. After this theory, the use of an electrical stimulus was increased to reduce pain [10].

During TENS therapy, electrical stimuli are produced by a pulse generator. This stimulus is then delivered through the intact skin by using electrodes. There are different techniques used in TENS therapy. The most common are Conventional TENS therapy, Acupuncture like TENS therapy, Intense TENS therapy [11,12].

Unfavorable events from TENS are rare. Sometimes it is reported that due to an improper technique of applying electrode pads, there are mild chances of electrical burns at the site by a TENS machine. Some patients have an incident of minor skin irritation underneath the electrodes. The absolute contraindications for TENS therapy were patients who had cardiac pacemakers and bleeding. It is also not used on the abdominal part among pregnant women and at the site of nerve damage. Electrodes should not be applied over sites of active malignancy directly, excluding patients in the palliative center with the guidance of an expert. It should be used very carefully in patients with epilepsy. Electrodes should not be applied overhead and neck areas in a patient with epilepsy. TENS is not appropriate for use on the front side of the neck because of the threat of acute hypotension by inducing a vasovagal response. Some safety measures should be used while using TENS therapy to prevent unpleasant events. These are:

- TENS electrodes should not be applied near to transdermal patch of transporting the drug system to the body.
- TENS electrodes should never be placed on sites of un-intact skin or damaged skin.^{10,12}

TENS can be used in conjunction with pharmacotherapy because TENS therapy has no recognized drug interactions [12].

Desmeules F et al. (2016) [9] conducted a Cochrane systemic review on the rotator cuff tendinitis patients for the efficiency of transcutaneous electrical nerve stimulation therapy. EMBASE, CINHALL, PeDRO and

PubMed databases were explored for randomized control trials till April 2015. Six clinical trials were included in this review with a different number of subjects. The mean methodological score for the quality of trials was $49\% \pm 16\%$, pointing out an overall poor quality. Only two studies had a score of $>60\%$. This review involved a restricted study and there was a great chance of bias in these. Therefore, no inference was shown on the impact of TENS therapy to reduce pain and betterment of functional ability level in rotator cuff tendinopathy patients.

Page MJ et al. (2016) [6] conducted a Cochrane systemic review to assess the impact of electro modalities techniques on patients of rotator cuff disease. Randomized control trials and quasi-experimental studies were searched on databases like Cochrane central register of controlled trials, MEDLINE, Ovid EMBASE, the WHO ICTRP clinical trial registries, CINAHL Plus, and CTR.gov till March 2015. Based on poor quality evidence, they were unsure that transcutaneous electric nerve stimulation therapy is higher- up to placebo. And also unsure about other electrotherapy modalities whether they were superior over other active interventions.

Because of issues in trial design, the research evidence is conflicting utilizing TENS therapy to reduce pain [10]. There have been several systematic reviews done on this therapy admitting that evidence was indecisive because of many flaws in RCT methods [11]. The aim is to see the effect of transcutaneous electrical nerve stimulation (TENS) therapy on pain and functional disability level among patients with rotator cuff disease.

METHODS

A quantitative research approach and prospective, open-label, randomized parallel-group control trial design was used in the present study. It was conducted at Out Patient Departments of Orthopaedics and Physical Medicine Rehabilitation, AIIMS, Rishikesh, Uttarakhand, India.

Sampling

Based on previous studies, we hypothesized that subjects using intervention as TENS therapy would have a mean score of the pain of 2.1 ± 1.3 compared to other interventions with a mean score of the pain of 1.2 ± 0.7 . (Eyigor et al. 2010) [13]. Considering an alpha level of 5% and a power of 95%, using online G*Power software (<http://www.gpower.hhu.de/>), it was necessary to compare 30 subjects per group. Anticipating the fact that there would be some probability of drop out of samples, we increased the sample size by 25%. Therefore, the total number of subjects enrolled was 76 i.e.

Thirty-eight in the experimental group and 38 in the control group. Consecutive non- probability sampling technique was used to select the patients with rotator cuff disease.

Criteria for selection of sample: Table 1 shows the criteria for sample selection.

Inclusion criteria	Exclusion criteria
Patients with rotator cuff disease <ul style="list-style-type: none"> • Age between 18 to 65 years. • Willing to participate in the study for five consecutive days. • Patients do not have any cognitive disability. • Can understand Hindi or English language 	Patients with rotator cuff disease having <ul style="list-style-type: none"> • Bleeding disorders • Cardiac pace maker. • Nerve injuries of upper limbs. • Any other diagnosed orthopedic problems.

Table 1: Criteria for sample selection.

Randomization

Block randomization was used for the present study. Blocks of two were used to maintain proportional allocation between interventional and control groups. The randomization list was generated using specific online software. The primary researcher did not take part in the creation of a randomization list and wasn't aware of its contents. Allocation concealment was done with sequentially numbered opaque sealed envelopes (SNOSE) was used for allocation concealment of the patients to the interventional and control groups. The primary researcher did the final evaluation to ensure that each patient met the inclusion criteria. The envelopes were opened, after receiving informed consent from the patients, by the primary researcher who implemented the intervention. This study was an open clinical trial.

Intervention

Competency certificate for applying TENS therapy on patients and demonstrating shoulder range of motion exercises was obtained.

Intervention device:



Figure 1: TENS Machine

Intervention group:

TENS therapy stimulation was delivered as conventional mode, i.e. current with high frequency (100Hz) with a pulse duration of $120\mu\text{s}$ and low intensity (30- 40mA) for 20 minutes. This therapy was delivered once a day for five consecutive days. The primary researcher applied the intervention to the subjects. The principal researcher demonstrated shoulder ROM exercises. The patients did these exercises in the morning and evening times at their homes (twice a day). Tab. Etoricoxib OD (60 mg for less than sixty Kg weight and 90 mg for more than sixty Kg weight) was given to subjects whose pain level was $> 50\%$.

The telephonic call was placed to reinforce subjects for intervention and to ensure the integrity of shoulder ROM at home. No adverse action of treatment noted in groups.

Control group:

For the control group, patients received standard treatment, as followed at AIIMS, Rishikesh. The primary researcher demonstrated shoulder ROM exercises. The patients did these exercises in the morning and evening times at their homes (twice a day). Tab. Etoricoxib OD (60 mg for less than sixty Kg weight and 90 mg for more than sixty Kg weight) was given to patients whose pain level was > 50%. A telephonic call was placed to ensure the integrity of the shoulder ROM at home.

Outcomes

Outcomes were assessed by using a standardized SPADI scale (contains five items to measure pain, and eight items to measure disability and total items 13) were freely available at several sites.

Primary outcomes

The primary outcome was to see the effect of TENS therapy on pain and functional disability level among patients with rotator cuff disease. Shoulder Pain and Disability Index (SPADI) scale was used to assess those variables. The pre-intervention level of pain and functional disability was assessed after signing the informed consent by the patients for this study. After five days, post interventional pain and functional disability level were assessed.

Secondary outcomes

The secondary outcome of the study was to assess the total SPADI score between the experimental and control group.

Ethical consideration

Ethical approval was obtained from an ethical committee of AIIMS, Rishikesh reference no. ECR/736/Inst/UK/2015, 71/IEC/PGN/2018. The study registered under CTRI registration no CTRI/2018/09/015659. Participant information sheets and written informed consent were taken after a complete explanation about the study. Confidentiality and anonymity of subjects maintained throughout the study period

Pilot Study

A pilot study was conducted on a total of 08 patients (04 from each group). Study was found feasible and no changes were made in any method.

Data analysis

The result was presented in percentage, mean with standard deviation, median with interquartile range: Independent t-test, chi-square and Fisher exact tests used to compare variables of both groups. Wilcoxon rank-sum test was used to compare the median score between the groups. Wilcoxon sign rank test was used to find change within the group.

RESULTS

Figure 2 shows the trial consort flow chart for patients screening, treatment allocation, intervention, and analysis.

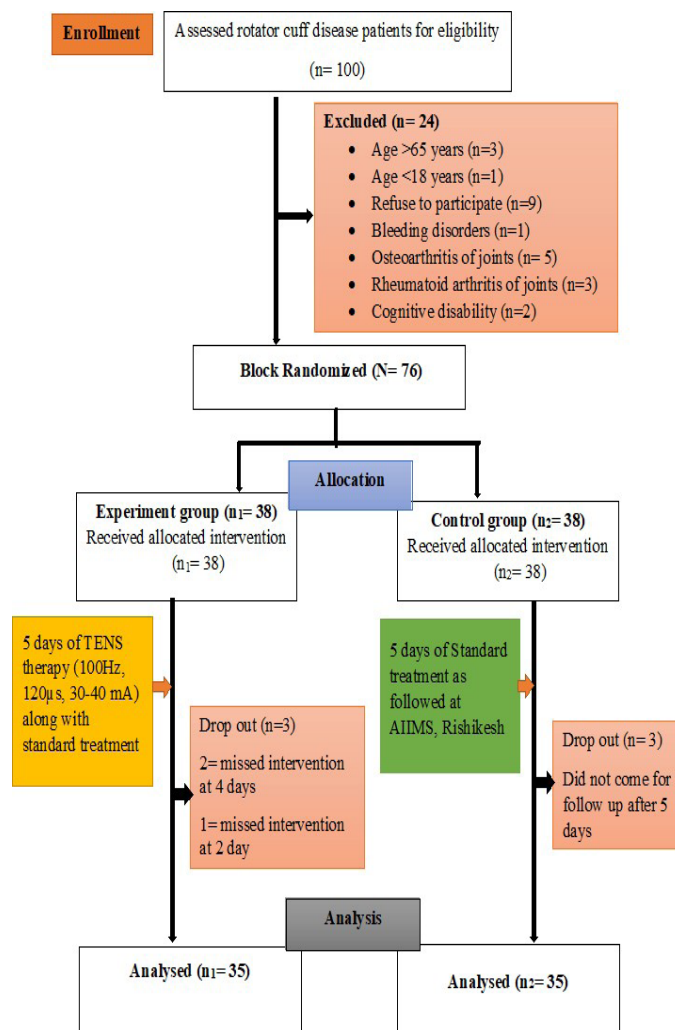


Figure 2: Consort Flow Diagram

Table 1(a): shows the socio-demographic profile of the subjects. Results show that both the groups were homogenous to the age of subjects, gender, marital status, educational qualification, occupation, and habitat ($p>0.05$) while the groups were not homogenous in terms of religion ($p<0.05$) which could be a matter of coincidence.

Table 1(a): Socio- demographic profile of the subjects (N= 70)

Variable(s)	Experimen- tal group (n1=35) f (%)	Control group (n2=35) f (%)	Total N= 70 f (%)	p-value ^b
Age (mean± SD)	47.48±13.75	47.28±9.91	47.39±11.90	0.945 ^a
Gender				
Male	16 (46)	16(46)	32 (46)	1.000
Female	19 (54)	19 (54)	38 (54)	
Marital status				
Married	28 (80)	34 (97)	62 (89)	0.063
Unmarried & others**	07 (20)	01 (03)	08 (11)	
Educational status				
Illiterate	08 (23)	08 (23)	16 (23)	
High school	11 (31)	05 (14)	16 (23)	0.333
Intermediate	06 (17)	06 (17)	12 (17)	

Graduate & above	10 (29)	16 (46)	26 (37)	
Religion				
Hindu	34 (97)	29 (83)	63 (90)	0.025*
Muslim & others***	01 (03)	06 (17)	07 (10)	
Occupation				
House wife	12 (35)	10 (28)	22 (31)	
Labour	04 (11)	09 (26)	13 (19)	0.388
Sportsperson & others****	19 (54)	16 (46)	35 (50)	
Habitat				
Rural	08 (23)	17 (48)	25 (36)	
Urban	23 (66)	15 (43)	38 (54)	0.118
Hilly Rural	03 (08)	02 (06)	05 (07)	
Hilly Urban	01 (03)	01 (03)	02 (03)	

Note: ^aIndependent t-test, ^bFisher's Exact test, * $p < 0.05$, **others include Widow/ Widower, ***others include Sikhism, ****others include government job, private job, self-business, student, a percentage is in round figure.

Table 1(b): shows the clinical profile of the subjects. Results show that both the group were homogenous in terms of duration of pain, previous history of trauma, previous history of treatment, site of involvement, dominant arm, and comorbidities. ($p > 0.05$)

Table 1(b): Clinical profile of the subjects (N= 70)

Variables	Experiment group (n1= 35) f (%)	Control group (n2= 35) f (%)	Total N= 70 f (%)	p-value ^b
Duration of Pain				
Acute pain (<6 months)	29 (83)	24 (69)	53 (76)	0.256
Chronic pain (>6 months)	06 (17)	11(31)	17 (24)	
Previous history of trauma				
Present	06 (17)	12 (34)	18 (26)	0.085
Not present	29 (83)	23 (66)	52 (74)	
Previous history of treatment				
Not any	25 (71)	18 (51)	43 (61)	
Analgesic drugs (oneself)	05 (14)	11 (31)	16 (23)	
Physiotherapy	01 (03)	01 (03)	02 (03)	0.356 ^c
AYUSH treatment	02 (06)	01 (03)	03 (04)	
Private hospital consultation	02 (06)	04 (12)	06 (09)	
Site of involvement				
Right shoulder	19 (54)	19 (54)	38 (54)	
Left shoulder	13 (37)	14 (40)	27 (39)	1.000
Both shoulders	03 (09)	02 (06)	05 (07)	
Dominant arm				
Right arm	31 (89)	32 (91)	63 (90)	
Left arm	04 (11)	03 (09)	07 (10)	1.000
Co-morbidities				
Not any	24 (68)	25 (70)	49 (70)	
Hypertension	05 (14)	03 (09)	08 (11)	
Diabetes mellitus	03 (09)	03 (09)	06 (09)	0.867
Both**	01 (03)	03 (09)	04 (06)	
Others***	02 (06)	01 (03)	03 (04)	

Note: ^bFisher's Exact test, ^c Chi-square test, * $p < 0.05$, **both include hypertension and diabetes mellitus, ***others include cardiovascular disease, thyroid disease, a percentage is in round figure.

Table 2: shows the effectiveness of TENS therapy on pain level among subjects. There was a significant reduction in pain scores of patients from pre-test to post-test in the experimental group (76(60- 90) vs. 30(08-34), $p = 0.000$). Also, there was a significant reduction in pain scores of patients from pre-test to post-test in the control group (72(64-88) vs.60(46-70), $p = 0.000$). But there is a significant reduction in pain scores of patients with rotator cuff disease in the intervention group as compared with the control group.

Table 2: Effectiveness of Transcutaneous Electrical Nerve Stimulation on Pain Level among Subjects

SPADI domain	Experimental group (n1= 35) Median (Q ₁ , Q ₃)	Control group (n2= 35) Median (Q ₁ , Q ₃) ^f	p-value ^e
Pain score			
Pre-test	76 (60- 90)	2 (64- 88)	0.715
Post-test	30 (08- 34)	60 (46- 70)	0.000*
p value^d	0.0000*	0.0000*	

Note: ^fQ₁= 25th percentile; Q₃= 75th percentile,^dwilcoxon signed rank test,^eWilcoxon rank sum test, * $p < 0.001$

Table 3: shows the effectiveness of Transcutaneous Electrical Nerve Stimulation on Functional Disability Level among Subjects There was a significant reduction in disability scores of patients from pre-test to post-test in the experimental group (68.75(47.69-87.50) vs.26.25(10-31.25), $p = 0.000$). Also, there was a significant reduction in disability scores of patients from pre-test to post-test in the control group (65(53.75-86.25) vs.50(40-71.25), $p = 0.000$). But there is a significant reduction in disability scores of patients with rotator cuff disease in the intervention group as compared with the control group.

Table 3: Effectiveness of Transcutaneous Electrical Nerve Stimulation on Functional Disability Level among Subjects

SPADI domain	Experimental group (n1= 35) Median (Q ₁ , Q ₃) ^f	Control group (n2= 35) Median (Q ₁ , Q ₃) ^f	p-value ^e
Disability score			
Pre-test	68.75 (47.69- 87.50)	65 (53.75- 86.25)	0.906
Post-test	26.25 (10- 31.25)	50 (40- 71.25)	0.000*
p value^d	0.000*	0.000*	

Note: ^fQ₁= 25th percentile; Q₃= 75th percentile,^dwilcoxon signed rank test,^eWilcoxon rank sum test, * $p < 0.001$

Table 4: shows the effectiveness of the Transcutaneous Electrical Nerve Stimulation on total SPADI score among Subjects. There was a significant reduction in total SPADI scores of patients from pre-test to post-test in the experimental group (70(60-86.15) vs.26.15(10-33.08), $p = 0.000$). Also, there was a significant reduction in total SPADI scores of patients from pre-test to post-test in the control group (68.46(57.69-86.15) vs.54.61(42.31-67.69), $p = 0.000$). But there is a significant reduction in

total SPADI scores of patients with rotator cuff disease in the intervention group as compared with the control group.

Table 4: Effectiveness of Transcutaneous Electrical Nerve Stimulation on total SPADI score among Subjects

SPADI domain	Experimental group (n1= 35) Median (Q1, Q3) ^f	Control group (n2= 35) Median (Q1, Q3) ^f	p-value ^e
Total SPADI Score			
Pre test	70 (60- 86.15)	68.46 (57.69- 86.15)	0.865
Post test	26.15 (10- 33.08)	54.61 (42.31- 67.69)	0.000*
p value^d	0.000*	0.000*	

Note: ^fQ1= 25th percentile; Q3= 75th percentile,^dwilcoxon signed rank test,^eWilcoxon rank sum test, *p<0.001

DISCUSSION

In the present study, the mean age of the rotator cuff disease patients was 47.39±11.9 years, with a 0.84: 1 ratio of male-female. A similar finding was shown by Singh S et al. (2015) [14] who reported that the mean age of subjects who perceived shoulder pain was 51.36±11.86 years. The majority of females was seen with a ratio of 0.81:1. In the present study, a significantly high number of patients (76%) were having acute pain with unilateral involvement (93%) and right-hand dominance (90%). The mean score of pain and disability was 74.05±15.72 and 67.85±21.3 and the total SPADI score means 70.49±17.78. The majority of patients with rotator cuff disease perceived a high level of pain and functional disability.

Contradictory findings were shown by Bhawana et al. (2016) [5], who reported that the mean score for shoulder pain and disability index was 40.43±21.82, and chronic pain was present in 58.78% peoples. This difference of the mean total SPADI score may have occurred because in the present study majority of patients had acute pain (76%) rather than chronic pain (24%). But some findings like the most common age group with pain (41-50years), unilateral pain in 82.04% of subjects were matching with the present study.

In the present study, TENS therapy as conventional mode (100Hz, 120µs, 30-40mA for 20 minutes per day) was used as an intervention among rotator cuff disease patients for five consecutive days. After the intervention the median pain, functional disability and total SPADI scores in subjects of the experimental group were 30(8-34), 26.25 (10-31.25) and 26.15(10-33.08) which were significantly lower than the scores in subjects of control group 60(46-70), 50(40-71.25) and 54.61(42.31-67.69) respectively. So, in this study TENS along with the standard treatment as followed at AIIMS, Rishikesh is effective in decreasing pain and functional disability among rotator cuff disease patients of intervention group as compared to control group (p=0.000) Similar results were reported by Gunay Ucurum S et al. (2018) [15]; Kocyigit et al. (2012) [16]. GunayUcurum S et al. (2018) [15] reported that significant changes occur based on the DASH score, the physical component of short-form 36 scores, and pain score (p<0.05).

But according to the results of a systemic review done by Desmeules F et al. (2016) [9] on the efficiency of TENS therapy on rotator cuff tendinitis patients, no decision could be formed on the effectiveness of TENS because of a little number of studies with greater risk of bias. Similarly, Page MJ et al. (2016) [6] conducted a Cochrane systemic review on the impact of different techniques of electrotherapy for management of disease related to rotator cuff and results executed that they were unsure whether TENS is higher-up to placebo because of very poor quality of evidence.

Both reviews suggested that there is a need for more methodological sound studies to provide evidence. The present study will provide a sound base for the effectiveness of TENS therapy among patients with rotator cuff disease and will be helpful as evidence for future systemic reviews.

Limitations: Study could not be blinded. The present study could not use probability sampling technique. The study was bound to 76 patients only (38 in experimental and 38 in the control group). The study was bound to only a few sessions of TENS therapy (once a day for five days).

CONCLUSION

Although, standard treatment as followed at AIIMS, Rishikesh has significant impact in reducing pain level and functional disability level among patients with rotator cuff disease in control group but transcutaneous electrical nerve stimulation therapy along with standard treatment has more significant role in reducing pain level and functional disability level among patients with rotator cuff disease as compared to control group. So, it should be routinely used as adjunctive therapy along with standard treatment for better outcomes among patients with rotator cuff disease.

Recommendations: A similar study can be replicated on a large sample to validate the findings and make a generalization. A study with long term follows-up can be undertaken to generate evidence about the effectiveness of TENS therapy on patients with rotator cuff disease. A study with a different mode of TENS therapy can be tackled to create evidence about the impact of it on rotator cuff disease patients. A survey can be done with other pathological conditions of shoulder to generate evidence about the effects of TENS therapy on pain and functional disability level.

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